

**AUDITING HEALTHCARE FACILITIES AGAINST THE
NATIONAL CORE STANDARDS FOR OCCUPATIONAL
HEALTH AND SAFETY AND INFECTION PREVENTION AND
CONTROL: COMPLIANCE, RELIABILITY AND IMPACT.**

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Dedication:

This thesis is dedicated to my wife Fayron, our daughter Scarlet, my parents, Jeff and Eleanor, for their love, support, sacrifice and understanding.

Acknowledgements:

I was the main researcher and made a considerable contribution to the conception and design of this project, data acquisition, collection, extraction, analysis, interpretation of data and the writing of this manuscript.

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Dissertation abstract

Auditing in health care has been recommended by many national organisations to improve patient safety and quality of care, despite inconclusive evidence to support its effectiveness. In South Africa, the National Core Standards for health establishments in South Africa (NCS) was published in 2011. The NCS recognises that staff are vital to ensuring that the health system delivers quality health care and therefore require protection against the risk of injury, infection and other occupational hazards, consistent with the South African Occupational Health and Safety act of 1993. The aim of this study was to determine: (a) the compliance of public sector primary healthcare (PHC) facilities with the NCS for occupational health and safety (OHS) and infection prevention and control (IPC), (b) the impact of the audits three years after baseline audits, at follow up self-assessment audits and (c) the reliability of self-assessment audits when compared to external audit results.

This dissertation is divided in three parts. Part A is the study protocol which received ethics approval in March 2015. Part B is a structured literature review covering standards for health care, the impact and effectiveness of accreditation/certification/auditing in health care, inter-rater reliability and factors associated with OHS/IPC compliance. Previous studies have failed to address whether evaluating occupational health and safety or infection prevention and control standards using accreditation/certification in a primary healthcare, low and middle income setting is effective or reliable. Part C is the journal ready manuscript presenting the results of the study in the form of a manuscript for an article for a named peer reviewed journal.

This was a cross-sectional study of NCS OHS/IPC audit data, with a longitudinal component, of a sample of public sector PHC facilities in the Western Cape province of South Africa between 2011 and 2015. Baseline PHC facility compliance with OHS/IPC measures was low. There was no significant improvement in compliance after three years. Poor inter-rater reliability indicates a large degree of measurement error. Practical implications of these results are the need to improve reliability of assessments and a process to convert low compliance scores into implemented improvement actions.

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Abbreviations/ acronyms:

CDC: Community day centres

CHC: Community health centres

DHIS2: District health information system version 2

FDA: Food and Drug Administration

IPC: Infection prevention and control

NCS: National Core Standards for Health Establishments in South Africa

NDoH: National Department of Health

OHS: Occupational health and safety

OHSA: South African Occupational Health and Safety Act of 1993

OHSC: Office of Health Standards Compliance

PEP: post exposure prophylaxis

PHC: Primary healthcare

LMICs: Low and middle income countries

UCT: University of Cape Town

WCG:H: Western Cape Government: Department of Health

WC: Western Cape

WHO: World Health Organisation

QA: Quality assurance

Glossary of terms

Accreditation: Process of review that healthcare facilities participate in to demonstrate the ability to meet predetermined criteria and standards of accreditation (set at maximum achievable level to stimulate improvement over time) established by a recognised professional agency.

Audit: A systematic evaluation against explicit criteria with the aim of quality improvement.

Baseline audit: First NCS audit conducted on health facilities by the Health Systems Trust, an external non-government organisation in 2011/12.

Certification: Process by which a recognised authority (e.g. a professional association) appraises and recognises an organisation as having met pre-determined requirements (set at a minimum level to ensure minimum risk).

Compliance: Conforming to a rule, such as a standard or law.

Clinic: Eight hour nurse-driven clinic with basic limited services.

Community day centre (CDC): Eight hour health facility with nurses and full time medical officers (doctors) offering services such as mother and child health, health promotion, geriatrics, chronic disease management, occupational therapy, physiotherapy, psychiatry, speech therapy, communicable disease management.

Community health centre (CHC): 24 hour CDC with some additional services including emergency centre/room.

District: Municipal administration divisions/regions within each province in South Africa.

Functional area: Specific area or department or service within a health facility for example clinic manager, clinical services, pharmacy or maintenance support.

Health facility: Any clinic, CDC, CHC or hospital operated by the Western Cape Government: Department of Health.

Improvement: Increase scores achieved in NCS audits.

Infection prevention and control (IPC): Discipline concerned with preventing hospital acquired infections and factors related to the spread of infection within healthcare settings.

External (Office of Health Standards Compliance [OHSC]) audits: Unannounced, simulated NCS audits done by the OHSC inspectors (external).

Measure: Measures are the means or evidence for determining whether or not the criterion has been met.

National Core Standards for Health Establishments in South Africa: Mandatory minimum standards that will serve as a benchmark against which health establishments can be assessed for national certification of compliance.

National Health Insurance: A healthcare financing model intended to ensure that all South African citizens and legal residents benefit from healthcare financing on an equitable and sustainable basis.

Occupational health and safety (OHS): Activity concerned with employee health, safety and wellbeing and fostering a healthy and safe work environment.

OHS and IPC measures of the NCS: Selected measures from the NCS that deal specifically with OHS or IPC related activities.

Province: One of nine geographically demarcated administrative divisions/regions in South Africa.

Reliability of the instrument: Degree of similarity of the results obtained when the assessment is done with the same instrument on the same health facility.

Self-assessment audits: Assessments performed by internal staff of the Western Cape Government: Department of Health consisting of a peer audit team conducting audits at facilities other than their own or a team from the district office.

Standard: A standard is a statement of an expected level of quality delivery

Type of facility: Refers to either a clinic, CDC, CHC

PART A: STUDY PROTOCOL

1. Introduction

1.1 Background

One key performance area for the National Department of Health (NDoH) is to improve health system effectiveness.[1] The flagship programme to achieve this is the National Health Insurance system with the aim of providing universal health coverage. The document National Core Standards for Health Establishments in South Africa (NCS), was published by the NDoH in 2011.[2] It was produced as a statement of what is essential and expected to deliver safe, quality care in both the public and private sectors. The National Health Amendment Act of 2013 provided for the establishment of the Office of Health Standards Compliance (OHSC) which must monitor and enforce compliance with the NCS. In September 2013, the OHSC was established.

The seven domains of the NCS are shown in Figure 1. Each domain is defined by the World Health Organisation (WHO) as an area of potential risk for quality and safety. The first 3 domains are involved directly in providing quality health care to patients. The other 4 domains relate to the support system that ensures the delivery of quality services.

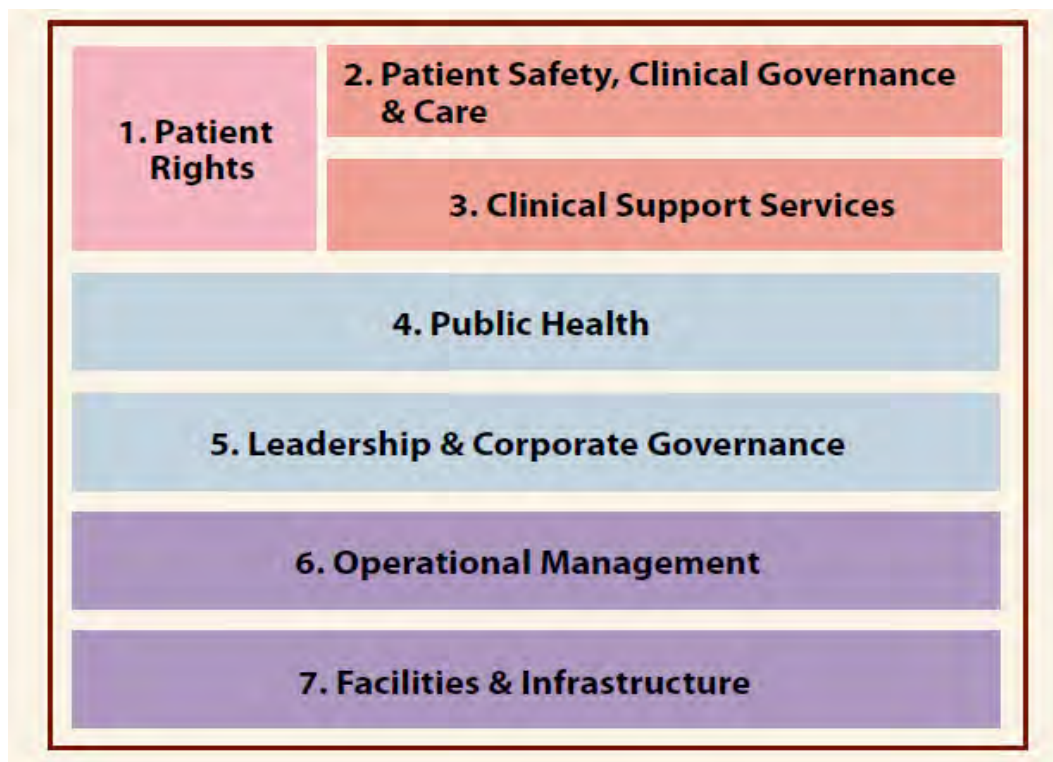


Figure 1: Seven domains of the NCS. (Reproduced from: NCS for health establishments in South Africa) [1]

The patient rights domain lays out how to ensure that patients' rights are respected and upheld. The domain of patient safety, clinical governance and clinical care covers aspects such as quality nursing, clinical care and ethical practice. Clinical support services deals with availability of medicines and provision of medical technology for diagnostic and therapeutic services. The domain of Public Health deals with collaboration between health facilities and non-governmental organisations, communities and other sectors to promote health and prevent illness. The Leadership and Governance domain covers senior management leadership, risk management, hospital boards, clinic committees and quality improvement. Operational Management covers day to day responsibilities, human resource management, finance, asset and consumables, information and record management. Lastly, the Facilities and Infrastructure domain covers physical infrastructure, hotel type support services and waste disposal.

Although the core business of the health system is delivering quality health care to its users, the NCS recognises that a support system that ensures the system delivers its core business is required and that staff are key in achieving this.

Independently, the South African Occupational Health and Safety Act of 1993 (OHSA) requires that an employer shall provide and maintain a working environment that is safe and without risk to the health of their employees.[3] Occupational health and safety (OHS) is concerned with employee health, safety and wellbeing and fostering a healthy and safe work environment. Infection prevention and control (IPC) has long been a responsibility of health facilities on the Duty of Care principle, and is concerned with preventing hospital acquired infections and factors related to the spread of infection within healthcare settings. Occupational health and safety (OHS) and infection prevention and control (IPC) measures cut across the 7 domains in the NCS.

In 2011 the NDoH awarded a tender to the Health Systems Trust to conduct *baseline audits* at public fixed health facilities nationally. These were conducted in the Western Cape (WC) province from 2011 to 2012. The Health Systems Trust is an independent non-governmental organisation established in 1992 to support the transformation of the health system in South Africa and are the publishers of the annual South African Health Review. They oversaw the audit process and compiled the data and generated the reports for the facilities involved.

Annual follow up *self-assessment* audits were then conducted in the WC Province by Western Cape Government: Department of Health (WCG:H) staff. The OHSC inspectors also conducted *external (OHSC) audits* at a sample of facilities after the baseline audits.

1.2 Motivation

The NCS will be enforced and monitored by the OHSC. It will be a requirement for all health facilities to achieve a pre-determined compliance level. The Quality assurance (QA) sub-directorate & QA managers at the various levels and districts will be thus considerably engaged with the NCS for the foreseeable future. It is therefore important to conduct research on the NCS audit process.

In addition, such research, will contribute significantly to a situational analysis of OHS in the WCG:H more generally, and will help to identify the gaps and corrective actions required to improve OHS in the department. Many of the requirements of the OHSA such as risk assessments, education and training of staff and provision of personal protective equipment are also found in the NCS.

Blitz inspections conducted by the Department of Labour on WCG:H's facilities in September 2014 and the resultant contravention notices with regard to the OHSA, further highlighted the need for improved OHS and IPC programmes within the WCG:H.

The situational analysis and recommended action plan will be the first steps in implementing a comprehensive (organisational) needs based occupational health programme for the WCG:H which will benefit employees significantly and indirectly improve the quality of healthcare services provided by them. It will also increase the level of compliance at public health facilities in the WC Province with both the OHSA and NCS and decrease their chances of receiving contravention notices from either the Department of Labour inspectors or the OHSC inspectors in the future.

However, the quality of the information depends on the reliability and validity of the assessment instrument or process.

No other studies in South Africa have analysed NCS audits for compliance with OHS and IPC measures. Generally, there is a dearth of studies evaluating OHS and IPC compliance with standards in primary healthcare (PHC) facilities, especially in low and middle income countries (LMICs). In addition, the comparison of self-assessment versus external assessment results in PHC in LMICs is under-researched. This study will add to the dearth of literature on the impact and reliability of auditing or accreditation of PHC facilities in a low resource setting.

1.3 Research questions

1. What is the degree of compliance of health facilities of the WCG:H with the NCS OHS & IPC measures?
2. What improvements were there at the health facilities in the NCS OHS and IPC measures from the baseline audits in 2011/12 to the 2014/2015 self-assessment audits?
3. What is the inter-rater reliability of these self-assessment NCS audits?

1.4 Objectives

- 1.4.1. To determine the compliance of health facilities with the NCS for OHS and IPC measures of the NCS.
- 1.4.2. To determine the impact of the audits at a sample of health facilities that had both a baseline (external) audits in 2011/12 and a 2014/15 follow up self-assessment audits.
- 1.4.3. To determine the reliability (repeatability) of the NCS follow up (self-assessment) audits when compared to external (OHSC) audit results.

2. Methods

2.1 Study design

This study will involve the secondary analysis of a subset of data that were collected during baseline (external), follow up (self-assessment) and external (OHSC) NCS audits done during the period 2011 to 2015 in WCG:H facilities. These audits amount to a descriptive cross-sectional survey of fixed health facilities operated by the WCG:H in the WC province of South Africa at specific times. All fixed health facilities in the WC were supposed to have had a baseline audit done and have conducted self-assessment audits annually.

Reliability will be determined by comparison of external (OHSC) audits with self-assessment audits at the same facility within the same period (01/04/14 to 30/06/15) at a sample of facilities.

2.2 Population and sampling

2.2.1 Study population

The study population is all WCG:H's fixed PHC facilities within the WC province of South Africa during the audit period. The WC province in South Africa has 6.1 million people, 75% of whom are served by the public health sector.[4] The WC province is divided into five rural district municipalities, namely Eden, Cape Winelands, Central Karoo, Overberg and the West Coast, and one metropolitan district, the Cape Town Metro District (appendix A). The Central Karoo covers the largest surface area (38 873 km²) whereas the Cape Town Metro District covers the smallest surface area (2 502 km²).[4] The Cape Town Metro District accommodates approximately 64 per cent of the population. The Cape Town Metro District is further divided into 4 substructures with 2 sub districts each, namely Western/Southern, Northern/Tygerberg, Eastern/Khayelitsha, Mitchells Plein/Klipfontein (appendix B).[4]

In April 2011 there were 46 fixed PHC facilities in the Cape Town Metro District's 4 substructures and 148 fixed PHC facilities in the 5 rural districts, equalling a total of 194 fixed PHC facilities (appendix C). In the Cape Town Metro District there are only community day centres (CDC) and community health centres (CHC) operated by the WCG:H. The City of Cape Town Municipality operates clinics in the Metro as well, but they will be excluded from this analysis as they are not managed by the WCG:H. The rural districts have clinics and CDCs operated by the WCG:H, but no CHCs and no municipal operated clinics. Satellite and mobile clinics will be excluded from this study, as will specialised clinics like dental and oral health and reproductive health clinics. Hospitals will be excluded from this analysis and will be the subject of a separate report. Appendix C gives a breakdown of all the fixed PHC facilities in the WC province as at April 2011.

Primary healthcare facilities will be included if they had a baseline (external) audit conducted in 2011/2012 and had a follow up self-assessment audit conducted between 01 April 2014 and 30 June 2015. PHC Facilities that were changed from clinics to CDCs/CHCS or moved to a new location during this time period will be excluded. For testing reliability, facilities that had both self-assessment and external (OHSC) audits within the same period between 01 April 2014 and 30 June 2015 will be included.

2.2.2 Sampling strategy & sample size

The 6 health districts of the WC province mentioned above are divided into 32 health sub-districts. A sampling frame of eligible facilities from all sub-districts will be generated, sampling will involve selecting 1 of each type of facility (clinic, CDC, CHC) within each sub-district. If there is more than 1 of a certain type of facility then at least 50% of them will be randomly selected using the Excel (Microsoft, 2013) random number generator function. These facilities (selected sample) will be requested to submit their audit data.

For objective 1 and 2 a random sample of facilities (50%) that had both a baseline (external) audit as well as a self-assessment audit 3-4 years later will be selected from each district/substructure.

For objective 3, a sample of PHC facilities in each rural district and each of the 4 metro substructures that had both an external (OHSC) audit and a self-assessment audit conducted within the same period 01 April 2014 to 30 June 2015 (15 months) will be selected.

2.3 Measurement

2.3.1 Data Collection

As noted above, the baseline audits at fixed health facilities were conducted by an external agency, the Health Systems Trust in 2011/12. They used their own assessors, oversaw the audit process, compiled the data and generated the NCS reports. Annual self-assessment audits were then conducted by WCG:H staff in 2013, 2014 and 2015. The OHSC inspectors have also conducted external (OHSC) audits at a sample of facilities after the baseline audits. Existing WCG:H staff who conducted self-assessment audits included quality assurance managers, facility managers, nursing and medical staff as well as administrative support staff. The teams did self-assessment audits on facilities other than their own. The instruments were in English. The scores were captured on hard copy assessment questionnaires and checklists, and then captured electronically at a later stage. The self-assessment audits were entered on the web based live District Health Information System version 2 (DHIS2) by the relevant QA manager or information officer responsible for each facility. Only the score for each question was captured online, checklists however were not loaded onto DHIS2, and therefore only reports of compliance scores and assessment questionnaires are available on DHIS2. Checklists may contain several items to score one question. The checklists for the baseline audits are not available. Electronic copies of the external (OHSC) audit reports are

available from the WCG: H provincial quality assurance sub-directorate, however the checklists are not available.

For this study, hard copies of all the NCS checklists and assessment questionnaires (audit tools) for facility self-assessments done will be sourced from the relevant quality assurance managers for each facility or district. They will be couriered to the Quality Assurance sub directorate at the Health Impact Assessment unit of the WCG:H. This unit has sub-directorates for epidemiology and disease, health research, programme impact evaluation, quality assurance and increasing wellness. Using the adapted assessment tools (data capture forms) for OHS and IPC, a research assistant will extract the relevant data from the hard copies or DHIS2 and electronically capture it on a pre-designed Excel (Microsoft, 2013) worksheet. The research assistant (English speaking) will be trained on how to extract and capture the relevant data to ensure only the relevant pre-identified OHS and IPC measures are captured. To determine reliability, comparison of the data from external (OHSC) audits and self-assessment audits conducted within the same 15 month period (01 April 2014 to 30 June 2015) will be captured using the same method.

2.3.2 Assessment tool

The audits were conducted using a standardised assessment questionnaire provided by the NDoH for NCS audits. There were 4 assessment questionnaires, one for clinics (20 pages long) one for CDCs/CHCs (44 pages long), one for district or sub district management offices (16 pages long) and one for hospitals (107 pages long). Each questionnaire covers the 7 domains of the NCS divided amongst several functional areas applicable to the type of facility (e.g. clinic manager, clinical services, pharmacy). Certain measures of the NCS have an associated multi-item checklist. Measures are either assessed by direct observation, patient or staff interview, patient record assessment or by reviewing documents. There is (a) yes or no questions scored 1 or 0 respectively and (b) checklist type questions where the relevant checklist is used to score the question between 0 and 1 (e.g. 4 out of 10 items on a checklist will score 0.4). As indicated above, the full assessment questionnaire covers patient rights (domain 1), patient safety (domain 2), clinical support services (domain 3), health promotion and disease prevention (domain 4), effective leadership (domain 5), operational management (domain 6) and facilities and infrastructure (Domain 7). The 4 NCS assessment tools were developed by the NDoH in consultation with provincial departments of health and partners such as private hospital groups. The assessment tools were amended following the baseline audits and again in October 2013 by the OHSC and thus there will be

some differences in the tools used at baseline in 2011 and after October 2013. The most notable change was in the risk rating categories of specific measures. While the NCS baseline 2011 version had three risk categories, the 2013 version had four risk categories with some measures being re-categorised.

The clinic and CDC/CHC assessment tools were scrutinised by the primary investigator and have been adapted to extract measures relevant to OHS and IPC only (appendices D & E) and these will serve as the data capture forms for this study. To allow for comparison between baseline (external) audit results and follow up self-assessment audit results, measures were classified into one of the four risk categories according to the NCS 2013 version of the tool.

2.3.3 List and definition of variables

CHCs/CDCs will have more variables than clinics due to size and services provided.

Table 1: List, definition and scale of variables.

Variable	Definition	Scale
District	District located	Categorical
Rural	Rural or Metro location	Categorical
Facility name	Name of health facility	Categorical
Facility type	Clinic or Community day centre or Community health centre	Categorical
Audit type	Baseline (external), self-assessment or external (OHSC) audit	Categorical
Month	Month audit conducted	Categorical
Year	Year audit conducted	Categorical
Functional area assessed	Department, service area or unit in health facility. E.g. Clinic manager, pharmacy, maternity	Categorical
Adequate infection prevention and control (IPC) policy	Checklist (score out of 10)	Numerical
IPC education/training plan on tuberculosis (TB) and universal precautions	Annual in service training/education plan on TB and universal precautions	Categorical
Educational material	For staff on IPC and occupational health and safety.	Categorical
Educational material	For patients on healthcare associated infections	Categorical
Food and Drug Administration approved respirators	Present and staff fit tested	Categorical

TB patient room separation	Adequate separate room or area for infectious TB patients	Categorical
Ventilation of consulting rooms	Adequate ventilation for respiratory IPC	Categorical
Standard precautions policy	Checklist (out of 10 for adequacy)	Numerical
Reporting system for needle stick injuries	Present or not	Categorical
Sharps disposal	Observation of sharps disposal-safe or not using checklist	Numerical
Annual hand hygiene campaign	Present	Categorical
Up to date decontamination policy	Compliance >80%	Categorical
Staff are able to explain sterilisation procedure	Checklist	Numerical
Evidence of medical examinations on at risk staff	Evidence/ records present	Categorical
Needle stick(NSI) injuries post exposure prophylaxis (PEP)	Records of PEP provision to staff and re-testing	Categorical.
Fire certificate	Present	Categorical.
Emergency drills	Conducted quarterly	Categorical.
No obvious safety hazards	Observation	Categorical
Cleaning materials/ equipment available, labelled and stored	Checklist	Categorical
Facility score for extreme measures	Outcome: average score for extreme measures	Numerical
Facility score for vital measures	Outcome: average score for vital measures	Numerical
Facility score for essential measures	Outcome: average score for essential measures	Numerical
Overall facility score	Outcome: Weighted facility score	Numerical
Compliance	Outcome: non-compliant, conditionally compliant or compliant based on facility score	Categorical.

2.3.4 Validity & Reliability

2.3.4.1 Data Quality

Data was collected during the self-assessment NCS audits by trained internal audit teams. The primary investigator will not have influence over this process. All assessment questionnaires and checklists (where applicable) used for these self-assessments will have to be checked for missing data, illegible entries or lost records. An attempt will be made by the author to verify or confirm missing or eligible entries with the facilities concerned

telephonically. However, if this cannot be corrected then this data will be omitted from the final analysis.

2.3.4.2 Instrument reliability

Standardised instruments (the assessment questionnaire and checklists) were used to do the self-assessments which should reduce random measurement error. These tools were developed by the NDoH and piloted in 2008, revised and piloted again in 2010 in a sample of public and private hospitals and CHCs. Amendments to the tool also occurred in November 2013. The NCS were developed to be generally applicable to all healthcare levels and settings and relevant to South Africa.[2] Self-assessment auditors were internal staff of the WCG:H. They consisted of facility and quality assurance managers and professional nursing staff, medical staff and administrative support staff who were internally trained on how to conduct the audits by the relevant QA manager for the district. This was conducted in order to reduce inter-observer variation. Comparison of external (OHSC) audits and self-assessment (internal) audits done within 15 months of each other will thus help determine the reliability of the tool.

2.3.4.3 Instrument validity

Validity of the instrument is defined as the extent to which the assessment questionnaires and checklists actually measures what it is meant to measure. Following extensive piloting of the assessment tools, significant technical input was used to revise them, including the benchmarking of the standards against other accreditation systems. South African legislation, guidelines from the NDoH, World Health Organisation and other relevant international standards for health quality service accreditation were incorporated into the NCS. Unfortunately, the NCS contain mainly structure measures with very few process and no outcome quality measures. The emphasis is on whether health establishments comply with structure quality measures such as the infrastructure, staffing of facilities and the capabilities of these staff, the policy environment, and the availability of resources within an institution. Actual patient outcomes such as morbidity, mortality, patient satisfaction and improved health status are not measured.

There may be information bias in the form of social desirability bias in the self-assessments conducted by peers/colleagues who are WCG:H staff and may have been reluctant to give their colleagues poor compliance scores. However, auditor training and the use of a standardised assessment tool with checklists should have limited this effect.

With regard to study representativeness, only eligible health facilities will be included in the main analysis, which may result in selection bias. In the instrument reliability part of the study, a random sample of eligible fixed PHC health facilities in each district will be chosen.

2.4 Pilot study

A pilot using hardcopy questionnaires and checklist data from one health facility in the MDHS and the DHIS2, will be conducted to test the logistical procedures and data capture system and quality of the data in March 2015 after ethics approval.

3 Analysis plan

3.1 Data management

The relevant OHS and IPC data will be captured electronically on Excel (Microsoft, 2013). All captured data will be double entered. The hard copies of the original and adapted questionnaires and checklists (capture form) will be stored in a locked store room at HIA unit when not in use. The computers used will be password protected and only accessible to the research assistant and the author. All original assessment questionnaires and checklists hard copies will be returned to the responsible QA manager after the study is complete. After capturing is complete, all electronic data will be stored on a password protected work computer of the author (and backed up on his password protected personal laptop) for the duration of the study.

3.1 Statistical analysis

Data analysis will be done using Stata statistical package version 12.[5] Exploratory data analysis will be carried out and help to clean the data. Descriptive statistics will be calculated

to summarise the data. Bivariate analysis will be conducted to assess associations between the key variables and type or location of facility.

Reliability (interrater agreement) will be analysed by using percentage agreement and the kappa statistic.

A confidence level of 95% will be used as the level of statistical significance.

While every effort will be made to verify missing data, missing data will not be included in the final analysis.

4. Ethics

4.1 Conflict of interest

The primary investigator was not involved in the NCS self-assessment audits or the capturing of data and therefore had no influence over this process. The primary investigator will rely on data previously collected for this study. This will also form part of his expected tasks as part of his work attachment to the quality assurance sub directorate at the HIA unit for the period September 2014 to June 2016.

4.2 Authorisation and access to data

All the formal processes and approvals required by the WCG:H for access to the required data and health facilities will be followed. The WCG:H requires formal ethics approval of a study before they will consider approval for studies at WCG:H health facilities. This process will entail informing the relevant QA managers and facility managers and acquiring the necessary permissions.

4.3 Confidentiality

A confidentiality memorandum of understanding between the WCG:H and the primary investigator will be signed based on the principles of the WCG:H policy on use of routine or other in house data. The research assistant will also have to sign this MOU. All hardcopy assessment questionnaires and checklist will be in a locked storeroom at the HIA unit when

not in use. Password protected computers will be used to capture the data. After capturing, all electronic data will be on the password protected work and personal laptop of the primary investigator. After the study all electronic data will be kept on the password protected work computer of the Deputy Director for QA at the HIA unit.

4.4 Benefits

The study findings will be used by the WCG:H to identify the gaps and corrective actions required to improve OHS and IPC at health facilities and make recommendations for health facilities regarding compliance with the OHSA and the NCS. This will help increase the level of compliance at public health facilities in the WC with both the OHSA and NCS and decrease their chances of receiving contravention notices from either the Department of Labour inspectors or the Office of Health Standards Compliance inspectors. The information could help to improve not only the quality of patient care but also the standard of OHS and IPC in public health facilities in South Africa. There will be community and individual (staff) benefit at these facilities where improvements are achieved. No studies have done an analysis of the NCS audits for OHS and IPC compliance.

4.5 Risks

Findings from this study may require significant resources to be expended by the WCG:H to achieve the required compliance with the NCS and OHSA.

5. Communication

The study will be conducted for the partial fulfilment of a Master of Medicine (MMed) degree in Occupational Medicine. The final report will be submitted to the University of Cape Town. The study findings will be in a “journal publication ready” manuscript format that will aid subsequent submission for publication in a suitable academic journal. A report will be submitted to the deputy director for quality assurance at the WCG:H for onward dissemination to all the facilities operated by WCG:H and the NDoH as well as presented at the relevant Provincial Quality Improvement Committee (PQIC) meeting which has representatives from all the districts in the WC.

6. Logistics

The study will commence in March 2015 once all approvals are obtained. Data collection and extraction will take 4 months and data analysis and write up a further 4 months.

7. Resources

The research assistant will be employed by the University of Cape Town (UCT) for a 3 month period initially and be extended if necessary. The hardcopy original assessment questionnaires and checklists will have to be transferred from all facilities to the QA sub-directorate office at the Health Impact Assessment (HIA) unit. Internal existing WCG:H transport methods will be used if available. Computer facilities at UCT and the HIA unit will be used at no additional cost. Training of the research assistant and primary investigator will be required on how to conduct a NCS self-assessment. Printing of assessment questionnaires and checklists will be done at the UCT School of Public Health & Family Medicine.

8. References

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PART B: LITERATURE REVIEW

1. Introduction

1.1 Background

Accreditation of healthcare facilities has been recommended by many national organisations as an intervention to improve patient safety and quality healthcare.[1] The South African National Department of Health (NDoH) has the responsibility of providing the best quality care to users of health services. A ten point plan for health sector improvement issued by the NDoH in 2010 has improvement of the quality of health services as one of its objectives.[2] The National Core Standards (NCS) for Health Establishments in South Africa [3] was published by the NDoH in 2011. The seven domains of the NCS are: 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.[3] Each domain is defined by the World Health Organisation (WHO) as an area of potential risk for quality and safety. It was produced as a statement of what is essential and expected to deliver safe, quality care in both the public and private sectors.[3] It provides definitions and standards of what is expected. The National Health Amendment Act of 2013 provided for the establishment of the Office of Health Standards Compliance (OHSC), which was established in September 2013, and must monitor and enforce compliance with the NCS. Healthcare managers in South Africa will be significantly engaged with the NCS as regulations governing the OHSC are set to be promulgated in the near future.

Although the main goal of the health system is delivering quality health care to its users, the NCS recognises that a support system that ensures the system delivers its core business is required and that healthy, productive staff are vital in achieving this objective.[3]

Independently, the South African Occupational Health and Safety Act 85 of 1993 (OHSA) *requires that an employer shall provide and maintain a working environment that is safe and without risk to the health of their employees.*[4] Occupational health and safety (OHS) is concerned with employee health, safety and wellbeing and fostering a healthy and safe work environment. Section nine of the OHSA requires employers to protect persons other than their employees such as patients, visitors, students, volunteers and contractors.

Infection prevention and control (IPC) has long been a responsibility of health facilities on the common law Duty of Care principle, which is that a person (healthcare worker in this case) acts and carries out their duties, with attention and caution, as a reasonable person in their circumstances would. If their actions do not meet this standard of care, then acts or

omissions could be considered negligent.[5] Every healthcare worker should ensure that no harm is done to patients, visitors or employees. IPC is concerned with preventing hospital acquired infections and factors related to the spread of infection within healthcare settings. There is therefore considerable overlap between IPC and OHS activities as they have a common goal to ensure the health and safety of patients, visitors and employees. OHS and IPC measures cut across the seven domains in the NCS.

1.2 Objectives of the literature review

The objective of this literature review is to review information on:

- a) auditing or measuring standards in healthcare facilities (with an emphasis on infection prevention and control and occupational health and safety) and the impact of such auditing;
- b) reliability (repeatability) of self-assessment (internal) audits compared to external audits of healthcare facilities
- c) factors associated with good compliance with OHS and IPC standards at healthcare facilities.

1.3 Search strategy

Several electronic sources of information were searched for relevant articles by the primary investigator including PubMed Central, EBSCOhost (Academic Search Premier, Medline, CINAHL) and Google Scholar using the following key words in combinations (using Boolean operators with truncation): national core standards, standard*, measure*, indicator*, audit*, , compliance, quality, quality assurance, accreditation, health facilit*, health establishment*, health care, health care facilit*, health care establishment*, hospital*, clinic*, community health cent*, medical facilit*, primary health care, performance, infection control, infection prevention and control, occupational health and safety, work or workplace health, reliability, validity, internal, self-assessment, external and research. Only English language articles were included that were published between 1990 and 2015. The author screened titles and abstracts for relevance and read full length articles for possible inclusion.

The references of selected articles and appropriate review articles were evaluated to identify additional studies. Websites of international accreditation/ certification agencies were also checked for publications and reports of accreditation processes in specific countries.

2. Standards for health care

2.1 Definitions

Quality in health care is defined in light of the providers' technical standards and the degree to which an organisation meets its users' needs and expectations.[6] The World Health Organisation (WHO) mentions six dimensions of quality that a health system should attempt to improve.[7] "These dimensions require that health care be effective, efficient, accessible, patient-centred, equitable and safe." [7] Safety incorporates the minimization of risks of detrimental adverse effects, injury, infection, or other dangers related to service delivery, and involves employees and the patient.[6]

Quality Assurance is a set of activities which focuses on systems and processes, uses data to analyse service delivery processes, and is carried out to set standards to evaluate and improve performance so as to meet the needs and expectations of users and the community.[6]

Continuous quality improvement aims to identify gaps between actual service delivery and the expectations of services. It continually attempts to achieve a standard of excellence in a healthcare system over time.[8]

"Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change." [9] The audit cycle is crucial to the audit concept and involves five stages which are: choosing a topic, specifying practice standards, testing actual practice against these standards, corrective action and finally demonstrating improvement in practice through subsequent data collection and closing the loop. [10]

2.2 Approaches to regulation of healthcare quality

Government and professional bodies generally use three main regulatory approaches to maintain, improve and ensure quality of healthcare. Each has a distinct role and a different focus, but certain features are similar. All three are based on external assessment against standards and they share a mutual goal of safeguarding the public and upholding quality health care.[11] *Licensing* is “a statutory mechanism by which a governmental authority grants permission to an individual practitioner to engage in an occupation (similar to registration) or to a healthcare organisation to operate and deliver services.”[11] For example, medical doctors usually require qualifications from an accredited university in order to be registered/licensed with the medical body or council for that country before being able to practice in that country. *Certification* is “a process by which a recognised authority appraises and recognises an individual or an organisation as having met pre-determined requirements (set at a minimum level to ensure minimum risk).”[11] For example, in many countries the international organisation for standardisation provides certification for hospital laboratory, radiology and quality assurance systems.[11] *Accreditation* is “a process of review that healthcare facilities participate in to demonstrate the ability to meet predetermined criteria and standards (set at maximum achievable level to stimulate improvement over time) established by a recognised professional agency.”[11] Although the terms accreditation and certification are often used interchangeably, accreditation usually applies only to organizations, while certification may apply to individuals, as well as to organizations. Accreditation has a strong performance improvement context and while traditionally a voluntary process, some countries have more recently made participation of healthcare organisations in accreditation programmes compulsory.[11] In developing countries a modification of accreditation, known as facilitated accreditation, has been used, where the accrediting organisation helps the facility to undertake quality improvement activities necessary to achieve adequate levels of compliance with the standards.[11]

Additional patient safety considerations which were highlighted by Abbing et al [12] as shortcomings in the European Union’s regulatory policies for healthcare are better pharmacovigilance legislation that ensures monitoring of medicines and adequate medical device regulation.

One alternative non-regulatory approach to health care quality assessment, is the use of report cards which have been used in the American health care system since the late 1980s.[13] The purpose of this public disclosure of information on quality is twofold: to facilitate informed choice and to stimulate quality improvement.

2.3 History of healthcare standards

As summarised by Whittaker et al [8], prior to 1950 sparse official assessment of quality in healthcare services occurred. An exception was the ground-breaking work done by Ernest Codman, a United States surgeon, resulting in many assessment processes used today, including: morbidity and mortality meetings, a systematic approach to patient post-surgery outcomes, standardisation of hospital practices and case report systems for adverse outcomes. Codman's efforts led to the establishment of the American College of Surgeons and its Hospital Standardisation Programme which ultimately became the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).[8] Between 1950 and 2000, many quality improvement methods and healthcare accreditation programmes were developed that were inspired by the Joint Commission on Accreditation of Healthcare Organizations. The Secretariat of the International Society for Quality in Health Care was founded in 1995, is currently based in Dublin, Ireland, and promotes quality improvement initiatives in health care globally.[8] Additionally, the International Society for Quality in Health Care is responsible for assessing the standards of organisations (accreditors) who set the benchmarks in healthcare safety.

In 1993, hospital accreditation was introduced in South Africa at pilot sites across the country including public and private hospitals.[8] In 1995, the Council for Health Service Accreditation of Southern Africa (COHSASA), a Non-Governmental Organisation, was formed to implement quality improvement initiatives and conduct accreditation of South African hospitals.[8] Council for Health Service Accreditation of Southern Africa's strategy was to promote steady step wise improvement that provides encouragement to attain accreditation. These methods have been shown to be useful in large public sector hospitals which initially had a low baseline score, but were able to attain adequate compliance within three years.[14] Council for Health Service Accreditation of Southern Africa identifies itself as a pioneer in the use of facilitated accreditation approach in developing countries.[8]

2.4 Infection prevention and control standards for health care

Healthcare staff are also at risk of infection, as well as other occupational hazards, that may affect their ability to provide the expected standard of quality care.[15-17] Safety includes providing health care that minimises risk and harm to the service users and staff. Infection prevention and control is thus an important component of quality in health care because it aims to reduce the risk of infection transmission within health facilities and to protect staff.

The WHO, Centres for Disease Control and Prevention, Joint Commission International (JCI) and various other networks or organisations have several tools and guidelines available for IPC, as well as audit or assessment tools such as the infection control assessment tool for PHC facilities which can be used for self-assessment of IPC and continuous improvement at PHC facilities.[18]

Domestically, the South African NDoH has a national IPC policy and strategy dated April 2007[19]. However poor infection control practices in PHC facilities in South Africa have been reported.[16, 20]

Hand hygiene is an important component of IPC. A systematic review by the WHO in 2013 evaluating the impact of hand hygiene improvement interventions to reduce transmission and/or infections by multidrug-resistant organisms found that the majority of papers showed strong evidence that improved hand hygiene practices lead to a reduction in healthcare-associated infections and/or transmission or colonization by multi drug resistant organisms. However the studies were in high income countries and there is a lack of studies in low and middle income countries. [21]

The NCS incorporates measures that make up standards for IPC based on some of the above mentioned guidelines [3].

2.5 Occupational health and safety standards for health care

Internationally, the International Labour Organisation (ILO), WHO and Centres for Disease Control and Prevention provides conventions, guidelines and/or standards for labour in the workplace. South Africa has ratified 27 ILO conventions, of which 23 are in force, 2 have been dropped, while 62 conventions are not ratified.[22] One of the ratified conventions, the ILO Occupational Safety and Health Convention no. 155 (of 1981) includes articles related to principles of national OHS policy, action at national level and at the level of employers. However, the ILO Occupational Health Services Convention No. 161 (of 1985) and its accompanying Recommendation (No. 171) that encourages countries to develop occupational health services for all workers, including those in the public sector, has not been ratified.[22]

The OHS assessment specification 18000 series is a widely recognised internationally applied British Standard for OHS management systems that comprises two parts (18001 and 18002).[24] The OHS assessment specification 18001 is an assessment specification for developing an OHS management system for risk control and performance improvement.[23,

24] It helps organisations (including healthcare providers) to control health and safety risks by putting in place the policies, procedures and controls needed to achieve the best possible working conditions.[23]

A systematic review of the effectiveness of OHS management systems found that mandatory OHS management system interventions resulted in positive effects including increased health and safety awareness, improved employee perception of the physical work environment, increased worker participation in health and safety activities, decrease in loss-time injury rates and increase in workplace productivity.[25] However, the authors concluded that there was insufficient evidence to recommend for or against specific OHS management system interventions.[25]

Domestically, the South African OHSA and regulations provide the minimum legally required standard for OHS.[4] The Department of Labour is responsible for inspecting workplaces and enforcing these standards. The main elements of the legislation are employer and employees responsibilities, appointment of persons responsible for OHS, selection, training and appointment of health and safety representatives, employee hazard education, workplace health risk assessment, medical surveillance of at risk employees and first aid provisions. The South African Society of Occupational Medicine's also publishes guidelines for OHS and has one for OH audits.[26]

The NCS incorporates measures that make up standards for OHS based on some of these above mentioned guidelines/legislation.[3]

2.6 The National Core Standards

The main purpose of the NCS is to develop a common definition of quality care, establish a benchmark against which healthcare facilities can be assessed and provide for the national certification of compliance of health establishments with mandatory standards.[3] There are seven domains as explained above. Each domain has sub-domains within which are a set of standards and each standard has a number of criteria that are measurable and achievable as reflected in the measures. Each criterion is broken down into measures which have been modified to be context specific (e.g. clinic, CDC/CHC or hospital). The assessment tools were piloted in 2008 and in 2010 before further revision including a risk based approach and benchmarking of the standards against other accreditation systems.[3] They were further revised after the baseline audits in 2011. However the majority of the measures remained the same. Important notable changes were that key IPC and OHS measures that were considered to be higher management level responsibility, were moved from the clinic and CDC/CHC

baseline version 2011 audit tools into a new district/sub district office tool (October 2013 version) which is for auditing district/sub district offices instead. Consequently, for example, the measure “Responsible persons are designated as specified in the OHS Act with signed letters which outline their responsibilities” and other legally required measures covering OHS committees, staff OHS education, risk assessment and medical surveillance are not assessed at PHC facility level in the NCS 2013 version of the tool.

One major deficit of the NCS is that there is an emphasis on structure measures and very little process or output measures. Structure measures look at system inputs such as human resources, infrastructure, availability of equipment and supplies.[27] Process measures address activities or interventions carried out within the organisation in the care of patients or the management of the organisation or staff such as patient education, medicine administration, equipment maintenance and clinical guidelines.[27] Outcome measures look at the effect of the intervention used on a specific health problem such as patient mortality and wound healing without complications like infection.[27] This makes assessment of actual patient outcomes and/or quality improvement difficult.

The component measures are classified according to a risk-rating framework adapted from the International Organisation for Standardisation 31000: 2009 risk management)[28] and are classified into four risk levels: Extreme, Vital, Essential and Developmental.

The proposed procedure when the OHSC conducts a NCS inspection at a healthcare facility, and generates an inspection report that shows non-compliance (score <50%), is that the facility manager will get a non-compliance notice and a quality improvement plan (QIP) template along with the inspection report. The facility manager will need to populate the QIP template with concrete actions to correct areas of non-compliance and implement it (with the relevant support), and then conduct a facility self-assessment within the stipulated time period given by the OHSC. A follow-up re-inspection or verification by the OHSC will then occur within the stipulated time period and if this reveals persistent significant non-compliance, enforcement actions in terms of the National Health Amendment Act 12 of 2013 may result.[OHSC, oral presentation, March 2015]

3. Accreditation/ certification/ audit: impact and compliance

3.1 Impact

The majority of the literature with regard to accreditation of health establishments was found to focus mainly on hospitals and/or high income countries.

A systematic review of 66 articles/documents by Greenfield et al [29] in 2008 aiming to identify and analyse research into healthcare accreditation categorised ten topics that impact on accreditation of health facilities. Only 2 topics, ‘promote change’ and ‘professional development’ showed consistent positive findings. Key findings are shown in Table 1.

Table 1 Summary of key findings from systematic review by Greenfield et al [28] by topic category

Category	Key Findings
1. Professions’ attitude to accreditation	Inconclusive. Accreditation programmes were both supported and criticised. Professionals from rural health services listed cost, difficulty in meeting standards and collecting data as significant reasons for not participating.
2. Promote change	The activity of preparing and undergoing accreditation promotes change in health organisations.
3. Organisational impact	Organisational impact remains unclear. Participative management and organisational support for the process affects outcomes positively.
4. Financial impact	Under-researched. A developing country (Zambia) study showed that overall financial sustainability was not possible.
5. Quality measures	Inconsistent findings with regard to whether accreditation programmes improve quality outcomes.
6. Programme assessment	Inconsistent results as to whether accreditation programmes are valid.
7. Patient satisfaction	Under-researched. No association found between patient satisfaction and hospital accreditation.
8. Public disclosure	Under researched.
9. Professional development	There is an association with improved health professional development and accreditation programmes.
10. Surveyor (auditor) issues	Under researched.

The key findings of more recent systematic reviews of the effects of accreditation and/or certification of hospitals on organisational processes and outcomes are summarised in Table 2.

Table 2: Systematic reviews of the effects of accreditation and/or certification of hospitals on organisational processes and outcomes
(adapted from Brubakk et al, 2015)[1]

Reference	Aim of review	Study design	Number of included studies	Key findings
Brubakk et al. 2015 [1]	To systematically assess the effects of accreditation and/or certification of hospitals on both organisational processes and outcomes	Several databases up until July 2014. No language restrictions. Included systematic reviews, randomised controlled trials (RCTs), nonrandomized controlled trials, controlled before and after studies (CBAs), and interrupted time series (ITS)	Four in total, 3 systematic reviews (in this table below) and 1 RCT (Salmon et al[27]).	Did not find evidence to support accreditation and certification of hospitals being linked to measurable changes in quality of care as measured by quality metrics and standards.
Flodgren et al 2011 [28]	To evaluate the effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour and patient outcomes.	Several databases up to May 2011. No language restriction or publication requirements. Included RCTs, controlled clinical trials (CCTs), ITSs & CBAs.	Two in total, 1 RCT, 1 ITS	Inconclusive due to the limited high quality controlled studies of effectiveness of external inspection systems. Salmon et al 2003 RCT discussed below.
Alkhenizan & Shaw 2011 [29]	To evaluate the impact of accreditation programmes on the quality of healthcare services	Several databases up until 2009. No language restrictions. Included clinical trials, observational studies and qualitative studies.	26 in total, 1 RCT.	Accreditation improves the process of care provided by healthcare services as well as clinical outcomes of a wide spectrum of clinical conditions.
Matrix Knowledge Group 2010 [30]	To produce an overview of the results and methodologies of studies assessing the impact of certification of hospitals	Several databases between January 2000 and 31 August 2010. Included studies containing an element of comparison.	56, 40 studies with a quantitative design of which 1 presented empirical data.	Majority of studies showed that certification procedures in hospitals have a positive impact on improving organisation, management and professional practice in hospitals. Limited studies on the association between accreditation/certification and improvement in health outcomes.

One randomised control trial from South Africa by Salmon et al [30], showed that hospitals (n=10) that started a facilitated accreditation programme increased compliance scores substantially (38% to 76%), compared to control hospitals (n=10) where the scores remained the same (37% to 38%). The score on the element health and safety increased from 35% to 75% in the intervention hospitals and from 28% to 32% in the control hospitals. The score on the element infection control increased from 45% to 88% in intervention hospitals and from 39% to 42% in control hospitals. However, of the 8 quality indicators measured, only one (nurses' perceptions of clinical quality) increased in the intervention hospitals compared to the control hospitals.[30] Furthermore, this study had methodological flaws including attrition and reporting bias.[1]

There are two additional relevant articles, not included in the reviews above, one by Mate et al[34] in 2014 studied accreditation as a path to universal quality health coverage, and showed that accreditation supports the efficient and effective use of resources in healthcare services. Another study by Ladha-Waljee et al [35] in 2014 that found that accreditation is associated with the promotion of quality and safety culture. In summary, the impact of hospital accreditation on organisational processes and outcomes is inconclusive. All the above studies were hospital based and not in a PHC setting.

When looking specifically at PHC, a review published by O'Beirne et al in 2013 evaluating the status of accreditation in PHC found a scarcity of evidence with regard to how accreditation affects outcomes and whether it improves quality, perceptions of care or costs.[36] Two more recent relevant studies were found, but they only evaluated perceptions of accreditation. The study by El Jardali et al[37] in Lebanon (2014) aiming to understand the impact of accreditation on quality of care showed that the perception amongst health providers and directors was that there was a positive impact on PHC centres and that accreditation was associated with improved health care and quality. In another study in the Netherlands, primary care professionals who participated in the practice accreditation programme in 2015 were interviewed to identify the determinants of impact of the programme. Factors perceived to be enablers of implementation were designating one responsible person for the programme, clear lines of communication and having enthusiasm for quality improvement. However it was perceived that patient care was not directly affected by the programme.[38]

According to a 2014 study, when comparing hospital accreditation in low- and middle-income countries (LMIC) with high income countries (HIC), while the basic structure and process of accreditation systems used is similar, the key difference is that in developing

countries the main focus is on improving overall nationwide care and supporting the weakest facilities. In developed countries accreditation focuses on identifying the best facilities.[39]

3.2 High income country compliance

In Australia, the National Safety and Quality Health Service Standards (NSQHS Standards) were developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC). The key negative findings in the 2011-2012 National Accreditation report were that five areas required further improvement, namely, workplace health and safety, risk management, emergency and disaster management and credentialing and scope of practice, and infection control programmes. However 89% (302/341) of facilities received full accreditation at the initial survey. [40]

The American based Joint Commission International has been accrediting American hospitals for a number of years. American hospitals have increased compliance with the Joint Commission's accreditation standards over time with the percentage of hospitals with a score greater than 95% increasing from 10% in 2002 to 81% in 2013.[41]

A key part of the Accreditation Canada on-site survey is determining whether organizations meet the 36 Required Organizational Practices. These are evidence-based practices that mitigate risk and contribute to improving the quality and safety of health services.[42] For Canadian healthcare organisations (n=277) that underwent assessments in 2012, in the element infection control, hand hygiene practices scored below the 85% compliance level (but improved from 73% in 2010 to 82% in 2012).[42]

The Care Quality Commission is the independent regulator of health and adult social care in England. In their 2014/15 state of health care report, primary medical services (total=976) were rated as follows: 4% inadequate, 11% require improvement, 82% good and 3% outstanding. [43]

In summary, in high income countries there is limited reporting on PHC compliance, with an emphasis on hospital accreditation, which has shown a positive trend over time in compliance scores.

3.3 Low-and middle-income country compliance

A study in Mali, a low income country, in 2001 to determine the impact of self-assessment on compliance with the quality of care standards showed that there was a significant

difference between the intervention group (54%) and the control group (44%) overall.[44] However, it is noted to be a resource intensive intervention.

Meanwhile in Iran, a middle income country, in a study to determine the compliance with the Joint Commission International organisation-based standards for IPC in 23 hospitals using a self-reported questionnaire on hospital staff, an excellent (> 75%) pooled mean hospital IPC score of 79%, was achieved.[45]

Country wide baseline public health facility audits done in South Africa, a middle income country, by the Health Systems Trust between 2011 and 2012 showed that the national average score for IPC was 47% in PHC facilities and 64% in hospitals, while in the Western Cape Province, the average IPC scored was 50% (includes hospitals and PHC facilities). [46] This percentage represents the mean score for all facilities and is based on all IPC measures in the audit for each facility. Nationally, the number of facilities compliant with the priority area of IPC was very low at 0.82% (32 out of 3880). The national average (mean) score for the functional area “management of occupational health and safety” was 76%, suggesting good compliance with regard to OHS, however the number of facilities classified as compliant with OHS was not reported.[46]

In summary, while limited studies in LMIC have shown the positive impact of accreditation on performance scores, again the focus is mainly on hospital accreditation. High income countries report higher initial compliance scores than LMICs. There is a dearth of reports on PHC facility compliance in both settings.

4. Self-assessment vs external assessment (Inter-rater reliability)

There are a limited number of studies evaluating reliability of quality indicators. Those that do exist are related to clinical care and not indicators for health establishment compliance with process and structure standards. Williams et al [47] assessed the reliability of self-reported standardised clinical performance indicators that were introduced by the Joint Commission on Accreditation of Healthcare Organisations in July 2002 and that were implemented in about 3400 accredited American hospitals. In 30 hospitals they compared self-reported data with re-abstracted data on the same medical records and found the mean data element agreement rate to be 92% and a mean kappa statistic of 0.68, indicating acceptable reliability for indicators used to assess and improve hospital performance on selected clinical topics. Hermida et al [48] in a study in Ecuador examined the reliability of self-assessment in measuring compliance with quality standards for maternal and new born care improvement intervention by reviewing medical records. The level of agreement with

external evaluators ranged from 0.36 to 0.81 (fair to almost perfect) using kappa statistics. Team leadership, understanding of the tools and facility size was not associated with level of agreement.[48]

In contrast, a systematic literature review in 2010 on the measurement properties of occupational health and safety management audits reported that studies of inter-rater reliability showed that it was frequently unacceptably low.[49]

5. Factors associated with IPC and OHS compliance

Studies showing the benefits of audits in improving infection control standards emphasise the requirement for a well-designed audit programme with explicit, evidence-based criteria and interventions.[50] User involvement in the audit and the interventions is vital to overcome barriers to change.[46] Furthermore, Bryce et al showed in a tertiary hospital that a standardised infection control audit can be used to implement change where 95% of 257 recommendations from the audits were implemented over a 13 year period. However the improvement relied on an infection control team and the audited unit staff to ensure implementation.[51]

Infection control performance was significantly higher in teaching hospitals than non-teaching hospitals in a 2005 Japanese study.[52] Teaching hospitals were found to have more infection control resources such as full time infection control practitioners, infection control link nurses and/or infection control teams than non-teaching hospitals. Hospital accreditation and larger size were also significantly associated with higher infection control performance scores.[52] In a scoping review by Kings College (London) in 2008, good leadership in hospitals at ward level and above was associated with effective action in infection control measures.[53] The type of leadership was also found to be important, with leaders who share the vision of what the organisation can be, who develop and stimulate others and are active and engaged with their teams having a greater impact.[53] However, even positive leadership was adversely affected by direct supervision of large numbers of staff. [53]

Equally important, compliance with OHS regulation was found to be associated with employer awareness of OHS regulations and employee OHS training and communication.[54, 55]

6. Conclusion

In conclusion, there are limited studies on both the compliance and the impact of accreditation assessments or IPC or OHS audits at PHC facilities, especially in LMICs. While there is some evidence that accreditation or certification assessments of hospitals improve compliance over time in high income countries, there is insufficient evidence for LMICs, with the barrier of resource intensiveness. Furthermore, there is inconclusive evidence to conclude that accreditation is associated with improved quality outcome indicators or improved OHS/IPC indicators. In addition, the comparison of self-assessment versus external assessment audit results in PHC facilities is also under-researched.

The current study will therefore contribute to the literature on (1) instrument or process reliability by comparing results from self-assessment of OHS and IPC against nationally mandated standards at PHC facilities in the Western Cape province of South Africa (LMIC setting) with those from external assessment; and (2) on impact of this process by analysing changes in compliance results/scores 3 years later at follow up assessment.

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PART C: Journal Ready Manuscript

This manuscript has been prepared in the format required by the journal, BioMed Central Health Services Research. The format of the article follows the journal's guidelines for authors (Appendix J) except for the tables and figures which are included in the main text.

Article abstract

Background: In 2011, the South African National Department of Health launched the National Core Standards (NCS) for health establishments in South Africa as a certification programme to improve quality across the full range of care. The study objectives were to determine (a) the compliance of healthcare facilities with the South African NCS for occupational health and safety (OHS) and infection prevention and control (IPC), (b) the impact of the audits three years after baseline audits, at follow up self-assessment audits, and (c) the reliability of self-assessments when compared to external audits results.

Methods: This was a cross-sectional study of NCS OHS/IPC audit data, with a longitudinal component, of a sample of public sector primary healthcare (PHC) facilities in the Western Cape Province (WCP) of South Africa (total=194) between 2011 and 2015. For the first two objectives, baseline (external) audits in 2011/2012 were compared with the follow up self-assessment (internal) audits at 60 PHC facilities in 2014/2015 using a paired t-test for the difference between two means or Wilcoxon sign rank test for difference between two medians, as appropriate. For differences between categorical variables, McNemar's test was performed. For objective c, Cohen's Kappa statistic and raw agreement percentage were used to determine the reliability/agreement of the results between self-assessment (internal) audits and external (Office of Health Standards Compliance) audits conducted at the same facility between 01/04/14 to 30/06/15 at 25 PHC facilities in the WCP.

Results: At baseline, 25% (15) of PHC facilities (N=60) were non-compliant (score<50%), 48% (29) conditionally compliant (score ≥ 50 <80) and 27% (16) compliant (score ≥ 80 %). There was an insignificant positive trend after three years, with only 35% (21) of PHC facilities reaching compliance overall according to self-assessment. There was no difference in the pooled facility mean OHS/IPC score (66%) for facilities at baseline and at follow up self-assessment. The level of agreement between self-assessment (internal) audits and external audits (N=25) ranged from 28-92% for percentage agreement with kappa statistics ranging from poor to moderate (-0.08 to 0.41).

Conclusions: Baseline PHC facility compliance with OHS/IPC measures was low. There was no significant improvement in compliance after three years. Poor inter-rater reliability indicates a large degree of measurement error. Practical implications of these results are the

need to improve reliability of assessments and a process to convert low compliance scores into implemented improvement actions.

Keywords: Audit, Primary healthcare, Occupational health and safety, Infection prevention and control, Inter-rater reliability

Introduction

Accreditation of healthcare facilities has been recommended by many national organisations to improve patient safety and quality of care. This is despite inconclusive evidence to support the effectiveness of hospital accreditation and/or certification on patient safety and quality outcomes.[1] Such evidence is important as accreditation programs require significant financial and labour investment.[1]

South Africa is a middle income country characterised by a high level of income and wealth inequality. In the Western Cape (WC) province, approximately 75% of the population are dependent on public sector health services.[2] In South Africa, strengthening health system effectiveness is one of four outputs of the National Service Delivery Agreement signed by the President of South Africa in 2014.[3]. The flagship programme to achieve this is the National Health Insurance system with the aim of providing universal healthcare coverage.[3]

In parallel, the National Core Standards for Health Establishments in South Africa (NCS), was published by the National Department of Health (NDoH) in 2011, outlining expectations for safe, quality care in both the public and private sectors.[4] The main purpose of the NCS is to create a benchmark against which healthcare facilities can be evaluated and provide for the national certification of compliance of health establishments with compulsory standards.[4] The National Health Amendment Act 12 of 2013 mandated establishing an Office of Health Standards Compliance (OHSC) to monitor and enforce compliance with the NCS. The seven domains of the NCS are: patient rights; patient safety, clinical governance and care; clinical support services; public health; leadership and corporate governance; operational management; and facilities and infrastructure.[4] Each domain is defined by the World Health Organisation (WHO) as an area of potential risk for quality and safety[4, 5] Although the core business of the healthcare system is delivery of quality care to its users, the NCS recognises that this requires a healthy, productive workforce.

As part of this requirement, healthcare workers need to be protected against risk of injury, infection and other occupational hazards.[6-8] Independently, the South African Occupational Health and Safety Act 85 of 1993 (OHSA) requires that employers provide and maintain a working environment that is safe and without risk to the health of their employees (and persons other than employees who may be affected by the work).[9] Occupational health and safety (OHS) is concerned with the health, safety and wellbeing of all persons in the workplace and fostering a healthy and safe work environment. Section nine of the OHSA requires employers to protect persons other than their employees such as patients, visitors, students, volunteers and contractors. Additionally, infection prevention and control (IPC) has long been a responsibility of health facilities on the common law Duty of Care principle, and is concerned with preventing hospital or healthcare facility acquired infections. There is therefore considerable overlap between IPC and OHS activities as they have a common goal to ensure the health and safety of patients, visitors and employees OHS and IPC measures/standards cut across the seven domains in the NCS.

In nationwide NCS baseline audits conducted in South Africa in 2011/12 by an external agency funded by the NDoH, the proportion of fixed public healthcare facilities fully compliant with IPC standards was very low at 0.82% (32 out of 3880). The national average (mean) facility IPC score (average score for all IPC variables in the audit averaged over all facilities) was 47% for primary healthcare (PHC) facilities and 64% for hospitals. [10] The national average (mean) facility score for occupational health and safety (OHS) was 76% (PHC facilities and hospitals). [10]

While there is some evidence that hospital accreditation or certification assessments improve compliance scores over time, there is insufficient evidence to conclude that this is associated with improved patient or quality outcome indicators or improved OHS indicators. Generally, there is a dearth of studies evaluating OHS and IPC compliance with standards in PHC facilities, especially in low and middle income countries (LMICs). In addition, the comparison of self-assessment versus external assessment results in PHC in LMICs is under-researched.

The objectives of this study were to determine: (a) the compliance of public sector PHC facilities with the NCS for OHS and IPC, (b) the impact of the audits three years after baseline audits, at follow up self-assessment audits and (c) the reliability of self-assessment audits when compared to external audit results.

Methods

Study Design

This was a cross-sectional study, with a longitudinal component, involving analysis of a subset of data collected during baseline (external), self-assessment and external (OHSC) NCS audits between 2011 and 2015 in the Western Cape Department of Health (WCG:H) PHC facilities.

Population and Sampling

All fixed public PHC facilities operated by the WCG:H were included in the sampling frame (total=194). For objective (a) and (b), facilities were eligible if they had a baseline audit conducted in 2011/2012 and a follow-up self-assessment audit conducted between 01 April 2014 and 31 March 2015. Facilities that changed functions or moved during this time period were excluded. To test audit reliability (objective (c)), all facilities that had both self-assessment and external audits conducted within the same period between 01 April 2014 to 30 June 2015 were eligible. This meant there were two datasets.

A multi-stage sampling strategy was used. The WC Province is divided into six health districts which are further divided into 32 health sub-districts (strata). In 2011, the number of PHC facilities in each district were: District A=46, District B=40, District C=49, District D=24, District E=26 and District F=9. Sampling involved selecting one of each type of facility (clinic, community day centre [CDC], community health centre [CHC]) within each sub-district. Where there was more than one of a certain type of facility then at least 50% of them were randomly selected using Excel's (Microsoft, 2010) random number generator function. These facilities (selected sample) were requested to submit their audit data. For objective (c), all eligible facilities in the Western Cape Province were requested to submit their external (OHSC) audit reports.

Data Management

The baseline NCS audits were conducted by the Health Systems Trust, an external non-governmental organisation, using the NCS baseline tools (version 2011) developed by the

NDoH, and described in detail elsewhere.[4, 10] The self-assessments (internal) in 2014/2015 were conducted by WCG:H staff using the NCS version 2013 tools. External audits in 2014/2015 were done by the OHSC, using NCS version 2013 tools. After each audit, the facility received a feedback report and had to generate a quality improvement plan and implement it to improve annual audit performance results.

Separate NCS audit tools were used for clinics and CDCs/CHCs. Based on an NCS risk rating framework, measures are classified into four (declining) levels of risk: Extreme, Vital, Essential and Developmental. Each NCS questionnaire/tool is divided into functional areas (e.g. clinic manager, clinical services, pharmacy) depending on the type of facility (Clinic or CDC/CHC). Some measures of the NCS have an associated multi-item checklist (for example measure number 2.6.1.1.1 is a checklist of 10 items with regard to an IPC policy that determines the score for that measure), while others are questions with a binary positive or negative response (for example measure number 2.6.3.1.2 asks whether the facility has a reporting system for needle stick injuries). Although specific items were amended, added or deleted over the 3 years, the majority remained the same. The most notable change was in the risk rating categories of specific measures. While the NCS baseline 2011 version had three risk categories, the 2013 version had four risk categories with some measures being re-categorised.

For this study, copies of baseline (external) audit questionnaires and reports, self-assessment questionnaires and checklists and external (OHSC) audit reports (of the selected sample of facilities) were requested from PHC facilities, district quality assurance managers and the Provincial quality assurance manager. The full NCS audit tools used for both clinics and CDCs/CHCs were carefully scrutinised by the author for measures that pertain to IPC and/or OHS. Only these measures were included in the data extraction sheets (see appendices D and E). Measures (variables) had to be present in both the baseline NCS 2011 version and the NCS 2013 version to be included in the data extraction sheet for the baseline and follow up comparison objectives (a) and (b). To allow for comparison between baseline (external) audit results and follow up self-assessment audit results, measures were classified into one of the four risk categories according to the NCS 2013 version. For the external (OHSC) versus self-assessment (internal) comparison (objective c), the data extraction sheet included OHS and IPC measures/variables from the NCS 2013 version.

Statistical Analysis

There were two types of variables/measures, one binary (i.e. the facility achieved a specific measure vs did not) and one continuous (a multi-item checklist composite score [e.g. 15 out of 20=score of 0.75]). Frequencies and percentages were calculated for each binary variable. Median or means were determined for each continuous variable score across facilities. As explained above, each variable/measure is further classified into one of four measure risk categories. The OHSC target compliance cut off levels per measure risk category were applied to the continuous variable/measure (checklist) scores: >0.7 for developmental measures, >0.8 for essential measures, >0.9 for vital measures and 1.0 for extreme measures. These scores were then converted to binary format with a compliant score equalling a positive response.

A mean score (continuous) was calculated for each of the four measure risk categories by averaging the score for all measures per risk category for each facility. Compliance cut off levels, as explained above, were applied to these four scores to determine facility compliance with each of the four measure risk categories (binary response). The four measure risk scores (continuous) were also used to calculate an overall (weighted) facility score which was graded as per the OHSC [OHSC, oral presentation, March 2015]. If this overall metric was less than 0.5 (50%), the facility was classified as non-compliant (Grade E), while a score of 50% or above resulted in various conditional compliance grades at intervals of 10% (grades D=50-59%,C=60-69%,B=70-79%) up to 80% or above (grade A), which signified (fully) compliant. A pooled mean overall (weighted) facility score was also determined.

The baseline (external) audits in 2011/2012 were compared with the follow up self-assessment (internal) audits done in 2014/2015 using a paired t-test for the difference between two means or Wilcoxon sign rank test for difference between two medians, as appropriate. For differences between categorical variables, McNemar's test was performed. A confidence level of 95% was used as the level of statistical significance.

Cohen's Kappa statistic[11] and raw agreement percentage were used to determine the reliability/agreement of the results between self-assessment (internal) audits and external (OHSC) audits in the same period. Kappa statistics were interpreted according to the descriptions used by Viera and Garret.[12] All data were analysed using Stata statistical software version 12.[13]

Results

The total number of fixed PHC facilities existing in 2011 were 194 (Table 1) consisting of 136 clinics and 58 CDC/CHCs, of which 185 (95%) had a baseline audit conducted. Ninety facilities (46% of 194) had a self-assessment audit conducted in 2014/15 (67 clinics and 23 CDC/CHCs) and were therefore eligible for inclusion. Sampling as described above resulted in 63 (32% of 194) of the eligible facilities selected from 27 (84%) health sub-districts, with a response rate of 95% (N=60) consisting of 40 clinics and 20 CDC/CHCs. One rural district (F) was not represented at all since it had no self-assessment audits done at PHC facilities in the study period. District A, a densely populated urban district, had only CDC/CHCs, i.e. no clinics represented, as clinics in this district are operated by the municipality rather than the province. Table 1 gives a breakdown of the sample included in this study by district.

A total of 30 external (OHSC) audits were done at PHC facilities (out of a total of 194) in the study inclusion period. Twenty six out of the 60 responding clinics above were eligible, with a response rate of 96% (N=25).

Table 1. Sampling of primary healthcare facilities by health district

Districts	No. of primary healthcare facilities in 2011[14]	No. of eligible primary healthcare facilities	Sampled	Data received and facility included in study
District A	46 ¹	17	16	15 (33% of 46)
District B	40	28 ²	18	17 (43%)
District C	49	4 ³	4	4 (8%)
District D	24	16	11	10 (42%)
District E	26	25	14	14 (54%)
District F	9	0 ⁴	0	0
Total	194	90 (46% of 194)	63 (32% of 194)	60 (31% of 194)

¹No clinics operated by WCG:H.

²No CDC/CHC self-assessment audits conducted in study period

³No clinic self-assessment audits conducted in study period.

⁴No PHC facility self-assessment audits conducted in study period.

The 2011/2012 baseline audit revealed that for seven out of the 16 measures, less than half of the facilities were compliant (Table 2), These measures were: having an adequate IPC policy, having an annual induction/training programme (that included IPC), having an annual hand washing/hygiene campaign, having an adequate decontamination policy, having

records of staff NSI and post exposure prophylaxis (PEP) management, having a fire certificate and doing quarterly emergency drills. For the rest of the measures the proportion of facilities compliant ranged from 52% to 82%. The proportion of facilities compliant at baseline with Essential and Vital measures was poor, while for Extreme measures it was 60% (Figure 1). The proportion of facilities (fully) compliant at baseline was low (27%).

At follow up self-assessments (2014/15), there was a general increase in the proportion of facilities compliant with all measures, except one (Table 2). This Extreme measure required facilities to have appropriate types of masks and Food and Drug Administration (FDA) approved respirators available and have fit tested all at risk staff. Of concern is that there was a statistically significant decline from 83% at baseline to 60% for this measure.

Of the measures that showed a positive trend, only three were statistically significant. These were: having an adequate IPC policy, having an annual induction/training programme (that included IPC) and having a fire certificate. All three of these were below 50% at baseline.

The proportion of facilities compliant with Essential measures showed the greatest improvement from 2% to 25% and was statistically significant (Figure 1). However, the proportion of facilities compliant with Vital measures stayed the same, while for Extreme measures it decreased. Although at follow up, the proportion of facilities non-compliant overall decreased by 5% and those compliant increased by 8%, this was not a statistically significant difference (Figure 1). Notably, the pooled mean overall facility (weighted) score at baseline was identical at follow up self-assessment (Table 2).

In general, clinics were worse off at baseline than were CDC/CHCs and showed the most improvement at follow up self-assessments. Community Day Centres/ Community Health Centres in general showed no improvement or declined in compliance (See Supplementary Table 1). This was evident as the number of clinics (n=40) that were compliant overall doubled from 8 (20%) to 16 (40%) facilities in comparison to CDC/CHCs (n=20) which decreased from 8 (40%) to 5 (25%) facilities compliant.

Table 2: Proportion of primary healthcare (PHC) facilities with positive responses (compliant) to measures in 2011/12 and 2014/15

CLINICS (Number[N])=40 ¹ & Community Day Centres (CDCS)/Community Health Centres(CHCS) (N=20) ² =Total PHC Facilities (N=60)				
Variables/measures		Baseline (external) 2011/2012	Self-Assessment (internal) 2014/2015	Difference & Significance % (95% CI) or p-value
<i>Functional area: Clinic/CHC manager</i>				
IPC policy (E checklist requires 80% for compliance)	Median score as % (IQR)	50% (16-80)	90% (50-100)	40% p=0.004 ^{3,4}
	Number of facilities compliant: n (%)	18 (30%)	32 (53%)	23% (4;43) ^{4,5}
The annual in service education & training plan includes IPC (esp. TB & universal precautions) (E)	n (%)	26 (43%)	42 (70%)	27% (7;46) ⁴
There is educational material available for staff on universal precautions: hand washing/respirator use/ sharps/ PPE/cough etiquette (E)	n (%)	44 (73%)	47 (78%)	5% (-10;20)
There is educational material available to patients on prevention of the spread of TB (E)	n (%)	49 (82%)	55 (92%)	10% (-4;24)
Appropriate types of masks and FDA approved respirators available & at risk staff fit tested (X)	n (%)	50 (83%)	36 (60%)	-23% (-40;-7) ⁴
Rooms used for infectious TB patients are separated by adequate physical barriers from non-TB patients (X)	n (%)	42 (70%)	44 (73%)	3% (-12;19)
Rooms used for accommodation/consultation of patients with respiratory infections have adequate natural or mechanical ventilation (E)	n (%)	47 (78%)	55 (92%)	14% (-0.001;27)
A comprehensive policy on standard precautions is available (E checklist)	Median score as % (IQR)	92% (75-100)	100 (85-100)	8% p=0.079
	n (%)	41 (68%)	46 (77%)	9% (-9;26)
Reporting system for needle stick injuries (V)	n (%)	50 (83%)	54 (90%)	7% (-8;21)
Randomly selected clinical area: Sharps safety (V checklist requires 90% for compliance)	Median score as % (IQR)	100% (86-100)	100% (100-100)	0 p=0.15
	n (%)	44 (73%)	50 (83%)	10% (-7;27)

Annual hand washing/hygiene campaign/drive held (V)	n (%)	21 (35%)	25 (42%)	7% (-12;25)
Up to date decontamination policy (E checklist)	Median score as % (IQR)	35% (0-78)	24% (0-100)	-11% p=0.96
	n (%)	15 (25%)	23 (38%)	13% (-3;29)
Staff able to explain used instrument sterilisation procedure (E Checklist)	Median score as % (IQR)	83% (0.54-100)	83% (0-100)	0 p=0.68
	n (%)	31 (52%)	33 (55%)	3% (-17;23)
Evidence of medical examinations on at risk staff⁷ (V)	n (%)	N/A ⁸	24 (40%)	N/A ⁸
Records show staff with NSI received PEP & have been re-tested (V)	n (%)	24 (40%)	31 (52%)	12% (-5;29)
The fire certificate for the facility is available (E)	n (%)	7 (12%)	24 (40%)	28% (12;47) ⁴
There are quarterly emergency drills (E)	n (%)	0	6 (10%)	10% p=N/A ⁵
Pooled overall facility (weighted) score as % (Weighting: X=40%,V=30%, E=20%, Developmental=10% (None))	Mean (Standard deviation)	66% (20)	66% (22)	0 (-6;7)
	Median (IQR)	72% (50-81)	66 (54-85)	-6% p=0.80

IQR:interquartile range: CI:confidence interval E:Essential measure risk category X:Extreme measure risk category V:Vital measure risk category FDA: Food and Drug Administration PEP:

post exposure prophylaxis

¹Excludes 3 districts (A, C, F).

²Excludes 3 districts (B, E, F).

³Wilcoxon signed rank test.

⁴Statistically significant at $\alpha=0.05$

⁵McNemar 's test .

⁶Not applicable because discordant pairs<10.

⁷Not included in overall facility score.

⁸Not asked at baseline.

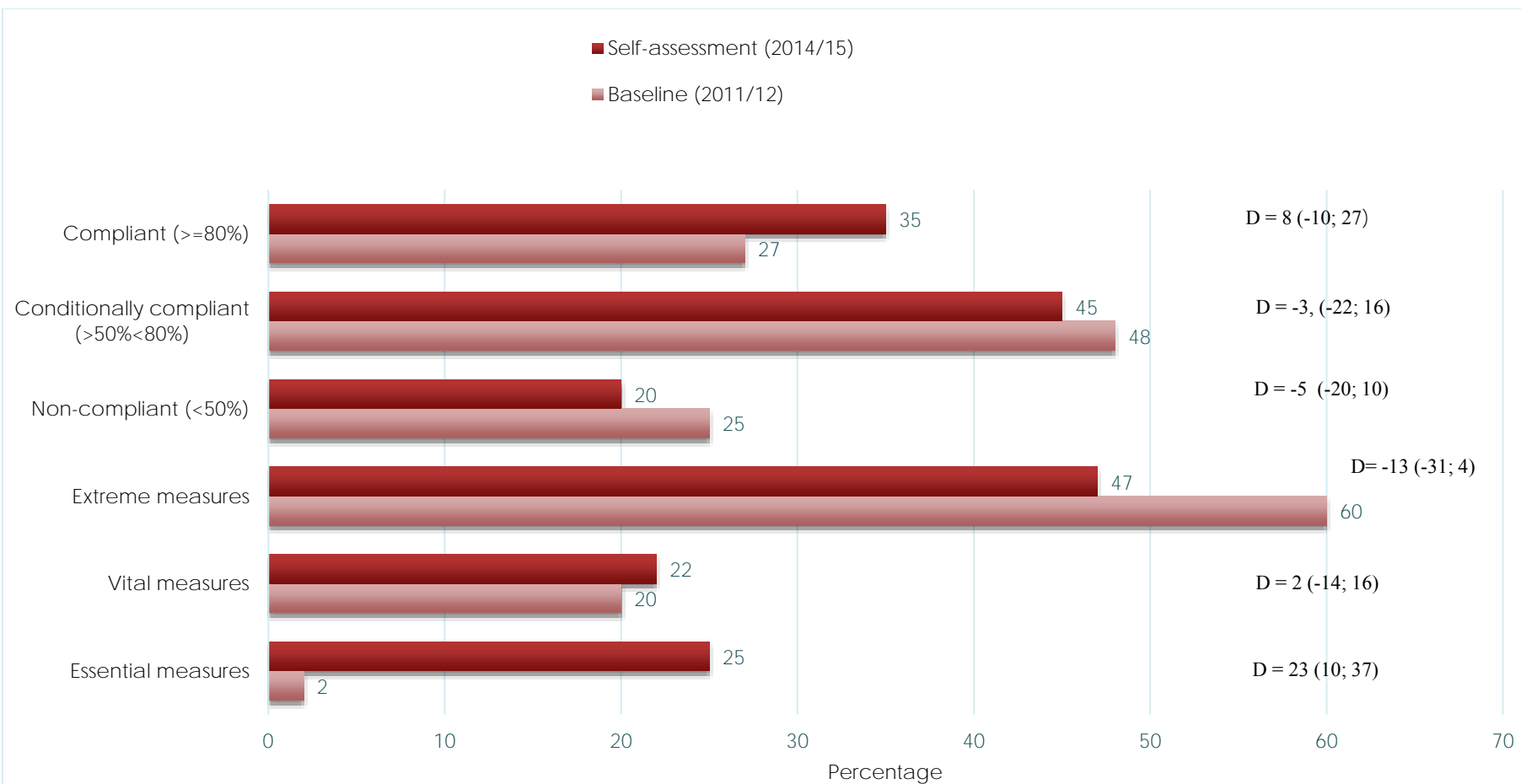


Figure 1. Proportion (%) of facilities (n=60) compliant overall and with each risk rating measure category.

[D () = absolute difference in proportions (95% confidence interval)]

The level of inter-rater agreement between assessors who conducted the external (OHSC) audit and those who conducted the self-assessment audit at the same clinic using the same tool in the same 15 month period is shown in Table 3. The median duration that elapsed between self-assessment and external audits was three months (IQR: 3 - 8; range: 1 - 14). All self-assessments were conducted prior to external assessments.

The percentage agreement ranged from 28% to 92% for individual measures, with the highest agreement being for whether quarterly emergency drills took place and the lowest for whether there was a comprehensive standard precautions policy available (Table 3).

Percentage agreement between self-assessment and external assessment was good for overall facility non-compliance and compliance. However, when the proportion of agreement expected due to chance was taken into account with kappa (κ) statistics, it was poor to moderate ranging from -0.08 to 0.41.[12] Notably, while self-assessment assessors found seven (28%) PHC facilities (fully) compliant, external auditors found none compliant. Only one measure achieved moderate agreement (0.41-0.60) [15]: assessment of adequate natural or mechanical ventilation in rooms for respiratory infectious patients ($\kappa=0.41$), with a 95% confidence interval excluding zero.

Overall, external assessors rated fewer clinics compliant with measures than did self-assessors on all but two measures. One of these was an Extreme risk measure requiring facilities to have FDA approved respirators that are fit tested on at risk staff, was rated present in 56% of facilities by self-assessors compared to 96% of facilities by external assessors ($\kappa = -0.08$). The other was an Essential measure related to the observation of adequate lighting and ventilation in facilities. This was rated as present in 83% of facilities by self-assessors and 96% by external assessors ($\kappa= 0.36$). The impact of this poor level of agreement with regard to FDA approved respirators on the pooled facility score for extreme measures is seen in the proportion of facilities compliant with extreme measures rated by self-assessors as 36% in contrast to the external assessors' rating of 80%.

Table 3: Clinic audits (number=25): Inter-rater comparison of reported compliance between self-assessment (internal) & external audits at same facilities in 2014/2015

Variables/ measures	Self-assessment (internal) audits Number of facilities compliant: n (%)	External (OHSC) audits Number of facilities compliant: n (%)	Percentage Agreement (95% confidence interval)	Kappa statistic (k) (95% confidence interval)
<i>Functional area: Clinic manager</i> IPC policy (E checklist requires 80% for compliance)	14 (56%)	0	44% (24;65)	Not applicable= N /A
The annual in service education & training plan includes IPC (esp. TB & universal precautions) (E)	19 (76%)	3 (12%)	36% (18;57)	0.08 (-0.03;0.19)
There is educational material available for staff on universal precautions: hand washing/respirator use/ sharps/ PPE/cough etiquette (E)	23 (92%)	9 (36%)	44% (24;65)	0.09 (-0.04;0.23)
There is educational material available to patients on prevention of the spread of TB (E)	24 (96%)	23 (92%)	88% (69;97)	-0.06 (-0.17;0.06)
Appropriate types of masks and FDA approved respirators available & at risk staff fit tested (X)	14 (56%)	24 (96%)	52% (31;72)	-0.08 (-0.23;0.07)
Rooms used for infectious TB patients are separated by adequate physical barriers from non-TB patients (X)	19 (76%)	21 (84%)	76% (55;91)	0.26 (-0.18;0.69)
Rooms used for accommodation/consultation of patients with respiratory infections have adequate natural or mechanical ventilation (E)	21 (84%)	21 (84%)	84% (64;95)	0.41 (-0.08;0.88)
A comprehensive policy on standard precautions is available (E checklist)	19 (76%)	3 (12%)	28% (12;49)	-0.03 (-0.21;0.14)
Reporting system for needle stick injuries (V)	25 (100%)	13 (52%)	52% (31;72)	N/A
Randomly selected clinical area: Sharps safety (V checklist requires 90% for compliance)	23 (92%)	8 (32%)	32% (15;54)	-0.04 (-0.22;0.13)
Annual hand washing/hygiene campaign/drive held (V)	9 (36%)	3 (12%)	60% (39;79)	-0.02 (-0.32;0.29)
Up to date decontamination policy (E checklist) (N=20 ²)	8 (40%)	0	68% (46;85)	N/A

Staff able to explain used instrument sterilisation procedure (E Checklist) (N=19 ²)	12 (63%)	4 (21%)	68% (46;85)	0.27 (0.01;0.53) ¹
Evidence of medical examinations on at risk staff ⁷ (V)	15 (60%)	0	40% (21;61)	N/A
Records show staff with NSI received PEP & have been re-tested (V) (N=19 ²):	11 (58%)	5 (26%)	68% (46;85)	0.22 (-0.13;0.56)
The fire certificate for the facility is available (E)	12 (48%)	1 (4%)	56% (35;76)	0.089 (-0.08;0.25)
There are quarterly emergency drills (E)	2 (8%)	0	92% (74;99)	N/A
Functional Area: Clinical Services Appropriate types of masks and FDA approved respirators available & at risk staff fit tested available (X) (N=24 ²):	13 (54%)	23 (96%)	52% (31;72)	-0.08 (-0.24;0.08)
Randomly selected clinical area: Sharps safety (V Checklist) (N=23 ²):	21 (91%)	11 (46%)	44% (24;65)	-0.02 (-0.23;0.19)
Lighting & ventilation adequate (E) (N=24 ²):	20 (83%)	23 (96%)	88% (69;97)	0.36 (-0.16;0.88)
No obvious safety hazards (V) (N=24 ²):	20 (83%)	20 (83%)	84% (64;95)	0.40 (-0.08;0.88)
Cleaning material/equipment available, appropriately labelled and stored (Vital checklist) (N=23 ²):	5 (22%)	1 (4%)	76% (55;91)	-0.08 (-0.23;0.07)
Pooled facility score for X measures as %, Mean (Sd) No. of facilities compliant (score=100%): n (%)	62% (35) 9 (36%)	92% (17) 20 (80%)	48% (28;69)	0.11 (-0.13;0.35)
Pooled facility score for V measures as %, Mean (Sd) No. of facilities compliant (score>=90%): n (%)	76% (14) 2 (8%)	48% (13) 0	92% (74;99)	N/A
Pooled facility score E measures as %, Mean (Sd) No. of facilities compliant (score>=80%): n (%)	69% (18) 7 (28%)	30% (12) 0	72% (51;88)	N/A
Pooled overall facility (weighted) score as %, Mean (Sd) (Weighting: X=40%,V=30%, E=20%, Developmental=10% (None))	68% (19)	64% (1)		
No of facilities non-compliant (<50%)	5 (20%)	3 (12%)	76% (55;91)	0.12 (-0.32;0.55)
No. of facilities conditionally compliant (>=50<80%)	13 (52%)	22 (88%)	48% (55;91)	-0.073 (-0.33;0.19)
No of facilities fully compliant (>=80%)	7 (28%)	0	72% (51;88)	N/A

N: number of observations PEP: Post-exposure prophylaxis FDA:Food and Drug Administration Sd: Standard deviation E:Essential measure risk category X:Extreme measure risk

category V:Vital measure risk category

¹Statistically significant

²Not applicable or missing data excluded.

Discussion

In order to determine the compliance with OHS and IPC standards of the NCS and the impact of NCS assessments (audits) and feedback on public fixed PHC facilities in the WC province of South Africa, we performed a cross sectional secondary analysis of a subset of NCS baseline (external) and follow up self-assessment audit data from 60 PHC facilities. To measure the reliability (inter-rater agreement) of follow up NCS self-assessment audits compared to external (OHSC) audits we analysed NCS self-assessment and external (OHSC) audit data conducted within a mean of 3 months of each other at the same 25 clinics.

Inter-rater reliability was poor with self-assessors generally rating the proportion of facilities compliant with measures higher than external assessors. This is consistent with a systematic literature review in 2010 on the measurement properties of occupational health and safety management audits which reported that studies of inter-rater reliability showed that it was frequently unacceptably low.[16] However, this is in contrast to a study in Ecuador comparing self-assessment to external assessment for measuring compliance with quality standards in hospitals, where kappa statistics ranged from fair to almost perfect and raw agreement ranged from 71 to 95%.[17] However, in this same study, where there were disagreements; self-assessors were inclined to report more positive findings than external assessors. In general, studies evaluating reliability of IPC/OHS audits in PHC facilities are scarce.

External (OHSC) assessments scored facilities lower in general on all measures except one, the extreme measure of FDA approved respirators and fit testing. This might be explained by the time lapse between self and external assessments (mean=3 months) with interval correction of this measure. It may have been easier to purchase equipment such as N95 respirators as opposed to updating an IPC/OHS policy, changing infrastructure, starting an education/induction programme or providing medical surveillance without the necessary expertise or resources available. As this one measure accounts for 20% of the overall facility score in this study, it has a large influence on the overall facility score. While not assessed in this study, poor reliability may be due to an inadequate measurement scale/tool and/or inadequate selection, training and supervision of assessors.[18] The external assessments by the OHSC cannot be viewed as the 'gold standard' at present as they are still in a process of conducting (OHSC) audits and making final amendments to the tools and reliability and validity still need to be determined. However they (external assessments) are considered by the OHSC to be more valid than self-assessments.

The poor reliability has implications for the interpretation of the other two objectives of the study, namely compliance and change in compliance over time. If the self-assessments results are unreliable, then the follow up self-assessment audit results may be inaccurate. This might not allow any meaningful interpretation to be made about the true impact of NCS self-assessment audits and feedback, resulting in a waste of financial and labour resources required to conduct these audits.

The proportion of PHC facilities compliant overall at baseline (2011/12) with IPC/OHS measures was low (27%). This was predictable given that facilities were just starting accreditation programmes.[5] This was also in agreement with a study in 2012 of 52 facilities in Kwazulu-Natal Province of South Africa that found that 80% of facilities were compliant with only 50% of the tuberculosis IPC measures, while another study in 2009 in the Western Cape Province on 10 PHC facilities found IPC to be inadequate.[19,20] Country wide baseline public health facility audits done in South Africa in 2011 reported a national average PHC facility score for IPC of 47% ,while the Western Cape Province scored 50% for all facilities (hospitals and PHC facilities).[10] Meanwhile, the national average (mean) score for the functional area “management of occupational health and safety” was 76%. The average (mean) facility IPC/OHS score in this study of 66% was in keeping with the average of the national IPC and OHS scores above (62%).

The underlying reasons for low compliance could be due to the historical neglect of OHS and IPC generally in PHC facilities, where it is generally regarded as an auxiliary activity with a low level of accountability amongst senior management.[21] Additionally, there is no provincial OHS or IPC unit or manager nor district OHS/IPC qualified personnel to co-ordinate and support OHS/IPC activities in the districts, with the majority of the limited OHS and IPC qualified staff attached to large urban hospitals. Furthermore, while there is evidence of policies, implementation thereof is lacking.[21]

There is a lack of studies evaluating and reporting on compliance with OHS/IPC standards for health care in PHC settings in LMICs.

It was disconcerting that the impact of NCS audits on PHC facilities was insignificantly positive overall, and while some individual facilities did show a positive trend, the mean facility overall score was identical at baseline and follow up self-assessment. The poor reliability and the trend of self-assessors generally scoring higher than external assessors indicates that the actual impact maybe even worse than indicated in table 2.

This is in contrast to reports and studies in high income countries showing gradual improvement over time in compliance, although these were in hospitals.[22-25] Additionally, a study in Mali in 2001 to determine the impact of self-assessment on

compliance with the quality of care standards reported a significant difference between the intervention group and the control group in overall compliance suggesting that self-assessment can have a significant effect.[26] In Iran in 2013 a study to determine the compliance with the Joint Commission International organisation-based standards for IPC in 23 hospitals using a self-reported questionnaire on hospital staff, an excellent (> 75%) pooled mean hospital IPC score of 79% was achieved.[27] Again, there is a lack of studies reporting on the impact of IPC or OHS auditing or accreditation in PHC as opposed to hospital settings.

In the current study, clinics generally showed a positive trend, offset by CDC/CHCs showing a negative trend from baseline to follow up self-assessments 3 years later. The explanation for this may be that clinics had a lower baseline to begin with. This is consistent with research that found the relative effects of clinical audit and feedback to be larger when baseline compliance with standards was low.[28]Whittaker et al also explained how facilitated gradual improvements in quality were beneficial in a large public sector hospital with a poor baseline and larger room for improvement, which took up to three years to reach acceptable levels for accreditation.[5] In a study in the Netherlands evaluating determinants of the impact of a primary medical care practice accreditation programme, factors perceived by primary care professionals to be enablers of impact were designating one person responsible for the programme, clear lines of communication and having enthusiasm for quality improvement.[29] The completion of a full audit cycle that includes monitoring implementation of changes and follow up assessments has been shown to improve impact.[25, 30]

None of the overall non-compliant facilities at baseline passed on the FDA respirator extreme measure, but surprisingly of those facilities that were compliant overall, only 50% passed this measure. This indicates that even though this respirator standard contributed 20% of the total score, it was not a good predictor of compliance (although it was a perfect predictor of non-compliance). Good infection control performance is associated with having IPC resources such as full time IPC practitioners when comparing hospitals.[31] The lack of this qualified resource in a PHC setting may be one explanation for the lack of improvement. Furthermore, good leadership at ward or operational level of staff who share the vision of the organisation, who develop and stimulate others, and who are active is associated with effective action on IPC measures.[32] However, this good leadership is adversely affected by direct supervision of a large number of staff which may be another reason for a lack of improvement in this LMIC setting.[32]

Strengths of this study include representative sampling of PHC facilities which had actually undertaken audits, under the control of a single provincial department of health. The

response rate among eligible facilities was very high. Also data were extracted from hard copies or scanned copies of original audit questionnaires or reports and not extracted from online capturing software, thus limiting data capturing errors.

Limitations include the constraint imposed by the number of PHC facilities that had undertaken self-assessments conducted in the study period. Two rural districts out of five were thus not adequately represented in the sample. Also, external (OHSC) audits by the OHSC, which could be regarded as more accurate, were too few and under representative of health facilities in the WC province to yield meaningful results on compliance and impact. These external (OHSC) audits were thus used for reliability testing only. Ideally, the same assessors who did the baseline assessments should have done the follow up self-assessments, but this was unachievable.

While every effort was made to verify missing data, missing data were not included in the final analysis. Of the 25 facilities compared in table 3, 6 (24%) of them had at least one measure not recorded. This may have resulted in a higher overall facility score for that facility and may have increased the overall pooled mean facility score. However this would affect both the baseline and the self-assessment audits for that particular facility.

Although there were some changes across different versions of the audit instrument, while the majority of the measures remained the same, notably some key legally required OHS measures were moved from the PHC NCS facility audit tools to the district/sub-district tool and therefore could not be evaluated in this study.

Conclusions

Accreditation of PHC against the NCS for IPC and OHS is now national policy and is set to continue as a means of quality improvement, with the attendant investment of time and effort. It is therefore important that the process be evidence based as far as possible. These findings add to the scarce literature on reliability and impact of auditing or accreditation in PHC facilities in a LMIC setting. Baseline PHC facility compliance with OHS/IPC measures was low. There was no significant improvement in compliance after three years. Poor inter-rater reliability indicates a large amount of measurement error that needs to be addressed... Continuous monitoring of inter-rater reliability and a quality improvement feedback mechanism for assessors will help improve reliability.[33]

These results indicate that in South Africa, audits with feedback alone cannot be relied upon to improve IPC and OHS standards in PHC facilities. Regular review of the implementation

of corrective actions from audit feedback is required. In addition, monitoring of its impact is required together with subsequent reliable accurate follow up assessments in order to close the loop and complete a full audit cycle.

Declarations: None

Competing interest: There were no competing interests

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Authors' contributions: Please refer to acknowledgements.

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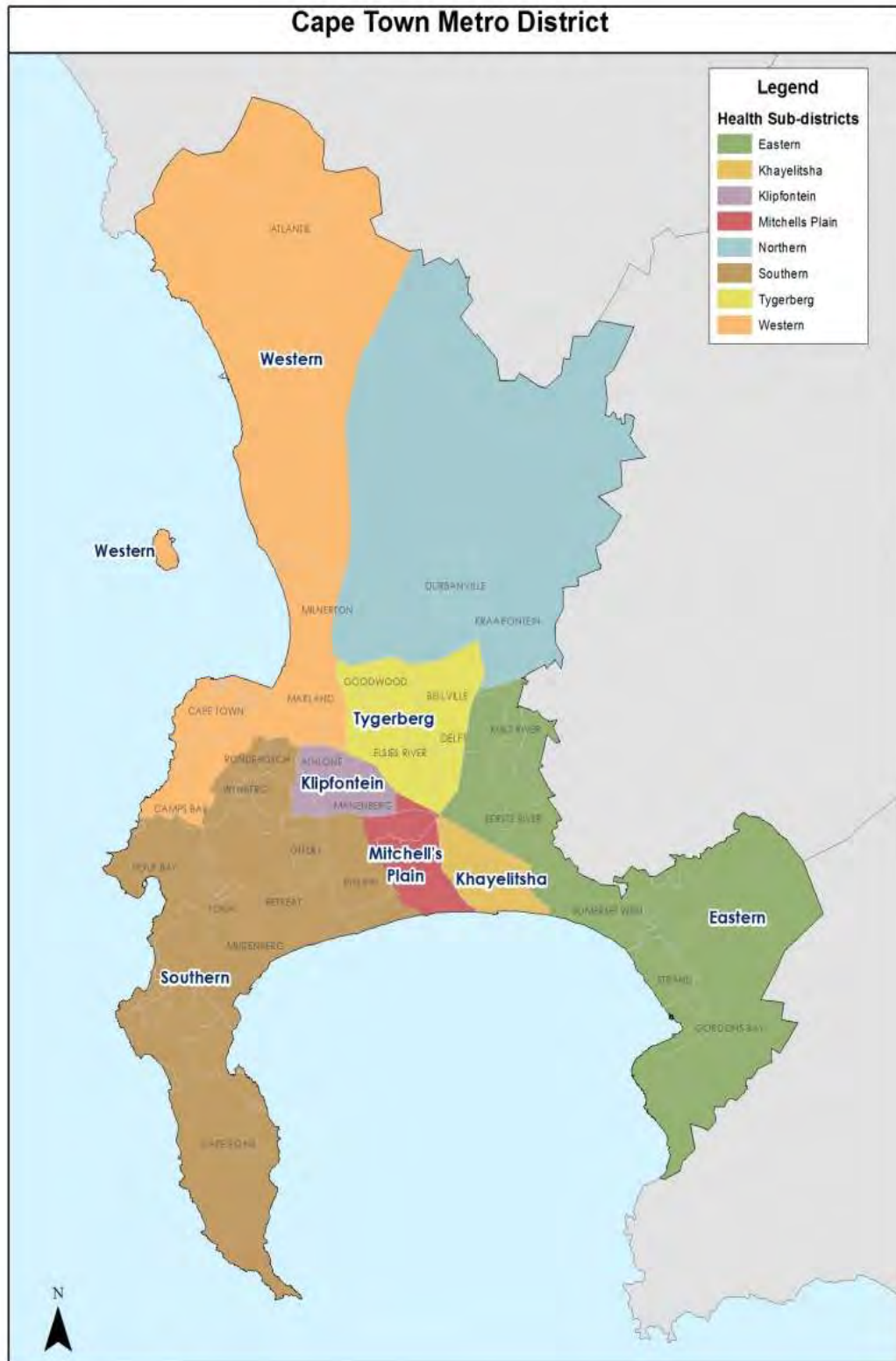
PART D: APPENDICES

Appendix A: Map of health districts/sub-districts in the Western Cape Province



(Reproduced from: Htonl - Own work, GFDL, <https://commons.wikimedia.org/w/index.php?curid=14824676>).

Appendix B: Map of sub-districts within the Cape Town Metro District.



(Reproduced from Western Cape Government: Health annual performance plan 2014/15, 2014)

Appendix C: Table 1: Western Cape Government: Health operated primary healthcare facilities within the Western Cape Province, South Africa in 2011

District	Sub-districts	Clinics	Community Day Centres	Community Health Centres
City of Cape Town Metropolitan	Western	0	7	1
	Southern	0	5	1
	Eastern	0	6	0
	Khayelitsha	0	1	1
	Mitchell's Plein	0	3	1
	Klipfontein	0	3	2
	Northern	0	2	1
	Tygerberg	0	8	2
(Subtotals)		(0)	(37)	(9)
Eden	Bitou	4	1	0
	George	10	2	0
	Hessequa	4	0	0
	Kannaland	4	0	0
	Knysna	5	0	0
	Mossel Bay	3	1	0
	Oudtshoorn	5	1	0
(Subtotals)		(35)	(5)	(0)
Cape Winelands	Breede Valley	6	1	0
	Drakenstein	14	2	0
	Langeberg	7	0	0
	Stellenbosch	8	1	0
	Witzenberg	8	1	0
(Subtotals)		(44)	(5)	(0)
Central Karoo	Beaufort West	5	1	0
	Laingsburg	1	0	0
	Prince Albert	2	0	0
(Subtotals)		(8)	(1)	(0)
Overberg	Cape Agulhas	5	0	0
	Overstrand	76	0	0
	Swellendam	5	0	0
	Theewaterskloof	(23)	1	0
(Subtotals)			(1)	(0)
West Coast	Bergrivier	3	0	0
	Cederberg	6	0	0
	Matzikama	5	0	0
	Saldanha Bay	8	0	0
	Swartland	4	0	0
(Subtotals)		(26)	(0)	(0)
Totals	32	136	49	9
Grand total				194

Appendix D: Data capture form for clinics

REVISED (OHS & IPC) NCS ASSESSMENT QUESTIONNAIRE (Clinics)*

*(Only selected items analysed in this study)

MC14A Clinic manager/HOD

<p>Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.1.1 An infection prevention and control policy is available which outlines the health establishments approach to the management of healthcare associated infections</p> <p>2.6.1.1.1 CHECKLIST - A policy regarding infection control in the health establishment/unit covers all aspects of infection prevention and control</p>		<table border="1"> <tr> <td>Doc</td> <td></td> </tr> <tr> <td>E</td> <td></td> </tr> </table>	Doc		E									
Doc														
E														
<p>Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.1.6 The organization provides education on healthcare associated infection control practices to the staff / patients and as appropriate family and other caregivers</p> <p>2.6.1.6.2 The annual in-service education and training plan includes infection control education / prevention of respiratory infections especially TB and universal precautions</p> <p>2.6.1.6.3 There is educational material available for staff on universal precautions including hand washing / respirator use / the safe use and disposal of sharps / use of personal protective equipment / cough etiquette</p> <p>2.6.1.6.4 There is educational material available for the public / patients on specific healthcare associated infections that require additional precautions such as swine flu / MRSA / cholera</p>		<table border="1"> <tr> <td>Doc</td> <td></td> </tr> <tr> <td>E</td> <td></td> </tr> <tr> <td>OBS</td> <td></td> </tr> <tr> <td>E</td> <td></td> </tr> <tr> <td>OBS</td> <td></td> </tr> <tr> <td>E</td> <td></td> </tr> </table>	Doc		E		OBS		E		OBS		E	
Doc														
E														
OBS														
E														
OBS														
E														
<p>Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.2.1 A programme for the prevention and control of respiratory infections is in place</p> <p>2.6.2.1.1 There is educational material available to patients on prevention of the spread of TB as well as other infection control precautions</p> <p>2.6.2.1.2 The health establishment provides appropriate types of masks and FDA approved respirators which are fit tested for all staff who are at risk of contracting TB or for all staff exposed to serious contagious respiratory infections</p>		<table border="1"> <tr> <td>OBS</td> <td></td> </tr> <tr> <td>E</td> <td></td> </tr> <tr> <td>OBS</td> <td></td> </tr> <tr> <td>X</td> <td></td> </tr> </table>	OBS		E		OBS		X					
OBS														
E														
OBS														
X														
<p>Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.2.2 Ventilation systems in the patient care units reduce the transmission risk of respiratory infections</p> <p>2.6.2.2.1 The health establishment's rooms to be used for confirmed infectious TB patients are separated by means of adequate physical barriers from non-TB patients</p> <p>2.6.2.2.2 The health establishment's rooms used for the accommodation/consultation of patients with respiratory infections have adequate natural or mechanical ventilation</p>		<table border="1"> <tr> <td>OBS</td> <td></td> </tr> <tr> <td>X</td> <td></td> </tr> <tr> <td>OBS</td> <td></td> </tr> <tr> <td>E</td> <td></td> </tr> </table>	OBS		X		OBS		E					
OBS														
X														
OBS														
E														

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.3.1 Policy and procedures related to Universal precautions to prevent healthcare associated infections are actively implemented and applied in all clinical areas of the health establishment

2.6.3.1.1 CHECKLIST - A comprehensive policy and procedure covering standard precautions is available

Doc		
E		

2.6.3.1.2 The establishment has a reporting system for needle stick injuries or other incidents related to failure of standard precautions

Doc		
V		

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.3.2 Sharps are safely managed and disposed of

2.6.3.2.1 CHECKLIST - A random selection of clinical areas show that sharps are safely managed and disposed of

OBS		
V		

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.3.3 Effective hand washing limits the spread of healthcare associated infections

2.6.3.3.1 There is evidence that a hand washing drive or campaign is held at least annually in the establishment

Doc		
V		

2.6.3.3.2 The results of hand washing audits show compliance within the health establishment of at least 80 percent

Doc		
E		

Domain 3 Clinical Support Services: 3.5.1.1 There is policy on the decontamination of surgical instruments

3.5.1.1.1 CHECKLIST - An up to date decontamination policy is available

Doc		
E		

3.5.1.1.2 CHECKLIST - Staff are able to explain the procedure by which used instruments are sterilised from start to finish

SI		
E		

(6.2.1.2.4 & 6.2.2.3.3 NOT in BASELINE!)

Domain 6 Operational Management: 6.2.1.2 Health and healthy lifestyles initiatives for staff are promoted and supported

6.2.1.2.4 There is evidence to demonstrate that staff participate in formal initiatives planned within the Employee Wellness programme such as wellness days and talks

Doc		
E		

Domain 6 Operational Management: 6.2.2.3 A medical surveillance plan for at risk staff is implemented based on the health risk assessment

6.2.2.3.3 Evidence shows that medical examinations are performed for all health care workers who are exposed to potential occupational hazards when performing their duties (eg radiation / infectious diseases including TB / chemicals)

Doc		
V		

Domain 6 Operational Management: 6.2.2.4 Measures are in place to minimise the transmission of critical occupationally acquired injuries and diseases

6.2.2.4.2 Records of needle stick injuries show that those staff have received post exposure prophylaxis and have been re-tested

Doc		
V		

Domain 7 Facilities and Infrastructure: 7.3.1.6 There is up to date documented certification from the Local Fire Authority that the establishment complies with relevant fire safety regulations

7.3.1.6.1 The Fire Certificate for the health establishment is available

Doc		
E		

Domain 7 Facilities and Infrastructure: 7.3.1.7 Emergency plan is available and indicates that patient well-being is at all times protected

7.3.1.7.1 There are quarterly emergency drills

Doc		
E		

Summary of Report:

Additional Observations:

Inspector Name:

Inspector Signature:

(Appendix D continued)

PC01 Clinical Services

(PC01 SELF-ASSESSMENT & EXTERNAL (OHSC) only, NOT in BASELINE)

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.2.1 A programme for the prevention and control of respiratory infections is in place

2.6.2.1.2 The health establishment provides appropriate types of masks and FDA approved respirators which are fit tested for all staff who are at risk of contracting TB or for all staff exposed to serious contagious respiratory infections

OBS		
X		

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.3.2 Sharps are safely managed and disposed of

2.6.3.2.1 CHECKLIST - A random selection of clinical areas show that sharps are safely managed and disposed of

OBS		
V		

Domain 4 Public Health: 4.3.1.3 The health establishment has an annually updated disaster management plan (including health emergencies)

4.3.1.3.1 An annually updated disaster management plan is available and displayed at strategic points

OBS		
E		

7.1.2.2.3 Lighting and ventilation is observed to be adequate

OBS		
E		

Domain 7 Facilities and Infrastructure: 7.1.4.1 The establishment holds regular / documented / comprehensive inspections of its physical facilities

7.1.4.1.2 No obvious safety hazards are observed during the visit such as loose electrical wiring / collapsing ceilings / unstable walls

OBS		
V		

Domain 7 Facilities and Infrastructure: 7.4.1.2 Appropriate cleaning materials and equipment are available and properly used and stored

7.4.1.2.1 CHECKLIST - Cleaning materials cloths / dusters / scourers and chemicals and equipment are available and stored in an appropriate safe lockable area / with clear labels for equipment used internally and externally

OBS		
V		

Domain 7 Facilities and Infrastructure: 7.5.4.1 General waste is stored and transported appropriately and securely and removed timeously

7.5.4.1.1 The outside bin/waste storage area is well maintained and poses no health risk

OBS		
✓		

Domain 7 Facilities and Infrastructure: 7.6.1.2 Policies and protocols are followed for the handling of all laundry in line with infection control and safety requirements

7.6.1.2.2 Areas for receiving soiled linen are separated from areas of clean linen

OBS		
✓		

Summary of Report:

--

Additional Observations:

--

Inspector Name:

--

Inspector Signature:

--

Appendix E: Data capture form for community day centres/ community health centres

REVISED (OHS & IPC) NCS ASSESSMENT QUESTIONNAIRE (CDC/CHC)*

*(Only selected items analysed in this study)

MC14C CHC Manager

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.1.1 An infection prevention and control policy is available which outlines the health establishments approach to the management of healthcare associated infections

2.6.1.1.1 CHECKLIST - A policy regarding infection control in the health establishment/unit covers all aspects of infection prevention and control

Doc		
E		

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.1.3 A formal surveillance and reporting systems is in place

2.6.1.3.1 The health establishment has a system for monitoring health acquired infections

Doc		
E		

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.1.4 A formal structure exists within the establishment to monitor all aspects of infection prevention and control and ensure appropriate actions are taken to reduce infection rates to the lowest possible level

2.6.1.4.3 Statistics on common health care associated infections demonstrate that they are being monitored monthly

Doc		
Y		

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.1.6 The organization provides education on healthcare associated infection control practices to the staff / patients and as appropriate family and other caregivers

2.6.1.6.2 The annual in-service education and training plan includes infection control education / prevention of respiratory infections especially TB and universal precautions

Doc		
E		

2.6.1.6.3 There is educational material available for staff on universal precautions including hand washing / respirator use / the safe use and disposal of sharps / use of personal protective equipment / cough etiquette

OBS		
E		

2.6.1.6.4 There is educational material available for the public / patients on specific healthcare associated infections that require additional precautions such as swine flu / MRSA / cholera

OBS		
E		

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.2.1 A programme for the prevention and control of respiratory infections is in place

2.6.2.1.1 There is educational material available to patients on prevention of the spread of TB as well as other infection control precautions

OBS		
E		

2.6.2.1.2 The health establishment provides appropriate types of masks and FDA approved respirators which are fit tested for all staff who are at risk of contracting TB or for all staff exposed to serious contagious respiratory infections

OBS		
X		

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.2.2 Ventilation systems in the patient care units reduce the transmission risk of respiratory infections

2.6.2.2.1 The health establishment's rooms to be used for confirmed infectious TB patients are separated by means of adequate physical barriers from non-TB patients

OBS		
X		

2.6.2.2.2 The health establishment's rooms used for the accommodation/consultation of patients with respiratory infections have adequate natural or mechanical ventilation

OBS		
E		

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.3.1 Policy and procedures related to Universal precautions to prevent healthcare associated infections are actively implemented and applied in all clinical areas of the health establishment

2.6.3.1.1 CHECKLIST - A comprehensive policy and procedure covering standard precautions is available

Doc		
E		

2.6.3.1.2 The establishment has a reporting system for needle stick injuries or other incidents related to failure of standard precautions

Doc		
V		

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.3.2 Sharps are safely managed and disposed of

2.6.3.2.1 CHECKLIST - A random selection of clinical areas show that sharps are safely managed and disposed of

OBS		
V		

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.3.3 Effective hand washing limits the spread of healthcare associated infections

2.6.3.3.1 There is evidence that a hand washing drive or campaign is held at least annually in the establishment

Doc		
V		

2.6.3.3.2 The results of hand washing audits show compliance within the health establishment of at least 80 percent

Doc		
E		

Domain 3 Clinical Support Services: 3.5.1.1 There is policy on the decontamination of surgical instruments

3.5.1.1.1 CHECKLIST - An up to date decontamination policy is available

Doc		
E		
SI		
E		

3.5.1.1.2 CHECKLIST - Staff are able to explain the procedure by which used instruments are sterilised from start to finish

Domain 3 Clinical Support Services: 3.5.1.2 Suitably qualified staff manage the functions of the sterilisation department

3.5.1.2.2 Training records show that staff working with sterilisation equipment receive training within the last financial year in the technical aspects of sterilisation and on use of the equipment

Doc		
E		

Domain 3 Clinical Support Services: 3.5.1.3 Clear lines of accountability exist for the decontamination cycle

3.5.1.3.1 A procedure detailing clear responsibilities for the various aspects in the decontamination cycle for the sterilisation services is available

Doc		
E		

Domain 3 Clinical Support Services: 3.5.1.4 The equipment for sterilisation meets legislative requirements

3.5.1.4.2 All sterilisation equipment is validated / licensed

Doc		
V		

3.5.1.4.3 There is a planned maintenance schedule / a log and service history for each machine

Doc		
E		

Domain 4 Public Health: 4.3.1.3 The health establishment has an annually updated disaster management plan (including health emergencies)

4.3.1.3.1 An annually updated disaster management plan is available and displayed at strategic points

OBS		
E		

4.3.1.3.2 The health establishment conducts at least yearly drills to test the preparedness of their disaster plan including emergency / disease outbreak / fire / natural disaster

Doc		
E		

4.3.1.3.3 CHECKLIST -3 Staff members are interviewed to evaluate their awareness of the disaster management plan including health emergencies and their role in the plan

SI		
E		

Domain 7 Facilities and Infrastructure: 7.1.6.1 A regular maintenance programme ensures that the health establishment grounds are safe for all users and provide an attractive environment

7.1.6.1.3 The records shows that nightly inspections are done to ensure adequate lighting on grounds for a safe environment for vehicles / staff and visitors at night

Doc

D

Domain 6 Operational Management: 6.2.1.2 Health and healthy lifestyles initiatives for staff are promoted and supported

6.2.1.2.4 There is evidence to demonstrate that staff participate in formal initiatives planned within the Employee Wellness programme such as wellness days and talks

Doc

E

Domain 6 Operational Management: 6.2.2.3 A medical surveillance plan for at risk staff is implemented based on the health risk assessment

6.2.2.3.3 Evidence shows that medical examinations are performed for all health care workers who are exposed to potential occupational hazards when performing their duties (eg radiation / infectious diseases including TB / chemicals)

Doc

V

Domain 6 Operational Management: 6.2.2.4 Measures are in place to minimise the transmission of critical occupationally acquired injuries and diseases

6.2.2.4.2 Records of needle stick injuries show that those staff have received post exposure prophylaxis and have been re-tested

Doc

V

Domain 7 Facilities and Infrastructure: 7.3.1.6 There is up to date documented certification from the Local Fire Authority that the establishment complies with relevant fire safety regulations

7.3.1.6.1 The Fire Certificate for the health establishment is available

Doc

E

Domain 7 Facilities and Infrastructure: 7.3.1.7 Emergency plan is available and indicates that patient well-being is at all times protected

7.3.1.7.1 There are quarterly emergency drills

Doc

E

(Appendix E continued)

PC01 Clinical Services

(PC01 SELF-ASSESSMENT & EXTERNAL (OHSC) only, NOT in BASELINE)

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.2.1 A programme for the prevention and control of respiratory infections is in place

2.6.2.1.2 The health establishment provides appropriate types of masks and FDA approved respirators which are fit tested for all staff who are at risk of contracting TB or for all staff exposed to serious contagious respiratory infections

OBS		
X		

Domain 2 Patient Safety / Clinical Governance / Clinical Care: 2.6.3.2 Sharps are safely managed and disposed of

2.6.3.2.1 CHECKLIST - A random selection of clinical areas show that sharps are safely managed and disposed of

OBS		
√		

Domain 3 Clinical Support Services: 3.2.2.2 Safety measures are applied to protect patients and staff members from unnecessary exposure.

3.2.2.2 All radiation workers wear valid registered dosimeters and there is evidence that these are monitored on a daily basis for radiation exposure

OBS		
E		

3.2.2.8 There is a recent report (in the last six months) of radiation safety measures showing actions that have been implemented to limit exposure

Doc		
E		

Domain 3 Clinical Support Services: 3.2.2.3 Films and reagents are stored and disposed of according to guidelines

3.2.2.3.1 Staff are able to explain how to store and dispose of films and reagents

SI		
E		

Domain 4 Public Health: 4.3.1.3 The health establishment has an annually updated disaster management plan (including health emergencies)

4.3.1.3.1 An annually updated disaster management plan is available and displayed at strategic points

OBS		
E		

Domain 7 Facilities and Infrastructure: 7.1.2.2 The layout of the health establishment is planned or adapted to ensure that there is space to meet service and patient needs

7.1.2.2.3 Lighting and ventilation is observed to be adequate	OBS E		
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Domain 7 Facilities and Infrastructure: 7.1.4.1 The establishment holds regular / documented / comprehensive inspections of its physical facilities

7.1.4.1.2 No obvious safety hazards are observed during the visit such as loose electrical wiring / collapsing ceilings / unstable walls	OBS V		
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Domain 7 Facilities and Infrastructure: 7.4.1.2 Appropriate cleaning materials and equipment are available and properly used and stored

7.4.1.2.1 CHECKLIST - Cleaning materials cloths / dusters / scourers and chemicals and equipment are available and stored in an appropriate safe lockable area / with clear labels for equipment used internally and externally	OBS V		
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Summary of Report:

Additional Observations:

Inspector Name:

Inspector Signature:

CC04C Pharmacy / Medicine cupboard

Domain 3 Clinical Support Services: 3.1.3.5 There is an up-dated computerised or manual (stock cards) inventory management system for medical supplies in place

3.1.3.5.2 CHECKLIST - Physical stock corresponds to stock on the inventory management system as per Checklist 31221	OBS E		
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Summary of Report:

Additional Observations:

Inspector Name:

Inspector Signature:



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



Appendix F: Ethics approval letter

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • Facsimile [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

09 February 2015

HREC REF: 075/2015

Prof R Ehrlich
Public Health & Family Medicine
Falmouth Building

Dear Prof Ehrlich

PROJECT TITLE: COMPLIANCE OF HEALTH CARE FACILITIES IN THE WESTERN CAPE WITH THE NATIONAL CORE STANDARDS OCCUPATIONAL HEALTH AND SAFETY AND INFECTION PREVENTION AND CONTROL MEASURES AND RELIABILITY OF THE ASSESSMENT INSTRUMENT (Masters candidate-Dr B Cloete)

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

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

Approval is granted for one year until the 28th February 2016.

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.

We acknowledge that the student, Dr Brynt Cloete will also be involved in this study.

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

Yours sincerely

Signature removed

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 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.

Appendix G: Ethics annual progress report/ renewal

FHS017: Annual Progress Report / Renewal 25 FEB 2016

Record Reviews/Audits/Collection of Biological Specimens/Repositories/Databases/Registers

HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
<input checked="" type="checkbox"/> Approved	Annual progress report	Approved until/next renewal date	28 2 2017
<input type="checkbox"/> Not approved	See attached comments		
Signature Chairperson of the HREC	Signature removed	Date Signed	24/2/16

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	23/02/16		
HREC REF Number	075/2015	Current Ethics Approval was granted until	28/02/16
Protocol title	COMPLIANCE OF HEALTH CARE FACILITIES IN THE WESTERN CAPE WITH THE NATIONAL CORE STANDARDS OCCUPATIONAL HEALTH AND SAFETY AND INFECTION PREVENTION AND CONTROL MEASURES AND RELIABILITY OF THE ASSESSMENT INSTRUMENT		
Principal Investigator	Prof. Rodney Ehrlich		
Department / Office Internal Mail Address	School of Public Health and Family Medicine: Division of Occupational Medicine Rodney.ehrlich@uct.ac.za		
1 1 Does this protocol receive US Federal funding?			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

2. Protocol status (tick ✓)

<input type="checkbox"/>	Research-related activities are ongoing
<input checked="" type="checkbox"/>	Data collection is complete, data analysis only

Please indicate (in the block below) the titles and HREC reference numbers of any projects currently making use of the Database/registry/repository

--

3. Protocol summary

Total number of records or specimens collected, reviewed or stored since the original approval	200
Total number of records or specimens collected, reviewed or stored since last progress report	200
Have any research-related outputs (e.g. publications, abstracts, conference presentations) resulted from this research? If yes, please list and attach with this report	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

4. Signature

Signature of PI	Signature removed	Date	23-02-16
-----------------	-------------------	------	----------



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



Appendix H: Ethics study protocol
amendments approval letter

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • Facsimile [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

09 February 2015

HREC REF: 075/2015

Prof R Ehrlich
Public Health & Family Medicine
Falmouth Building

Dear Prof Ehrlich

PROJECT TITLE: AUDITING HEALTH CARE FACILITIES AGAINST THE NATIONAL CORE STANDARDS FOR OCCUPATIONAL HEALTH AND SAFETY AND INFECTION PREVENTION AND CONTROL: COMPLIANCE, RELIABILITY AND IMPACT (Masters candidate-Dr B Cloete)

Thank you for your letter to the Faculty of Health Human Ethics Committee dated 24 March 2016.

It is a pleasure to inform you that the HREC has **approved** the study title change as mentioned above.

The HREC approves that the co-supervisor, Prof Annalee Yassi, be added to the study.

We acknowledge that the student, Dr Brynt Cloete will also be involved in this study.

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

Please quote the HREC REF in all your correspondence.

Yours sincerely

Signature removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE



**Appendix I: Western Cape Government: Health
approval letter**

REFERENCE: WC_2015RP53_23

ENQUIRIES: Ms Charlene Roderick

University of Cape Town
Anzio Road
Observatory
Cape Town
7935

For attention: **Dr Brynt Cloete and Prof Rodney Ehrlich**

Re: Compliance of health care facilities in the Western Cape with the National Core Standards occupational health and safety and infection prevention and control measures and reliability of the assessment instrument.

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Please contact the following people to assist you with any further enquiries in accessing the following sites:

West Coast	C Bester	Contact No: 022 487 9207
Cape Winelands	L Phillips	Contact No: 023 348 8120
Eden /Central Karoo	H Schumann	Contact No: 044 803 2752
Overberg	W Kamfer	Contact No: 028 214 5800
Khayelitsha/ Eastern	D Heyns	Contact No: 021 3604 622
Northern / Tygerberg	L Bitalo	Contact No: 021 713 7650
Southern / Western	K Grammer	Contact No: 021 202 0906
Mitchells Plain / Klipfontein	P Olckers	Contact No: 021 370 5007

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.

2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final report within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. The reference number above should be quoted in all future correspondence.

Yours sincerely

signature removed

DR A HAWKRIDGE 18/2/2015.
DIRECTOR: HEALTH IMPACT ASSESSMENT

DATE:

CC

R CROUS

K CLOETE

A VAN DEN BERG

CHIEF DIRECTOR: RURAL DHS

CHIEF DIRECTOR: METRO DHS

DEPUTY DIRECTOR: QUALITY ASSURANCE

Appendix J: Journal instructions for authors

Preparing your manuscript

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, institutional addresses and email 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 is a systematic review or 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. 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

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Acknowledgements

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Online database

Healthwise Knowledgebase. *US Pharmacopeia*, Rockville. 1998. <http://www.healthwise.org>. Accessed 21 Sept 1998.

Supplementary material/private homepage

Doe J. Title of supplementary material. 2000. <http://www.privatehomepage.com>. Accessed 22 Feb 2000.

University site

Doe, J: Title of preprint. <http://www.uni-heidelberg.de/mydata.html> (1999). Accessed 25 Dec 1999.

FTP site

Doe, J: Trivial HTTP, RFC2169. <ftp://ftp.isi.edu/in-notes/rfc2169.txt> (1999). Accessed 12 Nov 1999.

Organization site

ISSN International Centre: The ISSN register. <http://www.issn.org> (2006). Accessed 20 Feb 2007.

Dataset with persistent identifier

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Appendix K: Supplementary Table 1:

Proportion of primary healthcare (PHC) facilities with positive responses (compliant) to measures in 2011/12 and 2014/15 divided into clinic and community day centres/community health centres

CLINICS (N=40) ¹ & Community Day Centres (CDCs)/Community Health Centres(CHCS) (N=20) ²				
Variables/measures		Baseline (external) 2011/2012	Self-Assessment (internal) 2014/2015	Difference & significance % (95% CI) or p-value
<i>Functional Clinic/CHC manager</i>	Clinics:			
	Median Score as % (IQR)	40% (5-70)	95% (59-100)	45% p=0.001 ^{3, 4}
Adequate IPC policy (E checklist requires 80% for compliance)	Number of facilities compliant: n (%)	8 (20%)	24 (60%)	40% (18:62)
	CDC/CHCS:			
	Median score as % (IQR) n (%)	79% (47-85) 10 (50%)	70% (0-100) 8 (40%)	-9% p=0.53 -10% (-49:29)
The annual in service education & training plan includes IPC (esp. TB & universal precautions) (E)	Clinics: n (%)	14 (35%)	32 (80%)	45% (23:67)
	CDC/CHCs: n (%)	12 (60%)	10 (50%)	-10% (-46:26)
There is educational material available for staff on universal precautions: hand washing/respirator use/ sharps/ PPE/cough etiquette (E)	Clinics: n (%)	29 (73%)	36 (90%)	17% (-0.3:35)
	CDC/CHCs: n (%)	15 (75%)	11 (55%)	-20% p=N/A ⁶
There is educational material available to patients on prevention of the spread of TB (E)	Clinics: n (%)	33 (83%)	38 (95%)	12% (-4:29)
	CDC/CHCs: n (%)	16 (80%)	17 (85%)	5% p=N/A ⁶
Appropriate types of masks and FDA approved respirators available & at risk staff fit tested (X)	Clinics: n (%)	32 (80%)	24 (60%)	-20% (-41:11)
	CDC/CHCs: n (%)	18 (90%)	12 (60%)	-30% p=N/A ⁶
Rooms used for infectious TB patients are separated by adequate physical barriers from non-TB patients (X)	Clinics: n (%)	30 (75%)	32 (80%)	5% (-14:24)
	CDC/CHCs: n (%)	12 (60%)	12 (60%)	0 p=N/A ⁶

Rooms used for accommodation/consultation of patients with respiratory infections have adequate natural or mechanical ventilation (E)	Clinics: n (%)	31 (78%)	37 (93%)	15% p=N/A ⁶
	CDC/CHCs: n (%)	16 (80%)	18 (90%)	10% p=N/A ⁶
A comprehensive policy on standard precautions is available (E checklist)	Clinics: Median score as % (IQR) n (%)	100% (80-100) 28 (70%)	100% (100-100) 32 (80%)	p=0.0164 10% (-11:31)
	CDC/CHCs: Median score as % (IQR) n (%)	92% (70-100) 13 (65%)	92% (0-100) 14 (70%)	p=0.42 5% p=N/A ⁶
Reporting system for needle stick injuries (V)	Clinics: n (%)	31 (78%)	39 (98%)	20% (3:37)
	CDC/CHCs: n (%)	19 (95%)	15 (75%)	-20% p=N/A ⁶
Randomly selected clinical area: Sharps safety (V checklist requires 90% for compliance)	Clinics: Median score as % (IQR) n (%)	100% (80-100) 28 (70%)	100 (92-100) 36 (90%)	p=0.026 20% (2:38)
	CDC/CHCs: MS as % (IQR) n (%)	100% (93-100) 16 (80%)	100% (82-100) 14 (70%)	p=0.56 -10% (-46:26)
Annual hand washing/hygiene campaign/drive held (V)	Clinics: n (%)	11 (28%)	15 (38%)	10% (-13:33) p=0.35
	CDC/CHCs: n (%)	10 (50%)	10 (50%)	0 p=N/A ⁶
Up to date decontamination policy (E checklist)	Clinics: Median score as % (IQR) n (%)	35% (0-78) 10 (25%)	70% (0-100) 19 (49%)	p=0.19 24% (4:42)
	CDC/CHCs: MS as % (IQR) n (%)	35% (0-78) 5 (25%)	0 (0-34) 4 (20%)	p=0.0485 -5% p=N/A ⁶
Staff able to explain used instrument sterilisation procedure (E Checklist)	Clinics: Median score as % (IQR) n (%)	84% (54-100) 23 (58%)	100% (0-100) 24 (60%)	p=0.86 2% (-22:27)
	CDC/CHCs: MS as % (IQR) n (%)	73 (52-85) 9 (45%)	71% (0-91) 9 (45%)	p=0.68 p=N/A ⁶
Evidence of medical examinations on at risk staff⁷ (V)	Clinics: n (%)	N/A ⁸	20 (50%)	N/A ⁸
	CDC/CHCs: n (%)	N/A ⁸	4 (20%)	N/A ⁸
Records show staff with NSI received PEP & have been re-tested (V)	Clinics: n (%)	13 (33%)	22 (55%)	22% (4:41)
	CDC/CHCs: n (%)	11 (55%)	9 (45%)	-10% (-46:26)

The fire certificate for the facility is available (E)	Clinics: n (%)	4 (10%)	22 (55%)	45% (26:64)
	CDC/CHCs: n (%)	3 (15%)	2 (10%)	-5% p=N/A ⁶
There are quarterly emergency drills (E)	Clinics: n (%)	0	3 (8%)	8% p=N/A ⁶
	CDC/CHCs: n (%)	0	3 (15%)	15% p=N/A ⁶
Pooled facility score for X measures as %	Clinics: Mean (Sd)	78% (32)	70% (32)	-8% (-21:6)
	n (%)	25 (63%)	19 (48%)	-15% (-37:7)
No. of facilities complaint (score=100%): n (%)	CDC/CHCs: Mean (Sd)	75% (30)	60% (42)	-15% (-34:4)
	n (%)	11 (55%)	9 (45%)	-10% p=N/A ⁶
Pooled facility score for V measures as %	Clinics: Mean % (Sd)	55% (28)	69% (19)	14% (4:24)
	n (%)	6 (15%)	6 (15%)	0 p=1
No. of facilities complaint (score>=90%) : n (%)	CDC/CHCs: Mean % (Sd)	72% (22)	64% (28)	-8% (-26:10)
	n (%)	6 (30%)	7 (35%)	5% p=N/A ⁶
Pooled facility score E measures as %	Clinics: Mean % (Sd)	51% (16)	70% (15)	19% (14:25)
	n (%)	1 (3%)	13 (33%)	30% (12:48)
No. of facilities complaint (score>=80%): n (%)	CDC/CHCs: Mean % (Sd)	56% (15)	51% (24)	-5% (-27:-18)
	n (%)	0	2 (10%)	10% p=N/A ⁶
Pooled facility (weighted) score as % (Weighting: X=40%,V=30%, E=20%, Developmental=10% (None))	Clinics: Mean (Sd)	64% (20)	70% (18)	6% (-2:13)
	CDC/CHCs: Mean (Sd)	70% (19)	59% (27)	-11% (-24:3)
Pooled facility (unweighted) score as %	Clinics: Mean (Sd)	55% (18)	67% (17)	12% (7:18)
	CDC/CHCs: Mean (Sd)	68% (17)	58% (25)	-10% (-22:3)
	Overall: Mean (Sd)	64% (20)	59% (18)	-5% (-1:11)
No of facilities non-compliant (<50%): n (%)	Clinics:	11 (28%)	5 (12%)	-16% (-34:4)
	CDC/CHCs:	4 (20%)	7 (35%)	-15% p=N/A ⁶
No. of facilities conditionally compliant (>=50<80%): n (%)	Clinics:	21 (53%)	19 (48%)	-5% (-29:19)
	CDC/CHCs:	8 (40%)	8 (40%)	0 p=N/A ⁶

No of facilities compliant (>=80%)	Clinics:	8 (20%)	16 (40%)	20% (-1:41)
	CDC/CHCs:	8 (40%)	5 (25%)	-15% (-52:22)

N: number of health facilities IQR: interquartile range: FDA: Food and Drug Administration PEP: post exposure prophylaxis Sd: Standard deviation CI: confidence interval E:Essential measure risk category X:Extreme measure risk category V:Vital measure risk category

¹Excludes 3 districts (A, C, F).

²Excludes 3 districts (B, E, F).

³Wilcoxon signed rank test.

⁴Statistically significant at $\alpha=0.05$

⁵McNemar 's test .

⁶Not applicable because discordant pairs<10.

⁷Not included in overall facility score.

⁸Not asked at baseline.