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Title: Optimising primary care research participation: a comparison of three recruitment methods in data sharing studies

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Abstract

Aim

Recruitment of representative samples in primary care research is essential to ensure high-quality, generalisable results. This is particularly important for research using routinely recorded patient data to examine the delivery of care. Yet little is known about how different recruitment strategies influence the characteristics of the practices included in research. We describe three approaches for

recruiting practices to data sharing studies, examining differences in recruitment levels and practice representativeness.

Method

We examined three studies that included varying populations of practices from West Yorkshire, UK. All used anonymised patient data to explore aspects of clinical practice. Recruitment strategies were 'opt-in', 'mixed opt-in and opt-out', and 'opt-out'. We compared aggregated practice data between recruited and not-recruited practices for practice list size, deprivation, chronic disease management, patient experience and rates of unplanned hospital admission.

Results

The opt-out strategy had the highest recruitment (80%), followed by mixed (70%), and opt-in (58%). Practices opting-in were larger (median 7153 vs. 4722 patients, p=0.03) than practices that declined to opt-in. Practices recruited by mixed approach were larger (median 7091 vs. 5857 patients, p=0.04) and had differences in the clinical quality measure (58.4% vs 53.9% of diabetic patients with HbA1c <=59mmol/mol, p<0.01). We found no differences between practices recruited and not-recruited using the opt-out strategy for any demographic or quality-of-care measures.

Conclusion

Opt-out recruitment appears to be a relatively efficient approach to ensuring participation of typical general practices. Researchers should, with appropriate ethical safeguards, consider opt-out recruitment of practices for studies involving anonymised patient data sharing.

MeSH keywords: Family Practice; Primary Health Care; Research Subject Recruitment; Quality Improvement; Research Design; Electronic Health Records.

Background

For primary care to have effective impacts on patient and population health it needs to be based on sound evidence from high-quality, generalisable research. Yet primary care remains a difficult setting in which to carry out research, with particular challenges around achieving sufficient recruitment within limited resources. There are two main considerations when recruiting general practices to research studies: increasing participation rates; and improving sample representativeness.

Studies using anonymised electronic health records to identify suitable participants and assess outcomes offer a means of ensuring high participation levels. This technique has been used, for example, to predict health risks and assess quality of care[1-3]. While this is an efficient way to collect data there are recognised limitations in data quality. This method has also raised ethical concerns amongst patients and clinicians. The recent *care.data* initiative in the UK highlighted and perhaps amplified concerns about the use of anonymised data, despite assurances about how these data would be released[4]. The use of anonymised patient data and opt-out approaches to recruitment, whereby potential participants need to actively decline participation, offer potential advantages by maximising the ratio of recruitment yield to effort and resources. This means that opt-out data is a more appropriate use of limited research funding. It can include greater numbers of patients without some of the selection bias often associated with opt-in recruitment, and as such may be more representative[5].

Practices included in primary care research should ideally be representative of the wider population, in terms of patient population and practice characteristics. This increases confidence in the generalisability of findings. Where the study is examining quality of care, as presented here, the recruited practices should have representative levels of quality to promote external validity. Quality in primary care may be difficult to define, but is likely to involve a range of different indicators including clinical and patient experience measures. We have not encountered any previous work

that explores relationships between recruitment strategies in primary care studies and representativeness of recruited practices.

Objectives

We describe three approaches for recruiting general practices to data sharing studies and examine differences in recruitment levels and practice representativeness. We specifically focus on research which involves extraction of patient data (anonymised in our case) for analysis but which requires some type of approval or consent from the practice.

Methods

Setting and studies

The three studies compared in this analysis drew upon varying populations of practices in West Yorkshire, UK. The demographics of the 334 practices in West Yorkshire are broadly similar to the average characteristics of all practices across England, with the exception of higher levels of deprivation in West Yorkshire (Practice averaged Index of Multiple Deprivation (IMD) score 29.0 vs 21.8).

All three studies compared in this analysis used anonymised patient data to examine different aspects of clinical practice: the effects of incentivised case finding for depression in coronary heart disease and diabetes[6]; prescribing of opioids for chronic, non-cancer pain; and adherence to selected clinical guideline recommendations[7] (Table 1).

Each study examined quality improvement and assessed measures of quality of care. While the studies involved different clinical topics they were comparable in terms of the observational nature, no intervention or further actions required by recruited practices, and remote data sharing of

routinely collected anonymised records. Each study also had shared geographical boundaries and local health systems.

Recruitment strategies

Method 1: Opt-in. We included a one-off invitation to share anonymised data within the annual data sharing agreement from the then primary care trust. Practices that responded and agreed to participate were included in the study which examined the impact of financial incentives on depression case finding in patients with diabetes and coronary heart disease. There was no defined opt-in period; the annual data sharing agreement was mandatory and returned from all practices. The research consent was only completed and returned by practices which chose to take part in the study.

Method 2: Mixed opt-in and opt-out. Practices were approached with a combination of letters, emails and phone calls inviting practices to opt-in to sharing data on opioid prescribing in chronic, non-cancer pain. Despite this intensive approach involving three researchers over a 10 week period recruitment levels remained below target at 63%. Following discussion with the ethics committee, recruitment was changed to an opt-out method. Practices that had previously not responded were contacted again, explaining the change in recruitment and allowing them to be excluded from anonymous data collection. After a specified period of four weeks, practices that had not responded by phone, letter or email were included in the study.

Method 3: Opt-out. Based on previous experience of Method 2, an opt-out approach was used when contacting practices across West Yorkshire. Practices that did not opt-out of data sharing after four weeks by phone, letter or email had their anonymised data included in a study of the use of clinical guideline recommendations in routine care. Table 1 further describes these recruitment methods.

We developed the wording and format of the opt-out requests to practices in consultation with local clinical advisors to help ensure acceptability. Once included in the study practices did not need to undertake any further action as data were gathered remotely.

Outcomes

We assessed recruitment yield and representativeness of recruited practices according to demographic, structural and quality of care measures. Some practice characteristics have previously been associated with participation in research, including mix of GPs in the practice and patient demographics[5]. We selected three domains that reflect different aspects of quality in primary care: clinical quality, patient experience, and local service impact. We selected *a priori* one indicator from each domain.

Our indicator of clinical quality was taken from the Quality and Outcomes Framework (QOF). This national scheme incentivises adherence to evidence-based recommendations for clinical management, predominantly for long-term conditions. We selected an indicator from the 2012-13 QOF assessing the proportion of patients with diabetes mellitus where tight glycaemic control has been obtained (serum HbA1c less than or equal to 59mmol/mol). We selected this indicator as it has known wide variation in practice achievement and includes relatively high numbers of patients.[8] Incentive payments start at 45% achievement, with full payment if the target is met in 75% of patients. Patients with diabetes can be exempted from the QOF scheme for a variety of clinical and administrative reasons, but all patients were included in this analysis to reflect true population coverage.

Our patient experience quality indicator was from the national General Practice Patient Survey. Patients who have consulted with a clinician at their registered practice in the last 12 months may be selected to receive a postal survey about their experience. The survey includes a wide range of

questions about perceived accessibility, the consultation and their overall experience. These data are weighted according to local factors such as demographics to be more representative of the practice population. We selected a single indicator related to consultations with GPs as a measure of the quality of patient experience: the proportion of patients who rated their GP as good or very good on the item, "treating you with care and concern".

Finally, our local service use indicator of quality was defined as the unplanned hospital admission rate. This is an aggregated figure per practice from the Health and Social Care information Centre (HSCIC) Hospital Episode Statistics. With mounting pressure on acute hospital services, there is an increasing emphasis on reducing admissions, underpinned by an assumption that better quality of primary care management can prevent admissions.

Data collection and analysis

Only publicly available data aggregated at the practice level were used in this comparative analysis. We collated data including practice list size, number of GPs and Practice averaged Index of Multiple Deprivation, where IMD score is applied proportionally across the practice population[9].

Data from QOF achievement, national Patient Survey and Hospital Episode Statistics were obtained from HSCIC[10-12].

We compared characteristics and quality measures for practices recruited and not-recruited using each method. As this analysis used aggregated practice level data, simple comparative tests with assumptions made on the underlying distributions were not appropriate. For example, while two practices might have identical average IMD scores, one practice might have a similar level of deprivation amongst all patients, with little variance, while the other may encompass both highly deprived and less deprived groups. For this reason we compared recruited and non-recruited practices with Wilcoxon rank sum test and used Monte Carlo permutation sampling (with 10,000

permutations) to obtain estimated p-values and 95% confidence intervals. All data were collated and analysed using Stata version 12 (StataCorp LP, College Station, Texas).

Ethical considerations

Each study received National Health Service research ethics approval and was funded by the National Institute for Health Research. No patient-level data or study outcome data were used in this comparison of recruitment strategies. One author (RF) was principal investigator on all three studies and released information about practices that were approached and recruited using each recruitment method.

Results

The highest recruitment yield was with Method 3 (opt-out) (89 out of 111 practices; 80%), followed by Method 2 (mixed opt-in and opt-out) (110 out of 157; 70%), and Method 1 (opt-in) (64 out of 111; 58%; Table 2).

Practices recruited by opt-in were significantly larger (median list size 7153 vs. 4722, p=0.03) with more GPs in the practice (mean 5.3 vs. 4.2, p=0.03) than practices that declined to opt-in. Practices recruited by mixed opt-in and opt-out were also significantly larger (median list size 7091 vs. 5857, p=0.04) with higher numbers of male GPs (mean 2.6 vs. 2.0, p=0.02). We found no significant differences in deprivation and chronic disease prevalence for any recruitment method.

Practices recruited using Method 2 (mixed opt-in and opt-out) had a higher proportion of patients achieving the clinical quality target compared to non-recruited practices (58.4% vs 53.9% of diabetic patients with a HbA1c <=59mmol/mol, p<0.01). We found no significant differences between practices in local service impact or patient experience indicators for any of the recruitment methods.

Discussion

Opt-out recruitment produced the highest level of practice participation, with no associated difference in characteristics or measures of clinical quality between recruited and not-recruited practices. Lower participation levels and significant differences in practice characteristics occurred with both the opt-in and mixed recruitment methods.

Our study has five main limitations. First, we only examined three studies from one research group in one geographical area. As such, our findings should be regarded as exploratory and of limited generalisability. Second, our observed differences in recruitment could be related more to the varying characteristics of the three studies rather than the recruitment method itself, e.g. general practices could have been more (or less) motivated to participate in a study about opioid prescribing. However, all three studies shared common features, i.e. a focus on understanding or measuring professional behaviour, use of anonymised patient data, being led by the same research group with overlapping study catchment areas, and occurring within two years of one another. Apart from the clinical topics of interest, it might otherwise have been challenging to identify three more similar studies. Third, the absence of statistically significant differences between participating and non-participating practices in the analysis could in part be explained by limited numbers and precision. This is particularly the case in the comparisons where participation levels are markedly lower in any one group analysed. We analysed multiple variables and did not adjust for multiple testing in order to increase the sensitivity of our efforts to detect differences. Fourth, our comparators were imperfect. Measuring quality in primary care involves multiple factors [13]; previous studies used outcomes including guideline adherence, disease management, safety, and resources use[14-21]. Unplanned admission is a commonly used performance target in general practice and is used as a quality measure of local service impact in this analysis. However, there is evidence that patient factors influence unplanned admissions more than clinical practice[22]. Therefore, it is not

surprising that there were no differences in hospital admission rates between practices that did and did not participate in research, despite variations in practice demographics and clinical measures of care. We included total patient list size to account for potential capacity of infrastructure and ancillary staff, as well as GP workload. We acknowledge that this analysis cannot suggest which factors in large practices, compared to smaller practices, will influence the decision to opt-in to research. We still considered it informative to assess these outcomes to ensure that we explored a range of different markers. Finally, our comparison was limited by the absence of a cost analysis, as the data for this were not available. We have therefore been unable to quantify any efficiency gains of opt-out recruitment but would recommend future methodological work examining efficiency as well as representativeness.

Our findings are of direct interest to researchers working with similar integrated health care systems where primary care is based wholly or mainly on registered practice populations, such as the UK, the Netherlands and Canada. However, some elements of human, and hence professional, behaviour are universal; therefore the issue we addressed and the range of solutions are likely to be relevant to a wider audience.

Our analysis only focussed on studies of routinely collected data in general practice, but similar issues of recruitment and generalisability have been identified in interventional studies for chronic and acute illness in general practice[23]. These studies, along with ours, assume that greater recruitment increases representativeness, and therefore generalisability to the target population.

Our findings can be contextualised within the wider literature on research participation[24-26] by drawing upon the PRECEDE planning framework[27]. This framework recognises three types of factors can affect behaviour (in this case, general practices' participation in research). Predisposing factors include the knowledge, attitudes, beliefs, values and perceptions that motivate behaviour, for example, involving general practices in the selection of research questions and studies to ensure relevance, and highlighting potential benefits of research participation. Enabling factors facilitate

the performance of a behaviour, for example, active support from research staff to identify patients. Reinforcing factors include the rewards and feedback following adoption of a behaviour that encourage or discourage its continuation, for example, financial remuneration for patient recruitment and comparative feedback to practices on patient recruitment. We suggest that a balanced recruitment strategy should entail such a range of elements and that opt-out strategies mainly operate as an administrative enabling factor.

In data sharing studies using pre-collected data from networks or national recruitment schemes care must be taken to ensure that sampling is appropriate for the study question and population. Our findings provide some reassurance for researchers obliged to pursue 'opt-in' recruitment methods. However, we did find some interesting signals suggesting differences; it would be useful to explore these in further comparisons, ideally via experimental work. Whatever the recruitment method, we recommend that researchers report practice characteristics and comparisons with non-recruited practices, or demonstrate appropriate sampling of existing datasets to ensure representative samples.

Conclusion

Opt-out recruitment appears relatively efficient, producing a high yield for resource use in primary care data sharing studies. It resulted in a broadly representative sample and provided those practices which did not want to participate with opportunities to withdraw. Until better evidence emerges, we suggest that researchers consider opt-out approaches when gathering anonymised patient data from general practices.

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Disclosures

No conflicts of interest to disclose from any author.

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