

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Process evaluation of Fidelity and Costs of implementing the Integrated Chronic Disease Management Model in South Africa: Mixed Methods Study Protocol
AUTHORS	Lebina, Limakatso; Alaba, Olufunke; Kawonga, Mary; Oni, Tolu

VERSION 1 – REVIEW

REVIEWER	Michael Udedi University of Malawi, College of Medicine
REVIEW RETURNED	12-Feb-2019

GENERAL COMMENTS	Thank you for your manuscript and hard work. I would like to suggest a couple of things in order to improve your protocol: Include the dates when the study will begin The section conclusion should be discussion
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REVIEWER	Aaron Leppin Mayo Clinic, USA
REVIEW RETURNED	14-Feb-2019

GENERAL COMMENTS	Thank you for the opportunity to review this study protocol. This study represents a worthwhile effort to understand critical issues related to the implementation of a chronic care delivery model in South Africa. It will provide valuable information to stakeholders and the methods appear appropriate. It would be nice to have a bit more specifics, however, as I get a little lost. For example, can you provide a bit more clarity on exactly what information you will be collecting in surveys (and number of items) and how many people will complete the surveys? A table might be helpful to distinguish all the different data you are collecting, what measure and method you are using, and who you will be obtaining it from. Total numbers of expected participants will also be helpful. Readability might be improved with a more active voice that describes your process. For example, "we will go to this clinic and recruit 10 nurses to complete the such and such survey." Related to this, the protocol reads a bit hypothetical and vague. I don't believe this is reality so anything you can do to tighten up the specifics around your procedure will help. As it currently stands, it takes a good amount of effort to begin to think how I might replicate your procedure, for example.
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REVIEWER	Ozayr Mahomed Discipline of Public Health Medicine, University of KwaZulu Natal, South Africa
REVIEW RETURNED	09-Mar-2019

GENERAL COMMENTS	<p>The study proposal is satisfactorily articulated is an important study that will be relevant if it was conducted 4 years ago. I notice that you have not mentioned your time frame for evaluation in the study. I am sure you are aware that many other programme implementation aspects have superseded the implementation of the ICDM and therefore the relevance of your process evaluation at this point and time is questionable. In addition, it is more relevant to look at the ICSM and the ideal clinic dashboard and do a comparative analysis and assess fidelity and cost which will be more relevant. It is my opinion that the cost aspects were a second thought as you have not adequately described your costing approach using proper health economic variables. In addition when references are compiled they usually start at 1 and follow consecutively.</p> <p>- The reviewer also provided a marked copy with additional comments. Please contact the publisher for full details.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1	
<p>Thank you for your manuscript and hard work. I would like to suggest a couple of things in order to improve your protocol:</p> <ul style="list-style-type: none"> • Include the dates when the study will begin 	<p>Thank you for this comment, the methods section has been updated to include planned start and end dates.</p> <p><i>Line 319</i></p>
<p>The section conclusion should be discussion</p>	<p>Thank you for this comment, the section has been classified as conclusion according to the journal guidelines on writing protocols.</p>
Reviewer 2	
<p>Thank you for the opportunity to review this study protocol. This study represents a worthwhile effort to understand critical issues related to the implementation of a chronic care delivery model in South Africa. It will provide valuable information to stakeholders and the methods appear appropriate. It would be nice to have a bit more specifics, however, as I get a little lost. For example, can you provide a bit more clarity on exactly what information you will be collecting in surveys (and number of items) and how many people will complete the surveys? A table might be helpful to distinguish all the different data you are collecting, what measure and method you are using, and who you will be</p>	<p>Thank you for this comment, Table 1 (Summary of study objectives, methods and expected outcomes for <i>assessing the fidelity, impact of contextual factors and costs of the ICDM model implementation</i>) has been included to improve clarity on the methods.</p>

<p>obtaining it from. Total numbers of expected participants will also be helpful.</p>	
<p>Readability might be improved with a more active voice that describes your process. For example, "we will go to this clinic and recruit 10 nurses to complete the such and such survey." Related to this, the protocol reads a bit hypothetical and vague. I don't believe this is reality so anything you can do to tighten up the specifics around your procedure will help. As it currently stands, it takes a good amount of effort to begin to think how I might replicate your procedure, for example.</p>	<p>Thank you for this comment, the methods section has been revised to include more "active voice" sentences according to your recommendations</p> <p>Lines: 389 – 404; 4015 – 420 and 458 - 460</p>
<p>Reviewer 3</p>	
<p>The study proposal is satisfactorily articulated is an important study that will be relevant if it was conducted 4 years ago. I notice that you have not mentioned your time frame for evaluation in the study.</p>	<p>Thank you for this comment, the time frame of the study has been included (Line 319).</p>
<p>I cannot see the relevance of this "<i>ICDM model observed impact</i>" section in building your case for the study? is this not information that will be generated from your study that you could substantiate in your discussion</p>	<p>Thank you for this comment, the observed impact of the ICDM model is part of the problem statement to highlight some of the successes and challenges in the implementation of the ICDM model, and to emphasise that it's not clear if the observed failures are as a result of inherent faults in the model design or are due to low fidelity in the implementation of the model. The section has been revised for clarity.</p> <p>Lines 225 – 229</p>
<p>I am sure you are aware that many other programme implementation aspects have superseded the implementation of the ICDM and therefore the relevance of your process evaluation at this point and time is questionable. In addition, it is more relevant to look at the ICSM and the ideal clinic dashboard and do a comparative</p>	<p>Thank you for this comment, yes, the ideal clinic concept, was developed in 2011/12 and implemented from 2013, and the current 2018 manual is version 18 and there has been an increased focus on ideal clinic realisation and maintenance (ICRM) programme. One of the components of the ICRM programme is Integrated Clinical Services Management (ICSM) which focuses on four streams of care – acute, chronic, preventative and promotive and health support services. ICSM builds on the ICDM manual</p>

<p>analysis and assess fidelity and cost which will be more relevant.</p> <p>What will be its relevance moving forward?</p>	<p>and includes other health services other than the chronic conditions. A focus on chronic care health services only is best evaluated under the ICDM model manual. An evaluation of ICSM is very broad as it will have to include all the health services and will require more funding than we have received at this stage. However since the principles (good infrastructure, health service re-organization, clinical management support and assisted self-management) of the ICRM programme, ICSM and ICDM model are the same, lessons learned on fidelity of, and impact of contextual factors on implementation of the components of the ICDM model can be applicable to the ICRM programme and ICSM. We envisage lessons learnt from an evaluation of the ICDM model can be beneficial in the strengthening of implementation of the ICRM programme. The manuscript has been updated to include the applicability of this evaluation in the context of the ICSM and ICRM programme.</p> <p>Lines: 141 – 153 and 287 -293</p>
<p>It is my opinion that the cost aspects were a second thought as you have not adequately described your costing approach using proper health economic variables. It is better to separate your costing methods into:</p> <ol style="list-style-type: none"> 1. Capital cost- what will be done 2. Fixed cost- exactly what will be accounted for 3. Operational costs 	<p>Thank you for this comment, the section has been revised for clarity.</p> <p>Lines 443 – 453.</p>
<p>what is the evidence for this statement?</p>	<p>Thank you for this comment, the sentence has been deleted.</p>
<p>In addition when references are compiled they usually start at 1 and follow consecutively.</p>	<p>Thank you for this comment, the error in the references has been corrected.</p> <p>Lines 96 – 102.</p>
<p>This section should be separated under a sub-heading namely Implementation challenges during pilot phase</p>	<p>Thank you for this comment, section revised according to your recommendations.</p> <p>Lines 189 - 200</p>

This “ <i>description of PHC system in South Africa</i> ” is redundant information as it does not directly pertain to your study	Thank you for this comment, the section has been revised according to your recommendations.
Initially 16 “PHC clinics” are mentioned	Thank you for this comment, the sentence has been revised for clarity. Lines 400 – 402.

VERSION 2 – REVIEW

REVIEWER	Ozayr Mahomed University of KwaZulu Natal, Durban South Africa
REVIEW RETURNED	11-Apr-2019
GENERAL COMMENTS	This is a substantial improvement from previous version and flows adequately to make it easy to understand. The context is adequately described.

VERSION 2 – AUTHOR RESPONSE

Thank you very much for taking the time to review our manuscript entitled Process evaluation of Fidelity and Costs of implementing the Integrated Chronic Disease Management Model in South Africa: Mixed Methods study protocol.

Please see below the responses for each of the comments.

- We note that the terms and conditions of d-maps.com states that the exact URL where the original map comes from must be mentioned. Please update the figure legend accordingly.

Thank you for this comment, the figure legend has been updated to include the source.

- Please state the number of expected participants for each part of the study as originally requested by reviewer 2.

Thank you for this comment, the number of expected participants has been highlighted in Table 1 and line 316 of the manuscript. The fidelity assessment and cost analysis will be done at 16 and four clinics respectively.

- Please add the title "Ethics and dissemination" to the appropriate part of the main text as per our instructions for authors:

Thank you for this comment, the manuscript has been updated as requested in line 405