

# **The SAFE Study: Satisfaction and Adherence to Follow-Up with Colposcopy Exams**

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**TITLE**

The SAFE Study: Satisfaction and Adherence to Follow-Up with Colposcopy Exams

**LAY SUMMARY**

This study is intended to improve communication of colposcopy results and follow-up recommendations to patients. Current practice involves results being forwarded from the colposcopy clinic to the family/referring physician who then informs the patient. We are testing an intervention informed by focus groups in which a trained colposcopy nurse (patient liaison) contacts patients directly with their results and follow-up recommendations while providing education and support. We will examine whether this intervention improves patient satisfaction, reduces anxiety, and improves rates of adherence to follow-up and treatment appointments compared to the current practice.

**SUMMARY**

Cervical cancer is largely preventable with regular Pap smear screening that detects pre-cancerous changes that can be diagnosed and treated with colposcopy. This process is limited by patient adherence to the follow-up and treatment recommendations. Currently at Vancouver General Hospital (VGH), the largest colposcopy clinic in the province, results are forwarded from the colposcopy clinic to the family/referring physician who informs patients of results and recommendations. Inefficiencies, omissions or errors in this step may cause patient dissatisfaction, missed appointments, increased costs, and compromise patient outcomes. The primary objective of this study is to examine whether having a trained colposcopy nurse contact patients directly with their results and follow-up recommendations while providing education and support will improve patient satisfaction and reduce anxiety. The secondary aims are to compare the timeliness of receipt of results, rates of adherence to follow-up and treatment appointments, and potentially long-term clinical outcomes between the control and intervention groups.

The first phase of the study involves patient focus groups that will be interviewed about their experiences in colposcopy and what elements of a patient liaison interaction would be most important to them (REB#H16-01422). This information will inform the development of the patient liaison role and approaches to patient interaction to be utilized in the intervention in the second phase (current proposal). The second phase will entail a randomized controlled trial comparing patient anxiety, satisfaction and adherence to follow-up between a control group (current practice) versus the intervention group exposed to the patient liaison at the VGH Colposcopy Clinic. For the primary aim, a questionnaire containing items pertaining to patient anxiety and satisfaction with their experience of receiving their colposcopy results will be administered both to the intervention and control groups and the mean scores pertaining to anxiety and satisfaction will be compared using two-tailed t-tests. For the secondary aim, a chart review at 6-12 months following the initial colposcopy visit will examine the rates of compliance with the recommended follow-up or treatment visits and histologic diagnoses, and comparisons will be sought between the intervention and control groups using z-score test.

## **BACKGROUND AND SIGNIFICANCE**

Cervical cancer is the second most common cancer in women worldwide (incidence of 529,800 new cases annually), and the third leading cause of cancer death<sup>1,2</sup>. Given the natural history of cervical cancer, cytologic screening (Pap smears) for precursor neoplastic lesions with referral to colposcopy has significantly reduced the morbidity and mortality associated with invasive cervical carcinoma in jurisdictions with screening programs. However, the effectiveness of screening programs for this largely preventable cancer is limited by default rates from colposcopy, which range from 3-9% for initial appointments and 6-16% for subsequent treatment or follow-up visits<sup>1,7</sup>. A randomized trial found that 20% of women after a biopsy confirmed diagnosis of CIN (cervical intraepithelial neoplasia) did not attend their recommended treatment appointment<sup>5</sup>. Follow-up rates following initial treatment were also found to be poor in one prospective study in which only 31% of women attended the recommended follow-up colposcopy appointment and only 60% had follow-up at 17 months<sup>14</sup>. Delayed and missed appointments not only expose women to the risk of increased morbidity or disease progression, but they also reduce the efficiency of the colposcopy system for the wider population, thereby increasing costs<sup>1</sup>.

A critical step in the colposcopy pathway is communicating results and recommendations for further treatment or follow-up to patients. Communication delays, breakdowns in communication between specialists and primary care providers, and a lack of understanding by patients regarding the significance of their results and necessity for further intervention or follow-up have all been identified as potential contributors to default from colposcopy<sup>1,6,8</sup>. Ethnic minorities and those of low socioeconomic status are known to have lower rates of cancer screening associated with late-stage presentations and increased mortality. These patients are particularly vulnerable to breakdowns in the communication of results and follow-up plans, compounded by cultural and language barriers<sup>5,13</sup>. A recent qualitative focus group study found that patients value receiving results in a timely fashion from a clinically trained staff member with an understanding of the impact of the test result<sup>8</sup>. Correspondingly, studies have shown that adherence to screening, treatment and follow-up have improved with telephone-based interventions in which trained patient navigators contact patients with appointment reminders, education regarding the rationale for each test, follow-up for abnormal test results and counseling for barriers to attendance<sup>5,6</sup>. These interventions have also been found to be effective in ethnic or socioeconomic populations at higher risk for non-adherence<sup>13</sup>. Anxiety has been identified as a strong correlate of the colposcopy process, and is found to be elevated before, during, and after clinic procedures and may negatively impact adherence to recommendations<sup>6,12</sup>. There is evidence that providing patients simple (rather than complex) information significantly decreases their anxiety associated with colposcopy<sup>4,9,11</sup>.

In our setting, the Vancouver General Hospital (VGH) Colposcopy Clinic is the largest of its kind in British Columbia, comprised of seven clinics per week attended by ten physician specialists who see 15-20 patients per clinic for diagnostic and treatment services. Following a clinic visit, a colposcopy report with results and recommendations is issued to the patient's family/referring physician, typically within 2-3 weeks. It is the responsibility of the individual patient to follow-up with their provider for the results, or for the family physician/referring provider to initiate contact with the patient. The lack of direct contact between the colposcopy clinic and patients regarding test results or ongoing follow-up limits patient engagement and

increases opportunities for communication breakdown. This has the potential to compromise patient outcomes and patient satisfaction and contributes to inefficiencies in the healthcare system.

In the proposed second phase of this study, we aim to utilize information gathered from phase 1 to inform an intervention where a patient liaison nurse will serve as the link between new patients and the colposcopy clinic by communicating results along with treatment or follow-up recommendations to patients. She would explain the rationale behind recommendations and be available to answer patient questions. If this intervention is demonstrated to improve patient anxiety and satisfaction associated with colposcopy and adherence to follow-up and treatment, these results would then support larger studies and provide evidence to advocate for resources to offer this service to all colposcopy patients at VGH and beyond.

### **HYPOTHESIS AND OUTCOMES**

1. Primary outcome: We hypothesize that the intervention group will have lower mean state anxiety scores as measured by the State Trait Anxiety Inventory (STAI).
2. Primary outcome: We hypothesize that participants in the intervention arm will demonstrate higher:
  - A) Overall satisfaction with their colposcopy experience and interactions with colposcopy healthcare professionals; we anticipate higher patient satisfaction scores as well as positive qualitative themes from open-ended questions in the intervention group (PSQ-18 and VSQ-9 Inventories)
  - B) Satisfaction with the information and education they receive regarding colposcopy, their diagnoses and follow-up recommendations; we anticipate higher scores on questionnaire items that measure these factors in the intervention group (PSQ-18 and VSQ-9 Inventories)
3. Secondary outcome: We hypothesize that patients in the intervention group will receive results sooner.
4. Secondary outcome: We hypothesize that participants in the intervention arm will demonstrate greater:
  - A) Knowledge of their colposcopy diagnosis; we anticipate a higher rate of accuracy between the participant self-reported colposcopy diagnosis and actual diagnosis
  - B) Adherence to treatment and follow-up recommendations; we anticipate higher rates of follow-up/treatment visit attendance in the intervention group

### **STUDY DESIGN AND METHODOLOGY**

This is phase two of a two-part study. The first phase employs qualitative methodology with focus groups. Themes from these focus groups will inform development of the nurse-led patient liaison intervention to be employed in the second phase. The first phase has been reviewed in a separate Ethics application (REB#H16-01422).

This is a randomized controlled trial to compare patients who participate in the patient liaison intervention (intervention group) to those who continue with the current system of results reporting via the family/referring physician (control group). Following recruitment and consent, patients will be randomized to the intervention or control group. The control group will receive the standard of care for colposcopy results reporting via their referring physician. Following their

colposcopy visit, control patients are given a slip of paper reminding them to call their family/referring physician for their colposcopy results in three weeks if they have not yet been contacted. Upon receipt of the final pathology, colposcopy reports are prepared by the colposcopists and forwarded to family/referring physicians typically within 2-3 weeks of the visit. Patients then receive the results of their colposcopy report from their family/referring physician by whatever method of communication preferred by that provider.

The participants randomized to the intervention group will be exposed to the patient liaison in receiving their colposcopy report results and recommendations. Rather than receive results from their referring/family physician, an experienced colposcopy nurse will contact participants once the colposcopists complete the final colposcopy report. The colposcopy report will inform the referring provider that these patients will be informed of the results. The colposcopy nurse will provide an explanation of the colposcopy results and subsequent follow-up or treatment recommendations, be available to answer patient questions (within her scope), offer educational or support resources to patients. She will forward any patient questions beyond her scope to the patient's colposcopist who may then provide answers to the patient liaison or to the patient directly depending on the complexity and nature of the question.

The research coordinator (M. Bryce) will subsequently contact all participants (control and intervention groups) to complete a questionnaire following the communication of their colposcopy report. All participants following consent will be asked to provide their preferred contact method (email, telephone) and whether they prefer to access the questionnaire via an Internet link sent to their email or to complete it verbally via telephone with the research coordinator. Control participants will be contacted within 3-4 weeks of their initial colposcopy visit to permit time for communication of their results from their family/referring physician. Intervention group participants will be contacted once the patient liaison nurse has informed the research coordinator that the results have been communicated to the participant. Reminders to complete the questionnaire will be sent at weekly intervals—twice via email, and a third time via telephone. Patients who fail to complete the questionnaire after three reminders will be considered lost to follow-up.

- 1) The questionnaire will contain the following information and validated scales:
  - (a) Demographics\*
  - (b) Date of colposcopy appointment and date that results were communicated (to measure the time interval in days in which results were received by participants)
  - (c) Method of colposcopy results communication – family/referring MD versus patient liaison (to determine intention to treat versus per protocol)
  - (d) State-Trait Anxiety Inventory (STAI)
  - (e) Health Anxiety Inventory (HAI)
  - (f) Short-Form Patient Satisfaction Questionnaire (PSQ- 18)
  - (g) Patient Satisfaction Survey (VSQ-9)
  - (h) Self-reported colposcopy result and recommendation (to be compared to actual result on file)

\*Demographic information collected will include: Age, highest level of education, current employment, and ethnicity. This information is necessary to understand sample diversity, and generalizability of results.

Secondary aims in the randomized trial will be to assess the effectiveness and clinical impact of the patient liaison intervention by comparing: 1) the interval between generation of colposcopy reports and communication of these results to patients; 2) percentage of patients successfully contacted and number of contact attempts both by the patient liaison nurse and the research coordinator administering the questionnaire; 3) the accuracy of patient's understanding of their colposcopy result, measured by the comparison of self-reported and actual result; and 4) rates of patient compliance with recommended follow-up appointments for treatment or repeat colposcopy. Patient electronic charts will be reviewed in 6-12 months following the initial colposcopy visit to collect data regarding histologic diagnoses, adherence to subsequent follow-up or treatment appointments and number of missed/cancelled appointments.

## **PRELIMINARY DATA**

None

## **PARTICIPANTS**

### **Recruitment**

Participants will be patients recruited from the Vancouver General Hospital (VGH) Colposcopy Clinic who present for their initial colposcopy visit. Initial visits are already marked on the current clinic booking system utilized by the clinic healthcare providers. A clinical and research nurse who has previously been involved in recruitment of patients for other studies in the clinic will approach patients who meet inclusion criteria before or after their appointment as time permits and as patients prefer. Patients will be provided with a copy of the consent form that contains information about the study and the invitation to participate and will be given an opportunity to ask questions. Patients may then decide to participate in the study on the same day as their appointment and be consented by the research nurse in the clinic. The nurse will explicitly inform them that should they later choose to withdraw their consent, this may be done at any time with no impact on the care they receive. The decision of whether to participate will not impact any colposcopy visit that follows. All patient information will be stored on a password protected computer in an encrypted, password protected file. Following consent, patients will be randomized to the patient liaison intervention or control group. Thus, control participants will be recruited in the same manner as the intervention group participants.

### **Inclusion Criteria**

1. Must be 19 years of age or older
2. Must be patients presenting for an initial visit at the VGH Colposcopy Clinic

### **Exclusion Criteria**

1. Inability to speak conversational English- required to complete the questionnaire as well as provide informed consent to participate
2. Inability or refusal to provide consent
3. Pregnant – pregnant women do not usually have biopsies and their subsequent care may be much different than non-pregnant patients
4. Do not have a family physician or referring physician who will provide continuity of care following colposcopy – these patients do not have the option of getting results from a family or referring physician, so they would bias results.

## **Retention**

Recruitment is anticipated to commence in May or June 2017. With an anticipated 20-30 new patients per week in the VGH Colposcopy Clinic and capacity for nurses to approach 50% of these (10-15 patients per week), recruitment of 400 patients (with a 50% participation rate of 200 patients total) will be completed over approximately 9 months and be targeted for completion by the end of 2017. Each patient will be followed for approximately 6 months following their initial colposcopy visit via chart review at that interval, as it is anticipated that any recommended treatments or follow-up visits will take place by 6 months per the clinic standard. Thus, we anticipate completion of the trial by July 2018 for a total of 18 months.

## **Consent**

Consent will be obtained by the colposcopy research nurse at the VGH Colposcopy Clinic who will make initial contact with each patient in the waiting room prior to, or following, the colposcopy visit. After the patient has been presented with a consent form that includes information about the study and an invitation to participate, they will be given the opportunity to ask questions regarding participation in the study. Should they be interested in participating, the nurse will then review the consent form and the patient will be given the opportunity to sign the consent at that time. They will be informed that should they decline to participate or wish to withdraw their consent, they may contact the clinic to do so at any time and there will be no impact on the care they receive.

## **Use of Records**

Patient charts from Vancouver General Hospital (VGH) records will be extracted by Marguerite Bryce under the supervision of the Principal Investigator (Dr. M. Lee) who is a physician in the colposcopy group, and has access to clinical charts on routine basis. In the current standard practice at the VGH Colposcopy Clinic, patient electronic and paper charts are shared and utilized within the group of colposcopists in the direct provision of care and routine charting, and patients frequently will see a different physician for a follow-up appointment than for an initial visit. The key information to be drawn from the patient charts includes information regarding attended or missed follow-up appointments and adherence to follow-up and treatment recommendations-- this is already routinely collected and tracked by the clinic in order to optimize clinic efficiency and patient care. Additional information to be extracted from the patient chart within 6-12 months of the initial colposcopy visit includes the final pathologic result and pathologic diagnoses associated with any treatments, which will be used to compare patient self-reported colposcopy results to the actual results as well as assess the impact of patient adherence on clinical outcomes. Permission to access and utilize these clinical data will be obtained in the initial consent to participate in the study.

## **Criteria for Early Withdrawal of Participants**

Should any participant request to withdraw from the study prior to being contacted with their results by either the patient liaison or their family/referring physician, this will be noted on the colposcopy clinic chart and they will default to the clinic standard of care (upon generation of the colposcopy report, a note will be sent to the family/referring physician informing them that they must follow-up with the patient regarding their colposcopy results).

## **SAMPLE SIZE CALCULATION**

To achieve 90% power for a difference of 5.3 (half of a standard deviation is considered clinically significant) in mean anxiety scores (state subscale of the STAI) between the control and intervention groups with an assumed pooled standard deviation of 10.6 and alpha of 0.05, the required sample size is 85 per group. Accounting for about 15% loss to follow-up, we aim to recruit 100 per group with 200 participants in total. With an estimate of 50% participation, the research nurse will need to attempt to recruit approximately 400 patients to reach this target.

## **ANALYSIS**

The mean composite scores will be compared between the intervention and control groups with a significance level  $p<0.05$  specifically looking at:

- 1) Mean patient anxiety (quantified by the STAI state subscale and HAI scale) related to receipt of colposcopy results: The State Trait Anxiety Inventory is an established and widely-used anxiety measure with high internal consistency (Cronbach's  $\alpha = 0.83-0.95$  dependent on the population studied)<sup>10</sup>. It contains 20 self-reported items that measure situational or state anxiety, and patients rate their agreement with these statements on a four point Likert scale which are then aggregated for a composite score. Mean composite trait and state anxiety scores will be compared between the two groups using the two-tailed t-test.
- 2) Patient satisfaction with the timing and method of communication of their colposcopy results and satisfaction with the information they received concerning their diagnosis, procedures, or recommended management: these will be quantified by the validated PSQ-18 and VSQ-9 scales which have been previously used in patient satisfaction studies at the VGH Colposcopy Clinic. Mean scores on the subscales will be compared between the two groups using the two-tailed t-test.
- 3) The accuracy of participant understanding of their colposcopy diagnosis following the intervention: for all patients, self-reported colposcopy diagnosis will be compared to the diagnosis in the clinic chart and graded as correct or incorrect. A chi-square analysis will be performed to assess whether there is a significant difference between the two groups.
- 4) Timeliness and rates of communication of patient results: The mean interval in days between generation of colposcopy reports and the communication of the result to the patient as well as the mean percentage of successfully contacted participants will be compared between the two groups using t-tests and z-tests.
- 5) Participant adherence to follow-up: patient electronic charts will be reviewed in 6-12 months following the colposcopy. The proportion of patients who complete the recommended follow-up will be compared between groups using z-test.

## **BENEFITS**

Those who participate in the patient liaison intervention may benefit from more timely receipt of their colposcopy results and recommendations as well as an improved understanding of their pathology, the rationale for the recommendations, and support in the logistics of arranging their follow-up or treatment visits. The direct contact with the experienced colposcopy nurse who can offer support and counseling may also improve the overall patient satisfaction with the experience of receiving their results as well as decrease the anxiety or other negative emotions associated with the colposcopy process. They may also have the opportunity to access additional educational or support resources provided by the colposcopy nurse. Improved adherence to colposcopy follow-up and treatment may improve clinical outcomes for patients who participate in the intervention.

## **RISKS**

By participating in the Patient Liaison intervention, the intervention group will no longer primarily receive their colposcopy results from their family/referring physician and may thus experience decreased continuity of care with their referring physician. However, the referring physician will still receive a copy of the colposcopy results and recommendations; while they will be informed that the colposcopy nurse has already contacted the patient, patients will still be able to contact their referring physician or schedule additional follow-up visits at their discretion. During the intervention in which the patient liaison contacts the patient with her results, it is possible that the patient may have questions or concerns which are beyond the scope of the colposcopy nurse. To mitigate this, the colposcopy nurse will be supported by the colposcopists who are most responsible provider for each patient who can provide additional information or resources as needed. The nurse may then attempt to re-contact the patient at a later time, or request permission for the patient to be contacted directly by their colposcopist. In addition, there may be questions that are outside the scope of colposcopy care and patients will be asked to contact their primary care provider in these cases. Patients may encounter questions that they do not feel comfortable answering when completing the questionnaire. Should this occur, patients will be instructed that they may leave these unanswered, or at any time withdraw from the study. The final page of the questionnaire will include investigator contact information for any participant questions or concerns and will also list mental health resources for participants who are seeking further support.

## **CONFIDENTIALITY**

Individual study code numbers will be assigned to each participant that will not be derived from any identifying information in order to maintain confidentiality. A linking record that connects the participant code number with their patient file will be stored on a password-protected encrypted file on a password-protected computer belonging to the study nurse which is located in a private locked office. Aside from consent forms which will have the patient's name, all other databases and study information collected will contain only the patient's study number.

## **DATA STORAGE**

Study questionnaire data will be collected and managed using REDCap (Research Electronic Data Capture), an electronic data capture tool hosted and supported by the Women's Health Research Institute (WHRI). REDCap is a secure web-based application designed to support data capture for research studies that will identify patients only by their study code. Any questionnaires that are completed over the phone with the research coordinator rather than directly through the online link by participants will be entered by the coordinator onto REDCap using an iPad that is secured and locked in the private office of Dr. Lee or of the study nurse (and no data will be stored on the iPad itself). All files with identifying information will be stored on a password-protected encrypted file on a password-protected computer in the study nurse's private office. Hard copies of consent forms will be stored in a secured and locked area of the study nurse's private office.

The REDCap data collection application will be used for study data management. Only the patient's study number, and no identifying information, will be used to identify each participant within REDCap. REDCap, developed by an NIH- funded consortium of institutional partners,

provides a secure, web-based application for users to enter data and have real time validation rules (with automated data type and range checks) at the time of entry. The system offers data manipulation with audit trails for reporting, monitoring and querying patient records, and an automated export mechanism to statistical applications. REDCap was developed specifically around HIPAA security guidelines and has a proven track record with over 400 academic clinical research centres hosting the application. The Clinical Research Unit Data Coordinating Centre (DCC) will be used as a central location for data processing and management. The DCC will house the data in a dedicated, locked server room within the BC Women's Hospital main site, which is secured with 24- hour on-site security guards. Communication over public networks and between the web application is encrypted using secure socket layer (SSL) with 256-bit encryption or higher. Access between the web application and database is protected by a firewall.

### **EARLY STOPPAGE**

The entire study could be stopped early should it become evident that the patient liaison is not successfully able to contact a significant proportion of the intervention group participants with their colposcopy results and recommendations despite multiple attempts (greater than or equal to 15% by the interim analysis at 50% enrollment). This would be a safety concern given the importance of the communication of these results for adherence to treatment and follow-up visits, and the plan in this scenario would be to default to the standard of care which would be involving the family/referring physician in attempts to contact the patient. In this scenario, the investigators would contact all participants to inform them of the reason for the study stoppage, providing participants the opportunity to ask any questions or express any concerns at that time. Participants in the control arm would be unaffected as they would be proceeding with the current standard of care. Referring physicians for participants in the intervention arm would be contacted to inform them of the reason for study stoppage and the potential need to contact these participants with their colposcopy results and recommendations (return to the standard of care).

### **CONFLICTS OF INTEREST**

None to declare.

### **FUNDING**

Funding has been awarded by the Division of Gynaecologic Oncology Research Awards in the amount of \$13,515.

### **BUDGET**

Research Assistant (rate \$20.74/hour)

- Focus groups (2 groups of 8-10 patients) = 15 hours: **\$311**
- Questionnaire administration (n=200 patients x 30 mins/patient = 15 hours): **\$2,074**
- Documenting follow-up and treatment visit rates and outcomes (n=200 patients x 10-15 mins/patient = 40 hours): **\$830**

Research Nurse Recruitment and Patient Liaison (rate \$50/hour)

- Recruitment (400 patients x 50% success for n=200 patients x 15 mins/patient = 100 hours): **\$5,000**
- Patient liaison interaction with intervention group (n=100 patients x 30 mins/patient = 50 hours): **\$2,500**

Data Management

- iPad for questionnaire and data collection: **\$1,000**
- SPSS (\$400/year): **\$800**

Knowledge Translation

- Dissemination of findings (website, social media, conference presentation/poster): **\$1,000**

**Total: \$13,515**

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