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Exploring attitudes towards a randomised controlled trial of venous access devices – a nested pre-trial qualitative study.

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Abstract
Purpose: This pre-trial qualitative research study was carried out to explore patient and clinical staff attitudes to central venous access devices (CVADs). In addition, views about participation in a randomised controlled trial (RCT) were explored with the aim of maximising recruitment to an imminent RCT of three CVADs.
Methods: Three patient focus groups (each comprising three patients) and 23 interviews with clinical staff were conducted. Interviews and focus group discussions were digitally recorded, transcribed verbatim, anonymised, uploaded to the QSR NVivo10 qualitative software programme and thematically analysed.
Results: Analysis of focus group interviews revealed the added challenges that a CVAD poses to patients with cancer. Four key themes emerged: continuity of daily life, pain and discomfort, stigma (a mark of disgrace associated with certain conditions) and self-preservation. The findings show the impact of a CVAD on patients' ability to manage their condition. Clinical staff interviews highlighted several potential barriers to recruitment; a lack of equipoise (genuine clinical uncertainty as to which intervention is the most beneficial), concerns about the logistics of device insertion and a perceived requirement for education and training.
Conclusions: This qualitative study raises awareness of key areas of concern to patients who need a CVAD for chemotherapy delivery. It was identified that there is a need for clearer patient information around CVADs. Additionally it allows investigators to identify barriers to recruitment in a timely manner in order to minimise the potential for conflict between the roles of carer and researcher and consequently, maximise recruitment to the RCT.
Keywords: Cancer, Health professionals' attitudes, Patient attitudes, Qualitative research, Randomised controlled trials, Venous access devices.

Background

This paper presents the results of a nested pre-trial qualitative research study carried out to inform a randomised controlled trial (RCT) of central venous access devices (CVADs).
Qualitative and quantitative research are the two main research paradigms; whilst quantitative research tends to use numerical data, qualitative research uses language data either in the written or oral form (1). The value of utilising a mixture of quantitative and qualitative methods in developing and evaluating complex interventions is highlighted in recent Medical Research Council Guidance (2) and funders increasingly expect to see a qualitative research component incorporated in a study design. A nested qualitative study in a larger RCT serves to provide in-depth, explanatory

information to inform the main trial, provide additional explanatory information on the findings and to incorporate patient and service user involvement in the research.
A systematic review and meta-analysis evaluating the risks of complications associated with centrally inserted external catheters compared with totally implantable Ports in patients undergoing chemotherapy showed that totally implantable Ports are superior to external catheters in terms of catheter-associated complications (3). The National Institute for Health Research Health Technology Assessment Programme has commissioned the Cancer and Venous Access (CAVA) study (4), the first RCT to compare the clinical and cost-effectiveness of three venous access devices for chemotherapy delivery; tunnelled-cuffed central catheters, peripherally inserted central catheters (PICCs) and implantable chest wall Ports (Ports). The CAVA study opened to recruitment in November 2013. Each eligible patient will have four randomisation options: tunnelled-cuffed central catheters versus PICC versus Port, PICC versus Port, PICC versus tunnelled-cuffed central catheters or tunnelled-cuffed central catheters versus Port. The study aims to recruit 2,000 patients over 36 months from six UK centres.
The difficulties associated with recruitment, especially in multi-centre trials, have been well documented (5). A recent cohort study of 114 multicentre trials found that less than a third achieved their original target and more than half had to be extended (6). In recent years, qualitative research methods have been shown to be successful in increasing rates of randomisation in RCTs (7). To be effective and in particular to allow adequate time for the implementation of findings, qualitative research needs to be undertaken at the feasibility stage of a trial, or fully integrated into the design of the RCT (8, 9). Consequently, this qualitative research study was informed by a feasibility study (10) and incorporated into the design of the Phase III study from conception. This pre-trial qualitative research explores patient and clinical staff attitudes to the three CVADs and attitudes to participation in an RCT of CVADs in order to provide tailored strategies to aid recruitment to the CAVA study. The results of this qualitative research have been presented using the approach recommended for reporting a qualitative study, including selected verbatim quotations, which clearly illustrate particular points and which provide support for the findings (11).

Methods
A literature search was undertaken of the CINAHL database to include Medline, PsychInfo, Soc Index, Embase and PubMed. The search covered two main areas of research: firstly, patient and clinical staff attitudes to RCTs and secondly, patient and clinical staff attitudes to venous access devices. Many qualitative studies have explored the views of cancer patients to the process of RCTs, exploring informed consent (12, 13), understanding of equipoise (14), randomisation (15), recruitment (13, 14, 16) and participation in trial design (17). Despite this, recent research reveals health professionals' discomfort at approaching patients to discuss participation in an RCT at an already stressful period for the patient (17). In addition, whilst several qualitative studies examine patient experiences of a single device (18-23), few examine patients' attitudes to device choice; those which do, focus on educational and information needs in relation to device selection (24, 25). There is little in the literature to describe health professionals' attitudes to choice of venous access devices. Quantitative studies indicate that whilst factors such as cost, durability and ease of use for medical personnel all feature in device decision making, little or no consideration is given to participants' views or preferences (26, 27). The need for more studies to investigate the issue of patient satisfaction and quality of life in relation to venous access devices has been highlighted (28). The pre-trial study was carried out in the 9 months prior to recruitment. The study comprised two components: three focus groups with three patients in each and 23 interviews with clinical staff.

Focus groups
Following ethical and Research and Development (R&D) management approval of the study, patients were approached in chemotherapy clinics and day care units and invited to participate in the study. A patient information leaflet was sent out by post or handed out to interested patients. The

researcher followed up the initial contact with a telephone call to discuss any queries and to recruit participants. Patients were sampled purposively to include newly diagnosed as well as metastatic tumours and both solid and haematological malignancies, with the aim also to get a reasonable balance between women and men. Initial plans to hold one focus group of ten patients were modified when recruitment proved more difficult than anticipated. Barriers to focus group recruitment included ill-health, treatment schedules, travel issues, work commitments and a reluctance to join in a group discussion. Therefore, following consultation with the CAVA project management group, the decision was taken to recruit three separate focus groups. A total of nine patients receiving treatment for cancer at the lead centre (Beatson West of Scotland Cancer Centre (BWoSCC), Glasgow) took part in three separate focus groups of three participants each. Four males and five females participated. Participants' ages ranged from 48 to 66 years. All participants had solid tumours, including two with metastatic disease. Three had experience of an implanted Port, three of a PICC line and two of a tunnelled-cuffed central catheter. One had experience of both a PICC and a tunnelled-cuffed central catheter. Four participants had previously participated in an RCT. The focus group discussions took place in a private room and were facilitated by the researcher accompanied by an assistant. Signed consent to participation and to audio recording of the discussion was obtained. The focus group discussion followed a prepared schedule encompassing questions on participants' attitudes, experience and preferences relating to the three devices and on participants' understanding of the study design and willingness to participate in a randomised trial of the three devices. Aids included demonstration devices, laminated photographs of the devices in situ and copies of the patient information sheet for the trial. Each group discussion lasted around 1 hour. All focus group discussions were digitally recorded. Recordings were transcribed verbatim, anonymised, uploaded to the QSR Nvivo10 software programme and thematically analysed by the researcher.

Clinical Staff Interviews

Following ethical approval for the study and R&D management approval at each centre, clinical staff were contacted by email by the researcher and invited to participate in the interviews. A participant information sheet was emailed to the Principal Investigator and relevant members of staff at each centre and the initial contact was followed up to ascertain agreement to participation. Twenty three clinical staff (oncologists (4), radiologists (6), haematologists (3), anaesthetists (1) and nurses (9)) from across the six centres were recruited as it was anticipated that there would be variations in attitudes regarding equipoise across specialities and differences in local practice which might affect recruitment. The researcher visited each of the participating centre to interview staff. Written consent to participation and to audio recording of the interview was obtained prior to each interview. A prepared schedule was followed encompassing perceived barriers and facilitators to recruitment and attitudes to the three devices and to RCTs. Feedback was obtained on trial materials including patient information sheets and consent forms. Clinical staff interviews were digitally recorded. Recordings were transcribed verbatim, anonymised, uploaded to the QSR Nvivo10 qualitative software programme and thematically analysed by the researcher.

Results

Focus Groups

The focus group discussions generated a number of themes. These were continuity of daily life, pain and discomfort, stigma (a mark of disgrace associated with certain conditions) and self-preservation. These issues, whilst common within the experience of those suffering from cancer (29-33), appear to be magnified by the presence of a vascular access device. The key themes will be explored in turn below.

Continuity of daily life

The need to retain continuity of daily life emerged as a priority. Comments indicate that patients are motivated to adapt to the presence of the device and to focus on strategies to minimise disruption to their daily activities.

'.. it (was) really very, very simple, just sort of put the sleeve on and pop into your bath and you kept it sort of like... water free, it was good.' [Female, 48, Breast cancer, PICC]

Although discussions revealed that the Port could be seen to confer 'pure freedom' (a colloquial term conveying a high level of freedom), fatigue and other factors, including wound care, pain or complications with the venous access device, could limit activities and negate the perceived benefits of a totally implanted device.

'...but with an open wound on my back I couldn't go swimming anyway so, you know, I couldn't really see the benefits of the others.' [Female, 48, Breast cancer, PICC]

Conversely, the need for additional line care and maintenance in the case of the PICC and tunnelled-cuffed central catheter can lead to an undesirable dependency on health care professionals.
'You just feel as if your life's on hold.' [Male, 59, Metastatic colon cancer, PICC]

Pain and discomfort
A further burden for the patient is the fact that the vascular access device can be the cause of significant additional pain and discomfort: whether at the time of insertion and removal, due to complications or due to device malfunction necessitating alternative venipuncture. In addition, participants reported having underestimated the extent of the procedure (Port) and finding the process impersonal (tunnelled-cuffed central catheter). Insertion of the PICC line attracted the least comment.

'I don't think I appreciated the procedure of when it was put in, that how, you know, they would be actually, you know, making incisions in your neck and in your chest....' [Female, 57, Breast cancer, Port]

Stigma
Despite adapting to the practicalities of having a device in situ, the desire to hide the device emerged as a strong theme in discussions. Participants emphasised this point, using the words 'conceal', hide and 'cover' repeatedly.

'And as we said; you can cover it. It's not that you're embarrassed but it's likes of children come into the house...or grandchildren...or people that don't know anything about your disease or your sickness...and there might be something sticking out somewhere. No, no, no, no, no, no. I'll try and hide it as much as I can, you know.' [Male, 66, Metastatic colon cancer, PICC]

Whilst the Port is the most satisfactory in this regard, being almost undetectable, participants describe being able to successfully mask the other two devices with careful attention to the selection of appropriate clothing.

Self-preservation
Patients view the device as a 'necessary evil' and feel compelled to assume a defensive stance in relation to its care and maintenance, in extreme cases undertaking self-care.

'It's self-preservation and I have been quite happy to say to people ehm, 'excuse me, you don't know what you're doing, eh, don't touch my Hickman line.' [Female, 56, Breast cancer, Tunnelled-cuffed central catheter]

This theme of self-preservation can also be seen in the desire to retain some degree of control of aspects of care and treatment where possible, including control over choice of device.

'So personally, eh, if the computer choose me to have the PICC line, I would agree, but if they choose something else, I'm sorry to say I would like to know the computer's name, because I would disagree with him.' [Male, 66, Metastatic colon cancer, PICC]

A further protective mechanism is revealed in the need to avoid acknowledgement of the severity of the illness. In some instances patients appear reluctant to accept the need for an invasive procedure or obtrusive device in order to deliver treatment.

'I felt that (having) a Hickman, you know, having lost your hair (and) everything else, just gave you this vision of being very, very sick, when I didn't actually feel that sick.' [Female, 48, Breast cancer, PICC]

Clinical staff interviews

Three key themes emerged from clinical staff interviews. Firstly, a lack of equipoise in relation to the devices; secondly, the challenges of introducing or expanding a Port insertion service and thirdly, the need for extensive and comprehensive training in the care and maintenance of unfamiliar devices, mainly Ports.

Lack of equipoise (genuine clinical uncertainty as to which intervention is the most beneficial)

Equipoise provides the ethical basis for an RCT. Interviews with clinical staff revealed device preferences for certain subgroups of patients. As a result, only one centre will consider haematology patients for randomisations including Ports. In other centres haematologists expressed reservations regarding Ports and/or PICC lines or have yet to engage in the study.

'We are actually not familiar with (the Port) in adult Haematology or Oncology really I mean...it would be a major practical problem to be inserting it into our Haematology patients in terms of the insertion itself, there is a possibility that the bleeding risk and the infection risk could create more problems for my type of patients, because these are acute leukaemia patients….' [Haematologist, Leeds]

Logistics of Port insertion appointments

Secondly the introduction or expansion of a Port insertion service will inevitably create challenges, including training additional Port inserters, making sufficient Port insertion slots available, providing a service for Port removal and, in two centres, acquiring funding for Ports. Furthermore, the element of randomisation between devices has the potential to create an additional level of complexity in the process of commencing a patient on chemotherapy.

'I think that patient nurse specialists and the outpatient nurses in the Sarcoma practice and the young peoples' practice are dealing with a complex sequence of events around getting a patient started on chemotherapy and they will vary in their gratitude for a further complexity to be introduced.' [Oncologist, Leeds]

This is particularly relevant in Oncology and Haematology where the time from referral for line insertion to treatment can be short and any perceived potential delays to chemotherapy delivery will impact negatively on patient recruitment.

'I think, obviously you know kind of access to Interventional Radiology might be the decider here because if there is a waiting list to put a Port in, what have you, then your treatment targets have to be met either for cancer waiting time target or from a clinical need target type of thing.' [Oncologist, Newcastle]

The introduction of Ports for chemotherapy delivery also creates a requirement for Port removal appointments, in many centres this is in addition to current workload and therefore raises the issue of additional service provision. Responses to this varied across centres with the onus falling variously on surgical, radiology or anaesthetic departments to meet this new demand.

Lack of experience and training

Finally, an increase in the number of Ports in use for chemotherapy delivery has ramifications for ward and primary care staff involved in the care and maintenance of Ports, therefore training and education is a key issue in all centres. In some centres experience of Ports for chemotherapy delivery is limited and the need for additional training is apparent. The qualitative research interviews in Glasgow, drawing on experiences from the feasibility study, highlighted a lack of confidence and experience with Ports as a major concern. Despite a programme of training, the learning curve generated by the new device resulted in additional referrals to Interventional Radiology for assistance with maintenance issues and additional hospital visits by patients for procedures normally carried out by the Primary Care team.

'…as a nurse-led team we know the ramifications of the management within the hospital of new devices, and in the community. Little changes for us have massive ramifications for other areas…' [Procedure Team Manager, Manchester]

However, the qualitative research interviews did highlight the nursing staff's enthusiasm and commitment to developing the necessary skills.

'So that's a big buzz, eh, you know when we problem solve in a successful way. And I know that once we get used to Ports, we'll love them.' [Oncology Nurse, Glasgow]

Discussion

The presence of the venous access device challenges the patient's ability to manage their condition in several respects. The themes identified, continuity of daily life, pain and discomfort, stigma and self-preservation, whilst common within the experience of those suffering from cancer (29-33), appear to be magnified by the presence of a vascular access device. The need to avoid disruption to daily life in order to cope with chronic illness is well documented (29). Focus group discussions reveal that the device has the potential to impact significantly on this, requiring increased intervention by health care professionals. In addition, the potential for the device to add to the patient's level of pain and discomfort cannot be ignored. A significant degree of pain and discomfort was reported by some patients at the stage of insertion of the device. A particular consideration for recruiters to CAVA is the fact that participants may be randomised to any of the three devices and therefore need to be fully aware of insertion procedure for each device as well as the impact of the pre- and post-insertion period. A further concern to patients is the fear of stigma. It is recognised that stigma (or a mark of disgrace associated with certain conditions) is a central force in the lives of those with cancer (32). Focus group discussions reveal that the device represents an undesirable visible indicator of the disease and it may be concluded that the fear of stigma leads patients to

want to conceal the device. Unlike chemotherapy-induced alopecia (33), patients with a venous access device in situ can, and often do, choose to keep the presence of the device concealed from others and become adept at developing strategies to hide the device. Similarly, whilst patients recognise the catheter's central role in delivering treatment and hopefully a cure, they constantly fear complications (30). Thus the device is seen as both a lifesaving mechanism and a threat. Self-preservation takes many guises; from undertaking self-care of the device to the need to retain control of choice of device or treatment schedules. Patients therefore may be reluctant to participate in an RCT due to a desire to be actively involved in decision-making (34, 35). A further example of self-preservation is avoiding confrontation with the seriousness of the disease, a process recognised as cancer-specific denial and accepted as a recognised coping strategy in cancer patients (31). Cancer-specific denial may be a subtle influence in the preference for a less invasive or obtrusive device and consequently in the decision whether or not to enter a randomised study of venous access devices.

A review of relevant qualitative research has identified patient preference for one particular treatment arm as a major barrier to recruitment (9). A corresponding tendency by health professionals to accord with patient preferences, where they coincide with recruiters' own views, has also been highlighted in the literature (36). The benefit of being able to elicit and address patient preferences has been recognised and in this way recruiters may be able to gently challenge patients' preconceptions, as well as recognising and acknowledging their own bias in device preference. The findings from the pre-trial qualitative study reported here will allow CAVA recruiters to be alert to patients expressing concerns with regard to continuity of daily life, stigma, fear of pain and discomfort and above all self-preservation. Furthermore, the need to avoid confrontation with the seriousness of the disease or a need to retain control of device choice or ultimately whether or not to have a device in situ will impact on the decision to enter an RCT.

The analysis of pre-trial clinical staff interviews identified both local issues and themes common across centres. The main themes, lack of equipoise, logistics of service delivery and the need for education and training, could potentially present significant barriers to recruitment.

Current literature indicates that more subtle influences may prevail in the process of recruitment and clinicians and nurses' own attitudes and preferences whilst not immediately apparent, unconsciously affect recruitment (36). Recent studies reveal that, despite being strongly committed to the RCT, recruiters exhibited discomfort at the process of recruitment, occasionally openly but often covertly, displaying conflict between the roles of carer and researcher and demonstrating selectiveness in the choice of patients to approach (36). Therefore identifying and addressing issues likely to contribute to this conflict is of fundamental importance in maximising recruitment.

Services at each centre vary significantly and there is acknowledgement that there may be competing demands for slots for Port insertion in some centres. In others, Port insertion for chemotherapy is in addition to existing workload. Here the danger is that recruiters' own perceptions of organisational difficulties reinforce those of patients (36). As a result of the pre-trial qualitative research findings, the remit of the funded role of CAVA Champion (a dedicated member of the study team at each centre) has been developed to encompass not only recruitment and randomisation but also coordination and facilitation of device insertion appointments, communication and liaison across specialities and education and dissemination of knowledge.

The need for additional staff training, particularly in the use of Ports, will impact on recruitment initially, limiting randomisation for haematology patients to the two-way randomisation between PICCs and tunnelled-cuffed central catheters in some centres. Several approaches have been taken to address the need for training; details of effective training models and mannequins, sourced through Industry, have been shared between centres. In addition, nurses with experience of Ports will cascade the knowledge to other staff within individual centres. Notification of national training courses in device insertion, care and maintenance has been made to Principal Investigators at the launch meeting.

Despite some evidence of a lack of equipoise on the part of haematologists, there is an emerging opinion amongst some haematologists that this is an important question in this particular group of patients and there is optimism that there may be further engagement by haematologists across the period of recruitment.
This qualitative research is one of only a few fully integrated, qualitative research studies in large multi-centre RCTs. This integration has allowed the analysis, feedback and interventions to take place prior to the study opening to recruitment.

Conclusion
This pre-trial qualitative study raises awareness of key areas of concern to patients who need a venous access device for chemotherapy delivery. The findings show the potential for a venous access device to magnify existing difficulties, posing additional challenges to patients' ability to manage their condition. From the findings it was identified that there is a need for clearer patient information, education and training around CVADs.
Following presentation of the pre-trial qualitative research analysis Principal Investigators and CAVA Champions at each centre are able to recognise issues likely to adversely impact on recruitment including lack of equipoise in certain patient subgroups, potential logistical obstacles to device insertion appointments and the need for additional education and training in Port care and maintenance. As a result, investigators are able to consider and address potential difficulties in a timely manner, thus minimising the potential for conflict between the roles of carer and researcher identified in recent literature (36) and ultimately maximising recruitment to the CAVA trial.

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