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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Abbreviations: EPOC, Effective Practice and Organization of Care; ITS, interrupted time series.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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

>90% or $\kappa \geq 0.8$). Furthermore, 15 studies (20,22,26,32,35,39,44,46,50,53, 54,57,59,62,64) included objective laboratory assessment of glycemic control.

Of 27 studies reporting patient outcomes, 11 (29,34,39,40,51,54,56,57,59, 62,66) had over 80% follow-up. Follow-up data for the health care professionals/practices were explicitly stated in only 5 of 24 studies in which these were the unit of allocation.

In 24 studies (20–24,27,28–35,46–48,52,55,56,59,60,63,64), health care professionals or practices were the unit of allocation, and patients were directly allocated to groups in 15 studies (26,36, 37,39–41,44,50,51,53,54,57,61,62,66). Eighteen studies (20,22–24,29,30,32–35,46–48,52,56,59,63,64) did not use the same unit for both allocation and analysis (unit of analysis error). A priori power calculations were included in only six studies (20–22,30,48,66).

Professional interventions versus usual care

We identified 12 studies (20–24,26–32) in which the effectiveness of professional interventions was compared with usual care (Table 1). In four of these studies (22,23,27,29), the professional intervention was combined with patient education. Postgraduate education of health care professionals combined with local consensus procedures and/or reminders and/or audit and feedback improved the provision of diabetes care in all studies (20,21,23,24,26,27,31,32) that did not demonstrate a good standard of care at baseline. The effect on patient outcomes was less clear because such outcomes were rarely assessed. Improvements were described for glycemic control and serious foot lesions (20,23,26), although statistical significance was only achieved and reported in one study (23).

The three studies (22,29,30) evaluating education for both health care professionals and patients showed conflicting results. In one study (29), the intervention improved HbA_{1c}, BMI, and triglycerides. In another (22), there was no significant effect on HbA_{1c} and an apparently detrimental effect on BMI and triglycerides. The final study (30) was unable to demonstrate significant improvements because only 19% of the professionals successfully applied the intervention.

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 1—*Professional interventions versus usual care*

Reference	Design	Intervention i) intervention group c) control group	a) Number of providers b) Number of patients c) Number of practices	Setting	Follow-up (months)	Results		Conclusion
						Patient outcomes	Process measures	
Feder (21) 1995, U.K.	RCT	i) educational materials; local consensus processes; educational outreach visits; reminders c) no intervention	a) 39 physicians supported by nurses b) 390 c) 24	primary care physician office, capitation and item of service	12	NA	glyc (+) bp (+) weight (+) microv (+)	process +
Kinmonth (22) 1998, U.K.	RCT	i) educational materials/meetings; patient education (directed at 'patient centered care') c) educational materials/meetings; (focusing on use of guidelines and materials)	a) 43 doctors supported by 64 nurses b) 250 c) 41	primary care physician office; capitation and item of service	12	glyc (0) bp (0) chol (0) BMI (−) alb (0) well (+)	NA	patient 0 (well [+])
Litzelman (23) 1993, U.S.	RCT	i) educational materials; reminders; patient education; behavioral contacts with patients; reminders for patients c) no intervention	a) ? (physicians supported by nurses [education]) b) 396 c) 1	hospital-based academic primary care clinic; variable insurance arrangements*	12	microv (+)#	microv (+)#	patient + process +
Lobach (24) 1994 Lobach (25) 1997; U.S.	RCT	i) local consensus processes; audit and feedback; reminders c) no intervention	a) 30 primary care clinicians b) 359 c) 1	hospital-based academic primary care clinic; variable insurance arrangements	6	NA	glyc (−)# chol (+)# ur prot (+)# microv (0)# compl (+)#	process +
Mazze (26) 1994, U.S.	RCT	i) educational materials; educational meetings; local consensus processes; reminders c) no intervention	a) 8 family practitioners b) 26 c) 1	free-standing academic primary care clinic; variable insurance arrangements	6	glyc (+)	visits (+/−) microv (+/−) educ (+/−) hlth surv (+/−)	patient +/0[no statistical analyses but a positive trend] process +/−[no statistical analyses but a positive trend]
Mazzuca (27) 1990, U.S.	RCT	i1) educational meetings; reminders i2) i1; clinical materials i3) i2; patient education c) educational meetings	a) 98 internal medicine residents and faculty internists b) 2,791 c) 1	hospital-based academic primary care clinic; variable insurance arrangements	11	NA	glyc (+)	process + (i2)
Palmer (28) 1990, U.S.	RCT	i) educational materials; local consensus procedures; audit and feedback c) no intervention	a) ? b) 1,943 c) 8	free-standing nonacademic primary care practice; variable insurance arrangements	18	NA	compl (0)	process +
Pill (30) 1998, U.K.	RCT	i) educational meetings; educational outreach visits c) no intervention	a) ? b) 190 c) 29	primary care physician office; capitation and item of service	18	glyc (0)# bp (0)# BMI (0)# microv/macrov (0)#	att pat (0)#	patient 0 process 0
Ward (31) 1996, Australia	RCT	i) educational materials; educational outreach visits; audit and feedback by interview c) educational materials; postal feedback	a) 139 b) 386 c) ?	primary care physician office; fee-for-service with small sessional and capitation payments	8	NA	glyc (+)[within] bp (0)[within] chol (+)[within] weight (+)[within] alb (+)[within] microv (+)[within] compl (+)	process +

Carlson (32) 1991, Sweden	RCT	i) educational meetings; local consensus processes to identify problems and to create plans to improve diabetes care; educational outreach visits c) no intervention	a) ? (physicians, nurses, nurse assistants managers, administrators, and laboratory technicians) b) 4,492 (measurements on professional practice) 566 (measurements on HbA_{1c}) c) 34	primary health care center; salary	12	glyc (0)#	glyc (+)# microv (+)#	patient 0 process +
Benjamin (20) 1999, U.S.	CBA	i) educational materials/meetings; local consensus processes; audit and feedback c) no intervention	a) ? (physicians, residents, nurses, and nutritionist) b) 144 c) 2	free-standing academic primary care clinic; variable insurance arrangements	15	glyc (+)#	chol (+)# microv (+)#	patient + process $+^{within}$
Pieber (29) 1995, Austria	CBA	i) educational materials/meetings; patient education c) no intervention	a) 14 GPs b) 94 c) 14	primary care physician office; fee-for-service	6	glyc (+)# bp (0)# chol (0)# BMI (+)# microv (+)$\#^{within}$	NA	patient +

*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.

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. Furthermore, the data can be used to measure improvements in the performance of health care professionals and patient outcomes.

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, even assume some of the responsibilities of the physician. Patient education might be important for involving patients more in their own diabetes management and for improving self-management and compliance to therapy. Moreover, it might encourage patients to change their lifestyle with regard to diet, smoking habit, and physical exercise, all of which help to achieve good glycemic control and to postpone or prevent the development of complications.

Previous reviews of the effectiveness of interventions in improving professional practice have focused on preventive services, prescribing practices, and

Table 2—*Organizational interventions versus usual care*

Reference	Design	Intervention i) intervention group c) control group	a) Number of providers b) Number of patients c) Number of practices	Setting	Follow-up (months)	Results Patient outcomes	Results Process measures	Conclusion
Halbert (36) 1999, U.S.	RCT	i) arrangements for follow up (multiple reminders to patients) c) single reminder directed at patients)	a) ? b) 19,523 c) 1 health maintenance organization (HMO); the number of medical groups is not clear	practices affiliated with Network or Independent Practice Association (IPA) HMO	12	NA	microv (+)	process +
Hawkins (37) 1979 Hawkins (38) 1981; U.S.	RCT	i) revision of professional roles c) no intervention	a) ? (pharmacist, physicians [control group]) b) 315 c) 1	hospital-based academic primary care clinic; variable insurance arrangements*	29	glyc (0)	NA	patient 0
Jaber (39) 1996, U.S.	RCT	i) revision of professional roles; patient education c) no intervention	a) ? (pharmacist, physicians [control group]) b) 39 c) 1	hospital-based academic primary care clinic; variable insurance arrangements	4	glyc (+) bp (0)[within] chol (0)[no values reported] BMI (0)[no values reported] microv (0)[no values reported]	NA	patient +
Sadur (40) 1999, U.S.	RCT	i) clinical multidisciplinary teams; skill mix changes; case management; patient education c) no intervention	a) ? (physicians, 1 dietitian, 1 behaviorist, pharmacist, 1 diabetes nurse educator, and 2 diabetologists) b) 185 c) 1	capitated group/staff model HMO	6	glyc (+)	hosp (+)	patient + process +
Smith (41) 1986 Smith (42) 1987; the Netherlands	RCT	i) arrangements for follow up; patient education; appointment reminders for patients c) no intervention	a) ? b) 859 c) 1	hospital-based academic primary care clinic; variable insurance arrangements	12	NA	att pat (+)	process +
Branger (33) 1999, U.K.	CBA	i) changes in medical record systems (electronic communication system between physicians) c) no intervention	a) 32 GPs and 1 internal medicine consultant b) 275 c) 1 hospital and ? practices	primary care physician office; capitation (social)+ fee-for-service (private)	12	NA	glyc (+)# bp (+)# chol (+)# weight (+)# microv (0) att pat (0)	process +
Day (34) 1992, U.K.	CBA	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	a) ? (physicians + diabetes specialist nurse) b) 367 c) 3 clinics	new purposed-designed diabetes center; fee-for-service	36	glyc (+)#	NA	patient +[within]
De Sonnaville (35) 1997, the Netherlands	CBA	i) multidisciplinary team; formal integration of services; arrangements for follow up; communication and case discussion between distant health pro-	a) 28 physicians b) 505 c) ?	primary care physician office; capitation (social)+ fee-for-service (private)	24	glyc (+)# bp (0)# chol (+)# BMI (−)#	NA	patient +

		fessionals; changes to the setting/site of service delivery; changes in medical records systems; patient education c) no intervention						
Sullivan (43) 1991, U.K.	ITS	i) clinical multidisciplinary teams (A joint GP/nurse review system); arrangements of follow-up c) no intervention	a) 5 (4 GPs and practice nurse) b) 1983: 53, 1984: 51, 1985: 56, 1986: 61, 1987: 67, 1988: 70 c) 1	primary care physician office; capitation and item of service	36	NA	glyc (+/−) bp (+/−) weight (+/−) microv (+/−)	process +/− no statistical analyses but a positive trend

*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.

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 drop-out 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 ≤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).

Generalizability

The studies in this review often included selected practitioners who were willing to implement sometimes very complex interventions. In addition, the representativeness of the health care professionals and practices was variable, ranging from only one practice with one provider (58) to almost all local practices in a wide geographical area (31). Participating patients were a selected group that was motivated to consent to join the study. They are often younger, less ill, and more accommodating than the general population (72). It is not clear how well they represent the population of patients with diabetes. Studies were carried out in various primary care, outpatient, and community settings in the context of different local and national health care systems. Thus, conclusions from this review should be generalized to different settings with caution.

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-

Table 3—*Professional and organizational interventions versus usual care*

Author Year	Design	Intervention i) intervention group c) control group	a) Number of providers b) Number of patients c) Number of practices	Setting	Follow-up (months)	Results Patient outcomes	Results Process measures	Conclusion
Aubert (44) 1998 Sikka (45) 1999; U.S.	RCT	i) educational materials (detailed management algorithms); revision of professional roles (nurse case management); arrangements for follow-up; patient education c) no intervention	a) ? (nurse) b) 138 c) 2	capitated group/staff model HMO	12	glyc (+) bp (0) chol (0) BMI (0) s-rep health (+)	microv (+)	patient + process +
Hoskins (50) 1992, Australia	RCT	i) educational materials; educational outreach visits; arrangements for follow up (shared care) c1) routine care by GP c2) routine care by specialist diabetic clinic	a) ? (physician+nurse) b) 206 c) ?	shared care: primary care physician office and hospital; fee-for-service	12	glyc (+)[within all groups] bp (+)[within all groups] weight (+)[within shared care group]	att pat (−)[within all groups]	patient +[1) for all three groups that were compared] process −[within groups]
Hurwitz (51) 1993, U.K.	RCT	i) educational meetings; arrangements for follow-up; changes in medical record systems c) no intervention	a) ? (physicians) b) 181 c) 38 general practices and 2 hospital outpatient clinics	primary care physician office; capitation and item of service	30	glyc (0) microv (0) hosp (0)	glyc (+) microv (+) alb (+) att pat (+)	patient 0 process +
Marrero (53) 1995, U.S.	RCT	i) educational materials; a telecommunication system; skill mix changes; case management; changes in facilities and equipment; changes in medical record systems c) no intervention	a) ? (nurse practitioners) b) 106 c) 1	free-standing non-academic primary care practice; variable insurance arrangements*	12	glyc (0) qual life (0) hosp (0)	NA	patient 0
Naji (54) 1994, U.K.	RCT	i) educational materials; reminders; arrangements for follow up; changes in medical record systems c) patients received reminders for routine appointments	a) ? (GPs + clinic staff involved in diabetes care) b) 274 c) 1 clinic + 3 general practices	shared care: primary care physician office and hospital; capitation and item of service, and fee-for-service (specialist ambulatory care)	24	glyc (0) bp (0) BMI (0) creat (0)	glyc (+) bp (+) creat (0) microv (+) att pat (+)	patient 0 process +
Nilasena (55) 1995, U.S.	RCT	i) educational materials; reminders; changes in medical record systems c) no intervention	a) 35 b) 164 c) 2	hospital-based academic primary care clinic; federal program	6	NA	compl (0)[between groups, but within both groups (+)]	process +[within both groups]
Rutten (59) 1990, the Netherlands	RCT	i) educational materials; case management c) no intervention	a) ? (GPs supported by nurses) b) 149 c) 8	primary care physician office; capitation (social)+ fee-for-service (private)	12	glyc (+)# weight (0)#	NA	patient +
See Tai (60) 1999, U.K.	RCT	i) reminders; changes in medical record system (implementation of new diabetes templates) c) usual diabetes care (usual basic template), but implementation of new asthma templates	a) 17 GPs and 11 practice nurses b) 167 c) 6	primary care physician office; capitation and item of service	12	NA	compl (+)	process +[not statistically tested, but a positive trend]

Shultz (61) 1992, U.S.	RCT	i) a telecommunication system; changes in facilities and equipment; changes in medical record systems c) no intervention	a) ? (physicians) b) 30 c) 1	Veteran's Administration hospital clinic; federal program	15	glyc (+)	NA	patient +
Stein (62) 1974, U.S.	RCT	i) educational materials; revision of professional roles; patient education c) no intervention	a) nurse practitioner + clinic physician(s) b) 28 c) 1	hospital-based primary care clinic; variable insurance arrangements	6	glyc (0) weight (0)	NA	patient 0
Vinicor (64) 1987 Mazzuca (65) 1988; U.S.	RCT	For patient outcomes (39) i1) patient education i2) physician education: educational materials; local consensus processes; audit and feedback; reminders; communication and case discussion between distant health professionals; i3) patient education + physician education c) no intervention For process measures (58a) i) i2+i3 c) i1+c	a) 86 residents b) 532 c) 1	hospital-based academic primary care clinic; variable insurance arrangements	process measures: 11 patient: 26	glyc ($+^{i1,i2,i3}$)# bp ($+^{i1}$)# weight ($+^{i1,i3}$)#	glyc (+)# bp (0)# chol (+)# creat (0)# microv (0)#	patient + process +
Weinberger (66) 1995 Kirkman (67) 1994; U.S.	RCT	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 c) no intervention	a) ? b) 275 c) 1	Veteran's Administration hospital clinic; federal program	12	glyc (+) chol (0) weight (0) qual life (0)	NA	patient +
Boucher (46) 1987, U.K.	CBA	i) educational materials; educational meetings; arrangements for follow up; communication and case discussion between distant health professionals; changes in medical record systems c) no intervention	a) ? (physicians, supported by nurses) b) 217 c) 3	general medicine clinic; capitation and item of service	24	glyc (+)#^{within}	att pat (+/−)$^{no\ statistical\ analyses\ but\ a\ positive\ trend}$	patient $+^{within}$ process $+/-^{no\ statistical\ analyses\ but\ a\ positive\ trend}$
Deeb (47) 1988, U.S.	CBA	i) educational materials; educational meetings; educational outreach visits; clinical multidisciplinary team; patient education c) no intervention	a) ? (physician+nurses) b) 1,029 were identified and their records were reviewed at baseline. Only 636 of the patients were seen during the year after the intervention c) 6	federally funded primary care centers; variable insurance arrangements	12	NA	bp (0)# microv (+)#	process $+^{within}$

Hartmann (48) 1995 Hartmann (49) 1995; Germany	CBA	i) educational materials; educational meetings; audit and feedback; changes in medical record systems c) no intervention	a) 17 (physicians) b) 403 c) 17	primary care physician office; fee-for-service	12	NA	glyc (0)# bp (0)# chol (+)# weight (0)# creat (+)# microv (+)#	process 0(documented quarterly) process +(document ed yearly)
Legorreta (52) 1996, U.S.	CBA	i) educational materials; educational meetings; clinical multidisciplinary teams; skill mix changes; arrangements for follow up; changes in medical records systems c) no intervention	a) ? (physicians + nurses/physician assistant) b) Site A: 205, Site B: 195 c) ?	practices affiliated with Network or Independent Practice Association (IPA) HMO	18	glyc (+)#	NA	patient +
O'Connor (56) 1995, U.S.	CBA	i) local consensus procedures; skill mix changes; more aggressive educational outreach to patients c) no intervention	a) ? (physicians + nurses) b) 267 c) 2 clinics	capitated group/staff model HMO	18	glyc (+)#	glyc (+)#within both groups, no difference between both groups att pat (+/−)#	patient + process +within both groups, not statistically tested
Peters (57) 1998, U.S.	CBA	i) educational materials; audit and feedback; revision of professional roles; arrangements for follow up; changes in medical record systems c) no intervention	a) providers- ? (nurse practitioners) b) 164 c) 1 medical center vs. 1 HMO	practices affiliated with Network or Independent Practice Association (IPA) HMO	36	glyc (+) chol (+)within interv group	glyc (+) chol (+) microv (+)	patient + process +not statistically tested
Taplin (63) 1998, U.S.	CBA	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 c) no intervention	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	capitated group/staff model HMO	24	NA	compl microv (0)#	process 0
Rith-Najarian (58) 1998, U.S.	ITS	i) educational materials; reminders; clinical multidisciplinary team	a) 1 physician + 3 nurses (+nutritionist +registrar) b) 449 c) 1	Indian Health service clinic; federal program	36	microv (0)	microv (0)	patient 0 process 0

*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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