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'Just one interview': making visible the hidden workload associated with qualitative research in healthcare

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Abstract

Background: Appropriate costing and resource allocation for clinical research delivery is vital to ensure recruitment to time and target. However, there is little guidance on the workload associated with qualitative research.

Aims: To review planned versus actual research nurse workload (number of activities and time) within a qualitative sub-study following elective cardiac surgery in children.

Methods: Parents of children approached for a clinical trial, both consenters and decliners, were invited to participate in a semi-structured interview, either face-to-face or by telephone, to explore their perspectives on decision-making about their child's participation in the trial. An audit of research nurse workload was conducted using anticipated points of contact (POC) between the research nurse and parents, and duration of activity identified from the protocol/HRA statement of activities; these were compared with timed activities documented by the research nursing team.

Results: 38 families were approached and 26 parents took part in 23 interviews. Planned total research activity involved 3 POC (1.9 hours) per interview, 56.9 hours of total work. Actual research activity involved 5 (IQR 4-8) POC per interview, a total of 99.2 hours of work. Research nurse activity was 42.3 hours (74%, 5.6 days) greater than anticipated.

Conclusion: The workload associated with conducting a relatively straightforward qualitative sub-study of a clinical trial with a research-engaged patient group was not anticipated or captured by the current system.

Implications for practice: Understanding the hidden workload associated with qualitative research is invaluable to ensure realistic project timelines, recruitment targets and research staff funding.

Key words: Qualitative research, Interview, Cardiac surgery, recruitment, retention, research nurse, workload

Introduction

Recruitment and completion of research to time and target are key performance metrics for research delivery (National Institute for Health Research, 2021). Failure to recruit or retain participants can have serious implications, with studies requiring additional time and/or funding (Sully et al., 2013) or even being discontinued, wasting scarce research resources (Kasenda et al., 2014). The value of understanding participants' perspectives on research is therefore being increasingly recognised, particularly in contexts regarded as challenging, such as paediatrics (Caldwell et al., 2004, Knox et al., 2007, Sammons et al., 2007, Kanthimathinathan and Scholefield, 2014). Research nurses play a vital role in the day-to-day conduct and management of clinical research (Connolly et al., 2004, Mori et al., 2007, Pick et al., 2011, Gibbs and Lowton, 2012, Lawton et al., 2012, Jones et al., 2020). Despite this important role, there is a lack of data around optimum research staffing and service capacity (Hong et al., 2021) and tools to support workforce planning have focused primarily on oncology clinical trials (Good et al., 2013, Milani et al., 2017, Lee and Jeong, 2018). In the United Kingdom, the Schedule of Events Cost Attribution Template (SoECAT) has been developed as a cost attribution template for non-commercial research studies, identifying NHS support and treatment costs. However, it is not intended as a study costing tool and has limited applicability to qualitative research.

During the conduct of a qualitative study concerns were raised about unanticipated work associated with recruitment and retention of study participants. An audit was therefore conducted with objectives to identify research nurse workload and time associated with recruitment and retention, and to compare anticipated activity and time with actual study workload.

Methods

The qualitative study was to explore the perspectives of parents of children undergoing surgery for congenital heart disease towards participation in research (Drury et al., 2021). This was a single-centre sub-study of a multicentre, double-blind, randomised controlled trial (RCT), the Bilateral Remote Ischaemic Conditioning in Children (BRICC) trial (ISRCTN 12923441) (Drury et al., 2020). Parents who consented and those who declined the trial were approached following their child's discharge from the Paediatric Intensive Care Unit (PICU) to participate in a face-to-face or telephone interview, either during admission or following hospital discharge (Drury et al., 2021). The sub-study was funded for a team of research nurses to support recruitment to the study and an embedded nurse researcher to conduct the interviews.

The project reported in this paper was classified as an audit (NHS, 2021) and measured planned research nurse activity compared with actual practice. Audits are recognised as beneficial to identify where improvement is required and provide a baseline to evaluate if beneficial change occurs (Limb et al 2017, Twycross and Shorten 2014). Actual research nurse workload was documented contemporaneously by the research team and compared retrospectively to the planned activity as defined within the study protocol and the Health Research Authority (HRA) statement of activities completed by the Chief Investigator (table 1). In accordance with recommendations for reporting and publishing audit (Limb et al., 2017), it is reported according to the SQUIRE 2 guidelines (Ogrinc et al., 2016).

Two main measures were assessed: 1) planned points of contact (POC), defined as attempted or successful contact between the research nurse(s) or nurse researcher and the parents; 2) length of time spent on each research activity. Two research nurses from the study site independently timed all study activities using a stopwatch. The mean time for each activity was used to calculate an overall time per participant and a total time for all documented activities. Recruitment activities were defined

as those from the first approach to discuss participation through to signing the informed consent form, activities predominantly conducted by the research nursing team. Retention was defined as any activity following consent through to completion of the interview and were primarily performed by the Nurse Researcher. Where consent was obtained prior to undertaking the interview this was recorded as 0 (no new POC for retention). However, the time for the interview completion was documented as retention activity. The interview was initially envisaged to take place within two weeks of hospital discharge but extended to six weeks through an amendment.

Planned research activity involved three POC, two for recruitment (approach and informed consent) and one for retention (interview) (table 1). The anticipated workload was 0.7 hours/participant for recruitment and 1.2 hours/participant for retention, a total of 1.9 hours/participant. With a planned sample size of up to 30 participants, this equated to an anticipated workload of 56.9 hours or 7.6 days full time equivalent (7.5 hours/day).

Study documentation within the study site file was audited. Research nurses documented all attempted contacts with families, whether successful or unsuccessful. Data collection included the date of approach, all contact with parents, date of consent, method of communication (e.g., face to face, telephone, text message), location of contact and date of interview. Activities and method of contact were coded and entered into a spreadsheet for analysis (table 2). The number of POC and time spent on recruitment/retention per participant were identified and median (interquartile range) calculated.

Both the clinical trial (16/WM/0309, 5 August 2016) and the qualitative sub-study (17/WM/088, 28 April 2017) were approved by the West Midlands-Solihull NHS Research Ethics Committee and sponsored by the University of Birmingham (RG_14-025 and RG_17-005, respectively). This audit did not involve review of patient records and so no additional ethical review was required.

Results

Demographic data

Between September 2017 and June 2019, 46 families were approached about their child's participation in the trial, of whom 38 were eligible for interview and are included in the recruitment activity (figure 1). The parents of 28 children consented to interview and are included in the retention activity, with 26 parents participating in 23 interviews (Drury et al., 2021).

Recruitment

The sub-study protocol stated that parents would be approached on the ward following discharge from PICU, between two- and seven-days following surgery, with consent obtained 24 hours later. On reviewing study documentation, we found parents were approached at a median of 4 days (IQR 2-6.8), with consent obtained at 18 days (IQR 6-35.5). The anticipated two POC (0.7 hours/participant) took a median of 3 (2-4.8) POC, 1.4 hours/participant (1-1.7) (table 1). Recruitment activities for all 38 eligible families totalled 58.6 hours of work, 36.8 hours or 4.9 working days longer than expected; this included ten families who declined an interview, requiring a median of 5 (4-6) POC at 1.4 hours/participant, 8.2 hours in total.

Retention

The anticipated workload associated with retention was one POC at 1.2 hours/participant, with an overall workload of 35.1 hours for up to 30 participants. For the 26 parents (23 interviews) where an interview was successfully completed, a median of 3 POC (0.8-4) and 1.3 hours/participant (0.9-1.8) were required. For nine parents (seven interviews) the interview was conducted immediately after consent, therefore there were no new POC for retention (recorded as 0). Median time from consent to interview was 33.5 days (17.5-56.8), with eight interviews conducted beyond the intended 6-week period, with the latest conducted at 133 days following discharge (see table 3). Six parents from five families who had consented to participate withdrew or were lost to follow up without interview. A

median of 6 (4-9) POC and 1.6 hours (1.4-1.6) were spent in unsuccessful efforts to retain these participants.

Total workload

The total workload for all 38 approached families (28 who consented, 10 declined) was 5 (4-8) POC; summary data for each family is provided in the supplementary materials. A median of 2.7 hours (1.6-3.3) per participant was required from approach to completion of an interview, equating to 99.2 hours or 13.2 working days, which exceeded the anticipated workload by 42.5 hours (75%). The number of POC (5, IQR 4-6) required for the first 11 interviews was no different to those for the other 12 interviews (8, IQR 3.5-9.5) (p=0.22).

Method of contact

During recruitment, the predominant form of contact between the research nurses and parents was a ward visit (n=71), with 49 successful visits where the family was present and the research nurse was able to speak to them, and 22 failed visits where the family was not present (table 3). Thirty-two (24%) contacts were made via telephone call (22 answered, 10 unanswered) and 20 (15%) were in the outpatient department (19 parent(s) attended, 1 parent did not attend). In total, 6.3 hours of research nurse time was spent on failed visits or phone calls.

During retention following hospital discharge, the main method of contact was via telephone-69(70%), with 29 (42%) failed attempts to contact families. Unsuccessful phone calls took 3.7 hours of research nurse time.

Interview location and method

Participants were offered a choice about the method and location for the interview: 14 (61%) interviews were conducted by telephone, 5 (22%) in person during a hospital clinic appointment, and

four (17%) in person at a dedicated home visit. The latter took a considerable amount of time due to the additional travel, with a median of 2.2 hours (IQR 1.7-2.6) per interview.

Reasons for recruitment and retention challenges

Overall few reasons were captured about recruitment and retention challenges. Ten families declined to participate in an interview, eight who had consented to the trial and two who had declined. Six provided no reason, two stated they were not interested, and two reported they did not have time. Of the six parents who consented but did not proceed to interview, two withdrew (one due to complications following surgery) and one was not available for interview, although their partner did participate. The other three parents failed to respond to repeated research nurse contact so were classed as lost to follow up.

Discussion

In this audit of research nursing workload, we found that both the number of POC and the time required for recruitment and retention were much greater than anticipated and accounted for by existing systems at the outset.

Methods of engagement

Initially all contact between the research team and parents was planned to be face-to-face but this was promptly amended to allow other forms of communication. This proved to be prudent for study retention as 98 POC were needed to arrange the interviews, of which 88 (90%) were via telephone call, text message, email, or letter. Even with a simple study, involving only one follow up intervention (the interview), utilising commonly used strategies of reminders and using multiple methods to contact and communicate with participants (Robinson et al., 2007) are important to maximise engagement.

Reasons for declining participation reflected a lack of time and support for childcare, consistent with previous studies on the challenges faced by families of children undergoing surgery for congenital heart disease (Wray et al., 2018). Researchers wanting to engage with families need to offer flexibility in the timing and method of communication. Research Ethics Committees often suggest setting limits within the study protocol on the number of attempted or actual contact points with participants or setting a strict timeframe for recruitment. However, we caution against this. In this study, 48% of interviews required six or more POC and 35% were conducted more than 6 weeks following discharge. Without flexibility and consideration of their social circumstances, many families would have been excluded and the perspective of seldom-heard participants lost.

Accommodating participants' needs is also important in the location and method of conducting interviews. We initially envisaged that all participants would be interviewed face-to-face; however,

after we added the option of a telephone interview, 61% opted for this method of contact. This study was conducted prior to the Covid-19 pandemic but virtual approaches using online video platforms have since proved to be acceptable to participants, providing a more time- and cost-effective method to gather qualitative data (Schlegel et al., 2021). Offering a range of opportunities facilitates involvement of seldom-heard participants and with amendments requiring additional Research Ethics Committee we advise offering a wide range of methods from the study outset.

Skilled, knowledgeable workforce

Families became eligible for the sub-study once their child had been discharged from PICU to the ward following congenital heart surgery. At this time, they are often experiencing elevated levels of distress and anxiety (Jackson et al., 2015, Woolf-King et al., 2017) and being approached about research is recognised as an additional stressor (Kanthimathinathan and Scholefield, 2014, Menon et al., 2012). The initial approach about research is recognised to be extremely important to families of infants and children who are critically ill (Wilman et al., 2015, Menzies, 2018) and this was also the case in our study population (Drury et al., 2021). Demonstrating sensitivity to potential participants is crucial because positive parental perception of the researcher/research nurse is associated with greater likelihood to consent (Tait et al., 2003, Hoberman et al., 2013).

Research nurses have been identified as ideally placed to provide insight into the study purpose and support the informed consent process (Mori et al., 2007, Pick et al., 2011, O' Sullivan et al., 2021). Our audit provides evidence of their ability to sensitively navigate recruitment and retention with families who have experienced the challenges of their child undergoing cardiac surgery. Despite requiring more POC and time than initially envisaged, 74% of approached parents were successfully recruited and 82% of recruited parents went on to complete an interview. Their efforts enabled the qualitative research study to be conducted and provide insights into the views of not only parents who consented to the trial but also those who declined participation, a group that is seldom heard (Drury et al., 2021).

Workload

The flexibility offered by the team, whilst beneficial for the families, created challenges with predicting staff workload. Research nurses could set aside time to speak to families or to arrange interviews, only to find no one was available or it was not felt to be appropriate. Similarly, families who had not been engaging or answering phone calls would answer the phone and decide this was an optimum moment to conduct the interview. Our study team were able to support this enhanced level of involvement for free, but this level of resource and flexibility is not commonly available. In the UK, only 11/21 (52%) responding PICUs had permanent research delivery roles funded within their staffing establishment and only 2/21 (5%) units offered seven days per week cover, including our unit (Menzies et al., 2022). This level of support therefore may not be replicable in other centres. Understanding the workload associated with research is vital to ensure that staffing is planned appropriately and helps to make a case for additional staff recruitment (Gilardi et al., 2014).

Existing templates have been designed for clinical trials (Lee and Jeong, 2018, Good et al., 2013) or to consider treatment costs (National Institute of Health Research, 2019) but are unable to capture the workload associated with conducting qualitative or mixed methods research. Investigators are aware of key stages such as obtaining informed consent but the intermediate steps and decision-making surrounding the practice of research nurses are often poorly articulated and understood (Skea et al., 2017). This audit contributes a valuable insight into the nursing workload involved in conducting qualitative research and supports future research into better understanding the processes involved.

Limitations

This audit was conducted retrospectively and only reflects documented research activity, so it is possible that activity was missed and there may be an even greater difference between planned and actual workload. The accuracy of estimated time to conduct research activities is based on times specific to our IT systems and office location, so may not be directly applicable to other settings. In

addition, the study was conducted in a tertiary paediatric centre with a well-staffed research nursing team so may not be applicable to all centres or target populations. Our approach to the recruitment and retention of families may have evolved during the study, with less time required due to greater familiarity but more POC due to greater persistence knowing that it often paid off.

Conclusions

There was a significant hidden workload associated with conducting a relatively straightforward qualitative sub-study with a research-engaged patient group, which was not anticipated at the time of writing the study protocol and obtaining funding. Enhancing understanding of research nursing workload is invaluable to ensure realistic project timelines, recruitment targets, ensure sufficient funding for staff and reduce research waste (Kitterman et al., 2011, Kasenda et al., 2014). If research is to truly become core business within the NHS, it is vital that appropriate workload template(s) are developed to facilitate appropriate planning, funding, and staff recruitment.

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Table 1. Summary of all anticipated and actual recruitment and retention activity

Overall Activity	Anticipated	Actual activity (Median, IQR)
Recruitment	30	38
POC	2	3 (2-4.8)
Approach (days)	2-7 days	4 (2-6.8)
Consent (days)	3-8 days	18 (6-35.5)
Time/Participant (hrs)	0.7	1.4 (1-1.7)
Total Time (hrs) (includes decliners)	**21.8**	**58.6**
Decliners	0	10 (8 consented RCT, 2 declined RCT)
POC	0	5 (4-6)
Time/Participant (hrs)	0	1.4 (0.9-1.7)
Total time (hrs)	0	12.5
Retention	30	28
POC	1	3 (0.8-4)
Discharge to interview (days)	≤ 42	33.5 (17.5-56.8)
Time/Participant (hrs)	1.2	1.3 (0.9-1.8)
Total time (hrs) (includes withdrawn/ lost to follow up)	**35.1**	**40.7**
Total no. completed interviews	30	23 (26 participants): 21 consented RCT, 2 declined RCT
Withdrawn/ Lost to follow up	0	5 families (6 participants)
POC	0	6 (4-9)
Time/Participant (hrs)	0	1.6 (1.4-1.6)
Total time (hrs)	0	8.2
Total all activity	**30**	**38**
POC	3	5 (4-8)
Time/Participant (hrs)	1.9	2.7 (1.6-3.3)
Total Time (hrs)	56.9	99.2
Working days equivalent (7.5hrs)	7.6	13.2

Table 2. Codes for Research nurse activity and times calculated by research team

Code	Activity	Time (minutes)
a	Check patient status /location on IT system	2.5
b	Check IT system for upcoming appointment times	2.5
c	Phone ward	1
d	Walk to ward, locate and speak to allocated nurse	10
e	Introduce yourself and study and explain PIS	12
f	Arrange return visit	1.5
g	Visit Outpatient department, locate family and find quiet room to talk	25
h	Walk back to the office	4
i	Locate contact details	2
j	Compose and send text message	1
k	Make phone call	2.5
l	Call number, no answer	0.5
m	Leave message	1
n	Compose and print off letter	15
o	Insert required paperwork consent PIS etc	5
p	Post letter, walk to hospital post room and back	9
q	Compose and send email	12
r	Check for email response	1
s	Informed consent	15
t	Photocopy and File consent copies in patient notes	8
v	Conduct semi-structured interview	Variable- recorded on individual basis
w	Introduction and questions before interview	15
u	Travel to place of interview	Variable- not relevant to all interviews
x	Demographic data collection sheet completion	2.5
y	Informed of eligible patient	2
z	Added to screening and recruitment log	2
a1	Contact details completion	3
b1	Reconfirm consent	1
c1	Field notes	10
d1	Close down, end of interview	10
	Method of contact	
1W	Face to face on ward	
1O	Face to face in Outpatient	
2	Text message	
3	Phone call	
4	Phone call, no answer	
5	Ward visit, no family present	
6	Letter posted	
7	Email exchanged	
8	Did not attend outpatient appointment	
9	Patient home	

Table 3. Review of the method of contact and the number of POC and time spent

No. Points of Contact (POC)	Recruitment	Retention	Time spent (mins)	Recruitment	Retention
Ward contact total (%)	71 (53)	3 (3)	Ward contact total (%)	1863 (57)	131 (5)
Successful	49	3	Successful	1543	131
Unsuccessful	22	0	Unsuccessful	320	0
Outpatients Dept Total (%)	20 (15)	3 (3)	Outpatients Dept Total (%)	874 (27)	185 (7)
Successful	19	3	Successful	857	185
Unsuccessful	1	0	Unsuccessful	17	0
Phone calls Total (%)	32 (24)	69 (70)	Phone call Total (%)	270 (8)	1443 (59)
Successful	22	40	Successful	231	1222
Unsuccessful	10	29	Unsuccessful	39	221
Other methods (%)	12 (8)	23 (24)	Other methods (%)	274 (8)	707 (29)
Text message	6	15	Text message	26	35
Letter	5	1	Letter	163	30
Email	0	3	Email	0	35
Home visit	1	4	Home visit	85	607
Total no. POC (%)	**135 (100)**	**98 (100)**	**Total time spent (%)**	**3281 (100)**	**2466 (100)**

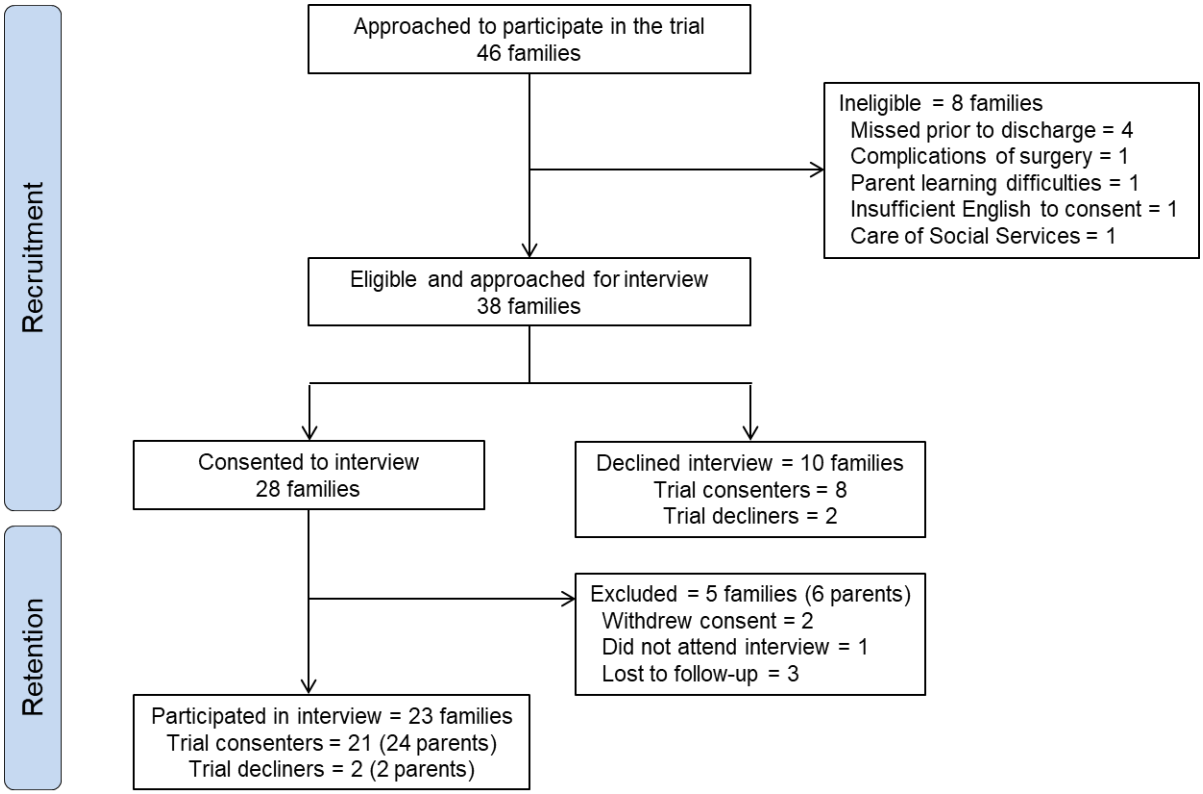

Figure 1. Participant flow diagram

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