The effects of clinical practice guidelines on patient outcomes in primary care: a systematic review

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Abstract

Objective: To assess the evidence for the effectiveness of clinical practice guidelines (CPGs) in improving patient outcomes in primary care.

Data sources: A search of the MEDLINE, HEALTHPLAN, CINAHL and FAMLI databases was conducted to identify studies published between Jan. 1, 1980, and Dec. 31, 1995, concerning the use of guidelines in primary medical care. The keywords used in the search were "clinical guidelines," "primary care," "clinical care," "intervention," "randomized controlled trial" and "effectiveness."

Study selection: Studies of the use of CPGs were selected if they involved a randomized experimental or quasi-experimental method, concerned primary care, were related to clinical care and examined patient outcomes. Of 91 trials of CPGs identified through the search, 13 met the criteria for inclusion in the critical appraisal.

Data extraction: The following data were extracted, when possible, from the 13 trials: country and setting, number of physicians, number of patients (and the proportion followed to completion), length of follow-up, study method (including random assignment method), type of intervention, medical condition treated and effect on patient outcomes (including clinical and statistical significance, with confidence intervals).

Data synthesis: The most common conditions studied were hypertension (7 studies), asthma (2 studies) and cigarette smoking (2 studies). Four of the studies followed nationally developed guidelines, and 9 used locally developed guidelines. Six studies involved computerized or automated reminder systems, whereas the others relied on small-group workshops and education sessions. Only 5 of the 13 trials (38%) produced statistically significant results.

Conclusion: There is very little evidence that the use of CPGs improves patient outcomes in primary medical care, but most studies published to date have used older guidelines and methods, which may have been insensitive to small changes in outcomes. Research is needed to determine whether the newer, evidence-based CPGs have an effect on patient outcomes.

Résumé

Objectif : Évaluer les données probantes pour déterminer l'efficacité des guides de pratique clinique (GPC) dans l'amélioration des résultats des patients en soins primaires.

Sources de données : On a effectué une recherche dans les bases de données MEDLINE, HEALTHPLAN, CINAHL et FAMLI pour trouver des études publiées entre le 1er janv. 1980 et le 31 déc. 1995 au sujet de l'utilisation des guides dans le domaine des soins médicaux primaires. Pour effectuer la recherche, on a utilisé les mots clés «clinical guidelines», «primary care», «clinical care», «intervention», «randomized controlled trial» et «effectiveness».

Sélection d'études : Les études portant sur l'utilisation des GPC ont été choisies si elles mettaient en cause une méthode expérimentale ou quasi expérimentale randomisée, si elles portaient sur les soins primaires, si elles avaient trait à des soins cliniques et si l'on y analysait des résultats chez les patients. Treize des 91 études portent sur des GPC repérées à la suite de la recherche satisfaisaient aux critères d'inclusion dans l'évaluation critique.

Extraction de données : On a extrait des 13 études, lorsque c'était possible, les données suivantes : pays et contexte, nombre de médecins, nombre de patients (et proportion de patients suivis jusqu'à la fin de l'étude), durée du suivi, méthode d'étude (y compris méthode de répartition aléatoire), type d'intervention, affection médicale traitée et effet sur les résultats des patients (y compris signification clinique et statistique et intervalles de confiance).

Synthèse des données : Les problèmes les plus fréquents étudiés ont été l'hypertension (7 études), l'asthme (2 études) et le tabagisme (2 études). Quatre des études ont porté sur des guides nationaux et 9, sur des guides locaux. Dans le cadre de 6 études, on a utilisé des systèmes de rappel informatisés ou automatisés, tandis que les autres ont été fondées sur des ateliers en petits groupes et des séances d'information. Seulement 5 des 13 études (38 %) ont produit des résultats significatifs sur le plan statistique.

Conclusion : Il y a très peu de données probantes démontrant que l'utilisation des GPC améliore les résultats pour les patients dans les soins médicaux primaires, mais la plupart des études publiées jusqu'à maintenant étaient fondées sur des méthodes et des guides plus âgés, qui n'étaient peut-être pas sensibles aux changements limités des résultats. Il faut effectuer des recherches pour déterminer si les nouveaux GPC fondés sur des données probantes ont un effet sur les résultats des patients.

C linical practice guidelines (CPGs) are systematically developed statements that assist in decision-making about appropriate care for specific clinical conditions.[1,2] There are now at least 2500 CPGs available.[3-5] Recently, CPGs have been developed on the basis of systematic evaluation of scientific evidence.[6] The approach now favoured is to develop guidelines using the principles of evidence-based medical care.[7-9] However, most of the existing CPGs were developed according to older, less systematic techniques such as peer review and consensus conferences.

Three types of evaluation of CPGs, which match the evolutionary stage of the guidelines, have been suggested.[10] These are: (1) evaluation of guidelines during their development, before they are implemented, (2) evaluation of health care programs in which guidelines play a central role and (3) evaluation of the effects of guidelines in a defined health care environment.

A review conducted in Britain of 59 published evaluations of CPGs found that, although most studies showed that guidelines had had some effect on the process of care, only 11 of them looked at the impact of guideline use on the outcomes of clinical care.[11] A systematic review conducted in Canada of 102 trials of interventions to improve medical practice found that dissemination-only strategies, such as conferences or mailing of unsolicited materials, produced little or no change in medical practice, whereas more complex interventions, such as the use of outreach visits or local opinion leaders, sometimes produced moderate reductions in inappropriate performance.[12] This study looked at all areas of medical practice. Another study conducted in the United Kingdom, which assessed trials of the effects of implementing CPGs, based on

methods similar to those of the Canadian Task Force on the Periodic Health Examination,[13] found that, of 35 high-quality trials of clinical care, 9 showed positive effects on patient outcomes but only 4 concerned medical conditions that would normally be dealt with in primary care.[14]

The bulk of medical care is delivered by primary care practitioners, who are interested in whether the use of CPGs has a beneficial effect on patient outcomes. This study falls into the third category of evaluation mentioned earlier: evaluation of guidelines in a defined health care environment. The objective of the study was to update the earlier reviews by assessing trials conducted in primary care settings to determine whether available CPGs have had any significant effect on patient outcomes.

Methods

Data sources

A search of the medical literature published from Jan. 1, 1980, to Dec. 31, 1995, was performed to identify studies that had assessed the effectiveness of CPGs in primary medical care. The electronic databases MEDLINE, HEALTHPLAN, CINAHL and FAMLI were searched with the use of the following keywords: "clinical guidelines," "primary care," "clinical care," "interventions," "randomized controlled trial" and "effectiveness." In addition, the bibliographies of 3 comprehensive articles about CPGs were searched for further studies.[11,12,14]

Study selection

A 3-step process was used to identify potentially rele-

vant studies and to exclude those that were not relevant to our objectives. First, studies were identified from the electronic search. Second, studies identified were classified according to whether they pertained to clinical care. Those that pertained to clinical care were studies involving care of patients with diagnosed medical conditions; those that did not involve clinical care were studies concerning the use of guidelines for preventive care or for investigative procedures such as radiography or laboratory screening tests. Third, studies of clinical care were then divided into those that examined the effects of CPGs on the process of care (i.e., Did clinicians adhere more closely to the recommended standards of care?) and those that looked at clinical outcomes (i.e., Was there a measurable change in the clinical condition of patients?). The studies that looked at patient outcomes of clinical care in a primary care setting were the subject of the detailed critical appraisal.

Data extraction

The data extracted from the reports of trials were country and type of medical setting, number of physicians or groups of physicians in the trial, number of patients studied and the proportion followed to completion of the study, duration of patient follow-up, study methods (including method of random assignment), type of guideline (produced by a national body or by local consensus), method of guideline implementation (whether the physicians were automatically reminded of the guidelines during encounters with patients or were expected to remember the guidelines after attending an education session), medical conditions studied, and the effect on patient outcomes and method of measuring this effect. When possible, we assessed whether the study had considered both statistical and clinical significance and whether the results included statistical confidence intervals.

Critical appraisal of trials

The critical appraisal of the trials was based on the method of Sackett and associates.[15] The use of CPGs was considered a "therapy" to improve the clinical performance of physicians, as measured by improvement in clinical outcomes among their patients. Table 1 shows the guides used to distinguish useful from useless therapy (in this case, the CPGs). Guides 1 and 6 were used to assess the validity of the studies, and guides 2 to 5 were used to assess whether the guidelines were feasible for a typical family practice, whether clinical outcomes were reported and whether both clinical and statistical significance were considered.

No attempt was made to assess whether the guidelines followed in the published trials adhered strictly to the principles of evidence-based medical care.

Was the assignment of patients really randomized? Random assignment gives each subject the same probability of receiving the intervention. Studies that assign subjects randomly are more sound than quasi-experimental studies, which do not and which run a greater risk that results may be due to initial differences among groups. Even in studies in which random assignment is used, problems may occur. If random assignment is by physician rather than by group of physicians, contamination may occur because study physicians discuss the guidelines with control physicians. Even worse is a design in which random assignment is by patient; in such studies, the same physician is expected to use the CPG for some patients and not for others. These effects may result in underestimates of the effectiveness of guidelines. Finally, it is important that the sample size used in statistical tests is the number of physicians, not the larger number of patients; otherwise, there is a risk of falsely concluding that results are statistically significant (Type I error).

Were all clinically relevant outcomes reported? Although it is almost impossible to report all clinically relevant outcomes, we felt that it was important to appraise clinical outcomes in addition to changes in the process of care, as outcomes are ultimately more important in assessing guideline effectiveness.

Were the study patients recognizably similar to your own? In the literature search, we looked for studies conducted in a primary care setting. It was easier to assess the setting in studies conducted in Canada and the United Kingdom, which have clearly defined primary care systems, than in studies that assessed guidelines used in health maintenance organizations and general internal medicine clinics in the US. However, when a US internal medicine clinic appeared to offer primary care services, it was included. The appraisal looked for medical conditions that would normally be treated by family physicians, such as hypertension, asthma, diabetes mellitus and obesity; we decided that cigarette smoking should be included.

Were both clinical and statistical significance considered? If the sample studied is large enough, even small changes in, for example, blood pressure or weight can be statistically significant. Such small changes are unlikely to be noticed by the patient or to be clinically relevant to the attending physician. By contrast, if the study sample is small, there is a

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Table 1: Six guides to distinguish useful from useless or even harmful therapy

- Was the assignment of patients really randomized?
- Were all clinically relevant outcomes reported?
- Were the study patients recognizably similar to your own?
- Were both clinical and statistical significance considered?
- Is the therapeutic manoeuvre feasible in your practice?
- Were all the patients who entered the study accounted for?

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greater possibility of a Type II error; that is, the study may fail to detect a real difference because of its limited power.

Is the therapeutic manoeuvre feasible in your practice? However effective a therapeutic manoeuvre is, it serves no end unless it can be used efficiently in a busy primary care practice. The appraisal looked at methods of introducing and implementing CPGs that would be possible for family physicians in nonacademic settings.

Were all the patients who entered the study accounted for? If a study's follow-up is poor, the final analysis can be significantly biased. In the case of CPG trials, the most appropriate unit of random assignment was the physician who had agreed to take part in the study; therefore, follow-up of the physicians was usually complete. However, since the physicians' performance was measured by the clinical outcomes among their patients, the proportion of patients accounted for in follow-up was also assessed; incomplete follow-up of patients can lead to spurious results.

Results

Study selection

The literature search identified 91 studies of clinical guidelines for primary care. Eighty-seven of these studies were found through our electronic database search. As well, the 3 reviews we consulted[11,12,14] furnished us with 1 study published before 1980 and 3 others published since 1980 that we had missed in the electronic search. Accordingly, we found and examined a total of 91 trials.

The 91 primary care trials were screened according to the criteria listed in the Methods section (Fig 1). Only 35 of the trials identified concerned clinical care; the remaining 56 dealt with preventive or investigative medicine. Of the 35 studies of clinical care, only 13 reported on clinical

outcomes. Details of these 13 studies and the data extracted for appraisal are shown in Table 2.

Conditions studied

In the 13 selected trials, the most common medical condition examined was hypertension; 6 trials studied guidelines concerning this condition.[18–22] The effectiveness of CPGs in changing the outcomes in asthma[26,29] and in reducing cigarette smoking[23,24] were each the subject of 2 trials. Other trials studied CPGs concerning obesity,[27] common conditions in children, such as cough, vomiting, rashes and bedwetting,[29] and the effects of a wide range of clinical interventions, including testing stools for occult blood, mammographic screening, weight-reduction diets, and influenza and pneumococcal vaccination on patient outcomes.[28]

Data synthesis and critical appraisal

Overall, 5 of the 13 studies showed a significant improvement in outcomes as a result of the use of CPGs.[23–25,27,29] In these 5 studies, improvement was noted for only a proportion of the conditions studied, for only certain subgroups of patients, or for only a limited period.

Four of the studies, involving hypertension and cigarette smoking, assessed guidelines that had been developed at a national level,[17,20,21,23] whereas the remaining 9 used locally based guidelines, developed either by local faculty members[19,25,27,28] or at small-group education sessions held for family physicians.[18,22,24,26,29] Of the 9 local guidelines, 4 produced significant improvements;[24,25,27,29] of the 4 nationally developed guidelines, there were significant results in only 1 study.[23]

Six studies used computerized or automated reminder systems, which prompted physicians when they were see-
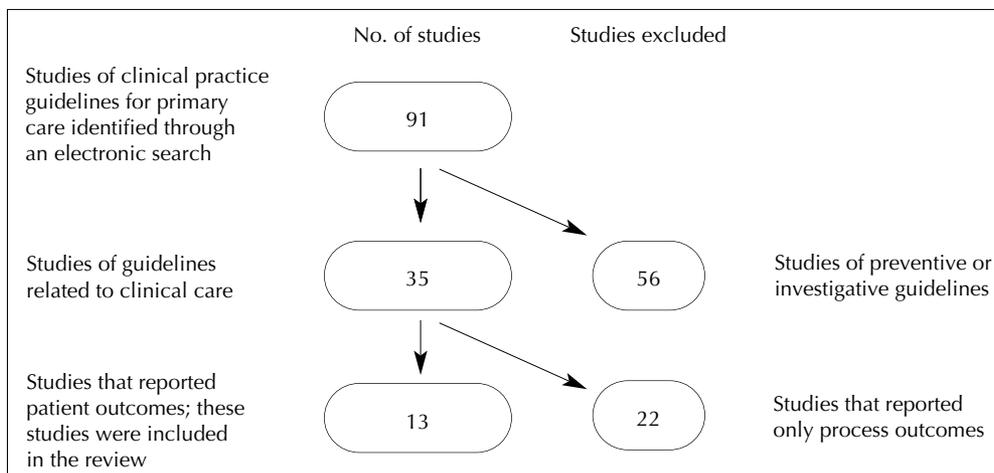

Fig. 1: Disposition of studies identified through a search for published articles concerning the evaluation of clinical practice guidelines in primary care. Screening criteria were applied to select studies for review.

ing patients;[17,18,20,25,27,28] significant improvement occurred in 2 of these studies.[25,27] The other studies relied on physicians' recall about CPGs presented in small-group or education sessions;[19,22–24,26,29] significant improvement occurred in 3 of these studies.[23,24,29]

Six of the trials may not have adequately controlled for contamination, either since the random assignment was by patient (and the physician was the same for both the intervention and control patients), or since the physicians were working in the same institution (and thus may have been in frequent contact with each other).[17,18,24,25,27,28] In only 4 trials were the physicians randomly assigned by practice, which is the soundest method.[19,20,23,26] Two studies used quasi-experimental designs; in such studies, the results are more likely to be due to initial differences between groups.[18,22]

In 2 studies[17,27] the size of the physician sample was not given, and in 3 other studies[28,18,26] the sample was less than 30, which raises concerns about these studies' power to detect changes. Five of the 9 trials involving more than 400 patients showed that the CPGs resulted in a significant improvement in at least some clinical outcomes, but all 4 studies with low or unspecified patient samples failed to show an effect. In 1 study, less than 60% of the patients were followed.[25]

Limitations of previous studies

Most CPG evaluation studies published to date have examined guidelines that were produced before the advent of evidence-based guideline development. We were unable to judge which studies used high-quality guidelines, but the publication date of some studies made the use of such guidelines unlikely. Also, it was difficult to estimate reliably the effect of CPGs on patient outcomes because so few studies have included sensitive outcome measures and sound methods.

Discussion

The studies reviewed showed little evidence that CPGs are effective in improving patient outcomes in primary care. Our literature search identified only 13 experimental or quasi-experimental studies that examined outcomes of primary patient care. Only 5 of these studies showed statistically significant improvements in outcome, and these improvements were only for some of the patients studied. The change in patient outcomes was usually modest, even when it was statistically significant. None of the studies was continued for long enough to measure any impact on mortality rates.

Only 2 of the 13 trials reviewed used appropriate methods and enrolled enough subjects to produce sound results.[20,23] Only 1 of these studies produced significant results, and only in the short term. Larger studies were more likely to show a significant improvement, but it was impossible to determine whether the increased power of these studies made insignificant clinical change appear statistically significant, or whether the lack of power in smaller studies meant that any real change was not detected.

Our literature review confirmed that most primary care studies conducted to date concerning the effects of CPGs have looked at the process of clinical care rather than the outcome for patients. For example, in Scotland, the use of guidelines resulted in more appropriate referral of infertile couples to specialist care;[30] in England, guidelines resulted in more complete recording of antenatal care;[31] a set of guidelines developed jointly by the Royal College of General Practitioners and the Royal College of Radiologists reduced the rate of inappropriate radiologic referrals in Wales.[32] Such results are promising if it is assumed that improvements in the process of care will eventually result in improved outcomes for patients.

It may be too pessimistic to state, on the basis of our study, that CPGs are unlikely ever to improve patient outcomes in primary care. The lack of evidence of their effectiveness may well be due to the lack of methodologically sound studies conducted. Also, many of the studies conducted to date, even those that are methodologically sound, may have examined guidelines that were not "correct" — the guidelines may have been based on out-of-date consensus statements or may have been poorly implemented. Another factor is whether the correct outcomes were considered; it may be easier but less appropriate to measure "hard" biochemical or physical outcomes rather than "soft" outcomes such as patient satisfaction or quality of life, which are also important in primary care.

Clearly, there is a need for more research on guidelines that include measures of patient outcomes; in particular, research should determine which aspects of guidelines have an effect on patient outcomes. A systematic review of 99 trials of continuing medical education emphasized the need for strategies to predispose physicians to the use of guidelines and to reinforce their use; as well, the review described the education exercises that worked best, but did not show that these exercises improved patient outcomes.[33] It is also uncertain whether involving patients in the process makes it more effective; a recent study of feedback of patients' experiences, provided to their family physicians, showed that such feedback had no effect on the physicians' management of these patients.[34] Qualitative research on the influences on physicians' management choices would be valuable in clarifying the issues of choice and would help guide educational responses; such research would probably be more useful than the publication of more guidelines.[35] Research needs to examine which implementation strategies for new evidence-based guidelines lead to improved patient outcomes.

Table 2: Characteristics of 13 trials of effectiveness of clinical practice guidelines (CPGs) on patient outcomes in primary care

Study setting	No. of physicians	No. of patients (% followed)	Length of follow-up	Study design	Intervention	Outcome measure	Result
Hypertension							
US hospital hypertension clinics[17]	Not given	116 (100)	14 mo	RCT*; patients were randomly assigned	Computer-prompted use of national CPGs v. normal physician treatment	Mean blood pressure	NS†
US general medicine clinics[18]	16 physician–nurse practitioner teams	Not clearly given	12 mo	Nonrandom assignment of teams to 2 groups based on team rankings in baseline period	Two types of computer-aided feedback on use of local CPGs v. no such feedback	Diastolic blood pressure ≤ 95 mm Hg or < 100 mm Hg	NS
Canadian solo and group practices[19]	41	198 (86)	12 mo	RCT (block design); practices were randomly assigned	Receipt of practice-oriented local CPGs for diagnosis, work-up, therapy and follow-up v. no receipt of guidelines	Mean diastolic blood pressure < 90 mm Hg	NS
Canadian family practices[20]	60	2833 (79)	Variable, > 16 mo	RCT; after stratification for partners working together, physicians were randomly assigned	Computer-aided feedback using a national "stepped care" protocol v. no computer-aided feedback	Mean diastolic blood pressure < 90 mm Hg	NS
US primary care physicians[21]	111	2044 (60)	11 mo	RCT; physicians were randomly assigned	Education intervention consisting of feedback reports, patient surveys, educational syllabus, and 1-hour telephone conference call on national CPGs v. no education intervention	Mean diastolic blood pressure < 90 mm Hg or < 95 mm Hg	NS
Canadian family practices[22]	40	Not given	18 mo	Random selection of physicians, but no random assignment to groups	Education workshop in which physicians were involved in establishing local criteria for hypertensive management v. receipt of criteria by mail v. no criteria	Mean blood pressure	NS
Cigarette smoking							
Canadian general practices[23]	83	2029 (95)	Variable, > 12 mo	RCT (block design); clinical practices were randomly assigned	Training sessions on national quit-smoking CPGs v. no training and normal care v. no training and giving patients advice and nicotine gum only	% of patients quitting over the short- and long-term	$p \leq 0.036$ for the short term only
US health maintenance centres[24]	81	2056 (77)	12 mo	RCT; physician units (groups with distinct space and office staff) were randomly assigned	Education sessions on local CPGs for helping smokers quit v. no such sessions	% of patients who (1) tried to quit or (2) abstained from smoking for ≥ 1 wk and ≥ 9 mo	(1) 5.7 (CI‡ –0.7–12.1, significant) (2) 2.7 (CI 0.3–5.0, NS) and 2.2 (CI 0.2–4.3, NS)

Diabetes

Condition/setting	No.	No. (%)	Duration	Study design	Intervention	Outcomes	Results
US hospital general medicine clinic[25]	45	532 (48)	26 mo	RCT (incomplete block design); resident clinic teams were randomly assigned	Local diabetes education program for patients to teach target behaviour for management of diabetes and program for physicians, consisting of written problem-oriented protocols and protocol-based computerized reminders, seminars, conferences, telephone hotlines and medical audits. Four groups: no education, patient education only, physician education only, and patient and physician education	Mean (1) fasting plasma glucose level, (2) glycated hemoglobin, (3) weight and (4) blood pressure	(1) $p \leq 0.05$ (2) $p < 0.05$ (3) $p \leq 0.05$ (4) $p < 0.05$

Asthma

Condition/setting	No.	No. (%)	Duration	Study design	Intervention	Outcomes	Results
English general practices[26]	27	454 (74)	30 mo	RCT; physicians were randomly assigned (there was only 1 physician per practice)	Education sessions about local CPGs for managing chronic asthma and devising strategies for care v. no education sessions	Asthma morbidity scores§	NS

Numerous conditions

Condition/setting	No.	No. (%)	Duration	Study design	Intervention	Outcomes	Results
Hypertension, obesity and renal disease US university clinic[27]	Not given	479 (77–95)	24 mo	RCT; patients and physicians were randomly assigned	Computer-automated reminders to adhere to local standards of care v. manual records	Mean (1) blood pressure, (2) weight and (3) % of patients with normal results of renal function, urinalysis and culture	(1) NS (2) $p = 0.023$ (3) $p = 0.0003$ (urinalysis) and $p = 0.028$ (urine culture)
15 clinical interventions US general medicine clinic[28]	27 physician teams	12 467 (90)	24 mo	RCT (block design); practice teams were randomly assigned	Computer-generated reminders about local rules of care v. no reminders	Mean values for several patient outcomes¶	NS
Acute cough, acute vomiting, bedwetting, itchy rash and recurrent wheezy chest English general practices[29]	84	1791 (82)	12 mo	Before and after study; replicated Latin square	Receipt of local written clinical standards developed by small groups of general practitioners v. no receipt of written standards	Mean (1) no. of days breathless, (2) no. of days wheezy, (3) improvement in cough and (4) frequency of bedwetting	(1) 3.0 (CI 1.5–4.5) (2) 3.6 (CI 1.8–5.3) (3) NS (4) NS

*RCT = randomized controlled trial.
†NS = not significant.
‡CI = confidence interval.
§Scores for breathlessness, wheezing, cough, night waking, 4 or more days off school or work, home visits by physician, 2 or more severe attacks, longest attack at least 1 day.
¶No. of hospital admissions, emergency department visits, serum glucose level, serum hemoglobin, serum potassium level, blood urea nitrogen level, diastolic blood pressure and weight.

A wealth of CPG studies is currently under way; we hope that they will shed light on these issues.

We do not know whether CPGs improve patient outcomes, or whether evidence-based CPGs work any better than consensus-based CPGs. Even if most CPGs for primary care seem to be ineffective so far, we do not know why they are ineffective. The CPGs themselves could be ineffective; there could be problems with their dissemination or implementation; or the method used to assess their effects could be flawed or insensitive.

Limitations of this study

There are several limitations to the present study. First, the electronic databases do not completely cover the world's biomedical literature. Evidence-based CPGs are still relatively young, so there has been little time to assess many of the more recent guidelines. The study was unable to assess whether the lack of effectiveness shown was due to the guidelines themselves, or to poor dissemination and implementation. A Type II statistical error may have occurred; that is, the number of studies may have been too small for any consistent effect to show up, even if such an effect exists.

Conclusion

To date, there is little evidence that the use of CPGs produces significant changes in clinical outcomes in primary care. Many guidelines have been developed, but little is known about the effects of most of them on clinical care outcomes. In their direct application to patient care, CPGs can be considered as a "medical technology."[10] In the same way that unbridled enthusiasm for new medical technologies has sometimes resulted in their widespread application before they have been evaluated, there may be a danger that CPGs will be adopted too enthusiastically and uncritically. Since CPGs are the main tool for introducing evidence-based medical care, research into their effectiveness in improving patient outcomes should be conducted. In primary care, the best researchers to conduct studies of the effectiveness of CPGs are probably family physicians themselves.

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