Author's response to reviews

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

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

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Abstract

BACKGROUND: Many patients with type 2 diabetes do not receive an adequate level of care despite the availability of treatment guidelines. Optimal use of guidelines in general practice demands specific implementation strategies aiming at the reduction of barriers to high quality care. However, a clear understanding on the mechanisms of change induced by a Quality Improvement Program (QIP) seems to lacking. The objective of this qualitative study was to assess the impact of an 18-month QIP on diabetes type 2 care provided by Family Physicians (FPs). The QIP was implemented to promote compliance with international diabetes care guidelines by FPs. METHODS: Twenty out of the 120 participating FPs in the QIP underwent semi structured interviews that focused on three areas: (i) How did diabetes care improve in your practice? (ii) What made you modify your approach to diabetes care? and (iii) What problems did you encounter? RESULTS: Most FPs reported that enhanced knowledge, improved motivation, and a greater sense of responsibility were the key factors that led to greater compliance with diabetes care guidelines and consequent improvements in diabetes care. Other factors were improved communication with patients and consulting specialists, and reliance on diabetes nurse educators. 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. The interventions of the QIP program were as such important facilitators of change as well as the changes in relational patterns and social context that were induced by the QIP. The QIP did not only improve FPs guideline adherence, but also their work pleasure and self-esteem. CONCLUSIONS: Qualitative research nested in an experimental trial may clarify the improvements that a QIP may bring about in a general practice, provide insight into FPs' approach to diabetes care and reveal the program's limits. Implementation of a QIP encounters an array of cognitive, motivational and relational obstacles that are embedded in a patient-health care provider relationship.

Keywords: type 2 diabetes mellitus; quality of care program; qualitative research; diabetes care guidelines
Introduction

Landmark studies have demonstrated that intensive management of hyperglycemia, hyperlipidemia and hypertension significantly reduce morbidity and mortality in patients with type 2 diabetes mellitus (T2DM). T2DM is a ‘silent disease’ until irreversible micro- (e.g., nephropathy, retinopathy, diabetic foot) and/or macrovascular (e.g., myocardial infarction, stroke) complications become apparent. Prevention of these complications rests on timely institution of drug therapy by the prescribing physician, usually a Family Physician (FP), and the patient's compliance with the treatment regimen and willingness to make lifestyle changes. A proactive follow-up of diabetic patients is essential and should include foot examinations, blood and urine tests, eye examination, etc. In addition, patients should be counseled about the dangers of diabetes and the importance of a healthy lifestyle, and impressed with the need for compliance with doctor's orders.

Unfortunately, many patients do not receive an adequate level of care despite the availability of internationally-accepted treatment guidelines. Optimal use of guidelines in general practice demands specific implementation strategies aiming at the reduction of barriers to high quality care. However, a clear understanding on how to overcome these barriers seems to lacking, despite previous studies which pictured the obstacles that prevent FPs from following the guidelines. Our study reports on 20 FPs who participated in an 18-month quality improvement program (QIP) that significantly improved diabetes-related outcomes. 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. However, not all FPs reported such good results. Accordingly, we conducted a complementary qualitative study (January to April 2008,) nested in the controlled trial, to gain better insight into what changes the FPs had actually made in diabetes care as a result of the QIP. To fully understand these changes, we relied on an ‘implementation model’ based on the one described by Grol et al., 2004.

Methods

To gain maximum information, the interviewees were randomly chosen from a stratified sample of participants according to clinical performance scores before and after the intervention. The clinical
practices were divided in four strata relying on baseline performance (stronger vs. weaker,) and on the degree of improvement during the project (modest vs. substantial). Within each stratum, five FPs were randomly chosen to be interviewed by a researcher not involved in the interviews. If a selected FP refused to participate, the next FP on the list in that stratum was invited.

Interviewees and interviewers were blinded to the practice stratum at the time of the interview. Our design called for 20 interviews with post-hoc analysis and evaluation of data saturation. Plans were made for additional interviews if the data saturation criterion was not met. Three main questions were asked in the semi structured interviews: 1. “How did you improve diabetes care as a result of the QIP?” 2. “What induced you to modify your approach to diabetes care?” and, 3. “What problems did you experience in making the changes?”

Subsequent discussions delved deeper into these topics by using an adaptation of “reflective listening,” a counseling technique that elicits a thorough disclosure of the interviewee's thoughts and feelings. It involves reflecting back to the interviewee what the interviewer believes was said in order to verify or clarify the interviewee's statements, and encourages interviewees to continue elaborating their views. 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. 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.

The interviews took 30 to 45 min and were conducted individually by two experienced researchers (GG and LBO,) one a practicing FP and the other a community nurse specializing in health care consultancy. All interviews were taped and transcribed.

Itemization was based on theory-based deduction using the ‘implementation model’ (Grol et al., 2004) that relates on different theories of behavioral changes with regard to an individual's cognitive, educational and motivational attributes, as well as social, organizational and economic factors. Items were categorized according to the level of action (individual FP, individual patient, contextual and organizational level) and divided into ‘barriers to high-quality diabetes care’ and ‘factors facilitating change’. The transcripts were
re-read as necessary, manually coded, and independently analyzed by GG and LBO to ensure reliability of the data.

Results

Population

Two FPs refused to participate in the interview and were replaced by the FP next in line. Data saturation was observed after 17 interviews. Table 1 shows the main characteristics of the interviewees which were felt to be typical of all 120 participants in the QIP. Table 2 shows the results of itemization. There were no major inconsistencies in the analyses performed by the two researchers.

All but four of the FPs confirmed the importance of improved adherence to the evidence-based guidelines. Most also reported improvements in follow-up procedures, evidence-based drug prescription practices, and referral rates. The more frequent follow-up visits included regular blood monitoring and general screening for complications. Several FPs mentioned better record keeping. Implementation of evidence-based treatment was evident in more timely adjustments in therapy if target criteria fell short, and in greater attention to cardiovascular risk factors, above and beyond conventional glycemic control. Finally, more patients were treated with insulin.

Some interviewees reorganized their practices to better comply with the guidelines. Others instituted regularly scheduled office visits, and some split the visits into two parts: one part dedicated to routine follow-up and the other to discussions of treatment and lifestyle. The interviewees noted better medication compliance and improved adherence to follow-up schedules by the patients.

Barriers to high-quality diabetes care and factors facilitating change.

Our analysis showed that the first barrier to successful diabetes care was FPs inadequate knowledge how to manage insulin therapy and cardiovascular risk. 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. 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. Finally, some FPs admitted being lax and several indicated that lack of time--because of suboptimal practice management--prevented them from providing good quality care.

Factors conducive to good care were also discussed. The consensus was that transparent treatment protocols and tailored post-graduate courses would go a long way in overcoming knowledge gaps. Benchmarking feedback confronted the FPs with their blind spots and weaknesses, and increased their awareness of shortcomings in their case management habits. Case coaching was identified as an important innovation in improving ‘knowledge on the spot’, especially in initiating and adapting insulin therapy. Several FPs confirmed that the three-month data collection exercise encouraged regular record keeping and a structured approach to patient follow-up.

BOX 1. Barriers and facilitating factors: FP’s knowledge and awareness.

- “Such a project with follow-up is important because it obliges you to question yourself. I thought my patients were reasonably well controlled, but the QIP-- especially the feedback-- makes you confront your problems and weaknesses”.

- “Since the start of the project, I became confident in starting insulin therapy, whereas before I would never initiate insulin therapy. The extra coaching was unique to this project and functioned like clockwork. You only had to make a phone call – that is very comforting to a FP.”

- “The constant support and the organized courses made the difference. The protocol map, which has become a reference work, also contributed a lot. Because of the feedback, I became aware that my performance on lipid lowering therapy was not good. This, together with information on vascular pathology as a major problem in diabetes, made me change my attitude. I have begun to prescribe more statins.”

BOX 2. Barriers and facilitating factors: FP’s attitude and practice organization
“I admit that I was lax before, but have changed during the project. Some patients were incredibly surprised that finally they were getting good care.”

“I do everything myself. I find it difficult to work in a team, and I am rather skeptical about the ‘soft sector’ (psychologists, educators…).”

“Evidence-based medicine is a relative term. … something might be evidence-based, but I have in mind other parameters that are much more important. In my alternative point of view, I do not care a lot about cholesterol, for example.”

“Policy-makers should use such programs for positive motivation. They should not connect results with negative implications (e.g., loss of accreditation).”

“I didn’t observe major behavioral changes in most patients, but this may be associated with my own passive attitude. I made no changes in my organization of care and I did not spend enough time at it.”

“The imposed record keeping of patient data put me under some pressure. Imposing a structure helps you handle your job more systematically. Since the project has stopped, this disciplined approach is beginning to wane again.”

The FPs also felt that care was compromised by the patients' insufficient understanding of diabetes, lack of awareness of serious complications, and of the importance that lifestyle plays. 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. The FPs also described the synergistic effect of several health care workers delivering the same message in inducing a sudden change in attitude. There was a consensus that a patient's attitude and lack of motivation are major barriers to implementing evidence-based treatment, especially when it involved a change in lifestyle. Finally, the FPs felt that about one third of the patients would be uncooperative no matter what changes were proposed, and most FPs agreed that changing entrenched lifestyle habits was difficult for most patients to achieve, whatever their initial motivation. For the most part, any such changes would be small and temporary.
BOX 3. Barriers and facilitating factors: Patients' insight into diabetes

- “The big change is the availability of the nurse educator. . . . She really took the time to explain the problem of diabetes. People have a better understanding of what HbA1c is. . . . people are afraid of needle sticks and this fear has decreased because of the project, thanks to the nurse educator.”

BOX 4. Barriers and facilitating factors: Patients’ attitude

- “Physical activity and weight control remain the main problems. The motivation to change lifestyle habits is often completely absent. Some patients deny the problem: ‘I don’t eat very much’.”

- “A minority-- about 30% --doesn’t want to hear anything. They won’t even go to see the nurse educator. Another 30% are somewhat motivated, but not too much, and the remaining 30% really cooperate. The added value of the project, probably, applies only to patients who are motivated and who can get motivated.”

- “If three professionals give the same message and if, moreover, patients receive the same message by television, and then a sudden change can occur.”

The FPs also mentioned social, organizational and legal barriers and facilitating factors. The interaction between a FP and his or her patients, especially when it concerns a long-term relationship, can itself hamper the transition to high-quality diabetes care. Several FPs described how patients were accustomed to certain situations and habits of their FPs, e.g., a limited use of drugs. They did not always understand or appreciate the sudden change in their FP’s attitude; this led to tensions in some cases and loss of contact in others. However, the project mitigated such unfortunate instances through counseling involving sessions the FPs, patients and nurse educators. The net effect was a strengthening of the physician-patient relationship and a motivational boost to the latter.

Most FPs held that a lack of a clear delineation of responsibilities leads to competition between the FP and the specialist, with the latter being perceived as holding the upper hand. 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 skewed situation was considered as an important factor that prevents many FPs from commencing timely insulin therapy.

The redefinition of the FP as a central ‘manager’, in the care of diabetic patients with explicit responsibilities, was much appreciated. It reinforced the FPs’ feeling of recognition, boosted self-esteem, promoted a greater sense of responsibility, and improved their professional relationships with specialists. Many FPs regarded the role of the nurse educator as complementary to their own and, feeling that they themselves lacked the requisite skills and time were relieved to relinquish patient education to them. One FP felt that the Belgian fee-for-service scheme was an important impediment to the delivery of quality care, explaining that a pay-for-performance system would be a better motivator. In addition, direct payment by patients was also seen as a significant factor that discouraged patient referrals and HBGM necessary to evaluate insulin therapy.

**BOX 5. Barriers and facilitating factors in patient-FP interaction**

- “Previously, some patients probably consulted me because I was easygoing. Since my participation in the project, I’ve pushed them more and so I lost two patients. They frankly told me ‘We’re leaving because you exaggerate things. What’s the matter with you?’ But patients and physicians must evolve together, although at a moderate pace.” II have started prescribing lipid-lowering drugs relatively recently. Before the project, I was rather reluctant to prescribe medications and my patients were not accustomed to my new attitude. So, I had to take a gradual approach.”

- “Diabetes patients themselves feel much more appreciated; because of that, the link between us and our patients has strengthened.”

**BOX 6. Barriers and facilitating factors in the social, organizational and legal context.**

- “Specialists gain too much control of referred patients and often exclude FPs from direct patient care. This is especially true of patients on insulin who get free instructions and monitoring kits at
the diabetes centers, unlike patients in primary care. So, it’s nearly impossible for FPs to hold on to patients on insulin.”

"The project did not merely create the illusion that the FP was pivotal in diabetes care, he or she actually became the central figure and this fact increased their job satisfaction. … This only became possible because of an attitude change on the part of the endocrinologists. Now they say 'you FPs have to do the job, but call me when necessary.' This is a big change from the usual 'let us do our work; after all we are the specialists and you may help a little bit.' We collaborate as one team -- there's mutual support! We’re on the same wavelength and feel we work together toward the same objectives.”

"To summarize this project: we started with a good protocol and established better channels of communication between primary and specialist care. … The delineation of responsibilities and degree of familiarity among the partners were very important in making it easier to me to refer more patients.

"I prefer to have the nurse educator bring up insulin therapy before I get to it. … After 30 years in general practice, I'm somewhat hesitant to get into a protracted struggle with patients to try to convince them of the need for insulin. 'If you're not interested, so be it,’ I tell them. The nurse educator is an invaluable asset in such cases.”

Discussion

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. To date, most research on barriers to high-quality care and the facilitating factors that promote better care has been done in primary care settings before QIPs came into vogue. Our study was based on interviews with FPs who have participated in a project aimed at optimizing diabetes care. This approach, combined with the ‘reflective listening’ technique, elicited disclosure of very personal feelings and experiences that the
changes engendered, thus providing insight into the mechanisms of change that operate at the individual and general practice levels.

The primary finding was that the project accomplished more than merely improving the quality of care. It also impacted the emotional and motivational status of the FPs. Previous focus group-based research had revealed that FPs working in the ‘usual’ setting in our country felt frustrated, partly because they felt inferior to specialists.\textsuperscript{28} We showed that role-redesign and delineation of responsibilities \textit{vis-à-vis} the specialists enhanced a FP’s self-esteem and sense of responsibility. All interviewees were unanimous that this project was very beneficial because it added value to their jobs, even though some were concerned that QIPs could have manipulative ends or lead to sanctions.

Secondly, most of the FPs demonstrated a major improvement in adherence to diabetes care guidelines, a major change in behavior and attitude. It should be noted that they had a certain degree of latitude in making decisions that altered their practice. According to the theory of planned behavior, decisions are made according to personal models and beliefs about the changes about to be made, and the perceived benefits and risks associated with them.\textsuperscript{29} 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. The FPs also observed attitudinal changes in their patients, e.g., better adherence to drug regimens and follow-up visits. Nevertheless, limitations of the QIP were also described. A significant minority of patients remained refractory to change, with many refusing to see a nurse educator. Most patients found it difficult to change their lifestyle, and even in the case of motivated individuals the changes were often minimal and temporary. These findings confirmed previous findings that sustainable lifestyle changes are hard to implement.\textsuperscript{16,30,31}

The study also revealed that some FPs were reluctant on to reorganize their practices to comply with the project’s requirements, or even to find the time for efficient patient follow-up. Accordingly, future QIPs should specifically address such issues. Moreover, while the project was indeed able to induce a change in attitude with regard to medical diabetes treatment, some other deeply rooted attitudes were more difficult to change. For example, several FPs asserted that nurse educators and other personnel in the so-called “soft sector” are of little value in good diabetes care.
Thirdly, a multifaceted QIP evokes complex changes that go beyond individual physicians and patients, since they form an interconnected and interdependent social continuum. 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. The QIP facilitated patient referrals to the nurse educator, despite certain resistance on the part of some patients or physicians. The nurse educator, in turn, contributed to patient care by ensuring follow-ups, providing information on insulin therapy and health lifestyles, and performing complementary examinations, i.e., carrying out functions for which the FP lacked time or did not possess adequate skills or motivation. Finally, the QIP also altered interpersonal relationships. Most FPs confirmed that the QIP strengthened their relationships with their patients and improved communications with specialists and other health care personnel. They also perceived a change in attitude on the part of the endocrinologists toward them, which markedly enhanced the FPs' motivation and sense of responsibility. These findings substantiated various theories and research findings that a positive relationship among health care providers is an important component of high-quality patient care.\textsuperscript{32,33}

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.

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.

The FP cohort selected for the study represented an additional limitation. The participants were part of a larger sample of volunteer FPs who were particularly interested in the project. This selection bias may well be reflected in their answers. In order to generate a broad spectrum of answers regarding barriers to change, we employed a targeted sampling procedure that took into account the performance of the FP's practice. Only their subjective feelings and views are covered here, although a more balanced picture would have
emerged if a joint patient-provider perspective had been offered. It remains for future research to include interviews with patients and, perhaps, employ mixed focus groups. In general, we feel this qualitative study has provided a very balanced overview of the QIP's strengths and weaknesses, and validated the quantitative findings that had been obtained.

In conclusion, qualitative research nested in an experimental trial may clarify the improvements that a QIP may bring about in a general practice, as well as reveal the program's limits. It has become obvious that implementation of a QIP encounters an array of cognitive, motivational and relational obstacles that are embedded in a patient-health care provider relationship.

**Sources of support**: The Belgian ‘National Institute for Health and Disability Insurance’ (NIHDI)

**Conflicts of interest**: none to declare
Reference List


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<th>S2 (N=5)</th>
<th>S3 (N=5)</th>
<th>S4 (N=5)</th>
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<th>All participants (N=120)</th>
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<td>Mean age (years)</td>
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<td>45</td>
<td>48</td>
<td>36</td>
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<td>Females (N)</td>
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<td>3</td>
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<td>2</td>
<td>3</td>
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<td>30%</td>
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### Table 2. Coded categories and themes.

**Perceived barriers to optimal diabetes care**

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<thead>
<tr>
<th>Level</th>
<th>Factor</th>
<th>Item</th>
</tr>
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<tbody>
<tr>
<td>Physician</td>
<td>Lack of knowledge</td>
<td>- global cardiovascular treatment beyond glycemic control</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- insulin therapy</td>
</tr>
<tr>
<td></td>
<td>Lack of awareness regarding</td>
<td>- personal practice performance ('blind spots')</td>
</tr>
<tr>
<td></td>
<td>Attitude and motivation</td>
<td>- need to reach treatment targets and regular follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- laxity regarding treatment targets and timely follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- attitude to polypharmacy</td>
</tr>
<tr>
<td>Practice organization</td>
<td></td>
<td>- skepticism regarding evidence-based treatment, top-down quality</td>
</tr>
<tr>
<td></td>
<td></td>
<td>improvement projects and shared care collaboration</td>
</tr>
<tr>
<td>Patient</td>
<td>Lack of knowledge</td>
<td>- no insight regarding complications, significance of HbA1c</td>
</tr>
<tr>
<td></td>
<td>Lack of awareness regarding</td>
<td>- personal dietary patterns</td>
</tr>
<tr>
<td></td>
<td>Attitude and motivation</td>
<td>- personal health status (HbA1c, blood pressure, cholesterol)</td>
</tr>
<tr>
<td></td>
<td>Routine behavior</td>
<td>- fear of insulin treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- lack of motivation for follow-up or to change lifestyle</td>
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<tr>
<td></td>
<td>Age and co-morbidity</td>
<td>- maintaining lifestyle change very difficult</td>
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<td></td>
<td></td>
<td>- adhering to planned follow-up visits is difficult</td>
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<tr>
<td>Context and</td>
<td>Relationships</td>
<td>- too strict control can be dangerous in older patients</td>
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<tr>
<td>organization</td>
<td></td>
<td>- immobility hampers physical exercise and shared care referral</td>
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<tr>
<td></td>
<td>Lack of teamwork</td>
<td>- between GPs and patients (inertia to change)</td>
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<tr>
<td></td>
<td></td>
<td>- competition between specialists and GPs</td>
</tr>
<tr>
<td></td>
<td>Financial barriers</td>
<td>- Need for clear description of each provider’s duties and responsibilities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Need for identical messages to the patients from all health care providers</td>
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<tr>
<td></td>
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<td>- out-of-pocket payments for education, dietary advice and HBGM material</td>
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<tr>
<td></td>
<td></td>
<td>- skewed reimbursement of HBGM material</td>
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<tr>
<td></td>
<td></td>
<td>- pay for performance doesn’t motivate GPs to deliver high quality care</td>
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**Perceived change facilitators**

<table>
<thead>
<tr>
<th>Level of impact</th>
<th>Item</th>
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<tbody>
<tr>
<td>Physician</td>
<td>Treatment protocol and post-graduate education; Benchmarking feedback</td>
</tr>
<tr>
<td></td>
<td>Case coaching; Timely data collection</td>
</tr>
<tr>
<td></td>
<td>Increased contact and communication with peers in other disciplines</td>
</tr>
<tr>
<td></td>
<td>Participation in team meetings</td>
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<tr>
<td></td>
<td>Attitude change on the part of specialists</td>
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<tr>
<td>Patient</td>
<td>Nurse educator and IDCT working as a team</td>
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<tr>
<td></td>
<td>Free services and free materials</td>
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<td></td>
<td>Identical messages from different sources (GP, specialist, educator, television)</td>
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<tr>
<td></td>
<td>Attitude change on the part of the GP</td>
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<tr>
<td>Context and organization</td>
<td>Role redesign and reassignment of responsibilities</td>
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<tr>
<td>--------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Serial removal of barriers</td>
</tr>
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<td></td>
<td>Task relief</td>
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**HBGM** = Home Blood Glucose Monitoring

**IDCT** = Interdisciplinary Diabetes Care Team (endocrinologist, nurse educator, dietician) installed at the primary care level