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Journal of Clinical Epidemiology 64 (2011) 525–530

Journal of Clinical Epidemiology

# Recruitment of newly diagnosed ovarian cancer patients proved challenging in a multicentre biobanking study

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Accepted 23 July 2010

**Abstract**

**Objective:** To explore the challenges of recruiting ovarian cancer patients and healthy controls to a cancer biobanking study.

**Study Design and Setting:** The study was set up in gynecological cancer centers in 10 National Health Service trusts across the United Kingdom. Women were approached if they were undergoing investigations/awaiting treatment for ovarian cancer, had a previous diagnosis of ovarian cancer, or were attending for annual screening in an ovarian cancer screening trial. Those who consented completed a detailed epidemiologic questionnaire, provided blood and tissue samples if appropriate.

**Results:** The overall proportion of those recruited compared with the expected targets was 76.4% for healthy controls, 86.0% for old cases, and 46.9% for new cases. Only 4 of 10 (40%) centers recruited over 50% of their target for new cases. Unwillingness to participate was reported as primarily because of patients being too unwell, wanting to focus only on their treatment, or having insufficient time because of conflicting medical appointments. Concerns about use of personal data or tissue and blood samples for genetic research and lack of direct benefit were reported as significant challenges to recruitment.

**Conclusion:** When setting recruitment targets for patients undergoing investigations or awaiting treatment for cancer (new cases), it is important to consider lower response rates because of various patient, logistical, and trial-specific challenges. 

*Keywords:* Biobanking; Recruitment challenges; Ovarian cancer; New cases; Old cases; Healthy volunteers

## 1. Introduction

In recent years, there have been concerted efforts to set up well-organized high-quality biobanks for future scientific research such as the UK Biobank [1] and the Swedish National Biobank program [2]. The initial emphasis was on organization, ethics, regulatory, and legal issues [3,4]. More recently, there has been a European directive on setting quality and safety standards [5] for biobanks, with a focus on data collection, sample processing, and storage. There are, however, only limited publications on possible barriers to recruitment to biobanking studies. This is in contrast to the extensive literature available on recruitment to randomized control trials [6], where participation might actually benefit the patient when compared with biobanking that offer no such direct benefit.

The United Kingdom Ovarian Cancer Population Study was set up in 2006 across 10 NHS trusts to explore genetic and epidemiologic risk factors, identify potential biomarkers, investigate symptoms in ovarian cancer, and store data and samples for future research. Recruitment was initiated at three centers in January 2006. Other centers joined in the course of that year, with the last center becoming active in February 2007. Confirmed and suspected ovarian cancer patients and healthy women were asked to provide extensive reproductive and lifestyle data and donate blood. Patients were also asked to donate tumor tissue excess to clinical requirement, where applicable. There was no personal benefit to the individuals taking part. This report explores the barriers and challenges encountered during recruitment to this study.

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0895-4356/$ - see front matter 
doi: 10.1016/j.jclinepi.2010.07.008

**What is new?**

Certain time points in the cancer treatment pathway offer significant challenges to biobanking studies, where participation confers no direct benefit to the patient.

Concerns about use of personal data or genetic material for research and lack of direct benefit are not significant barriers to recruitment to a biobank.

Recruitment of suspected cancer patients awaiting confirmation of diagnosis or those awaiting treatment imposes additional challenges when compared with those who have commenced/completed treatment or healthy volunteers.

When setting, recruitment targets for patients undergoing investigations or awaiting treatment for cancer (new cases), it is important to consider that response rates may be lower as patients are often unwell, wish to focus on their treatment, or have less time to spare because of conflicting medical appointments.

It is also necessary to address logistical issues, such as lack of dedicated recruitment space in busy hospital clinics, poorly performing centers, or centers withdrawing midway into the study.

## 2. Methods

Gynecological oncology centers that had successfully recruited participants to the ovarian cancer screening trials either in the general population (United Kingdom Collaborative Trial of Ovarian Cancer Screening, UKCTOCS) [7,8] or the ''high risk'' (United Kingdom Familial Ovarian Cancer Screening Study) were invited to participate in this biobanking study. The final list of 10 centers included NHS trusts in Belfast, Bristol, Gateshead, East Kent, London, Manchester, Middlesbrough, North Wales, Portsmouth, and Southend-on-Sea. The local teams consisted of the lead investigator and a dedicated part-time research nurse. The study was coordinated using a Web-based custom-built trial management system. This allowed centers to register participant details and log biological samples over the Web in real time.

The study duration was 2 years and before start of recruitment, targets were set for each center at 300 controls, 50 new cases and 50 old cases per year. These targets took into account the number of ovarian cancer patients and controls treated/followed up each year at these centers. This was considered to be achievable as it was 50–80% of the expected number of new and old ovarian cancer cases and 7–12% of healthy volunteers attending annual screening with serum CA125 in UKCTOCS at these centers. The two centers not participating in UKCTOCS were not expected to recruit healthy controls.

Women aged 18 and older were recruited if they had a suspected or confirmed primary ovarian or fallopian tube malignancy (including borderline epithelial). ''New cases'' were those whose cancer was only confirmed after recruitment, and these women were recruited while undergoing investigations or awaiting surgery/neoadjuvant chemotherapy. ''Old cases'' were women with a confirmed primary ovarian or fallopian tube cancer who had commenced or completed treatment at recruitment. Controls were recruited from postmenopausal women attending for annual screening in UKCTOCS and those attending for surgery for a suspected benign adnexal mass.

Patients were recruited when they attended preoperative assessment clinics, medical oncology clinics for chemotherapy/follow-up and when they were admitted on the ward, before surgery. Healthy controls were targeted when they attended UKCTOCS-screening clinics. An invitation letter, patient information sheet, and questionnaire were sent to healthy controls in advance of their clinic appointment. Most centers also sent invitations to women with a confirmed ovarian cancer diagnosis attending for follow-up appointments. However, invitations were not sent to women before clinic appointment if they had not received a definite ovarian cancer diagnosis because of the potential to cause additional anxiety.

At recruitment, women gave written consent for current research and for use of their samples and data in future ethically approved studies. They completed an epidemiologic and lifestyle questionnaire that was divided into two parts. The initial part that contained 24 items had to be completed at the center. Women had the option of completing the second part of 46 questions at home and returning it in a freepost envelope to the coordinating center. Questions included details on reproduction, contraception, medical and family history, as well as symptoms. The study documents can be accessed at http://www.instituteforwomenshealth.ucl.ac.uk/academic_research/gynaecologicalcancer/gcrc/ukops/.

Where possible, blood samples were taken at the same time as other routine blood tests. Each woman donated five 10-mL tubes of blood, which were processed according to a strict protocol by the research nurses. Contact time between nurses and patients or volunteers depended on whether they were cases or controls and whether they had previously been sent the invitation letter, patient information leaflet, and questionnaire. Healthy controls and ''old'' cases that had already received this information required the least contact time, which averaged 20 minutes. Patients being seen for the first time, however, required between 40 and 90 minutes depending on how quickly they could read and understand the information leaflet, consent forms, and complete the first part of the questionnaire. The nurse registered all recruited patients and logged essential sample details over the Web-based trial management system. Women could participate even if they were unwilling or unable to provide tissue samples and/or complete the questionnaire. The blood and tissue samples together with