Assessing the impact of the requirement for explicit consent in a hospital-based stroke study

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Assessing the impact of the requirement for explicit consent in a hospital-based stroke study

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Abstract

Background—Increasing regulation of medical research, in particular the requirement for explicit consent, may reduce the quantity and quality of clinical epidemiological research.

Aim—To assess the potential biases arising from the need for explicit consent in our hospital-based stroke research register.

Design—Comparison of patients enrolled into our stroke research register with those included in a concurrent clinical stroke audit that targeted the same population but did not require explicit consent.

Methods—We obtained the numbers of consenters, refusers, and those from whom consent was not sought for various logistical reasons. We compared characteristics of participants (those eventually included in the research register) versus non-participants.

Results—Of 1228 patients included in the stroke audit during an 18-month period, 1075 (88%) were also included in the research register, with higher participation among outpatients than inpatients. Only 1% of eligible patients refused involvement in any aspect of the research register. By far the largest number of non-participants was those from whom we could not seek consent for practical reasons. Comparison of baseline characteristics showed important differences between participants and non-participants that could affect outcome.

Conclusions—Very few patients refused inclusion in our research register, but the need for explicit consent reduced participation and introduced bias. An opt-out system avoiding the need for explicit patient consent for minimally intrusive clinical epidemiological studies would minimise bias and reduce the considerable time and costs associated with the consent process.

In recent years, medical research in the UK and elsewhere has become more and more regulated. In particular, increasingly stringent requirements for explicit consent from patients for the collection or use of their medical data for research have had a substantial impact on observational epidemiological research, increasing the time and resources required, and introducing the potential for ‘consent bias’.1 Thus, although designed to

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Author contributions: Caroline Jackson co-ordinated the stroke research register, carried out statistical analyses, prepared figures and tables, and wrote the paper. Laura Crossland checked and analysed data, helped to prepare figures, and commented on earlier drafts of the paper. Martin Dennis coordinates the stroke audit, contributed clinical and research expertise to the stroke register, and commented on earlier drafts of the paper. Joanna Wardlaw contributed neuroradiological and research expertise to the audit and stroke register, and commented on earlier drafts of the paper. Cathie Sudlow is principal investigator for and co-ordinated the research register, supervised data analyses and co-wrote the paper.

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protect individuals, requiring explicit consent may seriously reduce the quality and quantity of observational clinical research, with reduced benefits for society.

In the UK alone, there is an increasing body of complex legislation relating to the use of healthcare information (Table 1).2-8 Interpretation of the relevant acts of parliament is far from straightforward, and is made more challenging by the frequent introduction of new legislation, some of which differs north (Scotland) and south (England and Wales) of the border. The UK Data Protection Act 1998 makes exemptions from the need for explicit consent for some forms of medical research,5 while the Health and Social Care Act 2001 allows for the use of identifiable data without patients' explicit consent in particular restricted circumstances, but it applies only to England and Wales (not Scotland).2 Ambiguities in interpretation of the law and fear of legal actions have generally led to restrictive guidance by professional bodies (Table 1), so that explicit consent for observational research has become the default requirement for most regulatory bodies and research ethics committees, particularly for identifiable patient data.

Research involving patients unable to consent for themselves (e.g., because of dysphasia, cognitive impairment or reduced conscious level due to stroke), is particularly constrained by current legislation and guidance. Current UK legislation does permit proxy consent from relatives or legal guardians, but time and resource limitations can make this logistically challenging to obtain, and there is a lack of clear guidance on inclusion of patients for whom there are no substitute decision makers available. The Adults with Incapacity (Scotland) Act 2000, introduced early in the course of the research project described in this paper, does not allow for consent to participate in medical research by an impartial medical representative (waiver of consent) in these situations,3 but the Mental Capacity Act 2005 (England & Wales) permits such waiver of consent for research that is not ‘unduly invasive or restrictive’.4 In practice, the interpretation of the law currently resides with research ethics committees, and the onus has fallen on researchers to provide empirical evidence of the practical and scientific problems produced by the requirement for explicit consent.9

In this study, we were able to take advantage of a double standard in the UK, whereby explicit consent is usually required for observational clinical research but not for clinical audit.10 We assessed the impact of the consent process in our hospital-based stroke research register through comparisons with a concurrent clinical stroke audit, which did not require explicit consent. We sought consent not only for the use of clinical data for research purposes, but also to obtain a research blood sample and for follow-up by questionnaire, and so were able to assess patients' willingness to participate in non-intrusive - as well as in somewhat intrusive - aspects of our research register.

Methods

In our ongoing stroke audit, we collect data on process of care and key clinical variables on all patients with a stroke or transient ischaemic attack (TIA) admitted to - or seen in outpatient clinics at - an Edinburgh teaching hospital, with no requirement for explicit consent. Administrative and nursing staff in the audit team identify patients using comprehensive, multiple, overlapping, prospective and retrospective methods.

From October 2002 through March 2004, we collected additional data on patients from the same target population who consented to inclusion in our research register as well as from those whose data were not covered by the UK Data Protection Act 1998 because they died during admission. We used multiple, overlapping, prospective methods to identify patients, and discussed and clarified the clinical details and brain imaging findings of the patients included in the research register at a weekly meeting attended by stroke doctors and

neuroradiologists. A team of consultant geriatricians and neurologists, stroke registrars and stroke research fellows assessed the patients and sought consent from eligible patients during their time in hospital, with up to five such doctors involved in recruiting patients into the study at any one point in time.

Outpatients were given a brief, easily readable patient information leaflet describing the study, along with a short consent form, with time to read and consider these before the consultation with the clinic doctor. Patients who wanted further time to consider consenting for the study were given the option of returning the consent form to the study team by post. Inpatients (and / or their relatives) were provided with a similar information leaflet during their hospital stay, and given time to consider the information before being asked for consent. Patients gave signed consent, or - if unable to write but still able to understand - verbal consent signed by a witness. For patients with incapacity, we sought signed proxy consent from a relative whenever possible. We initially had research ethics committee approval for waiver of consent in some situations (patients with incapacity but no available proxy and patients who were seriously ill and died before consent could be sought), but the introduction of the Adults with Incapacity (Scotland) Act a few months after recruitment started meant that we could no longer recruit living, incapacitated patients with no available proxy. Patients (or their proxies) could consent to any or all of four subcategories, allowing us to: use their clinical data for research; obtain additional information from their family doctor; contact them in the future for follow-up by postal questionnaire; and store a sample of their blood for future genetic and other biological analyses. We obtained Multicentre Research Ethics Committee approval for the audit (as part of a Scotland-wide stroke audit) and Local Research Ethics Committee approval for the research register.

Numbers of consenters, refusers, and participants

For the period October 2002 through March 2004, we obtained the total number of patients with a stroke or TIA included in the audit. Of these, we determined the number who: were approached and gave consent for inclusion in the research register; refused consent; or were not approached for consent because they died in hospital before consent could be sought, were not identified prospectively by the stroke register, or were identified prospectively but not approached for consent for logistical reasons. Among consenters, we calculated the proportion with consent direct from the patient or from a relative. Among those from whom we sought consent, we calculated the proportion giving consent to each of the four consent subcategories. We defined and enumerated ‘participants’ as those included in the research register (i.e. those who gave consent and those who died in hospital before consent could be sought), and ‘non-participants’ as those not included in the research register (those who refused consent and those from whom consent was not sought, excluding those who died in hospital before consent could be sought).

Characteristics of participants versus non-participants

We assessed differences between participants and non-participants, comparing variables that had been collected by both the audit and the research register: age; sex; event subtype (cerebral transient ischaemic attack [TIA], eye attack [transient monocular blindness or retinal artery occlusion], or stroke classified according to the Oxfordshire Community Stroke Project syndromes11); socio-economic deprivation (using the Carstairs deprivation index12) and (for inpatients only) admission to stroke unit and length of stay. We performed statistical analyses with STATA (version 8.0). We analysed data for inpatients and outpatients separately, using the Mantel-Haenszel χ^2 test for categorical variables, and t-test for continuous variables. We adjusted for potential confounding by including all the variables in logistic regression models. We considered a p value of ≤ 0.05 to be statistically significant.

Results

Numbers of consenters, refusers, and participants

Of 1228 patients included in the audit and so eligible for the research register, the research register team prospectively identified 1199 (98%), and 1075 of the 1228 (88%) eventually participated in the research register (Figure 1). 1061 patients were approached for consent and we obtained consent from 1050 of these. 25 patients died in hospital before consent could be sought and were also included as participants. Of those from whom we obtained consent, 94% gave their own consent, and proxy consent from relatives accounted for the remaining 6%. There were 153 non-participants (12% of the 1228 patients included in the audit). Non-participants comprised: 11 of 1228 eligible patients (1%) who refused consent; 29 (2%) who were not identified prospectively by the research register but were picked up by the audit; and 113 (9%) identified by the stroke register but from whom consent was not sought (Figure 1). Reasons for not seeking consent from identified patients included discharge from hospital before consent could be sought by one of the research register team, and inability to meet with and obtain signed consent from relatives of patients who were unable to consent for themselves.

The proportion of patients from whom we sought and obtained consent was higher among outpatients than inpatients, resulting in higher participation rates in outpatients than in inpatients (697/731 [95%] vs 378/497 [76%], p<0.001) (Figure 2). Of the 1061 patients approached for consent, 1050 (99%) consented to use of their clinical data for research, 1048 (99%) to contact with their family doctor, 1031 (97%) to future direct contact for follow-up, and 1021 (96%) to storage of a blood sample.

Characteristics of participants versus non-participants

The characteristics of the 1075 participants and 153 non-participants are presented separately for inpatients and outpatients in Tables 2 and 3. Overall mean age was about 70 years, with approximately equal numbers of men and women, and no significant differences between participants and non-participants in age or gender. However, there were differences in other characteristics, particularly for inpatients, among whom participants were significantly more likely than non-participants to be admitted to a stroke unit (77% versus 45%, adjusted p value < 0.001), and to be more affluent (adjusted p value for trend across socioeconomic strata = 0.01). The unadjusted distribution of event type among inpatients also differed significantly between participants and non-participants (p = 0.001): participants had a smaller proportion of TIAs and eye attacks, a greater proportion of mild (lacunar or partial anterior circulation) strokes, and a slightly greater proportion of the most severe (total anterior circulation) strokes (Figure 3). However, the relationship became non-significant (p = 0.08) after adjusting for the other variables (Table 2).

Differences between participants and non-participants were less striking for outpatients, among whom the number and proportion of non-participants was small (34/731 = 5%) (Figure 2, Table 3). The only statistically significant difference (in both univariate and adjusted analyses) between participants and non-participants among outpatients was in the distribution of event type (Figure 3, Table 3).

The number of patients who refused consent (n=11) was too small to perform any meaningful comparison of characteristics with consenters.

Discussion

Our comparison between a stroke research register requiring explicit, written consent and a contemporaneous stroke audit not requiring explicit consent found that 88% of eligible

patients identified in the audit participated in the research register. A very small proportion of patients refused consent to be included in our research register (1% of those approached for consent, and < 1% of eligible patients); the main cause of non-participation was our inability to seek consent from 9% of eligible patients because of practical barriers. Almost all patients approached (99%) gave consent to use of their clinical data for research or contact with their family doctor, while only slightly fewer consented to questionnaire follow-up (98%) or storage of a blood sample for research analyses (96%). Consent rates were therefore very little affected by the additional request to obtain more intrusive data (questionnaire follow-up information and a research blood sample) not sought as part of routine clinical care. Thus, the logistical hurdles associated with the requirement to seek explicit consent, rather than patients' unwillingness to participate, was the main determinant of incomplete participation in the stroke register.

The very low refusal rate in our study would seem to reflect the willingness of this group of patients to participate in both entirely non-intrusive and somewhat intrusive aspects of observational clinical research. The refusal rate may have been minimised by the use of clear, brief, easily readable information leaflets and consent forms, and by consent being sought by doctors, on a background of good doctor-patient relationships. It may also partly reflect the patients' characteristics, including for example their age and cultural setting, as well as their perception of the seriousness of their condition and the need for research to improve our understanding of and treatments for stroke.

Contacting patients for follow-up by postal questionnaire and obtaining a blood sample would generally be considered intrusive. However, the very low refusal rates even for these components of our research register would suggest that the majority of patients in our study did not consider them an unwelcome intrusion. Indeed, with respect to the follow-up questionnaire, although not formally analysed for the purposes of this study, return rates were high (over 85% of questionnaires sent out were completed and returned), informal comments on the returned forms indicated that most patients and/or proxies were very happy that someone was interested in how they were getting on since their stroke, and only 4 patients (out of more than 1000 sent a questionnaire) asked that no further questionnaire be sent . With respect to blood sampling, although this is invasive, the risk of harm to the patient from the withdrawal of a small volume (a few mls) of peripheral venous blood is minimal. Furthermore, in a study such as ours, collection of a blood sample for research could quite feasibly be done at the same time as blood is taken for routine clinical investigations, minimising the invasiveness of this aspect of the study. We found evidence that the incomplete participation in our research register introduced potential bias, with important differences between participants and non-participants, which can mainly be explained by the practicalities of the consent process. Participants were more likely than non-participants to be outpatients, and so to have milder events, since it was relatively straightforward to seek consent from outpatients as a standard part of the clinic procedure, and more difficult to streamline the process for inpatients. Inpatient participants were more likely than non-participants to be admitted to a stroke unit (which we know from randomised trials leads to better outcomes13), reflecting the practical difficulties of obtaining consent from patients admitted to outlying wards in different parts of the hospital. The smaller proportion of TIA patients among participants reflects the difficulties in obtaining consent from patients with very mild events, who are often admitted to hospital for a short time only. The larger proportion of milder (lacunar and partial anterior circulation) strokes among participants compared with non-participants suggests that it was easier to obtain consent from patients with milder events, who were likely to be admitted for a long enough duration to be approached for their consent, and then to be able to consent for themselves, rather than having to wait for a relative to be available. The larger proportion of patients with very severe (total anterior circulation) strokes among participants could be

explained by their relatively high early case fatality11 coupled with our ability to include in the research register those patients who died in hospital before consent could be sought. Although there were statistically significant differences in the distribution of events among outpatients for participants versus non-participants, these did not follow an easily explainable pattern, perhaps because events among outpatients were mostly mild, and the number (n = 34) of non-participants was small.

Study limitations

First, the baseline characteristics that we could compare between participants and non-participants were restricted to variables collected by both the audit and the research register, using comparable methods and definitions. Second, we were unable to assess whether there were any differences in outcome between participants and non-participants, since patients identified by the audit are not routinely followed for further events.

Comparisons with other recent studies

Several other groups have reported on the practical difficulties of obtaining consent in various clinical epidemiological settings, important baseline differences between consenters and non-consenters, and serious outcome bias as a result of the requirement for explicit consent.1,14-17 One other study has investigated patient participation in a hospital-based stroke register. This was a multicentre Canadian study, in which the target population was all inpatient admissions for stroke15 The refusal rate (12% of eligible patients) was much higher and the overall proportion of eligible patients included (51%) much lower than in our study, even compared with only the inpatients in our register. These differences could have been due to: the added complexities of obtaining consent in a multicentre register compared with our single centre study; variation between the studies in the administrative demands of the consent process, and the resources available to meet them; research nurses rather than doctors seeking consent in the Canadian study; and perhaps cultural differences between the Scottish and Canadian populations. Notwithstanding the differences, the Canadian study also demonstrated that the practical difficulties in obtaining consent rather than explicit refusal was the main determinant of incomplete participation, and found differences between participants and non-participants in baseline characteristics and in-hospital mortality, suggesting that participants had milder strokes.

Conclusions and recommendations

Very few patients refused to be included in our stroke research register, but processes integral to the requirement for explicit consent reduced participation and introduced bias. Ideally, complete participation in observational research such as this is desirable to ensure that the results are representative of the target population studied, thereby avoiding the potential biases detected by our study and others. Consent bias is of course just one of a number of selection biases that may affect the generalisability of the results of observational research. However, the effects of consent bias cannot always be predicted or quantified. In the present study we were able to assess the potential for bias by comparison with a contemporaneous clinical audit, but in the current research environment the possibility of making such an assessment is increasingly unusual.

Although funding for clinically based research is limited,18 our study was reasonably well resourced, with administrative, secretarial, programming, research nursing and laboratory support, and help with recruitment from several consultants, specialist registrars and research fellows. A considerable proportion of these resources was required specifically for the consent process, although we did not formally record and quantify the time and costs involved. Limitless resources might have enabled us to seek consent from almost all of those eventually identified (both prospectively by the register mechanisms and subsequently via

the audit), but this would have been neither realistic nor cost effective. Indeed, we believe that the large amount of time and resources invested in obtaining explicit consent for the inclusion of patients in observational studies such as ours could be better invested in improving the quality and security of the data collected, better follow-up procedures, and in gaining more research insights from the data collected, for example through add-on projects. In addition, our anecdotal experience from encounters with large numbers of patients, as well as our personal experience of consent for clinical observational research,19 suggests that, for non-intrusive or minimally intrusive observational studies that could not conceivably be associated with significant harm, the rather cumbersome consent process itself can be an unnecessary intrusion in the clinical experience of vulnerable and often frightened people, inappropriately shifting the focus away from their needs and care. Indeed, we suggest that a system for clinical epidemiological studies in which all patients receiving medical care are given the opportunity to refuse use of their clinical data, medical records and clinical samples for research purposes, but explicit consent is not required, would minimise bias and reduce the time and cost associated with the consent process. Thus, consent would be implicit, and only patients specifically opting out would be excluded.

Allowing the use of implicit consent for more intrusive aspects of observational studies, such as follow-up by questionnaire or the use of blood samples (as in our study), might be regarded as controversial. However, a system of implicit consent (or often no consent at all) operates for the large amount of unsolicited ‘junk mail’ that most of us receive daily, and patients would be under no more obligation to complete and return a follow-up questionnaire than they are to respond to unsolicited marketing surveys. A requirement for explicit consent for taking additional blood samples for research purposes seems entirely appropriate, but implicit consent for the research use of small volume blood samples taken at the same time as those required in any case for clinical purposes would, in many cases, avoid the need for additional invasive sampling specifically for research purposes.

The appropriateness and mechanics of such an opt-out system would vary, depending on the patients, the disease and the study. Where considered appropriate, it would essentially require that the patient (or their proxy) be provided with an information leaflet detailing the information to be collected now and in the future (as is currently done in many hospitals with respect to the use of data for clinical audit), to allow an informed choice to be made at the time of clinical assessment or during hospitalisation, with a secure method for ensuring that the wishes of those who opt out are documented and respected. Studies would naturally still require scientific peer review and ethics committee approval, with full consideration of any risk to or ramifications for the patients, and would have to be performed in line with data protection laws and other relevant legislation.

A carefully designed opt-out system would not only increase participation and so reduce the potential for consent bias, but would also allow valuable and limited resources to be diverted from seeking explicit consent from potential participants and instead to improve the quality of, and increase output from, observational clinical research. Data on refusal rates and consent bias from studies such as ours, as well as studies demonstrating that research uses of identifiable clinical data without explicit consent are acceptable to patients and potential patients20, are needed to provide support for the view that more clinical observational research studies should be able to proceed without explicit consent.

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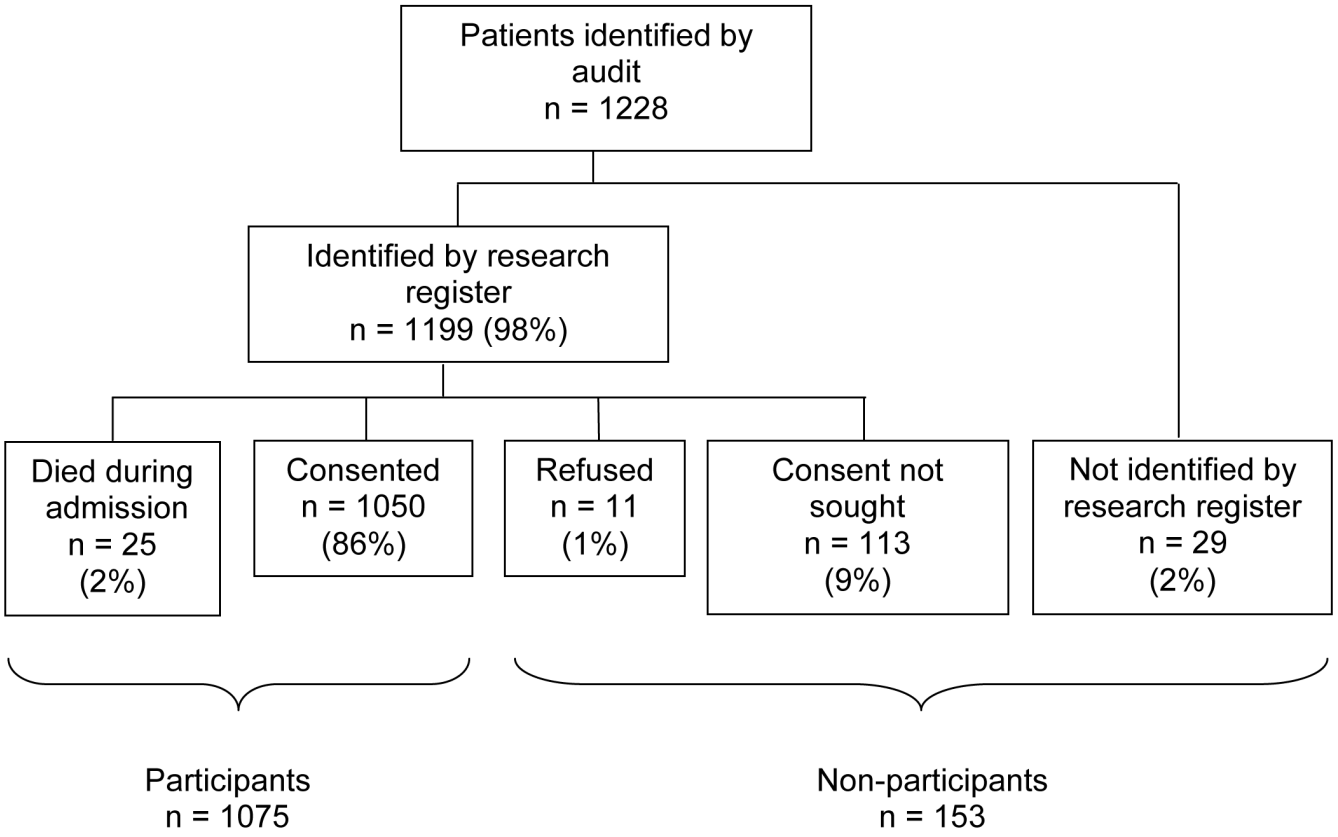

Figure 1.
Flow diagram showing participation and non-participation in the research register

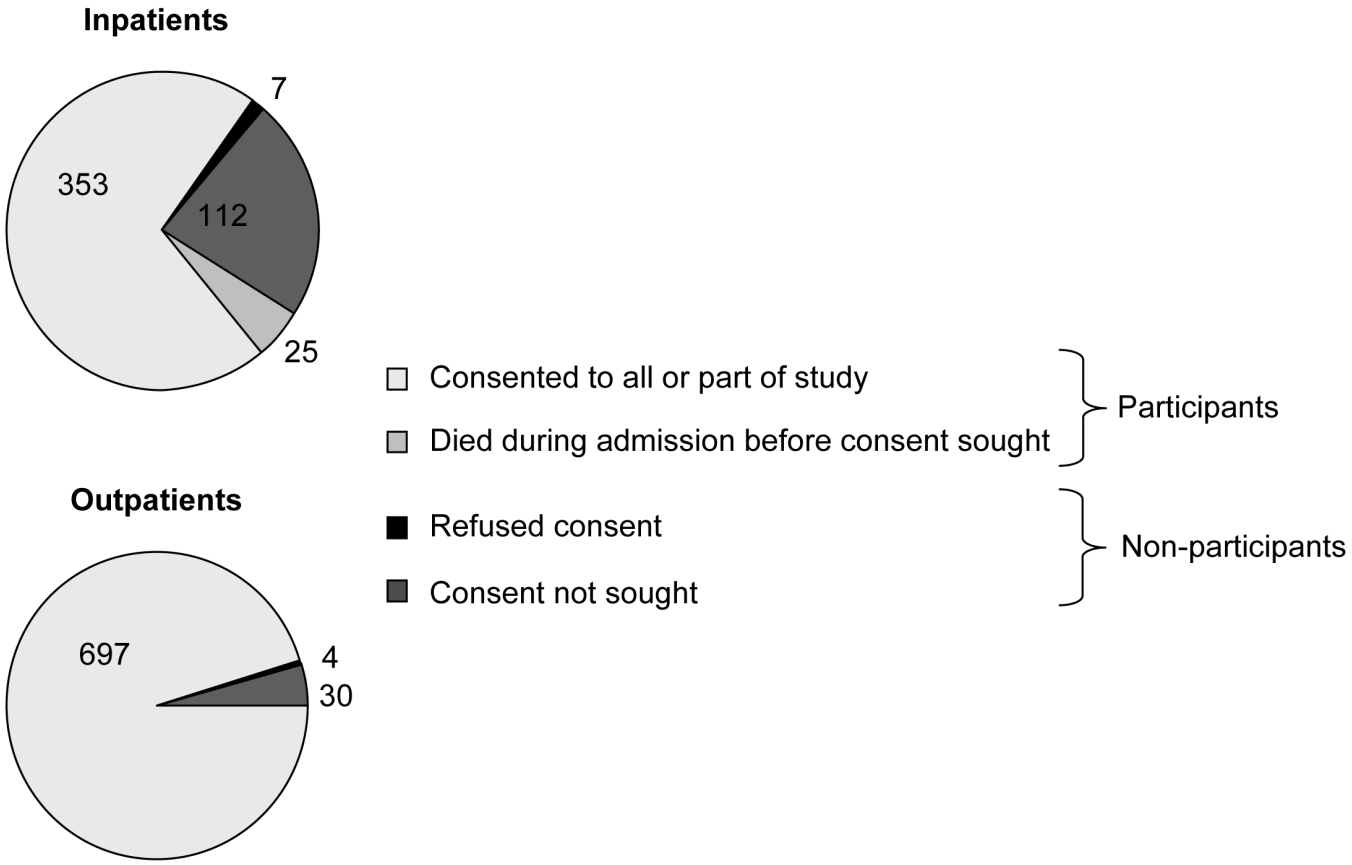

Figure 2.
Participation rates among inpatients and outpatients

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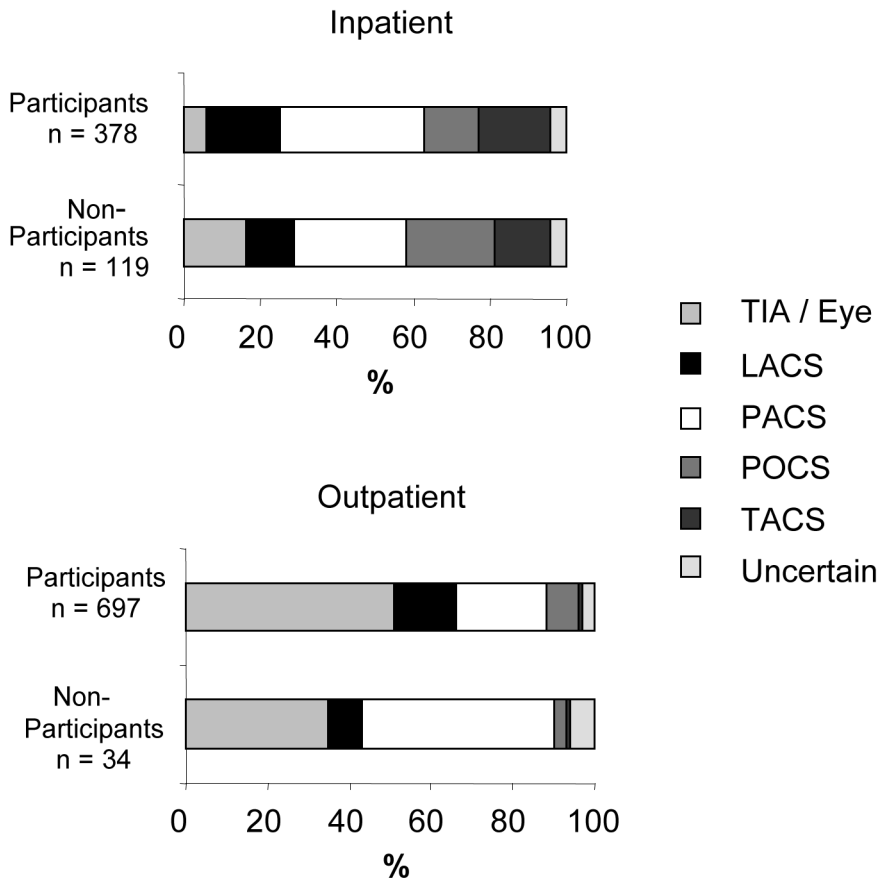

Figure 3.
Distribution of event type by participation, for inpatients and outpatients TIA / Eye = transient ischaemic attack or eye attack; LACS = lacunar stroke; PACS = partial anterior circulation stroke; POCS = posterior circulation stroke; TACS = total anterior circulation stroke; uncertain = uncertain stroke subtype

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Table 1

Statutory legislation and professional regulatory bodies issuing guidance relevant to observational epidemiological research in the UK

Statutory legislation
Health and Social Care Act 2001 (England & Wales)2
Adults with Incapacity (Scotland) Act 20003
Mental Capacity Act 2005 (England & Wales)4
UK Data Protection Act 19985
UK Human Rights Act (1998)6
Human Tissue Act 2004 (England & Wales)7
Human Tissue (Scotland) Act 20068
Professional bodies
General Medical Council
Confidentiality & Security Advisory Group for Scotland
Medical Research Council
British Medical Association
Department of Health and its Patient Information Advisory Group
Royal Colleges of Physicians

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Table 2

Characteristics of participants and non-participants among inpatients

Characteristic	All patients (N = 497) n (%)	Participants* (N = 378) n (%)	Non-participants† (N = 119) n (%)	Univariate p-value	Adjusted OR participants vs non-participants (95% CI)	p-value (LRT)‡
Mean age (years)	71	71	72	0.38	1.00 (0.98 to 1.01)	0.63
Male	226 (45)	176 (47)	50 (42)	0.39	1.00	0.24
Female	271 (55)	202 (53)	69 (58)		0.73 (0.46 to 1.16)	
Event type						
PACS	177 (35.6)	142 (37.6)	35 (29.4)	0.001	1.00	0.08
LACS	86 (17.3)	71 (18.8)	15 (12.6)		1.15 (0.57 to 2.32)	
POCS	81 (16.3)	54 (14.3)	27 (22.7)		0.63 (0.33 to 1.20)	
TACS	90 (18.1)	72 (19.1)	18 (15.1)		0.96 (0.49 to 1.89)	
Uncertain	22 (4.4)	17 (4.5)	5 (4.2)		1.07 (0.35 to 3.28)	
TIA / eye attack	41 (8.3)	22 (5.8)	19 (16)		0.34 (0.15 to 0.74)	
Socio-economic Deprivation score (n=495)						
1 (most affluent)	46 (9.3)	37 (9.8)	9 (7.6)	0.04≠	0.83 (0.72 to 0.96)	0.01
2	102 (20.6)	84 (22.3)	18 (15.1)			
3	93 (18.8)	71 (18.9)	22 (18.5)			
4	118 (23.8)	87 (23.1)	31 (26.1)			
5	85 (17.2)	62 (16.5)	23 (19.3)			
6	13 (3.8)	13 (3.5)	6 (5.0			
7 (least affluent)	22 (6.5)	22 (5.9)	10 (8.4)			
Length of stay (median days) (range)	17 (0-553)	17 (0-273)	17 (0-553)	0.976	0.60 (0.37 to 1.00)	0.05
Admission to stroke unit (n=495)	344 (69.4)	290 (76.9)	54 (45.4)	<0.001	4.21 (2.58 to 6.87)	<0.001

PACS = partial anterior circulation stroke; LACS = lacunar stroke; POCS = posterior circulation stroke; TACS = total anterior circulation stroke; TIA = transient ischaemic attack

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* Includes all consenting patients plus all patients who died soon after admission before consent could be obtained

† Includes patients who refused and from whom consent was not sought

‡ P-value of the log likelihood ratio statistic (comparing the model with and without the variable)

Test for trend

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QJM. Author manuscript; available in PMC 2008 October 17.

Table 3

Characteristics of participants and non-participants amongst outpatients

Characteristic	All patients (N = 731) n (%)	Participants* (N = 697) n (%)	Non-participants† (N = 34) n (%)	Univariate p-value	Adjusted OR participants vs non-participants (95% CI)	p-value (LRT)‡
Mean age (years)	70	70	69	0.36	1.02 (0.98 to 1.05)	0.63
Male	395 (54)	378 (54)	17 (50)	0.63	1.00	0.72
Female	336 (46)	319 (46)	17 (50)		0.88 (0.42 to 1.81)	
Event type						
PACS	172 (35.6)	156 (22.4)	16 (47.1)	0.03	1.00	0.02
LACS	110 (17.3)	107(15.4)	3 (8.8)		13.6 (1.01 to 13.2)	
POCS	55 (16.3)	54 (7.8)	1 (2.9)		5.3 (0.7 to 41.9)¶	
TACS	1 (18.1)	1 (0.1)	0 (0)		-	
Uncertain	23 (4.4)	21 (3.0)	2 (5.9)		1.0 (0.2 to 4.9)	
TIA / eye attack	370 (8.3)	358 (51.4)	12 (35.3)		3.2 (1.4 to 7.1)	
Socio-economic Deprivation score (n=495)						
1 (most affluent)	80 (11.0)	78 (11.3)	2 (6.1)	0.04#	1.10 (0.86 to 1.42)	0.45
2	131 (18.0)	120 (17.3)	12 (33.3)			
3	141 (19.0)	137 (19.8)	4 (12.1)			
4	191 (26.3)	182 (26.8)	9 (27.3)			
5	124 (17.1)	118 (17.0)	6 (18.2)			
6	41 (5.7)	41 (5.9)	0 (0)			
7 (least affluent)	18 (2.5)	17 (2.5)	1 (3.0)			

PACS = partial anterior circulation stroke; LACS = lacunar stroke; POCS = posterior circulation stroke; TACS = total anterior circulation stroke; TIA = transient ischaemic attack

*Includes all consenting patients

†Includes patients who refused and from whom consent was not sought

‡P-value of the log likelihood ratio statistic (comparing the model with and without the variable)

#Test for trend

¶POCS and TACS combined for purpose of regression modelling

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