Interventions to Improve the Management of Diabetes in Primary Care, Outpatient, and Community Settings

A systematic review

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OBJECTIVE — To review the effectiveness of interventions targeted at health care professionals and/or the structure of care in order to improve the management of diabetes in primary care, outpatient, and community settings.

RESEARCH DESIGN AND METHODS — A systematic review of controlled trials evaluating the effectiveness of interventions targeted at health care professionals and aimed at improving the process of care or patient outcomes for patients with diabetes was performed. Standard search methods of the Cochrane Effective Practice and Organization of Care Group were used.

RESULTS — A total of 41 studies met the inclusion criteria. The studies identified were heterogeneous in terms of interventions, participants, settings, and reported outcomes. In all studies, the interventions were multifaceted. The interventions were targeted at health care professionals only in 12 studies, at the organization of care only in 9 studies, and at both in 20 studies. Complex professional interventions improved the process of care, but the effect on patient outcomes remained less clear because such outcomes were rarely assessed. Organizational interventions that facilitated the structured and regular review of patients also showed a favorable effect on process measures. Complex interventions in which patient education was added and/or the role of a nurse was enhanced led to improvements in patient outcomes as well as the process of care.

CONCLUSIONS — Multifaceted professional interventions and organizational interventions that facilitate structured and regular review of patients were effective in improving the process of care. The addition of patient education to these interventions and the enhancement of the role of nurses in diabetes care led to improvements in patient outcomes and the process of care.

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Diabetes is a major and growing health care problem. Primarily because of the increasing prevalence of type 2 diabetes as well as the increase in cases of type 1 diabetes (1), it is expected that the number of people with diabetes will double by the year 2010 (2).

Diabetes accounts for a huge burden of morbidity and mortality through micro- and macrovascular complications (3,4). However, it is now clear that strict control of blood glucose, blood pressure, and cholesterol can reduce the risk of diabetes-related complications (5–8). To achieve strict control, structured care is needed (9).

Over the past 20 years, the responsibility for the care of people with diabetes has shifted away from hospitals to primary care (10,11). During this period, randomized trials have demonstrated that if regular review of patients is guaranteed, the standard of primary care can be as good or better than hospital outpatient care in the short term (9). Several guidelines and diabetes management programs have been developed nationally and locally to improve diabetes care in the community. However, empirical data suggest that compliance with diabetes clinical practice recommendations is inadequate in primary care (12–14) and that a large proportion of patients with diabetes remain at high risk (15,16).

Consequently, a wide range of interventions aimed at improving the provision of diabetes care and achieving better metabolic control for patients with diabetes have been implemented. This review addresses the issue of understanding the best way to narrow the gap between what is known to be effective in diabetes care and the care that is currently provided. Therefore, the objective was to determine the effectiveness of the different interventions targeted at health care professionals and/or the structure of care in order to
improve the management of patients with diabetes in primary care, outpatient, and community settings.

RESEARCH DESIGN AND METHODS

Identification of studies
This review was conducted within the Effective Practice and Organization of Care (EPOC) review group of the Cochrane Collaboration (17). The Cochrane Collaboration is an international organization that aims to help people make well-informed decisions about health care by preparing, maintaining, and promoting the accessibility of systematic reviews of the effects of health care interventions. Systematic reviews are reviews regarding a well-formulated clinical question that use systematic and explicit methods to identify, select, and critically appraise relevant research and to collect and analyze data from the studies that are included in the review. Cochrane reviews provide up-to-date, comprehensive, and unbiased summaries of the best available evidence. These reviews are published electronically in the Cochrane Library.

The EPOC search strategy was combined with free-text words and key words regarding “diabetes” and “primary care,” “community care,” or “outpatient care.” The following electronic databases were searched for relevant studies: Medline (1966–2000), Embase (1980–2000), Cinahl (1982–2000), the EPOC trials register (1999), and the Cochrane Clinical Trials Register (1999). Additionally, we scanned the reference lists of all relevant studies.

Study selection
We included studies that evaluated the effectiveness of interventions directed at health care professionals who care for nonhospitalized patients with type 1 or type 2 diabetes in primary care, outpatient, or community settings. Studies were included if they fulfilled the following EPOC group methodological and quality criteria (18): 1) randomized or quasi-randomized trials randomized by patient, health care professional, or practice; 2) interrupted time series (ITS) with a clearly defined intervention and at least three time points before and three after the intervention; and 3) nonrandomized studies controlled at a second site with data before and after the intervention and appropriate choice of control site.

Only studies using a reliable, objective, and predetermined measure of the process of health care or patient outcomes were included. Interventions were classified as professional interventions (such as education, audit, and feedback), organizational interventions (such as revision of professional roles, changes in medical record systems, and arrangements for follow-up), financial interventions (such as fee-for service and grants), or combinations of these (18). Studies that implemented only patient-oriented interventions (such as patient education and consumer participation in a health care organization) were excluded.

Data extraction
Data extraction was performed independently by two reviewers (C.M.R. and G.D.V.) using an adapted version of the EPOC Data Collection Checklist (18). Any discrepancies between reviewers were resolved by discussion or were referred to the editors of the EPOC group. The quality of eligible trials was assessed using the standard criteria described by the EPOC group. The most important recorded items were the unit of allocation and analysis, concealment of allocation, blinding, statistical power, follow-up of professionals and patients, comparability of baseline measurements, reliability of measurements, protection of the control group against contamination, setting, study population, and follow-up period.

Data analysis
Where possible, data were tabulated in terms of means ± SEM for patient outcomes and proportions for process measures; other data were presented as reported in the original source. Absolute differences and relative percentage improvement were calculated for study outcomes where possible (17). Baseline data were recorded to provide some indication of the comparability of study groups. For studies with a unit of analysis error (19), the point estimates of effects were presented without P values or 95% confidence intervals.

Because of the heterogeneity of interventions, settings, patient populations, and reported outcomes in combination with differences in guidelines, we decided a priori to not statistically pool the results of the studies. Instead, a qualitative assessment of the effects of the studies was made based on the quality of the study and the size and direction of the effect observed.

RESULTS — A total of 48 publications describing 41 studies met the inclusion criteria. Seven studies were described in multiple publications (24,25,37,38,41, 42,44,45,48,49,64–67). Of the included studies, 27 (21–24,26–28,30–32,36,37, 39–41,44,50,51,53–55,59–62,64,66) were randomized controlled trials, 12 (20,29,33–35,46–48,52,56,57,63) had a controlled before-after design, and 2 (43,58) were ITS. A wide range of organizational and professional interventions were evaluated, and in all of the studies, the intervention strategies were multifaceted.

In 27 studies, the interventions were based on clinical practice guidelines. In 14 (20,21,23,28,29,31,39,44,51–53,58, 59,64) of these, the guidelines were locally developed, in 11 studies (22,24,26, 27,32,35,36,47,55,57,60) they were based on national guidelines, and in 2 studies (46,54) the source of the guidelines was not specified.

Study quality
All studies had methodological limitations. Of 27 randomized controlled trials, only 6 (22,27,40,41,44,51) had adequate concealment of allocation. In 15 studies (22,26,33,37,39–41,46,50,51,53,55,62, 64,66), patients or health care professionals were randomized within a clinic or practice, thereby making them prone to contamination. In two studies, it was likely that the control group also received the intervention because it was stated that both the intervention and control clinic were staffed by the same personnel (34) or had a crossover design (61).

Similar baseline measurements between intervention and control groups were reported in only 13 of 42 studies (21,24,27–29,40,44,52,55,56,61,64,66). Outcomes were assessed blindly or were objective (assessed by a standardized test) in 21 studies (22–24,27–30,33,34,36,40, 41,47,51,52,56,58,60,61,63,66). In 14 studies, blinding of the outcome assessment was only partly adequate. In 18 studies (21,27–29,33,34,36,37,40,41, 47,51,52,56,60,61,63,66), the outcomes were all reliably assessed (outcomes obtained from an automated system or a reported agreement between two raters.
Organizational interventions versus usual care

Nine studies (33–37,39–41,43) compared organizational interventions with usual care (Table 2). Five (35,39–41) also included patient-oriented interventions, such as patient education and a learner-centered counseling approach, allowing patients to identify problems and agree on potential solutions (34).

Studies (34,39) in which a nurse or pharmacist assumed part of the physician’s role and provided diabetes care in combination with a patient-oriented intervention were associated with a small beneficial effect on glycemic control. However, because of the poor quality of these studies, the results have to be interpreted with caution. The effect on the process of care of the general practitioner and nurse jointly reviewing patients remains unclear because no statistical analysis was performed (43).

Arrangements for follow-up improved the process of care in terms of scheduled visits and rates of diabetic eye examinations, although there was variation with the type and intensity of the intervention used (36,41). Telephone calls for rescheduling missed appointments were more effective than sending multiple reminders to patients, which only affected process measures in the short term (36). The effectiveness of arrangements for follow-up on patient outcomes was rarely assessed. However, in two studies (35,40) in which multidisciplinary teams were implemented in combination with arrangements for follow-up and patient education, glycemic control and cholesterol improved significantly.

Combined professional and organizational interventions versus usual care

Twenty studies (44,46–48,50–64,66) implemented a complex intervention, consisting of a combination of professional and organizational interventions (Table 3). In 15 studies, in combination with organizational interventions, health care professionals received education through distribution of educational materials, through educational meetings, or through both. A common strategy targeted at the organization of care was a change in medical record systems (46,48,51,52,54,55,57,60,63). The systems were used for arranging follow-up (46,51,52), audit and feedback (48), generating reminders to the health care professional (55,60), or a combination of these (54,57,63). In six studies (44,47,56,62,64,66), patient education was added to professional and organizational interventions.

Computerized reminders, audit and feedback, or a combination of both seemed to improve process measures (48,54,55,60,63,64). However, only two studies (54,64) assessed the effects on patient outcomes and these produced conflicting results.

A centrally organized computerized database, which was used in combination with professional interventions to make arrangements for follow-up, to track patient appointments, and/or to generate reminder cards for patients, was associated with improvements in process measures (51,57). The addition of a nurse to this intervention led to improvements in patient outcomes (57). In studies in which patient outcomes were assessed, those that featured a greater involvement of nurses in diabetes management reported positive effects on these outcomes (44,50,52,56,57,66). Another recurring theme was that studies that reported a positive effect on patient outcomes often included patient education (44,56,57,66).

The effectiveness of using a telecommunication system (professional intervention) to assist in the outpatient management of insulin treatment in combination with organizational interventions remains unclear (53,61) because of contradictory results and limited methodological quality of the studies.

CONCLUSIONS — This review was performed to identify effective intervention strategies to improve the management of patients with diabetes in primary care, outpatient, and community settings. In addition to randomized controlled trials, studies with controlled before-after study and ITS design that fulfilled the EPOC group methodological and quality criteria and were published from 1966 to 2000 are included. Consequently, studies that did not fulfill the inclusion criteria or were published after the review timeframe were excluded. A total of 41 heterogeneous studies of variable quality met the inclusion criteria. In almost all of the studies included, postgraduate education was part of the complex interventions. The addition of postgraduate education...
<table>
<thead>
<tr>
<th>Reference</th>
<th>Design</th>
<th>Intervention</th>
<th>a) Number of providers</th>
<th>b) Number of patients</th>
<th>Setting</th>
<th>Follow-up (months)</th>
<th>Patient outcomes</th>
<th>Process measures</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feder (21) 1995, U.K.</td>
<td>RCT</td>
<td>i) educational materials; local consensus processes; educational outreach visits; reminders c) no intervention</td>
<td>a) 39 physicians supported by nurses</td>
<td>b) 390</td>
<td>primary care physician office, capitation and item of service</td>
<td>12</td>
<td>NA glyc (+)</td>
<td>bp (+)</td>
<td>weight (+)</td>
</tr>
<tr>
<td>Kinmonth (22) 1998, U.K.</td>
<td>RCT</td>
<td>i) educational materials/meetings; patient education (directed at ‘patient centered care’) c) educational materials/meetings; (focusing on use of guidelines and materials)</td>
<td>a) 43 doctors supported by nurses</td>
<td>b) 250</td>
<td>primary care physician office; capitation and item of service</td>
<td>12</td>
<td>glyc (0) bp (0) chol (0) BMI (−) alb (0) well (+)</td>
<td>microw (+)</td>
<td>patient 0 (well +)</td>
</tr>
<tr>
<td>Litzelman (23) 1993, U.S.</td>
<td>RCT</td>
<td>i) educational materials; reminders; patient education; behavioral contacts with patients; reminders for patients c) no intervention</td>
<td>a) ? (physicians supported by nurses [education])</td>
<td>b) 396</td>
<td>hospital-based academic primary care clinic; variable insurance arrangements*</td>
<td>12</td>
<td>NA</td>
<td>microw (+)</td>
<td>process +</td>
</tr>
<tr>
<td>Lobach (24) 1994 U.S.</td>
<td>RCT</td>
<td>i) local consensus processes; audit and feedback; reminders c) no intervention</td>
<td>a) 30 primary care clinicians</td>
<td>b) 399</td>
<td>hospital-based academic primary care clinic; variable insurance arrangements</td>
<td>6</td>
<td>NA glyc (−)</td>
<td>chol (+)</td>
<td>ur prot (+)</td>
</tr>
<tr>
<td>Mazze (26) 1994, U.S.</td>
<td>RCT</td>
<td>i) educational materials; educational meetings; local consensus processes; reminders c) no intervention</td>
<td>a) 8 family practitioners</td>
<td>b) 26</td>
<td>free-standing academic primary care clinic; variable insurance arrangements</td>
<td>6</td>
<td>glyc (+)</td>
<td>visits (+/−)</td>
<td>microw (+/−)</td>
</tr>
<tr>
<td>Mazzuca (27) 1990, U.S.</td>
<td>RCT</td>
<td>i) educational meetings; reminders c) no intervention</td>
<td>a) 98 internal medicine residents and faculty internists</td>
<td>b) 2,791</td>
<td>hospital-based academic primary care clinic; variable insurance arrangements</td>
<td>11</td>
<td>NA glyc (+)</td>
<td>compl (0)</td>
<td>process +/2</td>
</tr>
<tr>
<td>Palmer (28) 1990, U.S.</td>
<td>RCT</td>
<td>i) educational materials; local consensus procedures; audit and feedback c) no intervention</td>
<td>a) ?</td>
<td>b) 1,943</td>
<td>free-standing nonacademic primary care practice; variable insurance arrangements</td>
<td>18</td>
<td>NA compl (0)</td>
<td>process +</td>
<td></td>
</tr>
<tr>
<td>Pill (30) 1998, U.K.</td>
<td>RCT</td>
<td>i) educational meetings; educational outreach visits c) no intervention</td>
<td>a) ?</td>
<td>b) 190</td>
<td>primary care physician office; capitation and item of service</td>
<td>18</td>
<td>glyc (0)</td>
<td>att pat (0)</td>
<td>patient 0</td>
</tr>
<tr>
<td>Ward (31) 1996, Australia</td>
<td>RCT</td>
<td>i) educational materials; educational outreach visits; audit and feedback by interview c) educational materials; postal feedback</td>
<td>a) 139</td>
<td>b) 386</td>
<td>primary care physician office; fee-for-service with small sessional and capitation payments</td>
<td>8</td>
<td>NA</td>
<td>compl (0)</td>
<td>process +</td>
</tr>
</tbody>
</table>

**Table 1—Professional interventions versus usual care**
might be important in providing practitioners with the skills and knowledge to improve their performance, but they must be convinced of the importance of changing their practice and must be motivated to carry it out. In addition to the skills, knowledge, and motivations of individual care providers, organizational or other barriers can impede the implementation of change by care providers and must therefore be addressed. In the present review, postgraduate education seemed to improve the process of care when combined with other professional interventions. Moreover, interventions targeting arrangements for follow-up also improved process measures. This was achieved by central computerized tracking systems or by nurses who regularly contacted patients. This intervention may also decrease the number of patients lost to follow-up, which is particularly important because loss to follow-up is associated with an increased risk of diabetic complications (68).

Central computerized systems can be of additional value, as they may provide feedback to providers and can generate reminders to providers concerning the management of their patients. Further improvements in the performance of health care professionals and patient outcomes are possible, even if detailed management protocols are not available. In particular, combining patient education, a nurse, or both with arrangements for follow-up or multiple professional interventions led to improvements in patient outcomes as well as the process of care. Nurses can liaise with the patient and the physician, help facilitate patient and practitioner adherence, provide patient education, and, if they are trained and if detailed management protocols are available, may even assume some of the responsibilities of the physician. Patient education is important for involving patients in their own diabetes management and for improving self-management and compliance with medications. Moreover, it might encourage patients to change their lifestyle with regard to diet, smoking, and physical exercise.

In the U.S., most practices, whether hospital-based or not, care for patients under a variety of insurance arrangements: government (Medicare, Medicaid) or private (HMO or indemnity [fee-for-service]). *, positive effect; 0, no effect; −, negative effect; †, effect unclear; NA, not applicable; ±, possible unit of analysis error; within, differences are statistically tested within groups only, not between groups; alb, albumin; att pat, attendance patients; bp, blood pressure; comp, compliance care provider; CBA, controlled before-after study; creat, creatinine; glyc, glycemic control; HMO, health maintenance organization; hlth surv, health survey; hosp, hospitalizations; macrov, macrovascular complications; microv, microvascular complications; qual life, quality of life; RCT, randomized controlled trial.

<table>
<thead>
<tr>
<th>Practice</th>
<th>Study Design</th>
<th>Description</th>
<th>Setting</th>
<th>Education</th>
<th>Intervention</th>
<th>Patient</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carlson (32) 1991, Sweden</td>
<td>RCT</td>
<td>i) educational meetings; local consensus processes to identify problems and to create plans to improve diabetes care; educational outreach visits</td>
<td>primary health care center; salary</td>
<td>? (physicians, nurses, nurse assistants managers, administrators, and laboratory technicians)</td>
<td>b) 5492 (measurements on professional practice) 566 (measurements on HbA1c)</td>
<td>12</td>
<td>glyc (0) ± glyc (+) ± microv (+) ± patient 0 process +</td>
</tr>
<tr>
<td>Benjamin (20) 1999, U.S.</td>
<td>CBA</td>
<td>i) educational materials/meetings; local consensus processes; audit and feedback</td>
<td>free-standing academic primary care clinic; variable insurance arrangements</td>
<td>? (physicians, residents, nurses, and nutritionists)</td>
<td>b) 144</td>
<td>15</td>
<td>glyc (+) ± chol (+) ± microv (+) ± patient + process + within</td>
</tr>
<tr>
<td>Peres (29) 1995, Austria</td>
<td>CBA</td>
<td>i) educational materials/meetings; patient education</td>
<td>primary care physician office; fee-for-service</td>
<td>? (physicians, residents, nurses, and nutritionists)</td>
<td>b) 94</td>
<td>6</td>
<td>glyc (+) ± bp (0) ± chol (0) ± BMI (+) ± microv (+) ± patient 0 process +</td>
</tr>
</tbody>
</table>

*In the U.S., most practices, whether hospital-based or not, care for patients under a variety of insurance arrangements: government (Medicare, Medicaid) or private (HMO or indemnity [fee-for-service]). *, positive effect; 0, no effect; −, negative effect; †, effect unclear; NA, not applicable; ±, possible unit of analysis error; within, differences are statistically tested within groups only, not between groups; alb, albumin; att pat, attendance patients; bp, blood pressure; comp, compliance care provider; CBA, controlled before-after study; creat, creatinine; glyc, glycemic control; HMO, health maintenance organization; hlth surv, health survey; hosp, hospitalizations; macrov, macrovascular complications; microv, microvascular complications; qual life, quality of life; RCT, randomized controlled trial.
Table 2—Organizational interventions versus usual care

<table>
<thead>
<tr>
<th>Reference</th>
<th>Design</th>
<th>Intervention</th>
<th>a) Number of providers</th>
<th>b) Number of patients</th>
<th>c) Number of practices</th>
<th>Setting</th>
<th>Follow-up (months)</th>
<th>Patient outcomes</th>
<th>Process measures</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Halbert (36) 1999, U.S. RCT</td>
<td>i) arrangements for follow up (multiple reminders to patients) c) single reminder directed at patients</td>
<td>a) ? b) 19,523 c) 1 health maintenance organization (HMO); the number of medical groups is not clear</td>
<td>practices affiliated with Network or Independent Practice Association (IPA) HMO</td>
<td>12</td>
<td>NA</td>
<td>microv (+)</td>
<td>process +</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hawkins (37) 1979 Hawkins (38) 1981, U.S. RCT</td>
<td>i) revision of professional roles c) no intervention</td>
<td>a) ? (pharmacists, physicians [control group]) b) 315 c) 1</td>
<td>hospital-based academic primary care clinic; variable insurance arrangements*</td>
<td>29</td>
<td>glyc (0)</td>
<td>NA</td>
<td>patient 0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jaber (39) 1996, U.S. RCT</td>
<td>i) revision of professional roles; patient education c) no intervention</td>
<td>a) ? (pharmacists, physicians [control group]) b) 39 c) 1</td>
<td>hospital-based academic primary care clinic; variable insurance arrangements capitated group/staff model HMO</td>
<td>4</td>
<td>glyc (+) bp (0) within chol (0)* no values reported BMI (0)* no values reported microv (0)* no values reported</td>
<td>NA</td>
<td>patient +</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sadur (40) 1999, U.S. RCT</td>
<td>i) clinical multidisciplinary teams; skill mix changes; case management; patient education c) no intervention</td>
<td>a) ? (physicians, 1 diettian, 1 behaviorist, pharmacist, 1 diabetes nurse educator, and 2 diabetologists) b) 185 c) 1</td>
<td>hospital-based academic primary care clinic; variable insurance arrangements</td>
<td>6</td>
<td>glyc (+)</td>
<td>hosp (+)</td>
<td>patient + process +</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smith (41) 1986 Smith (42) 1987, the Netherlands RCT</td>
<td>i) arrangements for follow up, patient education; appointment reminders for patients c) no intervention</td>
<td>a) ? b) 859 c) 1</td>
<td>hospital-based academic primary care clinic; variable insurance arrangements</td>
<td>12</td>
<td>NA</td>
<td>att pat (+)</td>
<td>process +</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Branger (33) 1999, U.K. CBA</td>
<td>i) changes in medical record systems (electronic communication system between physicians) c) no intervention</td>
<td>a) 32 GPs and 1 internal medicine consultant b) 275 c) 1 hospital and 2 practices</td>
<td>primary care physician office; capitation (social)+ fee-for-service (private)</td>
<td>12</td>
<td>NA</td>
<td>glyc (+)# bp (+)# chol (+)# weight (+)# microv (0) att pat (0)</td>
<td>process +</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day (34) 1992, U.K. CBA</td>
<td>i) revision of professional roles; changes to the setting; a learner-centered counseling approach was adopted allowing patients to identify problems and agree potential solutions c) no intervention</td>
<td>a) ? (physicians + diabetes specialist nurse) b) 367 c) 3 clinics</td>
<td>new purpose-designed diabetes center; fee-for-service</td>
<td>36</td>
<td>glyc (+)#</td>
<td>NA</td>
<td>patient + within</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>De Sonnaville (35) 1997, the Netherlands CBA</td>
<td>i) multidisciplinary team; formal integration of services; arrangements for follow up; communication and case discussion between distant health pro-</td>
<td>a) 28 physicians b) 505 c) ?</td>
<td>primary care physician office; capitation (social)+ fee-for-service (private)</td>
<td>24</td>
<td>glyc (+)# bp (0)# chol (+)# BMI (−)#</td>
<td>NA</td>
<td>patient +</td>
<td></td>
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ordering of diagnostic tests rather than on a specific condition (69,70). Nevertheless, their findings that combinations of different interventions are the most effective are consistent with this review.

Methodological issues
On the basis of interventions, participants, settings, guidelines, and outcomes, this review has highlighted the heterogeneity of studies that determine the effectiveness of interventions to improve diabetes management. Even when one outcome, such as glycemic control, was assessed in several studies, a variety of different methods and reference values were used. This limited the degree to which the results could be compared and a uniform effect size could be calculated.

The methodological quality of the included studies was often limited; there was risk of contamination between groups, frequently no allocation concealment at outcome, high dropout rates that potentially reduced power and introduced bias, and unit of analysis errors that increased the apparent precision of estimates (19). Also, information about concealment of allocation and the number of professionals included in the study was often missing. The follow-up period of 25 of the studies was $\leq$1 year; it is therefore unclear whether the positive effects of the complex and often intensive interventions can be maintained in the long term. On the other hand, in some studies the evaluation may have been premature, as patients had not been exposed to the intervention for a sufficient amount of time to produce the anticipated benefits.

Although our literature search was extensive, we did not identify any unpublished studies. The apparent effectiveness of some of the interventions may have been overestimated due to the possibility of publication bias (71).

Implications for practice and research
In many ways, diabetes is a good model for the care of many chronic diseases (73,74). Changes in organization practice, such as enhancing the role of the nurse or implementing central computer systems that improve the delivery of complex packages of care, are likely to have an impact on the provision of care for a wide range of other conditions.

In the present review, only 15 of 41 identified studies reported both patient outcomes and process measures. Measures at both levels contribute to a better understanding of how to improve the quality of care. Measuring the process of care contributes to understanding heterogeneity in patient outcomes. Poor implementation of complex interventions (masked in the absence of process measures) may undermine adequately powered and well-designed and conducted studies. Thus, process measures and patient outcomes should be measured in future research.

Reported outcomes were corrected for clustering at the health care professional or practice level in only one study (22). The issue of clustering is particularly relevant because many of the interventions were directed at the health care professional or practice. Therefore, observations of patients within one health care professional or practice were not independent of each other. This issue should be taken into consideration for both sample size calculations and analysis.

More research on the long-term effectiveness of the different intervention strategies is needed, as the follow-up in most of the studies in the present review was short. The most frequently measured patient outcome was glycemic control, which only accounts for a proportion of the micro- and macrovascular risk in diabetes (6–8). Future studies should at-

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**Table: Studies (ITS)**

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Type</th>
<th>Stage</th>
<th>Intervention</th>
<th>Outcome</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sullivan (43)</td>
<td>1991, U.K.</td>
<td>ITS</td>
<td>i</td>
<td>clinical multidisciplinary teams (A joint GP/nurse review system); arrangements of follow-up</td>
<td>glyc (±)</td>
<td>36 NA</td>
</tr>
</tbody>
</table>
Table 3—Professional and organizational interventions versus usual care

<table>
<thead>
<tr>
<th>Author Year</th>
<th>Design</th>
<th>Intervention</th>
<th>i) intervention group</th>
<th>c) control group</th>
<th>a) Number of providers</th>
<th>b) Number of patients</th>
<th>c) Number of practices</th>
<th>Setting</th>
<th>Follow-up (months)</th>
<th>Results</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aubert (44) 1998</td>
<td>RCT</td>
<td>i) educational materials (detailed management algorithms); revision of professional roles (nurse case management); arrangements for follow-up; patient education</td>
<td>a) ? (nurse)</td>
<td>b) 138</td>
<td>c) 2</td>
<td></td>
<td></td>
<td>capitated group/staff model HMO</td>
<td>12</td>
<td>glyc (+)</td>
<td>patient + process +</td>
</tr>
<tr>
<td>Sikka (45) 1999, U.S.</td>
<td>RCT</td>
<td>i) educational materials; revision of professional roles (nurse case management); arrangements for follow-up; patient education</td>
<td>a) ? (nurse)</td>
<td>b) 138</td>
<td>c) 2</td>
<td></td>
<td></td>
<td></td>
<td>12</td>
<td>glyc (+)</td>
<td>patient + process +</td>
</tr>
<tr>
<td>Hoskins (50) 1992, Australia</td>
<td>RCT</td>
<td>i) educational materials; educational outreach visits; arrangements for follow up (shared care)</td>
<td>a) ? (physician+nurse)</td>
<td>b) 206</td>
<td>c) ?</td>
<td></td>
<td></td>
<td>shared care: primary care physician office and hospital; fee-for-service</td>
<td>12</td>
<td>glyc (+)</td>
<td>patient + process +</td>
</tr>
<tr>
<td>Hurwitz (51) 1993, U.K.</td>
<td>RCT</td>
<td>i) educational meetings; arrangements for follow-up; changes in medical record systems</td>
<td>a) ? (physicians)</td>
<td>b) 206</td>
<td>c)</td>
<td></td>
<td></td>
<td>primary care physician office; capitation and item of service</td>
<td>30</td>
<td>glyc (0)</td>
<td>patient 0 process +</td>
</tr>
<tr>
<td>Marrero (53) 1995, U.S.</td>
<td>RCT</td>
<td>i) educational materials; a telecommunication system; skill mix changes; case management; changes in facilities and equipment; changes in medical record systems</td>
<td>a) ? (nurse practitioners)</td>
<td>b) 106</td>
<td>c) 1</td>
<td></td>
<td></td>
<td>free-standing non-academic primary care practice; variable insurance arrangements*</td>
<td>12</td>
<td>glyc (0)</td>
<td>patient 0</td>
</tr>
<tr>
<td>Naji (54) 1994, U.K.</td>
<td>RCT</td>
<td>i) educational materials; reminders; arrangements for follow up; changes in medical record systems</td>
<td>a) ? (GPs + clinic staff involved in diabetes care)</td>
<td>b) 274</td>
<td>c) 1</td>
<td></td>
<td></td>
<td>shared care: primary care physician office and hospital; capitation and item of service, and fee-for-service (specialist ambulatory care)</td>
<td>24</td>
<td>glyc (0)</td>
<td>patient 0 process +</td>
</tr>
<tr>
<td>Nilaena (55) 1995, U.S.</td>
<td>RCT</td>
<td>i) educational materials; reminders; changes in medical record systems</td>
<td>a) 35</td>
<td>b) 164</td>
<td>c) 2</td>
<td></td>
<td></td>
<td>hospital-based academic primary care clinic; federal program</td>
<td>6</td>
<td>compl (0)</td>
<td>process +</td>
</tr>
<tr>
<td>Rutten (56) 1990, the Netherlands</td>
<td>RCT</td>
<td>i) educational materials; case management</td>
<td>a) ? (GPs supported by nurses)</td>
<td>b) 149</td>
<td>c) 8</td>
<td></td>
<td></td>
<td>primary care physician office; capitation (social) + fee-for-service (private)</td>
<td>12</td>
<td>compl (+)</td>
<td>process +</td>
</tr>
<tr>
<td>See Tai (60) 1999, U.K.</td>
<td>RCT</td>
<td>i) reminders; changes in medical record system (implementation of new diabetes templates)</td>
<td>a) 17 GPs and 11 practice nurses</td>
<td>b) 167</td>
<td>c) 6</td>
<td></td>
<td></td>
<td>primary care physician office; capitation and item of service</td>
<td>12</td>
<td>compl (+)</td>
<td>process +</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Design</th>
<th>Intervention Details</th>
<th>Control Details</th>
<th>Outcome Measures</th>
<th>Study Population</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shultz (61) 1992, U.S.</td>
<td>RCT</td>
<td>i) a telecommunication system; changes in facilities and equipment; changes in medical record systems</td>
<td>c) no intervention</td>
<td>Veteran's Administration hospital clinic; federal program</td>
<td>15 glyc (+) NA</td>
<td>patient +</td>
<td></td>
</tr>
<tr>
<td>Stein (62) 1974, U.S.</td>
<td>RCT</td>
<td>i) educational materials; revision of professional roles; patient education</td>
<td>c) no intervention</td>
<td>hospital-based primary care clinic; variable insurance arrangements</td>
<td>6 glyc (0) weight (0) NA</td>
<td>patient 0</td>
<td></td>
</tr>
<tr>
<td>Vinicor (64) 1987, Mazzuca (65) 1988; U.S.</td>
<td>RCT</td>
<td>For patient outcomes (39)</td>
<td>(i) patient education</td>
<td>hospital-based academic primary care clinic; variable insurance arrangements</td>
<td>process measures: glyc (+, +, +) bp (+, +) weight (+, +, +)</td>
<td>patient + process +</td>
<td></td>
</tr>
<tr>
<td>Weinberger (66) 1995 Kirkman (67) 1994; U.S.</td>
<td>RCT</td>
<td>i) patient mediated interventions (nurses attempted to telephone patients to facilitate compliance, monitor patients' health status, facilitate resolution of identified problems, facilitate access to primary care); arrangements for follow up; patient education</td>
<td>c) no intervention</td>
<td>Veteran's Administration hospital clinic; federal program</td>
<td>12 glyc (+) chol (0) weight (0) qual lifk (0) NA</td>
<td>patient +</td>
<td></td>
</tr>
<tr>
<td>Boucher (46) 1987, U.K.</td>
<td>CBA</td>
<td>i) educational materials; educational meetings; arrangements for follow up; communication and case discussion between distant health professionals; changes in medical record systems</td>
<td>c) no intervention</td>
<td>general medicine clinic; capitation and item of service</td>
<td>24 glyc (+) within att pat (+/−) no statistical analyses but a positive trend</td>
<td>patient 4 within process +/− statistical analyses but a positive trend</td>
<td></td>
</tr>
<tr>
<td>Deeb (47) 1988, U.S.</td>
<td>CBA</td>
<td>i) educational materials; educational meetings; educational outreach visits; clinical multidisciplinary team; patient education</td>
<td>c) no intervention</td>
<td>Federally funded primary care centers; variable insurance arrangements</td>
<td>12 NA</td>
<td>process + within bp (0# microv (+) #</td>
<td>process + within</td>
</tr>
<tr>
<td>Author (Year)</td>
<td>Country</td>
<td>Study Design</td>
<td>Key Interventions</td>
<td>No Intervention</td>
<td>Outcome Measures</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
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<td>----------------------------------------------------------------------------------</td>
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<td></td>
</tr>
<tr>
<td>Hartmann (48) 1995</td>
<td>Germany</td>
<td>CBA</td>
<td>i) educational materials; educational meetings; audit and feedback; changes in medical record systems</td>
<td>c) no intervention</td>
<td>a) 17 (physicians) b) 403 c) 17</td>
<td>primary care physician office; fee-for-service 12 NA glyc (0)# bp (0)# chol (+)# weight (0)# creat (+)# microv (+)# process of document ed quarterly process 4 (document ed yearly)</td>
<td></td>
</tr>
<tr>
<td>Legorreta (52) 1996</td>
<td>U.S.</td>
<td>CBA</td>
<td>i) educational materials; educational meetings; clinical multidisciplinary teams; skill mix changes; arrangements for follow up; changes in medical record systems</td>
<td>c) no intervention</td>
<td>a) ? (physicians + nurses/physician assistant) b) Site A: 205, Site B: 195 c) ?</td>
<td>practices affiliated with Network or Independent Practice Association (IPA) HMO 18 glyc (+)# NA patient +</td>
<td></td>
</tr>
<tr>
<td>O'Connor (56) 1995</td>
<td>U.S.</td>
<td>CBA</td>
<td>i) local consensus procedures; skill mix changes; more aggressive educational outreach to patients</td>
<td>c) no intervention</td>
<td>a) ? (physicians + nurses) b) 267 c) 2 clinics</td>
<td>capitated group/staff model HMO 18 glyc (+)# glyc (+) within both groups, no difference between both groups att pat (+/-)# patient + process 4 (within both groups, not statistically tested)</td>
<td></td>
</tr>
<tr>
<td>Peters (57) 1998</td>
<td>U.S.</td>
<td>CBA</td>
<td>i) educational materials; audit and feedback; revision of professional roles; arrangements for follow up; changes in medical record systems</td>
<td>c) no intervention</td>
<td>a) providers: ? (nurse practitioners) b) 16+ c) 1 medical center vs. 1 HMO</td>
<td>practices affiliated with Network or Independent Practice Association (IPA) HMO 36 glyc (+) chol (+) within interv group glyc (+) chol (+) microv (+) patient + process 4 (no statistically tested)</td>
<td></td>
</tr>
<tr>
<td>Taplin (63) 1998</td>
<td>U.S.</td>
<td>CBA</td>
<td>i) educational materials; local consensus processes; audit and feedback; reminders; marketing (establishing a team and after that, regular team meetings to discuss and achieve clinical goals); clinical multidisciplinary team; changes in medical record systems</td>
<td>c) no intervention</td>
<td>a) ? (physicians supported by nurses) b) ? (the number of patients that visited the practice for diabetes care is not reported separately). In total, 9,754 patients were included for studying compliance with guidelines for different areas c) 6</td>
<td>capitated group/staff model HMO 24 NA compl microv (0)# process 0</td>
<td></td>
</tr>
<tr>
<td>Rith-Najarian (58) 1998</td>
<td>U.S.</td>
<td>ITS</td>
<td>i) educational materials; reminders; clinical multidisciplinary team</td>
<td></td>
<td>a) 1 physician + 3 nurses (+ nutritionist + registrar) b) 449 c) 1</td>
<td>Indian Health service clinic; federal program 36 microv (0)# microv (0) patient 0 process 0</td>
<td></td>
</tr>
</tbody>
</table>

*In the U.S., most practices, whether hospital based or not, care for patients under a variety of insurance arrangements: government (Medicare, Medicaid) or private (HMO or indemnity [fee-for-service]). ?, not reported; +, positive effect; 0, no effect; –, negative effect; +/-, effect unclear; NA, not applicable; #, possible unit of analysis error; within, differences are statistically tested within groups only, not between groups; alb, albumin; att pat, attendance patients; bp, blood pressure; comp, compliance care provider; CBA, controlled before-after study; creat, creatinine; glyc, glycemic control; HMO, health maintenance organization; hlth surv, health survey; hosp, hospitalizations; macrov, macrovascular complications; microv, microvascular complications; qual life, quality of life; RCT, randomized controlled trial.
tempt to directly measure the risk of cardiovascular risk. Given the potential of these interventions for health gain, they merit rigorous evaluation.

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