What proportion of patients refuse consent to data collection from their records for research purposes?

RICHARD BAKER

CHRISTOPHER SHIELS

KEITH STEVENSON

ROBIN FRASER

MARGARET STONE

SUMMARY

In a randomised trial of the implementation of guidelines for asthma and angina, we sent questionnaires that included a request for consent to collect data from the patient's clinical records to 5069 patients in 81 general practices. Of these 3429 (67.6%) responded, of whom 335 (9.8% [95%, CI = 8.8%–10.8%]) refused consent. We conclude that consent should always be sought unless a research ethics committee has waived this requirement for pressing reasons.

Keywords: patient consent; general practice records; research; asthma; angina.

Introduction

THERE is professional consensus that consent must be obtained from patients prior to their inclusion in research studies, but there is less agreement when such involvement is restricted to collecting information from patient records. Since little has been reported on the proportion of patients who refuse consent to data collection from their general practice records, we report information from the first phase of a trial of the impact of guidelines on the management of patients with angina or asthma.

Although some believe that failure to seek consent is always wrong,[1] it has been argued that collection of data from records without seeking patient consent can be justified, provided certain minimal conditions are met.[2] In the United Kingdom (UK), National Health Service (NHS) organisations have appointed guardians to oversee the protection of patient information and the General Medical Council has issued strict new guidance on patient consent. The Royal College of Physicians has concluded that access to medical records requires neither patient consent nor independent ethical approval, provided that the patient's clinician has given consent, the recipient of the information is a senior professional, confidentiality is assured, and patient anonymity is maintained in any report of the findings.[3] The English Court of Appeal has recently ruled that the use of anonymised patient data does not breach confidentiality.[4]

R Baker, MD, FRCGP, director; C Shiels, BA, MPhil, research fellow; K Stevenson, MA, lecturer in clinical audit; R Fraser, MD, FRCGP, professor of general practice; M Stone, BA, PhD, research associate, Clinical Governance Research and Development Unit, Department of General Practice and Primary Health Care, University of Leicester.
Submitted: 6 October 1999; Editor's response: 2 February 2000; final acceptance: 15 May 2000.

Method

The trial took place in 81 volunteer practices. Random samples of patients aged 16 or above with either asthma or stable angina were identified in each practice. The Seattle Angina Questionnaire[5] was sent to patients with angina and the Living with Asthma measure[6] was sent to those with asthma, with a covering letter on practice notepaper explaining the purpose of the study, signed by their general practitioner (GP). Both questionnaires sought information about symptoms, enabling calculation of symptom severity scores from 0 (minimum severity) to 100 (maximum severity). The questionnaires also included questions about satisfaction with treatment, enabling the calculation of satisfaction scores on scales from 0 to 100.

A brief summary of the study was included in the covering letter from the GP. In addition, the questionnaires included a section informing patients that the study required additional information about their condition, collected from their records by nurses, and kept confidential. Patients were given the opportunity to withhold consent by marking a response box.

Results

Questionnaires were sent to 2679 patients with asthma and 2390 with angina. After a single reminder, 1719 (65.2%) patients with asthma and 1710 (71.6%) with stable angina responded, an overall response of 3429 (67.6%). A total of 335 (9.8%) refused consent to the collection of data from their clinical records (Table 1). There were no significant differences between patients who consented and those who did not for mean age, sex, severity of symptoms or satisfaction with care.

Discussion

We included a relatively large number of patients from a large number of practices, achieving a satisfactory response rate and good completion of the questionnaires. The findings have ethical and practical implications for the conduct of research. In particular, researchers should seek consent if data are to be collected from patients' records, and allowances should be made for the likely magnitude of refusal in calculating sample sizes. It should be noted that the findings concern the collection of data from patients' records and do not apply to the use of anonymised data.

The level of refusal of consent may be higher in other patient groups. This study involved only adult patients with angina or asthma, most of whom would be unlikely to regard information about their condition as particularly sensitive. The 9.8% refusal rate occurred among patients who had agreed to complete a questionnaire about their condition, and been reassured that the record review would be confidential and conducted by nurses. It is possible that the refusal rate would have been lower if the data collection had been undertaken by the patient's own doctor. Information about those patients who did not complete a questionnaire is not available, but it is likely that a similar — or higher proportion — would also have refused consent.

In conclusion, if researchers are to retain the trust of patients,

Table 1. Characteristics of patients and proportion withholding consent to record review (n = 3429; 16 patients with asthma and 33 with angina did not give information about age or sex).

Patient characteristics	Total n (%)	Patients with asthma n (%)		Patients with angina n (%)	
Refused consent	335 (9.8)	180 (10.5)		155 (9.1)	
95% CI	(8.8–10.8)	(9.1–12.0)		(7.7–10.5)	
		Consenting status		Consenting status	
		Yes	No	Yes	No
Mean age (years)		47.5	45.7	68.8	69.2
Mean severity score		33.8	32.1	38.8	38.3
Mean satisfaction score		79.1	77.0	85.0	85.1
Males n (%)		677 (90.1)	74 (9.9)	901 (92.0)	78 (8.0)
Females n (%)		849 (89.2)	103 (10.8)	623 (89.3)	75 (10.7)

individual consent should always be sought first before collecting data from records. The only exception should be when a research ethics committee has waived the requirement to seek consent for pressing and justifiable reasons.

References

1. Kale R. Failing to seek patients' consent is always wrong. *BMJ* 1997; **314:** 1081-1082.
2. Doyal L. Journals should not publish research to which patients have not given fully informed consent — with three exceptions. *BMJ* 1997; **314:** 1107-1111.
3. Working Group to the Royal College of Physicians Committee on Ethical Issues in Medicine. Independent ethical review of studies involving personal medical records. *J R Coll Physicians Lond* 1994; **28:** 439-443.
4. Richards T. Court sanctions use of anonymised patient data. *BMJ* 2000; **320:** 77.
5. Spertus JA, Winder JA, Dewhurst TA, *et al*. Development and evaluation of the Seattle Angina Questionnaire: a new functional health status measure for coronary artery disease. *J Am Coll Cardiol* 1995; **25:** 333-341.
6. Steen N, Hutchinson A, McColl E, *et al*. Development of a symptom-based outcome measure for asthma. *BMJ* 1994; **309:** 1065-1068.

Acknowledgements

We thank all patients who returned the questionnaires, and the volunteer practices. The study was funded by the NHS R&D Programme. The Clinical Governance Research and Development Unit is core funded by Leicestershire Health Authority.