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Challenges in Recruiting Participants in a Multi-centre Study on Symptom Experiences and Management of Bowel Symptoms following Colo-rectal Surgery

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Abstract

Aim: The purpose of this paper is to present some of the challenges found to be problematic in recruiting individuals following sphincter saving surgery for rectal cancer for a multicentre study. While the focus of the study is on symptom experiences and management of bowel symptoms following colo-rectal surgery, the paper will concentrate solely on the challenges experienced in recruiting a sample for the study.

Background Recruitment of an adequate number of participants is a challenge for researchers in any area of research involving patients. Enrolment of patients treated for rectal cancer poses particular challenges because the total population of this group in a given country can be small. The use of multiple centres was required to obtain the required number of participants for the current study.

Findings: In multicentre studies, researchers can encounter substantial challenges in obtaining ethical approval, accessing clinical sites and gaining direct access to patients. These challenges are embedded in a convoluted process involving many systems of communication, which can vary from one centre to another.

Conclusions: The process of obtaining ethical approval is prolonged in the absence of a central ethical review committee. A review process based on a standard application for researchers
seeking ethical approval for multi-centred studies central is necessary. Establishing and maintaining access to clinical sites requires co-operation from many individuals during the development of the proposal and continuing throughout the data collection process.

**Key Words:** Ethical approval, multi-centre study, recruitment, research access, symptoms, colo-rectal cancer.

**Key Points**

- In multicentre studies, researchers can encounter substantial challenges in obtaining ethical approval, accessing clinical sites and gaining direct access to patients.
- The process of obtaining ethical approval is prolonged in the absence of a central ethical review committee.
- A more centralised approach to ethical review is warranted
- Researchers require the help of healthcare professionals who serve as gate-keepers to potentially eligible study participants.

**Introduction**

In Ireland, the number of patients diagnosed per annum with colo-rectal cancer is approximately 2,750. This number is low compared to the incidence of other cancers such as non melanoma skin cancer and breast cancer. The challenges of recruiting patients following colo-rectal cancer can be heightened if only a subgroup of these patients is required. To date, little consideration has been given to the challenges facing researchers when recruiting a large number of patients following colo-rectal cancer including issues around ethical approval and access. The aim of this paper is to present challenges in recruiting patients for an Irish study on symptom experiences and symptom management of bowel symptoms following sphincter saving surgery for rectal cancer.

**Study Context**
Sphincter saving surgery is now viewed as an advance over the traditional approach involving abdominal perineal surgery which typically leaves patients with a stoma for life (Stamos and Murrell, 2007). Although a permanent stoma is avoided, bowel function may be compromised following sphincter saving surgery (Grumann et al, 2001, Schmidt et al, 2005) Rectal reservoir capacity is altered after restorative surgery which is due primarily to a reduction in the size of the rectal remnant (Hallböök and Sjödahl, 2000). As a consequence, sphincter saving procedures can lead to altered bowel symptoms both in the long and short term such as faecal incontinence, urgency and frequency resection (Desnoo and Faithfull, 2006). The aims of the study addressed in this paper were to investigate (i) patients’ symptom experiences and symptom management strategies following sphincter saving surgery for rectal cancer and (ii) whether a relationship exists between patients’ experiences of bowel symptoms and the self-care strategies used to manage symptoms.

A national sample of 194 patients following sphincter saving surgery is being recruited. This sample size was powered to meet the aims of the study. Data are currently being collected using a postal questionnaire across a total of ten sites. Access to multiple centres was necessary to recruit the required number of participants. According to Gold and Dewa (2005) a multi-site study has the potential to increase the sample size and enhance the external validity of the study. However, efforts to recruit study participants across multiple sites can be inherently complex involving layers of communication and administration. The challenges that we have experienced in recruiting study participants for the current study are addressed in this paper with regard to obtaining ethical approval, gaining access to clinical sites, and gaining direct access to participants.

**Obtaining Ethical Approval**
Ethics committees act as research gatekeepers to protect potential research participants. While it is essential that patients' interests are safeguarded, it is important also that ethical approval for research is obtained in an efficient and timely way. In 2004, the Irish Council for Bioethics published guidelines for operational procedures for research ethics committees which paved the way for easing the process of obtaining ethical approval. Guidance from this Council indicated that a research ethics committee (REC) “may agree to accept a scientific assessment of the proposal from another REC” and “RECs may agree to accept the conclusions of a single review committee” (p.27). However, the continuing situation in Ireland is that multi-centre studies must be approved by a host of ethical committees before a study can proceed. Therefore, researchers undertaking multi-centre studies are required to submit separate applications to the ethical review board associated with each individual centre.

Developments in Ireland to ease the process of seeking ethical approval are comparable to developments in other countries such as the United Kingdom (UK) and Canada. In the UK, the National Health Service (NHS) made recommendations for the setting up of research ethics committees in 1991. In 1997 one Multi-Centre Research Ethics committee (MREC) was established (NHS, 1997). Subsequently, the NHS Executive (1998) formulated guidelines for local ethics committees in a further effort to avoid undue delays in the review process. More recently, the Department of Health (NHS) has stipulated, that “the requirement for a single ethical judgement should apply generally to all multisite research in the UK” (National Research Ethics Service NHS, 2010, p.101). Thus, more standard guidelines are now in place for researchers engaging in multi-site research.

In Canada, the Medical Research Council (1987) suggested measures to improve inter-site communication such as joint meetings of representatives from the participating institutions to allow for discussion on issues raised by a local committee. More recently, the Canadian Working Committee of the Interagency Advisory Panel on Research Ethics (2008) suggested the need for researchers to highlight the key elements that cannot be changed in a multi-centre study “without invalidating the pooling of data from the participating institutions” (The Interagency Advisory Panel on Research Ethics, 2008, p.12). While acknowledging the need for individual ethics
committees to vocalise their concerns about a particular study, the establishment of multi-centre ethics committees has the potential to reduce the time, administration and overall financial costs inherent in undertaking multi-site research studies.

Due to the need to submit individual applications to the ethical review committee associated with each individual centre, the application process for research ethical approval in Ireland can be both laborious and time consuming. Obtaining and completing applications for research ethical approval can be overwhelming because as experienced for this study, there is much diversity between committees. For example, the length and detail of information required in application forms varies from one ethical committee to another. Also, the type and amount of supporting documentation required by individual ethical committees can differ. For example, in the case of our study, some ethical committees required separate information leaflets and consent forms whereas for other committees a combined form was required.

It is important that protocols are sufficiently detailed to permit each ethics committee to assess the ethical rigour of the proposal, as well as any potential risks to research participants. In this regard, Peck et al (2007) recommend that researchers consult with ethical committee administrators if they are in any doubt about any aspect of the application process. For our study, we contacted the administrator of six committees to seek clarification on some of the questions posed in the application form. This communication was invaluable as it not only prevented delays in the application process, it also allowed for a more accurate and comprehensive submission of documentation.

For our study, a total of six ethical review committees which extended over five geographical areas have been contacted (Figure 1). Of the six committees, an expedited review was granted by the chairperson of one committee. This committee has ethical jurisdiction for five of the ten clinical sites included in the study. Therefore, it was not necessary to submit a separate application for ethical
approval to each of these clinical sites. This requirement would have been time consuming and would have further delayed data collection. Approval was granted by the chairperson of a second committee within one month of application without any conditions set. A third committee gave approval two months after application which allowed for access to two major clinical sites specialising in colorectal cancer within the same geographical area.

However, the three remaining ethics committees requested ‘full review’ which meant that the research protocol had to be reviewed by all members of the committee. Two of these committees required the principal researcher (ML) to attend their review meeting to discuss the proposal and address any questions that might be raised by committee members. This gave the researcher the opportunity to interact directly with the review committee to exchange views and to hear their views about the study protocol and application for ethical approval. It also gave the researcher the opportunity to immediately clarify issues raised regarding specific aspects of the application which in turn expedited the process of obtaining ethical approval for the study. However, attendance at ethics committee meetings can be both costly and time consuming especially if it involves long distance travel which was the case for our study. One strategy that might offset this challenge is to provide researchers with the opportunity to interact directly with ethics committee members through the medium of video, or teleconferencing.

Gold and Dewa (2005) maintain that the diversity in the conduct of ethical review boards may be due not only to the lack of a standardised application form but also to the fact that these boards comprise of individuals of varying backgrounds and experiences. Thus, committee members can have a major influence on how a protocol can proceed through the review process. In addition, recommendations from individual boards can differ considerably. This could mean that some participants in a multi-site study are being given greater protection over others (Gold and Dewa, 2005). For the current study,
one ethical review committee recommended that before patients were posted the questionnaire, they should firstly be contacted either by the researcher, or by a nurse affiliated to the clinical site. In addition, this ethical review committee recommended that because patients eligible for the study had been discharged from hospital, their general practitioners should be contacted by the researchers to inform them about the study. A second committee recommended that patients should consent to take part in the study before being posted the questionnaire and that this consent should be obtained from hospital personnel. No such stipulations were imposed by the remaining ethics committees. This ethical committee also recommended that each participant be contacted by the researcher following the return of the questionnaire. The purpose of this communication was to determine if participants were distressed in any way by their involvement in the study.

A requirement of all ethics committees for the current study was that the support of surgeons who managed caseloads of patients undergoing sphincter saving surgery for rectal cancer was obtained prior to submitting applications for ethical approval. In many instances, this involved writing more than once to three or more surgeons at each clinical site. The interval between writing to surgeons and receiving their permission ranged from one week to four months. However, all surgeons were supportive of the study and all gave their permission to access patients from their caseloads. In three of the clinical sites, the attending surgeons were required to act as co-investigators. Before an application for ethical approval could be made to the relevant ethics committee, permission from the surgeons to act as co-investigators had to be secured.

While the varying recommendations of ethics committees are reasonable and understandable in terms of safeguarding patient groups being accessed for research, the time it takes to respond to the individual requirements of each ethical committee can potentially delay the commencement of a study (McCauley et al, 2009). For example, for the current study, the interval between sending
applications to six ethical research committees and receiving approval ranged from two days to six months which delayed the commencement of data collection in some centres (Figure 1). Some authors have questioned the effectiveness of a multi-system approach to securing ethical approval, advocating for a more centralised system of ethical review. It is the view of Green et al (2006) that an approach based on a standard application for researchers seeking ethical approval for multi-centre studies is required. They argue that a central committee constitutes a more manageable and less costly system than a multi-system approach (Green et al, 2006). Other authors purport that multi-centre studies which require numerous ethical applications are not very amenable to collaborative research endeavours (Gold and Dewa, 2005). Despite the publication of guidelines to facilitate prompt review of multi-centre studies such as in Ireland (The Irish Council for Bioethics (2004), little progress has been made to this end. Christie et al (2007) maintain that the need to hold on to a multi-centre system is linked to indemnity. Clinical institutions are increasingly concerned about the risks of being involved in a legal case with a patient should a negative health care outcome occur as a result of their involvement in a research study.

**Gaining Access to Clinical Sites**

To facilitate access to patients, researchers require the help of health-care professionals who serve as gatekeepers to potentially eligible study participants (Bond-Sutton et al, 2003; Savage and McCarron, 2009). Indeed, throughout the recruitment process, researchers are challenged to sustain the commitment and collaboration of healthcare professionals from a number of sites (Irving and Curley, 2008). Early and continued dialogue and collaboration between researchers and healthcare professionals are therefore important to optimize access toward recruiting sufficient numbers of study participants. On-going collaboration helps to develop and maintain trust between researchers and gatekeepers, and also promotes an understanding of both the research as well as the clinical practices needs (Bond-Sutton et al, 2003).
Due to the small number of patients who currently undergo sphincter saving surgery in Ireland, ten clinical sites specialising in colorectal cancer were approached to access patients for the study. One researcher (ML) had responsibility for gaining access to patients across all clinical sites and therefore was the person that communicated with various gatekeepers. In some clinical sites, a number of healthcare professionals, identified as key gatekeepers were unknown to the researcher. While email was the main method of communication used, the researcher initially telephoned key personnel to provide a brief background of the study and to determine the approximate number of potential participants from each of the ten clinical sites. For some sites, the researcher had face to face meetings with healthcare professionals. In some clinical sites, it was necessary to liaise with administrative personnel as well as healthcare professionals. Administrative requirements for access to patients were found to vary across clinical sites. For example, a specific requirement in two clinical sites was that the study had to be registered with the quality control department in these sites. This requirement necessitated the completion of additional forms for auditing purposes, which further delayed access.

Given the multiple gatekeepers involved, accessing participants in a multi-centre study is convoluted and involves many systems of communication which can vary from clinical site to another. For the current study, access through various gatekeepers was time consuming and delayed the commencement of data collection by two months in two sites. Although communication with multiple gatekeepers was necessary to facilitate access to patients, the support of clinical nurse specialists was invaluable. These nurses are key to assisting researchers in establishing whether a potential participant meets eligibility criteria (Chlan et al, 2009)

In order to investigate the bowel symptoms experienced following sphincter saving surgery,
patients who had not undergone surgery to reverse their stoma were excluded from the study. A small number of patients still had not undergone reversal surgery at 12 months (and beyond) postoperatively. The clinical nurse specialist in each clinical site knew from their records, which patients had not undergone surgery to reverse their stoma. These patients were readily identified by the clinical nurse specialists which, meant that they were not sent the study questionnaire to complete. In three of the clinical sites, administrative staff facilitated access. Most hospitals have electronic medical record systems in place, which allow for fast access to listings of patients’ names, their addresses and telephone numbers for research purposes. However, direct access to patient listings and to patients themselves was not always straightforward as illustrated in the next section of this paper.

Direct Access to Participants

Many of the challenges to recruitment already highlighted are interconnected, which also include challenges relating to access to participants themselves (Chlan et al, 2009; Savage & McCarron 2009). Above all, participants’ rights must be protected throughout each stage of the research process (Chlan et al, 2009) and patients should not feel obliged to take part in the research. However, some patients may feel pressurised to participate due to their vulnerable status (Bond-Sutton et al, 2005). These may include older patients, those with chronic disease, cancer or a terminal illness. Because of their specific health care needs, participants within these population groups are often at the centre of many investigations (Bond-Sutton et al, 2005) which may result in refusal to partake if previously involved in a number of studies.

For the current study, approval was granted by three ethical committees to contact participants directly, by mailing them information leaflets and the questionnaires. However, this was not feasible in sites associated with the three remaining committees, which required that hospital
personnel made the first point of contact with eligible patients. For example, a quality control manager accessed the names and addresses of patients from their respective institutions for the researcher. In addition, quality control managers sought verbal permission from patients before they were approached by the researcher. Another ethics committee requested that the letter of invitation to participants be sent directly from the attending surgeon. This letter provided the name, affiliations and contact details of the principal researcher. The one remaining committee required the attending surgeon to act as co-researcher, which meant that the letter of invitation to patients had to be signed by both the researcher and the attending surgeon.

In addition to letters of invitation to partake in the study, eligible patients also received an information leaflet which outlined the purpose of the study and what was required of them. Ensuring that information about a study is understood can be a further challenge in a study that involves a postal questionnaire. However, a follow-up phone call can address this challenge which in this study was found helpful to addressing any questions patients had about the study, or in supporting them to complete the questionnaire. It was felt that the personal contact with the individual might potentially increase their participation in the study. However, direct access to patients by telephone was not permitted by one ethical committee, which again illustrates the diversity in the conditions of approval.

Participants were telephoned about a week before they were due to submit the questionnaire. One patient required some help in the interpretation of one of the questions. Patients may have undergone more than one surgical procedure and it was important therefore, to clarify that the study related to patients views following the reversal of their stoma. The majority of patients when telephoned stated that they would be happy to share their experiences as they felt it would help another patient undergoing sphincter saving surgery.
Conclusion

The purpose of this paper was to present challenges found to be problematic in recruiting individuals following sphincter saving surgery for rectal cancer for a multicentre study. Among the specific challenges for the current study were the impact on time and resources, the differing procedures for ethical review for the same protocol at different sites, and the fact that there were some variations in the recommendations made by ethical committees. The current study presented minimal risk to participants provided that consent was secured and confidentiality and privacy maintained. A number of authors have called for a more centralised approach to ethical review, arguing that obtaining ethical approval is both time consuming and costly in the absence of a central review committee. We concur with this recommendation based on our experiences to date in the current study.

Researchers need to engage with a number of healthcare providers in clinical settings throughout the research process. The accessing process in this multi-centre study was convoluted and involved many systems of communication, which varied from one clinical site to another. The solutions to some of the challenges encountered by researchers relating to data collection are not always adequately dealt with in research textbooks. Decisions are often based on the experience of the researcher and advice gained from peers. Hence, there is a need for more academic dialogue around the challenges of accessing and recruiting eligible participants for research. Moreover, patients need to be reassured that their contribution to the research is valued and that their privacy will always be guaranteed. Although to date several challenges to access and recruitment have been experienced by the researchers they have not been insurmountable. In view of the dearth of the literature on the research topic, the extra time and resources required in accessing a suitable sample from a number of sites were small costs to endure, in return for obtaining the views and experiences of patients who
underwent sphincter saving surgery for rectal cancer. It is crucial therefore, that nurse researchers learn from each others’ experiences in order to gain knowledge, skills and confidence to recruit from multiple sites when populations are small, yet the concerns of these populations need to be voiced.

Conflict of Interest: None declared.

References


Figure 1: Process of Gaining Ethical Approval

- **Geographical Location (GL)**
  - GL 1
  - GL 2
  - GL 3
  - GL 4
  - GL 5

- **Process**
  - Site 1
  - Site 2
  - Site 3
  - Site 4
  - Site 5
  - Site 6
  - Site 7
  - Site 8
  - Site 9
  - Site 10

- **Chairperson’s Review**
  - Full Committee Review
    - Researcher Attendance
      - Meeting
      - Recommendations Made regarding the wording of the letter to participants.

- **Ethical Approval**
  - Granted 2 days Following Submission of Application
  - Granted 1 month Following Submission of Application
  - Granted 1 month Following Submission of Application
  - Granted 2 months Following Submission of Application
  - Granted 3 months Following Submission of Application
  - Granted 6 months Following Submission of Application

- **Outcome**
  - Ethical Approval
  - Granted 1 month Following Submission of Application
  - Recommended by Chairperson
  - Full Committee Review Required
  - Researcher Attendance Not Required
  - To Attend Meeting
  - Recommendations Made regarding the Application Form, Information Leaflet, and Letter to Participants

- **G L**
  - Full Committee Review Required
  - Researcher Attendance Not Required
  - To Attend Meeting
  - Recommendations Made regarding the Information Leaflet / Consent Form, Letter to Participants and Participant Recruitment