CANADIAN PARTNERSHIP AGAINST CANCER
PARTENARIAT CANADIEN CONTRE LE CANCER

Pan-Canadian Cervical Screening Initiative

# Reporting on Histopathology Specimens from the Cervix and Vagina – Consensus Statements

May 2013

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The views expressed herein represent the views of Canadian Partnership Against Cancer.

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This report is also available in French at www.cccincanada.ca.

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# Introduction

Cervical and vaginal histopathology specimens, most often taken during the investigation of abnormal cervical cytology, are reported on using various terminology systems. Squamous abnormalities are generally reported on using terms including dysplasia, cervical intraepithelial neoplasia (CIN) and squamous intraepithelial lesions. These systems are well established but their usage varies and currently there is no Canadian standard for reporting of cervico-vaginal histopathology.

**The Pan-Canadian Cervical Cancer Screening Initiative is dedicated to implementing the Canadian Partnership Against Cancer strategic initiative in cervical cancer control. The initiative focuses on continued implementation of effective cervical cancer screening programs and the integration of these programs with HPV vaccination, testing and surveillance initiatives.**

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The lack of standardization raises the potential for miscommunication between the pathologist and the clinician. These data are also an important component of cervical screening program performance evaluation. The recent *Cervical Cancer Screening in Canada Monitoring Program Performance 2006–2008* results report,[1] developed under the Pan-Canadian Cervical Cancer Screening Initiative (PCCSI), identified significant gaps in collecting cervical histopathology data throughout most jurisdictions. The development of reporting standards and common data elements is necessary for recording and analyzing complex data sets, for developing quality assurance processes and for improving patient outcomes.

Recently, consensus recommendations on lower anogenital squamous intraepithelial terminology for lesions associated with human papillomavirus (HPV) were released by the American Society for Colposcopy and Cervical Pathology and the College of American Pathologists (the LAST project).[2] The development of these recommendations included involvement from individual Canadian pathologists and colposcopists as well as representation from the Society of Canadian Colposcopists, the Society of Gynecologic Oncologists of Canada and the Society of Obstetricians and Gynaecologists of Canada. The recommendations outline a terminology system for squamous lesions of the cervix, vagina, vulva, penis, perianus and anus, as well as recommendations for superficially invasive squamous carcinomas and the use of biomarkers. The LAST project does not address report content, negative biopsies or glandular lesions.

The Cervical Screening Program of the National Health Service (NHS) in the U.K. recently released the second version of *Histopathology Reporting in Cervical Screening*.[3] This updated document provides advice on terminology and diagnostic criteria, including squamous, glandular and benign mimics.

These two documents, as well as the demonstrated gap in data collection, led to the development of a Canadian consensus process for a comprehensive reporting system for histopathology specimens from the cervix and vagina. The goal of the Canadian project was to standardize report content and terminology. The proposed system should facilitate patient care through consistent reporting formats and terminology; enable structured reporting; support national, provincial and territorial data collection; and support program monitoring and evaluation.

## Process

With the goal of establishing reporting standards for cervico-vaginal histopathology, a working group, led by PCCSI, was formed in the fall of 2012 (see Appendix C for working group membership). The working group used the LAST terminology and the NHS's *Histopathology Reporting in Cervical Screening* as foundational references for the development of the first draft of the Canadian-adapted cervico-vaginal histopathology consensus statements. As well, a survey of reporting practices by Canadian pathologists provided a baseline for terminology systems currently in place.

The initial draft of the Canadian-adapted statements developed by the working group (in October 2012) was circulated to a group of key stakeholder pathologists. These pathologists were identified by representatives from provincial and territorial cancer programs and by national professional organizations such as the Canadian Association of Pathologists (CAP). The statements were circulated via an online consensus platform, which displayed the draft statements and relevant references (results of this review are presented in Appendix A). Pathologists were asked to indicate their level of agreement with each statement on a scale from one to six and were able to add comments. In a parallel process, colposcopists from across Canada reviewed a standard set of colposcopy data elements that support both clinical service needs and monitoring of colposcopy and cervical program quality indicators (publication pending).

The feedback and level of consensus from this round of review was compiled and presented at a two-day workshop in November 2012, hosted by PCCSI. The workshop brought together the key stakeholder pathologists and colposcopists, cervical screening program staff and other key experts (the participant directory is presented in Appendix D). The goals of the workshop were to discuss and agree on standard terminology for pathology results on biopsy specimens for the cervix and vagina, including cervical cancer, precancer and benign categories. In addition, colposcopists were asked to help define a standard set of colposcopy data elements that

support both clinical service needs and monitoring of colposcopy and cervical program quality indicators.

The workshop featured a focused breakout session to discuss the results of the first round of review of the histopathology statements. A joint discussion involving both pathologists and colposcopists was also held to facilitate further collaboration and input and to inform the next revision of the statements.

Using the feedback from the workshop, the working group revised the histopathology consensus statements. Pathologists were then invited to participate in a second review via the online consensus platform in December 2012 (results of this review are presented in Appendix B). At that point, colposcopists were also invited to indicate their level of consensus with each statement and provide comments. The working group incorporated the December 2012 feedback and comments to produce the final version of the statements presented in this report, titled *Standardized Approach to Reporting on Histopathology Specimens from the Cervix and Vagina.*

This final version of the statements was widely circulated among pathologists and colposcopists in March 2013 with a request for final comments; no further questions or revisions were submitted.

The Executive Committee of the CAP officially endorsed the consensus statements in April 2013.

## Next Steps for Action

The consensus statements, *Standardized Approach to Reporting on Histopathology Specimens from the Cervix and Vagina,* presented in this report, are intended to stimulate discussion and inform practice.

Provinces and territories may wish to modify or enhance these recommendations to serve the needs in their jurisdictions. It is recognized that there are areas of contention that will require further discussion. Specifically, the inclusion of CIN terminology for high-grade lesions, especially in young women, should be influenced by clinical need. The forthcoming guidelines on colposcopic management from the Canadian Society of Colposcopists will likely provide guidance. It is also recognized that the “Indeterminate” category attempts to standardize a category that is inherently variable. Unless stringent criteria for further sectioning the use of biomarkers and second opinions are followed, this category could become a catch-all. Similar to

the “Atypical Squamous Cell of Undetermined Significance” category in cytology reporting systems, the use of the “Indeterminate” category should be monitored.

Finally, a comprehensive reporting system requires that the histopathological criteria for the diagnostic categories be delineated. As well, the increasing use of biomarkers to support diagnosis needs to be addressed and appropriate use described. To this end, the CAP is bringing together a steering committee to provide advice in these areas.

# Standardized Approach to Reporting on Histopathology Specimens from the Cervix and Vagina

## General Statements

1. A standardized approach to report content and terminology for histopathology specimens from the cervix and vagina has the potential to improve communication and the quality of patient care.

2. This reporting system should contain, at a minimum, data elements including type of specimen and diagnosis. The use of a "synoptic" format with distinct data fields could aid in data collection but is optional.

3. If interpretation is limited by sampling, fixation and/or preparation this should be stated with a description of the limitation. If there is no limitation then the adequacy of the specimen for interpretation is understood.

4. A statement regarding the presence or absence of transformation zone as determined by the presence of metaplastic squamous epithelium or underlying endocervical glands is optional.

## Reporting System

### Negative Specimens

5. Specimens that are **Negative for Intraepithelial Lesion and Malignancy** should be reported using a clear and unambiguous statement. The term "Intraepithelial Lesion" is inclusive of both squamous and glandular lesions. The addition of comments regarding specific benign conditions is optional.

### Squamous Lesions

6. Specimens that are positive for squamous intraepithelial lesions should be reported using a 2-tiered nomenclature. The recommended terminology is **Low Grade Squamous Intraepithelial Lesion (LSIL)** and **High Grade Squamous Intraepithelial Lesion (HSIL)**.

7. The SIL terminology may be further classified by the applicable **Intraepithelial Neoplasia** sub-categorization – for example, HSIL (CIN 2). The addition of sub-classification should be based on clinical decision/management pathways.

8. Specimens that contain an area of squamous intra-epithelial lesion which cannot be graded as either low or high due to limited sampling, substandard fixation and processing, and/or obscuring factors should be reported as **Squamous Intraepithelial Lesion, Ungraded**. There should be a comment regarding the nature of the uncertainty. This conclusion should only be reached after appropriate work up that may include further levels, consultation and biomarkers such as p16.

Glandular Lesions

9. Specimens that are positive for endocervical glandular preinvasive lesions should be reported using the term **Adenocarcinoma In Situ (AIS)**.

10. Specimens with lesser degrees of glandular atypia are not uniformly recognized and classified and reporting is not recommended (see also statement #11 Indeterminate for AIS).

Indeterminate Lesions

11. Specimens which contain some features of HSIL, AIS or malignancy but for which definitive conclusions cannot be reached due to limited sampling, substandard fixation and processing, and/or obscuring factors should be reported as **Indeterminate for - HSIL or AIS or Malignancy**. There should be a comment regarding the nature of the uncertainty. This conclusion should only be reached after appropriate work up that may include further levels, consultation and biomarkers such as p16.

Excisional Specimens

12. The reporting of single excisional biopsies (LEEP, Cone) with intraepithelial lesions should include a statement regarding the involvement of margins including an indication of which margin is involved, if possible – for example, endocervical, ectocervical, radial (deep).

13. Single excisional biopsies (LEEP, Cone) that are positive for malignancy should contain, where possible:
    a. Type of malignancy
    b. Depth of invasion
    c. Horizontal spread
    d. Presence or absence of lymph-vascular space invasion
    e. Involvement of margins

Superficially Invasive Squamous Cell Carcinoma

14. The term **Superficially Invasive Squamous Cell Carcinoma** (SISCCA) is recommended for minimally invasive SCC of the cervix that has been completely excised and is potentially amenable to conservative surgical therapy. Lymph-vascular invasion and pattern of invasion are not part of the definition of SISCCA.

15. SISCCA of the cervix (FIGO 1ai) is defined as an invasive squamous cell carcinoma that:
    a. Is not a grossly visible lesion, **AND**
    b. Has an invasive depth of 3mm or less from the basement membrane of the point of origin, **AND**
    c. Has a horizontal spread of 7mm or less in maximal extent, **AND**
    d. Has been completely excised

16. No recommendation is offered for early invasive squamous cell carcinoma of the vagina.

17. For cases of invasive squamous cell carcinoma with positive biopsy/resection margins, the pathology report should state whether:
    a. The examined invasive tumor exceeds the dimensions for a SISCCA, **OR**
    b. The examined invasive tumor component is less than or equal to the dimensions for a SISCCA and conclude that the tumor is ‘‘At least a superficially invasive squamous cell carcinoma’’

18. In cases of SISCCA, the following parameters should be included in the pathology report:
    a. The presence or absence of lymph-vascular space invasion
    b. The presence, number, and size of independent multifocal carcinomas (after excluding the possibility of a single carcinoma)

# Appendix A. First Online Review of Statements

The following is a summary of the first round of review conducted via the online consensus platform in October 2012. This report includes the statements submitted for consensus and the level of consensus for each statement. Please note that these statements are included only to demonstrate the process of consensus and are not the final statements to be referenced or used in practice.

| Statement | % Consensus |
|---|---|
| 1. A standardized approach to report content and terminology for histopathology specimens from the cervix and vagina has the potential to improve communication and the quality of patient care. | 100 |
| 2. This reporting system should contain, at a minimum, data elements including type of specimen and diagnosis. | 100 |
| 3. A statement on specimen adequacy or specimen limitations (i.e. regarding the reliability of a sample in detecting pathology) is optional. | 65 |
| 4. A statement on specimen adequacy or specimen limitations should include limitations due to fixation and preparation. | 88 |
| 5. A statement on specimen adequacy or specimen limitations should include presence or absence of transformation zone and/or endocervical tissue (depending on the specimen type). | 94 |
| 6. Specimens that are negative for intra-epithelial lesions and malignancy should be reported using a clear and unambiguous statement. | 100 |
| 7. Specimens that are negative for intra-epithelial lesions and malignancy should have a statement regarding the presence or absence of transformation zone as determined by the presence of metaplastic squamous epithelium or underlying endocervical glands. | 82 |
| 8. Specimens which contain some features of intra-epithelial lesion or malignancy but for which definitive conclusions cannot be reached due to limitations in specimen size or quality should be reported as indeterminate, and include a statement regarding the limiting factor(s). | 94 |
| 9. Specimens that are positive for squamous intra-epithelial lesions should be reported using a 2-tiered nomenclature. The recommended terminology is Low Grade Squamous Intra-epithelial Lesion and High Grade Squamous Intra-epithelial Lesion (LSIL, HSIL). | 94 |

| | |
|---|---|
| 10. The SIL terminology should be further classified by the applicable - Intraepithelial Neoplasia sub categorization (e.g. HSIL (CIN 2)). | 82 |
| 11. Specimens that contain an area of squamous intra-epithelial lesion which cannot be graded due to limited sampling, substandard fixation and processing, and/or partial obscuring should be reported as Squamous Intraepithelial Lesion, unqualified (SILQ). | 94 |
| 12. Specimens that contain an area of squamous intra-epithelial lesion which cannot be graded should have a comment regarding the nature of the uncertainty. | 94 |
| 13. Specimens that are positive for glandular preinvasive lesions of should be reported using the adenocarcinoma-in-situ terminology. | 100 |
| 14. Specimens with lesser degrees of glandular atypia are not uniformly recognized and classified and should not be reported. | 76 |
| 15. Specimens that are positive for malignancy should contain, where possible, type of malignancy. | 100 |
| 16. Specimens that are positive for malignancy should contain, where possible, depth of invasion. | 94 |
| 17. Specimens that are positive for malignancy should contain, where possible, lateral extent. | 94 |
| 18. Specimens that are positive for malignancy should contain, where possible, presence of lymph-vascular space invasion. | 100 |
| 19. Specimens that are positive for malignancy should contain, where possible, involvement of margins. | 100 |
| 20. The reporting of single excisional biopsies (LEEP, Cone) should include a statement regarding the involvement of margins including an indication of which margin is involved e.g. endocervical, ectocervical, radial (deep). | 100 |
| 21. The proposed system of reporting is complete, and there are no significant gaps in the recommendations. | 94 |
| 22. The proposed system of reporting is consistent with the literature and practice in other jurisdictions. | 88 |
| 23. The proposed system of reporting is appropriate for Canada's Pathologists and Laboratory System. | 94 |

| | |
|---|---|
| 24. I would make use of this reporting system in my professional decisions. | 100 |
| 25. I would recommend this reporting system for use in practice. | 100 |
| 26. The proposed system could be accommodated in the Laboratory information system in your area. | 88 |
| 27. The proposed system could be accommodated in the Hospital information system in your area. | 88 |
| 28. The proposed system could be accommodated in the Provincial/Territorial information system in your area. | 88 |
| 29. There are significant barriers to adopting this system in our region and/or province. If yes, please provide a comment using the tool above. | 24 |

# Appendix B. Second Online Review of Statements

The following is a summary of the second round of review conducted via the online consensus platform in December 2012. This report includes the statements submitted for consensus and the level of consensus for each statement. Please note that these statements are included only to demonstrate the process of consensus and are not the final statements to be referenced or used in practice.

| Statement | % Consensus |
|---|---|
| 1. A standardized approach to report content and terminology for histopathology specimens from the cervix and vagina has the potential to improve communication and the quality of patient care. | 100 |
| 2. This reporting system should contain, at a minimum, data elements including type of specimen and diagnosis. The use of a "synoptic" format with distinct data fields could aid in data collection but is optional. | 100 |
| 3. If interpretation is limited by sampling, fixation and/or preparation this should be stated with a description of the limitation. If there is no limitation then the adequacy of the specimen for interpretation is understood. | 100 |
| 4. A statement regarding the presence or absence of transformation zone as determined by the presence of metaplastic squamous epithelium or underlying endocervical glands is optional. | 87 |
| 5. Specimens that are Negative for Intraepithelial Lesion and Malignancy should be reported using a clear and unambiguous statement. The term "Intraepithelial Lesion" is inclusive of both squamous and glandular lesions. The addition of comments regarding specific benign conditions is optional. | 100 |
| 6. Specimens that are positive for squamous intraepithelial lesions should be reported using a 2-tiered nomenclature. The recommended terminology is Low Grade Squamous Intraepithelial Lesion and High Grade Squamous Intraepithelial Lesion (LSIL, HSIL). | 93 |
| 7. The SIL terminology may be further classified by the applicable – Intraepithelial Neoplasia sub categorization (e.g. HSIL (CIN 2)). The addition of sub-classification should be based on clinical decision/management pathways. | 100 |
| 8. Specimens which contain some features of HSIL, AIS or malignancy but for which definitive conclusions cannot be reached due to limited sampling, substandard fixation and processing, and/or obscuring factors should be reported as Indeterminate for HSIL or AIS or Malignancy. There should be a comment regarding the nature of the uncertainty. This conclusion should only | 100 |

| | |
|---|---|
| be reached after appropriate work up that may include further levels, consultation and biomarkers such as p16. | |
| 9. Specimens that contain an area of squamous intra-epithelial lesion which cannot be graded as either low or high due to limited sampling, substandard fixation and processing, and/or obscuring factors should be reported as Squamous Intraepithelial Lesion, Ungraded. There should be a comment regarding the nature of the uncertainty. This conclusion should only be reached after appropriate work up that may include further levels, consultation and biomarkers such as p16. | 100 |
| 10. Specimens that are positive for endocervical glandular preinvasive lesions should be reported using the term Adenocarcinoma In Situ. | 100 |
| 11. Specimens with lesser degrees of glandular atypia are not uniformly recognized and classified and should not be reported (see also statement #8, Indeterminate for AIS). | 93 |
| 12. The reporting of excisional biopsies (LEEP, Cone) with intraepithelial lesions should include a statement regarding the involvement of margins including an indication of which margin is involved e.g. endocervical, ectocervical, radial (deep). | 100 |
| 13. Single excisional biopsies (LEEP, Cone) that are positive for malignancy should contain, where possible, a) type of malignancy b) depth of invasion c) horizontal spread d) presence of lymph-vascular space invasion e) involvement of margins. | 100 |
| 14. The term superficially invasive squamous cell carcinoma (SISCCA) is recommended for minimally invasive SCC of the cervix that has been completely excised and is potentially amenable to conservative surgical therapy. Lymph-vascular invasion and pattern of invasion are not part of the definition of SISCCA. | 97 |
| 15. SISCCA of the cervix is defined as an invasive squamous cell carcinoma that is not a grossly visible lesion, AND has an invasive depth of 3mm or less from the basement membrane of the point of origin, AND has a horizontal spread of 7mm or less in maximal extent, AND has been completely excised. | 100 |
| 16. No recommendation is offered for early invasive squamous cell carcinoma of the vagina. | 93 |
| 17. For cases of invasive squamous cell carcinoma with positive biopsy/ resection margins, the pathology report should state whether: The examined invasive tumor exceeds the dimensions for a SISCCA. OR The examined invasive | 97 |

tumor component is less than or equal to the dimensions for a SISCCA and conclude that the tumor is ‘‘At least a superficially invasive squamous cell carcinoma.’’

| | |
|---|---|
| 18. In cases of SISCCA, the following parameters should be included in the pathology report: The presence or absence of lymph-vascular space invasion. The presence, number, and size of independent multifocal carcinomas (after excluding the possibility of a single carcinoma). | 97 |

# Appendix C. Working Group Membership

With the goal of establishing reporting standards in cervico-vaginal histopathology, a working group, led by PCCSI, was formed in the fall of 2012. The working group was composed of the following:

Dr. Meg McLachlin (Chair, PCCSI)

Susan Fekete (Director, Screening & Early Detection, Canadian Partnership Against Cancer)

Dr. Verna Mai (Expert Lead, Screening, Canadian Partnership Against Cancer)

Dr. Terry Colgan (Head, Section of Cytopathology, Department of Pathology and Laboratory Medicine, Mount Sinai Hospital)

Dr. Máire Duggan (Professor of Pathology and Cytopathology, University of Calgary)

Dr. Joan Murphy (Oncologist; Head, Division of Gynecologic Oncology, University Health Network; Associate Professor, Department of Obstetrics and Gynecology, University of Toronto).

# Appendix D. PCCSI Workshop Participants

In November 2012, PCCSI (under the Screening & Early Detection division of the Canadian Partnership Against Cancer) hosted a two-day workshop to discuss and agree on standard terminology for pathology results on biopsy specimens for the cervix, vulva and vagina, including cervical cancer, precancer and benign categories. Attendees were also asked to help define a standard set of colposcopy data elements that support both clinical service needs and monitoring of colposcopy and cervical program quality indicators.

The full list of workshop attendees, including the key stakeholder pathologists (who provided initial feedback on the statements) and colposcopists, cervical screening program staff and other key experts is below.

**Ahmed, Itrat**
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**Waghray, Ranjit**
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Calgary Lab Services

**Wilson, Peter**
Gynecologist
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**Yang, Huiming**
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Alberta Health Services

**Zhan, Yunzhi**
Canada Health Infoway,
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