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DEVELOPMENT

Recruiting patients and collecting data for an observational study using computerised record pop-up prompts: the PROG-RES study

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Background and Aim: Engagement of general practitioners (GPs) and recruitment of patients are ever present problems in primary care studies. This paper seeks to demonstrate that electronic prompts represent one method of easing the burden on GPs to recruit individual patients to studies and also provide the opportunity to collect research data during a normal consultation. **Methods:** Older adults consulting for non-inflammatory musculoskeletal pain from five general practices in Cheshire were recruited to a prospective cohort study (the PROG-RES study). Recruitment of patients was aided by a computer prompt during relevant consultations. When triggered by an appropriate Read code, a pop-up template appeared on the consultation screen prompting the GPs to record the answers to seven brief questions. A self-complete questionnaire was mailed to patients who had completed templates by the Keele GP Research Network team and permission was sought to access their medical records. A feasibility study suggested that the potential number of activated templates in the practice within four months would be 636. **Results:** The 44 GPs completed 650 electronic templates during the four-month recruitment period. Almost 40% of recruitment was within four weeks and greater than 95% of recruitment was within 16 weeks. Practices A–D completed electronic templates at a similar rate (1.61–1.86 templates per 1000 patients), although practice E completed templates at a lower frequency (0.76) due to internal difficulties. Completion of individual items ranged from 98% to 83% and completion of all seven questions was recorded in 63% of patients; 4% of patients had three or fewer responses recorded. **Conclusion:** Templates activated by appropriate codes in the GP consultation can facilitate recruitment to observational studies in primary care. It is possible to collect high-quality research data within a normal consultation. This may be a model for use in future studies in primary care.

Key words: computerised records; data collection; pop-up prompts; primary care; recruiting patients

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Introduction

Primary care research continues to represent a rapidly developing field prompted by the need to improve the evidence base of many of the clinical

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decisions commonly made in general practice (Sackett *et al*., 1996; de Wit *et al*., 2001; McKinstry *et al*., 2007). Randomised controlled trials (RCTs) represent the 'gold standard' of study design and much research has focussed on the practical aspects of conducting RCTs in primary care settings (Sackett *et al*., 1996; de Wit *et al*., 2001; Rollman *et al*., 2007; Treweek *et al*., 2010a). Although RCTs represent an important methodology for primary care researchers, not all clinical questions can be answered using this study design. Primary care clinicians are frequently interested in questions concerning aetiology and prognosis, which may be answered best through observational study designs. However, many of the challenges encountered with recruitment to RCTs are also highly pertinent to observational study designs, although they are less well investigated.

Previous research has examined methods to increase the participation of both patients and healthcare professionals to primary care studies, with much of the research to date focused on RCTs (Rollman *et al*., 2007; Rendell *et al*., 2008). For patients, several key principles have been suggested that lead to increased recruitment including (1) perceived importance of the research question, (2) ease and speed of access to the trial treatment, and (3) financial incentives (Foy *et al*., 2003; Huibers *et al*., 2004; Rollman *et al*., 2007). For the healthcare professional recruiting the patients, engagement appears to be strongly related to both the motivation of the recruiter as well as the techniques put in place both to aid and simplify the recruitment process (de Wit *et al*., 2001; Bower *et al*., 2007; Rendell *et al*., 2008; Treweek *et al*., 2010a). Despite this knowledge, in practice, adequate engagement of both healthcare professionals and patients in primary care research still continue to be a major concern (McDonald *et al*., 2006; Rollman *et al*., 2007; Treweek *et al*., 2010b).

This problem of recruitment to studies based in primary care has led to innovations to aid participation. One recent aid to primary care recruitment is the use of computer prompts or 'pop-ups', whereby the consultation record of eligible patients are electronically 'stamped' enabling searches of the practice records to be performed at a later date to establish a group of suitable patients to contact regarding taking part in studies. This method can clearly reduce the administrative burden associated with recruitment for the general practitioner (GP); however, its impact has only started to be investigated (Rollman *et al*., 2007; Treweek *et al*., 2010a). A further innovation to this method is the addition of real-time research data collection within the primary care records at the time of recruitment. Here, we report on the benefits of using such innovative methods during the general practice consultation to recruit patients to, and collect research data for, an observational study.

Methods

The PROG-RES study was a prospective cohort study investigating the prognosis of older people with joint pain in general practice (Mallen *et al*., 2006). Ethical approval for this study was obtained from the Central Cheshire Local Research Ethics Committee (REC Reference: 06/Q1503/60).

Before commencing the study, the study principal investigator (a GP) and a member of the Health Informatics Team, an integral part of the research network, visited individual practices. During a brief face-to-face meeting (no longer than 20 min) the purpose and nature of the study was discussed. Use of the electronic template was demonstrated and clinicians were encouraged to provide feedback and comment on how it would fit into their typical consultation. Box 1 presents a summary of the methods used in the *PROG-RES* study to maximise GP and patient participation, which represents a synthesis of the methods by which the 44 study GPs considered maximised GP and patient involvement, broadly in line with those found by other investigators (de Wit *et al*., 2001; Fletcher *et al*., 2007; McKinstry *et al*., 2007). Feedback from the recruiting GPs found methods one to six to be of most use. The final electronic template, although including far fewer questions, was very similar in design to templates routinely used in British general practice to collect information on chronic disease (http://www.icms.qmul.ac.uk/chs/ceg/contract_template_guides/index.html).

A total of 44 GPs in five Central Cheshire general practices participated in this study. All practices are members of the Keele GP Research Partnership. These practices undergo regular audit and consistently provide high quality data for research purposes (Porcheret *et al*., 2004). Older adults, aged 50 years and over, consulting their GP with non-inflammatory musculoskeletal

Box 1 Methods used in the PROG-RES study to maximise general practitioner (GP) and patient participation

1. Personal practice visit by lead investigator
2. Concise version of study information for clinicians, as well as more detailed practice pack
3. Regular clinician–clinician contact using different modalities (email, practice visits, telephone, letters)
4. Regular 'progress reports' (every month)
5. Clinical involvement with template design
6. Short period for recruitment (four months maximum)
7. Involvement of network of research GPs who encourage and inform patients
8. Clinically relevant topic
9. Simple inclusion/exclusion criteria
10. Support from Research Nurses and Health Informatics Team
11. Pop-up programme on general practice computer system
12. Research involvement *must* not increase GP workload
13. Small financial reimbursement (£5 per patient)
14. Providing educational materials/appraisal material (protocol paper, certificate of participation)

Table 1 Practice demographics

	Practice code				
	A	B	C	D	E
Number of general practitioners	15	9	12	4	4
List size (*n*)	20 625	14 755	11 149	10 325	6273
Patients 50+ years (*n*)	7469	5660	4341	2927	2399
Long-term limiting illness (%)[a]	12.8	13.0	21.1	20.8	21.1
Health 'not good' (%)[a]	5.7	5.8	10.3	11.8	10.3
White (%)[a]	98.7	97.8	98.5	97.5	98.5
Permanently sick or disabled (%)[a]	3.2	3.1	4.7	6.6	4.7
Unemployed (aged 16–74 years; %)[a]	2.4	0.9	2.5	4.4	2.5
Unpaid carer (%)[a]	9.2	11.7	12.3	8.9	12.3
Owner-occupied (%)[a]	89.5	98.2	81.0	65.9	81.0
QoF Score (0–1050)[b]	1049.3	1040.5	1046.0	998.4	1050.0

[a] Office of the Deputy Prime Minister, 2006 (now the Department for Communities and Local Government).
[b] The Information Centre for Health and Social Care, 2006.

pain were eligible for inclusion in this study. The practice demographic populations in this age group for the five participating practices are presented in Table 1.

The Health Informatics Team attended all participating practices and linked an automated electronic template to over 200 musculoskeletal pain Read codes. Read codes are a hierarchy of morbidity symptoms and process codes that are used to label consultations in UK general practice. When an eligible Read code was entered on the EMIS (Egton Medical Information Systems) computer system during a consultation the electronic template was activated; GPs used their discretion to exclude individuals (red flag, ie possible serious or life-threatening, pathology, inflammatory arthropathy or vulnerable groups) and could exit the template. If not excluded, the electronic template prompted the GP to ask and record the patient's responses to seven brief pain-related questions and provide their own opinion on the likely prognosis of the patient at six-month post consultation (Figure 1). The consultation then continued as per normal. The consultation

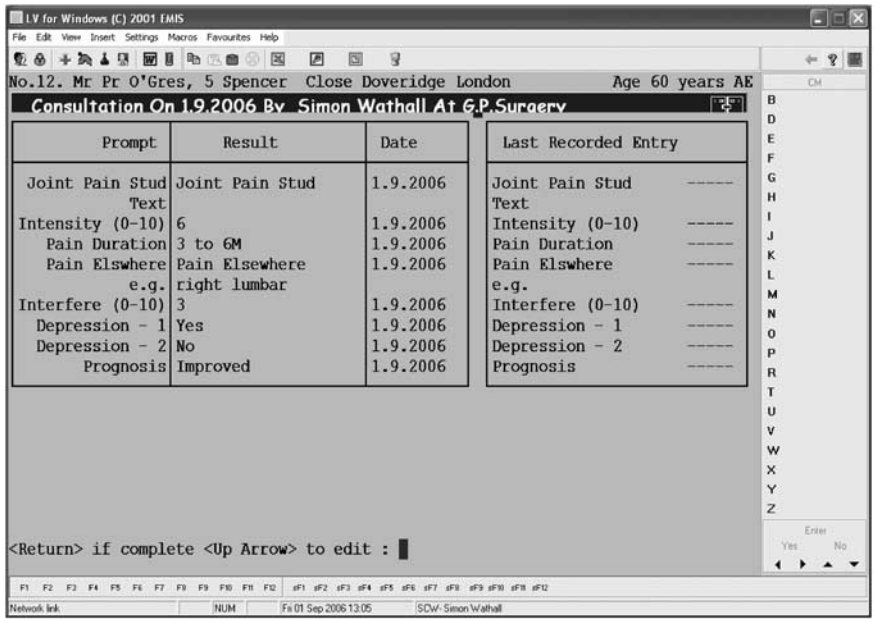

Figure 1 Pop-up electronic prompt activated by the appropriate musculoskeletal Read code in the PROG-RES study

record of that patient was electronically 'stamped'. The template would not activate if the patient had already had an eligible consultation within the study period, to ensure that patients were only sampled once.

The Health Informatics Team performed weekly searches to identify patients with completed templates. These patients were then sent a copy of a self-completion questionnaire and were asked for permission to access their medical records. Non-responders were sent a reminder postcard after two weeks and a further copy of the questionnaire if no response was received after one month. Patients responding to the questionnaire and giving permission to access their medical records where included in the follow-up (3-, 6-, and 12-month post consultation) stages of the study.

Sample size and statistical analysis

Using data from the 1991 National Survey of Morbidity in general practice and more recent data from the North Staffordshire Primary Care Research Consortium's database of consultations it was estimated that the frequency of consultation for musculoskeletal pain in those aged 50 years and over was 7 per 1000 registered patients per month, discounting repeat consultations within the same year (Porcheret *et al*., 2004; Jordan *et al*., 2007). The practice demographic population in this age group for the five participating practices was 22 796. Thus the potential number of activated electronic templates for a four-month period, that is, the recruitment period, would be $\sim$636 patients. Data from previous population-based surveys in older adults suggest that the combined non-response to the survey and non-consent to medical records would be $\sim$35% (Dunn *et al*., 2004). Hence, it was estimated that 413 would be eligible for inclusion in the follow-up stages of the study.

The absolute number of template completions was calculated for each practice on a weekly basis during the study period and the relative patterns of recruitment across practices were compared graphically. Recruitment rates, by 1000 registered patients, were also compared across the practices. The completeness of the pain and prognosis data collected in the consultation are presented overall and compared by practice and over the study period.

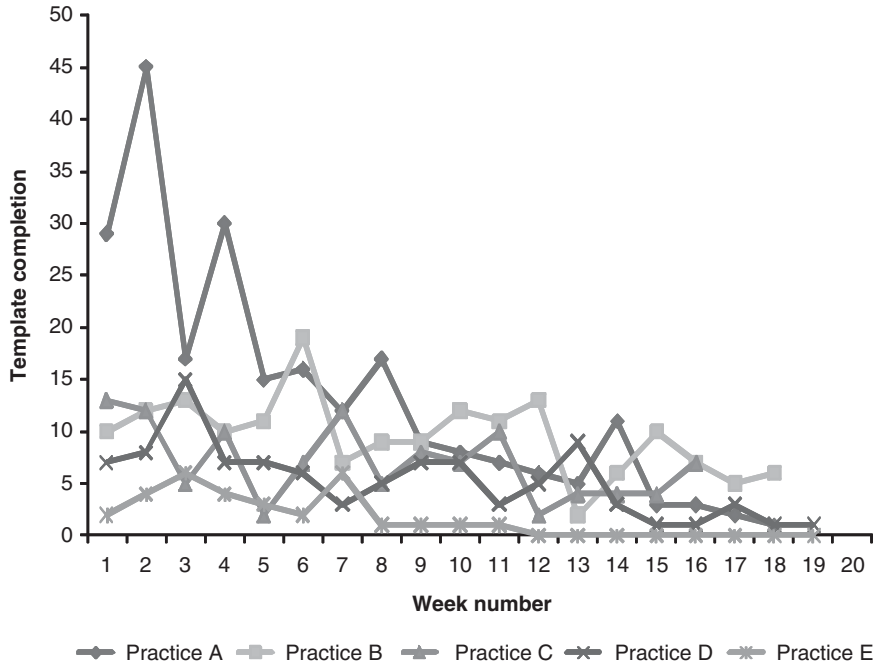

Figure 2 Rates of recruitment by practices over time in the PROG-RES study

Results

The 44 participating GPs activated the pop-up electronic template 650 times during the recruitment period of between 16 and 19 weeks.

Template completion was highest during the first month of the study and tailed off dramatically towards the end of the recruitment period (Figure 2). Almost 40% of recruitment occurred in the first four weeks and greater than 95% was completed within 16 weeks.

Most practices (A–D) completed electronic templates at a similar rate (1.61–1.86 templates per 1000 registered patients) and one practice (E) completed templates at a substantially lower frequency (0.76; Table 2). This practice had similar demographics to the others but had internal administrative difficulties during the recruitment period.

Of the 650 activated templates, 502 participants completed the baseline questionnaire and of these 428 also gave permission to access their medical records. Completion of individual items ranged from 98% (duration of pain) to 83% (anhedonia). Complete research data, that is, responses to all seven items, was recorded in 271 patients (63.3%); only 4% of patients had three or fewer responses recorded. There was some variation in the completion of individual items and the degree of complete research data across practices (82–42%). Moreover, there was a slight reduction in the amount of complete research data collected over the recruitment period – 70% in the first four-week period compared with 48% of the fifth four-week period, although this last figure was only based on 27 individuals.

Discussion

Summary of main findings

Although the number of pop-up templates completed by GPs reduced substantially towards the end of the recruitment period, which was relatively short, we were able to recruit the anticipated numbers of patients within the allocated time frame. Four of the five practices recruited at a similar frequency; the lowest recruiting practice had a similar demographic to the others but had internal difficulties during the study period that

Table 2 Recruitment rates and completion of research data collected

	Practice code					Total
	A	B	C	D	E	
Recruitment						
Period of recruitment (weeks)	17	18	16	19	17	
Templates completed (*n*)	236	172	112	99	31	650
Templates completed per 1000 registered patients aged 50+ years per week	1.86	1.69	1.61	1.78	0.76	
Research data collection						
Baseline responders who also gave permission to access medical records	159	112	76	63	18	428
Number of items completed						
7	131 (82%)	59 (53%)	32 (42%)	38 (60%)	11 (61%)	271 (63%)
6	22 (14%)	34 (30%)	25 (33%)	15 (24%)	7 (39%)	103 (24%)
5	3 (2%)	6 (5%)	7 (9%)	4 (6%)	0 (0%)	20 (5%)
4	2 (1%)	10 (9%)	3 (4%)	3 (5%)	0 (0%)	18 (4%)
3	0 (0%)	1 (1%)	0 (0%)	2 (3%)	0 (0%)	3 (1%)
2	1 (1%)	2 (2%)	4 (5%)	0 (0%)	0 (0%)	7 (2%)
1	0 (0%)	0 (0%)	5 (7%)	1 (2%)	0 (0%)	6 (1%)

affected recruitment. High completion level for the data collected during the consultation was seen overall, although, as expected, there was fluctuation between practices and over time. The measures taken to enhance participation to achieve the required recruitment numbers and collect research data within a regular primary care consultation in PROG-RES were highly successful. We suggest that this be taken forward as a model for efficient recruitment and data collection in future studies based in primary care.

Strengths and weaknesses of the study

The study recruited to time and demonstrated several techniques that in combination may lead to successful recruitment of patients and GPs to research studies in primary care. These recruitment techniques are interdependent and it is impossible in this study to isolate the single most successful component in the whole recruitment strategy.

Others have emphasised the importance of a pilot study to help guide the numbers that can be feasibly recruited (McCarney *et al*., 2002; McDonald *et al*., 2006). In PROG-RES, the number of eligible patients was not estimated by a pilot study but through the use of existing electronic consultation data, a method that this study has shown can produce accurate estimates: estimated number of templates 636 and observed number of templates 650.

The general practices taking part in this study were members of a long-time established primary care network and, as such, are not representative of all general practices in the United Kingdom. Developing and supporting a research network of GPs is time consuming and requires considerable effort to ensure consistent data quality but, as shown here, can be a contributing factor to successful patient recruitment (Porcheret *et al*., 2004). Carrying out a feasibility study enables the researchers to make informed decisions regarding the number of practices needed and the likely length of recruitment period, the latter of which is vitally important to the participating clinicians. The use of pop-up computer prompts at the time of consultation acted not only as a reminder for the GP that the patient was suitable for the study, by reinforcing the inclusion/exclusion criteria for the study, but also allowed real-time data collection at the time of the consultation. Moreover, the GP's administrative workload to recruit patients to the study is reduced as use of the template automatically stamps the patient's medical record, which the research team can then act upon.

The use of computerised record pop-up prompts requires highly skilled Health Informatics input, which is likely to be available for larger research units. Given the appropriate infrastructure and expertise, the use of this method of recruitment would be feasible to recruit patients

to larger multicentre studies and trials, providing a sound evidence base that could be used to inform the decisions of influential bodies such as the National Institute for Health and Clinical Excellence (NICE).

Because of the ethical constraints, we were only able to obtain information on patients for whom the template had been both activated and completed. Hence, the total population, that is, all the patients for whom the template was activated, was not known to us. However, we have some evidence to suggest that the gap between the total, unknown population and the observed population was not too great as the number estimated to consult in the feasibility study was very close to the number in the observed population.

Comparison to existing literature

The importance of motivated GPs to study recruitment must not be underestimated and has been emphasised by several authors (de Wit *et al*., 2001; Foy *et al*., 2003; Chew-Graham *et al*., 2007; Rendell *et al*., 2008). Both Chew-Graham *et al*. (2007) and Rendell *et al*. (2008) identified the perception of GPs that taking part in research increases workload; this was particularly evident when the GP ran a single-handed practice. Bower *et al*. (2007) noted in a review of randomised trials that if GPs were involved in obtaining consent only 12.5% of studies completed recruitment within 50% of the planned time period, whereas this figure rose to 61.5% when GPs were not involved in recruitment.

Other researchers have tested the methodology of electronic prompts in primary care studies (Rollman *et al*., 2007; Treweek *et al*., 2010a). In the study by Treweek *et al*. (2010a), the SARMA (Scottish Acute Recruitment Management Application) software system was installed on the GPs desktop computer and configured with the trial inclusion criteria. Suitable patients then triggered a pop-up on the computer screen, which allowed the GP to accept or decline the patient at the time of the consultation. If the inclusion criteria were achieved the patient was later contacted by the research team. The GPs participating in the study were reported to have found the pop-up 'user friendly' (Treweek *et al*., 2010a). In the United States, Rollman *et al*. (2007) devised a system whereby if anxiety or depression appeared in the problem list, the GP would 'click' a hyperlink to the research team who would then contact the patient, if thought suitable. The authors reported that the electronic system was an 'efficient recruitment tool', which led to a five-fold higher recruitment of non-white patients compared with their traditional case-finding method (Rollman *et al*., 2007).

The GP computer prompt system utilised to recruit patients to the PROG-RES study, triggered by the inputting of appropriate Read codes, has been used previously by the Keele Research Centre in both observational studies (Dunn and Croft, 2005; Foster *et al*., 2008) and RCTs (Hay *et al*., 2005; 2006; Hill *et al*., 2011). However, we believe that the PROG-RES study is the first example of the addition of real-time research data collection within the medical records.

Conclusion

The measures taken to enhance GP participation, achieve the required recruitment numbers and collect research data within a regular primary care consultation in PROG-RES were highly successful. We suggest that this be taken forward as a model for efficient recruitment and research data collection in future studies based in primary care.

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