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**AN EVALUATION OF THE CLINICAL AUDIT OF DIABETES  
MANAGEMENT AT COMMUNITY HEALTH CENTERS IN THE METRO  
DISTRICT OF THE WESTERN CAPE PROVINCE**

By

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## Abstract

Quality of care in the public health sector of South Africa suffers from a lack of resources, poor delivery systems and variable quality of diagnosis and treatment. Clinical audit is considered a tool that health providers can use to monitor and improve quality of care. The audit and feedback process is depicted as a simple cycle but evidence has shown that the action stage is a complex process influenced by context, leadership and health care worker attitudes. Most evidence comes from developed countries and there is a gap in the literature as to whether audit and feedback is of value or sustainable in developing countries, given the resource constraints in these settings. However, the relative effects on improvement are likely to be larger when the baseline adherence to recommended practice is low, which is often the case in developing countries.

Clinical audit was adopted by the Clinical Management forum of Metro District Health Services, in the Western Cape Province, as a quality improvement tool within the framework of clinical governance. Members of this forum chose to audit the management of diabetes at primary health care level. All Community Health Centres rendering a chronic care service were instructed to participate. The first audit in 2005 revealed poor quality of care at primary health care facilities in the Metro, and various interventions were implemented to address the deficiencies. Annual audits were conducted again in 2007, 2008 and 2009. After each round of "self-auditing" within the facility, chronic care teams were expected to formulate and commit to an action plan to improve the quality of care based on their results.

This study aimed to evaluate the long-term trend in quality improvement and determine whether there had been an increase in the performance of diabetic clinical processes. The evaluation applied the Skillings-Mack test statistic to pooled results from participating community health centres in the Metro district.

There were 40 community health centres that participated in the annual audit in 2005 which decreased to 30 in 2009. Except for 2 routine processes, the baseline medians in 2005 for 6 out of 9 processes were below 50%. The pooled audit results showed statistically significant improvements in 7 out of the 9 clinical processes. The findings indicate an association between the application of clinical audit and quality improvement in resource-limited settings. Support from the relevant government health programmes and commitment of health managers and front-line staff also contributed to the success of the audit. Access to secondary and tertiary services will have to be strengthened as the quality of primary health care improves and more patients in need of specialised care are identified.

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# An Evaluation of the Clinical Audit of Diabetes Management at Community Health Centers in the Metro District Health Services, of the Western Cape Province

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## 1. Introduction

### a) Research Problem

#### i. Quality of Health Care in the Public Sector

In 2001, the Policy on Quality in Health Care for South Africa became national policy by the South African National Department of Health (NDOH 2007). Because South Africa (SA) has a dual health system, comprising a public and private sector, this document outlined evidence on the state of quality in both sectors at the time. The public sector, that serves 85% of the population, was characterised by a “lack of resources, poor delivery systems and variable quality of clinical diagnosis and treatment” (NDOH 2000: 10). Ten years later the Honourable Aaron Motsoaledi, Minister of Health, stated in his speech during the occasion of the debate of the State of the Nation Address, that quality of care in the public sector is “ever in the minds and on the lips of our people” and reiterated the priority to improve the quality of health services as one of the key actions for improving the health profile of all South Africans in the Government’s Programme of Action 2009 (Motsoaledi 2010).

The Western Cape Province is one of nine provinces in SA and consists of six health districts: five rural and the Cape Metropole (Metro District). Personal primary health care services in the Metro district are provided by dual authorities; the Provincial Government of the Western Cape (PGWC) and the municipal authority known as the City of Cape Town (COCT). Community health

centers are primary health care (PHC) facilities run by the Provincial authority, known as the Metro District Health Services (MDHS) Within the MDHS, is the Clinical Management Meeting, which is a monthly forum comprising of clinical managers and principal medical officers from community health centers across all eight of the sub-districts in the Metro (Martell *et al.* 2005).

In 2005, following the introduction of clinical governance into the MDHS, members of this forum embarked on a quality improvement project for primary health care services. Clinical governance is defined as a framework through which health services are accountable for continuously improving the quality of their services and maintaining high standards of care (Wright 2003: 1). Clinical governance is also considered a core function of the Family Medicine specialists in the MDHS. The Clinical Management forum chose to use clinical audit as a means to operationalise the concepts of quality of care at PHC level. Clinical audit is defined as a quality improvement process that seeks to improve patient care and outcomes through the systematic review of care against explicit criteria and the implementation of change, and is considered a key and essential component of clinical governance (Copeland 2005: 3). An abbreviated version of the original 2000 Quality in Health Care policy document by the National Department of Health states that one of the causes of poor quality of care is health professionals with “erroneous, outdated or no information skills” (NDOH 2007: 6). Clinical audit is then described, amongst other methods in this policy document, as an instrument for service providers to monitor quality.

The Clinical Management forum developed a criterion-based clinical audit, described by Martell *et al.* in the 2005 *Metro District Health Services Audit Report on CVS Risk Factor Management*

(Martell *et al.* 2005). The criterion-based audit process entails comparing received care, for the condition of interest, against agreed criteria of best practice, developing action plans for improvement and re-auditing (Figure 1).

**Figure 1: The basic audit cycle**



**(NICE 2002)**

Clinical audit criteria are explicit statements that define what is being measured and are classified into those concerned with:

- Structure – The capital facilities and infrastructure that are needed to manage the condition of interest.
- Process – Administrative and clinical practices that are performed during the management of the condition of interest.
- Outcome – The expected outcome of care.

Clinical audit is differentiated from research in that research seeks new knowledge, and audit aims to ensure that existing knowledge is put into practice (Copeland 2005: 12). Target

standards are the levels of care to be achieved for any particular criterion and generally informed by research findings, national or provincial guidelines, or local protocols and policies (NICE 2002: 23).

The clinical audit process has been depicted as a deceptively simple spiral in which improvements are achieved through repetitions of the cycle with the aim of increasing the level of quality (NICE 2002: 3). However, published literature has shown that the action stage of the audit cycle is more of a complex process than a single, discrete event, and that contextual factors from national initiatives to local governance, exert significant influence (Balogh *et al.* 2001). Other studies have linked quality improvement, via the clinical audit process, to personality traits amongst health care workers that favour good communication, interpersonal skills and an appreciation for the relationship between quality improvement and patient benefits (Siddiqi *et al.* 2008). More recent reviews have concluded that the effects on quality improvement are likely to be larger when feedback, following an audit, is provided more intensely, such as by senior personnel, over a long period, face-to-face or combined with educational meetings (Jamtvedt *et al.* 2006). Thus, on the basis of these findings, clinical audit is considered a complex intervention (Siddiqi *et al.* 2008).

## **ii. Development of the Clinical Audit tool**

The decision to use the management of diabetes mellitus at PHC level as the initial audit topic, came in the wake of the 2000 Burden of Disease Study that found cardiovascular disease (CVD) to be the leading cause of death amongst men and women in the Western Cape (Bradshaw *et*

*al.* 2004). Diabetes is an independent risk factor for cardiovascular disease and although exact figures on the number of diabetic patients visiting PHC facilities are unknown, the consequences of poor diabetes care, such as premature blindness and amputations, are believed to be disproportionately prevalent in the population of the Metro District (Martell *et al.* 2005). Improving glycaemic control in diabetics has been associated with a reduction in health care costs and utilisation (Wagner *et al.* 2001). In addition, the audit decision was motivated by the availability of good evidence to inform target standards for the management of diabetes (Martell *et al.* 2005).

Members of the Clinical Management forum considered the initial audit in 2005 as an introduction to the concepts of clinical audit, and chose to work on the actual audit procedure within facilities, before expanding the range of audit criteria. For this reason, structural criteria related to diabetic care were limited to a few essential items, such as the availability of calibrated baumanometers and glucometers, and outcome criteria were excluded from the original tool (Martell *et al.* 2005). The focus of the first audit, and the results reported, pertain to diabetic clinical processes only. Table 1 below illustrates the pooled results of this audit against the agreed standards set by members of the Clinical Management forum, which provided a baseline on the quality of diabetes care in community health centers of the Metro district.

**Table 1: Results of initial diabetes audit**

<b>2005 Clinical Audit Criteria</b>	<b>Results</b>	<b>Agreed standards</b>
1) Mean number of visits/year (Minimum 4)	4.0	4
<b>Diabetic Processes</b>	<b>Percentage recorded</b>	<b>Agreed standards</b>
2) Weight (at each visit)	64%	100%
3) BMI (at each visit)	2%	100%
4) Glucose (at each visit)	89%	100%
5) Fasting glucose (at each visit)	8%	Not set
6) BP (at each visit)	86%	100%
7) Foot Exam (once/year)	21%	50%
8) Urine Protein (once/year)	72%	100%
9) Retina screen (once/year)	12%	40%
10) Cholesterol (once/year)	6%	100%
11) Creatinine (once/year)	10%	100%
12) Smoking status (once/year)	19%	100%
13) Smoking advice (once /year)	13%	100%
14) Diet education (once /year)	41%	100%
15) Exercise discussed (once/year)	26%	100%

**(Martell et al. 2005)**

By way of a patient folder review, the total number of diabetic visits in the year was used as the denominator for determining how often the patient's weight, blood pressure (BP), BMI (body mass index), glucose and fasting glucose measurements were recorded. These processes are expected to be performed routinely at each visit and ideally the numerator should be equal to the denominator. The target standards for the clinical processes numbered 7 to 15 in Table 1 were accepted as annual assessments.

Over the following years, the scope of the original tool increased to include structural and outcome elements (2007) and additional clinical processes (2008). In 2009, the MDHS made use of an integrated audit tool that assessed the management of four other chronic conditions, but employed the same methods of auditing and retained core diabetic process elements from the original tool. Since the audit cycle involves action plans to achieve the target standards, one

would expect subsequent audits to show a gradual improvement in the quality of care. Testing this expectation is one subject of this research report.

## **2. Research question:**

Did the implementation of clinical audit, between the years 2005 to 2009, lead to improvements in the quality of diabetes management in the Metro District Health Services of the Western Cape Province?

## **3. Justification**

The majority of published evidence in support of clinical audit as a quality improvement tool comes from developed countries, such as the UK NHS (Johnston *et al.* 2000) and Australia (Berk *et al.* 2003). However, there is a dearth of well-designed research to adequately assess whether these findings are applicable in developing countries (Siddiqi *et al.* 2005). Maher (Maher 1996) raises the point that a definition of quality of care must include public, patient and health care worker perspectives that are relative to the context within which it is applied. Further, obstacles to clinical auditing in developing countries are resource constraints that result in the practice being perceived as a non-priority and negative responses from health care workers to audit (Maher 1996). Siddiqi's review of interventions aimed at getting evidence into practice in developing countries concluded that audit and feedback were effective in bringing about improvement, at least in the short term, in compliance with set standards or clinical outcomes (Siddiqi *et al.* 2005).

In the latest update, a Cochrane review found divergent effects of audit and feedback on professional practice (Jamtvedt *et al.* 2006). Of the 118 randomised controlled trials included in the review, only 24 were judged to have a low risk of bias. The results ranged from a 16% absolute decrease in compliance with set standards (an adjusted risk difference of -0.16) to a 70% increase (adjusted risk difference of 0.70). The authors suggest that audit and feedback can be effective in producing generally small to moderate improvements and that these relative effects are likely to be larger when the baseline adherence to recommended practice is low. Pattinson's commentary on the review considered this finding applicable to under-resourced settings, since adherence to recommended practices is often low to begin with (Pattinson 2006). This was certainly the case with the 2005 diabetes audit in the Metro District Health Services.

The current evaluation was carried out primarily at the request of the Chronic Diseases programme coordinator for the WC Department of Health, but will also contribute to the scant evidence base on the effectiveness of clinical audit in under-resourced settings. Although the evidence implies that clinical audit is an intervention warranting both qualitative and quantitative methods of assessment (Siddiqi *et al.* 2008), this study makes use of quantitative methods only, to evaluate the trend in data that have been collected in the past five years.

#### **4. Objectives:**

1. The objective is to analyse the pooled audit results of clinical processes related to diabetes management, collected annually in 2005, 2007, 2008 and 2009, from participating facilities

in the Metro district, to determine whether there has been a statistically significant increase in the performance of these diabetes clinical processes.

## **5. Methods**

### **a) Population and Sampling Strategy**

Ethical approval was granted from the University of Cape Town Research Ethics Committee (Appendix A). All community health centers (CHC) in the Metro District rendering a chronic care service were instructed to participate in the audit when it began in 2005.

In light of the aim to foster a sense of responsibility amongst health care workers towards clinical audit and to empower them to take action in improving the quality of care in low-resource settings, the audit procedure in participating facilities was essentially a form of “self-audit”. The individuals responsible for sampling the folders and performing the audit were clinical staff members from the facility’s chronic care team, such as a senior medical officer or PHC nurse. During the month of February, in every year that the audit was done, the designated doctor or nurse had to systematically sample twenty diabetic folders from the total number of patients attending the diabetic clinic on one day, and conduct a folder review. Smaller facilities with clinics attending to fewer than thirty patients a day were allowed to audit every diabetic folder until the target was reached. While the sampling method remained unchanged from the inception of the project, in 2009 after three cycles of audit, the target sample size of twenty diabetic folders per facility was reduced to ten. This reduction was done to accommodate the implementation of the larger integrated audit tool that audited the management of five chronic

diseases, including diabetes. Had the initial sample size remained at twenty folders per condition, the administrative workload associated with conducting the integrated audit would have increased five-fold. For that reason, the sample size was decreased to ten folders per condition and clinical staff members were spared the overwhelming paper-work.

A sampled folder qualified for the folder review if the patient had been attending the clinic for at least one year and had at least two chronic care visits in the previous year. Data collection entailed extracting information from the clinical notes and entering it into the audit data collection form (Appendix B). This method proved cumbersome for the staff members involved, and as a consequence a clinical summary sheet was developed for use in the folders of patients receiving chronic care. From 2007 onwards, this summary tool, known as the MDHS Record Sheet, was implemented and functioned as the source document for the diabetes audit (Appendix C).

### **b) Data Management and Feedback**

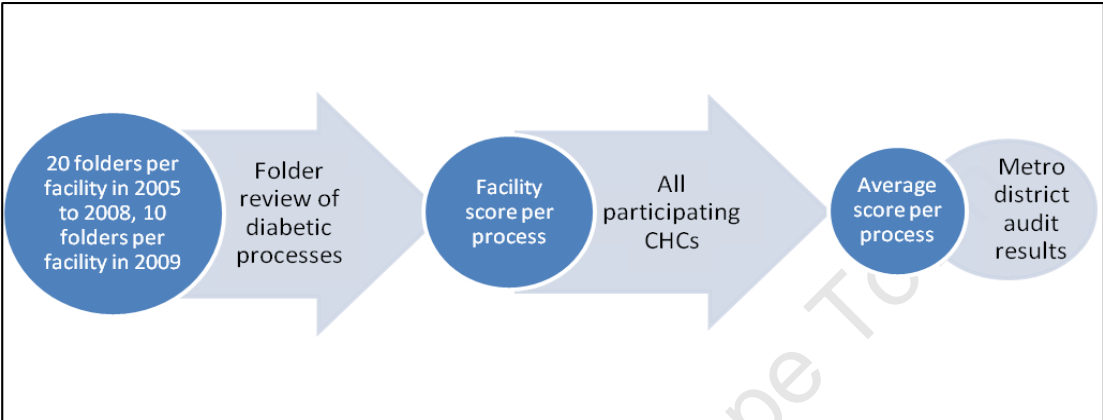
Once the audit was completed at a CHC, the form was submitted to the senior medical officer in the Clinical Management forum, for data capture and analysis. The audit was a paper-based tool and the results were transferred to an electronic master spreadsheet in Microsoft Excel. The same electronic file was used for all the results from 2005 to 2008, making allowances for changes along the way. With the introduction of the integrated audit tool in 2009, a new data collection tool was created. All audit reports and records have been stored in the office of the provincial project coordinator.

After each round of the annual audit, participating facilities received reports that graphically depicted their results using bar graphs generated in Microsoft Excel. Completing the audit cycle meant that chronic care teams at each CHC had to formulate and commit to an action plan to improve the quality of care based on these results. At the district level, the MDHS hosted an intervention called an “Appreciative Inquiry” (AI) that was prompted by the initial audit results of 2005 (Mash *et al.* 2008). From July 2007 to July 2008, health care workers involved in chronic care participated in a series of workshops aimed at addressing specific knowledge gaps related to diabetes management, supporting teamwork and leadership in their chronic care team and finding local solutions to improving the results of their audit.

Every year in which the audit took place, the senior medical officers or sub-district Family Medicine specialists were required to make a concerted effort during the month of the audit and within a reasonable period of up to 6 months afterwards, to obtain outstanding forms and missing or illegible data from the participating community health centers in their respective sub-districts. In spite of this, there were still data management mishaps: original audit forms without duplicate copies were misplaced or lost in the mail; data entry was illegible and there was no source document or the responsible person was unable to verify what had been written; data entry was incorrect or incomplete. Therefore, in the absence of source documents or verbal confirmation, indecipherable or missing information was excluded from the analysis and final reports.

Figure 2 below illustrates the audit data flow from the facility. The annual folder review resulted in a mean score per diabetic clinical process for each facility and the average of all participating facilities gave rise to the final Metro district score.

**Figure 2: Audit data flow**



Even though the original audit tool has evolved since 2005, core diabetic process elements, listed in Table 2 below, remained unchanged as part of the folder review. These elements form the basis of this evaluation.

**Table 2: Audit tool clinical processes**

<b>Number:</b>	<b>Diabetes Clinical Audit Indicators:</b>
1	Mean number of diabetic visits per year
	<b>Diabetic Clinical Processes:</b>
2	Number that had weight checked at each visit
3	Number that had blood pressure checked at each visit
4	Number that had annual feet exam
5	Number that had annual urine protein test
6	Number that had annual retinal screening
7	Number that had annual serum cholesterol test
8	Number that had annual serum creatinine test
9	Number that received diet education annually
10	Number that discussed exercise annually

### **c) Validity and Reliability**

The validity of the process indicators is based on minimum standards prescribed in the guidelines developed by the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) as well as technical expertise from the Departments of Endocrinology and Family Medicine at the University of Cape Town (Martell *et al.* 2005). Training workshops were held prior to the audit each year to ensure that clinical staff members responsible for the data collection were competent in the procedure.

## **6. Statistical analysis**

This evaluation will apply the Skillings-Mack (SM) test statistic to results on the performance of the clinical processes, for the Metro district, for each year of auditing. The SM test is a non-parametric, general Friedman-type statistic used to compare treatment effects in randomised block designs (Cunningham 2010). Here, effects are represented by the process results, and blocks by the four years. The Friedman Test is the non-parametric equivalent of the Analysis of Variance (ANOVA) Test used to compare the means of more than two samples, and either test would be applicable if the data set was balanced, that is retaining the same number of facilities each year. But in this case, use of the SM test is appropriate since the data are unbalanced and incomplete due to arbitrary non-response from some facilities or missing information on the submitted documents. Although this test will be used to indicate whether or not there is a statistically significant difference in the values by year, descriptive statistics (such as the weighted sum of centered ranks) and box and whisker plots will be used to illustrate these changes.

## **7. Ethics and Communication**

### **a) Ethics**

Ethical approval was initially granted in 2005 by the University of Cape Town Research Ethics Committee and an extension was granted in 2008 (Appendix D) and in May 2010 (Appendix E) to continue auditing and publish this evaluation.

As the folder review did not involve any patient contact and no personal identification was collected, informed consent was not considered. Patient anonymity has been maintained as there is no way to link the data collected on the audit tool to particular folders.

Regarding beneficence and non-maleficence, this evaluation will provide information on whether clinical audit has been a useful tool to improve the quality of diabetic care in this setting. In a broader context it is hoped that improvements in quality of care will be appreciated by all those who use or work at public health facilities. No individuals are at risk of any physical or mental harm as a result of this study.

All community health centers rendering a chronic care service in the Metro district were equally instructed to participate, and all the submitted results will be treated in the same manner.

## **b) Stakeholders**

Those that might have an interest in the findings of this study are:

1. Department of Health (DoH), Provincial Government Western Cape
2. MDHS Clinical Management forum
3. School of Public Health and Family Medicine, University of Cape Town
4. Staff and primary health care (PHC) managers involved in chronic care services at PHC facilities in the province
5. Patients attending community health centers for PHC services in the province.

### **c) Reporting**

The final report will be given to the WC Department of Health, through the Chronic Diseases project coordinator, for dissemination and to serve as a prototype for future evaluations. If the criteria are met, it will also be submitted to peer-review journals for publication.

## **8. Logistics**

### **a) Budget**

The source of funding for the clinical audit data collection has been the WC Department of Health. However, this evaluation is self-funded.

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## 9. References

1. Balogh R, Bond S. 2001. Completing the audit cycle: the outcomes of audits in mental health services. *International Journal for Quality in Health Care*. 13(2):135-142.
2. Bradshaw D, Groenewald P, Laubscher P, Nannan N, Nojilanan B, Norman R, Pieterse D, Schneider M, Bourne D, Timaeus I, Dorrington R, Johnson L. 2003. Initial Burden of Disease estimates for South Africa 2000. *S Afr Med J*. 93(9):682-688.
3. Copeland G. 2005. *A Practical Handbook for Clinical Audit*. NHS: Clinical Governance Support Team.
4. Cunningham M. 2010. A Nonparametric Method to Assess Treatment Effects for Unbalanced Designs Using SAS/IML®. *SAS Global Forum 2010*. Paper 275-2010.
5. Jamtvedt G, Young JM, Kristoffersen DT, O'Brien MA, Oxman AD. Audit and feedback: effects on professional practice and health care outcomes. 2006. *Cochrane Database of Systematic Reviews*. Issue 2. Art. No.: CD000259.DOI:10.1002/14651858.CD000259.pub2.
6. Johnston G, Crombie IK, Davies HTO, Alder EM, Millard A. 2000. Reviewing audit: barriers and facilitating factors for effective clinical audit. *Quality in Health Care*. 9:23-26.
7. Maher D. 1996. Clinical audit in a developing country. *Tropical Medicine and International Health*. 1(4):409-413.
8. Martell R, De Vries E. 2005. Audit Report on CVS Risk Factor Management. Western Cape Department of Health: Metro District Health Services.

9. Mash R, Levitt NS, Van Vuuren U, Martell R. 2008. Improving the annual review of diabetic patients in primary care: an appreciative inquiry in the Cape Town District Health Services. *South African Family Practice Journal*. 50(5):50.
10. Motsoaledi A. 2010. *African National Congress Parliamentary Caucus*. [Online]. Available: <http://www.anc.org.za/caucus/index.php?include=docs/sp/2010/sp0215b.html> (14 January 2011).
11. National Institute for Clinical Excellence. 2002. *Principles for Best Practice in Clinical Audit*. United Kingdom: Radcliffe Medical Press Ltd.
12. Pattinson RC. 2006. Audit and feedback: effects on professional practice and health-care outcomes: RHL commentary. *The WHO Reproductive Health Library*. Geneva: World Health Organisation.
13. Siddiqi K, Newell J, Robinson M. 2005. Getting evidence into practice: what works in developing countries? *International Journal for Quality in Health Care*. 17(5):447-453.
14. Siddiqi K, Volz A, Armas L, Otero L, Ugaz R, Ochoa E, Gotuzzo E, Torrico F, Newell JN, Walley J, Robinson M, Dieltiens G, Van Der Stuyft P. 2008. Could clinical audit improve the diagnosis of pulmonary tuberculosis in Cuba, Peru and Bolivia? *Tropical Medicine and International Health*. 13(4):566-578.
15. SOUTH AFRICA. National Department of Health. 2000. *A Policy on Quality in Health Care for South Africa*. [Online] Available: <http://www.doh.gov.za/docs/index.html> (16 December 2010).

16. SOUTH AFRICA. National Department of Health. 2007. *A Policy on Quality in Health Care for South Africa (Abbreviated Version)*. [Online] Available:  
<http://www.doh.gov.za/docs/index.html> (16 December 2010).
17. Wagner EH, Sandhu N, Newton KM, McCulloch DK, Ramsey SD, Grothaus LC. 2001. Effect of improved glycaemic control on health care costs and utilization. *JAMA*. 285(2):182-189.
18. Wright J, Hill P. 2003. *Clinical Governance*. United Kingdom: Elsevier Science Limited

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## Structured Literature Review

### Objectives

1. Highlight the extent of published research on clinical audit as a quality improvement tool, from *developed* countries.
2. Present and discuss the published research on clinical audit as a quality improvement tool, from *developing* countries, under the following categories:
  - a. Outcomes and findings of studies evaluating the impact of clinical audit in developing countries.
  - b. Future research implications for developing countries.

### Literature Search Strategy and Quality Criteria

The literature search strategy involved querying two online databases, PubMed and Academic Search Premier – via EBSCOhost, using the following keywords and terms listed in Table 1 below.

**Table 1: Literature Search Terms**

Search Terms
clinical audit + quality improvement
clinical audit + quality improvement + developing country
clinical audit + primary health care + developing country
clinical audit + primary health care + low resource setting
quality improvement + primary health care + developing country
quality improvement + low resource setting

Articles that were published after 1996 and available in English were considered for an initial appraisal. Thereafter, preferred articles for this review were those that used quantitative methods to report on the following:

1. The effect on quality of health care after at least two cycles of clinical audit.
2. Long-term trends in quality of care following the implementation of clinical audit.

Studies that supported the quantitative results with qualitative research were highly favoured. Those that used only qualitative research methods to document experiences with, or the history of, clinical audit within particular contexts, were judged on the detail and scope of the analysis. Studies that simply described the results of a single audit without repeating the cycle were excluded from the review. In addition, the bibliographies of the selected articles were evaluated for sources of evidence, particularly for research from developing countries in the case of systematic reviews, as well as websites of relevant organisations.

## Summary of interpretation of literature

### 1. Evidence from developed countries

The UK National Health Service (NHS) began investing in the process of clinical audit in 1990, with minimal evidence to support the idea that it would provide equal returns in quality improvement (Johnston *et al.* 2000). Nonetheless, it became rooted in professional practice within the structure of clinical governance (James *et al.* 2001; Johnston *et al.* 2000). Since then, numerous studies have been published describing, evaluating and criticising clinical audit practice in the NHS (Bowie *et al.* 2007; Bowie *et al.* 2010; Campbell *et al.* 2002; Foy *et al.* 2005; James *et al.* 2001; Johnston *et al.* 2000; Mian *et al.* 2004).

Johnston's review found that most of the published studies evaluating clinical audits in Britain were descriptive, and revealed a range of activities with varying depth of involvement across health services (Johnston *et al.* 2000). Some of the perceived audit benefits cited in these studies were: changes in health professionals' behaviour, and increased knowledge and performance that lead to improvements in patient care. Opposing opinions claimed that it increased workload, detracted from clinical work and restricted individualised care. An evaluation of blood transfusion procedures at three district hospitals in Britain showed that after four audit cycles over the course of ten years, the hospitals substantially reduced blood wastage and reduced unnecessary laboratory work (James *et al.* 2001). The positive outcome was attributed to a collaborative approach from clinical staff that focused on safety and quality, and supportive peer review. However, a more in-depth evaluation of the impact of auditing within the NHS mental health services provided different insights (Balogh *et al.* 2001). This retrospective review concluded that the action stage of the audit cycle is more of a complex process than a single discrete event, and that contextual factors, from national initiatives to local governance, exert significant influence. Therefore, attributing change within a clinical setting to single causes, such as individual audit projects, is somewhat short-sighted (Balogh *et al.* 2001).

Challenges associated with completing the audit cycle that involve negotiating and implementing change have also been pointed out (Bowie *et al.* 2007). The skills required to successfully follow through on a course of action go beyond technical knowledge of the basic audit cycle, and entail leadership, motivation and project management, qualities that differ from one health care worker to another (Bowie *et al.* 2007). These aspects have been

acknowledged as learning needs, requiring a minimum of formal teaching if frustration and apathy with the audit process are to be avoided (Bowie *et al.* 2007).

In a more recent qualitative study of the Scottish NHS board, clinical audit was regarded as “a time-consuming additional chore” and further labelled a “bureaucratic, managerially driven, tick-box exercise with the potential to apportion individual blame and which has no associated personal or professional rewards” (Bowie *et al.* 2010). After fifteen years of formal existence in the NHS, there appears to be a dichotomy between the audit rhetoric of policy makers and the reality of clinical practice at the front-line (Bowie *et al.* 2010). The authors suggest that perhaps it is time for a radical rethink on how best to overcome obstacles to audit practice, as these are likely to persist regardless of the quality improvement tool employed (Bowie *et al.* 2010).

While clinician workload and pessimistic staff attitudes towards audit were barriers to ongoing quality monitoring in the Barwon Health Mental Health Services in Australia, clinical audit practice led to the development of advanced patient information management systems that in turn allowed for an expansion in the audit scope and focus (Berk *et al.* 2003). During six years of annual auditing, audit recommendations decreased, had greater clarity and addressed more complex issues of quality of care (Berk *et al.* 2003). In addition, these recommendations were more likely to be taken up when applied across the service, instead of to individual service areas, and less easily implemented when challenging established practice or requiring attitudinal change (Berk *et al.* 2003).

The literature from developed countries points to a variety of responses to clinical audit, ranging from behaviour change amongst health professionals to advancements in health

information systems. In this context, successful audit outcomes appear to hinge on successful management, and negative outcomes and resistance from frontline staff probably reflect poor leadership during implementation rather than inherent flaws in the audit process.

## **2. Evidence from developing countries**

### ***a. A review of research evaluating clinical audit as a quality improvement tool***

Although the published evidence from developed countries with established clinical audit practice is encouraging, there is a dearth of well-designed research to adequately assess whether these findings are applicable in developing countries (Siddiqi *et al.* 2005). Maher (Maher 1996) raised the point that a definition of quality of care must include public, patient and health care worker perspectives that are relative to the context within which clinical audit is applied. Further, obstacles to clinical auditing in developing countries are resource constraints that result in the practice being perceived as a non-priority, and negative responses from health care workers.

For example, the Zambia Quality Assurance Program, despite successfully covering the entire country, was unsustainable in the public sector (Bouchet *et al.* 2002). An evaluation team visited 24 health facilities in 9 districts, representing all four regions in Zambia and interviewed 140 health and non-health staff, from both the public and private sectors and, although some of the facility-based quality improvement teams (QIT) were able to achieve measurable successes, such as lowering the malaria incidence or reducing waiting times, most facilities did not meet the requirements due to the absence of coaches or “link

facilitators” (Bouchet *et al.* 2002). QIT coaches who held other positions in the district health services did not have enough time for quality assurance activities, and successes were dependent on individuals willing to train health care workers and do support visits (Bouchet *et al.* 2002). However, in a case study of Queen Elizabeth Central Hospital in Blantyre, Malawi, one of the mechanisms in which clinical audit raised the standard of care was through performance feedback to health care workers that stimulated motivation and overall performance (Maher 1996).

A review of interventions aimed at changing professional behaviour in order to enhance the uptake of clinical guidelines, protocols and policies in developing countries, suggested that audit and feedback produced the most promising results in improving compliance with set standards or clinical outcomes (Siddiqi *et al.* 2005). However, the evidence in favour of audit and feedback contained in the review was limited, and the majority of these studies were poorly designed. In spite of this, successful outcomes were noted to result from “local consensus-based” approaches to developing guidelines and “targeted training”. Change was most evident when the audit design suited the local health culture and the recommendations took into account the available resources and existing practices.

Moreover, government implementation of audit and feedback for the purposes of quality improvement facilitated change more rapidly. The authors propose that audit and feedback could be a valuable tool for countries that face pressure to provide cost-effective quality services with limited resources, but the challenge is to maintain quality improvement in the long term (Siddiqi *et al.* 2005). Given the understanding that local context shapes the outcome of quality improvement initiatives, and the paucity of evidence from developing

countries, the authors are of the opinion that research evaluating tools that influence as well as measure professional practice should be high priority in developing countries (Siddiqi *et al.* 2005).

In a more selective systematic review, looking at the use of criterion-based clinical audit to improve obstetric practice, only two of the nineteen studies evaluated were conducted in developing countries (Kongnyuy *et al.* 2009). Both studies used a before-and-after study design and quantitative analysis to measure changes in the performance of key clinical processes (Wagaarachchi *et al.* 2001; Weeks *et al.* 2005).

The first study took place in four district hospitals, two in Jamaica and two in Uganda, and focused on the management of five life-threatening obstetric complications (Wagaarachchi *et al.* 2001). The authors chose not to go into country- or hospital-specific details as to why the audit was successful, but instead provided a general description of the process that was applied in all settings and presented pooled results. The baseline audit included 551 women over 66 hospital-months and 12 months later a re-evaluation of 338 patient records over 42 hospital-months was done. The review process identified relevant life-threatening cases from all sources and applied various mechanisms to minimise systematic bias, such as using length of stay as a proxy for severity in cases not originally identified. The pooled results of this cross-country study following the baseline audit and feedback showed statistically significant improvements in the management of three obstetric complications. The researchers deemed the feedback meetings the fundamental catalyst for change and boost for staff morale. Following this intervention, a practical field guide on criterion-based clinical

audit was developed for use in district hospitals in developing countries (Wagaarachchi *et al.* 2001).

The second study took place in a high-risk labour ward of a government-funded university teaching hospital in Kampala, Uganda. The objective was to improve the quality of clinical care for women with severe pre-eclampsia and entailed auditing 43 folders at baseline and for the re-evaluation 6 months later (Weeks *et al.* 2005). Subsequent to achieving this goal and a reduction in maternal deaths, the authors asserted that criterion-based audit can produce significant improvements in sub-Saharan Africa as it allowed health workers to “conduct their own quality assessments and seek their own solutions given the local financial restrictions” (Weeks *et al.* 2005). Although this hospital suffered medicine shortages and the relocation of the labour ward after a tetanus outbreak, the changes following the audit were sustained for at least 6 months. The support of senior department members was considered as vital to the success of the project as the participation of lower level staff in executing the recommendations. Aside from implementing the suggested solutions, the early involvement of subordinate staff enhanced their motivation and uptake of the process, which was regarded as a meaningful achievement in an under-resourced setting where staff morale was low (Weeks *et al.* 2005).

Because of the limitations in establishing a causal connection between the audit process and improved practice using a before-and-after study design, the authors of the systematic review stress the need for randomised controlled trials (RCT) to more efficiently assess the impact of clinical audit (Kongnyuy *et al.* 2009).

Two RCTs from countries in South East Asia illustrate how different methods of feedback can influence the duration of effect on quality improvement, as a result of audit (Moongtui *et al.* 2000; Wahlström *et al.* 2003).

In a regional hospital in Chiangmai, Thailand, researchers aimed to determine the effectiveness of a peer feedback program on the compliance rate of Universal Precautions guidelines on handwashing and glove usage (Moongtui *et al.* 2000). The participating health care workers (HCW) comprised 91 nurses and patient care aides from the emergency and trauma departments and intensive care unit, who were observed at baseline, during the intervention and one month after the intervention, between September 1997 and February 1998. Peer observers in the intervention group used validated tools to assess their co-workers, and feedback was provided every 3 days on a notice board as a group assessment without identifying individuals. The compliance rate from those receiving feedback increased significantly compared to the control group during the intervention phase, but this improvement was not sustained in the post-intervention period. The limitations in this case were the fact that the two groups were found to be not entirely comparable in terms of size of the sample and nature of the clinical area, despite being randomly assigned, as all 36 participants in the intervention group worked in the emergency department while the 55 controls were from other areas. Direct observations within the intervention group may have produced a Hawthorne effect, which is unintended confounding present in behavioural research when the “intervention” subjects are aware that they’re being observed and alter their habits (Holden 2001). Consequently the authors recommend further research of adjunct methods for motivating HCW to comply with guidelines (Moongtui *et al.* 2000).

At provincial hospitals in Lao People's Democratic Republic (PDR), an RCT design was used to evaluate the effectiveness of audit and feedback in improving case management of malaria, diarrhoea and pneumonia between June 1999 and August 2000 (Wahlström *et al.* 2003).

The 8 participating hospitals had a total of 24 randomised departments (out-patients including emergencies, paediatrics and internal medicine) with 122 prescribers that were introduced to the new Standard Treatment Guidelines, and each month Drug and Therapeutics Committees within hospitals were responsible for measuring the doctors' clinical management of the selected conditions. Indicator scores based on recorded treatment instead of observed practice were used to avoid influencing behaviour inappropriately, and the intervention took the form of monthly feedback sessions over 6 months with discussions on how to improve performance. The results were a statistically significant increase in the intervention group scores compared to the control group that remained for 6 months after the intervention period. Sources of bias in this study were possible contamination of control and intervention groups by doctors within hospitals that would have negatively affected the results, and the fact that participants were not blinded regarding their allocation, resulting in a greater behaviour change in the intervention group that would have positively affected the results. But since this had been an educational activity facilitated by local staff, it was concluded as evidence of the value that audit and feedback can bring to low-income clinical settings (Wahlström *et al.* 2003).

An interesting study set up to determine whether or not clinical audit could improve the diagnosis of pulmonary tuberculosis (TB), in three Latin American countries; Cuba, Peru and Bolivia, highlighted how the working environment and resources influence quality

improvement initiatives in developing countries (Siddiqi *et al.* 2008). Because clinical audit is considered a complex intervention, the research methods were an exploratory trial using an uncontrolled before-and-after design and a qualitative case study based on the Medical Research Council's (MRC) proposed framework for evaluating such interventions (Siddiqi *et al.* 2008). The study took place between January 2002 to December 2005, at 16 health centres in Peru and Bolivia and 10 health zones in Cuba, comprising a mixture of urban, semi-urban and rural settings. The quantitative analysis involved the formation of audit committees in each country, who developed measurable and clearly defined criteria and standards by a group technique of consensus development. The effectiveness of the audit cycle was measured by the improvement in these criteria regarding diagnosis and care of suspected TB patients. Performance feedback was provided every 6 months, and committees made recommendations and developed action plans in response to problems. Overall, the three Latin American countries showed statistically significant improvement in 15, and deterioration in 2, out of 24 audit criteria. However the difference across countries was large, as Cuba contributed to an improvement in 11 of the 24 criteria, as well as achieving the standards agreed by its committee.

The major contextual factors that promoted or hindered the process were revealed in interviews with key health professionals, as part of qualitative case studies from each country. Although participatory leadership was a factor that facilitated the audit's success in all three settings, the TB programme in Peru and Bolivia did not fully integrate or support the process compared to Cuba. The authors suggest that this is because of the implementation in these countries of World Health Organisation (WHO) guidelines that are neither suited to the local context nor in user-friendly format, and emphasise the need for

adequate preparation such as systematically developing and disseminating guidelines before introducing quality improvement projects (Siddiqi *et al.* 2008). Political interference resulting in constant staff changes was also quoted as a limiting factor in Peru and Bolivia, whereas Cuba reported a better working environment. Cuban and Bolivian successes were attributed to good communication and interpersonal skills, an appreciation for the link between quality improvement and patient benefits, and the provision of training opportunities and education for staff following the audit recommendations. All three countries were characterised by a lack of resources, but background information on the study sites revealed striking differences. At the time of the study, Cuba had a smear positive TB incidence that averaged 5.5 cases per 100,000 at both sites, compared to 179/100,000 in Peru and an average of 65/100,000 at both sites in Bolivia. As well as having almost twice the number of primary health care centres in their study sites compared to sites in Peru and Bolivia, Cuba also had 17 radiologists while Peru and Bolivia had none, and over 2000 general practitioners at their sites compared to 75 in Peru and 38 at sites in Bolivia (Siddiqi *et al.* 2008). It is not unreasonable to assume that these factors would have given Cuba an advantage when it came to achieving the target standards, but the authors regard the findings as evidence that clinical audit has the potential to influence clinical practice under a “favourable organisational environment” (Siddiqi *et al.* 2008). However, further research is required to determine whether it can generate health and efficiency gains to justify implementation (Siddiqi *et al.* 2008).

Three national facility-based mortality audits in South Africa (SA); the Confidential Enquiry into Maternal Deaths (CEMD), Perinatal Problem Identification Programme (PIPP) and Child

Healthcare Problem Identification Programme (Child PIP) face similar obstacles to quality improvement as those outlined in other developing countries. In reviewing SA's progress towards the Millennium Development Goals, the South Africa Every Death Counts Writing Group (SAEDCWG) point out that the success of audit is dependent on both data collection and subsequent action (SAEDCWG 2008). All three processes have positively influenced the quality of care at a local level where functioning supervisory and management systems exist, but effects at a population level are restricted by scarce human resources, infrastructure and supply systems. Quality services are dependent on the effective administration of sites and until this is achieved, audit data will continue to highlight the same gaps and repeat recommendations without noticeable or sustained change at a national level (SAEDCWG 2008).

***b. Implications for future research in developing countries***

In the latest update, a Cochrane Collaboration review found divergent effects of audit and feedback on professional practice (Jamtvedt *et al.* 2006). Of the 118 RCTs included in the review, only 24 were judged to have a low risk of bias. The results ranged from a 16% absolute decrease in compliance with set standards (an adjusted risk difference of -0.16) to a 70% increase (adjusted risk difference of 0.70). The authors reiterate the view that in order for research to adequately discern the effects of audit and feedback, trials need to be more rigorously designed, conducted and reported. However, they do also conclude that in professional practice, audit and feedback can be effective in producing generally small to moderate improvements. The relative effects are likely to be larger when the baseline adherence to recommended practice is low and when feedback is provided more intensely,

such as by senior personnel, over a long period, face-to-face or combined with educational meetings (Jamtvedt *et al.* 2006).

Foy *et al.* (2005) have argued that the Cochrane review falls short on providing practical guidance about whether or not audit and feedback could be used to improve quality of care, or how it could be optimised, when specifically applied to diabetes management at primary health care level. The authors found that most of the studies in the review did not adequately describe their interventions and displayed an inadequate understanding of the causal mechanisms behind the effects apparently exerted by these interventions. Because of weaknesses identified in the primary studies evaluating audit and feedback, the authors are of the opinion that audit and feedback are an unreliable approach to quality improvement and suggest that for future assessments, researchers make use of a conceptual framework that lists common elements within settings, and enables the identification of features that systematically influence the effectiveness of interventions (Foy *et al.* 2005).

In contrast, Pattinson (2006) believes that the Cochrane review findings are applicable to under-resourced settings since adherence to recommended practices is often low to begin with. And while the validity of some results remain questionable, there is no doubt that clinical audit has the potential to enhance other processes that contribute to quality of care, such as patient record keeping (Berk *et al.* 2003; SAEDCWG 2008).

A baseline clinical audit in the Metro District Health Services of the Western Cape Province revealed that the quality of care in the management of diabetes was below acceptable standards (Martell *et al.* 2005). Hence, the main purpose of this dissertation is to evaluate the findings of the primary health care diabetes audit conducted in 2005 to 2009 so as to contribute to the evidence on the effect of implementing clinical audit in a developing country. In addition, by making use of annual data collected since 2005, the evaluation will address another gap identified in the literature that is assessing long term trends in audit outcomes (Siddiqi *et al.* 2005; Siddiqi *et al.* 2008).

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## References

1. Balogh R, Bond S. 2001. Completing the audit cycle: the outcomes of audits in mental health services. *International Journal for Quality in Health Care*. 13(2):135-142.
2. Berk M, Callaly T. 2003. The evolution of clinical audit as a tool for quality improvement. *Journal of Evaluation in Clinical Practice*. 9(2):251-257.
3. Bouchet B, Francisco M, Øvretveit J. 2002. The Zambia Quality Assurance Program: success and challenges. *International Journal for Quality in Health Care*. 14(1):89-95.
4. Bowie P, Cooke S, Lo P, McKay J, Lough M. 2007. The assessment of criterion audit cycles by external peer review – when is an audit not an audit? *Journal of Evaluation in Clinical Practice*. 13:352-357.
5. Bowie P, Bradley NA, Rushmer R. 2010. Clinical audit and quality improvement – time for a rethink? *Journal of Evaluation in Clinical Practice*. DOI:10.1111/J.1365-2753.2010.01523.X
6. Campbell SM, Hann M, Hacker J, Durie A, Thapar A, Roland MO. 2002. Quality assessment for three common conditions in primary care: validity and reliability of review criteria developed by expert panels for angina, asthma and type 2 diabetes. *Quality and Safety in Health Care*. 11:125-130.
7. Foy R, Eccles MP, Jamtvedt G, Young J, Grimshaw JM, Baker R. 2005. What do we know about how to do audit and feedback? Pitfalls in applying evidence from a systematic review. *BMC Health Services Research*. 5:50.
8. Holden JD. 2001. Hawthorne effects and research into professional practice. *Journal of Evaluation in Clinical Practice*. 7(1):65-70.

9. James RM, Brown S, Parapia LA, Williams AT. 2001. The impact of a 10-year audit cycle on blood usage in a district general hospital. *Transfusion Medicine*. 11:371-375.
10. Jamtvedt G, Young JM, Kristoffersen DT, O'Brien MA, Oxman AD. Audit and feedback: effects on professional practice and health care outcomes. 2006. *Cochrane Database of Systematic Reviews*. Issue 2. Art. No.: CD000259.DOI:10.1002/14651858.CD000259.pub2.
11. Johnston G, Crombie IK, Davies HTO, Alder EM, Millard A. 2000. Reviewing audit: barriers and facilitating factors for effective clinical audit. *Quality in Health Care*. 9:23-26.
12. Kongyuy EJ, Uthman OR. 2009. Use of criterion-based clinical audit to improve the quality of obstetric care: A systematic review. *Acta Obstetrica et Gynecologica*. 88:873-881.
13. Maher D. 1996. Clinical audit in a developing country. *Tropical Medicine and International Health*. 1(4):409-413.
14. Martell R, De Vries E. 2005. Audit Report on CVS Risk Factor Management. Western Cape Department of Health: Metro District Health Services.
15. Mian S, Wagg A, Irwin P, Lowe D, Potter J, Pearson M. 2004. National audit of continence care: laying the foundation. *Journal of Evaluation in Clinical Practice*. 11,6:533-543.
16. Moongtui W, Gauthier DK, Turner JG. 2000. Using peer feedback to improve handwashing and glove usage among Thai health care workers. *American Journal of Infect Control*. 28:365-9.

17. Pattinson RC. 2006. Audit and feedback: effects on professional practice and health-care outcomes: RHL commentary. *The WHO Reproductive Health Library*. Geneva: World Health Organisation.
18. Siddiqi K, Newell J, Robinson M. 2005. Getting evidence into practice: what works in developing countries? *International Journal for Quality in Health Care*. 17(5):447-453.
19. Siddiqi K, Volz A, Armas L, Otero L, Ugaz R, Ochoa E, Gotuzzo E, Torrico F, Newell JN, Walley J, Robinson M, Dieltiens G, Van Der Stuyft P. 2008. Could clinical audit improve the diagnosis of pulmonary tuberculosis in Cuba, Peru and Bolivia? *Tropical Medicine and International Health*. 13(4):566-578.
20. South Africa Every Death Counts Writing Group. 2008. Every death counts: use of mortality audit data for decision making to save the lives of mothers, babies, and children in South Africa. *Lancet*. 371:1294-304.
21. Wagaarachchi PT, Graham WJ, Penney GC, McCaw-Binns A, Yeboah Antwi K, Hall MH. 2001. Holding up a mirror: changing obstetric practice through criterion-based clinical audit in developing countries. *International Journal of Gynaecology & Obstetrics*. 74:119-130.
22. Wahlström R, Kounnavong S, Sisounthone B, Phanyanouvong A, Southammavong T, Eriksson B, Tomson G. 2003. Effectiveness of feedback for improving case management of malaria, diarrhoea and pneumonia – a randomised controlled trial at provincial hospitals in Lao PDR. *Tropical Medicine and International Health*. 8(10):901-909.

23. Weeks AD, Alia G, Ononge S, Otolorin EO, Mirembe FM. 2005. A criteria-based audit of the management of severe pre-eclampsia in Kampala, Uganda. *International Journal of Gynaecology & Obstetrics*. 91(3):292-297.

# **Evaluating the clinical audit of diabetes management in the Western Cape Metropole.**

## **Running title:**

Metro district clinical audit

## **Introduction:**

Quality of care in the public health sector of South Africa suffers from a lack of resources, poor delivery systems and variable quality of diagnosis and treatment. Clinical audit is considered a tool that health providers can use to monitor and improve quality of care. The Metro District Health Services chose to audit the management of diabetes at primary health care facilities.

## **Objective:**

The objective was to determine whether there was an improvement in the performance of diabetic clinical processes in the Metro district, using pooled audit results collected annually in 2005, 2007, 2008 and 2009.

## **Methods:**

The evaluation applied the Skillings-Mack test to median values obtained each year for nine diabetic clinical processes to measure whether there were statistically significant differences between annual audits. Descriptive statistics, such as box-plots, were used to illustrate the order of values per process.

## **Results:**

There were 40 community health centres that participated in the annual audit in 2005 which decreased to 30 in 2009. Except for 2 routine processes, the baseline medians in 2005 for 6 out of 9 processes were below 50%. The pooled audit results showed statistically significant improvements in 7 out of the 9 clinical processes.

**Conclusions:**

The findings indicate an association between the application of clinical audit and quality improvement in resource-limited settings. Support from the relevant government health programmes and commitment of health managers and front-line staff also contributed to the success of the audit. Access to secondary and tertiary services will have to be strengthened as the quality of primary health care improves and more patients in need of specialised care are identified.

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**Keywords:** clinical audit, quality improvement, primary health care, developing country, Skillings-Mack

## Introduction

The quality of health care in South Africa (SA) is divided along the same line as the existing private and public sector health services in the country [NDOH 2001]<sup>1</sup>. In 2001 the national policy on Quality in Health Care for South Africa described the problems in the public sector, currently serving 85% of the population, as a “lack of resources, poor delivery systems and variable quality of clinical diagnosis and treatment” [NDOH 2001: 10]. Ten years later the Minister of Health, the Honourable Aaron Motsoaledi, stated that quality of care in the public sector is “ever in the minds and on the lips of our people” and reiterated the priority to improve the quality of health services as one of the key actions for improving the health profile of all South Africans in the Government’s Programme of Action 2009 [Motsoaledi 2010].

The Western Cape Province is one of nine provinces in SA, consisting of 6 health districts: 5 rural and the Cape Metropole (Metro District). Community health centres are primary health care (PHC) facilities located in all eight sub-districts of the Metro, and run by the Provincial authority known as the Metro District Health Services (MDHS). Within the MDHS is the Clinical Management Meeting, a monthly forum that includes clinical managers and principal medical officers from community health centres [Martell *et al.* 2005]. In 2005, following the introduction of clinical governance into the MDHS, members of this forum embarked on a quality improvement project using clinical audit as a means to operationalise the concepts of quality of care at PHC level.

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<sup>1</sup> International Journal for Quality in Health Care requires the Vancouver referencing style, but the author has used the Harvard referencing style for continuity.

Clinical audit is defined as a quality improvement process that seeks to improve patient care and outcomes through the systematic review of care against explicit criteria and the implementation of change, and is considered an essential component of clinical governance [Copeland 2005: 3]. An abbreviated version of the Quality in Health Care policy document states that one of the causes of poor quality of care in SA is health professionals with “erroneous, outdated or no information skills” and describes clinical audit, amongst other methods, as an instrument for service providers to monitor quality [NDOH 2007]. However, most evidence in support of clinical audit as a quality improvement tool comes from developed countries, leaving a gap in research to adequately assess whether these findings are applicable in developing countries [Balogh *et al.* 2001; Berk *et al.* 2003; Campbell *et al.* 2002; Johnston *et al.* 2000]. Further, obstacles to clinical auditing and quality improvement in developing countries include resource constraints that result in the practice being perceived as a non-priority, and negative responses from health care workers to audit [Bouchet *et al.* 2002; Maher 1996].

In 2005, the Clinical Management Meeting chose diabetes management as the initial audit topic after a Burden of Disease study reported that cardiovascular disease (CVD) was the leading cause of death amongst men and women in the Western Cape [Bradshaw *et al.* 2004]. Diabetes is an independent risk factor for cardiovascular disease and although exact figures on the number of diabetic patients visiting PHC facilities are unknown, the consequences of poor diabetes care, such as premature blindness and amputations, are believed to be disproportionately prevalent in the population of the Metro District [Martell *et al.* 2005]. Improving glycaemic control in diabetics has been associated with a reduction in health care costs and utilisation [Wagner *et al.* 2001]. In addition, the audit decision was

motivated by the availability of good evidence to inform target standards for the management of diabetes [Martell *et al.* 2005].

The development of the original audit tool has been described by Martell *et al.* [Martell *et al.* 2005]. The focus of the first audit was on clinical processes only and limited the audit of infrastructure and equipment, as well as excluding patient outcomes related to diabetes. Over the following years, the scope of the audit increased to include structural and outcome elements (2007) and additional clinical processes (2008). In 2009, an integrated audit tool was implemented to assess the management of five chronic conditions including diabetes mellitus, but employed the same audit methods and retained core diabetic process elements from the original tool. Since the audit cycle involves action plans to achieve the target standards, one would expect subsequent audits to show a gradual improvement in the quality of care.

Testing this expectation was a subject of this study, and was carried out at the request of the Chronic Diseases programme coordinator for the Western Cape Department of Health. The aim was to evaluate the long-term trend in quality improvement and determine whether there has been an increase in the performance of diabetic clinical processes. The data used are pooled audit results collected annually in 2005, 2007, 2008 and 2009 from participating community health centres in the Metro district.

## Methods

### *Population and Sampling Strategy*

According to routine health information, between April 2008 and March 2009 there were 3,725,339 PHC visits by an estimated Metro district population of 3.2 million people over the age of 5 years old to Community Health Centres (CHC) in the MDHS (WC DOH 2011). During the same period in these facilities, a reported total of 8,117 new diabetes mellitus cases were put on treatment and, although the figure fluctuated throughout the year, in March 2009 17,855 diabetes mellitus clients were reported to be recorded in the register (WC DOH 2011).

All CHCs in the Metro district rendering a chronic care service were instructed to participate in the first audit in 2005. The procedure was a form of "self-audit", with the intention of fostering a sense of responsibility amongst health care workers and empowering them to take action in improving the quality of care in low-resource settings. The individuals responsible for sampling the folders and performing the audit were clinical staff members from the facility's chronic care team, such as a senior medical officer or PHC nurse. During the month of February, in every year that the audit was done, the designated doctor or nurse had to systematically sample 20 diabetic folders from the total number of patients attending the diabetic clinic on one day, and conduct a folder review. This meant dividing the number of diabetic patient folders on that day by 20 and sampling every  $n$ th folder. Smaller facilities with clinics attending to fewer than 30 patients a day were allowed to audit every diabetic folder until the target was reached. Outpatient clinics at CHCs are known to be busy and under-resourced therefore clinical staff involved in the audit were allowed to choose the audit day in February at their convenience.

While the sampling method remained unchanged from the inception of the project, in 2009 after three cycles of audit, the target sample size of 20 diabetic folders per facility was reduced to 10. This reduction was done to accommodate the implementation of the larger integrated audit tool that audited the management of 5 chronic diseases, including diabetes. Table 1 lists the number of CHCs per health sub-district that comprise the Metro district and the number of CHCs that submitted results during for each year of the audit.

**Table 1: Health Sub-districts**

Sub-districts	Number of facilities:	Number of facilities that submitted results in:			
		2005	2007	2008	2009
Eastern	5	5	1	2	0
Khayelitsha	3	3	2	3	3
Mitchells Plain	3	3	2	3	3
Klipfontein	5	5	4	3	4
Tygerberg	11	11	11	10	9
Northern	3	3	3	2	2
Southern	5	3	1	4	5
Western	7	7	6	2	4
<b>Total</b>	<b>42</b>	<b>40</b>	<b>30</b>	<b>29</b>	<b>30</b>

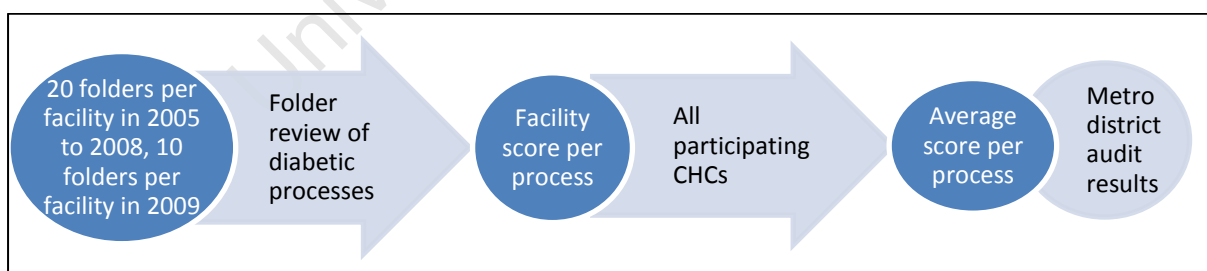
A sampled folder qualified for the folder review if the patient had been attending the clinic for at least one year and had at least two chronic care visits in the previous year. Data collection entailed extracting information from the clinical notes and entering it into the audit data collection form. This method proved cumbersome for the staff members involved, and as a consequence a clinical summary sheet was developed for use in the folders of patients receiving chronic care. From 2007 onwards, this summary tool known as the MDHS Record Sheet was implemented and functioned as the source document for the diabetes audit.

## Data Management and Feedback

Since clinical governance is considered a core function of the Family Medicine specialists and senior medical officers, they were required to champion the audit data collection in their respective sub-districts. Once the audit was completed at a CHC, the form was submitted to the senior medical officer in the Clinical Management forum for data capture and analysis. The audit was a paper-based tool and the results were transferred to an electronic master spreadsheet. After each round of the annual audit participating facilities received reports that graphically depicted their results and in order to complete the audit cycle, chronic care teams at each CHC had to formulate and commit to an action plan to improve the quality of care based on their results.

Figure 1 below illustrates the audit data flow from the facility. The annual folder review resulted in a mean score per diabetic clinical process for each facility and the average of all participating facilities gave rise to the final Metro district score.

**Figure 1: Audit data flow**



Despite the modifications to the original audit tool over the years, core diabetic process elements remained unchanged as part of the folder review. These elements formed the basis of this evaluation and are listed in Table 2 below.

**Table 2: Audit tool clinical processes**

<b>Number:</b>	<b>Diabetes Clinical Audit Indicators:</b>
1	Mean number of diabetic visits per year
	<b>Diabetic Clinical Processes:</b>
2	Number that had weight checked at each visit
3	Number that had blood pressure checked at each visit
4	Number that had annual foot examination
5	Number that had annual urine protein test
6	Number that had annual retinal screening
7	Number that had annual serum cholesterol test
8	Number that had annual serum creatinine test
9	Number that received diet education annually
10	Number that discussed exercise annually

The total number of diabetic visits in the year was used as the denominator for determining how often the patient's weight and blood pressure (BP) were recorded. These processes are expected to be performed routinely at each visit and ideally the numerator should be equal to the denominator. The target standards for clinical processes numbered 4 to 10 in Table 1 were accepted as annual assessments, for which the denominator was the total number of folders reviewed.

The validity of the indicators is based on minimum standards prescribed in the guidelines developed by the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) as well as technical expertise from the Departments of Endocrinology and Family Medicine at the University of Cape Town [Martell *et al.* 2005]. Training workshops were held prior to the audit each year to ensure that clinical staff members responsible for the data collection were competent in the procedure.

## *Statistical Analysis*

An exploratory data analysis revealed that data for each indicator were non-normally distributed and warranted the application of the Skillings-Mack (SM) test statistic. The SM test is a non-parametric, general Friedman-type statistic used to compare treatment effects in randomised block designs [Cunningham 2010]. The Friedman Test is the non-parametric equivalent of the Analysis of Variance (ANOVA) Test used to compare the means of more than two samples, and either test would have been applicable had the data set been balanced, that is retaining the same number of facilities each year. But use of the SM test was appropriate since the data were unbalanced and incomplete due to arbitrary non-response from some facilities or incomplete information on the submitted documents. The test was applied to the pooled Metro district results of the clinical processes for each year of auditing. Effects were represented by the process results and blocks by the four years. The SM test was used to determine whether or not there was a statistically significant difference in the values by year, while descriptive statistics and box plots were used to illustrate the trend of these changes. All data were entered into the Stata/IC version 10.1 programme, in which all analyses were performed.

## *Ethics*

Ethical approval was initially granted in 2005 by the University of Cape Town Research Ethics Committee and an extension was granted in 2008 and in May 2010 to continue auditing and publish this evaluation.

## Results

Because the primary analysis made use of facility scores, the number of patient folders reviewed each year is not reported. 40 CHCs out of a total of 42 in the Metro district submitted results after the first audit in 2005. But in subsequent years this number dropped to an average of 30 CHCs. All of the 8 sub-districts were represented by at least one facility every year except in 2009 when none of the CHCs in the Eastern sub-district submitted audit results. The mean number of chronic visits a year by diabetic patients was 4. Because the distribution of the data for clinical processes was initially skewed to the left and over time shifted to the right, median values were used to measure the audit results each year, listed in Table 3.

**Table 3: Median values per process per year**

Year (Number of participating facilities)	2005 (40)	2007 (30)	2008 (29)	2009 (30)
Mean number of diabetic visits per year	3.8	3.9	4.3	3.7
<b>Diabetic Clinical Processes:</b>	<b>Median values achieved per process</b>			
% Folders with weight recorded at each visit	59.5	62.5	57	78.5
% Folders with BP recorded at each visit	93	94.5	96.5	97.5
% Folders with annual foot exam recorded	30	10	50	45
% Folders with annual urine protein test recorded	95	90	95	90
% Folders with annual retinal screening recorded	15	5	25	40
% Folders with annual serum cholesterol recorded	0	0	25	50
% Folders with annual serum creatinine recorded	5	5	40	50
% Folders with annual diet education recorded	47.5	45	65	80
% Folders annual exercise advice recorded	37.5	12.5	35	55

The range of results submitted by participating facilities each year is also graphically represented as a series of box-plots in Figure 2. A wide range implies that facility scores on a

particular indicator were spread across high and low values, and a narrow range means that most facilities achieved similar scores for an indicator.

**Figure 2: Box-plots of clinical processes**



Table 4 lists the weighted sum of centered ranks (WSCR), the Skillings-Mack statistic and the number (N) of facilities used in calculating this statistic. Unlike the box-plots that are generated individually using results from every facility that submitted in a particular year, the SM statistic was calculated using only the facilities that submitted at least 2 results over 4 years. Simulated p-values were used to determine whether the difference between median values obtained each year was statistically significant at the  $\alpha = 0.05$  level, as the p-values from the chi squared approximation normally used are considered too conservative, especially for type I errors [Cunningham 2010]. The WSCR indicate the order of annual

values per process derived from the SM test. Higher WSCR values imply better performance of a clinical process relative to other years.

**Table 4: Results of Skillings-Mack test**

Clinical Process	2005		2007		2008		2009		Skillings-Mack statistic	Simulated P-value
	N	WSCR	N	WSCR	N	WSCR	N	WSCR		
% Weight recorded at each visit	36	-17.6	30	-8.9	28	8.2	30	18.4	7.7	0.056
% Blood pressure (BP) recorded at each visit	36	-28.8	30	-2.8	28	9.7	30	22.0	13.2	0.000*
% Annual feet examination recorded	36	-0.8	30	-22.7	29	9.3	30	14.1	8.2	0.033*
% Annual urine protein recorded	35	-1.5	30	-16.1	29	13.4	30	4.2	4.7	0.104
% Annual retinal screening recorded	36	-5.6	30	-24.7	29	12.7	30	17.5	11.3	0.003*
% Annual serum cholesterol recorded	36	-28.7	30	-28.2	27	15.4	27	41.5	36.5	0.000*
% Annual serum creatinine recorded	36	-23.3	30	-35.7	29	15.0	30	43.9	39.8	0.000*
% Annual diet education recorded	36	-8.3	30	-21.6	29	-2.6	30	32.4	15.9	0.001*
% Annual exercise advice recorded	36	1.9	30	-28.6	29	-10.4	30	37.1	23.1	0.000*

*\*Statistically significant at  $\alpha=0.05$*

N: Number of facilities

WSCR: Weighted sum of centered ranks

The 2005 baseline median for 6 out of 9 clinical processes, except for those considered to be routine such as blood pressure checks and urine dipstick tests, was below 50%. There was a relatively small increase in the median proportion of patient folders with a recorded weight at each visit, within a wide range of results every year, that was not statistically significant at  $\alpha = 0.05$  compared to baseline. In contrast, the increase in median proportion of annual foot exams, also within a wide range every year, was statistically significant at  $\alpha = 0.05$ . This could be attributed to the large difference in median values between 2007 and 2008 for annual foot exams. The median proportion of recorded BP readings at each visit was relatively high at baseline and improved further by considerably narrowing the range of results in 2009. Audit results for the annual urinary protein test show a narrower range over the years but not much change in the median value since baseline. Results for the annual retinal screen, serum cholesterol and serum creatinine show statistically significant differences over the years, and are illustrated by the box-plots as increases in both range and median proportions. Although results for annual diet education and exercise advice remained within a wide range for all 4 years, the median proportions increased and these differences were statistically significant.

## Discussion

The evaluation found an increase in performance in 8 out of 9 clinical processes in the management of diabetes from 2005 to 2009, with statistically significant changes in 7 out of 9. The performance of 2 processes, retinal screening and foot examinations, declined from baseline to 2007. This decline has been attributed to organisational restructuring in the Metro that left health workers in some sub-districts unsupported at the time. Nevertheless, as a result of the baseline audit, 3 interventions were introduced to assist health workers in improving the management of diabetic patients at CHCs. According to the Provincial Chronic Diseases programme coordinator, in 2006 NovoNordisk SA Ltd, a pharmaceutical company specialising in diabetes treatment, gave the programme a donation to purchase monofilaments (Van Vuuren U 2011, oral communication, 23<sup>rd</sup> March). Along with monofilaments, each facility received the SEMDSA foot screening guidelines and training by an endocrinologist in detecting peripheral neuropathy. In 2007, a non-mydratiac mobile fundal camera was purchased following a grant from the World Diabetes Foundation and after successfully piloting at 3 facilities the camera was extended to the remaining Metro CHCs in 2008 [Mash *et al.* 2007]. In addition, the grant allowed for the purchase of a second camera in 2009 and included funding for an ophthalmic staff nurse to manage the project. The roving camera and the “foot clinics” that were established allowed facilities to meet the audit criteria of annual examinations of diabetic patients’ feet and retinas (Van Vuuren U 2011, oral communication, 23<sup>rd</sup> March).

Between July 2007 and July 2008, the MDHS held a series of workshops for health workers at all levels; doctors, nurses, facility managers and health promoters responsible for diabetic care at the CHCs [Mash *et al.* 2008]. The intervention was a form of action research, called

an appreciative inquiry (AI), and encouraged health workers to formulate local solutions for overcoming commonly reported systemic barriers to adequate diabetes management at PHC level. The monofilaments, fundal camera and AI were adjunct interventions likely to have favourably influenced the outcome of subsequent audits, since they were implemented to address the deficiencies highlighted in the baseline audit of 2005. But in a low-resource context, attending to skills and infrastructure shortages is a necessary component in improving the quality of clinical care [SAEDCWG 2008].

The results of this study are consistent with research that has found the relative effects of clinical audit to be larger when the baseline adherence to recommended practice is low [Jamtvedt *et al.* 2006]. Additionally, support from the relevant government health programme, in this case Chronic Diseases, is regarded as a strong factor in facilitating change [Siddiqi *et al.* 2008]. The evidence from developing countries shows that audit and feedback is an effective tool for improving quality of care by boosting morale and empowering health workers to take action within restrictive circumstances [Moongtui *et al.* 2000; Wagaarachchi *et al.* 2001; Wahlström *et al.* 2003; Weeks *et al.* 2005]. However most of these studies provide evidence of effectiveness in the short-term or after a single intervention, and evidence of sustained behaviour change is non-existent [Siddiqi *et al.* 2005; Siddiqi *et al.* 2008].

There were a few limitations to this study. Firstly, the CHC response rate to the audit decreased by 25% from baseline compared to 2009, caused mainly by facilities in 2 sub-districts. Non-response was ascribed to the absence of a sub-district Family Medicine specialist to drive the project and might have produced a selection bias if these facilities were consistently under-performing, however this effect was not tested. If the project is to

be successfully implemented in the rural districts, the programme will have to consider task-shifting the role of audit champion in sub-districts where a Family Medicine specialist is yet to be appointed. Secondly, the fact that facilities were asked to “self-audit” must have introduced the potential for information bias as there was no external validation and given the workload, internal verification was not a prerequisite. Despite a concerted effort each year to obtain outstanding forms and missing or illegible information from the participating CHCs, there were still data management mishaps. Therefore, in the absence of source documents or verbal confirmation, indecipherable or missing information was excluded from the analysis and final reports. Even though the audit data collection relied on recorded clinical notes, as opposed to directly observing practice, the former method is in keeping with studies of this nature and is a preferred method if one is to avoid inappropriately influencing health worker behaviour [Moongtui *et al.* 2000]. On the other hand, using clinical notes led to the development and implementation of the MDHS Record Sheet which has improved patient record keeping.

Overall these findings indicate that quality improvement in resource-limited settings can be achieved through the application of clinical audit, with the support of relevant government health programmes and the commitment of health managers and front-line staff.

In this case, health service implications arise as a result of improved quality of care at PHC level when a greater number of patients in need of further treatment are identified and referred. Referral pathways to secondary and tertiary diabetic services, such as vascular or cataract surgery, must be strengthened to avoid any unethical practice associated with identifying patients in need when these services are not accessible or available [Mash *et al.* 2007]. Until public sector services can be counted on to meet the need, the Chronic

Diseases programme might have to consider making use of service providers in the private and non-governmental sectors.

Because clinical audit is considered a complex intervention [Holden 2001; SAEDCWG 2008], future evaluations should make use of qualitative information to determine what contextual factors contribute to audit success or failure at a local level, such as within a sub-district or facility. And finally, assessments of quality improvement should aim to go beyond the use of clinical processes and include information on clinical outcomes and patient satisfaction.

## **Acknowledgements**

This study was self-funded. The author would like to thank the members of the Metro District Clinical Management forum (Dr Angela De Sa, Dr Katy Murie, Dr Elma De Vries, Dr Mosedi Namane, Dr Strini Govender, Dr Arina Schlemmer, Dr Rob Martell) for all their work, the Division: District Health Services and Programmes of the Western Cape Department of Health, and Professor Bob Mash from the Division of Family Medicine and Primary Care at Stellenbosch University.

## References:

- 1) Balogh R, Bond S. 2001. Completing the audit cycle: the outcomes of audits in mental health services. *International Journal for Quality in Health Care*. 13(2):135-142.
- 2) Berk M, Callaly T. 2003. The evolution of clinical audit as a tool for quality improvement. *Journal of Evaluation in Clinical Practice*. 9(2):251-257.
- 3) Bouchet B, Francisco M, Øvretveit J. 2002. The Zambia Quality Assurance Program: success and challenges. *International Journal for Quality in Health Care*. 14(1):89-95.
- 4) Bradshaw D, Groenewald P, Laubscher P, Nannan N, Nojilanan B, Norman R, *et al*. 2003. Initial Burden of Disease estimates for South Africa 2000. *S Afr Med J*. 93(9):682-688.
- 5) Campbell SM, Hann M, Hacker J, Durie A, Thapar A, Roland MO. 2002. Quality assessment for three common conditions in primary care: validity and reliability of review criteria developed by expert panels for angina, asthma and type 2 diabetes. *Quality and Safety in Health Care*. 11:125-130.
- 6) Copeland G. 2005. *A Practical Handbook for Clinical Audit*. NHS: Clinical Governance Support Team.
- 7) Cunningham M. 2010. A Nonparametric Method to Assess Treatment Effects for Unbalanced Designs Using SAS/IML®. SAS Global Forum 2010. Paper 275-2010.
- 8) Holden JD. 2001. Hawthorne effects and research into professional practice. *Journal of Evaluation in Clinical Practice*. 7(1):65-70.
- 9) Jamtvedt G, Young JM, Kristoffersen DT, O'Brien MA, Oxman AD. Audit and feedback: effects on professional practice and health care outcomes. 2006. *Cochrane Database of Systematic Reviews*. Issue 2. Art. No.: CD000259.DOI:10.1002/14651858.CD000259.pub2.

- 10) Johnston G, Crombie IK, Davies HTO, Alder EM, Millard A. 2000. Reviewing audit: barriers and facilitating factors for effective clinical audit. *Quality in Health Care*. 9:23-26.
- 11) Maher D. 1996. Clinical audit in a developing country. *Tropical Medicine and International Health*. 1(4):409-413.
- 12) Martell R, De Vries E. 2005. Audit Report on CVS Risk Factor Management. PGWC: Metro District Health Services.
- 13) Mash B, Powell D, Du Plessis F, Van Vuuren U, Michalowska M, Levitt N. 2007. Screening for diabetic retinopathy in primary care with a mobile fundal camera – evaluation of a South African pilot project. *S Afr Med J*. 97(12):1284-1288.
- 14) Mash R, Levitt NS, Van Vuuren U, Martell R. 2008. Improving the annual review of diabetic patients in primary care: an appreciative inquiry in the Cape Town District Health Services. *South African Family Practice Journal*. 50(5):50.
- 15) Moongtui W, Gauthier DK, Turner JG. 2000. Using peer feedback to improve handwashing and glove usage among Thai health care workers. *American Journal of Infect Control*. 28:365-9.
- 16) Motsoaledi A. 2010. *African National Congress Parliamentary Caucus*. [Online]. Available: <http://www.anc.org.za/caucus/index.php?include=docs/sp/2010/sp0215b.html> (14 January 2011).
- 17) Siddiqi K, Newell J, Robinson M. 2005. Getting evidence into practice: what works in developing countries? *International Journal for Quality in Health Care*. 17(5):447-453.

- 18) Siddiqi K, Volz A, Armas L, Otero L, Ugaz R, Ochoa E, *et al.* 2008. Could clinical audit improve the diagnosis of pulmonary tuberculosis in Cuba, Peru and Bolivia? *Tropical Medicine and International Health*. 13(4):566-578.
- 19) SOUTH AFRICA. National Department of Health. 2000. *A Policy on Quality in Health Care for South Africa*. Available: <http://www.doh.gov.za/docs/index.html> [16 December 2010]
- 20) SOUTH AFRICA. National Department of Health. 2007. *A Policy on Quality in Health Care for South Africa (Abbreviated Version)*. [Online] Available: <http://www.doh.gov.za/docs/index.html> (16 December 2010).
- 21) South Africa Every Death Counts Writing Group. 2008. Every death counts: use of mortality audit data for decision making to save the lives of mothers, babies, and children in South Africa. *Lancet*. 371:1294-304.
- 22) Wagaarachchi PT, Graham WJ, Penney GC, McCaw-Binns A, Yeboah Antwi K, Hall MH. 2001. *International Journal of Gynaecology & Obstetrics*. 74:119-130.
- 23) Wagner EH, Sandhu N, Newton KM, McCulloch DK, Ramsey SD, Grothaus LC. 2001. Effect of improved glycaemic control on health care costs and utilization. *JAMA*. 285(2):182-189.
- 24) Wahlström R, Kounnavong S, Sisounthone B, Phanyanouvong A, Southammavong T, Eriksson B, Tomson G. 2003. Effectiveness of feedback for improving case management of malaria, diarrhoea and pneumonia – a randomised controlled trial at provincial hospitals in Lao PDR. *Tropical Medicine and International Health*. 8(10):901-909.

- 25) Weeks AD, Alia G, Ononge S, Otolorin EO, Mirembe FM. 2005. A criteria-based audit of the management of severe pre-eclampsia in Kampala, Uganda. *International Journal of Gynaecology & Obstetrics*. 91(3):292-297.
- 26) Western Cape Department of Health. Western Cape Official Data till February 2011. Export date: 25/04/2011. Directorate: Information Management.

University of Cape Town



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E-mail : lemjedi@curie.uct.ac.za

08 June 2005

**REC REF: 221/2005**

Dr EM De Vries  
Health Economics Unit  
School of Public Health & Family Medicine  
Anzio Road  
Observatory  
7925

Dear Dr De Vries

Chronic care audit of hypertension and diabetes mellitus.

*Thank you for submitting your study to the Research Ethics Committee for review.*

*It is a pleasure to inform you that the Ethics Committee has formally approved the above-mentioned study on the 06 June 2005.*

**Please quote the REC. REF in all your correspondence**

Yours sincerely

Signature removed

**PROF. T. ZABOW**  
**CHAIRPERSON**

## Annexure 2



# METRO DISTRICT HEALTH SERVICES DIABETES CLINICAL AUDIT



Facility: \_\_\_\_\_

Name of person completing the form: \_\_\_\_\_

### Instructions for completion of the form

#### Please assess twenty folders for this audit.

6. Ethics approval for this study has been obtained from the Ethics committee at UCT Faculty of Health Sciences. Fortunately informed consent is not required for a clinical audit.
7. Selection of folders: we aim to do systematic sampling. You can choose a day in July on which you expect many diabetic patients to be seen (e.g. a diabetes club day). Estimate the number of diabetic patient that you expect to be seen on that day, and divide it by 20. For example, if you expect 40 diabetics, you will audit every second folder. For small facilities, if small numbers of diabetics are seen per day (<30), you may audit each diabetic folder until you reach 20. One option may be to select the folders from the pharmacy after the patients have been seen.
8. Inclusion criteria: The patient should have been attending your CHC for at least a year, and had at least two visits in 2004.
9. Look only at the visits for 2004, where the patient came for diabetic follow-up (exclude visits for other reasons e.g. trauma).
10. For each indicator, record the number of visits at which this had been recorded.
11. Please return the form to Dr R Martell by 2005.

#### A. STRUCTURAL INDICATORS

Please answer according to the current situation at your CHC. We would like to establish a baseline to work from. Please tick Yes or No.

1	Is there a process in place for calibrating baumanometers?	Yes	No
2	Have all baumanometers been calibrated in the past year?	Yes	No
3	Are obese cuffs available for obese patients?	Yes	No
4	Is there a process in place for calibrating glucometers?	Yes	No
5	Have all glucometers been calibrated in the past year?	Yes	No
6	Do you have a working scale?	Yes	No
7	Is there a height measurement available?	Yes	No
8	Are BMI charts or wheels available?	Yes	No







UNIVERSITY OF CAPE TOWN



Health Sciences Faculty  
Research Ethics Committee  
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19 November 2008

REC REF: 221/2005

Dr E De Vries  
Public Health & Family Medicine

Dear Dr De Vries

**PROJECT TITLE: CHRONIC CARE AUDIT OF HYPERTENSION AND DIABETES MELLITUS AT COMMUNITY HEALTH CENTRES IN CAPE TOWN**

Thank you for your letter to the Research Ethics Committee dated 17<sup>th</sup> November 2008.

Approval is granted to publish the data. We recommend that you apply to the Research Ethics Committee to establish a data registry which would cover ongoing audits of Diabetes and Hypertension clinical management. This would involve a new application in which you describe your aims for collecting the data, data collection methods and importantly, how the confidentiality of the data will be protected. Guidelines for establishing a database are available in our Standard Operating Procedures.

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

**Please quote the REC. REF in all your correspondence.**

Yours sincerely

Signature removed

**PROFESSOR M BLOCKMAN**  
**CHAIRPERSON, HSF HUMAN ETHICS**

pp



**Health Sciences Faculty  
Research Ethics Committee  
Room E52-24 Groote Schuur Hospital Old Main Building  
Observatory 7925  
Telephone [021] 406 6626 • Facsimile [021] 406 6411  
e-mail: shuretta.thomas@uct.ac.za**

06 May 2010

REC REF: 221/2005

**Dr I Govender & Dr E De Vries**  
Public Health & Family Medicine

Dear Drs Govender & De Vries

**PROJECT TITLE: CHRONIC CARE AUDIT OF HYPERTENSION AND DIABETES  
MELLITUS AT COMMUNITY HEALTH CARE CENTRES IN CAPE TOWN**

Thank you for your letters to the Research Ethics Committee dated 20 April 2010 and 30 April 2010.

It is a pleasure to inform you that the Ethics Committee has **granted an extension of approval** for the above study.

**Approval is granted until 15 May 2011.**

Please submit an annual progress report if the research continues beyond the expiry date. Please submit a brief summary of findings if you complete the study within the approval period so that we can close our file.

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

**Please quote the REC. REF in all your correspondence.**

Yours sincerely

Signature removed

**PROFESSOR M BLOCKMAN**  
**CHAIRPERSON, HSF HUMAN ETHICS**  
Federal Wide Assurance Number: FWA00001637.  
Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town 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) and Declaration of Helsinki guidelines.

The 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.

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### **1.3 Acknowledgements**

Contributors who do not meet the criteria for authorship as set out above may be named, with their permission, in the Acknowledgements. The corresponding author is responsible for obtaining written permission from all persons named in the Acknowledgements, and must include the following statement in the cover letter: 'I have obtained written permission from all persons named in the Acknowledgement.

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At the point of submission, IJQHC's policy requires that each author reveal any financial interests or connections, direct or indirect, or other situations that might raise the question of bias in the work reported or the conclusions, implications, or opinions stated - including pertinent commercial or other sources of funding for the individual author(s) or for the associated department(s) or organization(s), personal relationships, or direct academic competition. When considering whether you should declare a conflicting interest or connection please consider the conflict of interest test: Is there any arrangement that would embarrass you or any of your co-authors if it was to emerge after publication and you had not declared it?

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- Figures

Use double-spacing throughout the manuscript, including the references and tables.

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For regular **peer-reviewed articles**, appropriate length for the main body of text is **2500 to 3000 words**, excluding abstract, references, tables and figures. The number of references should 20 to 30 (more may be allowed for review articles). There should be no more than 5 tables or figures. However, brevity is not an end in itself. We will consider longer papers when a study is particularly important, and when the topic requires more extensive development.

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- running title (not more than 30 spaces)
- two word counts: one for the abstract and one for the text of the manuscript

The abstract should be structured. Headings for **Research articles**:

- Objective
- Design
- Setting
- Participants
- Intervention(s)
- Main Outcome Measure(s)
- Results
- Conclusions

Headings for **Review articles**:

- Purpose
- Data sources
- Study selection
- Data extraction
- Results of data synthesis
- Conclusion

Headings for **Quality in practice articles**:

- Quality problem or issue
- Initial assessment
- Choice of solution
- Implementation
- Evaluation

- Lessons learned

For **Methods articles** and **Perspectives on quality articles** the format of the abstract is free, but structure is recommended

## **2.6 Keywords**

Three to six keywords or concise key phrases should be given for indexing purposes. Use of terms from the Medical Subject Headings List in *Index Medicus* is preferred.

## **2.7 Text**

Research papers should consist of the sequence Introduction, Methods, Results, and Discussion. For other papers the sequence should replicate the structure of the abstract.

## **2.8 Reporting of statistical analyses**

Focus the statistical analysis at the research question.

Report simple analyses first, then only more sophisticated results.

Provide information about participation and missing data.

As much as possible, describe results using meaningful phrases (E.g., do not say "beta" or "regression coefficient", but "mean change in Y per unit of X"). Provide 95% confidence intervals for estimates.

Report the proportions as N (%), not just %.

Report most results with two significant digits (E.g., 2.1 not 2.137).

Report p values with 2 digits after the decimal, 3 if <0.01 or near 0.05. E.g., 0.54, 0.03, 0.007, <0.001, 0.048. Do not report p values greater than 0.05 as "NS".

Always include a leading zero before the decimal point (e.g., 0.32 not .32).

Do not report tests statistics (such as chi-2, T, F, etc).

## **2.9 Acknowledgment**

At the end of the text include acknowledgements of individuals who were of direct help in the preparation of the study.

## **2.10 Funding**

Details of all funding sources for the work in question should be given in a separate section entitled 'Funding'. This should appear after the 'Acknowledgements' section.

The following rules should be followed:

- The sentence should begin: 'This work was supported by ...'

- The full official funding agency name should be given, i.e. 'National Institutes of Health', not 'NIH' ([full RIN-approved list of UK funding agencies](#)) Grant numbers should be given in brackets as follows: '[grant number xxxx]'
- Multiple grant numbers should be separated by a comma as follows: '[grant numbers xxxx, yyyy]'
- Agencies should be separated by a semi-colon (plus 'and' before the last funding agency)
- Where individuals need to be specified for certain sources of funding the following text should be added after the relevant agency or grant number 'to [author initials]'

An example is given here: 'This work was supported by the National Institutes of Health [AA123456 to C.S., BB765432 to M.H.]; and the Alcohol & Education Research Council [hfygr667789].'

Oxford Journals will deposit all NIH-funded articles in PubMed Central. See [http://www.oxfordjournals.org/for\\_authors/repositories.html](http://www.oxfordjournals.org/for_authors/repositories.html) for details. Authors must ensure that manuscripts are clearly indicated as NIH-funded using the guidelines above.

## 2.11 References

Please ensure to include the heading "References" at the top of the references page.

Make sure that all references are cited (between square brackets) in numerical order in the text. Also make sure that, on the references page, they are numbered according to the order in which they appear.

Number references consecutively in the order in which they are first mentioned in the text. Identify references by Arabic numerals. Check the accuracy of the references against original sources.

Favour easily available references published in peer-reviewed journals. Avoid grey literature, and documents in languages that will not be understood by most readers. Avoid references to internet sites, except when unavoidable, because internet addresses tend to be unstable.

Format references in the **Vancouver style** (<http://www.icmje.org/>). For journal articles please do not include the issue numbers. For journal name abbreviations, use the abbreviation as published on Medline. Please see the example below.

Examples of the correct formats are as follows:

### *Journal article*

1. Laouri M, Kravitz RL, Bernstein SJI. Underuse of coronary angiography: application of a clinical method. *Int J Qual Health Care* 1997; 9: 15-22.

### *Book*

2. Steiner DL, Norman GR. *Health Measurement Scales: A Practical Guide to their Development and Use*. Oxford: Oxford University Press, 1995.

**Foreign language text; Chapter in book**

3. Molina CG, Giedion U, Rueda MC, Alviar M. Public investment in health and distribution of subsidies in Colombia. *In Study of Influence of the Public Social Investment (in Spanish)*. Santafé de Bogotá: Fedesarrollo, Departamento Nacional de Planeación

**Organization as Author**

4. National Centre for Clinical Audit. *Information for Better Healthcare*. London: NCCA, 1997.

**Multi-volume book**

5. Pan American Health Organization. Health in the Americas. Washington, DC: PAHO, 1998: Vol. 2, p. 108.

**Website**

6. Federal Ministry of Labour, Health and Social Affairs, Austria:  
<http://www.bmags.gv.at> Accessed [Date (i.e. date reference item accessed on organization website)].

'Unpublished observations' and 'personal communications' should not appear among the references. These should be inserted in parentheses in the text, and letters of permission from all individuals cited in this way should accompany the manuscript. Manuscripts that have been accepted for publication but have not yet been published may appear in the references: include the authors, manuscript title, and name of the journal followed by '(in press)'

## **2.12 Tables**

The total number of tables and figures should not exceed five.

The table header should permit the table to be understood without reference to the text. Number tables in the order in which they are cited in the text.

Every column in the table should have a heading. Define all abbreviations and indicate the units of measurement for all values. Explain all empty spaces or dashes. Indicate footnotes to the table with superscript Arabic numbers cited in order as you read the table horizontally.

## **2.13 Figures**

Figures must be supplied in electronic form. Letters, numbers and symbols should be clear throughout and should be large enough to remain legible when reduced for publication.

Legends should be typed on a separate page from the figure(s), double-spaced, and numbered with Arabic numerals corresponding to the figures. When symbols, arrows, numbers or letters are used to identify parts of a figure, each should be explained clearly in the legend or as a footnote. The legend should permit the figure to be understood without reference to the text.

## **3. SUBMISSION**

### 3.1 Initial submission

All manuscripts intended for publication should be submitted through the Journal's online submission system. (<http://mc.manuscriptcentral.com/intqhc>)

The copyright transfer form should be completed and sent to Oxford University Press only after the manuscript has been accepted for publication.

Before you start the online submission process, do the following:

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- If necessary, prepare any supplementary materials that are not intended for publication as separate files - e.g., related manuscripts, extensive appendices that would be posted on the journal website but not printed, PowerPoint slides, study instruments, etc. These should be uploaded as separate files.
- Have the manuscript file open as you submit. You will be asked to insert (cut and paste) the title, running title, abstract and key words into appropriate fields.
- Have the names, professional addresses and email addresses of all authors at hand. You will be asked to enter these into appropriate fields.
- Do two separate word counts, on the abstract and on the main body of text. You will be asked to insert these into appropriate fields.
- Prepare the submission letter. You will be asked to paste the letter into a box.
- If you are submitting a manuscript that does not have an abstract (letter to editor, editorial), type "none" into the abstract box. The system will not let you continue if you leave the abstract box blank.

### 3.2 Resubmission

**We would appreciate if you could submit a revised version of your manuscript within two months.**

**Do not submit a revised paper as though it were a new manuscript.** It is important that your manuscript keeps the same reference number throughout the review process. The system will automatically number your revised versions (ex: INTQHC 2005-00027, INTQHC 2005-00027.R1, ...).

Enter your Author Center and select the "Revised Manuscript" button. Then submit revised manuscripts via the same online system. You will be also be asked to insert your answers to the editor's and reviewers' comments into a box. Then click on the title of your manuscript to upload the revised version of the

manuscript.

When responding to comments, it is best to identify each of the reviewer's/editor comments separately (either copy or abbreviate) and to respond below. Indicate how you modified the paper in response to the comment, or why a modification is not appropriate.

### **3.3 Production process**

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