Evidence-Based Series 15-12 Version 2

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

The Organization of Colposcopy Services in Ontario: Recommended Framework

J. Murphy, N. Varela, L. Elit, A. Lytwyn, V. Wu, M. Yudin, M. Shier, S. El-Khatib, and the Cervical Cancer Screening Clinical Advisory Committee

An assessment conducted in February 2024 deferred the review of Evidence-based Series (EBS) 15-12 Version 2. This means that the document remains current until it is assessed again next year. The PEBC has a formal and standardized process to ensure the currency of each document (PEBC Assessment & Review Protocol)

EBS 15-12 Version 2 is comprised of 3 sections. You can access the summary and full report here:

https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/2096

Section 1: Guideline Recommendations
Section 2: Guideline Methods Overview and Evidence Review
Section 3: Internal and External Review

November 30, 2015

For information about this document, please contact
Dr. Joan Murphy through the PEBC via:
Phone: 905-527-4322 ext. 42822 Fax: 905-526-6775 E-mail: ccopgi@mcmaster.ca

For information about the PEBC and the most current version of all reports, please visit the CCO website at http://www.cancercare.on.ca/ or contact the PEBC office at:
Phone: 905-527-4322 ext. 42822 Fax: 905 526-6775 E-mail: ccopgi@mcmaster.ca

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PUBLICATIONS RELATED TO THIS REPORT

A recommended framework has been published in the peer-reviewed journal *Current Oncology* (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4530814/):

- Murphy J, Varela NP, Elit L, Lytwyn A, Yudin M, Shier M, et al. The organization of colposcopy services in Ontario: recommended framework. Curr Oncol. 2015 Aug; 22(4):287-96.

The original version of this report, which was released in 2008, has been published as a systematic review in the peer-reviewed *Journal of Lower Genital Tract Disease* (http://www.ncbi.nlm.nih.gov/pubmed/20040831):

- Fung-Kee-Fung M, Howlett RI, Oliver TK, Murphy J, Elit L, Strychowsky J, et al. The optimum organization for the delivery of colposcopy service in Ontario: a systematic review. J Low Genit Tract Dis. 2010 Jan;14(1):11-21.

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The Organization of Colposcopy Services in Ontario: Recommended Framework

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Evidence-Based Series #15-12 Version 2: Section 1

The Organization of Colposcopy Services in Ontario: Recommended Framework

Guideline Recommendations

J. Murphy, N. Varela, L. Elit, A. Lytwyn, V. Wu, M. Yudin, M. Shier, S. El-Khatib, and the Cervical Cancer Screening Clinical Advisory Committee

Report Date: January 20, 2015

GUIDELINE OBJECTIVES

To provide a framework by which colposcopy services in Ontario can be delivered with consistent quality, in the following areas:

1. Colposcopy training, qualification, and maintenance of competence:
   - Accessibility to training programs
   - Quality of training programs
   - Requirements to qualify as a colposcopist
   - Maintenance of competence

2. Practice setting requirements:
   - Group practice: hospital-based clinics and outpatient clinics located outside of hospitals
   - Individual office-based practice

3. Operational practices:
   - Referral criteria
   - Wait times
   - Strategies to reduce drop-out rates

4. Quality indicators and outcomes:
   - Quality assurance
   - Performance indicators

INTRODUCTION

The objective of this document is to help ensure the provision of high-quality colposcopy procedures in the province of Ontario, including those conducted as diagnostic procedures in follow-up to an abnormal cervical screening test. In Ontario, no prior efforts other than the good will of care providers, administrators, and other involved parties have been made to organize these services. The current document will provide guidance both for the time being and for the future on a variety of initiatives including the organization of colposcopy and integration with the Ontario Cervical Screening Program, the use of synoptic/electronic data capture, and the introduction of human papillomavirus (HPV) testing for triage to manage women with low grade abnormalities, for test of cure to assess the risk

of residual/recurrent cervical intraepithelial neoplasia (CIN) disease in treated women, and/or for primary HPV cervical cancer screening. The potential uses of each initiative will be examined as they are implemented. Each such initiative would contribute to the incremental organization of colposcopy, ultimately achieving a fully organized and managed system integrated with the cervical screening program. Each of these individual initiatives will be based on informed evidence and expert opinion and is intended to improve the seamless, consistent, and timely access to high-quality colposcopy care that is necessary as an adjunct to screening in order to achieve the optimum reduction in cervical cancer incidence and mortality rates.

This document provides recommendations on training and maintenance of competence for colposcopists in the practice setting where colposcopic evaluation and treatments are conducted, as well as recommendations on operational issues and quality indicators for colposcopy. Clinical practice recommendations on how to perform colposcopy or recommendations for improving the skill level of an individual colposcopist are beyond the scope of this document. Similarly, detailed clinical management pathways and colposcopy best practices are addressed in the *Clinical Guidance: Recommended Best Practices for Delivery of Colposcopy Services in Ontario* (Colposcopy Clinical Guidance) document. This document can be found at https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/43336. This Evidence-Based Series (EBS) provides an update to the 2008 Cancer Care Ontario (CCO) document EBS #15-12: "The Optimum Organization for the Delivery of Colposcopy Service in Ontario" (1).

Given the availability of current, high-quality, and relevant documents identified after a systematic review of guidelines, the sources of evidence to inform these recommendations are based on the endorsement or adaptation of existing recommendations from relevant guidelines published since 2008. A review of the primary literature was not undertaken. Further details related to the methodology for developing the evidentiary base can be found in Section 2. The quality assurance and performance metrics (see below) can be used to provide feedback to individuals to improve performance on quality indicators when necessary and to monitor performance at the system level to improve the overall quality of colposcopy in Ontario.

TARGET POPULATION

These recommendations apply to all healthcare providers and administrators involved with the provision of colposcopy examination in Ontario.

INTENDED USERS

These recommendations are intended for clinicians and institutions performing colposcopy in Ontario, and to policy makers and program planners involved in the delivery of colposcopy services.

GUIDELINE DEVELOPMENT PROCESS

Through a systematic search, several guidelines were identified that addressed the objectives outlined above. Recommendations from the earlier 2008 CCO colposcopy guideline were reviewed along with recommendations from five other guidelines published since that time (identified below). These guidelines were appraised for quality using the Appraisal of Guidelines for Research and Evaluation (AGREE) II Tool (http://www.agreetrust.org/) (Table 1, Section 2). Modifications and additions to the original 2008 CCO recommendations are noted. Details of the methods can be found in Section 2.

FORMATION OF GUIDELINE WORKING GROUP

CCO Prevention and Cancer Control (CCO-PCC) asked the Program in Evidence-Based Care (PEBC) to develop a guideline on the organization for colposcopy services in Ontario. In consultation with CCO-PCC, a Working Group was identified. This Working Group consisted of two gynecologic oncologists, three gynecologists, one pathologist, one registered nurse, and one methodologist (Appendix 1).

FORMAT OF THE RECOMMENDATIONS

Recommendations from the 2008 version of this guideline were first assessed for their relevance to the current practice environment. These recommendations were endorsed where appropriate. The new modified or revised recommendations are labelled as defined below:

- *NEW Consensus*: this recommendation is a new consensus recommendation developed by this guideline Working Group
- *RANZCOG*: this recommendation is adapted from the 2011 guideline (2) developed by the Royal Australian and New Zealand College of Obstetricians and Gynecologists (RANZCOG) in conjunction with the Australian Society for Colposcopy and Cervical Pathology (ASCCP) working party
- *NHSCSP*: this recommendation is adapted from the 2010 or the 2011 guideline (3) developed by the National Health Service Cervical Screening Programme (NHSCSP) in the United Kingdom
- *ECCSN*: this recommendation is adapted from the 2008 guideline (4) developed by the European Cervical Cancer Screening Network (ECCSN)

At the end of each major section of the recommendations a justification is provided.

RECOMMENDATIONS AND JUSTIFICATION

Qualification, Training, and Maintenance of Competence

1. Accessibility to Training Programs

Besides practicing obstetricians and gynecologists, the following practitioners should be eligible for colposcopic training programs:

- Residents and fellows in obstetrics and gynecology programs
- Other colposcopy service providers (e.g., family physicians, nurse practitioners) who meet the knowledge requirements as described below

To qualify for colposcopy training programs, health practitioners should demonstrate current knowledge of:

- HPV, including its biology, epidemiology, and natural history
- The natural history of lower genital tract dysplasia and cancer
- New and emerging therapies that impact clinical practice
- Cancer screening, including primary and secondary prevention
- Colposcopic clinicopathological correlations and standard terminology
- Indications for referral to colposcopy, as per the Ontario Cervical Screening Guideline (5) (*NEW Consensus*)

- Existing guidelines for referral (intake), treatment, re-referral, follow-up, and discharge as per the Colposcopy Clinical Guidance document. This document can be found at https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/43336.
- The Society of Canadian Colposcopists (SCC) 2012 publication (6) *(NEW Consensus)*
- Quality assurance principles and components

2. Training Programs and Qualification Requirements

All colposcopists should complete a colposcopy training program. Colposcopy training programs should be conducted by supervised, suitably trained personnel who are part of a well-established colposcopy program and whose competence and teaching abilities are recognized. Systems to provide certification of training programs and to ensure competence are evolving in other jurisdictions than Ontario, so no formal criteria for such programs can be recommended. However, ideally, colposcopy training programs should:

- Include attendance at a formally recognized course or program
- Be a minimum of three months in length, or equivalent, which ideally should be completed within a year
- Involve both theoretical and practical components, where practical training is under the direct supervision of a competent colposcopist preceptor and includes the four core components of diagnoses, therapeutic modalities, documentation, and maintenance of competence
- The training program should involve a minimum of 100 new cases, approximately 30% of whom should be patients with histologically documented low- or high-grade squamous intraepithelial lesions (LSIL or HSIL), endocervical adenocarcinoma in situ, or cancer including vulva, vagina, and vaginal squamous neoplasia. Of the 100 new cases, the preceptor should be present throughout the colposcopy examination for approximately 75 cases, and for the other 25 cases the trainer should be available if help is needed
- Include components of surgical pathology and cytopathology to allow understanding of laboratory investigation of lower genital track neoplasia, including assessment of morphology, immunohistochemistry and molecular testing *(NEW Consensus)*
- Involve a review of case logs
- Involve a formal evaluation confirming the successful completion of training
- To achieve better patient outcomes, all clinicians providing colposcopy services are expected to incorporate the Royal College of Physicians and Surgeons of Canada CanMeds competencies (Medical Expert, Communicator, Manager, Health Advocate, Scholar, and Professional) into their practice *(NEW Consensus)*

The training and qualification requirements to perform laser, cryotherapy, or loop electrosurgical excision procedures as part of treatment for cervical abnormalities should involve:

- The successful completion of a formal, procedure-specific course or program, e.g., laser certification (as noted above)
- A minimum of 10 procedures should be completed in a year in a given treatment modality under direct supervision before performing them independently
- The review of pathology and its correlation with clinical findings by a colposcopist preceptor
- A formal evaluation by a colposcopist preceptor that the trainee has demonstrated competence in each respective modality

To qualify as a colposcopist preceptor, practitioners should:

- Maintain a minimum of 100 new colposcopy cases per year with exposure to the spectrum of disease
- Work within an interdisciplinary team environment in an established clinic or practice, usually a hospital-based unit
- Be associated with a formal colposcopy program

3. Accreditation/Certification

Although a formal accreditation process for colposcopists is not implemented at present in Ontario, it is considered a standard of care in many other jurisdictions. Therefore, it is recommended that such a process be developed in Ontario, based on the process used by the NHSCSP (3) *(NEW Consensus)*.

4. Maintenance of Competence

To maintain competence, colposcopists should:

- Manage a sufficient number of patients with abnormal cervical cytology to develop, maintain, and improve their skills in this area of practice. Ideally, a clinical volume of approximately 100 colposcopies per year should be performed. Although the optimal proportion of new patients is not known, 25% is generally considered to be an absolute minimum
- Regularly attend and/or provide accredited continuing medical education (CME) events related to lower genital tract preinvasive diseases, at least once every two years
- Participate regularly in clinical audits as a component of continuing education
- Practice in compliance with the Colposcopy Clinical Guidance document. This document can be found at https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/43336.

Justification

The members of the Working Group endorse the accessibility to training programs, the training and qualification requirements, and the program scope recommendations contained in the 2008 CCO guideline (1).

The recommendations for maintenance of competence represent the consensus of the Working Group members based on guidance provided by the NHCSP in the United Kingdom (3), the RANZCOG in conjunction with the ASCCP Working Party (2), and the 2008 CCO guideline (1). Two additional recommendations related to CME from the 2008 CCO guideline (1) were endorsed. While the evidence base underpinning the volume-related practice recommendations is sparse and of poor quality, there is a convergence of opinion across different guideline developers internationally and among the members of this panel.

Practice Setting Requirements

The recommendations for practice setting requirements reflect current practice in Ontario where colposcopy services are delivered either in hospitals, outpatient clinics (located outside of hospitals), or individual office practices. The recommendations are presented separately for group and individual practices, not because of different recommendations in quality but in recognition of differences in resources, roles, and responsibilities (1). It is desirable that all colposcopy services whether in hospitals, outpatient clinics, or individual office practices achieve the same standard of patient care. Although the settings vary, each setting should have adequate personnel, appropriate facilities, and documentation and patient-management strategies in place. Each organized program or

individual provider should provide the continuum of care for diagnosis through treatment and follow-up to discharge.

1. Group Practices: Hospital-Based and Outpatient Clinics Located Outside of Hospitals

Group practices should have:

A. Personnel

- Colposcopists who meet the training requirements described in the previous section on qualification, training, and the maintenance of competence should see a sufficient case load to ensure and maintain the skills needed for the colposcopy program (see "Maintenance of Competence" above)
- Physician colposcopists, including a lead clinical colposcopist with a specialist team specific to the colposcopy unit. The physician colposcopists and the lead clinic colposcopists should maintain responsibility for quality assurance and management of protocols
- An experienced clinical colposcopist should be available to cover leave or other absences *(RANZCOG)*
- A pathologist or cytopathologist lead with specific competence in preinvasive lower genital tract disease who is responsible for collaborating in quality assurance processes
- A nurse lead responsible for clinic organization, patient education, and the coordination of collaborative services
- Nurses should have the appropriate training and knowledge:
    - All colposcopy nurses should complete training and/or coursework specific to colposcopy and best colposcopic practice
    - Nursing staff should be able to explain, and educate the patient about, the purpose of colposcopy, biopsy, treatment options, follow-up, fertility, risk factors, and possible side effects
    - There should be an educational component in every new patient history where the education provided by the nurse can be documented. Nurses have an opportunity to educate women at every visit *(NEW Consensus)*
    - Defining adequate nursing complement to meet the standard of care is determined by patient volumes, logistics, patient characteristics and other factors specific to each practice setting *(NEW Consensus)*
- Positive and active relationships with personnel from cytology and pathology services.
- An established liaison with a gynecological oncology unit or a gynecological oncologist(s) *(RANZCOG)*
- Adequate support personnel, clerical staff, and information technology staff

B. Facilities

The necessary physical resources and collaborative services deemed necessary to provide colposcopy should include:

- Compliance with infection control best practices, including access to instrument sterilizing facilities in accordance with provincial guidelines *(NEW Consensus)*
- A suitable information system for the collection of data
- Adequate safety guidelines for laser or diathermy equipment if in use, with all staff trained in their operation. Clearly written and easily accessible emergency guidelines should also be available *(NHSCSP)*
- Mechanisms to record wait times for patient consultations and treatments
- Adequate facilities and protected time for the training of staff (in the larger colposcopy units)

- Where required to comply with provincial standards for healthcare facilities, accessible resuscitation equipment and staff with appropriate training should be available *(RANZCOG)*
- Mechanisms to ensure the patient flow process provides privacy and dignity during the colposcopy visit *(NEW Consensus)*

C. Documentation and Patient Management

The following should be available or provided to the patients:

- Evidence-based provincial educational materials (written, online, or otherwise) and patient resources related to cervical screening that are standardized throughout the province. The educational materials should address risk factors, therapeutic and diagnostic procedures, aftercare following treatment, and appropriate follow-up strategies *(NEW Consensus)*
- A record-keeping process (ideally computerized) for the documentation of quality outcomes to allow audits and quality improvement initiatives, and to facilitate consistent reporting
- A relationship with all referral sources, including primary care and regional public health cervical screening services
- Referral for treatment is the responsibility of the colposcopists making the original diagnosis, and should occur in a seamless and timely manner *(NEW Consensus)*
- Written management protocols consistent with provincial and national guidelines
- Regular documented meetings to discuss case management protocols and quality issues
- If training is provided within the facility, maintenance of documented evaluations, course materials, and a roster of identified preceptors
- Documentation of all CME events should be maintained, including rounds and lectures for the clinic team, referring clinicians, and clinics
- A clinic-based systematic recall mechanism for patients *(NEW Consensus)*
- Regional access for the provision of care, including
    - Access for the physically challenged, and
    - Culturally appropriate information with translation into the primary language of the client
- Appropriate and sensitive enquires regarding sexual history may be made, but only under the auspices of an ethically approved study or if the patient presents with a specific indication *(NHSCSP)*

2. Individual Office-Based Practices

Individual office-based practices should:

- Have a formal, clearly defined relationship with a regional or hospital-based colposcopy program
- Participate in quality assurance and quality control activities, CME events, and educational meetings of the regional or hospital-based colposcopy programs
- See a sufficient number of patients each year. Ideally, 25 new patients for a total of at least 100 colposcopies each year should be the absolute minimum number seen
- Maintain record-keeping processes for documentation of quality outcomes and to permit audits and quality improvement initiatives (to facilitate consistent reporting)
- Comply with infection-control best practices, including access to instrument sterilizing facilities in accordance with provincial guidelines *(NEW Consensus)*
- Have the necessary physical resources for and access to collaborative services deemed necessary for providing colposcopy, which may include:
    - A proper examination room in accordance with provincial guidelines

- Access to resuscitation equipment if treatment is being provided
- A suitable information system for the collection of data

Justification

The members of the Working Group endorse the practice setting requirements (group practice and individual office-based practice) recommendations contained in the 2008 CCO guideline (1), except for the recommendations listed below, which are based on guidance provided by the RANZCOG and ASCCP working party (2), the NHSCSP (3), or consensus of the Working Group:

Under the personnel domain, the members of the Working Group endorse the clinical lead colposcopist standards contained in the RANZCOG and ASCCP document published in 2011 (2), except that the colposcopist designation used by the RANZCOG and ASCCP Working Party was modified from "*experienced colposcopist*" to "*clinical lead colposcopist*". Regarding nursing staff, at least two nurses for each clinic are recommended. However, the Working Group members recognized that for low-volume units in some geographic regions in Ontario it may be difficult to achieve this recommendation. It was concluded by consensus that, for low-volume units, one nurse may suffice.

Under the facilities domain, the members of the Working Group endorse the recommendation related to resuscitation equipment, contained in the RANZCOG and ASCCP document (2). The recommendation for the clinical facilities and patient flow process providing privacy and dignity is the consensus of the Working Group.

The recommendations under the documentation and patient management domain are based on guidance provided by the NHSCSP in the United Kingdom (3), and the 2008 CCO guideline (1).

While the individual study evidence underpinning these recommendations is sparse and of poor quality, there is international consensus about the key best practices to support these optimal practical settings requirements.

OPERATIONAL PRACTICES

1. ***Referral Criteria***

Women should be referred for colposcopy according to the Ontario Cervical Screening Program Clinical Guideline (https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/2156).

Justification

The recommendations for referral criteria are based on guidance provided by CCO's 2011 Cervical Screening Guidelines (5).

2. ***Wait Times***

Patients with abnormal cytology should be seen for colposcopy within a reasonable time, given the risk of high-grade changes and the psychological stress associated with an abnormal cytology result. Although there is limited biological information to fully inform wait times recommendation, we recommend that under the following conditions women should ideally be seen in a colposcopy clinic within the following time of referral:

- Women with atypical squamous cells cannot exclude HSIL (ASC-H) or atypical glandular cells (AGC) should be seen in a colposcopy clinic within six weeks of referral
- Women with HSIL should be seen in a colposcopy clinic within four weeks of referral
- Women with a Pap test suggestive of carcinoma should be seen in a colposcopy clinic within two weeks of referral

- All other women with abnormal results should be seen in a colposcopy clinic within 12 weeks of referral

Justification

The members of the Working Group endorsed the wait times recommendations from the 2012 clinical practice guidelines developed by the SCC (6). These recommendations are opinions of respected authorities, based on clinical expertise, descriptive studies, or reports of expert committees.

3. Strategies to Reduce Drop-Out Rates

System-wide mechanisms and follow-up procedures are needed to maximize attendance and improve patient outcomes:

- Women should be advised that they should notify the clinic of any change of their address and other contact details *(RANZCOG)*
- Ideally, the drop-out rate should be less than 15%
- Protocols to minimize the nonattendance of patients should be established
- Standardized, culturally appropriate information should be made available *(NHSCSP)*
- Women should be able to have a friend or relative present if they wish *(NHSCSP)*
- Audits should include analysis of the records of defaulters to identify avoidable causes of default at first consultation *(NHSCSP)*
- Effective information and communication are crucial to reducing anxiety. They include providing women with an understanding of the procedure, and of how and when information will be communicated to them and the referring practitioner *(NHSCSP)*
- Optimal practice requires that the referring clinician's details should be recorded for each new patient (*RANZCOG*)
- A documented system needs to be in place to notify or recall patients who default at first consultation, treatment or follow-up *(RANZCOG)*

Justification

The recommendations for reducing drop-out rates are based on guidance provided by the 2008 CCO guideline (1), the RANZCOC-ASCCP (2), and NHSCSP (3).

QUALITY INDICATORS AND OUTCOMES

There are multiple aspects of assuring high-quality care:

Quality management involves quality planning, quality control, quality assurance, and quality improvement to improve system performance and outcomes.

Quality assurance is an administrative or procedural activity in a quality system to ensure that the goals of the service are achieved. It is systematically measured and associated with an effective feedback loop.

Quality improvement is a systematic, continuous approach to making changes that lead to better patient outcomes, stronger system performance and enhanced professional development. It involves all stakeholders, including healthcare professionals, patients, families, planners, researchers, and educators.

Performance indicators are metrics that allow evaluation of how well (or poorly) a system's goals are being met. These metrics are compared with an appropriate benchmark that

reflects the system's desired performance. Performance indicators, which are carefully chosen to reflect strategic goals, allow a measure of progress toward these goals.

1. Quality Care

- An organized provincial colposcopy information and quality control system should be established to monitor the quality of colposcopy services. This system should include paired evaluations of colposcopy diagnoses, managerial evaluations, and the development of quality control indicators
- Colposcopy clinics (large and small) should undergo annual reviews for quality assurance
- Clinical audits should occur at the regional and provincial levels with appropriate feedback to clinicians
- All colposcopists should participate in regular quality and auditing activities that may include:
    - Colposcopists should ensure good practice, compliance with protocols and adequate data collection, and should monitor whether quality standards are attained and maintained
    - Lead clinical colposcopists should develop written protocols for local use that work toward achieving quality
    - Regular meetings of colposcopists, pathologists, and allied health professionals should occur to allow for the discussion of cytological and histological slides and colposcopic pictures, and to correlate (review discordance and concordance) cytology, histology, and colposcopy opinions
    - Correlations between cervical cytology and colposcopic diagnosis should be reviewed
    - Clinics should undergo annual reviews for quality assurance purposes with an opportunity for referring providers and patients to provide feedback on the colposcopy services
    - Clinical audits should take place at the provincial level to ensure consistent results
    - Data should ideally be captured on standardized electronic information collection systems to ensure quality and to facilitate quality improvement initiatives
    - Colposcopic findings should be recorded in the patient's record *(ECCSN)*
    - Reports on colposcopy procedures should be completed in specially designed reporting formats (preferably consistent across the province), and include information on findings, treatment, and recommendations for follow-up
    - Colposcopy reports should be followed to ensure compliance. If the patient's family physician is not the source of referral for colposcopy, the colposcopy report should be sent to the family physician (unless expressly prohibited by the patient) as well as to the referring colposcopy service provider. If the colposcopist records a referral to other services in the report (e.g., gynecology, oncology), then the colposcopist should follow up to ensure the referral takes place
    - Colposcopists should audit their work to confirm that their colposcopic assessment and colposcopically directed treatment is aligned with internationally agreed standards *(ECCSN)*
- Colposcopists should regularly participate in quality assurance activities including *(RANZCOG)*:
    - Meeting defined clinical indicators
    - Conducting tissue audits (e.g., excisional biopsies, microinvasive cancer, glandular neoplasms, and other pathology of interest. Audits of excisional

treatments should occur with particular emphasis on specimen quality and clinical outcome)
    - Reviewing patient satisfaction surveys (e.g., a survey form suitable for collecting data in consulting rooms or clinics. Data from 100 consecutive patients could be collected as part of an individual, group or institutional practice improvement activity)
    - Reviewing service audits (e.g., wait times for women with high- and low-grade abnormalities, distances travelled, quality of documentation, the proportion of women treated under general anesthesia, and the proportion of women found to have neoplasia)
- In practice, quality assurance baseline data should be collected *(RANZCOG)*

Justification

The recommendations for quality improvement are based on guidance provided by the 2008 CCO guideline (1), the RANZCOG in conjunction with the ASCCP Working Party (2), and the ECCSN (4). The members of the Working Group recognize that quality assurance activities such as clinical indicators, tissue audits, patient satisfaction surveys, and service audits are helpful to understand the distribution of disease in the population.

2. Performance Indicators

Individual clinics should implement clinic-specific performance indicators that could include *(RANZCOG)*:

- Colposcopy-biopsy concordance
- Complication after treatment
- Readmission for complications after treatment
- Residual disease after treatment
- Retreatment rate

Justification

The members of the Working Group endorsed the guidance provided by the ECCSN regarding key performance indicators for monitoring the cervical screening process (4), and adapted the guidance from the RANZCOG and the ASCCP Working Party regarding performance standards that should be used to monitor quality assurance in colposcopy (2).

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Updating

All PEBC documents are maintained and updated
as described in the PEBC Document Assessment and Review Protocol.

Contact Information

For information about this document, please contact
Dr. Joan Murphy through the PEBC via:
Phone: 905-527-4322 ext. 42822 Fax: 905-526-6775 E-mail: ccopgi@mcmaster.ca

For information about the PEBC and the most current version of all reports,
please visit the CCO website at http://www.cancercare.on.ca/ or contact the PEBC office at:
Phone: 905-527-4322 ext. 42822 Fax: 905 526-6775 E-mail: ccopgi@mcmaster.ca

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The Organization of Colposcopy Services in Ontario: Recommended Framework

Guideline Methods Overview and Evidence Review

J. Murphy, N. Varela, L. Elit, A. Lytwyn, V. Wu, M. Yudin, M. Shier, S. El-Khatib, and the Cervical Cancer Screening Clinical Advisory Committee

Report Date: January 20, 2015

THE PROGRAM IN EVIDENCE-BASED CARE

The Program in Evidence-Based Care (PEBC) is an initiative of the Ontario provincial cancer system, Cancer Care Ontario (CCO). The PEBC mandate is to improve the lives of Ontarians affected by cancer through the development, dissemination, and evaluation of evidence-based products designed to facilitate clinical, planning, and policy decisions about cancer care.

The PEBC supports a network of disease-specific panels, termed Disease Site Groups (DSGs), as well as other groups or panels called together for a specific topic, all mandated to develop the PEBC products. These panels are comprised of clinicians, other healthcare providers and decision makers, methodologists, and community representatives from across the province.

The PEBC produces evidence-based and evidence-informed guidelines, known as Evidence-based Series (EBS) reports, using the methods of the Practice Guidelines Development Cycle (7,8). The EBS report consists of an evidentiary base (typically a systematic review), an interpretation of and consensus agreement on that evidence by our Groups or Panels, the resulting recommendations, and an external review by Ontario clinicians and other stakeholders in the province for whom the topic is relevant. The PEBC has a formal standardized process to ensure the currency of each document, through the periodic review and evaluation of the scientific literature and, where appropriate, the integration of that literature with the original guideline information.

The PEBC is supported by the Ontario Ministry of Health and Long-Term Care. All work produced by the PEBC is editorially independent from the Ministry.

This EBS is comprised of the following sections:

- *Section 1: Guideline Recommendations*. Contains the clinical recommendations derived from a systematic review of the clinical and scientific literature and its interpretation by the Group or Panel involved, as well as, a formalized external review in Ontario by review participants.
- *Section 2: Guideline Methods Overview and Evidence Review*. Summarizes the EBS development process and the recommendations development process.
- *Section 3: Internal and External Review Process*. Summarizes the results of the formal internal and external review of the draft version of the EBS.

INTRODUCTION

Due to inequity in the availability and quality of cancer screening, globally, cervical cancer is the third most common cancer with 528,000 estimated new cases in 2012. It is the fourth leading cause of death for women worldwide with an estimated 266,000 deaths in the same year (9). In Ontario, there were 610 new cases of cervical cancer in 2013 and 150 women will die of their disease (10). In part, Ontario's low incidence and mortality rates reflect the presence of a provincial cytology-based screening program that leads to identification of lesions, which, if removed, can minimize the occurrence of cancer.

Colposcopy is the examination of the lower genital tract using five- to 30-fold binocular magnification with a colposcope. Colposcopy provides a visual diagnosis and allows the colposcopist to biopsy suspicious precancerous or cancerous lesions. Colposcopy plays an important diagnostic role in cervical cancer prevention in women with an abnormal screen test. It is important to optimize the quality of colposcopy services in Ontario, including their appropriateness, efficiency, and effectiveness.

The quality and clinical effectiveness of colposcopy has been shown to be variable in several jurisdictions (2,3). Therefore, several organizations have created quality assurance guidelines, including the PEBC of the CCO, which created the 2008 CCO guidance document "The Optimum Organization for the Delivery of Colposcopy Service in Ontario". At that time, the members of the 2008 guideline development group believed that the level of evidence to support the colposcopy recommendations was very modest. Therefore, the recommendations in the 2008 CCO guideline were adapted from other guidance documents from credible organizations or government bodies. The 2008 CCO guideline addressed the following domains: colposcopist qualification and training, practice setting requirements, quality assurance and control activities, and institutional characteristics that contribute to the quality of colposcopy services.

In 2012, the CCO Prevention and Cancer Control (CCO-PCC) determined that an update of the 2008 CCO guideline was necessary, but no improvement in the quality of the evidence was believed to have occurred. Therefore, PEBC and the CCO-PPC Program decided that the most effective way to update the 2008 CCO guideline would be through the adaptation of new recommendations identified in guidelines published after 2008 from other jurisdictions and organizations. A systematic review of the primary literature would only be considered if absolutely necessary and time resources allowed. The goal of this update was to identify areas where the 2008 CCO guideline recommendations were either incomplete or no longer reliable, and to modify those recommendations only when recommendations from more recent guidelines clearly indicated a change was necessary.

This updated guideline is intended to support quality improvement for colposcopy for all indications including the follow-up of an abnormal cervical screen test and to work up lower genital tract lesions that are not clearly malignant. The objective is to form the basis of a quality assurance program for colposcopy, regardless of indication, to improve the quality and consistency of colposcopy in the province and ultimately to reduce the incidence of cervical/lower genital tract cancers.

FORMATION OF GUIDELINE WORKING GROUP

In consultation with the CCO-PCC, the PEBC identified a Working Group to be the primary developers of this guideline. This Working Group consisted of two gynecologic oncologists, three gynecologists, one pathologist, one registered nurse, and one methodologist. The Cervical Cancer Screening Clinical Advisory Committee of the CCO-PCC was identified as the Expert Panel for this guideline. Members of this group took responsibility for providing feedback on the guideline as it was being developed and for the approval of the

document before its release for internal and external review. Together, the Working Group and the Cervical Cancer Screening are referred to in this remainder of this document as the Colposcopy Quality Assurance Guideline Development Group.

GUIDELINE OBJECTIVE

To provide a basis for a quality assurance program for all colposcopy procedures performed in the province of Ontario, including colposcopy in the following areas:

1. Colposcopy training, qualification, and maintenance of competence
   - Accessibility to training programs
   - Quality of training programs
   - Requirements to qualify as a colposcopist
   - Maintenance of competence

2. Practice setting requirements
   - Group practice: hospital-based clinics and outpatient clinics located outside of hospitals
   - Individual office-based practice

3. Operational practices
   - Referral criteria
   - Wait times
   - Strategies to reduce drop-out rates

4. Quality indicators and outcomes
   - Quality assurance
   - Performance indicators

SEARCH FOR NEW GUIDELINES

METHODS

This evidentiary base was developed using a planned three-stage method, summarized here and described in more detail below.

1. *Identification of high-quality clinical practice guidelines through a systematic search and quality appraisal*: If one or more existing guideline(s) were identified that addressed any aspect(s) of colposcopy relevant to the objectives and were of reasonable quality, then new recommendations would be developed by adapting those guidelines.

2. *Identification of high-quality systematic reviews through a systematic search*: If existing guidelines were of insufficient quality and/or evidence gaps in coverage of the topic area were identified, and time and available resources allowed such work, then a systematic search and review would be conducted to identify high-quality systematic reviews that could inform recommendations to fill those gaps.

3. *Systematic review of the primary literature*: If no systematic reviews were identified or if evidence gaps remained, study selection criteria would be developed and a

search for primary literature would be conducted. This review would focus on those areas not covered by existing reviews, if any are located and accepted.

Search for Existing Practice Guidelines

The electronic databases MEDLINE and EMBASE were searched from January 2008 to March 2013 (and updated in January 2014). Previous years were not searched because evidence-based clinical practice guidelines for colposcopy older than five years are very unlikely to provide evidence that would alter the recommendations written in the original 2008 document. The full literature search strategy used to identify potentially relevant evidence-based guidelines from MEDLINE and EMBASE is presented in Appendix 2.

Websites of international guideline developers, Canadian provincial and national cancer agencies, and the Standards and Guidelines Evidence (SAGE) Directory of Cancer Guidelines on the Canadian Partnership Against Cancer (CPAC) website (www.cancerview.ca) were searched for existing evidence-based practice guidelines using the word "colposcopy". The guideline databases and associations searched are listed in Appendix 3.

Guidelines Selection Criteria

Guidelines that addressed any aspect of colposcopy relevant to the domains listed in the guideline objectives section, and published in or after 2008, were considered in this evidentiary base. Guidelines published before 2008 were excluded from this evidentiary base, because they are very unlikely to provide evidence that would alter the recommendations written in the 2008 CCO guideline. Guidelines in a language other than English were excluded because resources were not available for translation services.

Quality Appraisal of Identified Guidelines

The quality assessment of the identified guidelines was conducted by two independent members of the Working Group, using the Appraisal of Guidelines Research and Evaluation (AGREE II) Tool (11). The purpose of the AGREE instrument is to provide a framework for assessing the quality of each guideline through 23 key items organized within six domains, each rated on a scale of 1 to 7. For each key item, a rating of 1 indicates strong disagreement and a rating of 7 indicates strong agreement. Ratings between 2 and 6 indicate that the item does not meet the full criteria and therefore the score should be assigned depending on the completeness and quality of reporting.

Based on previous experience, it was expected that few identified guidelines would be strongly evidence-based and, therefore, most identified guidelines would have been evaluated as having mediocre to poor quality using the AGREE II methods. Therefore, because the AGREE II methods are resource-intensive, AGREE II in full was only contemplated for guidelines under the following circumstances:

1. If multiple guidelines were applicable to a particular objective, and
2. The Working Group members scored all of items 7 through 10 in domain 3 of the AGREE II ("rigour of development") at 4 or greater. Those domains items are:

    - Systematic methods used to search for evidence
    - Clearly described criteria for selecting the evidence
    - Clearly described strengths and limitations of the body of evidence
    - Clearly described methods for formulating the recommendations

Scores for each domain were calculated by summing up all the scores of the individual items in a domain, and scaling the total as a percentage of the maximum possible score for that domain.

Evaluation of Identified Guideline Recommendations and Selection of Guidelines for Adaptation

The recommendations in the guidelines that met the selection criteria were evaluated:

1. To determine whether there were recommendations in the new guidelines that contradicted, altered, or modified the 2008 CCO recommendations
2. To identify areas where new recommendations could be adopted or endorsed to address gaps or unaddressed areas in the 2008 CCO guideline

If a new guideline's recommendations were substantially similar to the 2008 CCO guideline's recommendations, they were reported but not considered further. For particular objectives where more than one guideline was found to be applicable, the Working Group included the recommendations from a Canadian guideline if any were found, or else from other guidelines where their recommendations were found to be applicable to colposcopy practice in Canada. Also, if more than one guideline was identified on a particular topic, the AGREE II quality scores were used to consider which guideline should be given more weight in the adaptation process.

RESULTS

Practice Guidelines

Of 366 guidelines found, 13 were identified as potentially relevant and considered for full-text review. From these, five guidelines were retained because they significantly overlapped in scope with the objectives of this review (2-6). Reasons for exclusion are presented in Appendix 4.

Design and Quality Appraisal of Newly Identified Guidelines

Results from the quality assessment of newly identified guidance documents from Canada (5,6), Australia-New Zealand (2), the United Kingdom (3), and Europe (4) are presented in Table 1, and described thereafter. Of these guidelines only one, the PEBC 2011 Cervical Screening guideline, met the test described in the methods for a complete AGREE II evaluation. However, the members of the Working Group, in consultation with the PEBC, decided that a full AGREE II evaluation of the guideline developed by the PEBC was not appropriate because the PEBC would be in a position of assessing the quality of its own work.

Table 1. Colposcopy-Related Guidance Documents Identified in the Search for Existing Practice Guidelines and Results of the Appraisal of Guidelines for Research and Evaluation (AGREE) II: "Rigour of Development" domain.

Author/Group, Year (Reference)	Origin	Title	AGREE II: "Rigour of Development" Scores
SCC, 2012 (6)[1]	Canada	Colposcopy management of abnormal cervical cytology and histology	52%

[1] Opportunistic colposcopy program

PEBC, 2011 (5)[2]	Canada	Cervical screening	82%
RANZCOG-ASCCP, 2011(2)[3]	Australia New Zealand	Standards in colposcopy and treatment	50%
NHSCSP, 2010 (3)[3]	United Kingdom	Colposcopy and programme management	50%
ECCSN, 2008 (4)[3]	Europe	European guidelines for quality assurance in cervical cancer screening	55%

SCC (Society of Canadian Colposcopists); PEBC (Program in Evidence-Based Care); RANZCOG-ASCCP (The Royal Australian and New Zealand College of Obstetricians and Gynecologists and the Australian Society for Colposcopy and Cervical Pathology); NHSCSP (National Health Service Cervical Screening Programme); ECCSN (European Cervical Cancer Screening Network).

[2] Province-wide organized program for cervical screening
[3] Organized national colposcopy program

Colposcopy Management of Abnormal Cervical Cytology and Histology: Society of Canadian Colposcopists (SCC), 2012 (6).

This clinical practice guideline was developed to facilitate the implementation of common standards on colposcopy care across Canada. It provides guidance for managing abnormal cytology results after screening for cervical cancer, to clarify the appropriate algorithms for follow-up after treatment, and to promote the best possible care for women while ensuring efficient use of available resources. This guideline was prepared by the Executive Council of the SCC and approved by the SCC/Society of Gynecologic Oncology of Canada/SCC Policy and Practice Guidelines Committee, the Executive and Council of the Society of Gynecologic Oncology of Canada and the Executive and Council of the SCC. The recommendations contained in this guideline are based on expert opinion from published peer-reviewed literature and evidence from clinical trials.

Cervical Screening: PEBC, 2011 (5).

The 2011 PEBC guideline is an update of the 2005 publication "Cervical Screening: A Clinical Practice Guideline". This guideline focuses on cervical screening algorithms for primary screening with human papillomavirus (HPV) DNA testing (assuming the existence of an organized screening program in Ontario), and endorsed the cervical screening algorithms contained in the 2005 version for primary screening with cytology (current standard of practice) because HPV testing is not funded at this time for primary screening in Ontario. The recommendations for primary screening with cytology (referral criteria) are evidence- and consensus-based up to 2011. The guideline is intended for use by all family physicians, care providers, and gynecology specialists involved in screening women for cervical cancer and its precursors. It was developed by the Cervical Screening Guideline Working Group and approved by the Cervical Screening Expert Panel of CCO's PEBC. The Expert Panel comprised members of the PEBC Gynecologic Cancer Disease Site Group (Gyne DSG), and the CCO Cervical Clinical Advisory Committee who were not part of the Working Group.

Standards in Colposcopy and Treatment: Royal Australian and New Zealand College of Obstetricians and Gynecologists and Australian Society for Colposcopy and Cervical Pathology (RANZCOG-ASCCP), 2011 (2).

The RANZCOG-ASCCP Working Party was formed to develop a series of recommendations on colposcopy and treatment to be considered by members of the RANZCOG, the ASCCP, and those practitioners and institutions responsible for the management of women with abnormal cervical cytology. Four main areas are covered: (i) colposcopy service (personnel, information, facilities, other – documentation and patient default); (ii) diagnostic colposcopy (treatment and follow-up); (iii) monitoring of standards in colposcopy (clinical indicators, standards, practice improvement activities); and (iv) training, education and certification (basic training, advanced training, maintaining professional standards, certification or a recognition award). Recommendations are mainly based on performance standards identified through a national project involving 12,105 patients who underwent colposcopy.

Colposcopy and Programme Management: National Health Service Cervical Screening Programme (NHSCSP), 2010 (3).

The 2010 NHSCSP guideline is an update of the 2004 publication "Colposcopy and Programme Management: Guideline for the NHS Cervical Screening Programme". It was reviewed by the National Quality Assurance Colposcopy Group, the British Society of Clinical Cytology, the National Laboratory Quality Assurance Group, and the National Primary Care Quality Assurance Group. It focuses on two key aspects of developing a colposcopy service: reaching women at increased risk of cervical cancer and improving the quality of the colposcopy service overall. All aspects of this guideline related to colposcopy services rather than to cervical screening were considered in this evidentiary base. Recommendations are based on published evidence and expert consensus.

European Guidelines for Quality Assurance in Cervical Cancer Screening: European Cervical Cancer Screening Network (ECCSN), 2008 (4).

The 2008 ECCSN is an updated and expanded version of the 1993 "European Guidelines for Quality Assurance in Cervical Cancer Screening". The recommendations are focused on the essential aspects of developing organized population-based program policies that minimize adverse effects and maximize benefits of screening, and are targeted to general practitioners, gynecologists, and cytopathologists. Only information relevant to colposcopy services was reviewed for this evidentiary base. This guideline was prepared by a multidisciplinary team of experts appointed by the European Commission from a former ECCSN with the technical and scientific support of the International Agency for Research on Cancer. The final recommendations and standards of best practice in this revised and updated second guideline edition are based on available systematic reviews and published meta-analyses. Some of the recommendations are based on mathematical models and expert opinion, without scientific evidence.

Overall, the specific domains addressed by each of the guidelines described above are presented in Table 2.

Table 2. Domains addressed by the 2008 Cancer Care Ontario guideline and the newly identified guidance documents

Group, Year / Domains	PEBC, 2008	SCC, 2012	PEBC, 2011	RANZCOG-ASCCP, 2011	NHSCSP, 2010	ECCSN, 2008
Qualification and training	✓					
Accessibility to training Programs	✓					
Training and qualification requirements	✓				✓	
Program scope	✓					
Maintenance of competence	✓			✓	✓	
Practice setting requirement	✓			✓		
Group practice	✓			✓	✓	
Individual office-based practice	✓			✓		
Operational practices						
Referral criteria		✓	✓			
Wait times	✓	✓			✓	
Reducing dropout rates	✓			✓	✓	✓
Quality indicators and outcomes						
Quality assurance	✓			✓	✓	✓
Performance indicators				✓		✓

PEBC (Program in Evidence-Based Care); SCC (Society of Canadian Colposcopists); RANZCOG-ASCCP (The Royal Australian and New Zealand College of Obstetricians and Gynecologists and the Australian Society for Colposcopy and Cervical Pathology); NHSCSP (National Health Service Cervical Screening Programme); ECCSN (European Cervical Cancer Screening Network).

Search for Existing Systematic Reviews and Primary Literature

According to the planned three-stage method described in the methods, no search for existing systematic reviews nor primary literature was conducted because the guidelines identified in the first stage addressed the aspects of colposcopy listed in the objectives of the present document.

DISCUSSION

As noted previously, this document was developed using the same "guideline of guidelines" approach used in the 2008 CCO document Evidence-based Series #15-12: "The Optimum Organization for the Delivery of Colposcopy Service in Ontario" (1). This approach has some drawbacks. For example, because the methodology does not include the systematic review of the available primary evidence, it is possible that important evidence may not have been considered. Also, using guidelines from other jurisdictions can create difficulties in

terms of adapting recommendations for the Ontario context. The "guideline of guidelines" approach is a practical way to generate consensus and expert opinion based recommendations to establish best practices within Ontario. Through a consensus-based, multidisciplinary process, the recommendations presented in this document have been adopted or adapted from recent national and international-level documents providing guidance related to colposcopy services.

CONCLUSIONS

This document, while not intended to specifically address clinical care algorithms, summarizes similar documents that exist globally addressing the standards for provision of colposcopy services with particular emphasis on the establishment and maintenance of competence, practice setting requirements, quality initiatives and an initial discussion of quality indicators. The document will serve as a framework on which initiatives intended to lead to further organization of colposcopy in Ontario will be based. As is the case for all evidence-based documents guiding care, updates will take place as indicated and/or as per PEBC/CCO protocol. Where shown by evidence to contribute to the reduction in cervical cancer incidence and mortality rates, efforts will be made to introduce systems to more fully manage colposcopy care including recognition of training and maintenance of competence processes, facilitation of appropriate and timely referral for women with abnormal screen tests, reduction of rates of loss to follow-up, and integration of quality assurance and quality improvement initiatives into colposcopy services. Electronic data collection systems to facilitate such reporting and analysis currently do not exist and will be required.

INITIAL PROPOSED RECOMMENDATIONS

Using the guidelines described above, the members of the Working Group developed a set of initial recommendations. These initial recommendations were primarily based on the recommendations of the 2008 CCO guideline (1). The Working Group members identified areas where there were discrepancies between the 2008 version and newly identified guidelines, and areas where new recommendations on topics not explicitly addressed by the 2008 version were necessary. Then, recommendations from the newly identified guidelines were adapted as necessary to ensure all necessary recommendations were present. This development process and the initial recommendations are presented for reference in Appendix 5. Where the 2008 CCO recommendations were endorsed, they are not repeated.

Information about the previous version of this document and the colposcopy guideline report history is presented in Appendix 6.

CONFLICT OF INTEREST

Information regarding conflict of interest declarations can be found in Section 3, Appendix 1.

Evidence-Based Series #15-12 Version 2: Section 3

The Organization of Colposcopy Services in Ontario: Recommended Framework

Internal and External Review

J. Murphy, N. Varela, L. Elit, A. Lytwyn, V. Wu, M. Yudin, M. Shier, S. El-Khatib, and the Cervical Cancer Screening Clinical Advisory Committee

Report Date: January 20, 2015

INTERNAL REVIEW

As is the case for almost all Programs in Evidence-Based Care (PEBC) documents, this Evidence-based Series underwent internal review conducted by the Expert Panel and the Report Approval Panel (RAP). The members of the Working Group were responsible for incorporating the feedback and the required changes of both of these panels. Both panels had to approve the document before it could be sent to External Review.

Expert Panel Review and Approval

The Cancer Care Ontario (CCO) Cervical Cancer Screening Clinical Advisory Committee acted as the Expert Panel for this document. Members of this group were required to submit conflict-of-interest declarations before reviewing the document. A complete list of members of the Cervical Cancer Screening Expert Panel, and their conflict-of-interest declarations are presented in Appendix 1. The document was approved by formal vote. To be approved, 75% of the Cervical Cancer Screening Expert Panel members must cast a vote or abstain, and of those that voted, 75% must approve the document. At the time of the voting, the Cervical Cancer Screening Expert Panel members could suggest changes to the document and possibly make their approval conditional on those changes. In those cases, the members of the Colposcopy Quality Assurance Guideline Development Group were responsible for considering the changes, and if those changes could be made without substantially altering the recommendations, the altered draft would not need to be resubmitted for approval again.

Of the 10 members of the Cervical Cancer Screening Clinical Advisory Committee, nine members cast votes and one abstained, for a total of 90% response. Of those that cast votes, all approved the document (100%). The main comments from the Expert Panel along with the Working Group's responses are outlined below (relatively minor formatting or wording changes are not included):

Context of the Recommendations

1. Regarding the "Accessibility to Training Programs" domain: Nongynecologists, who are often trying to serve specialized or poorly served populations, have had to go to sympathetic gynecologist preceptors in the community. It is therefore suggested that

there be a specific recommendation that training programs should be responsive to accommodating nongynecologists.

- The members of the Working Group acknowledge that colposcopy services are also provided by other professionals such as family physicians and nurse practitioners. This recommendation has been changed to read:

  "Besides practicing obstetricians and gynecologists, the following practitioners should be eligible for colposcopy training programs:

  - Residents and fellows in obstetrics and gynecology programs
  - Other colposcopy service providers (e.g., family physicians, nurse practitioners) who meet the knowledge requirements."

2. Several comments were made regarding resource/capacity issues (e.g., who will enforce, evaluate, or accommodate different activities?) and infrastructure (e.g., additional resources to carry out quality assurance activities).
   - This document is intended to address best practice of care. Further direction regarding resource or capacity issues and infrastructure are considered by the Working Group members to be beyond the scope of this document

3. Suggesting interdisciplinary teams for hospital/outpatient clinics but not in physician offices: can this different standard be justified (e.g., by distinguishing between complex versus routine cases)?
   - The purpose of this document is to ensure quality within both settings; however, there may be different practice issues in clinic and hospital settings. The members of the Working Group recognize the limitations of their advice for private practitioners but these limitations do not change the standards

4. Who will do the clinical audits for maintenance of competence? What agency would be responsible for auditing and enforcement? This is a big administrative undertaking.
   - This is a challenge for the colposcopy community to address. Jurisdictional processes would be necessary to address this recommendation

5. A comment was made about sterilization of instruments, which would be a specific standard unlikely to be met, especially in physician offices.
   - As suggested by members of the RAP, the list of physical resources for and access to collaborative services, are now presented as strategies that may be used to achieve the main recommendation, but not as recommendations per se. The members of the Working Group have reworded this strategy to read as:

     "A proper examination room in accordance with provincial guidelines"

6. Under the "Personnel" domain, is it practical or necessary that for leaves or absences there be another colposcopist "present"? Would it not be appropriate to have someone in another institution be available for referral/consultation?
   - The members of the Working Group approved this change, and it is reflected in the document

7. Regarding facilities, the requirement for resuscitation equipment and personnel to use it could be problematic and unnecessary for facilities located in outpatient clinics outside of hospitals. For community practitioners, this is only a requirement if they are providing treatment.
   - The members of the Working Group agreed with this comment and the recommendation was reworded to read:

"Where required to comply with provincial standards for healthcare facilities, accessible resuscitation equipment and staff with appropriate training should be available"

8. A comment was made about why the physical facilities presented in the 2008 Cancer Care Ontario (CCO) guideline are not listed in this document, and why suitable electronic equipment for collection of data is recommended, if data could be collected manually, using tally charts if necessary?
    - Specific physical resources and collaborative services should not be listed in this document because these are examples of what is deemed necessary for providing colposcopy services rather than recommendations per se. The suitable electronic equipment recommendation was reworded to read:
        "A suitable information system for the collection of data"
9. Why a recommendation for postmenopausal women with a repeat Pap test result of atypical squamous cells of uncertain significance (ASCUS) or greater at one-week follow-up after a course of intravaginal estrogen preceded by low-grade squamous intraepithelial lesion (LSIL)? Is this not part of the guidelines for Paps?
    - The members of the Working Group agreed with this comment, and the recommendation was deleted
10. Regarding counselling under the "Strategies to Reduce Drop-Out Rates", what type of counselling does this involve (emotional impact counselling or educational type)?
    - The original recommendation was modified to read:
        "Effective information and communication are crucial to reducing anxiety. They include providing women with an understanding of the procedure, and of how and when information will be communicated to them and the referring practitioner"
11. The recommendation about information leaflets under the "Strategies to Reduce Drop-Out Rates" domain could be more specific about what type of information needs to be available. A comment was also received regarding default at first consultation.
    - As suggested by members of the RAP, the list of recommendations under effective information and communication, as well as the list of those under a documented system to notify or recall patients, were removed from the document because these are strategies that may be used to achieve the recommendation, but not recommendations per se
12. Under the "Quality Assurance" domain it is recommended that colposcopy clinics undergo annual reviews. Is this a recommendation for both large and small clinics?
    - This recommendation has been slightly modified to read:
        "Colposcopy clinics (large and small) should undergo annual reviews for quality assurance"
13. For "Quality Assurance" it is recommended that data be captured on a computerized information collection system. Why computerized, as long as they are collected?
    - This recommendation was modified to read:
        "Data should ideally be captured on standardized electronic information collection systems to ensure quality and to facilitate quality improvement initiatives"
14. Overall, the recommendations should include input from the nurse practitioners as well as, rather than only from the physicians, because many nurse practitioners make

referrals for colposcopy. The recommendation contains two different ideas that should be separated or clarified (the report and the tracking of referrals to other providers).

- The members of the Working Group approved this change, and as suggested by other reviewers the recommendation has been reworded to read:

> *"Colposcopy reports should be followed to ensure compliance. If the patient's family physician is not the source of referral for colposcopy, the colposcopy report should be sent to the family physician (unless expressly prohibited by the patient) as well as to the referring colposcopy service provider. If the colposcopist records a referral to other services in the report (e.g., gynecology, oncology), then the colposcopist should follow up to ensure the referral takes place"*

15. To achieve the quality indicators, standardized reporting terminology is desirable. Do the Working Group want to mention the Canadian Partnership Against Cancer (CPAC) recommendations for histopathological reporting of 2-12 (released in spring of 2013)?
    - CPAC has published a document making recommendations for standardized reporting terminology that is currently being evaluated by the pathology community
16. The document seems to assume that pathologists are on site for meetings, etc. This is increasingly less common.
    - The members of the Working Group highly value participation of pathologists in attending meetings, either in person or via telemedicine

RAP Review and Approval

The purpose of the RAP review is to ensure the methodological rigour and quality of the PEBC documents. The RAP consists of nine clinicians with broad experience in clinical research and guideline development, and the PEBC Director. For each document, three RAP members review the document: the PEBC Director and two clinicians. RAP members must not have had any involvement in the development of the guideline before Internal Review. All three RAP members must approve the document, although they may do so conditionally. If there is a conditional approval, the members of the Working Group are responsible for ensuring the necessary changes are made, with the PEBC Assistant Director of Quality and Methods making a final determination that the RAP's concerns have been properly addressed. Key issues raised by RAP are outlined below, along with the Working Group responses (relatively minor formatting or wording changes are not reported):

Consistency/definitions of terms

1. Is this a guideline, a framework, a consensus statement, or a consensus framework? One term should be adopted and used consistently. Consensus statement was suggested as the term to be adopted.
    - This document has largely been developed through a process of endorsing or adapting recommendations from existing guidelines, rather than through a consensus development. For this reason the members of the Working Group believe that "recommended framework" is the most appropriate term for this document. Either the term "recommended framework" or 'the term "recommendation" is now consistently used throughout the document

2. The term "test of cure" used in the guideline objective section should be clarified.
    - This term was modified to read
      "*….test of cure to assess the risk of residual/recurrent cervical intraepithelial neoplasia (CIN) disease in treated women*"
3. A statement on the lack of previous organization does not consider how all health services in the province are currently organized. This statement should be moved from introduction to the discussion section.
    - The members of the Working Group believe that this statement is highly relevant and should be in the front of the document. The process of organizing colposcopy services, and integrating them with cervical cancer screening, would allow the possibility of evaluating quality management and resources
4. Clarify how the recommendations were developed and whether a primary literature search was conducted.
    - The last paragraph of the "Guideline Objective" section was modified to read:
      "*Given the availability of current, high quality, and relevant documents identified after a systematic review of guidelines, the sources of evidence to inform these recommendations are based on the endorsement or adaptation of existing recommendations from relevant guidelines published since 2008. A review of the primary literature was not undertaken*"
5. Under the "Target Population" domain, it is stated that these recommendations apply to all healthcare providers and administrators providing colposcopy. Administrators do not provide colposcopy exams. Wording should be changed to clarify.
    - The wording was changed to read:
      "These recommendations apply to all healthcare providers and administrators involved with the provision of colposcopy examination in Ontario"
6. Drop the word "standards" throughout. It is old language not used anymore by CCO.
    - The members of the Working Group approved this change, and it is reflected in the document

Context of the Recommendations

1. It will be helpful to summarize how current training occurs – are there any studies that could be summarized?
    - This document provides a list of recommendations that can be used to underpin qualification, training, and maintenance of competence of colposcopists. Further summarization of current training courses was considered by the members of the Working Group to be beyond the scope of this document
2. Training programs are currently open to all colposcopy service providers and it is not necessary to list them. Neither is it necessary to highlight the knowledge required to qualify for training. These recommendations should be dropped.
    - The members of the Working Group believe that these recommendations are important because current knowledge, experience, and training is inconsistent among different colposcopy service providers. Therefore, these recommendations will stay

3. The numbers on case volumes surrounding maintenance of competence are not evidence based. It may be helpful to discuss how the members of the Working Group considered the available data and studies informing this document.
    - The members of the Working Group acknowledge that the evidence underpinning threshold numbers for competence in colposcopy is sparse and of poor quality, but a good reason to modify the threshold presented in the CCO 2008 guideline was not found. Therefore, the members of the Working Group agreed that a threshold of 100 colposcopies per year with an absolute minimum of 25 new patients would be acceptable to maintain colposcopy competence. The fact that this recommendation is not supported by good evidence is now stated under the justification to read:

        "While the evidence base underpinning the volume-related practice recommendations is sparse and of poor quality, there is a convergence of opinion across different guideline developers internationally and among the members of this panel"

4. If at least two nurses are required where colposcopy services are delivered, then the recommendation regarding one nurse for low-volume units is not acceptable. The authors may consider solving the dilemma of the low-volume centre by considering the change made in the wording of this recommendation.
    - The recommendation for high-volume clinics was reworded and it now reads as:

        "Regarding nursing staff, at least two nurses for each clinic are recommended. However, the Working Group members recognized that for low-volume units in some geographic regions in Ontario it may be difficult to achieve this recommendation. It was concluded by consensus that, for low-volume units, one nurse may suffice"
    - The members of the Working Group decided to keep the recommendation concerning low-volume centres to clarify that one nurse may suffice if she/he is able to meet all of the needs.

5. The document lists some physical resources and collaborative services deemed necessary for providing colposcopy services; however, this is not the role of this document.
    - The Working Group members have changed the wording of this recommendation to clarify that these are just examples of resources and services that may be needed to provide colposcopy services. It now reads as:

        "The physical resources and collaborative services deemed necessary to provide colposcopy may include:"

6. Educational material and patient resources that are standardized throughout the province should not be recommended because they do not exist.
    - The members of the Working Group recognized that these resources are not available, and this recommendation was removed

7. Referral criteria are in the realm of clinical management, while most of the document deals with training, facility, and quality assurance standards. It may be helpful to remove this section on clinical management, and consider for another document?
    - The members of the Working Group agreed that referral criteria belong to the scope of clinical management. However, in the Project Plan, the referral criteria were listed under the "Operational Practices" domain as an area where recommendation will be provided. For this reason, recommendations surrounding referral criteria will be maintained

8. Preventing anxiety is not a good justification to reduce wait times from 12 to eight weeks in women with abnormal results. Preventing anxiety is not good enough unless there is good evidence that women are actually anxious and strategies to relieve anxiety are not better. In addition, the numbers on wait times are not evidence based.
    - The members of the Working Group agree that reducing wait times is not the only way to reduce anxiety in women at low risk of having significant underlying lesion. Due to the lack of evidence supporting any modification to the wait times presented by the Society of Canadian Colposcopists (SCC), the members of the Working Group decided to endorse instead of adapting their recommendations. The recommendations presented in this document have been modified to reflect the original wait times recommended by the SCC. The fact that these recommendations are not evidence-based is now stated under the justification provided after the recommendations to read:

        "The members of the Working Group endorsed the wait times recommendations from the 2012 clinical practice guideline developed by the SSC. These recommendations are opinions of respected authorities, based on clinical expertise, descriptive studies, or reports of expert committees"

9. The strategies to reduce drop-out rates presented by the guidelines for the National Health Service Cervical Screening Programme (NHSCSP) should be presented or referenced in this document.
    - The members of the Working Group believe that these strategies are prescriptive and should not be presented as recommendations

10. The level of detail provided as sub-bullets for the recommendation regarding information and communication, under the "Strategies to Reduce Drop-out Rates" domain, should be dropped. This should be captured in the main recommendation which could be expanded to read: *"Effective information and communication are crucial to reducing anxiety. They include providing women with an understanding of the procedure and of how and when information will be communicated to them and the referring practitioner."*
    - The Working Group approved this change, and it is reflected in the document

11. The level of detail provided for the recommendation regarding a documented system to notify or recall patients who default at first consultation, under the "Strategies to Reduce Drop-out Rates" domain, is prescriptive and should not be presented as recommendations. The main recommendation is that there is a system of recall.
    - The members of the Working Group agreed that these are strategies to meet the recommendation of a system recall, and removed them from the document

12. The recommendation under the "Quality Assurance" domain stated that a comprehensive report should be provided to the patient's family physician, and that referrals to gynecology or oncology services should be followed to ensure compliance. Is this a report specific to an individual patient or a report on how the system works when referrals are required to gynecology or oncology?
    - The wording in the recommendation was changed to clarify that this is a recommendation specific to how the system works when referrals are required. It now reads as:

        "Colposcopy reports should be followed to ensure compliance. If the patient family physician is not the source of referral for colposcopy, the colposcopy report should be sent to the family physician (unless

expressly prohibited by the patient) as well as to the referring colposcopy service provider. If the colposcopist records referral to other services in the report (e.g., gynecologists, oncologists), then the colposcopist should follow up to ensure the referral takes place"

13. Under the domain "Quality Assurance", it is recommended that colposcopists should regularly participate in quality assurance activities including "Reviewing patient satisfaction surveys (e.g., a survey form suitable for collecting data in consulting rooms or clinics. Data from 100 consecutive patients could be collected as part of an individual, group, or institutional practice improvement activity)." It would be far more effective if there was real-time feedback on the patient experience in the colposcopy unit. The delays in the availability of survey information and their general lack of granularity make it difficult to effect change.
    - The members of the Working Group agreed that real-time feedback will be more useful; however, this is an adaptation from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and for that reason the wording would stay as is. In addition, it should be noted that surveys in consulting rooms or clinics are just examples of how to collect the data. Expectation is that people do what they believe to be the best approach.
14. Is there any explanation for why the Working Group did not adopt the percentages for the various performance indicators recommended by RANZCOG?
    - This document provides a list of indicators that can be used to underpin a quality assurance program in Ontario. Further direction on how these indicators should be measured is beyond the scope of this document, unless there is really compelling evidence to support them.

EXTERNAL REVIEW BY ONTARIO CLINICIANS AND OTHER EXPERTS

The PEBC external review process is two-pronged and includes a targeted peer review that is intended to obtain direct feedback on the draft report from a several specified content experts and a professional consultation that is intended to facilitate dissemination of the final guidance report to Ontario practitioners. Refer to the PEBC Handbook [https://www.cancercareontario.ca/sites/ccocancercare/files/PEBCHandbook.pdf] for additional detail.

Targeted Peer Review

Five targeted peer reviewers from British Columbia, Québec, Nova Scotia, and the United Kingdom who are considered to be clinical and/or methodological experts on the topic were identified by the Working Group and the CCO Cervical Cancer Screening Clinical Advisory Committee. Four agreed to be the reviewers and their responses were received. Their affiliations and conflict-of-interest declarations are listed in Appendix 1. Key results of the feedback survey are summarized in Table 3. The main written comments from targeted peer reviewers and the Working Group's modifications/actions/responses are summarized in Table 4.

Table 3. Responses to nine items on the targeted peer reviewer questionnaire

	Reviewer Ratings (N=4)				
Question	Lowest Quality (1)	(2)	(3)	(4)	Highest Quality (5)
1. Rate the guideline development methods	0	0	0	3	1
2. Rate the guideline presentation	0	0	1	2	1
3. Rate the guideline recommendations	0	0	0	4	0
4. Rate the completeness of reporting	0	0	0	2	2
5. Does this document provide sufficient information to inform your decisions? If not, what areas are missing?	0	0	1	1	2
	Strongly Disagree (1)	(2)	Neutral (3)	(4)	Strongly Agree (5)
6. Rate the overall quality of the guideline	0	0	0	4	0
7. I would make use of this guideline in my professional decisions*	0	0	0	0	2
8. I would recommend this guideline for use in practice*	0	0	0	0	2

* Two reviewers did not answer the question as recommendations contained in this guideline are not applicable in their jurisdictions.

9. What are the barriers or enablers to the implementation of this guideline report?

Some of the targeted peer reviewers believed that the implementation of this guideline depends not only on evidence, but also on strong support from stakeholders such as regional leads with dedicated time to support monitoring and auditing adoption. They felt that financial and personnel-related support is also needed from administrators to assist with providing the adequate resources for such activities. The possibility that certain practitioners may be resistant to change, and the question of what the penalty for noncompliance would be, were also highlighted.

Table 4. Modifications/actions/responses regarding main written comments from targeted peer reviewers.

Main Written Comments	Modifications, Actions, or Responses
1. It was suggested that existing practice guidelines that may not been published from other provinces should be included as examples in the appendix	The Working Group did not include unpublished guidelines from other provinces because this document only considers evidence that is available in the public domain
2. Include other professional competencies such as communication	The members of the Working Group agreed with this comment, and it is reflected in the document

3. Although some of the guidance for example on referral pathways, reporting formats, follow-up and drop-out rates is all in place and discussed, I think it would be useful to make their relationship to "failsafe" of the system explicit	The members of the Working Group recommended that a documented system needs to be in place to notify or recall patients who default at first consultation, treatment or follow-up. Further direction is considered by the members of the Working Group to be beyond the scope of this document
4. Several comments were made regarding different recommendations listed for different settings (hospital-based versus individual office practices) when standards should be universal	The Working Group clarified under the "Practice Setting Requirements" domain that the standard of care for every patient should be the same regardless of practice settings. It now reads as: *"It is desirable that all colposcopy services whether in hospitals, outpatient clinics, or individual office practices, achieve the same standard of patient care. Although the settings vary, each setting should have adequate personnel, appropriate facilities, and documentation and patient-management strategies in place. Each organized program or individual provider should provide the continuum of care for diagnosis through treatment and follow-up to discharge"*
5. I would give an operational definition of what is a high volume or low volume clinic	The members of the Working Group believe that it is not possible to specify a particular number as a threshold to hire two nurses versus one, as this will vary based on many other factors. The recommendation has been changed to read: *"Defining adequate nursing complement to meet the standard of care is determined by patient volumes, logistics, patient characteristics and other factors specific to each practice setting"*
6. Some comments were made regarding referral criteria and follow-up under different settings	The members of the Working Group decided to refer the readers to the original guideline document, instead of listing them. The recommendation surrounding referral criteria now reads as: "*Women should be referred for colposcopy according to the Ontario Cervical Screening Program Clinical Guideline (*https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/2156*)*
7. I would urge to promote the use of	The members of the Working Group believe

standardized data collection to promote data collection and benchmarking of services in Ontario	that this is not currently feasible in Ontario; however, the use of standardized electronic information systems has been recommended. The recommendation now read as: *"Data should ideally be captured on standardized electronic information collection systems to ensure quality and to facilitate quality improvement initiatives"*
8. Some comments were made to clarify definitions	The members of the Working Group approved the comments, and they are reflected in the document

Professional Consultation

Feedback was obtained through a brief online survey of health care professionals and other stakeholders who are the intended users of the guideline. All medical obstetricians, gynecologists and colposcopists in the PEBC database were contacted by email to inform them of the survey. One hundred and forty-five professionals were included, 131 from Ontario and 14 from outside Ontario. Twenty-eight (19%) responses were received. Six stated that they did not have interest in this area or were unavailable to review this guideline at the time. The key results of the feedback survey from 22 professionals are summarized in Table 5. The main comments from the professional consultation and the Working Group's modifications/actions/responses are summarized in Table 6.

Table 5. Responses to four items on the professional consultation survey

	Reviewer Rating (N=22)*				
General Question: Overall Guideline Assessment	Lowest Quality (1)	(2)	(3)	(4)	Highest Quality (5)
1. Rate the overall quality of the guideline report	**0**	**0**	**0**	**11**	**10**
	Strongly Disagree (1)	(2)	Neutral (3)	(4)	Strongly Agree (5)
2. I would make use of this guideline in my professional decisions	**0**	**0**	**3**	**6**	**12**
3. I would recommend this guideline for use in practice	**0**	**0**	**1**	**7**	**13**

*One reviewer provided feedback but did not rate the guideline

4. What are the barriers or enablers to the implementation of this guideline report?

The professional consultants had the same concerns as the targeted peer reviewers. They also felt that the recommendations for quality assurance procedures may be difficult to implement due to the lack of province wide standardized reporting forms and performance metrics, the lack of uniformity in Electronic Medical Records (EMR) software, and the inability of hospital-based records departments to communicate with private offices for quality

assurance and quality improvement initiatives. There is also a lack of synoptic reporting of biopsies and apparent disagreement in pathology regarding the use of low- or high-grade squamous intraepithelial lesion metrics (LSIL/HSIL) versus CIN1/2/3. Also, smaller centres or sparsely populated areas may have difficulty maintaining the targeted colposcopies procedure numbers, organizing interdisciplinary clinics, and collecting and recording data. The need for the provincial government to fund human papillomavirus (HPV) testing, to provide consistency in training and clinical performance assessment, to support national goals for reducing drop-out rates, and to support implementation strategies in the community was recognized. Some of the professional consultants believe that the implementation of this guideline also requires a significant commitment from physicians and hospital administrations.

Table 5. Modifications/actions/responses regarding main written comments from professional consultants.

Main Written Comments	Modifications, Actions, or Responses
1. Quality control in colposcopy is mandatory; therefore, it should be written somewhere that it is a very important issue	The members of the Working Group approved this comment and is now reflected in the document
2. The recommendations on training programs and qualifications should include a dedicated time commitment by surgeons and cytopathologists to maintain in depth understanding of dysplasia and its variants on cytology and tissue preparations. There must be a mechanism for documented feedback for continuous improvement to obtain full competence	The members of the Working group believes that this is outside the scope of this document
3. Under "*Maintenance of Competence", and* continuing medical education CME events – given or attended?	The members of the Working Group reworded the recommendation to read: *"Regularly attend and/or provide accredited continuing medical education (CME) events related to lower genital tract preinvasive diseases, at least once every two years"*
4. "Practice Setting Requirements" should add a pathologist with experience in gynecologic surgery and cytopathology for quality assurance activities	The recommendation was modified to read: *"A pathologist or cytopathologist lead with specific competence in preinvasive lower genital tract disease who is responsible for collaborating in quality processes"*
5. Under "Personnel", it may be hard to find a pathologist to collaborate with quality assurance processes in some clinics due to pathology service workload	The members of the Working Group highly values the participation of a pathologist in quality care activities. Therefore, the recommendation will stay

6. Under "Individual Office-based Practices", "formal" relationship should be defined. This may be a barrier to implementation	The members of the Working Group reworded the recommendation to read: *"Have a formal, clearly defined relationship with a regional or hospital-based colposcopy program"*
7. Shouldn't individual office-based practices have instrument sterilizing facilities?	The members of the Working Group agreed with this comment, and it is reflected in the document
8. The development of standardized education materials for patients should be recommended so that consistent messaging can be provided to patients across the province	The members of the Working Group reworded the recommendation to read: *"Standardized, culturally appropriate information should be made available"*
9. Regarding wait times for "other women with abnormal results", I would propose eight weeks maximum. It is not rare that a low grade abnormality hides a high grade	The members of the Working Group did not modify the numbers on wait times from the 2013 clinical practice guideline developed by the Society of Canadian Colposcopists (SCC) due to the lack of evidence supporting any change
10. Some comments were made to clarify the recommendations related to drop-out rates	The members of the Working Group reviewed the related recommendations and reworded them as appropriate. They can be reviewed under *"strategies to reduce drop-out rates"*
11. Quality assurance, data collection and submission with adequate clinical information and patient history in the requisition sent to surgical pathology and cytopathology labs should be added. Also, there should be a mechanism to do a multisource feedback 360 evaluation to include feedback from patients, ancillary staff, and other healthcare professionals	The members of the Working Group believed that both of these comments have already been addressed sufficiently in the existing wording of the recommendations
12. Some patients don't want their family doctor to get a report; these people usually get Paps done at the health unit or elsewhere, and only see their family doctor for nongynecological problems	The members of the Working Group reworded the recommendation to read: *"*Colposcopy reports should be followed to ensure compliance. If the patient's family physician is not the source of referral for colposcopy, the colposcopy report should be sent to the family physician (unless expressly prohibited by the patient) as well as to the referring colposcopy service provider. If the colposcopist records a referral to other services in the report (e.g., gynecology, oncology), then the colposcopist should follow up to ensure the referral takes place"

13. Should the recommendations rationalize the utilization of resources to improve care?	This document is intended to address best practices. Further direction regarding resource utilization and capacity issues is considered by the members of the Working Group to be beyond the scope of this document

Conclusion

This guideline report reflects the integration of feedback obtained through the external review process with final approval given by the CCO Cervical Cancer Screening Clinical Advisory Committee and the Report Approval Panel of the PEBC. Updates of the report will be conducted in accordance with the PEBC Document Assessment and Review Protocol (available at: https://www.cancercareontario.ca/sites/ccocancercare/files/assets/CCOPEBCDARP.pdf?redirect=true)

ACKNOWLEDGEMENTS AND AUTHORSHIP

The members of the Colposcopy Quality Assurance Guideline Development Group would like to thank the following individuals for their assistance in developing this report:

- James Bentley, Melissa Brouwers, Margaret Cruickshank, Marie-Héléne Mayrand, Sheila McNair, Hans Messersmith, and Lesley Sadownik for providing feedback on draft versions.
- Harkanwal Randhawa for conducting a data audit.
- Sara Miller and Janet Rowe for copyediting.

A complete list of the members of the Colposcopy Quality Assurance Guideline Expert Panel and the Working Group, with their affiliations and conflict of interest information, is provided in Appendix 1.

Appendix 1. Members of the Colposcopy Quality Assurance Guideline Working Group, Expert Panel, and Targeted Reviewers, and their Conflict-of-Interest Declaration.

Colposcopy Quality Assurance Guideline Development Group

Members	Affiliations	Conflict of interest
Joan Murphy	Clinical Lead, Ontario Cervical Screening Program, Cancer Care Ontario. Gynecologic Oncologist, Division of Gynecologic Oncology, University Health Network, Toronto, Ontario	No Conflict
Laurie Elit	Gynecologic Oncologist, Division of Gynecologic Oncology, Juravinski Cancer Centre, Hamilton, Ontario	No Conflict
Alice Lytwyn	Pathologist, Juravinski hospital, Hamilton, Ontario	No Conflict
Michael Shier	Gynecologist, Sunnybrook Health Sciences Centre, Toronto, Ontario	No Conflict
Mark Yudin	Gynecologist, St. Michael's Hospital, Toronto, Ontario	No Conflict
Vincent Wu	Gynecologist , Barrie, Ontario	No Conflict
Sirine El-Khatib	Registered Nurse, Sunnybrook Health Sciences Centre, Toronto, Ontario	No Conflict
Norma Varela	Health Research Methodologist, Program in Evidence-Based Care, McMaster University/Cancer Care Ontario, Hamilton, Ontario	No Conflict

Cervical Cancer Screening Clinical Advisory Committee – Expert Panel

Members	Affiliations	Conflict of interest
Lindsey Crawford	Vice President, Regional Cancer Program, Royal Victoria Hospital, Barrie, Ontario	No Conflict
William Chapman	Pathologist, St. Joseph's Health Centre, Toronto, Ontario	No Conflict
Terence Colgan	Pathologist, Pathology and Laboratory Medicine, Mount Sinai Hospital, Toronto, Ontario	Employed as a signing pathologist at Mt. Sinai Hospital and Lifelabs, a medical diagnostic company.

		Provides medicolegal consultant regarding the objectives of study in public capacity
Janet Dollin	Associate Professor, Department of Family Medicine, University of Ottawa, Ontario	No Conflict
Sheila Dunn	Director, Family Practice Health Centre, Women's College Hospital, Toronto, Ontario	Received Ministry of Health funding for a demonstration project of an innovative model of colposcopy service for underserved women
Carol McDowell	Nurse Practitioner, Women's Health Centre, Group Health Centre, Sault Ste. Marie, Ontario	No Conflict
Susan McFaul	Obstetrician and Gynecologist, Ottawa General Hospital, Riverside Campus, Ottawa, Ontario	Published an editorial, commentary, or other clear opinion regarding any of the objects of study: Journal of Obstetrics and Gynaecology Canada 2012; 34(12):1188-1202 Journal of Lower Genital Tract Disease 2013; 17(12) 51-527
Meg McLachlin	Program Head of Pathology, London Health Sciences Centre, London, Ontario	No Conflict
Peter Scheufler	Chief and Medical Director, Women's and Children's Health System (Obstetrics and Gynecology), Trillium Health Partners, Mississauga, Ontario	No Conflict
Doug Tkachuk	Vice President, Chief Medical Officer, Lifelabs, Toronto, Ontario	Employed by Lifelabs, a medical diagnostic company. Owner of Objective Pathology

Targeted Peer Reviewers

Members	Affiliations	Conflict of interest
Lesley Sadownik	Assistant Professor, Gynecologic Oncology,	

	Gordon and Leslie Diamond Health Care Centre, Vancouver, British Columbia	No Conflict
Marie-Héléne Mayrand	Assistant Professor, Department of Obstetrics and Gynecology, and Department of Social and Preventive Medicine, Université de Montréal, Québec	Received a research grant from Qiagen, and was principal investigator for a vaccine trial reported by Merck.
James Bentley	Associate Professor and Division Head, Gynecology Oncology, Dalhousie University, Halifax, Nova Scotia	Received GlaxoSmithKline (GSK) honoraria per year to act in a consulting capacity, as well as travel support 2011/2013. Received research support from GSK/Merck for vaccine trials, and is the principal investigator for the clinical trial "Post marketing trial of Luviva device in colposcopy triage". Dr. Bentley is the principal author of the Society of Canadian Colposcopists (SCC)/ Society of Obstetricians and Gynaecologists of Canada (SOGC) colposcopy management guidelines Journal of Obstetricians and Gynaecology Canada Dec. 2013.
Margaret Cruickshank	Professor, Personal Chair (clinical), MacGillivray Academic Centre, Aberdeen Maternity Hospital, Aberdeen, United Kingdom	No Conflict

Appendix 2. MEDLINE and EMBASE Search Strategy Used to Identify Potential Relevant Guidelines.

15-12 Colposcopy March 25_ 2013 EMBASE MEDLINE COMBINED

1. (cervical and abnormal:).ti.
2. colposcopy.ab.
3. colposcopy.ti.
4. or/1-3
5. letter.pt.
6. comment.pt.
7. editorial.pt.
8. exp randomized controlled trial/
9. randomized controlled trial.mp.
10. exp clinical trial/
11. comparative study/
12. or/5-11
13. pooling.mp.
14. pooled analysis.mp.
15. exp Meta-analysis/
16. meta-analyses.mp.
17. systematic review.mp.
18. exp evidence based medicine/
19. clinical practice guideline.mp. or exp practice guideline/
20. or/13-19
21. 20 not 12
22. 21 and 4
23. limit 22 to yr="2008 -Current"
24. remove duplicates from 23

Appendix 3. Guideline Databases and Professional Associations searched for existing guidelines.

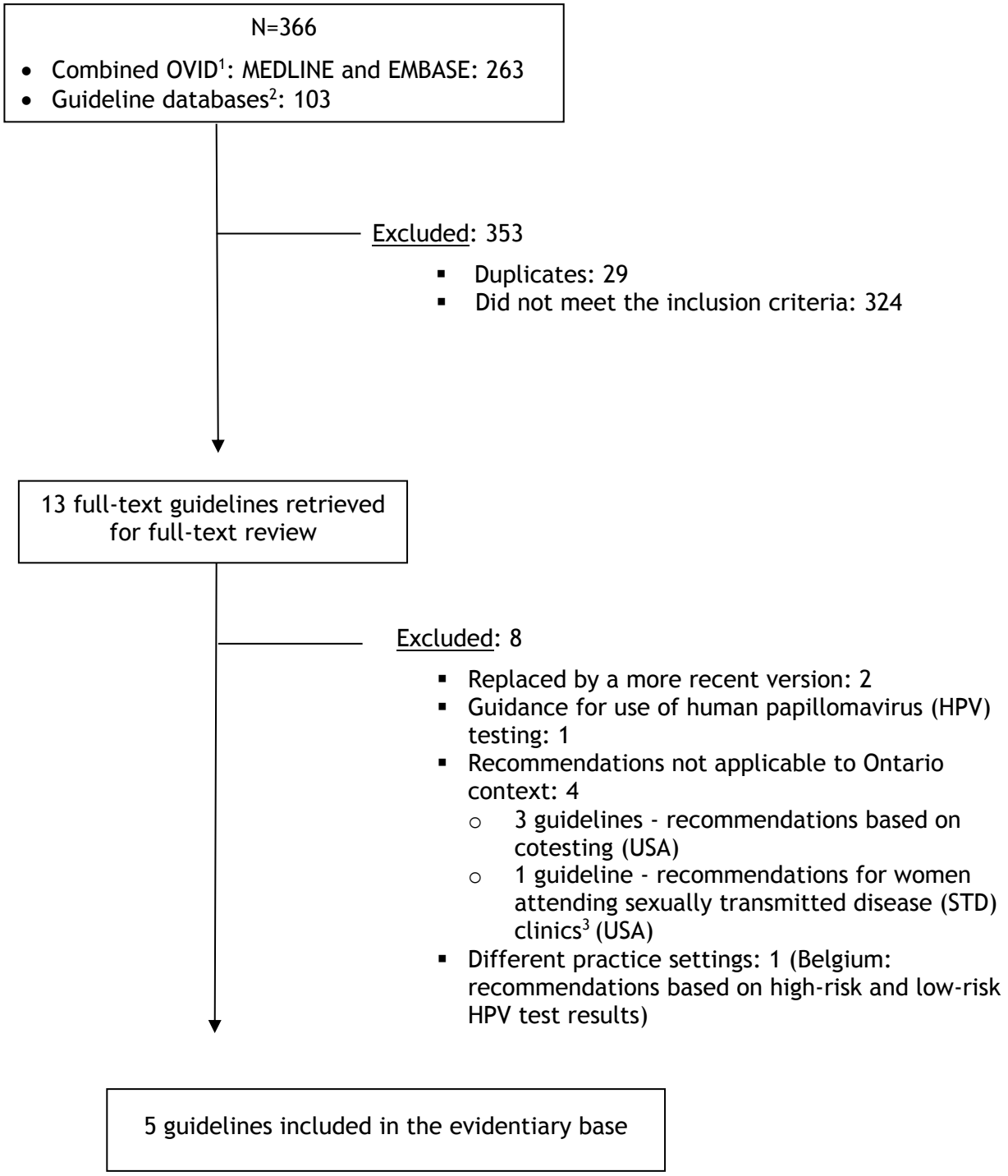
✓ Inventory of Cancer Guidelines (Standards and Guidelines Evidence): http://www.cancerguidelines.ca/Guidelines/inventory/index.php
x National Guideline Clearing House: http://www.guideline.gov/
x Canadian Medical Association Infobase: https://www.cma.ca/En/Pages/clinical-practice-guidelines.aspx

International Guideline Developers:
✓National Institute for Health and Care Excellence (UK): http://www.nice.org.uk/guidance
x Scottish Intercollegiate Guidelines Network (UK): http://www.sign.ac.uk/guidelines/index.html
x American Society of Clinical Oncology (US): http://www.asco.org/quality-guidelines/guidelines
x National Comprehensive Cancer Network (US): http://www.nccn.org/ (consensus-based)
x National Health and Medical Research Council (Aus): http://www.nhmrc.gov.au/guidelines/publications/subject/Cancer
✓New Zealand Guidelines Group: http://www.nzgg.org.nz/

Associations:
x Canadian Task Force on Preventive Health Care
✓Society of Canadian Colposcopists (SCC)
✓Society of Obstetricians and Gynecologists of Canada (SOGC)
x Society of Gynecologic Oncologists of Canada (GOC)
✓Program in Evidence-Based Care (PEBC) guideline (2008)
✓American Society for Colposcopy and Cervical Pathology
x American College of Obstetrics and Gynecology
x Royal College of Obstetricians and Gynaecologists (UK)
✓National Health Services Cervical Screening Programme
✓British Society for Colposcopy and Cervical Pathology
x Australian Society for Colposcopy and Cervical Pathology (ASCCP)
✓Royal Australian College of Obstetricians and Gynecologists (RANZCOG)
✓Europe Against Cancer Programme (European Guidelines for Quality Assurance in Cervical Cancer Screening)
x Joint Commission on the Accreditation of Healthcare Organizations (US)

X: No relevant reports found
✓: Relevant reports found

Appendix 4. Flow Diagram of Results from Literature Search.



[1] Search strategy available in Appendix 2
[2] Guideline databases, searched using the word "colposcopy", are listed in Appendix 3
[3] In Ontario, this population does not need different recommendations

Appendix 5. Initial Proposed Recommendations Submitted for Internal Review.

Final recommendations are presented in Section 1.

QUALIFICATION, TRAINING, AND MAINTENANCE OF COMPETENCE

1. Accessibility to Training Programs

The 2008 Cancer Care Ontario (CCO) guideline included a review of 12 documents (12-23) providing guidance regarding the disciplines and minimum requirements that should be considered for admission to the training program for new colposcopists. It also provided consensus-based guidance regarding the required knowledge base and skill set to be eligible to participate in colposcopy training programs. No additional recommendations that would alter guidance related to accessibility to colposcopy training programs were addressed by the newly identified guidelines. The members of the Working Group endorsed the recommendations from the 2008 CCO guideline (1) because they remain relevant.

2. Training Programs and Qualification Requirements

The 2008 CCO guideline identified two guidance documents (20,22) providing recommendations regarding the training for laser, cryotherapy, or loop electrosurgical excision procedures. Five guidance documents (13-15,18,22) outlined the requirements for colposcopic trainers or preceptors. Other than consensus, there was no evidence presented in these guidance documents to help inform minimum training requirements for the given treatment modalities. Therefore, the members of the Working Group agreed that recommendations related to training and qualification requirements to perform laser, cryotherapy, or loop electrosurgical excisions should ensure sufficient exposure to the different treatment modalities needed to effectively treat cervical abnormalities, but should not be overly restrictive or onerous. Evidence supporting the minimum requirements for colposcopy trainers or preceptors identified in the five guidance documents was modest and supported the statement that the number of new colposcopies per year should be sufficiently high to ensure that preceptors maintain their colposcopy skills in a busy practice with good quality assurance practices. No additional evidence related to training and qualification requirements that would alter the recommendations presented in the 2008 CCO document were found in the newly identified guidelines. The members of the Working Group endorsed the recommendations from the 2008 CCO guideline (1), because they remain relevant.

The 2008 CCO guideline included a review of 10 documents providing guidance regarding the scope of clinical training necessary to become a competent colposcopist (12-14,16-22). No additional guidance on the scope of colposcopy training programs that would alter the recommendations presented in the 2008 CCO guideline were found in the newly identified guidelines. The members of the Working Group endorsed the recommendations from the 2008 CCO guideline (1), because they remain relevant.

3. Accreditation/Certification

Eight documents identified by the 2008 CCO guideline recognized participation in courses or meetings as a component of continuing education (12,14,16-20,23). The frequency of participation suggested ranged from two to three years, and participation in clinical audits and quality assurance programs were also noted as components of continuing medical education (1). Two new documents were found to provide guidance for continuing education and accreditation processes or recognition awards (2,3).

The National Health Service Cervical Screening Programme (NHSCSP) (3) recommends that all colposcopists in a team should be certified through the British Society for Colposcopy

and Cervical Pathology/Royal College of Obstetricians and Gynecologists training scheme, and compliance with the recertification process every three years is highly desirable.

The Royal Australian and New Zealand College of Obstetricians and Gynecologists (RANZCOG) and Australian Society for Colposcopy and Cervical Pathology (ASCCP) Working Party (RANZCOG-ASCCP) (2) highlighted the difference between the concepts of recognition award and certification, and recommended a recognition award over a certification by concluding that the latter approach may be expensive and unlikely to be undertaken by Fellows. According to RANZCOG-ASCCP *certification* is a formal process that involves supervised training, ongoing assessment, and logbooks, while a *recognition award* indicates that a practitioner has participated in certain professional development and quality of care activities such as continuing education and practice improvement programs.

The members of the Working Group recognize that most other jurisdictions have some methods of accreditation of colposcopy skills followed by maintenance of competence practices. The group members endorse the idea that similar practices, currently absent, be adopted in Ontario to ensure that all Ontario women in need of colposcopy services are assured a similar level of high-quality care. The initial recommendation is presented below.

Although a formal accreditation process for colposcopists is not implemented at present in Ontario, it is considered standard of care in many other jurisdictions. Therefore, it is recommended that such a process be developed in Ontario, based on the process used by the NHSCSP (3).

4. Maintenance of Competence

The 2008 CCO guideline included a review of 10 documents addressing the issues of maintenance of competence (12-20,23) and provided guidance related to colposcopy volume and continuing medical education. The members of the Working Group recognized that the identified literature varied in the requirements needed to maintain competence and concluded that the minimum recommendations should ideally be adhered to where possible (1).

The identified literature in the 2008 CCO guideline varied. The requirements for the maintenance of colposcopy skills ranged from a minimum of 30 colposcopies every three years to 100 new cases each year (12,15-18). Based on this information, the 2008 CCO guideline recommended a clinical volume of approximately 100 colposcopies per year; with at least 25% of cases being new patients, to maintain competence. For this version of the guideline two new documents were found to provide guidance for colposcopy minimum volumes (2,3).

The NHSCSP (3) recommends that colposcopists practising within the NHSCSP see at least 50 new abnormal cytology referrals per year. The RANZCOG and the RANZCOG-ASCCP (2) highlighted that recommendations about numbers are not appropriate, and recommends that colposcopists manage sufficient numbers of patients with abnormal Pap smear problems to develop, maintain and improve their skills in this area of their practice.

The members of the 2008 CCO Guideline Development Group also acknowledged that the smaller population of some geographic regions in Ontario may make their recommendation difficult to achieve (1). To that end, and consistent with the guidance documents reviewed, the Working Group maintained the 2008 version volumes (100 colposcopies per year) and proportion that should be new patients (25%) but modified the wording to make it more clear that these are ideal, suggested values and that the goal of such targets is to ensure that colposcopists see a sufficient number of patients to maintain and improve their skills. This modified initial recommendation is presented below, together with two additional recommendations endorsed from the 2008 CCO guideline (1), because they remain relevant:

- Manage sufficient number of patients with abnormal Pap smears to develop, maintain, and improve their skills in this area of practice; ideally, a clinical volume of approximately 100 colposcopies per year. Although the optimal proportion of new patients is not known, 25% is generally considered to be an absolute minimum
- Participate regularly in continuing medical education events related to lower genital tract preinvasive diseases at least *once every two years* (1)
- Participate regularly in clinical audits as a component of continuing education (1)

PRACTICE SETTING REQUIREMENTS

The members of the Working Group of the 2008 CCO guideline identified seven guidance documents informing practice setting requirements for the provision of colposcopy services (12,14,15,17,19,20,23). The evidence was sparse and existing recommendations at that time were almost entirely based on expert consensus. However, most of the recommendations derived from these documents were adapted by the 2008 CCO guideline as part of good practice as they were applicable to Ontario.

Two newly identified documents (2,3) provided guidance consistent with that presented by the 2008 CCO guideline. Items to consider in practice include staffing, physical setting, instrumentation, data collection, and patient management. Both documents provided several additional points that the members of the Working Group believed were worth adding to the 2008 CCO recommendations. These were:

- The need for resuscitation equipment as noted in the RANZCOG guideline
- A recommendation on safety with respect to laser and diathermy equipment and a recommendation from the NHSCSP guideline about the ethical handling of questions regarding sexual history

These points were considered to be good practice by the members of the Working Group and provided needed clarification to the previous recommendations.

OPERATIONAL PRACTICES

1. Referral Criteria

CCO published a guideline on Cervical Screening in 2011 (5), which provided a set of criteria for colposcopy in the context of both cytology as primary screening and HPV testing as primary screening. These recommendations were endorsed by the members of the Working Group and were consistent with the criteria found in the newly identified SCC guideline (6). In addition, the Working Group members added a clarification of the referral criteria with respect to women <21 years of age who had received cytology-based primary screening as necessary to highlight the need for conservative management in these women to avoid harm.

2. Wait Times

In addition to the 2008 CCO guideline (1), two guidelines were found that addressed the issue of referral times to colposcopy after abnormal screening test results (3,6). Guidance provided by eight documents, reviewed by the members of the 2008 CCO Working Group, was consistent in the message that the higher the grade of lesion, the sooner the patient should be referred to colposcopy, with immediate or within two weeks appointments recommended for the more severe cases. Although there was no evidence demonstrating poorer patient outcomes as a result of longer colposcopy wait times, the 2008 CCO guideline recommended the following:

"Where colposcopy is indicated, every effort should be made to provide colposcopy in the shortest reasonable time period after referral.

- *Generally, less-severe cytological findings should be followed up with colposcopy within eight to 12 weeks, while more severe findings should be followed up within a shorter time frame. In special circumstances, such as pregnancy, high-risk patients, clinical suspicion of cancer, etc., women should have an initial assessment as soon as possible. As a minimum standard, time from referral to colposcopy should not exceed six months.*
- *A follow-up protocol should be established to maximize attendance if a colposcopy has not been scheduled or if the woman has not attended a colposcopy clinic."*

The newly identified guidelines provided more detailed recommendations regarding wait times that were substantially shorter than the 2008 CCO guideline. The NHSCSP provides standards for colposcopy wait times in the United Kingdom as follows (3):

- *Women should be referred for colposcopy after three consecutive inadequate samples. At least 90% of women should be seen in a colposcopy clinic within eight weeks of referral*
- *Women should be referred for colposcopy after three tests reported as borderline nuclear change in squamous cells in a series, without the woman being returned to routine recall. At least 90% of women should be seen in a colposcopy clinic within eight weeks of referral*
- *Women should be referred for colposcopy after one test reported as borderline nuclear change in endocervical cells. At least 90% of women should be seen in a colposcopy clinic within eight weeks of referral*
- *Women should be referred for colposcopy if they have had three tests reported as abnormal at any grade in a 10-year period. At least 90% of women should be seen in a colposcopy clinic within eight weeks of referral*
- *Ideally, women should be referred for colposcopy after one test reported as mild dyskaryosis, but it remains acceptable to recommend a repeat test. Women must be referred after two tests reported as mild dyskaryosis without a return to routine recall. At least 90% of women should be seen in a colposcopy clinic within eight weeks of referral*
- *Women must be referred for colposcopy after one test reported as moderate dyskaryosis (100%). They should be seen within four weeks of referral (90%)*
- *Women must be referred for colposcopy after one test reported as severe dyskaryosis (100%). They should be seen within four weeks of referral (90%)*
- *In England, women referred with a high-grade cytological abnormality must enter a 62-day cancer pathway. Once cancer has been excluded these women must enter the 18-week pathway (100%)*
- *Women must be referred for colposcopy after one test reported as possible invasion (100%). They should be seen urgently, within two weeks of referral (90%)*
- *Women must be referred for colposcopy after one test reported as possible glandular neoplasia (100%). They should be seen urgently, within two weeks of referral (90%)*

The SCC Statement on Wait Times in Obstetrics and Gynecology (6) recommends colposcopy assessment within three weeks for high-grade squamous intraepithelial lesion (HSIL) cytology, within six to eight weeks for atypical squamous cells cannot exclude HSIL (ASC-H) or low-grade squamous intraepithelial lesion (LSIL), and within six weeks for an atypical glandular cells (AGC) cytology result (6). Recommendations were developed based on opinions of respected authorities, clinical experience, descriptive studies, or reports of expert communities. As recognized by the Executive Council of the Society of Canadian

Colposcopists, their recommendations are similar to the standards of the NHSCSP recommendations listed above. Because the SCC recommendations are specific to Canada and likely familiar to the practice community, the members of the Working Group endorsed those recommendations as presented below.

Patients with abnormal screening tests should be seen for colposcopy within a reasonable time, given the risk of high-grade changes and psychological stress associated with an abnormal cytology result. Therefore, under the following conditions, women should ideally be seen in a colposcopy clinic within the following time from referral:

- Within two weeks
    - Women with AGC or adenocarcinoma in situ cytology or with cytology suggestive of carcinoma (e.g., after one test reported as possible invasion, possible glandular neoplasia, abnormal cervix, or any other manifestation of cervical cancer)

- Within four weeks
    - Women with HSIL and ASC-H

- Within eight to 12 weeks
    - All other women with abnormal results (e.g., after cytology result of atypical squamous cells of undetermined significance (ASCUS), LSIL, or three consecutive unsatisfactory Pap test results)

Although it is medically reasonable for women at low risk of significant underlying lesion to be seen within 12 weeks in accordance with the 2012 Society of Canadian Colposcopists practice guideline (6), it is the opinion of the members of the Working Group that these women should be seen within eight weeks to reduce anxiety related to wait times.

3. Strategies to Reduce Drop-Out Rates

In addition to the 2008 CCO guideline (1), three guidance documents were found to address the drop-out rates domain (2-4). The members of the Working Group of the 2008 CCO guideline identified and reviewed two guidance documents that aimed to reduce the default from colposcopy clinics (12,17). The members of the 2008 CCO Working Group recognized the relevance of their recommendations and endorsed them after concluding that guidance from these two documents was applicable to the Ontario context (1).

Standards related to strategies for reducing drop-out rates have also been published by the NHSCSP in the United Kingdom (3). The NHSCSP standards are detailed below:

The following information should be given to women having outpatient treatment:

- *To avoid using tampons for four weeks following treatment*
- *To abstain from vaginal intercourse for four weeks following treatment*
- *To avoid swimming for two weeks following treatment*
- *That they may drive following loop excision or local treatment, unless advised otherwise by the examining colposcopist*
- *That they may consume alcohol in moderation*
- *That other normal activities, including light exercise, may continue*
- *That although there are no known health grounds for avoiding travel following treatment, overseas medical attention for complications arising from the treatment may not be covered by insurance*
- *That there may be a temporary change in the menstrual pattern following loop excision*

- *That single conization, cervical diathermy and loop excision are each associated with a small but significant increase in the incidence of preterm labour and preterm prelabour rupture of membranes*

Effective information and communication are crucial to reduce anxiety:

- *Each woman should be offered verbal information and sent written information before and after cervical screening and before colposcopy (95%)*
- *Counselling must be available as an integral part of colposcopy*
- *Women must be sent an appropriately worded invitation with a contact name, telephone number, and clinic times*
- *Information concerning the visit to the clinic and the results of investigations should be communicated to the patient within four weeks of her attendance (best practice 90%) or eight weeks (minimum standard 100%)*
- *In addition to the national information leaflets, individualized information leaflets should be available at each clinic*
- *Results and management plans should be communicated to the referring practitioner within four weeks of the patient's attendance at the clinic (best practice 90%) or eight weeks (minimum standard 100%)*

With respect to patient nonattendance:

- *There must be written protocols for the management of nonattenders*
- *Audit should include analysis of the records of defaulters to discern any patterns that could be addressed to reduce the default rate*
- *The default rate should be less than 15%*

With respect to visitors to the clinic:

- *Women should be able to have a friend or relative present if they wish. The patient's consent should be sought before colposcopy if anyone not essential for its performance is to be present (such as trainees, undergraduates or visitors)*

Recommendations provided by the European Cervical Cancer Screening Network (ECCSN) (4) are similar to the standards of the NHSCSP in the United Kingdom, listed above.

The RANZCOG and the RANZCOG-ASCCP recommend the establishment of a documented system to notify or recall patients who default at fist consultation, treatment or follow-up (2).

The members of the Working Group endorsed the 2008 CCO and 2011 RANZCOG-ASCCP recommendations, and adapted the standards provided by the NHSCSP. The first recommendation from the RANZCOG-ASCCP Working Party under "Default at first consultation" stated that patients should be offered another appointment. The Working Group adapted this recommendation to provide more guidance about how patients should be contacted for another appointment. The adapted recommendation states that attempts at telephone contact together with a letter to schedule another appointment should be offered to patients. The initial recommendations are presented below.

System-wide mechanisms and follow-up procedures are needed to maximize attendance and improve patient outcomes:

- Women should be advised that they should notify the clinic of any change of their address and other contact details *(RANZCOG)*
- Ideally, the drop-out rate should be less than 15%
- Protocols to deal with the nonattendance of patients should be established

- Culturally appropriate information should be made available *(NHSCSP)*
- Women should be able to have a friend or relative present if they wish *(NHSCSP)*
- Audits should include analysis of the records of defaulters to discern any patterns that could be addressed to reduce the default rate *(NHSCSP)*
- Effective information and communication are crucial to reducing anxiety *(NHSCSP):*
    - Ideally, women should be offered written information before their colposcopy visit
    - Counselling should be available as an integral part of colposcopy
    - Women should be sent an appropriately worded invitation with a contact name, telephone number, and clinic times
    - Information concerning the visit to the clinic and the results of investigations should be communicated to the patient within a reasonable time (ideally within four weeks)
    - Information leaflets should be available at each clinic
    - Results and management plans should be communicated to the referring practitioner (ideally within four weeks of the patient's attendance at the clinic)
- Optimal practice requires that the referring clinician's details should be recorded for each new patient (*RANZCOG*)
- A documented system needs to be in place to notify or recall patients who default at first consultation, treatment or follow-up *(RANZCOG)*

a) <u>Default at first consultation</u>
    - Attempts at phone contact together with a letter to schedule another appointment should be offered to patients
    - The referring clinician should be notified in writing that the patient did not attend

b) <u>Default for treatment</u>
    - Patient should be contacted and another treatment time arranged
    - Two or three attempts to arrange treatment would appear to be reasonable current practice
    - For patients with high-grade lesions who refuse or default treatment, it should be clearly documented that they have been informed in writing of the possibility of their developing cancer

c) <u>Default at follow-up</u>
    - Recall letters should be sent to patients missing appointments
    - Two or three attempts would appear to be reasonable current practice
    - Contact should be made with the referring clinician to encourage patient return or to make alternative arrangements
    - The role of any Provincial Screening Registry in the identification of defaulters should be considered as an adjunct to the above system and not as a replacement

QUALITY INDICATORS AND OUTCOMES

There are multiple aspects of assuring high-quality care:

Quality management involves quality planning, quality control, quality assurance, and quality improvement to improve system performance and outcomes.

Quality assurance is an administrative or procedural activity in a quality system to ensure that the goals of the service are achieved. It is systematically measured and associated with an effective feedback loop

Quality improvement is a systematic, continuous approach to making changes that lead to better patient outcomes, stronger system performance and enhanced professional development. It involves all stakeholders, including health care professionals, patients, families, planners, researchers, and educators

Performance indicators are metrics that allow evaluation of how well (or poorly) a system's goals are being met. These metrics are compared with an appropriate benchmark that reflects the system's desired performance. Performance indicators, which are carefully chosen to reflect strategic goals, allow a measure of progress toward these goals

1. Quality Assurance

The 2008 CCO guideline reviewed eight guidance documents reporting requirements for quality assurance and control of colposcopy services (12-14,16-19,23). The 2008 CCO guideline reported that the recommendations from these older guidance documents reflected good practice and were applicable to current colposcopy practice in Ontario. As a result, through the consensus of the members of the Working Group, many of the recommendations were included in the 2008 CCO guideline (1).

Two additional documents were identified to provide guidance related to quality improvement (2,4). These documents both provided important additional information and clarifications to the 2008 CCO Guideline recommendations. Therefore, the members of the Working Group endorsed the 2008 CCO recommendations, as well as key sections of the ECCSN and RANZCOG guidelines. These initial recommendations are summarized below:

QUALITY ASSURANCE

The Expert Panel endorses the following recommendations contained in the 2008 CCO guideline (1).

- Colposcopy clinics should undergo annual reviews for quality assurance
- Clinical audits should take place at both the regional and provincial levels to ensure consistent results and provide appropriate feedback to clinicians
- All colposcopists should participate in regular quality and auditing activities:
    - Colposcopists should ensure good practice, compliance with protocols and adequate data collection, and monitor whether quality standards are attained and maintained
    - Lead clinicians should develop written protocols for local use that work toward achieving quality
    - Regular meetings of colposcopists, pathologists, and allied health professionals are needed to allow for the discussion of cytological and histological slides and colposcopic pictures, and to correlate (review discordance and concordance) cytology, histology, and colposcopy opinions
    - Correlations between Pap tests and colposcopic diagnosis should be reviewed

- Clinics should undergo annual reviews for quality assurance purposes with an opportunity for referring physicians and patients to participate in feedback and review activities
- Clinical audits should take place at the provincial level to ensure consistent results
- Data should be captured on computerized information collection systems
- Colposcopic findings should be recorded in the patient's record (ECCSN).
- Reporting colposcopy procedures should be completed in specially designed reporting formats (preferably consistent across the province), and include information on findings, treatment, and recommendations for follow-up
- A comprehensive report should be provided to the patient's family physician, and referrals to gynecology or oncology services should be followed to ensure compliance. This report should also include the opportunity for input from referring physicians and patients
- An organized provincial colposcopy information and quality control system should be established, possibly within the auspices of the Ontario Cervical Screening Program, to monitor the quality of care. This system should include paired evaluations of colposcopy diagnoses, managerial evaluations, and the development of quality control indicators
- Colposcopists should audit their work to confirm that their colposcopic assessment and colposcopically directed treatment is in keeping with internationally agreed standards (ECCSN)

The following is a Working Group consensus recommendation, based on a standard document published by the RANZCOG-ASCCP (2).

- Colposcopists should regularly participate in quality assurance activities including:
  - Meeting defined clinical indicators
  - Conducting tissue audits (e.g., excisional biopsies, microinvasive cancer, glandular neoplasms and other pathology of interest. Audits of excisional treatments should occur with particular emphasis on specimen quality and clinical outcome)
  - Reviewing patient satisfaction surveys (e.g., a survey form suitable for collecting data in consulting rooms or clinics. Data from 100 consecutive patients could be collected as part of an individual, group, or institutional practice improvement activity)
  - Reviewing service audits (e.g., assessment of wait times for women with high- and low-grade abnormalities, distances travelled, quality of documentation, proportion of women treated under general anesthesia and the proportion of cervical intraepithelial neoplasia (CIN) in treated patients)
- In practice, quality assurance baseline data should be collected

The Expert Panel endorses the following recommendations detailed by the ECCSN (4):

- Colposcopists should audit their work to confirm that their colposcopic assessment and colposcopically directed treatment is in keeping with internationally agreed standards
- Colposcopic findings should be recorded in the patient's record

2. Performance Indicators

According to a National Quality Assurance in Colposcopy Project completed by the RANZCOG and the ASCCP Working Party (RANZCOG-ASCCP), the minimum performance standards in colposcopy that should apply to all practitioners should be as follows (2):

- Colposcopy-biopsy concordance within one histologic (CIN) degree >80%
- Complication after treatment <5%
- Readmission for complications after treatment <2%
- Residual disease after treatment <5%
- Retreatment rate <3%

The Expert Panel of this document adapted the standards from RANZCOG-ASCCP on performance indicators, related specifically to colposcopy. The recommendations are presented below (2):

Individual clinics should implement clinic-specific performance indicators such as *(RANZCOG)*:

- Colposcopy-biopsy concordance
- Complication after treatment
- Readmission for complications after treatment
- Residual disease after treatment
- Retreatment rate

Appendix 6. Guideline Document History.

GUIDELINE VERSION	SYSTEMATIC REVIEW		PUBLICATIONS	NOTES and KEY CHANGES
	Search Dates	Data		
Original 2008	1996 to 2006	Full Report	Peer review publication Web publication	N/A
Version 2 2015	2008 to 2014	Full Report	Updated web publication	Significant changes

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