A pragmatic randomised controlled trial of a prompt and reminder card in the care of people with epilepsy

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SUMMARY

Background: The quality of epilepsy care has often been noted to be poor and fragmentary. Most people with epilepsy are solely under the care of their general practitioner (GP). Many patients report medication side-effects and poor seizure control. Most GPs accept responsibility for epilepsy care; however, many report problems with knowledge of epilepsy and nearly all support guidance on epilepsy management.

Aim: To determine whether a GP-completed prompt and reminder card is effective in improving the quality of epilepsy care when used opportunistically.

Design of study: Primary care-based pragmatic cluster-randomised controlled trial.

Setting: People with active epilepsy (n = 1275) from 82 practices.

Method: Practices were randomly categorised as 'control', 'doctor-held card' (card in patient records), or 'patient-held card' practices.

Results: Compared with control practices, recording of seizure frequency was significantly increased in doctor-held card practices (57.4% versus 42.8%, P = 0.003) but not in patient-held card practices (44.6% versus 42.8%). No differences were found in the proportion of seizure-free patients (doctor-held card [56.0%] versus control [51.5%]; patient-held card [58.1%] versus control [51.5%]) or in the proportion on monotherapy. Patients in both intervention groups reported more medication-related side-effects and patients in doctor-held card practices were less satisfied with information provision about epilepsy. Participating GPs found the card useful. The doctor-held card was retrieved and completed more often than the patient-held card.

Conclusions: A doctor-held prompt and reminder card is effective in improving the recording of key clinical information for people with epilepsy, is felt to be useful by GPs, and is completed more often than a patient-held card. However it does not improve outcomes and may result in less patient-centred care.

Keywords: epilepsy; prompt and reminder card; randomised controlled trial.

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Introduction

EPILEPSY care has been described as poor and fragmented[1] and the importance of improving the quality of care has been highlighted.[2,3] Although most people with epilepsy are solely under the care of their general practitioner (GP),[4,5] there have been few large-scale evaluations of community-based interventions to improve care. Moreover, many GPs perceive their knowledge of epilepsy as inadequate and nearly all would like guidelines for epilepsy management.[6] Reminder systems for clinicians provide a means of assisting doctors in the management of chronic diseases and have been shown to be one of the most effective single interventions for improving compliance with guidelines.[7] A structured record card (a 'prompt' card) used in a practice audit has been shown to improve epilepsy care (Lloyd-Jones, personal communication, 1995). However, this needs to be systematically evaluated. A prompt and reminder card for doctors (where the 'reminder' is an evidence-based summary of key clinical information to aid decision making) was therefore developed for such an evaluation.

The aims of this study were to measure the effectiveness, acceptability, and utility of an epilepsy prompt and reminder card for doctors in improving the care of people with epilepsy in the community; and to assess whether such a card should be held by the patient or placed in the medical records.

Method

Protocol

Practices in four areas of Greater Manchester (Stockport, South Manchester, Salford and Trafford, and Bury and Rochdale) were randomly selected and approached to participate in this study. The study was conducted between April 1997 and August 1999. Adults with 'active' epilepsy (either a seizure recorded in the medical records in the past two years or being on anticonvulsant medication for epilepsy) on the list of consenting GPs were eligible to participate. Temporary residents, individuals with severe learning disability, and children (individuals under 16 years of age) were excluded.

Intervention

The intervention consisted of an evidence-based epilepsy prompt and reminder card for GPs to complete. The card had two main parts: first, 'prompts' to collect key clinical information about an individual's epilepsy; and secondly, evidence-based information ('reminders') on which to then base any subsequent patient management decision. The

HOW THIS FITS IN

What do we know?

The care of people with epilepsy is often poor, with very little information about epilepsy recorded in clinical notes. Many general practitioners feel that their knowledge of epilepsy is poor and want guidance on management. Reminder systems are the most effective single interventions to improve the implementation of guidelines. Structured care results in better outcomes for other chronic diseases.

What does this paper add?

An epilepsy prompt and reminder card for general practitioners placed in the medical records significantly improved the recording of clinical information about epilepsy, was felt to be helpful by general practitioners but did not result in better seizure control. A prompt and reminder card carried by patients did not result in improved recording or in improved seizure control but was more acceptable in terms of patient satisfaction with information provision than when the card was placed in the medical records.

final version of the prompt and reminder card was passport-sized, bright yellow in colour, and consisted of nine sections (including seizure frequency and pattern, seizure classification, medication, side-effects and indications for medication withdrawal, checking serum levels, information provision, and monitoring).

Assignment

The study was a pragmatic randomised trial. Practices were stratified into small (fewer than three partners in practice) or large (three or more partners in the practice). Using a random number table, practices were either allocated to the 'control' group, to the 'doctor-held card' group (where the card was inserted into the patients' records) or to the 'patient-held card' group (where the patient held the card). The card was used opportunistically over the course of one year for most subjects.

The primary outcome measures were recording of seizure frequency and self-reported seizure frequency in the previous year. Secondary outcome measures were the retrieval rate and completion rate of the epilepsy card, the proportion of patients on monotherapy with anticonvulsants, the proportion of patients reporting medication side-effects, whether serum levels of anticonvulsants were checked appropriately, the levels of patient satisfaction with GP care, and level of satisfaction with information provision by the GP.

The outcome measures used were items from the Liverpool Assessment Battery[8] and information recorded in GP medical records. The Liverpool Assessment Battery comprises several scales (including the Seizure Severity scale[8], the HAD questionnaire[9]) and individual items to measure the quality of life and the quality of care for people with epilepsy. Baseline questionnaire data were collected before

randomisation with further questionnaire data being collected after the intervention. Data from medical records were extracted on two separate occasions (for baseline year and intervention year information).

Ethical approval was obtained from the relevant ethical committees (South Manchester, Bury and Rochdale, Salford and Trafford, and Stockport) prior to commencing recruitment.

Statistical methods

The sample size calculations were based on an estimated 10% reduction in seizure frequency[9] and recorded seizure frequency (with 80% power and a 5% significance level). As randomisation was by practice, an intra-class correlation coefficient of 0.02 was estimated for outcome measures to account for clustering within practices. Previous studies had found that each GP had about 10 patients with epilepsy and that the average practice size was 3.5 GPs. It was calculated that 20 practices in the three arms of the study with 600 patients in each arm would yield enough power to detect this difference in seizure frequency.

Statistical analyses were based on generalised estimating equations,[10] in which the intra-cluster correlation is accounted for using an exchangeable correlation model assuming a logistic model for binary outcomes. Prior to analysis, covariates that were potential predictors of outcome were identified and included in the model to improve efficiency and reduce chance bias. Analyses were carried out using the STATA statistical software.[11] Where baseline covariates were missing, an additional 'missing' category level was used or an imputed value was assigned for continuous variables.

For each outcome, comparison was made between the three groups by means of a 0.05 two-tailed significance level using a Wald χ^2 test. Where there was evidence of difference between groups, pair-wise tests were carried out between the control and each of the intervention groups using a 0.025 two-tailed significance level. Analysis was done on an intention-to-treat basis.

Results

Participant flow and follow-up

Eighty-two out of 204 practices that were approached participated in the study, and 1313 out of the 2326 patients eligible in participating practices consented to participate in the study (a response rate of 56%). (See Figure 1 for summarised information on participation and drop-out rates.) Non-responders were younger and less likely to be on more than one drug for their epilepsy than responders. The average age of study responders was 50 years and 52% were female. In the year prior to entry in the study, 51% of responders had been seizure-free, 97.5% were on anticonvulsant medication, 52% felt they were getting side-effects from their medication, and 34% had seen a specialist for their epilepsy. The groups were comparable at baseline for key characteristics (using binary logistic regression).

At the end of the study year, information was available from the medical records of 1210 participants and from 976 patient-completed questionnaires.

Commentary

Pity the poor quantitative researcher. Thirteen hundred patients consented; two-and-a-half years of data gathering; and meticulous chasing of non-responders and losses to follow-up. All this to demonstrate that a simple and intuitively sensible intervention — namely, placing a structured data record in the patient's notes — improves process measures (there is a more than evens chance that the doctor will fill it in). However, the impact on patient-relevant outcomes (seizure frequency) was marginal and, in retrospect, the study was underpowered to address these anyway.

The study illustrates well the inherent difficulty of demonstrating a significant change in clinical bottom line from a short, sharp, simple intervention directed at a complex problem. We already know from the work of the Cochrane Effective Practice and Organisation of Care Group that a patient-specific prompt at the time of the clinical encounter consistently improves the process of care.[1] We know from studies on other chronic conditions (notably diabetes) that a structured approach to disease surveillance improves both process and outcome of care.[2] And we know that epilepsy is a miserable condition that is often poorly managed, both within primary care and across the interface with hospital specialist teams.[3]

The research question — whether a 'prompt and reminder' (actually it was neither) card would be used opportunistically and lead to improved process of care — was a reasonable one. The finding — that it was and did, but not dramatically so — is unsurprising, as is the fact that patients forgot to bring their cards with them every time. Nevertheless, all this adds a little to the body of knowledge.

Where now? My own questions are qualitative. What was the experience of GPs who discovered yet another research project data collection card when they opened a set of notes during a busy surgery? Did they really focus on recording the data at the expense of hearing the narrative or witnessing the suffering? Did a very few patients gain a much better quality of life, so that even though there was little change overall, particular individuals benefited significantly? If so, what are the stories of those individuals and how can we spread such benefits further? Or was this largely an exercise in incidental paperwork that both doctors and patients barely noticed?

If the conclusion from this (as from every) underpowered, underfunded study is that more research is needed, the next intervention study surely needs a qualitative dimension. Bradley and colleagues describe a method that might be applied here.[4] As they say, 'even if an approach or technology can be clearly grounded in theory and evidence,' (and, implicitly, especially if it cannot) 'it must still be operationalised and evaluated among specific practitioners and patients.'

If there is to be a Phase 2 in this intervention, please could someone talk to the participants in the trial and ask 'How was it for you'? What are the perceived needs of patients and practitioners in relation to clinical reviews and the recording of data in the ongoing care of epilepsy? What makes the process of care run more — and less — smoothly? How might a prompt and reminder system be made to work more effectively? And if the whole exercise had no impact on the clinical bottom line, why not?

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Analysis

Recording of seizure frequency (Table 1). Recording of seizure frequency during the intervention year was significantly higher for patients in the doctor-held card group than for patients in the control group during the same period (57.4% versus 42.8%, $P = 0.003$, odds ratio [OR] = 1.82, 95% confidence interval [CI] = 1.23 to 2.69). There was no significant difference in the recording of seizure frequency between patients in the patient-held card group and patients in the control group during the intervention period (44.6% versus 42.8%, $P = 0.49$, OR = 1.16, 95% CI = 0.76 to 1.77).

Self-reported seizure frequency (Table 2). The proportion of patients who reported themselves seizure free was not significantly different between the control and the doctor-held groups (56.0% versus 51.5%, $P = 0.238$, OR = 1.33, 95% CI = 0.83 to 2.13), and the control and the patient-held groups (58.1% versus 51.5%, $P = 0.38$, OR = 1.47, 95% CI = 0.88 to 2.46).

Medication use and side-effects (Table 3). There were no significant differences in the rate of monotherapy, checking of phenytoin levels, and number of anticonvulsants used between the three groups. Patients in the control group reported significantly fewer side-effects than patients in either of the intervention groups.

Satisfaction scores (Table 3). Patients in the doctor-held card group were less satisfied with information provision by the GP than patients in the control group. There were no significant differences in overall scores of patients' satisfaction with GP care of their epilepsy between the three groups.

Card retrieval rate and patient perspectives on using the card. The card retrieval rate was considerably higher for patients in the doctor-held card group than for patients in the patient-held card group (91.5% versus 43.4%). For patients who had a record of attending surgery in the intervention year, card completion rates (for retrieved cards) were higher for patients in the doctor-held card group than for patients in the patient-held card group (56.4% versus 49%). The majority (65.4%) of responding patients in the patient-held card group expressed an opinion about the epilepsy card, and most of these (71.3%) felt the epilepsy card was or could be helpful for epilepsy care. However, many patients reported problems with using it, with patients forgetting to bring or present the card being the major problem (38% of those who had been to see their GP in the previous year).

GP perspectives on the use of the card. Of the 216 GPs eligible for the study, 125 (57.6%) returned usable questionnaires (one single-handed GP withdrew from the study during the intervention year). These GPs were from 64 out of the 81 (79%) participating practices at the end of the study. Some practices specifically stated that they had a consensus within the practice reflecting their opinions. Forty-six out of 56 (82.1%) of responding GPs in the doctor-held card group viewed the card as being useful, compared with 58.4% (21/36) of doctors in the patient-held card group. Being too busy to use the card was the main barrier to its use for GPs in both intervention groups.
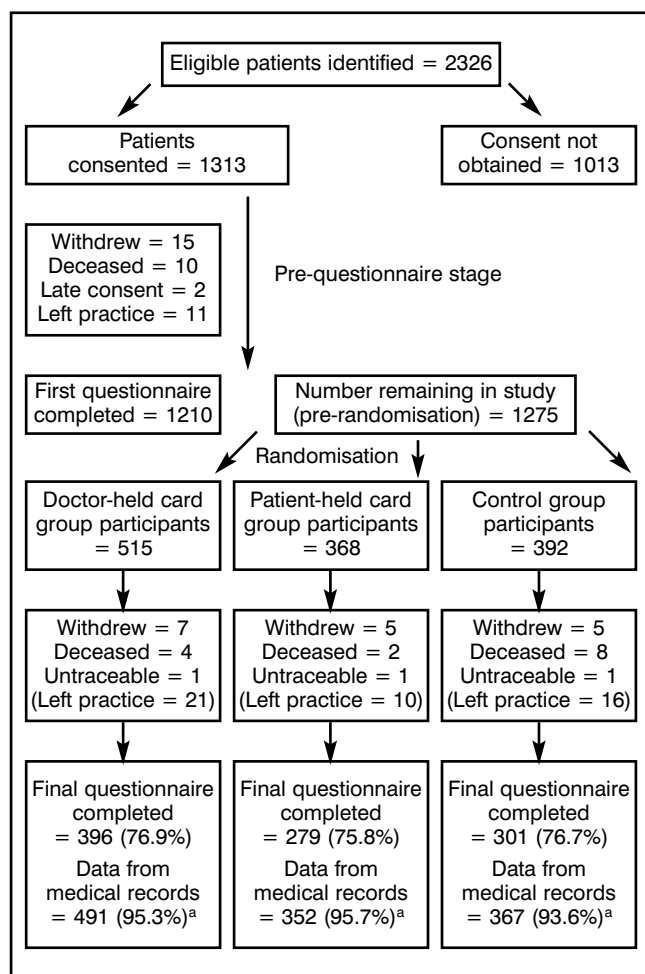
Figure 1. Trial profile: consent and drop-out rates. [a]Information from some of these individuals is included.

Discussion

The limitations of this study need to be noted. First, not all practices approached agreed to participate. Participating practices were, however, comparable to non-participating practices in terms of size, training status, and deprivation scores. The participation rate was comparable to other recent studies of educational interventions in general practice.[12] Paperless practices were excluded but represented less than 2% of practices initially approached. Secondly, not all patients in consenting practices agreed to participate and non-consenters were more likely than consenters to be at the extremes of the age group included (lower in patients aged less than 20 years and in patients aged over 80 years), and on monotherapy for their epilepsy. This pattern of lower participation rates in those with less severe illness is well established for treatment trials.[13] The issue of misdiagnosis may be also be relevant.[14] However, this was a pragmatic trial and we used the standard method of patient identification used in other community-based research.[4,15] Finally, not all patients who commenced the study completed the final questionnaire. However, data from medical records was collected for over 90% of the eligible sample at the end of the study. Dropout rates were low and were comparable across groups (Figure 1). Moreover, an intention-to-treat method using baseline value carryover was also used in the analysis.

This study reports the findings of a pragmatic randomised controlled trial of an epilepsy prompt and reminder card for GPs. The main findings of the study were that recording of key clinical information improved significantly in the doctor-held card group. Self-reported seizure frequency was not significantly improved in the intervention groups and patients in both intervention groups were more likely to report anticonvulsant medication-related side-effects than patients in the control group. Patients in the doctor-held card

Table 1. Recording of seizure frequency, either in medical records or on card in previous year.

	Control	Doctor held	Patient held	Overall
Baseline				
In medical notes % (*n*)	37.8 (143/378)	36.6 (186/508)	36.5 (133/364)	37 (462/1250)
Intervention year				
Medical notes or card % (*n*)	42.8 (157/367)	57.4 (281/489)	44.6 (158/356)	49.3 (596/1210)
Adjusted[a] odds ratio relative to control group (95% CI)	–	1.82 (1.23–2.69)	1.16 (0.76–1.77)	
Wald χ^2 comparing intervention with control[a] (one degree of freedom)	–	$P = 0.003$	$P = 0.49$	$P = 0.0058$[b]

Intra-class correlation coefficient = 0.051. [a]Adjusted for baseline recording of seizure, health problems, and visit to specialist in baseline year. [b]Wald χ^2_2 comparing three arms (two degrees of freedom).

Table 2. Reported seizure frequency during the baseline and intervention year.

Seizure status in previous year	Control	Doctor held	Patient held	Overall
Baseline year				
Seizure free % (*n*)	48.3 (181/374)	51.6 (247/479)	52.0 (179/344)	50.7 (607/1197)
Intervention year				
Seizure free % (*n*)	51.5 (151/293)	56.0 (219/391)	58.1 (158/272)	55.2 (528/956)
Adjusted[a] odds ratio relative to control group (95% CI)	–	1.33 (0.83–2.13)	1.47 (0.88–2.46)	
Wald χ^2 comparing intervention with control[a] (one degree of freedom)	–	$P = 0.238$	$P = 0.137$	$P = 0.297$[b]

Intra-class correlation coefficient = 0.022. [a]Adjusted for baseline seizure frequency, health problems, age, and visit to specialist in baseline year. [b]Wald χ^2 comparing three arms (two degrees of freedom).

Table 3: Summary of other results on medication use, side-effects, and monitoring and on satisfaction with GP care during the baseline and intervention year.

	Control	Doctor held	Patient held
Medication use			
On more than one epilepsy drug in baseline year % (n)	28.8 (106/368)	28.1 (131/467)	32.1 (110/343)
On more than one epilepsy drug in intervention year % (n)	28.9 (83/287)	30.3 (113/373)	29.9 (79/264)
Adjusted[a] odds ratio relative to control group (95% CI)	–	0.76 (0.41–1.44)	1.51 (0.74–3.07)
Wald χ^2 comparing intervention with control[a] (one degree of freedom)	–	$P = 0.401$	$P = 0.253$
Medication side effects			
Medication side effects reported by patient during baseline year % (n)	52.8 (182/345)	50.8 (229/450)	53.2 (173/326)
Medication side effects reported by patient during intervention year % (n)	43.6 (120/275)	49.3 (182/369)	50.8 (125/246)
Adjusted[b] odds ratio relative to control group (95% CI)		1.54 (1.10–2.17)	1.60 (1.10–2.32)
Wald χ^2 comparing intervention with control[b] (one degree of freedom)		$P = 0.013$	$P = 0.016$
Checking of phenytoin serum levels in previous year (for those patients on phenytoin)			
Phenytoin serum levels checked in baseline year % (n)	31.2 (39/125)	28.1 (52/185)	32.6 (42/129)
Phenytoin serum levels checked in intervention year % (n)	31.5 (34/108)	28.7 (45/157)	39.2 (40/102)
Adjusted[c] odds ratio relative to control group (95% CI)		0.93 (0.44–1.97)	1.37 (0.61–3.09)
Wald χ^2 comparing intervention with control[c] (one degree of freedom)		$P = 0.851$	$P = 0.447$
Satisfaction with information provision by the GP in previous year (for those patients who reported seeing the GP in the previous year)			
Satisfied with information provided by the GP in baseline year % (n)	67.7 (195/288)	64.4 (239/371)	65.1 (183/281)
Satisfied with information provided by the GP in intervention year % (n)	76.1 (175/230)	66.0 (195/295)	76.2 (162/213)
Adjusted[d] odds ratio relative to control group (95% CI)		0.57 (0.38–0.86)	0.98 (0.62–1.54)
Wald χ^2 comparing intervention with control[d] (one degree of freedom)		$P = 0.006$	$P = 0.943$
Rated GP care of their epilepsy as high (either excellent or good) (for those patients who reported seeing the GP in the previous year)			
Rated GP care of their epilepsy as high in baseline year % (n)	77.2 (223/289)	76.7 (284/370)	77.5 (217/280)
Rated GP care of their epilepsy as high in intervention year % (n)	79.0 (181/229)	73.6 (220/299)	83.6 (179/214)
Adjusted[e] odds ratio relative to control group (95% CI)		0.70 (0.45–1.07)	1.35 (0.80–2.21)
Wald χ^2 comparing intervention with control[e] (one degree of freedom)		$P = 0.10$	$P = 0.27$

[a]Adjusted for baseline number of epilepsy drugs, tonic clonic seizures, GP attendance's intervention year. [b]Adjusted for baseline presence of medication side-effects, other long-term illness, age. [c]Adjusted for baseline checking of phenytoin levels and age. [d]Adjusted for baseline information provision and age. [e]Adjusted for baseline satisfaction with care and age.

group were less satisfied with information provision by the GP than patients in the control group. For retrieved cards, the doctor-held card was considerably more likely to be completed than the patient-held card.

Given that this was a pragmatic intervention with minimal intervention from the research team, the findings that the recording of key clinical information improved in the doctor-held card group was important. Documentation of seizure frequency has been noted to be poor in the past and is a key requirement for monitoring of epilepsy.[16] The results at baseline are similar to the findings of other community-based studies of epilepsy.[4,5] There have been no similar intervention studies in epilepsy to compare these improvements against. However, the levels of improvement in recording of clinical information found in this study are similar to those found in a trial of asthma guidelines.[17]

We also examined whether improved outcomes followed from the use of the prompt and reminder card. Although reductions in seizure frequency were larger in both intervention groups than in the control group, there were no significant differences in reported seizure frequency between the three groups. Assessing whether interventions improve health outcomes can be difficult in view of the multifactorial

influences on health outcomes.[18] In the present study, although improvements in process measures of care occurred, no improvements in patient outcome were demonstrated. Given that the intervention produced a much larger improvement in the recording of clinical information than in outcomes such as seizure frequency, the most likely explanation is that the study lacked sufficient power to detect the lower (approximately 5%) improvement in self-reported seizure frequency that occurred (although it was correctly powered to detect the larger improvements in recording of clinical information).

There were no differences in the rate of monotherapy between the intervention groups and the control group. Patients in the control group were, however, less likely to report side-effects which they attributed to their anticonvulsant. This finding may either be owing to a true difference (perhaps because more medication adjustment was made in the doctor-held group to improve seizure control) or increased reporting of side-effects owing to increased awareness of medication side-effects, as there was a specific prompt to ask about several specific side-effects on the card. The latter explanation seems more plausible as patients in both intervention groups reported more side-

effects and no differences in seizure frequency were found.

The finding that patients in the doctor-held card group were less satisfied with information provision about their epilepsy and, furthermore, that there was a fall in overall satisfaction with GP care of their epilepsy in this group (although overall post-intervention satisfaction scores were not significantly different between the three groups) needs closer examination. These lower satisfaction scores may reflect the reduction in consultation time necessitated by filling in the card and the more doctor-orientated approach this may have encouraged. There is a considerable body of literature in epilepsy related to the need for the epilepsy patient to retain control of their illness[19] and patient satisfaction being related more to interpersonal rather than technical aspects of care.[20]

Although the patient-held card was more acceptable in terms of patient satisfaction, the card retrieval rate was much lower than for the doctor-held card. This was the first systematic evaluation of patient-held cards in a chronic disease so it is important to consider the reasons for problems in retrieval of the card. Although all patients were prompted to provide an explanation for non-return of the card, only a minority of patients who did not return a card did so. This explanation generally related to not finding or not recalling receiving a card. It has to be investigated whether the effectiveness of a patient-held card is improved using a different strategy for card delivery, in view of the greater acceptability of a patient-held card than a doctor-held card.

Conclusion

A doctor-held prompt and reminder card improved recording of key clinical information in patient records and was felt to be useful by most doctors. However, no improvements in outcomes were obtained and findings suggested the need for awareness of patient perspectives and the use of the card in a more patient-centred manner.

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