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# Fidelity and Costs of implementing the Integrated Chronic Disease Management Model in South Africa

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MChB (UCT), MPH (Liverpool)

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1. **Lebina L**, Alaba O, Kawonga M, Oni T. Process evaluation of fidelity and costs of implementing the Integrated Chronic Disease Management model in South Africa: mixed methods study protocol. *BMJ Open*. 2019;9(6):e029277. Published 2019 Jun 3. doi:10.1136/bmjopen-2019-029277
2. **Lebina L.**, Alaba, O., Ringane, A., Hlongwane, K., Pule, P., Oni, T., & Kawonga, M. (2019). Process evaluation of implementation fidelity of the integrated chronic disease management model in two districts, South Africa. *BMC health services research*, 19(1), 965. <https://doi.org/10.1186/s12913-019-4785-7>
3. **Lebina L**, Oni T, Alaba OA, Kawonga M. A mixed methods approach to exploring the moderating factors of implementation fidelity of the integrated chronic disease management model in South Africa. *BMC Health Serv Res*. 2020;20(1):617. Published 2020 Jul 6. doi:10.1186/s12913-020-05455-4.
4. **Lebina L**, Kawonga M, Alaba OA, Khamisa N, Otjombe K, Oni T. Organizational Culture and the Integrated Chronic Diseases Management Model Implementation Fidelity in South Africa. (BMJ Open –In press.)
5. **Lebina L**, Kawonga M, Oni T, Kim HY, Alaba OA. The cost and cost implications of implementing the integrated chronic disease management model in South Africa. *PLoS One*. 2020;15(6):e0235429. Published 2020 Jun 26. doi:10.1371/journal.pone.0235429

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## List of acronyms and abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
CCMDD	Centralized Chronic Medication Dispensing and Distribution
CDs	Communicable Diseases
CDM	Chronic Diseases Management
CCM	Chronic Care Model
CHCW	Community Healthcare workers
COPD	Chronic Obstructive Airway Disease
DALY	Disability-Adjusted Life Year
DCST	District Clinical Specialist Team
DKK	Dr. Kenneth Kaunda
DM	Diabetes Mellitus
DOC	Denison organizational culture
DOT	Directly observed therapy
DOH	Department of Health
GDP	Gross Domestic Product
ICCC	Innovative Care for Chronic Conditions
ICDM	Integrated Chronic Disease Management
ICRM programme	Ideal clinic realization and maintenance programme
ICSM	Integrated clinical services manual
IQR	Interquartile range
HIV	Human Immunodeficiency Syndrome

HPT	Hypertension
LMIC	Low and middle-income countries
MRC	Medical Research Council
NCDs	Non-communicable Diseases
NHI	National Health Insurance
NIMART	Nurse-Initiated Management of Antiretroviral Therapy
PHC	Primary Health Care
RE-AIM	Reach, Effectiveness, Adoption, Implementation and Maintenance
SA	South Africa
SD	Standard deviation
TB	Tuberculosis
WR	West Rand
WBOTs	Ward-based outreach teams
WHO	World Health Organization

## Abstract

**Background:** The health systems in many low-middle income countries are faced with an increasing number of patients with non-communicable diseases within a high prevalence of infectious diseases. Integrated chronic disease management programmes have been recommended as one of the approaches to improve efficiency, quality of care, and clinical outcomes at primary healthcare level. The South African Department of Health has implemented the Integrated Chronic Disease Management (ICDM) Model in primary health care (PHC) clinics since 2011. Some of the expected outcomes of implementing the ICDM model have not been achieved, and there is a dearth of studies assessing implementation outcomes of chronic care models, especially in low-middle income countries. This thesis aims to assess two implementation outcomes, fidelity and costs. Specifically, the thesis assessed the degree of ICDM implementation fidelity, moderating factors of fidelity, the impact of organizational factors on fidelity, and costs associated with the implementation of the ICDM model in South African PHC clinics.

**Methods:** The thesis was a cross-sectional study design using mixed methods and following the process evaluation conceptual framework. A total of sixteen PHC clinics in the Dr. Kenneth Kaunda (DKK) health district of the North-West Province and the West Rand (WR) health district of the Gauteng Province – all ICDM pilot sites – were included in the study. The degree of fidelity in the implementation of the ICDM model was evaluated using a fidelity criteria developed for this study from the four major components of the ICDM model as described in the guidelines as follows: facility reorganization, clinical supportive management, assisted self-support, and strengthening of the support systems. Fidelity was assessed through interviews and observations at all 16 PHC clinics. In addition, Carroll's implementation fidelity framework was utilized to guide the assessment of moderating factors of ICDM implementation fidelity. The data on fidelity moderating factors were obtained by interviewing 30 purposively selected healthcare workers. The abbreviated Denison Organizational Culture (DOC) survey was administered to 90 healthcare workers to assess the impact of three cultural traits (involvement, consistency, and adaptability) on fidelity. Cost data from the provider's perspective were collected in 2019. The costs of implementing the

ICDM model current activities for three components (facility reorganization, clinical supportive management and assisted self-management), and additional costs of implementing with enhanced fidelity, were estimated. Cost data was collected from budget reviews, interviews with management teams, and other published data. Descriptive statistics (medians, interquartile ranges, means, standard deviations) were used to describe participants and clinics. Fidelity scores were summarized using medians and converted to proportions and compared across facilities and health districts. Qualitative data on moderating factors were analysed thematically. Pearson's correlation coefficient was utilized to assess the association between fidelity and organizational culture. The annual ICDM model implementation costs for 2019 were presented in US dollars per PHC clinic and patient per visit.

**Results:** The 16 PHC clinics had comparable patient caseload, and a median of 2430 (IQR: 1685-2942) patients older than 20 years received healthcare services in these clinics over six months. The overall implementation fidelity of the ICDM model median score was 79% (125/158, IQR: 117-132); WR was 80% (126/158, IQR: 123-132); while DKK was 74% (117/158, IQR: 106-130),  $p=0.1409$ . The highest clinic fidelity score was 86% (136/158), while the lowest was 66% (104/158). The fidelity scores for the four components of the ICDM model were very similar. A patient flow analysis indicated long waiting times (2-5 hours) and that acute and chronic care services were combined into one stream. Interviews with healthcare workers revealed that the moderating factors influencing implementation fidelity of the ICDM model were the existence of facilitation strategies (training and clinical mentorship); intervention complexity (healthcare worker, time and space integration); and participant responsiveness (observing operational efficiencies, compliance of patients, and staff attitudes). Participants also indicated that poor adherence to any one component of the ICDM model affected the implementation of the other components. Contextual factors that affected fidelity included supply chain management, infrastructure and adequate staff, and balanced patient caseloads. The overall mean score for the DOC was 3.63 (Standard Deviation (SD) = 0.58); the involvement cultural trait had the highest mean score (3.71; SD = 0.72), followed by adaptability (3.62; SD = 0.56), and consistency (3.56; SD = 0.63). Although there were no statistically significant differences in cultural scores between PHC clinics, culture scores for all three traits were significantly higher in WR (involvement 3.39 vs 3.84,  $p=0.011$ ; adaptability

3.40 vs 3.73,  $p= 0.007$ ; consistency 3.34 vs 3.68,  $p= 0.034$ ). The mean annual cost of implementing the ICDM model was \$148 446.00 (SD: \$65 125.00) per clinic, with 84% (\$124 345.00) for current costs; additional costs for higher fidelity accounted for 16% (\$24 102.00). The mean cost per patient per visit was \$6.00 (SD: \$0.77).

**Conclusion:** There was some variability across PHC clinics and health districts in the fidelity scores for the different components of the ICDM model in PHC clinics, and there were multiple interrelated moderating factors (context, participant responsiveness, intervention complexity, and facilitation strategies) that influence the implementation fidelity of the ICDM model. Organizational culture must be purposefully influenced to enhance adaptability and consistency in the cultural traits of clinics to enhance the ICDM model's principles of coordinated, integrated, patient-centred care. Small additional costs are required to implement the ICDM model with higher fidelity.

**Recommendations:** Interventions to enhance the fidelity of chronic care models should be tailored to specific activities that have low degree of adherence to the guidelines. Addressing some of the moderating factors like providing training and mentoring of staff members, role clarification, and strengthening of supply chain management could contribute to enhanced fidelity. Organizational cultural changes are recommended prior to the implementation of new innovative interventions to ensure that the prevailing culture is aligned with the planned quality advancements. Further research on the cost-effectiveness of the ICDM model in middle-income countries is recommended.

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## Chapter 1: Introduction

### 1.1. Context

Morbidity and premature mortality due to chronic diseases are a growing health and developmental challenge throughout the world, especially in low and middle-income (LMIC) countries<sup>1</sup>. Chronic diseases (infectious and non-infectious) are a significant (60%) cause of death amongst adults<sup>2</sup>. Poorest countries are worst affected, with 80% of deaths due to chronic disease occurring in LMIC countries<sup>2</sup>. Aging populations and lifestyle challenges and increase in risk factors such as obesity, pollution, unhealthy diets, physical inactivity, alcohol abuse and smoking have resulted in an increase in non-communicable diseases (NCDs) in the presence of a high burden of infectious diseases<sup>1, 3-5</sup>. It is estimated that, by 2030, NCDs will account for three quarters of the disease burden in middle-income countries<sup>1</sup>. There is also a complex interaction of risk factors, disease management, and health outcomes between communicable diseases (CDs) and NCDs<sup>3</sup>. For example, use of tobacco predisposes one to both tuberculosis and chronic obstructive pulmonary disease, and HIV and diabetes are risk factors for chronic kidney disease<sup>3</sup>.

South Africa is currently experiencing an epidemiological transition of a rapid surge of NCDs with the co-existence of high prevalence of CDs<sup>6</sup>. The leading causes of mortality are NCDs (diabetes, cardiovascular diseases), accounting for 51.3% of all deaths; CDs responsible for 38.4% of deaths; and, of the communicable diseases, HIV/AIDS is the third leading cause of mortality<sup>6</sup>. South Africa, similar to many Sub-Saharan African countries, has been severely affected by the HIV/AIDS epidemic, with 7.1 million people living with HIV<sup>7</sup>. There is also a high prevalence of chronic (infectious and non-communicable) disease multimorbidity (23%), with TB, HIV and NCDs accounting for 45% of all primary health care consultations<sup>9, 8</sup>. In some studies, 24% of the population had a chronic disease diagnosis with hypertension being the most prevalent at 11%<sup>9</sup>.

These chronic diseases (NCDs and CDs) often affect economically productive adults, require expensive long-term treatment and care, and frequently leads to some degree of disability, low quality of life, and consequent negative impact on household and national economies<sup>1, 2</sup>. The increased expenditure on health and welfare, reduced labour supply and outputs, high

costs to employers, and reduced tax revenues cost countries 1% to 7% of the national gross domestic product (GDP)<sup>1</sup>. The impact on households is reduced income and economic opportunities, and increased out-of-pocket payments for health services and medication<sup>1, 2</sup>. Chronic diseases also put excessive pressure on health systems due to increased demand for healthcare, as they are complex to treat and require multiple interactions with healthcare providers<sup>1</sup>. Chronic diseases account for 75% of healthcare costs in Africa<sup>4</sup>. Health systems require significant adaptation to address the increasing burden of these chronic diseases effectively<sup>1</sup>.

Health system restructuring is vital to achieving proposed disease control targets, like 95% reduction in TB deaths by 2035<sup>10</sup>; access to antiretroviral treatment<sup>11</sup> for 90% of HIV-infected people; 25% relative reduction in the prevalence of raised blood pressure and premature mortality from cardiovascular diseases by 2025; and bringing to a complete halt the rise in the incidence of diabetes and obesity<sup>2</sup>. The World Health Organization (WHO) developed the chronic care model (CCM) and Innovative Care for Chronic Conditions (ICCC) framework to enhance comprehensive coordinated prevention and treatment programmes for chronic diseases<sup>12,13</sup>. ICCC is based on a triad consisting of family and the patient, the community, and the health team<sup>14</sup>. These frameworks aim to reduce costs of care for chronic conditions as they promote prevention and self-management support, minimize the fragmentation of services, and provide effective treatment through quality interactions between patients and skilled healthcare providers<sup>14</sup>.

## **1.2. Chronic disease management programmes**

Health systems, especially in LMIC countries, have primarily focused on infectious diseases, resulting in unstructured approaches to NCDs in clinical care<sup>15</sup>. However, primary health care must play a significant role in the delivery of prevention and quality clinical care for chronic diseases in the context of scarce resources<sup>15, 16</sup>. Numerous countries have begun implementing chronic disease management programmes that cover screening, prevention and control of disease using CCM/ICCC framework principles or expanding existing TB and/or HIV programmes to include NCDs<sup>16</sup>. The experience from HIV programmes have shown the

importance of community-based programmes as they not only expand the reach of clinical services but also encourage patient and family involvement in chronic care and these lessons can be applied to patients with other chronic conditions<sup>17</sup>. South Africa, Malawi, Ethiopia and Zambia have adapted their HIV-care programmes to include other chronic conditions with an increase in home-based programmes<sup>17</sup>. In Kenya, adaptations in medicine delivery in adherence clubs have been implemented solely in the context of antiretroviral therapy (ART) for HIV treatment, but this has not been applied in the context of NCD care. Chronic disease management must have an emphasis on prevention because some behavioural changes (increased physical activity, health diets) can reduce the incidence of disease and prevent worsening of existing diseases<sup>12,1</sup>. However, secondary prevention requires time, commitment and support of the family, community, and healthcare professionals. As such, chronic disease management programmes must focus on a holistic approach to a patient's psychological, social, emotional and physical needs <sup>12,13</sup>. In Nova Scotia, Canada, integration of care incorporates physical, functional, psychosocial and vocational considerations <sup>18</sup>.

The South African Department of Health (DOH) used the ICC framework to develop and implement the Integrated Chronic Disease Management (ICDM) model to improve efficiencies and quality of care for chronic patients at primary healthcare clinics<sup>19</sup>. The expected outcomes of the ICDM model are to improve facility-level competence and efficiency, patients' understanding and involvement in the management of their chronic conditions, and satisfactory experience of the healthcare workers and the patients<sup>19</sup>. Some of the gaps identified in the provision of care for people living with chronic conditions at primary healthcare (PHC) level in South Africa include low rates of diagnosis, failure to achieve treatment targets, lack of crucial equipment, medication shortages, long waiting periods, shortage of healthcare workers, and inadequate consultation time<sup>20, 21</sup>. Healthcare workers' knowledge of chronic diseases was observed to be poor because of insufficient training, unavailability of guidelines, and lack of supervision<sup>21</sup>. Some of these challenges are meant to be addressed by the ICDM model. It is therefore essential to evaluate how ICDM model implementation has affected these observed challenges in chronic disease management.

An evaluation of how an evidence-based innovative intervention or program is being put into practice is comprehensively done through implementation research<sup>22</sup>. Therefore,

implementation research examines the process of implementation and how the contextual factors affect these processes and the outcomes observed<sup>22</sup>. The implementation strategies provide the “how-to” of delivering the proposed interventions or initiatives, but usually underplay the effects of diverse contexts and health systems<sup>22</sup>. Furthermore, implementing human service technologies is more complicated because it is affected by the actions of the individuals and the organizations, and the multi-layered social contexts<sup>23</sup>. Implementation outcomes that include acceptability, adoption, feasibility, fidelity, appropriateness, implementation costs, coverage, and sustainability should be evaluated to achieve full understanding of the effects of context on an intervention<sup>22</sup>. Implementation outcomes are indicators of implementation success, proximal indicators of implementation processes, and serve as necessary preconditions for attaining subsequent desired changes in service outcomes<sup>24</sup>.

### 1.3. Rationale for the study

The aims of integration of chronic health services are to increase the quality of care provided to chronic patients; enhance health outcomes; use resources efficiently; and improve overall experience and satisfaction of patients and healthcare workers<sup>12</sup>.

Fragmented care for chronic conditions frequently results in inappropriate use of health services, overcrowding, delays, errors, inefficiency, and general dissatisfaction in users and providers<sup>12</sup>.

The studies on the ICDM model in South Africa have shown that implementation of the ICDM improves the quality of patient records and health outcomes (CD4-count recovery) for patients on ART<sup>25, 26</sup>. However, failure to achieve some of the expected outcomes – like reduced waiting times – has also been reported<sup>27</sup>. **It is not clear whether these perceived gains and shortcomings are as a result of the inherent faults in the design of the model, or failure to adhere to the prescribed activities for successful implementation (fidelity).** Failure to achieve satisfactory outcomes could also be due to contextual factors like insufficient resources for the ICDM model, poor acceptability of the ICDM model by healthcare workers and patients, and PHC facilities characteristics.

Routine data collected on the ICDM model focuses on the proportion of facilities implementing the model, healthcare workers trained, and progress on implementation at facility level<sup>19</sup>. While these indicators are essential, they do not provide information on the fidelity of implementation, the costs of each of the major activities, or how the contextual factors have affected implementation. Moreover, with budget reductions and expected task shifting, there is the need to be more effective with resources in the healthcare system. These data are urgently needed in South Africa to enhance the model as part of the response to the increased utilization of the health services for chronic conditions.

There is a need for more research on the best practices of effective clinical and community interventions that improve health outcomes for chronic diseases<sup>16, 28</sup>. It is therefore essential to have a better understanding of how the ICDM model intervention processes have been executed, if there have been any adaptations of the model, and the impact of such adaptations. An assessment of the level of implementation fidelity of the model will provide information on best practices for continuous improvement, identify any innovations that could improve model processes, and support systematic implementation of the model. Evaluating the costs of implementing the various activities of the ICDM model will assist with planning and budgeting, as well as inform the scalability and sustainability of the model. The results from these studies provide timely data for the upscaling and the sustainability of the ICDM model including ways to improve the model and, subsequently, the management of chronic conditions in primary healthcare facilities. This information is critical for the South African health system that is undergoing a primary healthcare transformation and planned transition into the national health insurance (NHI).

#### **1.4. Aim and research questions**

##### **Study aim**

This PhD thesis aimed to provide an evaluation of selected implementation outcomes of the ICDM model: fidelity and implementation costs and the impact of contextual factors on ICDM model implementation fidelity in two health districts in two different provinces where ICDM

was piloted, in order to better understand the processes of successful implementation of the ICDM model and how the model can be optimized.

### **Research question**

What are the implementation outcomes of the ICDM model in two health districts in South Africa?

#### *Research Sub-questions*

1. What is the degree of fidelity in the implementation of the recommended ICDM model?
2. How do contextual factors affect the implementation fidelity of the ICDM model?
3. What are the implementation costs of the ICDM model?

## **1.5. Overall thesis description**

This thesis was a cross-sectional study that used mixed methods and followed the process evaluation conceptual framework. Two ICDM model pilot districts (Dr. Kenneth Kaunda district in North-West and the West Rand district in Gauteng) were selected for the study. The study was divided into three sub-studies to address each of the specific objectives.

### **Sub-study one: The degree of implementation fidelity**

**The degree of implementation fidelity** was assessed by using fidelity criteria developed from the ICDM model manual. The four major components of the ICDM model assessed were: reorganization of the facility for efficiency, clinical supportive management, assisted self-support, and strengthening of support systems. Each clinic received a score for each activity recommended for the implementation of the ICDM model; activity scores were summed-up per component, and fidelity scores were compared between components, facilities and districts.

### **Sub-study two: Influence of contextual factors**

**Influence of contextual factors** on the implementation fidelity was studied through structured interviews with healthcare workers to understand their perceptions on moderating factors affecting implementation fidelity. We also assessed the impact of

facilities' characteristics such as patient case load, staffing levels and infrastructure on the degree of fidelity. Qualitative data were thematically analysed, while linear regression and descriptive statistics were used to analyse quantitative data. In addition, we assessed the impact of organizational culture on implementation effectiveness as measured by fidelity. The abbreviated Denison organizational culture (DOC) survey tool was administered to staff members to evaluate involvement, consistency, and adaptability cultural traits. The DOC survey consisted of a total of 45 items (each cultural trait has three indices with five items) which were scored on a Likert scale ranging from one (strongly disagree) to five (strongly agree). The mean scores were calculated for each item, cultural traits, and indices. The Pearson's correlation coefficient was used to assess the association between fidelity and culture.

### **Sub-study three: Implementation costs of the ICDM model**

**Implementation costs of the ICDM model** from the provider's perspective were estimated by adding the current costs of implementing the ICDM model activities for three components: facility reorganization, clinical supportive management, and assisted self-management. The additional costs of implementing these three components with enhanced fidelity were also included. Cost estimates were based on interviews with management, budget reviews, and other published data. We performed one-way sensitivity analyses for critical parameters by varying required infrastructure, patient caseloads, and staff. The ICDM model implementation costs were presented as annual costs per PHC clinic and per patient per visit.

## **1.6. Outline of thesis**

**Chapter 2:** The Literature Review presents detailed information on chronic disease management models in different countries, review of benefits and challenges and costs. The ICDM model components and different activities are explained and critiqued. The various implementation outcomes with a focus on chronic disease management models are also discussed.

**Chapter 3:** The methods chapter describes the setting where the study was conducted and outlines the processes that were followed in the study planning, data collection and data analysis. This has been summarized as a published publication entitled “*Process evaluation of fidelity and costs of implementing the Integrated Chronic Disease Management model in South Africa: mixed-method study protocol.*”

**Chapters 4 – 7:** The results section of the thesis are presented as published manuscripts, each describing the results of the specific objectives of the thesis as summarized in Table 1.1.

The contributions of the authors for each manuscript have been included in each of the manuscripts. The Doctoral Degree Board of the University of Cape Town has granted approval for the inclusion of all five manuscripts in this thesis and was satisfied that they represented the scientific work of the candidate.

*Table 1.1: Summary of the research objectives and results chapters*

Objective	Chapters	Summary of Chapter
To assess the degree of fidelity in the implementation of the ICDM model	4	The level of fidelity in the implementation of the ICDM model; data on 89 recommended activities were collected, and the scores compared between clinics and health districts.
To assess moderating factors of implementation fidelity of the ICDM model.	5	The results of the moderating factors of implementation fidelity of the ICDM model based on the modified Carroll’s conceptual framework on implementation fidelity explained.
To evaluate the influence of organizational culture on the implementation fidelity of the ICDM model	6	The abbreviated Denison organizational culture survey results for three cultural traits (involvement, consistency and adaptability) and their association with level of fidelity, are presented.
To estimate the implementation costs of the ICDM model	7	Cost data from the provider’s perspective for implementing three components (facility reorganization, clinical supportive management and assisted self-management) and additional implementation costs with enhanced fidelity of the ICDM model, are outlined.

**Chapter 8:** The discussion, conclusion and recommendations sections of the thesis provide an overall summary and implications of the thesis on fidelity and the costs of implementing the ICDM model. The aims, methodologies utilised and key research findings, as well as strengths and limitations are discussed in this chapter, demonstrating coherence of this body of work. In addition, contributions to science, recommendations for health systems research, and future research are also described.

## Chapter 2: Literature review of chronic disease management models in primary healthcare settings

### 2.1. Literature review introduction

The chronic care model and the innovative care for chronic conditions framework have been recommended to health systems to enhance access, integration, and continuity of care <sup>12</sup>. Consequently, several countries have implemented and evaluated various forms or components of chronic disease management models and shown that they improve health outcomes while reducing costs of care <sup>29-35</sup>. The challenge is that there is no homogenous implementation of the chronic disease management (CDM) model or activities, and a lack acceptability of some of the principles or processes of the chronic disease management models is a potential implementation barrier. The CDM model implemented in South is integrated chronic disease management (ICDM) model, and improved treatment outcomes for HIV disease objectives<sup>36</sup>. However, the ICDM model did not achieve improved treatment outcomes for patients with hypertension <sup>36</sup>. Assessment of implementation outcomes provide an effective method for appraising an intervention.

This literature review forms the theoretical background for this thesis. In this chapter, the burden of chronic diseases, with a focus on South Africa is described, as well as how these diseases are managed in primary healthcare settings. Literature was sourced from multiple databases, as well as reference reviews and other published reports to highlight the current knowledge on CDM models. The landscape of CDM models, and a critical analysis of benefits, challenges and perceptions of the providers and patients are outlined. Examples of CDM models are also presented to describe the various components of CDM models further. The characteristics of the South African ICDM model and its shortcomings are described. In addition, the concept and evaluation of implementation outcomes, as a measure of effectiveness of for healthcare interventions has been expounded. Lastly, research gaps that will be addressed in this thesis are considered.

This systematized literature review aimed to explore and critique key issues on the implementation of chronic diseases management models in primary healthcare setting for various chronic diseases.

### **2.1.1. Chronic diseases and multi-morbidity**

Chronic communicable diseases (CDs) and non-communicable diseases (NCDs) are a major public health problem in both LMIC and high-income countries and are responsible for 60% of all deaths <sup>1, 37, 38</sup>. Data from high-income countries like the USA – by age 70 – 60.7% of the population suffers from hypertension and 55% is affected by arthritis <sup>39</sup>. The most prevalent conditions in adults with multi-morbidities in Spain are hypertension (50.64%-60.03%) and osteoarticular conditions (59.08%-67.80%) <sup>40</sup>. Diabetic and hypertensive patients contribute 13% and 12% respectively to visits to PHC centres in Al Ain in the United Arab Emirates<sup>41</sup>. In another study, the overall prevalence of multimorbidity in sixteen European countries was 37.3% in 2006. It varied from 24.7% in Switzerland to 51.0% in Hungary, and by 2015 it was 41.5% <sup>42, 43</sup>. Multimorbidity is associated with higher healthcare utilization, reduced functional capacity, and depression<sup>42, 43</sup>. Rising prevalence of multimorbidity is also observed amongst HIV-infected patients in care, and in one USA cohort it increased from 8.2% in the year 2000 to 22.4% in 2009 <sup>44</sup>. However, amongst Syrian refugees in Jordan, hypertension was prevalent among 9.7% of the population, and arthritis, 6.8% <sup>45</sup>. A retrospective review of data from 182 general practices in England showed that 16% of patients had multi-morbidities and accounted for 32% of consultations <sup>46</sup>.

LMIC countries are more affected by chronic diseases as they have an increasing prevalence of NCDs like diabetes and cardiovascular diseases against the backdrop of a high incidence of chronic CDs like HIV/AIDS and tuberculosis (TB)<sup>38, 47</sup>. Some of the reasons for this epidemiological transition include ageing population, changes in behaviour (decreased physical activity, poor dietary options), urbanization, and economic developments <sup>39, 48, 49</sup>. Moreover, there is a complex interaction of risk factors, management and health outcomes between CDs and NCDs <sup>3</sup>, for example, diabetes increases the risk for TB and tobacco use is a risk factor for TB and diabetes <sup>50</sup>. In addition, these countries are challenged with other social determinants of health such as low health literacy and weak healthcare systems <sup>51</sup>. Surveillance studies in Bolivia found that 50% of participants reported two or more NCDs <sup>51</sup>;

in Kosovo, 83% of elderly patients had at least one chronic condition, and 45% had multi-morbidities<sup>52</sup>. In South Africa, chronic conditions account for 82% of consultations in PHC clinics, and 65% of those patients suffer from multimorbidities<sup>53</sup>. In a different cross-sectional study conducted in Soweto, Gauteng, half the participants reported having at least one NCD<sup>54</sup>. The burden of the most prevalent diseases for South Africa, with its population of 58 million,<sup>55</sup> are presented in Table 2.1.

*Table 2.1: Summary of the most prevalent chronic diseases in South Africa*

Disease	Prevalence		References
	Number of people	Proportion	
HIV/AIDS	7 700 000		7
Tuberculosis incidence	301 000		56
Diabetes		3%	57
Hypertension in 18+ years		27%	58
Mental health in adults		16%	59

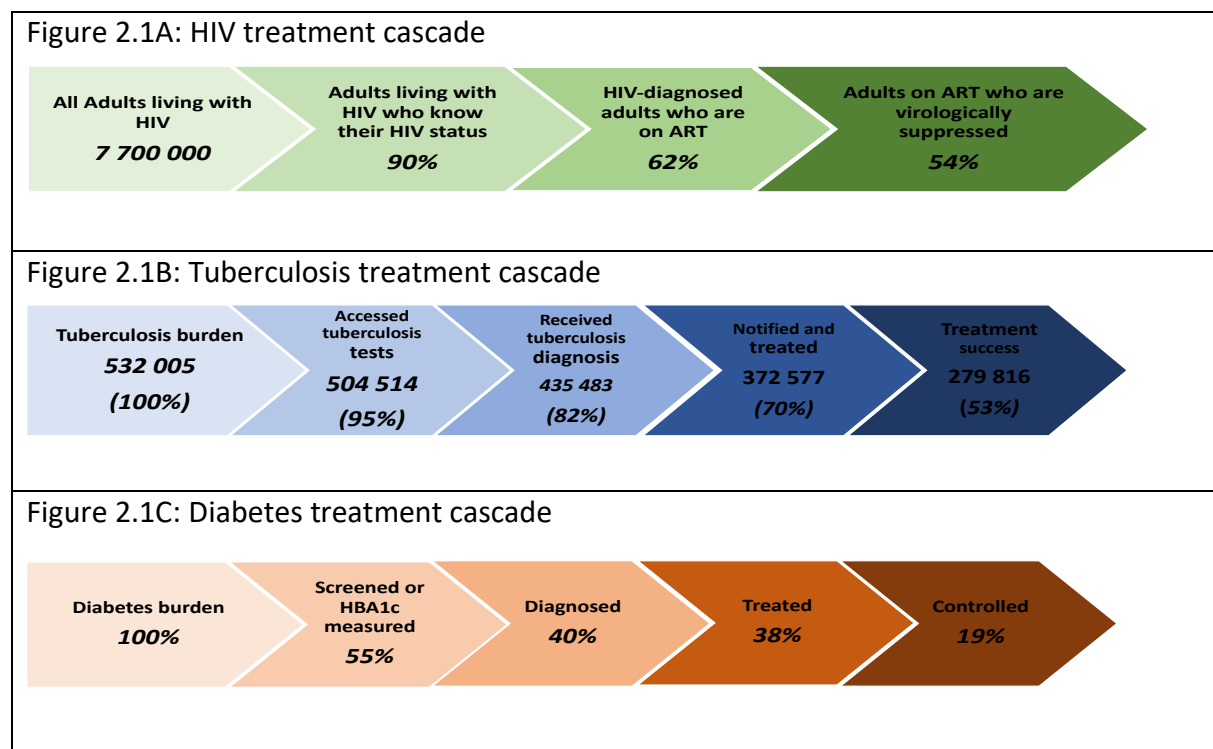
### 2.1.2. Management of chronic diseases in primary health care settings

Many health systems globally, irrespective of the country's income status, are not effectively coping with the high burden of chronic diseases<sup>4, 60-75</sup>. The primary healthcare (PHC) systems, which is the cornerstone of any health system, has been underfunded worldwide, and countries need to increase investments for PHC and consider policies that would enhance universal coverage, innovation, and effective delivery of care<sup>76-78</sup>. Some of the challenges observed in high-income countries include poor adherence to quality indicators, barriers (costs, no after-hours services) to access care and treatment (especially for those without insurance), and inadequate integration<sup>4, 60-66</sup>. However, LMIC countries have even more challenges that include dearth of political commitment, lack of financial resources and technologies, insufficient human resources, no appropriate policies or research to inform practice, barriers to access (costs, health literacy, few facilities), and inadequate supplies management for equipment and consumables<sup>67-75, 79</sup>. South Africa also has shortcomings in the provision of chronic diseases management including inconvenient opening times; long waiting times; shortage of medication, equipment and medical supplies; low rates of diagnosis and inadequate clinical supervision; and failure to achieve treatment targets<sup>20, 21,</sup>

<sup>80</sup>. A review of treatment cascades (Figure 2.2) for some of the prevalent chronic diseases in South Africa shows that more interventions are required to increase access to diagnosis and treatment and improve treatment outcomes <sup>7, 81, 82</sup>.

Health systems recommendations for appropriate chronic disease management include partnering with empowered patients, incorporating community-based health services, use of technology, quality patient-centred care, feedback systems to inform healthcare, inter-professional collaboration, addressing human resources shortages and updating educational programmes for nurses and doctors <sup>4, 83-91</sup>.

Figure 2.1: Treatment cascades for the prevalent chronic diseases in South Africa <sup>7, 81, 82</sup>.



Review of the HIV programme in sub-Saharan Africa has found that chronic disease management at PHC level can be enhanced by the provision of essential medicines, task shifting, training and retaining of clinical staff, and integrating HIV services with those of other chronic diseases (NCDs and CDs) <sup>92</sup>. Consequently, many health systems are evaluating how to enhance and scale-up integration of care as part of the PHC restructuring initiatives, as well as which funding and multi-disciplinary collaboration models to implement <sup>62, 87, 93, 94</sup>.

In light of the high burden of chronic diseases, and failure of health systems to effectively manage patients with chronic diseases, a literature review on the implementation of CDM models in primary healthcare settings was conducted.

## 2.2. Methodology of the literature review

This literature review followed a systematized review typology <sup>95</sup> with the aim to be comprehensive on what is already known on the implementation of chronic diseases management models in primary healthcare settings and some of the research gaps. The systematized review was applied as it was not feasible to have more than one reviewer as recommended for systematic literature review <sup>95</sup>, hence a quality assessment of each article was not performed. The Medline, EBSCO and Web of Science databases were searched for literature published between February 2010 to January 2020. The results were limited to English language articles that assessed the management of chronic diseases in adults at primary healthcare facilities. In addition, grey literature sourced from government and health organizations in South Africa and globally was also included in the articles for screening. The search terms utilized are summarized in Table 2.2.

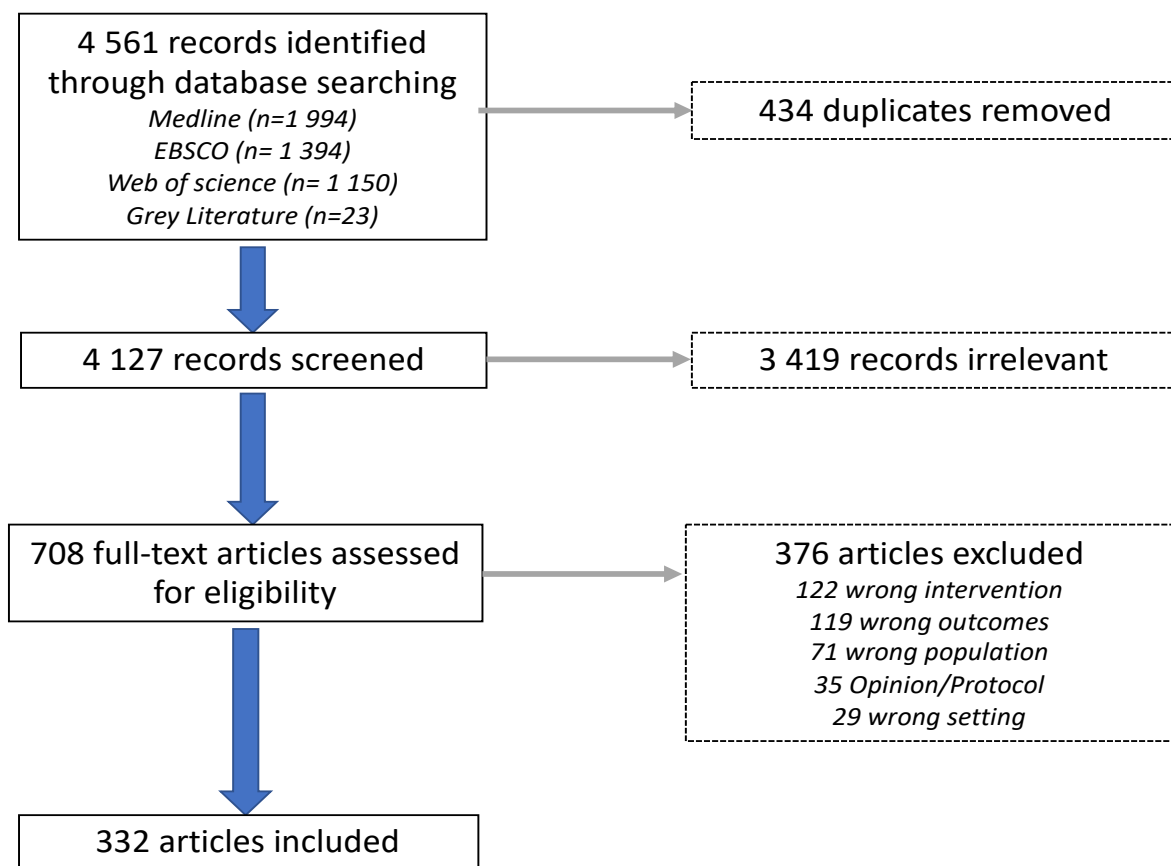
*Table 2.2: Search terms for the literature review*

<b>Key search terms</b>
“Integrated Chronic Disease Management model” OR “ICDM model” OR “Chronic Care Model” OR “CCM” AND “Primary Healthcare” OR “PHC” OR “Community Healthcare center*” OR “CHC” OR “Clinics” AND “Implementation Outcomes” OR “Fidelity” OR “Costs” OR “organization* culture” OR “Economic*” OR “Acceptab*”

Research articles that focused on other chronic conditions not included in the ICDM model – like chronic arthritis, hepatitis, pain management, kidney disease and cancer, as well as antenatal conditions or those particular to children or adolescents – were excluded. Studies considered for inclusion pertained to one chronic disease or multimorbidity. Furthermore,

studies that were conducted in settings other than primary healthcare centres like hospitals, nursing homes, and pharmacies, were also excluded. Figure 2.2 outlines a summary of the articles identified, screened and included. Both qualitative and quantitative studies, as well as systematic literature reviews, were included. In addition, the references of the articles included, as well as guidelines and reports, were reviewed for inclusion in other articles.

Figure 2.2: PRISMA flow diagram on summary of reviewed articles



## 2.3. Chronic disease management models

### 2.3.1. Landscape of chronic disease management models

A Chronic Care Model (CCM) was developed in the 1990s and further improved into the Expanded Care Model to address the problems of reactive health systems, poor health

outcomes, high economic costs of chronic diseases, and fragmentation of care <sup>12</sup>. Based on the CCM principles, the World Health Organization (WHO) developed an Innovative Care for Chronic Conditions (ICCC) framework <sup>13, 96</sup>. The ICCC framework is based on a triad consisting of the health team, family, and the patient and the community <sup>14</sup>. These chronic care models aim to reduce healthcare costs, promote prevention and self-management support, and minimize fragmentation of services<sup>14</sup>. As a result, many countries have developed various adaptations of the chronic disease management models after the CCM and the ICCC framework as summarized in Table 2.3 <sup>41, 97-108</sup>. Valentijn, *et al.* also developed the Rainbow model of integrated care as a framework to describe the dimensions of integration from macro (system integration) to meso (professional and organisational integration) and micro (clinical, normative and functional integration) levels <sup>109</sup>.

In LMIC countries, an additional focus has been on leveraging the experiences from HIV programmes to integrate with NCDs <sup>110-117</sup>. Research conducted in Malaysia showed that implementing the CCM components in LMIC countries is feasible despite various constraints <sup>118</sup>. The South African Department of Health developed and has been implementing the integrated chronic disease management (ICDM) model at PHC level<sup>19</sup> since 2011. The ICDM model is founded on the principles of the CCM and the ICCC frameworks and adapted to the context of South African PHC clinics <sup>19</sup>. Context-adapted chronic care models are more appropriate for LMIC countries as they integrate chronic care into the existing health system structures and do not require a lot more additional resources <sup>119</sup>. Some of the objectives of the ICDM model are to improve the quality and efficiency of services to patients with chronic diseases, and the experiences of healthcare workers and patients <sup>19</sup>. The ICDM model implementation is also part of the primary healthcare reengineering initiative and the ideal clinic realization and maintenance (ICRM) programme that aims to integrate care and support clinics in acquiring essential administrative processes, infrastructure, equipment and human resources<sup>120, 121</sup>. Others have described chronic care models as based on the organization of care, the clinical focus, and support for model delivery <sup>122</sup>. An evaluation of integrated care in 28 European Union countries under the Innovating Care for People with Multiple Chronic Conditions (ICARE4EU) project indicated that practices that focus on a particular disease are less integrated compared to those that manage multiple diseases <sup>123</sup>.

Table 2.3: Summary of the different integrated chronic disease management (CDM) models implemented in high-income countries

CDM Model	Description	Diseases Managed	Components/Activities
<b>Healthcare home model or medical homes</b> <sup>97-101</sup>	Endorsed by the American Public Health Association to increase access to care through dedicated care managers; expanded access to health practitioners; data-driven analytic tools; and the use of incentives	Diabetes, depression, asthma, COPD	Decision support, delivery system redesign, self-management support, and strengthening of support systems
<b>Dedicated chronic disease clinic</b> <sup>41</sup>	Al Ain in the United Arab Emirates offers a different stream of care for patients with chronic diseases	Diabetes and hypertension	Delivery system redesign
<b>Proven Health Navigator</b> <sup>102</sup>	Implemented since 2006 to increase resources at PHC level for more services and reduce duplication of services	Diabetes, renal failure, ischaemic heart disease and stroke	Delivery system redesign Healthcare worker integration
<b>Mobile integrated healthcare</b> <sup>103</sup>	Home-based or workplace physician-led team to support care transitions	Mental health, COPD, chronic heart failure	Healthcare worker integration
<b>The functional medicine model of care</b> <sup>104</sup>	Patient-centred approach to reverse illness, promote health, and optimize function	Mental health, diabetes, hypertension, infections, cancer	Self-management Holistic personalized therapeutic programme*
<b>Casalud</b> <sup>105</sup>	A model implemented in Mexico to enhance PHC services with physical and human resources and appropriate technologies	NCDs, overweight, obesity and diabetes	Strengthening of support systems; self-management; training of personnel
<b>Medicare Enhanced Primary Care</b> <sup>124</sup>	Australian government supports integrated allied health and general medical practitioner care.	Diabetes	Healthcare worker integration, self-management
<b>Collaborative care models</b> <sup>106</sup>	Integrated care for patients with mental health and other chronic diseases	Mental Health	Team-based care; system-level redesign, clinician decision support, clinical information systems and self-management
<b>The Care of Mental, Physical and Substance-use Syndromes (COMPASS)</b> <sup>107</sup>	Multi-condition collaborative model for mental health patients that was expanded to include other chronic diseases	Depression, diabetes, cardiovascular diseases	Healthcare worker integration Self-management
<b>Profile of Pathology (IPP) model</b> <sup>108</sup>	Proactive management of patients at PHC level and comprehensive assessments at secondary and tertiary levels	Mental health, disability, renal failure, COPD, diabetes, cardiovascular diseases, cancers	Care coordination from prevention to terminal disease management* Healthcare worker integration

\*Additional components or activities that are not included under the ICC framework

## 2.4. Components of chronic disease management models

Based on the CCM and the ICC framework principles, the recommended innovative activities for health systems to address chronic diseases have been grouped into four actions that can be performed at the PHC or health organization level <sup>12, 13, 96</sup>. These are the re-orientation of health systems to achieve operational efficiency and integrated coordinated care; clinical supportive management to develop informed and motivated healthcare teams that deliver quality care; support self-management and prevention and promote partnerships and use of information systems <sup>12, 13, 96</sup>. Research on the implementation and effectiveness of these four-component chronic care models is reviewed below.

*Delivery system redesign:* The application of Lean Six Sigma principles at PHC level can enhance workflow efficiencies and physician productivity without compromising on the quality of clinical care <sup>125</sup>. Training of healthcare workers has been shown to improve the administrative and environmental factors in PHC clinics<sup>126</sup>. Some of the challenges of implementing delivery system redesign are personal protective equipment and healthcare environment architecture <sup>126, 127</sup>.

*Clinical supportive management:* Decision support for clinical staff members is provided through training, treatment and referral algorithms, feedback reports, communication with specialists for complicated cases, and decision support improves the quality of care provided to patients with chronic diseases<sup>92, 128-132</sup>. Nonetheless, computerised clinical decision support does not improve health outcomes <sup>133</sup>. The coordination of care between the PHC level and specialist physician results in better compliance in clinical guidelines and health outcomes <sup>134</sup>. Clinical supportive management has also been demonstrated to be effective and cost-effective at PHC level<sup>135</sup>. However, one study indicated that the involvement of specialists in the integrated care increases costs of care <sup>134</sup>.

*Assisted self-management:* Assisted self-management through community-based programmes like directly observed therapy (DOT) and community medication deliveries have resulted in improved health outcomes (retention in care, adherence, treatment targets) and

patient experiences and involvement in their care <sup>136-145</sup>. Medication adherence reduces acute health services utilization for patients with chronic diseases <sup>146</sup>. Hence, training or technological support for healthcare workers on the implementation of motivational interviewing, counselling, and shared decision-making at PHC level is imperative to increase the uptake of self-management support <sup>147-152</sup>. However, there are mixed results on whether adherence counselling or patient coaching is the most effective strategy for achieving treatment targets or reducing costs <sup>146, 153-155</sup>. A systematic review of 184 studies on assisted self-management found that only a few studies reported reductions in healthcare services utilization or improvements in quality of life <sup>156</sup>. Another review of 58 studies demonstrated that a structured patient-provider exchange is essential to ensure that the self-management plan and personalized feedback addresses the patient's needs <sup>157</sup>.

Based on patient surveys, medication delivery systems are convenient, and improve understanding of medication and communication with healthcare workers<sup>158</sup>. Longer duration prescriptions are also associated with reduced costs to the health system <sup>159</sup>, and community delivery of medication also reduces patient's costs of accessing care <sup>138</sup>. Another cost-effective assisted self-management strategy that has been implemented in South Africa is adherence clubs for patients with chronic diseases, especially HIV-infected patients on antiretroviral medication. These clubs were found to be acceptable to healthcare workers and patients and assist in achieving treatment targets and recommended lifestyle changes <sup>160-164</sup>. In Kenya, adherence clubs were concluded to save time, reduce stigma, and provide patients with health education <sup>165</sup>.

Community healthcare workers (CHCWs) in both high-income and LMIC countries provide a broad range of healthcare support, including health system navigation, education, advocacy, and basic clinical services and have been successful as a bridge between the community and the health system <sup>84, 156, 166-173</sup>. Although CHCWs value their work, they are concerned about low levels of oversight, role clarification, salary structures, collaboration and coordination with PHC clinics, and required practical training <sup>84, 174-179</sup>. Community-based programmes in South Africa have resulted in the improvement of efficiency of healthcare services (personalised care, referral pathways and adherence), access to relevant health information, and reduced costs <sup>180, 181</sup>. Assisted self-management programmes are cost-effective if they

reduce health services utilization, and more research is needed to assess which elements are most effective <sup>156, 182</sup>.

*Strengthening of support systems:* Health information technology is an essential element in the implementation of CDM models, as it can augment collaborative care and patient adherence to medication, reduce costs and improve health outcomes <sup>183-185</sup>. However, there are often difficulties when introducing health information technologies as part of strengthening of support systems<sup>185</sup>. Secondly, health information technology has not been shown to enhance the management of prescriptions<sup>184, 185</sup>.

The research on CDM models did not indicate which of the components was implemented, and therefore the next section examines the benefits and challenges of implementing these components in combination.

#### **2.4.1. Review of chronic disease management models**

*Benefits:* Most of the research on chronic disease management (CDM) models has concentrated on health outcomes. As a result, there is sufficient evidence that integrated care reduces mortality, increases screening and diagnosis, and improves clinical outcomes for HIV, diabetes, hypertension, COPD, and mental health <sup>99, 186-211</sup>. Secondly, the health system benefits include appropriate utilization of health services (reduced hospitalizations and emergency departments visits), improved access to coordinated quality services, improved adherence to clinical guidelines, and overall enhanced efficiency and reduced costs <sup>186, 192, 194, 196, 198, 202, 211-229</sup>. Thirdly, a few studies highlighted that integrated care also benefits patients with satisfactory experience, promotes health equality, reduces barriers to care, and improves quality of life and patient knowledge and understanding of their disease <sup>186, 196, 198, 205, 216, 219, 228, 230-232</sup>. Very few studies mention that healthcare workers also have a satisfactory experience with chronic disease models <sup>186, 207</sup>. The implementation of CCM components (healthcare organisation, delivery system design, self-management support and decision support) and other activities (payment reform and advanced access) have also been shown to improve diabetes management and reduce overall costs at PHC level <sup>233-239</sup>. Integration

has also been proven to reduce gender and socioeconomic inequalities in health outcomes<sup>240</sup>.

*Challenges:* The implementation of chronic disease management models has been reported to be challenging due to the heterogeneous application of the CCM components; as a result, it is difficult to associate a particular component or activity with observed effectiveness<sup>186, 191, 194, 230, 241, 242</sup>. There were also a few studies that did not show a clear positive impact of CDM models in terms of patient-related outcomes, cost reduction and enhanced experiences with the integrated care<sup>117, 243-245</sup>. Conversely, despite CDM models not implementing all the CCM principles, there were clinical benefits<sup>186</sup>. Some of the concerns were that CDM models are inadequate to support the complexities of clinical management for patients with multi-morbidities at PHC level<sup>246</sup>. There has a proposal to modify the ICC framework to take into consideration multi-morbidity, patient workload (treatment load, capacity) and healthcare worker capacity<sup>247</sup>. An additional challenge is that detecting an improvement in clinical outcomes and reduction in costs could take up to for 3-4 years<sup>227</sup>. A systematic review of CDMs for diabetes pointed out that improvements in diabetes management are also not consistent and more often attained in studies with limited follow-up (<1 year), and in programmes that implemented more than two components<sup>248, 249</sup>. Therefore, there is a need to clarify the key components for effective implementation in the scaling up and scaling out of CDMs<sup>250</sup>. Some countries still consider horizontal health services essential components to improve delivery of health services and patient satisfaction<sup>251</sup>.

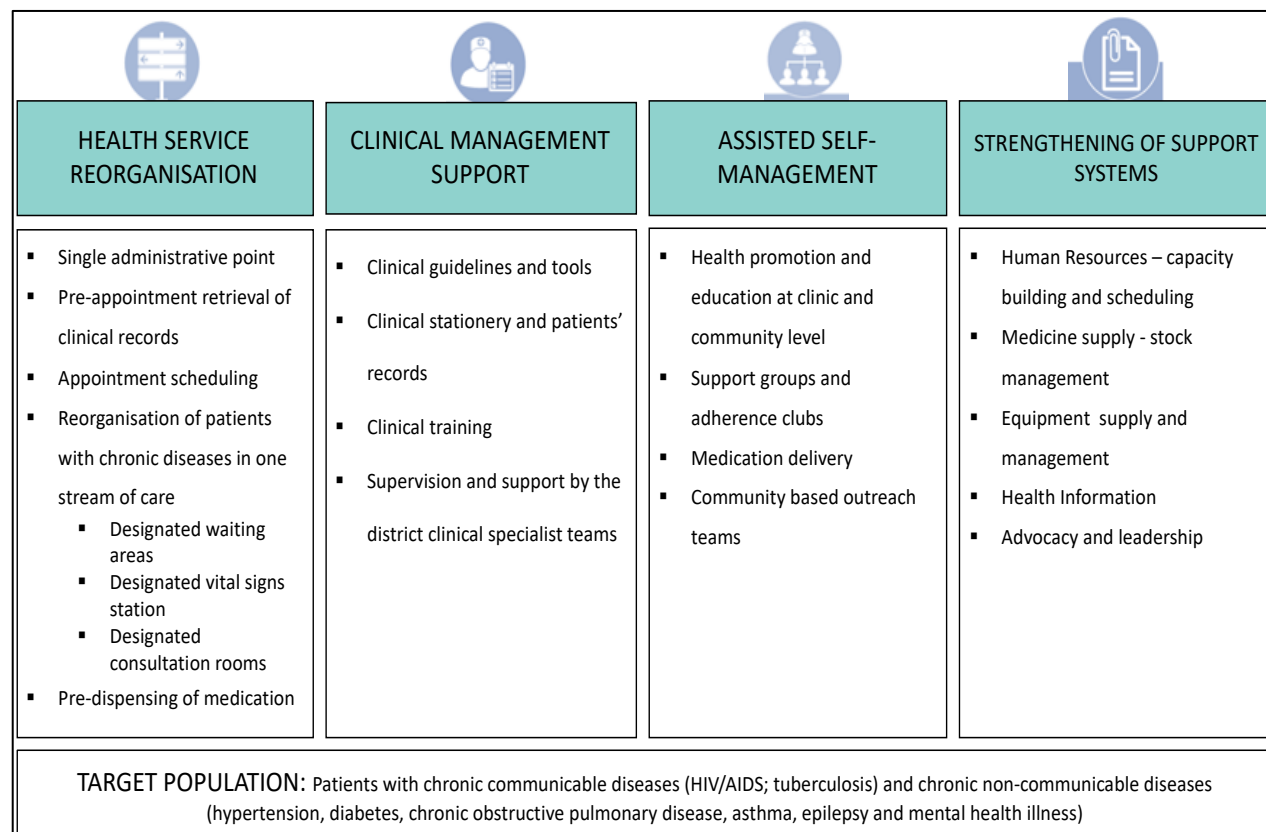
*Patients' perspectives:* Patients who participated in several quantitative and qualitative studies on CDM models indicated that they were satisfied with the coordination, communication, holistic quality of care, and attitudes of healthcare workers<sup>125, 252-258</sup>. In one study, patients mentioned that the CDM model provided a renewed sense of control and improved their health-related motivation<sup>259</sup>. In Nigeria, one of the highlighted advantages of integrating epilepsy care with other chronic diseases at PHC level was that it reduced the cost of travel and made care convenient, accessible and affordable<sup>260</sup>. However, patients also stated that CDM models do not adequately meet the needs of patients with multi-morbidities, or provide sufficient information on self-management; yet it entails high costs

and do not focus on the patient and family as a whole <sup>125, 242, 254, 258, 261-263</sup>. Healthcare workers sometimes do not take into consideration the socioeconomic status, health literacy, and functional capacity that might affect the recommended treatment plan <sup>264</sup>. Although the CDM model was cited as a solution for the long waiting times and stigma by some patients in South Africa <sup>265</sup>, there were still complaints about long queues and unacceptable staff attitudes in clinics that implemented the ICDM model <sup>266, 267</sup>. Since the South African ICDM model is the focus of this thesis, its components and implementation effectiveness assessments are expanded on in the next section.

#### **2.4.2. The South African integrated chronic disease management model**

The South African ICDM model was developed in 2011, and piloted in three health districts<sup>268</sup>: West Rand in Gauteng Province, Bushbuckridge in Mpumalanga, and Dr. Kenneth Kaunda in the North-West Province. This pilot phase conducted in 42 clinics was supported by quality improvement initiatives, consultation with healthcare workers at PHC clinics, and health district management to refine the model even further <sup>268</sup>. The four major components and recommended activities of the ICDM model and the target population are outlined in Figure 2.3. The ICDM model aims to minimize fragmentation and provide quality care for patients with chronic diseases at PHC level so they can achieve optimal clinical outcomes<sup>19</sup>. For example, optimal clinical outcomes include controlled blood pressure for patients with hypertension, viral suppression for HIV infected patients<sup>19</sup>. Stewardship and ownership are the overarching principles that underpin the patient's empowerment to take ownership of their health, and improve staff values and attitudes<sup>19</sup>. The essential building blocks are health information, human resources, pharmaceutical supply and management, equipment, and mobile technology<sup>19</sup>. The inconsistent availability of some of these building blocks has resulted in a hybrid of models during implementation of the ICDM model<sup>268</sup>. These building blocks are also addressed under the ICRM programme, which is a comprehensive systematic process to improve PHC clinics to the point of conforming to national standards for human resources, equipment and medicines supply and management<sup>120, 121</sup>. Additionally, the ICDM model principles have been expounded to cover preventative, acute and other allied health services under the integrated clinical services manual (ICSM)<sup>121</sup>.

Figure 2.3: Illustrative representation of the integrated chronic disease management model components, key activities, and target population



The ICDM model guidelines are very prescriptive, with no indication of what components or activities are non-adaptable, and which ones could be modified as necessary depending on the context. Lack of clear description of flexible components could reduce fidelity to the guidelines<sup>269, 270</sup>. The other limitation of the ICDM model is that the activities required at the population level and community level are also vaguely described. Majority of the factors on prevention for chronic diseases lies far upstream with policy, but the ICDM model interventions are fairly downstream. Moreover, the collaborations required with other sectors for policy development and implementing supportive provisions is not accentuated in the ICDM model guidelines.

An evaluation of the effectiveness of the ICDM model to enhance quality care and adherence to clinical guidelines revealed that clinical records and clinical outcomes for patients on

antiretroviral medication had improved; however, there were no improvements for patients with hypertension<sup>25, 26</sup>. Moreover, patients were concerned that the non-flexible appointment system of the ICDM model was a barrier to accessing care. It further prolonged waiting times because of personnel shortages, and fostered stigmatization of patients visited by community healthcare workers<sup>27</sup>. All these studies indicate that the implementation of the ICDM model has not achieved some of the expected outcomes, which could be as a result of inherent design faults of the model or failure to adhere to the prescribed activities of the model. Although the ICDM model was adapted to the South African setting, there could be other contextual factors that affect its successful implementation. The effectiveness of implementation of an intervention can be suitably assessed by measuring implementation outcomes<sup>24, 37</sup>, which is further explained below.

## **2.5. Implementation Outcomes**

Implementation research is a multidisciplinary, systematic research conducted in real life settings to assess how the planning, implementation and monitoring of an interventions is achieved<sup>271</sup>. Implementation strategies are the approaches that are utilized to enhance the adoption of an intervention within a particular setting<sup>272</sup>. Implementation review would also provide information on the adaptations that have been done to the intervention to enhance adoption, scaling-up and scaling-out<sup>273</sup>. Outcomes in implementation research have been divided into service outcomes, client outcomes and implementation outcomes<sup>23, 24</sup>.

### **2.5.1. Definitions of implementation outcomes**

Service outcomes relate to the efficiency, effectiveness, safety, timeliness, equity, and patient-centeredness of an intervention outcome<sup>23</sup>. Satisfaction, function and symptomatology are the features of client outcomes<sup>23</sup>. Implementation outcomes are indicators of implementation success, proximal indicators of implementation processes and serve as necessary preconditions for attaining subsequent desired changes in service and client outcomes<sup>24</sup>. Implementation outcomes are therefore different from health outcomes as they describe the activities or processes to deliver an intervention<sup>22, 24</sup>. Proctor et. al. describe eight implementation outcomes outlined below<sup>22, 24</sup>.

*Appropriateness:* The perceived helpfulness, relevance and compatibility of the intervention according to the various stakeholders

*Adoption:* The uptake of the proposed intervention by organizations, a community or individuals.

*Feasibility:* The actual suitability of the intervention for integration and incorporation into existing programmes for everyday use.

*Acceptability:* Individual stakeholders' perceptions and satisfaction with the various components of the intervention.

*Penetration:* The level of spread and normalization of the intervention in a particular setting.

*Sustainability:* Continuous maintenance of integration, normalization and routinization of the new intervention.

*Fidelity:* The degree to which delivery of an intervention follows the original outlined programme design.

*Implementation costs:* The actual overall costs or marginal costs, as well as cost effectiveness and cost benefit of implementing the intervention.

### **2.5.2. Appropriateness**

Appropriateness is the perceived ability of an intervention to address a certain problem and its compatibility and usefulness a given setting or population<sup>24</sup>. Therefore, appropriateness could be measured from the perspective of an organization, or intervention providers or recipients<sup>24</sup>. Perceived relevance, fit, practicability and suitability are other terms in the literature that have been used to describe appropriateness<sup>24</sup>. Although acceptability and appropriateness are theoretically similar, they are however distinct in that an acceptable intervention is not necessarily appropriate<sup>24</sup>. Evaluation of appropriateness can provide some information on some of the contextual factors (individual or organizational culture, climate, training) that may affect the adoption of an intervention<sup>24</sup>. Hence appropriateness assessments should be done before the adoption of an intervention<sup>24</sup>.

### 2.5.3. Adoption

Adoption is the initial intentional decision to implement an evidence-based innovative intervention<sup>24</sup>. Adoption is therefore measured from the perspective of the intervention providers or organizations during the early to mid-implementation phases through direct observations or reviewing administrative reports<sup>24</sup>. Uptake, utilization, intention to try and initial implementation are some of the terms commonly used in literature for adoption<sup>24</sup>. In the RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) framework, adoption is defined as a proportion of settings and providers that have agreed to take part in the program<sup>274</sup>. Provider trainings are some of the approaches that could be used to improve the adoption of a new intervention<sup>274</sup>.

### 2.5.4. Feasibility

Feasibility is the extent to which an intervention can be successfully implemented within a given setting, and the required practice change and resources for effective implementation<sup>24, 275</sup>. Feasibility evaluations are often done retrospectively as part of pilot studies before full scale implementation to understand the interventions success or failures<sup>24</sup>. Suitability, utility and actual fit are some of the terms used in the literature to refer to feasibility<sup>24</sup>. Many implementation studies in literature evaluate both the feasibility and acceptability of an intervention<sup>276</sup>. Research approaches can be multi-centre studies, randomized controlled trials and observational studies<sup>275</sup>.

### 2.5.5. Acceptability

Most healthcare interventions are complex and acceptability has to be a key consideration in their design, evaluation and implementation<sup>276</sup>. Acceptability is a multi-faceted view of the stakeholders on whether the intervention or its components are appropriate, agreeable and satisfactory within a certain context based on their anticipated or actual experience with the intervention<sup>24, 276, 277</sup>. Therefore, acceptability has an emphasis on the procedures of the intervention and does not address other factors like outcomes and goals<sup>277</sup>. The stakeholders

include healthcare workers (providers), researchers, administrators, patients (consumers/recipients)<sup>24,277</sup>. The acceptability of an intervention is dynamic and can change throughout the implementation phase as the stakeholder's experiences with the intervention change<sup>24</sup>. Therefore, acceptability assessments should be done during adoption, active implementation and sustainment phase of an implementation<sup>24</sup>. Factors that affect the acceptability of an intervention include costs and ethical consequences<sup>276</sup>.

#### **2.5.6. Penetration**

Penetration is defined as the integration of an intervention within a service setting<sup>24</sup>. Service access, level of institutionalization, spread and access are some of the terms that have been used for penetration in literature<sup>24</sup>. Hence, penetration is usually measured from the perspective of the provider<sup>24</sup>. Penetration can also be calculated as the number of people accessing the service divided by the number of people eligible for that service<sup>24</sup>. An assessment of providers' penetration can be calculated as the number of providers implementing the intervention divided by the number of providers that have been trained or expected to implement the intervention<sup>24</sup>. Penetration outcomes is also similar to the component of reach (proportion of persons who participate) in the RE-AIM framework<sup>24,274</sup>. Penetration evaluations from case audits or checklists are appropriately done mid-late in the implementation phase<sup>24</sup>. This outcome was not included in this study as it would require a large sample size.

#### **2.5.7. Sustainability**

Sustainability is the extent to which a new intervention is maintained with a service setting's routine stable operations<sup>24</sup>. It also includes the integration of new interventions into organizations culture through policies and practice<sup>24</sup>. Some of the components of sustainability are maintenance of the system within functional limits and eco-efficiency<sup>278</sup>. Incorporation, continuation, routinization and sustained use are some of the terms used in literature to for sustainability<sup>24</sup>. In the RE-AIM framework, sustainability is referred to as maintenance<sup>24</sup>. At an individual level, sustainability is the maintenance of primary outcomes

for more than six months, while at an organizational level maintenance captures sustainability of the delivered intervention<sup>274</sup>. Sustainability is examined in the late phases of implementation of an intervention<sup>24, 279</sup>. Sustainability evaluations are usually performed on administrators, and or organizations using data collected from semi-structured interviews, questionnaires and checklists<sup>24</sup>. Some of the factors that can affect the sustainability of a new intervention are intervention characteristics and acceptability, implementation costs, the context, processes and capacity of an organization<sup>24, 280</sup>.

### 2.5.8. Fidelity

The degree of fidelity in the implementation of an intervention affects how well it will succeed in achieving the original fundamental objectives<sup>270</sup>. A proper assessment of fidelity links the intervention to intended outcomes<sup>270</sup>. Hence, fidelity evaluations include the structure and processes followed in service delivery<sup>281</sup>. The length, intensity, content, and procedures of the activities are often included in the fidelity criteria<sup>24</sup>. Similarly, the roles of service provider, qualifications and activities of staff, and the inclusion and exclusion principles of the target population should be well defined<sup>24</sup>.

While it is generally accepted that core elements need to be maintained in order to achieve expected outcomes<sup>273</sup>, there has been some debate on whether CDM models need to be adapted to the context, especially in LMIC countries<sup>119</sup>. According to one study that interviewed staff members and patients, the key components of integrated care are collocation and continuity of comprehensive quality care, well-functioning collaborative teams, and patient-centeredness<sup>250</sup>. Contextual adaptations in the scaling out and scaling up of these innovative interventions could also be regarded as indicators of fidelity<sup>269</sup>. There are very few studies that evaluate the degree of fidelity in the implementation of CDM models. Self-reported fidelity by 253 healthcare workers had small to moderate correlations with the level of integration as assessed by the key structure and processes indicators in a study conducted in the USA that explored collaborative care management models of integrated care<sup>282</sup>. A general observation of adherence to CDM model guidelines is that there is no homogenous implementation of the different components, which makes it difficult to link activities to observed outcomes<sup>186, 191, 194, 230, 241, 242</sup>.

### 2.5.9. Implementation costs

Depending on the complexity of an intervention, approaches for delivery, and contextual factors in that setting, the implementation costs of an intervention can differ substantially<sup>24</sup>. In public health, economic evaluation is defined as a comparative analysis of costs and consequences of different interventions for management and prevention of diseases<sup>283</sup>. It is important to account for both economic and financial costs during an implementation cost calculation to improve the accuracy and credibility of the evaluation because in many public health interventions, there are hidden costs like volunteers' time, donated equipment, etc<sup>284</sup>.

Table 2.4: Examples of economic evaluations of chronic disease management models or components

The setting	Diseases Managed	Results
<b><i>Integrated chronic disease management programmes</i></b>		
Patient medical centre homes	Diabetes	49% HbA1c intervention improvement rate and \$7898 per quality-adjusted life year <sup>291</sup>
Multi-condition collaborative treatment programme compared with usual primary care	Depression and diabetes	Lower mean outpatient health costs of \$594 per patient in collaborative care <sup>239</sup> .
Improvement collaborative care in the UK	Diabetes	The incremental costs per quality-adjusted life year were £1937 for men and £1751 for women <sup>292</sup> .
Coordinated care health insurance claims	Chronic diseases and mental health	Unadjusted financial claim per patient was higher for uncoordinated care (€234.52) than for coordinated care (€224.41) patients <sup>293</sup> .
Asheville care management model	Diabetes	Overall healthcare costs decreased by an average of \$2704 per patient per year <sup>294</sup> .
<b><i>Assisted self-management</i></b>		
Health coaching in primary healthcare level	Diabetes, hypertension, and/or hyperlipidaemia	The average healthcare costs for the coaching group was \$3207 compared with \$3276 for the control group (P = 0.9) for a year <sup>295</sup> .

Several studies have been conducted on the costs of implementing CDM models in high-income countries; however, there is a dearth of studies from LMIC countries on the costs of

CDM models. The cost of providing care and treatment for patients with chronic diseases increases with the number of comorbidities<sup>285, 286</sup>. The cost of implementing CDM models are influenced by the chosen CDM model, components implemented, and the context<sup>287, 288</sup>. The cost of implementing a CDM model in the USA from development, roll-out and stabilization over 29 months, was \$2 304 787 for human resources<sup>289</sup>. Modelling studies indicate that a national community health worker workforce programme in England would cost approximately £2.22 billion a year<sup>290</sup>.

Although the cost of implementing a CDM model is high, overall there are cost savings due to improved health outcomes and quality-adjusted life years<sup>31, 35, 239, 288, 291-299</sup>. A few examples of the scale of cost savings are summarized in Table 2.4. In addition, patients managed under CDM models have less expenses in terms of inpatient care, specialist consultations, and primary care visits<sup>29-35</sup>.

However, some studies did not demonstrate any cost-effectiveness when CDM model interventions were compared to standard care<sup>295</sup>. In some studies, although the health outcomes improved, the costs of care under the CDM model increased compared to usual care costs<sup>300</sup>. A systematic review of 26 manuscripts found that most (84.6%) of the studies reported a positive economic impact of integrated care models for diabetes, schizophrenia, and multiple sclerosis management<sup>301</sup>. Moreover, another review of 18 studies found that assisted self-management was cost-effective<sup>302</sup>.

The cost of integrating HIV services into other programmes was also found to be lower compared to HIV vertical programmes in a systematic review of 46 manuscripts, mostly from sub-Saharan Africa and other LMIC countries, and in another study conducted in Ukraine<sup>303, 304</sup>. Management of epilepsy at PHC level in LMIC countries has also been shown to be cost-effective<sup>305</sup>. The implementation of CDM models also reduces the costs associated with accessing care and medication adherence for patients with chronic diseases<sup>306</sup>.

There are some overlaps and interconnections amongst the implementation outcomes<sup>24</sup>. Acceptability, adoption, appropriateness, and feasibility implementation outcomes are more appropriate when evaluating a novel intervention<sup>22</sup>, whereas existing interventions would

benefit more from an evaluation of fidelity, costs and penetration <sup>22</sup>. Therefore, in evaluating the implementation of the ICDM model that was initiated over 7 years ago, fidelity and implementation costs are assessed and explained in detail. The impact of contextual factors on fidelity are also discussed.

#### **2.5.10. Contextual factors**

The two major components of fidelity are adherence and moderating factors<sup>270</sup>. Moderating factors include intervention complexity, facilitation strategies, quality of delivery, and participant responsiveness<sup>270</sup>. These moderating factors influence adherence to the original design of the model<sup>270</sup>. Several studies have assessed how contextual factors influence the implementation of CDM models and their components in various settings. Table 2.5 summarizes the CDM model implementation facilitators, while Table 2.6 summarizes the observed barriers.

The three major themes that emerged as barriers/facilitators in the implementation of CDM models or principles are leadership, human resources, and organizational culture. Leadership at higher or governmental level must ensure that the appropriate policies to support integration of care are in place<sup>307, 308 309</sup>. Engaged, strong and committed leadership and support at the organizational level was recognized as an important facilitator for the implementation of CDM models and their components<sup>125, 309, 310</sup>. Trained, experienced staff members that function collaboratively in a multi-disciplinary team were considered pivotal to implementing CDM models, especially assisted self-management activities<sup>84, 105, 137, 158, 311-313</sup>. The acceptability of the intervention to staff members and patients was also one of the key facilitators of successful CDM model implementation<sup>311</sup>. Preparing and supporting staff members and patients for the proposed changes and throughout implementation are essential for promoting acceptability <sup>311, 314</sup>. Recommended strategies to improve integration at PHC level include prioritization of selected programme metrics, financial support, continuous improvement, capacity building through education, committees and champions, customizing electronic health records, and standardizing workflows<sup>315, 316</sup>. An organizational culture that is conducive to quality improvement, collaboration, patient-centred care, and

change has been highlighted as a necessary factor for the adoption of the recommended CDM model activities<sup>84, 125, 158, 192, 310, 312, 313, 317-320</sup>.

In South Africa, quality improvements at PHC level have been challenged by passive leaders that are resistant to change<sup>317</sup>. The HIV programme showed that the successful implementation of clinical supportive management includes structured training, followed by facility-based clinical mentorship, continuous medical education, and coordination with management<sup>321</sup>. Some of the facilitators identified for ICDM model implementation in rural South Africa include the availability of nurses with experience in the management of NCDs, functional equipment, medication, and the need to improve the link with traditional healers<sup>322</sup>.

Table 2.5: Organizational and team factors that are considered facilitators for the implementation of chronic disease management models and their components

	Overall CDM Model	Facility Reorganization	Clinical Supportive Management	Assisted Self-Management	Strengthening of support systems
Organization/Setting Factors	<ul style="list-style-type: none"> <li>Leadership</li> <li>Financial resources</li> <li>Strong quality culture</li> <li>Networks and communication</li> <li>Multidisciplinary, patient-centred care culture</li> <li>Clinical and administrative champion-led culture shift</li> <li>Training</li> <li>Appropriate role definition</li> <li>Clinical information systems</li> <li>Templates and protocols</li> <li>Fidelity to the CCM principles</li> <li>Active patient participation</li> <li>Integrated health information technology<sup>137, 310, 312, 318, 323-327</sup></li> </ul>	<ul style="list-style-type: none"> <li>Leadership</li> <li>Quality improvement culture</li> <li>Consolidated clinical record systems</li> <li>Collocated interdisciplinary teams</li> <li>Organizational culture</li> <li>Health information technology</li> <li>Well-defined workflows</li> <li>External incentives<sup>189, 192, 318, 319</sup></li> </ul>	<ul style="list-style-type: none"> <li>Team meetings</li> <li>Case conferencing</li> <li>Adequate technical clinical databases</li> <li>Structured training<sup>192, 226, 326, 328</sup></li> </ul>	<ul style="list-style-type: none"> <li>Leadership</li> <li>Incentives</li> <li>Inclusive work culture</li> <li>Community resources</li> <li>Patient advocacy</li> <li>Communication</li> <li>Clinic support</li> <li>Patient health literacy<sup>84, 137, 158, 313, 329, 330</sup></li> </ul>	<ul style="list-style-type: none"> <li>Adaptable programmes</li> <li>Supporting infrastructure<sup>105, 238</sup></li> </ul>
Characteristics of Implementing Teams	<ul style="list-style-type: none"> <li>Skilled, enthusiastic champions</li> <li>Staff knowledgeable and experienced with CCM principles</li> <li>Accountability culture</li> <li>role clarification</li> <li>Established relationship with patients</li> <li>Involving patients in their care<sup>310, 316, 318, 323, 329, 331-333</sup></li> </ul>	<ul style="list-style-type: none"> <li>Adequate staffing levels<sup>192</sup>.</li> </ul>	<ul style="list-style-type: none"> <li>Interprofessional teams</li> <li>Active role of specialists<sup>192, 226, 326, 328</sup></li> </ul>	<ul style="list-style-type: none"> <li>Experienced, knowledgeable staff</li> <li>Committed staff</li> <li>Shared vision</li> <li>Passion to serve the community culture</li> <li>Career progression prospects for community healthcare workers<sup>84, 137, 158, 313</sup></li> </ul>	<ul style="list-style-type: none"> <li>Health information champion</li> <li>Functional quality improvement teams<sup>105, 238</sup></li> </ul>

Table 2.6: Organizational and team factors considered barriers to the implementation of chronic disease management models and their components

	Overall CDM Model	Facility Reorganization	Clinical Supportive Management	Assisted Self-Management	Strengthening of support systems
<b>Organization/Setting Factors</b>	<ul style="list-style-type: none"> <li>Lack of leadership</li> <li>Obsolete administrative practices</li> <li>Insufficient financial resources</li> <li>Increased workloads (intervention multiple processes)</li> <li>Inadequate infrastructure</li> <li>Lack of medication</li> <li>Absence of IT support</li> <li>Funding exclusive to vertical programmes</li> <li>No clear societal benefits <sup>105, 309, 310, 318, 320, 326, 329, 334-336</sup></li> </ul>	<ul style="list-style-type: none"> <li>Democratic, non-hierarchical organizational culture <sup>125</sup></li> </ul>	<ul style="list-style-type: none"> <li>Multiple vertical programmes</li> <li>Limited communication</li> <li>Absence of automated clinical support <sup>328</sup></li> </ul>	<ul style="list-style-type: none"> <li>Limited drug supplies</li> <li>Irregular salary payments <sup>84</sup></li> </ul>	<ul style="list-style-type: none"> <li>Siloed infrastructure</li> <li>Competing programmes</li> <li>Inadequate time allocation to tasks</li> <li>Top-down initiation</li> <li>Not considered relevant at PHC level<sup>238, 337</sup>.</li> </ul>
<b>Characteristics of Implementing Teams</b>	<ul style="list-style-type: none"> <li>Deeply held professional identities</li> <li>Hierarchies-focused culture</li> <li>High staff turnover</li> <li>Staff shortages</li> <li>Intervention unacceptable to staff</li> <li>Staff with minimal knowledge and skills on CCM principles</li> <li>Lack of motivation to change <sup>323, 334, 336</sup></li> </ul>	<ul style="list-style-type: none"> <li>No clear staff roles</li> <li>Insufficient information on the intervention's effectiveness for staff <sup>125</sup></li> </ul>	<ul style="list-style-type: none"> <li>Loss of key personnel <sup>328</sup></li> </ul>	<ul style="list-style-type: none"> <li>Negative feedback from other colleagues</li> <li>Staff shortages</li> <li>No appropriate supervision</li> <li>Inadequate training</li> <li>No role clarification<sup>84, 330</sup></li> </ul>	<ul style="list-style-type: none"> <li>High staff turnover</li> <li>No shared vision</li> <li>No visible champion</li> <li>Failure to identify and link with patient needs <sup>238, 337 238</sup></li> </ul>

### 2.5.11. Organizational culture

Organizational culture has been described as an important factor that influences the functioning of multidisciplinary teams and how they implement CDM models and related activities<sup>84, 125, 158, 192, 310, 312, 313, 317-320</sup>. Unethical and disruptive workplace cultures have a negative impact on the quality of care provided to patients, as well as job satisfaction for the staff members<sup>338, 339</sup>. Some of the recognized disruptive cultures include low rate of error reporting, non-punitive response to errors, poor quality, and inadequate patient safety<sup>340, 341</sup>. Positive work culture is one of the factors that could assist with recruitment and retention of healthcare workers<sup>342-344</sup>.

Although there is a complex interaction with work culture and capabilities and use of infrastructure, effective leadership is essential to initiating organizational culture transformation<sup>344-346</sup>. Organizational culture in the healthcare sector has been linked to healthcare outcomes<sup>347, 348</sup>. An example is the Bureaucratic Caring Theory, which is based on ethical quality principles that promote caring values and norms and was associated with improved diabetes treatment targets<sup>349</sup>. Adherence to guidelines is encouraged in a culture that is hierarchical, rational, and with an emphasis on particular performance standards<sup>350</sup>. Organizational culture change is an evolving process that requires regular critical review of values, assumptions, practices and approaches in patient management<sup>351</sup>.

Healthcare organizational culture is also a slow process of doing and thinking differently while keeping in mind the desired new values<sup>351</sup>. Culture change requires staff and management that is willing to frequently and collaboratively solve both mundane and complex setbacks and negotiate with team members in implementing the necessary changes<sup>351-353</sup>. Healthcare organizational change could be challenged by traditional organizational structures, insufficient resources to implement significant changes, inadequate human resources, and high staff turnover<sup>354</sup>.

Staff members in UK hospitals identified professional practice and support (adequate time for training, development, team meetings), and workforce and service delivery (minimal staff

turnover and shortages) as important cultural traits for delivering quality care<sup>344</sup>. A patient-centred culture supports patients to achieve treatment targets and enjoy improved physical functioning<sup>355</sup>. A survey of 154 staff members in PHC clinics in South Africa indicated that the current values are not compatible with patient-centred care. These values include not sharing information, confusion, manipulation, and blame<sup>356</sup>. The organizational culture in this setting requires the adoption of values that are congruent with patient-centred care, such as community involvement, results orientation, and accountability<sup>356</sup>.

## **2.6. Summary of chronic care models' literature review and knowledge gaps**

The reviewed publications revealed that chronic diseases are a major public health problem in many countries, and contribute to significant morbidity and mortality. Yet many healthcare systems are not adequately managing chronic diseases, especially at the primary healthcare level, and this results in poor health outcomes. For example, in South Africa, the achieved treatment targets for HIV, tuberculosis, and diabetes are below 60%. Barriers related to political commitment, financial resources, technologies, and human resources seem to play a key role in primary healthcare reengineering.

The challenge is that there is no homogenous implementation of the chronic disease management (CDM) model or activities, and a lack acceptability of some of the principles or processes of the chronic disease management models. The integrated chronic disease management model was also implemented in South Africa and improved treatment outcomes for HIV disease, but did not achieve all its objectives. Assessment of implementation outcomes provide an effective method for appraising implementation bottlenecks for an intervention.

A fidelity (level of adherence to guidelines) assessment may enable researchers to connect effectiveness of implementation of an intervention to its intended outcomes. There are very few studies that evaluate the degree of fidelity in the implementation of CDM models. However, several studies have been conducted in high-income countries that show cost savings in the implementation of CDM models. Nonetheless, a few studies did not

demonstrate that CDM models are cost-effective. Contextual factors also influence costs and fidelity in the implementation of the CDM models. Leadership, human resources, and organizational culture are the barriers or facilitators most cited for the realization of successful CDM model activities. Organizational culture that is conducive to quality improvement, collaboration, and patient-centred care is essential for the adoption and sustainability of the principles and activities of CDM models.

This literature review has shown the dearth of studies assessing implementation outcomes, especially fidelity and the costs associated with CDM models in LMIC countries, and the ways contextual factors could have affected fidelity. There are also very few studies and chronic disease management models that include both NCDs and CDs, and understanding how these integration is realised under the ICDM model will be important for countries with high prevalence of both NCDs and CDs. It is therefore important to have a better understanding of how the ICDM model components and activities have been executed, and if there have been any adaptations to the model and the impact of those adaptations. Some of the CDM models did not achieve the intended outcomes, but it has not been outlined as whether this was as a result of failure to adhere to the activities of the CDM model during its implementation or inherent design faults of the model. Assessing the cost of implementing the various activities of the ICDM model will then assist with planning and budgeting, as well as inform scalability and sustainability of the model in similar settings. There is also an expectation that the ICDM model would reduce healthcare costs with reduced health services utilization and optimal health outcomes and hence estimating the implementation costs can inform further economic evaluations is also imperative. This thesis on the fidelity and its moderating factors, and costs of implementing the ICDM model will significantly address some of this knowledge gaps.

## Chapter 3: Methodology

The data for this thesis on the degree of implementation fidelity, moderating factors of fidelity and estimated costs of implementing the ICDM model in primary healthcare clinics in South Africa was collected over the course of a year in two health districts. This was a cross-sectional mixed methods study. The details of the methodology have been outlined in a manuscript.

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**The relevance of the publication to the thesis:** This manuscript describes the study protocol that was approved and followed in the research on fidelity and costs of implementing the Integrated Chronic Disease Management (ICDM) model. The South African Department of Health developed and implemented the ICDM model to respond to the increased utilization of primary healthcare (PHC) services due to the co-existence of a surge of non-communicable diseases with a high prevalence of communicable diseases. However, some of the expected outcomes for implementing the ICDM model have not been achieved. The protocol manuscript outlines how the implementation research principles would be applied to provide data on the degree of fidelity (adherence to guidelines) for optimizing the model, what moderating factors affected the level of fidelity, and the costs of implementing the model to inform resource allocation and economic evaluations.

# BMJ Open Process evaluation of fidelity and costs of implementing the Integrated Chronic Disease Management model in South Africa: mixed methods study protocol

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## ABSTRACT

**Introduction** The South African Department of Health has developed and implemented the Integrated Chronic Disease Management (ICDM) model to respond to the increased utilisation of primary healthcare services due to a surge of non-communicable diseases coexisting with a high prevalence of communicable diseases. However, some of the expected outcomes on implementing the ICDM model have not been achieved. The aims of this study are to assess if the observed suboptimal outcomes of the ICDM model implementation are due to lack of fidelity to the ICDM model, to examine the contextual factors associated with the implementation fidelity and to calculate implementation costs.

**Methods and analysis** A process evaluation, mixed methods study in 16 pilot clinics from two health districts to assess the degree of fidelity to four major components of the ICDM model. Activity scores will be summed per component and overall fidelity score will be calculated by summing the various component scores and compared between components, facilities and districts. The association between contextual factors and the degree of fidelity will be assessed by multivariate analysis, individual and team characteristics, facility features and organisational culture indicators will be included in the regression. Health system financial and economic costs of implementing the four components of the ICDM model will be calculated using an ingredient approach. The unit of implementation costs will be by activity of each of the major components of the ICDM model. Sensitivity analysis will be carried out using clinic size, degree of fidelity and different inflation situations.

**Ethics and dissemination** The protocol has been approved by the University of Cape Town and University of the Witwatersrand Human Research ethics committees. The results of the study will be shared with the Department of Health, participating health facilities and through scientific publications and conference presentations.

## INTRODUCTION

Chronic diseases and multimorbidity are increasing in developing countries due to epidemiological transition of increasing prevalence of non-communicable diseases (NCDs) in the presence of rampant infectious

## Strengths and limitations of this study

- This study uses implementation research principles to provide data on the degree of fidelity to the Integrated Chronic Disease Management (ICDM) model for optimising the model.
- Process evaluation will provide an indication of how the ICDM model has been modified in different contexts and explain variability in the implementation outcomes.
- Implementation cost assessments are essential in public health programmes to inform resource allocation during planning and budgeting and to inform economic evaluations.
- The reliance on the service provider to accurately provide information on the implementation activities or insufficiencies of those activities is a limitation of this study.
- Although the clinics may not be representative of all districts and clinics in the country, the results of this study could be applied to clinics similar in size or patient load and other integrated disease management models.

diseases.<sup>1 2</sup> By 2025, it is estimated that the burden of NCDs in sub-Saharan Africa will be higher than that of communicable diseases (CDs).<sup>3</sup> The increase in urbanisation, economic development, ageing, decrease in physical activity and poor dietary options are some of the contributing factors to the increasing prevalence of NCDs in developing countries.<sup>4 5</sup> There is also a complex interaction of risk factors, management and health outcomes between NCDs and CDs, resulting in a rise in chronic disease multimorbidity.<sup>6 7</sup> Multimorbidity often results in reduced levels of physical capability, high rates of health services utilisation and attendant costs and higher mortality rates.<sup>8 9</sup> The double burden (NCDs and CDs) of diseases is costly to the health systems (increased utilisation, medication), the economies, households and individuals.<sup>2</sup> Therefore, chronic disease

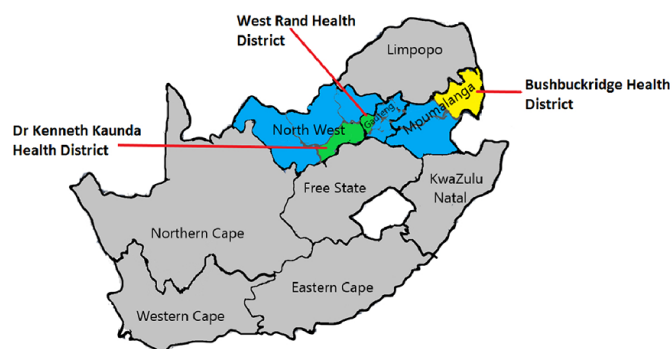
management needs to be comprehensive and take into consideration these interactions in disease prevention, management and control.

In South Africa, the current leading health problems are NCDs, accounting for 51.3% of all deaths, followed by CDs 38.4% and injuries 10.3%.<sup>10</sup> South Africa like many Sub-Saharan African countries has been severely affected by the HIV/AIDS epidemic, with 7.1 million people living with HIV and 18.9% of people between the ages of 15 and 49 years being HIV infected.<sup>11</sup> As a result, there is an increase in the prevalence of multimorbidity.<sup>12</sup> Tuberculosis, HIV and NCDs (mainly hypertension and diabetes mellitus) account for 45% of all primary healthcare consultations, with a multimorbidity prevalence of 22.6%.<sup>9,13</sup>

Unresponsive health systems often provide services that are not aligned with the health requirements of the population being served.<sup>14</sup> A more comprehensive chronic disease management model, combining both CDs and NCDs that reduces health utilisation and promotes self-management, is one of the strategies that have been recommended to address the challenges associated with the management of multimorbid chronic diseases.<sup>2,14</sup> The Chronic Care model and Innovative Care for Chronic Conditions framework have been recommended as health system approaches to deal with multimorbidity.<sup>15</sup> However, there have been significant resources and strategies allocated to the implementation of HIV programmes and consequently the non-communicable chronic diseases have been overlooked. To rectify this imbalance, the South African National Department of Health developed and has begun implementation of the Integrated Chronic Disease Management (ICDM) model in order to improve efficiencies and quality of care in primary healthcare clinics for patients with chronic diseases.<sup>16</sup>

### Integrated Chronic Disease Management model

The ICDM model was piloted from 2011 in 42 clinics from three health districts in three different provinces (figure 1) of South Africa as follows: West Rand in Gauteng Province, Bushbuckridge in Mpumalanga and Dr Kenneth Kaunda in North West Province.<sup>17,18</sup> As part of a broader national approach to revitalise primary



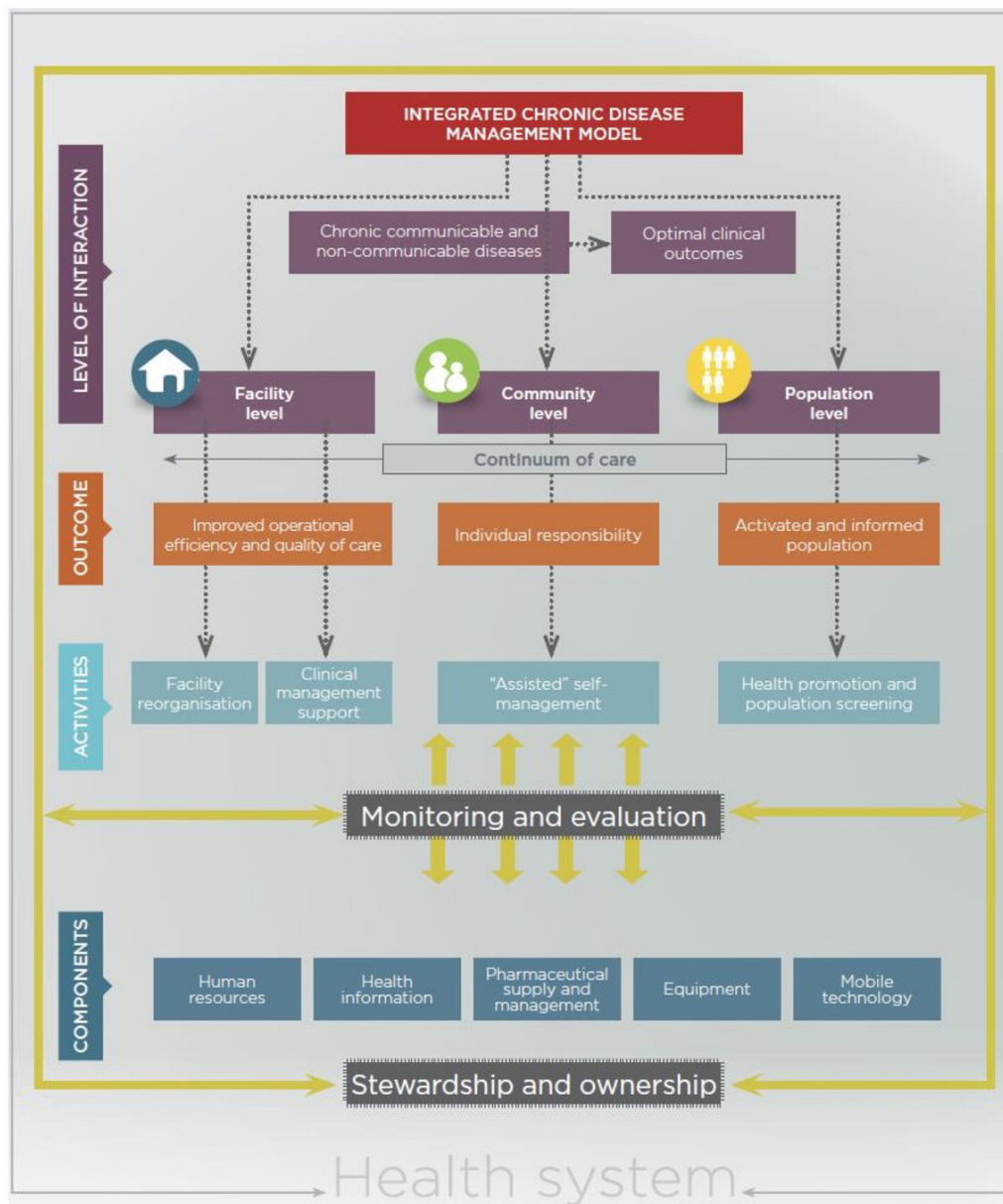
**Figure 1** Map of South Africa with the Integrated Chronic Disease Management model pilot sites highlighted.

healthcare (PHC) services, reduce fragmentation of services and ensure that each PHC facility meets national minimum standards, the ‘ideal clinic’ initiative was also started in 2019.<sup>19</sup> The principles of the ‘ideal clinic’ incorporate the majority of the activities required for ICDM implementation and provide standard operating procedures for the Ideal Clinic Realisation and Maintenance (ICRM) programme.<sup>20,21</sup> One of the components of the ICRM programme is Integrated Clinical Services Management (ICSM), which focuses on health services being structured in four (acute, chronic, preventive and promotive and health support) streams.<sup>20,21</sup> The principles of the ICRM, ICSM and the ICDM model cover integration of services, good administrative processes, functional infrastructure and equipment, adequate personnel, ensuring adequate levels of medicines and supplies and the use of applicable protocols and guidelines in diseases management.<sup>19–21</sup>

The four major components (action points) of the ICDM implementation are as follows: facility reorganisation for efficiency, clinical supportive management, assisted self-support and strengthening of support systems (figure 2).<sup>16</sup> The ICDM priority and core standards are (1) improving the values and attitudes of staff, (2) patient safety and security and infection prevention and control and (3) availability of medicines and supplies.<sup>16</sup> Assuming full implementation of the ICDM as recommended, the expected outcomes include improved operational efficiency and quality of care, improved individual responsibility towards their health and an activated and informed community.<sup>16</sup> The ICDM model also provides guidelines on booking systems for patients with chronic diseases, clinic flow, organisation of waiting areas and consultation rooms and dispensing medication practices that promote adherence and minimise medication shortages. In order to avoid fragmentation of services, the ICDM recommends a multidisciplinary treating team to provide care to all patients with chronic illnesses and be trained on how to assess and manage drug-drug interactions and disease interactions. Mentoring, supervision and training of the PHC nurses to be provided by the district Clinical Specialist Team (DCST).<sup>16</sup> The DCST's other responsibilities include monitoring of patient clinical outcomes through clinical audits and strengthening of referral systems for complicated patients.<sup>16</sup> The components or building blocks for ICDM model include human resources, health information, mobile technology, equipment and pharmaceutical supply and management.<sup>16</sup>

### ICDM model pilot phase implementation

The pilot phase was supported with quality improvement reviews and consultation with all staff members at the facility, district and province levels to refine the model even further.<sup>18</sup> Some of the implementation challenges identified in these consultations were lack of key equipment, an emphasis on curative health services with minimal focus on prevention, the ill-defined role of community healthcare workers and delayed formation of



**Figure 2** Integrated Chronic Disease Management model.<sup>16</sup>

out-of-facility chronic medication collection sites.<sup>18</sup> Lack of these necessary building blocks for the ICDM model has resulted in the implementation of hybrids of the original model.<sup>18</sup> The limitations of the ICDM model identified include its focus on secondary and tertiary prevention of disease within the healthcare facilities and the lack of guidelines on social and environmental changes for the prevention of risk factors and onset of chronic diseases.<sup>16</sup>

### Management of chronic conditions in PHC facilities

An evaluation of PHC services in South Africa showed low rates of diagnosis for chronic diseases, and the few that are diagnosed are not managed appropriately and do not achieve the treatment targets.<sup>22 23</sup> The lack of key equipment in PHC clinics to diagnose and monitor total cholesterol, blood pressure and blood glucose contribute to these challenges, with patients reporting the need to

travel to higher levels of care to access certain medication and diagnostic tests.<sup>22</sup> Additional barriers included the insufficient consultation time that patients report with their healthcare providers even after long waiting periods at the facility due to high volumes of patients<sup>22</sup>; poor knowledge on chronic disease, shortage of medication and shortage of healthcare workers resulting in long waiting periods at PHC clinics.<sup>24</sup> The nurses knowledge of chronic diseases was also found to be poor due to inadequate training, unavailability of guidelines and lack of supervision.<sup>24</sup>

The implementation of an innovative intervention can be affected by the design of the intervention, context and/or implementation outcomes.<sup>25</sup> New innovative interventions could fail to achieve intended objectives because of implementation barriers or failures in the design.<sup>25</sup> The

observed impact of the ICDM model in the management of chronic diseases has been an improvement in the patients' records, compliance with clinical guidelines and health outcomes for patients on antiretroviral medication but not those on hypertension treatment.<sup>26 27</sup> Irregular supplies and stock-outs of hypertension medication were also not improved after the implementation of the ICDM model.<sup>28</sup> The patients' perspectives on the ICDM model inconveniences were a non-flexible appointment system that affected access to services, long waiting times because of personnel shortages and stigmatisation of patients that are visited by community healthcare workers.<sup>28</sup> However, it is not clear whether these observed and perceived gains and shortcomings are as a result of the inherent faults in the design of the model or failure to adhere to the prescribed activities and/or the impact of contextual factors.

The successful implementation of the ICDM model requires a high degree of fidelity to the recommended processes of delivering healthcare services with clear intervention priorities and expected outcomes.<sup>29 30</sup> Although monitoring and evaluation tools exist for the ICDM model implementation, they do not provide data on implementation outcomes such as adoption, fidelity, penetration, acceptability, sustainability and costs. Process evaluation of the ICDM model implementation would optimise practice of the four major components and scale-up of the model, and the quality of care for individuals affected by chronic illness, especially those with multimorbidity.

Implementation of any intervention within a large complex health system is generally unpredictable. An assessment of fidelity on the implementation of the model will additionally measure quality of practice for continuous improvement, identify any innovations that can improve models' processes and support systematic implementation of the model. Although the implementation of the ICDM model was subsequently followed by the ICRM programme that consists of the ICSM, which has a broader focus beyond chronic diseases, both these interventions have similar principles, standards and aims of ensuring that patients get quality patient-centric care that achieves the desired health outcomes.<sup>19–21</sup> We envisage that lessons learned from an evaluation of the ICDM model can be beneficial in the strengthening of implementation of the ICRM programme.

Interviews with the actors in the ICDM model implementation will provide information on their perceptions and experiences with implementation and how contextual factors have affected fidelity to the model's guidelines. This can improve comparability, generalisability and replicability of the results of this study. Assessing the cost of implementing the various activities of the ICDM model will then assist with planning and budgeting, as well as inform scalability and sustainability of the model.

Therefore, the *aim* of this study is to evaluate selected implementation outcomes of the ICDM model: fidelity and implementation costs, and to assess the influence

of contextual factors on ICDM model implementation fidelity in two health districts where the ICDM has been piloted, from two different provinces in order to better understand the processes of successful implementation of the ICDM model and how the model can be optimised. The *objectives* of the study are as follows:

1. To assess the degree of fidelity in the implementation of the ICDM model.
2. To evaluate the influence of contextual factors on the implementation fidelity of the ICDM model.
3. To estimate the implementation costs of the ICDM model.

## METHODS AND ANALYSIS

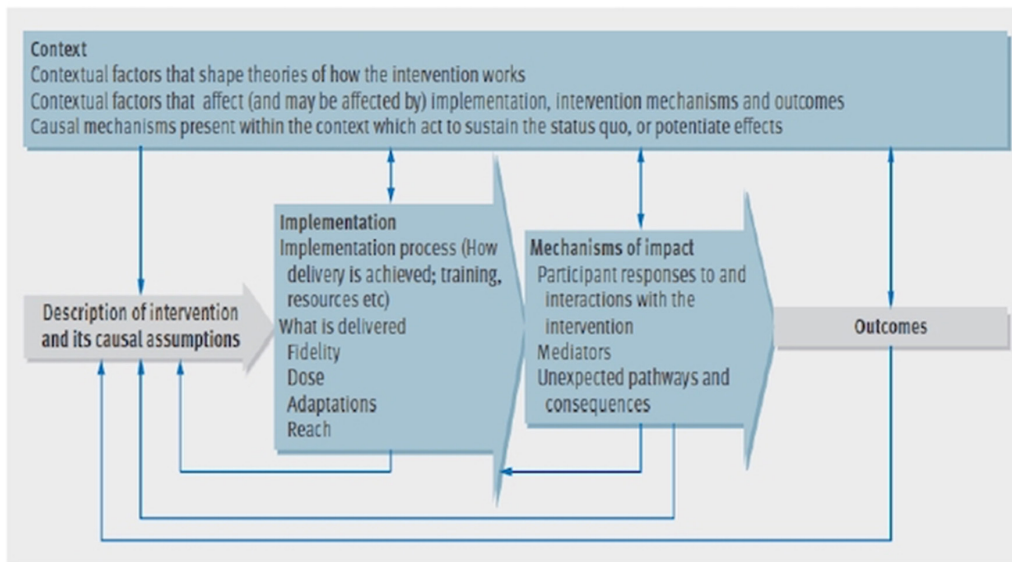
### Setting

This study will be conducted from August 2018 to July 2019 in two health districts (Dr Kenneth Kaunda in North West Province and West Rand District in Gauteng) that were the pilot sites for the ICDM model implementation. Both districts are within socioeconomic quantile 4 (1 is most deprived and 5 is least deprived); however, comparing the North West to Gauteng province, poverty prevalence (33% vs 27%) and informal housing (21% vs 19%) are slightly higher in the North West Province.<sup>31 32</sup> The provincial HIV prevalence is 13.3% in North West Province and 12.4% in Gauteng.<sup>33</sup> The prevalence of hypertension is high (31%–39.7%) in both districts, a reflection of large number of people accessing health services for chronic NCD.<sup>31</sup> The prevalence of diabetes in South Africa is 8.27% (2.6 million) and 31.9% among adults (20–79 years), with 1.2 million people with diabetes estimated to be undiagnosed.<sup>34</sup>

### Theoretical framework

#### Process evaluation of complex interventions

Process evaluation frameworks assist in understanding the functioning of a complex intervention by reviewing implementation processes and the influence of contextual factors.<sup>35 36</sup> A complex intervention implementation process has multiple components, which interact to produce change, and/or are difficult to implement and/or target a number of organisational levels.<sup>35 37</sup> Process evaluation is therefore useful for assessing (figure 3) fidelity (dose, adaptations, frequency and reach), clarifying the usual mechanisms and processes and identifying the impact of contextual factors on the variations in processes and outcomes.<sup>38</sup> A process evaluation framework will be applied in this study to evaluate whether the processes for implementing the intervention (the ICDM model) are being applied as intended according to the design (fidelity) of the intervention and how contextual factors influence the implementation fidelity (figure 4). The costs, quantity and quality of programme activities provided and evaluating the generalisability of the results in other different contexts are important especially for a programme that is already established.<sup>38</sup>



**Figure 3** The process evaluation framework for complex interventions.<sup>38</sup>

**Study design**

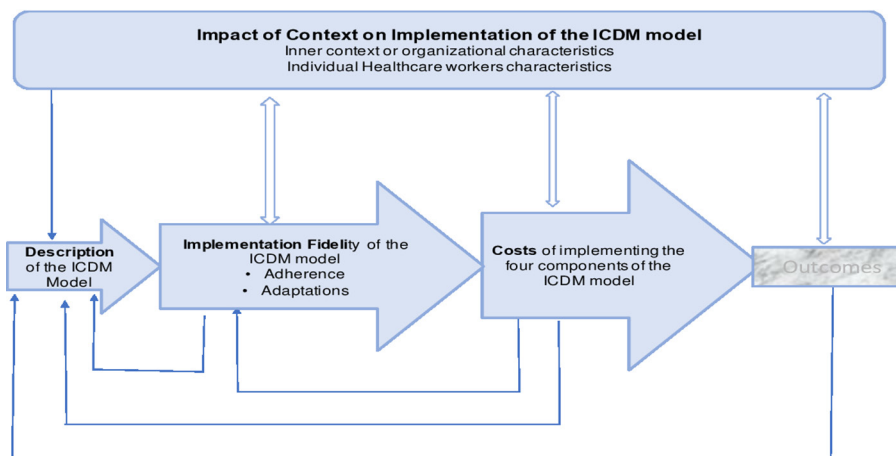
This is a process evaluation study using mixed methods to assess the degree of fidelity, costs and impact of context on the implementation fidelity of the ICDM model.

**Objective-specific methodology**

Fidelity assessment will be carried out to review if implementation of the ICDM model adheres to content, coverage, frequency and duration as prescribed in the ICDM model manual in 16 (8 in North West and 8 in Gauteng) clinics. As there are no fidelity criteria in the literature that are suitable to adapt for assessing the ICDM model implementation, we developed fidelity criteria based on the ICDM model guidelines,<sup>16</sup> the ICRM programme monitoring tools<sup>21</sup> and published literature on the ICDM model.<sup>18 26 28 30</sup> The basis of the criteria are the four (facility reorganisation, clinical supportive management, assisted self-management and strengthening of the support systems) major components of the ICDM model.<sup>16</sup> The outlined prescribed activities are the

variables to be assessed on the implementation fidelity criteria. The expected outcome of the fidelity criteria is to warrant that all the essential activities required for successful implementation of the ICDM model have been captured. Each criterion under the four major components will be listed as an item to be scored on the fidelity criteria. We will assess the fidelity criteria in a pilot study and finalise it on the basis of the results of the pilot study. Sixteen clinics from the 20 ICDM pilot clinics located in those districts will be considered for inclusion if the clinic has been open and running without any major interruptions (renovations, closures) in the last 2 years. At each clinic, we will collect data using structured observations, review of facility records and interviews with the healthcare workers (table 1).

Contextual factors (facility characteristics and characteristics of individuals and teams) on fidelity will be examined in four clinics. Based on the degree of fidelity, *two clinics*, one with a high and one with a low degree



**Figure 4** Modified process evaluation framework for assessing the fidelity and cost of the ICDM model implementation. ICDM, Integrated Chronic Disease Management.

**Table 1** Summary of study objectives, methods and expected outcomes for assessing the fidelity, impact of contextual factors and costs of implementing the ICDM model

	Objective	Methods	Outcomes
Degree of fidelity assessment	To assess the degree of fidelity in the implementation of the ICDM model	Quantitative: fidelity evaluation in <i>16 ICDM model pilot PHC clinics</i> using the fidelity criteria scoring checklist template. Data sources: key informant interviews, structured observations and review of facility records	Degree of the ICDM model implementation fidelity for each activity and component of the ICDM model and overall scores by clinic and district
Impact of contextual factors on ICDM fidelity	To evaluate the influence of contextual factors on the implementation fidelity of the ICDM model	Qualitative interviews with <i>30 HCW</i> in four (two per district) facilities using structured interview guides and organisational culture survey. Quantitative data to assess association between contextual factors and degree of ICDM model fidelity	Health workers' perceptions of contextual factors that influence implementation fidelity of the ICDM model. Establish influence of contextual factors on the degree ICDM model implementation fidelity
Costs of implementing the ICDM model	To estimate the implementation costs of the ICDM model	Ingredient approach to health system costs in <i>four PHC clinics</i> —two facilities per district using The WHO CostIt software 2007. Data sources: budgets, key informant interviews, direct observations and literature search. Annualise capital costs Adjust all costs for inflation and discount Develop a cost profile for providing each component of the ICDM model	The cost of implementing each of the components of the ICDM model. Sensitivity analysis to determine cost drivers in the implementation of the ICDM model.

ICDM, Integrated Chronic Disease Management ; PHC, primary healthcare.

of fidelity, will be selected from each of the two districts. The organisational contextual factors to be considered include communication style, decision process and culture.<sup>39</sup> Individual level data for the implementing teams will include demographics (age, gender, race, education level), position role within the clinic, years in that role and their participation in the delivery of the ICDM model. External (to the facility) context factors (socioeconomic level, policies and legislation) will not be evaluated in order to keep the study scope manageable. We will use mixed methods (interviews, facility assessments and culture surveys) approach to assess the influence of context on implementation fidelity. We will conduct qualitative interviews with 30 healthcare workers, purposively selected to represent different cadres of staff members that implement and manage the ICDM model intervention for more than 6 months (table 1). The interviews will be done on a one-to-one basis to minimise having group dynamics.

Participants' confidentiality will be protected at all times during the study, and no electronic record will contain individual identifiers. A master list that contains the participants' identifiers will be kept in a separate lockable area. The results will also be presented in such a way that respondents cannot be identified.

### Costs

The financial and economic costs of implementing the ICDM model from the health system perspective will be

evaluated in the same four clinics. The health system implementation costs are an all-inclusive costing valuation that considers costs incurred by the providers of the service.<sup>40</sup> Assessing the implementation costs will be a partial economic evaluation as it will only focus on the costs of implementation and not the outcomes. The unit of implementation costs will be by activity of each of the major components of the ICDM model. Service level costs such as those pertaining to the development of the ICDM model will not be included as these costs were incurred in 2010/11. The focus will be on post start-up annual costs required for the full implementation of the ICDM model in a typical year (table 1). Both direct and indirect, and fixed and recurrent costs will be calculated.

### Capital costs

Annualised equipment and capital costs will be calculated according to the volume being used for the ICDM model. Estimating annual costs will include adding up the acquisition, operation, maintenance and disposal costs.

### Operational costs

In the financial documents review, key operational costs that we will check and categorise include human resources, office supplies and travel. Based on the useful life and the discount rate, an appropriate annualisation factor will be determined. If there are any donations for programme implementation (volunteers, healthcare workers not allocated to ICDM but assisting in service

delivery, donated equipment or office supplies), they will be included. Medical and support staff labour costs will be calculated based on the full-time equivalent, duration of involvement in the ICDM model implementation and the gross salary of the personnel.

A proportion of overhead costs of running the health facility like electricity, rent and water will be included in the implementation costs. Administrative costs at district and provincial level (which are beyond the facility) will not be included in the analysis.

#### Patient and public involvement

Previous research has shown that patients do not like some of the components of the ICDM model<sup>26</sup> and that was the basis of the research question. Patients will not be enrolled in the study; however, results will be shared with them through community and health facilities leadership.

#### Data management and analysis plan

The data will be collected using paper-based questionnaires and later captured into an electronic database. There will be no identifying features (eg, date of birth, addresses) in the database. The health facilities and healthcare workers that participated will be allocated a study number. Source documents will be safely kept and only accessible to study personnel. The data on costs will be manually entered into the CostIt software 2007<sup>41</sup> according to the provided major categories. CostIt software is a template designed to capture and automatically analyse cost data for different (hospital, PHC and programme) levels of the healthcare system.<sup>41</sup>

Descriptive statistics (frequency, median, interquartile ranges and percentages) will be used to examine the general quantitative variables of the clinics, such as size, number of chronic patients, services offered, clinic team characteristics and overall functioning status. Following the evaluation, each clinic will receive a score for each of the fidelity criteria items. Item scores will be summed per component to give four overall ICDM component fidelity scores per facility. An overall ICDM model implementation fidelity score will be calculated per facility by summing the four component scores. The implementation fidelity scores will be summarised using descriptive statistics and compared between components, facilities and districts. The outcome of interest will be the degree of implementation fidelity.

The experiences and perceptions of the healthcare workers from the interviews will be analysed with REDCap software for Likert scaled questions and using thematic content analysis for barriers and facilitators of implementation fidelity for qualitative data. The six steps recommended by Braun and Clarke<sup>42</sup> for thematic content analysis that will be followed: familiarisation, generating initial codes, searching for themes throughout the database, reviewing and naming themes and summarising the findings.<sup>42</sup> Multivariate analysis using STATA V.14 econometric software will be used to assess the effect of various contextual factors on the implementation fidelity of the

ICDM model. The impact of both the organisational (case mix, financial flexibility and culture) and implementing team (work experience, cadre of HCW, training and perceptions of ICDM) level factors on the degree of the ICDM model implementation fidelity will be assessed. The initial analysis will include description of the sample, followed by a bivariate analysis that includes t-tests and ANOVA to examine the influence of contextual factors on implementation fidelity of the ICDM model.

Costs: Capital costs and other costs that have a life span of several years will be annualised over the useful life span to get the equivalent annual costs. All costs will be adjusted for inflation and discount. Equipment will be depreciated according to the South African Accounting principles.<sup>43</sup> Sensitivity analyses will be conducted for other possible variations in estimated costs. Sensitivity analyses will also be carried out to explore different scenarios including size of clinic, degree of implementation fidelity and other factors that could possibly affect costs based on literature.

#### Ethics and dissemination

##### Ethical conduct of the study

This study has been approved by the University of Cape Town (Ref: 127/2018) and University of the Witwatersrand (Ref: R14/49) Human Research ethics committees. Approvals have also been received from the Gauteng and the North West Provincial Department of Health. The participants for the interviews will be consented individually prior to taking part in the study.

##### Dissemination of the results

The results of this study will be shared with the various stakeholders to inform the implementation of the ICDM model in South Africa and other models of integrated care. Brief summary of results will be presented to the provincial and districts departments of health (DOH). The full results will be presented at local research days in each province and district. Facility managers and local clinic staff that participated in the study will be given feedback on the outcomes of the study. The results will also be presented through publications and conference presentations to enhance scientific knowledge. Authorship will be determined by substantial contributions to the study according to the recommendations for the conduct, reporting and publication of research in medical journals. Once the data collection and cleaning are complete, it will be made open and publicly accessible.

#### CONCLUSION

Many health systems are challenged with increased demand for healthcare for chronic diseases. Despite this service need, there is minimal integration of services for the management of chronic diseases resulting in inefficiencies in service delivery, high costs and poor health outcomes. The ICDM model has been developed to address this challenge, the success of which will be influenced by the degree to which the model is accurately

implemented. This highlights the need for data to assess the degree of fidelity to the ICDM model intervention and for data that explore how fidelity of implementation is affected by contextual factors. Data generated from this study will inform integration of chronic care services at the PHC level and scalability of the ICDM model, of relevance in South Africa and other low-income and middle-income countries increasingly facing a growing tide of chronic disease multimorbidity.

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**Competing interests** None declared.

**Patient consent for publication** Not required.

**Ethics approval** The protocol has been approved by the University of Cape Town and University of the Witwatersrand Human Research ethics committees. Any changes required, will have to be submitted to both ethics committees.

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## Chapter 4: Level of fidelity in the implementation of the ICDM model

The degree of fidelity in the implementation of the ICDM model results are described in this chapter as a published manuscript.

*Lebina L, Alaba O, Ringane A, Hlongwane K, Pule P, Oni T, Kawonga M. Process evaluation of implementation fidelity of the integrated chronic disease management model in two districts in South Africa. BMC Health Services Research. 2019 Dec 16;19(1):965. doi: 10.1186/s12913-019-4785-7.*

This section addresses the first objective of the study to assess the degree of fidelity in the implementation of the ICDM model.


**The relevance of the publication to the thesis:** This manuscript describes the results on the degree of fidelity in the implementation of the Integrated Chronic Disease Management model in two health districts in South Africa. The use of implementation research principles implies that this research ensures evidence-based decisions on the improvement of ICDM model implementation and how the lesson learned could affect scaling up, scaling out, and policies. Based on the findings of this study, there was a high level of fidelity of implementation of the ICDM model in the two health districts, with some variability in ICDM model scores across ICDM model components and PHC facilities. The ICDM model items described as having lower degrees of fidelity (different streams of care, administration, and health promotions) provide opportunities for improvement of the current implementation of the ICDM model and how to support normalization into the routine practice of the model. The application of patient flow analysis also identified specific inefficiencies in the delivery of chronic health services streams in the study clinics. The variability in levels of fidelity between clinics and health districts was explored in subsequent papers on the influence of organizational culture and moderating factors on fidelity.

RESEARCH ARTICLE

Open Access



# Process evaluation of implementation fidelity of the integrated chronic disease management model in two districts, South Africa

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## Abstract

**Background:** The Integrated Chronic Disease Management (ICDM) model has been implemented in South Africa to enhance quality of clinical services in Primary Healthcare (PHC) clinics in a context of a high prevalence of chronic conditions and multi-morbidity. This study aimed to assess the implementation fidelity (adherence to guidelines) of the ICDM model.

**Methods:** A cross-sectional study in 16 PHC clinics in two health districts in South Africa: Dr. Kenneth Kaunda (DKK) and West Rand (WR). A fidelity assessment tool with 89 activities and maximum score of 158 was developed from the four interrelated ICDM model components: facility re-organization, clinical supportive management, assisted self-management and strengthening of support systems. Value stream mapping of patient flow was conducted to analyse waiting time and identify operational inefficiencies. ICDM items were scored based on structured observations, facility document reviews and structured questionnaires completed by healthcare workers. Fidelity scores were summarized using medians and proportions and compared by facilities and districts using Chi-Square and Kruskal Wallis test.

**Results:** The monthly patient headcount over a six-month period in these 16 PHC clinics was a median of 2430 (IQR: 1685–2942) individuals over 20 years. The DKK district had more newly diagnosed TB patients per month [median 5.5 (IQR: 4.00–9.33) vs 2.0 (IQR: 1.67–2.92)], and fewer medical officers per clinic [median 1 (IQR: 1–1) vs 3.5 (IQR: 2–4.5)] compared to WR district. The median fidelity scores in both districts for facility re-organization, clinical supportive management, assisted self-management and strengthening of support systems were 78% [29/37, IQR: 27–31]; 77% [30/39 (IQR: 27–34)]; 77% [30/39 (IQR: 28–34)]; and 80% [35/44 (IQR: 30–37)], respectively. The overall median implementation fidelity of the ICDM model was 79% (125/158, IQR, 117–132); WR was 80% (126/158, IQR, 123–132) while DKK was 74% (117/158, IQR, 106–130),  $p = 0.1409$ . The lowest clinic fidelity score was 66% (104/158), while the highest was 86% (136/158). A patient flow analysis showed long (2–5 h) waiting times and one stream of care for acute and chronic services.

**Conclusion:** There was some variability of scores on components of the ICDM model by PHC clinics. More research is needed on contextual adaptations of the model.

**Keywords:** Intervention adherence, ICDM model, Chronic care model, Implementation research, Value stream mapping

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## Background

Delivering integrated, patient-centred health services is a global public health priority [1]. One of the recommended strategies of the World Health Organization (WHO) to improve the delivery of integrated chronic care at primary care level is the Innovative Care for Chronic Conditions framework, which reduces fragmentation of care and supports partnerships with communities and families in disease management [2]. Based on this recommendation, many countries have implemented various models of integrated care for chronic conditions, including community-based programmes with repeat collection of medication [3–5], nurse-managed programmes [5] and integrated mental health, diabetes and cardiovascular disease services [6]. In South Africa, the Integrated Chronic Disease Management (ICDM) model was adopted as a national programme for implementation at primary care level. The goal was to reduce fragmentation of care for people living with multiple chronic conditions, to improve efficiency and the satisfaction experience of healthcare workers and patients, and ultimately clinical outcomes [7]. This was also in response to the high quadruple burden of communicable, non-communicable, injury-related and perinatal diseases and associated multi-morbidity [8–11].

### The ICDM model

The ICDM model is an approach to managed care that was developed based on the principles of the chronic care management model and the Innovative Care for Chronic conditions (ICCC) [2, 12]. A pilot phase of introducing the model in PHC clinics in South Africa started in 2011 [13]. The ICDM model provides technical interventions on how to strengthen health services for patients with chronic multi-morbidity through four interrelated components of action points. These components are as follows [7]:

- *Facility re-organization* to strengthen administration, infrastructure, human resource and dispensing of medication for operational efficiency;
- *Clinical supportive management* to enhance quality care using appropriate clinical guidelines with the assistance of the district clinical specialist team;
- *Assisted self-management* which entails empowering patients to take responsibility for their disease control and providing community-based point-of-care testing and medication delivery by outreach teams; and
- *Strengthening of support systems* through partnerships with external structures, equipment, medicine and information management [7].

The ICDM model's priority standards are designed to align with the national core quality standards for PHC

facilities, which include patient safety and infection control, improving values and attitudes of staff, improving waiting times and cleanliness, and ensuring availability of medicines and supplies [7]. The chronic diseases that are included in the ICDM model are non-communicable [mental health, epilepsy, asthma, hypertension, diabetes and chronic obstructive pulmonary disease (COPD)] and communicable diseases [HIV/AIDS and all forms of tuberculosis (TB)] [7]. Continuum of care is supported at facility, community and population level under the ICDM model [7].

The ICDM programme is an integral part of the PHC re-engineering initiative [7], a major health system strengthening focus of which is the South African Department of Health's (DOH) efforts to strengthen their focus as it works towards achieving universal health coverage through a national health insurance plan [14–16]. This includes the ongoing ideal clinic realisation and maintenance (ICRM) programme that was commenced in 2013 [17]. The ICRM programme is a comprehensive systematic process of improving and maintaining PHC facilities' conformance to national standards on functional infrastructure and equipment, adequate personnel and medicines and supplies, good administrative processes and the use of applicable protocols and guidelines in diseases management [17]. The Integrated Clinical Services Manual (ICSM) was included in the ICRM programme to extend the application of the ICDM model components to acute, preventative and health support services as part of scaling-out [18]. Chronic diseases has been included as one of the streams of the ICSM [18]. A scaling-out of interventions (delivery in new systems/populations) or scaling-up within the same context implies that the original core elements are maintained to achieve expected outcomes [19]. However, contextual adaptations to the intervention while maintaining the core components in the scale-up and scale-out could also be regarded as propensity towards adherence [20]. Studies on the effectiveness of the ICDM model have shown its contribution to improvements in patients records management through administrative re-organization and improved clinical outcomes through clinical supportive management and assisted self-management for patients on antiretroviral medication [21, 22]. However, some of the expected benefits have not been achieved [23]. It is not clear whether this limited success indicates low effectiveness of the model or low implementation effectiveness.

The field of implementation science provides approaches for assessing implementation effectiveness [24, 25]. Implementation research assists in assessing whether the failure of an intervention to achieve its outcomes is as a result of intervention failure or implementation failure [24]. Implementation effectiveness or success can be determined by measuring implementation outcomes such

as fidelity (the extent to which the ICDM model is implemented according to the planned prescribed activities) or other outcomes (including acceptability, adoption, reach, implementation costs and sustainability) that serve as intermediate indicators of intervention or innovation effectiveness [24, 26]. Fidelity of implementation – the extent to which delivery of an intervention or programme follows the original design – affects how well the intervention or programme achieves its expected outcomes [27, 28]. Fidelity is also referred to as adherence to intervention guidelines [28]. As conceptualised by Carroll, the degree of adherence to the implementation plan or guidelines can be influenced by moderating factors like intervention complexity, strategies to support implementation, quality of delivery and participant responsiveness [28]. Planned or accidental adaptations in implementing interventions could also be viewed as strategies to enhance feasibility, reach, adoption, and acceptability of the intervention in a specific context [29, 30]. However, adaptation could affect the fidelity and effectiveness of the intervention, especially if its core components have been removed or modified [19, 29, 30]. Therefore, there is a constant tension between fidelity and modifying interventions to be suitable for a particular context [29, 30]. Since the ICDM model development was an adaptation of the ICCG for the South African health context [7], it would be expected that it would be implemented with minimal adaptations and high fidelity, but this has not been evaluated. Moreover, in a decentralized health system, like South Africa, sub-national levels (provinces and districts) may further adapt innovations for a better fit with their contexts [31]. However, whether and the extent to which such further adaptations have been done has not been evaluated.

In South Africa, following the pilot and scale-up of the ICDM model [32], there is a dearth of studies on the implementation fidelity of the ICDM model. This study assesses the implementation fidelity, which we define as adherence to the prescribed activities in the ICDM model as outlined in the implementation manual [7]. This study aims to evaluate the implementation fidelity of the ICDM model in two health districts in South Africa. The lessons learned on assessing fidelity of the ICDM model could be applied to the ICSM in the context of the ICRM programme. Assessing the ICDM model implementation fidelity will identify areas that need strengthening to promote the sustainability of the model's principles.

## Methods

This was a cross-sectional study conducted between August 2018 to March 2019 in two health districts in South Africa. It is a sub-study of a larger study that assessed the fidelity of implementation, its contextual determinants and the costs of implementing the ICDM model [33].

## Study setting

The South African health system is divided into 52 health districts across nine provinces, with health service administration decentralized to district health management teams [16, 34]. Most of the population is uninsured (82%) and utilizes state facilities where most healthcare services are free or provided at a low user fee [14, 35, 36]. Nurse-driven primary care services in each district are provided at PHC clinics (8-h service) and community health centres (24-h service) that provide preventative and curative (acute and chronic) services. As part of the PHC re-engineering framework, each clinic should have ward-based outreach teams (WBOTs) of community healthcare workers (CHCW) providing home- and community-based health services [17, 37]. Each health district is required to have a District Clinical Specialist team (DSCT) consisting of specialist nurses and doctors that provide supportive supervision and clinical governance [17, 38]. The ICDM model activities for the WBOTs and CHCW include adherence support, home-based care and community campaigns, while the DSCT activities include mentoring, training and clinical audits [7, 18].

The ICDM model was piloted from 2011 in three health districts: West Rand (WR) in Gauteng, Bushbuckridge in Mpumalanga and Dr. Kenneth Kaunda (DKK) in North West [13]. Two (WR and DKK) of these health districts were included in this study. Both the WR and DKK health districts are divided into four sub-districts and have similar population sizes, 810,000 in WR and 715,000 in DKK [39]. There are four community health centres and 39 PHC clinics in WR, while DKK has nine community health centres and 27 PHC clinics. Although the literacy rate is slightly higher in WR (98% vs 90%), employment is higher (75% vs 71%) in DKK [40]. In WR, the proportion of informal housing is 19%, while in DKK it is 21% [40]. In Gauteng, more people (34%) are considered to be obese or overweight compared to the 16% in North West [41]. There is also a high prevalence of hypertension (36 and 39%) [39] and diabetes (8 and 13%) [41] in WR and DKK, in that order. TB incidence is higher (696 vs 440 per 100,000) in DKK [39], and the human immune deficiency syndrome (HIV) prevalence in antenatal women is 28% in both provinces [42].

## Study sample

There were eight ICDM model pilot clinics in DKK and 12 in WR that were considered for inclusion in this study. The ICDM model pilot clinics were selected for inclusion based on the number of patients that receive health services per month (headcounts) to ensure that clinics had comparable patient case-loads. Four clinics from the WR district were excluded as the patient load in those clinics was much higher compared to DKK clinics. A total of 16 (eight per district) that were selected

were functional without major interruptions (closures, renovations) in the 2 years preceding participation in the study. Six to eight healthcare workers (administrators, nurses, pharmacists assistants, facility managers, ICDM champions) were interviewed (for completion of the structured questionnaire) or observed in each facility.

#### Data collection and measurement

The study aimed to collect data on the characteristics of the clinics, fidelity scoring on ICDM model activities and examination of patient flow against guidelines. The data collected on clinic characteristics included a facility headcount, caseloads for some (HIV/AIDS, TB, diabetes and hypertension), ICDM model conditions and number of different categories of personnel based on district health information system reports. The monthly patient data (headcounts, caseloads) were collected for a period of 6 months.

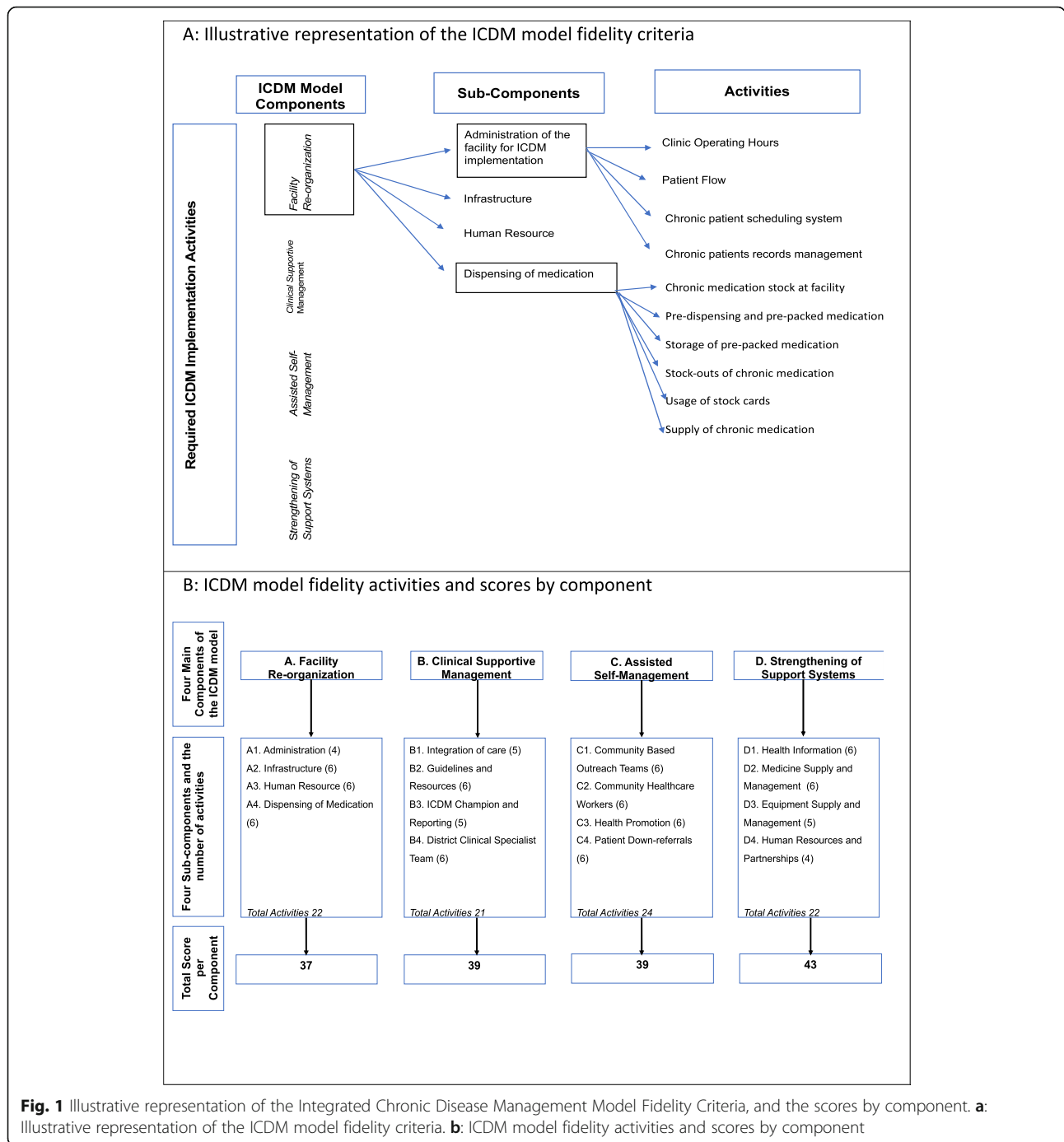
To measure fidelity (adherence to ICDM model activities), we first developed fidelity criteria based on the ICDM model manual [7] with a focus on the recommended activities, the recommended reporting tools for the ICDM model and ICRM programme assessment tools. Since no previous studies have assessed the implementation fidelity of the ICDM model, we developed an ICDM model implementation fidelity assessment tool for this study. Our ICDM fidelity assessment tool was designed to measure the extent to which activities under each of the four major components of the ICDM model (facility re-organization, clinical supportive management, assisted self-support and strengthening of support systems) [7] were implemented according to the ICDM model design. Each of the four ICDM model components has various activities that must be implemented to achieve the aims of the ICDM programme [7]. These activities were used to form the basis of the variables to be measured on the implementation fidelity assessment tool. Our fidelity tool was therefore a checklist of variables (activities) under each component. They were scored following similar principles as other chronic diseases management model evaluation studies [43]. As the ICDM model is prescriptive on how activities should be implemented to support integrated care for chronic patients, we posited that failure to implement the recommended activities was regarded as low fidelity.

Each of the four components of the ICDM model comprises four sub-components and each sub-component comprises of four to six activities as outlined in the ICDM model manual (Fig. 1a) [7]. A total of 89 activities or items (facility re-organization 22; clinical supportive management 21; assisted self-management 24, and strengthening of support systems 22) were thus measured in the fidelity assessment tool (Additional file 1). The activities were each scored on a scale, with activity scores ranging from 0 (not

implemented at all) to 4 (fully implemented as planned – adherent). The activity (item) scores varied depending on the details of the activity. For example, the scores for the activity “pre-dispensing and packing of chronic medication 2–3 days prior to visit” were zero if not implemented, and a maximum score of one if implemented, whereas the score for the activity “building” ranged from 0 (needs major repairs) to 2 (no major repairs needed and floors and walls clean). The total maximum possible fidelity score was 158 per facility (facility re-organization 37; clinical supportive management 39; assisted self-management 39 and strengthening of support systems 43; Fig. 1b).

The ICDM model activities fidelity assessment tool was piloted in four clinics and thereafter revised for clarity and consistency in scoring. Fidelity scoring for the 89 activities was performed through structured observations for such activities like the availability of guidelines and resources, infrastructure maintenance and medicine supply and management. For other items of the ICDM model where observation would be challenging, such as training of healthcare workers, support provided by the DCST and the activities of the WBOT and CHCW in the community were scoring was based on structured questionnaires with healthcare workers. Staff members involved in the implementation of the ICDM model's various components were selected for further data collection using structured questionnaires interviews. The interviews in this study were structured with the aim of assessing how certain activities of the ICDM model that could not be assessed by record review or observations had been performed in the facilities. In addition, all available documents relevant to ICDM model implementation at each facility (human resource and administration files, medicine, and equipment management documents) were reviewed to score the scheduling system and dispensing of medication, among others. Data collection was done over a period of 8 months with multiple visits to the health facilities on different days of the week and times of the month to gather data on a variety of activities. The research team was trained on the protocol and the data collection tools. This team then conducted the pilot and refining of the fidelity assessment tool prior to data collection and fidelity scoring in all the PHC facilities for consistency.

To further examine adherence to the ICDM model guidelines and cross verification of the fidelity scores, we also conducted a patient flow analysis using value stream mapping [44] to ascertain if the processes followed are aligned with the ICDM model guidelines. Patient flow analysis following the value stream mapping was done in four clinics, one with the highest and one with the lowest fidelity scores per district, but with comparable average monthly PHC headcounts. The data collected on the structured observations of patient flow included where and who provided various services for patients with chronic diseases, time for



the service, the waiting times and areas of inefficiency. An average of 15 patients with a chronic disease per facility were observed from entry into facility till exit.

**Data management and analysis**

The data collected on the paper-based ICDM model fidelity assessment tool in the field were captured into a REDCap electronic database [45]. Each facility was allocated a number for study identification and no identifiers were

included in the password-protected REDCap database. As part of data cleaning, the data were checked for apparent discrepancies, missing variables and incorrect data. The data were exported into Excel and Statistical Analysis Software (SAS) Enterprise Guide 7.1 for analysis [46].

Descriptive statistics (frequency, median, interquartile ranges, percentages) were used to summarize the data on general clinic characteristics, like personnel, the number of chronic patients, and the services offered.

Fidelity item scores were summed per component to give four ICDM model component fidelity scores per facility. An overall ICDM model implementation fidelity score was determined per facility by summing the four sub-component scores. The ICDM model implementation fidelity scores were summarized using descriptive statistics (medians and IQR, and converting scores to proportions) and compared across facilities and districts using the Kruskal Wallis and Chi-square tests. In the South African DOH ICRM programme, facilities are scored for ideal clinic status as silver (70–79%), gold (80–89%) and platinum (90–100%), based on assessment on 208 elements, categorized into 10 components covering administration, clinical services provision and health outcomes [17]. A score below 70% or failure to achieve a minimum percentage in the vital elements is rated as not having achieved ideal clinic status [17]. Although the fidelity assessment of the ICDM model in this study did not encompass all the elements of the ideal clinic, we used similar categories (silver, gold and platinum) in interpreting the fidelity scores because there are no existing norms regarding what constitutes high fidelity of implementation for a chronic care model.

#### Ethical considerations

This study was approved by the University of the Witwatersrand (Ref: R14/49) and University of Cape Town's (Ref: 127/2018) Human Research ethics committees. The Gauteng and the North West provincial departments of health also gave their approval.

## Results

### Characteristics of the clinics

All the PHC facilities provided nurse-driven curative and preventative health services and had been implementing the ICDM model since 2011. As shown in Table 1, the 16 PHC facilities that were included in the study sample provided health services to a varied number of patients every month, with a median of 2430 (IQR: 1685–2942) patients aged > 20 years accessing care per facility per month. However, the PHC monthly headcount varied ranging from an average of 857 to 4946 patients seeking health services. When comparing the two districts, the DKK district had significantly ( $p = 0.0117$ ) more [median 5.5 (IQR: 4.00–9.33) vs 2.0 (IQR: 1.67–2.92)] patients  $\geq 5$  years diagnosed with TB monthly. The WR district had significantly more medical officers [3.5 (IQR: 2–4.5) vs 1.0 (IQR: 1.0–1)] and enrolled nurses [3.5 (IQR: 3–5.5) vs 0.0 (IQR: 0.0–1.5)] per facility. All facilities had access to at least one medical officer, and each facility had a facility manager. Six facilities did not have a pharmacist assistant.

### ICDM model implementation fidelity

The overall (summation of all component scores) ICDM implementation fidelity score per facility ranged from 68% (108/158) to 86% (136/158). The overall fidelity score was 70 to 79% (silver status) in six clinics,  $\geq 80\%$  in eight clinics (gold status) and below 70% (not achieved) in two clinics. The median ICDM implementation fidelity score was 125/158 (IQR: 119–131; 79%) across both health districts. Strengthening of support

**Table 1** Characteristics of the Primary Health Care Clinics by health district

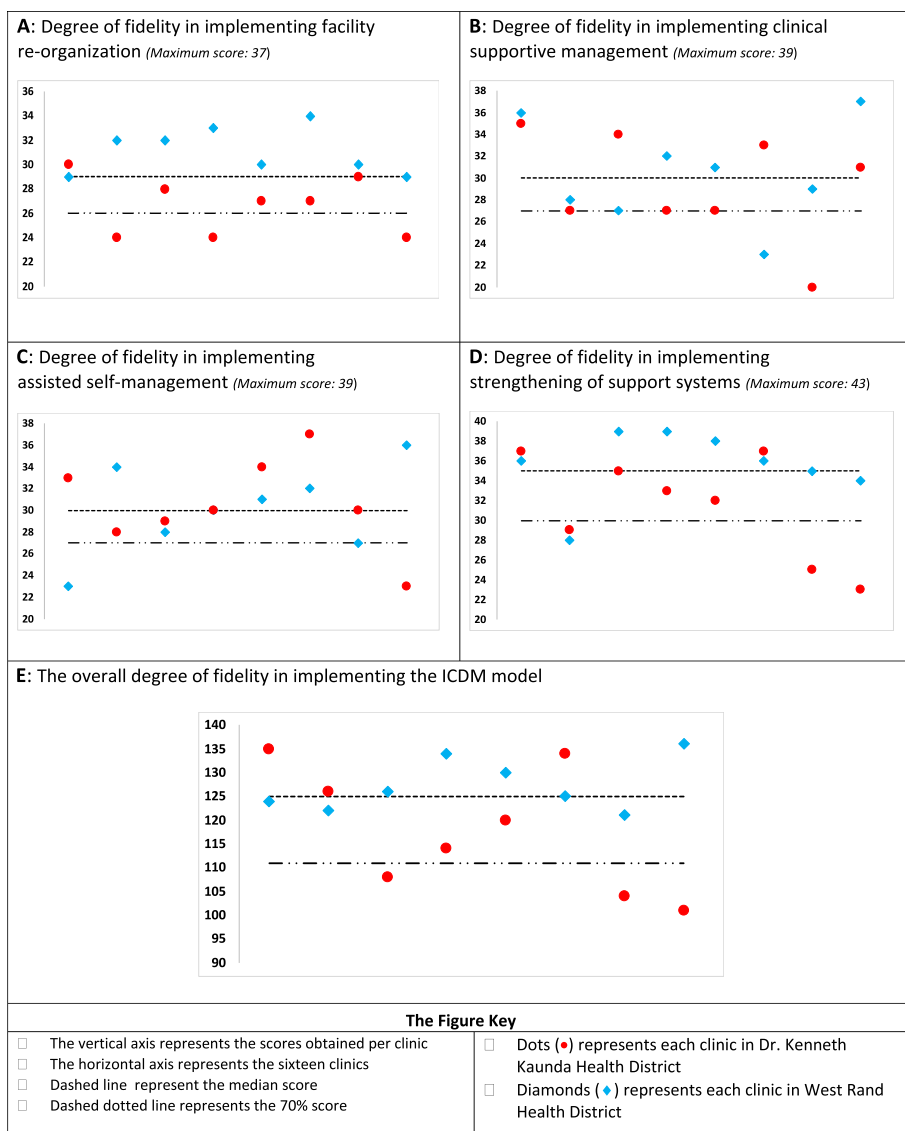
Variables	WR District Median (IQR)	DKK District Median (IQR)	P-Value
Primary healthcare headcount per month per facility	3361 (2430–4173)	3690 (2083–3953)	0.9164
Primary healthcare headcount of patients > 20 years old per month per facility	2277 (1685–3098)	2626(1584–2942)	0.8336
Number of HIV/AIDS Adult remaining on ART per facility	1525 (1070–1816)	1572 (624–2114)	0.9164
Number of new Tuberculosis cases ( $\geq 5$ years old) per month per facility	2 (1.67–2.92)	5.5 (4.00–9.33)	0.0117
Number of new Diabetic patients ( $\geq 40$ years) per month per facility	8.83 (5.08–10.5)	9.67 (4.00–13.2)	0.6982
Number of diabetic patients case load per month	66.3 (43.5–89.3)	67.8 (36.1–91.4)	0.7527
Number of hypertensive patients case load ( <i>visits</i> ) per month per facility	286 (252–395)	252 (233–405)	0.4622
Number of Professional Nurses per facility	7.0 (5.5–9.0)	5.5 (5.0–11)	0.7105
Number of Enrolled Nurses per facility	3.5 (3.0–5.5)	0.00 (0–1.5)	0.0053
Number of Medical Officers per facility	3.5 (2.0–4.5)	1.0 (1.00–1)	0.0012
Number of counselors per facility	3.0 (3.0–3)	4.5 (2.5–6.5)	0.1685
Ratio of Nurses to PHC monthly headcount per facility	305 (224–358)	408 (303–738)	0.1415
Ratio of Medical Officers PHC monthly headcount per facility	1137 (901–1410)	3690 (2083–3953)	0.0087

systems and facility re-organization were the highest (silver) scoring ICDM model components with a score of 79%, while assisted self-management score was 78% and the clinical supportive management was the lowest with 76%. The Cronbach's alpha (internal consistency of the activities fidelity scoring questions) on clinical supportive management and strengthening of support systems was 0.69, while for facility re-organization and assisted self-management support it was 0.53 and 0.56 respectively. A calculated score of the Cronbach's alpha that is closer to one indicates a high level of inter-relatedness of the items within a scale [47].

The ICDM model's four component activity scores (added and individually) were also compared between clinics and health districts.

**Facility re-organization**

The overall score for facility re-organization was silver status (79%; 462/584), and the lowest scoring clinic had a score of 65% (24/37), while the highest clinic score was 92% (34/37). The median facility re-organization score was 29/37 (IQR: 27–31; 78%) (Fig. 2). The scheduling of appointments and different streams of care were the least implemented. Nine clinics scored below 75% (6/8)



**Fig. 2** Graphic representation of the degree of fidelity for the four major components of the ICDM model and overall in the implementation of ICDM model in sixteen clinics. **a:** Degree of fidelity in implementing facility re-organization (Maximum score: 37). **b:** Degree of fidelity in implementing clinical supportive management (Maximum score: 39). **c:** Degree of fidelity in implementing assisted self-management (Maximum score: 39). **d:** Degree of fidelity in implementing strengthening of support systems (Maximum score: 43). **e:** The overall degree of fidelity in implementing the ICDM model

on dispensing medication and one clinic could not be assessed as it had pharmacy support from a hospital-based pharmacy and medication storage and dispensing was not done at the clinic. Half of the clinics obtained scores of 75% or higher on administrative procedures, infrastructure, personnel training and allocation. Medication is stored in the consulting rooms in most (15/16) of the facilities to improve efficiency according to the ICDM guidelines. However, the medicine supply and management principles (e.g. stock cards, temperature monitoring) were only applied to the medication storage room and not in the consulting rooms where some of the medication is being stored.

#### **Clinical supportive management**

The clinical supportive management overall score across the two districts was silver status (76%; 477/624). The lowest score obtained per facility was 51% (20/39), and the highest score was 95% (37/39). The median clinical supportive management score was 30/39 (IQR: 27–34; 77%) (Fig. 2). Only six clinics had the appropriate clinical guidelines available and accessible. Three clinics did not have access to a DSCT. Half of the clinics had a score of 31/39 (80%) or more on clinical supportive management (Fig. 2). The scores were high due to the high scores on the activities relating to integration (space, time, healthcare worker, medical records) of care and monitoring and reporting on ICDM implementation. Although all the seven chronic conditions recommended for inclusion into one stream of care, TB services had a separate stream (separate medical records, healthcare worker, and consulting rooms).

#### **Assisted self-management**

The overall score for assisted self-management was also silver status (78%; 485/624). The minimum facility score was 59% (23/39) and the maximum facility score was 95% (37/39). The median assisted self-management score was 30/39 (IQR: 28–34; 77%). Nine clinics scored  $\leq 63\%$  on health promotion as they did not have regular health promotion talks or chronic diseases' resource material for patients. The score per facility for about two thirds (10/16) of the clinics was above 30/39 (76%). Almost all (15/16) of the clinics had functional WBOTs and were therefore able to implement down referrals and other pick-up points for chronic medication collection in the community.

#### **Strengthening of support systems**

The overall score for strengthening of support systems across the two districts was silver status (79%; 536/675). The lowest score obtained per facility was 53% (23/43), while the highest score was 91% (39/43). The median strengthening of support systems score was 35/43 (IQR:

30–37; 81%). The lowest (23/43; 53%) scoring clinic failed on health information as it did not use the appropriate data collection tools. The least implemented activities were the school health team and equipment supply and management. Ten (10/15; 67%) clinics had a stock visibility system and still used the manual stock cards for medication stock levels monitoring. Most (11/16) of the clinics scored  $\geq 75\%$  (33/43) on strengthening of support systems.

Although the median overall fidelity score for WR was higher than for DKK, the difference was not statistically significant (126, IQR: 123–132 vs. 117, IQR: 106–130;  $p = 0.1409$ ). The median facility re-organization fidelity score was significantly higher in the WR than in the DKK (31 vs 27/37;  $p = 0.0030$ ) health district (Fig. 3). There was no significant difference in the supportive management, assisted self-managed and strengthening support systems fidelity scores between the two districts (Fig. 3), even though the WR district median scores for all three of those components were higher than those of the DKK district.

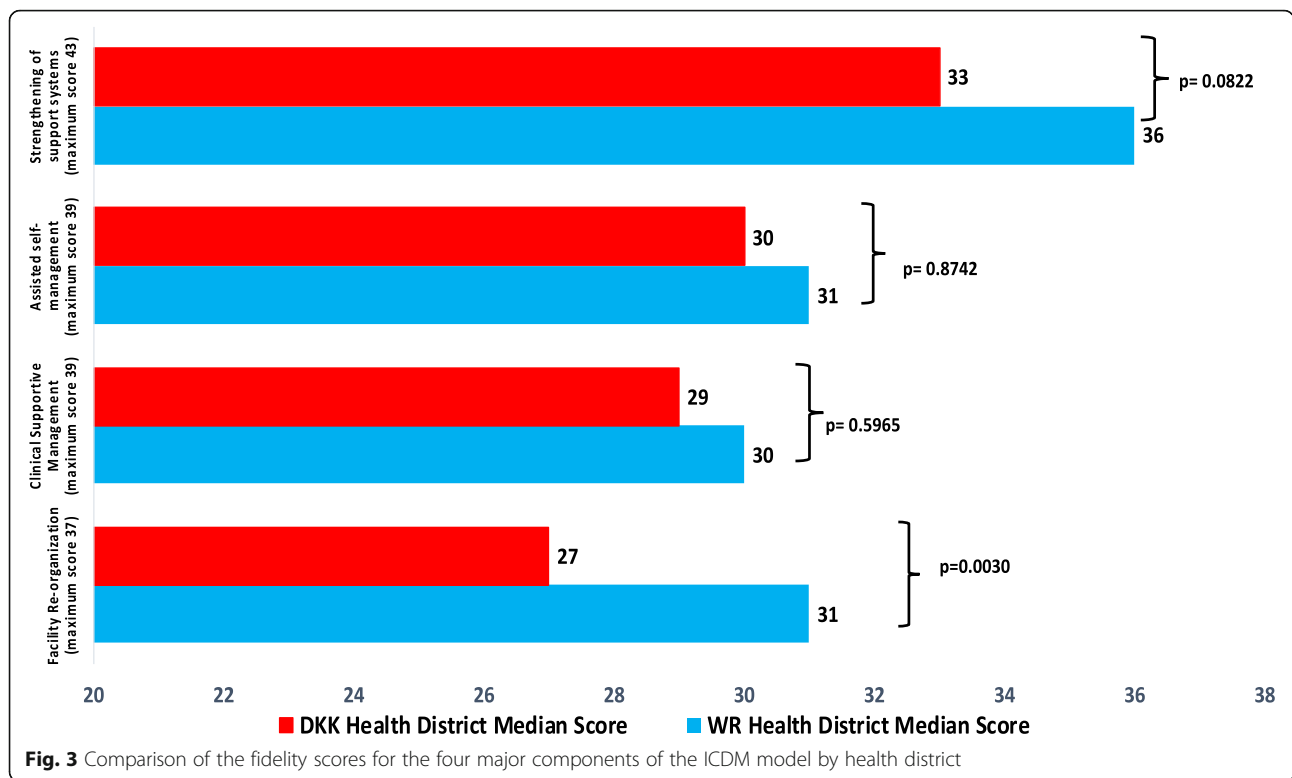
#### **Value stream mapping of patient flow**

##### **Administration**

There was poor adherence to the ICDM recommendation to have files pre-retrieved the day before for booked patients, except in one clinic. Administrators only retrieved the medical records for patients that have submitted a clinic card or identity document. The administrator would then update the PHC paper-based and electronic registers before patients move to the vital signs station. All the facilities had a separate stream of care for mother-and-child (preventative and promotive) and TB services. However, there was only one stream for chronic and acute care services. In some cases, the next appointment for review was scheduled for 6 months after blood tests, and this could delay issuing of results and taking the necessary clinical actions depending on the received results, like the change of medication, adherence counselling etc. Observed inefficiency was on excess personnel motion as nurses did not have all the required resources in one consultation room and completion of multiple similar documents like a script in the file and for central chronic medicines dispensing and distribution (CCMDD).

##### **Dispensing of medication**

Although the clinics did not pre-pack medication, a 2 months' supply of medication was issued at each visit. Repeat medication collection followed the spaced and fast-line appointment. However, the collection was from the same consulting room or the pharmacy assistant. CCMDD was accessible at three clinics. The allocation of PHC nurses to CCMDD or pharmacy



management reduced the number of nurses available to provide primary health care consultations.

**Waiting and service times**

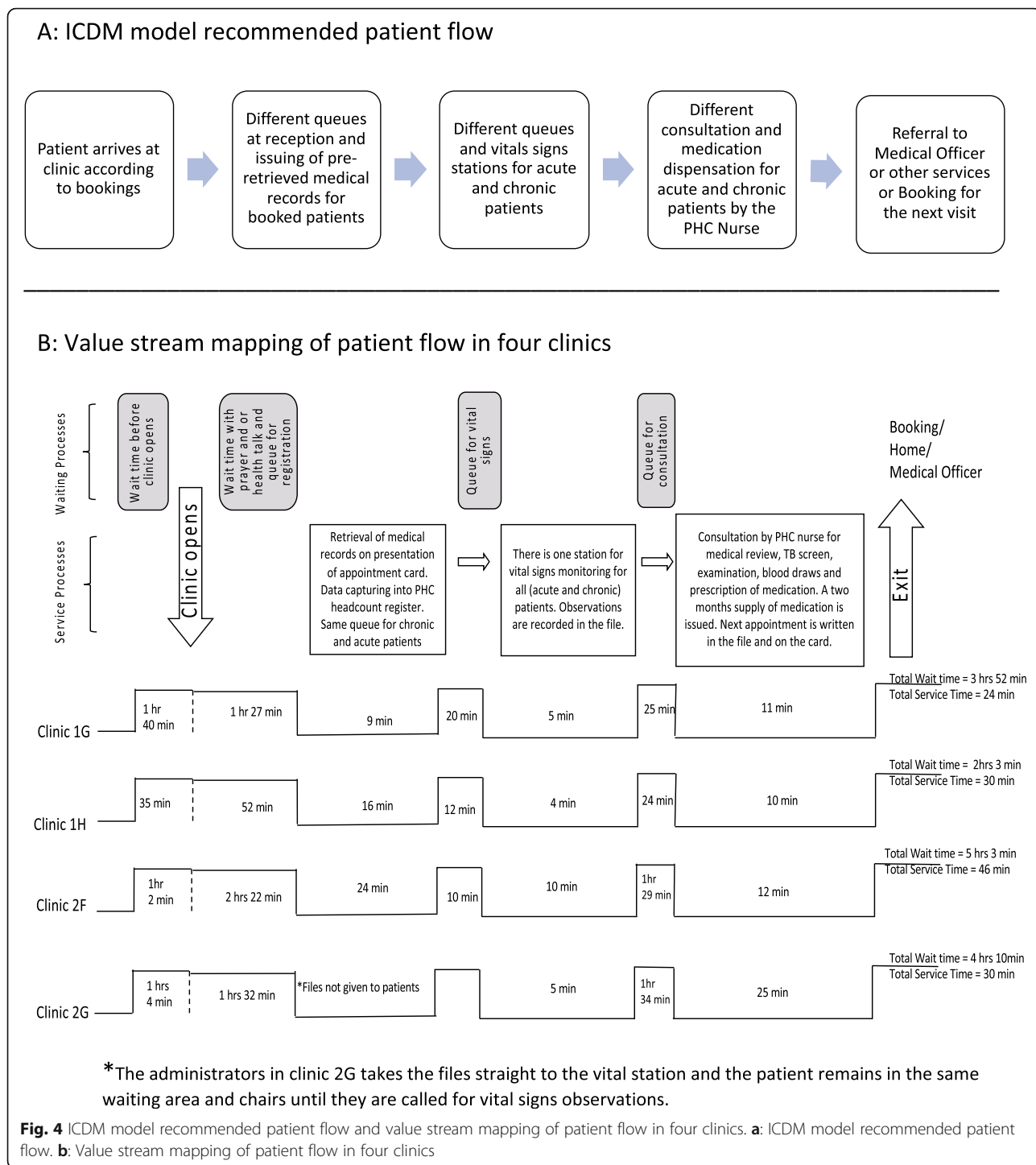
On average, patients spent a total of 4 h 20 min (minimum: 2 h 33 min. and maximum: 5 h 49 min.) at the facility to access health services (Fig. 4). Most (87%; 3 h; 47 min) of the time was spent waiting for care and 13% (33 min) for receiving services. The majority (70%; 43/61) of the observed patients spent 3 h or more at the PHC facility. At the clinic that had the shortest waiting time, patients arrived at different times throughout the day, and the average wait prior to retrieval of medical records was 1 h 27 min, compared to 3 h in the other clinics.

**Discussion**

Based on the structured questionnaires, objective observations and facility record reviews, the implementation fidelity of the ICDM model was 79% in the two health districts, with some variability between PHC facilities. Fourteen PHC clinics had a an ICDM implementation fidelity score of  $\geq 70\%$  on implementation of the ICDM model. The clinics in the WR health district had higher fidelity scores compared to those in DKK for all four ICDM components, but the differences were not statistically significant except for the for the facility re-organization component. Scheduling of appointments, pre-retrieval of medical records, different streams of care, and equipment supply and

management were the least implemented ICDM model activities. In addition, access to clinical guidelines and support by the DCST was inadequate at some of the clinics. There were high fidelity scores on integration of care, infrastructure, functional WBOTS and medicine supply and management. Waiting time for services was over 3 h, mostly at the medical records retrieval station. Observed unintended consequences of implementing the ICDM model guidelines included reduced personnel for patient care when nurses are allocated to CCMDD or pharmacy, and medication management in consulting rooms. The findings from this study give valuable information on the level of fidelity in the implementation of the ICDM model at a time that the South African DOH is focusing on primary healthcare revitalization in preparation for the national health insurance [14–16].

Although the scoring for the ICDM model fidelity scoring did not contain all the components included in the ICRM programme, applying the ICRM scale [silver (70–79%), gold (80–89%) and platinum (90–100%)] to our study would imply that 12.5% (2/16) clinics in this study did not achieve ideal clinic status on chronic disease health services. Silver status (70–79%) was obtained by 37.5% (6/16) of the assessed clinics, while 50% (8/16) achieved gold status (80–89% on chronic services). No clinic score fell into the platinum category in this study. The higher number of clinics scoring silver and gold status compared to not achieved ideal clinic status (12.5%



vs 87.5%) could be indicative of broad improvements in clinic functioning (infrastructure, personnel and supply chain management) under the ICRM programme [17]. In a peer-peer review conducted in 2016 under the ICRM scale-up process, the number of clinics scoring over 70% (achieved ideal clinic status) was noted to have increased from 139 in 2013 to 445 [17]. No previous

studies on ICDM model fidelity are available. However, studies that have looked at implementation of other chronic diseases management models, highlighted a high variability in the combination of components included the chronic disease models and the ways in which they are implemented [43, 48]. In our study, the overall level of implementing the chronic care model

elements according to guidelines varied between 55 and 89% [48–50]. The highest (89%) level of fidelity observed was in a continuum of care programme, with 16 of the 18 components implemented according to the guidelines [48].

In our study, there was variability between health facilities on the level of fidelity in the implementation of the ICDM model, with facility re-organization component having a significantly higher level of fidelity in WR, compared to the DKK health district. In studies on the integration of services for various chronic diseases in primary healthcare practices, there was also high level of variability in the level of implementation on each of the components [49, 50]. Although the primary healthcare monthly headcount of patients was slightly higher in the participating clinics of the DKK district, the district had fewer medical officers and nurses. The lower human resource (clinical personnel) level could have contributed to the lower fidelity in the implementation of the ICDM model in the DKK health district compared to the WR. Other contextual factors that have been described as facilitators for successful implementation and sustainability of chronic care models and were not assessed in this study, include the commitment and support of the leadership, training of personnel, participants responsiveness, sufficient funding, acceptability of the intervention and collaboration with other sectors [43, 48, 51–53]. The observed variability in fidelity level across ICDM model components and health districts could indicate adaptations to the model to fit different contexts. The availability of infrastructure and resources, the capacity of the implementing teams and time constraints are some of the factors that could lead to spontaneous adaptations of an intervention to enhance its suitability to context [29, 30]. Low fidelity in the implementation, especially if the core components have been removed, could affect the effectiveness of the intervention [30]. The impact of contextual factors on the variability in the implementation fidelity of the various activities of the ICDM model in the two health districts and how this variability affects ICDM programme effectiveness needs further research. In addition, that data would inform the implementation of the ICDM model in other health systems or populations (scaling-out).

The ICDM model activities that had low (< 70%) fidelity in our study included administration (pre-retrieval of medical records and different streams of care), health promotion and clinical supportive management by the DCST. Improvements in clinical outcomes and operations have been documented in chronic care models that provide decision support and delivery system design [43]. Lack of clinical leadership could adversely affect the expected outcomes and sustainability of the ICDM model [32, 38]. Redesign of service delivery, integration of services and decision support were also inadequately implemented in other chronic care

models evaluations, with scores of 39–46%; 46 and 58% respectively [49, 50]. Clinical management decision support should be enhanced in this setting where nurses' knowledge on chronic diseases is inadequate and guidelines are not readily available [54–57]. Although there was a high level of integration (time, healthcare provider, space) TB patients had a separate stream from patients with other chronic conditions, despite the recommendations by WHO and UNAIDS to integrate TB and HIV services [58, 59].

A high level of fidelity was discovered on integration of services and the facilitated self-management and community support with WBOTs and CHCW. Assisted self-management support was also the most prominent component of several chronic care models and resulted in improvements in health outcomes [43], and in an evaluation of other primary healthcare practices on the level of implementation on the chronic care model components, self-management support scored 48% [50]. Contextual adaptations (modifying the adaptable while maintaining key components of interventions) may be needed to enhance feasibility, reach, and acceptability [19, 20, 29, 30]. The ICDM model guidelines do not, but should clearly outline which are the adaptable and which key components of the model to optimise implementation fidelity, and facilitate scale-out, scale-up and process evaluations.

Regarding waiting times, 3 hours is the maximum time patients are expected to spend in a health facility when accessing services, based on the ideal clinic standards in South Africa [18]. In this study, 70% of observed patients were at the PHC facilities for 3 h or more. The high median waiting time in our study was similar to the findings of Egbugie et al., which showed that some clinics in South Africa have reduced while others have increased waiting time after the implementation of the ICRM programme [60]. Observed inefficiencies in our study included excessive waiting time and nurses' motion and rework. There were also unintended consequences like poor adherence to guidelines on medication management in consulting rooms and redundancy of clinical staff when allocated to non-clinical ICDM model activities. The ICDM model and ICRM programme also follow the lean thinking principles on waste reduction like waiting time, excess inventory, underutilized staff and excess people motion [7, 18]. Our study found that the participating PHC facilities did not perform well on waste reduction according to these lean principles .

### Strengths and limitations

This study has a number of strengths. Firstly, multiple visits to health facilities over 8 months to observe the level of fidelity in the implementation of the ICDM model allowed us to assess clinics when they had different patient and personnel numbers. Secondly, the use of implementation research principles implies that this

research ensures evidence-based decisions on ICDM model implementation improvements and on how the lesson learned could affect scale-up and scale-out and policies. Thirdly, application of patient flow analysis identified specific areas of inefficiencies in the delivery of chronic health services stream.

Limitations of this study included that the weighting of the scores of the fidelity criteria was based on the number of activities required, and not on how critical that activity was in achieving the ICDM model objectives. Some of the items on the fidelity criteria were scored based on the data provided in the structured questionnaire by the implementing healthcare workers, and this could have introduced social desirability bias. Assessments focused significantly on the presence of systems and processes that have been recommended, and not the quality of the implementation of the components.

## Conclusion

There was a high level of fidelity of implementation of the ICDM model in the two health districts, with some variability across ICDM model scores on components and PHC facilities. The highest median scores were on the ICDM model components of facility re-organization and strengthening of support systems. Relentless and continuous monitoring and evaluation of the PHC clinics on the ICRM programme and integrated clinical services is essential to ensure that these gains are not lost. Increased focus on quality in the implementation of elements that had high levels of fidelity like facility re-organization, assisted self-management and facilitated community support could further enhance efficiencies. The ICDM model items that were described as having lower degrees of fidelity (different streams of care, administration and health promotions) indicate opportunities for improvement of the current implementation of the ICDM model and how to support normalization into routine practice of the model. More research is needed to identify the determinants of ICDM model implementation fidelity and on innovative adaptations that can improve models' processes and its implementation at local level without affecting the intended model's outcomes.

## Supplementary information

**Supplementary information** accompanies this paper at <https://doi.org/10.1186/s12913-019-4785-7>.

**Additional file 1.** Implementation Fidelity of the Integrated Chronic Disease Management Model – Assessment Tool Activities.

## Abbreviations

CCMDD: Centralized chronic medication dispensing and distribution; DOH: Department of Health; HIV: Human Immune Deficiency Syndrome; HPT: Hypertension; ICDM: Integrated chronic disease management; ICRM: Ideal clinic realisation and maintenance programme; ICSM: Integrated

clinical services management; MRC: Medical Research Council; PHC: Primary healthcare; TB: Tuberculosis; WHO: World Health Organization

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## Authors' contributions

LL was involved in the conception, study design, data collection, data cleaning and analysis and writing of the manuscript. OAA, MK and TO contributed to the conception, study design and critical review of the manuscript.

AR and PP were involved in data collection, data cleaning and review of the manuscript. KH was involved in the data cleaning and analysis, and review of the manuscript. All authors read and approved the final manuscript.

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## Availability of data and materials

The data on the implementation fidelity of the ICDM model is available on Figshare, via the following URL: <https://doi.org/10.6084/m9.figshare.9339029.v1>

## Ethics approval and consent to participate

The protocol was approved by the University of Cape Town and University of the Witwatersrand's Human Research ethics committees.

## Consent for publication

Not Applicable

## Competing interests

The authors declare that they have no competing interests.

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## Chapter 5: ICDM model implementation fidelity moderating factors

The results of the ICDM model implementation fidelity moderating factors are presented in the form of a manuscript.

*Lebina L, Oni T, Alaba OA, Kawonga M. A mixed methods approach to exploring the moderating factors of implementation fidelity of the integrated chronic disease management model in South Africa. BMC Health Serv Res. 2020;20(1):617. Published 2020 Jul 6. doi:10.1186/s12913-020-05455-4*

This chapter covers the second objective (to assess moderating factors of implementation fidelity of the ICDM model) of the thesis.

**The relevance of the publication to the thesis:** This manuscript describes the moderating factors that influence the implementation fidelity of the Integrated Chronic Disease Management model. The results of this study also present approaches on the factors to be addressed in primary healthcare clinics to enhance fidelity. Knowledge of the moderating factors that affect the implementation of the chronic care model would enhance sustainability, scaling up and scaling out of the model. This paper highlights the existence of interrelated fidelity-moderating factors, such as time, space, healthcare worker integration, training, infrastructure, adequate staff, and empowered and compliant patients. The participants' views suggest that addressing some of the moderating factors, such as supply chain management and leadership support, and enhancing facilitation strategies (training, clinical mentorship) could improve adherence to the ICDM model guidelines. The results outlined in this manuscript explain some of the variability in the degree of fidelity between clinics and health districts. Although space and healthcare worker integration scored high on process evaluation, more than 20% of participants perceived some of the recommended activities not appropriate.

RESEARCH ARTICLE

Open Access



# A mixed methods approach to exploring the moderating factors of implementation fidelity of the integrated chronic disease management model in South Africa

Limakatso Lebina<sup>1,2\*</sup> , Tolu Oni<sup>2,3</sup>, Olufunke A. Alaba<sup>4</sup> and Mary Kawonga<sup>5</sup>

## Abstract

**Background:** Chronic care models like the Integrated Chronic Disease Management (ICDM) model strive to improve the efficiency and quality of care for patients with chronic diseases. However, there is a dearth of studies assessing the moderating factors of fidelity during the implementation of the ICDM model. The aim of this study is to assess moderating factors of implementation fidelity of the ICDM model.

**Methods:** This was a cross-sectional mixed method study conducted in two health districts in South Africa. The process evaluation and implementation fidelity frameworks were used to guide the assessment of moderating factors influencing implementation fidelity of the ICDM model. We interviewed 30 purposively selected healthcare workers from four facilities (15 from each of the two facilities with lower and higher levels of implementation fidelity of the ICDM model). Data on facility characteristics were collected by observation and interviews. Linear regression and descriptive statistics were used to analyse quantitative data while qualitative data were analysed thematically.

**Results:** The median age of participants was 36.5 (IQR: 30.8–45.5) years, and they had been in their roles for a median of 4.0 (IQR: 1.0–7.3) years. The moderating factors of implementation fidelity of the ICDM model were the existence of facilitation strategies (training and clinical mentorship); intervention complexity (healthcare worker, time and space integration); and participant responsiveness (observing operational efficiencies, compliance of patients and staff attitudes). One feature of the ICDM model that seemingly compromised fidelity was the inclusion of tuberculosis patients in the same stream (waiting areas, consultation rooms) as other patients with non-communicable diseases and those with HIV/AIDS with no clear infection control guidelines. Participants also suggested that poor adherence to any one component of the ICDM model affected the implementation of the other components. Contextual factors that affected fidelity included supply chain management, infrastructure, adequate staff, and balanced patient caseloads.

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**Conclusion:** There are multiple (context, participant responsiveness, intervention complexity and facilitation strategies) interrelated moderating factors influencing implementation fidelity of the ICDM model. Augmenting facilitation strategies (training and clinical mentorship) could further improve the degree of fidelity during the implementation of the ICDM model.

**Keywords:** Chronic care model, Ideal clinic, Primary healthcare, Contextual factors

## Contributions to the literature

- Chronic diseases are a major cause of morbidity and mortality, yet, there is limited data on the implementation of chronic care management models in low and middle-income countries. This study provides timely information on the evaluation of moderating factors that affect fidelity (adherence) to the guidelines of a chronic care model in a middle-income country.
- The results of this study also presents approaches on what factors to be addressed in primary healthcare clinics to enhance fidelity.
- Knowledge on the moderating factors that affect the implementation of the chronic care model would enhance sustainability, scale-up and scale out of the model.

## Background

The World Health Organization (WHO) describes a health intervention as any activity performed with or for an individual or groups of people with the aim of assessing, improving, promoting and maintaining good health [1]. The implementation of complex health interventions requires a high degree of exactness (fidelity) to the original design if the intervention is to be effective [2, 3]. An intervention's failure to achieve expected results cannot be attributed to design error if a degree-of-fidelity evaluation has not been performed [3, 4]. In the scale-up and scaling-out of interventions, even if adaptations are made to enhance relevance, the critical components of an intervention should be implemented with a high degree of fidelity to the original design [5]. A description of the intervention's non-adaptable key components in the guidelines could promote implementation fidelity as it would make it easy to modify the flexible components only [5, 6].

The degree of fidelity during the implementation of an intervention can be greatly influenced contextual factors [1, 7]. Contextual factors are the distinctive characteristics of a society, community, particular group or individuals that can influence how interventions are adopted and implemented [8]. The consolidated framework for the evaluation of contexts in the implementation of complex interventions separates context into outer

context (socio-economic and political environment), and inner setting (organizational structural features, networks and culture), as well as the process of implementation and intervention, and the implementing team's characteristics [8]. Systematic reviews, mainly of studies conducted in developed countries, found facilitators of implementation of chronic care models include communication, provider knowledge on the principles, strong committed leadership, funding, patient participation and different stakeholders' interest in collaboration [9–11].

Carroll et al. (2007) describe four fidelity moderating factors (intervention complexity, facilitation strategies, quality of delivery and participant responsiveness) in their conceptual framework for implementation fidelity. The four factors are outlined below [6].

### Intervention complexity

Simple interventions that are well described with sufficient specific information are more likely to have a high level of implementation fidelity compared to complex ones [6].

### Facilitation strategies

Training, the provision of guidelines and monitoring increases the level of fidelity [6].

### Quality of delivery

Poor delivery of the activities or components of an intervention will have an impact on the overall level of fidelity of implementation [6].

### Participant responsiveness

The degree of fidelity in the implementation is affected by the acceptability of that intervention to the implementers and the recipients of the intervention [6].

The factors discussed above are not detached, but interrelated, with one moderator potentially predicting the other [6]. Hasson et al. reviewed and modified Carroll's conceptual framework to include two additional constructs, recruitment and context [12]. In their study, contextual factors directly affecting fidelity include the positive experience of staff with similar programmes, financial resources, support for the patients' relatives and external collaborations [12]. Challenges with the recruitment of participants into the programme (unwillingness

to participate and not meeting inclusion criteria) were also recognized as another moderating factor for fidelity [12]. There is a dearth of studies that assess moderating factors influencing implementation fidelity of chronic disease management models in low- and middle-income countries.

In South Africa, a middle-income country, the Department of Health implemented the integrated chronic disease management model (ICDM model) in 2011 [13, 14]. This followed the principles of the of Chronic Care Model (CCM) and Innovative Care for Chronic Conditions (ICCC) frameworks, which aim to enhance efficiency of health services and health outcomes for patients with chronic disease at primary healthcare (PHC) level [13, 14]. The ICDM model's four major interrelated components are clinical supportive management (clinical mentorship), facility re-organization (administrative and patient flow for efficiency), assisted self-support (adherence support) and strengthening support systems [13]. The objectives of the ICDM model are to improve waiting times, cleanliness, the attitude of staff, the availability of medicine and equipment, and patient safety and quality of care [13]. The ICDM model incorporates both communicable diseases (HIV/AIDS and tuberculosis (TB)) and non-communicable diseases (diabetes, hypertension, asthma, mental health, chronic obstructive pulmonary disease [COPD], epilepsy) [13]. The implementation of the ICDM model delivered results such as improvements in patients' records, compliance with clinical guidelines and better health outcomes [15, 16]. However, the implementation processes and outcomes (acceptability, adoption and sustainability) varied between health districts and health facilities [15–18].

We evaluated the implementation fidelity of the ICDM model in 16 facilities across two health districts, which

were the pilot sites for ICDM implementation before scale-up in South Africa [19]. We found that the degree (level) of fidelity varied by district, and facility – two facilities had low (< 70%), six had medium (70–79%) and eight had high (80–89%) fidelity scores [19]. The objectives of this study were to assess the moderating factors affecting implementation fidelity of the ICDM model in those two districts, and the impact of facilities' characteristics on fidelity. Specifically, this study describes the moderating factors and their perceived influence on implementation fidelity, from the perspective of the healthcare workers and administrators responsible for implementing the ICDM at PHC facilities in South Africa.

## Methods

### Study setting

This study was conducted in the two health districts, the Dr. Kenneth Kaunda (DKK) district in the North West province and the West Rand (WR) district in the Gauteng province. These two health districts were the pilot sites for the ICDM model implementation, and were the sites of our larger study on ICDM model implementation [13, 19]. The two districts differ with regard to disease burden, socio-economic status and population size, as summarized in Table 1 [20–23]. The South African National Department of Health plans to introduce national health insurance (NHI) to increase access to health services and to revitalize primary health care services [24]. In addition to this, an ideal clinic realization and maintenance (ICRM) programme was initiated, with additional room in the budget to support PHC facilities with adequate infrastructure, staff, medicines and supplies, as well as regular evaluations on performance as part of the primary healthcare re-engineering [25]. It is

**Table 1** Demographic and health indicators for Dr. Kenneth Kaunda and West Rand Health Districts

Indicator	Dr. Kenneth Kaunda District	West Rand District
Population	716,272	810,613
Unemployment rate	25.4%	28.6%
Deprivation Index	1.92	1.76
Literacy rate	89.6%	97.6%
Informal Housing	21%	19.2%
Health Facilities	1 Regional Hospital; 3 District Hospitals; 9 Community Health Centres; 27 PHC Clinics; 6 satellite clinics and 2 mobile clinics	1 Regional Hospital; 2 District Hospitals; 4 Community Health Centres; 39 PHC Clinics
PHC Nurse workload (clients per nurse per day)	24.5	26.1
PHC Doctor workload (clients per doctor per day)	13.2	25.3
TB Incidence per 100,000	696	440
TB Successful Treatment	60.1%	80.6%
Hypertension Prevalence	39.1%	36.1%
Mental Health admission rate	2.05%	1.5%

within this context that the PHC clinics are implementing the ICDM model.

#### Description of the intervention (ICDM model)

The ICDM model targets both adults and children who have communicable or non-communicable chronic diseases [13]. The main implementers of this chronic care model at facility level are administrators, primary health-care nurses and medical officers (generalist doctors), ICDM champions (nurse advocates for ICDM model activities), the district clinical specialist team (DCST), ward-based outreach teams (WBOTs) and community health-care workers (CHCWs) [13]. The main activities of the ICDM model are overall health services re-organization, strengthening of support structures (supply chain management), clinical management support (DCST) and assisted self-management (WBOTs and CHCW) [13].

The ICDM model activities are organized into four major components, these being facility re-organization, clinical supportive management, assisted self-management, and strengthening of support systems [13]. Facility re-organization entails the management of patient flow to improve operational efficiency, reducing waiting time and patient satisfaction with the health services [13]. The second component of the ICDM model promotes quality care for patients with chronic diseases and support for the health-care workers with appropriate training, guidelines and clinical mentoring by the DCST [13]. The WBOTs and the CHCWs assist the patients with self-management of their chronic diseases and provide adherence monitoring, screening for complications and point-of-care testing in the community [13]. The ICDM model's fourth component is aligned with the ideal clinic initiative of enhancing supply chain management and collaborations with other stakeholders, such as school health teams [13].

#### Study design

The study used a cross-sectional mixed method as part of a larger protocol that assessed the fidelity and costs of implementing the ICDM model in 16 PHC clinics (8 in the WR and 8 in the DKK health districts). The full study design has been described elsewhere [26], and the

findings of the fidelity assessment have also been presented in another manuscript [19]. The results of that fidelity assessment were used to select the PHC clinics for inclusion in this study.

As part of that broader study, the level of implementation fidelity of the ICDM model was assessed in the 16 facilities, using an 89-item fidelity score designed to measure adherence to nationally-recommended ICDM model activities grouped within four ICDM model components [19]. Following the process evaluation framework, we scored at each facility the level of adherence (fidelity) to each recommended activity [19]. Fidelity scores for each of the four components (component score) and the overall fidelity score (sum of component scores) were compared across facilities and between the two health districts [19]. We applied the South African Ideal clinic rating system [not achieved (< 70%), silver (70–79%), gold (80–89%) and platinum (90–100%)] [25] to interpret the degree of fidelity per facility and per district. The assessment found that the WR district had a higher median fidelity score than the DKK district [19].

Based on the results of the fidelity assessment [19], four facilities were selected for healthcare workers interviews on their perceptions of moderating factors for fidelity – in each district, one clinic with the highest and one with the lowest fidelity score. In the WR district, the two selected facilities had fidelity scores of 86.1% (136/158) and 76.6% (121/158), while in the DKK district the selected facilities had scores of 84.8% (134/158) and 65.8% (104/158) (Table 2). The modified implementation fidelity conceptual framework [6, 12] was applied in the four facilities for identifying potential moderators that may have influenced fidelity of implementation of the ICDM model.

Healthcare workers (nurses, administrators and ancillary staff) who provide services to patients with chronic diseases were purposively selected to participate in this study on moderating factors. They were considered eligible for inclusion if they had worked in the study facility for six or more months and were willing to provide written informed consent for participation. A total of 30 healthcare workers were interviewed from the four

**Table 2** The degree of implementation fidelity of the integrated chronic disease management model for the four clinics that were selected for interviews with healthcare workers

	Overall	Higher Fidelity level Clinics	Lower Fidelity Level Clinics	P-values
<b>Level of fidelity in the implementation of the ICDM model Median (IQR)</b>				
Facility Reorganization ( <i>max*</i> : 37)	29 (28–30)	28 (27–29)	30 (29–30)	0.2207
Clinical Supportive Management ( <i>max*</i> : 39)	31 (25–35)	35 (33–37)	25 (20–29)	0.1213
Assisted Self-Management ( <i>max*</i> : 39)	33 (29–37)	37 (36–39)	29 (27–30)	0.1213
Strengthening of Support Systems ( <i>max*</i> : 43)	35 (30–36)	36 (34–37)	30 (25–35)	0.4386
Overall Fidelity score ( <i>max*</i> : 158)	128 (113–135)	135 (134–136)	113 (104–121)	0.1213

\* Max = maximum possible fidelity score

health facilities during August 2018 to March 2019, 15 from the two facilities that had highest implementation fidelity and 15 from facilities that had the lowest implementation fidelity.

The process evaluation framework was applied in collecting data on the characteristics of the 16 facilities as a guide to assess processes in implementation of complex interventions like the ICDM model, and impact of contextual factors [27].

#### Data collection and measurement

The structured interview tool included standardized open-ended and closed fixed-response questions (see supplemental file). The first section of the interview guide collected data on the participants' demographics such as age, current role in the facility and years in that role. In keeping with Carroll's conceptual framework on implementation fidelity, as modified by Hassan et al. [6, 12], we also collected data on the potential moderators for implementation fidelity as outlined below.

*Intervention characteristics:* Participants were questioned on the features of the ICDM model (the four components and recommended activities) to determine which they felt were straightforward and which were vague, and their views on whether and how those features affected fidelity.

*Facilitation strategies:* The participants were questioned on what strategies at facility level they thought may have supported the implementation of the various activities of the ICDM model in their respective facilities. They were also asked to list some of the barriers experienced in implementing the ICDM model as recommended.

*Participant responsiveness:* The healthcare workers' perceptions of the ICDM model principles (including, integration of all patients with chronic diseases, designated waiting areas, consultation rooms and vital signs stations for patients with chronic diseases) were evaluated using a Likert scale as follows: 1-strongly disagree, 2-disagree, 3-neither or undecided, 4- agree and 5-strongly agree. Although patients (users) were not included in this study, the measure of participants' responsiveness with regard to users was assessed by measuring staff's perceptions of patient responsiveness.

*Context:* In the qualitative component, participants in the study were asked to identify facility specific issues (context) that might hinder or support implementation fidelity of the ICDM model. In addition, quantitative data were collected from 16 facilities on facility characteristics such as budgeting style (consolidated for all clinics or customized by clinic), space (total area under-roof), number of consulting rooms, numbers of staff members by category, workload (PHC headcount over a six-month period) and number of patients that received

care for chronic conditions at the facility over the same time period. The choice of facility characteristics to include was based on the literature [9–11], and initial findings from the larger study. Data on the characteristics of the clinics was collected by direct observations, measurements and interviews with clinic and district level managers as recommended under the process evaluation framework [27].

*Quality of delivery* was not included in this assessment as there were no other programmes or studies that we could consult to benchmark the quality as recommended in the framework [6]. Recruitment was also not included as it was not applicable to this setting.

The data collection tools were piloted in a few facilities and revised for clarity prior to administration. The interviews were conducted by two trained research assistants according to the structured interview questionnaire (see supplemental file). Each participant was interviewed individually. Responses were written verbatim on paper-based answer sheets and the data were later captured into the REDCap electronic database [28]. The data quality management involved reviewing data for apparent discrepancies, incorrect data and missing variables prior to capturing and as part of data cleaning. The data were exported from REDCap into NVivo (version 12) and the Statistical Package for the Social Science (SPSS Inc., version 25.0) [29, 30].

#### Data analysis

Descriptive statistics – medians with interquartile ranges (IQR) and proportions were used to analyse participants demographics and perceptions on the ICDM model principles. The Likert scale scores on participants perceptions of principles for agree and strongly agree were combined and those for strongly disagree and disagree were combined to simplify interpretation and the reporting of results. A deductive thematic analysis approach was used to identify and describe the potential moderating factors of implementation fidelity of the ICDM model. The thematic analysis followed the six steps recommended by Braun and Clarke [31] (familiarization, generating initial codes, searching, naming and reviewing themes and summarizing the findings). Coding was structured around predefined concepts based on the modified Carroll's conceptual framework on implementation fidelity [6, 12], and literature [9]. One researcher analyzed all the data for codes, and combined code outputs into themes. The code outputs and themes were submitted for review and discussion with the other researchers. A few illustrative quotes were selected to represent the views of the participants on some of the ICDM model implementation fidelity moderating factors. Facilities-specific factors associated with fidelity to the ICDM model were evaluated using univariate

regression where the parameter estimate, standard error, 95% confidence interval and *p*-values were determined. As there was only one facility-level factor associated with fidelity to the ICDM model guidelines on the univariate analysis, we were unable to perform multivariate analyses.

### Ethics approval

The study was approved by the Medical Human Research Ethics Committees of the University of the Witwatersrand (Ref: R14/49) and the University of Cape Town (Ref: 127/2018). Written informed consent was received from all participating healthcare workers.

## Results

### Participants' demographics

The median age of the 30 healthcare workers that participated in the study was 36.5 (IQR: 30.8–45.5) years, and they had been in their current roles for a median of 4.0 (IQR: 1.0–7.3) years. The majority (80.0%; 24/30) of the participants were females. Half (50.0%, 15/30) were nurses; 26.7% (8/30) were administrative staff and 23.3%

(7/30) were in the “others” category (management, counsellors, pharmacy assistants).

### Intervention complexity

**Facility reorganization:** Most (80.0%; 24/30) of the participants agreed that administrative integration (same-day, common booking system and medical records) of health services for patients with chronic disease and a separate stream of care with designated consulting rooms are appropriate and straightforward ICDM model principles to implement (Table 3). There was moderate support for using the same consulting room for all eight chronic conditions (73.3%; 22/30) and having a designated waiting area (73.3%; 22/30) and vital signs stations (66.7%; 20/30) for patients with chronic diseases.

The interviewed staff members found that consultation of patients with TB disease in the same stream (waiting areas, consultation rooms) as other patients with non-communicable diseases and those with HIV/AIDS were the features of the ICDM model that was vague and that compromised fidelity. The guidelines were not specific about when patients with TB should be incorporated into the chronic diseases stream. The participants'

**Table 3** Perceptions of healthcare workers on the ICDM model principles and recommended activities for patients with chronic diseases

Variable	Agree	Disagree	Undecided
<b>Facility re-organization</b>			
1. Time Integration	27 (90)	3 (10.0)	–
2. Consulting room space integration	22 (73.3)	8 (26.7)	–
3. Booking system integration	28 (93.3)	2 (6.7)	–
4. Medical records integration	29 (96.7)	1 (3.3)	–
5. Pre-pack medication	22 (73.3)	7 (23.4)	1 (3.3)
6. Designated <i>waiting areas</i>	22 (73.3)	7 (23.4)	1 (3.3)
7. Designated <i>vital signs stations</i>	20 (66.7)	9 (30.0)	1 (3.3)
8. Designated <i>consultation rooms</i>	25 (83.3)	5 (16.7)	–
9. Segregation of patients maintains order	25 (83.4)	4 (13.3)	1 (3.3)
10. Patients with communicable diseases should be in separate waiting areas	22 (73.3)	5 (16.7)	3 (10.0)
<b>Clinical Supportive Management</b>			
11. Healthcare worker integration	21 (70)	8 (26.7)	1 (3.3)
12. Nurses allocated for chronic diseases patients manage all eight conditions effectively	27 (90.0)	2 (6.7)	1 (3.3)
13. Care for patients with chronic diseases is enhanced when attended to by one nurse	23 (76.7)	7 (23.3)	–
14. Nurses have adequate training to be able to manage all the eight chronic diseases	16 (53.3)	7 (23.4)	7 (23.3)
<b>Assisted self-management</b>			
15. The ward-based outreach teams contribute to the management of patients with chronic diseases	27 (90.0)	2 (6.7)	1 (3.3)
16. The community healthcare workers team contributes to the management of patients with chronic diseases	27 (90.0)	–	3 (10.0)
<b>General principles</b>			
17. Management of patients with chronic diseases has improved since the introduction of the ICDM model	24 (80.0)	2 (6.7)	4 (13.3)
18. Patients with chronic disease like the ICDM model principles	26 (86.7)	2 (6.6)	2 (6.7)
19. Recommend that the ICDM model should be implemented in all clinics in South Africa	27 (90.0)	1 (3.3)	2 (6.7)
20. Recommend that the ICDM model should be implemented in other countries	27 (90.0)	–	3 (10.0)

opinion was that it should be detailed that patients with TB should be incorporated in the chronic disease management stream after they had initiated TB treatment and have been assessed to no longer be infectious.

*“TB patients are infectious and will infect the diabetes patients, a patient with TB must not mix with some other patients.”* (FI16–3; Nurse).

*“A TB patient comes with MDR (TB) then that patient should be separated from others because they might infect other patients.”* (FI007–8; Nurse).

The participants experienced the more complex elements of the ICDM model to be the highly administrative tasks and separating patients by different streams of care. The healthcare workers that were interviewed felt that this requires more staff. The current staff shortage was regarded as one of the limiting factors when implementing the recommended ICDM model with activities such as bookings, pre-packing of medication and designated stream of care for chronic patients with fidelity to the ICDM model guidelines.

**Clinical supportive management:** The recommendation that all patients with one of the eight chronic conditions have to be included in one stream and have to be attended to by one healthcare worker could result in low fidelity if the nurse does not have experience in managing all the conditions. Although 90.0% (27/30) of the participants agreed that one nurse would be able to effectively manage all eight conditions, there were still concerns that some of the conditions (TB, mental health) should not be integrated with all other conditions to be managed under the ICDM model. The reasons for the concerns included that mental health patient management is a tedious and specialized. Participants also highlighted that not all nurses are experienced in the management of all eight conditions included in the ICDM model, especially HIV/AIDS, TB, COPD and mental health. This makes it difficult to provide quality care for all patients.

#### **Fidelity facilitation strategies**

**Training:** Participants viewed training of all staff (clinical and administrative) on the ICDM model principles as one of the factors that would foster adoption and the sustainability of high implementation fidelity to the model. Further to that, participants indicated that the nurses would need additional training for the management of patients with HIV/AIDS, mental health and COPD.

*“The management must make sure that nurses get proper training on ICDM to avoid making small mistakes. So, with training they going to improve*

*and know exactly what to do and understand what they are doing.”* (FI4–2; Data Capturer).

*“In this clinic we only have one specialist nurse and I think all nurses should (attend) adult primary healthcare (training)”* (FI4–7; Nurse).

**Clinical mentoring:** A total of 73.3% (22/30) of the interviewees confirmed that the clinics had access to DCST, but only 46.7% agreed that the DCST provides clinical mentoring. DCST mentoring and support for the clinical management of patients with chronic diseases was stressed as an important facilitator in adhering to the ICDM model guidelines. Furthermore, clinical record audits by the DCST should be carried out as recommended with feedback on what should be improved. The participants also indicated that access to clinical advice from the DCST by phone would help with the clinical management of complicated cases.

*“We need support and mentoring especially for those with PHC, they (DCST) only come for audits and not supporting us.”* (FI4–1; Nurse).

#### **Participant responsiveness**

**Compliance by patients:** The greatest challenge that some participants (46.7%; 14/30) felt affected the quality of delivery of ICDM model activities was patients' poor attendance of scheduled appointments and poor adherence to prescribed medication for their conditions. For example, patients who have uncontrolled hypertension or diabetes or an unsuppressed HIV viral load cannot be included in the fast lane appointments or alternative medication pick-up lines. As a result, adherence by the clinics to the recommended ICDM model guideline activities for both assisted self-management (spaced and fast-lane appointments and adherence clubs), and facility reorganization (medication pre-packaging and pre-retrieval of medical records) was low. A total of 56.7% (17/30) of the participants viewed adherence clubs as beneficial to patients and 53.3% (16/30) viewed them as beneficial to clinic operational efficiency.

Participants mentioned that empowered patients who understand their conditions were a possible factor in patients' willingness to be in different stream of care for chronic diseases and down-referral to adherence clubs. They establish profound relationships with the healthcare workers. Other participants indicated that if patient feedback and community engagement on the services provided is considered, that would also enhance fidelity to the ICDM model and patient satisfaction.

*“Patients defaults because they never adhere to their appointments and we had already pre-packed their medication but they never come”* (FI7–3; Nurse).

*“To teach people to adhere to their appointment date, because of retrieval of files. We retrieve 10 files and only two comes.”* (FI16–2; Data Capturer).

**Stigma and discrimination:** Another concern that was highlighted was that separate medical records, waiting areas, vital signs stations and queues would reveal the medical conditions of patients to other clinic attendees and this would stir up stigma and discrimination. The participants proposed that the ICDM model should provide guidance on how the segregation of patients into different various streams by reason for consultation should be achieved while preventing discrimination and stigmatization.

*“They feel like they are being isolated and they feel stigmatized and that other patients can see.”* (FI7–1; Nurse).

*“Stigma, if people see you in the queue and seeing you with a chronic patient file, so I think patients need their privacy, and separating is invading their privacy.”* (FI4–2; Data Capturer).

**Staff attitudes:** Participating staff members also indicated that there should be a structured change management process and willingness among employees to implement the ICDM model’s principles to improve adherence to its recommendations.

**Role clarification:** Although 90.0% (27/30) of the participants indicated that the CHCW and WBOTs contribute substantively to the management of patients with chronic diseases, they also indicated that overall performance in their roles is not easy to assess. They commented that the roles and key performance areas of the CHCW and WBOTs are not properly defined in the ICDM model.

*“With WBOT there isn’t clear what they are supposed to do in the clinic. Because there is still overflow of patients.”* (FI-6; Nurse).

## Context

**Adequate staff:** Providing sufficient staff members on a rotational basis would support a higher degree of fidelity in the implementation of the ICDM model. An example is that if the staff member allocated to the fast-lane (issuing of medication to booked and stable patients) is not on duty, that service would not be provided according to guidelines until there is sufficient staff.

*“We don’t have enough staff, even now we rely on nurses doing their community service.”* (FI11–6; Nurse).

**Supply chain management:** Lack of proper supply and management of batteries, booking books, printed materials on the chronic diseases, essential equipment and other consumables were also cited as factors that could reduce adherence to the ICDM model guidelines. The availability of technology to collect accurate data and to enhance communication between the clinic and the patients was thought to also potentially improve fidelity by enhancing precise bookings and adherence to clinic appointments.

**Balanced patient caseloads:** Staff members cited that high numbers of patients requesting services and inadequate staff and resources result in failure to adhere to ICDM guidelines. Secondly, participants felt that patients seeking services at facilities far from where they stay lead to low fidelity to the activity of CHCW and WBOT teams tracing defaulters.

**Infrastructure:** The healthcare workers indicated that due to the existing infrastructure (small waiting areas, few consulting rooms) of the clinics, it is difficult to implement four streams of care and have separate waiting areas, vital signs stations and consultation rooms designated only for patients with chronic diseases. Ample infrastructure, space and the design of the clinic were considered important pre-requisites to adherence to the prescribed ICDM model activities. Participants mentioned that a bigger filing space is also required to adequately implement the pre-retrieval of medical records.

*“Even now we combine acute patients with chronic because we do not have sufficient space.”* (FI11–5; Nurse).

*“The facility infrastructure should be revamped. Even now, we currently do not have water. Therefore, we need proper infrastructure, backup electricity, and water supply.”* (FI16–2; Administrator)

## The impact of facility-level factors on ICDM model implementation fidelity

The characteristics of the participating health facilities are summarised in Table 4. The maximum score on the level of implementation fidelity at the sixteen facilities was 158, and the fidelity scores ranged from 101 to 136 (min, max), with a median score of 125 (IQR: 117–132). Univariate linear regression indicated that customizing the budget for each facility ( $\beta = 9.50$ ), and increasing in the number of consulting rooms ( $\beta = 2.01$ ), enrolled nurses ( $\beta = 1.88$ ), medical officers ( $\beta = 1.18$ ), and

**Table 4** Characteristics of the 16 facilities that had implementation fidelity of the integrated chronic disease management model assessments

Variable	Mean (SD)
Budget customized by clinic	1 (1)
Distance from the district offices in km	40 (28)
Facility area under roof	657 (667)
Number of consulting rooms	6 (2)
Number of Professional Nurses	8 (4)
Number of Enrolled Nurses	2 (2)
Number of Medical Officers	2 (2)
Number of Pharmacy Assistants	1 (1)
Nurse-Patient Ratio	394 (205)
Medical Officer-Patient Ratio	2182 (1420)
Number of total patients per month	3241 (1193)
Number of total patients above 20 years per month	2352 (861)
Number of TB Cases Diagnosed in a month	5 (5)
Monthly Diabetic consultations	68 (35)
Monthly mental health consultations	26 (32)

pharmacy assistants ( $\beta = 2.0$ ) are associated with an increase in the level of fidelity to the implementation of the ICDM model (Table 5). An increase in the proportion of patients over 20 years old and those consulting for diabetes and mental health correlate with a decrease in fidelity.

## Discussion

This study provides quantitative and qualitative information on the facilities and intervention's interrelated moderating factors that affect implementation fidelity to the ICDM model. Time, space and healthcare worker integration and administrative tasks were some of the ICDM model features that need further clarification to enhance fidelity. There were concerns about nosocomial TB transmission if TB patients are included in one stream (staff and space integration) with all other patients with chronic diseases. Fidelity facilitation strategies (training and clinical mentorship) and participant responsiveness (empowered compliant patients and staff attitudes) were also highlighted as moderating factors that influence the fidelity. Adequate staff and infrastructure and observed efficiencies were stressed as some of the contextual moderating factors that foster fidelity to the guidelines. The qualitative results were consistent with some of the quantitative findings that adequate staff (pharmacy assistants, nurses and medical officers) and infrastructure (consulting rooms) are associated with a higher degree of fidelity in the implementation of the ICDM model.

There were concerns about nosocomial TB transmission to other patients with chronic diseases if TB patients are included in the same stream of care with all patients with chronic diseases. These concerns have also been raised at other TB and HIV single facility integration services, especially if the facilities are not designed to have adequate ventilation [32, 33]. WHO recommends both administrative (rapid identification, separation and treatment of TB patients) and environmental

**Table 5** Univariate Linear regression assessing the impact of facility characteristics on the implementation fidelity of the ICDM model

Variable	Univariate		
	$\beta$ (SE)	95% CI	p-value
Budget customized by clinic	9.50 (5.1)	-1.33 – 20.33	0.810
Distance from the district offices	-0.76 (0.1)	-2.96 – 0.14	0.473
Facility area under roof	0.01 (0.0)	-0.00 – 0.02	0.140
Number of consulting rooms	2.01 (1.2)	-0.63 – 4.65	0.125
Number of Professional Nurses	-0.17 (0.7)	-1.57 – 1.23	0.803
Number of Enrolled Nurses	1.88 (1.2)	-0.77 – 4.53	0.150
Number of Medical Officers	1.18 (1.9)	-2.82 – 5.17	0.539
Number of Pharmacy Assistants	2.00 (5.6)	-10.07 – 14.07	0.727
Nurse-Patient Ratio	0.01 (0.0)	-0.04 – 0.05	0.740
Medical Officer-Patient Ratio	-0.00 (0.0)	-0.005 – 0.004	0.768
Mean number of total patients per month	0.00 (0.0)	-0.00 – 0.01	0.740
Proportion of mean number of total patients above 20 years per month to total patients	-1.00 (0.4)	-1.80 – -0.21	0.017*
Proportion of mean monthly diabetic consultations to total patients	-2.16 (1.3)	-4.93 – 0.62	0.118
Proportion of mean monthly mental health consultations to total patients	-4.84 (2.6)	-10.39 – 0.71	0.082

\* Statistically significant at the 0.05 level

(ventilation systems, masks and ultraviolet germicidal irradiation lights) measures to minimize nosocomial TB transmission [34]. These strategies to prevent nosocomial TB transmission should be a critical pre-requisite in the implementation of the ICDM model, as the clinics diagnose a median of six new TB patients monthly and there is a high prevalence of drug-resistant (DR) TB and a decentralization of DR-TB services to PHC clinics in South Africa [35].

Training and clinical mentorship were mentioned as ICDM model implementation fidelity facilitators. These are similar to what was identified as facilitators in the implementation of chronic disease models in other studies such as appropriate data to support start-up and ongoing evaluations, effective clinical leadership and skills and training of healthcare workers [36–38]. Optimal clinical leadership has also been cited as a facilitator for adherence and sustainability of the ICDM model in another study [17]. The literature review illustrates that if there are no skilled and experienced staff to undertake the new proposed responsibilities, it would be difficult to adhere to guidelines [38].

Compliance to prescribed medication; patient adherence to appointments; and the attitudes and undefined roles of staff members were emphasized as moderating factors (participant responsiveness) of implementation fidelity. An intervention in healthcare should be acceptable to both patients and healthcare workers in order to be successfully implemented [38]. According to patients who had been interviewed in another study, they did not like the rigid appointment system under the ICDM model [39]. Acceptance and adoption of the chronic care models was also shown to be influenced by providing staff members with information in an appropriate manner to persuade them that the proposed intervention is beneficial [38]. The attitude of staff was also considered to be affecting the sustainability and acceptability of the ICDM model in other assessments [17, 39]. Clearly defined roles and communication within a multi-disciplinary team were considered crucial in the implementation of chronic care models [38]. Management is essential in supporting staff members throughout the change process [38]. In our study some of the concerns were that the ICDM model reinforces stigma and discrimination as it segregates patients by reason for consultation, and in other studies healthcare workers indicated that it reduces the stigma around HIV/AIDS patients when they are in one stream with patients with other chronic conditions [39].

Participants in this study emphasized that observing improvements in operational efficiency following the implementation of the ICDM model principles leads to high fidelity. The consistent use of recommended procedures and manuals on another chronic disease

management model was also associated with high fidelity [37]. This, however, creates a vicious circle of cause and effect, as adherence to the ICDM model guidelines is dependent on other contextual factors.

Contextual factors that were identified as moderating factors for fidelity in the implementation of the ICDM model included adequate infrastructure, staff and supply chain management. Supply chain management, adequate staff and infrastructure were also identified as the most important factors to be addressed by the national and provincial departments of health in South Africa if the PHC facilities' quality of services is to be improved [25]. Stock-outs of medication, malfunctioning or unavailable equipment (e.g. blood pressure machines) and consumables (pre-packaging bags) were also identified as factors that affected efficiency under the ICDM model according to the providers and the patients [39].

The findings of systematic reviews of studies conducted in developed countries are comparable to the results of this study, in that financial resources (infrastructure and more personnel), leadership and acceptability of the model to staff and patients and training of the chronic disease management model are important to support implementation of the model [9–11]. The need for communication, and a culture that promotes quality improvements was not identified as important in this study unlike the findings from the systematic reviews. In addition, supply chain management identified as important in this middle-income setting did not emerge as a challenge in developed countries [9–11].

### Strengths and limitations

One of the strengths of this study was that we used a mixed method in our efforts to identify the moderating factors of implementation fidelity to the ICDM model. The interviews with the staff members who were implementing the ICDM model at the PHC facilities provided an end-users' perspective on how adherence to the ICDM model guidelines can be enhanced. The study also included facilities with different levels of implementation fidelity, and as such minimized selection and exposure bias.

One of the limitations of this study was that the effect of patient perceptions of the ICDM model was not assessed, as this was beyond the scope of the study. PHC facilities' implementation fidelity to the ICDM model could have been influenced by both the responsiveness of the patients and the implementers. In addition, the perceptions the healthcare workers shared could also have been influenced by social desirability bias. Their focus may have been to improve their working conditions and not necessarily patient-centred care. The study did not assess the potential impact of the differences in disease burden and socio-economic status between the

two health districts on the ICDM model fidelity. Finally, the sample size of the health facilities included in the study was small from the perspective of conducting quantitative analysis. The small sample size limits the generalizability of the results. However the methods and findings could be applicable to other healthcare settings with similar characteristics.

## Conclusion

Our review of the ICDM model characteristics, fidelity facilitation strategies, participants' responsiveness and the context has revealed a number of interrelated fidelity-moderating factors. These include time, space and healthcare worker integration, training, infrastructure, adequate staff and empowered compliant patients. The participants views suggest that addressing some of the moderating factors, such as supply chain management and leadership support, and enhancing facilitation strategies (training, clinical mentorship) could improve adherence to the ICDM model guidelines. As the PHC facilities observe the operational efficiency subsequent to following the ICDM model guidelines, they will be encouraged to increase the adoption and sustainability of the model. More research that includes a larger sample size could provide additional moderating factors that affect the implementation fidelity of the ICDM model.

## Abbreviations

CCM: Chronic Care Model; CHCWs: Community Healthcare workers; COPD: Chronic Obstructive Airway Disease; DCST: District Clinical Specialist Team; ICC: Innovative Care for Chronic Conditions; ICDM: Integrated Chronic Disease Management; ICRM programme: Ideal clinic realization and maintenance programme; HIV: Human Immune Deficiency Syndrome; NHI: National Health Insurance; PHC: Primary Health Care; SA: South Africa; TB: Tuberculosis; WBOTs: Ward-based outreach teams; WHO: World Health Organization

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## Authors' contributions

LL was involved in the conception, study design, data collection, data cleaning and analysis and the writing of the manuscript. OAA, MK and TO contributed to the conception, study design and critical review of the manuscript. All authors have read and approved the manuscript.

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## Availability of data and materials

The dataset supporting the conclusions of this article is available in the Figshare repository, [<https://doi.org/10.6084/m9.figshare.11791176.v1>].

## Ethics approval and consent to participate

The protocol was approved by the University of Cape Town and University of the Witwatersrand's human research ethics committees. All participants provided written informed consent.

## Consent for publication

N/A

## Competing interests

The authors have no conflict of interest to declare.

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## Chapter 6: Influence of organizational culture on ICDM model implementation fidelity

The results of the assessment of the influence of organizational culture on the ICDM model implementation fidelity are described in a manuscript.


*Lebina L, Kawonga M, Alaba OA, Khamisa N, Otjombe K, Oni T. Organizational Culture and the Integrated Chronic Diseases Management Model Implementation Fidelity in South Africa. (BMJ Open –In press.)*

This chapter covers the third objective (to evaluate the influence of organizational culture on the implementation fidelity of the ICDM model) of the thesis.

**The relevance of the publication to the thesis:** This manuscript describes how organizational culture influences the fidelity of implementation of the Integrated Chronic Disease Management model at primary health care (PHC) clinics in South Africa. The paper addressed an evidence gap from low and middle-income countries and contributes to the knowledge of how the organizational culture of the public health sector may affect the implementation of new interventions. Three cultural traits (adaptability, involvement and consistency) that could be linked to the performance and objectives of an organization were assessed. The strongest organizational cultural trait in these clinics was involvement, while consistency and adaptability were weaker. Overall, the organizational culture of the clinics had more internal than external focus, and need improvement in terms of customer focus, capability development, coordination, and integration.

The clinic leadership (at facility and district levels) need to explore ways of engaging the patients and staff members on purposefully shaping the culture to improve healthcare services.

# BMJ Open Organisational culture and the integrated chronic diseases management model implementation fidelity in South Africa: a cross-sectional study

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## ABSTRACT

**Objective** To assess whether organisational culture influences the fidelity of implementation of the Integrated Chronic Disease Management (ICDM) model at primary healthcare (PHC) clinics.

**Design** A cross-sectional study.

**Setting** The ICDM model was introduced in South African clinics to strengthen delivery of care and improve clinical outcomes for patients with chronic conditions, but the determinants of its implementation have not been assessed.

**Participants** The abbreviated Denison organisational culture (DOC) survey tool was administered to 90 staff members to assess three cultural traits: involvement, consistency and adaptability of six PHC clinics in Dr. Kenneth Kaunda and West Rand (WR) health districts.

**Primary and secondary outcome measures** Each cultural trait has three indices with five items, giving a total of 45 items. The items were scored on a Likert scale ranging from one (strongly disagree) to five (strongly agree), and mean scores were calculated for each item, cultural traits and indices. Descriptive statistics were used to describe participants and clinics, and Pearson correlation coefficient to assess association between fidelity and culture.

**Results** Participants' mean age was 38.8 (SD=10.35) years, and 54.4% (49/90) were nurses. The overall mean score for the DOC was 3.63 (SD=0.58). The involvement (team orientation, empowerment and capability development) cultural trait had the highest (3.71; SD=0.72) mean score, followed by adaptability (external focus) (3.62; SD=0.56) and consistency (3.56; SD=0.63). There were no statistically significant differences in cultural scores between PHC clinics. However, culture scores for all three traits were significantly higher in WR (involvement 3.39 vs 3.84,  $p=0.011$ ; adaptability 3.40 vs 3.73,  $p=0.007$ ; consistency 3.34 vs 3.68,  $p=0.034$ ).

**Conclusion** Leadership intervention is required to purposefully enhance adaptability and consistency cultural traits of clinics to enhance the ICDM model's principles of coordinated, integrated, patient-centred care.

## INTRODUCTION

There is often a gap or lag between the growing knowledge of efficacious evidence-based

## Strengths and limitations of this study

- The strength of this study is that it addresses an evidence gap from low-income and middle-income countries and contributes to the knowledge of how the public health sector organisational culture might affect the implementation of new interventions.
- The Denison organisational culture survey tool that has been validated in organisations of different sizes and industries and previously used in the South African healthcare context was used to assess the cultural traits of the clinics.
- Three (adaptability, involvement and consistency) cultural traits that could be linked to an organisations performance and objectives such as effectiveness were assessed.
- Some of the limitations of the study are that the research was conducted in only six primary healthcare (PHC) clinics, with a few purposively selected staff members that might be an under-representation of PHC clinics and healthcare workers.
- Although attempts were made to conduct surveys with participants within their places of work where there was privacy, the risk of social desirability bias could have influenced responses.

interventions and public health practice.<sup>1–3</sup> Implementation science closes this gap by examining the process of how new research findings or interventions are translated into routine practice (implementation) and how contextual and other factors affect implementation.<sup>2–4</sup> Effective implementation of interventions is vital for achieving the intended outcomes.<sup>5</sup> Implementation effectiveness, including fidelity (adherence to intervention guidelines) can be affected by factors relating to the intervention itself, the implementers and the organisational context within which the intervention is applied.<sup>5</sup> The organisational contextual factors include leadership, policies, skills, funding, communication style, decision-making processes and organisational

culture.<sup>5–7</sup> Organisational culture needs to be understood and purposefully shaped if necessary as it can either hinder or support implementation fidelity of policies and interventions.<sup>8–10</sup> However, there is a dearth of studies on how organisational culture affects implementation, especially in low-income and middle-income countries. This innovative study assesses the impact of organisational culture on implementation effectiveness in South Africa, a middle-income country. Specifically, the research uses fidelity as an indicator of implementation effectiveness, focusing on the implementation of a chronic care model in a primary care setting.

### Organisational culture and implementation of new innovations

Organisational culture is defined as the shared beliefs, values and behaviour that a group has adopted over a course of time as a way to survive and succeed.<sup>10–12</sup> Organisational culture is also influenced by the structure and design of an organisation.<sup>13</sup> It is also regarded as a foundation for organisational management principles and practices.<sup>10 14</sup> A culture that is resistant to change could slow down the process and increase the costs of implementing a new intervention.<sup>15</sup> Whereas a culture that is receptive to new interventions usually has communications processes that promote openness to change and minimises other competing demands.<sup>5 15</sup> A positive culture is one of the contextual factors that accelerates organisational learning and improves the adoption of evidence-based practices.<sup>16</sup>

In the healthcare sector, positive (collaborative, supportive, cohesive and inclusive) organisational culture has been associated with improved service outcomes indicated by patient satisfaction and quality of care.<sup>17</sup> Implementation of new interventions without understanding the cultural forces might have unpredicted or unwanted outcomes.<sup>18</sup> For example, a negative culture in an organisation could make staff members have emotional burnout, become depersonalised and less innovative, which negatively affect implementation effectiveness of interventions.<sup>18 19</sup> Therefore, organisational culture assessments are important as they could assist leaders to understand how organisational culture impacts intervention implementation and other contextual factors, and necessary changes to improve implementation effectiveness, including fidelity.<sup>10 14</sup>

### The Denison organisational culture (DOC) model

There are different recommended models, tools and approaches<sup>13 20</sup> for culture assessment of an organisation, each with varying foci, strengths and weaknesses.<sup>9 20–22</sup> The DOC model seemed most appropriate for this study on examining the organisational culture of PHC clinics in South Africa and impacts of culture on implementation of a new intervention—the integrated chronic disease management (ICDM) model. The DOC model approach is appropriate as it focuses on linking the culture to the organisation's objectives and performance indicators like quality and effectiveness.<sup>10 11 13 20 23</sup> The DOC model has

been validated and applied previously in 160 organisations of different sizes and industries in the USA, Europe, Asia and Middle East.<sup>24</sup> The DOC survey has also been used previously in a South African healthcare context, and it is easy to administer and applies to all levels (executive management to workers) of an organisation.<sup>20 23</sup>

The DOC model and survey tool was developed following research into various sectors and companies of different sizes to assess four inter-related cultural determinants (traits) that have been linked to bottom-line performance indicators like quality, profit and effectiveness.<sup>10 11</sup> The four (mission, adaptability, involvement and consistency) cultural traits that Denison describes as affecting the organisation's sustainability and long-term effectiveness are as follows<sup>10 11</sup>:

#### Mission

Long-term strategic intent and direction with clear objectives, and the three indices under mission are strategic direction and intent, goals and objectives and vision.

#### Adaptability

The three cultural indices under the adaptability trait are creating change, customer focus and organisational learning. An organisation that has a high score of adaptability is innovative, constantly reviewing the environment and responding appropriately while anticipating upcoming changes. This also includes understanding the customer current and possible future needs and flexibility to change processes and crucial behaviour if necessary.

#### Involvement

The three cultural indices of involvement are empowerment, team orientation and capability development. A high level of empowerment in an organisation indicates that employees have a greater sense of ownership and authority to initiate and manage the work. A team-orientated organisation values working cooperatively to complete tasks. Capability development includes investment in developing staff members' skills to give the organisation a competitive advantage.

#### Consistency

Core values, agreement and coordination and integration are the three cultural indices under the consistency cultural trait. The core values give employees a clear set of expectations and could make it easier to agree on crucial matters. An organisation that has a high level of coordination and integration is simple to bring staff members from different units to work together.

In the DOC model, successful organisations are the ones that have strengths in all the four cultural traits.<sup>10 11</sup> Although overall balance in all the traits is the objective, the results of the DOC survey can also be used to build on a particular area of the culture<sup>10 11</sup> depending on the objectives of the organisation at a specific time.

In this study, we used the DOC survey to understand how organisational culture has affected the implementation of the ICDM model.

## The ICDM model

The ICDM is a chronic care model that was introduced in three provinces in South Africa as a pilot implementation phase in 2011.<sup>25</sup> The ICDM model was developed by the national department of health and cascaded down to the provincial and district health management for implementation.<sup>26</sup> In the current setting of the South African healthcare system context where primary healthcare re-engineering is a key focus, the ICDM model is among several PHC system strengthening strategies being followed to improve quality of services and patient outcomes.<sup>25</sup> The ICDM was introduced as a result of an increasing prevalence of non-communicable diseases (accounting for 51.3% of all deaths) in the background of an epidemic of communicable diseases like HIV/AIDS and tuberculosis (TB),<sup>27 28</sup> which resulted in a surge of multimorbidity,<sup>29</sup> to which a health system that is fragmented, inefficient and overcrowded is struggling to respond.<sup>30 31</sup> The following conditions are managed under the nurse-led ICDM model: HIV/AIDS, TB, asthma, diabetes, hypertension, chronic obstructive airway disease, epilepsy and mental health.<sup>25</sup> The ICDM model is an integral part of the ideal clinic initiative that started in 2013 as part of PHC re-engineering and evolved into the Ideal Clinic Realisation and Maintenance (ICRM) programme in 2014— programme supporting clinics to attain and maintain recommended standards for clinical and other dimensions of quality.<sup>32</sup>

The ICDM model includes prescriptive guidelines on facility restructuring to improve patient flow, clinical supportive management, strengthening of service delivery support systems and assisted self-management.<sup>25</sup> Other administrative recommendations under the ICDM model include booking of patients, design of waiting areas and consultation rooms and dispensing of medication.<sup>25</sup> All these are structural initiatives requiring leadership support and change of work routines. Effective management of chronic conditions like diabetes, asthma and heart failure has been enhanced by the chronic care models resulting in less adverse events and better health outcomes.<sup>33</sup> However, the effectiveness of the ICDM model has not been adequately demonstrated, necessitating the research on how efficiently it has been implemented.

Previous assessments have indicated that some of the factors that may affect the scale-up of this ICDM innovation are cultural factors such as lack of clinical leadership and negative attitudes and behaviour of staff towards prescribed operational changes.<sup>26</sup> The objective of this study was therefore to apply the Denison model to understand the organisational culture of six PHC clinics that were pilot sites for the implementation of the ICDM model and assess how culture could influence implementation effectiveness. The study uses existing data on fidelity as the marker of implementation effectiveness.

## METHODS

### Study design and setting

This was a cross-sectional study conducted in six PHC clinics in two health districts in South Africa between November 2018 and August 2019, Dr. Kenneth Kaunda (DKK) in North West Province and West Rand (WR) in Gauteng province. This study was part of a larger study assessing the fidelity and costs of implementing the ICDM model in South Africa,<sup>34</sup> and the fidelity results have been reported comprehensively in another manuscript.<sup>35</sup>

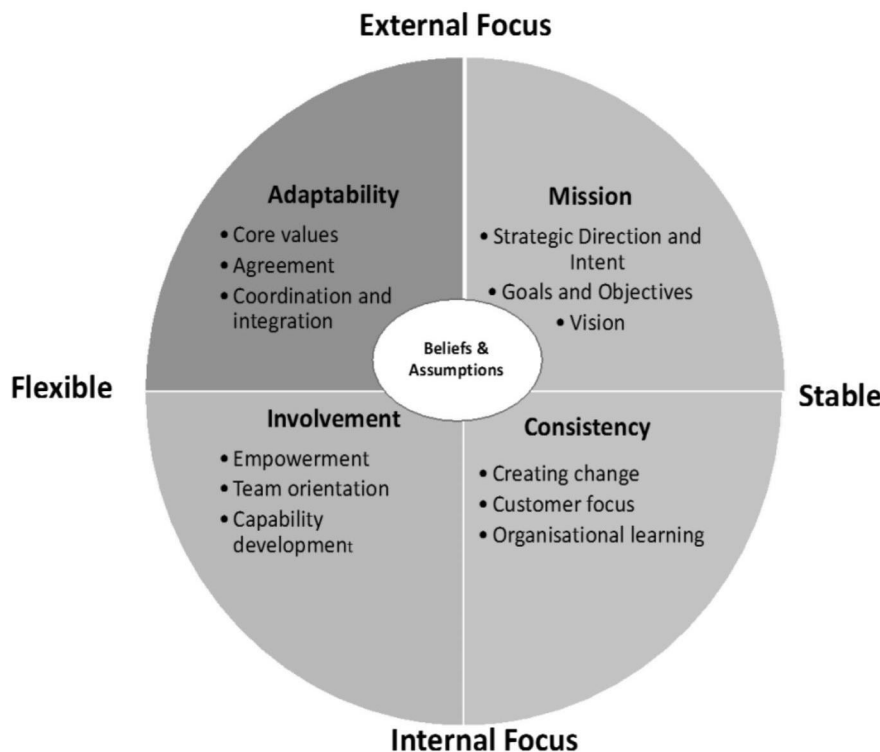
There are 52 health districts across the nine provinces in South Africa, and although the planning supervision and administration is supposed to be decentralised to districts, management is still very centralised with decision making at national and provincial levels.<sup>36</sup> Both study districts were pilot sites for the ICDM model since 2011. Both districts provide primary care services ranging from community based, through PHC clinics, to district hospital platforms. PHC clinics usually provide primary care services 8–12 hours a day and managed by facility managers (commonly with a nursing training) who are accountable to the health district management.<sup>36</sup>

As part of the ideal clinic initiative, PHC clinics in South Africa are assessed against multiple service provision and quality standards and can receive a maximum score of 100%.<sup>32</sup> In the ICRM programme, clinics that score  $\geq 90\%$  are considered platinum,  $\geq 80\%$  gold,  $\geq 70\%$  as silver and those that score below 70% as not achieved ideal clinic status.<sup>32</sup> Over the years, there has been a steady increase in clinics that have been assessed and those that scored 70% or above increased from 139 to 513 by 2016.<sup>32</sup>

### Sampling and study participants

The six PHC clinics were selected from the 16 clinics included in our broader study analysing the fidelity of implementation (FOI) and cost of implementing the ICDM model.<sup>34</sup> As part of the broader study, we measured FOI at clinics and applied a similar ICRM programme scale<sup>32</sup> to categorise clinics into three groups: high (gold: fidelity score  $\geq 80\%$ ), medium (silver:  $\geq 70\%$  and  $< 80\%$ ) and low (not achieved:  $< 70\%$ ). The FOI criteria was based on the various activities recommended under each of the four components of the ICDM model.<sup>32 34</sup> Each clinic was then scored on each activity according to how accurately it implemented the activities and scores were then summed up per component and overall for each PHC clinic.<sup>34 35</sup> Eight PHC clinics had high, six PHC clinics had medium and two had low FOI scores.<sup>34 35</sup> The overall FOI was higher in WR health district compared with DKK (80% vs 74%,  $p=0.1409$ ).<sup>35</sup> For the organisational culture assessment for this paper, we randomly selected two clinics each (with comparable monthly patient loads) from the high, medium and low level of FOI categories. Two clinics (one high and one medium FOI score) were based in WR health district and four (one high, one medium and two low FOI score) in DKK health district.

At each of the six clinics in our sample, the clinic staff members that were involved in the implementation



**Figure 1** Diagrammatic representation of the Denison organisational culture.

of the ICDM model were eligible for enrolment if they had worked in the study clinic for more than 6 months and were willing to provide written informed consent for participation. All staff members that offer services (administration, adherence support, clinical care and allied health services) to patients with chronic diseases were approached in person to request their participation in the study. We purposively recruited 90 clinical and administrative staff members, 15 per clinic. The sample size calculation was based on a difference of 0.15 in mean scores with 80% statistical power.

### Data collection

An abbreviated DOC survey tool was used to collect data on the participants' rating of the cultural traits of their respective facilities, with only three of the four cultural traits in Denison's framework were assessed in our study. The mission trait of the DOC framework was not included as long-term strategic and vision development are outlined at district and provincial departments of health levels, not a PHC clinic level. The abbreviated DOC survey tool used in our study therefore assessed the three cultural traits: involvement, consistency and adaptability (figure 1), with each trait comprising three indices.<sup>10 11 13</sup>

Each of the three indices has five items, giving a total of 45 items for our abbreviated Denison scale. Each item is presented as a statement scored on a Likert scale ranging from one to five, with one being strongly disagree and five being strongly agree. The statements are in simple everyday language yet provide a comprehensive analysis of the organisational culture by assessing the underlying cultural traits and management.<sup>10</sup>

In addition, we collected data on the clinic characteristics such as personnel by category, monthly patient headcount for a period of 6 months and ratio of nurse or medical officer to the patient headcount. The number of patients that consult for chronic diseases (HIV/AIDS, hypertension, diabetes and mental health) per month over the same period and new cases of TB diagnosed per month was included to compare workloads of clinics. Existing data on FOI of the ICDM model was used to compare the overall level of fidelity and on the four (facility reorganisation, clinical supportive management, assisted self-management and strengthening of support systems) major components of the ICDM model.

### Interpretation of results

The guidelines provided in the literature on the DOC survey<sup>10 11 24</sup> were followed in the interpretation of the results of the survey. The focus of the DOC model is to link organisational culture scores and key performance indicators like innovation, quality and employee and customer satisfaction.<sup>11</sup> For example, high scores on involvement and consistency indicate the strength of internal focus and that the organisation has quality operations and high employee satisfaction,<sup>11</sup> while high scores in adaptability and involvement demonstrate a flexible organisation that is innovative and strives to understand the external environment and meet the needs of their clients.<sup>11</sup> Therefore, the DOC survey results can be linked to the organisations' goals to identify gaps that need to be addressed.<sup>11</sup>

Data were collected by trained research assistants interviewing the 90 participants using the paper-based

abbreviated DOC survey. The research assistants explained the study, the survey tool, interviewed participants and manually completed the survey tool. All interviews were conducted in English and or Zulu/Sotho/Tswana. A few of the participants requested to complete the survey on their own.

### Data management and analysis

The collected data were captured into a REDCap electronic database.<sup>37</sup> As part of the data quality management plan, data were checked for missing variables, obvious discrepancies, incorrect data and amended appropriately. The data were exported from REDCap into Excel and Statistical Package for Social Science (SPSS V.25) for analysis.<sup>38</sup> Descriptive statistics (means, SD and proportions) were calculated to describe the demographics of the participants and clinics' characteristics. Six questions in the survey tool were negatively worded,<sup>24</sup> and the scores for those questions were reversed prior to analysis. The abbreviated DOC score was determined by calculating the mean score from the three cultural traits scores. Data were largely complete with only two questions with missing data. For these, we conducted a complete case analysis where the denominators were adjusted accordingly. Descriptive statistics (mean scores and SD) were used to describe the overall PHC clinic organisational culture score and mean scores for each of the three traits based on the DOC survey guidelines and examples.<sup>10 24</sup> The Pearson correlation coefficient was calculated to measure the association between DOC scores and the degree of FOI of the ICDM model. In addition, clustered univariate and multivariate modelling was conducted to assess the risk factors for low culture scores. We used the independent sample t-test,  $\chi^2$  and the one way analysis of variance (ANOVA) to assess for statistically significant differences in clinic characteristics, participants demographics and DOC scores between clinics with high, medium and low ICDM model FOI scores. The level of significance was set at 0.05. The *Cronbach's alpha* test was calculated for three cultural traits and nine cultural indices.

### Patient and public involvement

In this study, we conducted the survey among healthcare workers only. Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

### Ethical approvals

The participants provided individual written informed consent. Each facility and participant were allocated a study identification number, and no identifiers were included in the electronic password-protected database.

## RESULTS

### Characteristics of clinics and participants demographics

Of the 90 staff members enrolled in the abbreviated DOC survey and interviewed, almost half (49/90; 54.4%)

were nurses. Others were administrative personnel (data capturers and administrators) (18/90; 20%) and counsellors/health promoters/support staff (23/90; 25.6%). These participants had been working in their roles for a mean of 6.4 (SD=6.26) years. The mean age of the participants was 38.8 (SD=10.35) years, and 86.7% (78/90) were women (table 1), and there were no significant differences in the demographics of participants across the three clinic categories by FOI. A mean of 2420 (SD=592.47) patients above 20 years received healthcare services per month per clinic. There were no significant differences in the number of personnel and ratio of nurse or medical officer to patients between clinics with a high, medium or low FOI scores (table 1). However, the overall FOI of the ICDM model for the activities of the four components scores was significantly different ( $p=0.001$ ) with the one-way ANOVA test. Further analysis indicated that the difference was significant between the high and low fidelity ( $p=0.002$ ) and between the low and the medium, as well as the high and medium ( $p=0.013$ ), fidelity level clinics.

### DOC scores

#### Cultural traits

The *Cronbach's alpha* test of reliability for the overall survey was 0.94 (table 2). The *Cronbach's alpha* test for involvement was 0.89, while for consistency was 0.86 and adaptability was 0.81. The overall mean DOC score was 3.63 (SD=0.58). The involvement cultural trait had the highest mean score (3.71; SD=0.72), followed by adaptability (3.62; SD=0.56) and consistency (3.56; SD=0.63).

#### Cultural indices

The top three mean scores on the indices of the DOC survey (table 2) were on team orientation (3.88; SD=0.90), core values (3.79; SD=0.68) and empowerment (3.76; SD=0.89). The lowest three mean scores were on creating change (3.44; SD=0.76), agreement (3.44; SD=0.80) and coordination and integration (3.45; SD=0.78). Capability development (3.47; SD=0.74) was the lowest under involvement trait. Customer focus (3.67; SD=0.66) scored lower than organisational learning (3.75; SD=0.65) under the adaptability cultural trait. Core values scored higher (3.79; SD=0.68) than agreement (3.44; SD=0.80) under the consistency trait. The *Cronbach's alpha* test of reliability for the nine cultural indices ranged from 0.58 to 0.82 (table 2). The cultural indices with low *Cronbach's alpha* test were included in the analysis as the content of the questions had been validated in other settings and in South Africa.<sup>20 23 24</sup>

### Comparison between high, medium and low FOI clinics

The overall pattern of the organisational culture of the three sets of clinics was similar, with features like the lower score on capability development compared with empowerment and team orientation under involvement trait and core values attaining a higher score than agreement and coordination and integration under consistency trait.

**Table 1** Characteristics of high, moderate and low implementation fidelity clinics

Variable	All clinics	High fidelity	Medium fidelity	Low fidelity	P value
<b>Participants' demographics</b>	n=90	n=30	n=30	n=30	
Females (N; %)	78 (86.7)	25 (83.3)	28 (93.3)	25 (83.3)	0.421
Age (mean; SD)	38.8 (10.35)	39.4 (9.38)	38.7 (12.07)	38.6 (9.73)	0.951
Years in this role (mean; SD)	6.4 (6.26)	6.03 (6.45)	7.0 (7.19)	6.2 (5.12)	0.810
<b>Role (N; %)</b>					
Nurses	49 (54.4)	15 (30.6)	17 (34.7)	17 (34.7)	
Administrators	18 (20.0)	7 (23.3)	6 (20.0)	5 (16.7)	
Other support staff	23 (25.6)	8 (26.7)	7 (23.3)	8 (26.7)	
<b>Clinic characteristics</b>	n=6 clinics	n=2 clinics	n=2 clinics	n=2 clinics	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
<b>Personnel</b>					
Nurses	10 (5.67)	6 (1.41)	8 (4.24)	16 (6.36)	0.231
Medical officers (generalist doctors)	2 (1.63)	1 (0.00)	3 (2.82)	1 (0.00)	0.465
Administrative staff	5 (3.08)	3 (1.41)	7 (4.95)	4 (2.83)	0.619
Ratio: head counts per nurse	410 (179.21)	532 (281.7)	423 (75.1)	274 (92.61)	0.445
Ratio: headcounts per doctor	2847 (1250.14)	2992 (938)	1597 (1108)	3953 (308.3)	0.150
<b>Patient consultations</b>					
Total PHC consultations per month	3389 (825.31)	2992 (938)	3224 (1194)	3953 (308)	0.592
Patients >20 years per month	2420 (592.47)	1994 (656)	2372 (697)	2895 (142)	0.390
Adults in care for HIV/AIDS	1724 (744.89)	1490 (1113)	1605 (657)	2077 (846)	0.797
New TB diagnosis per month	6 (4.91)	3 (1.65)	4 (1.53)	11 (6.36)	0.233
Diabetic patient consultation per month	88 (39.21)	81 (24.28)	126 (41.60)	56 (17.32)	0.199
Hypertensive patient consultations per month	385 (207.32)	294 (71.06)	617 (212.60)	244 (24.87)	0.115
Mental health patients in care	98 (68.59)	15 (9.19)	147 (45.25)	133 (16.26)	0.330
<b>ICDM implementation fidelity score</b>					
Facility reorganisation (max: 37*)	27.7 (2.16)	28.0 (1.41)	28.5 (2.12)	26.5 (3.54)	0.735
Clinical supportive management (max: 39*)	28.8 (5.81)	35.0 (2.83)	28.0 (1.41)	23.5 (4.95)	0.920
Assisted self-management (max: 39*)	32 (4.24)	36.5 (0.71)	30.5 (4.95)	29.0 (1.41)	0.164
Strengthening of support systems (max: 43*)	32 (4.38)	35.5 (2.12)	33.5 (2.12)	27.0 (2.83)	0.075
Overall fidelity score (max: 158*)	120.5 (13.05)	135.0 (1.41)	120.5 (0.71)	106.0 (2.83)	0.001†

\*Max=maximum possible fidelity score.

†Statistically significant at the 0.05.

ICDM, Integrated Chronic Disease Management; PHC, primary healthcare; TB, tuberculosis.

The low FOI clinics attained higher scores on all the three cultural traits: involvement (3.87; SD=0.64), consistency (3.66; SD=0.50) and adaptability (3.66, SD=0.55). When comparing the PHC clinics' DOC indices, the low fidelity level clinics had higher scores on three (team orientation, core values and empowerment) indices compared with the medium and high-fidelity clinics (table 2). The differences on mean scores of cultural traits and indices between the three groups of clinics were not statistically significant.

#### Pearson's correlation coefficient

There was a weak negative correlation between the overall FOI of the ICDM model and the DOC scores ( $r=-0.117$ ;  $p=0.272$ ). A similar association was also

observed with facility reorganisation ( $r=-0.114$ ;  $p=0.287$ ), clinical supportive management ( $r=-0.184$ ;  $p=0.083$ ) and strengthening of support systems ( $r=-0.123$ ;  $p=0.247$ ) fidelity scores and culture scores. However, there was a weak positive correlation between fidelity scores on assisted self-management and DOC mean scores ( $r=0.076$ ;  $p=0.474$ )

#### Comparison between the two health districts

At the health district level, there were statistically significant differences on all three (involvement, consistency and adaptability) cultural traits (table 3). Consistency cultural trait scored the lowest in both health districts. When comparing the DOC indices mean scores across the two health districts, DKK health district had higher

**Table 2** The abbreviated Denison organisational culture scores: comparing high, medium and low ICDM model implementation fidelity in PHC clinics

Cultural traits	Culture indices	Overall mean scores for all PHC clinics		Level of implementation fidelity of the ICDM model						P value
		Mean	SD	High PHC Clinics n=30		Medium PHC Clinics n=30		Low PHC Clinics n=30		
Involvement	Empowerment ( $\alpha=0.82$ )	3.76	0.89	3.66	0.96	3.65	0.84	3.99	0.84	0.246
	Team orientation ( $\alpha=0.82$ )	3.88	0.90	3.95	0.89	3.64	1.05	4.05	0.68	0.177
	Capability development ( $\alpha=0.58$ )	3.47	0.74	3.49	0.69	3.35	0.71	3.57	0.83	0.533
	Overall involvement cultural trait ( $\alpha=0.89$ )	3.71	0.72	3.70	0.77	3.55	0.74	3.87	0.64	0.228
Consistency	Core values ( $\alpha=0.67$ )	3.79	0.68	3.72	0.71	3.65	0.68	4.01	0.60	0.098
	Agreement ( $\alpha=0.72$ )	3.44	0.80	3.46	0.86	3.30	0.93	3.56	0.58	0.453
	Coordination and integration ( $\alpha=0.74$ )	3.45	0.78	3.41	0.92	3.53	0.67	3.43	0.74	0.818
	Overall consistency cultural trait ( $\alpha=0.86$ )	3.56	0.63	3.53	0.74	3.49	0.65	3.66	0.50	0.548
Adaptability	Creating change ( $\alpha=0.72$ )	3.44	0.76	3.39	0.83	3.37	0.73	3.55	0.72	0.595
	Customer focus ( $\alpha=0.59$ )	3.67	0.66	3.70	0.62	3.67	0.70	3.63	0.67	0.926
	Organisational learning ( $\alpha=0.58$ )	3.75	0.65	3.63	0.65	3.81	0.62	3.80	0.67	0.490
	Overall adaptability cultural trait ( $\alpha=0.81$ )	3.62	0.56	3.58	0.59	3.62	0.56	3.66	0.55	0.839
	Overall Denison organisational culture ( $\alpha=0.94$ )	<b>3.63</b>	<b>0.58</b>	<b>3.60</b>	<b>0.66</b>	<b>3.55</b>	<b>0.59</b>	<b>3.73</b>	<b>0.50</b>	<b>0.476</b>

$\alpha$ =Cronbach's alpha reliability coefficient.

Overall values are given in bold.

ICDM, Integrated Chronic Disease Management; PHC, primary healthcare.

scores on all the nine indices, and the difference was statistically significant on creating change, core values and team orientation (figure 2). In both health districts, agreement scored lower than coordination and integration and core values under the consistency cultural trait.

The highest scoring cultural indices in WR were customer focus (3.65; SD=0.64), organisational learning (3.51, SD=0.56) and core values (3.49, SD=0.77), while in

DKK, it was team orientation (4.1, SD=0.70), core values (3.94; SD=0.57) and empowerment (3.92; SD=0.76). Controlling for gender, the clustered multivariate analysis showed that clinics in WR health district are associated with lower mean organisational culture scores compared with clinics in DKK health district (table 4).

## DISCUSSION

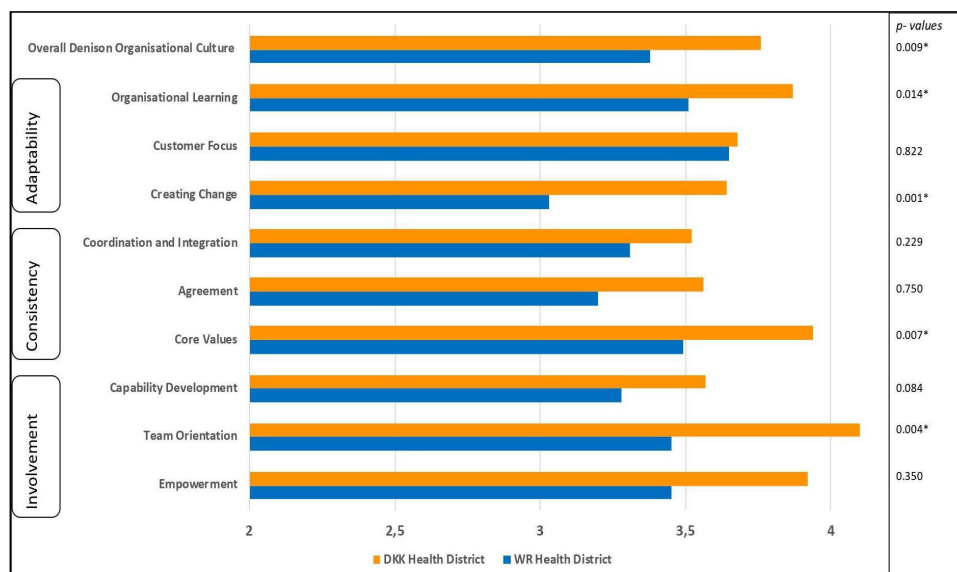
This study provides timely information on the organisational culture of six PHC clinics that were assessed for the implementation fidelity of the ICDM model and how culture could have affected the implementation fidelity of this intervention. Organisational culture improvements are the focus of many healthcare organisations.<sup>8</sup> The overall pattern of the DOC survey for the six clinics shows PHC clinics have a balanced both the internal (involvement and consistency) and external (adaptability) focus. The abbreviated DOC survey showed good reliability. The abbreviated DOC survey results showed that the strongest cultural trait was involvement, and adaptability and consistency scored the lowest. The highest scoring cultural

**Table 3** The abbreviated Denison organisational culture traits mean scores results compared between the two health districts

Cultural traits	WR health District n=30		DKK health District n=60		P values
	Mean	SD	Mean	SD	
Involvement	3.39	0.87	3.84	0.60	0.011*
Adaptability	3.40	0.54	3.73	0.54	0.007*
Consistency	3.34	0.77	3.68	0.52	0.034*

\*Statistically significant at the 0.05 level.

DKK, Dr. Kenneth Kaunda; WR, West Rand.



**Figure 2** The abbreviated Denison organisational culture indices and mean scores comparing the two health districts. \*Statistically significant at the 0.05 level. DKK, Dr. Kenneth Kaunda; WR, West Rand.

indices were team orientation, core values and empowerment and the lowest were creating change, agreement and coordination and integration. In the involvement trait, capability development scored the lowest compared with empowerment and team orientation. Core values scored higher than coordination and integration, and agreement under the consistency cultural trait. Creating change was the lowest scoring index under adaptability trait, compared with customer focus and organisational learning. Organisational learning scored the highest in the low and medium FOI clinics. There was a weak negative correlation between organisational culture and the degree of FOI of the ICDM model. Organisational culture is a critical contextual factor, yet we did not observe a statistically significant differences in mean scores of cultural traits and indices between the clinics that had low, medium and high FOI of the ICDM model. However, there were some statistically significant differences between the two health districts on all three cultural traits (involvement, consistency and adaptability) and indices (creating change, core values and team orientation). WR district was associated with lower mean culture scores.

The strongest cultural trait in these six clinics that participated in the study was involvement, adaptability and consistency had lower scores. Involvement cultural trait covers empowerment, team orientation and capability development. These are indispensable cultural strengths for an organisation that is aiming to improve the performance indicators and quality of services.<sup>24</sup> Employee involvement has been positively associated with a large number of significant changes in quality care improvements and chronic illness management as engaged employees collaborate, perform at a higher level and are innovative.<sup>9 39</sup> A qualitative study on constraints for adopting health innovations into practice indicated that the hierarchical culture of the South African health system does not support innovation and creating change at facility level.<sup>40</sup> Creating change cultural index also obtained a low score in this study. Decisions on what new innovative interventions to be introduced are usually concluded at higher (district and provincial) management level with very little bottom-up communication or consultation.<sup>40</sup> Adaptability cultural trait is a critical strength in an organisation that is undergoing a

**Table 4** Clustered univariate and multivariate analysis of the factors associated with Denison organisational culture mean scores

Variable	Univariate		Multivariate	
	Beta Coefficient (SE)	P value	Beta Coefficient (SE)	P value
Overall fidelity score	-0.006 (0.008)	0.499		
District: WR versus DKK	-0.381 (0.083)	0.010	-0.379 (0.082)	0.010
Age	-0.0002 (0.006)	0.971		
Gender: female versus male	-0.030 (0.178)	0.874	-0.048 (0.175)	0.793
Role: clinical versus non-clinical	0.008 (0.123)	0.952		

DKK, Dr. Kenneth Kaunda; WR, West Rand.

transformation,<sup>11</sup> and this trait would need to be fortified in these PHC clinics as part of the primary healthcare re-engineering. Adaptability cultural trait is even more crucial in this setting as the proposed changes under the ICDM model support customer focus and coordination and integration.

In the six clinics that participated in this study, team orientation, core values and empowerment scored the highest on the DOC survey. A lower score for capability development compared with empowerment and team orientation might indicate that some employees in the PHC clinics are making decisions that they may not be capable of making and comply with team dynamics without much commitment and ownership.<sup>11</sup> A high level of teamwork and involvement were also observed in another study that assessed organisational culture in an HIV programme, and this protected the staff members from burnout, emotional exhaustion and depersonalisation.<sup>19</sup> In a study on organisational values and culture of primary healthcare services in Cape Town, South Africa, the cultural values that were aligned with primary healthcare re-engineering were teamwork and community partnership.<sup>41</sup>

The lowest scoring indices were creating change, agreement and coordination and integration in our study. A higher score for core values compared with agreement (under the consistency trait) might imply that even if the organisation has good intentions, the leadership is unresponsive to employees' concerns.<sup>11</sup> In the adaptability cultural trait, organisational learning scored higher than customer focus, which suggests that the organisation might be excellent at recognising best practices and creating new guidelines but unable to translate this knowledge into routine practice.<sup>11</sup> An ideal organisational culture in the healthcare sector is one that emphasises patient-centred care (customer focus) and fosters less emphasis on profits.<sup>8</sup> A supportive cultural environment that is characterised by team orientation, customer orientation, collaboration and sharing of information was the most desired cultural trait by staff members overemphasis on rewards cultural qualities in a PHC setting in Cyprus.<sup>42</sup>

Capability development scored the lowest compared with empowerment and team orientation in the involvement trait. Although empowerment and team orientation are important organisational culture strengths, capability development is also essential to enhance staff skills and engagement in the implementation of new changes in an organisation.<sup>43</sup> In the consistency cultural trait, core values scored higher than coordination and integration, and agreement.

Customer focus was scored lower in the medium and low FOI clinics compared with high FOI clinics. Patient experience was also observed to have a low organisational value in primary healthcare service in Cape Town metro.<sup>41</sup> The employees in private health facilities in South Africa have been reported to view customer focus as the strongest cultural index of their organisation and scored coordination and integration and empowerment

lower.<sup>20</sup> The organisational culture in the private health sector is different from the public health sector in that the customer focus was scored higher than the organisational learning and creating change, which might denote that the sector understands the current needs of their customers but is not anticipating and preparing for future changes in the external environment.<sup>10 20</sup> The inference from this survey as perceived by other researchers is that South Africa has adequate legislature and guidelines to provide quality health services, but governance and stewardship need to be improved to achieve these good intentions.<sup>30 44</sup> The implementation fidelity of the ICDM model would have been facilitated by a culture that is customer focused as the objectives of the model are to improve patient satisfaction with the service and their health outcomes.<sup>25</sup> Similarly, it is also a good intervention to introduce to organisations that have low coordination and integration cultural index.

There were no statistically significant differences in mean scores of cultural traits and indices between the clinics that had low, medium and high implementation fidelity of the ICDM model, although the low fidelity clinics had three higher scores. Lack of statistically different organisational culture mean scores could have been due to low numbers of clinics and participants and that the fidelity scores were the summation of scores for multiple activities.<sup>35</sup> In another study on organisational culture conducted among staff members from 42 PHC facilities, the differences on predominant cultural dimensions were observed between gender groups, years of experience in their role and not at clinic level.<sup>42</sup> Gender, age and role were not correlated with DOC survey results in this study. When comparing the DOC survey results between the two health districts, there were statistically significant differences in all the three cultural traits and three indices (creating change, core values and team orientation). The consistent cultural traits scoring between the clinics that had low, medium and high implementation fidelity of the ICDM model and significantly different scores by health districts might also be an indication of the impact of central management of PHC facilities by the health district leadership.<sup>36</sup> Desired and experienced cultural values were noted to be similar for healthcare workers based in two health districts in a Botswana study.<sup>45</sup>

Many healthcare organisations have commenced organisational culture enhancements and purposefully influence the cultural environment to be conducive to effective implementation of policies and interventions.<sup>8 9</sup> For example, a 2-year 'Leadership Saves Lives' intervention that aimed to support hospitals to improve their culture and promote learning, psychological safety, commitment and senior management support have resulted in improvements in the use of evidence-based strategies and better health outcomes.<sup>16</sup> Adherence to clinical guidelines on treating tobacco use in a PHC setting was shown to be associated with 'group' (human resource development) and hierarchical (stable) cultural context.<sup>46</sup> In our study setting, any interventions that



promote organisational cultural changes will need to include the district leadership and not just focus at the PHC clinic level. Cultural changes also require a high level of leadership support to foster the new mission and provide the necessary resources to implement the change.<sup>43</sup> There is evidence that cultural changes are feasible and sustainable especially if the vision is aligned with actions, the change implementation is collaborative and small-scale at a time.<sup>43</sup> Some of the recommendations for organisational change in the study clinics to promote effective implementation of the ICDM model could include an emphasis on customer feedback processes and rewarding staff members that demonstrate patient-centred care as part of improving customer focus. A participatory management style has also been recommended as another strategy to facilitate bottom-up communication and consultation and innovations adoption.<sup>40</sup> Organisational culture assessments as well as strategies on how to shape the culture needs to be in place prior to introduction of new interventions.

### Strengths and limitations

A key strength of this study is that it addresses an evidence gap from low-income and middle-income countries and contributes to the knowledge of how public health sector organisational culture might affect the implementation of new interventions. In addition, we used the DOC survey tool that has been validated in organisations of different sizes and industries and previously used in the South African healthcare context to assess the cultural traits of the clinics. Furthermore, three (adaptability, involvement and consistency) cultural traits that could be linked to an organisations performance and objectives such as effectiveness were assessed. The study had a number of limitations. The research was conducted in only six PHC clinics, with a few purposively selected staff members that might be an under-representation of PHC clinics and healthcare workers. There is potential for social desirability bias as the survey was conducted with employees while at their place of work. The risk of this bias was limited by ensuring privacy for the interview. In addition, the face-to-face nature of interviews conducted by the researchers could have resulted in interviewer bias. Lastly, the results from these clinics were not compared with other organisations within the large DOC global database as recommended<sup>11</sup> due to costs.

### CONCLUSION

This is a timely study that provides more understanding of the organisational cultural environment in PHC clinics that are the focus of healthcare system reform. The strongest organisational cultural trait in these clinics was involvement, while consistency and adaptability were their weaker cultural traits. Overall, the clinics' culture had more internal than external focus and need improvement on customer focus, capability development and coordination and integration. There were no significant

differences in cultural traits between the clinics with various levels of implementation fidelity of the ICDM model. However, there were differences in the results of the culture by the health districts.

The leadership of the clinics (at facility and district levels) need to explore ways of engaging the patients and staff members on how to purposefully shape the culture to improve healthcare services. The weaker cultural traits that need enrichment are customer focus, capability development, and coordination and integration to make the context more conducive for the implementation of an intervention like the ICDM model that promotes coordinated, integrated, patient-centred care. In addition, evaluations on how staff attitudes and buy-in to the ICDM model principles may affect organisational culture is also important. The results of this study can also be used to set targets for improvements on organisational cultural traits and indices that are essential as the South African healthcare system is being reformed in preparation for the implementation of the national health insurance.

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**Data availability statement** Data are available in a public, open access repository. The data on Organizational Culture and the Integrated Chronic Diseases Management Model Implementation Fidelity in South Africa is available on Figshare via the following URL: <https://doi.org/10.6084/m9.figshare.11365721.v2>

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## Chapter 7: The costs of implementing the ICDM model

The estimated costs of implementing the ICDM model in primary healthcare clinics in South Africa results have been presented in the form of a manuscript that is embedded in this chapter.

*Lebina L, Kawonga M, Oni T, Kim H, Alaba OA. The cost and cost implications of implementing the integrated chronic disease management model in South Africa. (PLOS ONE – under review.)*

This chapter covers the fourth objective (to estimate the implementation costs of the ICDM model) of the thesis.

**The relevance of the publication to the thesis:** This manuscript describes the estimated cost of implementing the ICDM model in primary healthcare (PHC) clinics in South Africa. Cost data from the provider's perspective were estimated for the implementation of the ICDM model current activities for three components (facility reorganization, clinical supportive management, and assisted self-management) and additional costs of implementing with enhanced fidelity. Budgeted costs were utilized as proxy in instances where actual expenditure reports were not available. The recommended ICDM model activities were not included in the cost analysis as the activities are extensive and most of the costs would be incurred by collaborating organizations. Due to lack of data on the effectiveness of the ICDM model in terms of optimizing clinical outcomes, a cost analysis was done by means of empirical micro-costing. As standard healthcare costs like medication, laboratory investigations, and management of complications are not related to the ICDM model activities, they were excluded from this analysis. One-way sensitivity analyses were performed on all cost estimates that were major components of both current and additional costs.

This paper also shows that the greater portion of the costs is current costs. The additional cost of implementing the ICDM model with higher fidelity was minimal and comprised mainly of costs for facility reorganization and training of personnel. Furthermore, this manuscript provides information on the additional resources required to enhance the fidelity of the

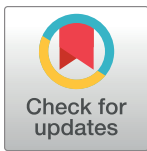
## RESEARCH ARTICLE

# The cost and cost implications of implementing the integrated chronic disease management model in South Africa

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## Abstract

### Background

A cost analysis of implementation of interventions informs budgeting and economic evaluations.

### Objective

To estimate the cost of implementing the integrated chronic disease management (ICDM) model in primary healthcare (PHC) clinics in South Africa.

### Methods

Cost data from the provider's perspective were collected in 2019 from four PHC clinics with comparable patient caseloads (except for one). We estimated the costs of implementing the ICDM model current activities for three (facility reorganization, clinical supportive management and assisted self-management) components and additional costs of implementing with enhanced fidelity. Costs were estimated based on budget reviews, interviews with management teams, and other published data. The standard of care activities such as medication were not included in the costing. One-way sensitivity analyses were carried out for key parameters by varying patient caseloads, required infrastructure and staff. Annual ICDM model implementation costs per PHC clinic and per patient per visit are presented in 2019 US dollars.

### Results

The overall mean annual cost of implementing the ICDM model was \$148 446.00 (SD: \$65 125.00) per clinic. Current ICDM model activities cost accounted for 84% (\$124 345.00) of

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the annual mean cost, while additional costs for higher fidelity were 16% (\$24 102.00). The mean cost per patient per visit was \$6.00 (SD:\$0.77); \$4.94 (SD:0.70) for current cost and \$1.06 (SD:0.33) for additional cost to enhance ICDM model fidelity. For the additional cost, 49% was for facility reorganization, 31% for adherence clubs and 20% for training of nursing staff. In the sensitivity analyses, the major cost drivers were the proportion of effort of assisted self-management staff and the number of patients with chronic diseases receiving care at the clinic.

## Conclusion

Minimal additional cost are required to implement the ICDM model with higher fidelity. Further research on the cost-effectiveness of the ICDM model in middle-income countries is required.

## Background

Chronic diseases are a major public health challenge, accounting for 60% of all deaths, with 35% and 40% of deaths due to chronic diseases occurring in low and middle income countries respectively [1–3]. Chronic diseases can cost up to 7% of a country's gross domestic product (GDP) due to the undesirable effect these diseases have on economic activities and increased public health and social welfare expenditure [3, 4]. In high-income settings such as the USA, Europe and Spain, the cost of the increasing number of chronic illnesses account for 75%, 80% and 77% of the total healthcare cost respectively [5, 6]. The key drivers of cost in health systems are increased utilization of services, medication and health system adaptation of service delivery [3].

South Africa, like many low and middle-income countries, has a dual burden of chronic diseases, with a high prevalence of both communicable and non-communicable chronic diseases [7, 8]. Data from Free State Province indicate that 24% of the population suffer from chronic diseases [9]. Results from a Cape Town study showed that prevalence of multi-morbidity is approximately 23%, and chronic diseases account for 45% of all primary healthcare (PHC) consultations [10]. Nevertheless, the diagnostic tools, training and supervision of clinical staff as they manage and provide care for chronic conditions are inadequate, particularly at the PHC level [11, 12]. In an effort to address this challenge, the South African Department of Health developed and implemented the integrated chronic disease management (ICDM) model [13]. The ICDM model was developed based on the principles of the chronic care model (CCM) and innovative care for chronic conditions (ICCC) framework [13, 14]. Research in other settings has indicated that integrated chronic care models improve patient care and health outcomes [15–17].

The aim of the ICDM model is to provide a comprehensive chronic disease management model that reduces healthcare utilization and promotes self-management among patients with chronic diseases [13, 14]. Patients who are incorporated into the ICDM model include adults and children with chronic communicable (HIV/AIDS and tuberculosis) and non-communicable (hypertension, diabetes, asthma, chronic obstructive pulmonary disease, mental health and epilepsy) diseases [13]. The ICDM model consists of four inter-related components, namely facility reorganization, clinical supportive management, assisted self-management and strengthening of support systems [13, 14].

Facility reorganization activities include management of patient flow, bookings and records to enhance clinic operational efficiency [13]. Clinical supportive management includes the activities of the district clinical specialist team (DCST) and the training of nurses on primary healthcare and management of the conditions included in the ICDM model [13]. Assisted self-management activities aim to empower patients to become involved in their disease management and be supported at community level [13]. Community level support is provided by ward-based outreach teams (WBOTs) and community healthcare workers (CHCW). Patients with chronic conditions who are stable on treatment are offered the option of collecting pre-packed medication at the PHC clinic or at other outlets under the central chronic medicine dispensing and distribution (CCMDD) programme [13]. The strengthening of support systems promotes collaborations between the clinic and other departments like school health and support structures for health services delivery such as community organizations [13]. An assessment of the ICDM model implementation has shown enhancements in patients' records, improved health outcomes for HIV-positive patients on antiretroviral medication, but no substantial improvements for patients with hypertension [18, 19].

Developing, implementing and evaluating effectiveness and implementation outcomes are essential in public healthcare research [20]. The implementation outcomes or measures of successful implementation an intervention or a programme, include amongst others, fidelity, implementation costs, acceptability and sustainability [21]. Implementation costs of interventions reveals the feasibility, scalability and sustainability of proposed integrated care interventions [20]. Implementation costs is one of the implementation outcomes that also allows decision makers to determine and choose which interventions are efficient and equitable [20]. Fidelity is the degree to which the implementation of a programme follows the original design as outlined in the guidelines [22, 23]. A process evaluation of the implementation fidelity of the ICDM model indicates that the level of fidelity (adherence) to guidelines varies between clinics, with some clinics having high scores (80%-89%), and others having medium (70%-79%) and low (<70%) scores [24]. Chronic care models are also cost-effective as they reduce healthcare services utilization and improved disease management [15–17]. However, there are no data on the cost of implementing the ICDM model in South Africa. The objective of this study was to estimate the empirical implementation cost of each of the components of the ICDM model in two health districts to inform planning, scaling-up and further economic evaluations. In addition, we assessed if the degree of fidelity to the ICDM model guidelines has an impact on the cost of implementing the ICDM model.

## Methods

### Overview

This analysis is nested within a larger study to assess the level and determinants of fidelity in the implementation of the ICDM model in the two health districts in South Africa [25]. We evaluated the cost of implementing three (facility reorganization, clinical supportive management, assisted self-management) of the four components of the ICDM model from the health system perspective. The strengthening of support systems was not included in the cost analysis as the activities are extensive and most of the costs are covered by collaborating organizations. In addition to evaluating the current cost of operating the ICDM model, we estimated the costing of the additional activities or infrastructure required to implement the ICDM model with a high degree of fidelity in a PHC clinic per annum. Due to lack of data on the ICDM model's effectiveness in optimizing clinical outcomes, we conducted a cost analysis using the empirical micro-costing. Standard healthcare service costs like medication, laboratory investigations and management of complications were excluded from the analysis to keep the focus on the ICDM

model activities. The standard costs would be incurred irrespective of the ICDM model and their inclusion would overestimate the costs of the ICDM model activities.

### The setting

The study was conducted in two health districts in South Africa, the West Rand (WR) district in the Gauteng province and the Dr. Kenneth Kaunda (DKK) district in the North West province [25]. These two health districts, as well as Bushbuckridge health district in Mpumalanga, were the pilot sites for implementing the ICDM model in South Africa on the initiative the South African National Department of Health in 2011 [26]. The two health districts were selected for this study as they have comparable population sizes and burden of disease. The population sizes in the two districts are similar (811 000 in WR and 716 000 in DKK health district) [27]. In 2011, the provincial HIV prevalence was also comparable (12.4% and 13.3% in Gauteng and North West, respectively [28]). Hypertension prevalence is high (31%- 39.7%) in both health districts, with high health service utilization for chronic non-communicable diseases [27]. In Gauteng, 63% of the households rely on state health facilities (clinics and hospitals) for health services, while 73% of the households in North West depend on state health facilities [29]. We selected these two districts as the ICDM model had been implemented in these districts for over 7 years. The cost analysis would therefore be representative of medium to long-term scale-up scenarios.

### Ethics approval

The study was approved by the ethics committees of the University of Cape Town (Ref: 127/2018) and the University of the Witwatersrand (Ref: R14/49).

### Data collection

**Clinic selection.** Four of the 16 PHC clinics that formed part of the larger ‘degree of fidelity’ study [25] were selected based on their ICDM model implementation fidelity scores and patient caseloads. One of the clinics with the highest [clinics A (87.%) and B (84.8%)] fidelity scores and one of the clinics with the lowest [clinics C (76.6%) and D(65.8%)] fidelity scores [24]. were chosen per health district for the cost analysis. The four clinics had comparable characteristics (personnel and patient consultations) as summarized in Table 1. However, clinic A had more consulting rooms and fewer patients consulting for chronic diseases management.

**Estimation of costs.** Costs were stated according to the 2019 prices and converted to US dollars (US\$) at an exchange rate of ZAR 14.42 equal to US\$ 1 [30]. The costs are reported as annual costs per PHC clinic and per patient with chronic disease per visit. The current cost and the additional cost of required infrastructure or unexecuted recommended ICDM model activities were estimated as outlined below.

**Facility reorganization cost.** The current costs were estimated based on interviews with key personnel, budget reviews and estimating the proportion of resources allocated to patients with chronic disease based on the clinic consultations records. On average, 59% of the patients attending the four PHC clinics were consulting for chronic disease care. Therefore, we used this proportion to apportion facility reorganization costs for the current activities. Items included in the cost estimate for current facility reorganization were building (reception, waiting areas, vital signs station and consulting rooms), equipment and furniture, and building maintenance costs. Additional infrastructure cost for facility reorganization were based on the estimates according to the guidelines, as well as current cost. The ICDM model guidelines recommend that patients with chronic diseases should have separate waiting rooms, a vital signs

**Table 1. Characteristics of the primary healthcare clinics included in the cost analysis of implementing the Integrated Chronic Disease Management (ICDM) model.**

Variable	Clinic A	Clinic B	Clinic C	Clinic D
<i>Fidelity to the ICDM model</i>				
	Score (Percentage)			
Overall fidelity of the ICDM model implementation	<b>136/158 (87.3)</b>	<b>134/158 (84.8)</b>	<b>121/158 (76.6)</b>	<b>104/158 (65.8)</b>
Facility reorganization	29/37 (78.4)	27/37 (73.0)	30/37 (81.1)	29/37 (78.4)
Clinical supportive management	37/39 (94.9)	33/39 (84.6)	29/39 (74.4)	20/39 (51.3)
Assisted self-management	36/39 (92.3)	37/39 (94.9)	27/39 (69.2)	30/39 (76.9)
Strengthening of support systems	34/43 (79.1)	37/43 (86.1)	35/43 (81.4)	25/43 (58.1)
<i>Number of Personnel</i>				
Professional nurses	4	5	6	10
Enrolled nurses	3	0	5	1
Medical officers	1	1	5	1
Pharmacists assistant	0	0	1	0
Administrative staff	5	8	3	1
Counsellors	2	6	4	7
WBOT <sup>^</sup> Leaders	4	2	4	2
WBOT <sup>^</sup> /CHCW <sup>#</sup>	4	13	50	17
Nurse patient ratio	333	731	370	340
Medical officer patient ratio	2328	3655	814	3735
<i>Patient consultations per month, per facility mean (SD)</i>				
Total primary healthcare headcount	2328 (150)	3655 (206)	4068 (146)	3735 (245)
Total patients >20 years per month per facility	1530 (126)	2457 (187)	2865 (106)	2795 (233)
Total patients with chronic diseases consultations*	981 (67)	2653 (133)	2922 (302)	1802 (144)
Proportion of patients with chronic diseases consultation to total headcount	42%	73%	72%	48%
Adults in care for HIV/AIDS	687 (38)	2240 (27)	2004 (48)	1434 (13)
New TB diagnosis	2 (1)	4 (5)	3 (1)	14 (3)
Diabetic patients consultation	63 (8)	90 (24)	144 (30)	57 (4)
Hypertensive patients consultations	243 (34)	344 (119)	768 (157)	227 (126)
Nurse patient ratio	259	406	452	414
<i>Infrastructure</i>				
Total area in m <sup>2</sup>	557	1367	491	442
Number of consulting rooms	8	5	2	3
Vital signs stations	1	1	1	1
Waiting areas	2	1	1	2
Reception/Medical Reocords	1	1	1	1

<sup>^</sup>WBOT–Ward-based outreach teams

<sup>#</sup>CHCW–Community healthcare worker

\*Based on the number of patients with each disease. and not taking into consideration multi-morbidity

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station and consultation rooms. On evaluation of the fidelity and patient flow analysis, some clinics did not meet the guidelines for adequate infrastructure. Therefore, the additional facility reorganization cost was calculated by calculating the cost of building an additional three consultation rooms for clinics C and D only, as clinics A and B had adequate consultation rooms according to the guidelines. Furthermore, additional facility reorganization costs included building a waiting area, a vital signs station, a CCMDD kiosk and a multi-purpose meeting room for adherence clubs meetings for each of the four clinics. The South African building cost of US\$ 561.17 per m<sup>2</sup> was used to estimate the cost of building the additional

recommended areas based on valued office building costs [31]. The size of the rooms, furniture and equipment requirements were based on the data collected and the guideline recommendations [32, 33]. The cost of the equipment and furniture were sourced from large furniture and medical supplies stores. A discount rate of 7% [34] was applied to calculate the annual cost of buildings, furniture and equipment with an estimated life span of 20 years, 10 years and 5 years respectively.

**Clinical supportive management cost.** The current cost of clinical supportive management were calculated based on costs of the DCST providing support to each PHC in the district. The DCST in the DKK district did not provide support to PHC clinics on management of patients with chronic diseases, so the cost of providing the DCST in the WR district was used for the DKK district. The proportion of time apportioned to patients with chronic diseases was determined by interviewing the DCST leader in the WR health district. The proportion allocation of personnel (family physician, senior pediatric medical officer, pediatric nurse and senior PHC nurse) costs and telecommunication costs for the DCST to ICDM model was calculated and divided by number of clinics in each health district. The additional cost of clinical supportive management was for training nurses on PHC- and nurse-initiated management of antiretroviral treatment (NIMART) [13]. The training cost was obtained from a training organization that delivers the two training courses on behalf of the Department of Health. We worked on the assumption that all professional nurses at the clinics would have to be trained to account for staff turn-over. Travel cost was not included as the training is usually delivered in the district.

**Assisted self-management cost.** The current costs of CHCW, WBOT and supervision was estimated according the current salaries and the proportion of time allocated by the staff members to support patients with chronic diseases. Staff salary values were informed by the National Department of Health salary scales. All four of the PHC clinics had no functional adherence clubs, thus the additional cost of training staff on adherence support and ongoing provision of the adherence clubs was sourced from the literature [35]. Data on adherence clubs' cost were only available for 2011 [35], and the average inflation of 5.4% was applied to estimate the costs for 2019.

**Sensitivity analysis.** One-way sensitivity analyses were performed on all cost estimates that were major (> 4%) components of the cost for both current and additional costs. We varied the discount rate from 4% to 9% (based on data for the last 5 years [34]) to assess the different scenarios of cost for current and additional building costs. In addition, under the current cost, building and building maintenance were varied for the proportion of patients that consult for chronic disease using one standard deviation of the mean of 59% as this was applied in the initial analysis. For the additional costs, building cost was varied depending on whether additional consulting rooms are required. One standard deviation (SD) was applied to calculate the highest and lowest cost for WBOTs and WBOT supervision from the mean effort of 62% and 52% respectively. The mean number of patients and the SD were used in the sensitivity analyses for the adherence club cost. The SD of the numbers of nurses that have to be trained was applied for the NIMART and PHC training sensitivity analysis.

## Results

### Implementation cost of the ICDM model

**The overall ICDM model implementation cost.** Based on the data collected from the four PHC clinics, the annual cost (current and additional costs) of implementing the ICDM model per PHC clinic varied from \$77 726.00 in clinic A to \$232 103.00 in clinic C (Table 2). The mean overall annual cost of implementing the recommended activities of the ICDM

**Table 2. The estimated annual current and additional costs to enhance the fidelity to the ICDM model recommended activities in the four study clinics—A and B high fidelity, C moderate and D low fidelity.**

	ICDM Model Component	Items	Clinic A	Clinic B	Clinic C	Clinic D
Current Costs	Facility reorganization	Building	\$12 432.88	\$52 559.23	\$18 681.49	\$11 321.36
		Furniture	\$1 580.38	\$2 162.55	\$1 726.56	\$1 346.59
		Equipment	\$746.67	\$ 867.02	\$443.22	\$390.56
		Building maintenance	\$ 3 118.68	\$13 184.02	\$4 686.08	\$2 839.86
	Clinical supportive management	DCST	\$1 019.93	\$1 218.25	\$1 019.93	\$1 218.25
	Assisted self-management	WBOT Supervision	\$31 128.78	\$29 288.06	\$31 128.78	\$29 288.06
		WBOT	\$ 11 618.26	\$37 759.34	\$145 228.22	\$49 377.59
Total current costs			<b>\$61 645.58</b>	<b>\$137 038.46</b>	<b>\$202 914.28</b>	<b>\$ 95 782.28</b>
Additional Costs to enhance Fidelity	Facility reorganization	Building	\$ 7 395.30	\$7 395.30	\$9 296.95	\$9 296.95
		Furniture	\$150.46	\$150.46	\$1 630.84	\$1 630.84
		Equipment	\$56.45	\$56.45	\$807.28	\$ 807.28
		Building maintenance	\$1 855.05	\$1 855.05	\$2 332.06	\$2 332.06
	Clinical supportive management	NIMART Training	\$1 715.08	\$ 2 143.85	\$2 572.61	\$ 4 287.69
		PHC Training	\$1 400.83	\$1 751.04	\$2 101.24	\$3 502.07
	Assisted self-management	Adherence Club	\$3 507.47	\$9 485.54	\$10 447.32	\$6 442.87
	Total additional costs			<b>\$16 081</b>	<b>\$22 838</b>	<b>\$29 188</b>
Estimated total costs of implementing ICDM model in each PHC clinic (Current costs + additional costs to enhance fidelity)			<b>\$77 726.21</b>	<b>\$159 876.14</b>	<b>\$232 102.59</b>	<b>\$124 082.04</b>
Costs per patient per visit						
Current costs per patient per visit			\$5.24	\$4.30	\$5.79	\$4.43
Additional costs per patient per visit			\$1.37	\$0.72	\$0.83	\$1.31
Total mean costs per patient per visit			\$6.60	\$5.02	\$6.62	\$5.74

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model per facility was \$148 447.00 (SD: \$65 125.00), and the mean cost per patient per visit was \$6.00 (SD:\$0.77). Capital costs were 24% (\$35 760.09) of the total annual mean costs. Current cost contributed 84% (\$124 345.00) of the total annual mean cost, while additional cost accounted for 16% (\$24 102.00) (Table 3). Almost two-thirds of the current cost came from the personnel cost of the WBOTs/CHCW and their supervision under assisted self-management (66%; \$91 204.00). For the additional annual cost, facility reorganization accounted for 49% (\$9 668.64), while adherence clubs and the training cost for nurses were 31% (\$7 470.80) and 20% (\$4 868.60) respectively. The additional recurrent costs to achieve higher ICDM model fidelity per patient per visit was \$0.62 (SD: 0.15).

In all of the four PHC clinics, the current cost was higher than the additional (infrastructure, training and adherence clubs) cost required to enhance the degree of fidelity. The cost per patient per visit for each of the four clinics for the current cost ranged from \$4.30 to \$5.79 (mean: \$4.94; SD:0.70) and the additional cost from \$0.72 to \$1.37 (mean: \$1.06; SD:0.33). The clinics with the higher level of ICDM model implementation fidelity had a lower additional annual cost [clinic A (\$16,081) and clinic B(\$22,838)], compared to those with lower degree of fidelity [clinic C (\$29,188) and clinic D (28,299)].

**Facility reorganization.** The mean cost of facility reorganization contributed 25.8% (\$32 021.79) to the current annual cost and 49% (\$9 668.64) to the additional annual cost. The building costs for clinic B are higher compared to the other clinics as it is based in a large repurposed manunicipality building. These additional facility reorganization cost included the capital investment of building additional facilities dedicated for chronic patients, such as a vital signs station, a waiting area, a CCMDD kiosk and a multi-purpose room in all four clinics, as well as three consulting rooms in two of the clinics. The cost of maintaining the

**Table 3. Mean current and additional annual costs of implementing the recommended activities for ICDM model per PHC clinic.**

	ICDM Model Component	Items	Estimated annual costs Mean (SD)	Proportion of costs
Current Costs	Facility reorganization	Building	\$23 748.74 (19 478)	19.1%
		Furniture	\$1 704.02 (343)	1.4%
		Equipment	\$611.87 (231)	0.5%
		Building maintenance	\$5 957.16 (4 886)	4.8%
	Clinical supportive management	DCST	\$1 119.09 (115)	0.9%
	Assisted self-management	WBOT Supervision	\$30 208.42 (1 063)	24.3%
		WBOT	\$60 995.85 (58 333)	49.1%
<i>Total current costs</i>			<b>\$124 345.15 (60 776)</b>	100%
Additional Costs	Facility reorganization	Building	\$8 346.12 (1 098)	34.6%
		Furniture	\$890.65 (855)	3.7%
		Equipment	\$431.87 (433)	1.8%
		Building maintenance	\$2 093.55 (275)	8.7%
	Clinical supportive management	NIMART Training	\$2 679.81 (1 128)	11.1%
		PHC Training	\$2 188.80 (928)	9.1%
	Assisted self-management	Adherence Club	\$7 470.80 (3 146)	31.0%
	<i>Total additional costs</i>			<b>\$24 101.60 (6 040)</b>
Current costs			\$124 345.15	85%
Additional costs			\$24 101.60	15%
Total mean costs of implementing ICDM model			<b>\$148 446.75 (65 125)</b>	100%

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additional spaces, for instance ensuring cleanliness, water and sanitation was estimated at \$2 093.55 per annum. The mean cost of equipment and furniture was estimated at \$1 322.52 per annum.

**Clinical supportive management.** Clinical supportive management activities accounted for 0.9% (\$1 119.09) of the total current annual cost of implementing the ICDM model. The mean cost of the DCST providing support to each health facility was low as the proportion of time allocated to support each clinic was low. The DCST cost varied slightly between the two health districts; the cost in WR was \$1 022.76 while in the DKK it was \$1 221.63. The cost for providing NIMART and PHC training for the nurses was significantly higher and accounted for 20% (\$4 868.60) of the additional annual cost.

**Assisted self-management.** Interviews with managers and a review of the reports of the CHCW and WBOT staff members indicated that WBOTs/CHCW allocate 62% (SD: 43%) of their time to adherence support and tracing defaulters on chronic medication. The mean number of WBOT/CHCW per facility was 21 (SD:20) (Table 1), and each earns \$242 72 per month. The WBOTs and CHCW are supervised by nurses for a portion of their time at a mean of mean 52% (SD:12%). In two of the PHC clinics, two professional nurses provided supervision (clinic A and C) clinics and in the other two, four enrolled nurses provided this service (clinic B and D). The estimated current mean annual cost of providing assisted self-management was \$60 995.85 (SD:\$58,33) for WBOTs/CHCW and \$30 208.42 (SD:1,063) for their supervision. The costs per clinic for WBOTs/CHCW differed by clinic as it is greatly affected by the number of WBOTs/CHCW based at each clinic according to the number of community wards. For example the cost for clinic C was \$145 228.22 for 50 WBOTs/CHCW versus \$11 618.25 in clinic A for 4 WBOTs/CHCW. The additional cost of providing adherence clubs for assisted self-management varied from \$3 507.47 in a clinic with 981 patients with chronic disease consultations per month (Clinic A) to \$10 477.32 in a clinic with almost 3000 patients per month (Clinic C).

**Sensitivity analysis.** The key parameters in the cost model and the one-way sensitivity analyses are outlined in Table 4 and Fig 1. The current building cost was \$18 513.18 at discount rate from 4% and \$25 625.80 at 9%; while additional building cost was \$6 506.17 and \$9 005.79 for 4% and 9% discount rates. Based on the one-way sensitivity analysis, the major cost drivers are the proportion of effort of the WBOTs/CHCW per WBOTs supervisor and the number of patients accessing chronic disease care. Varying the building cost according to whether or not additional consulting rooms are included also revealed that building is a major cost driver in the additional cost (Fig 1B).

## Discussion

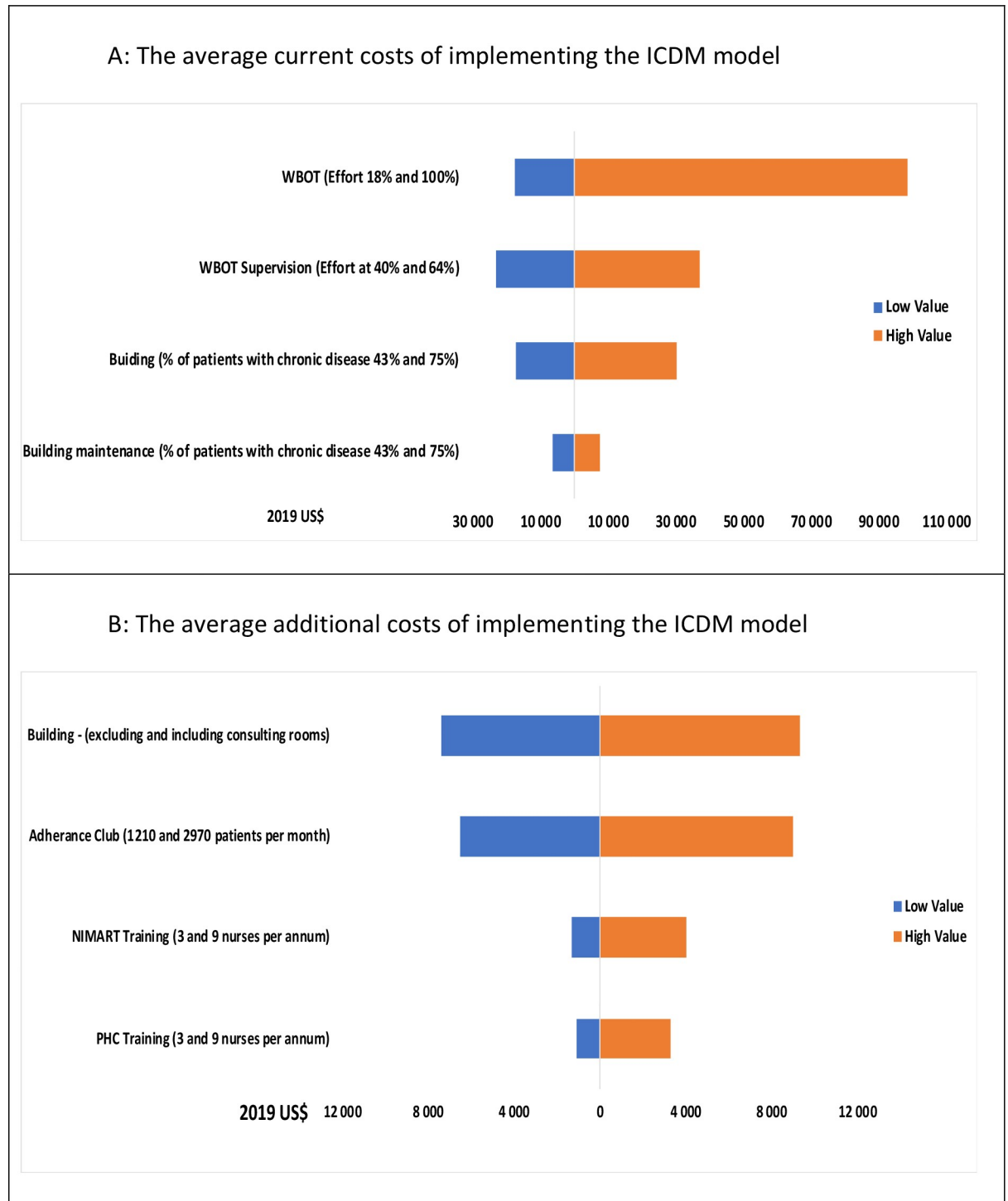
From the provider's perspective, we estimated that the annual mean cost of implementing the ICDM model activities are \$148 446.75 per clinic or \$6.00 per patient with chronic disease per visit. The current cost was the largest component of the overall ICDM model implementation cost. The additional costs were lower for clinics with a higher degree of implementation fidelity. Facility reorganization accounted for 49%, adherence clubs 31% and training of nursing staff 20% of the additional mean cost. Assisted self-management was the most costly component of the ICDM model to implement, and it contributed 73% of the current cost and 31% of the additional cost. The overall ICDM model implementation cost varied between the four study PHC clinics. The major cost drivers were the number of patients accessing services for chronic disease management and associated WBOTs to support assisted self-management and the required additional infrastructure.

The annual cost of implementing the ICDM model activities was \$148,446.75 per clinic. The cost of implementing a team-based chronic care model in another study conducted in northern California, USA, was estimated at \$2 304 787.00 over 29 months (\$79 475.41 per month) [36]. Chronic disease management, particularly in the context of multimorbidity, is the largest expense for health systems [4–6]. More research and strategies to improve the effectiveness of the ICDM model to enhance health outcomes for all chronic diseases are important to support such an expenditure [18, 19]. A systematic review showed other types of integrated care for chronic diseases, based on similar principles as the ICDM model to be cost-effective by reducing health utilization and improving health outcomes [16]. All the studies that were reviewed had been conducted in high-income countries [16]. In this study, the current cost was the largest component of the total estimated mean annual cost of the ICDM model. This

**Table 4. The range of key parameters in the costs model.**

Key cost parameter	Baseline ( <i>mean</i> )	Standard deviation	Range
<b>Current costs</b>			
Building—proportion of patients with chronic diseases	59%	16%	43% -75%
Building maintenance—proportion of patients with chronic diseases	59%	16%	43% -75%
WBOT supervision—effort on ICDM model activities	52%	12%	40%– 64%
WBOT—effort on ICDM model activities	62%	43%	18% - 100%
<b>Additional costs</b>			
Building—including or excluding additional consulting rooms	3	N/A	0–3
Adherence club—number of patients with chronic diseases	2 090	880	1 210–2 970
NIMART training—number of nurses to be trained per annum	6	3	3–9
PHC training—number of nurses to be trained per annum	6	3	3–9

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**Fig 1. Torando diagram summarizing one-way sensitivity analyses of mean and cost of implementing the recommended activities of the ICDM model per PHR clinic. Middle line = zero costs.**

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reflects the increased allocation of financial resources by the South African Department of Health to PHC clinics to ensure that there is adequate infrastructure, medicines and supplies at PHC clinics [32].

The major contributor to the additional cost was additional infrastructure required for facility reorganization activities. These costs are lower than the cost of assisted self-management and clinical supportive management. However, the expenditure requires capital investment for which the health system might not have an available allocated budget. Clinical supportive management activities were the least costly, contributing 6% of the total cost. A report from South Africa has revealed that chronic diseases (diabetes, hypertension, asthma and epilepsy) are not adequately managed at PHC clinics, and there are few healthcare workers with adequate and competent training [37]. Our study findings support the view that a relatively low-cost investment in clinical supportive management can potentially have a high yield, improving quality of care for patients with chronic diseases.

Assisted self-management was the most costly component of the ICDM model to implement, and contributed 73% of the current cost and 31% of the additional cost. There was a great variability among clinics as some clinics were allocated more personnel. Human resource cost was also the highest cost in a team-based chronic care model [36]. In a study in Poland, the addition of integrated home-orientated services that included education and family support for patients with advanced chronic obstructive pulmonary disease (COPD) reduced the overall cost of care from the health system perspective [38]. The main reasons for cost reduction were reduced hospitalizations and disease exacerbations [38]. However, in other studies, the chronic care model reduced costs related to unplanned hospitalization, but increased costs for out-patient consultations and medication [39, 40]. Community-based adherence support and delivery of medication reduces the cost of accessing care from the patient's perspective. Cost has been mentioned as the greatest barrier to seeking care among 47% of patients in South Africa [41]. Affordability is greatly affected by travel cost as many of the PHC clinics are not within a walking distance of patients, especially in rural areas [42]. Despite the high cost of assisted self-management, it is an important component of chronic disease management to support adherence and reduce overcrowding at PHC clinics.

The cost of implementing the ICDM model activities varied across the four study PHC clinics, and the major cost drivers were the number of patients with chronic diseases consulted, as well as personnel for assisted self-management and the required additional infrastructure. High building costs for large clinics also contributed to some of the variation in clinic costs. A systematic review of chronic disease management programmes implemented in high-income countries showed that 14/16 (88%) of the studies demonstrated cost-effectiveness based on quality-adjusted life-year, while two studies had less than US\$30 000 per life-year gained. Some of the reasons for the differences in the outcomes include the components of the chronic disease management programme that were implemented, the type of chronic disease being treated and level of comprehensiveness in measuring the costs [43]. In another study on a diabetes quality improvement project in five clinics in the USA, the cost of providing chronic care services per patient with diabetes per year varied from \$6 in large clinics to \$68 in small clinics [44].

### Strengths and limitations

The strength of this study is that it is one of the few studies that provides a cost analysis of implementing a chronic disease management model in a middle-income country. Moreover, most of the costs in the cost analysis are based on the actual costs for clinics to implement the ICDM model recommended activities. The results of this cost analysis could also be used for additional economic evaluations of the ICDM model. As data were collected from only four PHC clinics, a limitation of the study is that this small sample size could have resulted in large variability in the observed results. The generalizability of these results could also be limited by

this small sample size. However, we minimized this by including clinics with different degrees of implementation fidelity to the ICDM model from two different provinces. Therefore, this data would be informative for budgeting and resource allocation for clinics with similar characteristics. Another limitation of this analysis is that it does not include a full cost-effectiveness analysis as there is limited data on the effectiveness of the ICDM model in South Africa. The standard healthcare costs, like laboratory investigations, treatment of complications and medication was not included in the calculations and that leads to an underestimation of the overall cost of providing care to patients with chronic diseases. Lastly, only three of the four components of the ICDM model were included in the analysis. Therefore more research is needed on the implementation costs of the ICDM model activities related to strengthening of support systems.

## Conclusion

The estimated mean cost of implementing the ICDM model activities was \$6.00 per patient with chronic disease per consultation. The greater portion of the costs are current costs. The additional cost of implementing the ICDM model with higher fidelity was minimal and comprised mainly of costs for facility reorganization and training of personnel. The mean cost of implementing the ICDM model activities varied between clinics and were affected by patient case load and the required additional infrastructure. The results of this cost analysis can enable additional ICDM model cost evaluations and budgetary planning for scale-up and scale-out of the ICDM model or similar models in countries with a similar disease burden and resources. Furthermore, this study provides information on the additional resources required to enhance the fidelity to the implementation of the ICDM model. Further research is needed on the cost-effectiveness of implementing the ICDM model for the management of patients with chronic diseases in South Africa and other similar contexts, as most of the studies published on cost-effectiveness of chronic care models are from high-income countries.

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## Chapter 8: Discussion, conclusion and recommendations

### 8.1. Overview

This chapter presents a summary of key findings on the study on fidelity and the costs of implementing the integrated chronic disease management model in South Africa. The aims, methodologies utilised and key research findings, as well as strengths and limitations are discussed in this chapter, demonstrating coherence of this body of work. In addition, contributions to science, recommendations for health systems research, and future research are also described.

### 8.2. Thesis aim and methods

Chronic diseases are a major cause of morbidity and mortality in South Africa<sup>6, 7, 56-59</sup>. The primary healthcare (PHC) system has gaps in the provision of chronic disease management including inconvenient opening times; long waiting times; shortage of medication, equipment and medical supplies; low rates of diagnosis; inadequate clinical supervision; and failure to achieve treatment targets<sup>20, 21, 80</sup>. The ICDM model was developed and implemented at PHC level to improve operational efficiency and quality of care provided to patients with chronic diseases<sup>268</sup>. As outlined in literature review chapter, there is a dearth of studies assessing the implementation of CDM models in LMIC countries and CDM models that include both NCDs and CDs. The aim of this study, therefore, was to assess the degree of fidelity and implementation costs of the ICDM model and identify moderating factors of implementation fidelity of the ICDM model. The ICDM model activities have been categorized into four components, namely, facility reorganization, clinical supportive management, assisted self-management, and strengthening of support systems<sup>268</sup>. The eight conditions to be managed under the ICDM model are tuberculosis, HIV/AIDS, diabetes, hypertension, mental health, epilepsy, asthma, and chronic obstructive airway disease<sup>268</sup>.

This was a cross-sectional study conducted between August 2018 and August 2019 in Dr. Kenneth Kaunda (DKK) health district in North-West Province, and West Rand (WR) health district in Gauteng Province. The study was conducted in 16 clinics (8 in DKK and 8 in WR) in the two health districts that were the pilot sites for the ICDM model implementation<sup>268</sup>. The

process evaluation framework was applied to evaluate how well the clinics adhered to the ICDM model guidelines and to estimate the ICDM model implementation costs. The process evaluation framework is useful for assessing fidelity and clarifying the usual mechanisms and processes and identifying the impact of contextual factors on the variations in processes and outcomes<sup>357</sup>.

*Table 8.1: The four research questions and the methodology in the study on fidelity and implementation costs of the ICDM model*

Research Question	Methodology
1. To assess the degree of fidelity in the implementation of the ICDM model	Scored each clinic on fidelity criteria with 89 activities and a maximum score of 158. Value stream mapping of patient flow to analyse waiting time and identify operational inefficiencies.
2. To identify moderating factors of implementation fidelity of the ICDM model.	Qualitative interviews with a total of 30 healthcare workers from four clinics with different levels of implantation fidelity. Quantitative data was collected on clinic characteristics to assess factors associated with a higher fidelity of the ICDM model.
3. To assess whether the organizational culture (as a moderating factor) influences fidelity in the implementation of the ICDM model	The abbreviated Denison organizational culture (DOC) survey tool was administered to 90 staff members to assess three cultural traits – involvement, consistency, and adaptability – of six study clinics.
4. To estimate the cost of implementing the integrated chronic disease management (ICDM) model	Current and additional costs of implementing the ICDM model with higher fidelity for the activities of three components of the ICDM model were estimated from budget reviews, interviews with management teams, and other published data

Although the initial plan was to also follow the process evaluation framework (Figure 8.1A and B) for identifying the moderating factors that influence the degree of fidelity, the implementation fidelity framework was incorporated into this assessment (Figure 8.1C). The conceptual framework for implementation fidelity describes the four fidelity moderating factors as intervention complexity, facilitation strategies, quality of delivery, and participant responsiveness<sup>270</sup>. Figure 8.2 outlines how the two frameworks (process evaluation and implementation fidelity) were merged in this study. In Table 8.1, the four research questions and the methodology are summarized.

Figure 8.1: The process evaluation framework<sup>357</sup>, the modified process evaluation framework and the modified Carroll's conceptual framework on implementation fidelity<sup>358</sup>.

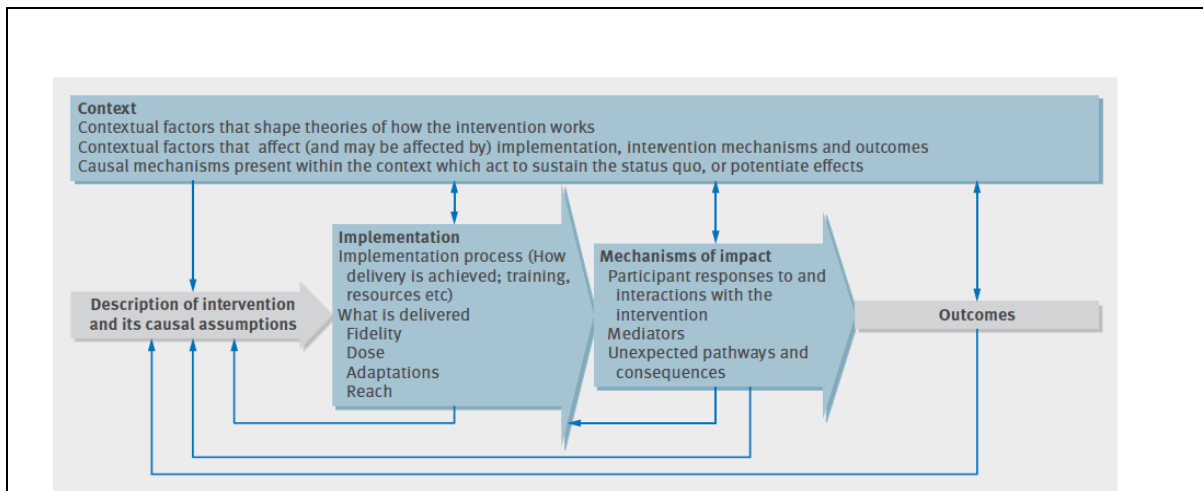


Figure 8.1A: Key Components and their relationships of Process Evaluation<sup>357</sup>

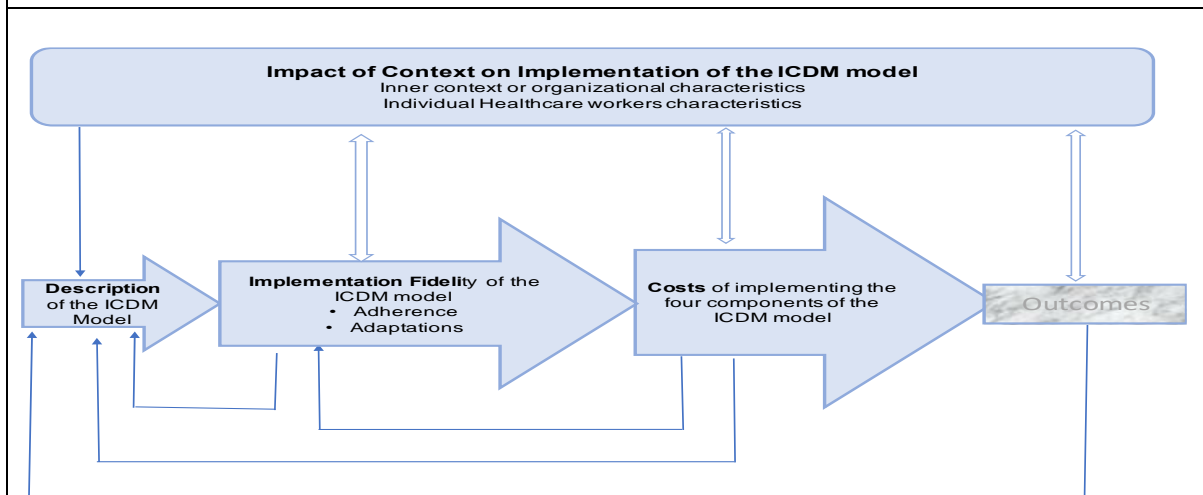


Figure 8.1B: Modified Process Evaluation Framework for assessing the fidelity and cost of the ICDM model implementation

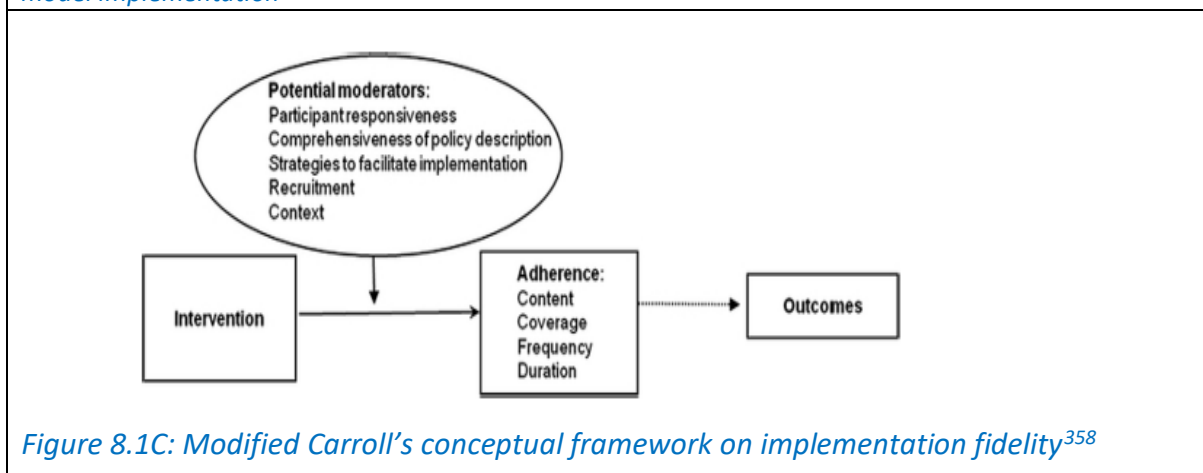
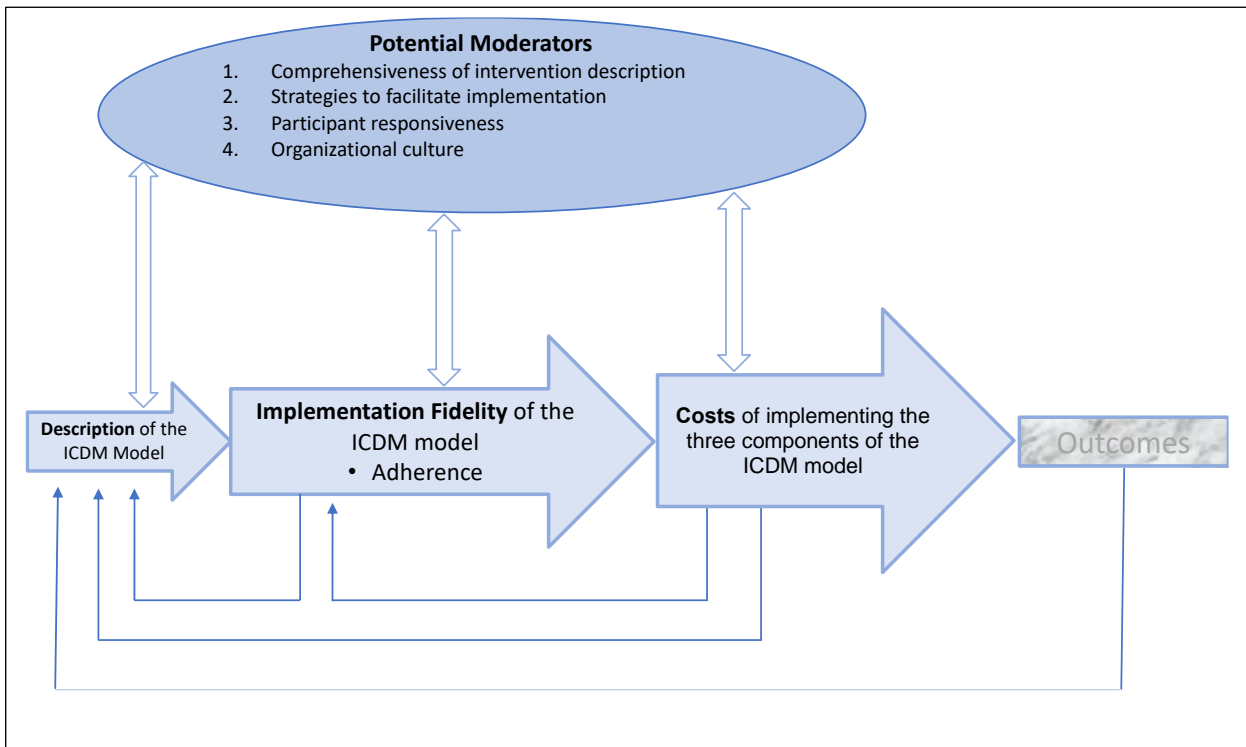


Figure 8.1C: Modified Carroll's conceptual framework on implementation fidelity<sup>358</sup>

Figure 8.2: The modified and merged process evaluation and the implementation fidelity frameworks as applied in this study



### 8.3. Discussion of findings

The findings from the thesis were presented and discussed in the four manuscripts included in Chapter 4 to 7 as part of the thesis. Figure 8.1 and 8.2 show how the research questions and findings are linked. In summary, the study clinics had a moderate to a high degree of fidelity in the implementation of the ICDM model and required an estimated additional one US dollar per patient per visit to enhance the level of fidelity. The moderating factors for implementation fidelity were training and clinical mentorship, integration, compliance of patients, and staff attitudes. The key findings are outlined below.

#### 8.3.1. Fidelity in the implementation of the ICDM model

The median overall fidelity score for the 16 participating clinics was 79%. The strengthening of support systems and facility reorganization had the highest scores of 79% each, whereas the scores for assisted self-management was 78%, and clinical supportive management scored lowest at 76%. The highest ICDM model implementation fidelity score for a clinic was 86%, while the lowest was 66%. An application of the South African ideal clinic scoring system<sup>120</sup> resulted in six clinics receiving silver status (70-79%), eight clinics gold (80-89%), and two clinics not achieving minimum requirements.

Integration (medical records, healthcare worker, time, space), functional ward-based outreach teams, and alternative medication collection were the recommended ICDM model activities with the highest degree of fidelity. The activities implemented with the lowest fidelity were scheduling of appointments, separate streams of care, availability of clinical guidelines, chronic disease resource material for patients, regular health promotion talks, and equipment and supplies management. The district clinical specialist team did not provide clinical mentoring and support to all the clinics. The clinics in Dr. Kenneth Kaunda health district had lower median fidelity score compared to those in the West Rand health district (74% vs. 80%), but the difference was not statistically significant. However, the facility reorganization scored significantly higher in the West Rand health district. Failure to adhere to some of the recommended activities were as a result of other initiatives to improve operational efficiency. For example, medication is stored in the consulting rooms in 15 of the 16 clinics; however, the medicine supply and management principles (e.g. stock cards, temperature monitoring) were only applied to the medication storage room.

Preretrieval of medical records a day before a booked visit was only implemented in one clinic, and that resulted in long waiting periods (a mean of 3 hours) before patients could have their medical records on the day of the visit. On average, patients were at the clinic for a total of 4 hours and 20 minutes, and only 13% (33 minutes) of that was for receiving services.

### 8.3.2. ICDM model implementation fidelity moderating factors

The staff members that were interviewed cited the following issues as the likely moderating factors for the ICDM model implementation fidelity.

*Intervention complexity:* Facility reorganization (a separate stream of care with dedicated waiting areas, vital signs station and consulting rooms) as recommended by the ICDM model principles was described as a disputable and problematic activity to implement with a high degree of fidelity. This was because there concerns of infection control for TB patients and inadequate infrastructure in some clinics. In addition, the expectation of a single nurse effectively managing all eight chronic diseases under the ICDM model was also considered highly demanding.

*Fidelity facilitation strategies:* Healthcare workers that were interviewed indicated that training of all staff members and clinical mentoring for doctors and nurses would foster the adoption and sustainability of high implementation fidelity of the ICDM model.

*Participant responsiveness:* Staff attitudes, poor compliance by patients (appointments and disease management plan), and stigma and discrimination were highlighted as some of the barriers to fidelity to recommended activities of the ICDM model.

*Context:* Adequate staff members, supply chain management, infrastructure (consulting rooms, waiting areas and filing room) and balanced caseload were some of the factors that eased the implementation of the ICDM model in clinics. The univariate analysis also indicated that increasing the number of consulting rooms, medical officers, nurses and pharmacy assistants is associated with an increase in the level of fidelity. However, mean monthly total patients and ratio of patients to clinical staff members did not have a significant effect on the clinic's fidelity levels.

### **8.3.3. Influence of organizational culture on ICDM model implementation fidelity**

In the six clinics that participated in the organizational survey part of the study, the involvement (aggregate of empowerment, team orientation, and capability development indices) cultural trait had the highest mean score compared to adaptability and consistency. Similarly, the top three mean scores on the cultural indices were for team orientation, empowerment, and core values. The cultural indices of integration, creating change and agreement, and coordination had the lowest mean scores. There were no significant differences in cultural traits or indices in clinics with low, medium or high implementation fidelity level of the ICDM model. However, there were statistically significant differences for all three (involvement, consistency, and adaptability) cultural traits between the two health districts, with West Rand having higher mean scores.

The high mean score for involvement is a vital cultural strength for an organization intending to improve the performance indicators and quality of services<sup>359</sup>. Organizational learning scored higher than customer focus under the adaptability cultural trait, which might indicate that, although best practices and new guidelines have been acknowledged, the clinics are unable to translate this knowledge into routine practice<sup>360</sup>. The low score for creating change could be attributed to decisions about new interventions made at higher (district and provincial) management level with very little bottom-up communication or consultation<sup>361</sup>. The significant variability in organizational culture mean scores between the two health districts could suggest that leadership and management from the district level has had an impact on staff engagement, motivation and organizational culture<sup>344</sup>.

### **8.3.4. The costs of implementing the ICDM model**

The estimated annual cost of implementing the three components of the ICDM model was \$148 447.00. There was a high variability (\$77 726.00 to \$232 103.00) in the annual cost of implementing the ICDM model in the four clinics that were part of the cost analysis study. However, the mean cost per patient per visit was US\$6.00, and there was an insignificant difference between the clinics. The current costs were higher than the estimated additional

costs to enhance the degree of fidelity in the implementation of the ICDM model at all four clinics. The clinics with a higher degree of fidelity had lower additional costs compared to those with lower levels of implementation fidelity. Personnel costs for assisted self-management accounted for most of the current costs. Training for nurses, additional infrastructure, and adherence clubs were the major contributors to additional costs. In the sensitivity analysis, the proportion of effort of the assisted self-management personnel and their supervisors and the number of patients accessing chronic disease care were the key cost drivers.

In conclusion, this study has shown that most clinics have moderate to high level of fidelity, and there are a few gaps that need to be addressed to enhance the degree of fidelity even further. It would be possible to address most of the barriers identified. The additional costs estimated for the enhancement of fidelity are not that high.

## **8.4. Conclusions and Recommendations**

### **8.4.1. Contributions to science**

Both high-income and LMIC countries are confronted with a high burden of chronic communicable and non-communicable diseases that contribute significantly to national morbidity and mortality figures<sup>1, 37, 38</sup>. Moreover, chronic disease – especially multi-morbidity – is associated with reduced functional capacity, depression, and higher utilisation of health services<sup>42, 43</sup>. Consequently, a greater proportion of health system resources are apportioned to the management of chronic diseases<sup>12, 362</sup>. One of the significant drivers of costs is the health system adaptation of service delivery to accommodate patients with chronic diseases<sup>1</sup>. Hence, many health systems have also implemented variants of chronic disease management models<sup>19, 41, 102-104</sup>. However, there is a dearth of studies that evaluate the implementation fidelity of chronic disease management models. Yet, implementation of an intervention in a large, complex, generally unpredictable health system that is resistant to change can be challenged.

The significance of the findings from this thesis is that it provides data on how the ICDM model intervention processes have been executed, and what the moderating factors to fidelity and the costs of implementing the intervention are. The identified activities that had low degree of fidelity and moderating factors are areas requiring quality improvement, identify any innovations that can improve models' processes and support systematic implementation of the model. These lessons could also be applied in other settings or countries, especially those similar to South Africa, that are implementing chronic disease management models. These data will also inform scaling up and scaling out of the ICDM model or other comparable interventions. Many health systems are also focusing on organizational culture reformations that emphasize desired outcomes. The organizational culture survey results could serve as a baseline prior to the execution of any interventions to enhance the culture to be more patient-centred, collaborative and caring. The implementation cost estimations would be valuable in budgeting and planning to enhance fidelity or for scaling up, as well as other economic evaluations.

#### **8.4.2. Implications and recommendations for health systems**

*Fidelity in the implementation of the ICDM model:* There is a high variability of scores on the degree of fidelity in the implementation of the ICDM model across clinics and health districts. Interventions to enhance fidelity should be tailored for addressing the observed gaps. Some clinics had high or gold status scores, and they could serve as advisors or mentors to other clinics that had low (< 70%) scores. Relentless and continuous monitoring of the silver and gold status clinics should be continued to ensure that these clinics maintain or improve their status. The activities with low fidelity scores indicate opportunities for improvement of the current implementation of the ICDM model. For example, improving access to clinical guidelines and clinical mentoring and support by the district specialist team could improve the quality of care provided to patients with chronic diseases. The unintended consequences of implementing the ICDM model, like poor adherence to medication storage guidelines in consulting rooms, also need to be addressed. The identified bottlenecks such as registration and consultation in patient flow could be targeted in improving waiting time in the PHC clinics.

*Moderating Factors:* The results provide various factors that could serve as facilitator or barrier to implementing the ICDM model with high fidelity. Some of these moderating factors such as training and mentoring of staff members, role clarification, and supply chain management could easily be amended for enhanced fidelity in the implementation of the ICDM model. However, some of the moderating factors require financial resources such as increasing and enlarging the infrastructure and providing additional staff members. Staff members observing the operational efficiency of implementing ICDM model activities may be reinvigorated to enhance the fidelity and sustainability of the model.

*Organizational culture:* The abbreviated Denison organizational culture survey showed excellent reliability in assessing the culture of clinics in South Africa. This survey is easy to administer and could be conducted as part of planning and quality improvement initiatives in the public healthcare sector in South Africa and other similar settings. Although the clinics showed a good balance of both internal and external focus, improvements are required in terms of integration, creating change, agreement, and coordination. Organizational culture improvements are recommended to ensure that the prevailing culture is aligned with the planned quality advancements prior to the implementation of new innovative interventions.

*Costs of implementing the ICDM model:* The health system is already expending 84% of the total costs required to implement the ICDM model with high fidelity. Only an additional one US dollar per patient per visit is required to enhance the care of patients with chronic diseases even further. Considering the high burden of chronic diseases in South Africa<sup>6,7,56-59</sup> and other countries<sup>1,37,38</sup>, it is defensible to plead for capital investment to augment the quality of care for patients with chronic diseases. Although there are no data from South Africa, the CDM models are effective in the management of the conditions incorporated in the guidelines<sup>99,186-211</sup>. There are ample data on the cost-effectiveness of chronic disease management models from other settings<sup>186,192,194,196,198,202,211-229</sup>, and further research is needed to show cost-effectiveness in South Africa.

## **8.5. Strengths and limitations of the thesis**

*Strengths:* The most important strength of this thesis is that it addresses an evidence gap from low and middle-income countries and contributes to knowledge of the level of implementation fidelity to chronic disease management model principles within the public health sector. This thesis is also one of a few studies that provide a cost analysis of implementing a chronic disease management model in LMIC countries and the results of this cost analysis could also be used for additional economic evaluations of the ICDM model. Moreover, most of the costs in the cost analysis are based on the actual costs for clinics to implement the ICDM model recommended activities. Sixteen clinics were selected from two health districts based in two different provinces in South Africa to minimize confounding factors. The fidelity assessment and value stream mapping of patient flow was conducted over multiple visits to the clinics in eight months to observe the level of fidelity in the implementation of the ICDM model. This allowed the researchers to assess clinics when they had different patient and personnel numbers. Implementation research principles were applied in this thesis to ensure that the findings could contribute to the implementation of the ICDM model improvements and its scaling up and scaling out. Value stream mapping of patient flow and analysis identified particular areas of inefficiency in the delivery of chronic health services that could be targeted as opportunities for improvement. Interviews with healthcare workers involved in the implementation of the ICDM model provided an end-user's perspective on the moderating factors that affect fidelity. The organizational culture survey with the Denison organizational culture survey tool that has been validated in organizations of different sizes and industries and previously utilized in the South African healthcare context, provided reliable results. Furthermore, the organizational survey assessed cultural traits that could be linked to an organization's performance and objectives.

*Limitations:* The sample size of 16 clinics and interviews with selected staff members was small, and might not be representative (patient characteristics, resources) of several PHC clinics and healthcare workers in South Africa, thereby limiting the generalizability of the results. This limitation was slightly mitigated by including clinics from two different health districts under different provinces. Despite the potential for minimal generalizability, there may be some settings that these clinics may be more representative of and the findings from this thesis could be applicable. Another limitation of this thesis is the potential for social desirability bias, as some information on adherence to guidelines (fidelity) and all the data on

moderating factors was collected by interviewing healthcare workers. The face-to-face interviews may have also resulted in interviewer bias. Interviews were conducted as privately as possible by trained researchers to minimize social desirability and interviewer bias. Fidelity evaluations focused predominantly on the presence or absence of systems and processes that have been recommended in the ICDM model guidelines, and not the quality of the implementation of the activities. In addition, the weighting of the scores of the fidelity criteria was based on the number of activities required, and not on how critical that activity was for achieving the ICDM model objectives. The results from these clinics on their organizational culture scores were not compared to other organizations in the larger Denison organizational culture global database as recommended<sup>360</sup> due to limited resources for the thesis research. Patient perceptions of the ICDM model moderating factors were not assessed to keep the scope of this thesis manageable. The total estimated costs of implementing the ICDM model in this thesis is an underestimate of the full cost of providing care for patients with chronic diseases because the standard of care costs such as medication, laboratory investigations, and treatment of complications were not included in the cost analysis. Lastly, the cost analysis did not include a full cost-effectiveness analysis as there are no data on the effectiveness of the ICDM model in South Africa.

## **8.6. Recommendations for future research**

This thesis focused on fidelity and costs of the implementation of the ICDM model. To keep the scope manageable, the thesis was not exhaustive in assessing other applicable implementation outcomes such as acceptability and penetration. Therefore, research in other implementation outcomes are recommended to further enrich our understanding of the implementation of the ICDM model and build on the findings from this thesis. The quality of implementation and unintended consequences of implementing the ICDM model necessitates further research.

Further research on the ICDM model could include identifying adaptations that can improve model processes and implementation at the local level without affecting the model's intended outcomes. A well-defined description of what components or activities could be

modified and which ones are prescriptive would assist in the adoption of the ICDM model. Acceptability of the various activities and components of the ICDM model also needs further evaluations. The perceptions of the providers and the recipients on the processes of the ICDM model would provide more data on activities that are agreeable and satisfactory in a specific context. The sustainability or maintenance of the ICDM model evaluation will also be important for scaling-out of the model in other countries or different diseases.

There have not been evaluations of the effectiveness of the ICDM model to achieve treatment outcomes for all the 8 conditions included in the ICDM model. This would be valuable for settings that have a high prevalence of both NCDs and CDs as this is one of the few models that includes both. The effectiveness assessments would also contribute to the potential cost-effectiveness analysis of the ICDM model. The results of the organizational culture in this thesis were not compared to other organizations in the Denison organizational culture global database. That would substantiate the findings on the organizational culture scores and what areas to address to promote a culture that's conducive to ICDM principles. Perceptions of patients who receive health services in the study clinics on the moderating factors would also provide more information on how the adherence to the ICDM model components could be enhanced.

In addition, the ICDM model principles have been adopted to include other health services (acute at primary integrated clinical services manual [ICSM])<sup>121</sup>. Therefore, it would be necessary to assess the implementation outcomes (appropriateness, adoption, feasibility and fidelity) of the scaling out of the ICSM to other healthcare services such as cancer, renal failure and secondary and tertiary health services. I am planning to assess the correlation of the fidelity assessments scores from this thesis with the ideal clinic assessment scores as part of my post-doctoral fellowship work. The fidelity to the ICDM model criteria could possibly inform an abbreviated ideal clinic assessment.

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