RESEARCH ETHICS

Impact of privacy legislation on the number and characteristics of people who are recruited for research: a randomised controlled trial

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Background: Privacy laws have recently created restrictions on how researchers can approach study participants.
Method: In a randomised trial of 152 patients, 50–74 years old, in a family practice, 60 were randomly selected to opt-out and 92 to opt-in methods. Patients were sent an introductory letter by their doctor in two phases, opt-out before and opt-in after introduction of the new Privacy Legislation in December 2001. Opt-out patients were contacted by researchers. Opt-in patients were contacted if patients responded by email, free telephone number or a reply-paid card.
Results: Opt-in recruited fewer patients (47%; 43/92) after invitation compared with opt-out (67%; 40/60); (−20%; [−4% to −36%]). No proportional difference in recruitment was found between opt-in and opt-out groups varied by age, sex or socioeconomic status. The opt-in group had significantly more people in active decision-making roles (+30%; [10% to 50%]; p = 0.003). Non-significant trends were observed towards opt-in being less likely to include people with lower education (−11.8%; [−30% to 6.4%]; p = 0.13) and people who were not screened (−19.1%; [−40.1% to 1.9%]; p = 0.08). Opt-in was more likely to recruit people with a family history of colorectal cancer (+12.7%; [−2.8%, 28.2%]; p = 0.12).
Conclusions: The number of participants required to be approached was markedly increased in opt-in recruitment. Existing participants (eg, screening attendees) with a vested interest such as increased risk, and those preferring an active role in health decision making and with less education were likely to be recruited in opt-in. Research costs and generalisability are affected by implementing privacy legislation.

Over the past decade, privacy legislation relating to the use of health and personal information in research has been introduced in a number of countries.[1–4] Such legislation aims at providing greater protection to people who may previously have had information accessed by insurance companies, direct marketing groups, researchers and others, without their consent.

Most of the new laws are designed to prevent disclosure of personal information to a third party without permission, on the grounds that personal information should be used only by the entity to which it is given and for the purpose given. The boundaries of the entity and purpose, however, are often unclear and clinical and public health researchers, as well as the general public, may be confused by the overlapping roles of research and clinical practice. In practice, guidelines have been developed to help clinicians and researchers implement the new laws their interpretation may be overly cautious to protect against litigation.

In the US, researchers are allowed to review personal health information to identify but not to contact potential research participants.[5 6] Authorisation by the person is required and must specify the personal health information to be used or disclosed, to whom it is available and for what purpose, the right to revoke authorisation, view records, a disclosure of any compensation received by the covered person and a warning that once disclosed, the personal health information may not be protected.[1] It has been argued that such requirements are unnecessarily onerous for patients, clinicians and researchers and that they will hinder the conduct of clinical research.[1 5 7]

In January 2003, the UK Medical Research Council updated their guidelines for the use of personal information in medical research[2] after the introduction of the 1998 Data Protection Act and Human Rights Act. This guideline allows the possibility of disclosure of personal information without consent in some circumstances, including for research purposes. It is suggested that hospitals and practices develop procedures to make their patients aware in advance that their information may sometimes be used in research and that the benefits to society resulting from this disclosure outweigh the loss of confidentiality. But the disclosure of limited personal contact details for the purpose of contact by researchers, however, might be subject to legal challenge and many ethics committees are reluctant to approve such protocols. These guidelines and their corresponding legislation, similar to their US counterpart, have been accused of impeding epidemiological and clinical research.[8 9]

After the introduction of the new privacy legislation in December 2001, The National Health and Medical Research Council of Australia recommended that the person be made aware of the purpose for which information is being collected and that it should not be used for any other purpose without consent.[3] Disclosure of limited health information is permitted for the public good such as to cancer and infectious disease registries. Australian researchers, however, are facing difficulties in obtaining ethical approval to contact representative community samples under these requirements and are calling for flexibility in legislation to facilitate research.[10]

One of the few documented examples of the potential impact of privacy legislation on research has come from Canadian researchers who observed that the 2001 Personal Information Protection and Electronic Documents Act[4] may have contributed to selection biases in the Registry of the

Abbreviations: FOBT, faecal occult blood testing; SES, socioeconomic status

Canadian Stroke Network.[11] They estimated that the written consent requirements imposed by the legislation cost approximately $C500 000 in the first 2 years and an under-representation of fatal stroke cases on the register.

Although some discussion has taken place on the impact of privacy legislation on public health research, particularly the integrity and accessibility of deidentified data, there has been only very limited evaluation of the impact of privacy laws on the characteristics of patients recruited to research under the imposed restrictions. Woolf *et al*[12] showed in a cross-sectional survey that patients in an urban family practice centre who gave consent for medical record access to researchers were more likely to be old, of poorer health, male or African American. Ward *et al*[13] report on low response rates, an excess of healthcare workers in their sample and the potential for selection bias in recruiting community-based controls within a case–control study under UK ethical restrictions.

Although such descriptive studies raise the possibility of an association between new privacy laws and recruitment outcomes, evidence from a randomised trial evidence is required to document a causal relationship between the two.

We conducted a randomised trial comparing the effect of opt-in requirements in new privacy laws (2001) with an opt-out direct approach by researchers that was permissible previously. We measured the effect of opt-in requirements on recruitment numbers and on demographic and behavioural characteristics of the study sample.

METHOD

Setting and participants

Currently, Australia has no organised population-screening programme for colorectal cancer, but a pilot implementation programme was completed in October 2004. In late 2001, we started the pilot phase of a general practice-based randomised trial to evaluate six tailored decision aids for screening of colorectal cancer by faecal occult blood testing (FOBT). The pilot study was carried out in a university-affiliated general practice in an outer suburb of Sydney, Australia. The practice database was used to identify all patients aged 50–74 years who were potentially eligible for FOBT screening according to the Australian Government guidelines.[14] Of 183 patients, 31 were excluded by their doctor because they spoke poor English, were nursing home residents, had dementia, serious mental or physical disability or a personal history of colorectal cancer.

Intervention

The 152 potential study participants were stratified into three age groups, 50–54, 55–64 and 65–74 years, for the purpose of testing the decision aids. A random sample of 60 people was generated by computer, reflecting the age distribution of the practice across the three strata. Participants were blinded to allocation, as they were not aware that there would be a different recruitment method imposed after the implementation of the privacy laws.

We had received a staged approval from the human research ethics committee for the pilot study that allowed for an opt-out recruitment protocol. The 60 participants from the pilot study received an introductory letter from their doctor, advising them that the practice was participating in our study and should they not wish to be contacted by the researchers they could advise the practice (usually by telephone) and their contact details would be withheld.

At around the time that the pilot study was being completed, new privacy legislation came into effect in Australia and our subsequent submission to the human research ethics committee for the main multicentre trial required a change to an opt-in recruitment protocol. The remaining 92 patients randomly selected from three age strata and also reflecting the age distribution of the practice were subsequently sent an introductory letter from their doctor advising them that the practice was participating in our study. This time, however, participants could be contacted by the researchers only if they returned a reply-paid card, contacted a free telephone number or emailed the researchers with their contact details. Recruited study participants were contacted by telephone by one of the research team and underwent a brief interview.

Outcomes

Deidentified age, sex and postcode details were available from practice records for all 152 eligible participants. Further information could not be obtained about eligible participants who did not opt in or who chose to opt out.

Participants were allocated their corresponding area-based score of relative socioeconomic disadvantage Socioeconomic Index for Area; based on the Australian census data.[15] As the distribution of postcode scores within the practice sample was skewed toward the higher socioeconomic status (SES) quantiles, low SES was defined as being below the 75% quantile. Educational status was designated as low if the highest level achieved was $\leqslant$16 years. If the participant lived alone this was also noted. Health status was measured by self-report as poor, fair, good, very good or excellent. This was dichotomised by combining poor and fair self-ratings.

Further information was available on those who were recruited. Details of a family history of colorectal cancer were obtained from participants to verify eligibility for FOBT screening, along with screening history of colorectal cancer, a willingness to be subjected to FOBT screening and a preferred role for participation in health decision making (Degner).[16] People were designated as wanting an active role if they stated a preference for shared or more active participation (Degner roles A–C: patients want total control over health decision making, the final say after considering doctor's advice or to share the decision equally with their doctor, respectively).

The proportion of people recruited was compared between the two arms of the trial. Proportions were also compared in subgroups defined by age, sex and SES, and subgroup differences were tested for heterogeneity using the Breslow–Day test. The remaining characteristics were compared between participants recruited in the two study arms. All authors were involved in the analysis of results.

Ethical approval

The University of Sydney Human Research Ethics Committee approved both opt-in and opt-out recruitment strategies.

RESULTS

Table 1 shows the study participant characteristics (n = 152).

Table 2 shows the effects of age, sex and SES on the participants of both the study groups.

Table 1 Characteristics of opt-in and opt-out participants at baseline (n = 152)

Characteristic	Opt-in (n = 92)	Opt-out (n = 60)	p Value
Age distribution in years (%)			
50–54	30 (32.6)	20 (33.3)	0.99
55–64	40 (43.5)	26 (43.3)	
65–74	22 (23.7)	14 (23.3)	
Sex, male (%)	29 (31.5)	24 (40.0)	0.30
SEIFA score below 75% quantile (lower socioeconomic status)	12 (13.0)	8 (13.3)	0.96

SEIFA, Socioeconomic Index for Area (score of relative socioeconomic disadvantage). Provided by the Australian Bureau of Statistics.

Table 2 Effect of opt-in and opt-out on proportion of participants recruited by age, sex and socioeconomic status

	Opt-in (n = 92)	Opt-out (n = 60)	p Value
Age in years (%)			
50–54	12/30 (40)	10/20 (50)	0.49
55–64	22/40 (55)	21/26 (80.1)	0.03*
65–74	10/22 (45.6)	9/14 (64.3)	0.27
Sex			
Male	13/29 (44.8)	17/24 (70.1)	0.06
Female	31/63 (49.2)	23/36 (63.9)	0.16
SES			
Low	6/12 (50)	4/8 (50)	1.0
High	38/80 (47.5)	36/52 (69.2)	0.01*

SES, socioeconomic status.
Values in parentheses are percentages.
Each value is the number participating as a proportion of the number eligible from the sample.
*Significant at p = 0.05.

Table 3 shows the effect of opt-in and opt-out strategies on recruitment of characteristics of the recruited sample.

Primary outcome: recruitment

The opt-in recruitment method resulted in a smaller proportion of those invited actually being recruited (47% *v* 67%; fig 1). With the opt-out method, 6 (10%) people contacted the practice requesting that their contact details be withheld, 10 (17%) could not be contacted and 4 (7%) refused to participate when contacted. In contrast, with the opt-in method, 45 (49%) people did not opt in and 4 (4%) opted in but could not be contacted. Once opting in, all agreed to participate. Both methods recruited less people aged 50–54 years compared with underlying (baseline) samples.

We also explored whether those who opted in were more likely to subsequently stay in the decision aid trial and return a questionnaire. We found no significant difference in the proportion of people who returned their trial questionnaires subsequently between the participants recruited by opt-in and opt-out methods (opt-out 55%; opt-in 41%; difference −14% (−30% to 2%)).

Effect of opt-in on age, sex and SES

We found no evidence that the proportional difference in recruitment between opt-in and opt-out groups varied by age, sex or SES. (Breslow–Day test for homogeneity $\chi^2 = 0.76$, $p = 0.3$; $\chi^2 = 0.46$, $p = 0.5$; $\chi^2 = 0.86$, $p = 0.53$, for age, sex, SES, respectively.)

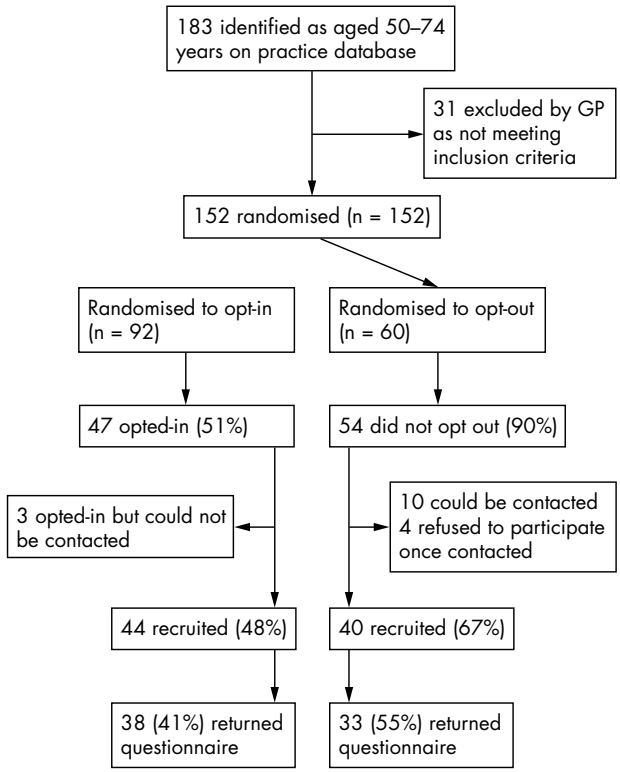

Figure 1 Flow diagram of opt-in compared with opt-out trial.

Demographic and general health characteristics of recruited samples

When considering the characteristics of the study samples that are ultimately recruited, we found no significant difference between the opt-in and the opt-out methods for the proportion of people living alone (25% opt-in *v* 20% opt-out; p = 0.73). We found a non-significant trend towards less people from lower educational background being recruited in opt-in compared with that of the opt-out (18.2% opt-in *v* 30% opt-out; p = 0.13).

Table 3 Effect of opt-in and opt-out strategies on recruitment of characteristics of the recruited sample

Outcome	Opt-in (n = 44)	Opt-out (n = 40)	Percentage difference (95% CI)
Lives alone	11 (25)	8 (20)	5% (−29.9% to 39.9%) p = 0.73
Finished education<16 years	8 (18.2)	12 (30)	−11.8% (−30% to 6.4%) p = 0.13
Self-reported fair or poor health	5 (11.4)	6 (15)	−3.6% (−18.1% to 10.9%) p = 0.65
Known to have a relative with bowel cancer	10 (22.7)	4 (10)	12.7% (−2.8% to 28.2%) p = 0.12
Not previously screened for colorectal cancer	18 (40.9)	24 (60)	−19.1% (−40.1% to 1.9%) p = 0.08
Willing to screen for colorectal cancer with faecal occult blood testing	41 (93.2)	34 (85)	8.2% (−5.1% to 21.5%) p = 0.11
Active decision-making role preference*	33 (75)	18 (45)	30.0% (10% to 50%) p = 0.003

Values in parentheses are given in percentages.
*Active role preference categorised by Degner roles A, B and C: patients want (A) total control over health decision making , (B) the final say after considering doctor's advice or (C) to share the decision equally with their doctor.

We found no difference between methods in the proportion of people who reported their health as poor (11.4% opt-in *v* 15.0% opt-out; p = 0.65).

Attitudinal and behavioural characteristics of recruited samples

The opt-in method resulted in the recruitment of a significantly higher proportion of people who preferred an active role in health decision making (75% opt-in *v* 45% opt-out; p = 0.003). The results also suggest that the opt-in method was more likely to recruit people who would be willing to undergo FOBT screening (93.2% opt-in *v* 85.0% opt-out; p = 0.11) and less likely to recruit people who had not been screened in the past (40.9% opt-in *v* 60.0% opt-out; p = 0.08). People with a known family history of colorectal cancer also seemed more likely to opt in (22.7% opt-in *v* 10.0% opt-out; p = 0.12), although these results did not reach significance.

DISCUSSION

This is the first randomised trial to measure the effect of new privacy laws on recruitment for research. It has shown that opt-in requirements markedly reduce the proportion of people ultimately recruited into a trial compared with the opt-out approach that was once commonplace. It has also shown that by increasing the number of eligible people approached to opt in, a demographically similar study sample can be obtained. Furthermore, a study sample recruited by opt-in is more likely to include active, preventive health-seeking participants and those with a personal motivation such as a higher risk. Opting in did not seem to have a different effect by age, sex or SES.

Smith *et al*[17] noted considerable variability in the recruitment of community controls in a large case–control study across socioeconomic areas in the UK. Our finding that opt-in methods tend to under-recruit people from lower educational background strengthens Smith *et al's* hypothesis by using a randomised trial design.

The sample size for this study was limited by the size of the general practice in which the study was undertaken and the ethical constraints arising from the implemented privacy legislation, with some of the observed effects not reaching statistical significance. Nevertheless, the trends reflect a consistent pattern across outcomes with a general picture that opt-in affects recruitment numbers and affects the educational and behavioural characteristics of the recruited sample. Given that the participating practice was university affiliated in a relatively affluent region and quite homogeneous the effects are probably an underestimate of those that may be found in the general community.

Under-representation of people from lower educational background has potentially negative implications for the generalisability of research, particularly where interventions and the measurement of their effect require a certain level of literacy. The accuracy of prevalence estimates of attitudes and behaviour may be compromised, as was noted by Woolf *et al*.[12] Such limitations come at a time when there is growing concern about information inequality, a digital divide within the community and low health literacy levels.[18 19] The ability to apply research findings within a range of literacy levels is of increasing importance and potentially compromised.

We increased the number of eligible participants approached by 50% to obtain a similar recruited sample size under the new privacy laws. Because of the university affiliation of the practice used, this may be an underestimate and this figure can also vary with the research question under consideration. We found that people with a personal interest in the research question because of a family history were more likely to opt in, and we were less able to recruit people who were eligible for FOBT screening. Trials relating to preventive health strategies may therefore incur a greater effect on recruitment by the privacy laws.

This is contrary to the Australian public opinion, which indicates that 76% of the community is interested in health and medical research with disease prevention programmes being the subject of greatest interest (43%).[20] Of those surveyed, 59% said they would be prepared to participate in a clinical trial, with only 8% indicating that concerns about security and confidentiality of personal health information was an important reason for them to not participate in research. Our results with opt-in methods on a preventive health topic are therefore inconsistent with those of this public opinion poll, although our opt-out results are more closely aligned. This suggests a mismatch between community values and research practice imposed by privacy laws and deserves greater scrutiny.

Although trials conducted with opt-in methods may prove to be internally valid, our results suggest that they are more likely to include participants who are active health decision makers and participate in preventive health behaviours such as screening. Thus estimates of behavioural outcomes, such as adherence to treatment and participation in screening programmes, may be inaccurate under opt-in requirements.

CONCLUSION

Privacy, including that of informational privacy, is a basic human right. Well-intended privacy legislation may not have been implemented in line with community views, particularly with regard to the use of personal information for health research. The concerns of the research community about the effect of privacy legislation on the conduct of clinical research may be well founded. A balance needs to be achieved between the person's right to privacy and the highest-quality research for the public good. It has already been suggested that access to data registries and medical records would be highly acceptable to patient advocacy groups.[9] This research shows that the characteristics of a study sample are affected by current implementation of privacy laws. It therefore highlights the need for greater debate on acceptable compromises to privacy legislation that would facilitate research for the benefit of the community.

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