CHRONIC DISEASE CARE IN PRIMARY HEALTH CARE FACILITIES IN RURAL SOUTH AFRICAN SETTINGS

By

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A THESIS

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Declaration

I, Soter Sunday Ameh declare that this thesis is my original work. Contributions made by other people to this body of work have been duly acknowledged. It is being submitted for the degree of Doctor of Philosophy in Public Health in the University of the Witwatersrand, Johannesburg, South Africa. It has not been submitted before for any degree or examination at this or any other university.

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Dedication

I dedicate this thesis to my family: to you Florence for your patience, support and commitment during the PhD period; to you David for enduring the period you reached your developmental milestones without me cheering you on. I dedicate it to you mama for those encouraging words for us your children to continue to struggle and work hard. I dedicate it to you baba for your assurance of daily prayers and blessings throughout the PhD period, even on your sick bed. I dedicate this thesis to you my siblings: Christian, Grace, Priscilla and Cosmas for your unwavering support and prayers.

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XIV. Soter Ameh, Kerstin Klipstein-Grobusch, Lucia D'Ambruoso, Kathleen Kahn, Stephen M. Tollman and Francesc Xavier Gómez-Olivé. A paradox of HIV stigmatisation in an integrated chronic disease management model in a rural South African setting. An oral presentation at the 12th annual conference of the Public Health Association of South Africa (PHASA), 19th-22nd September 2015, East London, South Africa.

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Abstract

Background: South Africa has a dual high burden of HIV and non-communicable diseases (NCDs). In a response to the dual burden of these chronic diseases, the National Department of Health (NDoH) introduced a pilot of the Integrated Chronic Disease Management (ICDM) model in June 2011 in selected Primary Health Care (PHC) facilities, one of the first of such efforts by an African Ministry of Health. The main aim of the ICDM model is to leverage the successes of the innovative HIV treatment programme for NCDs in order to improve the quality of chronic disease care and health outcomes of adult chronic disease patients. Since the initiation of the ICDM model, little is known about the quality of chronic care resulting in the effectiveness of the model in improving health outcomes of chronic disease patients.

Objectives: To describe the chronic disease profile and predictors of healthcare utilisation (HCU) in a rural population in a South African municipality; and assess quality of care and effectiveness of the ICDM model in improving health outcomes of chronic disease patients receiving treatment in PHC facilities.

Methods: An NDoH pilot study was conducted in selected health facilities in the Bushbuckridge municipality, Mpumalanga province, northeast South Africa, where a part of the population has been continuously monitored by the Agincourt Health and Socio-Demographic Surveillance System (HDSS) since 1992. Two main studies were conducted to address the two research objectives. The first study was a situation analysis to describe the chronic disease profile and predictors of healthcare utilisation in the population monitored by the Agincourt HDSS. The second study evaluated quality of care in the ICDM model as implemented and assessed effectiveness of the model in improving health outcomes of patients receiving treatment in PHC facilities. This second study had three components: (1) a qualitative and (2) a quantitative

evaluation of the quality of care in the ICDM model; and a (3) quantitative assessment of effectiveness of the ICDM model in improving patients' health outcomes. The two main studies have been categorised into three broad thematic areas: chronic disease profile and predictors of healthcare utilisation; quality of care in the ICDM model; and changes in patients' health outcomes attributable to the ICDM model.

In the first study, a cross-sectional survey to measure healthcare utilisation was targeted at 7,870 adults 50 years and over permanently residing in the area monitored by the Agincourt HDSS in 2010, the year before the ICDM model was introduced. Secondary data on healthcare utilisation (dependent variable), socio-demographic variables drawn from the HDSS, receipt of social grants and type of medical aid (independent variables) were analysed. Predictors of HCU were determined by binary logistic regression adjusted for socio-demographic variables.

The quantitative component of the second study was a cross-sectional survey conducted in 2013 in the seven PHC facilities implementing the ICDM model in the Agincourt sub-district (henceforth referred to as the ICDM pilot facilities) to better understand the quality of care in the ICDM model. Avedis Donabedian's theory of the relationships between structure, process, and outcome (SPO) constructs was used to evaluate quality of care in the ICDM model exploring unidirectional, mediation, and reciprocal pathways. Four hundred and thirty-five (435) proportionately sampled patients ≥ 18 years and the seven operational managers of the PHC facilities responded to an adapted satisfaction questionnaire with measures reflecting structure (e.g. equipment), process (e.g. examination) and outcome (e.g. waiting time) constructs. Seventeen dimensions of care in the ICDM model were evaluated from the perspectives of patients and providers. Eight of these 17 dimensions of care are the priority areas of the HIV treatment programme used as leverage for improving quality of care in the ICDM model: supply

of critical medicines, hospital referral, defaulter tracing, prepacking of medicines, clinic appointments, reducing patient waiting time, and coherence of integrated chronic disease care (a one-stop clinic meeting most of patients' needs). A structural equation model was fit to operationalise Donabedian's theory using patient's satisfaction scores.

The qualitative component of the second study was a case study of the seven ICDM pilot facilities conducted in 2013 to gain in-depth perspectives of healthcare providers and users regarding quality of care in the ICDM model. Of the 435 patients receiving treatment in the pilot facilities, 56 were purposively selected for focus group discussions. An in-depth interview was conducted with the seven operational managers within the pilot facilities and the health manager of the Bushbuckridge municipality. Qualitative data were analysed, with MAXQDA 2 software, to identify 17 a priori dimensions of care and emerging themes. In addition to the emerging themes, codes generated in the qualitative analysis were underpinned by Avedis Donabedian's SPO theoretical framework.

A controlled interrupted time-series study was conducted for the 435 patients who participated in the cross-sectional study in the ICDM pilot facilities and 443 patients proportionately recruited from five PHC facilities not implementing the ICDM model (Comparison PHC facilities in the surrounding area outside the Agincourt HDSS) from 2011-2013. Health outcome data for each patient were retrieved from facility records at 30-time points (months) during the study period. We performed autoregressive moving average (ARMA) statistical modelling to account for autocorrelation inherent in the time-series data. The effect of the ICDM model on the control of BP (<140/90 mmHg) and CD4 counts (>350 cells/mm^3) was assessed by controlled segmented linear regression analysis.

Results: Seventy-five percent (75%) of the 7,870 eligible adults 50+ responded to the health care utilization survey in the first study. All 5,795 responders reported health problems, of whom 96% used healthcare, predominantly at public health facilities (82%). Reported health problems were: chronic non-communicable diseases (41% - e.g. hypertension), acute conditions (27% - e.g. flu), other conditions (26% - e.g. musculoskeletal pain), chronic communicable diseases (3% e.g. HIV and TB) and injuries (3%). Chronic communicable (OR=5.91, 95% CI: 1.44, 24.32) and non-communicable (OR=2.85, 95% CI: 1.96, 4.14) diseases were the main predictors of healthcare utilisation.

Out of the 17 dimensions of care assessed in the quantitative component of the quality of care study, operational managers reported dissatisfaction with patient waiting time while patients reported dissatisfaction with the appointment system, defaulter-tracing of patients and waiting time. The mediation pathway fitted perfectly with the data (coefficient of determination=1.00). The structural equation modeling showed that structure correlated with process (0.40) and outcome (0.75). Given structure, process correlated with outcome (0.88). Patients' perception of availability of equipment, supply of critical medicines and accessibility of care (structure construct) had a direct influence on the ability of nurses to attend to their needs, be professional and friendly (process construct). Patients also perceived that these process dimensions directly influenced coherence of care provided, competence of the nurses and patients' confidence in the nurses (outcome construct). These structure-related dimensions of care directly influenced outcome-related dimensions of care without the mediating effect of process factors.

In the qualitative study, manager and patient narratives showed inadequacies in *structure* (malfunctioning blood pressure machines and staff shortage); *process* (irregular prepacking of drugs); and *outcome* (long waiting times). Patients reported anti-hypertension drug stock-outs;

sub-optimal defaulter-tracing; rigid clinic appointments; HIV-related stigma in the community resulting from defaulter-tracing activities; and government nurses' involvement in commercial activities in the consulting rooms during office hours. Managers reported simultaneous treatment of chronic diseases by traditional healers in the community and thought there was reduced HIV stigma because HIV and NCD patients attended the same clinic.

In the controlled-interrupted time series study the ARMA model showed that the pilot facilities had a 5.7% (coef=0.057; 95% CI: 0.056,0.058; $P<0.001$) and 1.0% (coef=0.010; 95% CI: 0.003,0.016; $P=0.002$) greater likelihood than the comparison facilities to control patients' CD4 counts and BP, respectively. In the segmented analysis, the decreasing probabilities of controlling CD4 counts and BP observed in the pilot facilities before the implementation of the ICDM model were respectively reduced by 0.23% (coef = -0.0023; 95% CI: -0.0026,-0.0021; $P<0.001$) and 1.5% (Coef= -0.015; 95% CI: -0.016,-0.014; $P<0.001$).

Conclusions: HIV and NCDs were the main health problems and predictors of HCU in the population. This suggests that public healthcare services for chronic diseases are a priority among older people in this rural setting. There was poor quality of care reported in five of the eight priority areas used as leverage for the control of NCDs (referral, defaulter tracing, prepacking of medicines, clinic appointments and waiting time); hence, the need to strengthen services in these areas. Application of the ICDM model appeared effective in reducing the decreasing trend in controlling patients' CD4 counts and blood pressure. Suboptimal BP control observed in this study may have been due to poor quality of care in the identified priority areas of the ICDM model and unintended consequences of the ICDM model such as work overload, staff shortage, malfunctioning BP machines, anti-hypertension drug stock-outs, and HIV-related stigma in the community. Hence, the HIV programme should be more extensively leveraged to

improve the quality of hypertension treatment in order to achieve optimal BP control in the nationwide implementation of the ICDM model in PHC facilities in South Africa and, potentially, other LMICs.

Keywords: Adults; predictors; healthcare utilisation; HIV; Chronic non-communicable diseases (NCDs); Primary Health Care (PHC); Health Outcomes; Integrated Chronic Disease Management (ICDM) Model; Avedis Donabedian; Quality of care; Structural equation model; Interrupted Time-Series; Segmented regression; multilevel regression; Agincourt HDSS study site; South Africa.

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thinking I was another visitor because I was never there to play the role of a father. I promise to make it up to you by spending quality time with you very soon. God bless mum and Christian for taking good care of dad when he was hospitalised for months.

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Table of Contents

List of Figures

List of Tables

Appendices

List of abbreviations/Acronyms

AANCC	Age-associated non-communicable co-morbidities
AIDS	Acquired immune deficiency syndrome
ARMA	Autoregressive moving average
ART	Antiretroviral therapy
BP	Blood pressure
CD	Coefficient of determination
CFA	Confirmatory factor analysis
CFI	Comparative fit index
CHWs	Community health workers
DHS	District health system
DCST	District clinical specialist team
DM	Diabetes mellitus
FGDs	Focus group discussions
HBC	Home-based carer
HCU	Health care utilization
HDSS	Health and socio-demographic surveillance system
HIV	Human immunodeficiency virus
ICCC	Innovative care for chronic conditions
ICDM	Integrated chronic disease management
ISHP	Integrated school health programme
LMICs	Low- and middle-income countries
MDGs	Millennium Development Goals
MLMV	Maximum likelihood for missing values
MRC	Medical Research Council, South Africa
NCD	Non-communicable disease
NDoH	National Department of Health
OM	Operational manager
PHC	Primary Health Care
PLWHIV	People living with HIV
PSNCQQ	Patient satisfaction with nursing care quality questionnaire
PSQ	Patient satisfaction questionnaire

RMSEA	Root mean squared error of approximation
SDGs	Sustainable Development Goals
SEM	Structural equation model
SES	Socio-economic status
SPO	Structure, process, and outcome
SSA	Sub-Saharan Africa
TB	Tuberculosis
TLI	Tucker-Lewis index
UNAIDS	The Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization
WBOT	Ward-based outreach team

Preface

"We need a comprehensive, integrated approach to service delivery. We need to fight fragmentation".

Margaret Chan, Director General of the World Health Organization, 2007.

"An Ideal Clinic is defined as a clinic with good infrastructure, adequate staff, adequate medicine and supplies, good administrative processes, and sufficient adequate bulk supplies. It uses applicable clinical policies, protocols and guidelines, and it harnesses partner and stakeholder support".

National Department of Health, Republic of South Africa, 2015.

There had been a global consensus that the vertically controlled HIV treatment programme resulted in fragmented chronic disease care; hence, the clamour led by Margaret Chan to fight this fragmentation through the integration of HIV and NCD services. I was therefore extremely excited to discover that my PhD research was about monitoring chronic diseases and HIV progression and management in rural primary health care (PHC) in South Africa. This was an opportunity for me to conduct a study that would contribute to understanding chronic disease care by evaluating an intervention initiated to address the colliding epidemics of chronic non-communicable diseases (NCDs) and HIV in South Africa.

The timing of my PhD seemed appropriate because the NDoH in South Africa was "re-engineering" its PHC facilities, of which the Integrated Chronic Disease Management (ICDM)

model is a component. The ICDM model seeks to leverage the successes of the vertical HIV treatment programme for the poorly managed non-communicable diseases (NCDs) in order to improve the quality of care for NCDs with the expectation of improving health outcomes of chronic disease patients. Guided by my supervisors on arrival in South Africa, I commenced an extensive review of the literature on existing theoretical frameworks for evaluating health interventions. I was overwhelmed by the plethora of theoretical frameworks used to evaluate health interventions or health services and unsure which of these frameworks to adapt as my conceptual framework. Further literature search revealed that Avedis Donabedian's structure, process, and outcome framework, proposed in the 1960s, underpinned the planning and implementation of the pilot of the ICDM model in South Africa; hence, the rationale for adapting Donabedian's framework in evaluating the quality of care in the ICDM model in my PhD research.

This encounter with the literature and constant guidance by my supervisors gave me a sense of how to develop a thesis protocol that focused on evaluating the quality of care in the ICDM model and the effectiveness of the ICDM model in improving patients' health outcomes.

This thesis adopts a modern style (thesis with publications style) of thesis writing by incorporating an integrating narrative with four journal articles. The thesis presents the findings of the chronic disease profile in the population served by the health facilities in which the pilot of the ICDM model was implemented. Moving from the population to the public health facilities, this thesis also provides the results of an evaluation of the quality of care in the ICDM pilot facilities and the changes in patients' health outcomes attributable to the ICDM model.

This thesis is divided into two parts: part one is the integrating narrative which synthesises the results of all the thesis papers and their implications; while part two presents the four papers that make up this thesis.

1.0 Introduction

The World Health Organization (WHO) defines chronic diseases as those requiring "ongoing management over a period of years or decades" covering a wide range of health problems expanding beyond chronic non-communicable diseases (NCDs) to include some communicable diseases such as the Human Immunodeficiency Virus (HIV) infection and the Acquired Immunodeficiency Syndrome (AIDS) (1). This is due to the recognition of the transformation of HIV/AIDS to a chronic condition as a result of increasing life expectancy which is an outcome of rapidly expanding roll-out of Antiretroviral Treatment (ART) (2, 3).

South Africa has a dual high burden of HIV/AIDS and NCDs. The combined and growing epidemics of these chronic conditions have implications for South Africa's healthcare system which has yet to adapt to the long-term continuity of care for chronic diseases (4). The NDoH in South Africa introduced an integrated chronic disease management (ICDM) model in a response to the dual high burden of HIV/AIDS and NCDs. In 2011, a national pilot of the ICDM model commenced in selected Primary Health Care (PHC) facilities in three of South Africa's nine provinces, i.e. Gauteng, North West and Mpumalanga. The main aim of the ICDM model was to leverage the innovative HIV treatment programme for NCDs in order to improve the quality of chronic disease care and health outcomes of chronic disease patients. The ICDM model is a major initiative of the NDoH, one of the first of such efforts by an African Ministry of Health.

This thesis evaluated quality of care in the ICDM model and assessed effectiveness of the model in improving health outcomes of chronic disease patients receiving treatment in PHC facilities in the Bushbuckridge municipality situated in Mpumalanga province, northeast South Africa.

1.1 Problem statement

Societies experience an epidemiologic transition as they strive to achieve modernisation. Epidemiological transition, a concept developed by Abdel Omran in 1971, refers to transition from high mortality and fertility to low mortality and fertility as a country undergoes the process of modernisation from a developing nation to a developed nation (5). Omran described three "ages" in the process of modernisation: the 'age of pestilence and famine,' 'age of receding epidemics' and 'age of degenerative and man-made diseases' (5). Many Low- and Middle-Income Countries (LMICs) are at different ages of the epidemiological transition and the speed at which each country moves from one phase to another depends on country-specific geographical, cultural and socio-political factors.

Modernisation and economic growth have engendered biomedical innovations leading to the replacement of infectious diseases with chronic conditions. The latter are due to increasing life expectancy which is stimulated by improved public health services; water and environmental sanitation; and increasing socio-behavioural risk factors such as tobacco use, physical inactivity, harmful use of alcohol and unhealthy diet.

However, Omran's theory of sequential transition from one age to another was stalled or even reversed due to the HIV/AIDS epidemic in sub-Saharan Africa (6), with some countries

experiencing a high mortality at younger ages. The expanded use of Anti-Retroviral Treatment (ARTs) increased life expectancy which is defined as the probable number of years a person will live after a given age as determined by the mortality rate in a given geographic area (7). Consequently, there has been a rise in the burden of age-associated non-communicable co-morbidities (AANCC) among people living with HIV (PLWHIV) comparable to the general population (2, 3). On the other hand, some opportunistic illnesses associated with HIV infections (e.g. cervical cancer) are NCDs in their own right (2). Hence, African countries are witnessing an increasing dual burden of NCDs and HIV.

Non-communicable diseases are currently the leading cause of death globally (8). Nearly three-quarter of these deaths occur in LMICs (8) which have age-adjusted mortality rates nearly twice that of high-income countries (9). Mortality due to NCDs will increase in the next two decades (10) with Africa having the greatest increase (11).

Since the beginning of the HIV/AIDS epidemic, over 78 million people have been infected with the virus and 39 million people have died of AIDS (12); thereby, making HIV/AIDS one of the most explosive epidemics the world has ever witnessed. In 2011, nearly 70% of the 34 million PLWHIV worldwide resided in SSA (12).

Similar to some African countries, South Africa is experiencing a dual burden of HIV and NCDs which have been described as diseases on a collision course (13). In 2014, the prevalence of HIV in South Africa was estimated at 10%, one of the highest in Africa (14) while NCDs accounted

for 43% of all deaths (15). The high NCD-related mortality in South Africa has been attributed to poor management of NCDs within the healthcare system (16, 17) and fragmented chronic diseases services (4, 18). It has been reported in the literature that poor management of NCDs is a consequence of non-systematic implementation of treatment guideline; non-consultative process with relevant stakeholders in the development of guidelines; skepticism about durability of the guideline; conflict with local practices; health system problems and patient beliefs (16). Patients' poor knowledge of their conditions and drug prescriptions not being recorded in the medical records have also been identified as factors adversely affecting optimal management of NCDs (17). The high morbidity/mortality associated with NCDs and the fragmentation of chronic disease care have implications for South Africa's public healthcare system which has yet to adapt to the long-term continuity of care for chronic diseases (4, 18).

Tackling the dual burden of HIV/AIDS and NCDs seems feasible due to the commonalities that are related to their progression; prevention; and control. For instance, HIV and NCDs have minimal or no symptoms at early stages of onset, thus requiring a model of care different from acute care model. Both HIV and NCDs require ongoing clinic appointment/attendance, adherence to medication, necessitating approaches such as developing appropriate appointment and medication reminder systems, adherence, community follow-up, self-management and referrals (2).

Following the evidence that integrated chronic disease care improves patient's health outcomes and minimises HIV-related stigma (19), the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommends an integrated approach for chronic disease management (2), using the

building blocks described in the Innovative Care for Chronic Conditions (ICCC) framework (1). In a response, the NDoH in South Africa initiated the Integrated Chronic Disease Management (ICDM) model which is a component of the PHC reengineering strategy to strengthen the public healthcare system. (20-22). The ICDM model adopts a diagonal approach in leveraging the innovations of the vertical HIV programme for scaling up or supporting services for NCDs (22). Such innovations include ***programme approaches*** (peer programmes, defaulter tracing initiatives, multidisciplinary teams, and community engagement); ***tools*** (registers, charts, forms and medical records) and ***systems*** (monitoring and evaluation, improving quality, supply chain and procurement, referring people and processing of specimens) (2).

Following the initiation of the pilot of the ICDM model in South Africa, there is a paucity of published literature on the effectiveness of the model in improving the quality of integrated chronic care and health outcomes of chronic disease patients.

1.2 Study justification

Initiation of the ICDM model as a response to the dual high burden of HIV and NCDs in South Africa presents an urgent necessity to better understand how the model works. Although a pilot study in Cambodia demonstrated the feasibility of an integrated care for HIV and NCDs (2, 19), there is a pressing need for local data on an integrated chronic disease approach in Africa given the socio-economic and geo-cultural differences across settings.

In Uganda, a multidisciplinary initiative for integrated management of NCDs was formed in 2013 with an aim of reframing integrated health service delivery, but there was no data to show

the feasibility of this initiative in improving the quality of integrated chronic care and health outcomes of chronic disease patients (23).

Two proof-of-concept pilot studies to further understand the status of NCD services and the feasibility and effectiveness of adapting HIV programme-related tools and systems for patients with diabetes mellitus (DM) have been conducted in health facilities in Swaziland and Ethiopia (24). Significant gaps in the strategies, systems and tools used to support DM services in both countries were identified and a continuum of approaches in leveraging HIV programme for NCDs was recommended to implementers and policy makers. These approaches included integration of chronic disease services, parallel "side-by-side" services for the longitudinal management of all chronic diseases, and an intermediate approach in which clinical services are not integrated, but the systems behind these services (e.g. use of guidelines, training, procurement of drugs and supplies, laboratory systems, and monitoring and evaluation) are shared (24). Although data on process indicators were measured, there was a dearth of information on the health outcomes of both HIV and DM patients to identify opportunities for diffusion of innovations in the HIV programme.

In South Africa, little is known about the effectiveness of the ICDM model in improving the quality of chronic disease and health outcomes of patients since initiation of the model as a pilot programme in 2011. This study will add to the existing body of knowledge by contributing to the national and global debate on the feasibility of leveraging the successes of the innovations of the

HIV treatment programme to support or scale-up services for NCDs, particularly in LMICs, by evaluating the ICDM model used in South Africa.

1.3 Hypothesis, research aim, and research objectives

1.3.1 Hypothesis

I hypothesise in this thesis that the ICDM model has led to changes in key health outcome indicators of patients (e.g. blood pressure (BP) and CD4 counts) since the model was implemented in 2011 in selected PHC facilities in the rural Bushbuckridge municipality of Mpumalanga province.

1.3.2 Research aim

1. To profile chronic diseases and determine the predictors of healthcare utilisation by adults 50 years and older in the population; evaluate the quality of care provided in the ICDM model implemented in selected PHC facilities in a rural South African setting; and assess the effectiveness of the model in improving key health outcomes of patients receiving treatment for chronic diseases.

1.3.3 Research objectives

1. To profile chronic diseases and determine the predictors of healthcare utilisation by adults 50 years and older in the population in 2010, the year before the ICDM model was initiated.

2. To evaluate the quality of care provided in the ICDM model in 2013.

3. To assess the perception of patients (P) and operational managers (OM) regarding quality of care in the ICDM model in 2013.

4. To assess the effectiveness of the ICDM model in controlling patients' CD4 counts (>350cells/mm3) and blood pressure (<140/90 mmHg) from 2011 to 2013.

1.4 Thesis themes

1.4.1 Overall theme

The overarching theme in this thesis is an evaluation of the ICDM model which was initiated as a response to the dual burden of HIV and NCDs in South Africa, a LMIC undergoing a rapid health transition.

1.4.2 Specific themes

1. Chronic disease profile and predictors of healthcare utilisation: This theme describes the main chronic diseases and predictors of healthcare utilisation among adults ≥ 50 years in the year before the ICDM model was initiated. This population profile of chronic diseases provides a sense of what is to be expected in the PHC facilities where these adults seek healthcare.

2. Quality of care in the ICDM model: This theme has quantitative and qualitative components that contribute to understanding the quality of care in the ICDM model which determines the effectiveness of the model in improving key indicators of patients' health outcome.

3. Changes in patients' health outcomes attributable to the ICDM model: Objective assessment of the changes in patients' health outcomes provides a better understanding of the

effectiveness of the ICDM model in impacting the health of patients for whom the model was intended.

Table 1: Relationship between the thesis themes, research objectives and the papers responding to the research objectives

Themes and research objectivess	Papers			
	I	II	III	IV
Theme 1: Chronic disease profile and predictors of healthcare utilisation Research objective 1: What were the main chronic diseases and predictors of healthcare utilisation by adults 50 years and older in 2010 the year before the ICDM model was initiated?	✓	✓	✓	✓
Theme 2: Quality of care in the ICDM model Research objective 2 (Quantitative method): What was the quality of care in the ICDM model? Research objective 3 (Qualitative method): How did the patients and operational managers perceive the quality of chronic disease care in the ICDM model?		✓	✓	
Theme 3: Changes in patients' health outcomes attributable to the ICDM model Research objective 4: Was the ICDM model effective in controlling patients' CD4 count (>350cells/mm^3) and blood pressure (<140/90 mmHg)?				✓

1.5 Conceptual framework

Figure 1 shows the conceptual framework for this PhD thesis. It was adapted from the WHO's Innovative Care for Chronic Conditions (ICCC) framework (1), which also underpins the ICDM model developed by the NDoH in South Africa (20). The ICCC framework acknowledges that healthcare services for chronic conditions are inherently different from healthcare services for acute problems; therefore, acute care models cannot be applied to chronic disease care. The framework highlights the hierarchical levels of interaction between relevant stakeholders, roles and activities of stakeholders, and expected outcomes of these interactions all of which are necessary for long-term continuity of care for the management of chronic conditions.

The micro-, meso-, and macro-levels of healthcare refer to the patient interaction level, the healthcare organisation/community level and the policy level, respectively (1). These levels are described as building blocks that can be used to create or redesign a healthcare system that can more effectively manage long-term health problems. At the micro-level, optimal outcomes occur when there is a triad of partnership between patients and families, healthcare teams, and community supporters, with an underlying notion that each member of the triad needs to be informed, motivated and prepared to manage chronic diseases. Furthermore, the framework recognises increased attention to patient behaviour as well as healthcare worker communication for optimal health outcomes. At the meso-level, community resources must be integrated to make significant gain, while healthcare organisations need to streamline services, build capacity of the health workforce, focus on prevention, and establish a reliable health information tracking system for patients receiving treatment for chronic conditions. Governments need to guide policy-making and set standards for quality of care at the macro-level.

The interactive feedback loops in the roles and activities of stakeholders at various levels highlight how events at one level influence actions and events at another level. For instance, patients' interaction with health workers at the micro-level may elicit responses from healthcare organisation/community at the meso-level. The latter are responsive to policies at the macro-level which in turn influence patients at the micro-level and the feedback loops perpetuate.

Interactions between stakeholders at various levels are expected to produce outcomes; conducive policy environment, better quality of care and optimal patient health outcomes at the macro-, meso-, and micro-level, respectively. Further details of the ICCC framework have been provided in the literature review section as one of the initiatives to reduce chronic disease burden.

This thesis, through the three green-coloured oval-shaped callout bubbles in Figure 1, assessed and/or evaluated the expected outcomes of the hierarchical levels of interaction between relevant stakeholders in the pilot implementation of the ICDM model: availability of and an analysis of an ICDM policy to create an enabling environment for the operational implementation of the ICDM model (macro-level), quality of care in the health facilities (meso-level) and optimal patient health outcomes (micro-level).

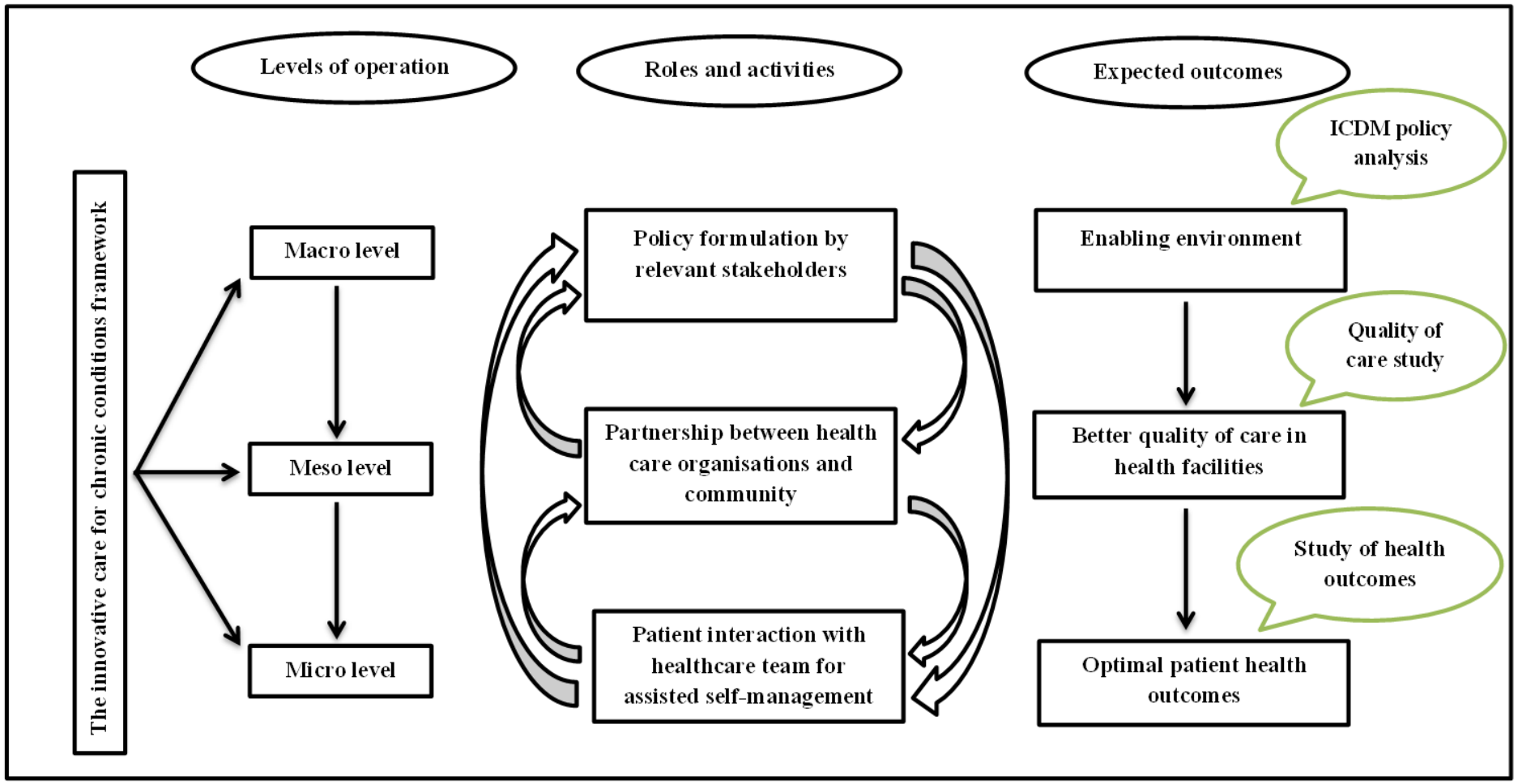

Figure 1: A conceptual framework for evaluating the ICDM model used to address South Africa's dual burden of HIV and NCDs. Adapted from the WHO's Innovative Care for Chronic Conditions (ICCC) framework (1)

2.0 Literature review

This section presents a review of the literature on the epidemiologic transition theory that underpins the dual burden of HIV and NCDs in LMICs and South Africa, initiatives to strengthen health systems, and strategies to reduce chronic disease burden. Subsequent sections highlight South Africa's core quality standards; the link between the ICDM model and the national core quality standards; the link between the ICDM model and the Primary Health Care (PHC) re-engineering initiative of South Africa's NDoH and theoretical frameworks for evaluating health interventions.

2.1 Epidemiological transition in low- and middle-income countries

Several LMICs are at different stages in their epidemiological transition. However, the speed at which each country transits depends on context-specific geographical, cultural and socio-political factors. In the 1950s, progress was slow in countries barely out of the "age of pestilence and famine" where life expectancy was low. This was because the advances in the control of infectious diseases benefited only a fraction of the population, mostly urban (25). At a later stage, life expectancy increased because the health systems reached their full capacity to contain widespread endemic diseases, as was the case in Chile and Korea. However, as these LMICs moved closer to life expectancy levels reached in high-income nations, the pace slowed again in the 1980s because there was no longer much to be gained in the field of infectious diseases (25). Although Tunisia in north Africa continued to make gains in life expectancy, the pace slowed drastically in Zimbabwe, Zambia, Botswana, Rwanda, Namibia in southern Africa and Uganda in east Africa with the arrival of the HIV/AIDS epidemic (Figure 2) (26). In South Africa, the HIV/AIDS epidemic significantly contributed to the drastic reduction in life expectancy from 62 years in 1990 to 50 years in 2007, when the use of ARTs started to became more available (27).

However, there has been a significant reduction in population-level mortality following the roll-out of ARTs in South Africa in 2014 (28) and other sub-Saharan African countries (29, 30).

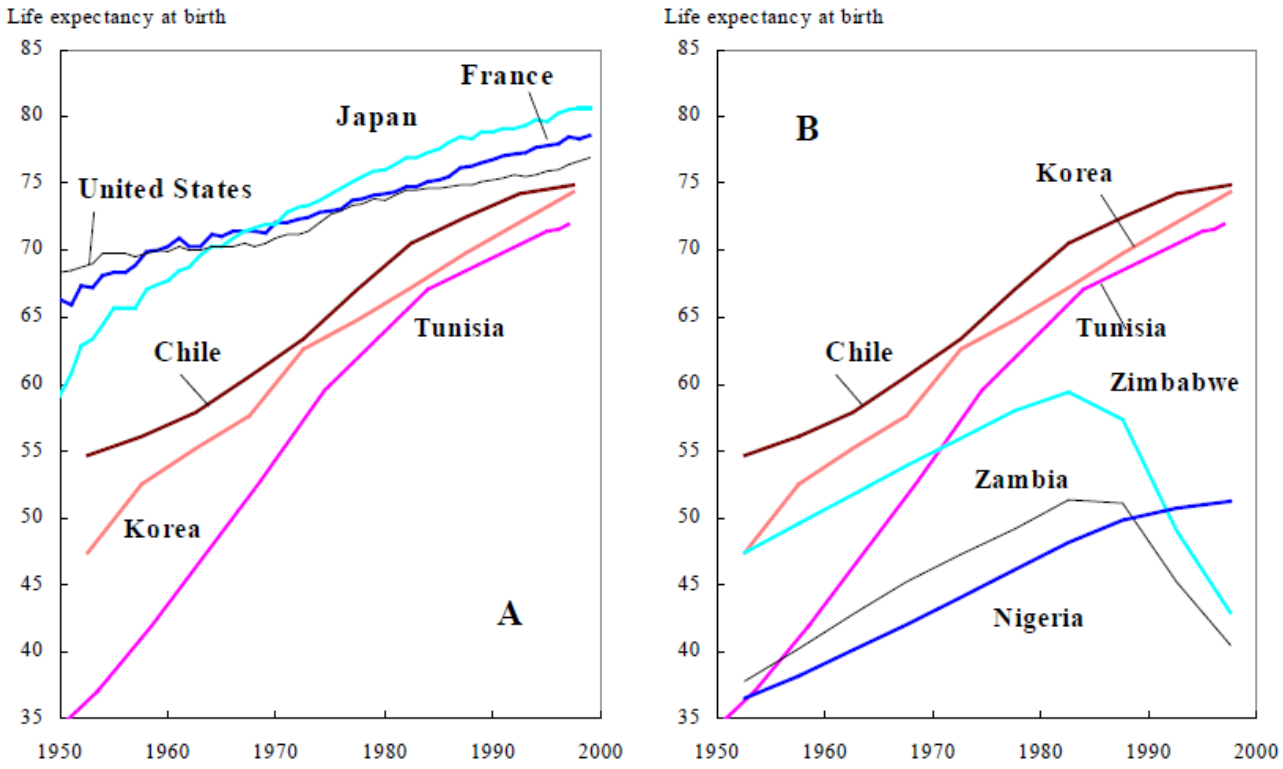

Figure 2: Changes in life expectancy since the 1950s: North-South convergences (A) and South-South divergences (B)
Source: United Nations 2001 (25)

2.1.1 Epidemiological transition in South Africa

In South Africa, there is an emergence of a pattern of multi-morbidity (co-existence of more than one chronic disease) different from that previously described in the literature. This is referred to as comorbid non-communicable and infectious chronic diseases (e.g. TB) and is common in younger age due to the high prevalence of HIV/AIDS in young people (31). These multi-morbidities have been attributed to increasing life expectancy due to ART roll-out; and the risk

of dysglycaemia (32) and cardiometabolic syndrome (33) associated with some antiretroviral drugs.

Use of ART is not the only contributor to the epidemiological transition reported in many LMICs. Obesity has also been reported as a major contributor to the emergence of diet-related NCDs (e.g. cardiovascular diseases and diabetes) in adults (34). Childhood obesity has also been reported in South Africa (Kimani) and other LMICs (Kelishadi 8), and is a driving force behind the emergence of cardiovascular complications, and type I and type II diabetes (Reilly 9). Of further concern is the fact that obese children are likely to become obese adults; hence, fueling the epidemic of NCDs and the attendant cardiometabolic syndrome over time (Reilly 9).

2.2 Burden of chronic communicable and non-communicable diseases

Chronic non-communicable diseases (NCDs) are responsible for two-thirds of all mortalities worldwide, with 80% of these deaths occurring in LMICs (8). The total annual number of deaths from NCDs is estimated to increase to 55 million by 2030 (10), with Africa having the greatest increase of 27% (11). NCDs will have a remarkable impact on the world's overall disease burden and healthcare because they are the leading cause of mortality in six middle-income countries (China, Ghana, India, Mexico, Russia, and South Africa) that host 42% of the world's 1.4 billion people aged 50 years and older. South Africa has the highest prevalence of hypertension among these countries (35).

But chronic conditions are not limited to NCDs alone. There is increasing recognition of the transformation of chronic communicable diseases such as Human Immunodeficiency Virus

(HIV) to a chronic condition due to rapidly expanding Antiretroviral Treatment (ART) which fuel the emergence of age-related chronic conditions (2, 3). Chronic diseases now include all health problems that require ongoing management over a period of years or decades expanding beyond the traditional NCDs to include HIV (1).

In South Africa, there is a dual burden of HIV/AIDS and NCDs (13). In 2014, NCDs accounted for 43% of all deaths (15) and the overall prevalence of HIV was estimated at 10.2% (14); making South Africa the country with highest HIV prevalence in Africa. The main NCDs in South Africa are hypertension and diabetes mellitus with reported prevalence of 78% (36) and 7% (37) in the adult population. The combined epidemics of HIV and NCDs have implications (e.g. overburdened infrastructure) for South Africa's public healthcare system which is yet to adapt to the long-term continuity of care for chronic disease patients. The challenge posed to the overburdened and weakened public healthcare system by these chronic diseases demands an extraordinary response (38). Given the increasing burden of chronic diseases which require a chronic care model for long term continuity of care, it is crucial to strengthen the already overburdened and weakened healthcare systems for improved health outcomes of chronic disease patients. The next section highlights international and national initiatives to strengthen health systems and tackle chronic disease burden.

2.3 Health system strengthening

In rethinking the link between health and development, arguments were made by the World Bank in the 1990s in favour of a policy on increased investment in the health system (39). The health sector therefore became a prime target for reforms based on the ideological assumption

that market-based systems are the most efficient ways to produce and distribute healthcare (40). Although this policy led to improvements in human development indices in many high income countries, it resulted in health inequality and worsened poverty levels in many LMICs (40). Following, at least, a decade of huge investments, there was a paradigm shift from market-oriented health systems to the notion of health system strengthening having realised that market-based systems will not automatically protect poor people or guarantee universal access to healthcare (41).

2.3.1 A health system framework

The WHO defines a health system as *consisting of all organisations, people and actions whose primary intent is to promote, restore or maintain health* (42). In 2007, the WHO developed a framework for action to address the urgent need to improve performance of health systems. This framework has six building blocks: service delivery; health workforce; information; medical products, vaccines and technologies; financing; and leadership and governance (Figure 3). These six building blocks are considered necessary to improve outcomes through desirable attributes such as access, coverage, quality and safety. These building blocks also seek to identify WHO's priorities and provide a means of identifying gaps for addressing county-specific challenges.

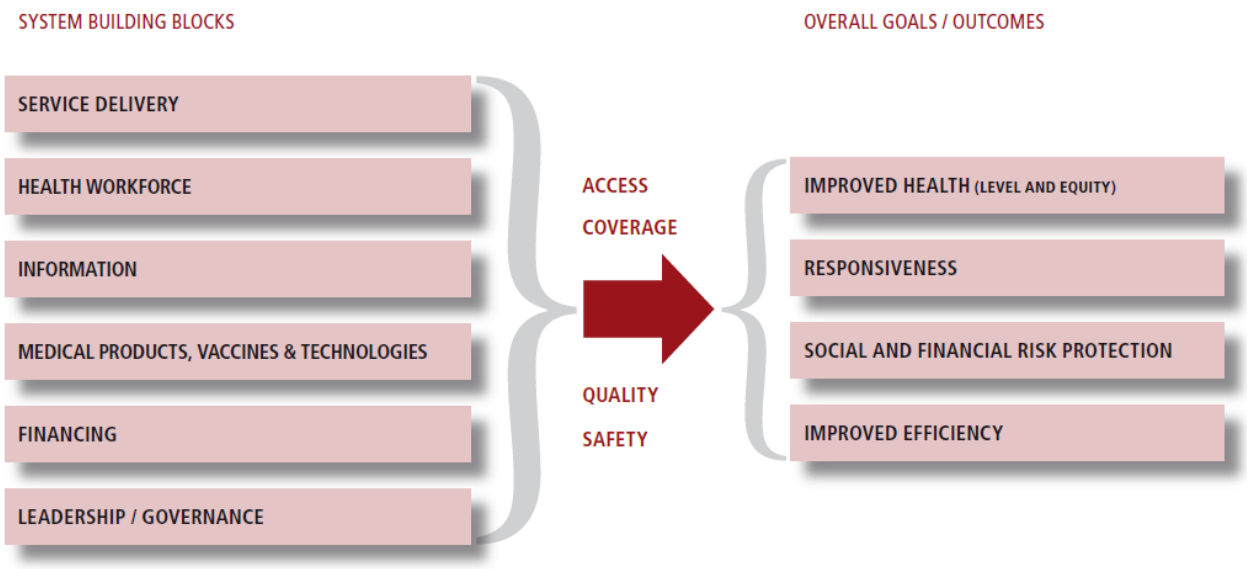

Figure 3: The six building blocks of a health system

Source: World Health Organization 2007 (42)

However, addressing country-specific health system challenges may not be feasible using the simplistic approach outlined in the WHO's distinct building blocks (42). A pragmatic response to health system challenges facing many countries should recognise the interactions and interrelationships between the six building blocks of the health system and between the various individuals within the health system (Figure 4). In 2009, de Savigny et al. offered a fresh and practical approach to strengthening health systems through "systems thinking" when they stated that *"the building blocks do not constitute a system any more than a pile of bricks constitutes a functioning building. It is the multiple relationships and interactions among the blocks – how one affects and influences the others, and is in turn affected by them – that converts these blocks into a system"* (43). They emphasised that health systems are often seen as a monolith in which little attention is paid to the interactions among its component parts. de Savigny et al. suggested a people-centred health system in which individuals, civil society organisations and stakeholder

networks are placed at the centre of the health system framework and are key actors with health workers, managers and policy makers in influencing each of the building blocks of the health system (43). Health systems are shaped by both structural or hardware (e.g. organizational, policy, legal and financing frameworks) and social or software (e.g. norms, traditions, values, roles and procedures) elements of the health system, which in turn, influence health system performance (44). In order to identify actions to strengthen health systems, researchers and policy-makers should consider making changes that are likely to improve health systems performance by targeting its hardware and software components (44).

Figure 4: The interconnections among the building blocks of a health system
Source: de Savigny and Adam, 2009;32 (43)

2.3.2 Primary health care (PHC) re-engineering

With the growing recognition that the health-related MDGs will not be met by September 2015 without improving the health system (45) through primary health care approach (41), a PHC strategy has been applied as the health system's organisational strategy and underlying philosophy in South Africa (46). There is evidence that strengthened primary level of care leads to improved population health in LMICs such as Brazil, Costa Rica and Cuba (47). Lessons learned from Brazil informed the NDoH in South Africa to re-engineer its PHC system (48). The PHC re-engineering framework of the NDoH is shown in Figure 5.

The PHC re-engineering currently underway in South Africa consists of three streams: a District Clinical Specialist Team (DCST) to strengthen referral mechanism between PHC clinics and referral hospitals; a Ward-based Outreach Team (WBOT) consisting of professional nurses, enrolled nurses and community health workers (CHWs) interacting directly with the community to conduct health education campaigns as well as primary prevention through screening of high-risk individuals; and an integrated school health programme (ISHP) to assist with early detection of chronic diseases and the appropriate referral of these high-risk patients (20). Ongoing efforts in this initiative should ensure that the composition of a defined comprehensive primary care package of services extend beyond services traditionally provided in health facilities. With CHWs playing a key role, the services which are aimed at reducing health inequality should now be population-oriented with extensive community outreach and home-based services (20). The next section presents specific initiatives to reduce chronic disease burden.

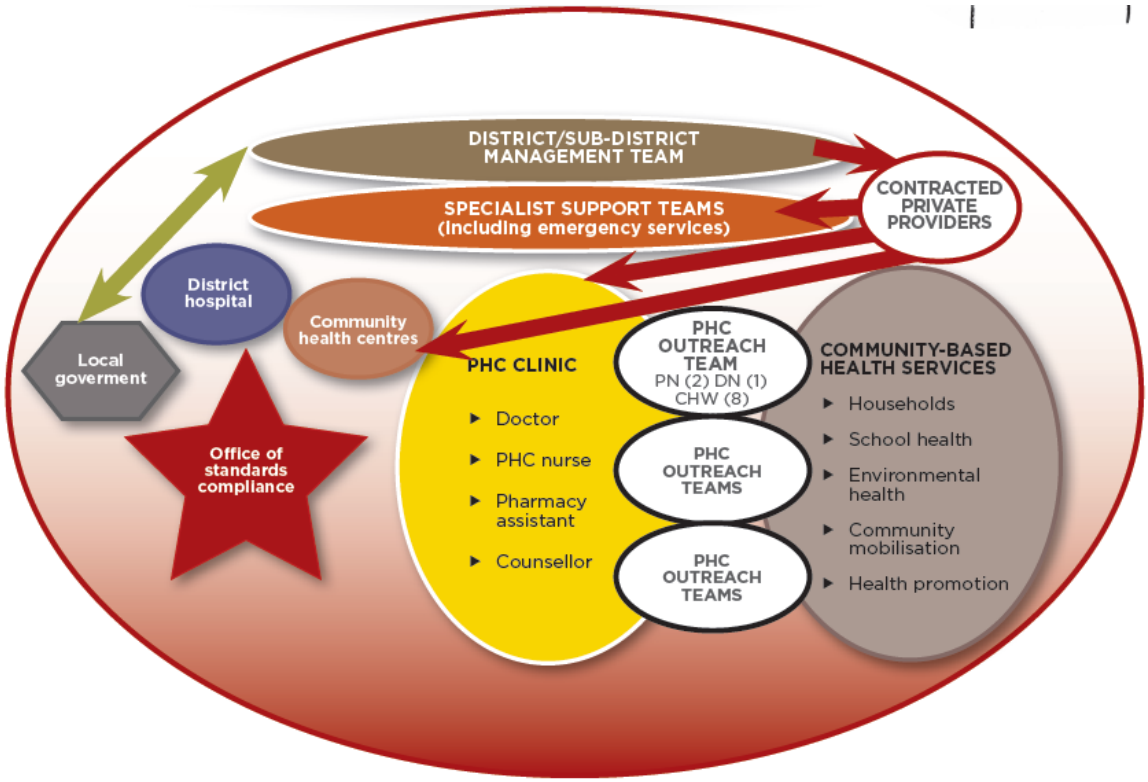

Figure 5: The primary health care re-engineering framework based on the district health model
Source: The Integrated Chronic Disease Management Manual 2014 (20)

2.4 Health service delivery initiatives to reduce chronic disease burden

2.4.1 The innovative care for chronic conditions (ICCC) framework

The ICCC framework was introduced by the WHO in 2002 (1) as an expansion of an earlier model, the Chronic Care Model, which was developed by Wagner et al. in the mid-1990s to present a structure for organising healthcare for chronic conditions (49). Innovation in healthcare for chronic conditions is the introduction of new ideas, methods, or programmes to change the way chronic conditions are prevented and managed (1). The healthcare perspective of this

framework is that chronic diseases should not be viewed as discrete problems or according to the traditional categories of communicable and non-communicable diseases. Innovative care is not based on the aetiology of a chronic condition, but is based on the demands that the health problem places on the health system. Such demands entail reorienting healthcare systems in a way that outcomes valued by the system are the ones that are produced.

The ICCC framework recognises that patients' needs transcend biomedical interventions. Patients need integrated care that cuts across time and settings. Innovative care recognises that patients and their families can most effectively manage chronic conditions with the support of their healthcare teams and their communities. Each entity needs to be linked and each is integrally important to the other in a manner that patients, communities and healthcare organisations each have important roles to play in improving outcomes for chronic conditions.

In this regard, innovation in care for chronic conditions is the integration of "building blocks" from the micro-, meso- and macro-levels of the health system by leveraging the previous successes of the HIV/AIDS programme into better care for other chronic conditions (Figure 6). It must be acknowledged that the ICCC's building blocks are different from the WHO's six building blocks. The triad at the centre of the ICCC framework represents the micro-level and consists of informed, motivated and prepared partnership of patient and family, community partners and healthcare team working together to achieve positive outcomes for chronic conditions. The meso- and macro-levels are respectively the community resources and policy framework that enable the triad of the patient/family, community partners and healthcare team to function at its best.

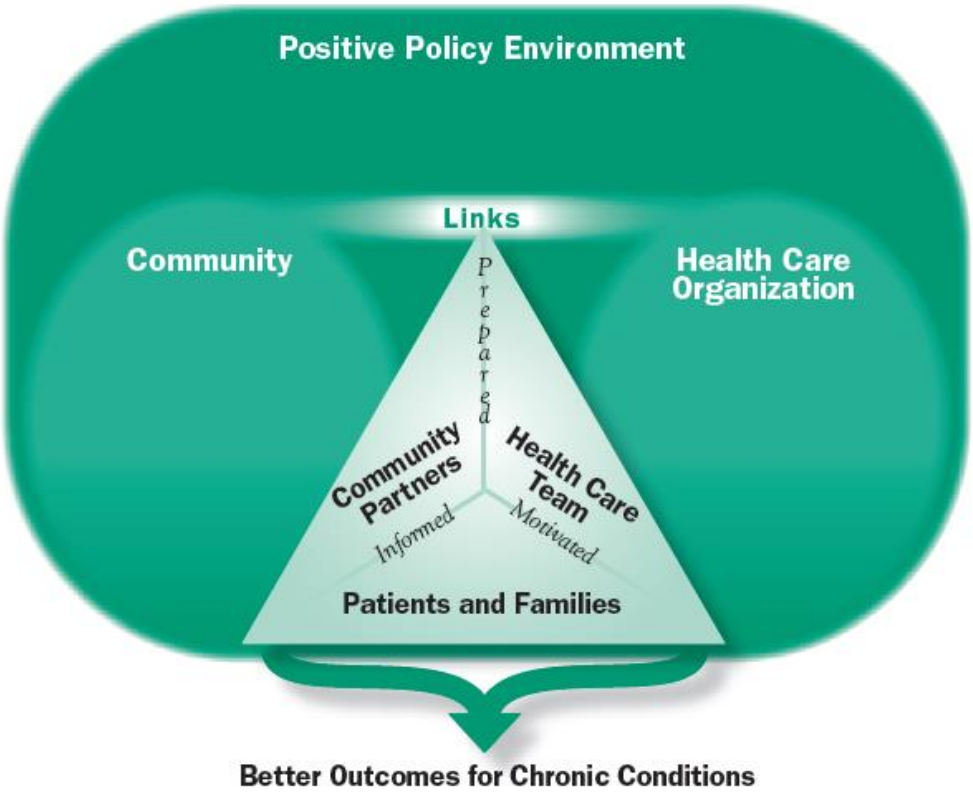

Figure 6: The innovative care for chronic conditions framework
Source: World Health Organization 2002 (1)

2.4.2 The Integrated Chronic Disease Management (ICDM) model

Integrated healthcare has multiple meanings and usages, and has been a source of polarised debate (45). Some examples of integrated health service include: combining two or more disease-specific care at one service delivery point (e.g. integrated management of childhood illness); continuity of care over time across different levels (appropriate referral system); integrating disease-specific (vertical) programmes with general healthcare system; multi-sectoral collaboration; or even a combination of all of these (45). The World Health Organization (WHO) defines integrated healthcare as *"the organisation and management of health services so that people get the care they need, when they need it, in ways that are user-friendly, achieve the desired results and provide value for money*" (45).

The Joint United Nations Programme on HIV/AIDS (UNAIDS) recommends a globally comprehensive and integrated approach to the delivery of chronic disease care. This approach requires leveraging the successful HIV programme innovations to support or scale-up services for NCDs (2, 50) in the context of the ICCC framework (1). Beyond the UNAIDS mandate for the implementation of an integrated chronic care model, integrating services for HIV and NCDs could also minimise fragmented chronic disease care arising from the management of the HIV pogramme in a 'silo' within the general healthcare system, leverage resources and more efficiently meet patients' healthcare needs (4, 13, 38). Evidence from the Cambodian pilot study on integrating services for HIV with hypertension and diabetes showed increased CD4 count, reduced blood pressure and reduced stigma (19). However, high mortality and low median CD4 counts were reported early in the study and this was attributed to large number of PLWHIV not having access to HARRT. Another limitation of the Cambodian study was that almost 30% of diabetes patients were lost to follow up in the first three months due to the perception that diabetes is not a life threatening condition and use of alternative care through private providers (19).

In heeding the UNAIDS' recommendation, the NDoH in South Africa initiated the ICDM model as part of the effort to re-engineer its PHC system. "The ICDM model is a model of managed care that provides for integrated prevention, treatment and care of chronic patients at PHC level to ensure a seamless transition to "assisted" self-management within the community". The aim of the ICDM is to improve the quality of chronic disease management and achieve optimal clinical outcomes for patients with chronic communicable and non-communicable diseases using the health system building blocks approach (20).

The pilot study of the ICDM model was commenced in June 2011 in selected PHC facilities in three of South Africa's nine provinces (Gauteng, North West and Mpumalanga) (20). At the crux of the ICDM operational framework are facility reorganisation and clinical management support to improve operational efficiency and quality of care at the facility level; "assisted" self-management to promote individual responsibility at the community level; and health promotion and population screening in the population to increase the awareness of chronic diseases at the population level (Figure 7) (20).

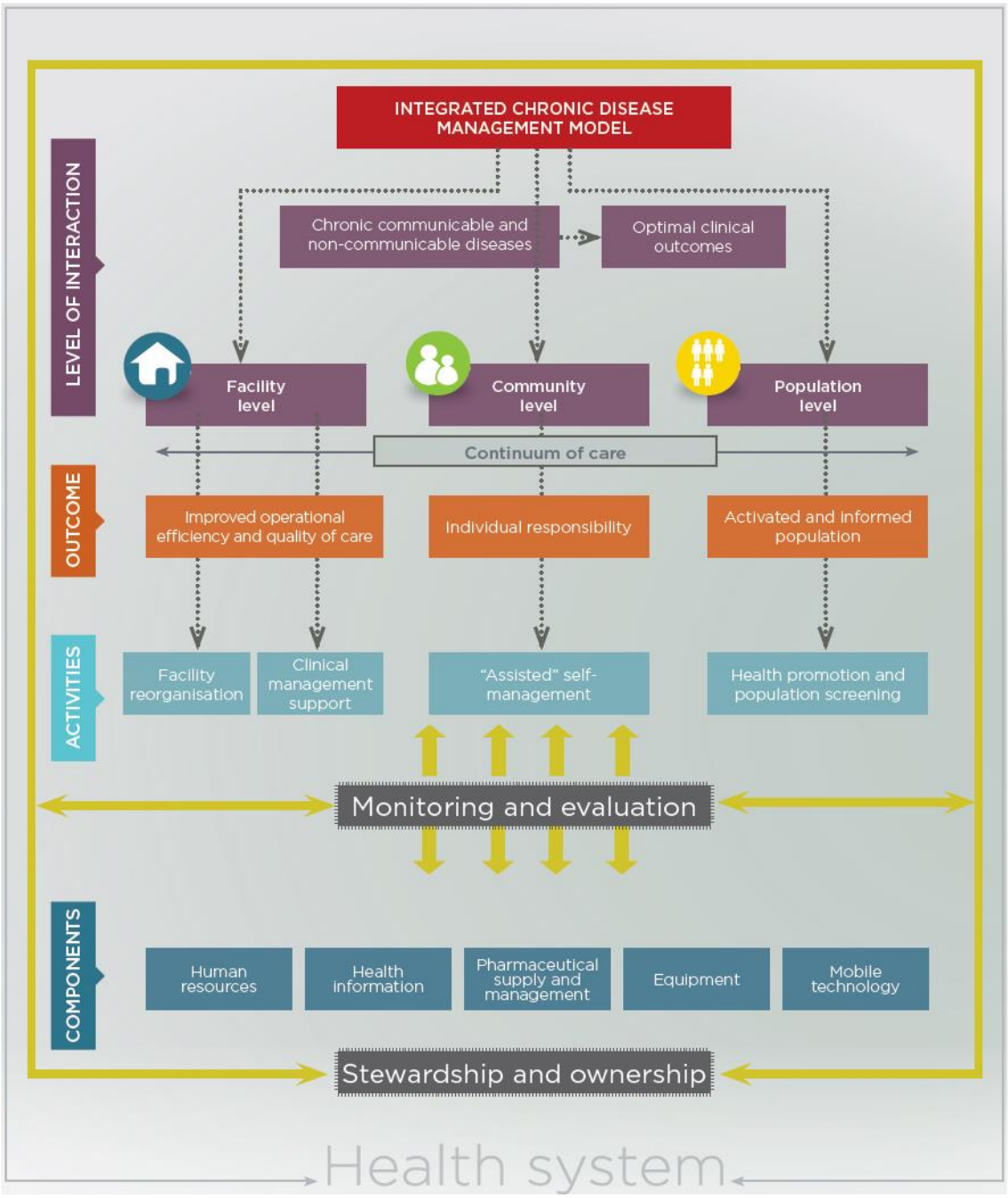

Figure 7: The integrated chronic disease management (ICDM) model

Source: National Department of Health 2014 (20)

The facility component entails many areas of focus such as: designation of chronic care area; use of guidelines for management of chronic diseases; human resource audit; capacity building; supply of critical medicines; prepacking of medication; and appropriate referral. To prepare the community for chronic disease care, each clinic has a ward-based outreach teams (WBOT) operating within the community that the clinic serves, and consists of one professional nurse, three staff nurses, and six Community Health Workers (CHWs). It is anticipated that at least 80% of defined health problems of the catchment population would be managed with the outreach team responsible for 6000 individuals in 1500 households (250 households per 1 CHW) (20). The ICDM model addresses the following disease categories: HIV/AIDS, tuberculosis, hypertension, diabetes, chronic obstructive pulmonary disease, asthma, epilepsy and mental health illnesses that are to be managed at PHC level (20).

2.4.3 The ideal clinic

The ideal clinic programme was initiated by the NDoH in July 2013 and launched on 18 November 2014 to further support the PHC reengineering of which the ICDM model is a component (51, 52). The aim of the ideal clinic is to improve the quality of care, including chronic disease services through the ICDM model, offered in PHC facilities. An ideal clinic is defined as a clinic with good infrastructure, adequate staff, adequate medicine and supplies, good administrative processes, and sufficient adequate bulk supplies An ideal clinic uses applicable clinical policies, protocols and guidelines, and it harnesses partner and stakeholder support. All these contribute to the provision of good quality health services to the community (52).

The Ideal Clinic Realisation and Maintenance (ICRM) segment of the Operation Phakisa initiative, which has ocean economy and health components, seeks to transform all public sector clinics into ideal clinics which will provide good quality care to all communities. Operation Phakisa was derived from Malaysia's Big Fast Results Methodology through which the Malaysian government achieved significant economic transformation within a very short time by addressing poverty, crime and unemployment. With the support of the Malaysian government, the Big Fast Results approach was adapted to the South African context. In highlighting the urgency of its delivery, the approach was renamed Operation Phakisa ("phakisa" means "hurry up" in Sesotho language) with the purpose of fast tracking the implementation of South Africa's National Development Plan (51, 52). A national overview of ideal clinic status determination was conducted in 2015 among 962 facilities representing 85% of the total facilities in South Africa. The best-performing province was the Eastern Cape, while the worst-performing provinces were Mpumalanga (where the study setting of this research is situated in), Free State, Northern Cape and Limpopo (52).

2.5 The National Core Quality Standards

The national core quality standards for health establishments in South Africa was revised in 2010 by the NDoH with support from its national and provincial staff and private sector partners. The main purpose of the national core quality standards is to develop a common definition of quality of care, which should be found in all health establishments in South Africa as a guide to the public and to managers and staff at all levels; establish a benchmark against which health establishments can be assessed, gaps identified, strengths appraised; and provide a national framework to certify health institutions as compliant with standards (53). The standards have

been developed into seven cross-cutting domains where service quality or safety can be at risk (Figure 8).

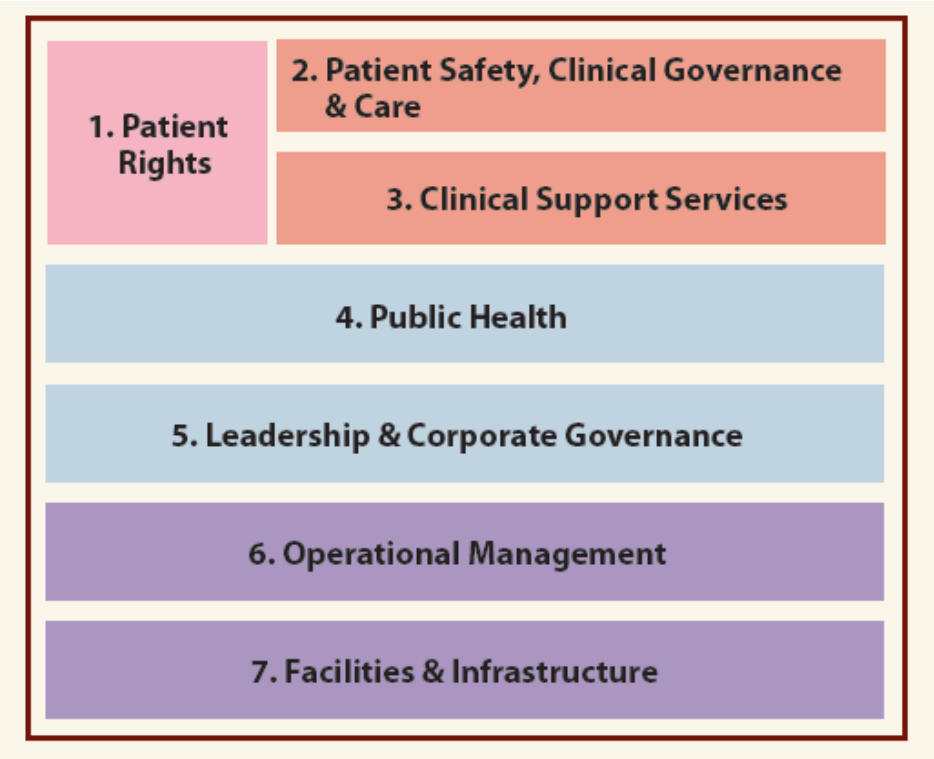

Figure 8: The seven domains of the National Core Quality Standards
Source: National Department of Health, 2011 (53)

2.6 Overlaps between the ICDM model and the national core quality standards

The NDoH identified six priority areas of the core quality standards to fast-track improvement in the delivery of health services generally. These include: improving staff values and attitudes; waiting times; cleanliness; patient safety and security; infection prevention and control; and availability of medicines and supplies (Figure 9). The purpose of the ICDM model is to more specifically improve the quality of chronic disease care. This requires ensuring implementation

of, or compliance with, the core quality standards. Hence, the ICDM model addresses the six

priority areas of the national core quality standards (20).

Figure 9: Overlaps between ICDM model and the six priority areas of the national core quality standards

Source: National Department of Health 2014 (20)

2.7 Overlaps between the ICDM model and PHC re-engineering framework

The ICDM model is a component of the ongoing PHC re-engineering framework designed to strengthen South Africa's health system at the primary care level. The ICDM model integrates and works synergistically with the three streams of the PHC re-engineering framework (Figure 10). The DCST exercises oversight over the quality of care by mentoring and supervising the process of care provided and undertakes clinical audits of the professional healthcare workers' services (20). The WBOT ensures continuity of care by interacting directly with the community

during which health education campaigns and primary prevention through screening of high-risk individuals will be conducted. The WBOT visits at-risk households to provide or support "assisted" self-management, do secondary health promotion, and identify complications that require referral to PHC facilities (20). The ISHP teams conduct education and awareness campaigns at the schools, provide screening services for the early detection of chronic diseases and refer these high-risk patients to PHC facilities (20). In addition to these three streams, the district management team performs an oversight and stewardship role in monitoring the implementation of the ICDM model and addresses systemic challenges that impede the implementation process and service delivery (20).

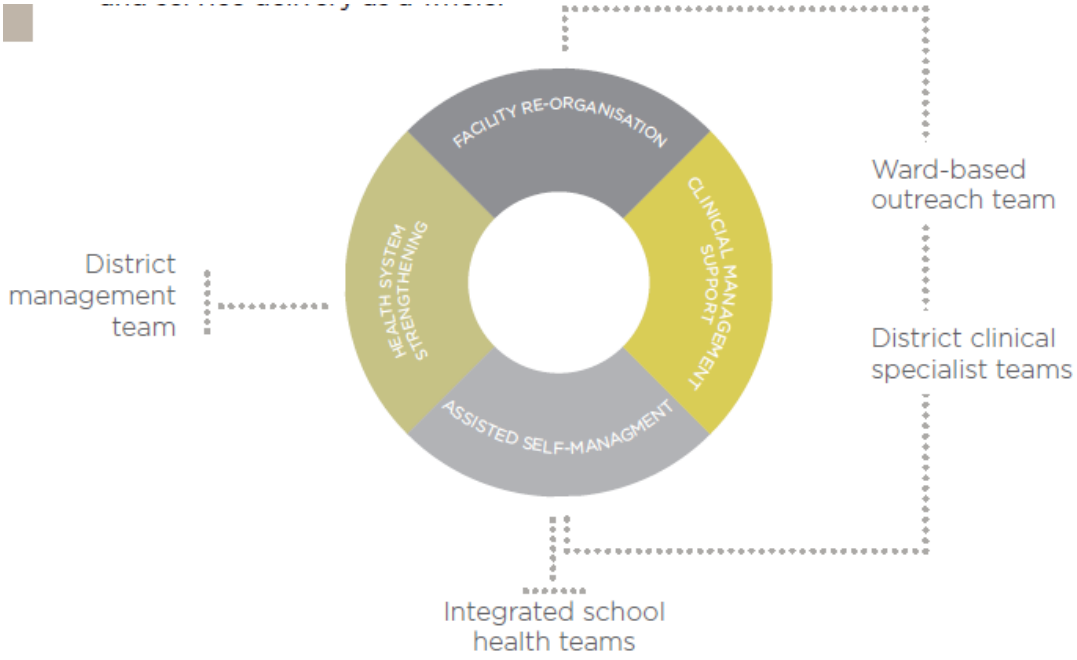

Figure 10: Overlaps between integrated chronic disease management and the primary health care re-engineering framework

Source: National Department of Health 2014 (20)

2.8 Theoretical framework for evaluating the ICDM model

"Quality of medical care" is highly contextual and a difficult concept to define. Although it is a reflection of values and goals in the medical care system and in the larger society which it is a part of, quality can be almost anything anyone wishes it to be (54). Klein et al. conclude that patient care, like morale, cannot be defined by a unitary concept and that it seems unlikely that there will be a single criterion by which to measure the quality of patient care (55). The subsequent paragraphs in this section describe some theoretical frameworks that were considered for evaluating the ICDM model and their advantages and disadvantages.

In 1966, Avedis Donabedian described seven elements of quality of medical care: efficacy, effectiveness, efficiency, equity, optimality, acceptability and legitimacy (56). **Efficacy** is the care provided under optimal conditions. Although it is not measurable in real life, efficacy is the basis against which measurements are made. **Effectiveness** refers to the outcome of interventions when the interventions are implemented as they would be in real life; **efficiency** speaks to the reduction of costs without compromising effects; **equity** is the fairness in which healthcare is distributed among populations and among some specific groups within these populations; **optimality** refers to balancing the costs and benefits of healthcare; **acceptability** encompasses sub-elements, such as interpersonal patient-provider interaction and accessibility of healthcare; and **legitimacy** is the social acceptability of the healthcare institution. The choice and relative prioritisation of these elements should be contextual and guided by the circumstances in which quality of care is assessed (56).

Avedis Donabedian postulated that there are relationships between structure, process and outcome (SPO) constructs based on the premise that good structure should promote good process and good process should in turn promote good outcome (unidirectional pathway). The SPO framework, often represented by a chain of three boxes containing SPO constructs connected by arrows (56), can be used to draw inferences about the quality of healthcare (57). Donabedian defines "structure" as the professional and organisational resources associated with the provision of healthcare (e.g. availability of medicines/equipment and staff training); "process" as the things done to and for the patient (e.g. defaulter tracing and hospital referrals) and "outcome" as the desired result of care provided by the health practitioner (e.g. patient satisfaction with quality of care). Donabedian distinguished between two types of outcomes: i) technical outcomes, which are the physical and functional aspects of care, such as absence of complications and reduction in disease, disability and death; and ii) interpersonal outcomes which include the patients' satisfaction with care and influence of care on patients' quality of life as perceived by the patient (58).

This research used Avedis Donabedian's SPO framework to evaluate the ICDM model. This is because Donabedian's SPO theory is the touchstone and dominant framework for evaluating the quality of medical care (59) and because the SPO framework is used by South Africa's National Department of Health for the implementing the ICDM model (20). Another justification for selecting Donabedian's framework is because it overlaps considerable with four domains outlined in the WHO's framework (effectiveness, efficiency, equitability and acceptability). Moreover, researchers from Sweden showed statistically significant relationships between SPO

constructs using Donabedian's theory in a study of quality systems conducted among department managers and quality coordinators in 386 hospitals(60).

To my knowledge, this is the first study to apply Donabedian's theory in evaluating the quality of care in the ICDM model in South Africa.

3.0 Methodology

3.1 Study setting and population

3.1.1 Physical and demographic characteristics

This research was conducted in the Bushbuckridge municipality, Mpumalanga Province, northeast South Africa. The health and demographic patterns of the population in the Agincourt sub-district in the Bushbuckridge municipality have been monitored since 1992 by the MRC/Wits Rural Public Health and Health Transitions Research Unit (Agincourt) from the School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg (61).

The communities monitored by the Agincourt health and socio-demographic surveillance system (HDSS), henceforth referred to as the MRC/Wits-Agincourt Unit, cover about 420km^2 and are situated 500 km northeast of Johannesburg close to the border with Mozambique (Figure 11). The population under surveillance in the HDSS as of 1st July 2011 was 90,000 people in 20,000 households in 27 villages (61). A part of the former Gazankulu homeland, Tsonga is the most widely spoken language. A third of the population are Mozambicans who immigrated into South Africa mainly as war refugees in the early- and mid-1980s and through the years have intermarried with host the South African population with whom they share similar cultures. Despite some receiving group refugee status in 1993 and a history of long stay in South Africa, the majority of these Mozambicans are still socio-economically disadvantaged (62, 63).

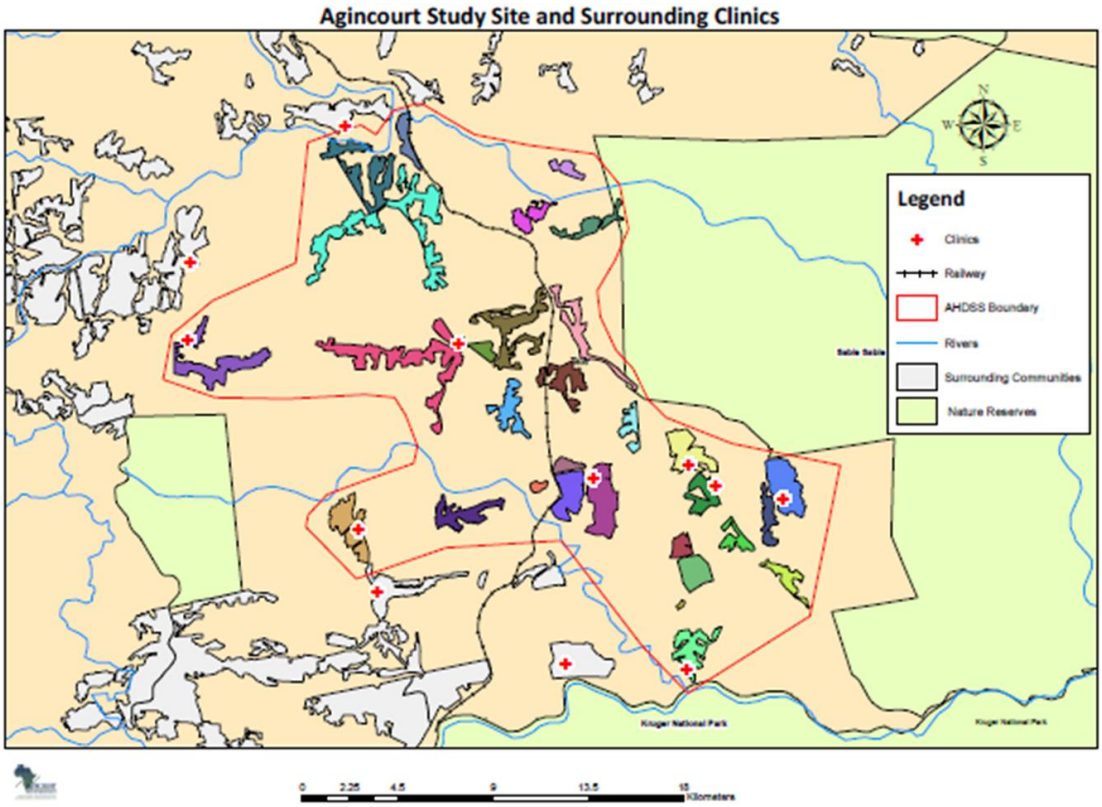

Figure 11: Map of Agincourt HDSS

3.1.2 Health service infrastructure and health profile

The national vision for health system in South Africa is primary health care through a decentralised, municipal-based, district health system (DHS). In the late 1990s, the government of South Africa began the process of decentralising provision of health services by dividing the country into 53 health districts to ensure that citizens have access to a comprehensive package of primary health care and district hospital services (64, 65). In the South African PHC model, the nurse is the provider of services in the clinics and comprehensive health centres which are the first point of entry to the health system. Located within the reach of rural, semi-rural and urban communities, these facilities are the cornerstone of the public health system through provision of

comprehensive and integrated “preventive, promotional, curative and rehabilitation services” (66).

The range of services provided in PHC clinic include: maternal and child care, immunization, family planning, treatment of sexually transmitted infections, minor trauma and care for chronic diseases (e.g. diabetes and hypertension). Additional services offered by PHC centres include 24 hour maternity services, accident and emergency services, up to 30 beds for observation for a maximum of 48 hours, and a procedure room (not an operating theatre). With the exception of emergency cases which are referred to the hospitals (secondary level of care), the clinics and health centres offer services to ambulatory patients for 8 hours/day and 24 hours, respectively (66). Medical doctors visit the PHC facilities at intervals to offer support to the nurses (66). In the Bushbuckridge municipality, there are 38 PHC facilities and three referral hospitals situated 25 and 45 km from these PHC facilities (61).

A dual burden of HIV/AIDS and NCDs has been reported in the MRC/Wits-Agincourt Unit study site (4). In the 1992-2005 periods, all-cause mortality increased substantially by 87%, largely because of a six-fold rise in infectious and parasitic diseases (mainly HIV/AIDS and TB) and a modest increase in NCDs. The increase in mortality from infectious and parasitic diseases was significant for all age and sex groups except children aged 5-14 years and adults 65 years and above. The increase in mortality from NCDs was significant for men but showed little change for women (4). In a more recent HIV/cardiometabolic risk factor survey in 2010-2011, HIV prevalence was 26% in women and 19% in men and the prevalence of hypertension was

high (40% in women; 30% in men) (67). In the MRC/Wits-Agincourt study site, there is evidence that women live longer than men (4) probably because they are more aware of their conditions, report higher prevalence of factors associated with higher mortality and utilise healthcare services (68). The dual burden of HIV and NCDs in the MRC/Wits-Agincourt study site is a reflection of the health transition in South Africa (38) which has been addressed through the introduction of the ICDM model that was evaluated in this thesis.

3.1.3 Socio-economic status and social infrastructure

With Mpumalanga province a having poverty rate of 64%, one of the highest in South Africa (69), the study area is characterised by high levels of poverty. Unemployment levels are generally high and estimated at 29% for men and 46% for women (70-72). Sixty percent (60%) of labour migration is accounted for by men aged 35-54 years and an increasing proportion of labour migrants is seen among younger men and women (63). This pattern of labour migration has resulted in a disproportionately higher proportion of older women permanently residing in the area. The main sources of income for the formally employed people, particularly men, are the mining sector; security and construction firms; and nearby plantations and game reserves. Formally employed women work as domestic workers and on farms. Some families are supported by government support grants such as child support grant and old-age pensions (70-72).

Despite the current government's development initiatives which have led to improved housing and access to potable water, electricity, and social security grants, social infrastructure in the area is still limited. The main methods of sewage disposal range from traditional pit latrines to

ventilated improved pit latrines; hence, the poor sanitary conditions in the area. The main means of public transport is privately-owned taxis which are limited in number; hence, the high costs of transportation (62, 63, 73).

3.2 Data and methods

This study has two main components. The first study designed to address the first research objective was an analysis of secondary data on healthcare utilisation (HCU) to describe disease profiles and predictors of healthcare use in the population monitored by the MRC/Wits-Agincourt Unit (Table 1). Analysis of the HCU data informed the development of the second study which I designed, named "Vunene Study" and implemented for my doctoral research. The word "Vunene" means "goodwill" in Tsonga language and is an appropriate name for the second study because it reflects the goodwill of the Minister of Health, Dr. Aaron Motsoaledi, in introducing the pilot of the ICDM model as a health intervention to tackle the dual high burden of HIV and NCDs in South Africa. The Vunene study was a facility-based research project consisting of three sub-studies which addressed the second, third and fourth research objectives outlined in Table 1. The HCU and Vunene studies contribute to the three broad themes of this thesis: chronic disease profile and predictors of healthcare utilisation; quality of care in the ICDM model; and changes in patients' health outcomes attributable to the ICDM model. The next subsections describe the methods (study design; sampling; data collection and quality control measures; data management and statistical analysis) underpinning the studies that address these themes.

3.2.1 Chronic disease profile and predictors of healthcare utilisation

3.2.1.1 Study design

This was a cross-sectional analytical survey of 10,249 older adults registered in the 2009 census database. This population-based study involved adults aged 50 years and older who responded to the healthcare utilisation survey conducted in 2010, the year before the ICDM model was introduced.

3.2.1.2 Sampling

Of the 10,249 adults registered in the database, 7,870 persons with permanent residency status were eligible and targeted for the 2010 HCU survey (Figure 12). Eligibility criteria for the interviews were: (i) being 50 years or older; (ii) residency status of 21 days or more before the survey for those prospective participants who immigrated in the study site before the 2010 survey; and (ii) availability of the prospective participants at home after a maximum of two revisits by field workers.

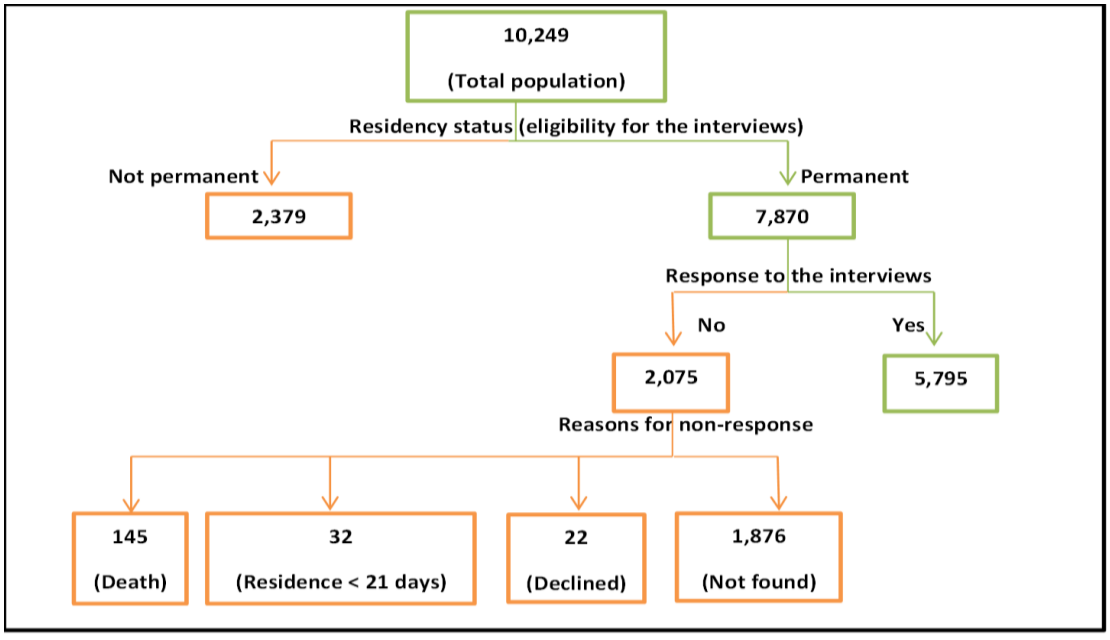

Figure 12: Sampling of study participants in the predictors of healthcare utilisation study

3.2.1.3 Data collection and quality control

Field workers were trained for two days in the administration of the HCU questionnaire as part of the preparation for the Agincourt Unit census. Field work was closely supervised for a week, after which a new training session was run to review and tackle challenges. Data were collected by field workers during the census period.

Quality control followed a four-step system where field workers, supervisors, quality checkers and data entry clerks assured good quality of the data. First, field workers double- checked all questionnaires before leaving the household of the interviewee and again at the office before submission to the supervisors. Secondly, supervisors randomly checked the questionnaires for inconsistencies and blank questions before submitting to the quality checkers. The third step involved quality checkers identifying inconsistencies and other errors in the questionnaires before submitting to the data entry clerks. Finally, data entry clerks identified forms with errors during data entry through automated validation checks done in Microsoft SQL server 2005 and returned them to the field for correction, after which the whole process of quality control was engaged prior to final data was accepted and archived in the final database.

3.2.1.4 Data management and statistical analysis

Data management

The dependent variable was healthcare utilisation (defined as the need for and access to healthcare, at least once, less than one year before the HCU survey in 2010) which was a binary (Yes vs. No) variable. Independent variables were age, education, access to medical aid, need for healthcare, nationality of origin, socio-economic status, looking for a paid job, receipt of a social grant, previous hospitalization, disability, type of illness, and actions taken during illness. Age in years was calculated at 1st August 2010 using the census date of birth for all potential

participants. Responders were then categorised into 10 year age intervals: 50-59, 60-69 and 70+. The cut-off for defining old age was fifty years.

Years of formal education were obtained from the 2007 MRC/Wits Agincourt Research Unit census round which was the latest updated education information before 2010. Years of education were categorised according to the WHO levels of education: no formal education, less than six years and six or more years. Medical aid was categorised to reflect responders with: (i) medical aid to visit the doctor (ii) health insurance for specific disease (iii) medical aid in employer's clinic/hospital (iv) access to free public hospital care and (v) no medical aid/don't know. The variable "last time healthcare was needed" was categorised into: (i) < 1 year, (ii) 1 - 3 years, (iii) > 3 years and (iv) never. In order to minimise errors due to recall bias, analysis of the predictors of HCU was restricted to responders who reported needing healthcare less than one year preceding the survey. The justification for using less than one year as the cut-off was based on the assumption that it was easier for responders to recall experiences with HCU in less than one year than in 1-3 years or > 3 years.

Nationality of origin was grouped into South Africans and Mozambicans. Socio-economic status (SES) was constructed from the household asset score in the 2009 census data. A principal component factor analysis technique was used to construct SES based on thirty variables on access to water and electricity, type and size of dwelling, appliances, ownership of livestock and transport available. Subsequently, responders were categorised into quintiles in the ascending order of lowest, middle low, middle, middle high, and highest socio-economic status (71).

In order to ascertain employment status, the variable "looking for a paid job" was categorised as 'Yes' or 'No'. Receipt of type of social grant was recorded as none, old age, and disability, accordingly. Hospitalisation, HCU (defined as the need for and access to healthcare, at least once, less than one year before the HCU survey in 2010) and disability were all binary variables (Yes vs. No). Apart from acute conditions (fever and flu) and chronic communicable disease (HIV and TB), other types of illness were generated by recoding the reasons for visiting health facilities into non-communicable disease (e.g. hypertension, diabetes, stroke, sleep disorder, chronic pain in joints, depression, anxiety, cancer, heart problems), injuries and others types of illness (musculoskeletal pain and nutritional deficiency). Actions taken during an illness episode less than one year before the survey included: visiting public and private health facilities. Other actions included practicing self-medication, consulting faith/traditional healers and taking no action.

Statistical analysis

Data were extracted into Stata 12.0 (College Station, TX, USA) for statistical analysis. Socio-demographic variables and patterns of healthcare use were described. At *p*-value of 0.05, bivariate analysis compared responders who used healthcare services with those who did not. The cut-off point for univariate binary logistic regression analysis was set at *p*-value of ≤ 0.2 and variables that were significantly associated with HCU were used to model the multivariate binary logistic regression analysis (*p*-value ≤ 0.05). Multiple imputation by chained equations (MICE) approach for categorical variables was used to impute for "socio-economic status" and "looking for a paid job," which had 1.3% and 12.4% missing values, respectively. Multiple imputation is a simulation-based method for analysing incomplete variables. It predicts missing values as close as possible to the true ones by replacing missing data with probable values based on other

available information (74). Imputation is considered to have less estimation bias and valid statistical inference than list-wise deletion because the latter leads to loss of statistical power (75).

3.2.2 Quality of care in the ICDM model

A quantitative study and a qualitative study were used to evaluate the quality of care in the ICDM model. A combination of methodological and data triangulation was used to enhance validity of the data on quality of care in the ICDM pilot facilities. Methodological triangulation involved the use of quantitative and qualitative methods to gather data while data triangulation was achieved through data collection from different population subsets at different times and spaces.

3.2.2.1 Study design of the quantitative quality of care study

The quantitative sub-study was a cross-sectional primary survey of patients 18 years and above receiving treatment in the ICDM pilot PHC facilities between August and November 2013. Considering the burden of chronic diseases in the study area, patients with markers of chronic diseases for HIV, hypertension, and diabetes in the health facilities were included in the study, while those with other chronic diseases were excluded. Other study participants were the seven operational managers (professional nurses-in-charge) of the ICDM pilot facilities. The dataset was used to assess patients' and operational managers' satisfaction with the dimensions of ICDM services and evaluate the quality of care in the ICDM model using Avedis Donabedian's theory of relationships between structure, process, and outcome constructs.

Sub-sections 3.2.2.2 and 3.2.2.3 show how the ICDM pilot facilities and patients receiving treatment in these facilities were sampled, respectively. Sub-section 3.2.2.4 describes the study instrument used for the data collection and sub-section 3.2.2.5 shows how data were collected from the selected patients.

3.2.2.2 Sampling of ICDM pilot facilities in the quantitative quality of care study

The ICDM model was implemented in 17 of the 38 PHC facilities in the municipality at the time the study on quality of care was conducted. From these, the seven health facilities serving the communities in the Agincourt sub-district monitored by the MRC/Wits-Agincourt Unit were purposively selected into the ICDM pilot arm of the study.

3.2.2.3 Sampling of patients in the quantitative quality of care study

Inclusion criterion was patients who had hypertension, diabetes and HIV managed for at least five months before the initiation of the ICDM model until the time the study commenced in August 2013. The reason for including patients receiving treatment five months before the ICDM model was implemented was to assess the levels of satisfaction of patients who had received treatment before the implementation of the ICDM model and continued to receive treatment during its implementation in efforts to gauge possible changes in the quality of care for hypertension, diabetes and HIV attributable to the ICDM model. Patients diagnosed with other chronic diseases and minors less than 18 years were excluded from the study because they were considered to be below the age of autonomy for judging satisfaction with the quality of care for hypertension, diabetes and HIV provided in the health facilities. Elderly patients with reduced capacity for comprehension during informed consent were also excluded from the study. Diminished capacity for comprehension was determined by the inability of prospective patients

to comprehend or respond to the information verbally provided by the interviewer during informed consent.

Using the subjects-to-variables ratio (minimum of 10 subjects per variable in the study instrument) for estimating sample size for studies utilising factor analysis (76, 77), a sample size of 390 patient respondents was calculated (17 subjects per each of the 23 variables in the study instrument). The minimum sample size of approximately 435 patients was reached after adjusting for 10% (390/0.9) non-response. All the seven operational managers of the PHC facilities, the maximum number possible, were selected because they offered clinical services to the patients and the authors perceived their role as managers of the health facilities more important than the professional nurses in understanding the quality of the ICDM model.

Patients were identified through a multi-stage sampling technique using the facility rosters in July 2013, the month before the study was commenced (Figure 13). First, the number of patients recruited in each of the seven health facilities was determined by proportionate sampling. Secondly, the patients in each health facility were proportionately sampled by HIV, hypertension, and diabetes status in order to get a representative sample of the patients with markers of chronic diseases using a health facility-specific sampling frame. Finally, the numbers of patients specified in step two were recruited for a daily interview until the desired sample size in each clinic was achieved (See appendix 2a for details on the sampling technique).

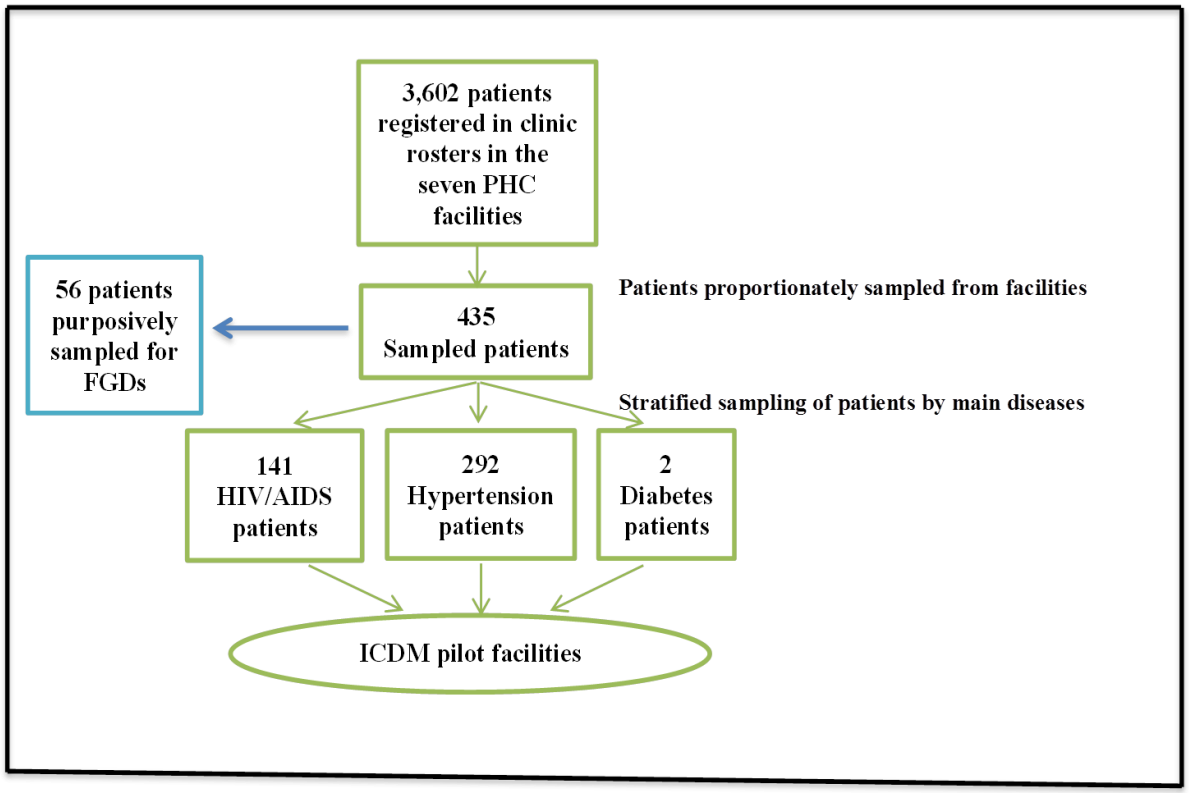

Figure 13: Sampling of study participants in the quality of care in the ICDM model study

3.2.2.4 Study instrument used to evaluate quality of care

Some study instruments have been recommended and were considered for assessing patient satisfaction with healthcare. The Patient Satisfaction with Nursing Care Quality Questionnaire (PSNCQQ) was designed by Laschinger et al. in 2005 (78). It has 19 items with three additional questions designed to measure the validity and enable assessment of overall satisfaction with the quality of care and treatment during the hospital stay, overall quality of nursing care, and intentions to recommend the hospital to family and friends. All items in the PSNCQQ focus on process-related care offered by nurses, while none of the items explored structure-related (e.g. availability of equipment) or outcome-related (e.g. patient waiting time) aspects.

The multi-scale patient satisfaction questionnaire (PSQ-18) was developed by Ware et al. (79). The PSQ-18 comprises 18 items derived from the full-length version (50-item) PSQ-III counterpart (79). The PSQ-18 assesses multiple dimensions of patient satisfaction and includes general satisfaction, technical quality, interpersonal relations, communication, financial aspect, time spent with health provider, and accessibility and convenience (Appendix 1). The PSQ-18 sub-scales show acceptable reliability and correlate with the sub-scales in the PSQ-III (80). Furthermore, PSQ-18 is appropriate for use in situations where there is need for brevity (80) as was the case in this study where it was administered to patients leaving the health facility after consultations with the nurses (patient exit interviews).

The PSQ-18 instrument was selected because the PSNCQQ is not reflective of Donabedian's SPO constructs. Furthermore, the PSQ-18 succinctly measures satisfaction with dimensions of care for which SPO constructs are intended. I am not aware of any study that has used the PSQ-18 as a study instrument to operationalise Avedis Donabedian's SPO theoretical framework in SSA.

The quantitative quality of care study compared self-reported satisfaction of the patients and self-reported satisfaction of the operational managers with the dimensions of care listed in the ICDM model using the multi-scale PSQ-18. This is in view of literature depicting views of health care providers differing from users regarding the quality of health care (81). Responses to statements were scored on a five-point Likert scale ranging from 4 (strongly agree) to 0 (strongly disagree) for positively-phrased statements, and from 4 (strongly disagree) to 0 (strongly agree) for

negatively-phrased statements for the purpose of undertaking confirmatory factor analysis and structural equation modeling.

Similar to another study in which the PSQ tool was adapted to measure patient satisfaction with pharmacy services (82), this study adapted the PSQ-18 by altering a number of statements to fit the ICDM model. For example, the structure-related statement, "*I have easy access to the medical specialists I need*," was changed to the ICDM-process-related dimension, "*Health care providers usually refer me to the doctor/hospital when there is need for the doctor to review me* - P5" (Appencices 1, 3 and 4). One structure-related (supply of critical medicines) and two process-related (defaulter tracing of patients and prepacking of medicines) variables were included in the adapted questionnaire. One process-related statement in the PSQ-18 was changed from "*health care providers act too business-like and impersonal toward me*" to "*Health care providers are professional in the conduct of their clinical duties*". Two outcome statements on "*satisfaction with perfect health care*" and "*dissatisfaction with some care*" in the PSQ-18 were changed to the dimension on "*satisfaction with coherent integrated chronic disease care*" and "*dissatisfaction with coherent integrated chronic disease care*", respectively. Regarding the types of outcome constructs (technical and interpersonal) specified by Donabedian, the focus of this quantitative study on quality of care was on the subjective interpersonal outcome.

Two statements around the financial costs of health care (D1 and D2) were dropped during the adaptation of the PSQ-18 (Appencices 1, 3 and 4). This is because the government of the Republic of South Africa implements a pro-equity policy, a component of free health care for

everyone using the public primary health system (83). However, transport-related costs were not considered in this study because it is not the responsibility of South Africa' Department of Health to provide transport for the implementation of the ICDM model. The 17 dimensions of care in the adapted questionnaire are shown in Figure 14, and details of the adapted PSQ tool used in the current study for patients and operational managers are shown in Appendices 3 and 4, respectively.

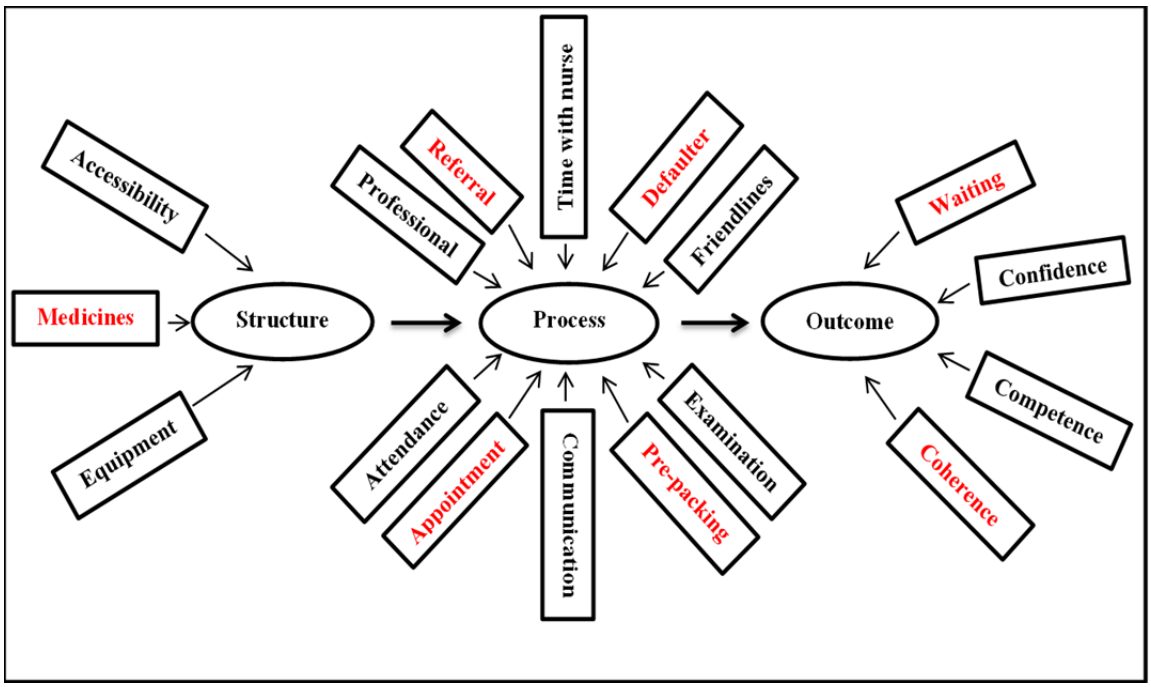

Figure 14: The dimensions of care in the ICDM model for which the structure, process and outcome constructs were intended.

The dimensions in red colour indicate the priority areas of HIV programme leveraged for chronic diseae care in the ICDM model.

Eight dimensions of care were identified by experts on quality of care in the study team as priority areas for enhancing service efficiency and quality of care: supply of critical medicines, hospital referral, defaulter tracing, prepacking of medicines, clinic appointments, patient waiting

time, and coherence of integrated chronic disease care (20). This is because these priority areas are components of the tools and systems used in the successful HIV programme which is being leveraged to support or scale-up services for improving the quality of care for NCDs (Figure 13).

3.2.2.5 Data collection and quality control in the quantitative quality of care study

Having consulted with the professional nurses and received their medicines, the prospective study participants were invited to a (consultation) room designated for patient interviews. Only the interviewer had access to this consultation room. Patients were invited to take part in the satisfaction survey after explaining the purpose of the study. They were assured that there will be no penalty or loss of benefits to which they were entitled to if they chose to not participate in this study or decide to discontinue participation in this study. Written informed consent was obtained from the patients who were willing to participate in the study and interviews were conducted with the patients. Refusal was less than 1%.

The adapted PSQ tool was forward translated to Tsonga (the local language) and back-translated to English by two experienced field workers who were blinded to each other. An experienced quantitative field worker was trained on how to administer the adapted PSQ tool. A pilot study was conducted in Cork clinic, a PHC facility situated outside the study site, to assure understanding and correct use of the PSQ tool. Only a few statements had to be rephrased after the pilot study. An important characteristic of the original PSQ-18, which was considered in the adaptation of the study instrument, is the control for Acquiescent Response Set (ARS) - a tendency to agree with statements of opinion regardless of their content (84). Six variables were

phrased in opposite directions, bringing the total number of variables in the adapted questionnaire to 23 (Appendices 3 and 4). These measures are beneficial in detecting skewness toward satisfaction (84) and identifying specific programme areas in which respondents are satisfied or dissatisfied.

3.2.2.6 Data management and statistical analysis in the quantitative study

Data management and the operationalisation of Donabedian's theoretical framework

A priori identification of 17 dimensions of care for which the SPO constructs were intended was undertaken to reflect Donabedian's theory of the relationships between these constructs (Figure 13). Of the 17 dimensions of care assessed in this study, 10 were adapted from the Patient Satisfaction Questionnaire (PSQ-18) (79) used as study tool in the exit interviews. The remaining eight dimensions of care were identified by the study team as priority areas for improving quality of care in the ICDM model: supply of critical medicines, hospital referral, defaulter tracing, prepacking of medicines, clinic appointments, reducing patient waiting time, and coherence of integrated chronic disease (20). These priority areas are the tools and systems in the HIV programme used for leveraging services for NCDs.

The adapted PSQ also contained measures reflective of three of the six priority areas of the National Core Quality Standards. There was no clear division of the statements in the adapted study instrument into SPO constructs under which the dimensions of care have been categorised. However, these statements have been categorised under these constructs in Appendices 3 and 4 for clarity and ease of comprehension. In order to minimise bias that may result from assessing

the acquiescent response set, the positive and negative statements did not follow each other in the questionnaire as shown in Appendices 3 and 4.

Responses to statements were scored on a five-point Likert scale ranging from 4 (strongly agree) to 0 (strongly disagree) for positively-phrased statements, and from 4 (strongly disagree) to 0 (strongly agree) for negatively-phrased statements. Satisfaction scores of the patients were used for conducting confirmatory factor analysis and structural equation modeling (SEM). The respondents were judged to be satisfied with the dimensions of care if the total relative frequency was ≥ 50% for "strongly agree" and "agree" responses to positively-phrased statements. Similarly, the respondents were judged to be satisfied with the dimensions of quality of care if the total relative frequency was ≥ 50% for "strongly disagree" and "disagree" responses to negatively-phrased statements. A satisfaction score of at least 50% was considered an average score using a scale of 0% to 100%.

The patients (P) and operational managers (OM) were scored comparatively on their (dis)satisfaction with the dimensions of care in the ICDM model. The quality of care in the ICDM model was measured by conducting structural equation modelling (SEM) using the data on patients' (dis)satisfaction with the dimensions of care in the ICDM model. However, SEM could not be performed with the data collected from the operational managers because of the very small sample size (seven operational managers).

The following linear pathways were specified in the SEM (Figure 15): (1) the unidirectional pathway which states that good structure promotes good process and good process in turn promotes good outcome; (2) the mediation pathway which posits that good structure directly promotes good outcome; good structure promotes good process and good process in turn promotes good outcome; and (3) the reciprocal pathway which hypothesises that good structure promotes good process, good process promotes good outcome and good outcome promotes good process. The last two pathways were examined in this study to explore other linear relationships between SPO constructs other than the unidirectional pathway originally postulated by Donabedian (Figure 15).

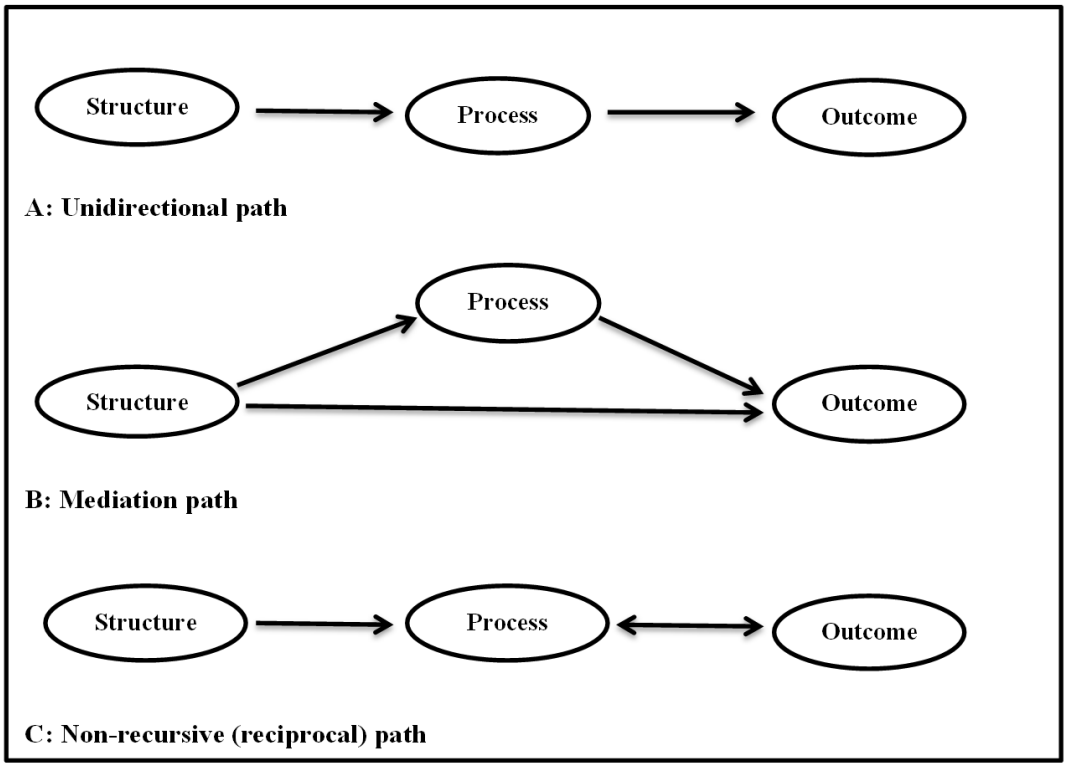

Figure 15: The path models for operationalising Donabedian's theory in the ICDM model of care in South Africa

Fitting of the proposed pathways involved a four-step systematic process using patient data. First, a priori identification of the variables for which the SPO constructs were intended was performed by the experts on quality of care on the study team in order to assess the validity of the adapted questionnaire (Appendices 3 and 4). This method was adopted by Kunkel et al. in which a panel of experts categorised variables in a questionnaire into SPO constructs (60).

Secondly, Cronbach's alpha (range: 0-1) which is a measure of internal consistency was used to quantify the reliability of the multi-item variables in the adapted PSQ in measuring the SPO constructs. Cronbach's alpha coefficient of reliability was categorised as excellent ($\alpha \geq 0.9$), good ($0.7 \leq \alpha < 0.9$), acceptable ($0.6 \leq \alpha < 0.7$), poor ($0.5 \leq \alpha < 0.6$) and unacceptable ($\alpha < 0.5$) (85).

Next, the negative statements in the pair of statements phrased in opposite directions were dropped if there was no evidence of ARS. The fit of each construct and its individual items were assessed to remove any of the remaining variables with low coefficient of determination (CD < 0.2). Variables with low CD contribute high levels of error in the structural equation modelling (86). Thereafter, Confirmatory Factor Analysis (CFA) was conducted to identify and remove the variables that did not load significantly (factor loading < 0.300) onto their intended constructs.

The following step used structural equation modelling (SEM) to assess the specific pathways, as used elsewhere (87) in order to determine the relationships between the SPO constructs in Figure

14. Selection of the final path model was based on the variables that reflected their intended factors (factor loading ≥ 0.300). The Maximum Likelihood for Missing Values (MLMV) technique was used to impute for S5, P1 and P11 variables with 0.5%, 0.25% and 0.25% missing observations, respectively. The MLMV is a technique that handles missing data by estimating a set of parameters that maximise the probability of getting the data that was observed. It is a more superior and preferable method for handling missing data than the more popular multiple imputation (88), which is a simulation-based method that predicts missing values as close as possible to the true ones by replacing missing data with probable values based on other available information (74).

Assessment of the fit of the pathways using MLMV approach was based on two or more of the fit indices described in this paragraph (89): Chi-squared (χ^2) test is an absolute fit index that assesses the discrepancy between observed and expected covariance matrices - χ^2 p-value > 0.05 is a good fit. However, χ^2 test may not be a reliable fit index because it is almost always statistically significant for models with sample size ≥ 400 (86); Root Mean Squared Error of Approximation (RMSEA) is another absolute fit index that measures how well a model with optimally chosen parameter estimates fit the population's covariance matrix - RMSEA value ≤ 0.06 is a good fit; Comparative Fit Index (CFI) is an incremental fit index that assesses the improvement in fit of the hypothesised model compared with a baseline (null) model, when population covariance is assumed to be zero - (CFI ≥ 0.90 is a good fit); Tucker-Lewis Index (TLI) is also an incremental fit index that corrects for model complexity by favouring parsimonious models over more complex ones - (TLI ≥ 0.90 is a good fit); and (v) Coefficient of determination (CD) indicates how well data fit a statistical model. We used CD to decide the

model that explained the most variability. CD value of 1.00 is a perfect fit. The higher the number of criteria used, the better the fit of the model with the data (86).

Statistical analysis

Data were entered into Access 2010 and imported into Stata 12.0 (College Station, TX, USA) for statistical analysis. Relative frequencies were used to quantify socio-demographic variables, chronic disease status of patients and satisfaction of the patient and operational managers with the dimensions of integrated chronic disease services. At p-value ≤ 0.05, CFA and SEM were used to fit the specified structural path models in order to determine the quality of care in the ICDM model from the patients' perspective.

3.2.2.7 Study design of the qualitative component of the quality of care study

The qualitative component of the quality of care study was a case study of the ICDM pilot facilities which also used Donabedian's theoretical framework to assess quality of care in the ICDM model based on healthcare user and provider perspectives.

3.2.2.8 Sampling of participants in the qualitative study

Of the 435 patients who responded to the quantitative exit interviews in the ICDM pilot facilities, 70 were purposively selected for seven focus group discussions ((FGDs) i.e. 10 patients per FGD) and 10 were purposively selected for one FGD for clinic defaulters with at least one patient selected from each of the seven clinics). Focus Group Discussions (FGDs) were conducted to obtain in-depth data from multiple patients to capitalise on group interactions and communication regarding lived experiences based on provider-user interface. Of the 70 selected patients, 56 participated in the FGDs and five of the 10 selected patients participated in the FGD for clinic defaulters. The Exit interviews preceded the FGDs to make it easy to access patients

and to provide a large sampling frame from which prospective participants in the FGDs were to be purposively selected. Patients for the FGDs were selected from all clinics during official working hours (8.00am - 4.30 pm local time) from Monday to Friday. The FGDs were held on Saturdays at a time that was convenient for most of the patients.

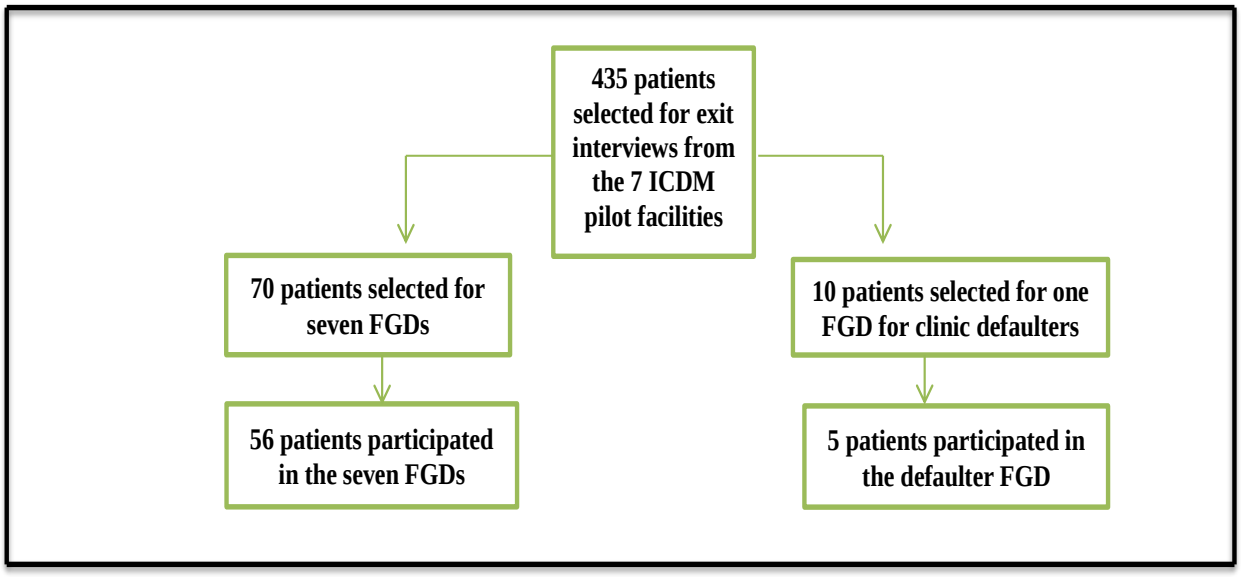

Figure 16: Sampling of patients for the focus group discussions

In-depth interviews were held for the seven operational managers of the health facilities and the health manager of the Bushbuckridge municipality to get the depth and breadth of provider perspective on the quality of care in the ICDM model. A range of 6-10 patients was targeted for FGDs in each health facility. After the exit interviews, patients were briefed about the purpose and scheduled dates of the upcoming FGDs. Those who volunteered to participate in the FGDs were invited to do so based on the following: i) having commenced treatment for the markers of chronic conditions in the study area (HIV, hypertension and diabetes) six months before the implementation of the ICDM model; ii) having participated in the exit quantitative interviews

organised by the research team before the FGDs; iii) and willingness to participate in the study irrespective of nationality. The exit interviews were used as a means of identifying patients who overwhelmingly reported satisfaction or dissatisfaction with the quality of care in the priority areas of the ICDM model and purposively selecting these patients for FGDs to further explore their in-depth perspectives on the quality of care in the ICDM model. The operational managers were selected for in-depth interviews because of their roles and responsibilities which were previously described. The municipality health manager was interviewed in order to understand the policy environment for the operational implementation of the ICDM model. The FGDs and in-depth interviews were held in parallel.

3.2.2.9 Data collection and quality control in the qualitative study

The 17 dimensions of care in the adapted PSQ were used as the thematic areas in the qualitative component of the quality of care study. A total of eight FGDs were conducted. The FGDs were held in a centrally-located neutral venue within the catchment area of the health facility to enable the patients to freely express and communicate their lived experiences with healthcare services. Seven FGDs were held for 5-9 patients of similar age and mixed gender recruited from within the seven PHC facilities, with each session lasting 60-90 minutes; and one FGD was held for five clinic defaulters (those who missed three consecutive clinic appointments as was observed through the review of clinic records) from within the seven health facilities. The purpose of selecting participants of similar age was to provide a conducive environment for the participants to freely discuss their experiences with the health system without fear or intimidation. Moreover, eight interviews lasting 30-40 minutes were conducted with the seven operational managers and the municipality health manager. I administered the respective topic guides for the in-depth interviews to the operational managers and the municipality health manager.

I ran a two-day training session with two female experienced qualitative field workers, with at least ten years of field experience in the Agincourt HDSS. During the training, I briefed the field workers about the purpose of the study and on how to administer the topic guide to the patients. One field worker audiotaped and moderated the discussions while the other took notes during the FGDs which were held in Tsonga. In order to assure quality of the data, the FGD audio recordings were translated and transcribed into English by these qualitative field workers. A third qualitative field worker in the Agincourt HDSS validated the transcriptions by listening to two of the seven audiotapes and also translated them into English. A comparison of the earlier and latter transcriptions showed no major differences in the participants' experiences and opinions regarding the dimensions of quality of care in the ICDM model. Similar procedures were used to assure data quality for the in-depth interviews.

3.2.2.10 Data processing and analysis of the qualitative study

The transcribed FGDs and interviews were thematically analysed using MAXQDA 2 software. A combined deductive and inductive approach was used for data analysis. The deductive analysis was based on the pre-identified themes focusing on the in-depth inquiry of the dimensions of care in the ICDM model. Inductive analysis was undertaken for an emerging theme that was not anticipated at the outset and not included among the 17 dimensions of care covered in the topic guide. I coded the data while a qualitative researcher verified the coded data through the reading and rereading of the quotes. A codebook was developed based on recurring pre-identified themes and emerging themes. Reliability of the coded data was verified through discussion of inconsistent codes with a qualitative researcher and supervisors until agreement was reached.

3.2.3 Changes in patients' health outcomes attributable to the ICDM model

Five facilities outside the Agincourt HDSS were randomly selected into the comparison arm from the 21 PHC facilities in the Bushbuckridge municipality where the ICDM model was not implemented. Hence, this sub-study had the ICDM pilot and comparison study arms to enable a comparative assessment of patients' health outcomes attributable to the ICDM model. Unlike the quantitative sub-study on quality of care in the ICDM model which focussed on the subjective interpersonal assessment of outcomes specified by Avedis Donabedian, the focus of this sub-study was on the objective technical assessment of patients' health outcomes (e.g. CD4 counts and BP) (58) .

3.2.3.1 Study design

This was an interrupted time-series analysis of data retrieved from facility records in the ICDM pilot and comparison facilities to determine the effectiveness of the ICDM model in improving patients' health outcomes. The defining feature of ITS design is that each participant in the sample is observed multiple times before and after an intervention (90). The ITS study design is the strongest quasi-experimental design to evaluate longitudinal effects of a non-experimental intervention implemented by someone other than the evaluation researcher (90), as was the case in this study.

3.2.3.2 Sampling of patients

A minimum sample size of 435 patients in each study arm after adjusting for a 10% non-response using Diggle's sample size formula for repeated measures in which a continuous outcome variable is consistently compared between two groups across 30 time points (months) of observation in a longitudinal study (91), assuming an effect size of 0.22; 0.90 correlations of

repeated outcomes; 90% power (Z_{β}=1.28); and 5% significance level for a two-sided hypothesis test ($Z_{\alpha/2}$=1.96).

Overall, 435 patients were recruited in the ICDM pilot and 443 patients in the comparison facilities (Figure 17). The multi-stage proportionate sampling previously described in the quantitative sub-study on quality of care was applied in the recruitment of the 443 patients in the comparison facilities (See appendix 2b for details on the sampling technique).

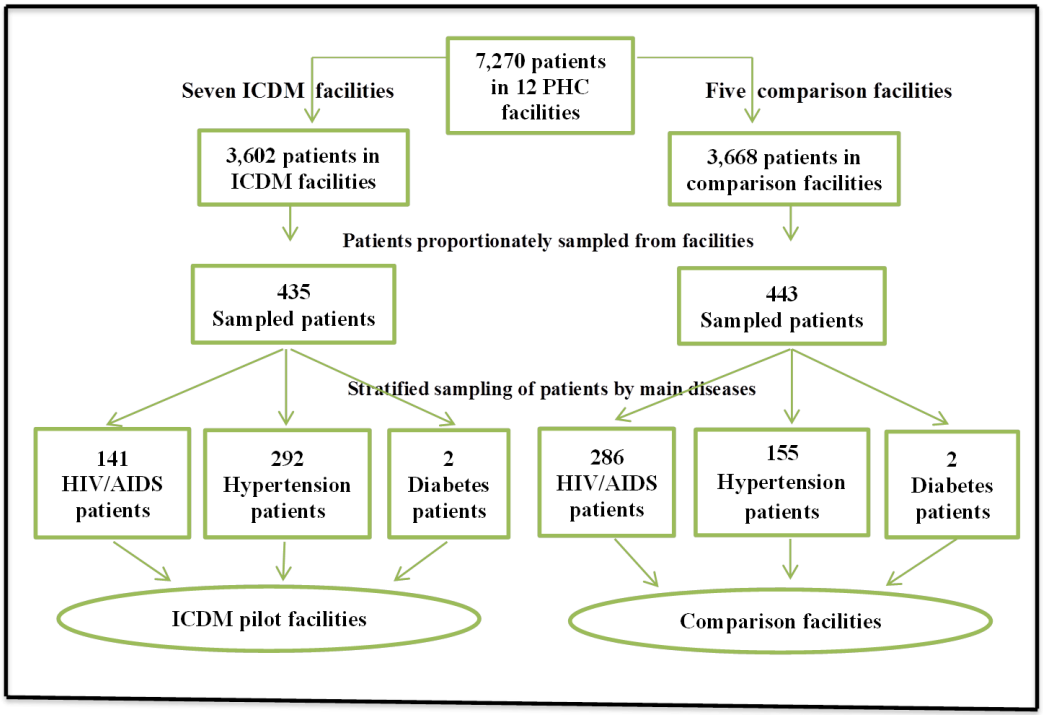

Figure 17: Sampling of study participants in the patients' health outcomes study

3.2.3.3 Data collection and quality control

A retrospective records' review of health outcomes (e.g. viral load, CD4 count and blood pressure) of 435 patients in the pilot facilities and 433 patients in the comparison facilities was

performed in the January 2011 to June 2013 periods. The unique identifiers of these patients were anonymised and study numbers generated.

3.2.3.4 Data management and statistical analysis

At the time of the study, eligibility criteria for ART initiation were CD4 count ≤ 350 cells/mm^3; WHO clinical stage 3 or 4; and pregnancy or breastfeeding status (92). For those on ART, viral load was repeated every 12 months and CD4 count repeated six monthly for ART monitoring purposes with the expectation that CD4 count would be > 350 cells/mm^3; henceforth, referred to as "controlled CD4 count" in this thesis. Appendix 5 shows the treatment regimens recommended for HIV/AIDS patients in South Africa throughout the duration of the study (92). At every visit, adherence to ART was assessed by pill-count and record of clinic attendance. A pill count of more than 95% of ART doses was considered good adherence (92). Unstable patients were reviewed monthly until stability was achieved while stable patients were reviewed every two to three months. All patients were routinely referred to the doctor for review every six months.

Hypertension is defined as currently taking antihypertensive drugs; or systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 on three separate measurements two to three days apart (92). Controlled hypertension in this thesis refers to BP <140/90 mmHg. Antihypertensive drugs used in the study setting are shown in Appendix 5.

The main hypothesis was that the ICDM model leads to changes in the CD4 counts and blood pressure of patients receiving care in the PHC facilities implementing the ICDM model with an allowance of a minimum of eight time points before and after initiation of the model (93)

Statistical analyses

Data were entered into Access 2010 and imported into Stata 12.0 (College Station, TX, USA) for statistical analyses. Controlled segmented regression analysis, a statistical method for estimating the effects of longitudinal intervention in interrupted time series data, was used for modelling the data (90, 93). Two time periods were specified: (1) pre-intervention (January-June 2011) - six months before initiation of the ICDM model, including the month of June 2011 when the model was initiated; and (2) post-intervention (July 2011-June 2013) - 24 months of implementation of the model. Two segmented analytical approaches were done: first, the autoregressive moving average (ARMA) time series model, and secondly, segmented linear regression to determine the effect of the ICDM model over the two specified time periods. The probability of having controlled CD4 counts or blood pressure was derived from the person-level analysis using mixed effects models which adjusted for the clinics (cluster) in which patients received healthcare and other covariates such as age. As a way of smoothing the observed percentages on outcomes, propensity scores were derived after the mixed effect regression analysis to show the probability of controlling for the outcome of interest in the patients. After collapsing and aggregating these health outcomes using the mean percentages of the monthly time points and associated standard deviations, the smoothed percentages of the datasets used in the segmented analysis was created.

The first segmented analysis was based on the ARMA model in which the data for the ICDM pilot and comparison facilities were aggregated and the second segmented analysis was based on linear regression on the two time periods. The main effects as well as the interactions of period and intervention/control were modelled across the whole time span to assess the effect of the intervention. The goodness of fit of the model was assessed by testing the residuals for normality in addition to the visual assessment of the fitted versus observed time series plots.

Propensity score matching (psmatch2) was done to balance the effect of covariates which varied in distribution between the study groups (e.g. age) (94). The ordinary least squares regression line was fit to each segment of the independent variable (time) assuming a linear relationship with the outcome variables within each segment. The regression model was specified to estimate the changes in the level (intercept) and trend (slope) for the patients whose BP and CD4 counts were controlled at the two time periods (segments) in both study groups (90). The absolute difference in the slopes between the segments was calculated by subtracting the original value from the final value. The inverse of the standard deviations were used in the segmented analysis models as the analytic (importance) weights. The p-values and the 95% confidence interval of the parameters were reported to ascertain statistical significance (p-value<0.05).

3.3 Summary of study designs, nature of outcome variables, data source and type of analysis according to thesis themes

The study designs, data sources and analytical approaches used to assess the three thematic areas on chronic disease profile and predictors of healthcare utilisation (I); quality of care in the ICDM

model (II); and changes in patients' health outcomes attributable to the ICDM model (III) are shown in Table 2 below.

Table 2: Summary of study designs, type of outcome variables, data sources and type of analysis according to the three thematic areas in this thesis

Theme	**Study design**	**Type of variables**	**Data source**	**Type of analysis**
I	Cross-sectional analytical	Binary	Agincourt 2010 HCU module (secondary data)	Univariate and multivariate binary logistic regression modeling
II	Cross-sectional analytical Case study of healthcare facilities	Ordinal (Likert scale from strongly agree to strongly disagree) -	Primary data Primary data	Structural equation modeling Thematic content analysis
III	Interrupted time-series study	Continuous	Data retrieved from patients' facility records	Segmented linear regression

**For only HIV/AIDS patients*

3.4 Ethical considerations

The three key ethical principles of autonomy, beneficence and justice were upheld by ensuring that: patients' information were encrypted in a computer programme that keeps the information in a form that does not allow anyone to interpret it, except the study team, and that ptients' unique identifiers are not reported in scientific journals; participants who prefer not to participate in the study or decide to discontinue participation in the study are free to do so; there will be no penalty or loss of benefits to which participants are otherwise entitled; there is no risk of harm or

injury for participating in the study; and there are no direct benefits to participants during the study. Ethical approval for the conduct of the research was granted by the Committee for Research on Human Subjects (Medical) of the University of the Witwatersrand, Johannesburg, South Africa (Ref No. M120943) and the Mpumalanga Provincial Research and Ethics Committee. The research that generated the data for the secondary analysis received ethical clearance from the Committee for Research on Human Subjects (Medical) of the University of the Witwatersrand, Johannesburg, South Africa (Ref No. M960720).

4.0 Results

The results of the two main studies with their component sub-studies have been integrated to reflect the three themes of this thesis. These themes are preceded by the patients' socio-demographic characteristics. The themes are (i) chronic disease profile and predictors of healthcare utilisation (subsection 4.1); (ii) quality of care in the ICDM model (subsection 4.2); and (iii) changes in patients' health outcomes attributable to the ICDM model (subsection 4.3). Table 14 presents the summary of the results of the three thesis themes by the four papers as outlined earlier in Table 1.

4.1 Chronic disease profile and predictors of healthcare utilisation

4.1.1 General characteristics of study participants

The general characteristics of the 5,795 study participants in the healthcare utilisation study (Figure 11) are described in this subsection.

4.1.2 Comparison of responders with non-responders by socio-demographic characteristics

Response rate, defined as the number of respondents divided by the number of eligible subjects in the sample (95), was 75% [5,795/(7,870-145)]. A comparison of 5,795 responders and 2,075 non-responders showed that the responders were older (mean age = 66 vs. 64 years, $p<0.001$) and predominantly women (74.8% vs. 55.4%, $p<0.001$), whereas non-responders had more of formal education (19.1% vs. 12.9%, $p<0.001$) and highest asset score (25.9% vs. 22.5%, $p<0.001$) – (See Table 3).

Table 3: Socio-demographic characteristics of responders and non-responders to the 2010 healthcare utilisation survey in the Agincourt sub-district

VARIABLES	Responders (n=5,795)	Non-responders (n=2,075)	Total (n=7,870)	*p*-value[†]
Age group (years)				
50 – 59	1,933 (33.3)	920 (44.4)	2,853 (36.2)	<0.001
60 – 69	1,703 (29.4)	515 (24.8)	2,218 (28.2)	
≥ 70	2,158 (37.3)	640 (30.8)	2,799 (35.6)	
Mean age in years	66.1 (65.8 , 66.4)	64.0 (63.5 , 64.5)	65.6 (65.3 , 65.8)	
Gender				
Female	4,333 (74.8)	1,149 (55.4)	5,482 (69.7)	<0.001
Male	1,462 (25.2)	926 (44.6)	2,388 (30.3)	
Education (in completed years)				
No formal education	3,680 (63.5)	1,263 (60.9)	4,943 (62.8)	<0.001
≤ 6	1,369 (23.6)	415 (20.0)	1,784 (22.7)	
> 6	746 (12.9)	397 (19.1)	1,143 (14.5)	
Nationality of origin				
South Africa	4,032 (69.6)	1,396 (67.3)	5,428 (69.0)	0.052
Mozambique	1,763 (30.4)	679 (32.7)	2,442 (31.0)	
Socio-economic status				
Lowest	927 (16.0)	339 (16.4)	1,266 (16.1)	
Middle low	1,160 (20.0)	391 (18.8)	1,551 (19.7)	<0.001
Middle	1,239 (21.4)	359 (17.3)	1,598 (20.3)	
Middle high	1,091 (18.8)	421 (20.3)	1,512 (19.2)	
Highest	1,301 (22.5)	538 (25.9)	1,839 (23.4)	
Missing	77 (1.3)	27 (1.3)	104 (1.3)	
Medical aid cover				
Free public hospital care	5,422 (93.6)	-		
Whenever I need to see the doctor	118 (2.1)	-		
Health insurance for specific disease	7 (0.1)	-		
Employer's clinic/hospital	188 (3.2)	-		
No medical aid/don't know	60 (1.0)	-		
Occupation				
Not working for cash payment	5,016 (86.6)	-		
Working for cash payment	779 (13.4)	-		
Looking for a paid job				
Yes	508 (8.8)	-		
No	4,567 (78.8)	-		
Missing	720 (12.4)	-		
Type of grant				
Old age	3,437 (59.3)	-		
Disability	182 (3.1)	-		
None	2,176 (35.6)	-		

[†]*Chi square test p-value of difference between responders and non-responders*

4.1.3 Socio-demographic characteristics of adults who used public and private healthcare facilities

Table 4: Socio-demographic characteristics and type of healthcare facility used in the Agincourt sub-district in 2010

Variables	Type of healthcare facility n (%)			*p*-value[†]
	Public (n=4,089)	Private (n=363)	Total (n=4,452)	
Age (years)				
50 – 59	1,365 (33.4)	140 (38.6)	1,505 (33.8)	0.093
60 – 69	1,186 (29.0)	104 (28.6)	1,290 (29.0)	
≥ 70	1,538 (37.6)	119 (32.8)	1,657 (37.2)	
Gender				
Female	3,186 (77.9)	243 (66.9)	3,429 (77.0)	<0.001
Male	903 (22.1)	120 (33.1)	1,023 (23.0)	
Education (completed years)				
No formal education	2,613 (63.9)	201 (55.4)	2,814 (63.2)	<0.001
≤ 6	979 (23.9)	73 (20.1)	1,052 (23.6)	
> 6	497 (12.2)	89 (24.5)	586 (13.2)	
Nationality of origin				
South Africa	2,868 (70.1)	274 (75.5)	3,142 (70.6)	
Mozambique	1,221 (29.9)	89 (24.5)	1,310 (29.4)	0.032
Medical aid cover				
Free public hospital care	3,878 (94.8)	283 (77.9)	4,161 (93.5)	<0.001
Whenever I need to see the doctor	25 (0.6)	73 (20.1)	98 (2.2)	
Health insurance for specific disease	2 (0.1)	1 (0.3)	3 (0.1)	
Employer's clinic/hospital	168 (4.1)	4 (1.1)	172 (3.8)	
No medical aid/don't know	4 (0.1)	1 (0.3)	5 (0.1)	
Occupation				
Working for cash payment	493 (12.1)	74 (20.4)	567 (12.7)	
Not working for cash payment	3,596 (87.9)	289 (79.6)	3,885 (87.3)	<0.001
Socioeconomic status				
Lowest	654 (16.0)	36 (9.9)	690 (15.5)	<0.001
Middle low	837 (20.5)	58 (16.0)	895 (20.1)	
Middle	904 (22.1)	66 (18.2)	970 (21.8)	
Middle high	768 (18.8)	66 (18.2)	834 (18.7)	
Highest	870 (21.2)	137 (37.7)	1,007 (22.6)	
Missing	56 (1.4)	0 (0.0)	56 (1.3)	
Looking for a paid job				
Yes	350 (8.6)	17 (4.7)	367 (8.2)	<0.001
No	3,277 (80.1)	279 (76.8)	3,556 (79.9)	
Missing	426 (11.3)	67 (18.5)	529 (11.9)	
Type of grant				
Old age	2,415 (59.1)	211 (58.1)	2,626 (59.0)	0.914
Disability	153 (3.7)	13 (3.6)	166 (3.7)	
None	1,521 (37.2)	139 (38.3)	1,660 (37.3)	

[†]*Chi square test p-value of difference between public and private healthcare facilities*

Socio-demographic characteristics of the study participants by use of public or private health facilities are shown in Table 4. Overall, there were more female than male participants utilising the healthcare facilities (77% vs. 23%, $p<0.001$). Of the 4,452 adults who visited healthcare facilities less than one year preceding the survey, 4,089 (92%) and 363 (8%) visited public and private healthcare facilities, respectively. Analysis to compare use of public and private healthcare facilities showed significant differences ($p<0.05$) in all socio-demographic characteristics, except age ($p=0.093$) and type of grant ($p=0.914$).

4.1.3.1 Chronic disease profile

Health-seeking behavior and disease profile are stratified by gender in Table 5. Of the 5,795 respondents, 5,056 (87%) needed healthcare less than one year preceding the survey. Chronic NCDs were the most reported health problem (41%) with a higher occurrence in women than men (43% vs. 35%, $p<0.001$). In descending order, other reasons for needing healthcare less than one year preceding the survey included acute conditions - 27%, other conditions - 26%, chronic communicable disease (including HIV/AIDS) - 3%, and injuries - 3%. All 5,795 responders reported health problems, of whom 96% used healthcare, predominantly at public health facilities (82%). A subgroup (4,452 adults) of the total study participants who utilised public or private health facilities reported a higher use of the former than latter (92% vs. 8%, $p<0.001$) (96). Of the 5,056 adults who needed healthcare less than one year preceding the survey, 1,344 (27%) were hospitalised while 274 (5%) had disabilities. There were significant differences ($p<0.001$) in health problems by gender, but there was no significant difference by gender in disability ($p=0.353$) and HCU ($p=0.164$).

Table 5: Health-seeking behaviour, by gender among 5,795 responders to the adult healthcare utilisation survey in the Agincourt sub-district in 2010

Variables	**Women n (%)**	**Men n (%)**	**Total n (%)**	***p*-value**[†]
Last time healthcare was needed (n=5,795)				
< 1 year	3,863 (89.2)	1,193 (81.6)	5,056 (87.2)	
1 - 3 years	204 (4.7)	84 (5.7)	288 (5.0)	<0.001
> 3 years	266 (6.1)	185 (12.7)	451 (7.8)	
Health problems needing healthcare < 1 year before survey (n=5,056)				
Non-communicable diseases*	1,649 (42.7)	422 (35.4)	2,071 (41.0)	
Acute diseases**	1,053 (27.3)	295 (24.7)	1,348 (26.6)	<0.001
Other diseases***	977 (25.3)	351 (29.4)	1,328 (26.3)	
Chronic communicable disease****	99 (2.6)	71 (6.0)	170 (3.4)	
Injuries	85 (2.5)	54 (4.5)	139 (2.7)	
Hospitalisation < 1 year before survey (n=5,056)				
No	2,866 (74.2)	846 (70.9)	3,712 (73.4)	0.025
Yes	997 (25.8)	347 (29.1)	1,344 (26.6)	
Disability requiring treatment < 1 year before survey (n=5,056)				
No	3,660 (94.8)	1,122 (94.0)	4,782 (94.6)	0.353
Yes	203 (5.2)	71 (6.0)	274 (5.4)	
Healthcare utilisation by responders who needed healthcare < 1 year before survey (n=5,056)				
No	129 (3.3)	50 (4.2)	179 (3.5)	0.164
Yes	3,734 (96.7)	1,143(95.8)	4,877 (96.5)	
Actions taken by responders who utilised healthcare < 1 year before survey (n=4,877)				
Public health facility	3,132 (83.9)	881 (77.1)	4,013 (82.3)	
Private health facility	239 (6.4)	120 (10.5)	359 (7.4)	0.001
Other*****	229 (6.1)	105 (9.2)	334 (6.9)	
Self-medication	105 (2.8)	28 (2.5)	133 (2.7)	
Faith or traditional healer	14 (0.4)	3 (0.2)	17 (0.3)	
None	15 (0.4)	6 (0.5)	21 (0.4)	

[†]*Chi square test p-value of difference between gender*

** Hypertension, diabetes, stroke, sleep disorder, chronic pain in joints, depression, anxiety, cancer, heart problems*
******* *Fever and flu*
**** Musculoskeletal pain*
***** HIV and TB*
****** Change diet and exercise*

4.1.3.2 Predictors of healthcare utilisation

Table 6: Predictors of healthcare utilisation among 5056 adults aged 50+ who used healthcare less than one year before the survey in the Agincourt sub-district in 2010

Variables	**Healthcare use (N=5056)**	
	Univariate binary logistic regression model OR (80% CI)	**Multivariate binary logistic regression model OR (95% CI)**
Age (years)		
50 – 59	1	Not included in the final model
60 – 69	1.05 (0.81 , 1.35)	
≥ 70	0.90 (0.71 , 1.13)	
Gender		
Male	1	1
Female	1.27 (1.02 , 1.57)	1.34 (0.96 , 1.89)
Education (in completed years)		
No formal education	1	1
≤ 6	0.87 (0.70 , 1.08)	0.85 (0.59 , 1.21)
> 6	2.49 (1.63 , 3.81)	2.49 (1.27 , 4.86)
Nationality of origin		
Mozambique	1	1
South Africa	1.26 (1.03 , 1.55)	1.07 (0.76 , 1.49)
Occupation		
Presently working for cash payment	1	Not included in the final model
Not presently working for cash payment	1.09 (0.82 , 1.44)	
Socioeconomic status		
Lowest	1	
Middle low	0.84 (0.11 , 1.17)	
Middle	0.79 (0.58 , 1.09)	Not included in the final model
Middle high	1.12 (0.79 , 1.59)	
Highest	1.11 (0.79 , 1.55)	
Looking for a paid job		
No	1	1
Yes	0.70 (0.49 , 0.99)	0.75 (0.44 , 1.28)
Type of grant		
None	1	Not included in the final model
Old age	1.07 (0.87 , 1.31)	
Disability	1.63 (0.84 , 3.18)	
Health problems		
Acute conditions*	1	1
Chronic communicable disease**	5.51 (2.19 , 13.87)	5.91 (1.44 , 24.32)
Non-communicable diseases***	2.95 (2.32 , 3.76)	2.85 (1.96 , 4.14)
Injuries	2.97 (1.39 , 6.37)	3.13 (0.97 , 10.08)
Other	1.83 (1.44 , 2.33)	1.83 (1.27 , 2.66)

** Fever and flu*
*** HIV and TB*
**** Hypertension, diabetes, stroke, sleep disorder, chronic pain in joints, depression, anxiety, cancer, heart problems*

Chronic communicable diseases (e.g. HIV) and NCDs had significantly higher odds of predicting healthcare utilisation than acute conditions (Table 6). Similarly, more years of education predicted higher healthcare utilisation than no formal years of education (96).

4.1.3.3 Reasons for not utilising healthcare

The main reason for not utilising healthcare among the 4% who did not visit a health facility was not feeling sick enough (48%) - Figure 18.

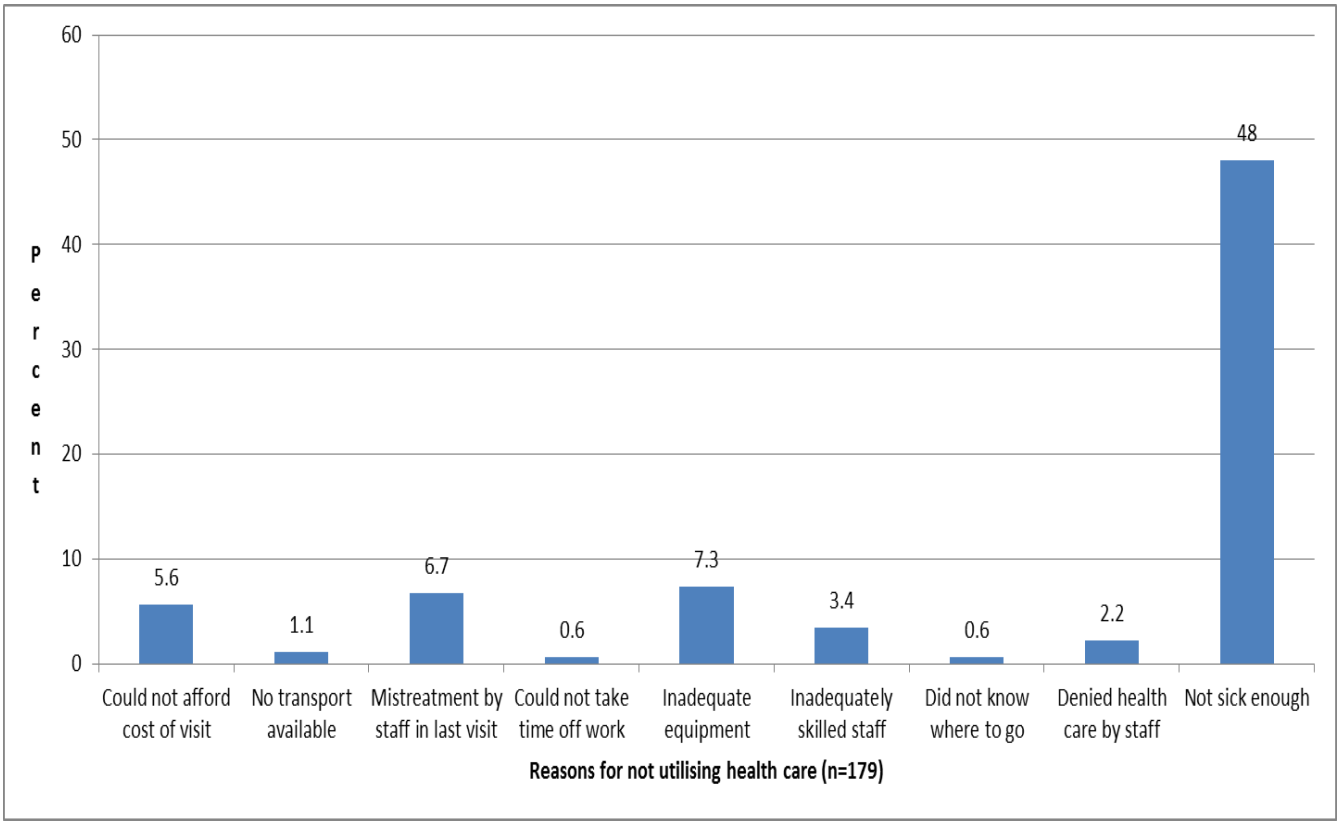

Figure 18: Reasons for not using healthcare among 179 adults who did not use healthcare less than one year before the survey in the Agincourt sub-district, 2010.
NB: Reasons for not using healthcare were multiple response answers

4.2 Quality of care in the ICDM model

4.2.1 General characteristics of the study population

Table 7: Socio-demographic characteristics and chronic disease status of patients in the ICDM pilot and comparison facilities in the Bushbuckridge municipality

Variable	**Study groups n (%)**			
	ICDM pilot facilities (n = 435)	Comparison facilities (n = 443)	Total (n = 878)	p-value of difference
Age group (years)				
18-29	19 (4.4)	39 (8.8)	58 (6.6)	<0.001
30-39	60 (13.8)	119 (26.9)	179 (20.4)	
40-49	59 (13.6)	92 (20.8)	151 (17.2)	
50-59	84 (19.2)	85 (19.2)	169 (19.2)	
≥ 60	197 (45.3)	105 (23.7)	302 (34.4)	
Missing	16 (3.7)	3 (0.6)	19 (2.2)	
Gender				
Female	363 (83.4)	368 (83.1)	731 (83.3)	0.881
Male	72 (16.6)	75 (16.9)	147 (16.7)	
Education (completed years)				
No formal education	172 (39.6)	167 (37.7)	339 (38.6)	0.170
1-6	174 (40.0)	169 (38.1)	343 (39.1)	
> 6	71 (16.3)	73 (16.5)	144 (16.4)	
Missing	18 (4.1)	34 (7.7)	52 (5.9)	
Looking for a paid job				
Yes	126 (29.0)	120 (27.0)	246 (28.0)	0.725
No	291 (66.9)	301 (68.0)	592 (67.4)	
Missing	18 (4.1)	22 (5.0)	40 (4.6)	
Type of grant				
None	202 (46.4)	210 (47.4)	412 (46.9)	0.927
HIV	5 (1.2)	8 (1.8)	13 (1.5)	
Disability	15 (3.5)	13 (2.9)	28 (3.1)	
Old age	195 (44.8)	190 (42.9)	385 (43.9)	
Missing	18 (4.1)	22 (5.0)	40 (4.6)	
Chronic disease status				
Hypertension	210 (48.3)	91 (20.5)	301 (34.3)	<0.001
HIV	141 (32.4)	282 (63.7)	423 (48.2)	
Diabetes	2 (0.5)	2 (0.5)	4 (0.5)	
Co-morbidities	82 (18.8)	68 (15.3)	150 (17.0)	

[†] *Chi square test p-value of difference between ICDM pilot and comparison facilities*

[a] *Analysis for diabetes patients was not done because of the small sample size (two in each study arm)*

[b] *Five patients in the ICDM model facilities were transferred to other facilities also implementing the ICDM model. This was also the case for three patients in the comparison facilities.*

[c] *Two patients in the ICDM model facilities and one in the comparison arm were transferred to health facilities in other provinces*

[d] *One HIV patient died in the ICDM model study arm while three deaths (one hypertension and two HIV/AIDS patients) were recorded in the comparison facilities.*

The response rate was 99%. Table 7 showed the mean age of the 435 hypertension, diabetes and HIV patients to be 55 ± 16 years in the cross-sectional quality of care study (Figure 12). Eighty-three percent were females; 48% had no education; 29% looking for a paid job; and 45% received old age grants. Forty-eight percent (48%) of the patients were receiving treatment for hypertension and 32% were being managed for HIV/AIDS.

In the qualitative study, there were 56 black adult participants (15 males and 41 females) in the eight FGDs. All seven operational managers who participated in the in-depth interviews were female professional nurses with an age range of 40-55 years and 15-20 years of nursing experience. A 55 year-old male senior health staff member was interviewed on behalf of the municipality health manager. A 55 year-old male senior sub-district health staff was interviewed on behalf of the sub-district health manager because the latter could not be interviewed due to busy administrative schedules. The race of the FGD participants reflects the dominance of black people in the study setting. The gender imbalance of the participants in the FGDs (15 males and 41 females) corroborates the gender constitution of the population in the study setting (female vs. male: 70% vs. 30%) and the gender composition of the 345 patients from which the FGD participants were recruited (female vs. male: 83% vs. 17%) (Ameh et al., under review).

4.2.2 Satisfaction with the dimensions of services in the ICDM model

This subsection describes the results on satisfaction with the dimensions of services in the ICDM model which have been categorised into quantitative and qualitative components. The quantitative component focuses on comparing satisfaction of patients and operational managers with the 17 dimensions of care. The quantitative findings are complemented by the qualitative

result showing the depth and breadth of patient and provider satisfaction with services in the ICDM model.

4.2.2.1 Satisfaction with structure-related dimensions of care in the ICDM model

Figure 19 showed that the patients (P) and operational managers (OM) reported being satisfied (scores ≥ 50%) with all the structure-related dimensions of care in the ICDM model. There were no statistically significant differences ($p>0.05$) between the satisfaction scores of the patients and operational managers with structure-related dimensions of care, except for availability of equipment (S1): P-97% vs. OM-52%, $p<0.001$.

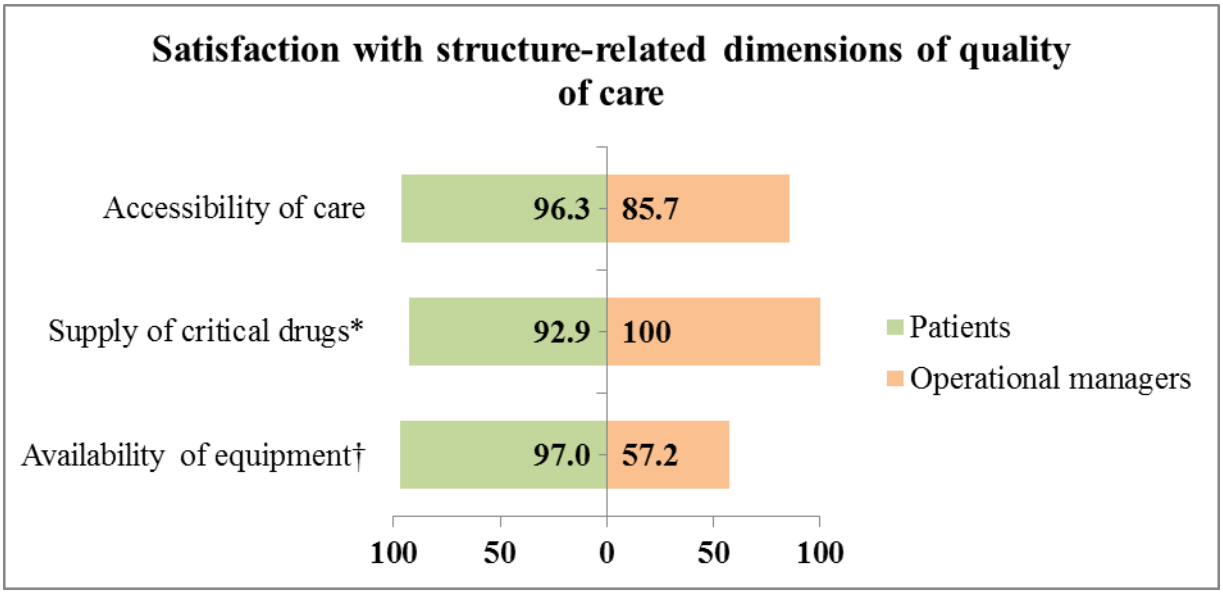

Figure 19: Satisfaction scores of the patients and operational managers with structure-related dimensions of care in the ICDM model

** Priority dimensions of care in the ICDM model*
† Statistically significant differences in the satisfaction scores of the patients and operational managers

The next section shows the results of the qualitative analysis of the availability of the structure-related ICDM policy, and satisfaction of patients and operational managers with structure-related dimensions of care.

The ICDM policy

We have got the ICDM manual to guide us on how to implement the ICDM model in the PHC facilities [Municipal health manager].

The municipal health manager reported use of the ICDM treatment manual by professional nurses in the ICDM pilot facilities when interviewed on the availability of a policy document to create an enabling environment for the implementation of the ICDM model in health facilities.

Patient and provider narratives on satisfaction with structural dimensions of care showed the following results:

Critical medicines

Patients reported inconsistent supply of critical medicines for the treatment of hypertension in the health facilities.

> *When my treatment is not available at the clinic they do tell me that this month my treatment is not available; then they gave me the one that is available that day. When the treatment is not out of stock, they do give me all the treatment that I am getting every month [Respondent 2 (man), Clinic 1]*.

In this study, hypertension patients reported receiving monthly prescribed medication when there was a regular supply of medicines. However, there were occasional drug stock-outs in some health facilities; hence, the frustration of patients with irregular supply of anti-hypertension medicines.

Equipment

Hypertension patients reported concern for the lack of functioning blood pressure (BP) machines in the health facilities they received care.

> *We have stayed for two to three months without BP machine. They were just giving us treatment without knowing whether our BP was high or not. … It gives us problem when we have to travel to another clinic to check our BP [Respondent 1 (woman), Clinic 7].*

Patients thought it was abnormal to not have their BP checked by nurses while taking anti-hypertensive drugs. Patients described their experiences of travelling to other health facilities with functioning BP machines to ascertain whether or not their BP was under control.

An operational manager acknowledged that her health facility did not have functioning BP cuffs (a component of BP equipment tied in the arm) and other medical equipment.

> *[She laughs] what can I say? I think three weeks back Mr. X [a project site manager at institution Y] was here to give us different kinds of BP cuffs because we didn't have them.*

I really can't say that the clinic has all the different medical equipment to take care of all those patients or bring quality nursing care to the patients [Operational Manager, clinic 3].

This operational manager expressed frustration in her ability to provide quality care to patients due to the lack of equipment. She further indicated that a project manager working in a non-governmental research institution donated BP cuffs to her health facility to enable nurses to monitor patients' BP more effectively.

4.2.2.2 Satisfaction with process-related dimensions of care in the ICDM model

Figure 20 showed that the operational managers reported being satisfied (scores ≥ 50%) with all process-related dimensions of care in the ICDM model. However, the patients were not satisfied (scores < 50%) with defaulter tracing of patients (P7-29%) and appointment systems (P14-20%). Of all the process-related dimensions of care, there were statistically significant differences in the scores of the patients and operational managers in appointment system (P14): P-20% vs. OM-100%, $p<0.001$; physical examination of patients (P11): P-96% vs. OM-57%, $p<0.001$; defaulter tracing of patient (P7): P-29% vs. OM-86%, $p=0.001$; hospital referral of patients (P5): P-62% vs. OM-100%, $p=0.039$; and friendliness of the nurses to patients (P4): P-92% vs. OM-71%, $p=0.041$.

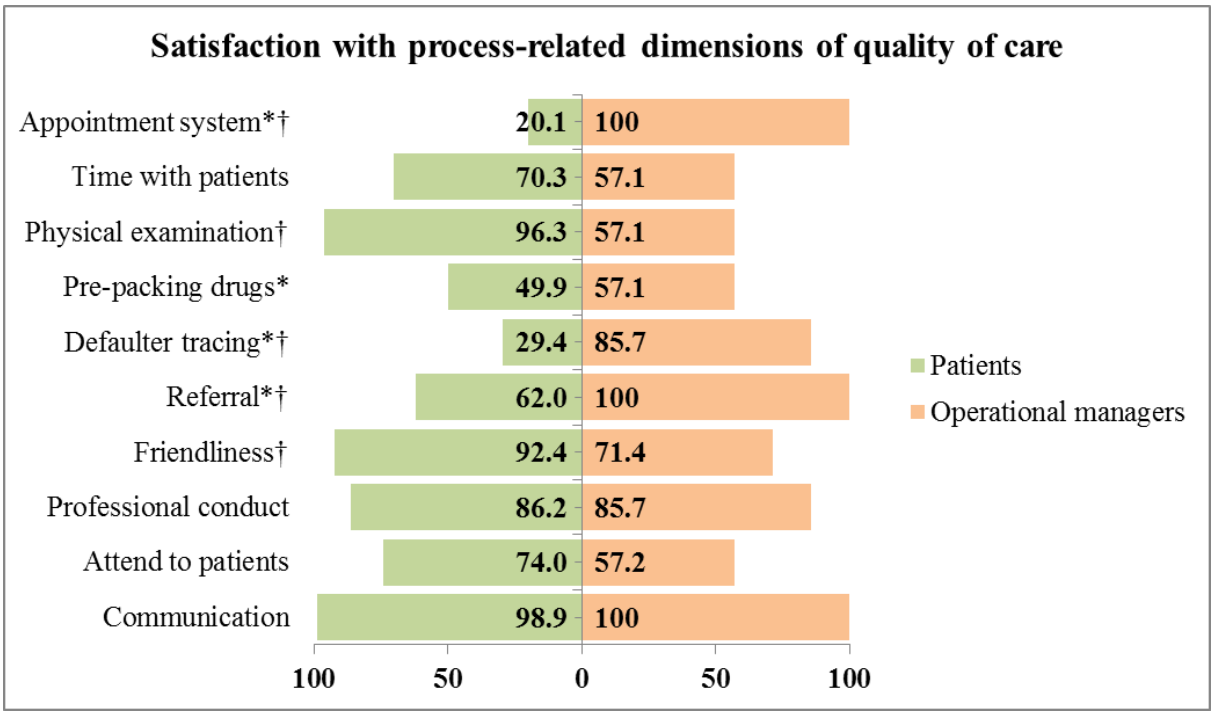

Figure 20: Satisfaction scores of the patients and operational managers with process-related dimensions of care in the ICDM model

** Priority dimensions of care in the ICDM model*
† Statistically significant differences in the satisfaction scores of the patients and operational managers
Qualitative analysis showed the following results in the process-related dimensions of care in the ICDM model.

Prepacking drugs

The ICDM manual stipulates that nurses prepack patients' medicines before patients' arrival at the facilities to reduce patient waiting time during consultation with nurses. The nurses' inability to regularly prepack medicines was reported as a factor militating against the delivery of services.

Sometimes we do prepacking the day before clinic appointment. Sometimes when we are short-staffed, we are unable to do it. Another challenge is that we don't have prepacking bags [Operational Manager, Clinic 4].

A narrative from an operational manager showed that prepacking patients' drugs before scheduled appointments was done sometimes in her health facility. The manager identified staff shortage and unavailability of prepacking bags as obstacles to regular prepacking of patients' drugs before clinic visits. Hence, prepacking was sometimes done during or after consultation with nurses or it was not done in instances when there were no prepacking bags.

Appointment system

Patients reported a rigid appointment system in which they were unable to access services for sudden-onset illnesses occurring before their scheduled appointment dates.

When your date is still far you can't go to the clinic even when you have other illnesses [Respondent 2 (woman), Clinic 3].

In the ICDM model of care, patients with chronic diseases are given appointment dates for their next clinic visits. These predetermined scheduled appointments are usually on a monthly basis for unstable/uncontrolled cases [e.g. BP>140/90 mmHg for hypertension patients and CD4 count < 350 cells/$mm^3$for HIV patients] or two monthly for stable/controlled cases [e.g. BP<140/90 mmHg for hypertension patients and CD4 count > 350 cells/$mm^3$for HIV patients].

Patients also reported that those of them who missed previous clinic appointments were being made to wait in the queues during subsequent visits until nurses had attended to patients who were on the appointment list for that day; hence, one of the reasons constituting long patient waiting time.

> *When they [nurses] shout at us it is because when they tell you to come today at nine, you find that you miss your appointment date and come at another day. When I missed my appointment and went there the other day, they [nurses] delayed me even when I arrived at the clinic early. All the patients that came after my arrival collected their treatment and went home and left me at the clinic. And I don't think they [nurses] are wrong because you [patient] are the one who missed your appointment [Respondent 2 (woman), Clinic 1].*

Home-Based Carer process factors

Patients reported that home-based carers (HBCs) who visited patients in their homes divulged their clients' clinical details to people in the neighbourhood.

> *I told them [HBCs] not to come to my house any more. When I tell them something, I expect them to report it to their seniors and not to tell the whole community. So when I'm sick, I will go to the clinic [Respondent 5 (woman), Clinic 2].*

Patients recognised the role of home-based carers [HBCs] in patient management such as assisting patients with domestic chores and delivering their drugs from the health facilities. However, some patients reported that HBCs breached their clients' confidentiality by disclosing

their clinical information to persons other than those entrusted with patient care and management.

An operational manager described a situation in which community members stigmatised ill people who were visited by HBCs.

> *Home-based carers are not accepted. They [patients] are thinking that other people [community members] will think that they are HIV positive and that is why the HBCs are coming to visit them [Operational manager, Clinic 1]*.

Community members were said to have perceived patients visited by HBCs to be ill due to HIV/AIDS; hence, the justification for the home-based care and visits. Such patients responded by not allowing HBCs to visit their homes. This reported HIV-related stigma constitutes a community barrier to accessing health services.

Nurse- and patient-related process factors

Operational managers and patients reported diverging viewpoints of how behaviours expressed by healthcare providers and users influenced process factors in the health facilities. In the quote below, a patient expressed dissatisfaction with the professional conduct of a nurse.

> *When you are in the consulting room with her [referring to a nurse], she will send you to go and take the tablets in the locker [referring to where drugs are kept]. Do I know the tablets I have to use? Sometimes she will send a cleaner to go and take the tablets; does the cleaner know the treatment? I have seen it several times and am saying that these nurses are going to kill us [Respondent 2 (woman), Clinic 4].*

On the other hand, an excerpt below indicates how an operational manager noted that patients challenged the ability of HBCs to trace clinic defaulters who resorted to traditional means of seeking healthcare in places far away from where they [patients] received biomedical care.

> *We [nurses] have tried our level best even to trace patients who missed their appointment using HBCs and by telephone calls. Some of our patients move around seeking care in many places because they believe in both western civilization treatment and traditional healers. You find that a patient is receiving treatment in village X and the next thing you will hear from the relative that he (the patient) is at village Y [about 50 Km away from village X] because there is a traditional healer there who is busy treating him. That gives us a problem in tracing them [Operational manager, Clinic 3].*

4.2.2.3 Satisfaction with outcome-related dimensions of care in the ICDM model

Figure 21 showed that the patients and operational managers reported being satisfied (scores ≥ 50%) with three of the four outcome-related dimensions of care in the ICDM model. On the other hand, the patients and operational managers were not satisfied (scores < 50%) with patient waiting time (O4): P-17% vs. OMs-43%. A comparison of the satisfaction scores of the patients and operational managers with all the outcome-related dimensions of care showed no statistically significant differences (p>0.05).

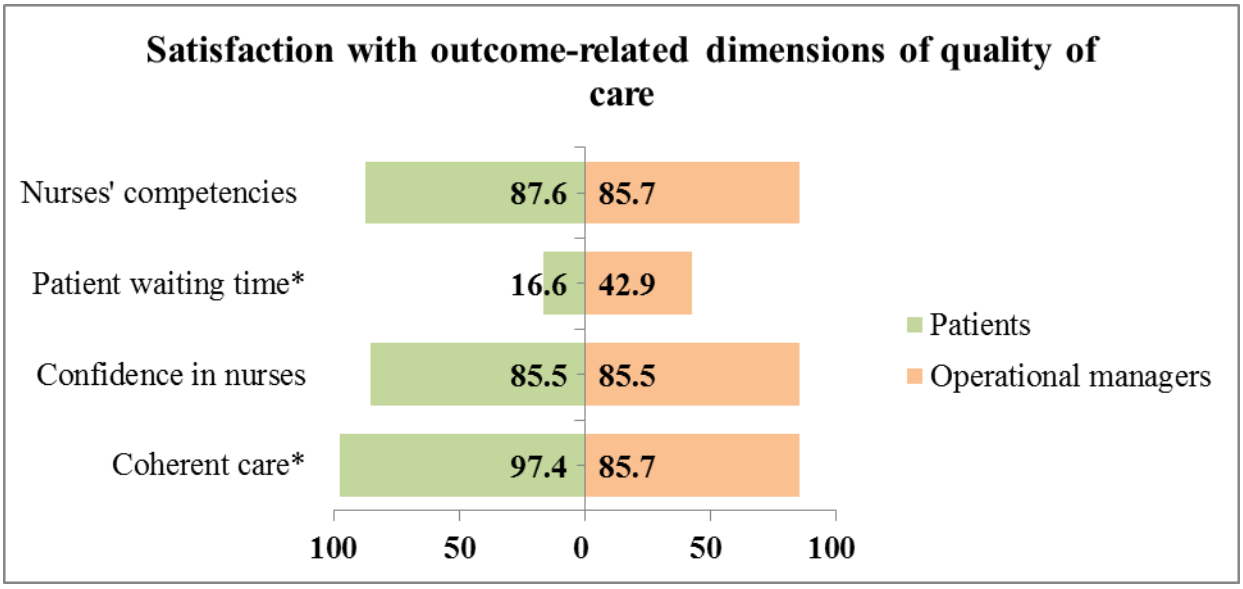

Figure 21: Satisfaction scores of the patients and operational managers with outcome-related dimensions of care in the ICDM model

** Priority dimensions of care in the ICDM model*

In the qualitative analysis, reduced stigma attributable to coherent integrated services and long waiting time were reported as out-related dimensions of care in the ICDM model.

Reduced stigma

An operational manager reported that coherence and integration of services conferred an advantage on people living with HIV (PLWHIV) because of reduced stigma due to non-segregation of patients managed for chronic disease in the same clinic in the health facilities.

> *Previously we were grouping them according to their diseases, but now they are put together. Patients living with HIV/AIDS are satisfied because they are mixed with those who are having hypertension and diabetes (Operational Manager, Clinic 6).*

Reduced HIV stigma was attributed to the innovative integrated chronic disease services in which patients were not segregated or attended to by nurses based on their disease status. Non-segregation of patients or consultation rooms in the clinics implied that it may not have been easy for patients to identify who was being managed for HIV/AIDS; hence, the reduced HIV-related stigma.

Long waiting time

Patients and operational managers reportedly attributed long patient waiting time in the health facilities in this study to several factors. Patients said waiting time was long due to late arrival of filing clerks and nurses; long morning prayer sessions before commencement of clinical duties; staff meetings; prolonged tea or lunch breaks; nurses giving preferential treatment to friends or

relatives who skip the queues; and nurses engaging in trading activities (e.g. buying and selling of household products) in the consultation room during consultation hours.

> *We arrive at six in the morning and stay outside the gate and they will open the gate at eight o'clock. Sometimes they will start to check you at one o'clock. You will get your treatment very late despite early arrival at the clinic [Respondent 2 (man), Clinic 7]*.

On the other hand, operational managers reported long waiting time was due to staff shortage and patients missing their clinic appointments.

> *We are booking a certain number of patients and if that number becomes extra because of those who didn't come on their appointment dates; you find that we have a lot of patients and they (those who missed their previous appointment) have to wait (Operational Manager, Clinic 1).*

4.2.2.4 Emerging themes from the qualitative study

Staff shortage and inability to afford costs of transportation to health facilities were reported as emerging themes in the qualitative analysis.

Staff shortage

Operational managers and patients identified staff shortage as a key human resource challenge impacting the delivery of quality care in the health facilities.

> *I'm alone and I have to do all the programmes with the staff nurse. I'm to manage the deliveries, antenatal clinics, integrated chronic disease clinic, minor illness,*

immunization and all those programmes. I can't! ..... Sometimes if I am forced to do the work alone I end up making some stupid mistakes (Operational Manager, clinic 3).

Today, they [referring to nurses] are two and they get tired and become complicated [Respondent 1 (woman), Clinic 6].

An operational manager reported making mistakes due to work overload arising from staff shortage. A patient described how staff shortage in a health facility led to work-related exhaustion and 'complicated' behaviour of nurses, an indication of how the lack of adequate human resources negatively impacts the provision of quality services.

Inability to afford costs of transportation

Patients reported inability to afford costs of transportation as a barrier to accessing clinics or when referred by nurses, from clinics to doctors in the hospitals.

If I am working for someone and that person doesn't pay me, I have to wait until the person pays me before I have to go to the clinic or hospital [Respondent 4 (woman), Clinic 1].

In a rural South African setting with high unemployment levels, people's reliance on paid jobs as means of livelihood also affected their healthcare seeking behaviour. Delay in clinic or hospital visits was influenced by late payment for services rendered.

4.2.3 Quality of care

This subsection shows the relationships between structure, process, and outcome constructs as a measure of quality of care in the ICDM model using patient satisfaction scores.

4.2.3.1 Relationships between structure, process and outcome constructs

Figure 22 showed the result of the relationships between structure, process and outcome constructs as a measure of quality of care in the ICDM model assessed using structural equation model. The Cronbach's alpha coefficients of reliability of all variables intended for their respective SPO constructs ranged from acceptable to good: structure (0.790), process (0.702), and outcome (0.600), an indication that the variables were a reliable measure of their intended constructs (85).

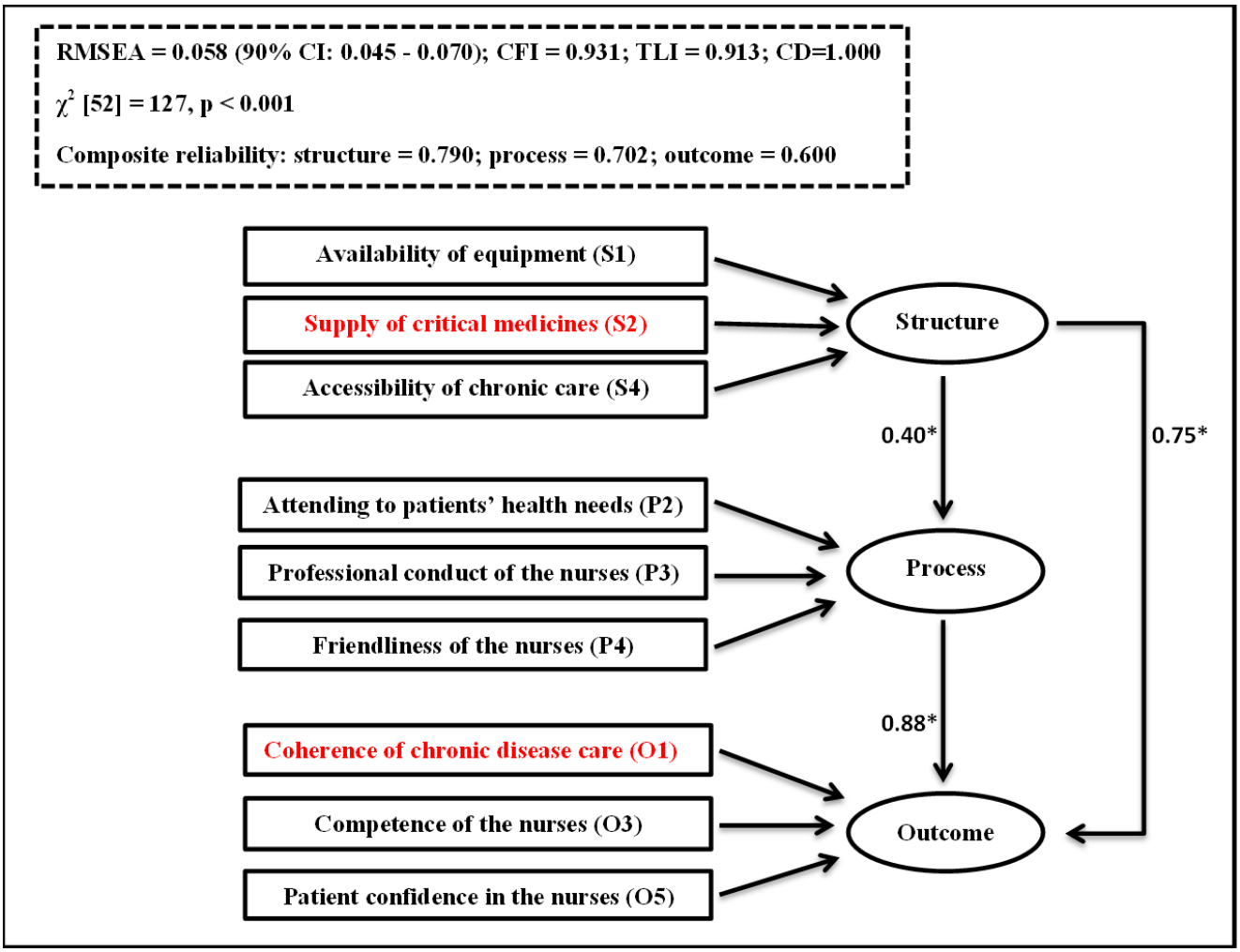

Figure 22: Goodness-of-fit, reliability and correlation assessment of the relationships between structure, process and outcome

**Relationships between the constructs represented by the Pearson correlation values*
NB: The dimensions in red colour are the priority areas of the ICDM model

RMSEA - Root Mean Squared Error of Approximation (≤ 0.06 is a good fit)
CFI - Comparative Fit Index (CFI ≥ 0.90 is a good fit)
TLI - Tucker-Lewis Index (TLI ≥ 0.90 is a good fit)
CD - Coefficient of determination (range 0-1. There is a perfect fit of the data with the model if CD=1)
Cronbach's alpha coefficient of reliability (≥ 0.6 is acceptable)

Before running confirmatory factor analysis (CFA), six negatively phrased statements (S3, P6, P8, P10, P13 and O2) in the adapted questionnaire were dropped because there was no evidence of acquiescent response set (ARS) in the pair of statements phrased in opposite directions (Figure 23).

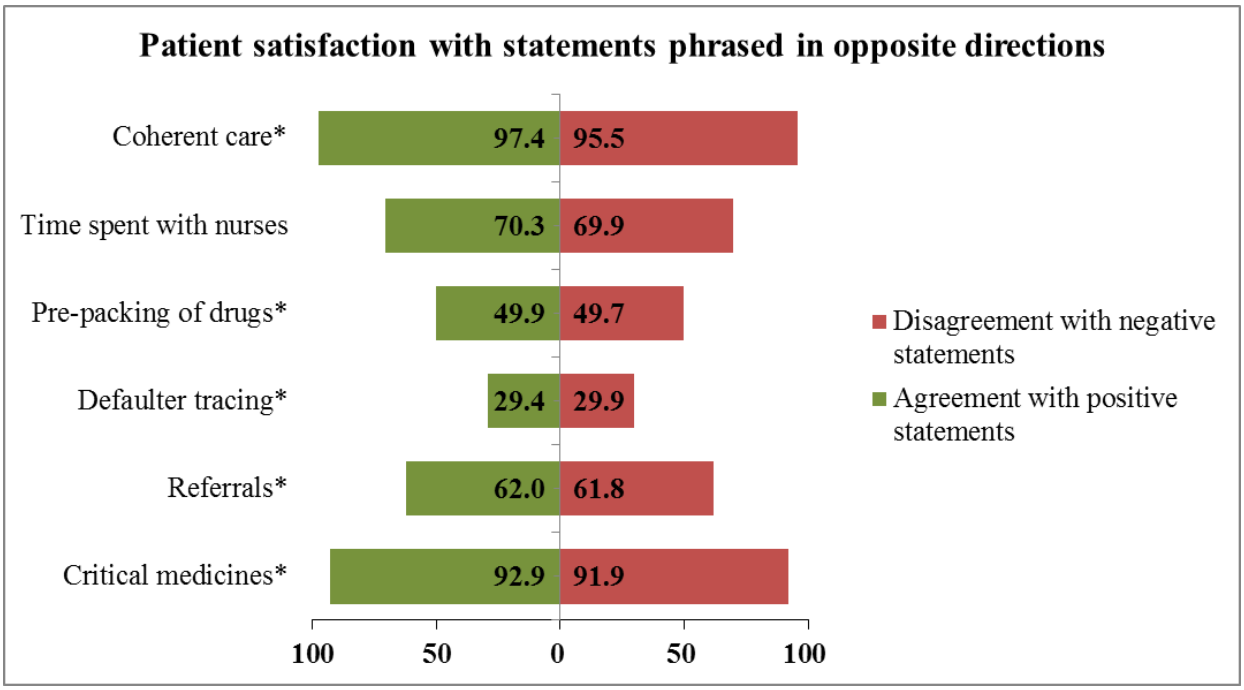

Figure 23: Agreement with positive statements and disagreement with negative statements

** Priority dimensions of care in the ICDM model*

In assessing the fit of the constructs and the remaining 17 variables, three process-related variables: communication with patients (P1), hospital referral (P5) and physical examination of patients (P11) with coefficient of determination values < 0.20 were dropped (86). Of the remaining 14 variables, four process-related variables: defaulter tracing of patients (P7), prepacking of drugs before clinic visit (P9), time patients spent with nurses during consultation

(P12) and appointment system (P14); and one outcome-related variable: patient waiting time (O4) did not load significantly (factor loadings < 0.3) onto their intended constructs in the CFA (Table 8), and were dropped after CFA.

Table 8: Factor loading of variables intended for structure, process and outcome constructs in the assessment of quality of care in the ICDM model

Constructs	Variables	Loading	Standard error
Structure			
	Availability of equipment (S1)	0.462*	0.038
	Supply of critical medicines (S2)	0.994*	0.012
	Accessibility of services (S4)	0.383*	0.041
Process			
	Attendance to patients' needs (P2)	0.664*	0.035
	Professionalism (P3)	0.758*	0.032
	Friendliness (P4)	0.669*	0.035
	Defaulter tracing (P7)	0.200	0.056
	Prepacking of drugs (P9)	0.268	0.055
	Time spent with nurses (P12)	0.074	0.056
	Appointment system (P14)	0.163	0.053
Outcome			
	Coherence (O1)	0.310*	0.057
	Competence (O3)	0.485*	0.053
	Waiting time (O4)	0.229	0.058
	Confidence (O5)	0.651*	0.054

**Variables with factor loading ≥ 0.300*

Nine variables reflected their intended SPO constructs (factor loading > 0.300) in the structural equation model (Figure 22). These were three structure-related dimensions: availability of equipment (S1), supply of critical medicines (S2) and accessibility of chronic disease care (S4); three process-related dimensions: attending to patients' health needs (P2), professional conduct of the nurses (P3) and friendliness of the nurses (P4); and three outcome-related dimensions: coherence of integrated chronic disease care (O1), patient confidence in the nurses (O3), and competence of the nurses (O5).

The fit indices of the three specified pathways are as follows: (a) unidirectional pathway - [χ^2[52]=145, p<0.001; RMSEA=0.064 (90% CI - 0.052-0.077); CFI=0.915; TLI=0.892; CD=0.911], (b) mediation pathway - [χ^2[52]=127, p<0.001; RMSEA=0.058 (90% CI - 0.045-0.070); CFI=0.931; TLI=0.913; CD=1.00] and (c) reciprocal pathway – [χ^2[59]=147, p<0.001; RMSEA=0.059 (90% CI - 0.047-0.070); CFI=0.919; TLI=0.910; CD=0.632].

Table 9 showed that when using at least two criteria, all the specified path models fit the data, but only the mediation pathway fulfilled all the criteria used except the chi-squared criterion, which is expected because the sample size of this study was greater than 400. In addition, the mediation pathway showed a perfect fit with a CD value of 1.00.

Table 9: Goodness of fit of the specified path models in evaluating the quality of care in the ICDM model

Criteria	Specified path models		
	Unidirectional	Mediation	Reciprocal
χ^2 test p value > 0.05*	P<0.001	P<0.001	P<0.001
RMSEA value ≤ 0.06	0.064 (90% CI - 0.052-0.077)	0.058 ✓ (90% CI - 0.045-0.070)	0.059 ✓ (90% CI - 0.047-0.070)
CFI ≥ 0.90	0.915 ✓	0.931 ✓	0.919 ✓
TLI ≥ 0.90	0.892	0.913 ✓	0.910 ✓
CD close to 1.00 (perfect fit is preferred if CD value=1.00)	0.911 ✓	1.00 ✓	0.632
Ranking**	3rd	1st	2nd

✓*Show goodness of fit*

***The mediation model ranked first because it fulfilled four criteria (RMSEA, CFI, TLI and CD). In addition, it showed a perfect fit based on CD value of 1.00*

***The reciprocal model ranked second because it fulfilled three criteria (RMSEA, CFI and TLI)*

***The unidirectional model ranked third because it fulfilled two criteria (CFI and CD). However, it did not show a perfect fit based on CD value of 0.911*

4.3 Changes in patients' health outcomes attributable to the ICDM model

4.3.1 General characteristics of the study population

For the controlled interrupted time series study conducted to assess changes in patient's health outcomes attributable to the ICDM model, Table 5 showed that a significantly (P<0.001) higher percentage of patients in the ICDM pilot (67%) than the comparison (43%) facilities were aged 50 years and older. There were no statistically significant differences (p>0.05) between the study populations by other socio-demographic variables. The percentage of hypertension patients was significantly higher in the ICDM pilot facilities (48% vs. 21%; P<0.001) whereas the comparison facilities had more HIV/AIDS patients (64% vs. 32%; P<0.001).

4.3.2 Changes in patients' health outcomes

This subsection presents the results of the effectiveness of the ICDM in improving patients' CD4 counts and blood pressure.

4.3.2.1 Health outcomes of HIV patients

The ARMA (1,1) model in Table 10 showed statistically significant coefficients of 0.68 (95% CI: 0.64,0.72; P<0.001) for the autoregressive (AR) and -0.81 (95% CI: -0.85,-0.78; P<0.001) for the moving average (MA) component. Overall, the pilot facilities had a 5.7% greater likelihood of controlling patients' CD4 counts than the comparison facilities (coef=0.057; 95% CI: 0.056,0.058; P<0.001) given that both study arms had 91% likelihood of controlling patients' CD4 count (constant in Table 10). The interaction of study groups and time in Table 10 showed that CD4 count control was greater by 0.2% in the pilot than comparison facilities during the 24 months of implementation of the ICDM model (coef=0.002; 95% CI: 0.001,0.003; P<0.001).

Table 10: The autoregressive moving average model for CD4 count control in primary health care facilities in the Bushbuckridge municipality from January 2011 to June 2013

Variables	**Coefficient**	**Standard error**	**Confidence interval**	**p-value**
Reference attributes Comparison facilities Pre-intervention period				
ICDM pilot facilities	0.057	0.0002	0.056,0.058	<0.001
Post-intervention period	-0.003	0.0001	-0.004,-0.002	<0.001
ICDM pilot*Post-intervention period	0.002	0.0003	0.001,0.003	<0.001
Constant	0.91	0.0001	0.90,0.92	<0.001
Autoregressive moving average (ARMA) modeling				
Autoregressive component (L1)	0.68	0.0212	0.64,0.72	<0.001
Moving average component (L1)	-0.81	0.0185	-0.85,-0.78	<0.001

The residuals in Figure 24 below show a good normal distribution confirming the good fit of the model and the data.

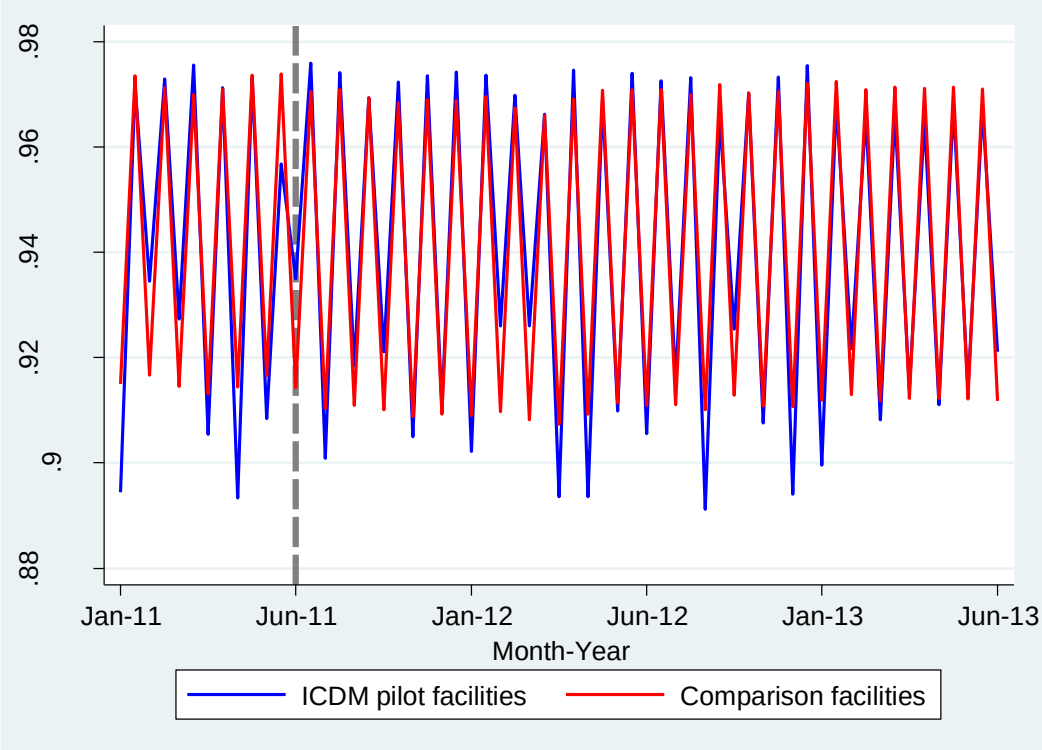

Figure 24: Monthly probabilities of having a CD4 count > 350 cells/mm3 by study groups

**Dotted gray lines show the month the ICDM model was initiated.*

The probability of controlling patients' CD4 counts in the pilot and comparison facilities decreased in the six month period before initiation of the ICDM model. However, this decrease nearly stabilised in both study arms during the 24 months of implementation of the ICDM model in the pilot facilities (Figures 25 and 26). After propensity score matching, there was a reduction in the differences in the probability of controlling patients' CD4 counts between the pilot and comparison facilities (Figures 25 and 26). Figure 26 showed that the pilot facilities had a consistently higher probability of controlling patients' CD4 counts than the comparison facilities six months before the initiation of the ICDM model (97.5% vs. 94.5%) and two years after the model was implemented (96.5% vs. 94.0%).

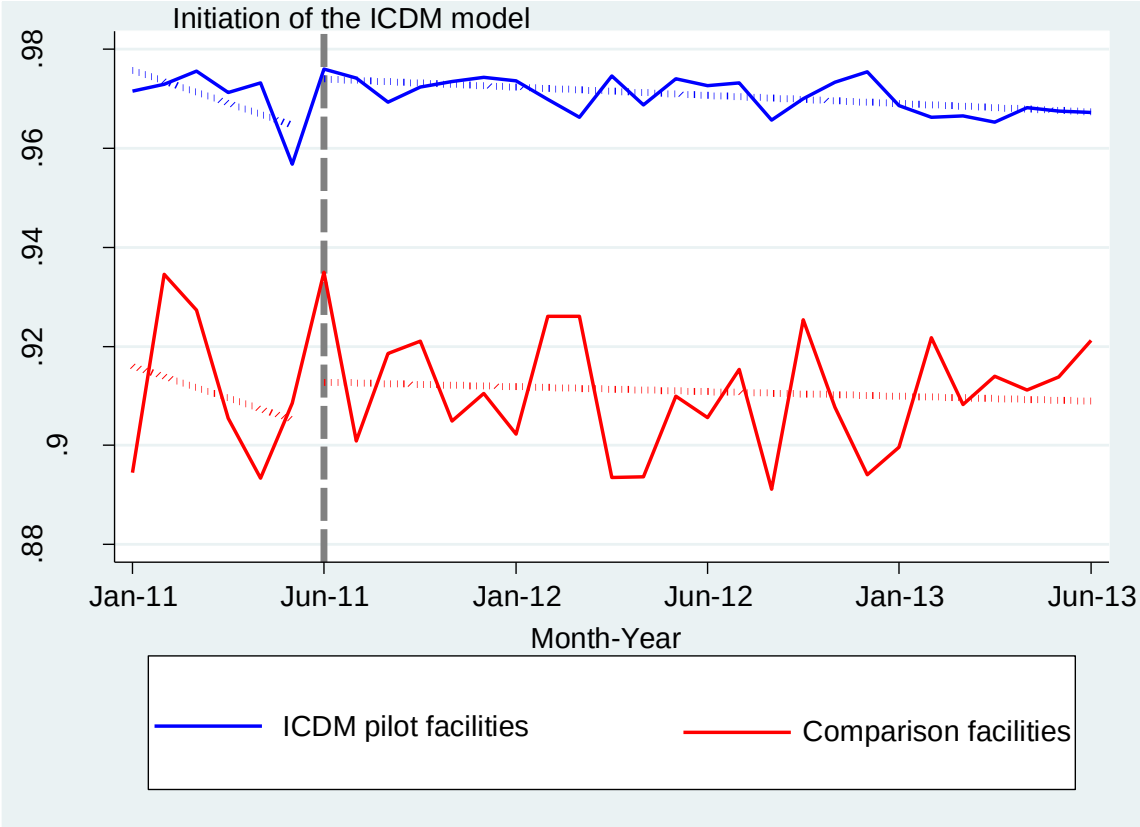

Figure 25: Monthly probabilities of having a CD4 count > 350 cells/mm3 by study groups before propensity score matching.
**Dotted gray line shows when the ICDM model was initiated.*

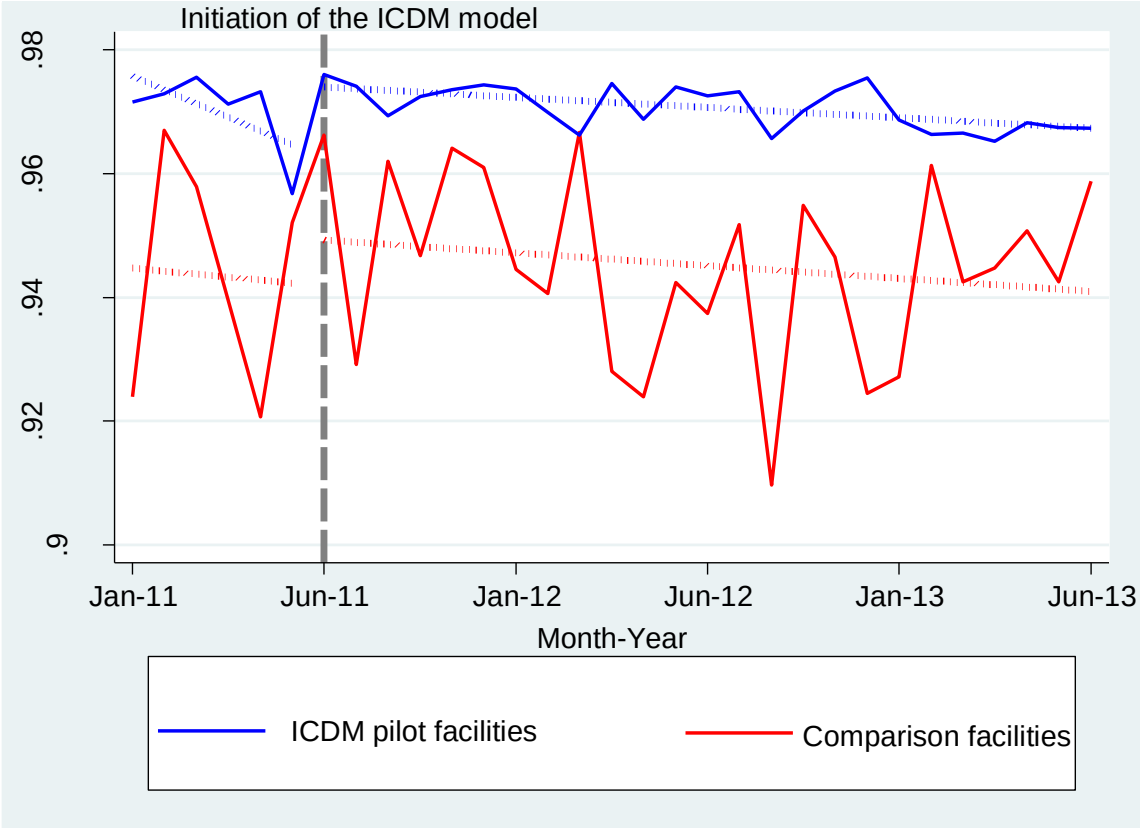

Figure 26: Monthly probabilities of having a CD4 count > 350 cells/mm3 by study groups after propensity score matching.
**Dotted gray line shows the month the ICDM model was initiated.*

The segmented linear regression results in Table 11 (section A) showed a 0.26% monthly decrease in the probability of patients having a controlled CD4 count before the initiation of the ICDM model in the pilot facilities (coef = -0.0026; 95% CI: -0.0027,-0.0025; *P*<0.001). After the initiation of the model, the probability of patients having a controlled CD4 count decreased month-in-month by 0.03% (coef = -0.00032; 95% CI: -0.00033,-0.00031; *P*<0.001). Hence, there

was a 0.23% reduction in the decreasing monthly probability of controlling CD4 counts observed at baseline (coef = -0.0023; 95% CI: -0.0026,-0.0021; *P*<0.001).

In the comparison facilities (Table 11, section B), the monthly changes in the probability of patients having a controlled CD4 count decreased monthly by 0.17% (coef = -0.0017; 95% CI: -0.0024,-0.0010; *P*<0.001) and 0.02% (coef = -0.00018; 95% CI: -0.00024,-0.00013; *P*<0.001) before and after the initiation of the ICDM model, respectively. The decreasing monthly trend for CD4 count control observed before the initiation of the ICDM model was reduced by 0.15% during implementation of the ICDM model (coef = -0.0015; 95% CI: -0.0022,-0.0008; *P*<0.001).

Table 11: Estimated level (intercept) and trend (slope) changes in controlled CD4 counts (> 350 cells/mm3) following implementation of the ICDM model in the ICDM pilot and comparison health facilities in the Bushbuckridge municipality from January 2011 to June 2013

Estimates	**Pre-intervention period**		**Post-intervention period**	
Section A **ICDM pilot facilities**	**Intercept**	**Trend**	**Intercept**	**Trend**
Coefficient (%) Standard error p-value 95% confidence interval	2.56 0.03 <0.001 2.49,2.63	-0.0026 0.00005 <0.001 -0.0027,-0.0025	1.17 0.004 <0.001 1.16,1.18	-0.00032 0.00005 <0.001 -0.00033,-0.00031
Change in trend	Coefficient= -0.0023; 95% CI= -0.0026,-0.0021; p<0.001			
Section B **Comparison facilities**	Intercept	Trend	Intercept	Trend
Coefficient (%) Standard error p-value 95% confidence interval	1.96 0.22 <0.001 1.53,2.39	-0.0017 0.0004 <0.001 -0.0024,-0.0010	1.06 0.02 <0.001 1.03,1.10	-0.00018 0.00003 <0.001 -0.00024,-0.00013
Change in trend	Coefficient= -0.0015; 95% CI= -0.0022,-0.0008; p<0.001			

*Segmented linear regression analysis after propensity score matching

4.3.2.2 Health outcomes of hypertension patients

The ARMA (1,2) model for BP control showed a significant coefficient of 0.47 (95% CI: 0.35,0.58; *P*<0.001) for the AR component. The MA parts were also statistically significant at coefficients of -0.46 (95% CI: -0.55,-0.37; *P*<0.001) and 0.33 (95% CI: 0.28,0.38; *P*<0.001) - Table 12. Overall, the pilot facilities had a 1.0% greater chance of controlling BP than the comparison facilities (coef=0.010; 95% CI: 0.003,0.016; *P*=0.002) given that 50% or more of the patients in both study arms were likely to have their blood pressure controlled (constant in Table 12). The interaction between the study groups and time showed the pilot facilities had a 3.6% greater chance of controlling BP than the comparison facilities during the 24 months of implementation of the ICDM model (coef=0.036; 95% CI: 0.029,0.043; *P*<0.001).

Table 12: The autoregressive moving average model for blood pressure control in primary health care facilities in the Bushbuckridge municipality from January 2011 to June 2013

Variables	**Coefficient**	**Standard error**	**Confidence interval**	**p-value**
Reference attributes Comparison facilities Pre-intervention period				
ICDM pilot facilities	0.010	0.0031	0.003,0.016	0.002
Post-intervention period	-0.030	0.0030	-0.036,-0.024	<0.001
ICDM pilot*Post-intervention period	0.036	0.0029	0.029,0.043	<0.001
Constant	0.50	0.0030	0.49,0.51	<0.001
Autoregressive moving average (ARMA) modeling				
Autoregressive component (L1)	0.47	0.0576	0.35,0.58	<0.001
Moving average component (L1) Moving average component (L2)	-0.46 0.33	0.0480 0.0272	-0.55,-0.37 0.28,0.38	<0.001 <0.001

Figure 27 below showed a reasonable normal distribution of the residuals for BP control except for a slight skewness to the right due to a few extreme values.

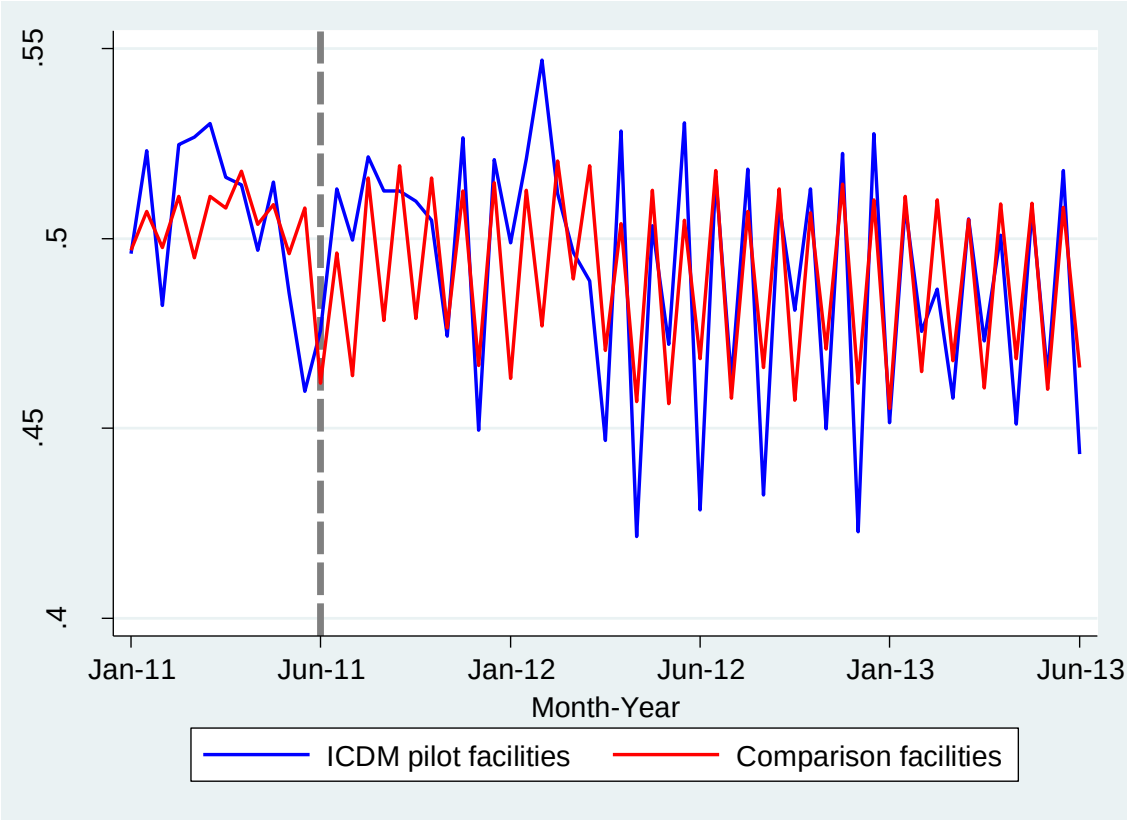

Figure 27: Monthly probabilities of having a BP < 140/90 mmHg by study groups
**Dotted gray lines show the month the ICDM model was initiated.*

There was a decreasing probability of patients having a controlled BP in the pilot and comparison facilities before the ICDM model was initiated and this decrease was more rapid in the pilot than in the comparison facilities (Figures 28 and 29). Following initiation of the ICDM model, there was a reduction in the decreasing probability of controlling patients' BP in both study arms and this was much more so in the pilot than in the comparison facilities. The ICDM model appeared to have reduced the steep downward slope for the control of patients' BP observed in the pre-ICDM model period (Figures 28 and 29). A comparison of the two study arms in Figure 29 showed a consistently higher probability of controlling patients' BP in the pilot facilities than in the comparison facilities six months before the initiation of the ICDM

model (50% vs. 47%) and two years after the model was implemented (47% vs. 40%). The pilot facilities also had less zig-zag fluctuations in BP control than the comparison facilities.

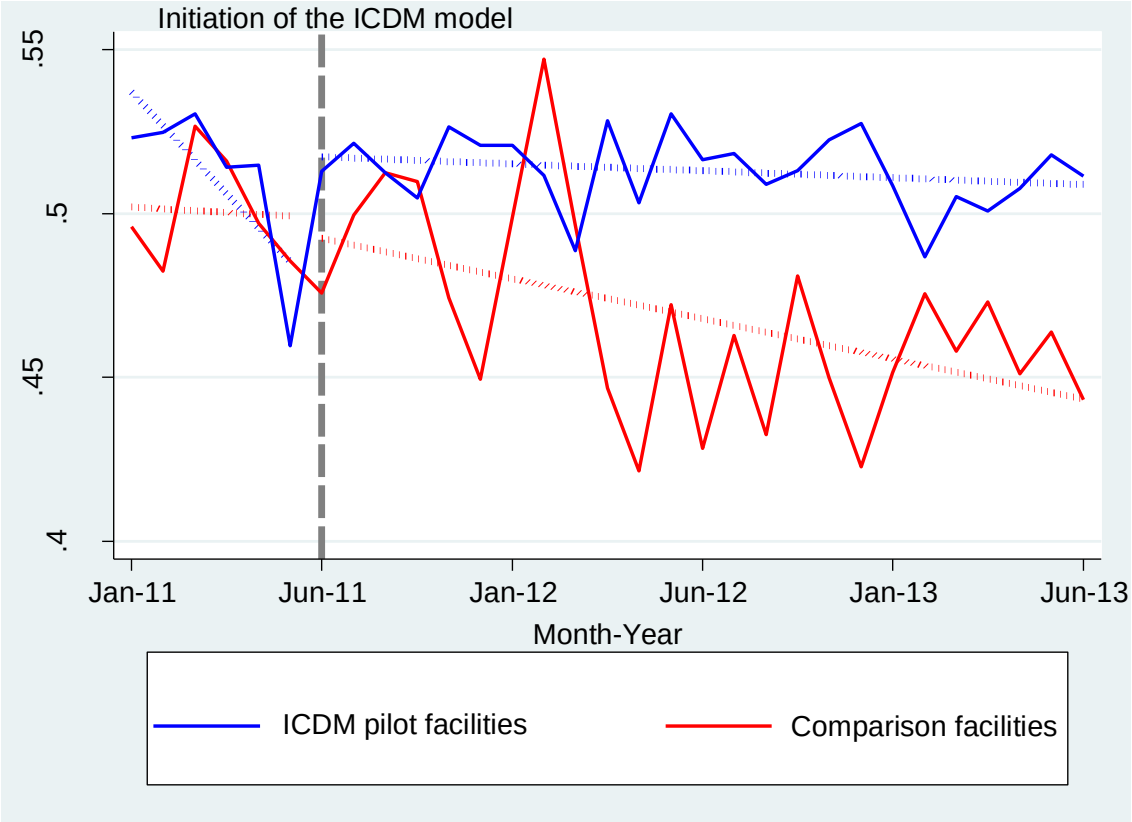

Figure 28: Monthly probabilities of having a BP < 140/90 mmHg by study groups before propensity score matching.
**Dotted gray line shows the month the ICDM model was initiated.*

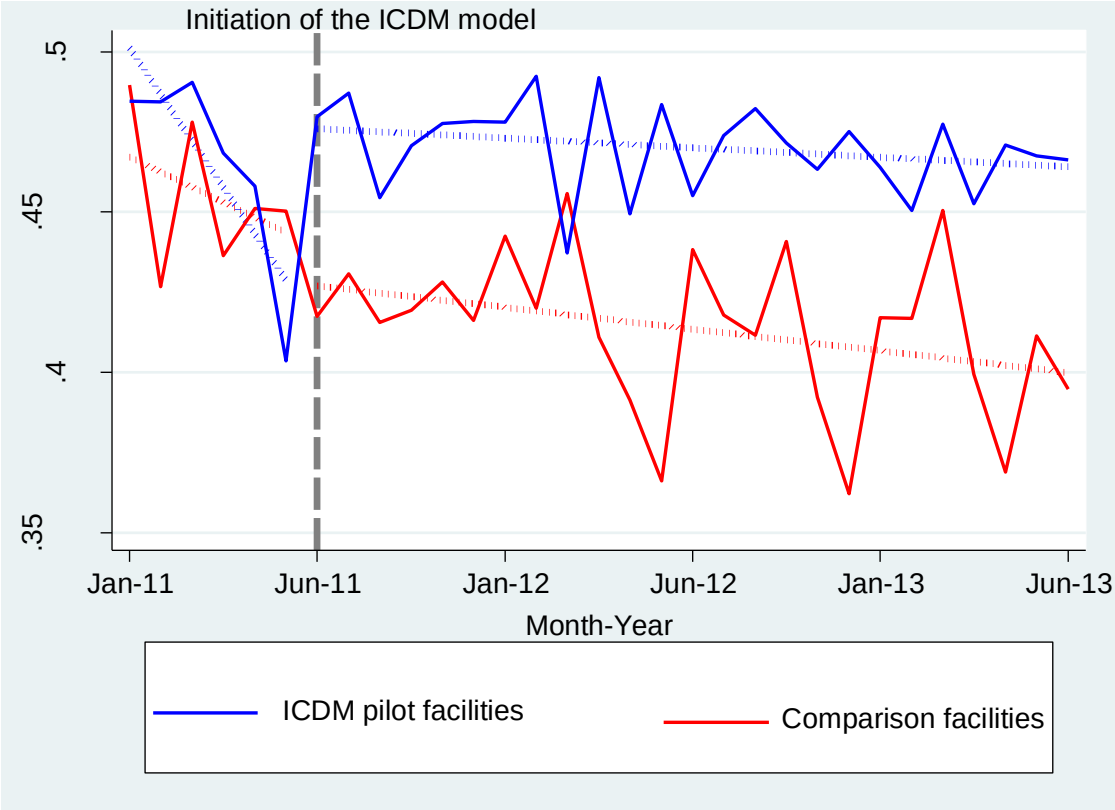

Figure 29: Monthly probabilities of having a BP < 140/90 mmHg by study groups after propensity score matching.
**Dotted gray line shows the month the ICDM model was initiated.*

The segmented regression analysis in Table 13 (section A) showed a 1.6% monthly decrease in the probability of controlling patients' BP in the pre-ICDM model intervention period in the pilot facilities (Coef= -0.016; 95% CI: -0.017,-0.015; *P*<0.001). During the 24 months of implementation of the model, there was a 0.11% decrease in the probability of patients having their BP controlled (Coef= -0.0011; 95% CI: -0.0012,-0.0010; *P*<0.001). A pre-post initiation comparison of the change in trend showed that the steeply decreasing probability of controlling patients' BP observed before initiation of the model was cut back by 1.5% (Coef= -0.015; 95% CI: -0.016,-0.014; *P*<0.001).

There was a 0.2% monthly decrease in the probability of patients having a BP < 140/90 mmHg in the comparison facilities (coef = -0.002; 95% CI: -0.004,-0.001; *P*=0.001) - Table 13, section B. During implementation of the model, the probability of patients having a controlled BP decreased monthly by 0.09% (coef = -0.0009; 95% CI: -0.0011,-0.0008; *P*<0.001). Hence, the pre-post initiation change in trend showed a 0.1% cut back in the steeply decreasing probability of controlling patients' BP observed in the pre-ICDM model era (coef = -0.001; 95% CI: -0.0028,-0.0001; *P*<0.001) – Table 13, section B.

Table 13: Estimated level (intercept) and trend (slope) changes in controlled blood pressure (< 140/90 mmHg) following implementation of the ICDM model in the ICDM pilot and comparison health facilities in the Bushbuckridge municipality from January 2011 to June 2013

Estimates	**Pre-intervention period**		**Post-intervention period**	
Section A **ICDM pilot facilities**	**Intercept**	**Trend**	**Intercept**	**Trend**
Coefficient (%) Standard error p-value 95% confidence interval	10.3 0.20 <0.001 9.90,10.70	-0.016 0.0003 <0.001 -0.017,-0.015	1.13 0.02 <0.001 1.09,1.18	-0.0011 0.00004 <0.001 -0.0012,-0.0010
Change in trend	Coefficient= -0.015; 95% CI= -0.016,-0.014; p<0.001			
Section B **Comparison facilities**	Intercept	Trend	Intercept	Trend
Coefficient (%) Standard error p-value 95% confidence interval	1.87 0.44 <0.001 1.00,2.73	-0.002 0.0007 0.001 -0.004,-0.001	1.01 0.04 <0.001 0.94,1.08	-0.0009 0.00006 <0.001 -0.0011,-0.0008
Change in trend	Coefficient= -0.001; 95% CI= -0.0028,0.0001; p<0.001			

*Segmented linear regression analysis after propensity score matching

Appendix 6 showed the number of monthly visits of sampled patients who utilised PHC facilities from January 2011 to June 2013 in the two study arms. These monthly visits which have been stratified by hypertension and HIV showed a fluctuating pattern of health care utilisation.

4.4 Summary of the results of the three themes

Table 14 below summarises the results of this thesis by presenting how the four papers cover the three research themes and address the four research objectives.

Table 14: Summary of the key findings of the themes by papers

Themes	Key findings by papers			
	Paper I	Paper II	Paper III	Paper IV
Chronic disease profile and predictors of healthcare utilisation Research objective 1: What were the main chronic diseases and predictors of healthcare utilisation by adults 50 years and older in 2010, the year before the ICDM model was initiated?	1. High prevalence of self-reported NCDs in the population 2. Low prevalence of self-reported HIV/AIDS in the population 3. HIV/AIDS and NCDs were the main predictors of healthcare utilisation in adults aged 50 years and older			
Quality of care in the ICDM model Research objective 2 (Quantitative method): What was the quality of care in the ICDM model?		1. Operational managers reported satisfaction with all dimensions of care in the ICDM model except patient waiting time (Figure 19). 2. Patients reported satisfaction with all dimensions of care in the ICDM model except appointment system, defaulter tracing of patients and patient waiting time (Figures 16-18). 3. The mediation path model		

Themes	Key findings by papers			
	Paper I	Paper II	Paper III	Paper IV
		had the best goodness of fit. This implies that structure construct directly influenced process construct which in turn directly influenced outcome construct. Structure construct directly influenced outcome construct without the mediating effect of process construct. (Figure 22). Nine of the 17 dimensions of care assessed were significantly associated with good quality of care in the ICDM model. Of the eight priority areas, supply of critical medicines and coherence of care were significantly associated with good quality of care (Figure 22).		
<u>Research objective 3 (Qualitative method):</u> How did the patients and operational managers perceive the quality of chronic disease care in the ICDM model?			1. Nurses thought there was reduced HIV-related stigma because patients receiving treatment for HIV and NCDs attended same clinic. 2. Nurses and patients reported occasional anti-hypertension drug stock-outs, malfunctioning blood pressure machines,	

Themes	Key findings by papers			
	Paper I	Paper II	Paper III	Paper IV
			staff shortage, dysfunctional prepacking of drugs and long patient waiting time. 3. Nurses and patients reported diverging opinions on defaulter tracing activities rigid clinic appointments and defaulter tracing activities. 4. Emerging themes were staff shortage and patients' inability to afford the cost of transportation to the health facilities and hospitals	
Theme 3: Changes in patients' health outcomes attributable to the ICDM model Research objective 4: Was the ICDM model effective in controlling patients' CD4 count (>350cells/mm^3) and blood pressure (<140/90 mmHg)?				The ICDM model appears to have decreased the downward trajectory in the control of CD4 counts and blood pressure observed in the period before the initiation of the model.

5.0 Discussion

This thesis evaluated the use of an ICDM model to address management of HIV and hypertension in selected PHC facilities in a typical rural South African municipality. The dual burden of HIV and NCDs in a rural setting in South Africa was also explored in this thesis.

The next sections discuss the results of this thesis which have been organised into three thematic areas: chronic disease profile and predictors of healthcare utilisation in the population, quality of care in the ICDM model and changes in patients' health outcomes attributable to the ICDM model.

5.1 Chronic disease profile and predictors of healthcare utilisation

Key findings

- High prevalence of self-reported NCDs in the population
- Low prevalence of self-reported HIV/AIDS in the population
- HIV/AIDS and NCDs were the main predictors of healthcare utilisation in the population aged 50 years and older

A high prevalence of NCDs (41%), particularly hypertension, was self-reported by adults 50 years and over in the study area. This high prevalence of hypertension was previously reported in the study area (4, 68, 97-99) and has been described as significantly contributing to the chronic disease burden in South Africa (13, 38). The high prevalence of NCDs in the current study is a reflection of the ongoing health transition attributed to lifestyle changes and has been suggested to also be related to the expanded ARV roll-out in South Africa (4, 13, 38).

Self-report of HIV/AIDS was low (3%), and well below the local HIV prevalence among adults (17%) as recently estimated in the study site (100); 2010 national estimate (10.5%) (101); and 2014 national estimate (14). This suggests significant under-reporting of HIV infection, possibly related to stigma associated with HIV infection (102).

Similar to other studies in LMICs showing education as a strong predictor of use of facility-based maternal health services (103-105), and consistent with evidence in the literature showing that higher education is an important determinant for positive behavior or motivation toward HCU (105), this study showed that having more years of education was associated with higher healthcare utilisation

Perhaps the reasons for which NCDs and HIV/AIDS predicted healthcare utilisation were because of the high prevalence of these chronic conditions in the study setting (98, 100), and the fact that most of the healthcare utilisation occurred in the public health facilities (the largest group utilised in the study setting). This may have implications for South Africa's primary healthcare system, which is yet to adapt to not only long-term continuity of care for patients living with chronic diseases (4) mostly in the public sector but also to prepare for increasing utilisation by those who are not yet accessing chronic disease services. Despite the higher self-reported prevalence of NCDs than HIV/AIDS, the latter was a stronger predictor of healthcare utilisation. This may be explained by significant under-reporting of HIV infection possibly related to stigma associated with HIV infection (102) and the general low level of awareness of

hypertension (106) due to the lack of symptoms among diagnosed individuals. Furthermore, those who reported being infected with HIV were already engaged in the healthcare system.

Fifty years was adopted as the cut-off for defining older age in this study, in line with the cut-off that has been used in the Study on Global Ageing and Adult Health (SAGE) (107) in the study setting and aligned with the cut-off set for the Minimum Data Set (MDS) project on ageing - supported by the World Health Organization (WHO) and the U.S National Institute on Ageing - to refer to the older population in Africa (108, 109). Although there is no United Nations (UN) standard numerical criterion for old age, the agreed cut-off for defining old age is generally 60 years and above (109). The chronological age of 60 or 65 is said to be the beginning of old age in most developed countries because it is roughly equivalent to retirement age (110). In Africa, the majority of older people do not expect formal retirement or retirement benefits because they live in rural communities and earn a living outside the formal sector (109). Southern Africa is the region with the highest prevalence of HIV/AIDS in the African continent. Life expectancy has decreased from 61 years in 1990-1995 to 52 years in 2005-2010 in this region due to the impact of HIV/AIDS, and is not expected to recover from the pre-1990 levels until 2045 (111).

The Minimum Data Set (MDS) project on Ageing - supported by the World Health Organization (WHO) and the U.S National Institute on Ageing - has set 50 years and above as the cut-off to refer to the older population in Africa (108, 109). The same cut-off has been used in the Study on Global Ageing and Adult Health (SAGE) (107). Given these background information and and the evidence that the global population of persons aged 50 and over is expected to increase from

21% to 34% in 2050 (111), this thesis adopts 50 years and above to describe the population of older adults.

5.2 Quality of care in the ICDM model

Key findings

Quantitative study

- Operational managers reported satisfaction with all dimensions of care in the ICDM model except patient waiting time.
- Patients reported satisfaction with all dimensions of care in the ICDM model except appointment system, defaulter tracing of patients and patient waiting time.
- Availability of equipment, supply of critical medicines and accessibility of care (structure dimensions) directly influenced the ability of nurses to attend to patients' needs, be professional and friendly (process dimensions). These process factors directly influenced coherence of care, competence of nurses and patients' confidence in the nurses (outcome dimensions). These structure factors directly influenced outcome dimensions of care.
- Of the eight priority areas, supply of critical medicines and coherence of care were significantly associated with good quality of care.

Qualitative study

- Nurses thought there was reduced HIV-related stigma because patients receiving treatment for HIV and NCDs attended the same clinic.
- Nurses reported the use of traditional haelers by patients
- Patients reported HIV stigma due to defaulter tracing activities of home-based carers in the community
- Patients reported involvement of government nurses in private commercial activities during work
- Nurses and patients reported occasional anti-hypertension drug stock-outs, malfunctioning blood pressure machines, staff shortage, dysfunctional prepacking of drugs and long patient waiting time.
- Nurses and patients reported diverging opinions on defaulter tracing activities rigid clinic appointments and defaulter tracing activities.

The operational managers in this study reported satisfaction with 16 of the 17 dimensions of care in the quantitative sub-study on quality of care in the ICDM model, but this was less so for the patients who reported satisfaction with 14 dimensions of care. The significant differences in the satisfaction scores of the patients and operational managers in this sub-study supports evidence-based literature that suggests assessing satisfaction with quality of care from provider and patient (112) because of differing views (81). The patients rated satisfaction with the availability of equipment higher than the operational managers rated satisfaction. A possible explanation of this difference in satisfaction rating could be attributed to the fact that patients may not be fully aware of the lack of equipment such as sphygmomanometers, or their non-functionality or the low quality of the existing ones (113). The patients' satisfaction scores for friendliness of the nurses and physical examination of patients was higher than those of the operational managers. The operational managers who responded to the interviews are professional nurses who often perform a dual role of providing routine care to the patients and managing the facilities. In the course of performing their administrative duties in the office, these managers may not have the opportunity to see the professional nurses being friendly to patients in the consultation rooms. This may have accounted for the managers' lower satisfaction scores compared with the patients' scores.

The use of a qualitative method to triangulate data collection yielded in part results that were discrepant from those reported by patients in the quantitative sub-study on quality of care. In the qualitative part of the study, patients reported anti-hypertension drug stock-outs, malfunctioning blood pressure machines, dysfunctional prepacking of drugs, lack of confidentiality in defaulter-tracing activities, unprofessional conduct of nurses, rigid clinic appointment systems and long

patient waiting time. This is contrary to the high patient satisfaction scores observed in the quantitative part of the study, an indication that the patients were more at ease to express themselves in the FDGs compared to the quantitative survey.

Patient waiting time was the only dimension of care in the ICDM model in which the patients and operational managers unanimously reported low satisfaction scores. Similar studies assessing the quality of service in public clinics in South Africa showed that the clinics were easily accessible and services were of acceptable quality (114), but the time spent by patients at the clinic to complete the services was very long (114, 115). These findings suggest that public health services in South Africa, like in many resource-constrained LMICs, are characterised by long waiting times (116-118), which could be a consequence of operational challenges, such as performance of multiple tasks and work overload of health workers (112). In addition to staff shortage which was reported by operational managers and patients, the qualitative study on the quality of care in the ICDM model showed that patients who missed previous clinic appointments were being made to wait in the queues during subsequent visits until nurses had attended to patients who were on the appointment list for that day. Other factors reported by patients as contributing to long waiting time in the qualitative study were late arrival of filing clerks and nurses; long morning prayer sessions before commencement of clinical duties; staff meetings; prolonged tea or lunch breaks; and nurses giving preferential treatment to friends or relatives who skip the queues. These trading activities which are not related to professional work could potentially contribute to long patient waiting time in the clinics. Furthermore, preferential treatment to health workers' friends and relatives could also lead to patient dissatisfaction with services and prolonged waiting time. Therefore, educational programmes need to be targeted at

healthcare workers to change their attitudes and behaviours regarding the provision of quality services to patients.

Many African countries witnessed reductions in HIV-related prejudicial attitudes following ART rollout (119, 120). However, HIV stigma persists and remains a barrier to HIV treatment and care in South Africa (121, 122). Although it has been widely reported in the literature, the HIV-related stigma reported in the communities in this study can be considered to be an unintended consequence of the ICDM model, through the defaulter-tracing activities of HBCs, and has the potential to negatively impact the effectiveness of the model in improving patients' health outcomes. Furthermore, the use of traditional healers may interfere with pharmaceutical treatment which could result poor health outcomes of the patients.

One of the substantive findings obtained both by quantitative and qualitative methods in terms of how quality of care is conceptualised is the diverging views of providers and patients. Nurses and patients had high and low satisfaction scores in appointment systems and defaulter-tracing activities, respectively. Constraints experienced by each group (e.g. providers working under pressure due to chronic staff shortage, patients struggling to access services or their lack of trust in service providers) in the qualitative study may have led to a these different views on quality of care; hence, the need to address these challenges patients and healthcare workers face through a people-centred health system.

The healthcare provider-user interface reported in the quantitative sub-study corroborates the multi- and bi-directional relationship between structure, process, and outcome constructs postulated by Avedis Donabedian (59). Using satisfaction scores of service users, the patients' perception of quality of care in the ICDM model can be interpreted to mean that the provision of good structure (availability of functional equipment, supply of critical medicines, accessibility of chronic disease care) directly promotes good outcome (coherent chronic disease care, competence of nurses and patient confidence in nurses); and that the relationship between good structure and good outcome is mediated by good process (attendance to patients' needs, professional conduct of nurses and nurses' friendliness to patients).

In the qualitative part of the study, staff shortage and the lack of prepacking bags (structure factors) made it challenging for nurses to prepack patients' drugs (process factor) which in turn led to long patient waiting time (outcome factor). Patients who missed clinic appointments (process factor) felt nurses were unfriendly (process factor) to them during their subsequent clinic visit and punished them by delaying their consultation process (outcome factor). These dynamics contributed to avoidable long waiting periods (outcome factor), aside from other health facility-related factors, such as the late arrival of staff; long morning prayer sessions before commencement of clinical duties; morning staff meetings; and prolonged tea/lunch breaks. The positive and negative relationships in the SPO constructs observed respectively in the quantitative and qualitative part of the study highlight the need to use mixed methods to triangulate data in quality of care studies.

The municipal health manager reported availability of an ICDM treatment manual for the management of chronic disease when interviewed on the availability of an ICDM policy to create an enabling environment for the operational implementation of the ICDM model. Whether an ICDM policy was available in the municipality and the Provincial or National Departments of health could not be ascertained following the failure to receive permission to conduct a key informant interview with senior officers in the Department of Health in Mpumalanga province.

The race of the FGD participants reflects the dominance of black people in the study setting (Table 3). The gender imbalance of the participants in the FGDs (15 males and 41 females) corroborates the gender constitution of the population in the study setting (Table 3 - female vs. male: 70% vs. 30%) and the gender composition of the 345 patients from which the FGD participants were recruited (Table 7 - female vs. male: 83% vs. 17%).

5.3 Changes in patients' health outcomes attributable to the ICDM model

Key findings

- In the post-intervention period, the ICDM model appeared to have decreased the downward trajectory in the control of CD4 counts and blood pressure observed in the period before the initiation of the model. However, there was no overall clinical benefit for the patients.

The reduction in the decreasing trend for the control of CD4 counts observed in both study arms six months before the initiation of the ICDM model may be attributed to the existing vertical HIV programme. The latter has expanded access to ART in LMICs (123), particularly in South Africa which has the world's largest ART programme (124), with consequent improvement in health outcomes and increasing life expectancy (14). The ICDM model seemed to have enhanced the existing ART programme by cutting back on the downward trajectory in the control of CD4 counts in the post-intervention period. The lower rate of decline in the control of CD4 counts in the pilot than in the comparison facilities may have been due to reduced HIV stigma which was reported by operational managers in the qualitative sub-study of our broader research (Ameh et al., under review). This may have impacted positively on CD4 counts because HIV and NCD patients received care in the same consultation rooms as was reported in a Cambodia pilot study (2, 19).

The Cambodian study (19) provided early research evidence that informed the UNAIDS' recommendation of an integrated management approach to leverage positive lessons learned from HIV/AIDS programme to support or scale-up services for NCDs (2). Our study

corroborates the Cambodian study by demonstrating the feasibility of an integrated approach for the management of HIV and NCDs, specifically hypertension, in South Africa. Although the WHO recommends virological monitoring as the preferred approach to treatment monitoring for those on ART (125), we used CD4 counts as the indicator for assessing the effectiveness of the ICDM model in improving health outcomes of patients receiving ART. This is because viral load measurements were repeated in the study facilities annually compared with CD4 counts which were repeated every three to six months. Therefore, analysis of the viral load data posed a limitation because more data points were needed to undertake segmented regression analysis. Furthermore, CD4 counts are still important indicators for initiating and monitoring ART (126) and HIV disease progression (127) in resource-limited settings such as South Africa.

Optimal BP control is difficult to achieve (36, 128-132). Although there was a reduction in the decreasing trend for BP control, the suboptimal control of BP observed in the pilot facilities implies that the purpose for which the ICDM model was initiated - to leverage HIV programmes, tools and systems to scale up services for NCDs - is yet to be fully achieved. The failure to achieve optimal BP control in the study setting may in part be attributed to the condition of the health system and individual factors.

Four health system factors may have negatively impacted optimal BP control in this study. First, a study conducted at the time the ICDM model was initiated revealed that South Africa's public health sector vertical HIV programme was not administratively integrated with the horizontal general health system (18). Horizontal managers at the district and sub-district levels exercised

little authority in using HIV data, while vertical managers used HIV data in silos within the HIV sub-programmes (18). Therefore, full administrative or operational integration of HIV services with those of NCDs may be far from being achieved. Secondly, a quantitative component of our broader study (Ameh et al., under review) showed that five of the eight dimensions of care (referral system, defaulter tracing, prepacking of drugs, appointment system, and long patient waiting time) identified as the priority areas in the ICDM model were not significantly associated with good quality of care in the pilot facilities. These priority areas are the components of the HIV programme that are being leveraged to improve the quality of services for NCDs in the ICDM model. It is recommended that the ICDM model programme managers and service providers in the health facilities should focus on improving the quality of care in these priority areas for better health outcomes for NCD patients. The third reason for poor BP control may have been due to ineffective titration of treatment, as was reported by Basu et al. in the SAGE study (128).

Finally, the qualitative component of our broader study showed that facility managers and patients reported that nurses were overburdened by an increased workload resulting from integrated services. Furthermore, staff shortage, malfunctioning blood pressure machines and antihypertensive drug stock-outs were reported by patients and facility managers in these facilities (Ameh et al., under review). These suboptimal structure- and process-related factors could be considered unintended consequences of the ICDM model that may have resulted in suboptimal blood pressure control. Achieving optimal health outcomes in the ICDM model will require strengthening the health system in South Africa. Therefore, health system interventions that focus on improving performance of the structural/hardware or social/software components

of the health system's building blocks (e.g. governance, human resources, service delivery and medicines and technologies) are needed to strengthen South Africa's PHC system in which the ICDM model is embedded (44).

Individual-level factors that may have contributed to sub-optimal BP control in our study included ignorance of the complications of high BP; obesity and physical inactivity (130); poor adherence to pharmacological (131, 132) and non-pharmacological treatment; and low socio-economic status (132). This suggests that South Africa's health system needs to be strengthened through a people-centred model that addresses increased awareness of health promoting activities and the complications of poor compliance with treatment; and better patient self-management (44).

Although proportionate sampling was done using the facility rosters, the study arms were different in age distribution with the pilot facilities predominantly composed of people 50 years and older, whereas, the comparison facilities were made up of people younger than 50 years. This age difference may have accounted for the higher number cases of hypertension patients in the pilot facilities and more HIV patients in the comparison facilities. The difference in the age structure was standardised in the data analysis by the use of propensity score matching in order to minimise the potential for biased results.

Based on empirical evidence from the data, I am not aware of factors that may have accounted for the drop in the probability of controlling CD4 counts and BP before the implementation of the ICDM model in both study arms. Health system factors common to both study arms may have been responsible for the declining control of CD4 counts and BP because these facilities were being managed by the same administrative and managerial structures in the municipality. Further research is needed to better understand the factors predicting the poor control of CD4 counts and BP before the implementation of the ICDM model. The decline in the control of CD4 counts and BP in the pilot facilities was steeper than the decline in the comparison facilities. This may have been due to a crowding-out of routine training activities which typically occur before or during the implementation of an intervention programme as was the case in the pilot facilities (44).

My doctoral study was the first facility-based non-interventional research to be conducted in the Agincourt HDSS. Observational work (e.g. monitoring of vital events and residency status) has been ongoing in the Agincourt HDSS site since 1992. These studies focus on different stages along the life course; evaluation of national policy at population, household and individual levels; and examination of household responses to external shocks and their effects on health and well-being. More recently, population-based trials promoting psychosocial well-being, preventing HIV transmission and reducing metabolic risk of metabolic diseases have targeted children and adolescents (61, 63). It is important to underline that although the population receiving treatment in the pilot facilities has been under surveillance for nearly two decades, the impact of the Agincourt HDSS on the operations of the health facilities is minimal because the MRC/Wits Agincourt Unit does not manage the ICDM pilot facilities.

In this study, comparative data were not available on staffing and patient load in the ICDM pilot and comparison facilities. However, analysis of the qualitative data showed that patients reported malfunctioning BP machines and antihypertensive drugs stock-outs, while stock-outs of ART were rarely reported (Ameh et al., under review). This may have accounted for the difference in the nature of care relating to the control of CD4 counts and blood pressure.

Patients who received care in the ICDM pilot facilities had a different age structure and chronic disease profile from those in the comparison facilities. The majority of those in the ICDM pilot sites were hypertensive and ≥ 50 years while the majority of the study participants in the comparison facilities were below < 50 years of age and living with HIV. These observed differences in age and disease profiles could be a reflection of the dynamics between age and labour patterns. Three of the five communities served by the comparison facilities have contiguous boundaries with semi-urban towns; hence, the attraction of a young labour workforce to these towns. This sets the stage for young people residing permanently in the aforementioned three villages to travel daily or migrate temporarily to work in these semi-urban towns. Temporary migration of this nature has been reported to be associated with HIV infection (71), potentially accounting, therefore, for the higher number of younger people living with HIV in the comparison facilities. This is in contrast to the typically rural communities served by the ICDM pilot facilities. Out-migration from these communities, which is predominantly accounted for by younger people in the 35-54 age group, may have resulted in a disproportionately higher number of older people permanently resident in these rural communities (63). The higher prevalence of hypertension among the patients who received care in the ICDM model facilities may have been due to the reported trend in out-migration from the communities served by these facilities. A

previous study in these rural communities also reported a high prevalence of cardiovascular diseases (98) which corroborates the findings of our research.

5.4 Linkages between study findings and conceptual framework

The “Vunene study” findings revealed how the roles and activities of relevant stakeholders and patient-nurse interactions influenced patients’ perception of the quality of care at the meso-level. Patients thought that half of the 17 dimensions of care offered in the ICDM pilot facilities were of good quality. An objective assessment of patients’ health outcomes at the micro-level showed a decrease in the downward trajectory in the control of CD4 counts and blood pressure observed in the period before the implementation of the model. Policy analysis at the macro-level to examine the role of an ICDM policy in creating an enabling environment towards improved quality of care and patients' health outcomes was not feasible and needs further research.

5.5 A critical appraisal of Avedis Donabedian’s theoretical framework

Although Donabedian’s unidirectional framework continues to be the dominant touchstone paradigm for assessing the quality of health care, it has been described as too linear to recognise complex interactions between SPO constructs (59). Donebedian’s critics argue that his theory fails to incorporate patient characteristics which are important precursors in the evaluation of the quality of health services (133). However, these limitations do not affect the validity of our study for the following reasons. First, the linearity of Donabedian’s theory forms the basis of our study which assesses the linearity of the relationships between structure, process, and outcome constructs through the specified unidirectional, mediation and reciprocal pathways. The linearity of Donabedian’s theory would have been a limitation in our study if we sought to determine non-linear relationships between SPO constructs . Regarding the limitation of Donabedian’s theory

not accounting for patients' socio-demographic characteristics, it is important to note that patients' characteristics cannot be categorised as dimensions of care under SPO constructs in the ICDM model. This is because patients' characteristics do not fit into Donebedian's definition of SPO constructs and therefore have no role to play in explaining Donabedian's theory of quality of care; hence, the rationale for selecting his theoretical framework for evaluating the quality of care in the ICDM model.

5.6 Study limitations

Limitations of these studies have been categorised into selection and measurement bias.

5.6.1 Selection bias

Exclusion of people younger than 50 years of age, the age category most at risk of HIV/AIDS may have resulted in the low prevalence of self-reported HIV/AIDS in the healthcare utilisation study. There were differences between responders and non-responders in the HCU sub-study. Presenting the data for responders could be a source of selection bias. In the ICDM model study, inferences could not be made about the (dis)satisfaction of other professional nurses with services in the ICDM model, due to the small number of operational managers who were interviewed. All the studies in this thesis were conducted in a rural municipality of South Africa and our findings may not be reflective of PHC facilities in urban municipalities in Gauteng, Mpumalanga and North West provinces where the model is also being piloted.

5.6.2 Measurement bias

In the healthcare utilisation study, there may have been recall bias among study participants in reporting their experiences with healthcare in the period of 12 months before the survey was conducted. Although the qualitative research helped to identify contextual factors that could

contribute to understanding the quality of care provided in the ICDM model for the purpose of generating recommendations for policy and practice, it does not allow us to establish cause and effect relationships. Study findings in the secondary analysis of health outcome data retrieved from clinic records must be interpreted in the light of the limitations imposed by the use of routine healthcare data. More specifically, some facility-level data were incomplete or unavailable due to one or more of the following reasons: (1) missing laboratory results of CD4 counts and viral load and (2) missing records of BP measurements due to BP machines being out of order. Other limitations included the paucity of information on facility-level factors such as comparative data on staffing, patient load, medication supply chain, and our inability to obtain at least eight data time points (e.g. eight months) before the implementation of the ICDM model due to the unavailability of notebooks in which patients' clinical information were recorded. Most of these home-based notebooks were not in the facility records before January 2011 and may have been lost or misplaced during the process when patients transported the notebooks (in transit) between the homes and the health facilities.

5.7 Study strengths and contribution to knowledge

To the best of my knowledge, this is the first study in sub-Saharan Africa to evaluate the quality of care in the ICDM model and assess the effectiveness of the model in improving key health outcome indicators of patients receiving treatment for hypertension and HIV in PHC facilities. We are not aware of any studies that have applied Donabedian's theoretical framework for evaluating the ICDM model which is a major initiative of the NDoH in South Africa. Hence, this thesis contributes to the national and global debates on an integrated health systems approach for the management of chronic diseases.

In my view, the use of quantitative and qualitative methods to triangulate the data and methods was a major methodological strength of this thesis. Two types of triangulation were implemented in the studies that make up this thesis: methodological triangulation, in which more than one method (quantitative and qualitative) was used to gather data; and data triangulation involving collecting data from different population subsets at different time and space (134). A combination of methodological and data triangulation enhanced validity of the quality of care study in this thesis.

The qualitative method used was well suited to the study because of the dearth of contextual qualitative data on provider-patient perspectives on the quality of care in the ICDM model. The use of a combined deductive and inductive approach in collecting and analysing the qualitative data was also a major feature in this thesis.

5.8 Conclusion

HIV and NCDs were the main health problems and predictors of HCU in the population aged 50 years and older prior to the introduction of the ICDM model in 2011, suggesting the prioritisation of public healthcare services for chronic diseases among older people in this rural setting. In the quantitative study on quality of care, five of the eight priority areas used as leverage for the control of NCDs (referral, defaulter tracing, prepacking of medicines, clinic appointments and waiting time) did not reflect their intended constructs; hence, the need to strengthen services in these areas. In the qualitative study on quality of care, nurses and patients reported occasional anti-hypertension drug stock-outs, malfunctioning blood pressure machines, staff shortage, dysfunctional prepacking of drugs and long patient waiting time. Nurses thought

there was reduced HIV-related stigma because patients receiving treatment for HIV and NCDs attended the same clinic, whereas patients reported HIV stigma due to defaulter tracing activities of home-based carers in the community. Nurses and patients reported diverging opinions on defaulter tracing activities rigid clinic appointments and defaulter tracing activities. Nurses reported the use of traditional haelers by patients

Although the ICDM model did not reverse the downward trajectory in the control of CD4 counts and BP, it saw in the post-intervention period a decline in the worsening trend in the control of CD4 counts and blood pressure observed in the pre-ICDM model period. This implies that more time is needed to more effectively leverage the priority areas in the HIV treatment programme for NCDs in order to produce an upward trajectory in the control of patients' CD4 counts and BP. Suboptimal BP control observed in this study may have been due to poor quality of care in the identified priority areas of the ICDM model and unintended consequences of the model such as work overload, staff shortage, malfunctioning BP machines and anti-hypertension drug stock-outs.

An ideal clinic in a re-engineered PHC system that complies with the national core quality standards through provision of good quality chronic disease care (meso-level) that leads to optimal patient's health outcomes (micro-level) could be achieved in South Africa if the aforementioned health system challenges are adequately addressed.

5.9 Implications for future research

Future research is needed to better understand factors other than the ICDM model that may be associated with changes in patients' health outcomes. Further research is also needed to understand how the ICDM model is operationalised in urban PHC facilities and how effectively it serves to address tuberculosis, a chronic communicable disease, and other NCDs (e.g. diabetes, chronic obstructive pulmonary diseases, asthma, epilepsy and mental illnesses) prioritised in the ICDM model.

5.10 Policy implications

Although the ICDM approach appears to have reduced a declining trend for CD4 counts and blood pressure control in our study setting, the primary purpose of using the HIV programme as leverage for scaling up services for NCDs, specifically hypertension, is yet to be fully achieved. This is critical for the nationwide implementation of the ICDM model in all PHC facilities and the wider policy reforms around the PHC re-engineering and "Operation Phakisa Ideal Clinic Realisation and Maintenance Programme" currently underway in South Africa. Hence, there is a need to more effectively leverage the vertical HIV treatment programme for NCDs through the role and activities of the WBOTs (Ward-based Outreach Teams) and DCSTs (District Clinic Specialist Teams). The WBOTs will need to perform more screenings to increase the awareness of hypertension and other NCDs in the population and interact more directly with the community to ensure continuity of care. The DCSTs have to more effectively supervise the processes of care and perform more clinical audits of services provided by the ward-based outreach and integrated school health teams.

Another key finding from this research is that health system factors such as malfunctioning blood pressure machines, staff shortage, and anti-hypertension drug stock-outs need to be addressed in order to achieve the expected optimal benefits of the ICDM model in improving patients' health outcomes. System-level interventions targeting specific building blocks of the health system such as governance, human resources, service delivery, and medicines and technologies are needed to strengthen South Africa's PHC system in which the ICDM model is embedded.

The findings of the body of work in this thesis could have policy relevance for Uganda, Kenya, Ethiopia, Swaziland and perhaps other LMICs currently undertaking proof of concept studies to demonstrate the feasibility of planning and implementing an integrated chronic disease care model.

Appendix 1: Short-form of Patient Satisfaction Questionnaire (PSQ-18) (80)

Listed below are some things people say about healthcare. Please read each one carefully, keeping in mind the healthcare you are receiving now. (If you have not received care recently, think about what you would expect if you needed care today.) We are interested in your feelings, good and bad, about the healthcare you have received. The phrase "healthcare provider" includes physicians, physician assistants and nurse practitioners.

How strongly do you AGREE or DISAGREE with each of the following statements? (Circle One Number on Each Line)

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
1. Healthcare providers are good about explaining the reason for medical tests (P1).					
2. I think my healthcare provider's office has everything needed to provide complete medical care (S1).[a]					
3. The healthcare I have been receiving is just about perfect (O1).[b]					
4. Sometimes healthcare providers make me wonder if their diagnosis is correct (O3).					
5. I feel confident that I can get the healthcare I need without being set back financially (D1).					
6. When I go for healthcare, the provider is careful to check everything when treating and examining me (P11).					
7. I have to pay for more of my healthcare than I can afford (D2).					
8. I have easy access to the medical specialists I need (P5 & P6).[c]					
9. Where I get healthcare, people have to wait too long for emergency treatment (O4).					
10. Healthcare providers act too businesslike and impersonal toward me (P3).[d]					
11. My healthcare provider treats me in a very friendly and courteous manner (P4).					
12. Those who provide my healthcare sometimes hurry too much when they treat me (P13).					
13. Healthcare providers sometimes ignore what I tell them (P2).					
14. I have some doubts about the ability of the healthcare providers who treat me (O5).					
15. Healthcare providers usually spend plenty of time with me (P12).					
16. I find it hard to get an appointment for healthcare right away (P14).					
17. I am dissatisfied with some things about the healthcare I receive (O2).[e]					
18. I am able to get healthcare whenever I need it (S4).					

[a]Rephrased to reflect availability of functional equipment for chronic disease care (structure - S1)
[b]Rephrased to reflect satisfaction with coherence of integrated chronic disease care (outcome - O1)
[c]Statement changed to reflect referral of patients to the hospitals (process - P5 and P6)
[d]Statement changed to reflect professional conduct of the nurses during clinical duties (process - P3)
[e]Rephrased to reflect dissatisfaction with coherence of integrated chronic disease care (outcome - O2)

Appendix 2a: Sampling of the study participants in the ICDM pilot facilities

Health facilities	Number of patients recorded in the clinic appointment roaster in July 2013.				***Step 1 sampling**: proportionate sampling from the health facilities	****Step 2 sampling**: proportionate sampling by chronic disease status		
	ART	HPT	DM	Total		ART	HPT	DM
A	724	642	-	1366	165	88	77	0
B	146	715	-	861	104	18	86	0
C	41	325	7	373	45	5	39	1
D	84	274	6	364	44	10	33	1
E	66	50	-	116	14	8	6	0
F	50	215	-	265	32	6	26	0
G	49	208	-	257	31	6	25	0
Total	1160	2429	13	3602	435	141	292	2

[#]***ART, HPT and DM = HIV/AIDS, hypertension and diabetes mellitus patients, respectively.***

***Step 1: proportionate sampling for each health facility was achieved by multiplying the sampling fraction by the total number of patients in each health facility**

Sampling fraction = 435/3602 = 0.1207

Where 435 = calculated study sample size and 3602 = total sampling frame

Example of proportionate sampling for clinic A: 0.1207 x 1366 = 165, where 1366 is the total number of patients in health facility A.

****Step 2: proportionate sampling in each health facility**

Example of proportionate sampling in health facility A

53% (724/1366) and 47% (642/1366) of the total number of patients in health facility A were HIV and hypertension patients, respectively. Of the 165 patients recruited in health facility A, 53% (n=88) were HIV patients and 47% (n=77) were hypertension patients.

Appendix 2b: Sampling of the study participants in the comparison facilities

Health facilities	Number of patients recorded in the clinic appointment roaster in July 2013.				***Step 1 sampling**: proportionate sampling from the health facilities	****Step 2 sampling**: proportionate sampling by chronic disease status		
	ART	HPT	DM	Total		ART	HPT	DM
A	365	115	-	480	58	44	14	0
B	231	175	-	406	49	28	21	0
C	107	125	-	232	28	13	15	0
D	233	156	-	389	47	28	19	0
E	1426	713	22	2161	261	173	86	2
Total	2362	1284	22	3668	443	286	155	2

[#]***ART, HPT and DM = HIV/AIDS, hypertension and diabetes mellitus patients, respectively.***

***Step 1: proportionate sampling for each health facility was achieved by multiplying the sampling fraction by the total number of patients in each health facility**

Sampling fraction = 443/3668 = 0.121

Where 443 = calculated study sample size and 3668 = total sampling frame

Example of proportionate sampling for clinic A: 0.121 x 480 = 58, where 480 is the total number of patients in health facility A.

****Step 2: proportionate sampling in each health facility**

Example of proportionate sampling in health facility A

76% (365/480) and 24% (115/480) of the total number of patients in health facility A were HIV and hypertension patients, respectively. Of the 58 patients recruited in health facility A, 76% (n=44) were HIV patients and 24% (n=14) were hypertension patients.

Appendix 3: The adapted satisfaction questionnaire administered to patients attending health facilities in the Agincourt sub-district in 2013

Labels	Statements
Structure	
S1	I think my healthcare providers have functional equipment to provide complete chronic disease care
S2 +	I think this health facility has regular supply of medicines for the treatment of my illness[a]
S3 -	I think this health facility does not have regular supply of medicines for the treatment of my illness[a]
S4	I am able to get healthcare whenever I need it
Process	
P1	Healthcare providers are good about explaining the reason for medical tests
P2	Healthcare providers sometimes ignore what I tell them
P3	Healthcare providers are professional in the conduct of their clinical duties
P4	My healthcare providers treat me in a very friendly and courteous manner
P5 +	Healthcare providers usually refer me to the hospital when there is need for the doctor to review me[a]
P6 -	Healthcare providers do not refer me to the hospital when there is need for the doctor to review me[a]
P7 +	When I miss clinic appointment(s), the Community (volunteer) Health Workers visit my house to ask why I did not come to the clinic[a]
P8 -	The Community (volunteer) Health Workers do not visit my house when I miss clinic appointment(s)[a]
P9 +	Healthcare providers prepack my drugs the day before my clinic appointment(s)[a]
P10 -	Healthcare providers do not prepack my drugs the day before my clinic appointment(s)[a]
P11	When I visit the clinic, the providers are careful to check everything when treating and examining me
P12 +	Healthcare providers usually spend plenty of time with me
P13 -	Those who provide my healthcare sometimes hurry too much when they treat me
P14	I find it hard to get an appointment when I need it[b]
Outcome	
O1 +	I am satisfied with the quality of coherent integrated chronic disease care that I receive[b]
O2 -	I am dissatisfied with the quality of coherent integrated chronic disease care that I receive[b]
O3	Sometimes healthcare providers make me wonder if their diagnosis is correct
O4	When I come to receive healthcare, i have to wait for too long to access services[b]
O5	I have some doubts about the ability of the healthcare providers who treat me
Dropped	
D1 +	I feel confident that I can get the healthcare I need without being set back financially
D2 -	I have to pay for more of my healthcare than I can afford

[a]Priority areas of the ICDM model in South Africa

[b]Priority areas of the ICDM model in South Africa originally contained in the PSQ-18

+ sign indicates positive statements phrased in opposite directions

- sign indicates negative statements phrased in opposite directions

Dropped: statements excluded from the adapted PSQ because of free PHC service offered in South Africa

Appendix 4: The adapted satisfaction questionnaire administered to the operational managers of the health facilities in the Agincourt sub-district in 2013

Labels	Statements
Structure	
S1	I think the healthcare providers have functional equipment to provide complete chronic disease care
S2 +	I think this health facility has regular supply of medicines for the treatment of chronic diseases[a]
S3 -	I think this health facility does not have regular supply of medicines for the treatment of chronic diseases[a]
S4	The patients are able to get healthcare whenever they need it
Process	
P1	Healthcare providers are good about explaining the reason for medical tests
P2	Healthcare providers sometimes ignore what patients tell them
P3	Healthcare providers are professional in the conduct of their clinical duties
P4	Healthcare providers treat chronic disease patients in a very friendly and courteous manner
P5 +	Healthcare providers usually refer patients to the hospital when there is need for the doctor to review them[a]
P6 -	Healthcare providers do not refer patients to the hospital when there is need for the doctor to review them[a]
P7 +	When patients miss clinic appointment(s), the Community (volunteer) Health Workers visit their houses to ask why they did not come to the clinic[a]
P8 -	The Community (volunteer) Health Workers do not visit patients' houses when they miss clinic appointment(s)[a]
P9 +	Healthcare providers prepack patients' drugs the day before their clinic appointment(s)[a]
P10 -	Healthcare providers do not prepack patients' drugs the day before their clinic appointment(s)[a]
P11	When patients visit the clinic, the providers are careful to check everything when treating and examining them
P12 +	Healthcare providers usually spend plenty of time with patients
P13 -	Those who provide healthcare sometimes hurry too much when they treat patients
P14	Patients find it hard to get an appointment when they need it[b]
Outcome	
O1 +	I am satisfied with the quality of coherent integrated chronic disease care patients receive[b]
O2 -	I am dissatisfied with the quality of coherent integrated disease care patients receive[b]
O3	Sometimes healthcare providers make me wonder if their diagnosis is correct
O4	When patients come to receive healthcare, they have to wait for too long to access services[b]
O5	I have some doubts about the ability of the healthcare providers who treat the patients

[a]Priority areas of the ICDM model in South Africa

[b]Priority areas of the ICDM model in South Africa originally contained in the PSQ-18

+ sign indicates positive statements phrased in opposite directions

- sign indicates negative statements phrased in opposite directions

Appendix 5: Antiretroviral and antihypertensive drugs used in the study settings (96)

ART initiation and the criteria for initiation		
Regimen	**Criteria**	**ART**
1	1. CD4 count is ≤ 350 2. Viral load < 400 3. Stage 3 or 4 disease, pregnant or breastfeeding women regardless of CD4 count or viral load	Tenofovir (TDF), Lamivudine (3TC) and Efavirenz (EFV) OR Fixed Drug Combination (FDC) - Tenofovir/Emtricitabine/Efavirenz **NB:** 1. Efavirenz (EFV) is replaced with Nevirapine (NVP) for patients with depression or psychosis. 2. Regimen 1 is replaced with Zidovudine (AZT) if pregnant with depression, psychosis, known kidney disease, disease, hypertension or ≥ 2+ proteinuria and refer patient to doctor.
2	Viral load > 1000 on two occasions	Lopinavir/ritonavir (LPV/r), Lamivudine (3TC) and AZT (if currently using TDF) OR TDF [if currently using AZT or Stavudine (d4T)]
Antihypertensive and adjuvant drugs		
1	The most commonly prescribed antihypertensive drugs	Hydrochlorothiazide, Enalapril, Amlodipine and atenolol.
2	Adjuvant drugs prescribed for hypertension patients	Daily dose of simvastatin if the patient had Cardiovascular Disease (CVD) or a CVD risk > 20% Daily aspirin dose if patients had CVD and/or diabetes

**Criteria for referral to doctor: abnormal blood results, poor adherence, TB symptoms depression or psychosis*

Appendix 6: Number of monthly visits of the sampled patients who utilised primary health care facilities from January 2011 to June 2013 in the Bushbuckridge municipality

Years-Months	ICDM pilot facilities		Comparison facilities	
	Hypertension (n=210)	HIV (n=141)	Hypertension (n=91)	HIV (n=282)
2011				
January	88	17	18	15
February	136	23	51	16
March	137	19	52	12
April	110	10	23	18
May	102	29	28	31
June	102	69	40	32
July	96	26	54	11
August	107	12	41	18
September	118	21	27	18
October	136	21	50	36
November	119	16	29	16
December	105	18	28	30
2012				
January	109	15	35	25
February	141	18	33	12
March	123	39	53	25
April	114	13	41	41
May	116	22	36	53
June	124	12	29	42
July	126	17	24	41
August	95	13	26	53
September	104	17	22	40
October	117	15	25	25
November	97	23	31	37
December	113	15	23	62
2013				
January	122	19	35	60
February	128	24	26	34
March	101	22	32	40
April	95	26	22	58
May	91	34	32	38
June	92	12	28	29

*Number of patients managed for hypertension or HIV

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Original Papers

Paper I

Soter Ameh, Francesc Xavier Gómez-Olivé, Kathleen Kahn, Stephen M. Tollman and Kerstin Klipstein-Grobusch. Predictors of health care use by adults 50 years and over in a rural South African setting. Glob Health Action. 2014 Aug 1;7:24771. doi: 10.3402/gha.v7.24771. eCollection 2014

Conference proceeding

I. Soter Ameh, Francesc Xavier Gómez-Olivé, Kathleen Kahn, Stephen M Tollman and Kerstin Klipstein-Grobusch. Predictors of health care utilisation by adults 50 years and above in a rural South African population. An oral presentation at the 9th annual conference of the Public Health Association of South Africa (PHASA), 24-27th September 2013, Cape Town, South Africa.

Global Health Action

COACTION

ORIGINAL ARTICLE

Predictors of health care use by adults 50 years and over in a rural South African setting

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Background: South Africa's epidemiological transition is characterised by an increasing burden of chronic communicable and non-communicable diseases. However, little is known about predictors of health care use (HCU) for the prevention and control of chronic diseases among older adults.

Objective: To describe reported health problems and determine predictors of HCU by adults aged 50+ living in a rural sub-district of South Africa.

Design: A cross-sectional study to measure HCU was conducted in 2010 in the Agincourt sub-district of Mpumalanga Province, an area underpinned by a robust health and demographic surveillance system. HCU, socio-demographic variables, reception of social grants, and type of medical aid were measured, and compared between responders who used health care services with those who did not. Predictors of HCU were determined by binary logistic regression adjusted for socio-demographic variables.

Results: Seventy-five percent of the eligible adults aged 50+ responded to the survey. Average age of the targeted 7,870 older adults was 66 years (95% CI: 65.3, 65.8), and there were more women than men (70% vs. 30%, $p < 0.001$). All 5,795 responders reported health problems, of which 96% used health care, predominantly at public health facilities (82%). Reported health problems were: chronic non-communicable diseases (41% – e.g. hypertension), acute conditions (27% – e.g. flu and fever), other conditions (26% – e.g. musculoskeletal pain), chronic communicable diseases (3% – e.g. HIV and TB), and injuries (3%). In multivariate logistic regression, responders with chronic communicable disease (OR = 5.91, 95% CI: 1.44, 24.32) and non-communicable disease (OR = 2.85, 95% CI: 1.96, 4.14) had significantly higher odds of using health care compared with those with acute conditions. Responders with six or more years of education had a two-fold increased odds of using health care (OR = 2.49, 95% CI: 1.27, 4.86) compared with those with no formal education.

Conclusion: Chronic communicable and non-communicable diseases were the most prevalent and main predictors of HCU in this population, suggesting prioritisation of public health care services for chronic diseases among older people in this rural setting.

Keywords: *older adults*; *chronic diseases*; *predictors*; *health care use*; *Agincourt*; *South Africa*

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Population ageing has been described by the United Nations as one of the most distinctive demographic events of the 20th century, and an important population challenge in the 21st century. There were, respectively, 200 and 600 million older people (60 years and over) in 1950 and 2000, and it has been projected that there will be two billion older people globally in 2050. This depicts tripling of the number of older people in

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two consecutive 50 years, particularly in lower- and middle-income countries (LMIC) that already hosted 62% of the world's older population in 2000 (1).

In Africa, older people constituted 5.1% of the total population at the beginning of the 20th century. With the exception of Réunion (9.9%) and Mauritius (9%), the population of older people in South Africa (7.3%) was higher than the 5.1% for the African continent at the turn of the 20th century (2). It has also been projected that the population of older people in South Africa will be more than one person in 10 by 2025 (3), due to ageing and scale-up of antiretroviral drugs (ARVs).

Although there is no United Nations (UN) standard numerical criterion for old age, the agreed cut-off for defining old age is generally 60 years and above (4). While the ageing process is a biological activity, it is also a construct that is dependent on how each society makes sense of it. The chronological age of 60 or 65 is said to be the beginning of old age in most developed countries because it is roughly equivalent to retirement age (5). In Africa, the majority of older people do not expect formal retirement or retirement benefits because they live in rural communities and earn a living outside the formal sector (4). Southern Africa is the region with the highest prevalence of HIV/AIDS in the African continent. Life expectancy has decreased from 61 years in 1990–1995 to 52 years in 2005–2010 in this region due to the impact of HIV/AIDS, and is it not expected to recover from the pre-1990 levels until 2045 (6).

The Minimum Data Set (MDS) project on Ageing – supported by the World Health Organization (WHO) and the U.S. National Institute on Ageing – has set 50 years and above as the cut-off to refer to the older population in Africa (4, 7). The same cut-off has been used in the Study on Global Ageing and Adult Health (SAGE) (8). Given this evidence and the fact that the global population of persons aged 50 and over is expected to increase from 21% to 30% in 2050 (6), this paper adopts 50 years and above to describe the population of older adults.

One of the expected consequences of ageing is increasing prevalence of non-communicable diseases (NCDs). In 2008, NCDs were responsible for two-thirds of all mortality worldwide – with 80% of these deaths occurring in LMICs (9). But quite unlike children and women whose health problems have been included in the agenda of the Millennium Development Goals (MDGs), those of older people were not clearly visible in most global policy dialogue until 2011 (10). This could have implications for health care services for older adults in LMICs (2), particularly if health systems are ill-prepared to deal with the long-term care for the management of chronic diseases (11).

The Constitution of the Republic of South Africa asserts that 'everyone has the right to have access to health care services' (12). Successive post-apartheid African National Congress-led governments have continued to consolidate on the pro-equity policies, many of which are elements of the Reconstruction and Development Programme (RDP). The health-related component of the RDP includes free Primary Health Care (PHC) for every person using public health facilities and waived income-related user fees in public hospitals (13). Consequently, there has been an improvement in the use of public PHC services by all age groups in South Africa (14, 15). Increasing use of health services has also been reported in Uganda and Mali, where cost sharing or user fees were discontinued (16, 17).

With the increasing prevalence of NCDs in South Africa mainly due to ageing, lifestyle changes and expanded ARV roll-out (11), increase in health care demands are anticipated. There is a plethora of evidence of increasing health problems (8, 11, 18–21) and self-reported health care use (HCU) among older people (18, 21). Yet, the predictors of HCU to tailor provision of services for the prevention and control of chronic diseases have not been addressed in detail. The purpose of this study was to describe the health problems of adults 50 years and over living in a rural South African population, and to determine the predictors of HCU.

Methodology

Study setting

The study used data from the MRC/Wits Agincourt Research Unit situated in Ehlanzeni Health District, Mpumalanga Province, South Africa. Trained local field workers collect and update vital events (births, deaths, and migration) on a yearly basis since 1992. This is complemented by additional information at different time intervals such as on HCU, education level, labour, migration, and household assets (22). The current population under follow-up in the MRC/Wits Agincourt Research study site as on 1st July 2011 was approximately 90,000 people in 16,000 households living in 27 villages (23).

The study area covers about 420 km^2. Tsonga is the most widely spoken language. One-third of the population are of Mozambican origin, having immigrated into South Africa mainly as war refugees in the early- and mid-1980s. Despite the current government's development initiatives, which have led to improved housing, access to potable water, electricity and social security grants, infrastructure in the area is still limited. Unemployment rates remains high, with 60% of labour migration being accounted for by men aged 35–54 years and an increasing proportion of labour migrants seen among young men and women (22). The pattern of labour migration has resulted in a disproportionately higher proportion of older women permanently resident in the area. There are eight health facilities in the study area: one public health centre, six government satellite

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clinics, and one private community health centre in a public–private partnership. There are three referral hospitals situated 25 and 45 km from the study setting (23).

Health service infrastructure

The government of South Africa decentralised the provision of health services by dividing the country into 53 health districts to ensure that citizens have access to a comprehensive package of PHC and district hospital services. In the South African PHC model, the nurse is the provider of services in the clinics and comprehensive health centres – which are the first point of entry to the health system. Located within the reach of rural, semi-rural, and urban communities, these facilities are the cornerstone of the public health system through provision of comprehensive and integrated 'preventive, promotional, curative and rehabilitation services' (24).

The range of services includes maternal and child-care, immunisation, family planning, treatment of sexually transmitted infections, minor trauma, and care for chronic diseases (e.g. diabetes and hypertension). Additional services provided by the health centres include 24-hour maternity services, accident and emergency services, up to 30 beds for observation for a maximum of 48 hours, a procedure room (not an operating theatre). With the exception of emergency cases which are referred to the hospitals (secondary level of care), the clinics and health centres offer services to ambulatory patients for 8 hours/day and 24 hours, respectively (24).

Study design and sampling

This was a cross-sectional study of all eligible older adults aged 50 years and older in the study site. Of the total 10,249 older adults registered in the 2009 census database, 7,870 persons with permanent residency status were eligible and targeted for the 2010 HCU survey. Eligibility criteria for the interviews were 1) residency status of 21 days or more before the survey for those prospective participants who moved out of the study site after the 2009 census and relocated to the study site before the 2010 survey and 2) availability of the prospective participants at home after two revisits by field workers (Fig. 1).

Training and quality control

Field workers were trained for two days in the administration of the HCU questionnaire, as part of preparation for the general census. Field work was closely supervised for a week, after which a new training session was run to review and tackle challenges. Quality control followed a four-step system where field workers, supervisors, quality checkers, and data entry clerks assured good quality of the data: 1) The field workers double-checked all questionnaires before leaving the household of the interviewee, and again at the office before submission to the supervisors. 2) The supervisors randomly checked the questionnaires for inconsistencies and blank questions before submitting to the quality checkers. 3) The quality checkers identified inconsistencies and other errors in the questionnaires before submitting to the data entry clerks. 4) Data entry clerks identified forms with errors during data entry and returned them to the field for correction, after which the whole process of quality control was engaged prior to final data entry.

The questionnaire for the 2010 adult HCU survey was based on a HCU questionnaire used previously in the site to gather information on the older adult population (18). The questionnaire was used to collect information on socio-demographic variables, reception of any type of social grant, access to medical aid, need for and access to health care, type of disease, disability and hospitalisation.

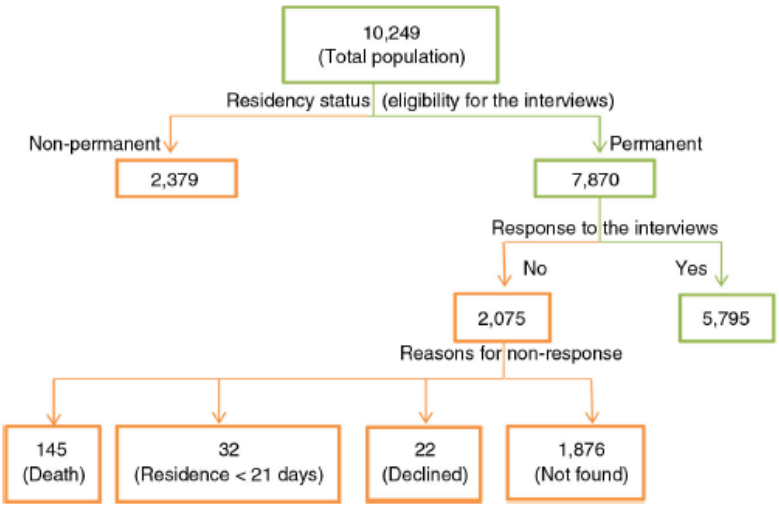

Fig 1. Sampling of eligible study participants.

Variables

Age in years was calculated on 1st August 2010 using the census date of birth for all potential participants. Responders were then categorised into 10-year age intervals: 50–59, 60–69, and 70+. Years of formal education were obtained from the 2007 MRC/Wits Agincourt Research Unit database, which was the latest updated information. Years of education were categorised according to the WHO levels of education: no formal education, <6 years, and ≥ 6 years. Medical aid was categorised to reflect responders with: 1) medical aid to visit the doctor, 2) health insurance for specific disease, 3) medical aid in employer's clinic/hospital, 4) access to free public hospital care, and 5) no medical aid/do not know. The variable 'last time health care was needed' was categorised into: 1) <1 year, 2) 1–3 years, 3) >3 years, and 4) never. In order to minimise errors due to recall bias, analysis of the predictors of HCU was restricted to responders who reported needing health care less than one year preceding the survey. The justification for using less than one year as the cut-off was based on the assumption that it is easier for responders to recall experiences with HCU in <1 year than in 1–3 years or >3 years.

Due to the influx of Mozambican refugees into Agincourt sub-district, nationality of origin was grouped into South Africans and Mozambicans. Socio-economic status (SES) was constructed from a household asset score in the 2009 census data. A principal component factor analysis technique was used to construct SES based on 30 variables on access to water and electricity, type and size of dwelling, appliances, ownership of livestock, and transport available. Subsequently, responders were categorised into quintiles in the ascending order of lowest, middle low, middle, middle high, and highest SES (25).

In order to ascertain employment status, the variable 'looking for a paid job' was categorised as yes or no. Reception of social grant was recorded as none, old age and disability. Hospitalisation, HCU (defined as the need for and access to health care, at least once, less than one year before the HCU survey in 2010) and disability were all binary variables (yes vs. no). Apart from acute conditions (fever and flu) and chronic communicable disease (HIV and TB), other types of illness were generated by recoding the reasons for visiting health facilities into NCD (hypertension, diabetes, stroke, sleep disorder, chronic pain in joints, depression, anxiety, cancer, and heart problems), injuries and others type of illness (musculoskeletal pain and nutritional deficiency). Actions taken during an illness episode less than one year before the survey were: visiting public and private health facilities. Other actions included practicing self-medication, consulting faith/traditional healers, and taking no action.

Statistical analysis

Validation checks were done during data entry in MicrosoftSQL server 2005 database. Data were extracted into Stata 12.0 (College Station, TX, USA) for statistical analysis. At p-value of 0.05, bivariate analysis compared responders who used health care services with those who did not. The cut-off point for univariate binary logistic regression analysis was set at p-value of ≤ 0.2 and variables that were significantly associated with HCU were used to model the multivariate binary logistic regression analysis (p-value ≤ 0.05). Multiple imputation by chained equations (MICE) approach for categorical variables was used to impute for 'socio-economic status' and 'looking for a paid job', which had 1.3% and 12.4% missing values, respectively. Multiple imputation is a simulation-based method for analysing incomplete variables. It predicts missing values as close as possible to the true ones by replacing missing data with probable values based on other available information (26). Imputation is considered to have less estimation bias and valid statistical inference than list-wise deletion because the latter leads to loss of statistical power (27).

Ethical clearance

Ethical clearance for the MRC/Wits Rural Public Health and Health Transitions Research Unit (Agincourt) was granted by the Committee for Research on Human Subjects (Medical) of the University of the Witwatersrand, Johannesburg, South Africa (Ref No. M960720).

Results

Comparison of responders with non-responders

Of the 10,249 adults aged 50 years and older registered in the rosters of the 2009 census, analysis was restricted to 7,870 (77%) older adults who were permanently resident in the study site. Of those, 5,795 responded to the HCU questionnaire while 32 people (0.4%) were ineligible because they lived in the study site less than 21 days before the survey. We were unable to contact 1,876 people (23.8%) who could not be found at home by the field worker after two revisits. Others who could not participate in the survey were 145 (1.9%) who died before the survey and 22 (0.3%) who declined participation. Response rate, defined as the number of respondents divided by the number of eligible subjects in the sample (28), was 75% [5,795/(7870–145)] (Fig. 1).

A comparison of 5,795 responders with 2,075 non-responders (Appendix A) showed that the responders were older (mean age = 66 vs. 64 years, $p<0.001$) and predominantly women (74.8% vs. 55.4%, $p<0.001$), whereas non-responders had more years of formal education (19.1% vs. 12.9%, $p<0.001$) and highest asset score (25.9% vs. 22.5%, $p<0.001$).

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Table 1. Health-seeking behaviour, by gender among 5,795 responders to the adult HCU survey in Agincourt sub-district in 2010

	Women	Men	Total	
Variables	n (%)	n (%)	n (%)	*p*
Last time health care was needed (n = 5,795)				
<1 year	3,863 (89.2)	1,193 (81.6)	5,056 (87.2)	
1–3 years	204 (4.7)	84 (5.7)	288 (5.0)	<0.001
>3 years	266 (6.1)	185 (12.7)	451 (7.8)	
Health problems needing health care <1 year before survey (n = 5,056)				
Non-communicable diseases[a]	1,649 (42.7)	422 (35.4)	2,071 (41.0)	
Acute diseases[b]	1,053 (27.3)	295 (24.7)	1,348 (26.6)	
Other diseases[c]	977 (25.3)	351 (29.4)	1,328 (26.3)	<0.001
Chronic communicable disease[d]	99 (2.6)	71 (6.0)	170 (3.4)	
Injuries	85 (2.5)	54 (4.5)	139 (2.7)	
Hospitalisation <1 year before survey (n = 5,056)				
No	2,866 (74.2)	846 (70.9)	3,712 (73.4)	0.025
Yes	997 (25.8)	347 (29.1)	1,344 (26.6)	
Disability requiring treatment <1 year before survey (n = 5,056)				
No	3,660 (94.8)	1,122 (94.0)	4,782 (94.6)	0.353
Yes	203 (5.2)	71 (6.0)	274 (5.4)	
Health care use by responders who needed health care <1 year before survey (n = 5,056)				
No	129 (3.3)	50 (4.2)	179 (3.5)	0.164
Yes	3,734 (96.7)	1,143 (95.8)	4,877 (96.5)	
Actions taken by responders who used health care <1 year before survey (n = 4,877)				
Public health facility	3,132 (83.9)	881 (77.1)	4,013 (82.3)	
Private health facility	239 (6.4)	120 (10.5)	359 (7.4)	
Other[e]	229 (6.1)	105 (9.2)	334 (6.9)	0.001
Self-medication	105 (2.8)	28 (2.5)	133 (2.7)	
Faith or traditional healer	14 (0.4)	3 (0.2)	17 (0.3)	
None	15 (0.4)	6 (0.5)	21 (0.4)	

[a]Hypertension, diabetes, stroke, sleep disorder, chronic pain in joints, depression, anxiety, cancer, heart problems.
[b]Fever and flu.
[c]Musculoskeletal pain.
[d]HIV and TB
[e]Change diet and exercise.

Analysis of socio-demographic characteristics, by gender, of the 5,795 adults who responded to the 2010 HCU survey showed significant differences in all variables, except nationality (data not shown). The men were older (mean age = 67 years, 95% CI 66.1; 67.1) than the women (mean age = 66 years, 95% CI 65.6; 66.3). The men also had more years of formal education (18% vs. 11.0%, $p < 0.001$) and higher asset score (26% vs. 22%, $p = 0.011$). More men than women were presently working for cash payment (17% vs. 12%, $p < 0.001$), looking for a paid job (12% vs. 10%, $p = 0.019$), and receiving an old age grant (61% vs. 59%, $p < 0.001$).

Reasons for using health care

Of the 5,795 respondents, 5,056 (87%) needed health care less than one year preceding the survey (Table 1). From these, 4,877 (96%) reported using health care services. The majority (82%) of the 4,877 who used health care visited public health facilities. In descending order, reasons for needing health care less than one year preceding the survey included: NCD −41%, acute conditions −27%, other conditions −26%, chronic communicable disease −3%, and injuries −3%. Of the 5,056 adults who needed health care less than one year preceding the survey, 1,344 (27%) were hospitalised, while 274 (5%) had disabilities. Table 1 also showed significant differences ($p < 0.001$) in health problems by gender, but there was no significant difference by gender in disability ($p = 0.353$) and HCU ($p = 0.164$).

Reasons for not using health care

Of the 5,056 responders who needed health care less than one year preceding the survey, 179 did not use health care

for the following main reasons: 86 (48%) did not think they were sick enough, 10 (6%) could not afford the cost of health facility visit, 13 (7%) thought that drugs or treatment was seemingly inadequate, and 12 (7%) reported being treated poorly during previous visits (Fig. 2).

Socio-demographic characteristics of adults who used public and private health facilities

Of the 4,452 adults who visited health care facilities less than one year preceding the survey, 4,089 (92%) and 363 (8%) visited public and private health care facilities, respectively (Table 2). Analysis to compare use of public and private health care facilities showed significant differences ($p < 0.05$) in all socio-demographic characteristics, except age ($p = 0.093$) and type of grant ($p = 0.914$).

Predictors of HCU

Table 3 showed the results of the binary logistic regression analysis of predictors of HCU (in- and out-patient care). In the univariate binary logistic regression analysis, gender, education, nationality, looking for a paid job, and type of illness predicted HCU. In the multivariate binary logistic regression model, adults with six or more years of education had a two-fold increased odds (OR = 2.13, 95% CI: 1.19, 3.82) of using health care compared to those with no formal education. Also in the multivariate model, compared with respondents with acute health conditions, those with chronic communicable diseases (OR = 5.91, 95% CI: 1.44, 24.32), NCDs (OR = 2.85, 95% CI: 1.96, 4.14) and other health problems (OR = 1.83, 95% CI: 1.27, 2.66) had significantly higher odds of use of health care.

Discussion

The main findings of this study showed a high prevalence of chronic communicable and NCDs, HCU in cases where it was needed and access to public health care facilities. The main factors predicting HCU were chronic communicable diseases and NCDs, as well as higher educational attainment.

In a setting with a high prevalence of HIV (29) and cardiovascular risk factors (30) among older people, it is expected that HCU by the study population will also increase. In the current study, almost all adults (96%) who needed health care less than one year preceding the survey used health facilities. The self-reported HCU in this study is about twice as high as previously reported for the national Study on Global Ageing and Adult Health (SAGE, 45%), which was commenced in the study site in 2006, four years earlier than this study was implemented (18).

The main health problems self-reported in the study population were (in descending order): chronic NCDs, acute diseases, other diseases, chronic communicable diseases, and injuries. Self-report of chronic communicable diseases such as HIV and TB was low (3%), and well below the 2010 national HIV prevalence (10.5%) (31),

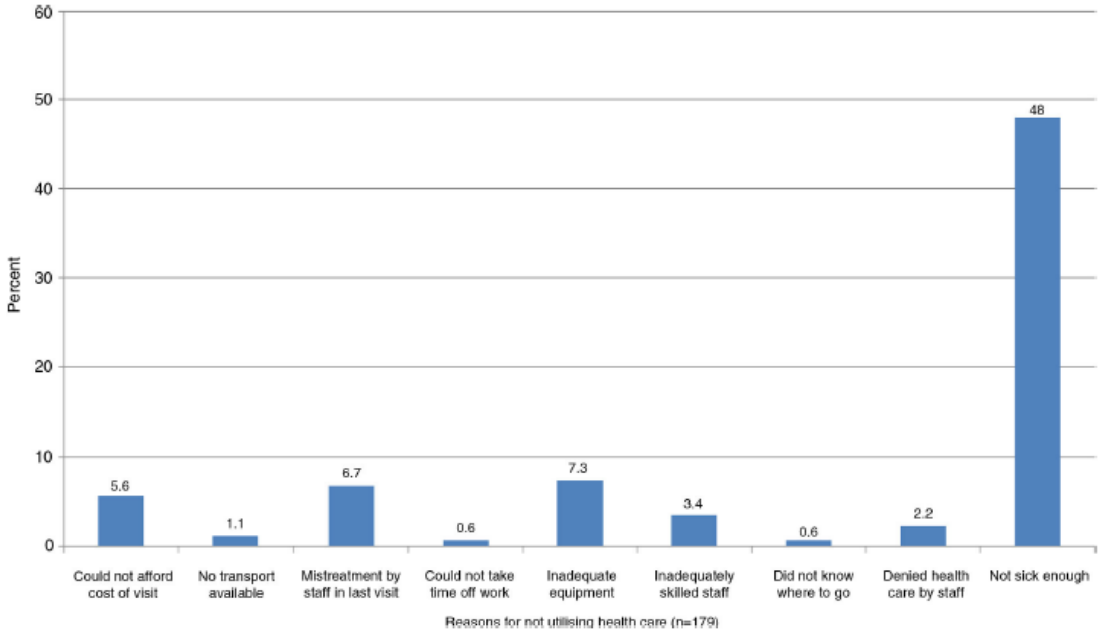

Fig 2. Reasons for not using health care among 179 adults who did not use health care less than one year before the survey in Agincourt sub-district, 2010.
NB: Reasons for not using health care were multiple response answers.

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Table 2. Socio-demographic characteristics and type of health care facility used in Agincourt sub-district in 2010

	Type of health care facility n (%)			
	Public	Private	Total	
Variables	(n = 4,089)	(n = 363)	(n = 4,452)	*p*
Age (years)				
50–59	1,365 (33.4)	140 (38.6)	1,505 (33.8)	
60–69	1,186 (29.0)	104 (28.6)	1,290 (29.0)	0.093
≥70	1,538 (37.6)	119 (32.8)	1,657 (37.2)	
Gender				
Female	3,186 (77.9)	243 (66.9)	3,429 (77.0)	<0.001
Male	903 (22.1)	120 (33.1)	1,023 (23.0)	
Education (completed years)				
No formal education	2,613 (63.9)	201 (55.4)	2,814 (63.2)	
≤6	979 (23.9)	73 (20.1)	1,052 (23.6)	<0.001
>6	497 (12.2)	89 (24.5)	586 (13.2)	
Nationality of origin				
South African	2,868 (70.1)	274 (75.5)	3,142 (70.6)	0.032
Mozambican	1,221 (29.9)	89 (24.5)	1,310 (29.4)	
Medical aid cover				
Free public hospital care	3,878 (94.8)	283 (77.9)	4,161 (93.5)	
Whenever I need to see the doctor	25 (0.6)	73 (20.1)	98 (2.2)	
Health insurance for specific disease	2 (0.1)	1 (0.3)	3 (0.1)	<0.001
Employer's clinic/hospital	168 (4.1)	4 (1.1)	172 (3.8)	
No medical aid/do not know	4 (0.1)	1 (0.3)	5 (0.1)	
Occupation				
Working for cash payment	493 (12.1)	74 (20.4)	567 (12.7)	<0.001
Not working for cash payment	3,596 (87.9)	289 (79.6)	3,885 (87.3)	
Socio-economic status				
Lowest	654 (16.0)	36 (9.9)	690 (15.5)	
Middle low	837 (20.5)	58 (16.0)	895 (20.1)	
Middle	904 (22.1)	66 (18.2)	970 (21.8)	<0.001
Middle high	768 (18.8)	66 (18.2)	834 (18.7)	
Highest	870 (21.2)	137 (37.7)	1,007 (22.6)	
Missing	56 (1.4)	0 (0.0)	56 (1.3)	
Looking for a paid job				
Yes	350 (8.6)	17 (4.7)	367 (8.2)	
No	3,277 (80.1)	279 (76.8)	3,556 (79.9)	<0.001
Missing	426 (11.3)	67 (18.5)	529 (11.9)	
Type of grant				
Old age	2,415 (59.1)	211 (58.1)	2,626 (59.0)	0.914
Disability	153 (3.7)	13 (3.6)	166 (3.7)	
None	1,521 (37.2)	139 (38.3)	1,660 (37.3)	

the 2005 Provincial estimate in pregnant women (32), and the local HIV prevalence among adults aged 50+ (17%) as recently estimated in the study site (29). This suggests significant under-reporting of HIV infection, possibly related to stigma associated with HIV infection (33).

The high prevalence of NCDs in the current study is a reflection of the on-going epidemiological transitional changes in South Africa, due to lifestyle changes and expanded ARV roll-out (11, 19, 20). Despite the high prevalence of NCDs, communicable diseases were a stronger predictor of HCU. This may be explained by the general low level of awareness of hypertension (34), which is the most prevalent NCD in the study site (30), possibly due to the lack of symptoms among diagnosed individuals.

Table 3. Predictors of health care use among 5,056 adults aged 50+ who used health care less than one year before the survey in Agincourt sub-district in 2010

	Health care use (N = 5,056)	
Variables	Univariate binary logistic regression model OR (80% CI)	Multivariate binary logistic regression model OR (95% CI)
Age (years)		
50–59	1	
60–69	1.05 (0.81, 1.35)	Not included in the final model
≥ 70	0.90 (0.71, 1.13)	
Gender		
Male	1	1
Female	1.27 (1.02, 1.57)	1.34 (0.96, 1.89)
Education (in completed years)		
No formal education	1	1
≤ 6	0.87 (0.70, 1.08)	0.85 (0.59, 1.21)
> 6	2.49 (1.63, 3.81)	2.49 (1.27, 4.86)
Nationality of origin		
Mozambican	1	1
South African	1.26 (1.03, 1.55)	1.07 (0.76, 1.49)
Occupation		
Presently working for cash payment	1	Not included in the final model
Not presently working for cash payment	1.09 (0.82, 1.44)	
Socio-economic status		
Lowest	1	
Middle low	0.84 (0.11, 1.17)	
Middle	0.79 (0.58, 1.09)	Not included in the final model
Middle high	1.12 (0.79, 1.59)	
Highest	1.11 (0.79, 1.55)	
Looking for a paid job		
No	1	1
Yes	0.70 (0.49, 0.99)	0.75 (0.44, 1.28)
Type of grant		
None	1	
Old age	1.07 (0.87, 1.31)	Not included in the final model
Disability	1.63 (0.84, 3.18)	
Health problems		
Acute conditions[a]	1	1
Chronic communicable disease[b]	5.51 (2.19, 13.87)	5.91 (1.44, 24.32)
Non-communicable diseases[c]	2.95 (2.32, 3.76)	2.85 (1.96, 4.14)
Injuries	2.97 (1.39, 6.37)	3.13 (0.97, 10.08)
Other	1.83 (1.44, 2.33)	1.83 (1.27, 2.66)

[a]Fever and flu.
[b]HIV and TB.
[c]Hypertension, diabetes, stroke, sleep disorder, chronic pain in joints, depression, anxiety, cancer, and heart problems.

The main reason why 179 study participants (most of whom reported NCDs) also reported not using health care was the 'thought of not being sick enough'. This evidence supports a study in Tanzania in which there was low use of health care services by hypertensive patients following a screening programme (34). Health education programmes that focus on continuing care through regular clinic visits could promote the health of people living with chronic diseases, who do not normally seek health care because of the thought of not being sick.

Chronic communicable diseases were the foremost predictor of HCU by responders in the study area, possibly

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due to the fact that those who reported being infected with HIV were already engaged in the health care system. Perhaps the reasons for which chronic communicable and NCDs predicted HCU were because of the high prevalence of these chronic conditions in the study setting (29, 30), and the fact that most of the HCU occurred in the public health facilities (the largest group used in the study setting). This may have implications for South Africa's PHC system, which has yet to adapt to long-term continuity of care for patients living with chronic diseases (11) and those not yet accessing chronic disease services.

Similar to other studies showing education as a strong predictor of use of facility-based maternal health services (35–37), and consistent with evidence in the literature showing that higher education is an important determinant for positive behaviour or motivation towards HCU (37), this study showed that having more years of education was associated with higher HCU. In agreement with the evidence that women are more likely than men to report their blood pressure status (18, 21), female respondents in this study were observed to be more likely than their male counterparts to use health care.

The main strength of this study was the use of a community-based survey of older adults to describe self-reported health problems and health-seeking behaviours, and to determine the predictors of HCU in a rural South African setting. The main limitation of this research was information bias. This was evidently the case in the under-reporting of chronic communicable diseases, such as HIV, due to stigmatisation. The response rate was 75%. Although a response rate of at least 60% in surveys of this type is reasonable (38), non-response bias may have influenced the results. This is in view of the evidence that non-responders differed significantly in part from responders. The characteristics (relatively younger men with more years of education and highest asset score) of these non-responders have been reported among labour migrants in another research in the study site (25). There may have been recall bias among these older adult study participants in reporting their experiences with health care less than one year before the survey. Unfortunately, there was no information on the number of in- and outpatient visits and hospitalisations. The availability of these data would have enabled the authors to further interrogate and interpret the context in which the number of health facility visits or hospitalisations may have accounted for the high level of the reported HCU.

Conclusion

Chronic communicable and NCDs were prevalent and also important predictors of HCU. This suggests the need to prioritise public health care services for chronic diseases among older people in rural South African settings. The on-going pilot implementation of the Integrated Chronic Disease Management model (39) in South Africa presents a unique opportunity to tailor health care services for the prevention and control of chronic diseases in the study area.

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Conflict of interest

There were no conflicts of interest between the authors and funders of this research.

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Appendix A: Socio-demographic characteristics of responders and non-responders to the 2010 health care use survey in Agincourt sub-district

Variables	Responders (n = 5,795)	Non-responders (n = 2,075)	Total (n = 7,870)	*p*
Age group (years)				<0.001
50–59	1,933 (33.3)	920 (44.4)	2,853 (36.2)	
60–69	1,703 (29.4)	515 (24.8)	2,218 (28.2)	
≥ 70	2,158 (37.3)	640 (30.8)	2,799 (35.6)	
Mean age in years	66.1 (65.8, 66.4)	64.0 (63.5, 64.5)	65.6 (65.3, 65.8)	
Gender				<0.001
Female	4,333 (74.8)	1,149 (55.4)	5,482 (69.7)	
Male	1,462 (25.2)	926 (44.6)	2,388 (30.3)	
Education (in completed years)				<0.001
No formal education	3,680 (63.5)	1,263 (60.9)	4,943 (62.8)	
≤ 6	1,369 (23.6)	415 (20.0)	1,784 (22.7)	
> 6	746 (12.9)	397 (19.1)	1,143 (14.5)	
Nationality of origin				0.052
South African	4,032 (69.6)	1,396 (67.3)	5,428 (69.0)	
Mozambican	1,763 (30.4)	679 (32.7)	2,442 (31.0)	
Socio-economic status				<0.001
Lowest	927 (16.0)	339 (16.4)	1,266 (16.1)	
Middle low	1,160 (20.0)	391 (18.8)	1,551 (19.7)	
Middle	1,239 (21.4)	359 (17.3)	1,598 (20.3)	
Middle high	1,091 (18.8)	421 (20.3)	1,512 (19.2)	
Highest	1,301 (22.5)	538 (25.9)	1,839 (23.4)	
Missing	77 (1.3)	27 (1.3)	104 (1.3)	
Medical aid cover				
Free public hospital care	5,422 (93.6)	–		
Whenever I need to see the doctor	118 (2.1)	–		
Health insurance for specific disease	7 (0.1)	–		
Employer's clinic/hospital	188 (3.2)	–		
No medical aid/do not know	60 (1.0)	–		
Occupation				
Not working for cash payment	5,016 (86.6)	–		
Working for cash payment	779 (13.4)	–		
Looking for a paid job				
Yes	508 (8.8)	–		
No	4,567 (78.8)	–		
Missing	720 (12.4)	–		
Type of grant				
Old age	3,437 (59.3)	–		
Disability	182 (3.1)	–		
None	2,176 (35.6)	–		

Paper II

Soter Ameh, Francesc Xavier Gómez-Olivé, Kathleen Kahn, Stephen M. Tollman and Kerstin Klipstein-Grobusch. Relationships between structure, process and outcome to assess quality of integrated chronic disease management in a rural South African setting: applying a structural equation model (Revised manuscript resubmitted, BMC Health Serv Res).

Conference proceedings

I. Soter Ameh, Francesc Xavier Gómez-Olivé, Kathleen Kahn, Stephen M. Tollman and Kerstin Klipstein-Grobusch. The quality of care in the integrated chronic disease management model: lessons learned from primary health care facilities in rural South Africa. An oral presentation at the Faculty of Health Sciences Research day, University of the Witwatersrand, 17th September 2014, Johannesburg, South Africa.

II. Soter Ameh, Francesc Xavier Gómez-Olivé, Kathleen Kahn, Stephen M. Tollman and Kerstin Klipstein-Grobusch. Satisfaction with the quality of care in the integrated chronic disease management model in rural South Africa. A poster presentation at the Faculty of Health Sciences Research day, University of the Witwatersrand, 17th September 2014, Johannesburg, South Africa.

III. Soter Ameh, Francesc Xavier Gómez-Olivé, Kathleen Kahn, Stephen M. Tollman and Kerstin Klipstein-Grobusch. The quality of care in the integrated chronic disease management programme in South Africa. A poster presentation at the 14th World Conference on Public Health, 11-15th February 2015, Kolkata, India.

IV. Soter Ameh, Francesc Xavier Gómez-Olivé, Kathleen Kahn, Stephen M. Tollman and Kerstin Klipstein-Grobusch. The relationships between structure, process and outcome as a measure of quality of care in the integrated chronic disease management model in rural South Africa: A structural equation model. An oral presentation at the 11th Annual Conference of the Public Health Association of South Africa (PHASA), 7-9th October 2015, Durban, South Africa.

V. Soter Ameh, Kerstin Klipstein-Grobusch, Eustasius Musenge, Kathleen Kahn and Francesc Xavier Gómez-Olivé. Effectiveness of an integrated chronic disease management model in improving patients' health outcomes in rural South Africa: controlled interrupted time-series and multilevel analyses. An oral presentation at the INDEPTH Network Scientific Conference, 11-13th November 2015, Addis Ababa, Ethiopia.

VI. Soter Ameh, Francesc Xavier Gómez-Olivé, Kathleen Kahn, Stephen M. Tollman and Kerstin Klipstein-Grobusch. The relationships between structure, process and outcome as a measure of quality of care in the integrated chronic disease management model in rural South Africa: A structural equation model. An oral presentation at the INDEPTH Network Scientific Conference, 11-13th November 2015, Addis Ababa, Ethiopia.

Relationships between structure, process and outcome to assess quality of integrated chronic disease management in a rural South African setting: applying a structural equation model

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Abstract

Background: South Africa faces a complex dual burden of chronic communicable and non-communicable diseases (NCDs). In response, the Integrated Chronic Disease Management (ICDM) model was initiated in Primary Health Care (PHC) facilities in 2011 to leverage the HIV/ART programme to scale-up services for NCDs, achieve optimal patient health outcomes and improve the quality of medical care. However, little is known about the quality of care in the ICDM model. The objectives of this study were to: i) assess patients' and operational managers' satisfaction with the dimensions of ICDM services; and ii) evaluate the quality of care in the ICDM model using Avedis Donabedian's theory of relationships between structure (resources), process (clinical activities) and outcome (desired result of healthcare) constructs as a measure of quality of care.

Methods: A cross-sectional study was conducted in 2013 in seven PHC facilities in the Bushbuckridge municipality of Mpumalanga Province, north-east South Africa - an area underpinned by a robust Health and Demographic Surveillance System (HDSS). The patient satisfaction questionnaire (PSQ-18), with measures reflecting structure/process/outcome (SPO) constructs, was adapted and administered to 435 chronic disease patients and the operational managers of all seven PHC facilities. The adapted questionnaire contained 17 dimensions of care, including seven dimensions identified as priority areas in the ICDM model - critical drugs, referral, defaulter tracing, prepacking of medicines, clinic appointments, waiting time, and coherence. A structural equation model was fit to operationalise Donabedian's theory, using unidirectional, mediation, and reciprocal pathways.

Results: The mediation pathway fit perfectly with the data (coefficient of determination=1.00). Structure correlated with process (0.40) and outcome (0.75). Given structure, process correlated

with outcome (0.88). Of the 17 dimensions of care in the ICDM model, three structure (equipment, critical drugs, accessibility), three process (professionalism, friendliness and attendance to patients) and three outcome (competence, confidence and coherence) dimensions were significantly associated with good quality of care.

Conclusion: While nine of 17 dimensions of care reflected good quality of care, dimensions of care on five (referral, defaulter tracing, prepacking of medicines, appointments, and patient waiting time) of the seven priority areas of the ICDM model were not associated with good quality of care; hence the need to strengthen services in these areas.

Keywords: Integrated Chronic Disease Management (ICDM) Model; Avedis Donabedian; Constructs; Quality of care; Satisfaction; Chronic communicable diseases; Non-communicable chronic diseases; Structural equation model; Primary Health Care (PHC); Mpumalanga province; South Africa.

Introduction

South Africa faces a dual burden of chronic communicable (HIV and TB) and chronic non-communicable diseases (NCDs - e.g. cardiovascular diseases, diabetes, cancer and chronic respiratory diseases), with the prevalence of HIV estimated at 10% in 2014 (1) and mortality due to NCDs estimated at 43% in 2012 (2). Effectively responding to this dual burden of chronic diseases requires an integrated approach to the delivery of care at the Primary Health Care (PHC) level.

The Joint United Nations Programme on HIV/AIDS (UNAIDS) recommends a globally comprehensive and integrated approach to the delivery of chronic disease care. This approach requires leveraging HIV programmes to support or scale-up services for NCDs (3, 4). There is evidence that the integrated management of chronic diseases leads to improvement in patient health outcomes (e.g., CD4 count, glycosylated haemoglobin, and blood pressure) and patient satisfaction with the delivery of chronic disease care (5). Beyond the UNAIDS mandate for the implementation of an integrated chronic care model, integrating services for HIV and NCDs could also minimise fragmented chronic disease care arising from the management of the HIV pogramme in a 'silo' within the general healthcare system, leverage resources and more efficiently meet patients' healthcare needs (6-8).

In response to UNAIDS recommendation to integrate HIV and NCD services, the National Department of Health (NDoH) in South Africa initiated the Integrated Chronic Disease Management (ICDM) model (9). The pilot of the ICDM model commenced in 2011 in selected

PHC facilities in three of South Africa's nine provinces (Gauteng, Mpumalanga and North West), (9) with the expectation of enhancing the quality of chronic disease services and improving patient health outcomes.

At the crux of the ICDM operational framework are facility reorganisation to improve operational efficiency and quality of care in the health facilities; "assisted" self-management to promote individual responsibility in the communities; and health promotion and population screening in the population (9). The facility component entails many areas of focus such as: designation of chronic care area; use of guidelines for management of chronic diseases; human resource audit; capacity building; supply of critical medicines; prepacking of medication; and appropriate referral. To prepare the community for chronic disease care, each clinic has a PHC outreach team operating within the community that the clinic serves, and consists of one professional nurse, three staff nurses, and six Community Health Workers (CHWs). With the outreach team responsible for 6000 individuals in 1500 households (250 households per 1 CHW), it is anticipated that at least 80% of defined health problems of the catchment population would be managed (9). This study focuses on the facility component of the ICDM model.

Multiple meanings of "Integrated health care" exist in the literature. These include the provision of health care for multiple diseases at one service delivery point (e.g. integrated management of childhood illness); continuity of care over time across different levels of health care (e.g. an appropriate referral system); integrating vertical programmes (programmes that are separately funded and administratively managed in a 'silo') with the general health care system; multi-

sectoral collaboration; or a combination of two or more of these meanings (10). The World Health Organization (WHO) defines "*integrated health care" as "the organisation and management of health services so that people get the care they need, when they need it, in ways that are user-friendly, achieve the desired results and provide value for money*." (10). In this study, the ICDM model refers to the 'one-stop-shop' for the management of chronic diseases in PHC facilities as well as continuity of care in the form of referral of patients.

Theoretical framework for evaluating quality of care in the ICDM model

"Quality of medical care" is highly contextual and a difficult concept to define. Although it is a reflection of values and goals in the medical care system and in the larger society which it is a part of, quality can be almost anything anyone wishes it to be (11). Klein et al. conclude that patient care, like morale, cannot be defined by a unitary concept and that it seems unlikely that there will be a single criterion by which to measure the quality of patient care (12).

Avedis Donabedian described seven elements of quality of medical care: Efficacy, Effectiveness, Efficiency, Equity, Optimality, Acceptability and Legitimacy. Although *Efficacy* is hard to measure, it refers to care provided under optimal conditions and is the basis against which measurements should be made. *Effectiveness* describes the outcome of interventions; *Efficiency* refers to cost reductions without compromising effects; *Equity* refers to the fairness in the distribution of healthcare in populations; *Optimality* is about balancing the costs and benefits of healthcare; *Acceptability* encompasses accessibility of healthcare and interpersonal patient-provider interaction; and *Legitimacy* refers to the social acceptability of the healthcare institution

regarding the manner in which healthcare is delivered. The choice of which of these elements, as well as their relative prioritisation, should be guided by the contexts in which quality of care is being assessed (13).

Donabedian's definition of quality of care can be assessed as a triad of structure, process and outcome (SPO) constructs. He postulated that there are relationships between SPO constructs based on the idea that good structure should promote good process and good process should in turn promote good outcome (unidirectional pathway). The SPO framework, often represented by a chain of three boxes containing SPO constructs connected by arrows (13), can be used to draw inferences about the quality of health care (14). Donabedian defines *Structure* as the professional and organisational resources associated with the provision of health care (e.g. availability of medicines/equipment and staff training); *Process* as the things done to and for the patient (e.g. defaulter tracing and hospital referrals) and *Outcome* as the desired result of care provided by the health practitioner (e.g. patient satisfaction with quality of care). Donabedian distinguished between two types of outcomes: i) technical outcomes, which are the physical and functional aspects of care, such as absence of complications and reduction in disease, disability and death; and ii) interpersonal outcomes which include patients' satisfaction with care and influence of care on patient's quality of life as perceived by the patient (15).

Avedis Donabedian's SPO framework was used to evaluate the quality of care in the ICDM model not only because it is the dominant framework for evaluating the quality of medical care (16), but because the SPO framework is used by South Africa's National Department of Health

for the implementing the ICDM model (9). A study of quality systems conducted among department managers and quality coordinators in 386 hospitals in Sweden showed statistically significant relationships between SPO constructs, using Donabedian's theory (17). To the authors' knowledge, this is the first study to apply Donabedian's theory in evaluating the quality of care in the ICDM model in sub-Saharan Africa (SSA).

A systematic review to examine the effectiveness of integrating primary health services in Low- and Middle-Income Countries (LMICs) showed the main focus to be on the provider side of service provision, with virtually no considerations for lay or demand side perspective (18). For South Africa, little is known about satisfaction with the quality of care in the ICDM model. With supporting evidence that satisfaction is a major component and key determinant of quality of healthcare (15), this study examined satisfaction of both service providers and users with the quality of care in the ICDM model. The objectives of this study were to: i) assess patients' and operational managers' (nurses-in-charge of health facilities) satisfaction with the dimensions of ICDM services; and ii) evaluate the quality of care in the ICDM model, based on the satisfaction scores of patients, using Donabedian's SPO theoretical framework.

Methodology

Study setting and sites

This study was conducted in PHC facilities in the rural Agincourt sub-district situated in the Bushbuckridge municipality, Mpumalanga province, northeast South Africa. At the time this study was conducted, the ICDM model was being implemented in 17 of the 38 PHC facilities in

the sub-district. Seven of these 17 health facilities implementing the ICDM model are situated in Agincourt sub-district which covers an area of about 420km^2. The sub-district underpinned by a robust Health and Demographic Surveillance System (HDSS) which has been monitoring the population in these villages for two decades. The population under surveillance in the HDSS as at 1st July 2011 was 115,000 people in 20,000 households in 27 villages (19). Three referral hospitals are situated 25 km to 45 km from the study setting. The pilot of the ICDM model was commenced in these facilities in June 2011 (field diary of interviews with the operational managers and the sub-district health manager in July 2013), but preceded by two months of pre-implementation preparedness which started in April 2011 (9). Tsonga is the most widely spoken language in the study area. Having immigrated into South Africa mainly as war refugees in the early- and mid-1980s, one-third of the population in the study site are Mozambicans (19).

In the South African PHC model, the professional nurse is the service provider at the PHC facilities, which is the first point of entry into the public health system. Services provided by the nurses include: maternal and child care, immunization, family planning, treatment of sexually transmitted infections, minor trauma, care for chronic diseases and referrals. Medical doctors visit the PHC facilities at intervals to offer support to the nurses (20).

Study design and study population

This was a cross-sectional descriptive survey conducted between August and November 2013. It was part of a broader four-year longitudinal study (January 2011 and December 2014), with qualitative and quantitative components, designed to contribute to understanding the

effectiveness of the ICDM model in improving the quality of healthcare and technical health outcomes of chronic disease patients. The study population consisted of patients 18 years and above receiving treatment for chronic diseases in the sub-district health facilities. Other study participants included the operational managers (professional nurses-in-charge) of the selected seven PHC facilities in the sub-district.

Inclusion and exclusion criteria for the patients

The ICDM model addresses the following chronic diseases: HIV/AIDS, tuberculosis, hypertension, diabetes, chronic obstructive pulmonary disease, asthma, epilepsy and mental health illnesses that are to be managed at the PHC level (9). Patients with the markers of chronic diseases (HIV, hypertension and diabetes) in the health facilities were included in the study, while those with other chronic diseases were excluded. Patients who had their chronic condition(s) managed five months before the initiation of the ICDM model until the time the study commenced in August 2013 were identified for recruitment. The reason for including patients receiving treatment five months before the ICDM model was implemented was to assess the levels of satisfaction of patients who had received treatment before the implementation of the ICDM model and continued to receive treatment during its implementation in efforts to gauge possible changes in the quality of chronic disease care attributable to the ICDM model. Minors less than 18 years were excluded from the study because they were below the age of autonomy (≥18 years) for judging satisfaction with the quality of services provided in the health facilities. The elderly with reduced capacity for comprehension during informed consent were also excluded from the study. Diminished capacity for comprehension was determined by the

inability of prospective patients to comprehend or respond to the information verbally provided by the interviewer during informed consent.

Sample size determination and sampling of study participants

Using the subjects-to-variables ratio (minimum of 10 subjects per variable in the study instrument) for estimating sample size for studies utilising factor analysis statistical technique (21, 22), a sample size of 390 patient respondents was calculated (17 subjects per each of the 23 variables in the study instrument). The minimum sample size of approximately 435 (390/0.9) patients was reached after adjusting for 10% non-response. All the seven operational managers of the PHC facilities, the maximum number possible, were selected because they offered clinical services to the patients and the authors perceived their role as managers of the health facilities critically important to understanding the quality of the ICDM model more than other professional nurses.

The study participants were identified through a three-step process (Additional file 1). First, the number of patients recruited at each of the seven health facilities was determined by proportionate sampling. The sampling fraction of 435/3602 (435 represents the desired sample size out of a total of 3602 HIV, hypertension, and diabetes registered patients) was multiplied by the number of these chronic disease patients in each health facility to determine the number of patients to be recruited per facility. Secondly, the patients in each health facility were stratified by HIV, hypertension, and diabetes status in order to get a representative sample of the patients with markers of chronic diseases using a health facility-specific sampling frame. Finally, the

numbers of patients specified in step two were recruited for a daily interview until the desired sample size in each clinic was achieved.

Study tool and variables

In this study, we used the multi-scale patient satisfaction questionnaire (PSQ-18) which was developed by Ware et al. (23). The PSQ-18 comprises 18 items derived from the full-length version (50-item) PSQ-III counterpart (23). The PSQ-18 assesses multiple dimensions of patient satisfaction and includes general satisfaction; technical quality; interpersonal relations; communication; financial aspect; time spent with health provider; and accessibility and convenience (Additional file 2). The PSQ-18 sub-scales show acceptable reliability and correlate with the sub-scales in the PSQ-III (24). Furthermore, PSQ-18 is appropriate for use in situations where there is need for brevity (24), as was the case in this study where it was administered to patients leaving the health facility after consultations with the nurses (patient exit interviews). The PSQ-18 instrument is reflective of Donabedian's SPO constructs and succinctly measures patient satisfaction with dimensions of care for which SPO constructs are intended. The authors are not aware of any study that has used the PSQ-18 as a study instrument to operationalise Avedis Donabedian's SPO theoretical framework in SSA.

This study compared self-reported satisfaction of the patients and self-reported satisfaction of the operational managers with the dimensions of care listed in the ICDM model using the multi-scale PSQ-18. This is in view of literature depicting views of health care providers differing from users regarding the quality of health care (25). Responses to statements were scored on a five-

point Likert scale ranging from 4 (strongly agree) to 0 (strongly disagree) for positively-phrased statements, and from 4 (strongly disagree) to 0 (strongly agree) for negatively-phrased statements for the purpose of undertaking confirmatory factor analysis and structural equation modeling.

Similar to another study in which the PSQ tool was adapted to measure patient satisfaction with pharmacy services (26), this study adapted the PSQ-18 by altering a number of statements to fit the ICDM model. For example, the structure-related statement, "*I have easy access to the medical specialists I need*," was changed to the ICDM-process-related dimension, "*Health care providers usually refer me to the doctor/hospital when there is need for the doctor to review me* - P5" (Additional files 2, 3 and 4). One structure-related (supply of critical medicines) and two process-related (defaulter tracing of patients and prepacking of medicines) variables were included in the adapted questionnaire. One process-related statement in the PSQ-18 was changed from "*health care providers act too business-like and impersonal toward me*" to "*Health care providers are professional in the conduct of their clinical duties*". Regarding the types of outcome constructs (technical and interpersonal) specified by Donabedian, the focus of this study was on the subjective interpersonal outcome. Two outcome statements on "*satisfaction with perfect health care*" and "*dissatisfaction with some care*" in the PSQ-18 were changed to the dimension on "*satisfaction with coherent integrated chronic disease care*" and "*dissatisfaction with coherent integrated chronic disease care*", respectively.

Two statements around the financial costs of health care (D1 and D2) were dropped during the adaptation of the PSQ-18 (Additional file 3). This is because the government of the Republic of South Africa implements a pro-equity policy, a component of free health care for everyone using the public primary health system (27). However, transport-related costs were not considered in this study because it is not the responsibility of South Africa' Department of Health to provide transport for the implementation of the ICDM model. The 17 dimensions of care in the adapted questionnaire are shown in Figure 1, and details of the adapted PSQ tool used in the current study for patients and operational managers are shown in additional files 3 and 4, respectively.

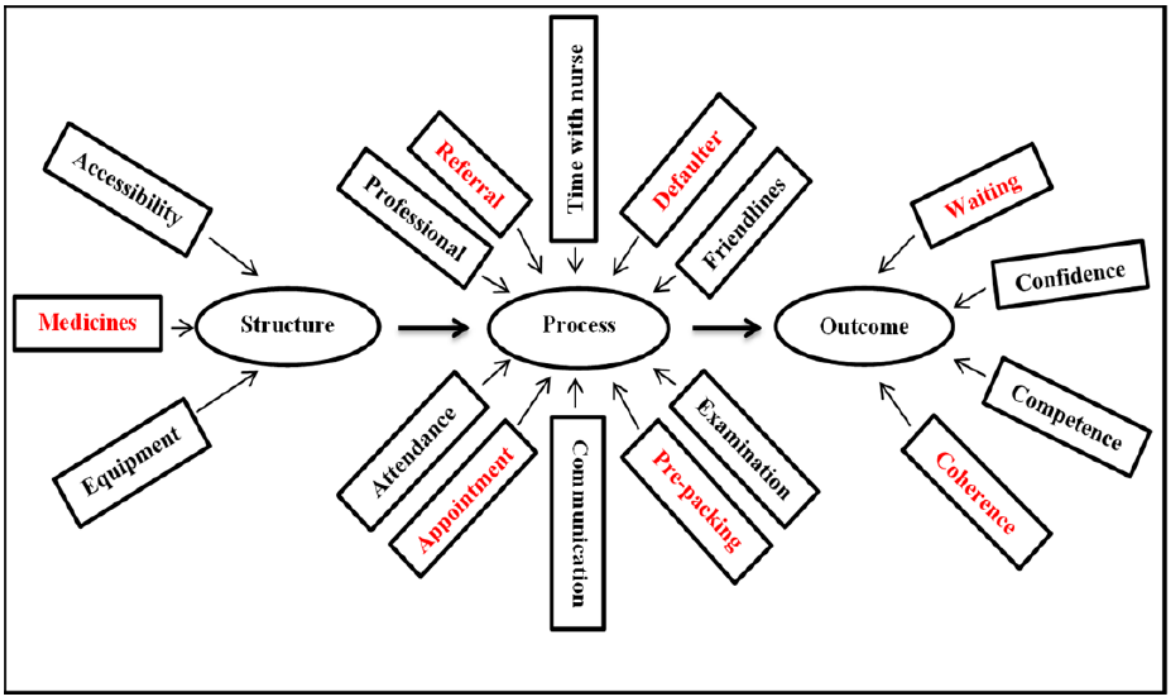

Figure 1: The 17 dimensions of care for which the structure, process and outcome constructs were intended

**The dimensions in red colour indicate the priority areas in the ICDM model*

Seven dimensions of care were identified by experts on quality of care in the study team as priority areas for enhancing service efficiency and quality of care: supply of critical medicines, hospital referral, defaulter tracing, prepacking of medicines, clinic appointments, patient waiting time, and coherence of integrated chronic disease care (Appendix 1) (9). This is because these priority areas are components of the tools and systems used in the successful HIV programme which is being leveraged to support or scale-up services for improving the quality of care for NCDs and patients interfaced directly with these areas in the health facilities (Figure 1).

Quality assurance

The adapted PSQ tool for the patients was forward translated to Tsonga (the local language) and back-translated to English by two experienced field workers who were blinded to each other. An experienced quantitative field worker was trained on how to administer the adapted PSQ tool. A pilot study was conducted in Cork clinic, a PHC facility situated outside the study site, to assure understanding and correct use of the PSQ tool. Only a few statements had to be rephrased after the pilot study.

An important characteristic of the original PSQ-18, which was considered in the adaptation of the study instrument, is the control for Acquiescent Response Set (ARS) - a tendency to agree with statements of opinion regardless of their content (28). Six variables were phrased in opposite directions, bringing to 23 the total number of variables in the adapted questionnaire (Additional files 3 and 4). These measures are beneficial in detecting skewness toward

satisfaction (28) and identifying specific programme areas that respondents are satisfied or dissatisfied with.

Data collection

Having consulted with the professional nurses and received their medicines, the prospective study participants were invited to a (consultation) room designated for patient interviews. Only the interviewer had access to this consultation room. Patients were invited to take part in the satisfaction survey after explaining the purpose of the study. They were assured that there will be no penalty or loss of benefits to which they were entitled to if they chose to not participate in this study or decide to discontinue participation in this study. Written informed consent was obtained from the patients who were willing to participate in the study and interviews were conducted with the patients.

The operationalisation of Donabedian's theoretical framework

The adapted PSQ contained measures reflective of SPO constructs and was used to assess satisfaction of patients and operational managers with the dimensions of integrated chronic disease services. There was no clear division of the statements in the adapted PSQ tool into the respective constructs. However, these statements have been categorised under these constructs in additional files 3 and 4 for clarification. In order to minimise bias that may result from assessing acquiescent response set, the positive and negative statements did not follow each other in the questionnaire as shown in additional files 3 and 4. The respondents were judged to be satisfied

with the dimensions of care if the total relative frequency was ≥ 50% for "strongly agree" and "agree" responses to positively-phrased statements. Similarly, the respondents were judged to be satisfied with the dimensions of quality of care if the total relative frequency was ≥ 50% for "strongly disagree" and "disagree" responses to negatively-phrased statements. A satisfaction score of at least 50% was considered an average score using a scale of 0% to 100%.

The patients and operational managers were scored comparatively on their (dis)satisfaction with the dimensions of care in the ICDM model to measure the first objective of the study. Determining the quality of care in the ICDM model was the second objective of this study which was measured by conducting structural equation modelling (SEM) using the data on patients' (dis)satisfaction with the dimensions of quality of care in the ICDM model. However, SEM could not be performed with the data collected from the operational managers because of the very small sample size (seven operational managers).

The following linear pathways were specified in the SEM: (1) the unidirectional pathway which states that good structure promotes good process and good process in turn promotes good outcome, (2) the mediation pathway which posits states that good structure directly promotes good outcome, good structure promotes good process and good process in turn promotes good outcome; and (3) the reciprocal pathway which hypothesises that good structure promotes good process, good process promotes good outcome and good outcome promotes good process. The last two pathways were examined in this study to explore other linear relationships between SPO constructs other than the unidirectional pathway originally postulated by Donabedian (Figure 2).

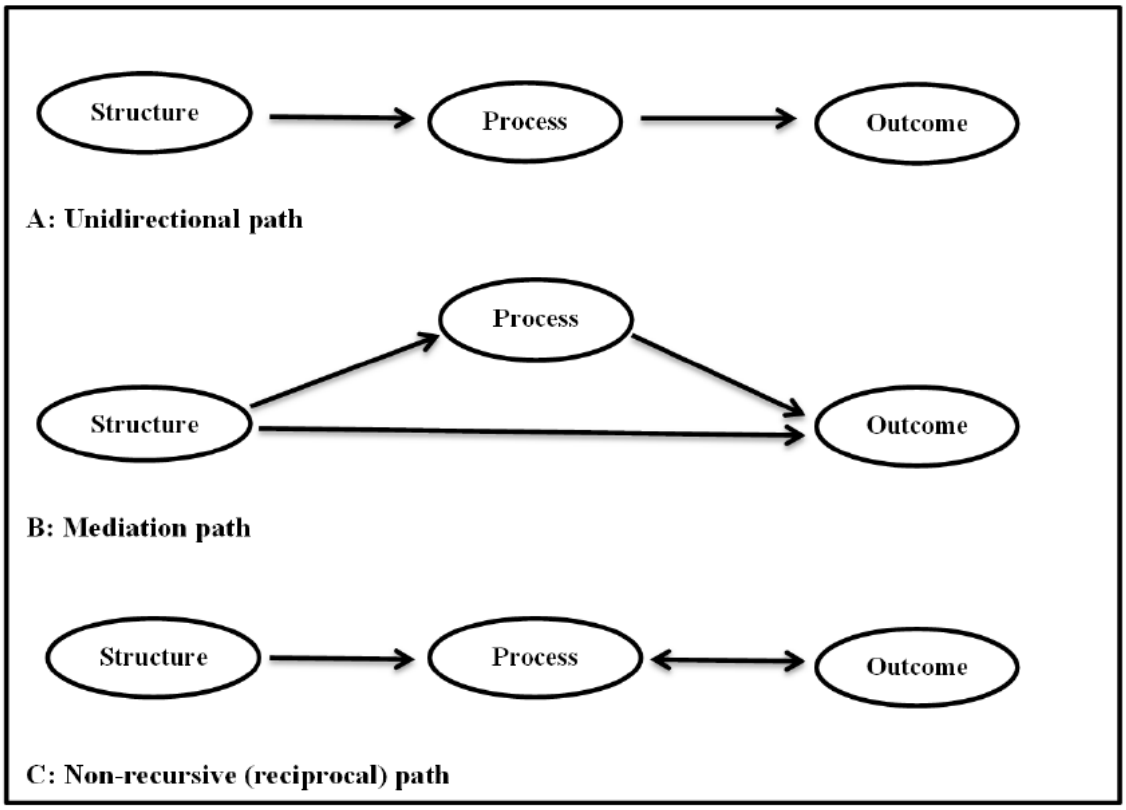

Figure 2: Pathways for operationalising Donabedian's theory in the ICDM model of care in South Africa

Fitting of the proposed pathways involved a four-step systematic process using patient data. First, a priori identification of the variables for which the SPO constructs were intended was performed by the experts on quality of care on the study team in order to assess the validity of the adapted questionnaire (Additional files 3 and 4). This method was adopted by Kunkel et al. in which a panel of experts categorised variables in a questionnaire into SPO constructs (17).

Secondly, Cronbach's alpha (range: 0-1), which is a measure of internal consistency, was used to quantify the reliability of the multi-item variables in the adapted PSQ in measuring the SPO constructs. Cronbach's alpha coefficient of reliability was categorised as excellent ($\alpha \geq 0.9$), good ($0.7 \leq \alpha < 0.9$), acceptable ($0.6 \leq \alpha < 0.7$), poor ($0.5 \leq \alpha < 0.6$) and unacceptable ($\alpha < 0.5$) (29).

Next, the negative statements in the pair of statements phrased in opposite directions were dropped if there was no evidence of ARS. The fit of each construct and its individual items were assessed to remove any of the remaining variables with low coefficient of determination (CD < 0.2). Variables with low CD contribute high levels of error in the structural equation modelling (30). Thereafter, Confirmatory Factor Analysis (CFA) was conducted to identify and remove the variables that did not load significantly (factor loading < 0.300) onto their intended constructs.

The following step used structural equation modelling (SEM) to assess the specified pathways, as used elsewhere (31), in order to determine the relationships between the SPO constructs (Figure 2). Selection of the final path model was based on the variables that reflected their intended factors (factor loading ≥ 0.300). The Maximum Likelihood for Missing Values (MLMV) technique was used to impute for S5, P1 and P11 variables with 0.5%, 0.25% and 0.25% missing observations, respectively. The MLMV is a technique that handles missing data by estimating a set of parameters that maximise the probability of getting the data that was observed. It is a more superior and preferable method for handling missing data than the more popular multiple imputation (32), which is a simulation-based method that predicts missing

values as close as possible to the true ones by replacing missing data with probable values based on other available information (33).

Assessment of the fit of the pathways using MLMV approach was based on two or more of the following fit indices (34): (i) Relative/normed Chi-squared test statistic is an absolute fit index that assesses the discrepancy between observed and expected covariance matrices. It minimizes the impact of sample size on the model and is derived by dividing the Chi square value by the degrees of freedom (χ^2/df). Although there is no concensus regarding the acceptable ratio for this statistic, values ranging from 2 to 5 are recommended as good fit indices. (30); (ii) Root Mean Squared Error of Approximation (RMSEA) is another absolute fit index that measures how well a model with optimally chosen parameter estimates fit the population's covariance matrix - RMSEA value ≤ 0.06 is a good fit; (iii) Comparative Fit Index (CFI) is an incremental fit index that assesses the improvement in fit of the hypothesised model compared with a baseline (null) model, when population covariance is assumed to be zero - (CFI ≥ 0.90 is a good fit); (iv) Tucker-Lewis Index (TLI) is also an incremental fit index that corrects for model complexity by favouring parsimonious models over more complex ones - (TLI ≥ 0.90 is a good fit); and (v) Coefficient of determination (CD) indicates how well data fit a statistical model. We used CD to decide the model that explained the most variability. CD value of 1.00 is a perfect fit. The higher the number of criteria used, the better the fit of the model with the data (30).

Statistical analysis

Data were entered into Access 2010 and imported into Stata 12.0 (College Station, TX, USA) for statistical analysis. Relative frequencies were used to quantify satisfaction of the patient and operational managers with the dimensions of integrated chronic disease services. At p-value $\leq$ 0.05, CFA and SEM were used to fit the specified structural path models in order to determine the quality of care in the ICDM model from the patient perspective.

Ethical clearance

Ethical clearance for this research was granted by the Committee for Research on Human Subjects (Medical) of the University of the Witwatersrand, Johannesburg, South Africa (Ref No. M120943) and the Mpumalanga Provincial Research and Ethics Committee. In addition to the efforts to ensure confidentiality earlier mentioned during data collection, patients' information were encrypted in a computer programme that keeps the information in a form that does not allow anyone to interpret it, except the study team, and a study number was generated for each patient.

Results

Socio-demographic characteristics of the patients

Table 1 shows the mean age of the 435 chronic disease patients to be 55 ± 16 years. Forty-eight percent of the patients were hypertensive; 81% females; 96% South Africans; 99% unemployed;

and 90% were not looking for a paid job. Most of the patients received an old age grant (69%) and 88% of them had no formal or less than six years of education.

Table 1: Socio-demographic characteristics of the patients attending health facilities in Agincourt sub-district in 2013 (n=435)

Variable	Frequency (%)
Age (years)	
18-29	23 (5.3)
30-39	69 (15.8)
40-49	68 (15.6)
50-59	88 (20.3)
60-79	187 (43.0)
Mean ± SD (55 ± 16.5); Median = 56	
Gender	
Female	354 (81.4)
Male	81 (18.6)
Education (years)	
No formal education	164 (37.6)
≤ 6	217 (49.9)
> 6	54 (12.5)
Type of grant	
None	91 (20.9)
Old age[a]	299 (68.7)
Disability	44 (10.1)
HIV	1 (0.3)
Labour status	
Not presently working	431 (99.0)
Presently working	4 (1.0)
Nationality	
South African	415 (95.5)
Mozambican	20 (4.5)
Chronic disease status[b]	
Hypertension	292 (67.0)
HIV	141 (32.4)
Diabetes	2 (0.5)

[a]*Old age grant is a social security grant given to South Africans ≥ 60 years of age*
[b]*Diagnoses of chronic diseases were retrieved from the patients' clinic records*

Satisfaction with structure-, process- and outcome-related dimensions of care in the ICDM model

Figure 3A shows that the patients (P) and operational managers (OM) reported being satisfied (scores ≥ 50%) with all the structure-related dimensions of care in the ICDM model. There were no statistically significant differences ($p>0.05$) between the satisfaction scores of the patients and operational managers with structure-related dimensions of care, except for availability of equipment (S1): P-97% vs. OM-52%, $p<0.001$.

Figure 3B shows that the operational managers reported being satisfied (scores ≥ 50%) with all process-related dimensions of care in the ICDM model. However, the patients were not satisfied (scores < 50%) with defaulter tracing of patients (P7-29%) and appointment systems (P14-20%). Of all the process-related dimensions of care, there were statistically significant differences in the scores of the patients and operational managers in appointment system (P14): P-20% vs. OM-100%, $p<0.001$; physical examination of patients (P11): P-96% vs. OM-57%, $p<0.001$; defaulter tracing of patient (P7): P-29% vs. OM-86%, $p=0.001$; hospital referral of patients (P5): P-62% vs. OM-100%, $p=0.039$; and friendliness of the nurses to patients (P4): P-92% vs. OM-71%, $p=0.041$; .

Figure 3C shows that the patients and operational managers reported being satisfied (scores ≥ 50%) with three of the four outcome-related dimensions of care in the ICDM model. On the other hand, the patients and operational managers were not satisfied (scores < 50%) with patient waiting time (O4): P-17% vs. OMs-43%. A comparison of the satisfaction scores of the patients and operational managers with all the outcome-related dimensions of care showed no statistically significant differences ($p>0.05$).

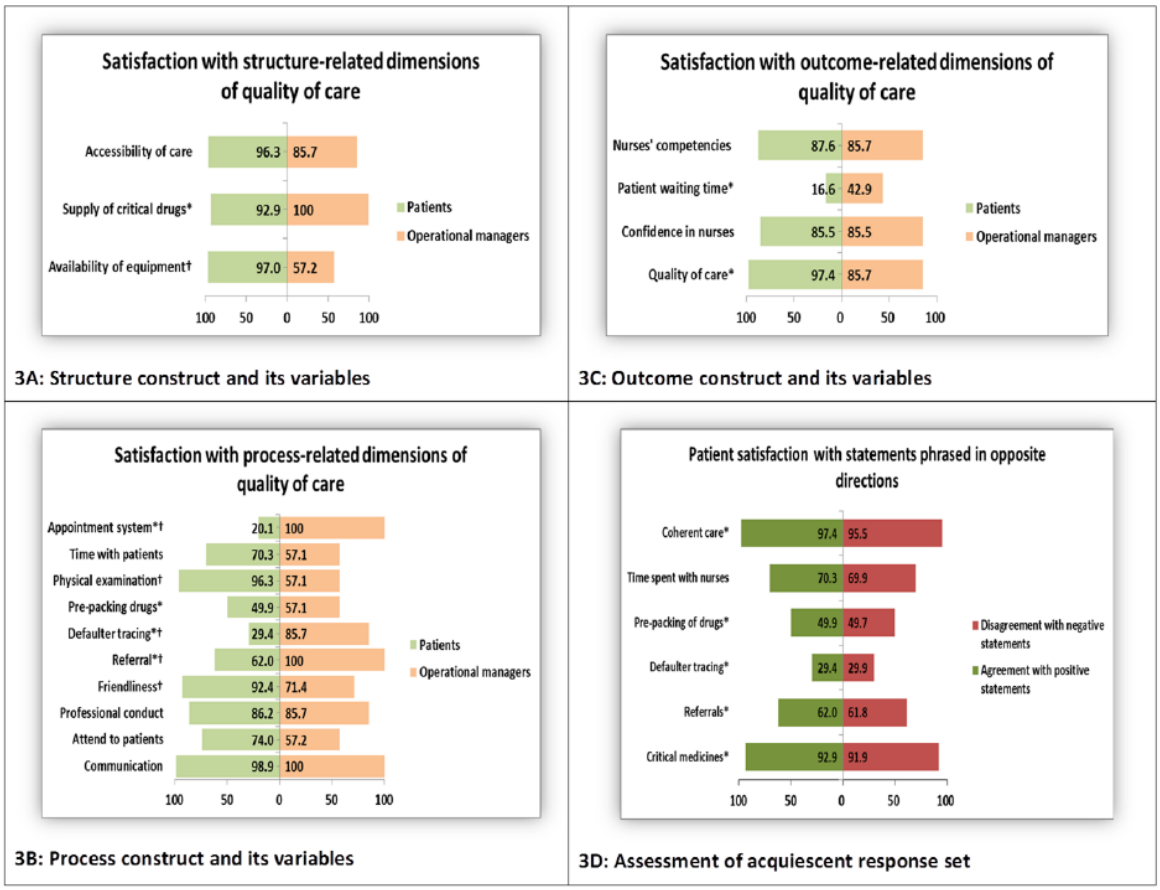

Figure 3: Satisfaction of respondents with the ICDM model and assessment of acquiescent response set for patients

**Priority areas in the ICDM model* $^{\dagger}p\text{-value} < 0.05$

Acquiescent response set

Figure 3D shows patients' satisfaction scores for the positively- and negatively-phrased statements: supply of critical drugs (93% vs. 92%), hospital referrals (62% vs. 62%), defaulter tracing (29% vs. 30%), prepacking of drugs before clinic visits (50% vs. 50%), time nurses spent

with patients during consultation (70% vs. 70%) and coherence of integrated chronic disease care (97% vs. 96%). There were no statistically significant differences ($p>0.05$) in the responses of the patients to the pair of positively- and negatively-phrased statements.

Fitting of the proposed structural pathways

Figure 4 shows that the Cronbach's alpha coefficients of reliability of the variables intended for their respective SPO constructs ranged from acceptable to good: structure (0.790), process (0.702), and outcome (0.600), an indication that the variables were a reliable measure of their intended constructs (29).

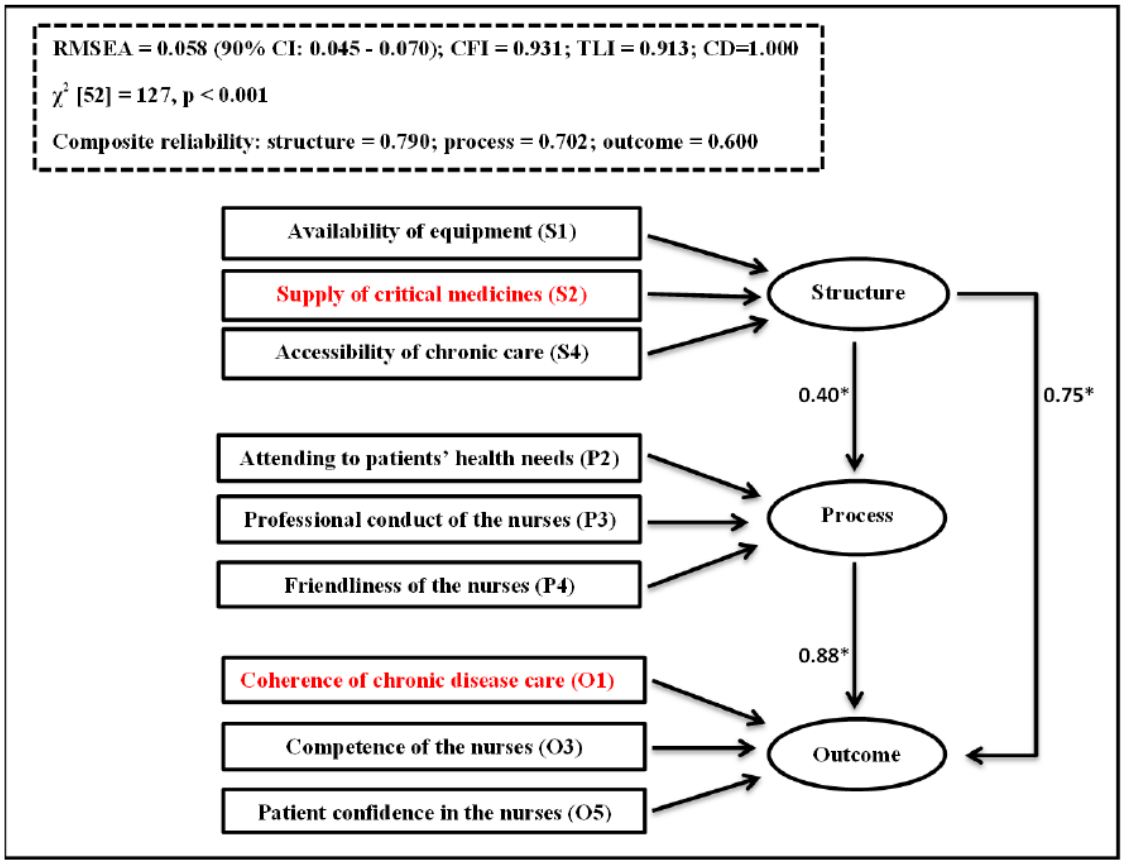

Figure 4: Goodness-of-fit, reliability and correlation assessment of the relationships between structure, process and outcome

**Relationships between the constructs represented by the Pearson correlation values*
NB: The dimensions in red colour are the priority areas in the ICDM model

RMSEA - Root Mean Squared Error of Approximation (≤ 0.06 is a good fit)

CFI - Comparative Fit Index (CFI ≥ 0.90 is a good fit)

TLI - Tucker-Lewis Index (TLI ≥ 0.90 is a good fit)

CD - Coefficient of determination (range 0-1. There is a perfect fit of the data with the model if CD=1)

Cronbach's alpha coefficient of reliability (≥ 0.6 is acceptable)

Before running the factor analysis, six negatively phrased statements (S3, P6, P8, P10, P13 and O2) in the adapted questionnaire were dropped because there was no evidence of ARS in the pair of statements phrased in opposite directions. In assessing the fit of the constructs and the remaining 17 variables, three process-related variables: communication with patients (P1), hospital referral (P5) and physical examination of patients (P11) with coefficient of determination values < 0.20 were dropped (30). Of the remaining 14 variables, four process-related variables: defaulter tracing of patients (P7), prepacking of drugs before clinic visit (P9), time patients spent with nurses during consultation (P12) and appointment system (P14); and one outcome-related variable: patient waiting time (O4) did not load significantly (factor loadings < 0.3) onto their intended constructs in the CFA (Table 2), and were dropped after CFA.

Table 2: The result of the confirmatory factor analysis

Constructs	Variables	Loading	Standard error
Structure			
	Availability of equipment (S1)	0.462*	0.038
	Supply of critical medicines (S2)	0.994*	0.012
	Accessibility of services (S4)	0.383*	0.041
Process			
	Attendance to patients' needs (P2)	0.664*	0.035
	Professionalism (P3)	0.758*	0.032
	Friendliness (P4)	0.669*	0.035
	Defaulter tracing (P7)	0.200	0.056
	Prepacking of drugs (P9)	0.268	0.055
	Time spent with nurses (P12)	0.074	0.056
	Appointment system (P14)	0.163	0.053
Outcome			
	Coherence (O1)	0.310*	0.057
	Competence (O3)	0.485*	0.053
	Waiting time (O4)	0.229	0.058
	Confidence (O5)	0.651*	0.054

**Variables with factor loading ≥ 0.300*

Assessment of fit indices of the specified path models

Figure 4 also shows the remaining nine variables that reflected their intended SPO constructs (factor loading > 0.300) in the structural equation model. These were three structure-related dimensions: availability of equipment (S1), supply of critical medicines (S2) and accessibility of chronic disease care (S4); three process-related dimensions: attending to patients' health needs (P2), professional conduct of the nurses (P3) and friendliness of the nurses (P4); and three outcome-related dimensions: coherence of integrated chronic disease care (O1), patient confidence in the nurses (O3), and competence of the nurses (O5).

The fit indices of the three specified pathways are as follows: (a) unidirectional pathway - [χ^2[52]=145, p<0.001; RMSEA=0.064 (90% CI - 0.052-0.077); CFI=0.915; TLI=0.892; CD=0.911], (b) mediation pathway - [χ^2[52]=127, p<0.001; RMSEA=0.058 (90% CI - 0.045-0.070); CFI=0.931; TLI=0.913; CD=1.00] and (c) reciprocal pathway – [χ^2[59]=147, p<0.001; RMSEA=0.059 (90% CI - 0.047-0.070); CFI=0.919; TLI=0.910; CD=0.632].

Table 3 showed that when using at least two criteria, all the specified path models fit the data, but only the mediation pathway fulfilled all the criteria used except the chi-squared criterion, which is expected because the sample size of this study was greater than 400. In addition, the mediation pathway showed a perfect fit with a CD value of 1.00.

Table 3: The result of the goodness of fit of the specified path models

Criteria	Specified path models		
	Unidirectional	Mediation	Reciprocal
Relative Chi square statistic (χ^2/df)	127/52 = 2.44✓	164/52 = 3.15✓	145/52 = 2.78✓
RMSEA value ≤ 0.06	0.064 (90% CI - 0.052-0.077)	0.058 ✓ (90% CI - 0.045-0.070)	0.059 ✓ (90% CI - 0.047-0.070)
CFI ≥ 0.90	0.915 ✓	0.931 ✓	0.919 ✓
TLI ≥ 0.90	0.892	0.913 ✓	0.910 ✓
CD close to 1.00 (perfect fit is preferred if CD value=1.00)	0.911 ✓	1.00 ✓	0.632
Ranking**	3rd	1st	2nd

***The mediation model ranked first because it fulfilled all five criteria (*Relative/normed Chi square statistic, *RMSEA, CFI, TLI and CD). In addition, it showed a perfect fit based on CD value of 1.00*

***The reciprocal model ranked second because it fulfilled four criteria (*Relative/normed Chi square statistic, *RMSEA, CFI and TLI)*

***The unidirectional model ranked third because it fulfilled three criteria (*Relative/normed Chi square statistic, *CFI and CD).*

Summary of the main findings

The patients and operational managers' were satisfied (scores ≥ 50%) with the following SPO related dimensions of care:

i) structure-related construct: availability of equipment; supply of critical medicines; and accessibility of chronic disease care.

ii) process-related construct: communication of the nurses with patients; attendance of the nurses to patients' health needs; professional conduct of the nurses; nurses' friendliness with patients; hospital referral of patients, pre-packing of medicines; physical examination of patients; and time nurses spent with patients during consultation

iii) outcome-related: coherence of integrated chronic disease care; and competence of the nurses, and patients' confidence in the nurses.

The patients and operational managers' were less satisfied (scores < 50%) with patient waiting time (an outcome construct). The patients recorded satisfaction scores < 50% for two process-related dimensions of care, defaulter tracing of patients and appointment systems. There were statistically significant differences ($p<0.05$) in the satisfaction scores of the patients and operational managers with regard to availability of equipment; friendliness of the nurses; hospital referral of patients; defaulter tracing of patients; physical examination of patients; and appointment systems.

Findings from the mediation path model (Figure 4) showed that three structure-related dimensions of care (availability of equipment; supply of critical medicines; and accessibility of chronic disease care) correlated directly with three outcome-related dimensions of care (coherence of integrated chronic disease care; and competence of the nurses and patient confidence in the nurses) and three process-related dimensions of care (nurses' friendliness with patients; professional conduct of the nurses; and attendance of the nurses to patients' health needs). Independent of structure, good process correlated with good outcome, an indication that good process mediated the relationship between good structure and good outcome.

Discussion

In view of the increasing emphasis on health system strengthening and integration, this study contributes to the global debate on the feasibility of integrating HIV services with those of NCDs. More specifically, we examined the satisfaction of patients and operational managers with the dimensions of integrated chronic disease services and evaluated the quality of care in the ICDM model from patient perspectives using Donabedian's theory of the relationships between SPO constructs as a measure of the quality of care.

Similar to a Togolese study in which the majority of service providers positively viewed the impact of integrating family planning services to the routine expanded programme on immunisation (35), the operational managers in this study reported being satisfied with 16 of the 17 dimensions of quality of care in the ICDM model. However, this was less so for the patients who reported satisfaction with 14 of these dimensions of care. The significant differences in the satisfaction scores of the patients and operational managers in this study supports evidence-based literature that suggests assessing the satisfaction of the quality of care from the perspectives of both health providers and users (18) because of differing views (25). The patients rated satisfaction with availability of equipment higher than the operational managers because the patients may not be aware of the lack of equipment. The patients' satisfaction scores for friendliness of the nurses and physical examination of patients was higher than those of the operational managers because the managers may not see the professional nurses being as friendly as patients view them to be nor performing physical examination on patients, respectively. The operational managers who responded to the interviews are professional nurses who often perform a dual role of providing routine care to the patients and managing the facilities. In the course of

performing their administrative duties in the office, these managers may not have the opportunity to see the professional nurses being friendly to patients in the consultation rooms. This may have accounted for the managers' lower satisfaction scores compared with the patients' scores.

An earlier household survey conducted in the study site reported health system weakness as one of the barriers to chronic disease care. At the time of the said survey in 2004, community members attended public hospitals for diagnosis and treatment of chronic illness due to the lack of capacity and services in the PHC facilities (36). A decade after the 2004 survey and two years after the initiation of the ICDM model in South Africa, community members now have access to chronic disease services in PHC facilities in their local areas. These facilities have a regular supply of critical drugs and trained professional nurses who are better able to provide integrated services for the diagnosis and treatment of chronic diseases.

In this study, patient waiting time was the only dimension of care in the ICDM model in which the patients and operational managers reported low satisfaction scores. Similar studies assessing the quality of service in public clinics in South Africa showed that the clinics were easily accessible and services were of acceptable quality (37), but the time spent by patients at the clinic to complete the services was very long (37, 38). These findings suggest that public health services in many resource-constrained LMICs are characterised by long waiting periods (39-41), which could be a consequence of operational challenges such as performance of multiple tasks and work overload of health workers (18). In addition to staff shortage which was reported by operational managers and patients, the qualitative component of the broader mixed methods

study showed that patients who missed previous clinic appointments were being made to wait in the queues during subsequent visits until nurses had attended to patients who were on the appointment list for that day. Other factors reported by patients as contributing to long waiting time in the qualitative study were late arrival of filing clerks and nurses; long morning prayer sessions before commencement of clinical duties; staff meetings; prolonged tea or lunch breaks; and nurses giving preferential treatment to friends or relatives who skip the queues (Soter et al., submitted manuscript).

The lack of an Acquiescent Response Set (ARS) found in this study does not support literature evidence that suggests patient satisfaction surveys are almost always skewed toward satisfaction with positively worded statements (23). The reasonable explanation for the absence of ARS in this study can be attributed to two factors: (1) the fieldworker received training on how to read the statements in the interviewer-administered questionnaire very slowly and carefully to the patients in a way that the statements were understood, and (2) the questionnaire was pre-tested to provide feedback to the study team. The purpose of testing for ARS in this study was to ascertain if the patients understood the statements in the adapted PSQ-18. However; we understand that the implementation of ARS does not eliminate coercion. Therefore, to address the possibility of coercion, which is more likely to occur in people of low socioeconomic status, patients were assured there would no penalty or loss of patient benefits if they chose not to participate or decided to discontinue participation at any point in the study. We think that our data is valid because of these measures taken to prevent coercion, a source of collection/information bias.

A Swedish study used Donabedian SPO theoretical framework to show a statistically significant relationship between SPO constructs through the mediation pathway (17). This research corroborates the Swedish study and further reinforces the usefulness of Donabedian's theory in evaluating the quality of healthcare generally, and more specifically in the context of the ICDM model. The perception of the patients about the quality of care in the ICDM model can be interpreted to mean that the provision of good structure directly promotes good outcome; and that the relationship between good structure and good outcome is mediated by good process. More specifically, the patients thought that the provision of equipment, drugs and accessibility of chronic disease services contributed to the nurses' ability to be professional in their duties, become friendly to patients and attend to patients health needs. If the nurses performed these duties, the patients had confidence in the nurses, thought that the nurses were competent, and perceived there was coherence in the services provided by the nurses.

Although Donabedian's unidirectional framework continues to be the dominant touchstone paradigm for assessing the quality of health care, it has been described as too linear to recognise complex interactions between SPO constructs (16). Donebedian's critics argue that his theory fails to incorporate patient characteristics which are important precursors in the evaluation of the quality of health services (42). However, these limitations do not affect the validity of our study for the following reasons. First, the linearity of Donabedian's theory forms the basis of our study which assesses the linearity of the relationships between structure, process, and outcome constructs through the specified unidirectional, mediation and reciprocal pathways. The linearity of Donabedian's theory would have been a limitation in our study if we sought to determine non-linear relationships between SPO constructs . Regarding the limitation of Donabedian's theory

not accounting for patients' socio-demographic characteristics, it is important to note that patients' characteristics cannot be categorised as dimensions of care under SPO constructs in the ICDM model. This is because patients' characteristics do not fit into Donebedian's definition of SPO constructs and therefore have no role to play in explaining Donabedian's theory of quality of care; hence, the rationale for selecting his theoretical framework for evaluating the quality of care in the ICDM model.

Implications

Of the seven priority areas in the ICDM model (supply of critical medicines, hospital referral, defaulter tracing, prepacking of medicines, clinic appointments, reducing patient waiting time, and coherence of integrated chronic disease care), the supply of critical medicines and coherence of integrated chronic disease care reflected their intended constructs in the final model. This is an indication that these two priority areas have been well implemented. On the other hand, the remaining five priority areas (hospital referral, defaulter tracing, prepacking of medicines, clinic appointments, and reducing patient waiting time) were not significant indicators of good quality of care. Perhaps the reason why defaulter tracing was not a significant predictor in the final model is because the pilot of the PHC community outreach component of the ICDM model, which is one of the ways of tracing defaulters, was not being implemented in the study settings at the time this study was conducted. Defaulter tracing activities in the study settings are done by volunteer home-based workers, an approach that may not be effective due to little or no remuneration for these workers.

The authors suggest an interaction of factors responsible for the poor implementation of hospital referral, defaulter tracing, prepacking of medicines, clinic appointments, and reducing patient waiting time in the study settings. For instance, patient waiting time may have been unnecessarily prolonged in the study settings due to many factors. The purpose of prepacking medicines before patient arrival is to reduce patient waiting time; however, the high rate of patient's missed appointments and unavailability of prepacking bags could have served as a deterrent from nurses prepacking medicines. A qualitative inquiry is further needed to unpack the reasons for the poor implementation of these five priority areas in order to seek ways to better improve the quality of chronic disease care in the study settings.

Study strengths and limitations

The main strength of this study was the use of the patient satisfaction survey to evaluate the quality of care in the ICDM model in PHC facilities in a rural setting in South Africa using Donabedian's theory. In addition, we assessed satisfaction with integrated chronic disease services, from the perspectives of healthcare providers and users. This study also provided insight on the priority areas of the ICDM model that have been well implemented (supply of critical medicines and coherence of integrated chronic disease care) as well as those that require improvement in the delivery of services (hospital referral, defaulter tracing, prepacking of medicines, clinic appointments, and patient waiting time) in the study settings. Study findings should be interpreted in light of the following limitations: (1) Causal relationships between SPO constructs cannot be inferred because this study was cross-sectional by design, (2) Data on interpersonal outcomes (dis)satisfaction with care do not necessarily reflect technical outcomes

(e.g. reduced diseases, disabilities and deaths) in the ICDM model of care in the study settings, (3) The perspectives of clinic defaulters were not taken into account, and (4) Inferences could not be made about the (dis)satisfaction of other professional nurses with services in the ICDM model, due to the small number of operational managers who were interviewed.

Conclusion

The patients and operational managers were satisfied with many areas of the integrated chronic disease services, but had divergent opinions about satisfaction with some dimensions of care. Of the 17 dimensions of care assessed in the ICDM model, nine were significantly associated with good quality of care. However, services for five of the seven priority areas in the ICDM model were found to be poor (hospital referral, defaulter tracing, prepacking of medicines, clinic appointments, and patient waiting time); hence the need to strengthen services in these areas.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

SA, FXG, SMT and KK developed the study protocol. SA conducted the statistical analysis and interpreted the results. All authors critically reviewed the manuscript and approved the final version.

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Appendix 1: Table of definition of terms used in the article

Terms	Definition
Critical medicines	Anti-hypertension, antiretroviral and anti-diabetic drugs
Hospital referral	Referral of chronic disease patients by the professional nurses to the district hospitals
Defaulter tracing	Search for patients who did not attend a clinic following previous clinic appointment
Prepacking of medicines	Packing of patients' medicines before commencement of routine clinic activities
Clinic appointments	An appointment system in which a healthcare worker books a patient for a subsequent follow-up visit
Patient waiting time	The period between the arrival of patients to a health facility and when they leave the health facility
Coherence of integrated chronic disease care	Consistency and continuity in the provision of care that is convenient for patients

Paper III

Soter Ameh, Kerstin Klipstein-Grobusch, Lucia D'Ambruoso, Kathleen Kahn, Stephen M. Tollman and Francesc Xavier Gómez-Olivé. Quality of integrated chronic disease care in rural South Africa: user and provider perspectives (Revised manuscript resubmitted, Health Policy Plan)

Conference proceedings

I. Soter Ameh, Kerstin Klipstein-Grobusch, Lucia D'Ambruoso, Kathleen Kahn, Stephen M. Tollman and Francesc Xavier Gómez-Olivé. Quality of integrated chronic disease care in rural South Africa: user and provider perspectives. A poster presentation at the 21st International AIDS Conference, 18th-22nd July 2016, Durban, South Africa.

II. Soter Ameh, Kerstin Klipstein-Grobusch, Lucia D'Ambruoso, Kathleen Kahn, Stephen M. Tollman and Francesc Xavier Gómez-Olivé. Quality of integrated chronic disease care in rural South Africa: user and provider perspectives. An oral presentation at the 12th annual conference of the Public Health Association of South Africa (PHASA), 19th-22nd September 2015, East London, South Africa.

III. Soter Ameh, Kerstin Klipstein-Grobusch, Lucia D'Ambruoso, Kathleen Kahn, Stephen M. Tollman and Francesc Xavier Gómez-Olivé. A paradox of HIV stigmatisation in an integrated chronic disease management model in a rural South African setting. An oral presentation at the 12th annual conference of the Public Health Association of South Africa (PHASA), 19th-22nd September 2015, East London, South Africa.

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Quality of integrated chronic disease care in rural South Africa: user and provider perspectives

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Abstract

The integrated chronic disease management (ICDM) model was introduced as a response to the dual burden of HIV/AIDS and non-communicable diseases (NCDs) in South Africa, one of the first of such efforts by an African Ministry of Health. The aim of the ICDM model is to leverage HIV programme innovations to improve the quality of chronic disease care. There is a dearth of literature on the perspectives of healthcare providers and users on the quality of care in the novel ICDM model. This paper describes the viewpoints of operational managers and patients regarding quality of care in the ICDM model.

In 2013, we conducted a case study of the seven PHC facilities in the rural Agincourt sub-district in northeast South Africa. Focus group discussions ($n=8$) were used to obtain data from 56 purposively selected patients ≥18 years. In-depth interviews were conducted with operational managers of each facility and the sub-district health manager. Donabedian's *structure*, *process* and *outcome* theory for service quality evaluation underpinned the conceptual framework in this study. Qualitative data were analysed, with MAXQDA 2 software, to identify 17 a priori dimensions of care and unanticipated themes that emerged during the analysis.

The manager and patient narratives showed the inadequacies in *structure* (malfunctioning blood pressure machines and staff shortage); *process* (irregular prepacking of drugs); and *outcome* (long waiting times). There was discordance between managers and patients regarding reasons for long patient waiting time which managers attributed to staff shortage and missed appointments, while patients ascribed it to late arrival of managers to the clinics. Patients reported anti-hypertension drug stock-outs (*structure*); sub-optimal defaulter-tracing (*process*); rigid clinic appointment system (*process*). Emerging themes showed that patients reported HIV stigmatisation in the community due to defaulter-tracing activities of home-based carers, while managers reported treatment of

chronic diseases by traditional healers and reduced facility-related HIV stigma because HIV and NCD patients attended the same clinic.
Leveraging elements of HIV programmes for NCDs, specifically hypertension management, is yet to be achieved in the study setting in part because of malfunctioning blood pressure machines and anti-hypertension drug stock-outs. This has implications for the nationwide scale up of the ICDM model in South Africa and planning of an integrated chronic disease care in other low- and middle-income countries.

Key words: HIV, non-communicable diseases (NCDs), integrated chronic disease management, quality of care, health outcomes, primary health care, Agincourt study site, South Africa

Key Messages

- An integrated chronic disease management (ICDM) model was initiated as a national pilot in 2011 in selected primary health care (PHC) facilities in South Africa to leverage an established HIV treatment programme for improving quality of care for non-communicable diseases (NCDs). This study was a novel evaluation of a major initiative of the national department of health, one of the first of such efforts by an African ministry of health.
- An in-depth perspective of the quality of care in the ICDM model was assessed from the viewpoints of healthcare providers and users using Avedis Donabedian's structure, process, and outcome theoretical framework for evaluating the quality of healthcare. The manager and the patient narratives showed the inadequacies in *structure* (malfunctioning blood pressure machines and staff shortage); *process* (irregular prepacking of drugs); and *outcome* (long waiting times). Patients reported anti-hypertension drug stock-outs; sub-optimal defaulter-tracing; and rigid clinic appointments. Managers thought there was reduced HIV stigma because HIV and NCD patients attended the same clinic.
- These findings suggest that the purpose for which the ICDM model was initiated - to use the HIV programme as leverage for scaling up services for NCDs - is yet to be achieved. This has implications for the nationwide scale up of the ICDM model in PHC facilities in South Africa and planning of an integrated chronic care of communicable and non-communicable conditions in other low- and middle-income countries.

Background

Many low- and middle-income countries (LMICs) are witnessing an increasing burden of chronic non-communicable diseases (NCDs) (WHO 2010). Chronic conditions include all health problems that require ongoing management for at least six months encompassing NCDs (e.g. hypertension), but also expanding to include HIV (WHO 2002). This is due to the growing recognition of the transformation of HIV to a chronic condition as a result of rapidly expanding Antiretroviral Treatment (ART) resulting in increasing life expectancy (UNAIDS 2011).

Chronic non-communicable diseases are responsible for two-thirds of all mortalities worldwide with 80% of these deaths occurring in LMICs (WHO 2014a). It is estimated that the annual number of deaths from NCDs will increase to 55 million by 2030 (WHO 2013b) and Africa will have the greatest increase by 27% (WHO 2008b). Since the beginning of the HIV/AIDS epidemic, over 78 million people have been infected with the virus and 39 million people have died of HIV-related causes (WHO 2015). In 2011, nearly 70% of the 34 million people living with HIV (PLWHIV) worldwide resided in sub-Saharan Africa (SSA) (WHO, 2015). Thirty six million deaths due to chronic diseases could have been averted globally by 2015 if health systems were strengthened and small set of interventions were directed towards whole populations and high-risk individuals (Beaglehole *et al.* 2007).

In 2008, NCDs accounted for 29% of all deaths in South Africa (WHO 2011) and in 2012, mortalities due to NCDs had increased to 43% (WHO 2014b). The increase in NCD-related mortalities in South Africa may be attributed to the rising prevalence of NCDs which is an outcome of improved life expectancy (Mayosi *et al.* 2009) in part due to the increased roll-out of Antiretroviral Treatment (ART). The increasing burden of NCDs in South Africa (Tollman *et al.* 2008) is occurring against the background of the gradually declining but persisting HIV infection with a prevalence rate estimated at 10% in the general population in 2014 (Statistics South Africa 2014), one of the highest in Africa. These numbers present the urgent necessity to address the dual burden of HIV and NCDs in South Africa.

Chronic disease services are fragmented with the HIV programme vertically controlled and administered in a 'silo' within the health system (Kawonga *et al.* 2013). Although the achievements of vertical programmes have been widely acknowledged (the smallpox eradication programme is a case in point) (Unger *et al.* 2003), these programmes address only a fraction of the need for healthcare; create duplication; lead to inefficient facility utilisation by recipients; and may lead to gaps in care (Brown 2001). In confronting the challenges posed by vertical programmes, Margaret Chan, the Director General of the World Health Organization (WHO) stated emphatically: 'We need a comprehensive, integrated approach to service delivery. We need to fight fragmentation' (Chan 2007).

The WHO defines integrated healthcare as 'the organisation and management of health services so that people get the care they need, when they need it, in ways that are user-friendly, achieve the desired results and provide value for money' (WHO 2008a). Following evidence that integrated chronic disease care improves patient health

outcomes (Janssens *et al.* 2007), the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommended an integrated approach for chronic disease management. This approach leverages the innovations of the HIV programme to support or scale up services for NCDs (UNAIDS 2011) using the building blocks described in the Innovative Care for Chronic Conditions (ICCC) framework (WHO 2002).

In line with this recommendation, the National Department of Health (NDoH) in South Africa initiated the Integrated Chronic Disease Management (ICDM) model which uses a diagonal approach to health systems strengthening (Mahomed *et al.* 2014). The diagonal approach integrates the vertical HIV programme with the horizontal general health system (Knaul *et al.* 2015). The national pilot of the ICDM model commenced in June 2011 in selected PHC facilities in three of South Africa's nine provinces, i.e. Gauteng, North West and Mpumalanga (NDoH 2014). This is one of the first of such efforts by an African ministry of health.

The ICDM model has health facility, community and population components. Services in health facilities have been reorganised to improve operational efficiency and quality of care. In the communities, ward-based PHC outreach teams provide 'assisted' self-management to promote individual responsibility. The population component involves health promotion and screening (NDoH 2014). The priority areas of facility reorganization include coherence of care; reduced waiting time; defaulter-tracing activities; appointment systems; supply of critical medicines; prepacking of medication; and appropriate referral. In community-oriented integrated chronic disease care, an outreach team consisting of one professional nurse, three staff nurses and six community health workers operates within the community the clinic serves. The outreach team is responsible for 6000 individuals in 1500 households (250 households per 1 community health worker), and is expected to manage at least 80% of defined health problems of the catchment population (NDoH 2014).

Quality of care and quality assessment

Several frameworks have been recommended for evaluating quality of care (Donabedian 1988a;WHO 2006; Hulton *et al.* 2000; Parasuraman *et al.* 1985). However, Avedis Donabedian's model has been used extensively in evaluating quality of healthcare and is regarded as a classic conceptual framework. Avedis Donabedian described seven elements of quality of medical care: efficacy, effectiveness, efficiency, equity, optimality, acceptability and legitimacy (Donabedian 2003). He argued that the choice and relative prioritization of these elements should be contextual and guided by the circumstances in which quality of care is assessed (Donabedian 2003). Donabedian described the quality assessment as a triad of structure, process, and outcome (SPO) constructs. He defined *structure* as the factors that affect the context in which care is provided (e.g. availability and functionality of equipment); *process* as the actions that make up healthcare (e.g. examination of patients); and *outcome* as the effects of healthcare on patients (e.g. waiting time). He postulated the relationships between SPO constructs based on the premise that good structure should promote good process, and good process should in turn promote good outcome. The SPO framework often represented by a chain of three boxes depicting the relationships between SPO constructs (Donabedian 2003) can be used to draw inferences about the quality of healthcare (Donabedian 1988a).

Integrated healthcare programmes have been well researched quantitatively (Huntington and Aplogan 1994; Briggs and Garner 2006) from the perspective of healthcare providers and relatively less so from a user perspective (Briggs and Garner 2006). Furthermore, differing views of healthcare providers and users have been reported in few quantitative surveys that assessed provider-user perspectives and interactions on quality of integrated healthcare programmes (Briggs and Garner 2006). However, little is known about the use of a qualitative method to assess the quality of care in the ICDM model from the perspectives of and interactions between healthcare providers and users. The aim of this study was to assess the perspectives of healthcare providers and users and their interactions regarding the quality of care in the ICDM model in PHC facilities in a rural South African setting, using qualitative research to operationalise Donabedian's theoretical framework.

Methodology

Study setting

This research was conducted in PHC facilities in the rural Agincourt sub-district of Mpumalanga province, northeast South Africa. At the time of the study, the ICDM model was being implemented in 17 of the 38 PHC facilities in the sub-district. Seven of the 17 facilities implementing the ICDM model are situated in an area covered by the Agincourt Health and Demographic Surveillance System (HDSS), which has been monitoring the population in the area for two decades. The population under surveillance in July 2011 was 90 000 people in 16 000 households in 27 villages in which Tsonga is the most widely spoken language (Kahn *et al.* 2012). Government's development initiatives have led to improved housing and access to potable water, electricity and social security grants. However, infrastructure in the area is still limited and unemployment rates remain high (Kahn *et al.* 2007). All PHC health facilities in the Agincourt HDSS were selected for the study. Three referral public hospitals that serve these PHC health facilities are situated 25 km to 45 km from the study area (Kahn *et al.* 2007). These primary and secondary public health facilities serve socio-economically vulnerable populations in the study area.

Study design and study population

This qualitative study was a component of a broader mixed methods research project which evaluated the quality of care in the ICDM model and assessed the effectiveness of the model in improving patients' health outcomes in the study setting (Ameh *et al.* under review). This research was a case study of the seven PHC facilities implementing the ICDM model in the study area. The study population consisted of patients 18 years and above receiving treatment for chronic diseases at the health facilities; seven operational managers (nurses-in-charge) of the selected PHC facilities; and the sub-district health manager. Focus Group Discussions (FGDs) were conducted to obtain in-depth data from multiple patients to capitalise on group interactions and communication regarding lived experiences based on provider-user interface. In-depth interviews were held for the seven operational managers of the health facilities and the sub-district health manager to get the depth and breadth of providers' perspective on the quality of integrated chronic care and policy environment for implementing the ICDM model, respectively.

Inclusion and exclusion criteria for research participants

The ICDM model addresses the following disease categories: HIV/AIDS, tuberculosis, hypertension, diabetes, chronic obstructive pulmonary disease, asthma, epilepsy and mental health illnesses that are to be managed at PHC level (NDoH 2014). Considering the burden of chronic diseases in the study area, patients with markers of chronic diseases for HIV, hypertension, and diabetes in the health facilities

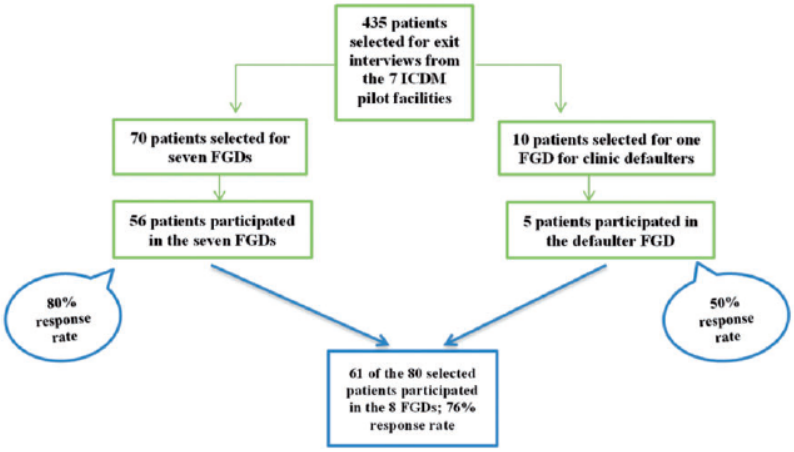

Figure 1. Sampling of patients for focus group discussions

were eligible to participate in the study. The criteria for recruiting patients for FGDs were i) having commenced treatment for the markers of chronic conditions in the study area six months before the implementation of the ICDM model; ii) having participated in the exit quantitative interviews organised by the research team before the FGDs and iii) willingness to participate. Participation in the exit quantitative interview was a criterion for recruiting patients for FGDs because the broader mixed methods research was designed for the quantitative and qualitative components to be conducted in series with the exit interviews preceding the FGDs. The purpose was to use the exit interviews as a means of identifying patients who overwhelmingly reported satisfaction or dissatisfaction with the quality of care in the priority areas of the ICDM model and purposively selecting these patients for FGDs to further explore their in-depth perspectives on the quality of care in the ICDM model. Patients receiving treatment six months before the ICDM model was implemented were selected to assess their levels of (dis)satisfaction with the quality of chronic disease care before and after the implementation of the ICDM model in efforts to gauge possible changes in the quality of chronic disease care that can be attributed to the ICDM model.

Out of the 435 randomly selected patients who responded to the exit interviews, 70 were purposively selected for seven FGDs (i.e. 10 patients per clinic). Ten (10) clinic defaulters were identified and purposively selected for FGD with at least one patient from each of the seven health facilities. Clinic defaulters were defined as those who missed three consecutive clinic appointments as was observed through the review of clinical records. Of the 70 selected patients, 56 participated in the FGDs and five of the 10 defaulters participated in the FGD for clinic defaulters. Sixty one of the 80 patients selected for discussions participated in the FGDs giving a response rate of 76%: 80% for the seven FGDs and 50% for the defaulter FGD (Figure 1). The Exit interviews were conducted from August to October 2013 and preceded the FGDs to make it easy to recruit patients for the FGDs and to provide a large sampling frame from which prospective FGD participants were to be purposively selected. Prospective FGD participants were selected from all clinics during official working hours (8.00 am - 4.30 pm local time) from Monday to Friday when the exit interviews were held. The FGDs were conducted in November and December 2013 and were held on a Saturday at a time that was convenient for most of the patients.

The operational managers, who were also professional nurses, were selected for the in-depth interviews because of their roles and responsibilities as managers of the health facilities. These roles were perceived to be critical to better understanding the quality of care in the ICDM model than other nurses who often rotated their clinical duties at predetermined intervals in other service provision areas such as acute care, antenatal clinic, postnatal clinic and child welfare clinics. The sub-district health manager was interviewed in order to understand the policy environment for the operational implementation of the ICDM model.

Conceptual framework for assessing quality of care in the ICDM model

This study utilized Donabedian's SPO framework, used in Sweden (Kunkel *et al.* 2007), as it is a classic framework for evaluating the quality of medical care (Mitchell *et al.* 1998), and because the NDoH in South Africa adopted this framework for the ICDM implementation (NDoH 2014).

Figure 2 shows the conceptual framework for this study. In this article, the relationships between structure, process and outcome constructs are non-predictive. The postulated relationships are thematically assessed using qualitative analytical techniques to generate recommendations for policy and practice. The conceptual framework indicates that, for instance, the provision of good structure (e.g. equipment and critical medicines) leads to a good process, (e.g. examination of patients) which in turn leads to good outcome (e.g. reduced waiting time).

Data collection

The FGDs were preceded by the health facility patient exit interviews, which were conducted as a component of the broader study. After the exit interviews, the patients were briefed about the purpose and scheduled dates of the upcoming FGDs. Those who volunteered to participate in the FGDs were invited to do so based on the inclusion criteria previously described. Seven FGDs were held for 5–9 participants of similar age recruited from within the seven PHC facilities, with each session lasting 60-90 min. The purpose of interviewing participants of similar age was to gain collective rather than individual accounts and to provide a conducive environment for the

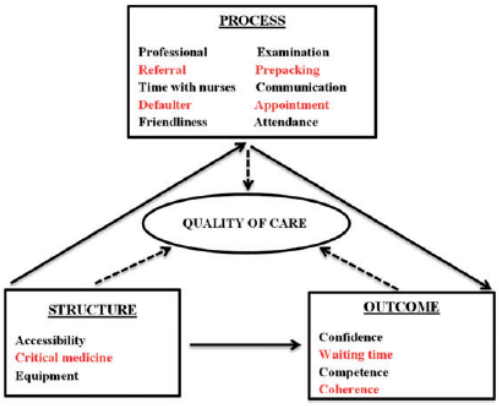

Figure 2. Conceptual framework of quality of care in the ICDM model*

*The 17 dimensions of care and their intended constructs used to operationalise Avedis

Donabedian's theory in the ICDM model in Bushbuckridge sub-district in 2013

(The dimensions in red colour are the priority areas of the ICDM model)

participants to freely discuss their experiences with the health system without fear of being intimidated. One FGD was also held for five clinic defaulters from within the seven health facilities; hence, a total of eight FGDs were conducted. The FGDs were held in a centrally located neutral venue within the catchment area of the health facility to enable the patients to freely express and communicate their lived experiences with healthcare services. Finally, eight in-depth interviews lasting 30–40 min were conducted with the seven operational managers and the sub-district health manager in designated health facilities.

A priori identification of the 17 dimensions of care (Figure 2) for which the SPO constructs were intended was undertaken by experts on quality of care in the study team to reflect Donabedian's definitions of SPO domains and the theory of the relationships between SPO constructs; henceforth, referred to as themes. This approach was used to develop the respective topic guides.

Of the 17 dimensions of care assessed and categorised under SPO themes, ten were adapted from the Patient Satisfaction Questionnaire (PSQ-18) (Ware *et al.* 1976) used as a study tool in the exit interviews. The remaining seven dimensions were identified by the study team as priority areas for improving quality in ICDM: supply of critical medicines, hospital referral, defaulter tracing, prepacking of medicines, clinic appointments, reducing patient waiting time, and coherence of integrated chronic disease (NDoH 2014). These priority areas (Figure 2) are the key components of the tools and systems used in the successful HIV programme that is being leveraged to support or scale-up services for improving the quality of care for NCDs (NDoH 2014). The FGD and interview guides for operational managers contained statements on the 17 dimensions that were intended to elicit healthcare providers' and users' perspectives of quality of care in ICDM. The study participants were asked to raise their concerns about unanticipated dimensions of care not originally included in the topic guides.

The first author (S.A.) ran a two-day training session with two experienced qualitative field workers, with at least 10 years of field experience in the HDSS. During the training, the field workers were briefed about the purpose of the study and on how to administer the structured topic guide to the patients. One field worker audiotaped and moderated the discussions while the other took notes during the FGDs which were held in Tsonga. The first author conducted and audiotaped the in depth interviews with the operational managers and sub-district health manager according to the respective topic guides written in English language.

Quality assurance

The FGD audio recordings were translated and transcribed into English by two qualitative field workers. A third qualitative field worker in the Agincourt HDSS validated the transcriptions by listening to two of the eight audiotapes and also translated them into English. A comparison of the early and latter transcriptions showed no major differences in the participants' experiences and opinions regarding the dimensions of quality of care in the ICDM model. Similar procedures were used to assure data quality for the in-depth interviews.

Data analysis

The transcribed FGDs and interviews were thematically analysed using MAXQDA 2 software. A combined deductive and inductive approach was used for data analysis. The deductive analysis was based on the pre-identified themes focusing on the in-depth inquiry of the dimensions of care in the ICDM model. Inductive analysis was undertaken for an emerging theme that was not anticipated at the outset and not included among the 17 dimensions of care covered in the topic guide. The data were coded by S.A. and verified by the co-authors through the reading and re-reading of the quotes. A code book was developed based on recurring pre-identified themes and emerging themes. Reliability of the coded data was verified through discussions of inconsistent codes among co-authors until agreement was reached.

Ethical considerations

Written informed consent was obtained from the study participants after reading out the content of the information sheet and explaining the purpose of the FGD. Because confidentiality during the FGDs could not be guaranteed, participants chose whether to disclose the chronic disease(s) for which they were receiving treatment in the health facilities and were urged to respect the privacy of fellow discussants who voluntarily disclosed this information. Anonymity was guaranteed by removing all identifiable information from the narratives reproduced in study reports.

Results

Healthcare provider and user perspectives on the quality of care in the ICDM model are discussed below using Donabedian's structure, process and outcome framework for health service evaluation. Verbatim quotes are used to illustrate the analysis.

Socio-demographic characteristics

There were 61 black adult South African participants (43 females and 18 males) in the eight FGDs. The race of the FGD participants reflects the dominance of black people in the study setting. The gender imbalance of the 61 participants in the FGDs (43 (70%) females and 18 (30%) males) corroborates the gender constitution of the participants of a population-based research in the study setting (female vs. male: 70% vs. 30%) to determine the predictors of health care

utilisation (Ameh *et al.* 2014) and the gender composition of the 345 patients who participated in the exit interviews from which the FGD participants were recruited (female vs. male: 81% vs. 19%) (Ameh *et al.* under review).

All seven operational managers who participated in the in-depth interviews were female professional nurses with an age range of 40–55 years and 15–20 years of nursing experience. A 55-year-old male senior sub-district health staff was interviewed on behalf of the sub-district health manager because the latter could not be reached due to busy administrative schedules.

Structure-related dimensions of care

Critical medicines

Hypertension patients reported receiving monthly prescribed medication. However, there were occasional drug stock-outs in some health facilities and participants expressed frustration with irregular supplies of anti-hypertension medicines.

> *When my treatment is not available at the clinic they do tell me that this month my treatment is not available; then they gave me the one that is available that day. When the treatment is not out of stock, they do give me all the treatment that I am getting every month [Respondent 2 (man), Clinic 1].*

Equipment

Hypertension patients expressed concerns about the lack of functioning blood pressure (BP) machines in the facilities. Patients reported expectations of BP checks by nurses while taking anti-hypertensive drugs. They also described their experiences of travelling to other health facilities to assess their BP.

> *We have stayed for two to three months without BP machine. They were just giving us treatment without knowing whether our BP was high or not. . . . It gives us problem when we have to travel to another clinic to check our BP [Respondent 1 (woman), Clinic 7].*

An operational manager acknowledged that her facility did not have functioning BP cuffs (a component of BP equipment) and other medical equipment. This nurse expressed frustration in her ability to provide quality care to patients due to lack of equipment. She further indicated that a project manager working in a non-governmental research institution donated BP cuffs to her health facility to enable nurses to monitor patients' BP more effectively.

> *[Laughs] what can I say? I think three weeks back Mr. X [a project site manager at institution Y] was here to give us different kinds of BP cuffs because we didn't have them. I really can't say that the clinic has all the different medical equipment to take care of all those patients or bring quality nursing care to the patients [Operational Manager, clinic 3].*

Process-related dimensions of care

Prepacking of drugs

The ICDM manual stipulates that nurses prepack patients' medicines before their arrival at the facilities to reduce patient waiting times during consultations. Nurses' inability to regularly prepack medicines was reported as a factor militating against their ability to effectively deliver services. An operational manager reported that prepacking of drugs before appointments was sometimes done, but that staff shortage and unavailability of prepacking bags were obstacles to regular prepacking of drugs. Hence, prepacking was sometimes done during or after consultations or was not done in instances when there were no prepacking bags.

> *Sometimes we do prepacking the day before clinic appointment. Sometimes when we are short-staffed, we are unable to do it. Another challenge is that we don't have prepacking bags [Operational Manager, Clinic 4].*

Appointment system

Patients reported a rigid appointment system in which they were unable to access services for sudden-onset illnesses occurring outside scheduled appointment dates.

> *When your date is still far you can't go to the clinic even when you have other illnesses [Respondent 2 (woman), Clinic 3].*

In the ICDM model, patients with chronic diseases are given appointment dates for their next clinic visits. These predetermined scheduled appointments are usually on a monthly basis for unstable/uncontrolled cases [e.g. BP > 140/90 mmHg for hypertension patients and CD4 count < 350 cells/mm^{3}for HIV patients] or two monthly for stable/controlled cases [e.g. BP < 140/90 mmHg for hypertension patients and CD4 count > 350 cells/mm^{3}for HIV patients].

Patients also reported that missing clinic appointments led to punishment through being made to wait in queues during subsequent visits until the nurses had attended to patients who were on the appointment list for that day. This resulted in long patient waiting times.

> *When they [nurses] shout at us it is because . . . they tell you to come today at nine, you find that you miss your appointment date and come at another day. When I missed my appointment and went there the other day, they [nurses] delayed me even when I arrived at the clinic early. All the patients that came after my arrival collected their treatment and went home and left me at the clinic. And I don't think they [nurses] are wrong because you [patient] are the one who missed your appointment [Respondent 2 (woman), Clinic 1].*

Unprofessional behaviour of clinical staff

Patients recognised the role of home-based carers [HBCs] in patient management such as assisting patients with domestic chores and delivering drugs from the facilities. However, some patients reported that HBCs breached confidentiality by disclosing their clinical information to persons other than those entrusted with patient care and management.

> *I told them [HBCs] not to come to my house any more. When I tell them something, I expect them to report it to their seniors and not to tell the whole community. So when I'm sick, I will go to the clinic [Respondent 5 (woman), Clinic 2].*

Patients reported how the behaviours of healthcare providers influenced their perception of quality of care in the health facilities. In the quote below, a patient expressed dissatisfaction with the professional conduct of a nurse.

> *Eish! [A popular exclamation in South Africa often used to describe a frustrating or appalling experience] there is a new nurse that arrived at the clinic. She is fat and tall [Man 1 and 2 nod in agreement]. When you are in the consulting room with her [referring to the new nurse], she will send you to go and take the tablets in the locker [referring to where drugs are kept]. Do I know the*

tablets I have to use? Sometimes she will send a cleaner to go and take the tablets; does the cleaner know the treatment? I have seen it several times and am saying that these nurses are going to kill us [Respondent 2 (woman), Clinic 4].

Outcome-related dimensions of care

Reduced stigma in the health facilities

An operational manager reported that the ICDM model conferred an advantage on PLWHIV because of the reduced stigma due to non-segregation of patients managed for chronic disease in the same clinic. Non-separation of patients or consultation rooms in the clinics implied that it may not have been easy for patients to identify who was being managed for HIV/AIDS; hence, the reduced HIV-related stigma.

Previously we were grouping them according to their diseases, but now they are put together. Patients living with HIV/AIDS are satisfied because they are mixed with those who are having hypertension and diabetes (Operational Manager, Clinic 6).

Waiting time

Patients and operational managers attributed long patient waiting time in facilities to several factors. Patients noted the late arrival of filing clerks and nurses; long morning prayer sessions before commencement of clinical duties; staff meetings; prolonged tea or lunch breaks; nurses giving preferential treatment to friends or relatives who skip the queues; and nurses engaging in trading activities (e.g. buying and selling of household products) in the consultation room during consultation hours.

We arrive at six in the morning and stay outside the gate and they will open the gate at eight o'clock. Sometimes they will start to check you at one o'clock. You will get your treatment very late despite early arrival at the clinic [Respondent 2 (man), Clinic 7].

Operational managers by contrast reported long waiting times due to staff shortage and patients missing appointments.

We are booking a certain number of patients and if that number becomes extra because of those who didn't come on their appointment dates, you find that we have a lot of patients and they [who missed previous appointments] have to wait (Operational Manager, Clinic 1).

The overall findings show that the aim of leveraging the HIV programme for NCD care, such as hypertension, may be yet to be achieved due to anti-hypertension drug stock-outs; malfunctioning blood pressure machines; sub-optimal defaulter tracing activities; rigid clinic appointments; and a dysfunctional prepacking system. Long patient waiting time was also reported as problematic by the service providers and users.

Emerging themes

Staff shortage

Both users and providers identified staff shortage as a key challenge impacting the delivery of quality care in facilities. A manager described making mistakes due to work overload arising from staff shortage, and a patient described how staff shortage led to work-related exhaustion and 'complicated' behaviour of nurses, negatively impacting the provision of quality services.

I'm alone and I have to do all the programmes with the staff nurse. I'm to manage the deliveries, antenatal clinics, integrated chronic disease clinic, minor illness, immunization and all those programmes. I can't! .... Sometimes if I am forced to do the work alone I end up making some stupid mistakes (Operational Manager, clinic 3).

Today, they [referring to nurses] are two and they get tired and become complicated [Respondent 1 (woman), Clinic 6].

Unaffordable transportation costs

Patients reported unaffordable transportation costs as a barrier to accessing clinics or when referred by nurses from clinics to doctors in the hospitals. In a rural South African setting with high unemployment levels, people's reliance on paid jobs as a means of livelihood affects health-seeking behaviour.

If I am working for someone and that person doesn't pay me, I have to wait until the person pays me before I have to go to the clinic or hospital [Respondent 4 (woman), Clinic 1].

HIV stigmatisation due to home visits by home-based carers

An operational manager described a situation in which community members stigmatised ill people who were visited by HBCs. Community members were said to have perceived persons visited by HBCs to have HIV/AIDS, and that patients responded by not allowing HBCs visit their homes. This reported stigma constitutes a barrier to accessing home-based health services.

Home-based carers are not accepted. They [patients] are thinking that other people [community members] will think that they are HIV positive and that is why the HBCs are coming to visit them [Operational manager, Clinic 1].

Use of traditional healers

An operational manager noted that patient behaviours presented challenges for HBCs to trace clinic defaulters who use traditional medicine in places far away from where they [patients] received biomedical care. Furthermore, the use traditional medicine for the treatment of chronic diseases could potentially interfere with the use of modern pharmaceuticals.

We [nurses] have tried our level best even to trace patients who missed their appointment using HBCs and by telephone calls. Some of our patients move around seeking care in many places because they believe in both western civilization treatment and traditional healers. You find that a patient is receiving treatment in village X and the next thing you will hear from the relative that he (the patient) is at village Y (about 50 Km away from village X) because there is a traditional healer there who is busy treating him. That gives us a problem in tracing them [Operational manager, Clinic 3].

Discussion

This study shows that the innovative ICDM model provides non-segregated services for chronic disease patients and appears to have benefited PLWHIV due to reduced HIV-related stigma. This was also reported in a pilot study in Cambodia (Janssens *et al.* 2007; UNAIDS 2011). However, the ICDM model did not show benefits for patients receiving treatment for hypertension as a result of occasional stock-outs of anti-hypertension drugs and malfunctioning BP

machines. This was corroborated in the quantitative component of the broader study which showed suboptimal blood pressure (BP) control (Ameh *et al.* under review). The widely reported suboptimal BP control could impact the WHO's target for the 25% reduction in premature mortality (i.e. deaths among persons 30–69 years of age) due to NCDs by 2025 (WHO 2013a).

The inability to deliver effective hypertension services in the ICDM model can be attributed to policy and health system factors. Notable among these is the failure of the Innovative Care for Chronic Conditions (ICCC) framework to significantly incorporate the complexities associated with multiple morbidities; (Oni *et al.* 2014) South Africa's public health sector vertical HIV programme not being administratively integrated with the horizontal general health system; (Kawonga *et al.* 2013) and the lack or breakdown of equipment to measure blood pressure (Thorogood *et al.* 2004). Most chronic diseases are presently managed in separate disease-specific public health facilities in South Africa (Oni *et al.* 2014) and suboptimal care has been reported for hypertension patients receiving treatment in these facilities (Steyn *et al.* 2008). This justifies the prioritization of optimal management of non-communicable diseases in the ongoing PHC re-engineering and ICDM model implementation (NDoH 2013) within the ICCC framework forming the cornerstone of these reforms (NDoH 2013).

Defaulter-tracing activities in the study setting were not done by the ward-based PHC outreach teams, but by volunteer HBCs who receive little or no remuneration. This was because the pilot of the PHC outreach team was being implemented in other communities in the Bushbuckridge Municipality at the time this study was conducted. Although the HBCs visited homes to do domestic chores and trace clinic defaulters, they were not generally accepted because the patients feared lack of confidentiality often arising from the disclosure of their disease status to community members by HBCs.

Unprofessional conduct of some nurses was identified as a barrier to the effective implementation of the ICDM model. Some patients reported nurses were involved in buying and selling of household products during official working hours. These illicit trading activities which are not related to professional work could potentially contribute to long patient waiting time in the clinics. Furthermore, preferential treatment to health workers' friends and relatives could also lead to patient dissatisfaction with services and prolonged waiting time. Therefore, educational programmes need to be targeted at healthcare workers to change their attitudes and behaviours regarding provision of quality services to patients.

Emerging theme were staff shortage and patients' inability to afford the cost of transportation to the PHC health facilities and hospitals on referral as previously reported in our study setting (Goudge *et al.* 2009). Therefore, financial constraint remains a barrier to accessing free services and treatment in public PHC facilities in South Africa. Other emerging themes were HIV stigmatization due to home visits by HBCs and use of traditional healers. Ill persons did not welcome HBCs into their homes because of the stigma attached to such visits which is often associated with chronic illness specifically HIV/AIDS. These practices have been reported in the literature in an integrated HIV/TB programme elsewhere in South Africa (Uwimana *et al.* 2012). The reported HIV-related stigma in the communities is a barrier to accessing home-based health services and has the potential to negatively impact the effectiveness of the model in improving patients' health outcomes. Defaulter tracing was reportedly challenging because of combined use of PHC facilities and traditional healers in communities far away from where they received biomedical care. This pattern of health-related migration in the study setting has been attributed to the use of plural healing such as use of biomedicine, traditional healers, prophets and churches as viable alternatives for the treatment of stroke-like symptoms and other diseases (Thorogood *et al.* 2007). The use of traditional healers may interfere with pharmaceutical treatment which could result in poor health outcomes of patients.

The healthcare provider-user interface reported in this study corroborates the multi- and bi-directional relationship between structure, process, and outcome constructs postulated by Donabedian (Mitchell *et al.* 1998). Staff shortage and the lack of prepacking bags (structure factors) made it challenging for nurses to prepack patients' drugs (process factor) which in turn led to long patient waiting time (outcome factor). Patients who missed clinic appointments (process factor) felt nurses were unfriendly (process factor) to them during their subsequent clinic visit, and punished them by delaying their consultation process (outcome factor). These dynamics contributed to avoidable long waiting periods (outcome factor), aside from other health facility-related factors, such as the late arrival of staff; long morning prayer sessions before commencement of clinical duties; morning staff meetings; and prolonged tea/lunch breaks. Healthcare providers and users consistently reported long waiting periods in the health facilities as has been described in other resource-constrained LMICs (Babirye *et al.* 2014). This could be a reflection of operational challenges such as performance of multiple tasks, staff shortage, and work overload (Briggs and Garner 2006).

A substantive finding in terms of how quality of care is conceptualised relates to the diverging views of providers and patients. Constraints experienced by each group (e.g. providers working under pressure due to chronic staff shortage and patients struggling to access services or their lack of trust in service providers) result in pronounced provider-patient disconnect. Hulton's framework of quality of care, which incorporates the user's experience of care with care provided (Hulton *et al.* 2000, Hulton *et al.* 2007) is an interactional notion of quality of care and underscores the need to address these challenges through people-centred health systems research.

The purpose of leveraging HIV programme for NCDs, especially hypertension, is yet to be achieved in PHC health facilities in the study setting due to malfunctioning blood pressure machines and anti-hypertension drug stock-outs. This has implications for the nationwide scale up of the ICDM model in South Africa and planning of integrated chronic care of communicable and non-communicable conditions in Swaziland and Ethiopia (Rabkin *et al.* 2012) and Uganda (Schwartz *et al.* 2015).

Strengths and limitations

The limitations of our study have been categorised as general and specific. Although qualitative methods do not necessarily require probability sampling techniques, the patients were not randomly selected and may not be representative of the chronic disease subpopulation in the selected health facilities. Furthermore, the qualitative methods used to preclude the establishment of cause and effect relationship as would be established in quantitative research. Instead, explanations of phenomena are developed through eliciting lived experiences and systematising these into valid forms of knowledge on the relationships between problems and their causes. Specifically, this study was conducted in a rural sub-district of South Africa and our findings may not be generalized to PHC facilities in semi-urban and urban areas in the provinces where the pilot of the ICDM model is ongoing. Future research is needed to understand how the ICDM model works in urban PHC facilities.

Although the qualitative methods used do not establish cause and effect relationships, they help to identify contextual factors that

could contribute to understanding the quality of care in the ICDM model for the purpose of generating recommendations for policy and practice. Despite these limitations, our methodology was well suited for the study because of the dearth of contextual qualitative data on provider and patient perspectives on the quality of care in the ICDM model. To our knowledge, this is the first application of Donabedian's theory, using qualitative methods, to assess the quality of care in the ICDM model in Africa. The use of a combined deductive and inductive approach in data collection was a major strength.

Conclusion

A key finding was that patients reported anti-hypertension drug stock-outs (structure); sub-optimal defaulter-tracing activities (process); and a rigid clinic appointment system (process). Nurse and patient narratives showed the inadequacies in structure (malfunctioning blood pressure machines and staff shortage); process (irregular prepacking of drugs); and outcome (long waiting times). There was discordance between managers and patients regarding reasons for long patient waiting time which managers attributed to staff shortage and missed appointments, while patients ascribed it to late arrival of managers to the clinics. Emerging themes showed that patients reported HIV stigmatization in the community due to defaulter-tracing activities of home-based carers, while managers reported treatment of chronic diseases by traditional healers in the community and reduced facility-related HIV stigma because HIV and NCD patients attended the same clinic.

Acknowledgement

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Paper IV

Soter Ameh, Kerstin Klipstein-Grobusch, Eustasius Musenge, Kathleen Kahn, Stephen M. Tollman and F. Xavier Gómez-Olivé. Effectiveness of an integrated approach to HIV and hypertension care in rural South Africa: controlled interrupted time-series analysis. (Submitted, AIDS).

Conference proceedings

I. Soter Ameh, Kerstin Klipstein-Grobusch, Eustasius Musenge, Kathleen Kahn, Stephen M. Tollman and F. Xavier Gómez-Olivé. Effectiveness of an integrated chronic disease management model in improving patients' health outcomes in rural South Africa: controlled interrupted time-series and multilevel analyses. An oral presentation at the 11th Annual Conference of the Public Health Association of South Africa (PHASA), 7-9th October 2015, Durban, South Africa.

II. Soter Ameh, Kerstin Klipstein-Grobusch, Eustasius Musenge, Kathleen Kahn and F. Xavier Gómez-Olivé. Effectiveness of an integrated chronic disease management model in improving patients' health outcomes in rural South Africa: controlled interrupted time-series and multilevel analyses. An oral presentation at the INDEPTH Network Scientific Conference, 11-13th November 2015, Addis Ababa, Ethiopia.

III. Soter Ameh, Kerstin Klipstein-Grobusch, Eustasius Musenge, Kathleen Kahn and F. Xavier Gómez-Olivé. Effectiveness of an integrated chronic disease management model in improving patients' health outcomes in rural South Africa: controlled interrupted time-series and multilevel analyses. An oral presentation at the symposium organised by the

NCD leadership training programme, University of the Witwatersrand, 20th November 2015, Johannesburg, South Africa.

IV. Soter Ameh, Kerstin Klipstein-Grobusch, Eustasius Musenge, Kathleen Kahn, Stephen M. Tollman and F. Xavier Gómez-Olivé. Effectiveness of an integrated chronic disease management model in improving patients' health outcomes in rural South Africa: controlled interrupted time-series and multilevel analyses. An oral presentation at the 7th Cross-Faculty Symposium, University of the Witwatersrand, 1st and 2nd March 2016, Johannesburg, South Africa.

V. Soter Ameh, Kerstin Klipstein-Grobusch, Eustasius Musenge, Kathleen Kahn, Stephen M. Tollman and Francesc Xavier Gómez-Olivé. Effectiveness of an integrated chronic disease management model in improving patients' CD4 count and blood pressure in a rural South African setting: a controlled interrupted time series analysis. A poster presentation at the 21st International AIDS Conference, 18th-22nd July 2016, Durban, South Africa.

VI. Soter Ameh, Kerstin Klipstein-Grobusch, Eustasius Musenge, Kathleen Kahn, Stephen M. Tollman and Francesc Xavier Gómez-Olivé. Effectiveness of an integrated chronic disease management model in improving patients' CD4 count and blood pressure in a rural South African setting: a controlled interrupted time series analysis. An oral presentation at the 21st International AIDS Conference, 19th-22nd September 2016, East London, South Africa.

Full title: Effectiveness of an integrated approach to HIV and hypertension care in rural South Africa: controlled interrupted time-series analysis

Short title: Integrated chronic disease management model in rural South Africa

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Conflicts of Interest

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Abstract

Objective: South Africa faces a dual burden of HIV/AIDS and non-communicable diseases. In 2011, a pilot Integrated Chronic Disease Management (ICDM) model was introduced by the National Health Department into selected primary health care (PHC) facilities. The objective of this study was to assess the effectiveness of the ICDM model in controlling patients' CD4 counts (>350 cells/mm^3) and blood pressure [BP (<140/90 mmHg)] in PHC facilities in the Bushbuckridge municipality, South Africa.

Design: A controlled interrupted time-series study was conducted using the data from patients' clinic records collected multiple times before and after the ICDM model was initiated in PHC facilities in Bushbuckridge.

Methods: Patients ≥18 years were recruited by proportionate sampling from the pilot (n=435) and comparison (n=443) PHC facilities from 2011 to 2013. Health outcomes for patients were retrieved from facility records for 30 months. We performed controlled segmented regression to model the monthly averages of individuals' propensity scores using auto regressive moving average model at 5% significance level.

Results: The pilot facilities had 6% greater likelihood of controlling patients' CD4 counts than the comparison facilities (coefficient=0.057; 95% CI: 0.056, 0.058; P<0.001). Compared with the comparison facilities, the pilot facilities had 1.0% greater likelihood of controlling patients' BP (coefficient=0.010; 95% CI: 0.003, 0.016; P=0.002).

Conclusions: Application of the model had a small effect in controlling patients' CD4 counts and BP, but showed no overall clinical benefit for the patients; hence, the need to more extensively leverage the HIV program for hypertension treatment.

Keywords: Agincourt; Health Outcomes; HIV; Integrated; Hypertension; Primary Health Care; Non-communicable diseases; South Africa.

Introduction

The World Health Organization (WHO) defines chronic conditions as those requiring "ongoing management over a period of years or decades" covering a wide range of health problems expanding beyond the traditional non-communicable diseases (NCDs) to include some communicable diseases such as human immunodeficiency virus and acquired immunodeficiency syndrome (HIV/AIDS) (1). This is due to the increasing recognition of the transformation of HIV to a chronic condition as a result of rapidly expanding Antiretroviral Treatment (ART) which fuels the emergence of age-related chronic diseases (2, 3).

Non-communicable diseases are the leading cause of death globally (4). In 2012, NCDs accounted for 38 million (68%) of the world's 56 million deaths, and nearly three-quarter of these deaths occurred in Low- and Middle-income Countries (LMICs) (4). Mortality due to NCDs is estimated to increase to 55 million by 2030 (5); the greatest increase (27%) between 2010 and 2020 is projected for Africa (6).

South Africa is undergoing an epidemiological transition with a dual burden of HIV and NCDs. In 2014, NCDs were responsible for 43% of all deaths (7) and an estimated 10.2% of the total population was HIV positive (8), one of the highest in Africa.

The combined epidemics of HIV and NCDs have implications for South Africa's healthcare system which is yet to adapt to the long-term continuity of care for chronic disease patients. Chronic disease care is fragmented within the public healthcare system in South Africa (9, 10). The relatively well-managed HIV program is vertically controlled (10) while services for NCDs, which account for the highest morbidity and mortality, are poor (11, 12).

The concept of integration as a strategic approach to tackle NCDs is due to shared risk factors. Joint action on these risk factors is an efficient and effective way of reducing the burden of NCDs (13) within the primary health care (PHC) framework (14). The argument for an integrated approach for NCD management becomes more compelling in the light of multiple morbidities and the consequent rising prevalence of polypharmacy due to drug interactions and side effects (15).

A study in Cambodia demonstrated the feasibility of integrating HIV/AIDS services with those for NCDs (16). Median CD4 count increased from 53 cells/mm^3 at baseline to 218 cells/mm^3 at month 12 and 316 cells/mm^3 at month 24 of treatment. Of all hypertension patients on regular treatment for more than six months, 68% had blood pressure values equal to or below the target of 160/90 mmHg and 57% of diabetes patients had glycosylated hemoglobin values below or equal to 9% (16). Following this evidence, the Joint United Nations Program on HIV/AIDS (UNAIDS) recommends an integrated approach in which the successful program, tools and approaches of the vertical HIV treatment program are leveraged to support or scale up services for NCDs (2).

Integrated chronic care for HIV and NCDs is underway in some African Countries. In 2013, a multidisciplinary initiative for integrated management of NCDs was formed in Uganda (17). In Swaziland and Ethiopia, pilot studies have been conducted in health facilities to further understand the status of NCD services, and the feasibility and effectiveness of adapting HIV program-related tools and systems for patients with diabetes mellitus (18). In Ethiopia, the quality of care provided to diabetes patients improved significantly after six months (2). A study in Kenya showed the feasibility of integrating NCD care for HIV patients along with HIV-negative patients in primary care (19).

In South Africa, the National Department of Health (NDoH) in 2011 initiated a national Integrated Chronic Disease Management (ICDM) model pilot program in selected PHC facilities in three of South Africa's nine provinces (Gauteng, North West and Mpumalanga) (20-22). The ICDM model aims to improve health outcomes for patients being managed for HIV/AIDS, tuberculosis, hypertension, diabetes, chronic obstructive pulmonary disease, asthma, epilepsy and mental health illnesses in PHC facilities (20).

There is a dearth of information on the effectiveness of the ICDM model in improving health outcomes of patients since initiation of the ICDM model. The objective of this study was to assess the effectiveness of the ICDM model in improving key indicators of health outcomes, e.g. patients' CD4 count and blood pressure (BP), using the data from patients' clinic records in PHC facilities in a rural municipality of South Africa.

Methods

Study setting

This study was conducted in 12 PHC facilities in the Bushbuckridge municipality situated in Ehlanzeni health district, Mpumalanga province, northeast South Africa. The ICDM model was being implemented in 17 of the 38 PHC facilities in the municipality at the time this study was commenced in June 2013. Seven of these 17 health facilities serve the population in the Agincourt sub-district monitored since 1992 by the Medical Research Council/Wits Agincourt Research Unit using a Health and Demographic Surveillance System (HDSS). The population under surveillance in the Agincourt HDSS as of 1st July 2011 was 90,000 people in 16,000 households in 27 villages (23). The seven facilities, referred to as the ICDM pilot facilities in this paper, were purposively selected in this study. Five of the 21 PHC facilities which were not implementing the ICDM model outside the Agincourt HDSS site were randomly selected into the comparison arm of this study; henceforth referred to as the comparison facilities.

Study design and population

This was a controlled interrupted time-series (ITS) study of chronic disease patients 18 years and older receiving treatment in the PHC facilities in the study settings. The defining feature of ITS design is that each participant in the sample is observed multiple times before and after an intervention (24). The ITS study design is the strongest quasi-experimental design to evaluate longitudinal effects of a non-experimental intervention (24). This quantitative research is part of a larger mixed method study that aimed to contribute to understanding the effectiveness of the ICDM model in improving patients' health outcomes and the quality of integrated chronic disease care.

At the time of the study, eligibility criteria for ART initiation were CD4 count ≤ 350 cells/mm^3; WHO clinical stage 3 or 4; and pregnancy or breastfeeding status (25). For those on ART, viral load was repeated 12 monthly and CD4 count repeated six monthly for ART monitoring purposes with the expectation that CD4 count would be > 350 cells/mm^3. Supplemental Digital Content (SDC) 1 shows the treatment regimens recommended for HIV/AIDS patients in South Africa during the duration of the study (25). At every visit, adherence to treatment was assessed by pill-count and record of clinic attendance. A pill count of more than 95% of ART doses was considered good adherence (25). Adherence to hypertension treatment was subjectively assessed by nurses based on the number of anti-hypertension medicines remaining from the last visit and brought forward to the index visit; and documented as good or poor in patients' clinic records. Unstable (uncontrolled) HIV and hypertension patients were reviewed monthly until stability was achieved, while stable patients were reviewed every two to three months. All patients were routinely referred to the doctor for review every six months.

Hypertension is defined as currently taking antihypertensive drugs; or systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 on three separate measurements two to three days apart (25). Antihypertensive drugs used in the study setting are shown in SDC 1.

Inclusion and exclusion criteria for the patients

Study participants comprised patients 18 years and older receiving treatment for HIV, hypertension or diabetes in the selected PHC facilities from January 2011 to June 2013. Patients transferred between ICDM pilot and comparison facilities after the study was commenced were excluded.

Sample size calculation and sampling technique

We calculated a minimum sample size of 435 patients in each study arm after adjusting for a 10% non-response using Diggle's sample size formula for repeated measures in which a continuous outcome variable is consistently compared between two groups across 30 time points of observation in a longitudinal study (26), assuming an effect size of 0.22; 0.90 correlations of repeated outcomes; 90% power (Z_{β}=1.28); and 5% significance level for a two-sided hypothesis test ($Z_{\alpha/2}$=1.96).

A three-step process was used to recruit the study participants (see Supplemental Digital Content 2a and 2b). First, the number of patients to be recruited in each of the 12 health facilities was determined by proportionate sampling. Second, the patients in each health facility were stratified by HIV, hypertension and diabetes using the health facility-specific sampling frame. Third, systematic sampling (sampling interval determined by disease-specific sampling fraction) was used to recruit patients in the disease-specific clinic appointment roster daily until the desired sample size in each clinic was achieved. A total sample of 435 patients from the ICDM pilot facilities and 443 patients from the comparison facilities were included in this study.

Data collection and variables

Clinic records of patients were reviewed to collect the data for this study. After patient recruitment in June 2013, data were collected retrospectively from January 2011 to June 2013. The HIV treatment form was designed for monthly recording of CD4 count and viral load results, blood pressure values and other variables. Depending on the level of control, the blood pressure (BP) records of HIV-negative hypertension patients were documented during each clinic visit which varied between one to three months. We retrieved key outcome variables such

as viral load, CD4 count and blood pressure values during the 30-month period of data collection. Blood pressure and CD4 count control were defined as BP <140/90 mmHg and CD4 count >350 cells/mm^3, respectively.

Data management and statistical analyses

We hypothesized that the ICDM model leads to changes in the CD4 counts and blood pressure of patients receiving care in the PHC facilities implementing the ICDM model with an allowance of a minimum of eight time points before and after initiation of the model (27).

Data were entered into Access 2010 and imported into Stata 14.0 (College Station, TX, USA) for statistical analyses. Two time periods were specified: (1) pre-intervention (January-June 2011) - six months before initiation of the ICDM model, including the month of June 2011 when the model was initiated; and (2) post-intervention (July 2011-June 2013) - 24 months of implementation of the model.

Two dependent stages of analysis were conducted in our study. The first stage was the individual patient level analysis with binary outcomes (CD4 counts > 350 vs. ≤ 350 cells/mm^3 or BP < 140/90 vs. BP ≥ 140/90 mmHg) using mixed effects logistic regression models adjusting for the study arms (clusters) in which patients received health care. This yielded the post logistic regression probabilities (propensity scores) of controlling CD4 counts or BP for each person on each visit. We did a propensity score matching to balance the effects of age, sex, looking for a paid job and reception of grant (28).

The second stage of the analysis was based on the monthly averages of all the individuals' propensity scores seen in that month (continuous outcomes) from stage one. We performed a segmented analysis using the autoregressive moving average (ARMA) models on

the monthly average data over time. The segmented analytical approach is a statistical method for estimating the effects of longitudinal intervention in interrupted time-series data (24, 27). Autocorrelation inherent in the time-series data were accounted for via the ARMA models.

The ARMA models considered the main effects (i.e. controlled CD4 counts and BP) as well as the interactions of the time periods and intervention/control arms across the whole time span to assess the effect of the intervention. The inverse of the standard deviations was used in the ARMA models as the analytic (importance) weights.

The p-values and the 95% confidence interval of the parameters were reported to ascertain statistical significance (p-value<0.05). The goodness of fit of the models was assessed by testing the residuals for normality in addition to the visual assessment of the fitted versus observed time-series plots.

Analysis of diabetes patients could not be undertaken because of the small number in each of the study groups (n=2).

Ethical considerations

Ethical clearance for this research was granted by the Committee for Research on Human Subjects (Medical) of the University of the Witwatersrand, Johannesburg, South Africa (Ref No. M120943) and the Mpumalanga Provincial Research and Ethics Committee. Written informed consent was obtained from the study participants and confidentiality was assured.

Results

A significantly (P<0.001) higher percentage of patients in the ICDM pilot (67%) than the comparison (43%) facilities were ≥ 50 years (Table 1). The percentage of hypertension patients was significantly higher in the ICDM pilot facilities (48% vs. 21%; P<0.001), whereas the comparison facilities had more HIV patients (64% vs. 32%; P<0.001).

Figure 1 showed that the slopes of the probability of controlling patients' CD4 counts in the pilot and comparison facilities decreased in both pre- and post-ICDM model periods. The pilot facilities had a consistently higher probability of controlling patients' CD4 counts than the comparison facilities at the time of initiation of the ICDM model (97.5% vs. 95.0%) and two years after the model was implemented (96.5% vs. 94.0%).

Figure 2 showed decreasing slopes of the probability of patients having a controlled BP in the pilot and comparison facilities before the ICDM model was initiated. Following initiation of the ICDM model, comparison of the two study arms showed a consistently higher probability of controlling patients' BP in the pilot facilities than in the comparison facilities at the time the ICDM model was initiated (50% vs. 47%) and two years after the model was implemented (47% vs. 40%).

The ARMA (1,1) model was fit with the covariates shown in Table 2. The pilot facilities had about 6% greater likelihood of controlling patients' CD4 counts than the comparison facilities (coefficient=0.057; 95% CI: 0.056, 0.058; P<0.001). There was a 0.3% drop in the probability of controlling patients' CD4 counts in the post-intervention period (coefficient=-0.003; 95% CI: -0.004, -0.002; P<0.001). The interaction of study groups with the periods showed that CD4 count control was greater by 0.2% in the pilot facilities during the 24 months

of implementation of the ICDM model compared with the comparison facilities during the six months preceding the initiation of the ICDM model (coefficient=0.002; 95% CI: 0.001, 0.003; $P<0.001$).

The covariates in the ARMA (1,2) model for BP control are shown in Table 2. The pilot facilities had a 1.0% greater likelihood of controlling patients' BP than the comparison facilities (coefficient=0.010; 95% CI: 0.003, 0.016; $P=0.002$). The post-intervention period had a 3% decrease in the probability of controlling patients' BP (coefficient=-0.030; 95% CI: -0.036, -0.024; $P<0.001$). The interaction of study groups with period showed that BP control was greater by 4% in the pilot facilities during the 24 months of implementation of the ICDM model compared with the comparison facilities during the six months preceding initiation of the ICDM model (coefficient=0.036; 95% CI: 0.029, 0.043; $P<0.001$).

The numbers of monthly visits of sampled patients who utilized PHC facilities from January 2011 to June 2013 in the two study arms are shown in Supplemental Digital Content 3.

Discussion

To the best of our knowledge, this is the first study in sub-Saharan Africa to assess the effectiveness of an integrated chronic disease model in improving health outcomes of hypertension and HIV patients receiving treatment in PHC facilities. The main findings showed that the ICDM model had a small but significant effect in controlling patients' CD4 counts and BP compared with the pre-intervention period. However, there was no overall clinical benefit for the patients due to non-reversal of the downward trends observed before the implementation of the model.

The higher percentage in the control of CD4 counts in the pilot than in the comparison facilities may have been due to reduced HIV stigma in settings of integrated care which was reported by operational managers in the qualitative sub-study of our broader research (29). Reduced HIV/AIDS-related stigma may have led to increased uptake of HIV services because HIV and NCD patients received care in the same consultation rooms as was reported in a Cambodia pilot study (2, 16). Although the WHO recommends virological monitoring as the preferred approach to treatment monitoring for those on ART (30), we used CD4 counts for treatment monitoring because CD4 counts are still important indicators for initiating and monitoring ART (31) and HIV disease progression (32) in resource-limited settings such as South Africa.

Our study showed small but significant control of patients' CD4 count and BP. A similar study conducted in Cambodia using cohort analysis showed an increase in median CD4 count and the percentage of hypertension patients with controlled BP after two years of implementation

of the pilot study [18]. From a health system perspective, our study does not entirely support the findings of the Cambodian study in terms of achieving optimal control of patients' BP.

Optimal BP control is difficult to achieve (33-38). The suboptimal (<50%) control of BP observed in the pilot facilities implies that the purpose for which the ICDM model was initiated - to leverage HIV programs, tools and systems to scale up services for NCDs - is yet to be fully achieved. The failure to achieve optimal BP control in the study setting may be attributed to health system and individual factors.

Three health system factors may have negatively impacted optimal BP control in the study setting. First, a study conducted at the time the ICDM model was initiated revealed that South Africa's public health sector vertical HIV program was not administratively integrated with the horizontal general health system (10). Second, a quantitative component of our broader study (29) showed that five of the eight dimensions of care (referral system, defaulter tracing, prepacking of drugs, appointment system, and long patient waiting time) identified as the priority areas for leveraging the HIV program for NCDs in the ICDM model did not reflect their intended constructs for good quality of care (Ameh et al., under review). Finally, the qualitative component of our broader study showed that facility managers and patients reported that nurses were overburdened by an increased workload resulting from integrated services. Furthermore, staff shortage, malfunctioning BP machines and antihypertensive drug stock-outs were reported by patients and facility managers in these facilities (29).

Based on literature evidence, individual-level factors that may have constituted a bottleneck in achieving optimal BP control in our study included ignorance of the complications

of high BP (35); obesity and physical inactivity (36); poor adherence to pharmacological (37, 38) and non-pharmacological treatment; and low socio-economic status (38).

We are not aware of factors that may have accounted for the decline in the probability of controlling CD4 counts and BP before and during the implementation of the ICDM model in both study arms. Health system factors common to both study arms may have been responsible for these declines because these facilities were being managed by the same administrative and managerial structures in the municipality.

Achieving optimal health outcomes in the ICDM model used in South Africa will require strengthening of the health system in which the ICDM model is embedded. Health system interventions that focus on improving performance of the structural/hardware or social/software components of the health system's building blocks are needed (39). Furthermore, a people-centered interventional model targeting hypertension patients could lead to increased awareness of the complications of poor compliance with treatment and better patient self-management (39).

The steeper decline in the control of CD4 counts and BP in the pilot facilities than in the comparison facilities before implementation of the model may have been due to a "crowding-out" of the integrated services through routine training activities in preparation for the implementation of the ICDM model (39).

Strengths and limitations

The main strengths of this study were the ability to control for secular trends in the data; evaluate outcomes using the covariates adjusted propensity scores; and presentation of the results graphically. Our study findings must be interpreted in the light of the limitations imposed by the use of routine healthcare data. More specifically, some facility-level data were incomplete or

unavailable due to one or more of the following reasons: (1) missing laboratory results of CD4 counts and viral load and (2) missing records of BP measurements due to BP machines being out of order. Other limitations included the paucity of information on facility-level factors such as unavailability of comparative data on staffing, patient load, medication supply chain, and our inability to obtain at least eight observations before implementation of the ICDM model due to unavailability of notebooks in which clinical information of the patients were recorded during the same period.

Our study contributes to the national and global debates on an integrated health systems approach. The main findings of our research have implications for the nationwide implementation of the ICDM model that is underway in PHC facilities in South Africa and for the planning of an integrated chronic care in other LMICs.

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Authors SA, KKG, SMT, KK and FXGO designed the study protocol and directed its implementation. Authors SA, KKG and FXGO supervised field activities. Authors EM and SA analyzed the data and interpreted the results. Authors SA, KKG, EM, SMT, KK and FXGO conducted the literature review and prepared the Methods and the Discussion sections of the manuscript.

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Table 1: Socio-demographic characteristics of the patients in the ICDM pilot and comparison facilities, Bushbuckridge municipality, 2011-2013.

Characteristic	Total (n = 878) No.	%	ICDM fac. (n = 435) No.	%	Comparison fac. (n = 443) No.	%	Two-sided *P* value of difference
Age group (years)							
18-29	58	6.6	19	4.4	39	8.8	<0.001
30-39	179	20.4	60	13.8	119	26.9	
40-49	151	17.2	59	13.6	92	20.8	
50-59	169	19.2	84	19.2	85	19.2	
≥ 60	302	34.4	197	45.3	105	23.7	
Missing	19	2.2	16	3.7	3	0.6	
Gender							
Female	731	83.3	363	83.4	368	83.1	0.881
Male	147	16.7	72	16.6	75	16.9	
Education (completed years)							
No formal education	339	38.6	172	39.6	167	37.7	0.170
1-6	343	39.1	174	40.0	169	38.1	
> 6	144	16.4	71	16.3	73	16.5	
Missing	52	5.9	18	4.1	34	7.7	
Looking for a paid job							
Yes	246	28.0	126	29.0	120	27.0	0.725
No	592	67.4	291	66.9	301	68.0	
Missing	40	4.6	18	4.1	22	5.0	
Reception of grant							
None	412	46.9	202	46.4	210	47.4	0.927
HIV	13	1.5	5	1.2	8	1.8	

Disability	28	3.1	15	3.5	13	2.9	
Old age	385	43.9	195	44.8	190	42.9	
Missing	40	4.6	18	4.1	22	5.0	
Chronic disease status							
Hypertension	301	34.3	210	48.3	91	20.5	<0.001
HIV	423	48.2	141	32.4	282	63.7	
Diabetes	4	0.5	2	0.4	2	0.5	
Co-morbidities	150	17.0	82	18.8	68	15.3	

Abbreviation: fac, facilities

[a]Five patients in the ICDM model facilities were transferred to other facilities also implementing the ICDM model. This was also the case for three patients in the comparison facilities.
[b]Two patients in the ICDM model facilities and one in the comparison facilities were transferred to health facilities in other provinces
[c]One HIV patient died in the ICDM model facilities while three deaths (one hypertension and two HIV/AIDS patients) were recorded in the comparison facilities.

Table 2: The autoregressive moving average model for CD4 count control in primary health care facilities in the Bushbuckridge municipality

Characteristic	**Coefficient**	**Standard error**	**95% confidence interval**	***P*-value**
Facility				
Comparison	1			
ICDM model pilot	0.057	0.0002	0.056, 0.058	<0.001
Period				
Pre-intervention	1			
Post-intervention	-0.003	0.0001	-0.004, -0.002	<0.001
Interaction of facility and period				
Comparison*pre-intervention	1			
ICDM pilot*post-intervention	0.002	0.0003	0.001, 0.003	<0.001

Table 3: The autoregressive moving average model for blood pressure control in primary health care facilities in the Bushbuckridge municipality

Characteristic	Coefficient	Standard error	95% confidence interval	*P*-value
Facility				
Comparison	1			
ICDM model pilot	0.010	0.0031	0.003, 0 .016	0.002
Period				
Pre-intervention	1			
Post-intervention	-0.030	0.0030	-0.036, -0.024	<0.001
Interaction of facility and period				
Comparison*pre-intervention	1			
ICDM pilot*post-intervention	0.036	0.0029	0.029, 0.043	<0.001

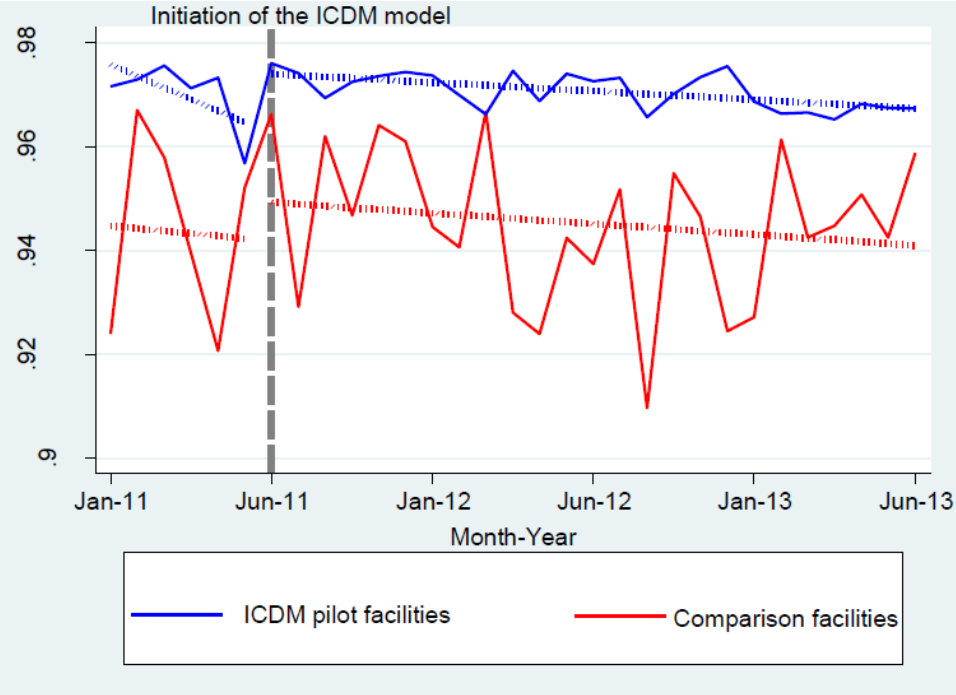

Figure 1: Monthly probabilities of having a CD4 count > 350 cells/mm^3 after propensity score matching in the ICDM pilot and comparison facilities in the Bushbuckridge municipality, 2011-2013.

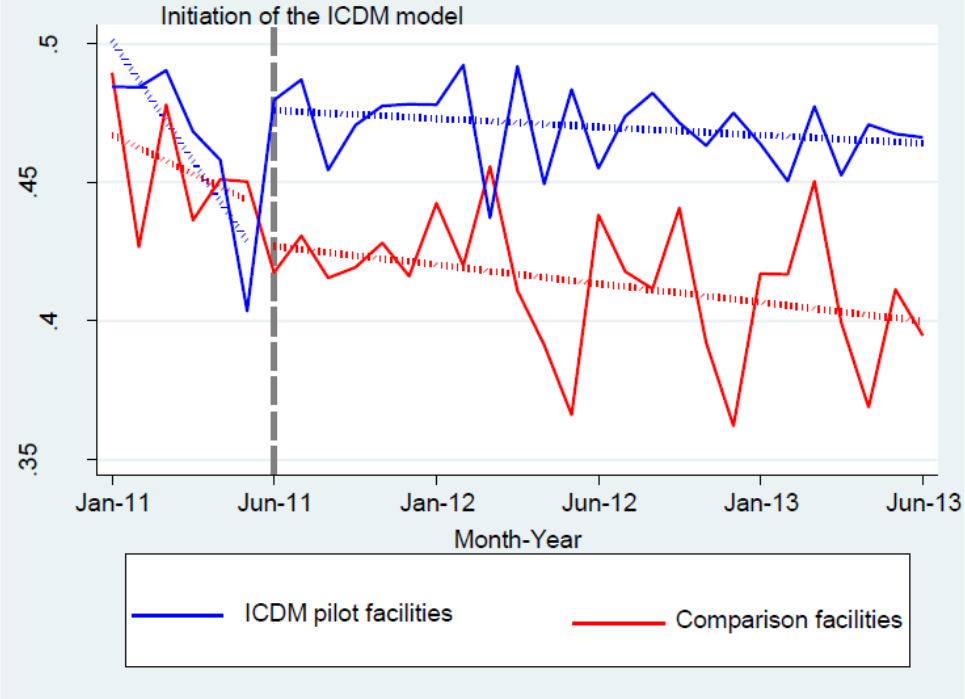

Figure 2: Monthly probabilities of having a BP < 140/90 mmHg after propensity score matching in the ICDM pilot and comparison facilities in the Bushbuckridge municipality, 2011-2013.

Supplemental Digital Content 1: Antiretroviral and antihypertensive drugs used in the health facilities in the Bushbuckridge Municipality, 2013.

ART initiation and the criteria for initiation		
Regimen	**Criteria**	**ART**
1	1. CD4 count is ≤ 350 2. Viral load < 400 3. Stage 3 or 4 disease, pregnant or breastfeeding women regardless of CD4 count or viral load	Tenofovir (TDF), Lamivudine (3TC) and Efavirenz (EFV) OR Fixed Drug Combination (FDC) - Tenofovir/Emtricitabine/Efavirenz **NB:** 1. Efavirenz (EFV) is replaced with Nevirapine (NVP) for patients with depression or psychosis. 2. Regimen 1 is replaced with Zidovudine (AZT) if pregnant with depression, psychosis, known kidney disease, disease, hypertension or ≥ 2+ proteinuria and refer patient to doctor.
2	Viral load > 1000 on two occasions	Lopinavir/ritonavir (LPV/r), Lamivudine (3TC) and AZT (if currently using TDF) OR

		TDF [if currently using AZT or Stavudine (d4T)]
Antihypertensive and adjuvant drugs		
1	The most commonly prescribed antihypertensive drugs	Hydrochlorothiazide, Enalapril, Amlodipine and atenolol.
2	Adjuvant drugs prescribed for hypertension patients	Daily dose of simvastatin if the patient had Cardiovascular Disease (CVD) or a CVD risk > 20% Daily aspirin dose if patients had CVD and/or diabetes

*Criteria for referral to doctor: abnormal blood results, poor adherence, TB symptoms depression or psychosis

Supplemental Digital Content 2a: Sampling of the study participants in the ICDM pilot facilities

Health facilities	Number of patients recorded in the clinic appointment roaster in July 2013.				***Step 1 sampling**: proportionate sampling from the health facilities	****Step 2 sampling**: proportionate sampling by chronic disease status		
	ART	HPT	DM	Total		ART	HPT	DM
A	724	642	-	1366	165	88	77	0
B	146	715	-	861	104	18	86	0
C	41	325	7	373	45	5	39	1
D	84	274	6	364	44	10	33	1
E	66	50	-	116	14	8	6	0
F	50	215	-	265	32	6	26	0
G	49	208	-	257	31	6	25	0
Total	1160	2429	13	3602	435	141	292	2

[#]***ART, HPT and DM = HIV/AIDS, hypertension and diabetes mellitus patients, respectively.***

***Step 1: proportionate sampling for each health facility was achieved by multiplying the sampling fraction by the total number of patients in each health facility**

Sampling fraction = 435/3602 = 0.1207

Where 435 = calculated study sample size and 3602 = total sampling frame

Example of proportionate sampling for clinic A: 0.1207 x 1366 = 165, where 1366 is the total number of patients in health facility A.

****Step 2: proportionate sampling in each health facility**

Example of proportionate sampling in health facility A

53% (724/1366) and 47% (642/1366) of the total number of patients in health facility A were HIV and hypertension patients, respectively. Of the 165 patients recruited in health facility A, 53% (n=88) were HIV patients and 47% (n=77) were hypertension patients.

Supplemental Digital Content 2b: Sampling of the study participants in the ICDM pilot facilities

Health facilities	Number of patients recorded in the clinic appointment roaster in July 2013.				*Step 1 sampling: proportionate sampling from the health facilities	**Step 2 sampling: proportionate sampling by chronic disease status		
	ART	HPT	DM	Total		ART	HPT	DM
A	365	115	-	480	58	44	14	0
B	231	175	-	406	49	28	21	0
C	107	125	-	232	28	13	15	0
D	233	156	-	389	47	28	19	0
E	1426	713	22	2161	261	173	86	2
Total	2362	1284	22	3668	443	286	155	2

[#]***ART, HPT and DM = HIV/AIDS, hypertension and diabetes mellitus patients, respectively.***

***Step 1: proportionate sampling for each health facility was achieved by multiplying the sampling fraction by the total number of patients in each health facility**

Sampling fraction = 443/3668 = 0.121

Where 435 = calculated study sample size and 3668 = total sampling frame

Example of proportionate sampling for clinic A: 0.121 x 480 = 58, where 480 is the total number of patients in health facility A.

****Step 2: proportionate sampling in each health facility**

Example of proportionate sampling in health facility A

76% (365/480) and 24% (115/480) of the total number of patients in health facility A were HIV and hypertension patients, respectively. Of the 58 patients recruited in health facility A, 76% (n=44) were HIV patients and 24% (n=14) were hypertension patients.

Supplemental Digital Content 3: Number of monthly visits of the sampled patients who utilised primary health care facilities from January 2011 to October 2014 in the Bushbuckridge municipality

Years-Months	ICDM pilot facilities		Comparison facilities	
	Hypertension (n=210)	HIV (n=141)	Hypertension (n=91)	HIV (n=282)
2011				
January	88	17	18	15
February	136	23	51	16
March	137	19	52	12
April	110	10	23	18
May	102	29	28	31
June	102	69	40	32
July	96	26	54	11
August	107	12	41	18
September	118	21	27	18
October	136	21	50	36
November	119	16	29	16
December	105	18	28	30
2012				
January	109	15	35	25
February	141	18	33	12
March	123	39	53	25
April	114	13	41	41

May	116	22	36	53
June	124	12	29	42
July	126	17	24	41
August	95	13	26	53
September	104	17	22	40
October	117	15	25	25
November	97	23	31	37
December	113	15	23	62
2013				
January	122	19	35	60
February	128	24	26	34
March	101	22	32	40
April	95	26	22	58
May	91	34	32	38
June	92	12	28	29

Table shows the number of patients managed for hypertension or HIV