

# “Cold calling” in psychiatric follow up studies: is it justified?

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**Background:** The ethics of cold calling—visiting subjects at home without prior appointment agreed—in follow up research studies has received little attention although it is perceived to be quite common. We examined the ethical implications of cold calling in a study of subjects with defined neurotic disorders followed up 12 years after initial assessment carried out to determine outcome in terms of symptoms, social functioning, and contact with health services. The patients concerned were asked at original assessment if they would agree to be followed up subsequently and although they agreed no time limit was put on this.

**Objectives:** To decide if cold calling was ethically justifiable and, if so, to set guidelines for researchers.

**Design:** The study was a cohort study of patients with neurotic disorder treated initially for 10 weeks in a randomised controlled trial.

**Findings:** At follow up by a research medical practitioner 18 of the 210 patients had died and of the remaining 192 patients 186 (97%) were seen or had a telephone interview. Four patients refused and two others did not have interviews but agreed to some data being obtained. However, only 104 patients (54%) responded to letters inviting them to make an appointment or to refuse contact and the remainder were followed up by cold calling, with most patients agreeing readily to the research interview. The findings illustrate the dilemma of the need to get the maximum possible data from such studies to achieve scientific validity (and thereby justify the ethics of the study) and the protection of subjects’ privacy and autonomy.

**Conclusions:** More attention needs to be paid to consent procedures if cold calling is to be defended on ethical grounds but it is unreasonable to expect this to be obtained at the beginning of a research study in a way that satisfies the requirements for informed consent. A suggested way forward is to obtain written consent for the research at the time that cold calling takes place before beginning the research.

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Ethical aspects of contacting patients enrolled in studies in which information is required repeatedly is a relatively neglected issue. Ideally the scientific and ethical aspects of such studies are equivalent, since equity and justice are observed, benefit is maximised, and harm is minimised. There is a tension, however, between the need to avoid loss to follow up by contacting as many patients as possible of those enrolled into a trial or epidemiological study, and ethical considerations, which allow a patient to withdraw at any time without prejudice, sometimes removing all their data from analysis. In such instances “ethical considerations should be paramount” and to do otherwise is not only unethical but could impair the quality of information, since a “coerced” patient may provide less accurate data than a cooperative one. There is evidence, too, that physicians in general are less than satisfactory in their following of ethical guidelines, and need firm advice on their conduct.<sup>2</sup> Problems are created, however, if the numbers of patients completing any investigation are too low to allow precise conclusions to be drawn, or the withdrawals result in biased conclusions. In these cases the studies themselves may become unethical, as the claims in the initial consent procedures to ask participants to engage in a scientific enquiry that will enhance knowledge are vitiated.

Because of this, attempts are often made both in randomised controlled trials and epidemiological studies in which there is repeated follow up, to improve the contact rate in various ways, using the initial consent of the patient to access information systems and obtain other information. For example, telephone numbers, to maintain contact and overcome potential difficulties (such as change of address),

changing names (getting married), and changing work patterns (shift work), that could impair contact at times of planned assessment. Although this approach, best termed anticipated consent as it is moving forward in time, has merits and certainly aids follow up rates<sup>3</sup> it can pose ethical difficulties. In obtaining consent for such investigations it has been noted that “the more that patients know before they are invited to participate in a trial, the better equipped they are to cope with the informed consent procedure”.<sup>4</sup> While this may be feasible for the initial phases of a trial it would be very difficult to achieve in a study that involved follow up at some time in the distant future.

This is relevant to arguments about the merits of “cold calling”, the practice of calling on people who have not formally agreed to take part in a research investigation but who have not actively refused, and, in some cases, have given anticipated consent. Those who disapprove of such a practice point to the possible infringement of liberty by such assertive behaviour, particularly when it is not accompanied by any benefit to the individuals concerned, and maintain that non-response to an invitation to be interviewed should be interpreted as passive refusal. An alternative view is that many who do not respond to letters or other forms of inquiry have genuinely expressed no opinion and therefore are open to further invitation. When these are taken together the second may take precedence over the first in the search for more complete data that enables more precise conclusions to be drawn.

We have recently completed a 12 year follow up of a group of patients with common anxiety and depressive disorders in which a high follow up rate was achieved, but only after cold

**Table 1** Comparison between initial and cold call responders for selected initial variables

Baseline variables	Initial responders (n=100)	Cold call responders (n=84) (%)	Summary statistics (95% CI)*	Statistic and p value**
Gender				
Male	29	30 (36)	1.0	$\chi^2=0.9$ , p=0.33
Female	71	54 (64)	1.36 (0.73 to 2.53)	
Personality disorder				
Present	35	29 (35)	1.0	$\chi^2=0.0$ , p=0.97
Absent	62	52 (62)	0.99 (0.53 to 1.87)	
NK	3	3 (4)		
Social class				Ns (except for social class 1&2 v rest)
1	6	1 (1)	1.0	$\chi^2=4.5$ (after Yates correction), p<0.035
2	13	5 (6)	0.32 (0.10 to 0.96)	
3	20	20 (24)	0.33 (0.11 to 0.92)	
4	34	33 (39)	0.34 (0.11 to 0.99)	
5	27	25 (30)		
Marital status				
Married	42	32 (38)	1.0	$\chi^2=1.3$ , p=0.52
Separated/divorced/widowed	29	21 (25)	1.05 (0.51 to 2.18)	
Single	29	31 (37)	0.71 (0.36 to 1.42)	
Initial treatment				
Drug	45	28 (33)	1.0	$\chi^2=3.8$ , p=0.15
CBT	34	40 (48)	0.53 (0.27 to 1.02)	
Self help	21	16 (19)	0.82 (0.36 to 1.83)	
Initial diagnosis				
GAD	36	27 (32)	1.0	$\chi^2=2.0$ , p=0.37
Dysthymia	25	29 (35)	0.65 (0.31 to 1.35)	
Panic	39	28 (33)	1.04 (0.52 to 2.11)	
Age at entry				
<20	5	4 (5)		1.26 (-2.11 to 4.63) $t_{180}=0.74$ , p=0.46
20-29	28	26 (31)		
30-39	30	29 (35)		
40-49	25	15 (18)		
50-59	8	7 (8)		
60+	4	3 (4)		
Mean	35.9	34.6		

\*Odds ratios or differences between means, reference categories indicated with OR=1.0.  
\*\* $\chi^2$  for binary and categorical variables,  $\chi^2$  for trend for ordinal variables; t test or Mann-Whitney test for continuous variables.  
CBT, cognitive behaviour therapy.

calling. The ethical and practical implications of cold calling are discussed in the light of the findings.

## METHOD

The main purpose of the study, part of the Nottingham Study of Neurotic Disorder, begun in 1983,<sup>5</sup> was to follow up and record the clinical, personality, and social status of a cohort of 210 patients with dysthymic, generalised anxiety or panic disorders (diagnosed originally using a structured interview) (SCID (structured clinical interview for DSM-III))<sup>6</sup> who were seen at general practice psychiatric clinics over 46 months between 1983 and 1987. The subjects were randomly allocated to drug treatment, cognitive behaviour therapy, and self help. The main hypotheses were that personality diagnosis is more important than clinical diagnosis in predicting the outcome of neurotic disorder and that outcome is independent of the mode of treatment.

Information had already been collected on eight occasions between baseline and two years<sup>5,7</sup> and assessment by notes alone at five years.<sup>8</sup> Patients had given consent for the initial study and for follow up interviews, although the frequency of these was not specified at baseline since funding was uncertain. At 12 years it was felt important to get as good a follow up rate as possible, particularly as those with personality disorders had been found to be more likely than others to drop out of care,<sup>9</sup> and a differential drop out could complicate interpretation of the findings.

## PLACE OF COLD CALLING IN FOLLOW UP PROCEDURE

The procedure used to contact patients on the 12th anniversary of their inclusion in the study was as follows:

- standard letter written to last known address inviting a follow up appointment. If the patient chose refusal of contact in their response no further action was taken;
- if the patient replied positively within four weeks a follow up appointment was made;
- if no reply or patient thought to have moved the family health service authority (FHSA) was contacted to determine any change of address;
- if no reply, and original address thought to be correct, a second copy of the standard letter was sent with a handwritten letter, explaining the project again;
- similar approaches made to new addresses of patient if thought to have moved;
- if no response made the patient was either telephoned or called upon without prior appointment to see if patient was still living at the address and to introduce the project. If the patient agreed the follow up interview took place at this time, and if the patient refused, no further action was taken.

Phase (f) of this procedure is cold calling, and was only used when no other contact had been established with the patient and all letters (which included stamped addressed envelopes on every occasion) had failed to be returned.

## ANALYSIS

To identify if there were any inherent characteristics between those who responded and those who were cold called a comparison was made between selected variables at baseline. It was essential to select variables as more than 100 of these were recorded in the study and there could be numerous chance associations. The ones chosen were a consequence of

**Table 2** Distribution of 84 patients who were cold called and summary of their responses

	Number of patients	Category of assistance (see coding below)*	Examples
Positive response to cold calling (n=58) (including 3 who were very positive)	45	0	
	4	1	patient was taking antidepressants irregularly (<1/day); advised to take prescribed dose and GP informed
	1	2	referral to CRUSE for patient who had unresolved suffering following bereavement
	3	3	assertive help to elderly patient living alone
	3	4	referral of patient to day hospital after first failing to attend because of agoraphobia
	2	5	error found in medical records in which patient confused with another one of same name with schizophrenia
	Neutral response to cold calling (n=16)	14	0
	2	3	patient reluctant to see researcher at first but later disclosed information about past abuse that had not been disclosed previously. Intervention viewed as a positive experience
Negative response to cold calling (n=10) (including 2 who were very dissatisfied)	8	0	
	1	3	patient very concerned about researcher examining GP notes but described many family difficulties at interview for which solutions were found
	1	5	patient subsequently became involved in antisocial acts and police contacted researchers about his dangerousness—reassured that this was unlikely and no further action taken

\*0 = not particularly helped, 1 = helped via contact with GP, 2 = helped by contact with voluntary agencies, 3 = helped by personal support at interview, 4 = helped by referral to mental health services, 5 = helped in other ways.  
NB: 17 (20%) gave information that was perceived as valuable to care. This compared with 6 (6%) of the 100 patients who responded to the initial referral letter and were not cold called.

the following hypotheses concerning “passive refusal” and the need for cold calling:

- (i) they would be more isolated than others and therefore would be more likely to be single, have personality disorders, and to be older at the time of inclusion in the study;
- (ii) they would be less likely to be in contact with health services.

In addition, the outcome in the two groups was analysed by initial diagnostic and treatment groups, although it was appreciated that in the case of diagnosis this would be of less significance at follow up because of the many changes in diagnostic status over time.<sup>10</sup> This led to seven variables being selected: age; gender; personality status (measured using the Personality Assessment Schedule (PAS))<sup>11</sup>; social class; marital status; initial treatment, and diagnosis (using SCID).

## RESULTS

Two hundred and three of the 210 patients had follow up information after 12 years. Eighteen had died and information about cause of death obtained, and 184 patients were interviewed, 4 by telephone. Eighty four of these (46%) were cold called. The differences between those who replied and had planned assessments and those who were cold called are shown in table 1. No significant differences were shown in any of the variables, with only social class showing a possible trend, with those of higher social class being more likely to respond to the initial invitations than others ( $p=0.09$ ).

Of those that were cold called an assessment of the response to the visit was made by HS. In several instances, the visit was welcomed enthusiastically despite no indication that this would be the case in advance. On other occasions, the reception was negative, but these were less common than the welcoming responses, and on several other occasions (see table 2) a positive intervention was made as a consequence of the assessment. One patient agreed to be interviewed in full but subsequently withdrew from the study because she took exception to the way in which her whereabouts had been identified. The high follow up rate has allowed firm conclusions to be made about the main hypotheses tested and

has been particularly relevant in interpreting evidence that personality status changes over a long period of time.<sup>12</sup>

## DISCUSSION

The key question posed in this paper: “was cold calling justified in this and similar follow up studies?”, is difficult to answer. The proportion of interviews achieved after cold calling (97%) was excellent and clearly helps to validate the scientific results of the study, a conclusion that would have been doubtful if data collection had ceased because no further action had been taken with the 46% of subjects who did not respond to the first letter of invitation to be interviewed. This low response rate to the initial invitation is characteristic of long term follow up studies, and yet it could be argued that further attempts to follow up were unethical. It is instructive to give the arguments for both sides.

### Cold calling is an unethical practice unless consent is obtained from subjects in advance

The World Medical Association Declaration of Helsinki<sup>13</sup> makes it clear that participants in research studies are volunteers and the right “to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimise the impact of the study on the subject’s physical and mental integrity and on the personality of the subject” (clause B21). In order to ensure that these precautions are taken it is necessary for “the subject to be informed of the right to abstain from participation in the study or to withdraw consent at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject’s freely given informed consent, preferably in writing (clause B22).

Cold calling does not respect privacy. It takes the view that the failure to respond to a letter of invitation to take part in a study constitutes tacit compliance to become involved. Thus persistent efforts to contact people by a range of means can then be justified on the grounds that at no time has the subject refused to take part. This view has at its core the belief that “all subjects involved in a research study should be regarded as cooperating in the research until proved otherwise”. Such a belief runs counter to the notion of informed consent and is

indefensible. The only way in which cold calling can be justified under such circumstances is for all subjects to be informed at the time of original enrolment that at the time of follow up cold calling is being envisaged, and consent for this to be obtained. At each follow up interview consent needs to be obtained again (refreshed consent) in case circumstances have changed. The complaint that people cannot appreciate all these points at initial contact cannot be sustained; when full information is given to patients involved in clinical trials they are generally satisfied with the amount of information given to them.<sup>14</sup>

#### **Cold calling is ethical in the context of long term follow up studies provided that coercion is prevented**

This view is a more pragmatic one that takes account of the circumstances that are common to long term studies: (i) difficulties in predicting the exact timing and nature of follow up; (ii) unsatisfactory nature of informed consent in advance; (iii) uncertainty as to whether communications have been received, and (iv) changes in ethical practice over time. All these pose separate obstacles that would be insurmountable if agreement for cold calling had to be pursued in advance.

Very few investigators can predict the timing of a long term follow up study, mainly because of uncertainties over funding, the level of motivation of the researchers, and the obvious impact of initial results which may make follow up more or less likely and alter its frequency and timing. It would therefore be almost impossible to give anything more than a vague indication of the follow up at the time of initial enrolment to a study. Under such circumstances, the notion of informed consent to an inquiry that is hedged by many conditions constitutes a major problem. Geographical mobility is very common with psychiatric patients<sup>15</sup> and in our follow up study 132 (63%) of the total sample had moved address (with 11 (5%) moving to adjacent counties and 19 (9%) moving to distant counties (mainly Lancashire, Sussex, London, Cornwall, Wales, and Warwickshire), where interviews took place. One patient had also emigrated to Italy by the time of follow up. Forty three (20%) of the patients had changed their surnames over the 12 years (with three people changing their names twice and one five times), so identification of the individuals presented problems even before follow up began. One positive aspect of cold calling is to establish that a subject no longer lives at the address to which correspondence has been sent.

Changes in ethical practice are very frequent and informed consent obtained 12 years ago may be regarded as unethical now. The Nottingham Study of Neurotic Disorder was set up in 1983 and involved comparison of two psychological treatments with two drug treatments and a placebo control.<sup>5</sup> At that time there was no special ethical requirement to obtain consent for follow up even though it was referred to in the original consent obtained. There was some concern over the use of placebo medication in the trial and it was only after a personal letter of support to PT for a placebo control on scientific grounds by Richard Doll that the Nottingham ethical committee agreed for placebo to be included. Today this would have been regarded as unethical since clause 29 of the Helsinki declaration states that trials should not use placebos when effective treatments exist,<sup>13</sup> even though Richard Doll's views remain the same.<sup>16</sup> The trial, if carried out today, would probably not satisfy the requirements for equipoise now considered desirable to give ethical justification for randomisation.<sup>17</sup> Investigators could therefore be placed in the invidious position of having obtained informed consent properly at time A only to learn later that this consent was invalid as a consequence of developments by time B, an example of an unacceptable after the event analysis.

A final concern is specific to psychiatric patients and other vulnerable groups such as children and those with intellectual disability. Such patients are much more difficult to investigate

and treat in research trials, not least because of past ethical abuses, but also because they are generally more difficult to engage, maintain in treatment, and follow up than others. If we add the ethical dimension to these difficulties, and it is often brandished with enthusiasm by those who oppose research,<sup>18</sup> we disadvantage research in areas which are already under researched and this in itself could be regarded as unethical. It can be argued that until research offers a level playing field with "adequate representation" of all groups<sup>19</sup> it will be failing the health of those it aims to serve. As Doll concludes: "strict application of the declaration's principles would make a wide range of clinical, biological, and epidemiological research impracticable or invalid",<sup>16</sup> and this would include most follow up studies of psychiatric patients.

#### **Resolution of problem**

It is clear that there is limited room for compromise between these two positions. We suggest, however, that the following statement could satisfy the advocates of both:

Cold calling in follow up studies may be justified if there is reason to believe in advance that the population being studied is likely to respond poorly to correspondence and other conventional means of communication at the time of the follow up. If contact with a subject is made through cold calling, and agreement reached for the research to proceed, written consent from the subject, preferably witnessed, should be obtained before the research data are obtained. At the time of the original study the written consent should include agreement for cold calling if necessary and if this is not granted the subjects should be excluded.

A stricter requirement would be for an additional "cooling off period" after the second consent was obtained so that the subject would not feel pressured into interview at the time of cold calling.

We believe this satisfies the Helsinki requirements of respect for privacy and safeguarding the integrity of individuals involved in research and sets a standard that allows inclusion without exploitation. Studies that were planned long before the Helsinki agreement was reached cannot be expected, however, to have anticipated such requirements and in these cases the written agreement to participate in the research immediately contact has been made is deemed to be sufficient.

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## LETTER.....

### Why I don't believe in moral values: a comment on Culyer

In his paper, Culyer talks about “values” and “value judgments” in relation to equity.<sup>1</sup> He says: “The focus is on equity in the allocation of health care resources .... These are value laden questions because any idea of “equity” must embody value judgments about what it is that makes for a good society”. He says too: “Equity in health care policy, as in other arenas of policy, is a question of ethics and therefore of values”.

I disagree with this way of talking: it suggests a sort of “postmodernist” moral relativism. It sounds as if there might be, say, socialist beliefs which were vouched for by socialist values while conflicting moral beliefs might be vouched for by, for instance, liberal values. Relative to the values of yet other people and/or other cultures there will be—so it might seem—yet other moral truths. If there are socialist values, then why not socialist moral virtues and socialist moral truths?

Don't say that there are socialist values and, for instance, conservative values. Say, if you must talk of “values”, that socialists tend to value such and such and that conservatives tend to value something else or the same thing to a different extent. Say too that, regarding

any particular evaluation, the socialists might be right and the conservatives wrong and vice versa.

Ethics is not reducible to values. It is not even about values. It is true that it will rain next Thursday—and, if true, it will be true today—if it is the case that, next Thursday, it will rain. Truth is independent of what we value and of what our evaluations are. It is true that, say, we ought not wantonly to kill another human being if—and independently of what we value and of what our evaluations are—it is the case that we ought not wantonly to kill another human being.<sup>2</sup>

What we value and what our evaluations are might cause us to make and to believe particular statements but this will not affect the truth or falsity of the particular statements that we happen to make or happen to believe. I might thus be caused to say—and, perhaps, even to believe—that the Scottish international football team will, one day, reach the quarter finals of the FIFA World Cup. A more pessimistic person who is also a supporter of the Scottish team is more likely to be led by his “values” to deny and to disbelieve this. Often, those things which it is most in our interests to believe and those statements which,

most of all, we want to be true are what we find the most difficult to believe.

Things are not good or true or right because we happen to value them. If they are good or true or right, then we should value them highly but their truth, rightness, and goodness is not dependent on our evaluations. Consider, for instance, “tolerance” and “justice”. These are not moral “values”: they are moral virtues. We should be just in our dealing with other people and, in many circumstances, be prepared to put up with people and practices which we loathe not because we value justice and tolerance (and even if we do not) but because we are morally obliged to be just and tolerant. Justice and tolerance are morally good even if not absolutely so.

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