Title: Barriers and Facilitators to Evidence Based Care of Type 2 Diabetes Patients: experiences of General Practitioners Participating to a Quality Improvement Program.

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Author's response to reviews: see over
Concerning: manuscript ID 1334381041253299, “The Complexity of Quality Improvement in the Management of Type 2 Diabetes Mellitus in General Practice”

Dear Editor,

We would like to thank you for editing this manuscript. We would also like to thank the reviewers for their excellent comments on the previous manuscript. These comments allowed for a major improvement of the manuscript. We would like to submit a revised version of the manuscript, with a new title (as suggested by one of the reviewers): “Barriers and Facilitators to Evidence Based Care of Type 2 Diabetes Patients: experiences of General Practitioners Participating to a Quality Improvement Program.” Please find below our answers to the reviewers. The text is somewhat long because we give a point-by-point response to all concerns of all the reviewers in a structured manner. First we give the concern of the reviewer. We just copied and pasted the original text (black text). Then we give an answer to the reviewer (blue text) and finally we indicate what we have changed in the manuscript (blue italic text). We hope that by this means we have been able to give a clear answer to the reviewers’ concern. We also formatted the manuscript to ensure that it conforms to the journal style. Especially, the references were revised using the Implementation Science output style for reference manager.

Once again, we would like to thank you for this possibility to publish our manuscript in your journal,

Sincerely Yours,

In the name of all co-authors,

Dr. Geert Goderis

Katholieke Universiteit Leuven

Department of General Practice
Reviewer's report

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

Version: 2 Date: 3 March 2009

Reviewer: Tim Rapley

Reviewer's report:

1. Major Essential Revision

You note that, from your interviewees, four FPs did *not* confirm the importance of improved ‘adherence’ to EBG. Given the importance of deviant (or negative) case analysis to claims making in qualitative research and given that the QIP was centred on FP working with EBG, I think you need to unpack this issue more. Did these four all share similar views, could they be grouped in some way, is there key factors that link them? Basically, in what sense are they deviant case – exceptions to the norm, something that reflexively shows us what is normal, or a group that means we have to re-evaluate and re-specify your findings as a whole?

Answer: These 4 GPs all belong to a stratum with stronger baseline performance. 3 of them belonged to the stratum with weaker improvement during the project, one with stronger improvement. All 4 affirmed that they ‘were doing a good, Evidence Based Job’ before and thus the project interventions were a bit superfluous. All affirmed the importance of evidence-based practice. Three of them revealed that they had previously followed an intensive course on diabetes management, the 4° is related to the university and president of CEBAM, the Belgian branch of the Cochrane society.

Proposition for the manuscript:

Results section: *The four GPs who did not experience improved adherence belonged to a stratum with a stronger baseline performance and three of them also belonged to the stratum with weaker improvement during the project. Three of them revealed that they had previously followed an intensive course on diabetes management. The 4° GP is still collaborating with the medical faculty of the university.*

Discussion section: “*At GP-level, four interviewees affirmed not having experienced a major impact of the QIP on their quality of care. In fact, they experienced the QIP somehow as superfluous since they already paid special attention to evidence based diabetes care before the start of the project.*”
2. Major Essential Revision

At various points you place interview quotes in boxes in the text without ever referring to them in the paper. At the very least you need to signal when the reader should refer to them. For me, you need to find some to better integrate your findings with your unfolding narrative.

We referred to the boxes within the narrative.

Also, ending the discussion section with a text-box, without some form of closing work does not work for me (but clearly I'm fussy).

We added a text at the end considering some implications: Previous research revealed numerous barriers to high quality diabetes care at the level of provider, patient and health care organization. However, most of this research was done outside the context of quality improvement. Our research reveals the viewpoints of physicians who experienced a quality improvement process and it allows for evaluating the complex interactions between barriers and facilitators during this process. It has become obvious that implementation of a QIP encounters an array of cognitive, motivational and relational barriers that are embedded in a patient-health care provider relationship. As their success may depend on overcoming key barriers, QIPs should incorporate mechanisms to actively detect and overcome these barriers or to cope with them. Moreover, several barriers appear to be interdependent, developing several ‘chains of barriers’. This phenomenon can be a reason why multifaceted QIPs acting on different barriers in a chain are likely to be more effective than single interventions.

Our research particularly revealed the GPs feelings on collaborative shared care. While some of them disagree on the added value of diabetes educators, a lot of GPs feel some uneasiness regarding the competition with specialist care. These feelings may be reinforced by the typical Belgian health care setting, but we believe that they are the expression of a very human nature and thus not unique to the Belgian situation. Literature on this issue however is very scarce. Our research also showed that these negative assumptions and feelings can be overcome by paying attention to them and by enhancing the personal contact and communication between the people involved.

The interviews also revealed the limits of a clinician-centered model of patient education and self-management and confirmed the quantitative results of the study on this issue. Future QIPs could incorporate and test innovative patient-centered methods, like different models on peer support for patients.

To round off, several interviewees reported real concerns on the applicability of the ‘traditional’ diabetes guidelines in a subset of the patient population, namely the elderly. These concerns have been
joined by specific geriatric guidelines. These findings show that quality improvement is not a unidirectional process from guideline to practice. Often, several practitioners express the same difficulties with implementing a guideline. In that case, it might actually reveal a flaw in that guideline rather than a barrier related to the practitioners. And thus QIPs should also be used as instruments to test the feasibility of guidelines and to highlight some flaws.

3. Major Essential Revision
At a few points in the discussion you raise an issue and then move on, without unpacking it and commenting further on the implications. 3a. You note that the nurse educator carries out functions that FPs lacked time or did not possess adequate skills or motivation. Additionally, giving such tasks to another is a nice way for FPs to sustain their ongoing relationships with patients, to distribute this work and the potential implications for problematising their relationship with this patient. And this distribution of rights, responsibilities, tasks – between patients, FPs, nurse educators and others – over time seems central.

Additional text in the discussion section: This task delegation allowed the GPs to sustain their ongoing relationship with the patients and to concentrate the efforts on their essential tasks, the medical management and follow-up of diabetes.

And a little bit further, we will discuss more in detail the problems of shared care (also answering to a comment of pr. Greenhalgh: “These findings complement previous reported difficulties in collaborative shared care. One of the major reported issues about shared care is the problem of suboptimal communication between the involved providers. This problem is associated with discontinuity in care and lower quality of care. Other problems are related to lack of clear division of tasks and responsibilities between the involved providers eventually leading to overlap and competing interests. Despite these problems, we think that shared care is necessary to guarantee high quality diabetes care because the management of this disease is too complex and too broad to get it provided by one person. However, the aforementioned problems are a real point of concern. Moreover, as our research shows, providers are not always willing to collaborate. Thus QIPs should pay special attention to eventual relational problems, to communication issues and to the distribution of rights, responsibilities and tasks between patients, GPs, nurse educators and specialists.”
3b. You raise the issue of change being neither ‘black’ nor ‘white’ and then give the examples of age and immobility. This issue is not even introduced in the results section and yet you offer it as a factor and don’t really explain its impact.

We have unpacked this issue in the results section and in the discussion section, also taking into account the remarks of prof. Greenhalgh:

**Results:**

*Several GPs also questioned the feasibility and desirability of implementing these guidelines in an older diabetes population. (BOX 2).*

**Box 2:**

- “Many of my patients are older than 80 years. I will not forbid them to eat a piece of cake. Indeed, my own attitude towards elderly people is a little bit more loosely.”
- “The recommendations on weight loss and physical activity are useless for a lot of elderly people who are too ill to be immobile to follow them.”

3c. You note that future work could involve interviews or focus groups with practitioners and patients. If part of the issue is the impact on interactions between health professional and patients – and you currently only have access to peoples retrospective reports of these issues - why not observe, audio-record or video-record the encounters?

We added this issue: (...) employ mixed focus groups or audio-or video-record observations of the clinician-patient encounters.

3d. You note that qualitative work may clarify the improvements, and can also reveal a program’s limits – could you show us, or be more explicit about this?

It was a summary sentence reflecting to the discussion above. Since this is not clear, we have split this sentence and cut/paste the two different parts to the concerned paragraph of the discussion in order not to repeat the messages. This intervention also pushed us to change the outline of the discussion section. We have put all the improvements together and all the limits/barriers together.

At the end of paragraph 1 in the discussion section: **As such, qualitative research nested in an experimental trial may clarify the improvements that a QIP may bring about in a general practice.**
4. Minor Essential Revision
It would be nice for the reader to have an overview – be it in chart or table form – of the QIP.
OK: one extra table (table1)

5. Minor Essential Revision
You refer to specific discursive and embodied practices used in the interview – formulations, reassuring intonation and body language. You then claim, that you feel this resulted “in answers with more depth than obtainable with the qualitative schedules normally used”. Such interactional work is pretty routine in the ‘how to’ literature on interviews, reports of how people claim they interview and actual empirical studies of interviewer-interviewee interaction. I just feel you could downgrade your claims about the uniqueness/specialness of your approach – it is really not essential for your argument.
Correct, we changed in this way: “body language in order to disclose their very personal feelings and experiences with this project.”

6. Minor Essential Revision
You note that you engaged in theory-based deduction using the ‘implementation model’ of Grol et al. Could you briefly unpack for the reader why you went with this model over any of the others that you could have drawn on?

We added in the method section: Before analyzing the transcripts, we discussed the analytical method to use. We decided to categorize the items by theory-based deduction using the ‘implementation model’ (Grol et al., 2004). We chose this model because it is based on a comprehensive overview of theories on implementation and behavioral change. These theories relate to the individual's cognitive, educational and motivational attributes, as well as social, organizational and economic factors. This model also reflects the basic structure of the interviews: barriers and facilitators of guideline implementation are well described. As such, this model allows for deductive coding and categorizing of the items according to the level of action. After a first discussion round, we reached consensus to categorize the items in three levels: 1) individual GP, 2) individual patient, 3) social interaction, context and organization. Items were divided into ‘barriers to high-quality diabetes care’ and ‘factors facilitating change’. Barriers at the individual level were further categorized into subcategories: ‘knowledge’, ‘awareness’, ‘attitude and motivation’, ‘routine’ and ‘others’. All transcripts were re-read when necessary and independently analyzed by GG and LBO to ensure reliability of the data. Transcripts were manually coded and the items were categorized using excel® spreadsheets.
Differences in coding were discussed and final decisions on items and categories were based on a consensus between the two interviewers.

7. Minor Essential Revision

You note that ‘Data saturation was observed after 17 interviews’. I’m never quite sure what this practically means (despite using and thinking with the concept myself). Could you, briefly, unpack what you mean by this?

Answer: see answer to the comment of prof. Greenhalgh. (p.11)

8. Discretionary Revisions

I realise that the tradition you work in is different, but, rather than refer to ‘adherence’ or ‘compliance’ the new vogue (initiated by Royal Pharmaceutical Society of Great Britain [1997] for some good theoretical, moral and practical reasons) is to refer to this as ‘concordance’.

References


We take note of this recommendation, but indeed, we work in a different tradition, and more specifically, Belgian GPs work in a very different context than British colleagues. In Belgium, primary health care is a ‘private’ issue and the debate to replace the concept of ‘therapeutic liberty’ by ‘evidence based practice’ (with adherence to guidelines and evaluation on this adherence) is still ‘in its infancy’. So, we are not quite sure if the contents of ‘concordance’ (in a British constellation) is the same as the contents of ‘adherence’ as we understand it in our Belgium setting. So we would like to keep the term ‘adherence’.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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

Declaration of competing interests:

I declare that I have no competing interests
Reviewer's report

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

Version: 2 Date: 3 March 2009
Reviewer: Trisha Greenhalgh

Reviewer's report:
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.

The problem here is that the QUALITY IMPROVEMENT PROGRAM ITSELF was both clinician- and patient-centered with however the major emphasis on clinician ‘empowerment’. The major paradigm was indeed the biomedical one with main emphasis on improving the diabetes related bio-medical outcomes. The majority of interventions were related to the clinician and there were no interventions in support of the patients in which other than professionals were engaged. As a consequence, the interviews could only focus on interventions that were ‘clinician-related’.
Regarding the background paradigm, the authors agree that it may be reductionist in a general practice (family medicine) context that is “naturally” holistic. However, we argue that the quality of diabetes care mainly suffers in the field of not achieving the targets (bio-clinical and lifestyle) and thus that quality improvement should mainly focus these problems. As you can see in table 1, the main objective of the QIP was to implement a protocol about target-driven treatment in general practice and even education by a nurse or dietician was related to the problem of not achieving the targets. It is however interesting that the interviewees described the limits of this model in its effect on changes in patients’ behavior.

Regarding the manuscript: we propose to make no changes in the results section (this is what the respondents said), but to include a paragraph in the discussion section on the limits of a clinician-centered QIP and we also referred to this issue in the conclusions (implications). Proposed addition in the discussion section: “These findings confirm previous findings that sustainable lifestyle changes are hard to implement in a clinician-centered models. Moreover, these models are labour- and resource-intensive and traditionally put the emphasis on imparting knowledge. Yet, in even the most successful trials of face-to-face education, many participants are not willingly or not able to attend the sessions. Therefore, ongoing research evaluates the effect of new models that are based on peer support. These models put the emphasis on coping with illness, rather than managing it. Peer support seeks to build on the strengths, knowledge and experience that peers can offer. Greenhalgh et al. has tested the effect of a narrative method (a person telling a story) vs. conventional nurse led education in a minority ethnic group of people with diabetes. The results show that unstructured story telling is associated with improvement of patients’ enablement and comparable changes in biomedical markers. Other self-management programs evaluate the effect of telephone counseling or web-based peer support. Future QIP may incorporate peer support interventions replacing or complementing clinician-centered patient education interventions.”

And further on: ‘implications’ (…)

The interviews also revealed the limits of a clinician-centered model of patient education and self-management and confirmed the quantitative results of the study on this issue. Future QIPs could incorporate and test innovative patient-centered methods, like different models on peer support for patients.

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”.

Yes, in the analysis we use the ‘straightforward’ assumption that collaborative, evidence based care (or more exactly ‘guideline based’ care) is the desired situation and we evaluated the participants’ agreement. There are different reasons for this approach. First, we consider guideline based practice – under certain conditions like the absence of lobbying or financial interests in guideline development – as the desired situation since guidelines (should) reflect the newest insights and incorporate the latest evidence in diabetes treatment. Moreover, guideline based medicine allows for reducing practice variability. Less variability in GPs performance is an advantage for the patients who can expect more or less the same care and the same quality of care whenever the GP he chooses or receives (cfr. comparison with an airbus pilot: the quality of ‘fly care’ is subject independent). Finally, there is a methodological reason for this assumption: it is relative easy to use a deductive method to code items into barriers to and facilitators of this “desired situation”. However, it is not true that we were not interested in the reasons offered by dissenters. We were particularly interested in exploring their reasons, not only vis-à-vis evidence based medicine and guidelines, but vis-à-vis all proposed objectives and recommendations during the QIP. We did not unpack all positions because of priority choices and the length of article. Since the positions vis-à-vis EBM is a matter of discussion, we propose to add in the narrative (results section) some arguments of the interviewees and we relate on these arguments in the discussion section.

We propose to add in the results section: Some GPs considered EBM only as background information describing the ideal situation to strive for, but not as a stringent, compulsory framework. One GP admitted that he had worked according to a fundamental different paradigm, close to alternative medicine. From this viewpoint he disagreed with the guideline on many aspects, such as the importance that was given to lipid control. Some GPs admitted being lax and several indicated that lack of time--because of suboptimal practice management--prevented them from providing good quality care. Several GPs also questioned the feasibility and desirability of implementing these guidelines in an older diabetes population. (BOX 2).

And in the discussion section: The role of EBM in daily practice remains a point of controversy. While many GPs accepted the existing guidelines, some did not. Some GPs fundamentally disagreed with EBM. Others accepted EBM as background support, but were afraid that EBM would be used to impose
coercive instructions for daily practice. Several GPs questioned the feasibility and desirability of the ADA-guideline based recommendations in the elderly or immobile people. Indeed, elderly patients are particularly sensitive to the adverse effects of drugs and polypharmacy, putting constraints on the classic diabetes treatment. Especially hypoglycemia is an important topic in the diabetes treatment of elderly people. Recent studies clearly indicate that hypoglycemia may be a contributing factor to morbidity and mortality in older patients. As such, strict adherence to guidelines for younger patients could be deleterious for the frail elderly. Geriatric guidelines on the management of type 2 diabetes accentuate that treatment should be holistic, targeting all important aspects of the geriatric patients with priorities in the treatment scheme. Diabetes-related targets should be individually adapted to the frail patients with special attention to avoidance of side effects.

Finally, we agree that when considered in its own, the aforementioned assumption is reductionist. Guideline based medicine can only be the absolutely desired situation if the guideline is perfect for a 100% and thus if science has succeeded to uncover all related aspects to diabetes care. As we know, we are far from this ideal situation and thus diabetes guidelines are in reality more consensus based that evidence based. Thus they might be wrong in some recommendations and inapplicable in some conditions. Therefore, we propose to add a paragraph in the discussion section (‘implications) on the possibility that QIP offer to test the applicability of guidelines (see below).

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).

We propose to add the following paragraph in the discussion section: “For example, several GPs asserted that nurse educators and other personnel in the so-called “soft sector” are of little value in good diabetes care. Collaborative shared care with specialists also remains a point of concern, despite the improvement observed during the project. One GP reported persistent problems with one local endocrinologist who was blamed for his disdainful attitude to general practice. Other GPs described minor remaining difficulties with endocrinologists despite overall satisfaction with the arrangements. These findings complement previously reported difficulties in collaborative shared care. One of the major reported issues about shared care is the problem of suboptimal communication between the involved providers. This problem is associated with discontinuity in care and lower quality of care. Other problems are related to lack of clear division of tasks
and responsibilities between the involved providers eventually leading to overlap and competing interests. Despite these problems, we think that shared care is necessary to guarantee high quality diabetes care because the management of this disease is too complex and too broad to get it provided by one person. However, the aforementioned problems are a real point of concern. Moreover, as our research shows, providers are not always willing to collaborate. Thus QIPs should pay special attention to eventual relational problems, to communication issues and to the distribution of rights, responsibilities and tasks between patients, GPs, nurse educators and specialists.”

And further on: implications (…)

Our research particularly revealed the GPs feelings on collaborative shared care. While some of them disagree on the added value of diabetes educators, a lot of GPs feel some uneasiness regarding the competition with specialist care. These feelings may be reinforced by the typical Belgian health care setting, but we believe that they are the expression of a very human nature and thus not unique to the Belgian situation. Literature on this issue however is very scarce. Our research also showed that these negative assumptions and feelings can be overcome by paying attention to them and by enhancing the personal contact and communication between the people involved.

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!
Answer: see below (p. 14), because this point is related to the final comment on the references.

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).

The added value of the quotes is to support the statements of the narrative in the results section by quoting the interviewees. The theoretical coherence is in the structure of the results section and derived from the theoretical implementation framework (Grol et al.)

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 “

We agree with this comment. “Data saturation” cannot be interpreted in an absolute way. In practice, before the start of the interviews – at the time of designing the study - we discussed the method of analysis (inductive vs. deductive). We chose to use a deductive method based on the implementation model of prof. Richard Grol. Then, a first round of some ‘test interviews’ was done to evaluate the interviewing scheme. Afterwards, all 20 interviews were finished and the first five of them were analyzed and discussed which allowed to reach consensus on the item classification (classified by 1) individual GP, 2) individual patient, 3) social interaction, context and organization). Then, all 20 interviews were analyzed, again with evaluation and discussion. It is in this context that we agreed that the last three interviews did not add new important themes to the rest of the interviews. We will use the more ‘nuanced’ and interpretive version mentioned above.

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.

There was indeed discussion between the two interviewers, but there were no discussions that ended without consensus. It was not necessary to make appeal to an “arbiter” (3° person). Most discussion time was spent before the interviews when designing the study. At that time we discussed the method of analysis: should we do it in an inductive or deductive way? Finally, we chose to code in a deductive way. Deduction was based on the above mentioned implementation model. Once the model was chosen, itemization was indeed a little bit ‘deterministic’ because items were classified in 2 major categories ‘barriers to optimal diabetes care’ and ‘facilitators to change’.

During the analysis process, a first point of discussion was how we should organize the different levels. In this implementation model, six domains related to facilitation and hampering implementation processes
are mentioned: (1) the guideline (‘innovation’) itself, (2) the individual professional, (3) the individual patient, (4) the social setting and network, (5) economic, administrative and organizational context, (6) implementation strategies themselves. (“Improving patient care, p. 42”). Already in the first round, we agreed that this kind of categorizing was not applicable in our design and would lead to a very fractionated manuscript. So we had to reduce the number of categories. Since most interviewees talked about their own practice and their patients, we agreed to focus on ‘physician’ and ‘patient’ and to bring domain 4 and 5 together. Domain 1 and 6 can be seen as ‘facilitators’ in this project (with some nuances especially regarding guidelines), related to the patient, the physician or context. This structuration is also in line with what we wanted to achieve: 1) “What barriers to high quality diabetes care (= care as described in the treatment protocol) did GPs - participating to a quality improvement - experience”? 2) ”What - according to their experience - were the facilitating mechanisms to improve the quality of care during their participation to a quality improvement program?” Once this structure was cleared out, it was relative easy to code the items and to find consensus. In our opinion, there is also a second reason why we relatively easily agreed. Despite several backgrounds (one nurse, one GP), we have been closely working together for 6 years now on different projects, all about quality improvement and we are aware that we are (and have become) quiet close together in our opinions on health care matters. This may be a weakness of the study design, but in general we do neither have the feeling that key themes or ambiguities in the data have been missed (because of the preparative discussions on the model and structure to use) nor that the perspective of one of the researchers has been marginalized. All interviews have been analysed using this structure.

Changes made in the method section: see answer to prof. Christiaens.

Changes made in the results section: Table 3 shows the results of itemization that was obtained in common consensus by the two researchers.

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”? ). This remark is absolutely correct: We changed it in this way: “The aim of this program was to improve diabetes-related patient outcomes through the implementation of evidence-based guideline recommendations. The different interventions of this QIP are described in Table 1. The program resulted in significant
improvements over time of HbA1c (-0.4%, CI95% [-4;-3]), Systolic Blood Pressure (-3 mmHg, CI95% [-4;-1]) and LDL-C (-13 mg/dl, CI95% [-15;-11]).”
(The best results were seen in patients whose initial values were out of control at baseline with e.g. a decrease of HbA1c by 1.6% in those patients with baseline HbA1c >8%). But we propose to delete this sentence because it doesn’t have a real added value and the manuscript is becoming long.

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!

Again correct. We changed it in this way: A researcher not involved in the interviews chose randomly five GPs within each stratum.

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”.

To be honest, we partially disagree with the reviewer. First, the point with which we disagree: we think that DCCT, UKPDS and STENO2 remain landmark studies. The value of the UKPDS study has recently been described in an exhaustive supplement of diabetic medicine: “the UKPDS was truly a national enterprise that has had profound effects on the understanding and management of type 2 diabetes worldwide.” (Horlman, R, 2008 Aug., Diabetic Medicine, 25 (Suppl. 2), 1 – introduction). Moreover, in a very recent publication, the benefice of lowering HbA1c levels on macro-vascular morbidity has been demonstrated, leading to the concept of “legacy” in glucose control (long term effects of lower glucose levels in patients with recently diagnosed DM2)¹ A recent update of the STENO2 study also confirmed the positive benefice of global, intensive and target-based treatment of diabetes related risk factors ². So we propose to keep this references and to add the more recent ones.

Second: the point with which we agree. Recent studies (ACCORD/ADVANCE, VA diabetes) have put some doubt on the chasing of very low HbA1C levels (6.1%). These studies concern glycemic lowering therapy and not antihypertensive and lipid lowering therapy. And as STENO II (Gaede 2003, 2008)
shows, a global treatment with target values of 7% for HbA1c, 100 mg/dl for LDL-C and 130 mm Hg for SBP significantly reduces macro and micro vascular morbidity and mortality. However, the results of ACCORD and ADVANCE are very interesting and show the complex reality with which researchers and clinicians are confronted. However, these studies do not show any evidence that a target of 7.0% - the target we put forward – is harmful to the majority of patients. As commented by Peter Gaede\textsuperscript{3} or by the ADA\textsuperscript{4}, the negative results in the ACCORD study may be due to the “way” glucose lowering was achieved rather than the glucose lowering itself. In Accord, glucose lowering was achieved in a very quick way, with drugs inducing hypoglycaemia and weight gain. Thiazolidinediones were frequently prescribed and the widespread use of these drugs is indeed controversial. ADVANCE shows no effect of intensive hypoglycemic therapy on macrovascular outcomes, but it does show effect on micro-vascular outcomes. These results are in line with the results of the ‘old’ UKPDS study. As a consequence, the newer trials and the recent publication of older trials (UKPDS, STENO) have caused an interesting debate in the diabetes research community. A possible consensus at this moment may be this one: chasing the lower HbA1c-levels as possible is desirable taking into account the method (kind of drugs, the tempo of lowering) and balancing the benefice against potential harms (essentially hypoglycemia). In the frail elderly, HbA1c targets between 7.5 and 8.5 seem realistic and beneficial.

We propose to add two recent references in the introduction and to refer to the accord study in the discussion by adding this paragraph: The role of EBM in daily practice remains a point of controversy. Whilst many GPs accepted the existing guidelines, some did not. Some GPs fundamentally disagreed with EBM. Others accepted EBM as a background support, but were afraid that EBM would be used to impose coercive instructions for daily practice. Several GPs questioned the feasibility and desirability of the ADA-guideline based recommendations in the elderly or immobile people. Indeed, elderly patients are particularly sensitive to the adverse effects of drugs and polypharmacy putting constraints on the classic diabetes treatment. Especially hypoglycemia is an important topic in the elderly with recent studies clearly indicating that hypoglycemia may be a contributing factor to morbidity and mortality in older patients. As such, strict adherence to guidelines for younger patients could be deleterious for the frail elderly. Geriatric guidelines on the management of type 2 diabetes accentuate that treatment should be holistic, targeting all important aspects of the geriatric patients with priorities in the treatment scheme. Diabetes related targets should be individually adapted to the frail patients with special attention to avoidance of side effects.

And further on: ‘implications’ (…)
To round off, several interviewees reported real concerns on the applicability of the ‘traditional’ diabetes guidelines in a subset of the patient population, namely the elderly. These concerns have been joined by specific geriatric guidelines. These findings show that quality improvement is not a unidirectional process from guideline to practice. Often, several practitioners express the same difficulties with implementing a guideline. In that case, it might actually reveal a flaw in that guideline rather than a barrier related to the practitioners. And thus QIPs should also be used as instruments to test the feasibility of guidelines and to highlight some flaws.

**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.
Reviewer's report

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

Version: 2 Date: 8 March 2009
Reviewer: Thierry Christiaens

Reviewer's report:
- Major Compulsory Revisions

(1) Title: the title is too general; the study tries to explore one small part of “The Complexity of Quality Improvement in the Management of Type 2 Diabetes Mellitus in General Practice” and not the whole problem.

Correct: we propose this change: “Barriers and Facilitators to Evidence Based Care of Type 2 Diabetes Patients: experiences of General Practitioners Participating to a Quality Improvement Program.”

(2) In the abstract the objective of the study is mentioned as “to assess the impact of a 18-month QIP on diabetes type 2 care provided by FPs”; one could question if qualitative research is able to “assess an impact” of a QIP, quantitative research is to prefer hereby. In the introduction the objective is “to give better insight into what changes the FPs had actually made in diabetes care as result of the QIP.” In fact (logically in a qualitative study) no objective changes are reported, only the perceptions, interpretations and experiences of the FPs. A clear formulation of the research question is necessary.

Correct: we are dealing with ‘subjective’ viewpoints, experiences and feelings.

Proposed changes to the abstract: “To evaluate the barriers and facilitators to high quality diabetes care as experienced by General Practitioners (GPs) who participated to an 18-month quality improvement program (QIP).”

Proposed change in the introduction: However, results widely varied between participating GPs. Accordingly, we conducted a complementary qualitative study (January to April 2008,) nested in the controlled trial, to gain better insight into what changes the GPs had actually experienced.

(3) Methodology: the choice of the methodology is not argued. Why qualitative research? Why semi structured interviews (and for instance not focus groups)?
We conducted this qualitative research to acquire a better understanding of the barriers to high quality diabetes care and into the mechanisms of change that eventually were induced by the QIP according to the experience of participating GPs. We opted for ‘one to one’ interviews in order to investigate the perceptions of the GPs about the QIP that essentially targeted the individual GP. We opted for semi-structured interviews in order to let the interviewees talk freely as well as to deepen the interviewees’ personal feelings about both the experienced barriers to high quality care and facilitators of change.

Why based on the ‘implementation method’? How were the interviews analyzed, which qualitative technique or software was used, were two independent persons analyzing all the material (or each a part), with a third one as fall-back in case of discordance?

We propose following text in the methodology section: Before analyzing the transcripts, we discussed the analytical method to use. We decided to categorize the items by theory-based deduction using the ‘implementation model’ (Grol et al., 2004). We chose this model because it is based on a comprehensive overview of theories on implementation and behavioral change. These theories relate to the individual’s cognitive, educational and motivational attributes, as well as social, organizational and economic factors. This model also reflects the basic structure of the interviews: barriers and facilitators of guideline implementation are well described. As such, this model allows for deductive coding and categorizing of the items according to the level of action. After a first discussion round, we reached consensus to categorize the items in three levels: 1) individual GP, 2) individual patient, 3) social interaction, context and organization. Items were divided into ‘barriers to high-quality diabetes care’ and ‘factors facilitating change’. Barriers at the individual level were further categorized into subcategories: ‘knowledge’, ‘awareness’, ‘attitude and motivation’, ‘routine’ and ‘others’. All transcripts were re-read when necessary and independently analyzed by GG and LBO to ensure reliability of the data. Transcripts were manually coded and the items were categorized using excel® spreadsheets. Differences in coding were discussed and final decisions on items and categories were based on a consensus between the two interviewers.

(4) The interviewers and the three main questions were very “subjective”: the interviewee was very openly confronted with a interviewer believing strongly in the QIP (persons he/she knew from former contacts as linked with the QIP) and with questions with an implicit positive message on the QIP-process.
By these type of questioning a FP e.g. in disaccord with the targets of the guidelines or with the proposed insulin policy was not invited to mention this. This is missing in the discussion.

We will put this in the discussion section because it is a possible bias. We think however that the GPs spoke very openly about their doubts and problems (about EBM for instance). We also encouraged them to do so at the beginning of the interview and during the interview.

We propose following addition: “This qualitative research presents some limitations. A first possible bias concerns the researchers who conducted the interviews. They previously were involved in the QIP and thus are known by the interviewees as promoters of this program. As a consequence, GPs in disaccord with some issues of the QIP-process may have been discouraged to mention them.”

(5) In the introduction several studies are mentioned concerning “obstacles that prevent FPs for following the guidelines”. The results of this study should be compared to the results of the former studies in the Discussion: what is the added value of the actual findings? What is linked with local factors and what can be generalized?

OK, we make a round up in the last paragraph “implications”. We did not make a summary of the findings of all these studies, because the topic is too broad (and the list of barriers too long), but we discussed what (we think) our study added to the existing knowledge.

- Minor Essential Revisions
The author can be trusted to make these. For example, missing labels on figures, the wrong use of a term, spelling mistakes.
(1) Some sentences are not so easy to understand or rather complicated and too long
Some examples
-in the abstract: Some FPs were reluctant to collaborate with specialists and especially with diabetes educators and dieticians, others claimed blamed poor compliance with the guidelines on lack of time, and most reported that a considerable minority of patients were unwilling to change their lifestyles.
Cut in three sentences.

- in Methods: In our interviews, not only were the assertions reflected back, but the interviewees were actively confronted on points of inconsistency in their remarks or objective data.
We changed it like this: *In our interviews, not only were the assertions reflected back. The interviewees were also actively confronted with eventual inconsistencies in their answers.*

Throughout, the interviewers provided reassurance by intonation and body language resulting, we feel, in answers with more depth than obtainable with the qualitative schedules normally used.

(last part in italic not suitable in a Methodology Section)

**We changed the sentence:** *Throughout, the interviewers provided reassurance by intonation and body language in order to disclose the very personal feelings and experiences of the interviewees.*

-in Results: The second barrier was their unawareness of ‘blind spots’ in their own performance, as well as of the importance of attaining clinical targets and regular follow-ups.

*A second barrier was the GPs’ lack of awareness of own performance because of ‘blind spots’. Several interviewees also affirmed that before the start of the project they did not truly understand the importance of attaining clinical targets and regular follow-ups (BOX 1).*

- Results: “This competition is reinforced by the skewed reimbursement schemes in favor of the specialist concerning patient education, and Home Blood Glucose Monitoring (HBGM) kits. This is a very ‘Belgian’ problem and must be mentioned as such: “by the skewed Belgian reimbursement…”

OK, we made it: by the skewed reimbursement schemes in Belgium in favor….

-Discussion: “This approach, combined with the ‘reflective listening’ technique, elicited disclosure of very personal feelings and experiences related to changes in performance. As such, qualitative research nested in an experimental trial may clarify the improvements that a QIP brings about in a general practice.” (The “thus” is certainly to question.)

OK, we cut this part of the sentence: *This approach, combined with the ‘reflective listening’ technique, elicited disclosure of very personal feelings and experiences related to changes in performance. As such, qualitative research nested in an experimental trial may clarify the improvements that a QIP brings about in a general practice.*

- Discussion: “Secondly, most of the FPs demonstrated a major improvement in adherence to diabetes care guidelines, a major change in behavior and attitude.” (demonstated ?, rather reported or claimed?)

‘Reported’ is better.
- Discussion: “Several FPs indicated that the changes resulted from a conscious decision based on key interconnected elements in the QIP: the need to keep up with knowledge, their increasing awareness of the need to improve their practice, and the realization that their attitude needs adjustment.”

We cut the sentence in two.

(2) “Previous studies have disclosed a significant gap between the quality of diabetes care commonly encountered and the recommended guidelines, a gap reflected in morbidity and mortality statistics” ref 12 this last part of the sentence is very drastic and the reference not strong enough to motivate such a controversial statement
OK, we cut it.

(3) The reference list has to be reviewed carefully.
The authors(group) is missing in 1,2,3,5,8,12;
We made the corrections.
no end page is mentioned in 28 and 32 (and 13?);
Note that articles published in open access journals (implementation science, BMC family practice, BMC health serv. Res) have another type of referencing, without end page.

a lot of points have to be added(4, 5,6, 15,30) and virgules to be removed (11,31); reference 11, 12, 27 are not complete
We made the corrections. We downloaded and used the “biomed central.os” in reference manager.

- Discretionary Revisions
These are recommendations for improvement which the author can choose to ignore. For example clarifications, data that would be useful but not essential. (1) In Results the subtitle “population” covers just the first paragraph but not what follows. Another subtitle is needed.
We cut the subtitle ‘population’

(2) Results: “benchmarking feedback” and “case coaching” are terms needing some explanations
We put the explanation in table 1 with explanation of the quality improvement program.

(4) Results: “The redefinition of the FP as a central ‘manager’, in the care of diabetic patients with explicit responsibilities, was much appreciated.” Which “redefinition” is this? That of the QIP?
Yes, we added this.

(5) One could discuss if the following paragraphs brings something new to the discussion
“Long-established physician-patient relationships may also impede change.
Tension may arise because patients may not be able to cope with a sudden change in attitude of their FP, making it all the more important that any changes in the management of diabetes be discussed with the patients beforehand.
We cut this sentence.

This study revealed certain limitations in the QIP approach, the first being the complexity and the multifaceted nature of any change. Change is neither 'black' nor 'white.' For example, factors such as age and immobility may interfere with implementation of an evidence-based protocol. One FP reported persistent problems with one local endocrinologist who was blamed for his disdainful attitude to general practice. Other FPs described minor remaining difficulties with endocrinologists despite overall satisfaction with the arrangements. For the sake of clarity, we constrained our discussion to the major barriers and facilitating factors. ”

This paragraph was reorganized in the discussion section and as we feel do have sense in this new structure of the discussion section.

Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:
I declare that i have no competing interests

Reference List

