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Process evaluation of Fidelity and Costs of implementing the Integrated Chronic Disease Management Model in South Africa: Mixed Methods study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-029277
Article Type:	Protocol
Date Submitted by the Author:	22-Jan-2019
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Keywords:	implement, ICDM, intervention evaluation

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Manuscripts

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3 Protocol

4 **Process evaluation of Fidelity and Costs of implementing the Integrated**
5 **Chronic Disease Management Model in South Africa: Mixed Methods study**
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8 Version 1.0, Dated 18 January 2018
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34 Keywords: implementation, ICDM model, intervention evaluation
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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 utilization of primary healthcare (PHC) services due to a surge of non-communicable diseases co-existing 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 sub-optimal 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 sixteen 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. Multivariate analysis will be used to examine the association between contextual factors and the degree of fidelity, individual and team characteristics, facility features and organizational 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 the through scientific publications and conference presentations.

Strengths and Limitations of this study

- This study uses implementation research principles to provide data on the degree of fidelity to the ICDM model for optimizing the model
- Process evaluation will provide an indication of how the ICDM model has been modified in different contexts can explain variability in the implementation outcomes.
- Implementation costs assessments are essential in public health programs 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.
- The results of this study could be applied to clinics similar in size or patient load but may not be representative of all districts in the country.

Background

Chronic diseases and multi-morbidity is increasing in developing countries due to epidemiological transition of increasing prevalence of non-communicable diseases (NCDs) in the presence of rampant infectious diseases^{6,7}. By 2025, it is estimated that the burden of NCDs in sub-Saharan Africa will be higher than that of communicable diseases (CD)⁸. The increase in urbanization, economic development, aging, decrease of physical activity and poor dietary options are some of the contributing factors to the increasing prevalence of NCDs in developing countries^{9,10}. There is also a complex interaction of risk factors, management and health outcomes between NCDs and CDs, resulting a rise in chronic disease mult morbidity^{11,12}. Multi-morbidity often results in reduced levels of physical capability, high rates of health services utilization and attendant costs and higher mortality rates^{13,14}. The double burden (NCDs and CDs) of diseases is costly to the health systems (increased utilization, medication), the economies, households and individuals⁷. 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%¹⁵. 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 15-49years being HIV infected¹⁶. As a result, there is an increase in the prevalence of multi-morbidity¹⁷. Tuberculosis (TB), Human Immune Deficiency Syndrome (HIV) and NCDs (mainly Hypertension (HPT) and Diabetes Mellitus (DM)) account for 45% of all primary health care consultations, with a multi-morbidity prevalence of 22.6%^{9,18}.

Unresponsive health systems often provide services that are not aligned with the health requirements of the population being served¹⁹. A more comprehensive chronic disease management model, combining both CDs and NCDs that reduces health utilization 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^{7,19}. The chronic care model (CCM) and Innovative Care for Chronic Conditions (ICCC) framework have been recommended as health system

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3 approaches to deal with multi-morbidity²⁰. However, there have been significant
4 resources and strategies allocated to the implementation of HIV programs and
5 consequently the non-communicable chronic diseases have been overlooked. To
6 rectify this imbalance, the South African National Department of Health developed and
7 has begun implementation of the Integrated Chronic Disease Management (ICDM)
8 model in order to improve efficiencies and quality of care primary health care clinics
9 for patients with chronic diseases²¹.
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17 **Integrated Chronic Disease Management Model**

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20 The ICDM model was piloted from 2011 in 42 clinics from three health districts in three
21 different provinces (Figure 1) of South Africa as follows: West Rand in Gauteng
22 Province, Bushbuckridge in Mpumalanga and Dr. Kenneth Kaunda in North West
23 Province^{22,1}. As part of a broader national approach to revitalize primary health care
24 (PHC) services, the “ideal clinic” initiative was also started in 2013²³. The principles of
25 the “ideal clinic” incorporate the majority of the activities required for ICDM
26 implementation and additionally provides a comprehensive, systematic process of
27 transforming all PHC facilities to conform to the National Health Insurance (NHI)
28 standards²³. The envisaged “ideal clinic” benchmarks include functional infrastructure
29 and equipment, adequate personnel and medicines and supplies, good administrative
30 processes and the use of applicable protocols and guidelines in diseases
31 management²³. The principles of the ICDM model cover integration of services, facility
32 improvement, use of ward-based PHC outreach teams and ensuring adequate levels
33 of medicines and supplies²³.
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46 The four major components (action points) of the ICDM implementation are: facility re-
47 organization for efficiency, clinical supportive management, assisted self-support and
48 strengthening of support systems (Figure 2)²¹. The ICDM priority and core standards
49 are 1) improving the values and attitudes of staff, 2) patient safety and security and
50 infection prevention and control, and 3) availability of medicines and supplies²¹.
51 Assuming full implementation of the ICDM as recommended, the expected outcomes
52 include improved operational efficiency and quality of care, improved individual
53 responsibility towards their health and an activated and informed community²¹. The
54 ICDM model also provides guidelines on booking systems for patients with chronic
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3 diseases, clinic flow, organization of waiting areas and consultation rooms and
4 dispensing medication practices that promote adherence and minimize medication
5 shortages. In order to avoid fragmentation of services, the ICDM recommends a multi-
6 disciplinary treating team to provide care to all patients with chronic illnesses and be
7 trained on how to assess and manage drug-drug interactions and disease interactions.
8 Mentoring, supervision and training of the PHC nurses to be provided the district
9 Clinical Specialist Team (DCST)²¹. The DCST other responsibilities include
10 monitoring of patient clinical outcomes through clinical audits and strengthening of
11 referral systems for complicated patients²¹. The components or building blocks for
12 ICDM model include human resources, health information, mobile technology,
13 equipment and pharmaceutical supply and management²¹.
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24 The pilot phase was supported with quality improvement reviews and consultation with
25 all staff members at the facility-, district- and province-levels to refine the model even
26 further¹. Some of the implementation challenges identified in these consultations were
27 lack of key equipment, an emphasis on curative health services with minimal focus on
28 prevention, the ill-defined role of community health care workers and delayed
29 formation of out of facility chronic medication collection sites¹. Lack for these
30 necessary building blocks for the ICDM model has resulted in the implementation of
31 hybrids of the original model¹. The limitations of the ICDM model identified include its
32 focus on secondary and tertiary prevention of disease within the healthcare facilities,
33 and the lack of guidelines on social and environmental changes for the prevention of
34 risk factors and onset of chronic diseases²¹. Furthermore, population level and
35 community level interventions are only vaguely described, and the collaborations
36 required with other sectors for policy development and implementing supportive
37 provisions is not accentuated.
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50 **Management of Chronic Conditions in PHC Facilities**

51 An evaluation of PHC services in South Africa showed low rates of diagnosis for
52 chronic diseases, and the few that are diagnosed, are not managed appropriately and
53 do not achieve the treatment targets^{24,25}. The lack of key equipment in PHC clinics to
54 diagnose and monitor total cholesterol, blood pressure and blood glucose contribute
55 these challenges, with patients reporting the need to travel to higher levels of care to
56 access certain medication and diagnostic tests²⁴. Additional barriers included the
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3 insufficient consultation time that patients report with their healthcare providers even
4 after long waiting periods at the facility due to high volumes of patients²⁴; poor
5 knowledge on chronic disease, shortage of medication and shortage of healthcare
6 workers resulting in long waiting periods at PHC clinics²⁶. The nurses knowledge of
7 chronic diseases was also found to be poor due to inadequate training, unavailability
8 of guidelines and lack of supervision²⁶.
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15 The observed impact of the ICDM model in the management of chronic diseases has
16 been an improvement in the patients' records and compliance with clinical guidelines
17 for hypertension, diabetes and HIV². The ICDM model was also shown to be effective
18 in improving control of HIV, but no significant improvements for patients on
19 hypertension treatment³. One possible explanation for this finding is that the ICDM
20 model had not successfully leveraged the HIV program to enhance service delivery
21 for NCDs like hypertension³. The patients receiving care at the ICDM clinics were
22 concerned with the irregular supplies and stock-outs of hypertension medication,
23 which affected their treatment adherence⁴. The patients' perspectives on the ICDM
24 model inconveniences were a non-flexible appointment system that affected access
25 to services, long waiting times because of personnel shortages and stigmatization of
26 patients that are visited by community healthcare workers⁴.
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38 Although monitoring and evaluation tools exist for the ICDM model implementation,
39 they do not provide data on implementation outcomes such as adoption, fidelity,
40 penetration, acceptability, sustainability and costs. The implementation of an
41 innovative intervention can be affected by the design of the intervention, context and
42 or implementation outcomes²⁷. New innovative interventions could fail to achieve
43 intended objectives because of implementation barriers or failures in the design²⁷.
44 Failure of the ICDM to achieve some of the expected outcomes has been described⁴.
45 However, it is not clear whether these observed and perceived gains and
46 shortcomings are as a result of the inherent faults in the design of the model or failure
47 to adhere to the prescribed activities and/or the impact of contextual factors. The
48 successful implementation of the ICDM model requires a high degree of fidelity to the
49 recommended processes of delivering health care services with clear intervention
50 priorities and expected outcomes^{5,28}. Process evaluation of the ICDM model
51 implementation would optimize practice of the four major components and scale-up of
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3 the model, and the quality of care for individuals affected by chronic illness, especially
4 those with multi-morbidity.
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6 Implementation of any intervention within a large complex health system is generally
7 unpredictable. An assessment of fidelity on the implementation of the model will
8 additionally measure quality of practice for continuous improvement, identify any
9 innovations that can improve models' processes and support systematic
10 implementation of the model. Interviews with the actors in the ICDM model
11 implementation will provide information on their perceptions and experiences with
12 implementation and how contextual factors have affected fidelity to the model's
13 guidelines. This can improve comparability, generalizability and replicability of the
14 results of this study. Assessing the cost of implementing the various activities of the
15 ICDM model will then assist with planning and budgeting, as well as inform scalability
16 and sustainability of the model
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27 Therefore, the **aim** of this study is to evaluate selected implementation outcomes of
28 the ICDM model: fidelity and implementation costs, and to assess the influence of
29 contextual factors on ICDM model implementation fidelity in two health districts where
30 the ICDM has been piloted, from two different provinces in order to better understand
31 the processes of successful implementation of the ICDM model and how the model
32 can be optimized. The **objectives** of the study are:
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- 36 1. To assess the degree of fidelity in the implementation of the ICDM model
- 37 2. To evaluate the influence of contextual factors on the implementation fidelity of the
38 ICDM model
- 39 3. To estimate the implementation costs of the ICDM model
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47 **Methods and Analysis**

48 **Setting**

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50 The National Department of Health (DOH), is divided into 52 districts across nine
51 provinces and has decentralized the responsibility for health service delivery to
52 provincial governments and district health management teams^{23, 29}. The majority of
53 the population (80%) utilize overstretched state facilities where most healthcare
54 services are free or at low cost, yet only 30% of doctors work in the public sector^{30, 31}.
55 PHC clinics are the first contact, and provide acute and chronic care, and preventative
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3 and curative services. A team of healthcare workers at a PHC clinic or a community
4 health centre usually includes nurses, a doctor, a social worker, a pharmacist, health
5 promoters and administration personnel. Each healthcare facility or clinic in South
6 Africa services a population of between 2000 to 20 000¹. Although there has been
7 some progress in revitalizing PHC, personnel shortages, the HIV/AIDS epidemic and
8 fragmentation of services continue to undermine these gains especially in rural
9 areas³². Subsequently, there is a plan to introduce more regulation and reduce
10 commercialization through the National Health Insurance (NHI)^{31, 33}. Additional
11 objectives of the NHI are to revamp the 3500 primary health care facilities in the
12 country, as well as reinforcing the community healthcare workers program,
13 environmental health and school health services²³.

24 This study will be conducted in two health districts (Dr. Kenneth Kaunda in North West
25 Province and West Rand District in Gauteng) that were the pilot sites for the ICDM
26 model implementation. Both districts are within socio-economic quantile four (1 is most
27 deprived and 5 is least deprived), however comparing the North West to Gauteng
28 province, poverty prevalence (33% vs. 27%) and informal housing (21% vs. 19%) are
29 slightly higher in the North West Province^{34, 35}. The provincial HIV prevalence is 13.3%
30 in North West Province and 12.4% in Gauteng³⁶. The prevalence of hypertension is
31 high (31%- 39.7%) in both districts, a reflection of large number of people accessing
32 health services for chronic NCD³⁴. The prevalence of diabetes in South Africa is 8.27%
33 (2.6 million), and 31.9% among adults (20-79 years) with 1.2 million people with
34 diabetes estimated to be undiagnosed³⁷.

35 **Theoretical Framework**

36 *Process Evaluation of Complex Interventions*

37 Process evaluation frameworks assist in understanding the functioning of a complex
38 intervention by reviewing implementation processes and the influence of contextual
39 factors^{38,39}. A complex intervention implementation process has multiple components
40 which interact to produce change, and or are difficult to implement and or target a
41 number of organizational levels^{38,40}. Process evaluation is therefore useful for
42 assessing (Figure 2) fidelity (dose, adaptations, frequency and reach), clarifying the
43 usual mechanisms and processes and identifying the impact of contextual factors on
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3 the variations in processes and outcomes⁴¹. A process evaluation framework will be
4 applied in this study to evaluate whether the processes for implementing the
5 intervention (the ICDM model) is being applied as intended according to the design
6 (fidelity) of the intervention, and how contextual factors influence the implementation
7 fidelity (Figure 3). The costs, quantity and quality of program activities provided and
8 evaluating the generalizability of the results in other different contexts is important
9 especially for a program that is already established⁴¹.
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17 **Study Design**

18 This is a process evaluation study using mixed methods to assess the degree of
19 fidelity, costs and impact of context on the implementation fidelity of the ICDM model.
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24 **Objective-specific methodology**

25 **Fidelity assessment** will be carried out to review if implementation of the ICDM model
26 adheres to content, coverage, frequency and duration as prescribed in the ICDM
27 model manual in sixteen (8 in North West and 8 in Gauteng) clinics. As there are no
28 fidelity criteria in the literature that are suitable to adapt for assessing the ICDM model
29 implementation, fidelity criteria have been developed based on the ICDM model
30 guidelines²¹, the quarterly ICDM model progress monitoring tool and published
31 literature on the ICDM model^{1, 3, 4, 28}. The basis of the criteria are the four (facility re-
32 organization, clinical supportive management, assisted self-management and
33 strengthening of the support systems) major components of the ICDM model²¹. The
34 outlined prescribed activities are the variables to be assessed on the implementation
35 fidelity criteria. The expected outcome of the fidelity criteria is to warrant that all the
36 essential activities required for successful implementation of the ICDM model have
37 been captured. Each criterion under the four major components will be listed as an
38 item to be scored on the fidelity criteria. The fidelity criteria will be assessed on a pilot
39 study, and finalized on the basis of the results of the pilot study. The twenty ICDM pilot
40 clinics located in those districts will be considered for inclusion if the clinic has been
41 open and running without any major interruptions (renovations, closures) in the last two
42 years. At each clinic, data will be collected by structured observations, review of
43 facility records and interviews with the healthcare workers.
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3 **Contextual factors** (facility characteristics and characteristics of individuals and
4 teams) on fidelity will be examined in four clinics. Based on the degree of fidelity, **two**
5 **clinics**, one with a high, one with a low degree of fidelity will be selected each of the
6 two districts. The organizational contextual factors to be considered include
7 communication style, decision process and culture⁴². Individual level data for the
8 implementing teams will include demographics (age, gender, race, education level),
9 position role within the clinic, years in that role, their participation in the delivery of the
10 ICDM model. External (to the facility) context factors (socio-economic level, policies
11 and legislation) will not be evaluated in order to keep the study scope manageable.
12 Mixed-methods (interviews, facility assessments and culture surveys) approach on
13 assessing the influence of context on implementation fidelity will be used to allow co-
14 information. The qualitative interviews will be conducted with thirty healthcare workers,
15 purposively selected to represent different cadres of staff members that implement
16 and manage the ICDM model intervention for more than six months. The interviews
17 will be done on a one-to-one basis to minimize having group dynamics.

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

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39 **Costs** (financial and economic) of implementing the ICDM model from the health
40 system perspective will be evaluated in the same four clinics. The health system
41 implementation costs are an all-inclusive costing valuation that considers costs
42 incurred by the providers of the service⁷². Assessing the implementation costs will be
43 a partial economic evaluation as it will only focus on the costs of implementation and
44 not the outcomes. The unit of implementation costs will be by activity of each of the
45 major components of the ICDM model. Service level costs such as those pertaining to
46 the development of the ICDM model will not be included as these costs were incurred
47 in 2010/11 . The focus will be on post start-up annual costs required for the full
48 implementation of the ICDM model in a typical year. Both direct and indirect, and fixed
49 and recurrent costs will be calculated.

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3 Annualized equipment and capital costs will be calculated according to the volume
4 being used for the ICDM model. Estimating annual costs will include adding up the
5 acquisition, operation, maintenance and disposal costs. In the financial documents
6 review, key input costs that will be checked and categorized include human resources,
7 office supplies and travel. Based on the useful life and the discount rate, an
8 appropriate annualization factor will be determined. If there are any donations for
9 program implementation (volunteers, healthcare workers not allocated to ICDM but
10 assisting in service delivery, donated equipment or office supplies) they will be
11 included. Medical and support staff labour costs will be calculated based on the full
12 time equivalent, duration of involvement in the ICDM model implementation and the
13 gross salary of the personnel. A proportion of overhead costs of running the health
14 facility like electricity, rent, water will be included in the implementation costs.
15 Administrative costs at district and provincial level (which are beyond the facility) will
16 not be included in the analysis.
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29 *Patient and Public Involvement:* Previous research has shown that patients do not like
30 some of the components of the ICDM model and that was the basis of the research
31 question. Patients will not be enrolled in the study, however results will be shared with
32 them through community and health facilities leadership.
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38 **Data Management and Analysis Plan**

39 The data will be collected using paper based questionnaires and later captured into
40 an electronic database. There will be no identifying features (e.g. date of birth,
41 addresses) in the database. The health facilities and healthcare workers that
42 participated will be allocated a study number. Source documents will be safely kept
43 and only accessible to study personnel. The data on costs will be manually entered
44 into the CostIt software 2007⁴³ according to the provided major categories. CostIt
45 software is a template designed to capture and automatically analyse cost data for
46 different (hospital, PHC and programme) levels of the healthcare system⁴³
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55 Descriptive statistics (frequency, median, interquartile ranges, percentages) will be
56 used to examine the general quantitative variables of the clinics, such as size, number
57 of chronic patients, services offered, clinic team characteristics and overall functioning
58 status. Following the evaluation, each clinic will receive a score for each of the fidelity
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3 criteria items. Item scores will be summed per component to give four overall ICDM
4 component fidelity scores per facility. An overall ICDM model implementation fidelity
5 score will be calculated per facility by summing the four component scores. The
6 implementation fidelity scores will be summarized using descriptive statistics and
7 compared between components, facilities and districts. The outcome of interest will be
8 the degree of implementation fidelity.
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15 The experiences and perceptions of the healthcare workers from the interviews will
16 be analysed with REDCap software for Linkert scaled questions and using thematic
17 content analysis for barriers and facilitators of implementation fidelity for qualitative
18 data. The six steps recommended by Braun and Clarke⁴⁴ for thematic content analysis
19 that will be followed: Familiarization, generating initial codes, searching for themes
20 throughout the database, reviewing and naming themes and summarizing the
21 findings⁴⁴. Multi-variate analysis using STATA 14 econometric software will be used
22 to assess the effect of various contextual factors on the implementation fidelity of the
23 ICDM model. The impact of both the organizational (case mix, financial flexibility and
24 culture) and implementing teams (work experience, cadre of HCW, training and
25 perceptions of ICDM) level factors on the degree of the ICDM model implementation
26 fidelity will be assessed. The initial analysis will include description of the sample,
27 followed by a bivariate analysis that includes t-tests and ANOVA to examine the
28 influence of contextual factors on implementation fidelity of the ICDM model.
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41 Costs: Capital costs and other costs that have a life span of several years will be
42 annualized over the useful lifespan to get the equivalent annual costs. All costs will be
43 adjusted for inflation and discount. Equipment will be depreciated according to the
44 South African Accounting principles⁴⁵. Sensitivity analyses will be conducted for other
45 possible variations in estimated costs. Sensitivity analyses will also be carried out to
46 explore different scenarios including size of clinic, degree of implementation fidelity
47 and other factors that could possibly affect costs based on literature.
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55 *Ethical conduct of the study:* This study has been approved by the University of Cape
56 Town (Ref: 127/2018) and University of the Witwatersrand (Ref: R14/49) Human
57 Research ethics committees. Approvals have also been received from the Gauteng
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3 and the North West Provincial departments of health. The participants for the
4 interviews will be consented individually prior to taking part in the study.
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6 *Results Dissemination:* The results of this study will be shared with the various
7 stakeholders to inform the implementation of the ICDM model in South Africa and other
8 models of integrated care. Brief summary of results will be presented to the Provincial
9 and districts DOH. The full results will be presented at local research days in each
10 province and district. Facility managers and local clinic staff that participated in the
11 study will be given feedback on the outcomes of the study. The results will also be
12 presented through publications and conference presentations to enhance scientific
13 knowledge. Authorship will be determined by substantial contributions to the study
14 according to the recommendations for the conduct, reporting and publication of
15 research in medical journals. Once the data collection and cleaning is complete, it will
16 be made open and publicly accessible.
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28 **Conclusion:** Many health systems are challenged with increased demand for
29 healthcare for chronic diseases. Despite this service need, there is minimal integration
30 of services for the management of chronic diseases resulting in inefficiencies in
31 service delivery, high costs and poor health outcomes. The ICDM model has been
32 developed to address this challenge, the success of which will be influenced by the
33 degree to which the model is accurately implemented. This highlights the need for data
34 to assess the degree of fidelity to the ICDM model intervention, and for data that
35 explores how fidelity of implementation is affected by contextual factors. Data
36 generated from this study will inform integration of chronic care services at the PHC
37 level, and scalability of the ICDM model, of relevance in South Africa and other low
38 and middle-income countries increasingly facing a growing tide of chronic disease
39 multimorbidity.
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4 **Acknowledgements:** We would like to acknowledge the people that have reviewed
5 this protocol and provided feedback: Leslie London, Edina Sinanovic, Maylene Shung
6 King and South African MRC Self-Initiated Research Grant division.
7

8
9 **Funding Statement:** The proposed study outlined in this protocol will be supported
10 by the South African Medical Research Council under a Self-Initiated Research Grant
11 (ID:494184). The views and opinions expressed are those of the author(s) and do not
12 necessarily represent the official views of the SA MRC. The sponsor appointed
13 reviewers have critically assessed the protocol and requested some changes to be
14 done prior to submission to ethics. The sponsor will have no role in data collection,
15 analysis or reporting.
16

17
18 **Author Statement:** LL was involved in the conception, design literature review and
19 writing. OA, MK and TO have contributed to the conception, design and critical review
20 of the manuscript.
21

22
23 **Conflict of Interest:** The authors have no conflict of interest to declare.
24

25 **Ethical Issues:** The protocol has been approved by the University of Cape Town and
26 University of the Witwatersrand Human Research ethics committees. Any changes
27 required, will have to be submitted to both ethics committees.
28

29 **Word Count:** 3889
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31 32 33 **Figures**

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35 *Figure 1: Map of South Africa with the ICDM model pilot sites highlighted*
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37 *Figure 2: Integrated Chronic Disease Management Model²¹*
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39 *Figure 3: The Process Evaluation framework for complex interventions⁴³*
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42 *Figure 4: Modified Process Evaluation Framework for assessing the fidelity and cost*
43 *of the ICDM model implementation*
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Figures

Figure 1: Map of South Africa with the ICDM model pilot sites highlighted

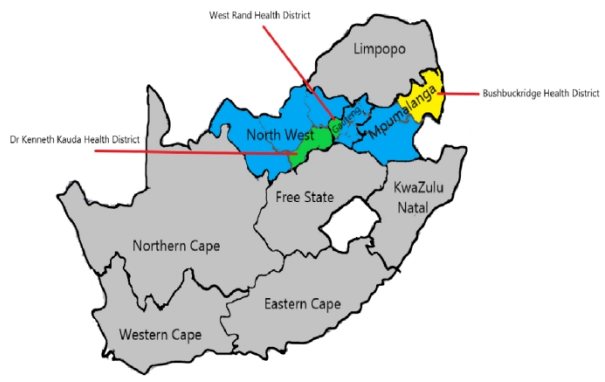


Figure 1: Map of South Africa with the ICDM model pilot sites highlighted
209x297mm (200 x 200 DPI)

Figure 2: Integrated Chronic Disease Management Model²¹

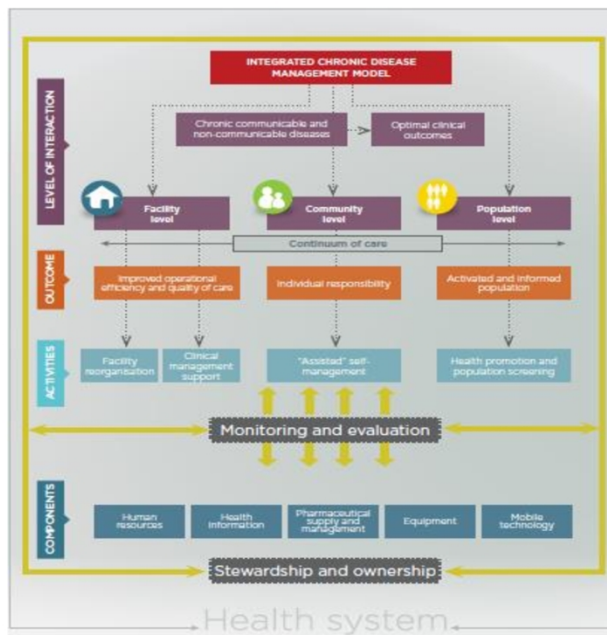


Figure 2: Integrated Chronic Disease Management Model

209x297mm (200 x 200 DPI)

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Figure 3: The Process Evaluation framework for complex interventions⁴³

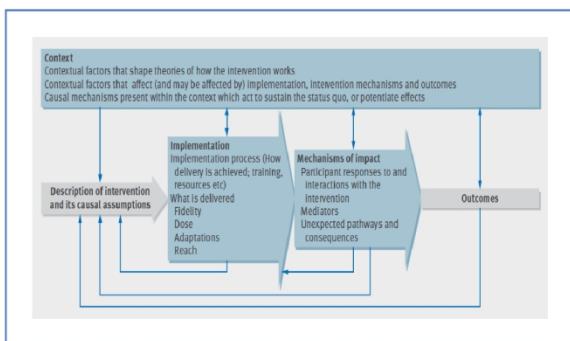


Figure 3: The Process Evaluation framework for complex interventions⁴³

209x297mm (200 x 200 DPI)

Figure 4: Modified Process Evaluation Framework for assessing the fidelity and cost of the ICDM model implementation

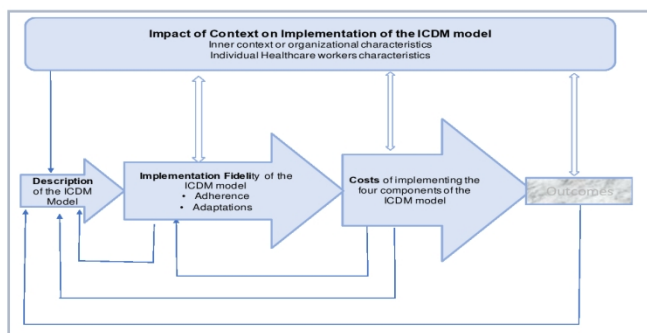


Figure 4: Modified Process Evaluation Framework for assessing the fidelity and cost of the ICDM model implementation

209x297mm (200 x 200 DPI)



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym ✓ - pg. 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry – N/A
	2b	All items from the World Health Organization Trial Registration Data Set. – N/A
Protocol version	3	Date and version identifier - ✓ - pg.1
Funding	4	Sources and types of financial, material, and other support ✓ - pg.18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors - ✓ - pg.18
	5b	Name and contact information for the trial sponsor N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities ✓ - pg.18
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) N/A
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention ✓ - pg. 2-4
	6b	Explanation for choice of comparators – N/A
Objectives	7	Specific objectives or hypotheses ✓ - pg. 7

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Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) – N/A
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Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained ✓ - pg. 7-8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) ✓ - pg. 9-10
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered – N/A
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) - N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) - N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial – N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended ✓ - pg. 11 – 12.
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) N/A
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations – N/A
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials) N/A

Allocation:

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2	Sequence	16a	Method of generating the allocation sequence (eg, computer-
3	generation		generated random numbers), and list of any factors for stratification.
4			To reduce predictability of a random sequence, details of any planned
5			restriction (eg, blocking) should be provided in a separate document
6			that is unavailable to those who enrol participants or assign
7			interventions
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10	Allocation	16b	Mechanism of implementing the allocation sequence (eg, central
11	concealment		telephone; sequentially numbered, opaque, sealed envelopes),
12	mechanism		describing any steps to conceal the sequence until interventions are
13			assigned
14			
15	Implementation	16c	Who will generate the allocation sequence, who will enrol participants,
16			and who will assign participants to interventions
17			
18	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial
19	(masking)		participants, care providers, outcome assessors, data analysts), and
20			how
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23		17b	If blinded, circumstances under which unblinding is permissible, and
24			procedure for revealing a participant's allocated intervention during
25			the trial
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Methods: Data collection, management, and analysis

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30	Data collection	18a	Plans for assessment and collection of outcome, baseline, and other
31	methods		trial data, including any related processes to promote data quality (eg,
32			duplicate measurements, training of assessors) and a description of
33			study instruments (eg, questionnaires, laboratory tests) along with
34			their reliability and validity, if known. Reference to where data
35			collection forms can be found, if not in the protocol ✓ - pg. 11-12
36			
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38		18b	Plans to promote participant retention and complete follow-up,
39			including list of any outcome data to be collected for participants who
40			discontinue or deviate from intervention protocols – N/A
41			
42	Data	19	Plans for data entry, coding, security, and storage, including any
43	management		related processes to promote data quality (eg, double data entry;
44			range checks for data values). Reference to where details of data
45			management procedures can be found, if not in the protocol ✓ - pg.
46			11-12
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49	Statistical	20a	Statistical methods for analysing primary and secondary outcomes.
50	methods		Reference to where other details of the statistical analysis plan can be
51			found, if not in the protocol - ✓ - pg. 11-12
52			
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54		20b	Methods for any additional analyses (eg, subgroup and adjusted
55			analyses) ✓ - pg. 11 -12
56			
57		20c	Definition of analysis population relating to protocol non-adherence
58			(eg, as randomised analysis), and any statistical methods to handle
59			missing data (eg, multiple imputation) N/A
60			

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed - N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial – N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval ✓ - pg. 1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) ✓ - pg. 1
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) N/A
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial ✓ - pg. 11
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site ✓ - pg. 1
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators ✓ - pg. 1
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation -N/A

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| Dissemination
policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
✓ - pg. 12 |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers - ✓ - pg. 13 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code ✓ - pg. 13 |

16 Appendices

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|-------------------------------|----|--|
| Informed consent
materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates – Appendix 1 |
| Biological
specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable – N/A |

25 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
26 Explanation & Elaboration for important clarification on the items. Amendments to the
27 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
28 Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)"
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BMJ Open

Process evaluation of Fidelity and Costs of implementing the Integrated Chronic Disease Management Model in South Africa: Mixed Methods Study Protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-029277.R1
Article Type:	Protocol
Date Submitted by the Author:	09-Apr-2019
Complete List of Authors:	Lebina, Limakatso; University of the Witwatersrand, Perinatal HIV Research Unit; University of Cape Town Faculty of Health Sciences, School of Public Health and Family Medicine Alaba, Olufunke; University of Cape Town, School of Public Health and Family Medicine Kawonga, Mary; University of the Witwatersrand, School of Public Health Oni, Tolu; University of Cape Town, School of Public Health and Family Medicine; University of Cambridge, MRC Epidemiology Unit
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Patient-centred medicine, Public health, Evidence based practice
Keywords:	implement, ICDM, intervention evaluation

SCHOLARONE™
Manuscripts

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3 1 **Process evaluation of Fidelity and Costs of implementing the Integrated**
4 2 **Chronic Disease Management Model in South Africa: Mixed Methods Study**
5 3 **Protocol**
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9 6 Version 2.0, Dated 06 April 2019
10 7

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Keywords: implementation, ICDM model, intervention evaluation

33 **Abstract**

34 **Introduction:** The South African Department of health has developed and
35 implemented the Integrated Chronic Disease Management (ICDM) model to respond
36 to the increased utilization of primary healthcare (PHC) services due to a surge of non-
37 communicable diseases co-existing with a high prevalence of communicable
38 diseases. However, some of the expected outcomes on implementing the ICDM model
39 have not been achieved. The aims of this study are to assess if the observed sub-
40 optimal outcomes of the ICDM model implementation are due to lack of fidelity to the
41 ICDM model; to examine the contextual factors associated with the implementation
42 fidelity, and to calculate implementation costs.

43
44 **Methods and Analysis:** A process evaluation, mixed methods study in sixteen pilot
45 clinics from two health districts to assess the degree of fidelity to four major
46 components of the ICDM model. Activity scores will be summed per component and
47 overall fidelity score will be calculated by summing the various component scores, and
48 compared between components, facilities and districts. Multivariate analysis will be
49 used to examine the association between contextual factors and the degree of fidelity,
50 individual and team characteristics, facility features, and organizational culture
51 indicators will be included in the regression. Health system financial and economic
52 costs of implementing the four components of the ICDM model will be calculated using
53 an ingredient approach. The unit of implementation costs will be by activity of each of
54 the major components of the ICDM model. Sensitivity analysis will be carried out using
55 clinic size, degree of fidelity, and different inflation situations.

56
57 **Ethics and Dissemination:** The protocol has been approved by the University of
58 Cape Town and University of the Witwatersrand Human Research ethics committees.
59 The results of the study will be shared with the department of health, participating
60 health facilities and the through scientific publications and conference presentations.

61

62 **Strengths and Limitations of this study**

- 63 • This study uses implementation research principles to provide data on the
64 degree of fidelity to the ICDM model for optimizing the model
- 65 • Process evaluation will provide an indication of how the ICDM model has been
66 modified in different contexts can explain variability in the implementation
67 outcomes.
- 68 • Implementation costs assessments are essential in public health programs to
69 inform resource allocation during planning and budgeting and to inform
70 economic evaluations
- 71 • The reliance on the service provider to accurately provide information on the
72 implementation activities or insufficiencies of those activities is a limitation of
73 this study.
- 74 • Although the clinics may not be representative of all districts and clinics in the
75 country, the results of this study could be applied to clinics similar in size or
76 patient load and other integrated disease management models.
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82 Background

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84 Chronic diseases and multi-morbidity is increasing in developing countries due to
85 epidemiological transition of increasing prevalence of non-communicable diseases
86 (NCDs) in the presence of rampant infectious diseases^{1,2}. By 2025, it is estimated
87 that the burden of NCDs in sub-Saharan Africa will be higher than that of
88 communicable diseases (CD)³. The increase in urbanization, economic development,
89 aging, decrease of physical activity and poor dietary options are some of the
90 contributing factors to the increasing prevalence of NCDs in developing countries^{4, 5}.
91 There is also a complex interaction of risk factors, management and health outcomes
92 between NCDs and CDs, resulting a rise in chronic disease mulitmorbidty^{6,7}. Multi-
93 morbidity often results in reduced levels of physical capability, high rates of health
94 services utilization and attendant costs and higher mortality rates^{8,9}. The double
95 burden (NCDs and CDs) of diseases is costly to the health systems (increased
96 utilization, medication), the economies, households and individuals². Therefore,
97 chronic disease management needs to be comprehensive and take into consideration
98 these interactions in disease prevention, management and control.

99
100 In South Africa, the current leading health problems are NCDs, accounting for 51.3%
101 of all deaths, followed by CDs 38.4%, and injuries 10.3%¹⁰. South Africa like many
102 Sub-Saharan African countries has been severely affected by the HIV/AIDS epidemic,
103 with 7.1 million people living with HIV; and 18.9% of people between the ages of 15-
104 49years being HIV infected¹¹. As a result, there is an increase in the prevalence of
105 multi-morbidity¹². Tuberculosis (TB), Human Immune Deficiency Syndrome (HIV) and
106 NCDs (mainly Hypertension (HPT) and Diabetes Mellitus (DM)) account for 45% of
107 all primary health care consultations, with a multi-morbidity prevalence of 22.6%^{9,13}.

108
109 Unresponsive health systems often provide services that are not aligned with the
110 health requirements of the population being served¹⁴. A more comprehensive chronic
111 disease management model, combining both CDs and NCDs that reduces health
112 utilization and promotes self-management is one of the strategies that have been
113 recommended to address the challenges associated with the management of
114 multimorbid chronic diseases^{2, 14}. The chronic care model (CCM) and Innovative Care
115 for Chronic Conditions (ICCC) framework have been recommended as health system

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3 116 approaches to deal with multi-morbidity¹⁵. However, there have been significant
4
5 117 resources and strategies allocated to the implementation of HIV programs and
6
7 118 consequently the non-communicable chronic diseases have been overlooked. To
8
9 119 rectify this imbalance, the South African National Department of Health developed and
10
11 120 has begun implementation of the Integrated Chronic Disease Management (ICDM)
12
121 model in order to improve efficiencies and quality of care in primary health care clinics
13
14 122 for patients with chronic diseases¹⁶.

15 123

17 124 **Integrated Chronic Disease Management Model**

18 125

20 126 The ICDM model was piloted from 2011 in 42 clinics from three health districts in three
21
22 127 different provinces (Figure 1) of South Africa as follows: West Rand in Gauteng
23
24 128 Province, Bushbuckridge in Mpumalanga and Dr. Kenneth Kaunda in North West
25
26 129 Province^{17,18}. As part of a broader national approach to revitalize primary health care
27
28 130 (PHC) services, reduce fragmentation of services and ensure that each PHC facility
29
30 131 meets national minimum standards, the “ideal clinic” initiative was also started in
31
32 132 2013¹⁹. The principles of the “ideal clinic” incorporate the majority of the activities
33
34 133 required for ICDM implementation and provides standard operating procedures for the
35
36 134 Ideal Clinic Realisation and Maintenance (ICRM) programme^{20, 21}. One of the
37
38 135 components of the ICRM programme is Integrated Clinical Services Management
39
40 136 (ICSM) which focuses on health services being structured in four (acute, chronic,
41
42 137 preventative and promotive and health support) streams.^{20, 21} The principles of the
43
44 138 ICRM, ICSM and the ICDM model cover integration of services, good administrative
45
46 139 processes, functional infrastructure and equipment, adequate personnel, ensuring
47
48 140 adequate levels of medicines and supplies and the use of applicable protocols and
49
50 141 guidelines in diseases management¹⁹⁻²¹.

51 142

52 143 The four major components (action points) of the ICDM implementation are: facility re-
53
54 144 organization for efficiency, clinical supportive management, assisted self-support and
55
56 145 strengthening of support systems (Figure 2)¹⁶. The ICDM priority and core standards
57
58 146 are 1) improving the values and attitudes of staff, 2) patient safety and security and
59
60 147 infection prevention and control, and 3) availability of medicines and supplies¹⁶.
148 Assuming full implementation of the ICDM as recommended, the expected outcomes
149 include improved operational efficiency and quality of care, improved individual

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3 150 responsibility towards their health and an activated and informed community¹⁶. The
4
5 151 ICDM model also provides guidelines on booking systems for patients with chronic
6
7 152 diseases, clinic flow, organization of waiting areas and consultation rooms and
8
9 153 dispensing medication practices that promote adherence and minimize medication
10
11 154 shortages. In order to avoid fragmentation of services, the ICDM recommends a multi-
12
13 155 disciplinary treating team to provide care to all patients with chronic illnesses and be
14
15 156 trained on how to assess and manage drug-drug interactions and disease interactions.
16
17 157 Mentoring, supervision and training of the PHC nurses to be provided the district
18
19 158 Clinical Specialist Team (DCST)¹⁶. The DCST other responsibilities include
20
21 159 monitoring of patient clinical outcomes through clinical audits and strengthening of
22
23 160 referral systems for complicated patients¹⁶. The components or building blocks for
24
25 161 ICDM model include human resources, health information, mobile technology,
26
27 162 equipment and pharmaceutical supply and management¹⁶.

28
29 163
30
31 164 **The ICDM Model Pilot Phase Implementation:** The pilot phase was supported with
32
33 165 quality improvement reviews and consultation with all staff members at the facility-,
34
35 166 district- and province-levels to refine the model even further¹⁸. Some of the
36
37 167 implementation challenges identified in these consultations were lack of key
38
39 168 equipment, an emphasis on curative health services with minimal focus on prevention,
40
41 169 the ill-defined role of community health care workers and delayed formation of out of
42
43 170 facility chronic medication collection sites¹⁸. Lack for these necessary building blocks
44
45 171 for the ICDM model has resulted in the implementation of hybrids of the original
46
47 172 model¹⁸. The limitations of the ICDM model identified include its focus on secondary
48
49 173 and tertiary prevention of disease within the healthcare facilities, and the lack of
50
51 174 guidelines on social and environmental changes for the prevention of risk factors and
52
53 175 onset of chronic diseases¹⁶.

54 176 55 177 **Management of Chronic Conditions in PHC Facilities**

56
57 178 An evaluation of PHC services in South Africa showed low rates of diagnosis for
58
59 179 chronic diseases, and the few that are diagnosed, are not managed appropriately and
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180 do not achieve the treatment targets^{22,23}. The lack of key equipment in PHC clinics to
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182 diagnose and monitor total cholesterol, blood pressure and blood glucose contribute
183
184 these challenges, with patients reporting the need to travel to higher levels of care to
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186 access certain medication and diagnostic tests²². Additional barriers included the

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3 184 insufficient consultation time that patients report with their healthcare providers even
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5 185 after long waiting periods at the facility due to high volumes of patients²²; poor
6
7 186 knowledge on chronic disease, shortage of medication and shortage of healthcare
8
9 187 workers resulting in long waiting periods at PHC clinics²⁴. The nurses knowledge of
10
11 188 chronic diseases was also found to be poor due to inadequate training, unavailability
12
13 189 of guidelines and lack of supervision²⁴.

14 190

15 191 The implementation of an innovative intervention can be affected by the design of the
16
17 192 intervention, context and or implementation outcomes²⁵. New innovative interventions
18
19 193 could fail to achieve intended objectives because of implementation barriers or failures
20
21 194 in the design²⁵. The observed impact of the ICDM model in the management of chronic
22
23 195 diseases has been an improvement in the patients' records, compliance with clinical
24
25 196 guidelines and health outcomes for patients on antiretroviral medication but not those
26
27 197 on hypertension treatment^{26,27}. Irregular supplies and stock-outs of hypertension
28
29 198 medication was also not improved after the implementation of the ICDM model²⁸. The
30
31 199 patients' perspectives on the ICDM model inconveniences were a non-flexible
32
33 200 appointment system that affected access to services, long waiting times because of
34
35 201 personnel shortages and stigmatization of patients that are visited by community
36
37 202 healthcare workers²⁸. However, it is not clear whether these observed and perceived
38
39 203 gains and shortcomings are as a result of the inherent faults in the design of the model
40
41 204 or failure to adhere to the prescribed activities and/or the impact of contextual factors.

42 205

43 206 The successful implementation of the ICDM model requires a high degree of fidelity to
44
45 207 the recommended processes of delivering health care services with clear intervention
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47 208 priorities and expected outcomes^{29,30}. Although monitoring and evaluation tools exist
48
49 209 for the ICDM model implementation, they do not provide data on implementation
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51 210 outcomes such as adoption, fidelity, penetration, acceptability, sustainability and
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53 211 costs. Process evaluation of the ICDM model implementation would optimize practice
54
55 212 of the four major components and scale-up of the model, and the quality of care for
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57 213 individuals affected by chronic illness, especially those with multi-morbidity.

58 214

59 215 Implementation of any intervention within a large complex health system is generally
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216 unpredictable. An assessment of fidelity on the implementation of the model will
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additionally measure quality of practice for continuous improvement, identify any

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3 218 innovations that can improve models' processes and support systematic
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5 219 implementation of the model. Although the implementation of the ICDM model was
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7 220 subsequently followed by the ICRM programme that consists of the ICSM which has
8
9 221 a broader focus beyond chronic diseases, both these interventions have similar
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11 222 principles, standards and aims of ensuring that patients get quality patient-centric care
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13 223 that achieves the desired health outcomes¹⁹⁻²¹. We envisage lessons learnt from an
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15 224 evaluation of the ICDM model can be beneficial in the strengthening of implementation
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17 225 of the ICRM programme.
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20 228 Interviews with the actors in the ICDM model implementation will provide information
21
22 229 on their perceptions and experiences with implementation and how contextual factors
23
24 230 have affected fidelity to the model's guidelines. This can improve comparability,
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26 231 generalizability and replicability of the results of this study. Assessing the cost of
27
28 232 implementing the various activities of the ICDM model will then assist with planning
29
30 233 and budgeting, as well as inform scalability and sustainability of the model.
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234

32 235 Therefore, the **aim** of this study is to evaluate selected implementation outcomes of
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34 236 the ICDM model: fidelity and implementation costs, and to assess the influence of
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36 237 contextual factors on ICDM model implementation fidelity in two health districts where
37
38 238 the ICDM has been piloted, from two different provinces in order to better understand
39
40 239 the processes of successful implementation of the ICDM model and how the model
41
42 240 can be optimized. The **objectives** of the study are:

- 43 241 1. To assess the degree of fidelity in the implementation of the ICDM model
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45 242 2. To evaluate the influence of contextual factors on the implementation fidelity of the
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47 243 ICDM model
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49 244 3. To estimate the implementation costs of the ICDM model
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246

52 247 **Methods and Analysis**

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54 249 **Setting**

55 250

56 251 This study will be conducted from August 2018 to July 2019 in two health districts (Dr.
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58 252 Kenneth Kaunda in North West Province and West Rand District in Gauteng) that were
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60 253 the pilot sites for the ICDM model implementation. Both districts are within socio-

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3 254 economic quantile four (1 is most deprived and 5 is least deprived), however
4
5 255 comparing the North West to Gauteng province, poverty prevalence (33% vs. 27%)
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7 256 and informal housing (21% vs. 19%) are slightly higher in the North West Province³¹,
8
9 257 ³². The provincial HIV prevalence is 13.3% in North West Province and 12.4% in
10
11 258 Gauteng³³. The prevalence of hypertension is high (31%- 39.7%) in both districts, a
12
13 259 reflection of large number of people accessing health services for chronic NCD³¹. The
14
15 260 prevalence of diabetes in South Africa is 8.27% (2.6 million), and 31.9% among adults
16
17 261 (20-79 years) with 1.2 million people with diabetes estimated to be undiagnosed³⁴.
18
19 262

263 **Theoretical Framework**

264 *Process Evaluation of Complex Interventions*

265 Process evaluation frameworks assist in understanding the functioning of a complex
266
267 intervention by reviewing implementation processes and the influence of contextual
268
269 factors^{35,36}. A complex intervention implementation process has multiple components
270
271 which interact to produce change, and or are difficult to implement and or target a
272
273 number of organizational levels^{35,37}. Process evaluation is therefore useful for
274
275 assessing (Figure 3) fidelity (dose, adaptations, frequency and reach), clarifying the
276
277 usual mechanisms and processes and identifying the impact of contextual factors on
278
279 the variations in processes and outcomes³⁸. A process evaluation framework will be
30
31 applied in this study to evaluate whether the processes for implementing the
32
33 intervention (the ICDM model) is being applied as intended according to the design
34
35 (fidelity) of the intervention, and how contextual factors influence the implementation
36
37 fidelity (Figure 4). The costs, quantity and quality of program activities provided and
38
39 evaluating the generalizability of the results in other different contexts is important
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41 especially for a program that is already established³⁸.
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48 **Study Design**

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50 281 This is a process evaluation study using mixed methods to assess the degree of
51
52 282 fidelity, costs and impact of context on the implementation fidelity of the ICDM model.
53
54 283

55 **Objective-specific methodology**

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57 285 **Fidelity assessment** will be carried out to review if implementation of the ICDM model
58
59 286 adheres to content, coverage, frequency and duration as prescribed in the ICDM
60

1
2
3 287 model manual in sixteen (8 in North West and 8 in Gauteng) clinics. As there are no
4
5 288 fidelity criteria in the literature that are suitable to adapt for assessing the ICDM model
6
7 289 implementation, we developed fidelity criteria based on the ICDM model guidelines¹⁶,
8
9 290 the ICRM programme monitoring tools²¹ and published literature on the ICDM model¹⁸,
10
11 291 ^{26, 28, 30}. The basis of the criteria are the four (facility re-organization, clinical supportive
12
13 292 management, assisted self-management and strengthening of the support systems)
14
15 293 major components of the ICDM model¹⁶. The outlined prescribed activities are the
16
17 294 variables to be assessed on the implementation fidelity criteria. The expected outcome
18
19 295 of the fidelity criteria is to warrant that all the essential activities required for successful
20
21 296 implementation of the ICDM model have been captured. Each criterion under the four
22
23 297 major components will be listed as an item to be scored on the fidelity criteria. We will
24
25 298 assess the fidelity criteria in a pilot study, and finalize it on the basis of the results of
26
27 299 the pilot study. Sixteen clinics, from the twenty ICDM pilot clinics located in those
28
29 300 districts will be considered for inclusion if the clinic has been open and running without
30
31 301 any major interruptions (renovations, closures) in the last two years. At each clinic,
32
33 302 we will collect data using structured observations, review of facility records and
34
35 303 interviews with the healthcare workers (Table 1).

34
35 304
36
37 305 **Contextual factors** (facility characteristics and characteristics of individuals and
38
39 306 teams) on fidelity will be examined in four clinics. Based on the degree of fidelity, **two**
40
41 307 **clinics**, one with a high, one with a low degree of fidelity will be selected each of the
42
43 308 two districts. The organizational contextual factors to be considered include
44
45 309 communication style, decision process and culture³⁹. Individual level data for the
46
47 310 implementing teams will include demographics (age, gender, race, education level),
48
49 311 position role within the clinic, years in that role, their participation in the delivery of the
50
51 312 ICDM model. External (to the facility) context factors (socio-economic level, policies
52
53 313 and legislation) will not be evaluated in order to keep the study scope manageable.
54
55 314 We will use mixed-methods (interviews, facility assessments and culture surveys)
56
57 315 approach to assess the influence of context on implementation fidelity. We will conduct
58
59 316 qualitative interviews with thirty healthcare workers, purposively selected to represent
60
317 different cadres of staff members that implement and manage the ICDM model
318 intervention for more than six months (Table 1). The interviews will be done on a one-
319 to-one basis to minimize having group dynamics.

320

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

325

326 **Costs:** The financial and economic costs of implementing the ICDM model from the
327 health system perspective will be evaluated in the same four clinics. The health system
328 implementation costs are an all-inclusive costing valuation that considers costs
329 incurred by the providers of the service⁴⁰. Assessing the implementation costs will be
330 a partial economic evaluation as it will only focus on the costs of implementation and
331 not the outcomes. The unit of implementation costs will be by activity of each of the
332 major components of the ICDM model. Service level costs such as those pertaining to
333 the development of the ICDM model will not be included as these costs were incurred
334 in 2010/11 . The focus will be on post start-up annual costs required for the full
335 implementation of the ICDM model in a typical year (Table 1). Both direct and indirect,
336 and fixed and recurrent costs will be calculated.

337

338 Capital costs: Annualized equipment and capital costs will be calculated according to
339 the volume being used for the ICDM model. Estimating annual costs will include
340 adding up the acquisition, operation, maintenance and disposal costs.

341 Operational costs: In the financial documents review, key operational costs that we
342 will check and categorize include human resources, office supplies and travel. Based
343 on the useful life and the discount rate, an appropriate annualization factor will be
344 determined. If there are any donations for program implementation (volunteers,
345 healthcare workers not allocated to ICDM but assisting in service delivery, donated
346 equipment or office supplies) they will be included. Medical and support staff labour
347 costs will be calculated based on the full time equivalent, duration of involvement in
348 the ICDM model implementation and the gross salary of the personnel.

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

352

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3 353 *Patient and Public Involvement:* Previous research has shown that patients do not like
4 354 some of the components of the ICDM model and that was the basis of the research
5 355 question. Patients will not be enrolled in the study; however results will be shared with
6 356 them through community and health facilities leadership.
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10 357

11 358 **Data Management and Analysis Plan**

12 359 The data will be collected using paper based questionnaires and later captured into
13 360 an electronic database. There will be no identifying features (e.g. date of birth,
14 361 addresses) in the database. The health facilities and healthcare workers that
15 362 participated will be allocated a study number. Source documents will be safely kept
16 363 and only accessible to study personnel. The data on costs will be manually entered
17 364 into the CostIt software 2007⁴¹ according to the provided major categories. CostIt
18 365 software is a template designed to capture and automatically analyse cost data for
19 366 different (hospital, PHC and programme) levels of the healthcare system⁴¹
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29 368 Descriptive statistics (frequency, median, interquartile ranges, percentages) will be
30 369 used to examine the general quantitative variables of the clinics, such as size, number
31 370 of chronic patients, services offered, clinic team characteristics and overall functioning
32 371 status. Following the evaluation, each clinic will receive a score for each of the fidelity
33 372 criteria items. Item scores will be summed per component to give four overall ICDM
34 373 component fidelity scores per facility. An overall ICDM model implementation fidelity
35 374 score will be calculated per facility by summing the four component scores. The
36 375 implementation fidelity scores will be summarized using descriptive statistics and
37 376 compared between components, facilities and districts. The outcome of interest will be
38 377 the degree of implementation fidelity.
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48 379 The experiences and perceptions of the healthcare workers from the interviews will be
49 380 analysed with REDCap software for Likert scaled questions and using thematic
50 381 content analysis for barriers and facilitators of implementation fidelity for qualitative
51 382 data. The six steps recommended by Braun and Clarke⁴² for thematic content analysis
52 383 that will be followed: Familiarization, generating initial codes, searching for themes
53 384 throughout the database, reviewing and naming themes and summarizing the
54 385 findings⁴². Multi-variate analysis using STATA 14 econometric software will be used
55 386 to assess the effect of various contextual factors on the implementation fidelity of the
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387 ICDM model. The impact of both the organizational (case mix, financial flexibility and
 388 culture) and implementing teams (work experience, cadre of HCW, training and
 389 perceptions of ICDM) level factors on the degree of the ICDM model implementation
 390 fidelity will be assessed. The initial analysis will include description of the sample,
 391 followed by a bivariate analysis that includes t-tests and ANOVA to examine the
 392 influence of contextual factors on implementation fidelity of the ICDM model.

393

394 Costs: Capital costs and other costs that have a life span of several years will be
 395 annualized over the useful lifespan to get the equivalent annual costs. All costs will be
 396 adjusted for inflation and discount. Equipment will be depreciated according to the
 397 South African Accounting principles⁴³. Sensitivity analyses will be conducted for other
 398 possible variations in estimated costs. Sensitivity analyses will also be carried out to
 399 explore different scenarios including size of clinic, degree of implementation fidelity
 400 and other factors that could possibly affect costs based on literature.

401

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

404

	Objective	Methods	Outcomes
Degree of Fidelity Assessment	To assess the degree of fidelity in the implementation of the ICDM model	Quantitative: Fidelity Evaluation in 16 ICDM model pilot PHC clinics using the Fidelity criteria scoring checklist template. Data Sources: Key informants 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 30 HCW in four facilities, two per district using structured interview guides and organizational 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 four PHC clinics – two facilities per district using The World Health Organization CostIt software 2007. Data sources: Budgets, key informants interviews, direct observations and literature search. Annualize 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.

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3 405 *Ethical conduct of the study:* This study has been approved by the University of Cape
4 406 Town (Ref: 127/2018) and University of the Witwatersrand (Ref: R14/49) Human
5 407 Research ethics committees. Approvals have also been received from the Gauteng
6 408 and the North West Provincial departments of health. The participants for the
7 409 interviews will be consented individually prior to taking part in the study.

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11 410 *Results Dissemination:* The results of this study will be shared with the various
12 411 stakeholders to inform the implementation of the ICDM model in South Africa and other
13 412 models of integrated care. Brief summary of results will be presented to the Provincial
14 413 and districts DOH. The full results will be presented at local research days in each
15 414 province and district. Facility managers and local clinic staff that participated in the
16 415 study will be given feedback on the outcomes of the study. The results will also be
17 416 presented through publications and conference presentations to enhance scientific
18 417 knowledge. Authorship will be determined by substantial contributions to the study
19 418 according to the recommendations for the conduct, reporting and publication of
20 419 research in medical journals. Once the data collection and cleaning is complete, it will
21 420 be made open and publicly accessible.

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33 423 **Conclusion:** Many health systems are challenged with increased demand for
34 424 healthcare for chronic diseases. Despite this service need, there is minimal integration
35 425 of services for the management of chronic diseases resulting in inefficiencies in
36 426 service delivery, high costs and poor health outcomes. The ICDM model has been
37 427 developed to address this challenge, the success of which will be influenced by the
38 428 degree to which the model is accurately implemented. This highlights the need for data
39 429 to assess the degree of fidelity to the ICDM model intervention, and for data that
40 430 explores how fidelity of implementation is affected by contextual factors. Data
41 431 generated from this study will inform integration of chronic care services at the PHC
42 432 level, and scalability of the ICDM model, of relevance in South Africa and other low
43 433 and middle-income countries increasingly facing a growing tide of chronic disease
44 434 multimorbidity.

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4 548 **Acknowledgements:** We would like to acknowledge the people that have reviewed
5 549 this protocol and provided feedback: Leslie London, Edina Sinanovic, Maylene Shung
6 550 King and South African MRC Self-Initiated Research Grant division.
7 551

8 552 **Funding Statement:** The proposed study outlined in this protocol will be supported
9 553 by the South African Medical Research Council under a Self-Initiated Research Grant
10 554 (ID:494184). The views and opinions expressed are those of the author(s) and do not
11 555 necessarily represent the official views of the SA MRC. The sponsor appointed
12 556 reviewers have critically assessed the protocol and requested some changes to be
13 557 done prior to submission to ethics. The sponsor will have no role in data collection,
14 558 analysis or reporting.
15 559

16 560 **Author Statement:** LL was involved in the conception, design literature review and
17 561 writing. OA, MK and TO have contributed to the conception, design and critical review
18 562 of the manuscript.
19 563

20 564 **Conflict of Interest:** The authors have no conflict of interest to declare.
21 565

22 566 **Ethical Issues:** The protocol has been approved by the University of Cape Town and
23 567 University of the Witwatersrand Human Research ethics committees. Any changes
24 568 required, will have to be submitted to both ethics committees.
25 569

26 570 **Word Count:** 3889
27 571

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29 573 **Figures and Tables**

30 574 **Figures**

31 575 *Figure 1: Map of South Africa with the ICDM model pilot sites highlighted*
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33 577 *Figure 2: Integrated Chronic Disease Management Model¹⁶*
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35 579 *Figure 3: The Process Evaluation framework for complex interventions³⁸*
36 580

37 581 *Figure 4: Modified Process Evaluation Framework for assessing the fidelity and cost
38 582 of the ICDM model implementation*

39 583 **Tables**

40 584 *Table 2: Summary of study objectives, methods and expected outcomes for assessing
41 585 the fidelity, impact of contextual factors and costs of the ICDM model implementation*
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Figure 1: Map of South Africa with the ICDM model pilot sites highlighted

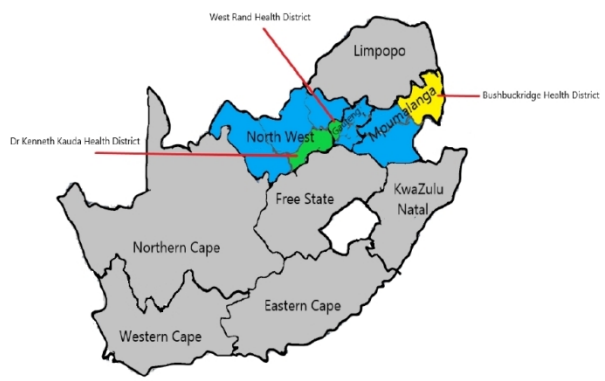


Figure 1: Map of South Africa with the ICDM model pilot sites highlighted
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Figure 1: Integrated Chronic Disease Management Model²¹

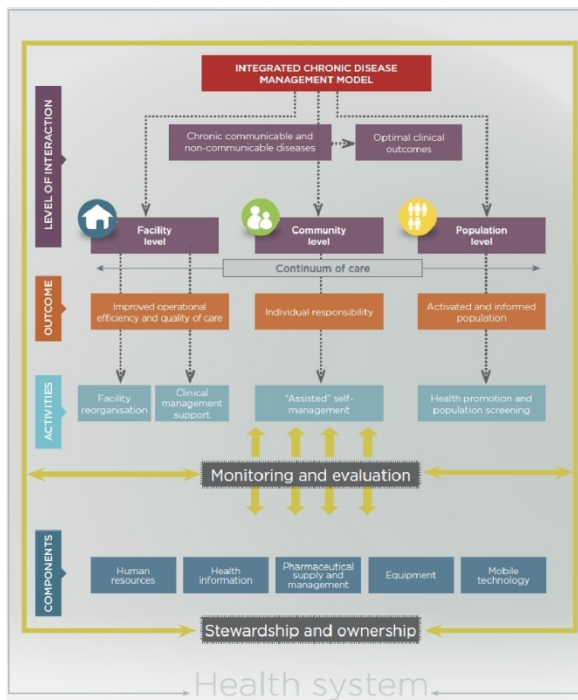


Figure 2: Integrated Chronic Disease Management Model 21

104x148mm (300 x 300 DPI)

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Figure 3: The Process Evaluation framework for complex interventions³⁸

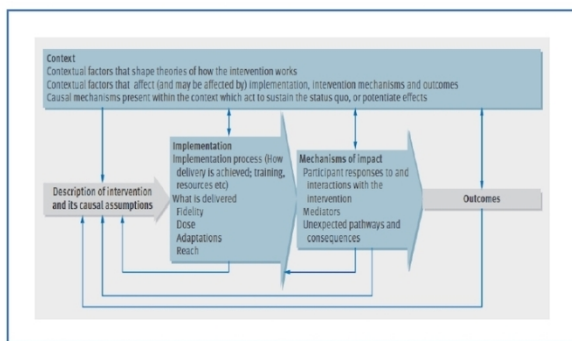


Figure 3: The Process Evaluation framework for complex interventions 38

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Figure 4: Modified Process Evaluation Framework for assessing the fidelity and cost of the ICDM model implementation

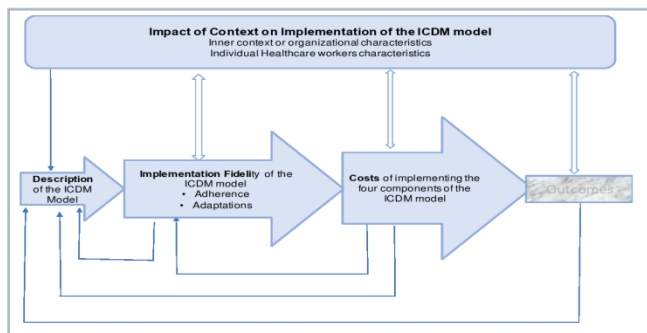


Figure 4: Modified Process Evaluation Framework for assessing the fidelity and cost of the ICDM model implementation

139x198mm (300 x 300 DPI)



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym ✓ - pg. 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry – N/A
	2b	All items from the World Health Organization Trial Registration Data Set. – N/A
Protocol version	3	Date and version identifier - ✓ - pg.1
Funding	4	Sources and types of financial, material, and other support ✓ - pg.18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors - ✓ - pg.18
	5b	Name and contact information for the trial sponsor N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities ✓ - pg.18
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) N/A
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention ✓ - pg. 2-4
	6b	Explanation for choice of comparators – N/A
Objectives	7	Specific objectives or hypotheses ✓ - pg. 7

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Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) – N/A
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Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained ✓ - pg. 7-8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) ✓ - pg. 9-10
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered – N/A
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) - N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) - N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial – N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended ✓ - pg. 11 – 12.
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) N/A
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations – N/A
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials) N/A

Allocation:

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2	Sequence	16a	Method of generating the allocation sequence (eg, computer-
3	generation		generated random numbers), and list of any factors for stratification.
4			To reduce predictability of a random sequence, details of any planned
5			restriction (eg, blocking) should be provided in a separate document
6			that is unavailable to those who enrol participants or assign
7			interventions
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10	Allocation	16b	Mechanism of implementing the allocation sequence (eg, central
11	concealment		telephone; sequentially numbered, opaque, sealed envelopes),
12	mechanism		describing any steps to conceal the sequence until interventions are
13			assigned
14			
15	Implementation	16c	Who will generate the allocation sequence, who will enrol participants,
16			and who will assign participants to interventions
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18	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial
19	(masking)		participants, care providers, outcome assessors, data analysts), and
20			how
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23		17b	If blinded, circumstances under which unblinding is permissible, and
24			procedure for revealing a participant's allocated intervention during
25			the trial
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Methods: Data collection, management, and analysis

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30	Data collection	18a	Plans for assessment and collection of outcome, baseline, and other
31	methods		trial data, including any related processes to promote data quality (eg,
32			duplicate measurements, training of assessors) and a description of
33			study instruments (eg, questionnaires, laboratory tests) along with
34			their reliability and validity, if known. Reference to where data
35			collection forms can be found, if not in the protocol ✓ - pg. 11-12
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38		18b	Plans to promote participant retention and complete follow-up,
39			including list of any outcome data to be collected for participants who
40			discontinue or deviate from intervention protocols – N/A
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42	Data	19	Plans for data entry, coding, security, and storage, including any
43	management		related processes to promote data quality (eg, double data entry;
44			range checks for data values). Reference to where details of data
45			management procedures can be found, if not in the protocol ✓ - pg.
46			11-12
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49	Statistical	20a	Statistical methods for analysing primary and secondary outcomes.
50	methods		Reference to where other details of the statistical analysis plan can be
51			found, if not in the protocol - ✓ - pg. 11-12
52			
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54		20b	Methods for any additional analyses (eg, subgroup and adjusted
55			analyses) ✓ - pg. 11 -12
56			
57		20c	Definition of analysis population relating to protocol non-adherence
58			(eg, as randomised analysis), and any statistical methods to handle
59			missing data (eg, multiple imputation) N/A
60			

Methods: Monitoring

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed - N/A
24 25 26 27 28 29 30 31 32 33 34	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
35 36 37 38 39 40 41 42 43 44 45	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval ✓ - pg. 1
26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) ✓ - pg. 1
26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) N/A
26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Confidentiality	27	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable N/A
26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial ✓ - pg. 11
26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site ✓ - pg. 1
26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators ✓ - pg. 1
26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation -N/A

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| Dissemination
policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
✓ - pg. 12 |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers - ✓ - pg. 13 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code ✓ - pg. 13 |

16 Appendices

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|-------------------------------|----|--|
| Informed consent
materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates – Appendix 1 |
| Biological
specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable – N/A |

25 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
26 Explanation & Elaboration for important clarification on the items. Amendments to the
27 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
28 Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)"
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BMJ Open

Process evaluation of Fidelity and Costs of implementing the Integrated Chronic Disease Management Model in South Africa: Mixed Methods Study Protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-029277.R2
Article Type:	Protocol
Date Submitted by the Author:	08-May-2019
Complete List of Authors:	Lebina, Limakatso; University of the Witwatersrand, Perinatal HIV Research Unit; University of Cape Town Faculty of Health Sciences, School of Public Health and Family Medicine Alaba, Olufunke; University of Cape Town, School of Public Health and Family Medicine Kawonga, Mary; University of the Witwatersrand, School of Public Health Oni, Tolu; University of Cape Town, School of Public Health and Family Medicine; University of Cambridge, MRC Epidemiology Unit
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Patient-centred medicine, Public health, Evidence based practice
Keywords:	implement, ICDM, intervention evaluation

SCHOLARONE™
Manuscripts

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3 1 **Process evaluation of Fidelity and Costs of implementing the Integrated**
4 2 **Chronic Disease Management Model in South Africa: Mixed Methods Study**
5 3 **Protocol**
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7 5
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9 6 Version 2.0, Dated 06 April 2019
10 7

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35 29 **Keywords: implementation, ICDM model, intervention evaluation**
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3 **Abstract**
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5 **Introduction:** The South African Department of health has developed and
6 implemented the Integrated Chronic Disease Management (ICDM) model to respond
7 to the increased utilization of primary healthcare (PHC) services due to a surge of non-
8 communicable diseases co-existing with a high prevalence of communicable
9 diseases. However, some of the expected outcomes on implementing the ICDM model
10 have not been achieved. The aims of this study are to assess if the observed sub-
11 optimal outcomes of the ICDM model implementation are due to lack of fidelity to the
12 ICDM model; to examine the contextual factors associated with the implementation
13 fidelity, and to calculate implementation costs.
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21 **Methods and Analysis:** A process evaluation, mixed methods study in sixteen pilot
22 clinics from two health districts to assess the degree of fidelity to four major
23 components of the ICDM model. Activity scores will be summed per component and
24 overall fidelity score will be calculated by summing the various component scores, and
25 compared between components, facilities and districts. Multivariate analysis will be
26 used to examine the association between contextual factors and the degree of fidelity,
27 individual and team characteristics, facility features, and organizational culture
28 indicators will be included in the regression. Health system financial and economic
29 costs of implementing the four components of the ICDM model will be calculated using
30 an ingredient approach. The unit of implementation costs will be by activity of each of
31 the major components of the ICDM model. Sensitivity analysis will be carried out using
32 clinic size, degree of fidelity, and different inflation situations.
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44 **Ethics and Dissemination:** The protocol has been approved by the University of
45 Cape Town and University of the Witwatersrand Human Research ethics committees.
46 The results of the study will be shared with the department of health, participating
47 health facilities and the through scientific publications and conference presentations.
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62 **Strengths and Limitations of this study**

- 63 • This study uses implementation research principles to provide data on the
64 degree of fidelity to the ICDM model for optimizing the model
- 65 • Process evaluation will provide an indication of how the ICDM model has been
66 modified in different contexts can explain variability in the implementation
67 outcomes.
- 68 • Implementation costs assessments are essential in public health programs to
69 inform resource allocation during planning and budgeting and to inform
70 economic evaluations
- 71 • The reliance on the service provider to accurately provide information on the
72 implementation activities or insufficiencies of those activities is a limitation of
73 this study.
- 74 • Although the clinics may not be representative of all districts and clinics in the
75 country, the results of this study could be applied to clinics similar in size or
76 patient load and other integrated disease management models.
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82 Introduction

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84 Chronic diseases and multi-morbidity is increasing in developing countries due to
85 epidemiological transition of increasing prevalence of non-communicable diseases
86 (NCDs) in the presence of rampant infectious diseases^{1,2}. By 2025, it is estimated
87 that the burden of NCDs in sub-Saharan Africa will be higher than that of
88 communicable diseases (CD)³. The increase in urbanization, economic development,
89 aging, decrease of physical activity and poor dietary options are some of the
90 contributing factors to the increasing prevalence of NCDs in developing countries^{4, 5}.
91 There is also a complex interaction of risk factors, management and health outcomes
92 between NCDs and CDs, resulting a rise in chronic disease mulitmorbidty^{6,7}. Multi-
93 morbidity often results in reduced levels of physical capability, high rates of health
94 services utilization and attendant costs and higher mortality rates^{8,9}. The double
95 burden (NCDs and CDs) of diseases is costly to the health systems (increased
96 utilization, medication), the economies, households and individuals². Therefore,
97 chronic disease management needs to be comprehensive and take into consideration
98 these interactions in disease prevention, management and control.

99
100 In South Africa, the current leading health problems are NCDs, accounting for 51.3%
101 of all deaths, followed by CDs 38.4%, and injuries 10.3%¹⁰. South Africa like many
102 Sub-Saharan African countries has been severely affected by the HIV/AIDS epidemic,
103 with 7.1 million people living with HIV; and 18.9% of people between the ages of 15-
104 49years being HIV infected¹¹. As a result, there is an increase in the prevalence of
105 multi-morbidity¹². Tuberculosis (TB), Human Immune Deficiency Syndrome (HIV) and
106 NCDs (mainly Hypertension (HPT) and Diabetes Mellitus (DM)) account for 45% of
107 all primary health care consultations, with a multi-morbidity prevalence of 22.6%^{9,13}.

108
109 Unresponsive health systems often provide services that are not aligned with the
110 health requirements of the population being served¹⁴. A more comprehensive chronic
111 disease management model, combining both CDs and NCDs that reduces health
112 utilization and promotes self-management is one of the strategies that have been
113 recommended to address the challenges associated with the management of
114 multimorbid chronic diseases^{2, 14}. The chronic care model (CCM) and Innovative Care
115 for Chronic Conditions (ICCC) framework have been recommended as health system

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3 116 approaches to deal with multi-morbidity¹⁵. However, there have been significant
4
5 117 resources and strategies allocated to the implementation of HIV programs and
6
7 118 consequently the non-communicable chronic diseases have been overlooked. To
8
9 119 rectify this imbalance, the South African National Department of Health developed and
10
11 120 has begun implementation of the Integrated Chronic Disease Management (ICDM)
12
13 121 model in order to improve efficiencies and quality of care in primary health care clinics
14
15 122 for patients with chronic diseases¹⁶.

16 123

17 124 **Integrated Chronic Disease Management Model**

18 125

19
20 126 The ICDM model was piloted from 2011 in 42 clinics from three health districts in three
21
22 127 different provinces (Figure 1) of South Africa as follows: West Rand in Gauteng
23
24 128 Province, Bushbuckridge in Mpumalanga and Dr. Kenneth Kaunda in North West
25
26 129 Province^{17,18}. As part of a broader national approach to revitalize primary health care
27
28 130 (PHC) services, reduce fragmentation of services and ensure that each PHC facility
29
30 131 meets national minimum standards, the “ideal clinic” initiative was also started in
31
32 132 2013¹⁹. The principles of the “ideal clinic” incorporate the majority of the activities
33
34 133 required for ICDM implementation and provides standard operating procedures for the
35
36 134 Ideal Clinic Realisation and Maintenance (ICRM) programme^{20, 21}. One of the
37
38 135 components of the ICRM programme is Integrated Clinical Services Management
39
40 136 (ICSM) which focuses on health services being structured in four (acute, chronic,
41
42 137 preventative and promotive and health support) streams.^{20, 21} The principles of the
43
44 138 ICRM, ICSM and the ICDM model cover integration of services, good administrative
45
46 139 processes, functional infrastructure and equipment, adequate personnel, ensuring
47
48 140 adequate levels of medicines and supplies and the use of applicable protocols and
49
50 141 guidelines in diseases management¹⁹⁻²¹.

51 142

52
53 143 The four major components (action points) of the ICDM implementation are: facility re-
54
55 144 organization for efficiency, clinical supportive management, assisted self-support and
56
57 145 strengthening of support systems (Figure 2)¹⁶. The ICDM priority and core standards
58
59 146 are 1) improving the values and attitudes of staff, 2) patient safety and security and
60
147 infection prevention and control, and 3) availability of medicines and supplies¹⁶.
148 Assuming full implementation of the ICDM as recommended, the expected outcomes
149 include improved operational efficiency and quality of care, improved individual

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3 150 responsibility towards their health and an activated and informed community¹⁶. The
4
5 151 ICDM model also provides guidelines on booking systems for patients with chronic
6
7 152 diseases, clinic flow, organization of waiting areas and consultation rooms and
8
9 153 dispensing medication practices that promote adherence and minimize medication
10
11 154 shortages. In order to avoid fragmentation of services, the ICDM recommends a multi-
12
13 155 disciplinary treating team to provide care to all patients with chronic illnesses and be
14
15 156 trained on how to assess and manage drug-drug interactions and disease interactions.
16
17 157 Mentoring, supervision and training of the PHC nurses to be provided the district
18
19 158 Clinical Specialist Team (DCST)¹⁶. The DCST other responsibilities include
20
21 159 monitoring of patient clinical outcomes through clinical audits and strengthening of
22
23 160 referral systems for complicated patients¹⁶. The components or building blocks for
24
25 161 ICDM model include human resources, health information, mobile technology,
26
27 162 equipment and pharmaceutical supply and management¹⁶.

28
29 163
30
31 164 **The ICDM Model Pilot Phase Implementation:** The pilot phase was supported with
32
33 165 quality improvement reviews and consultation with all staff members at the facility-,
34
35 166 district- and province-levels to refine the model even further¹⁸. Some of the
36
37 167 implementation challenges identified in these consultations were lack of key
38
39 168 equipment, an emphasis on curative health services with minimal focus on prevention,
40
41 169 the ill-defined role of community health care workers and delayed formation of out of
42
43 170 facility chronic medication collection sites¹⁸. Lack for these necessary building blocks
44
45 171 for the ICDM model has resulted in the implementation of hybrids of the original
46
47 172 model¹⁸. The limitations of the ICDM model identified include its focus on secondary
48
49 173 and tertiary prevention of disease within the healthcare facilities, and the lack of
50
51 174 guidelines on social and environmental changes for the prevention of risk factors and
52
53 175 onset of chronic diseases¹⁶.

54 176 55 177 **Management of Chronic Conditions in PHC Facilities**

56
57 178 An evaluation of PHC services in South Africa showed low rates of diagnosis for
58
59 179 chronic diseases, and the few that are diagnosed, are not managed appropriately and
60
180 do not achieve the treatment targets^{22,23}. The lack of key equipment in PHC clinics to
181
182 diagnose and monitor total cholesterol, blood pressure and blood glucose contribute
183
184 these challenges, with patients reporting the need to travel to higher levels of care to
185
186 access certain medication and diagnostic tests²². Additional barriers included the

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3 184 insufficient consultation time that patients report with their healthcare providers even
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5 185 after long waiting periods at the facility due to high volumes of patients²²; poor
6
7 186 knowledge on chronic disease, shortage of medication and shortage of healthcare
8
9 187 workers resulting in long waiting periods at PHC clinics²⁴. The nurses knowledge of
10
11 188 chronic diseases was also found to be poor due to inadequate training, unavailability
12
13 189 of guidelines and lack of supervision²⁴.

14 190

15 191 The implementation of an innovative intervention can be affected by the design of the
16
17 192 intervention, context and or implementation outcomes²⁵. New innovative interventions
18
19 193 could fail to achieve intended objectives because of implementation barriers or failures
20
21 194 in the design²⁵. The observed impact of the ICDM model in the management of chronic
22
23 195 diseases has been an improvement in the patients' records, compliance with clinical
24
25 196 guidelines and health outcomes for patients on antiretroviral medication but not those
26
27 197 on hypertension treatment^{26,27}. Irregular supplies and stock-outs of hypertension
28
29 198 medication was also not improved after the implementation of the ICDM model²⁸. The
30
31 199 patients' perspectives on the ICDM model inconveniences were a non-flexible
32
33 200 appointment system that affected access to services, long waiting times because of
34
35 201 personnel shortages and stigmatization of patients that are visited by community
36
37 202 healthcare workers²⁸. However, it is not clear whether these observed and perceived
38
39 203 gains and shortcomings are as a result of the inherent faults in the design of the model
40
41 204 or failure to adhere to the prescribed activities and/or the impact of contextual factors.

42 205

43 206 The successful implementation of the ICDM model requires a high degree of fidelity to
44
45 207 the recommended processes of delivering health care services with clear intervention
46
47 208 priorities and expected outcomes^{29,30}. Although monitoring and evaluation tools exist
48
49 209 for the ICDM model implementation, they do not provide data on implementation
50
51 210 outcomes such as adoption, fidelity, penetration, acceptability, sustainability and
52
53 211 costs. Process evaluation of the ICDM model implementation would optimize practice
54
55 212 of the four major components and scale-up of the model, and the quality of care for
56
57 213 individuals affected by chronic illness, especially those with multi-morbidity.

58 214

59 215 Implementation of any intervention within a large complex health system is generally
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216 unpredictable. An assessment of fidelity on the implementation of the model will
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218 additionally measure quality of practice for continuous improvement, identify any

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3 218 innovations that can improve models' processes and support systematic
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5 219 implementation of the model. Although the implementation of the ICDM model was
6
7 220 subsequently followed by the ICRM programme that consists of the ICSM which has
8
9 221 a broader focus beyond chronic diseases, both these interventions have similar
10
11 222 principles, standards and aims of ensuring that patients get quality patient-centric care
12
13 223 that achieves the desired health outcomes¹⁹⁻²¹. We envisage lessons learnt from an
14
15 224 evaluation of the ICDM model can be beneficial in the strengthening of implementation
16
17 225 of the ICRM programme.
18

226

227

20 228 Interviews with the actors in the ICDM model implementation will provide information
21
22 229 on their perceptions and experiences with implementation and how contextual factors
23
24 230 have affected fidelity to the model's guidelines. This can improve comparability,
25
26 231 generalizability and replicability of the results of this study. Assessing the cost of
27
28 232 implementing the various activities of the ICDM model will then assist with planning
29
30 233 and budgeting, as well as inform scalability and sustainability of the model.
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234

32 235 Therefore, the **aim** of this study is to evaluate selected implementation outcomes of
33
34 236 the ICDM model: fidelity and implementation costs, and to assess the influence of
35
36 237 contextual factors on ICDM model implementation fidelity in two health districts where
37
38 238 the ICDM has been piloted, from two different provinces in order to better understand
39
40 239 the processes of successful implementation of the ICDM model and how the model
41
42 240 can be optimized. The **objectives** of the study are:

- 43 241 1. To assess the degree of fidelity in the implementation of the ICDM model
44
45 242 2. To evaluate the influence of contextual factors on the implementation fidelity of the
46
47 243 ICDM model
48
49 244 3. To estimate the implementation costs of the ICDM model
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245

246

52 247 **Methods and Analysis**

53 248

54 249 **Setting**

55 250

57 251 This study will be conducted from August 2018 to July 2019 in two health districts (Dr.
58
59 252 Kenneth Kaunda in North West Province and West Rand District in Gauteng) that were
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253 the pilot sites for the ICDM model implementation. Both districts are within socio-

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2
3 254 economic quantile four (1 is most deprived and 5 is least deprived), however
4 255 comparing the North West to Gauteng province, poverty prevalence (33% vs. 27%)
5 256 and informal housing (21% vs. 19%) are slightly higher in the North West Province³¹,
6 257 ³². The provincial HIV prevalence is 13.3% in North West Province and 12.4% in
7 258 Gauteng³³. The prevalence of hypertension is high (31%- 39.7%) in both districts, a
8 259 reflection of large number of people accessing health services for chronic NCD³¹. The
9 260 prevalence of diabetes in South Africa is 8.27% (2.6 million), and 31.9% among adults
10 261 (20-79 years) with 1.2 million people with diabetes estimated to be undiagnosed³⁴.
11 262

18 263 **Theoretical Framework**

20 264 *Process Evaluation of Complex Interventions*

21 265 Process evaluation frameworks assist in understanding the functioning of a complex
22 266 intervention by reviewing implementation processes and the influence of contextual
23 267 factors^{35,36}. A complex intervention implementation process has multiple components
24 268 which interact to produce change, and or are difficult to implement and or target a
25 269 number of organizational levels^{35,37}. Process evaluation is therefore useful for
26 270 assessing (Figure 3) fidelity (dose, adaptations, frequency and reach), clarifying the
27 271 usual mechanisms and processes and identifying the impact of contextual factors on
28 272 the variations in processes and outcomes³⁸. A process evaluation framework will be
29 273 applied in this study to evaluate whether the processes for implementing the
30 274 intervention (the ICDM model) is being applied as intended according to the design
31 275 (fidelity) of the intervention, and how contextual factors influence the implementation
32 276 fidelity (Figure 4). The costs, quantity and quality of program activities provided and
33 277 evaluating the generalizability of the results in other different contexts is important
34 278 especially for a program that is already established³⁸.
35 279

36 280 **Study Design**

37 281 This is a process evaluation study using mixed methods to assess the degree of
38 282 fidelity, costs and impact of context on the implementation fidelity of the ICDM model.
39 283

40 284 **Objective-specific methodology**

41 285 **Fidelity assessment** will be carried out to review if implementation of the ICDM model
42 286 adheres to content, coverage, frequency and duration as prescribed in the ICDM
43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60

1
2
3 287 model manual in sixteen (8 in North West and 8 in Gauteng) clinics. As there are no
4
5 288 fidelity criteria in the literature that are suitable to adapt for assessing the ICDM model
6
7 289 implementation, we developed fidelity criteria based on the ICDM model guidelines¹⁶,
8
9 290 the ICRM programme monitoring tools²¹ and published literature on the ICDM model¹⁸,
10
11 291 ^{26, 28, 30}. The basis of the criteria are the four (facility re-organization, clinical supportive
12
13 292 management, assisted self-management and strengthening of the support systems)
14
15 293 major components of the ICDM model¹⁶. The outlined prescribed activities are the
16
17 294 variables to be assessed on the implementation fidelity criteria. The expected outcome
18
19 295 of the fidelity criteria is to warrant that all the essential activities required for successful
20
21 296 implementation of the ICDM model have been captured. Each criterion under the four
22
23 297 major components will be listed as an item to be scored on the fidelity criteria. We will
24
25 298 assess the fidelity criteria in a pilot study, and finalize it on the basis of the results of
26
27 299 the pilot study. Sixteen clinics, from the twenty ICDM pilot clinics located in those
28
29 300 districts will be considered for inclusion if the clinic has been open and running without
30
31 301 any major interruptions (renovations, closures) in the last two years. At each clinic,
32
33 302 we will collect data using structured observations, review of facility records and
34
35 303 interviews with the healthcare workers (Table 1).
36
37 304

34
35 305 **Contextual factors** (facility characteristics and characteristics of individuals and
36
37 306 teams) on fidelity will be examined in four clinics. Based on the degree of fidelity, **two**
38
39 307 **clinics**, one with a high, one with a low degree of fidelity will be selected each of the
40
41 308 two districts. The organizational contextual factors to be considered include
42
43 309 communication style, decision process and culture³⁹. Individual level data for the
44
45 310 implementing teams will include demographics (age, gender, race, education level),
46
47 311 position role within the clinic, years in that role, their participation in the delivery of the
48
49 312 ICDM model. External (to the facility) context factors (socio-economic level, policies
50
51 313 and legislation) will not be evaluated in order to keep the study scope manageable.
52
53 314 We will use mixed-methods (interviews, facility assessments and culture surveys)
54
55 315 approach to assess the influence of context on implementation fidelity. We will conduct
56
57 316 qualitative interviews with thirty healthcare workers, purposively selected to represent
58
59 317 different cadres of staff members that implement and manage the ICDM model
60
318 intervention for more than six months (Table 1). The interviews will be done on a one-
319
to-one basis to minimize having group dynamics.

320

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

325

326 **Costs:** The financial and economic costs of implementing the ICDM model from the
327 health system perspective will be evaluated in the same four clinics. The health system
328 implementation costs are an all-inclusive costing valuation that considers costs
329 incurred by the providers of the service⁴⁰. Assessing the implementation costs will be
330 a partial economic evaluation as it will only focus on the costs of implementation and
331 not the outcomes. The unit of implementation costs will be by activity of each of the
332 major components of the ICDM model. Service level costs such as those pertaining to
333 the development of the ICDM model will not be included as these costs were incurred
334 in 2010/11 . The focus will be on post start-up annual costs required for the full
335 implementation of the ICDM model in a typical year (Table 1). Both direct and indirect,
336 and fixed and recurrent costs will be calculated.

337

338 Capital costs: Annualized equipment and capital costs will be calculated according to
339 the volume being used for the ICDM model. Estimating annual costs will include
340 adding up the acquisition, operation, maintenance and disposal costs.

341 Operational costs: In the financial documents review, key operational costs that we
342 will check and categorize include human resources, office supplies and travel. Based
343 on the useful life and the discount rate, an appropriate annualization factor will be
344 determined. If there are any donations for program implementation (volunteers,
345 healthcare workers not allocated to ICDM but assisting in service delivery, donated
346 equipment or office supplies) they will be included. Medical and support staff labour
347 costs will be calculated based on the full time equivalent, duration of involvement in
348 the ICDM model implementation and the gross salary of the personnel.

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

352

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3 353 *Patient and Public Involvement*: Previous research has shown that patients do not like
4 354 some of the components of the ICDM model and that was the basis of the research
5 355 question. Patients will not be enrolled in the study; however results will be shared with
6 356 them through community and health facilities leadership.
7
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9

10 357

11 358 **Data Management and Analysis Plan**

12 359 The data will be collected using paper based questionnaires and later captured into
13 360 an electronic database. There will be no identifying features (e.g. date of birth,
14 361 addresses) in the database. The health facilities and healthcare workers that
15 362 participated will be allocated a study number. Source documents will be safely kept
16 363 and only accessible to study personnel. The data on costs will be manually entered
17 364 into the CostIt software 2007⁴¹ according to the provided major categories. CostIt
18 365 software is a template designed to capture and automatically analyse cost data for
19 366 different (hospital, PHC and programme) levels of the healthcare system⁴¹
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29 368 Descriptive statistics (frequency, median, interquartile ranges, percentages) will be
30 369 used to examine the general quantitative variables of the clinics, such as size, number
31 370 of chronic patients, services offered, clinic team characteristics and overall functioning
32 371 status. Following the evaluation, each clinic will receive a score for each of the fidelity
33 372 criteria items. Item scores will be summed per component to give four overall ICDM
34 373 component fidelity scores per facility. An overall ICDM model implementation fidelity
35 374 score will be calculated per facility by summing the four component scores. The
36 375 implementation fidelity scores will be summarized using descriptive statistics and
37 376 compared between components, facilities and districts. The outcome of interest will be
38 377 the degree of implementation fidelity.
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47 379 The experiences and perceptions of the healthcare workers from the interviews will be
48 380 analysed with REDCap software for Likert scaled questions and using thematic
49 381 content analysis for barriers and facilitators of implementation fidelity for qualitative
50 382 data. The six steps recommended by Braun and Clarke⁴² for thematic content analysis
51 383 that will be followed: Familiarization, generating initial codes, searching for themes
52 384 throughout the database, reviewing and naming themes and summarizing the
53 385 findings⁴². Multi-variate analysis using STATA 14 econometric software will be used
54 386 to assess the effect of various contextual factors on the implementation fidelity of the
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387 ICDM model. The impact of both the organizational (case mix, financial flexibility and
 388 culture) and implementing teams (work experience, cadre of HCW, training and
 389 perceptions of ICDM) level factors on the degree of the ICDM model implementation
 390 fidelity will be assessed. The initial analysis will include description of the sample,
 391 followed by a bivariate analysis that includes t-tests and ANOVA to examine the
 392 influence of contextual factors on implementation fidelity of the ICDM model.

393

394 Costs: Capital costs and other costs that have a life span of several years will be
 395 annualized over the useful lifespan to get the equivalent annual costs. All costs will be
 396 adjusted for inflation and discount. Equipment will be depreciated according to the
 397 South African Accounting principles⁴³. Sensitivity analyses will be conducted for other
 398 possible variations in estimated costs. Sensitivity analyses will also be carried out to
 399 explore different scenarios including size of clinic, degree of implementation fidelity
 400 and other factors that could possibly affect costs based on literature.

401

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

404

	Objective	Methods	Outcomes
Degree of Fidelity Assessment	To assess the degree of fidelity in the implementation of the ICDM model	Quantitative: Fidelity Evaluation in 16 ICDM model pilot PHC clinics using the Fidelity criteria scoring checklist template. Data Sources: Key informants 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 30 HCW in four (two per district) facilities using structured interview guides and organizational 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 four PHC clinics – two facilities per district using The World Health Organization CostIt software 2007. Data sources: Budgets, key informants interviews, direct observations and literature search. Annualize 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.

405 **Ethics and Dissemination**

406

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

412

413 *Results Dissemination:* The results of this study will be shared with the various
414 stakeholders to inform the implementation of the ICDM model in South Africa and other
415 models of integrated care. Brief summary of results will be presented to the Provincial
416 and districts DOH. The full results will be presented at local research days in each
417 province and district. Facility managers and local clinic staff that participated in the
418 study will be given feedback on the outcomes of the study. The results will also be
419 presented through publications and conference presentations to enhance scientific
420 knowledge. Authorship will be determined by substantial contributions to the study
421 according to the recommendations for the conduct, reporting and publication of
422 research in medical journals. Once the data collection and cleaning is complete, it will
423 be made open and publicly accessible.

424

425

426 **Conclusion:** Many health systems are challenged with increased demand for
427 healthcare for chronic diseases. Despite this service need, there is minimal integration
428 of services for the management of chronic diseases resulting in inefficiencies in
429 service delivery, high costs and poor health outcomes. The ICDM model has been
430 developed to address this challenge, the success of which will be influenced by the
431 degree to which the model is accurately implemented. This highlights the need for data
432 to assess the degree of fidelity to the ICDM model intervention, and for data that
433 explores how fidelity of implementation is affected by contextual factors. Data
434 generated from this study will inform integration of chronic care services at the PHC
435 level, and scalability of the ICDM model, of relevance in South Africa and other low
436 and middle-income countries increasingly facing a growing tide of chronic disease
437 multimorbidity.

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550
551 **Acknowledgements:** We would like to acknowledge the people that have reviewed
552 this protocol and provided feedback: Leslie London, Edina Sinanovic, Maylene Shung
553 King and South African MRC Self-Initiated Research Grant division.

554
555 **Funding Statement:** The proposed study outlined in this protocol will be supported
556 by the South African Medical Research Council under a Self-Initiated Research Grant
557 (ID:494184). The views and opinions expressed are those of the author(s) and do not
558 necessarily represent the official views of the SA MRC. The sponsor appointed
559 reviewers have critically assessed the protocol and requested some changes to be
560 done prior to submission to ethics. The sponsor will have no role in data collection,
561 analysis or reporting.

562
563 **Author Statement:** LL was involved in the conception, design literature review and
564 writing. OA, MK and TO have contributed to the conception, design and critical review
565 of the manuscript.

566
567 **Conflict of Interest:** The authors have no conflict of interest to declare.

568
569 **Ethical Issues:** The protocol has been approved by the University of Cape Town and
570 University of the Witwatersrand Human Research ethics committees. Any changes
571 required, will have to be submitted to both ethics committees.

572
573 **Word Count:** 3994

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576 **Figures and Tables**

577 **Figures**

578 *Figure 1: Map of South Africa with the ICDM model pilot sites highlighted*

579

580 *Figure 2: Integrated Chronic Disease Management Model¹⁶*

581

582 *Figure 3: The Process Evaluation framework for complex interventions³⁸*

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584 *Figure 4: Modified Process Evaluation Framework for assessing the fidelity and cost
585 of the ICDM model implementation*

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587 **Tables**

588 *Table 2: Summary of study objectives, methods and expected outcomes for assessing
589 the fidelity, impact of contextual factors and costs of the ICDM model implementation*

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Figure 1: Map of South Africa with the ICDM model pilot sites highlighted
Source: <https://d-maps.com>

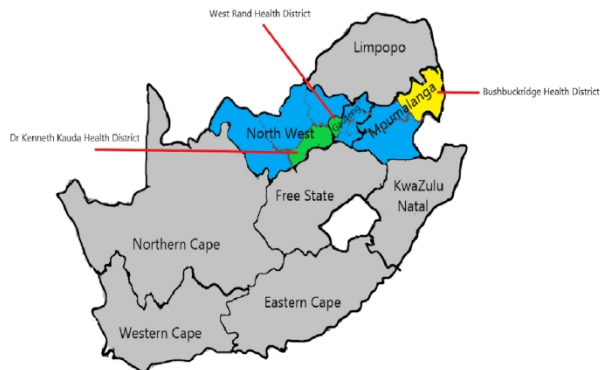


Figure 1: Map of South Africa with the ICDM model pilot sites highlighted
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Figure 2: Integrated Chronic Disease Management Model²¹

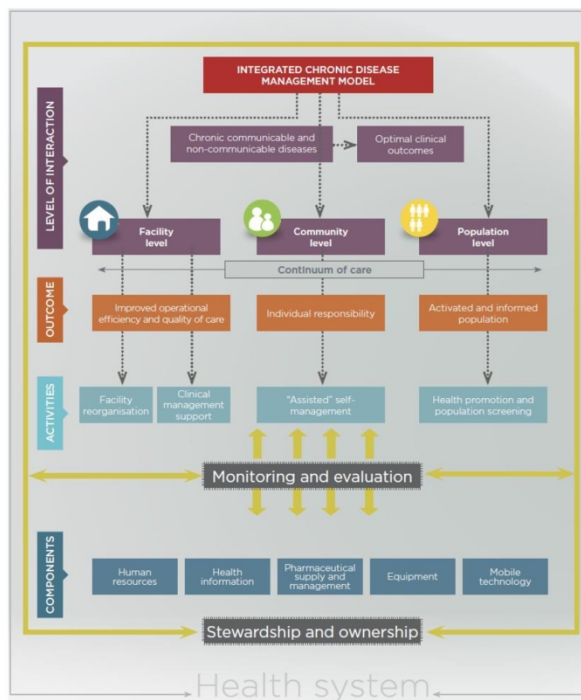


Figure 2: Integrated Chronic Disease Management Model 21

209x297mm (200 x 200 DPI)

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Figure 3: The Process Evaluation framework for complex interventions³⁸

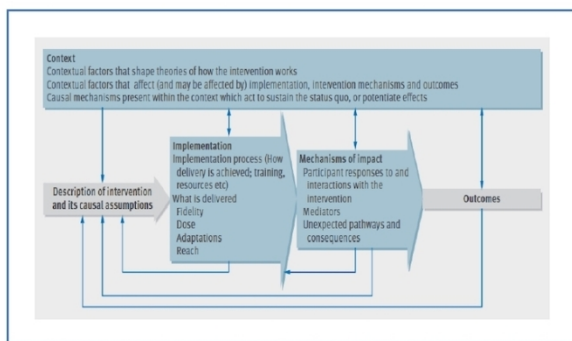


Figure 3: The Process Evaluation framework for complex interventions 38

90x127mm (300 x 300 DPI)

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Figure 4: Modified Process Evaluation Framework for assessing the fidelity and cost of the ICDM model implementation

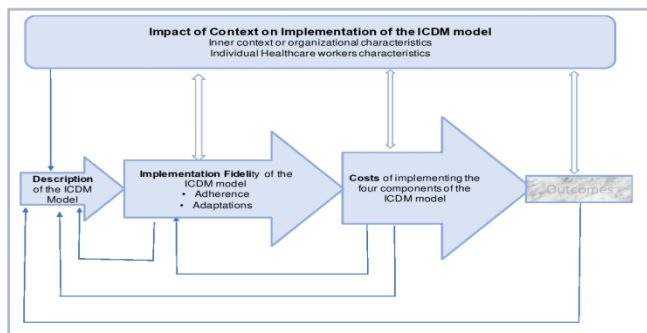


Figure 4: Modified Process Evaluation Framework for assessing the fidelity and cost of the ICDM model implementation

139x198mm (300 x 300 DPI)



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym ✓ - pg. 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry – N/A
	2b	All items from the World Health Organization Trial Registration Data Set. – N/A
Protocol version	3	Date and version identifier - ✓ - pg.1
Funding	4	Sources and types of financial, material, and other support ✓ - pg.18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors - ✓ - pg.18
	5b	Name and contact information for the trial sponsor N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities ✓ - pg.18
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) N/A
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention ✓ - pg. 2-4
	6b	Explanation for choice of comparators – N/A
Objectives	7	Specific objectives or hypotheses ✓ - pg. 7

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Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) – N/A
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Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained ✓ - pg. 7-8
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Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) ✓ - pg. 9-10
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Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered – N/A
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	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) - N/A
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	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) - N/A
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	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial – N/A
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Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended ✓ - pg. 11 – 12.
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Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) N/A
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Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations – N/A
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Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
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Methods: Assignment of interventions (for controlled trials) N/A

Allocation:

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2	Sequence	16a	Method of generating the allocation sequence (eg, computer-
3	generation		generated random numbers), and list of any factors for stratification.
4			To reduce predictability of a random sequence, details of any planned
5			restriction (eg, blocking) should be provided in a separate document
6			that is unavailable to those who enrol participants or assign
7			interventions
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10	Allocation	16b	Mechanism of implementing the allocation sequence (eg, central
11	concealment		telephone; sequentially numbered, opaque, sealed envelopes),
12	mechanism		describing any steps to conceal the sequence until interventions are
13			assigned
14			
15	Implementation	16c	Who will generate the allocation sequence, who will enrol participants,
16			and who will assign participants to interventions
17			
18	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial
19	(masking)		participants, care providers, outcome assessors, data analysts), and
20			how
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23		17b	If blinded, circumstances under which unblinding is permissible, and
24			procedure for revealing a participant's allocated intervention during
25			the trial
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Methods: Data collection, management, and analysis

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30	Data collection	18a	Plans for assessment and collection of outcome, baseline, and other
31	methods		trial data, including any related processes to promote data quality (eg,
32			duplicate measurements, training of assessors) and a description of
33			study instruments (eg, questionnaires, laboratory tests) along with
34			their reliability and validity, if known. Reference to where data
35			collection forms can be found, if not in the protocol ✓ - pg. 11-12
36			
37			
38		18b	Plans to promote participant retention and complete follow-up,
39			including list of any outcome data to be collected for participants who
40			discontinue or deviate from intervention protocols – N/A
41			
42	Data	19	Plans for data entry, coding, security, and storage, including any
43	management		related processes to promote data quality (eg, double data entry;
44			range checks for data values). Reference to where details of data
45			management procedures can be found, if not in the protocol ✓ - pg.
46			11-12
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49	Statistical	20a	Statistical methods for analysing primary and secondary outcomes.
50	methods		Reference to where other details of the statistical analysis plan can be
51			found, if not in the protocol - ✓ - pg. 11-12
52			
53			
54		20b	Methods for any additional analyses (eg, subgroup and adjusted
55			analyses) ✓ - pg. 11 -12
56			
57		20c	Definition of analysis population relating to protocol non-adherence
58			(eg, as randomised analysis), and any statistical methods to handle
59			missing data (eg, multiple imputation) N/A
60			

Methods: Monitoring

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed - N/A
		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial – N/A
	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval ✓ - pg. 1
	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) ✓ - pg. 1
	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) N/A
		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable N/A
	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial ✓ - pg. 11
	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site ✓ - pg. 1
	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators ✓ - pg. 1
	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation -N/A

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| Dissemination
policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
✓ - pg. 12 |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers - ✓ - pg. 13 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code ✓ - pg. 13 |

16 Appendices

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|-------------------------------|----|--|
| Informed consent
materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates – Appendix 1 |
| Biological
specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable – N/A |

25 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
26 Explanation & Elaboration for important clarification on the items. Amendments to the
27 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
28 Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)"
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