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The organization of colposcopy services in Ontario: recommended framework

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ABSTRACT

Objective The purpose of this guideline is to help ensure the provision of high-quality colposcopy practices in the province of Ontario, including those conducted as diagnostic procedures in follow-up to an abnormal cervical screening test.

Methods This document updates the recommendations published in the 2008 colposcopy guideline from Cancer Care Ontario, *The Optimum Organization for the Delivery of Colposcopy Service in Ontario*. A systematic review of guidelines was conducted to evaluate the existing evidence and recommendations concerning these key aspects of colposcopy:

- Training, qualification, accreditation, and maintenance of competence
- Practice setting requirements
- Operational practice
- Quality indicators and outcomes

Results This guideline provides recommendations on training and maintenance of competence for colposcopists in the practice settings in which colposcopic evaluation and treatments are conducted. It also provides recommendations on operational issues and quality indicators for colposcopy.

Conclusions This updated guideline is intended to support quality improvement for colposcopy for all indications, including the follow-up of an abnormal cervical screening test and work-up for lower genital tract lesions that are not clearly malignant.

The recommendations contained in this document are intended for clinicians and institutions performing colposcopy in Ontario, and for policymakers and program planners involved in the delivery of colposcopy services.

Key Words Cancer Care Ontario, colposcopy, cervical cancer screening, frameworks, guideline recommendations

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INTRODUCTION

Because of global inequities in the availability and quality of cancer screening, cervical cancer is the third most common cancer, with 528,000 new cases estimated worldwide in 2012[1]. Cervical cancer is also the fourth leading cause of death for women worldwide, having resulted in an estimated 266,000 deaths the same year[1]. In Ontario, 610 new cases of cervical cancer were diagnosed in 2013, and 150 women were expected to die of their disease[2]. Ontario's low incidence and mortality rates in part reflect the presence of a provincial cytology-based screening program that leads to the identification of lesions, which, if removed, can minimize the occurrence of this cancer.

Colposcopy uses binocular magnification (5×–30× magnification) with a colposcope to examine the lower genital tract. It 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 screening test. Optimizing the quality of colposcopy services in Ontario—including their appropriateness, efficiency, and effectiveness—is important.

The quality and clinical effectiveness of colposcopy has been shown to be variable in several jurisdictions[3,4].

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Several organizations, including the Program in Evidence-Based Care (PEBC) of Cancer Care Ontario (CCO), have therefore created quality assurance guidelines. At the time that the 2008 CCO guidance document *The Optimum Organization for the Delivery of Colposcopy Service in Ontario*[5] was created, the members of the guideline development group believed that the level of evidence to support the colposcopy recommendations was very modest. The recommendations in the 2008 guideline were therefore adapted from other guidance documents produced by credible organizations or government bodies. The 2008 CCO guideline addressed these domains:

- Colposcopist qualification and training
- Practice setting requirements
- Quality assurance and control activities
- Institutional characteristics that contribute to the quality of colposcopy services

In 2012, CCO's Prevention and Cancer Control program determined that an update of the 2008 CCO guideline was necessary, but no improvement in evidence quality was believed to have occurred. The PEBC and the Prevention and Cancer Control program therefore decided that the most effective way to update the 2008 CCO guideline would be to adapt new recommendations identified in guidelines published after 2008 by other jurisdictions and organizations. The goal of the update was to identify areas in which 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 that a change was necessary.

The objective of the present guideline 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 and lower genital tract cancers.

METHODS

This guideline was developed by the Cervical Cancer Screening Clinical Advisory Committee of CCO's PEBC using the methods of the practice guidelines development cycle[6]. The guideline is intended to promote evidence-based practice in Ontario. The PEBC is editorially independent of the Ontario Ministry of Health and Long-Term Care.

Research Questions

- Colposcopy training, qualification, accreditation, and maintenance of competence
  - Who is eligible and what knowledge is required to qualify for colposcopy training programs?
  - What criteria should be covered by a colposcopy training program?
  - What is the formal accreditation or certification process for colposcopists in Ontario?
  - What are the requirements for maintenance of competence for health practitioners performing colposcopy?
- Practice setting requirements
  - What are the acceptable colposcopy practice setting requirements for both group practices (hospital-based clinics and outpatient clinics outside hospitals) and individual office-based practices in Ontario?
- Operational practice
  - What are the recommended criteria for colposcopy referral in the management of women with abnormal cytology results?
  - What are the recommended waiting times for referrals to colposcopy?
  - What strategies should be implemented to maximize colposcopy attendance?
- Quality indicators and outcomes
  - What care aspects should high-quality colposcopy include?
  - What are the colposcopy clinic–specific performance indicators that should be implemented by individual clinics?

Target Population

The recommendations presented here apply to all health care providers and administrators involved with the provision of colposcopy examination in Ontario.

Systematic Review of New Guidelines

The core methodology used to develop this guideline was the identification of high-quality guidelines through a systematic search and quality appraisal. The electronic databases MEDLINE and EMBASE were searched for January 2008 to March 2013 (later updated to January 2014). Previous years were not searched because evidence-based guidelines for colposcopy more than 5 years old were very unlikely to provide evidence that would alter the recommendations written in the original 2008 CCO guideline. Using the word "colposcopy", the Web sites of international guideline developers and Canadian provincial and national cancer agencies and the Standards and Guidelines Evidence directory of cancer guidelines at the Web site of the Canadian Partnership Against Cancer (http://www.cancerview.ca/cv/portal/Home/TreatmentAndSupport/TSProfessionals/ClinicalGuidelines/GRCMain/GRCSAGE/GRCSAGESearch?) were searched for existing evidence-based guidelines. Guidelines that addressed any aspect of colposcopy relevant to the domains in the guideline research questions and published during or after 2008 were considered for the present document. Guidelines in a language other than English were excluded because resources for translation were not available. No search for existing systematic reviews or primary literature was conducted because the identified guidelines addressed the aspects of colposcopy listed in the objectives of the present document.

Two independent members of the PEBC's Cervical Cancer Screening Clinical Advisory Committee and methodologists used the AGREE II (Appraisal of Guidelines Research and Evaluation II) tool[7] to conduct a quality assessment of the identified guidelines. Data were extracted by one methodologist and verified through a data-auditing procedure. The updated systematic review of the guidelines on which the recommendations are based is available at the Cancer

Care Ontario Web site (https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=327346).

Development of Recommendations

The Cervical Cancer Screening Clinical Advisory Committee reviewed the recommendations in the existing 2008 CCO colposcopy guideline, together with the recommendations from five other guidelines identified as relevant in the updated guideline search and published during the period of interest. Recommendations in the 2008 CCO guideline were first assessed for their relevancy to the current practice environment, and their recommendations were endorsed when appropriate. Modifications and additions were based on evidence and the consensus of the Cervical Cancer Screening Clinical Advisory Committee. Recommendations found in new guidelines identified as relevant were evaluated to determine whether they contradicted, altered, or modified the 2008 CCO recommendations, and to identify areas in which new recommendations could be adopted or endorsed to address gaps in the 2008 CCO guideline. If a new guideline's recommendations were substantially similar to the 2008 CCO guideline recommendations, they were reported, but not considered further. For particular research questions to which more than one new guideline was found to be applicable, the members of the working group included the recommendations from a Canadian guideline (if found) or else from other guidelines whose recommendations were found to be applicable to colposcopy practice in Canada.

New, modified, or revised recommendations are labelled to identify their origin:

- NEW Consensus: A new consensus recommendation developed by the current guideline working group
- RANZCOG: Recommendation adapted from the 2011 guideline[4] 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: Recommendation adapted from the 2010 or the 2011 guideline[3] developed by the National Health Service Cervical Screening Programme (NHSCSP) in the United Kingdom
- ECCSN: Recommendation adapted from the 2008 guideline[8] developed by the European Cervical Cancer Screening Network (ECCSN)

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

Internal and External Review

Before submission of the draft report for external review, the systematic review of guidelines and the guideline recommendations were reviewed by the PEBC Report Approval Panel, which consists of two members, including an oncologist with expertise in clinical and methodology issues. The PEBC Report Approval Panel reviewed the draft systematic review of new guidelines and the updated guideline and provided feedback. The draft systematic review of guidelines and the updated guideline recommendations were distributed to health care providers in the province of Ontario. Results of those two sources of feedback can be found in the full guideline report on the CCO Web site (https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=327346).

RESULTS

Literature Search Results

Of 366 guidelines found, 13 were identified as potentially relevant and were considered for full-text review. From among those thirteen, five guidelines were retained because they significantly overlapped in scope with the research questions of the present review[3,4,8–10]. The remaining eight documents were excluded because they were either replaced by a more recent version (two documents) or were not applicable to the Ontario context (five documents). One document was excluded because it focused on a domain [guidance for testing for the human papillomavirus (HPV)] not included in the present report.

The retained documents—from Canada[9,10], Australia and New Zealand[4], Europe[8], and the United Kingdom[3]—are briefly described in the subsections that follow. Table I presents the specific domains addressed by each of the guidelines. Details of the AGREE II quality assessment of the guidelines can be found in the full guideline report on the CCO Web site (https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=327346).

Society of Canadian Colposcopists Guideline

The guideline from the Society of Canadian Colposcopists (SCC), *Colposcopy Management of Abnormal Cervical Cytology and Histology*[9], 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; for clarifying the appropriate algorithms for follow-up after treatment; and for promoting the best possible care for women, while ensuring efficient use of available resources. The guideline was prepared by the Executive Council of the SCC and was approved by the SCC, the Society of Gynecologic Oncology of Canada, the 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 the guideline are based on expert opinion from published peer-reviewed literature and evidence from clinical trials.

PEBC 2011 Guideline on Cervical Screening

The 2011 PEBC guideline on cervical screening[10] is an update of a 2005 publication titled *Cervical Screening: A Clinical Practice Guideline.* The guideline focuses on cervical screening algorithms for primary screening using HPV DNA testing (assuming the existence of an organized screening program in Ontario) and endorses the cervical screening algorithms contained in the 2005 version for primary screening using cytology (the current standard of practice) because HPV testing is not currently funded for primary screening in Ontario. The recommendations for primary screening using cytology (referral criteria) are evidence- and consensus-based up to 2011. The guideline

TABLE I Domains addressed by the 2008 Cancer Care Ontario guideline and the newly identified guidance documents on colposcopy practice

Domain	Reference					
	PEBC, 2008[5]	SCC, 2012[9]	PEBC, 2011[10]	RANZCOG–ASCCP, 2011[4]	NHSCSP, 2010[3]	ECCSN, 2008[8]
Qualification and training	X					
Accessibility to training programs	X					
Training and qualification requirements	X				X	
Program scope	X					
Maintenance of competence	X			X	X	
Practice setting requirements	X			X		
Group practice	X			X	X	
Individual office-based practice	X			X		
Operational practices						
Referral criteria		X	X			
Wait times	X	X			X	
Reducing dropout rates	X			X	X	X
Quality indicators and outcomes						
Quality assurance	X			X	X	X
Performance indicators				X		X

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

is intended for use by all family physicians, care providers, and gynecologic 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's members included the members of the PEBC's Gynecologic Cancer Disease Site Group and of CCO's Cervical Clinical Advisory Committee who were not part of the Working Group.

RANZCOG–ASCCP Guideline

The RANZCOG–ASCCP Working Party was formed to develop a series of recommendations on colposcopy and treatment[4] to be considered by the members of RANZCOG, the ASCCP, and practitioners and institutions responsible for the management of women with abnormal cervical cytology. Four main areas are covered:

- Colposcopy service (personnel, information, facilities, other—documentation and patient default)
- Diagnostic colposcopy (treatment and follow-up)
- Monitoring of standards in colposcopy (clinical indicators, standards, practice improvement activities)
- Training, education, and certification (basic training, advanced training, maintaining professional standards, certification or a recognition award).

Recommendations are based mainly on performance standards identified through a national project involving 12,105 patients who underwent colposcopy.

NHSCSP Guideline

The 2010 NHSCSP guideline[3] 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. Recommendations are based on published evidence and expert consensus. All aspects of the guideline related to colposcopy services rather than to cervical screening were considered for the present guideline.

ECCSN Guideline

The 2008 ECCSN guideline[8] 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 the adverse effects and maximize the benefits of screening and are targeted to general practitioners, gynecologists, and cytopathologists. Only information relevant to colposcopy services was reviewed for the present guideline. The ECCSN guideline is based on a former ECCSN guideline and was prepared, with the technical and scientific support of the International Agency for Research on Cancer, by a multidisciplinary team of experts appointed by the European Commission. 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.

DISCUSSION AND CERVICAL CANCER SCREENING CLINICAL ADVISORY COMMITTEE CONSENSUS

In a consensus-based multidisciplinary process, the recommendations presented here have been adopted or adapted from recent national- and international-level documents providing guidance related to colposcopy services. This "guideline of guidelines" approach is the same that used in the 2008 CCO evidence-based series 15-12 document, *The Optimum Organization for the Delivery of Colposcopy Service in Ontario*[11].

The "guideline of guidelines" approach is a practical way to generate consensus and expert opinion–based recommendations to establish best practices within Ontario; however, it has some drawbacks. For example, because no systematic review of the available primary evidence is performed, important evidence might possibly not have been considered. Also, using guidelines from other jurisdictions can create difficulties in terms of adapting recommendations for the Ontario context.

SUMMARY

The present document summarizes similar globally available documents that address standards for the 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.

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. The report will be updated in accordance with the PEBC's *Document Assessment and Review Protocol* (available at https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=285439).

RECOMMENDATIONS

Training, Qualification, Accreditation, and Maintenance of Competence

Accessibility to Training Programs

In addition to practicing obstetricians and gynecologists, these practitioners should be eligible for colposcopic training programs:

- Residents and fellows in obstetrics and gynecology programs
- Other colposcopy service providers (for example, family physicians, nurse practitioners) who meet the knowledge requirements described next

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 affect clinical practice.
- cancer screening, including primary and secondary prevention.
- colposcopic clinicopathologic correlations and standard terminology.
- indications for referral to colposcopy, per the Ontario cervical screening guideline[10] (NEW Consensus).
- existing guidelines for referral (intake), treatment, re-referral, follow-up, and discharge per the *Colposcopy Quality-Based Procedures Clinical Handbook* [http://www.health.gov.on.ca/en/pro/programs/ecfa/funding/hs_funding_qbp.aspx (pending)] (NEW Consensus).
- the SCC 2012 publication[9] (NEW Consensus).
- quality assurance principles and components.

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 jurisdictions other

than Ontario, and 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 3 months in length, or equivalent, which ideally should be completed within 1 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.
- involve a minimum of 100 new cases, approximately 30% of whom should be patients with histologically documented low- or high-grade squamous intraepithelial lesions; endocervical adenocarcinoma *in situ;* or cancer, including vulval, vaginal, and vaginal squamous neoplasia. The preceptor should be present throughout the colposcopy examination for approximately 75 of the 100 new cases; the trainer should be available for the other 25 cases if help is needed.
- include components of surgical pathology and cytopathology to allow for an understanding of laboratory investigation of lower genital tract 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.
- incorporate into practice, for all clinicians providing colposcopy services, the CanMeds competencies set out by the Royal College of Physicians and Surgeons of Canada (Medical Expert, Communicator, Manager, Health Advocate, Scholar, and Professional) so as to achieve better patient outcomes (NEW Consensus).

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

- successful completion of a formal, procedure-specific course or program—for example, laser certification (as noted earlier).
- completion, under direct supervision, of a minimum of 10 procedures in a given treatment modality within 1 year before such procedures are performed independently.
- a 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 in an interdisciplinary team environment within an established clinic or practice, usually a hospital-based unit.
- be associated with a formal colposcopy program.

Accreditation and Certification

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

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. A clinical volume of approximately 100 colposcopies per year should ideally be performed. Although the optimal proportion of new patients is not known, 25% is generally considered to be an absolute minimum.
- regularly attend or provide (or both) accredited continuing medical education (CME) events related to lower genital tract preinvasive diseases at least once every 2 years.
- participate regularly in clinical audits as a component of continuing education.
- practice in compliance with the *Colposcopy Quality-Based Procedures Clinical Handbook* [http://www.health.gov.on.ca/en/pro/programs/ecfa/funding/hs_funding_qbp.aspx (pending)] (NEW Consensus).

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[11].

The recommendations for maintenance of competence represent the consensus of the Working Group members based on guidance provided by the NHSCSP in the United Kingdom[3], the RANZCOG in conjunction with the ASCCP Working Party[4], and the 2008 CCO guideline[11]. Two additional recommendations related to CME from the 2008 CCO guideline[11] were endorsed. Although the evidence base underpinning the volume-related practice recommendations is sparse and of poor quality, there is a convergence of opinion among the various guideline developers internationally and the members of the panel responsible for the present document.

Practice Setting Requirements

The recommendations for practice setting requirements reflect current practice in Ontario, where colposcopy services are delivered either in hospitals, in outpatient clinics (located outside of hospitals), or in individual office practices. The recommendations are presented separately for group and individual practices, not because of different quality recommendations, but in recognition of differences in resources, roles, and responsibilities[11]. 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 from diagnosis through treatment and follow-up to discharge.

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

Personnel: Group practices should have

- colposcopists who meet the training requirements described in the subsection on qualification, training, and maintenance of competence. Those colposcopists should see a sufficient case load to ensure and maintain the skills needed for the colposcopy program (see the Maintenance of Competence subsection).
- physician colposcopists, including a lead clinical colposcopist with a specialist team specific to the colposcopy unit. Physician colposcopists and lead clinic colposcopists should maintain responsibility for quality assurance and management of protocols.
- an experienced clinical colposcopist 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 with the appropriate training and knowledge.
  - All colposcopy nurses should complete training or coursework (or both) specific to colposcopy and best colposcopic practice.
  - Nursing staff should be able to explain to patients and to educate patients about the purpose of colposcopy, biopsy, treatment options, follow-up, fertility, risk factors, and possible side effects.
  - An educational component should be present in every new patient history during which the education provided by the nurse can be documented. Nurses have an opportunity to educate women at every visit (NEW Consensus).
  - The nursing complement should be adequate to meet the standard of care 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 gynecologic oncology unit or one or more gynecologic oncologists (RANZCOG).
- adequate support personnel, clerical staff, and information technology staff.

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

- mechanisms to ensure 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 its 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 larger colposcopy units).
- where required to comply with provincial standards for health care facilities, availability of accessible resuscitation equipment and staff with appropriate training (RANZCOG).
- mechanisms to ensure that the patient flow process provides privacy and dignity during the colposcopy visit (NEW Consensus).

Documentation and Patient Management: These items should be available or be provided to 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. This process should allow for audit and quality improvement initiatives and facilitate consistent reporting.
- A relationship with all referral sources, including primary care and regional public health cervical screening services.
- Referral for treatment that is the responsibility of the colposcopists making the original diagnosis and that 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.
- Maintenance of documented evaluations, course materials, and a roster of identified preceptors, when training is provided within the facility.
- Maintenance of documentation for all CME events, 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 clients, and
  - culturally appropriate information, with translation into the primary language of the client.
- Appropriate and sensitive enquires about sexual history, but only under the auspices of a study with ethics approval or if the patient presents with a specific indication (NHSCSP).

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 the documentation of quality outcomes and to permit audit and quality improvement initiatives (to facilitate consistent reporting).
- comply with best practices in infection control, including access to instrument sterilizing facilities in accordance with provincial guidelines (NEW Consensus).
- have the necessary physical resources and access to collaborative services deemed necessary for providing colposcopy, which can 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 recommendations related to practice setting requirements (group practice and individual office-based practice) contained in the 2008 CCO guideline[11], except for the recommendations listed below, which are based on guidance provided by the RANZCOG and ASCCP Working Party[4], 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[4], 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 2 nurses for each clinic are recommended. However, the Working Group members recognize that for low-volume units in some geographic regions in Ontario, achieving that recommendation could be difficult. It was concluded by consensus that, for low-volume units, 1 nurse might 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[4]. The recommendation for the clinic facilities and patient flow process to provide 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 by the 2008 CCO guideline[11].

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

Operational Practice

Referral Criteria

Women should be referred for colposcopy according to the Ontario Cervical Screening Program clinical guideline (https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=124511).

Wait Times

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

- Women with atypical squamous cells that cannot exclude high-grade squamous intraepithelial lesions or atypical glandular cells should be seen in a colposcopy clinic within 6 weeks of referral.
- Women with high-grade squamous intraepithelial lesions should be seen in a colposcopy clinic within 4 weeks of referral.
- Women with a Pap test suggestive of carcinoma should be seen in a colposcopy clinic within 2 weeks of referral.
- All other women with abnormal results should be seen in a colposcopy clinic within 12 weeks of referral.

Strategies to Reduce Drop-Out Rates

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

- Women should be advised that they should notify the clinic of any change in their address and other contact details (RANZCOG).
- The drop-out rate should ideally 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 analyses of the records of defaulters to identify avoidable causes of default at first consultation (NHSCSP).
- Effective information and communication are crucial to reducing anxiety. Women should be provided 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 be recorded for each new patient (RANZCOG).

- A documented system has to be in place to notify or recall patients who default at first consultation, treatment, or follow-up (RANZCOG).

Justification: The recommendations for referral criteria are based on guidance provided in the CCO's 2011 *Cervical Screening* guideline[10].

The members of the Working Group endorsed the wait times recommendations from the 2012 clinical practice guidelines developed by the SCC[9]. Those recommendations are the opinion of respected authorities, based on clinical expertise, descriptive studies, or reports of expert committees.

The recommendations for reducing dropout rates are based on guidance provided by the 2008 CCO guideline[11], the RANZCOG–ASCCP guideline[4], and the NHSCSP guideline[3].

Quality Indicators and Outcomes

Quality Care

- An organized provincial colposcopy information and quality control system should be established to monitor the quality of colposcopy services. The 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:
  - 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 cytologic and histologic 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 in 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 consistently across the province) and should 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 (for example, gynecology, oncology), then the colposcopist should follow up to ensure that 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 (RANZCOG). They should
  - meet defined clinical indicators.
  - conduct tissue audits (for example, excisional biopsies, microinvasive cancer, glandular neoplasms, and other pathology of interest). Audit of excisional treatments should occur with particular emphasis on specimen quality and clinical outcome.
  - review patient satisfaction surveys (for example, 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.
  - review service audits (for example, 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[11], the RANZCOG in conjunction with the ASCCP Working Party[4], and the ECCSN[8]. 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 in understanding the distribution of disease in the population.

Quality Care Performance Indicators

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

- colposcopy–biopsy concordance.
- complications after treatment.
- readmissions for complications after treatment.
- residual disease after treatment.
- re-treatment 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[8] and adapted the guidance from the RANZCOG and the ASCCP Working Party about the performance standards that should be used to monitor quality assurance in colposcopy[4].

REVIEW AND UPDATE

Guidelines developed by the PEBC are reviewed and updated regularly. Please visit the CCO Web site (http://www.cancercare.on.ca) for the full evidence-based series report and subsequent updates (https://www.cancercare.on.ca/toolbox/qualityguidelines/clin-program/screening-ebs/).

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CONFLICT OF INTEREST DISCLOSURES

We have read and understood *Current Oncology*'s policy on disclosing conflicts of interest, and we declare that we have none.

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