Author’s response to reviews

Title: Effectiveness of the introduction of a Chronic Care Model-based program for type 2 diabetes in Belgium.

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Author’s response to reviews:

We would like to thank the Editor and the Reviewers for the constructive comments and for the opportunity to submit a revised manuscript. We have addressed the reviewers’ comments as outlined below.

Response to reviewers

Reviewer: David Whitford
This is a quality improvement report in the management of type 2 diabetes. Its main interest lies in its claim that it is the first development of this nature in Belgium. Data from a region that implemented a new chronic disease model in primary care were compared with data from a comparable control region. The two research questions are clearly stated at the end of the Background section. The methods are well described.

It is not clear from the description of the chronic care model as to what degree care has shifted from hospital to primary care based on the model of shared care (are patients discharged from hospital care, or sharing care, or sharing a system of care etc, ..). It is also not clear what proportion of the study population would be part of this chronic care model and how many are still attending hospital based care. This has implications for any conclusions that may be drawn as quality improvements could be related to improvements in hospital care as opposed to the chronic care model.
There is no description of what data cleaning process was used. I would assume that there was some error in the data with possible outliers.

A particular problem with the study is the way patients with type 2 diabetes are defined. There is no independent disease register, so patients in the study are defined by prescribing data. This has the effect of excluding all diet controlled patients with T2DM. These patients are likely to have good HbA1c results but they may see deterioration over the period of study. Of more relevance is the exclusion of patients on 3 or more insulin injections. The authors argue that patients will be excluded equally in both intervention and control regions. However, this may not be the case if diabetologists in the two regions prefer different insulin regimens. Equally, it may account for some improvement in HbA1c over time as it may serve to exclude the more poorly controlled type 1 and type 2 patients in, both regions who need to be treated with more complex insulin regimens and whose management is more challenging. The result is that the study is likely to be based on a heterogeneous group and I would have thought the inclusion of type 1 patients would have been more robust than the present population that cannot easily be defined. The major impact of this is the weakness in making any international comparisons as in the discussion.

The absence of hospital based diabetes centres in the control region deserves some comment. How is care delivered in the hospitals there? Are there the same number of diabetologists?

The quality indicators are more based on the availability of data in the research database than on current scientific evidence. This should be made more explicit. I am unsure what scientific evidence would suggest that keeping HbA1c below 10% is important? Where did this indicator come from? The targets for HbA1c and total cholesterol are quite high –where these appropriate targets in 2008? HbA1c > 7% and total cholesterol < 4 mmol/l would be more appropriate.

The research questions are clear and focus on quality improvement in process and intermediate outcomes. However, much more of the text in the background and discussion relates to aspects of the chronic disease programme that have already been described in previous publications- namely the ACIC scores. The relevance to this paper is hard to see as any quality improvement cannot be directly linked to one aspect of the model but is more likely the result of the complex intervention as a whole. Much of this could easily be removed without affecting the conclusions and would provide a greater focus for the paper. As previously mentioned, I cannot see the relevance of the whole section in the discussion labeled ‘Results in relation to the ACIC score’. The discussion is otherwise balanced.

I am not used to the phrase ‘Effect evaluation’ as in the title. Quality improvement would be a more appropriate description.

The paper does not add substantially to the published literature but is of some relevance in terms of the development of diabetes care in Belgium.
Response:

Major Compulsory Revisions

Reviewer’s comment:
1. Improve the description of the population and their site of care and model of shared care.

Response:
- We added information regarding the context of care under Background: The main characteristics of the Belgian health care system are summarized in box 1. Equity and freedom of choice are high priorities for health policy. There is no clearly defined gatekeeper function in place; every citizen has free access to medical specialists and hospital care, even as the first point of contact with the health system. Most care providers work as independent self-employed health professionals. The patient pays directly to the care provider and is entitled to a reimbursement by his sickness fund. Most services are reimbursed at a rate of 75%. In general, patient satisfaction with the health care system is high. In 2003, the region counted 83 GPs (GP to population ratio of 1:972), 70% of whom worked in a single-handed practice, most of them without any support staff. Diabetes teams in primary care were mostly loose networks of single-handed care providers. Structured self-management support programs were not in place in primary care. Patients on insulin therapy have the possibility to register in the hospital where they received care from a multidisciplinary team (diabetologist, diabetes educator, dietician). In 2003 there was little or no coordination regarding diabetes care delivery in the region and there were no formal shared care models in place.
- We also added a paragraph to motivate the relevance of the study: The last decade many countries have taken the first steps towards the adaptation of their health care system to a more chronic care oriented system and often the Chronic Care Model (CCM) has been used as a conceptual framework to design the interventions. Most knowledge on the effect of the introduction of CCM elements on the quality of chronic care originates from organizations or countries with a well-structured primary health care system. Information about efforts made in countries with a less well-structured primary health care system is still scarce. This study reports on the effectiveness of a CCM-based intervention in a high-income country with good health care facilities but with a primary health care system with limited structure.
- We added information regarding the target population under Study population: The intervention population included all type 2 diabetes patients in the defined area.
- Currently we are not able to provide a conclusive answer to whether care for diabetes patients has shifted from secondary to primary care or vice versa as result of the intervention. We agree that this is an important topic and we are currently exploring the data in relation to a cost-effectiveness analysis.

Reviewer’s comment:
2. Either discuss more fully the weakness in defining patients with T2DM or include all patients on anti-diabetic agents.

Response:
- We added information under Study population (Methods) to clarify this option: Patients treated with 3 or more insulin injections a day in 2003 were excluded from the study cohort in order to exclude most of the diabetes type 1 patients given the fact that they were not the target group of this intervention. In 2003, on average, 84%
of the diabetes type 1 patients in Belgium were treated with 3 or more insulin injections (personal communication ND, Institute of Public health (IPH)). Diabetes patients who moved to a more complex insulin scheme during the study period were not excluded.

-We also added some information under Limitations of the study (Discussion): Furthermore, we excluded patients treated with 3 or more insulin injections a day (8.6% of the diabetes patients on medication in 2003), in order to limit the presence of type 1 diabetes patients in the study cohorts. In doing so we inevitably also excluded type 2 diabetes patients treated with an intensive insulin scheme, accounting for about a quarter of the type 2 patients treated with insulin in 2003 (personal communication ND, IPH). Diabetes patients who moved to a more complex insulin scheme during the study period were not excluded. This information is of particular interest when our study results are compared with these of other study populations.

Reviewer's comment:
3. Explain of what relevance HbA1c < 10% is as a quality indicator and how the cutoffs were decided.

Response:
-To define the cutoffs of the outcome quality indicators we relied on the cutoffs currently used in the Quality and Outcomes Framework (QOF) in the UK. The percentage of patients with an HbA1c level of 10 or less (DM 7) gives information on the degree of metabolic regulation on population level. This outcome indicator was introduced in the QOF to encourage working with patients with a high HbA1c.

-We added information regarding the quality indicators and the cutoffs under Methods/Principal outcomes: We defined a set of quality indicators, six process and three outcome indicators, to evaluate the effect of the intervention in the region. To define the set of quality indicators we relied on the indicators currently used in the Quality and Outcomes Framework (QOF) and the availability of the data in the research database (Box 4). We included the prescription of statin therapy as a process indicator given the fact that cardiovascular risk prevention was a priority for change in the region. The prescription of an influenza vaccination (also included in the QOF) was added in order to evaluate the attention for the overall prevention strategies in the region. The cutoffs of the outcome quality indicators were defined according to the cutoffs currently used in the Quality and Outcomes Framework (QOF).

-We noticed a discrepancy between the text and the tables concerning the cutoff ≤ 7.5%. We adapted the figures in the table.

Reviewer's comment:
4. Rewrite and reduce the sections ACIC scores.

Response:
-We changed the title to: Results in relation to the CCM elements targeted.
-We would prefer to keep this section in the text. We added a paragraph to motivate the relevance of this part of the text: The ultimate purpose of the study was to inform health policy leaders about effective strategies to adapt primary health care to a more chronic care oriented system. In this light the moderate gain in quality of diabetes care in relation to the 4.05 progress in the overall ACIC score needs some reflection. Although the evaluation of a complex intervention is challenging given the fact that components of the intervention may act both independently and interdependently, we
tried to explain the study results in relation to the different CCM components targeted in the intervention. More insight in this relationship is also crucial in the light of future actions. Further, this information is also relevant for other countries struggling to implement CCM elements.

Minor Essential Revisions

**Reviewer's comment:**
1. There are a few typos through the text. These are particularly prominent in the references e.g. Ref 2 ‘tot’ instead of ‘to’. Ref 12 ‘population’ instead of ‘population’ etc.
**Response:**
- We made the necessary corrections.

Discretionary Revisions

**Reviewer's comment:**
1. Describe the data cleaning process.
**Response:**
- Data collection and data cleaning were executed following standardized procedures. The process of data collection and data cleaning has been described in a report for the commissioners of the study (Van Den Broeke C (CVDB), Bastiaens H, Beyltjens P (PB), Gederis G, Sunaert P, Ivanova A (AI), Carbenez A (AC), Vermeire E, Heyrman J: Eindrapport DiabetesProjectAalst-DiabetesProjectLeuven Deel 3: Procesevaluatie van de opbouw van de diabetesdatabank, 2009). This report is currently only available in Dutch. If necessary we can provide more information.
- We added some information under Methods/Data sources to reassure that the construction of the database has been performed carefully.

**Reviewer's comment:**
2. Describe the hospital care of diabetes in the control region.
**Response:**
- Thanks for the comment. We agree that the way we gave the information about specialty care in the intervention and control region was confusing. In 2003, two endocrinologists were active in the control region. Full accreditation of the diabetes centre of the hospital was on its way. We adapted the information in table 1 to avoid misinterpretation by the readers.

**Reviewer's comment:**
3. Consider changing the title
**Response:**
- We changed the title into: Effectiveness of the introduction of a Chronic Care Model-based program for type 2 diabetes in Belgium.
Response to reviewers
Reviewer: Gawaine Powell Davies
This is a very good paper reporting on what appears to be a well thought out and important research. They provide a good description of their previous research which evaluated an intervention to improve diabetes services, using the Chronic Care Model as a useful analytic framework. They have then made very good use of administrative data on diabetes care to measure changes in quality of care, using well recognised indicators of quality. The cohort is carefully selected, the analyses clearly described and the aim, purpose and findings well set out. The discussion is focused and does nothing to dissipate the impact of the findings. It deserves a wide readership.

Discretionary revisions

Reviewer's comment:
1. In Table 5, I would find it useful to have an indication of whether it was the control or intervention group that had significantly greater change between two measurement points - could be done with a simple symbol or superscript.
Response:
- Thanks for the advice. We adapted table 3, 4 and 5 as was proposed.

Reviewer's comment:
2. In the discussion relating to the QOF in the UK: it is surely worth noting that improving diabetes care was not just supported with investments in primary care: there were direct incentive payments for improving quality.
Response:
- We added some information on target payment in the text: The QOF, a pay-for-performance scheme based on meeting targets for the quality of clinical care, was introduced in England in 2004. In general this scheme has accelerated quality improvement in different aspects of clinical care, although some authors also warn against unintended consequences, including reductions in the quality of care not linked to incentives and in the continuity of care (Campbell SM et al).
Response to reviewers
Reviewer: Amer Kaissi

This manuscript constitutes a very important topic. The implementation of the Chronic Care Model in different settings and its evaluation is laudable and much needed. The analyses conducted by the authors are comprehensive and very appropriate. However, there are two areas on which the manuscript can be improved (minor essential revisions).

Minor Essential Revisions

Reviewer's comment:
1. The specification of variables should be more explicit and detailed. For example, why was influenza vaccination included as a process quality indicator? How are all the process quality indicators defined and measured?
The authors only discussed one variable (HbA1c test) in detail.
Response:
- We added some information under Methods/Principal outcomes: We defined a set of quality indicators, six process and three outcome indicators, to evaluate the effect of the intervention in the region. To define the set of quality indicators we relied on the indicators currently used in the Quality and Outcomes Framework (QOF) and the availability of the data in the research database (Box 4). We included the prescription of statin therapy as a process indicator given the fact that cardiovascular risk prevention was a priority for change in the region. The prescription of an influenza vaccination (also included in the QOF) was added in order to evaluate the attention for the overall prevention strategies in the region. The cutoffs of the outcome quality indicators were defined according to the cutoffs currently used in the Quality and Outcomes Framework (QOF).
- We also added some information under Methods/Data sources: In Belgium, all individuals entitled to health insurance (almost 99% of the population) have to register with a sickness fund. The services covered by the compulsory health insurance are described in a nationally established fee schedule and reimbursement of health care costs is linked to specific codes for each service delivered. An HbA1c test, for example, is registered as code 540750. By extracting the codes for a number of predefined services we were able to assess the process indicators.

Reviewer's comment:
2. It would be very interesting to compare the Belgian experience with other countries when they first implemented the CCM in the primary care setting, such as the U.S. for example.
Response:
- We referred to the experiences with the implementation of the CCM in the U.S. in the Discussion/Implications for health policy and future research: Comparable results have been seen in other settings starting to adapt their care system to a more chronic care oriented system as e.g. described in an evaluation of CCM implementation in primary care in the US (Minneapolis-St Paul Metropolitan region). Implementing the CCM elements in a system originally set up to deliver acute and episodic care, takes time. It demands to switch the focus of quality improvement efforts from the individual
level of patients and care providers to the system level. Further, strong leadership and a careful change management are continuous needed (Hroscikoski MC et al.).