



PERFORMANCE MONITORING
FOR
CERVICAL CANCER SCREENING PROGRAMS
IN CANADA



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Performance Monitoring for Cervical Cancer Screening Programs in Canada

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REPORT FROM THE SCREENING PERFORMANCE
INDICATORS WORKING GROUP, CERVICAL CANCER
PREVENTION AND CONTROL NETWORK (CCPCN)

PERFORMANCE MONITORING
FOR
CERVICAL CANCER SCREENING PROGRAMS
IN CANADA

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COLLABORATION WITH



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EXECUTIVE SUMMARY



- The purpose of this report is to define a core set of performance indicators for organized cervical cancer screening programs in Canada.
- The goals for establishing a pan-Canadian set of performance indicators are to promote high quality screening through monitoring and evaluation. Over time, with regular monitoring and reporting of these indicators, an evidence base will grow which will permit the setting of pan-Canadian targets.
- Cervical cancer control is undergoing tremendous development as knowledge of the causal relationship between the Human Papillomavirus (HPV) and cervical cancer continues to increase. Regular monitoring and reporting of these indicators will facilitate the evaluation of the impact of new technologies and interventions.
- The program performance indicators described were selected by the Screening Performance Indicators Working Group (SPIWG) through a consensus-based, iterative process. Feedback from content experts including researchers, clinicians and administrators across Canada was also sought.
- The program performance indicators reflect the current pan-Canadian screening practices, and include the following: coverage (i.e., participation and retention rates), cytology performance (i.e., specimen adequacy and Pap test results), system capacity (i.e. cytology turn around time and time to colposcopy), follow-up (i.e., biopsy rate, cytology-histology agreement) and outcomes (i.e., pre-cancer detection rate, cancer incidence, disease extent at diagnosis: cancer stage, screening history in cases of invasive cancer).
- The ongoing implementation of HPV immunization programs will have a significant future impact on cervical cancer in Canada. To detect changes in cervical cancer and cervical cancer screening attributable to HPV vaccine programs, the SPIWG recommends that relevant core performance indicators be monitored by 10-year age groups to detect early changes, and eventually by various HPV vaccination parameters (e.g., type of vaccine, fully/partially/not vaccinated, time since vaccination) to detect differences.
- It is challenging to define quantifiable performance indicators over the entire spectrum of activity for an organized screening program especially given that the body of literature is continually evolving as are the technologies and methods used to screen, diagnose and treat cervical cancer. In light of this, this core set of performance indicators is expected to be updated as pan-Canadian screening policy and management guidelines evolve over time. Future

indicators should include areas such as professional education initiatives, public education initiatives, letters of invitation, recruitment initiatives, program efficiency, HPV testing protocols, HPV immunization, among others.

- The implementation of HPV vaccine programs and the consideration of HPV testing as a primary screening test will require pan-Canadian experts to convene to develop new cervical screening policy and management guidelines. The SPIWG urges that the identification of performance indicators be included within the development of screening policy and management guidelines. This emphasizes the integral role of performance monitoring and evaluation in policy implementation.
- Much of this document is highly technical, however *Background*, and *Future Directions* sections, and *Appendix C* provide a general overview of the cervical screening in Canada and its evaluation.

BACKGROUND



Introduction

Since the introduction of the Papanicolaou (Pap) test within Canada in 1949, cervical cancer incidence and mortality rates have decreased substantially (e.g., 50% from 1979-2008 and 43% from 1979-2008 respectively)(1). The Pap test can detect lesions before they become cancerous or when the disease is at an early stage where treatment is more likely to be effective in preventing the loss of life and reducing the morbidity associated with treating advanced disease.

While invasive cervical cancer is largely preventable, it remains the 13th most common cancer among Canadian women of all ages(1) and the 3rd in women between 20 and 40 years of age(2). Furthermore, it is estimated that 1,300 Canadian women will be diagnosed with invasive cervical cancer and approximately 380 will die from the disease in 2008(1). Inadequate or lack of screening have been identified as the primary attributable factors(3).

Additionally, the volume of pre-cancerous lesions and abnormal Pap tests that require follow-up including assessment, diagnosis, and/or treatment poses a major health burden in terms of morbidity, and utilization of health care system resources. Using the range of reported rates of low-

grade squamous intraepithelial lesions and/or more advanced lesions (LSIL+) by Canadian cervical cancer screening programs (2 to 5%) (4-8) and the number of women that undergo a Pap test each year in Canada (more than 5,700,000 women)¹, one can extrapolate that between 115,731 to 289,327 Canadian women have an abnormal Pap test that requires follow-up each year.

In light of the ongoing burden that cervical cancer poses, an organized approach to cervical cancer screening has been recommended on a pan-Canadian basis in order to optimize the detection of pre-cancerous lesions and further reduce cervical cancer related incidence, morbidity and mortality(9-16). Historically, the delivery of cervical cancer screening in Canada has been conducted in an opportunistic manner which depends on the initiative of the individual woman and/or her health care provider. This may lead to inappropriate screening utilization and inadequate follow-up of abnormal results(17).

Organized cervical cancer screening programs can ensure that screening, follow-up, and treatment are accessible, delivered using a standardized approach,

¹ Data source: Canadian Community Health Survey, 2005

and that quality of service is evaluated. Specific components can be used to achieve high participation and retention such as an invitation to enter the program and reminders to be re-screened. The appropriate follow-up and treatment of abnormal test results can be assured through the use of protocols. Furthermore, using information systems, organized programs can ensure the data required for monitoring and evaluation is collected(18). Please refer to Appendix B for a summary of the widely accepted components of an organized screening program(19).

While direct comparisons of organized versus spontaneous cervical cancer screening by way of randomized trials are lacking, longitudinal data have demonstrated significant reductions in cervical cancer incidence over time periods following the introduction of organized screening programs (e.g., 60% reduction in Iceland from 1965 to 1975(20), 35% reduction in Britain from 1988 to 1995(21) 78% in British Columbia from 1955 to 1985(22), and 52% in Nova Scotia from 1971 to 2001(6)). It is not possible, however, to attribute these reductions to organized screening alone due to the possibility of spontaneous screening activities having occurred simultaneously.

Purpose

The purpose of this report is to define a core set of performance indicators for organized cervical cancer screening programs in Canada. Establishing a pan-Canadian set of performance indicators will provide a means to monitor the performance of the various components of the screening process, and facilitate inter-jurisdictional comparisons. Over time, with the regular monitoring and reporting of these indicators, an

evidence base will grow which will permit the setting of pan-Canadian targets and provide the baseline data required to evaluate the impact of new diagnostic technologies such as HPV testing and interventions, for example, the HPV vaccine.

Organized Cervical Cancer Screening in Canada

It was first recognized that cervical cancer screening should be implemented in the context of an organized program in 1973 at the Conference of Deputy Ministers of Health. Since then, pan-Canadian expert groups have reiterated this recommendation and produced reports which define an organized system and its essential components(9-16). Despite expert opinion and recommendations, the implementation of the required components of organized screening varies across Canada.

By 2006, no province or territory had implemented all of the recommended components of an organized cervical cancer screening program(23). Nevertheless, Saskatchewan's program most closely resembles a fully organized program. British Columbia and Nova Scotia have long established partially organized programs. Manitoba has an implementation plan for an organized program and Newfoundland is taking steps towards the establishment of an organized program. A number of the elements required to constitute an organized screening program are present in Ontario. New Brunswick has implemented a pilot project with many of the components of an organized program in half of their provincial health districts in order to facilitate the planning of a provincially funded program. Prince Edward Island lost their program coordinator in 2006

however; still have other elements of an organized program. The Northwest Territories, Yukon, Nunavut and Quebec deliver cervical cancer screening in an opportunistic manner(18).

Table 1 provides details of the progress made toward implementation of the components of an organized screening program for each jurisdiction. Note, not all essential components of an organized program are reflected.

History of Cervical Cancer Screening Program Performance Indicators in Canada

The Screening Performance Indicators Working Group (SPIWG) was formed in 2007 under the guidance of the Steering Committee for the Canadian Cervical Cancer Prevention and Control Network (CCPCN). The SPIWG was tasked to identify core performance indicators for cervical cancer screening programs in Canada to facilitate inter-jurisdictional comparisons. For a more detailed history of cervical cancer screening in Canada and the development of program performance indicators, refer to Appendix C.

Development of Performance Indicators

The core set of performance indicators described within this report were selected by the SPIWG in order to promote high quality screening which ultimately will lead to a reduction in the incidence, morbidity and mortality of cervical cancer while minimizing any associated risks.

In order to achieve these goals, the entire cancer screening pathway, from coverage and uptake to cervical

abnormality diagnosis and treatment, must be performed well. The evaluation of screening programs requires a mix of medical quality and health care system responsiveness indicators in order to monitor and evaluate how the principal components of the screening pathway function. The following criteria served as a guide during the performance indicator selection process(25):

- Data for the measures are available on a regular basis.
- Data for the measures are of high quality.
- Meaningful targets can be established as the evidence base builds.
- Measures and established targets can facilitate inter-jurisdictional comparisons.
- Regular monitoring of the measure is feasible and beneficial.
- Measures are widely accepted for use in program evaluation and cover the spectrum of the organized cancer screening pathway.

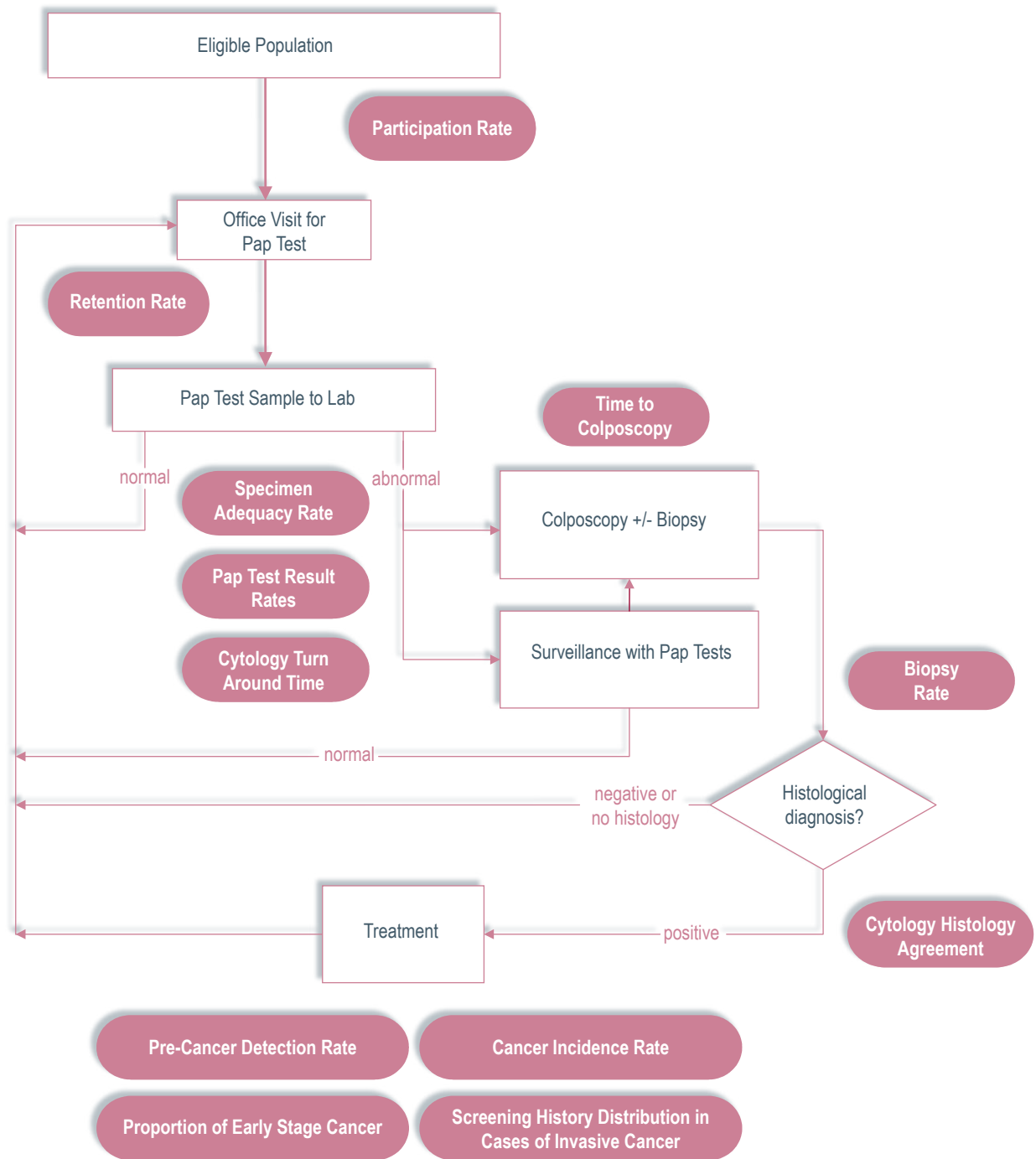
Furthermore, the selected performance indicators would be consistent with the concurrent development of general guidelines on performance measurement for organized cancer screening programs by Canadian Partnership Against Cancer{Screening Performance Measures Group, 2008 944 /id}. Each performance indicator within this report includes: a definition; the rationale for its inclusion; the method of calculation and other measurement details; published estimates for other countries that have screening programs (partially organized and organized). Figure 1 illustrates the cervical screening pathway developed by the CCPCN and the relationship among the selected core performance indicators.

Table 1. Cervical cancer screening programs in Canada as of 2006 (18;23;24)

| | Yukon Territory | Northwest Territories | Nunavut Territory | British Columbia | Alberta | Saskatchewan | Manitoba | Ontario | Quebec | New Brunswick | Nova Scotia | Prince Edward Island | Newfoundland and Labrador |
|-----------------------------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|--------------------|----------------------------------------|---------------------------------------|-------------------------------------------------|----------------|----------------|---------------------------------------|----------------------|---------------------------|
| Type of program | S | S | S | PO | PO | O | PO | PO | S | S | PO | S | PO |
| Year program initiated | - | - | - | 1960 | 2000 | 2003 | 1999 | 2000 | - | - | 1991 | 2001 | 2003 |
| Target age group (years) | 18+ | All women ^a or 18+ | 16-70 | All women ^a up to 69 | 18-69 ^a | 18-69 | 18-69 | 20-69 ^a | - | - | All women ^a or 21-75 | 20-69 | All women ^a |
| Recommended screening interval | Biennial after 3x normal ^b | Biennial after 3x normal ^b | Biennial after 3x normal ^b | Biennial after 3x normal ^b | Annual | Triennial after 2x normal ^b | Biennial after 3x normal ^b | Biennial-triennial after 3x normal ^b | - | - | Biennial after 3x normal ^b | Biennial | Annual |
| Conventional (C), liquid based cytology (LBC) or both (B) | C | LBC | LBC | C | B | C | C | B | C | B | C | C | LBC |
| HPV reflex testing for ASCUS available (Y/N) | N | Y ^c | Y ^c | N | N | N | N | Y | Y ^c | Y ^c | N | N | Y ^c |
| Administration | | | | | | | | | | | | | |
| Tracking of positive screens & appropriate follow-up | | | | ✓ | ✓ | ✓ | ✓ | | | | ✓ | | |
| Recall System to MD's for overdue Pap tests | | | | ✓ | ✓ | ✓ | | | | | ✓ | | ✓ |
| IT systems - Program databases | | | | | | | | | | | | | |
| Population-based for recruitment | | | | | | ✓ | | | | | | | |
| Cytology | | | | ✓ | ✓ | ✓ | ✓ | ✓ | | | ✓ | ✓ | ✓ |
| Histology | | | | ✓ | | ✓ | ✓ | | | | | ✓ | |
| Colposcopy | | | | ✓ | ✓ | ✓ | ✓ | | | | ✓ | | |
| Quality assurance | | | | | | | | | | | | | |
| Evidence based screening guidelines | | | | ✓ | ✓ | ✓ | ✓ | ✓ | | | ✓ | ✓ | ✓ |
| Program report with indicators | | | | ✓ | | | ✓ | ✓ | | | ✓ | ✓ | |
| Training manuals | | | | ✓ | | | ✓ | ✓ | | | ✓ | | ✓ |

S, Spontaneous, O, Organized and PO, Partially Organized; ^aIf ever sexually active; ^bWomen who get screened annually to start and if high-risk, annual screening continued; ^cHPV testing funded by province/territory

Figure 1. Screening Process



Programs are anticipated to compute additional performance indicators not included in this report, such as those necessary to evaluate program-specific operational issues and quality assessment procedures, to enable the continuous improvement of organized screening programs. Furthermore, in the absence of individual-based data, programs may also be required to carry out special studies to provide estimates (e.g., cancer staging distribution, hysterectomy rates). However, it is important to understand that reliance on program specific studies to generate estimates that are needed on a regular basis is inefficient and often delays effective decision-making.

Context of Performance Indicators

Age group of interest for monitoring performance indicators:

The target age group for cervical cancer screening in Canada varies across programs, with most recommending that cervical screening begin shortly after the onset of sexual activity and stop at age 69 (refer to Table 1).

For the performance indicators set out within this report, the age group of interest is 20 to 69 years of age. Human Papillomavirus (HPV) infection (the main aetiological factor in the development of cervical cancer) is very common after sexual debut. However, HPV infection often clears without any signs or symptoms. For those with a persistent infection, the average length of time for a high-risk HPV to develop into a pre-cancerous lesion is 24 months(27) and into invasive cervical cancer 8 to 12 years(28-31). Although an increasing number of females have their first sexual encounter in their

teens, the long transition time from HPV exposure to the development of a pre-cancerous lesion means most cervical abnormalities will not be detectable by Pap tests until women are in their 20's. Thus, the CCPCN recommends that all the performance indicators be reported for women older than 20.

Furthermore, even though the evidence does not define an upper age when Pap test should be stopped, most Canadian screening programs recommend the cessation of screening at age 69. Poor screening attendance in older women, a higher number of Pap tests of inadequate quality, and a decreased risk of developing cervical cancer are among the reasons for defining an upper age limit(32).

It is intended that the performance indicators (and pending pan-Canadian targets) will be applied to the entire age group of interest. However, it may be necessary for programs to compute additional analyses that stratify this group of women in terms of demographic characteristics, screening history, test modality, or HPV immunization status. In addition, it may be required to compute age-standardized results using the appropriate population as a standard when comparing results of programs within and outside of Canada.

Programmatic considerations:

Program performance is influenced by different program elements and these elements may vary between programs in several ways. These include the organization of the program, the target population, service access and provision, reporting thresholds for test results, follow-up and treatment, and screening interval recommendations. Factors external to the program can also affect the screening program performance such as number and availability of health care providers and facilities for diagnostic assessment

and treatment. Therefore, program comparisons must take into consideration how the screening programs have been operationalized in addition to relevant external factors.

Data source and data quality considerations:

Differences in data definitions and data collection systems may need to be taken into consideration. For instance, cervical cancers may be defined and staged differently by the different provincial cancer registries. Furthermore, completeness and accuracy of data may also influence results. As a result, care must be taken to separate program performance differences from measurement variations.

Measurement considerations:

Many of the performance indicators are inter-related and are only meaningful when considered in relation to each other and, in some cases, in relation to other pertinent data. For instance, age-standardized cervical cancer incidence rates should be considered in relation to the age-standardized incidence rate in the general population before the implementation of program-based screening. Furthermore, efforts to improve certain aspects of program performance may involve achieving a balance between particular rates or measures. For example, decreasing the rate of high-grade squamous intraepithelial lesions may increase the cytology-histology agreement, but may decrease the proportion of early-stage cancers that are detected.

PROGRAM PERFORMANCE INDICATORS



Coverage

1) Participation Rate

| | |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Definition | Percentage of eligible women in the target population (20-69 years of age) with at least one Pap test in a three-year period. |
| Rationale | <p>A significant decrease in the incidence of cervical cancer and mortality is expected by ensuring all eligible women have access to a regular Pap test(20;33). Therefore, one of the most important factors in determining the success of a screening program is the participation rate(34). Numerous factors can influence the participation rate in an organized screening program such as acceptability, accessibility, promotion of screening, program capacity, and policies/guidelines regarding the recruitment method, target age group and screening interval.</p> <p>For the performance indicators set out within this report, the age group of interest is 20 to 69 years of age. HPV infection (the main aetiological factor in the development of cervical cancer) is very common after sexual debut, however, it often clears itself without any signs or symptoms. For those with a persistent infection, the average length of time it takes for a high-risk HPV to develop into a pre-cancerous lesion is 24 months(27) and into invasive cervical cancer 8 to 12 years(28-31). Although an increasing number of females have their first sexual encounter in their teens, the long transition time from HPV exposure to the development of a pre-cancerous lesion means most cervical abnormalities will not be detectable by Pap tests until women are in their 20's. Thus, the CCPCN recommends that measurement of all the performance indicators should not begin before age 20. Furthermore, even though the evidence does not define an upper age when Pap tests should be stopped, most Canadian screening programs recommend the cessation of screening at the age of 69. The reasons for this include poor screening attendance in older women, a higher number of Pap tests of inadequate quality, and a decreased risk of developing cervical cancer(32).</p> <p>With respect to the optimal screening interval, it is necessary to achieve a balance between disease control and screening costs(32). A study by the IARC Working Group on Cervical Cancer Screening Programs provided evidence for an international recommendation for a three (or even less) year screening interval(35). In Canada, program screening interval recommendations vary from annual to triennial. Using a triennial screening interval in the measure of participation permits inter-jurisdictional comparisons.</p> |
| Calculation | $\frac{\text{Number of women (age 20-69) with at least one Pap test in a three-year period}}{\text{Number of women in the target population at year two}} \times 100 = \text{Participation Rate}$ |
| Details | <p>Eligible women include those who have never been diagnosed with invasive cervical cancer and have not had a complete hysterectomy. Since these data are often not accessible, the program should report their indicator with a notation stating the data limitations.</p> <p>The denominator should be obtained from the most recent census results and/or forecasts of the target population available from Statistics Canada.</p> <p>This performance measure should be monitored and reported by 10-year age groups (i.e., 20-29, 30-39, 40-49, 50-59 and 60-69) to provide information about age-specific participation. Age should be calculated in year two of the reporting period.</p> <p>Over time, this measure should be reported separately for HPV vaccinated and un-vaccinated women.</p> |
| Status | <p>International participation rates for organized cervical cancer screening programs vary widely for many reasons including differences in target age groups, screening intervals and eligibility criteria (e.g., may include or exclude women with hysterectomy or women who had a Pap test outside the organized program).</p> <p>Participation rates over 80% were reported for Finland(36), New Zealand(32), and Denmark (County of Funen)(37). Participation rates between 70-80% were observed in Iceland(38), Norway(39), U.K.(40), Belgium (Flemish region)(41), and Denmark (Copenhagen)(32). Participation rates between 60-70% were seen in the Netherlands(42), Australia(43), and Chile(44). In Sweden, participation rates ranged between 50–70% for most counties(45) and in Italy, 36.7% of women were screened in 76% of the programs(46).</p> |

Coverage

2) Retention Rate

| | |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Definition | Percentage of eligible women re-screened within three years after a negative Pap test in a 12 month period. |
| Rationale | To optimise the benefits of screening, regular participation in a screening program is essential. The intervals for retention of women with a negative result may vary by jurisdiction. However, a 36-month interval for cervical cancer is appropriate for inter-jurisdictional comparisons. Retention rates appear to be influenced by a number of factors including socio-economic status, perception of risk, access to a health care provider, and availability of a reminder notification system. It is important to note that retention rate is not a measure of appropriate utilization. |
| Calculation | $\frac{\text{Number of women (age 20-69) who have a subsequent Pap test within three years of the index test with a negative result}}{\text{Number of women with a negative Pap test in a 12-month period}} \times 100 = \text{Retention Rate}$ |
| Details | <p>Eligible women include those who have never been diagnosed with invasive cervical cancer, have not had a complete hysterectomy, and reside in the same province as when the index Pap test occurred. Since data on prevalence of invasive cervical cancer and complete hysterectomy are often not accessible, the program should report the indicator with a notation stating data limitations.</p> <p>This is a prospective calculation based on the age at index Pap test. The index Pap test is the last negative test recorded in the 12 month period. This performance measure should be monitored and reported for 10-year age groupings (i.e., 20-29, 30-39, 40-49, 50-59 and 60-69) to provide information about age-specific retention.</p> <p>Individual's eligibility to return for rescreening changes over time. A woman may have had a complete hysterectomy in the 3-year period, may no longer be age eligible, or may have died. The current crude measure of retention does not adjust for these conditions dynamically. Where possible, programs should consider using the Kaplan Meier Survival Data Analysis method to compute the retention rate.</p> <p>Over time, this measure should be reported separately for HPV vaccinated and un-vaccinated women.</p> |
| Status | Published retention rates for international organized cervical cancer screening programs are limited. In Australia, the percentage of women that were re-screened within a 21-month period after a normal Pap test was 26.2%(43). However, this reflects the proportion of women that were re-screened early (recommended two year re-screening interval) versus their retention. |

Cytology Performance Indicators

3) Specimen Adequacy

| | |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Definition | Percentage of Pap tests that are reported as unsatisfactory in a 12 month period. |
| Rationale | Specimen adequacy is an important indicator of program performance in terms of screening effectiveness and efficiency. Pap tests are classified in the laboratory on the basis of their adequacy for interpretation (i.e., “satisfactory”, “satisfactory but limited for interpretation” and “unsatisfactory”). The unsatisfactory rate may be influenced by several factors including specimen collection (individual and device dependent), sample preparation, and observer variation in the interpretation. The Bethesda System is used to classify cytological specimens on the basis of their perceived adequacy for interpretation(47). The “unsatisfactory” category is used when the Pap test has an insufficient number of cells to allow interpretation. Pap tests rejected because of specimens lost or incorrect patient demographics should not be included as unsatisfactory. |
| Calculation | $\frac{\text{Number of Pap tests with an unsatisfactory result}}{\text{Total number of Pap tests}} \times 100 = \text{Specimen Adequacy}$ |
| Details | This performance measure should be monitored and reported by 10-year age groups (i.e., 20-29, 30-39, 40-49, 50-59 and 60-69) to provide information about age-specific specimen adequacy. Age is determined at time of the Pap test (i.e., the date the test was performed and not the sign-out date from the laboratory). |
| Status | The proportion of unsatisfactory Pap tests was 4.7% in England (48), 4.7% in Norway(39), 3.8% in Chile(44), 3.1% in Italy(49), 1.3% in Iceland(38), 1.0% in the Netherlands(42), 0.6% in Belgium (Flemish region)(41), 0.01% in Finland(42) and 1.0% (50th percentile) in the US(50). |

Cytology Performance Indicators

4) Screening test results

| | | | | | | | | |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------------------------------|--------------------|-------|-------------------|-------------------|---------|
| Definition | Percentage of women by their most severe Pap test result in a 12 month period. | | | | | | | |
| Rationale | <p>Pap test results classified using the Bethesda system provide information about the quality of the cell sample and the types of cell changes found. The following Bethesda Pap test result categories should be monitored(47):</p> <ol style="list-style-type: none"> 1. Negative/benign changes 2. Atypical Squamous Cells of Undetermined Significance (ASCUS) 3. Atypical Glandular Cells (AGC) 4. Atypical Squamous Cells – high grade (ASC-H) 5. Low-grade squamous intraepithelial lesion (LSIL) 6. High grade squamous intraepithelial lesion (HSIL) or more severe <p>Pap test result rates may be influenced by several factors including incidence rates of cervical abnormalities in the population, specimen collection (both individual and device dependent), sample preparation, and observer variation in the interpretation.</p> | | | | | | | |
| Calculation | $\frac{\text{Number of women with a negative Pap test result}}{\text{Total number of women with a satisfactory Pap test}} \times 100$ | | = Proportion with negative Pap test result | | | | | |
| | $\frac{\text{Number of women with an ASCUS Pap test result}}{\text{Total number of women with a satisfactory Pap test}} \times 100$ | | = Proportion with ASCUS Pap test result | | | | | |
| | $\frac{\text{Number of women with an AGC Pap test result}}{\text{Total number of women with a satisfactory Pap test}} \times 100$ | | = Proportion with AGC Pap test result | | | | | |
| | $\frac{\text{Number of women with an ASC-H Pap test result}}{\text{Total number of women with a satisfactory Pap test}} \times 100$ | | = Proportion with ASC-H Pap test result | | | | | |
| | $\frac{\text{Number of women with a LSIL Pap test result}}{\text{Total number of women with a satisfactory Pap test}} \times 100$ | | = Proportion with LSIL Pap test result | | | | | |
| | $\frac{\text{Number of women with a HSIL+ Pap test result}}{\text{Total number of women with a satisfactory Pap test}} \times 100$ | | = Proportion with HSIL + Pap test result | | | | | |
| Details | <p>If a woman has multiple Pap tests performed in the 12 month period, the index Pap test is the Pap test with the most severe result as ranked from 1 to 6 in context of the above.</p> <p>This performance measure should be monitored and reported by 10-year age groups (i.e., 20-29, 30-39, 40-49, 50-59 and 60-69) to provide age-specific information on Pap test results. Age is determined at the time of the index Pap test.</p> <p>Over time, this measure should be reported separately for HPV vaccinated and un-vaccinated women.</p> | | | | | | | |
| Status | Published Pap test results from organized cervical cancer screening programs: | | | | | | | |
| | Source | Negative | ASCUS | AGC | ASC-H | LSIL | HSIL+ | ASC/SIL |
| | UK (48) | 96.8% ^a | | | | 1.9% ^b | 1.3% ^c | NR |
| | US(50) | NR | 2.4% | 0.1% | 0.2% | 1.3% | 0.3% | 1.7% |
| | Belgium (Flemish-Brabant) (41) | 97.4% | 1.4% | NR | NR | 0.7% | 0.5% | NR |
| | Norway(39) | 90.37% | 2.41% | 0.08% ^d | | 1.24% | 1.2% ^e | NR |
| | <p>NR, not reported; a, negative and borderline changes combined; b, mild dyskaryosis; c, moderate dyskaryosis, severe dyskaryosis and invasive or glandular neoplasia combined; d, AGUS; e, HSIL, ACIS, SCC and AC combined.</p> | | | | | | | |

System Capacity Indicators

5) Cytology Turn Around Time

| | |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Definition | The average time from the date the specimen is taken to the date the finalized report is issued over a 12 month period. |
| Rationale | Cytology turn around time is not necessarily a quality indicator but rather an indicator of system capacity for reporting of Pap tests. Lengthened turn around times may indicate insufficient personnel or resources devoted to Pap test reporting. |
| Calculation | The number of calendar days from when the specimen is taken to the day the report is finalized, is averaged over a 12 month time period. |
| Details | This calculation should be reported annually. |
| Status | In the US, half of the participating laboratories had mean turnaround times of 6 calendar days or less and were able to complete 90% of their cases within 8 calendar days (51) and in England approximately half were less than 4 weeks (48). |

System Capacity Indicators

6) Time to Colposcopy

| | | |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|
| Definition | Percentage of women with a positive Pap test (HSIL+/ASC-H) who had follow-up colposcopy within 3, 6, 9 and 12 months subsequent to the index Pap test. | |
| Rationale | <p>A Pap test identifies a small group of women who require further testing, most often by colposcopy examination and biopsy, to confirm a cervical abnormality.</p> <p>Time to colposcopy is a measure of system capacity with respect to the follow-up of an abnormal Pap test result. It is also a measure of timely compliance to follow-up, which is necessary to ensure the detection and treatment of cervical abnormalities. An abnormal screen result can induce morbidity because of the negative psychological impact it can have even if follow-up is ultimately negative. Furthermore, excessive delay to diagnosis may worsen prognosis. Work-up should therefore be completed expeditiously.</p> <p>The use of colposcopy to confirm a cervical abnormality may be influenced by several factors including criteria for the management of women based on cytology results, the cost and availability of colposcopy facilities.</p> | |
| Calculation | $\frac{\text{Number of women with colposcopy within n months of index Pap test reported date (with a HSIL+/ASC-H result)}}{\text{Total number of women with HSIL+/ASC-H reported in a 12 month period}} \times 100 =$ <p>Where n = 3, 6, 9 and 12 months</p> | Proportion with a HSIL+/ASC-H Pap test who had a follow-up colposcopy |
| Details | <p>If a woman had multiple Pap tests reported within the 12-month period, the index Pap test is the Pap test with the most severe result (see Pap test result) and the colposcopy date is the index Pap test date plus one week.</p> <p>Colposcopy performed within one week of the Pap test reported date is likely to be arranged based on clinical finding and/or a previous result. Unless the reason for colposcopy can be obtained and linked to the index Pap, colposcopy performed within one week of the Pap test reported date should be excluded.</p> <p>This performance measure should be monitored and reported by 10-year age groups (i.e., 20-29, 30-39, 40-49, 50-59 and 60-69) to provide age-specific information on time to colposcopy. Age is determined at time of index Pap test.</p> | |
| Status | Many programs do not have access to colposcopy data to be able to measure the duration of time from an abnormal test to colposcopy follow-up. However, results from a survey in the West Midlands region in England indicated that 8.6% of women waited more than 3 months for a colposcopy appointment from the date of their cytology result(52). Furthermore, results from a survey in Italy on women invited during 2003 and screened within the first four months of 2004 reported compliance to colposcopy was 84.7% among women referred due to ASCUS+ and 88.2% among those referred because of HSIL+ in 2004(46). | |

Follow-up

7) Biopsy Rate

| | |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Definition | Percentage of women with a positive screening test result (HSIL+/ASC-H) who received a histological diagnosis in a 12 month period. |
| Rationale | A screening test identifies a small group of women who require further testing, most often by colposcopic examination and biopsy, to confirm a cervical abnormality. However, a biopsy to obtain histological diagnosis is not always performed. Reasons may include patient pregnancy, or the inability to identify a suspected area to biopsy under the colposcope. Despite this, a low biopsy rate would indicate poor follow-up. |
| Calculation | $\frac{\text{Number of women with histologic diagnosis within 12 months of the HSIL+/ASC-H cytological finding}}{\text{Number of women with cytological finding of HSIL+/ASC-Hin a 12-month period}} \times 100 = \text{Biopsy rate}$ |
| Details | This performance measure should be monitored and reported by 10-year age groups (i.e., 20-29, 30-39, 40-49, 50-59 and 60-69) to provide age-specific information. |
| Status | To be determined |

Follow-up

8) Cytology-Histology Agreement

| | |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Definition | Proportion of positive Pap tests with histological work-up found to have a pre-cancerous lesion or invasive cervical cancer in a 12 month period. |
| Rationale | <p>The cytology-histology agreement is sometimes referred to as “positive predictive value”, as this measure is an indicator of the predictive validity of a Pap test. The factors that influence positive predictive value such as, the Pap test rate, pre-cancerous lesion detection, and cancer detection rates must be taken into consideration when evaluating the cytology-histology agreement. Specimen sampling may not be representative of the lesion and interpretation is subject to observer variation for cytology and to a lesser extent for histology.</p> <p>Cervical intraepithelial neoplasia (CIN) result reporting terminology is used to categorize histological diagnosis.</p> |
| Calculation | <p>a) $\frac{\text{Number of HSIL+ / ASC-H with histological confirmation of CIN III+}}{\text{Number of HSIL+ / ASC-H with histological work-up}} = \text{HSIL}_{\text{CIN III+}}$</p> <p>b) $\frac{\text{Number of HSIL+ / ASC-H with histological confirmation of CIN II+}}{\text{Number of HSIL+ / ASC-H with histological work-up}} = \text{HSIL}_{\text{CIN III+}}$</p> |
| Details | <p>The histological work-up should be completed within 12 months of the positive cytological finding.</p> <p>Some jurisdictions may have to limit to HSIL/CIN II+ reporting (i.e., calculation b) depending on their reporting standards.</p> <p>This performance measure should be monitored and reported by 10-year age groups (20-29, 30-39, 40-49, 50-59, 60-69) to provide age-specific information on the predictive validity of the Pap test.</p> <p>Over time, this measure should be reported separately for those HPV vaccinated and un-vaccinated women.</p> |
| Status | In Finland, the positive predictive value for a histologically confirmed finding following a positive Pap test was reported to be 49% for CIN I+ (488 CIN I+ lesions out of 999 women with Papanicolaou group III, IV or V) in 1996(53). In England, it was 78% for CIN II+ (29, 809 CIN II+ lesions out of 38,253 women) and 54.8% for CIN III+ (20,946 CIN III+ lesions out of 38,253 women) between 2005 and 2006(48). |

Outcome Indicators

9) Pre-Cancer Detection Rate

| | |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Definition | Number of pre-cancerous lesions detected per 1,000 women who had a Pap test in a 12 month period. |
| Rationale | This measure is an indicator of the prevalence of pre-cancer cervical abnormality in the population receiving Pap tests. Factors that could influence this measure include changes in screening tests, guidelines, target population, coverage, etc. This measure is also important to monitor over time as the uptake of HPV vaccine increases. However, HPV vaccine program implementation will likely prompt changes to the screening policy and/or screening test. Thus, this measure will need to be considered among others, as a decrease in the pre-cancer detection rate could be a sign of a successful vaccine program, or less effective screening test and/or screening policy. |
| Calculation | $\frac{\text{Number of women with histology CIN II and CIN III}}{\text{Number of women who had at least one Pap test}} \times 1,000 = \text{Pre-cancer detection rate}$ |
| Details | <p>This performance measure should be monitored and reported by 10-year age groups (i.e., 20-29, 30-39, 40-49, 50-59 and 60-69) to provide age-specific information on the pre-cancer detection rate.</p> <p>Over time, this measure should be reported separately for HPV vaccinated and un-vaccinated women.</p> |
| Status | The published pre-cancer detection rate from organized cervical cancer screening programs in Italy, where the unadjusted detection rate of histologically confirmed CIN II+ lesions in 2004, was 2.7 per 1,000 screened women (3.0 per 1,000, age-standardized on the Italian population, 25-64 years old)(46). In Australia, the unadjusted detection rate of histologically confirmed high grade abnormality was 7.6 per 1,000 women screened in 2004 (7.4 per 1,000, age-standardized, 20-69 years old)(43). |

Outcome Indicators

10) Cancer Incidence

| | |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Definition | <p>Age-standardized incidence rate (per 1,000 women) of invasive squamous carcinoma of the cervix per year.</p> <p>Age-standardized incidence rate (per 1,000 women) of adenocarcinoma (+adeno/squamous cancer) per year.</p> |
| Rationale | <p>As organized screening programs become more established, the age standardized incidence rates for invasive squamous carcinoma and adenocarcinoma of the cervix are expected to decrease. Incidence rates may be influenced by differences in hysterectomy rates and there may be some under reporting of cervical cancers that are identified as uterus, not otherwise specified(24).</p> |
| Calculation | $[\text{Sum age groups (Mar x Pas)}] / \text{Ps} \times 1000 = \text{Cancer Incidence (SDR1)}$ <p>Mar is the age-specific incidence rate for a given population</p> <p>Pas is the number of people in the age group in the standard population</p> <p>Ps is the total standard population.</p> |
| Details | <p>Age-standardized incidence rates are calculated by the National Cancer Institute of Canada, using the 1991 age distribution of the national population(1). These are computed directly from the age-specific projections. Incidence rates are estimated using weighted least squares regression.</p> <p>The following data will need to be collected by the program in order to carry out this calculation:</p> <ul style="list-style-type: none"> - Number of new cervical cancer cases in a given year - Age at diagnosis <p>Over time, this measure should be reported separately for HPV vaccinated and un-vaccinated women.</p> |
| Status | <p>Published age-standardized cancer incidence estimates from organized cervical cancer screening programs include: Iceland (squamous carcinoma: 10.6/100,000, adenocarcinoma: 3.6/100,000 and adenosquamous: 1.2/100,000 in 1992-2002)(54); Sweden (squamous carcinoma: 7.6/100,000 and adenocarcinoma 2.0/100,000 in 1989-1993)(45); Norway (squamous carcinoma:13.6/100,000 and adenocarcinoma approximately 3/100,000 in 1999-2000)(39); and Australia (squamous carcinoma: 6.2/100,000, adenocarcinoma: 1.9/100,000 and adenosquamous: 0.3/100,000 in 2002)(43).</p> |

Outcome Indicators

11) Disease Extent at Diagnosis: Cancer Stage

| | | | | | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|--------|------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|--------|-----------------------------------------|
| Definition | <p>Percentage of invasive squamous carcinoma of the cervix ≤stage I in a 12 month period.</p> <p>Percentage of adenocarcinoma (+adeno/squamous) ≤stage I in a 12 month period.</p> | | | | | | |
| Rationale | <p>Cancer stage is one of the best known prognostic indicators. Staging is based on the International Federation of Gynecology and Obstetrics (FIGO) Staging Classification System with stage I carcinoma being strictly confined to the organ of origin (i.e., cervix). FIGO staging is based on clinical data (i.e., clinical examination and colposcopy)(55).</p> <p>FIGO staging(55):</p> <ul style="list-style-type: none"> - Stage I - Carcinoma strictly confined to the cervix (extension to the corpus should be disregarded) - Stage IA - Invasive cancer identified only microscopically. All gross lesions even with superficial invasion are Stage IB cancers. Invasion is limited to measured stromal invasion with maximum depth of 5.0 mm and no wider than 7.0 mm - Stage IA1 - Measured invasion of stroma no greater than 3.0 mm in depth and no wider than 7.0 mm - Stage IA2 - Measured invasion of stroma greater than 3 mm and no greater than 5 mm and no wider than 7 mm - Stage IB - Lesions of greater dimensions than Stage IA2 whether seen clinically or not - Stage IB1 - lesions no greater than 4 cm in size - Stage IB2 - lesions > 4 cm in size | | | | | | |
| Calculation | <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; border-bottom: 1px solid black;"> $\frac{\text{Number of invasive squamous-cell cancers } \leq \text{ stage I}}{\text{Number of invasive squamous-cell cancers}}$ </td> <td style="text-align: center; vertical-align: middle;">x100 =</td> <td style="vertical-align: middle;">Percentage of invasive squamous carcinoma (≤stage I)</td> </tr> <tr> <td style="text-align: center; border-bottom: 1px solid black;"> $\frac{\text{Number of adenocarcinoma (+adeno/squamous) cancers } \leq \text{ stage I}}{\text{Number of adenocarcinoma (+adeno/squamous) cancers}}$ </td> <td style="text-align: center; vertical-align: middle;">x100 =</td> <td style="vertical-align: middle;">Percentage of adenocarcinoma (≤stage I)</td> </tr> </table> | $\frac{\text{Number of invasive squamous-cell cancers } \leq \text{ stage I}}{\text{Number of invasive squamous-cell cancers}}$ | x100 = | Percentage of invasive squamous carcinoma (≤stage I) | $\frac{\text{Number of adenocarcinoma (+adeno/squamous) cancers } \leq \text{ stage I}}{\text{Number of adenocarcinoma (+adeno/squamous) cancers}}$ | x100 = | Percentage of adenocarcinoma (≤stage I) |
| $\frac{\text{Number of invasive squamous-cell cancers } \leq \text{ stage I}}{\text{Number of invasive squamous-cell cancers}}$ | x100 = | Percentage of invasive squamous carcinoma (≤stage I) | | | | | |
| $\frac{\text{Number of adenocarcinoma (+adeno/squamous) cancers } \leq \text{ stage I}}{\text{Number of adenocarcinoma (+adeno/squamous) cancers}}$ | x100 = | Percentage of adenocarcinoma (≤stage I) | | | | | |
| Details | <p>Provinces with small numbers of cancers may also want to calculate this over several years.</p> <p>This performance measure should be monitored and reported by 10-year age groups (i.e., 20-29, 30-39, 40-49, 50-59 and 60-69) to provide age-specific information on disease extent at diagnosis.</p> <p>Over time, this measure should be reported separately for those HPV vaccinated and un-vaccinated women.</p> | | | | | | |
| Status | <p>Published estimates regarding cancer stage are limited; however, results from a Chilean national survey reported the proportion of women with stage I cervical cancer progressively increased from 30.4% in 1990 to 39.0% in 1996(44).</p> | | | | | | |

Outcome Indicators

12) Screening History in Cases of Invasive Cancer

| | | | | | | | | | | | | | | | | | |
|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|--------|---------------------------------------------------------------------------------------|------------------------------------------------|--|--|--|-----------------------------------------------------------------------------|--|--------|--------------------------------------------------------------------------------------------|------------------------------------------------|--|--|--|
| Definition | <p>Percentage of women diagnosed with invasive squamous carcinoma of the cervix by time since previous Pap test in a 12 month period.</p> <p>Percentage of women diagnosed with adenocarcinoma (+adeno/squamous) by time since previous Pap test in a 12 month period.</p> | | | | | | | | | | | | | | | | |
| Rationale | <p>The screening history of women who are diagnosed with invasive cervical cancer offers insights into program effectiveness. Cases are categorized by their screening history as “active” (0.5 to 3 years), “under screened” (> 3 to 5 years), and “inactive” (> 5 years or no history with the program).</p> <p>Cervical cancer incidence rate is affected by many factors including screening uptake in the population, sensitivity of the screening program, sensitivity of tests to identify pre-cancerous lesions, effectiveness of treatment for pre-cancerous lesions, and other patient-based factors.</p> | | | | | | | | | | | | | | | | |
| Calculation | <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%; border-bottom: 1px solid black; text-align: center;"> Number diagnosed with squamous carcinoma within T years since previous Pap test </td> <td style="width: 10%;"></td> <td style="width: 10%; text-align: center;">x100 =</td> <td style="width: 20%; text-align: right;">Percentage diagnosed with invasive squamous carcinoma by time since previous Pap test</td> </tr> <tr> <td style="border-bottom: 1px solid black; text-align: center;"> Total number diagnosed with squamous carcinoma </td> <td></td> <td></td> <td></td> </tr> <tr> <td style="border-bottom: 1px solid black; text-align: center;"> Number diagnosed with adenocarcinoma within T years since previous Pap test </td> <td></td> <td style="text-align: center;">x100 =</td> <td style="text-align: right;">Percentage diagnosed with adenocarcinoma (+adeno/squamous) by time since previous Pap test</td> </tr> <tr> <td style="border-bottom: 1px solid black; text-align: center;"> Total number diagnosed with squamous carcinoma </td> <td></td> <td></td> <td></td> </tr> </table> <p>Where T = 0.5 to 3 years, 3 to 5 years, or > 5 years/no history</p> | Number diagnosed with squamous carcinoma within T years since previous Pap test | | x100 = | Percentage diagnosed with invasive squamous carcinoma by time since previous Pap test | Total number diagnosed with squamous carcinoma | | | | Number diagnosed with adenocarcinoma within T years since previous Pap test | | x100 = | Percentage diagnosed with adenocarcinoma (+adeno/squamous) by time since previous Pap test | Total number diagnosed with squamous carcinoma | | | |
| Number diagnosed with squamous carcinoma within T years since previous Pap test | | x100 = | Percentage diagnosed with invasive squamous carcinoma by time since previous Pap test | | | | | | | | | | | | | | |
| Total number diagnosed with squamous carcinoma | | | | | | | | | | | | | | | | | |
| Number diagnosed with adenocarcinoma within T years since previous Pap test | | x100 = | Percentage diagnosed with adenocarcinoma (+adeno/squamous) by time since previous Pap test | | | | | | | | | | | | | | |
| Total number diagnosed with squamous carcinoma | | | | | | | | | | | | | | | | | |
| Details | <p>Provinces with small numbers of cancers will need to calculate this indicator over several years.</p> <p>It may not be possible for programs to identify Pap tests that are done for diagnostic purposes, therefore a buffer period of 6 months is used to exclude Pap tests that are less likely to be done for screening purposes. Further work may be required to identify a more appropriate buffer period.</p> <p>This performance measure should be monitored and reported by 10-year age groups (i.e., 20-29, 30-39, 40-49, 50-59 and 60-69) to provide age-specific information on screening history in cases of invasive cancer.</p> <p>Over time, this measure should be reported separately for those HPV vaccinated and un-vaccinated women.</p> | | | | | | | | | | | | | | | | |
| Status | <p>Results from a nationwide audit of the effectiveness of the organized cervical cancer screening program in Sweden defined an evaluable screening history as the availability of all smears and cervical histopathology specimens during the 6-year period that started 6.5 years before and ended 6 months before the date of cervical cancer diagnosis for case subjects or the corresponding date for the control subjects. Odds ratios and their 95% confidence intervals of cervical cancer according to screening history were presented (56). In the Netherlands, the screening history of women with cervical cancer from 1994 to 1997 that was invited for mass screening from 1994 to 1997 demonstrated that 14% were diagnosed at the time of the first invitation (i.e., around the time they were eligible for screening), 7% had a screening interval longer than 6 years and 19% had a screening interval less than 6 years whereas 55% had no previous smear(57). In the Netherlands, 58% of women with CIN 2/3, 48% with ICC stage I, and among 13% of women with stage II-IV were found to have an adequate screening history, i.e., having a normal Pap smear within the last four years of the screening period(58).</p> | | | | | | | | | | | | | | | | |

FUTURE DIRECTIONS



With the recent advances in cervical cancer screening involving a shift from the detection of cytologic abnormalities using the Pap test, to the detection and prevention of the HPV virus through testing (59;60) and vaccination(61), the establishment of a core set of program performance indicators in Canada has never been more important. The consideration of HPV testing as a primary screening test, and the implementation of HPV vaccine programs, will require pan-Canadian experts to convene to develop new cervical screening policy and management guidelines. The SPIWG urges that the identification of performance indicators be included within the development of screening policy and management guidelines. This emphasizes the integral role of performance monitoring and evaluation in policy implementation.

Many factors were weighed in the selection of the included performance indicators with priority given to those that would provide the best possible estimate of a reduction in morbidity resulting from cervical cancer screening. Other important considerations included data quality, timeliness, and meaningful targets. The uptake of these standardized indicators by programs within the provinces and territories will provide the surveillance information required for the following:

- Development, enhancement, and evaluation of provincial/territorial cervical cancer screening programs;
- Collective, periodic reporting in the form of a surveillance report and/or via the web;
- Inter-jurisdictional comparisons;
- Disclosure of areas requiring further development with regards to cervical cancer screening interventions and policies; and
- Development of a cervical cancer screening program evidence base which will assist in the setting of pan-Canadian targets and the assessment of new diagnostic tests (e.g., HPV testing) and interventions (e.g., HPV vaccine).

In order to compile the relevant surveillance information, access to multiple data sources is necessary. Furthermore, information systems specially designed to compile and automate the surveillance information are required(62). The SPIWG recognizes that some programs will need to establish access to the appropriate provincial/territorial data sources and develop information systems for managing these data.

It is challenging to define quantifiable performance indicators over the entire spectrum of activity of organized screening programs, especially for those activities

that have not been adopted as the standard of practice across Canada, such as HPV testing and the HPV vaccine. Future performance indicators should include areas such as:

- Professional education initiatives;
- Public education initiatives;
- Letters of invitation;
- Recruitment initiatives;
- Program efficiency (e.g., number of screening tests done before or after target age, or outside the recommended interval);
- HPV testing with cervical cytology (e.g., percentage of women with ASCUS who had a subsequent HPV test); and
- HPV immunization rates; among others.

The implementation of HPV immunization programs will have a significant impact on cervical cancer in Canada. An example of the impact that a successful HPV immunization program may have includes a decrease in pre-cancer detection rates, although these rates can also be influenced by changes in screening tests, guidelines, target population or coverage.

To detect changes in cervical cancer screening attributable to HPV vaccine programs, the SPIWG recommends that all core performance indicators (excluding Specimen Adequacy, Cytology Turn-Around Time and Time to Colposcopy) be monitored by 10-year age groups to detect early changes and eventually by various HPV vaccination parameters (e.g., type of vaccine, fully/partially/not vaccinated, time since vaccination). In the future, it is likely that the screening policy for vaccinated women will have to be adjusted, as the cohorts of vaccinated girls arrive

at the age of screening (i.e., older age to start, longer interval) and performance indicators will have to be modified accordingly.

Within the field of organized cervical cancer screening, the body of literature is continually evolving as are the technologies and methods used to screen, diagnose and treat cervical cancer. As a result, the evidence to support the use of the performance indicators within this report is subject to change and the indicators will need to be reviewed, evaluated, and updated periodically.

APPENDICES



Appendix A: *CCPCN Performance Indicators Working Group Members (SPIWG)*

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Appendix B: *Components of an organized screening program*

An organized screening program, as defined by an expert group of the International Union Against Cancer (UICC), has several essential elements including(19;34):

- A defined and identifiable target population;
- Strategies to ensure high coverage, such as personal invitations with times and places for screening;
- Adequate clinical facilities for taking Pap tests and laboratory services to examine them;
- Quality control programs for taking and interpreting Pap tests;
- Adequate clinical facilities for diagnosis, treatment and follow-up of women with a detected abnormality;
- An established referral system to help facilitate women through the screening process i.e., a link between the patient, laboratory and clinical facility for providing information about normal Pap test, diagnosis of an abnormal test and/or treatment of any detected abnormality;
- Organized evaluation and monitoring of the impact of the program with established data quality control programs.

Appendix C: *History of Cervical Cancer Screening and the Development of Program Performance Indicators in Canada*

The history of cervical cancer screening in Canada dates back to 1949 with the introduction of Pap test, and in 1960, the first provincial program was introduced in British Columbia. However, the need for organized screening programs was not recognized at a federal level until the Deputy Ministers of Health Conference in 1973. Three years later, a Task Force published the Walton Report which recommended support for the development of organized cervical cancer screening including appropriate information systems, recruitment and recall strategies, and quality assurance measures(9). However, results of a survey in 1980 demonstrated that the provinces had not implemented the recommendations of the Task Force(63). In response to this, the Task Force reconvened in 1980 and made recommendations regarding screening frequency, laboratory quality control and follow-up mechanisms. Also, the Task Force concluded that improving the quality and sensitivity of screening, recruiting women who have never been screened and the establishment of government-sponsored registries would likely be more effective in reducing cervical cancer incidence and mortality than attempts to increase the frequency of screening(10).

A National Workshop on Screening for Cancer of the Cervix held in 1989 brought to light the fact that cervical

cancer screening programs in Canada were not meeting their potential. Several recommendations were made at this workshop including: the age at which screening should be initiated, the recommended screening interval, the management of abnormalities, the need for informational systems, and the training and quality control requirements for both programs and laboratories(11). A meeting of Deputy Ministers of Health in 1990 accepted these recommendations and requested regular updates.

The Society of Obstetricians and Gynecologists of Canada, the Gynecologic Oncologists of Canada and the Society of Canadian Colposcopists also supported the development of formal screening programs and recommended that until adequate patient information systems and high-quality laboratory services are in place, sexually active women should continue to be screened annually(64).

In 1995, Health Canada sponsored a workshop (Interchange '95) in order to review the progress made, identify barriers and determine if previous recommendations were still relevant. Three specific components of cervical screening programs were identified as essential: information systems, quality management and recruitment. Furthermore, participants at Interchange '95 requested the involvement of the federal government to assist with the exchange of information between the provinces and territories, and to provide some direction in the area of standards and quality of care. As a result, the Cervical Cancer Prevention Network (CCPN) was formed(12;14).

Since the establishment of the CCPN in 1995, many meetings have been held to encourage collaborations and exchange of information to help implement or enhance organized cervical cancer

screening programs in the provinces and territories, including the Pan-Canadian Forum on Cervical Cancer Prevention and Control which took place in 2003. The objective of this meeting was to develop evidence based consensus recommendations on the delivery of cervical cancer screening, HPV education, HPV testing, and the optimal tool for cervical cytology within the Canadian health care system. The forum highlighted the ways in which the cervical cancer prevention landscape was rapidly changing with the introduction of liquid based cytology, and the likelihood of HPV vaccines being commercialized. It was recognized that public education and comprehensive screening programs would need to evolve in order to encompass these developments(15).

In 2004, the CCPN broadened its scope to include elements of vaccinology and sexually transmitted infection control, and became the Cervical Cancer Prevention and Control Network (CCPCN). Currently the CCPCN is lead by a Steering Committee, which is made up of representatives from provincial and territorial screening programs, infectious disease departments, medical professional associations, Public Health Agency of Canada and the Canadian Strategy for Cancer Control. In addition, there are three Working Groups of the CCPCN that are working on the development of communication strategies, HPV education and program performance indicators.

A planning workshop to develop common program performance indicators for cervical cancer screening was sponsored by Health Canada in 2000(65). Two years later, Health Canada published the first pan-Canadian surveillance report on the status of cervical cancer screening

in Canada in 1998. This report includes information on key areas of program performance including participation in cervical cancer screening, specimen adequacy, cytology results, and incidence and mortality of cervical cancer and serves as the basis for regular reporting on cervical cancer screening activities in Canada (24). In 2007, the Screening Performance Indicators Working Group (SPIWG) was formed under the guidance of the Steering Committee for the CCPCN. The SPIWG was tasked to identify core performance indicators for cervical cancer screening programs in Canada to facilitate regular comparisons at the inter-jurisdictional level.

Appendix D: Glossary of Terms

Adenocarcinoma

A malignant neoplasm (or tumor) of epithelial cells with a glandular or glandlike pattern.

Age standardization

The adjustment of a quantity to reflect the age structure of a reference population, allowing meaningful comparisons over time and between geographic areas.

Atypical glandular cells (AGC)

Abnormal glandular cells that line the cervical canal. The morphological changes are too pronounced for an inflammatory/reactive origin but insufficient to diagnose an adenocarcinoma.

Atypical squamous cells - high grade (ASC-H)

Abnormal squamous cells with potentially high grade changes. These cytologic changes are suggestive of HSIL, however lack the criteria required for a definitive interpretation.

Atypical squamous cells of undetermined significance (ASCUS)

Abnormal squamous cells of uncertain significance. These cytologic changes are suggestive of a squamous intraepithelial lesion but are quantitatively/qualitatively insufficient for a definitive interpretation; however, they differ from cytological changes that are within normal limits.

Bethesda System

A classification system developed at the National Cancer Institute in 1988 for cervical and vaginal cell specimens (Pap tests) used in cytopathologic diagnosis.

Carcinoma in situ

An early form of carcinoma defined by the absence of invasion of surrounding tissues.

Cervical intraepithelial neoplasia (CIN)

Dysplastic changes beginning at the squamocolumnar junction in the cervix that may be precursors of squamous cell carcinoma: CIN I (grade 1), mild dysplasia involving the lower one third or less of the epithelial thickness; CIN II (grade 2), moderate dysplasia with one third to two thirds involvement; CIN III (grade 3), severe dysplasia or carcinoma in situ, with two thirds to full-thickness involvement.

Colposcopy

A microscopic examination of the cervix via an endoscope performed to diagnose cervical abnormalities.

Cytology

Diagnostic procedure based on the study of cells using a microscope, e.g., Pap test.

Cytology - Histology Agreement

Also referred as the Positive Predictive Value. This measure is an indicator of the predictive validity of a Pap test. The factors that influence the positive Pap test rate, pre cancerous lesion detection, and cancer detection rates must be taken into consideration when evaluating the cytology-histology agreement.

Diagnosis

The determination of the nature of a case of disease. Cervical cancer is diagnosed on the basis of a histological specimen and not cytology (Pap test) which is only a screening tool.

Dysplasia

Morphological changes in the cells of the squamous epithelium of the cervix, giving them the characteristics of malignancy but without the involvement of the full thickness of the epithelium by basal type neoplastic cells.

Follow-up

Any diagnostic test or procedure that is recommended following an abnormal screening result. Since timely action may be important (particularly for severe abnormalities), the duration of time between an abnormal result and follow-up action will be considered an integral part of the follow-up.

High grade squamous intraepithelial lesion (HSIL)

A category combining moderate (CIN II) and severe dysplasia (CIN III).

Human Papillomavirus (HPV)

HPV is the common name for a group of related viruses, some of which occur on the cervix and are risk factors for cervical cancer.

HPV vaccine

A vaccine that targets certain sexually transmitted strains of human papillomavirus associated with the development of cervical cancer and genital warts.

Index Pap test

The index Pap test referred to within each performance indicator description is the Pap test that triggers the activity. When measuring time intervals between the index Pap test and other activities, it is defined according to the date the test was signed out of the laboratory (not the date the test was performed or received in the laboratory, nor the date the test result was received by the health care provider).

International Federation of Gynecology and Obstetrics (FIGO)

FIGO is the only worldwide organization that groups obstetricians and gynecologists. The mission of FIGO is to promote the well-being of women and to raise the standard of practice in obstetrics and gynecology.

Invasive cancer

Cancer that has spread beyond the layer of tissue where it first developed to involve adjacent tissues, also referred to as infiltrating cancer.

Liquid-based cytology (LBC)

A new variation of conventional cytology.

Low grade squamous intraepithelial lesion (LSIL)

A category combining mild dysplasia (CIN I) and cytologic atypia consistent with HPV infection.

Micoinvasive squamous cell carcinoma (MICA)

The earliest form of invasive squamous cell carcinoma detectable in patients with CIN. In MICA, one or more tongues of carcinoma extend down from the dysplastic epithelium and break through the basement membrane to invade the underlying stroma. There is no general agreement as to what exactly constitutes MICA.

Negative result

No abnormal cells are noted.

Opportunistic screening

Also referred to as spontaneous screening, refers to screening that is not scheduled as part of program guidelines intervals.

Pap Test

A screening test involving a microscopic examination of cells scraped from the cervix to detect pre-cancerous or cancerous conditions. Histological confirmation of the presence or absence of disease is required.

Positive predictive value

Also referred to as the Cytology - Histology Agreement.

Retention

Subsequent screening of a person, according to policy, after initial screening of that person under the program. This includes any person who has missed a scheduled round of screening.

Screen

Delivery of the Pap test for the purpose of identifying changes in cells before they turn into cancer.

Target population

This includes all women residing in Canada who meet specific criteria for cervical cancer screening program eligibility, including age, residence, and any other criteria that may be relevant to the cancer. The target population should not include women who have had a complete hysterectomy.

Unsatisfactory Pap test

The Pap test is not readable, i.e., an insufficient number of cells to allow interpretation.

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