

Follow-up of heavy drinkers: reflections on methodological challenges with implications for longitudinal study design.

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ABSTRACT

Aims: To (i) describe ethical and consenting issues encountered when recruiting and re-contacting difficult to reach, heavy, drinkers participating in a longitudinal study documenting alcohol consumption, and (ii) propose strategies to inform future study design to minimise the impact of confounding factors e.g. attrition.

Data sources: (i) Longitudinal study records documenting recruitment success at NHS hospital clinics (in- and out-patient settings) in two Scottish cities (baseline and three follow-up interviews); (ii) questionnaires documenting demographic data, last week's or 'typical' weekly alcohol consumption and harm score. Study participants were 639 patients (345 in Glasgow, 294 in Edinburgh) with serious health problems linked to alcohol.

Discussion: Baseline recruitment exceeded targets but attrition at first follow-up interview was considerable (64.5%). Baseline alcohol consumption was not predictive of loss-to-follow-up. A variety of factors (linked directly to alcohol purchasing) impacted on attrition: e.g. adopting abstinence, severe intoxication at interview, deaths, selling of phone, change of address and incarceration.

Conclusions: Longitudinal studies employing personal telephone or address details to facilitate follow-up of heavy drinkers face considerable challenges to minimise attrition. A key mitigating factor is the employment of flexible and experienced interviewers. The anticipated and reactive strategies documented here have important lessons for future study costing, design and data collection. However, approaches advocated to facilitate follow-up must not compromise ethical tenets.

Introduction

The World Health Organisation link alcohol consumption to around 3.3 million deaths, or 5.9% of all global deaths (WHO 2014). Within Scotland reactive governmental responses have employed policy and fiscal change. Important adjuncts to the informing evidence base are data relating specifically to the consumption patterns of drinker sub-groups for this knowledge can usefully inform targeted interventions. However, the shortcomings of consumption surveys in accurately quantifying consumption overall (Bellis *et al* 2015), or for specific drinker subgroups, are well described (Catto and Gibbs 2008). Indeed, in Scotland, population consumption surveys fail to account for around one half of sold alcohol (Beeston *et al* 2014).

One population group, the heaviest drinkers, often described as a 'hard to reach' group, merits particular attention. It is estimated that they are responsible for around 60% of the total societal cost of Scottish alcohol consumption (Mohapatra *et al* 2010), yet, for many reasons, they are likely to be omitted from most population surveys. A chaotic or secretive lifestyle can exclude them from the sampling frame or they may actively avoid survey participation (Livingston and Callinan 2015); consequently their drinking pattern is often poorly described. While the argument for intervening to address alcohol misuse amongst these consumers may seem convincing, self-evidently considerable challenges exist for research attempting to monitor longitudinally the impact of an intervention on consumption.

One important challenge is loss of study internal and external validity through attrition. Published research does provide guidance. Desmond *et al* (1995) and Maddux and Desmond (1974) from their studies of substance abusers claimed that the most important researcher requirements to enhance follow-up success were: patience, persistence, time and travel. Coen *et al* (1996) provided a comprehensive overview of the management of their longitudinal five

year study involving face-to-face interviews with 785 participants with serious and persistent mental illness. Average re-contact rates of 95% were ascribed to a range of factors including participant engagement techniques, ingenuity and perseverance of interviewers. Similar advice is offered by Marel *et al* (2015) in a recent study involving four follow-up interviews (615 heroin dependent participants) of whom around two thirds completed all interviews.

This paper describes the methodological challenges faced during a longitudinal study involving Scottish heavy drinkers. Four follow-up interviews were timetabled approximately 6 months apart; two pre, and two post, intervention. The proposed intervention was the enactment in Scotland of the Alcohol Minimum Pricing Act (Scottish Parliament 2012) which intends to set a minimum unit price (MUP) for all alcohol sold. (One UK alcohol unit is 8 grams/10 ml of ethanol.) Data collection began in 2012 in Edinburgh and Glasgow (Scotland's two largest cities). However, due to legislative challenges, MUP was not introduced but with a view to increasing the evidence base around the consumption patterns of a difficult to reach drinking group, the study continued as planned.

Aims

The aims of this paper are to:

- (i) Describe the methodological issues encountered when recruiting and re-contacting difficult-to-reach, heavy, drinkers within a longitudinal study documenting alcohol consumption.
- (ii) Discuss strategies for incorporation into future study designs to minimise the impact of potential confounding factors e.g. attrition.

Specifically, we describe the recruitment approach and success at each phase of our study; baseline and three follow-up interviews. We outline the challenges encountered at each

phase including consenting, ethical considerations and issues specific to this particular drinking group. Finally we discuss strategies which may improve recruitment and retention through recommendations for future study design.

Design:

A longitudinal single cohort study documenting drinking behaviour of heavy drinkers interviewed on four occasions at approximately six monthly intervals.

Settings:

Cognisance of the reputation of heavy drinkers as a 'difficult to reach group' prompted the utilisation of contact points with health services to maximise recruitment. Ten National Health Service (NHS) sites in both Edinburgh and Glasgow; general hospitals, alcohol treatment inpatient clinics (detoxification) and alcohol treatment out-patient and day-patient clinics were involved. (See Black *et al* 2014). Specific NHS sites were allocated to each of four research interviewers. (Only two conducted the final two interviews. All were part time.)

Initially, we planned that all four interviews would be conducted face-to-face at NHS-linked premises within each city. However, due to the burden placed on participant travelling time and the administrative time costs of missed appointments, we made the decision to conduct the final two follow-up interviews by telephone.

Participants

Consecutive patients were initially approached by clinical staff for permission to be interviewed and the interviewer then met with the patient to discuss the information sheet and, if appropriate, obtain consent.

Recruitment was from NHS alcohol services outpatient and day-patient clinics and from patients admitted to hospital with a diagnosis of a physical or psychiatric alcohol-related illness. **Their heavy drinking was linked to physical or psychological harm.** Exclusion criteria were: being under 18 years old, unable to understand the questions or give understandable answers in English, evidence of clinically significant memory impairment e.g. Korsakov's Dementia, being unwilling to be contacted for three further follow-up interviews. Given the challenging circumstances faced by some participants and the potential for loss of contact, in addition to contact telephone number and postal address, we attempted to collect personal email addresses, further phone numbers and details of a secondary contact.

Before the first (face-to-face) follow-up interview a letter was sent to each participant thanking them for participation and providing a brief summary of study progress. It requested notification of any change in contact details, providing a reply paid form and envelope. Additionally, at this time, the decision was made to issue a £10.00 voucher ("High Street pharmacy retailer") on completion of the interview. Second and third follow-up interviews were conducted by telephone using the same contacting protocol. A £10 voucher was despatched on completion of each interview. After the final (fourth) interview a letter thanking participants was also included.

At baseline we noted the number and the time-point of refusals at all recruitment sites and, in later phases, the number of participants who withdrew from the study.

Measurements

Interviewers administered a questionnaire (Black *et al* 2011) documenting in detail participant's most recent seven days of drinking using the time line follow-back method (Sobell and Sobell 1996), or their most typical week. Interviews were not time-limited and interviewers were able to probe and clarify detail where necessary. Typically, questionnaire completion took around 30 minutes although out-patients tended to complete this process more rapidly than in-patients. Age, gender and postcode were documented, the latter acting as a proxy for socioeconomic status using the Scottish Index of Multiple Deprivation (SIMD) (Scottish Government 2012). Participants self-completed the Alcohol Related Problems Questionnaire (ARPQ), an eleven point questionnaire used to assess severity of alcohol related problems (Patience *et al* 1997). During the interview, participants self-reported any illness or condition associated with their drinking, usually partly or wholly connected to presentation at health care services. Ethical constraints prevented verification of self-reported illness with clinical notes.

Data were analysed using SPSS v19. Group differences were investigated using the Mann Whitney-U non-parametric test. Chi-square tests of association were employed for categorical variables. An alpha value of 0.05, two-sided, was considered significant.

Favourable ethical opinion was granted by NHS Lothian Regional Ethics Committee (REC reference 08/S1101/9) and approval was gained from the relevant Caldicott Guardians.

Findings

639 participants completed the baseline interview. (See Table 1 for refusal numbers, and Figure 1 which summarises recruitment and attrition relating to the study.)

Figure 1 here

Table 1 here

Two interviews were rejected once completed as the accuracy of the consumption claims was questionable. Furthermore, 11 interviews were found to be duplicates through subsequent checking of the database (the same participant had been interviewed by two researchers independently at two different NHS settings); the most recent interview being retained.

Particular methodological issues relating to baseline and follow up participation are summarised in table 2.

Table 2 here

Baseline refusals

Despite meeting the inclusion criteria, 161 men and 83 women refused when approached for participation in the study. Their gender ratio (male to female) was very similar to that of the final study sample (~2:1). See table 3 for details of location and point of refusal.

Table 3 here

Clinical staff declined on behalf of 20 patients they considered too ill. Other reasons (n=46) included uncooperative patients, those in denial about their drinking and abusive patients. Despite clinicians' referrals, interviewers exercised their professional judgement and respectfully and tactfully declined to interview patients they considered too ill to consent (n=7). Further reasons (n=20) were: because the patient seemed confused or upset, interviewers suspected inability to read the information sheet (and therefore consent form) and some were admitted under police custody.

It is noteworthy that those individuals identified as refusals still had considerable time and resources allocated to them. All potential participants were given time to consider the information sheet and the interviewer could return later that day or the following day for their decision.

During the baseline phase of the study, 35 deaths were notified.

First follow-up Interview.

Sixty eight participants declined to participate further with several volunteering they were currently abstinent and, understandably, did not wish to recall previous drinking episodes. Interviewers declined to re-interview four participants as they were considered too difficult to interview. Others with whom contact was made still proved difficult to interview as they did not remember the study, seemed confused or were drunk. For these participants, interviewers used their discretion about whether to attempt re-contacting. Additionally a number of participants contacted caused concern to interviewers (e.g. intoxicated with extremely low mood). Such participants were either immediately brought to the attention of local services in the case of face-to-face interviews, or for telephone interviews, contact was made with the relevant clinical staff for treatment/care or to notify out-of-hours emergency health services (with consent from the participant). Such participants were no longer included within the study for ethical reasons (captured in the refusals).

Our strategy to employ a 'thank you' letter after the completion of baseline interviews was valuable; 126 reply forms were returned with 24 indicating they did not wish to participate further (captured in refusals). New contact details were provided by 86 (usually a new mobile phone number). However, despite updated contact details, we were unable to

arrange follow-up interviews for 29 of these 86. Another 40 letters were returned by the Royal Mail marked 'addressee gone away', 'not known at this address' or 'address not accessible' (e.g. property boarded up). Another reason for loss to follow-up was incarceration; the precise number in this category was uncertain.

Neither ARPQ score nor baseline consumption was associated with attrition at first follow-up. Glasgow participants were less likely to be lost to follow-up than their Edinburgh counterparts ($p=0.002$) with Glasgow outpatients less likely to be lost to follow-up than inpatients ($p=0.001$). (See Table 4.)

Table 4 about here

Predictably, successful re-contacting of a participant and the subsequent arranging of time and location for a follow-up interview, did not guarantee their attendance. For Edinburgh a total of 65 participants (43%) 'did not attend' (DNA). For Glasgow this number was 90 (39%). Attempts were made to rearrange interviews, which was successful in a small number of cases but did incur considerable extra administrative costs.

We interviewed a total of 227 participants during the first follow up phase (64.5% attrition). A further 26 deaths occurred during this phase.

Second and third follow-up (telephone interviews)

Attrition was less of an issue at these interviews; 165 were completed at second, and 145 at third follow-up. Some participants failed to answer their phone, despite having agreed an interview time. Seven participants refused at second follow-up. In another five cases the interviewer did make contact but then ended the interview discretely as the interviewee was either challenging or drunk. There were no refusals at third follow-up; deaths within each of

these phases were, respectively, 11 and 15. Additional deaths were reported since interviewing was completed, a total of 105 to the end of the study, representing 16.4%, (approximately one in six) of those initially recruited.

Discussion and Conclusions

This study aimed to recruit 500 participants, in practice 639 heavy drinkers provided informed consent. Our experience was that some welcomed the interview, candidly discussing their purchases and heavy consumption of alcohol – so whilst they may be considered ‘hard to reach’, and retain within a study, they are not necessarily hard to engage.

The potential power of the clinician-patient relationship, subconsciously encouraging recruitment to clinically based studies, may be evident in our data; 54.1% (n=132) of all initial refusals occurred in patients who confirmed to their clinician their wish to receive further study detail but, on subsequently meeting the interviewer, declined to participate. We had assumed that the neutrality, non-clinical identity, of the interviewer would be beneficial, encouraging candour during the subsequent interview and improving the accuracy of drink recording. However, this benefit may be counterbalanced by reduced recruitment.

Attrition at first follow-up was considerable with 412 participants (64%) not interviewed. Despite initial interest in the study, a genuine willingness for future participation and our extensive efforts to re-contact people, two thirds of the sample were simply ‘lost to follow up’. Reasons were numerous; deaths (16% overall), a reluctance to discuss drinking as now abstinent or attempting to reduce consumption, loss or pawning of mobile phone, domestic issues linked to heavy drinking, chaotic lifestyles, change of address or phone number, incarceration, and mental health issues, particularly paranoia. At baseline 34 participants

(5%) self-reported paranoia. Significantly 60.7% of participants self-reported having a mental health illness at baseline and it is possible that this figure of 5% represents an underestimate. Paranoia could explain a reluctance to answer a call from an unfamiliar telephone number.

Our experience underscores the challenges faced by longitudinal study designs, especially where follow-up occurs in a different setting to recruitment and crucially involves an ill population. Undeniably, the potential for individual circumstances **to change** during the two year course of the study, is high. We did not capitalise on contacts with General Practitioners (GP), clinic staff or alcohol support workers to access those not responding to interview invitations. These agencies may have been helpful. However their involvement would place additional demands on over-stretched health services and, crucially, raise important ethical and practical issues. In this regard, our study methods contrast with published longitudinal studies. Coen et al (1996) highlighted the 'ingenuity and resourcefulness of the interviewers' (p316) noting how they became acquainted with boarding home operators, visiting residential facilities on pay and medication days. They also visited soup kitchens and shelter locations achieving average re-contact rates of 95% in each of five follow-up years. Cottler et al (1996) reported a 96.6% 18 month (fourth interview) follow-up rate and also collected 16 sets of details in their 'future contact form' which included social security and driving license numbers and name and contact details of lawyers and probation officers. They conducted interviews within prisons. Desmond et al's (1995) locator form detailed 21 items including social security number, driver license number, physical description (including tattoos), address of close female relative in addition to the address of a friend who could help to locate them. They achieved a follow-up interview with 98% of 610 opioid users. Scott (2004) argues that successful follow-up studies require contacts to be made 7 days per week, 12-15 hours per day and also advocates the approach to various institutions within the catchment area of the study where participants may reside during follow-up to facilitate future potential

access. Ten or fewer contacts were required to collect data from around one third of participants, with more than 30 contacts associated with a 90% completion rate. All of the above studies were conducted within the US. Recent Australian work with ex-prisoners recommends that, subject to cost constraints, researchers should adopt a study protocol that facilitates continued contact during follow-up (David et al 2015) but caution that whilst repeat telephone contact will improve the likelihood of responding, there is a tipping point beyond which telephone calls have a diminishing return. Alternatively, Parker et al (1995) discuss replacing 'lost' participants with new recruits.

Our strategies to minimise attrition were governed by the need to meet the criteria imposed by NHS Research Ethics Committee, the Caldicott Guardians and Data Protection concerns. Certainly study budget was a consideration, significant costs were associated with participation fees and interviewer time. However, the fine line which exists between the exploitation of a variety of routes to permit successful re-contacting of participants, and risking harassment, must be addressed and recognised within the study protocol. The failure to respond to a third interview invitation letter may be due to the relocation of a participant, selling of a mobile phone for needed funds or purposeful ignoring of it as they exercise a right to withdraw from the study 'without giving a reason'.

We have some evidence that our 'thank you letter' distributed at the start of the first follow-up period had a beneficial effect. We cannot gauge the impact of the shopping voucher but future studies must recognise the major expense associated with incentive payments. In their study (baseline plus two follow-up interviews over an 18 month period) of UK adolescent drinkers (n=540) recruited within schools, Boys et al (2003) reported 92% follow-up success. They provided gift vouchers (plus the opportunity to participate in two prize draws) at a total cost of over £20k but considered it justified given the cost of additional resources required to trace non-responders. Similarly Marel *et al* (2015) conducted a 3 year longitudinal study of treatment outcomes for heroin dependence (baseline plus 4 follow-up

interviews) and paid \$20 (Australian dollars) for completing each interview (n=615 participants). The study achieved a final follow-up rate of 70%.

Baseline alcohol consumption amongst our participants was not predictive of attrition, nor was gender or self-reported harm score. We were aware of changes to treatment services during the first follow-up period and the differences in attrition we found by city or type of patient may be artefacts. This makes an important point; unless the delivery of treatment services remains consistent across recruitment sites for the duration of a longitudinal study, it may impact on numbers lost to follow-up. Published work has suggested that study attrition is associated with being male, younger, unemployed and with increased severity of substance use (Cottler *et al* 1996). Marel *et al* (2015) noted that the odds of completing all follow-up interviews was more than three times higher among participants who were in treatment or using other opiates at baseline. The highest predictor of completing a follow-up interview was having completed the previous one.

There were undoubtedly considerable gains for our study in recruiting experienced interviewers who were knowledgeable about relevant clinical issues, could time manage efficiently, work autonomously and liaise sensitively with busy clinical staff. This resonates with the views of Cottler *et al* (1996) viz. that the research team 'needs patience, persistence, enthusiasm and creative team work, time and money' (p215). Coen *et al* (1996) also note that key factors which will reduce attrition difficulties are the choice and training of the research interviewers. Like Patton *et al* (2011), we undertook to assign one interviewer, where possible, to each participant for all study interviews to engender a degree of trust and familiarity.

Howard (1992) reported that retention in a longitudinal project is seriously compromised by a lifestyle complicated by substance use; nearly 25 years later, our findings are in agreement. It is possible that the initial study focus, the impending introduction of MUP, was perceived as an issue that could have impacted considerably upon participant's daily lives. It may therefore have enhanced baseline recruitment, with the study perceived as an opportunity to contribute their voice to the debate. As the legal challenges delaying the implementation of MUP were well publicised, this loss of focus between baseline and first follow up may have contributed to attrition.

Future research must recognise the considerable impact on the study budget of participant fees and interviewer work patterns. At the design phase careful thought must be given to the extent and nature of baseline demographic data collected to facilitate re-contacting. An important challenge is to minimise attrition to ensure the collection of valid data with sufficient power to address the research question but with no compromise of participants' ethical rights.

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