Reviewer’s report

Title: The Complexity of Quality Improvement in the Management of Type 2 Diabetes Mellitus in General Practice

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Reviewer: Trisha Greenhalgh

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Referee’s report on Goderis et al “The Complexity of Quality Improvement in the Management of Type 2 Diabetes Mellitus in General Practice”

This paper addresses an important topic and I fully concur that qualitative studies nested within experimental trials are important to help develop our knowledge of mechanisms.

To be honest I am not sure this paper makes a sound or important contribution to the literature. There are some impressive features – for example the use of an established and credible technique for prompting reflection in the interviews – but it also has significant flaws.

Major Compulsory Revisions

First, the paper is written in a somewhat ‘mechanical’ and clinician-centred paradigm – i.e. it is built on the assumption that people with diabetes have ‘knowledge gap’, ‘motivation gap’ and ‘behaviour gap’ and that interventions by the doctor and/or nurse can make good these gaps so that the patient complies with the treatment plan and achieves the biomedical targets assigned to them. I think our knowledge of diabetes management has gone beyond this (see the literature on self management, peer support, illness narratives etc in which the clinician is substantially decentred). The paper contains numerous statements which read as uncritical, such as “The FPs described cases in which joint and coherent actions of several health workers effected a change in a patient’s attitude where a solitary FP failed.” and “Fear of insulin therapy (‘fear of the needle’) was also mentioned. However, these barriers were perceived as something that could be overcome by education, especially when provided by well-trained nurse educators.” – revealing the authors’ preconceptions of a clinician-centred model of change.

Second, and related to the above, the design of the qualitative study seems overly deterministic. The authors seem to have begun with the assumption that collaborative, ‘evidence based’ care is the desired situation and then effectively measured the participants’ agreement with this stance without exploring the reasons offered by dissenters. This is shown, for example, by statements such as “All but four of the FPs confirmed the importance of improved adherence to the evidence-based guidelines” and “The third barrier, expressed by several interviewees, was the presence of skepticism about evidence-based treatment
and of collaborative care, and their concerns about losing control and sanctions that may result from QIPs”. There is an emerging literature on the problems associated with multiple professionals attempting to collaborate around the care of long-term conditions (i.e. the pendulum is beginning to swing back towards the old-fashioned model of a single clinician providing true continuity of care and a holistic perspective). There is also an important emerging literature which questions the chasing of HbA1c targets in diabetes. Whether you agree with these developments or not, the data should be properly explored in the light of them. Perhaps your ‘non compliant’ FPs were actually ahead of the innovation game!

Third, I don’t get the feeling that the qualitative analysis is robust. The quotes in the results section read a little like a ‘laundry list’ (i.e. an unnecessarily long and unsystematic selection of interesting quotations, lacking theoretical coherence). Furthermore, the statement “Data saturation was observed after 17 interviews” is too quantitatively precise and implies (perhaps wrongly) that the authors have a rather naïve and positivistic perspective on qualitative data – i.e. that there were some facts to be found and that they had found all of them after 17 interviews. Since qualitative research is fundamentally interpretive, the whole notion of saturation is a little problematic (we would never say, for example, “after reading 17 commentaries on Shakespeare’s ‘Julius Caesar’, we had learnt all there is to know about this play”), though I recognize that saturation is a useful pragmatic concept that is widely used by clinical researchers. A more cautious framing such as “after about 20 interviews we found that few new themes were emerging” would make the qualitative analysis sound more interpretive and hence more credible. Similarly, the statement “There were no major inconsistencies in the analyses performed by the two researchers” suggests to me that ‘agreement’ between researchers is being viewed uncritically as a mark of robustness. Frankly I’ve never myself been involved in a qualitative study where a doctor and nurse researcher have not disagreed passionately about the meaning or significance of the data. The fact that in this study, ‘agreement’ was so readily and unproblematically achieved suggests that key themes and ambiguities in the data may have been missed or that the perspective of one of the researchers was marginalised.

Fourth, the paper contains some statements that don’t make sense. Perhaps this is because the authors are writing in a second language (and for the most part they do an excellent job). But the sentence “The best results were seen in patients whose HbA1c values dropped by 1.6 percentage points from a baseline >8%, and whose LDL cholesterol levels fell by 40 mg/dl from >130 mg/dl” would surely raise the eyebrows of a statistician (isn’t this like saying “the tallest children in the class were pretty tall”?). Another sentence that worries me is “Within each stratum, five FPs were randomly chosen to be interviewed by a researcher not involved in the interviews”. I’m sure there’s an explanation for this apparent impossibility!

Finally, the background references are out of date, especially the first few. They do not reflect, for example, the recent controversy about whether these large
trials were given an overly positive spin. I fully acknowledge that the QIP trial would have been designed at a time when these studies were seen as ‘the evidence base’, but the qualitative study might be re-written in a much more interesting and contemporary way with the general thrust “whilst many FPs accepted the existing guidelines, some did not, and this uneasiness has subsequently been found to have some scientific basis”.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

Loaded on behalf of reviewer.