CANADIAN PARTNERSHIP AGAINST CANCER
PARTENARIAT CANADIEN CONTRE LE CANCER

Screening Action Group

A Pan-Canadian Forum on Cervical Cancer Prevention and Control in the HPV Vaccine Era

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Key Messages

- Human Papilloma Virus (HPV) affects approximately 550,000 Canadian women annually and is the most common sexually transmitted infection in adults.
- The association between HPV and cervical cancer has been known for at least 2 decades.
- Mortality rates of cervical cancer have decreased 60% largely due to cervical cancer screening using the Papanicolaou (Pap) test. Opportunistic screening, low screening compliance, inconsistent specimen reporting and lack of a standardized reporting system for reporting cytology outcomes impedes optimal prevention and early detection.
- The HPV vaccine provides a novel opportunity for cervical cancer primary prevention through immunization.
- Integration of HPV immunization and cervical cancer screening is optimal to decrease cervical cancer incidence and to improve health outcomes as advanced screening technologies evolve.
- System preparedness for the integration of HPV vaccination and cervical cancer screening provides the opportunity for enhanced prevention and early detection of cervical cancer.
- Improved high risk HPV screening methods will increase screening intervals and automation, with Pap test cytology reserved for triage of HPV- positive women. This approach will contain costs and improve prevention and understanding of HPV.
- Cervical cancer screening programs do not consistently use an organized approach. Information systems are incomplete, limiting evaluation of HPV immunization programs and the impact on detection of cervical cancer and precancerous lesions.
- The HPV program consumes substantial resources and requires program evaluation.
- Key recommendations for moving forward include:
    - Furthering existing guidelines and clearly articulating national goals for a HPV vaccination program;
    - Articulating HPV vaccine uptake challenges and opportunities;
    - Changing the attitudes and beliefs of the public towards HPV vaccines;
    - Engaging in economic analyses of organized versus opportunistic HPV screening;
    - Furthering existing guidelines for acceptable HPV cervical screening;
    - Tracking the incidence, prevalence and distribution of HPV genotypes;
    - Ongoing monitoring and evaluation of programs and their integration;
    - Establishing a champion at key organizations to stimulate new opportunities;
    - Establishing national leadership to develop and evaluate strategies.

Executive Summary

Human Papilloma Virus (HPV) affects approximately 550,000 Canadian women annually and is the most common sexually transmitted infection in adults. There are approximately 100 known types of HPV; at least 15 are considered carcinogenic and 3 others possibly carcinogenic. The highest occurrence of HPV is in women less than 25 years, although some studies support a second peak at 45 years or greater.

The association between HPV and cervical cancer has been known for at least 2 decades. Mortality rates from cervical cancer have dropped approximately 60% in the past 30 years; largely due to cervical cancer screening using the Papanicolaou (Pap) test/ smear. Cervical cancer is almost completely preventable. However, opportunistic screening, low screening compliance in high risk populations (e.g. adolescents, Aboriginal women, women of low socio economic status), inconsistent specimen reporting and non standardized reporting of cytology outcomes impede optimal prevention and early detection. Optimizing screening to reach the 30% of women who are seldom or never screened is crucial.

We are now in a new age of primary prevention of cervical cancer with vaccine availability, through HPV immunization. The HPV vaccine provides effective immunization when administered to young women prior to sexual activity. It has minimal side effects but may require a booster for protection beyond 5 years. HPV immunization does not protect against women already exposed to the high risk HPV types nor against other types of HPV; but it may decrease current incidence rates in the long term.

The HPV program is consuming substantial public resources and requires program evaluation. Engaging in economic analyses and modeling of organized versus opportunistic screening can provide a systematic and evidence-based framework for assessing vaccination and screening strategies and their effectiveness in preventing cervical cancer. Models can sharpen thinking about assumptions and provide credible projections of future health and cost outcomes under various vaccination and screening strategies and scenarios.

Integrating these two pivotal prevention strategies has the potential to significantly decrease a universal threat to women's health. System preparedness for the integration of HPV vaccination and cervical cancer screening provides the opportunity for enhanced prevention and early detection of cervical cancer. Establishing comprehensive and integrated cancer information systems to optimize benefits of screening and vaccination (e.g. recruitment, recall, follow-up and program evaluation) is essential.

Maximizing population health and economic benefits via organized systematic reviews on screening and immunization, and monitoring screening outcomes, as cancer end-points, may be too distant. There is a need to customize screening algorithms to accommodate the ongoing monitoring of both immunized and non-immunized young women.

Over the past 10 years, health professionals, researchers, epidemiologists, economists and other decision-makers have generated recommendations in 4 areas that are pivotal in the prevention and outcomes related cervical cancer including:

- Cervical screening and status of guidelines, standards and updates for the future;
- Primary prevention with HPV vaccine and key surveillance and monitoring issues;
- Integration of immunization and screening in the health care system (system preparedness); and
- Program evaluation and moving research priorities forward in Canada.

In this Pan Canadian Forum, key note presenters informed four discussion groups to further articulate recommendations in these areas.

Cervical Cancer Screening Group

The top 3 priorities were to:

1. Further existing guidelines for acceptable cervical screening addressing

    - Screening tests and intervals,
    - Determining the appropriate age to commence cervical screening,
    - Management of abnormal tests,
    - Management of disease, treatment and follow-up;

2. Engage in economic modeling and analyses of organized versus opportunistic screening; and

3. Developing a balanced scorecard to be published nationally to encourage program development and support.

Other recommendations including (a) strengthening links to primary care services, (b) establishing key program components (e.g. recruitment, results, recall), (c) minimizing unnecessary screening, (d) creating a repository and mechanism for sharing standards and guidelines across Canada and (e) developing performance indicators for laboratories were considered important but of a less urgent nature at this time.

Primary Prevention with HPV Vaccine Group

Key recommendations included:

1. Tracking the incidence, prevalence and distribution of HPV genotypes associated with cervical, anogenital and oral precancerous and cancerous lesions through:
   - Developing and linking of data bases and registries (e.g. cancer, cervical screening, HPV genotype and vaccine);
   - Sentinel surveillance sites (involving active surveillance for specific circumstances for particular jurisdictions); and
2. Articulating vaccine uptake challenges and opportunities elucidating explanations for why some geographic areas have either higher or lower vaccine uptake. Targeting professional education and training, knowledge dissemination and education for parents and teenagers were considered potential opportunities.

Integration of Screening and Immunization Group

The top 3 priority recommendations included:

1. Establishing national leadership around development of strategies to integrate screening/ immunization formation systems;
2. Supporting the national leadership in developing strategies for integrating screening and immunization into STI information systems;
3. Assisting the national leadership in integrating key messaging to promote immunization and screening.

Program Evaluation/ Research Priorities Group

The top 3 priority recommendations included:

1. Recognizing that evaluation (ongoing monitoring) and research (more finite) are not the same; there are specific and generic needs for both;
2. Identifying a champion at key organizations such as the Canadian Institutes for Health Research to stimulate new opportunities. HPV and cervical cancer issues have not been a high priority and the new HPV vaccine experience can be used as a catalyst for intervention; and
3. Integrating a top down approach to solidify strategic direction and a bottom-up format for those in the field to be able to influence those at the top.

There is a window of opportunity NOW with the introduction of the HPV vaccine. If this window is missed, we may not be able to retrieve the opportunity again – therefore, it is important to move to action immediately.

Objectives

A Pan-Canadian Forum on Cervical Cancer Prevention and Control in the HPV Vaccine Era, sponsored by the Canadian Partnership Against Cancer, was held in Toronto on October 29-30, 2008. This forum was attended by health professional, researcher and administrative stakeholders (See Appendix for Participant List). The program included key note presentations by leading national and international experts and break out small group discussion sessions. Recommendations and timelines were articulated.

The objectives were: (a) to enhance integration of Cervical Cancer Screening and Immunization with the HPV vaccine, (b) to strengthen/ evaluate prevention programs, (c) to articulate research priorities and (d) to improve health outcomes for women.

More specifically defined objectives were to:

1. Comprehensively review existing key reports and initiatives from the national and international experience, guidelines, systematic reviews and consensus documents in 4 key areas including;

    - Cervical Cancer Screening,
    - Immunization with the HPV vaccine,
    - Integration of Screening and Immunization, and
    - Program evaluation/ research priorities

2. Summarize discussion within the key areas highlighting areas of consensus;

3. Prioritize recommendations within the key areas;

4. Articulate program evaluation/ research priorities within the key areas; and

5. Delineate time lines and next steps for 2009-2010.

In summary, this Pan-Canadian forum provided an opportunity "to reconvene and have a new conversation involving multiple experts to develop an integrated plan for cervical cancer prevention and control" (Bryant, 2008).

Introduction

Prevention of cervical cancer is optimally accomplished through HPV immunization and cervical cancer screening. Canada is one of the leaders in cervical cancer screening. Major benchmarks and landmark meetings have provided evidence-based recommendations; however, the most recent 2004 report produced no specific actions in a fast moving era of health care.

Since 2004, key research questions in the development of HPV vaccine policy have been identified. Reports, monographs and publications including the British Columbia Cancer Agency report (supported by Canadian Cancer Society) and the HPV Master's classes have resulted in 3 key forums on advanced vaccinology for HPV vaccines, modeling of HPV infection and economic analysis, and impact analyses of HPV vaccines and cervical screening programs. These initiatives have engaged individuals and agencies who have not traditionally met and have stimulated dialogue in a heterogeneous manner. Public health agencies have provided a leading role in integrating individuals and informing policy.

Background

Cervical cancer is almost completely preventable. Mortality rates for cervical cancer have dropped almost 60% in the past 30 years; largely due to cervical cancer screening using the Pap screening test/ smear and, within a new age of vaccine availability, through HPV immunization. Integrating these two pivotal strategies has the potential to further decrease mortality from cervical cancer and significantly reduce a universal threat to women's health.

Over the past 10 years, health professionals, researchers, epidemiologists, economists and other decision-makers have generated recommendations in 4 areas that are pivotal in the prevention and outcomes related cervical cancer have emerged including:

- Cervical screening and status of guidelines, standards and updates for the future;
- Primary prevention with HPV vaccine and key surveillance and monitoring issues;
- Integration of immunization and screening (system preparedness); and
- Program evaluation and moving research priorities forward in Canada.

Cervical Cancer Screening

Since the introduction of the Pap test, the rate of mortality from cervical cancer has steadily declined in Canada between 1973 and 1998. More than 50% of new cervical cancer diagnoses are in women who are seldom or never screened due to lack of knowledge, access to health care or non offering by clinicians. Opportunistic screening, low compliance (particularly for women who are older, immigrant, Aboriginal or from a lower socioeconomic status), inconsistent reporting of specimen inadequacy and lack of standardization in reporting of cytology outcomes have also precluded optimal cervical cancer prevention and early detection.

Immunization with the HPV Vaccine

HPV affects approximately 550,000 Canadian women annually and is the most common sexually transmitted disease in adults (Money & Roy, 2007). There are approximately 100 known types of HPV; at least 15 are considered carcinogenic and 3 others possibly carcinogenic (Provencher & Murphy, 2007).

HPV infections are ideally diagnosed through DNA testing, although this is not currently universally available. Epidemiologic studies indicate the highest occurrence of HPV is in young age groups (less than 25 years), although some studies support a second peak at 45 years or greater.

The majority of HPV infections go unnoticed and resolve spontaneously within 24-36 months. However, high risk species of HPV (Types 16 and 18) lead to persistent infections associated with cervical dysplasia and cancer. Lower risk HPV species (Types 6 and 11) are associated with genital warts. HPV specific genotyping will enhance clinical management. Three levels of prevention are recommended (Steben, 2007).

1. *Primary prevention* encompassing vaccination of young women prior to sexual debut. There are two HPV vaccines available for HPV protection and one for genital warts. Abstinence, limited sexual partners and targeted HPV education also constitute primary prevention strategies.

2. *Secondary prevention* reduces the risk of complications of HPV infection, decreasing the time of contagion and limiting the number of new cases. Cervical screening with the Pap test, use of condoms, Sexually Transmitted Infection (STI) prevention and caesarean section are secondary prevention methods.

3. *Tertiary prevention* focuses on reducing chronic incapacity from genital warts, precancerous/ cancerous conditions and their recurrence in vulnerable groups.

Integration of Screening and Immunization

Integrating HPV immunization and cervical cancer screening is optimal for the prevention and early detection of cervical cancer as advanced screening technologies evolve. In Canada, the conventional Pap test is the standard method for screening for cervical cancer and its precursers (Healey et al., 2001). Pap tests using Liquid-based cytology (LBC) allow for a more reliable assessment of cervical cancer than the conventional Pap test. (Payne, Chilcott, McGoogan, 2000). High risk HPV DNA testing is primarily indicated for women greater than 30 years who have Atypical Squamous Cells of Undetermined Significance (ASC-US), as a precursor for referral to diagnostic colposcopy. New guidelines need to be developed for the Pap test with LBC and HPV DNA testing in light of HPV immunization.

Improved methods of high risk HPV screening permit increased screening intervals and automation, with Pap cytology being reserved for triage of HPV-positive women. This focused approach will contain screening costs, improve accuracy in prevention programs and enhance women's understanding of HPV.

Program Evaluation and Research Priorities

Several Canadian meetings representing health professional, epidemiology, public health, economic, government and policy stakeholders have produced a composite of reports, systematic reviews, program evaluation and consensus

documents to evaluate prevention and treatment of cervical cancer. The most prominent of these deliberations include:

- Cervical Cancer Screening in Canada: 1998 Surveillance Report (Health Canada)
- 2006 Consensus Guidelines for the Management of Women with Abnormal Cervical Screening Tests (Journal of Lower Genital Tract Disease 11(4), 2007)
- Report of the 2003 Pan-Canadian Forum on Cervical Cancer Prevention and Control (Journal of Obstetrics and Gynaecology of Canada, November 2004)
- Liquid-Based Techniques for Cervical Cancer Screening: Systematic Review and Cost-Effectiveness Analysis (Canadian Agency for Drugs and Technology in Health, 2008)
- European Guidelines for Quality Assurance in Cervical Cancer Screening – Second Edition
- Canadian Consensus Guidelines on Human Papillomavirus
- EUROGIN (European Research Organization on Genital Infection and Neoplasm) Consensus Conference 2007
- Recommendations on a Human Papillomavirus Immunization Program (Canadian Immunization Committee, December, 2007).

The Keynote Presenters and Review Groups in the 2008 Pan-Canadian Forum reviewed the recommendations from these initiatives to set priorities, develop action items and deliverables and assign feasible timelines for moving forward.

Key Note Speakers – Day 1

Review of Environmental Scan in Canada

V. Mai

A survey on current cervical cancer screening, HPV immunization strategies and information systems practices was completed by all Canadian provinces and territories.

Cervical Cancer Screening

- Cervical screening practices are population-based (n=2), opportunistic (n=5) or both (n=6).
- The 8 provinces/ territories with screening programs recommended:
    - Commencement of screening at age 18 (n=3), within 2-3 years of sexual activity or at 21 (n=4), all ages of women who are sexually active (n=1);
    - Screening interval annually for 3 consecutive negatives and then every 2-3 years (n=3), annually for 3 consecutive negatives and then every 2 years (n=1), annually for 2 consecutive negatives and then every 3 years (n=1), annual moving to biennial (n=1), annual under review (n=2); and
    - Screening cessation at age 67 (n=1), age 69 (n=3), age 70 with 3 regular negatives in the past decade (n=2), age 75 (n=1), no upper age (n=1).

- Pap testing sampling technology utilized was by conventional cytology (n=9) and Liquid-based cytology (n=5).
- Screening programs were launched between 1960 and 2003 (majority in 1990s).
    - Of those with organized screening:
        - 2/8 sent personalized invitations and reminders; and
        - 7/8 targeted hard to reach populations.

- 9/13 jurisdictions have plans to establish or improve their screening programs.
- 4/13 jurisdictions reported use of HPV testing to triage women with abnormal screen results and reported trials/research use of HPV testing.

HPV Immunization Strategies

Of the 13 jurisdictions, 11 have HPV Immunization Programs, 1 is awaiting approval and 1 has none. Grade 6 is the most popular grade target (n=5) with Grades 4, 5 and 7 (2 programs each) and Grade 8 (1 program) also targeted. For 9 jurisdictions with catch-up programs, Grade 9 is the most popular (n=4) with Grades 6/7, 7, 8, Girls under 18 and Grades 11/12 moving down each being targeted in 1 jurisdiction. Diversity is common.

Of the 12 jurisdictions that have or are planning HPV Immunization programs:

- 4 launched their program in 2007; 8 launched/ will launch in 2008;
- 11/11 with immunization programs use materials to educate the population about the HPV vaccine and the link between HPV and cervical cancer;
- 10/13 have an organized HPV vaccine adverse event reporting system in place; and
- Outside program, HPV vaccine is available for purchase in pharmacies.

Information Systems Linkages

Database availability for monitoring varies widely with cancer data bases available in all jurisdictions, population data bases available in 12/13 jurisdictions, cervical screening in 10/13 jurisdictions, cervical screening follow-up in 7/13 jurisdictions, and immunization in 8/13 jurisdictions and HPV immunizations in 5/13 jurisdictions. These data bases and registries reside in different locations and under different governance in a wide variety of government departments, agencies and laboratories.

Wide variation exists in the availability of personal identifiers; name and health number being the most common for cervical screening and full address and date of birth being less common for HPV immunization.

The ability to link cervical screening data to other data bases is most frequent with cancer, cervical cancer follow-up data bases, followed by population data bases and least frequent with the immunization and HPV immunization data bases. Two jurisdictions with HPV data bases are able to link all 5 types of data bases.

Cervical cancer screening programs do not all use an organized approach and this could lead to incomplete data and less valid evaluation results. Furthermore, information systems integration is incomplete, limiting an evaluation of HPV immunization programs and the vaccine's impact and effectiveness.

Overview of European Guidelines – Organized Screening; New Technology; Benchmarking

M. McLachlin

In the European Union, there are 34,000 cases of cervical cancer per year from 500 million people; with a 10-15 fold variation between countries. Finland has one of the lowest rates of cervical cancer in the world while Romania has one of the highest. The first European Union document on Quality Assurance guidelines (1993) provided an initial iteration for screening guidelines. The second edition in 2007 focused on the essential aspects of developing an organized, population based program that minimizes the adverse effects and maximizes the benefits of screening.

Three key recommendations include:

1. Organized population based screening programs with quality assurance should exist at all levels. A defined screening program and a personal invitation are required; opportunistic screening should be discouraged. Program evaluation and action plans will enhance behaviour modification and change.
2. Introducing new technologies, implementation guidelines, follow-up diagnosis and treatment focusing on optimizing cancer prevention/ detection, feasibility, cost effectiveness, screening time, operational and human resource costs with recommendations to reduce unnecessary screening and inappropriate treatment.
3. Key performance indicators for monitoring screening process and for early identification with a focus on coverage (proportion of population being screened), consumption (woman having more Pap tests than required) and screening test performance (referral rate, repeat cytology and colposcopy).

A new key performance indicator document (sponsored through Cervical Cancer Prevention and Control network - funded from the Public Health Agency of Canada) is now available to monitor Pan Canadian performance. This guideline includes indicators focusing on available high quality data where meaningful targets could be established. Targets are grouped according to:

- Coverage;
- Performance (e.g. retention rate);
- System capacity (e.g. cytology turnaround time and time to colposcopy); and
- Follow-up and outcome indicators.

There is a need to develop core performance indicators by vaccination type and status.

Australia's Screening Guidelines and the Impact of HPV Vaccination on the Australian Cervical Screening Program

M. Saville

Screening started in 1991 as an organized approach with a single policy across Australia. This policy provided the basis for a mature program delivering the lowest mortality rate in the world and second lowest incidence. The policy stipulates routine screening with Pap smears every 2 years in asymptomatic women starting at 18-20 years or 1-2 years after start of sexual activity. Pap smears are stopped at age 70 if there are 2 normal Pap smears in last 5 years. Women over age 70 are not precluded from having Pap smears, especially if they have not had them as that is where burden of disease lies.

Women who have high grade abnormalities are referred for colposcopy as per guidelines but management was controversial around low grade abnormalities; now women have colposcopy if their abnormality persists for more than 1 year. HPV testing is only recommended in guidelines as a "test of cure" after treatment for a high grade abnormalities.

In 2006, a HPV vaccine program was announced for girls 12-13 years and, in 2007, an extensive catch-up program for girls 13-26 commenced. Presently, regular Pap smears occur every 2 years in the vaccinated cohort. Participation rates suggest that women understand the need for continued Pap smears, even after vaccination (although survey evidence suggests that only around 10% understand why).

It is anticipated that quadrivalent vaccination will result in a 50% reduction in high grade abnormalities identified through screening.

In Australia, there are 4 performance measures for laboratory cytology. Those that depend on a stable underlying prevalence of high grade abnormalities such as the standard for the detection rate for high grade will need to be adjusted with the changing prevalence.

LBC (Liquid Based Cytology) with imaging may have strategic advantages in the new environment including improved scientist productivity and maintenance of the absolute number of high grade abnormalities seen by scientists, important in maintaining quality.

Combining primary prevention (with HPV vaccination) and secondary prevention (screening) in its present form will lead to much lower cost effectiveness. Screening programs therefore need to be reformulated to operate in conjunction with vaccination programs. The possibility of primary screening with a HPV test and then using cytology as a triage test for those women with a positive HPV test requires further investigation. This approach may enable

significant inroads to be made in the prevention of adenocarcinoma of the cervix; a form of cancer not currently impacted using current screening methods. A formal review of evidence and modeling of proposed pathways is currently proposed.

Immunization/ Data Linkage

S. Dobson

When new vaccines are introduced in Canada, rapid acceptance with high uptake rates does not usually occur. Even with well accepted vaccine programs, uptake may be slow to increase; therefore, less accepted vaccines may take even more time.

The response from Public Health to HPV controversies in the media was low key; experience has taught us that this is usually the most effective tactic in the long run. The response, however, lacked passion and leadership was not well co-ordinated federally. Vaccine safety, well established from pre-licensure research and temporal associations of vaccine administration with a subsequent adverse event (not necessarily being causal) were explained poorly to the public and particularly parents. The very strict regulatory processes by Health Canada in evaluating the efficacy and safety of the HPV vaccine from data provided by the vaccine manufacturer were not articulated well. Even though a component of the National Immunization Strategy was developed to overcome problems and improve communicating rationales to the public, the risks to a daughter of not receiving the HPV vaccine was not communicated effectively.

Pre-adolescents were targeted for the introduction of the HPV program. The pattern of HPV spread after sexual debut was described to the public, but the impression that that would apply to "other daughters but not my own" was strong. This had been predicted by attitudinal research prior to the launch of programs, confirming that a more national approach to such research "in real time" would be supportive of vaccine programs. Concerns about the longevity of vaccine effectiveness created further anxieties in the public mind, even though all evidence suggests an enduring immune response.

There was also direct consumer advertising, due to lag between licensing of the vaccine in 2006 and the National Advisory Committee on Immunization recommendation in 2007. This may have deterred the public and or made public health professional's job more difficult.

The question about vaccine efficacy led to uncertainty of participating in HPV programs. The public needed to understand that in weighing the risk and benefit of immunization, there is also a risk in not taking part in the program as young women are at risk of acquiring high-risk HPV, vaccine preventable genotypes soon after sexual debut. The challenge is to find a novel way to reassure people that program effectiveness is continuously evaluated and if, for example, a future booster dose is required, programs will change.

For sure, in the future, cervical cancer registries will need to link with HPV vaccine registries to ensure that women, vaccinated or not, receive the

optimal cervical cancer screening. What form that screening should take can only be answered by having linked databases. The legislative framework around database linkage, provincially and federally, will be key to successful cervical cancer control.

In summary, the launch of provincial HPV vaccine programs across the country has been generally successful but uptake rates will take time to rise to the levels of other routine childhood immunizations. Lessons were learned. Moving forward in a context of uncertainty in the vaccine world in Canada is usual and acceptable. However, knowing through vaccine registries, who has and who has not been immunized will be very important to integrate with cervical cancer screening to maximize cancer prevention for Canadian women.

Cervical Cancer Prevention and Early Detection – From Scientific Promise to Public Health Impact

G. Pasut

In Ontario, the 2008 estimated incidence of cervical cancer was 7/100,000 and the mortality rate was 2/100,000; statistics that are similar to the incidence and mortality rates in Canada. However, at least 60,000 women in Ontario have an abnormal Pap test annually. Pap test screening is well integrated into primary care practice but 30% of Ontario women are seldom/never screened and approximately 50% of all cervical cancer occurs in women who are seldom/never screened. Furthermore, evidence across jurisdictions indicates that 20- 40% of women are lost to follow-up after an abnormal Pap test. However, cervical cancer screening can still be considered a notable success story.

HPV vaccine is a key advancement in primary cervical cancer prevention as it provides effective protection against most HPV infections that may lead to precancerous lesions and cervical cancer. This development supplements the success of existing cervical cancer screening programs in Canada.

In Ontario, childhood vaccines are primarily purchased by the provincial government, distributed by local health departments and administered by primary health care providers. A limited number of vaccines are delivered in school based clinics. There are school-based programs for HBV (2 dose schedule), conjugate Meningococcal C vaccines in grade 7. Significant planning is required to optimally sequence immunizations over the school year.

There are approximately 80,000 girls per grade cohort in Ontario. The Ontario Government Pharmacy and Medical Supply Services (OGPMSS) acts as procurement agent for provincial government with a single supplier. The province pays local health department a per dose fee to support administration of vaccine. There was a high level communications strategy to raise awareness of vaccine and disease at the time of introduction. This process was complicated by the Ontario election that coincided with the implementation of the vaccine program.

The HPV vaccine program is delivered by local public health units to Grade 8 girls. Solid relationships between public health officials and school officials and infrastructure are essential for rapid program implementation. School-based HPV programs are advantageous as they provide for (a) increased equity, (b) greater control over expensive vaccine, (c) decreased waste, (d) high up-take of existing vaccines *(HBV and MenC)*, (e) quick roll-out, (f) broadest

population reach, (g) potential to reach eligible under-screened populations and (h) data collection process for those who do and do not receive vaccine.

Initial implementation challenges included short lead times, communication restrictions due to election advertising legislation, procuring vaccine on short notice, fit and sequencing of HPV vaccine into existing HBV/MenC/Influenza programs, selecting the optimal grade level for immunization and supporting voluntary informed choice.

A key issue centered on public education about HPV and the vaccine. Initial media attention was focused on the benefits of a cancer prevention vaccine and the initial demand for the vaccine (positive stories) and the US debate on compulsory immunization (controversy). Initial public surveys showed limited awareness or knowledge of HPV and the causal link with cervical cancer but there was strong acceptability for HPV vaccine once an explanation was provided.

The media coverage at the time the program was launched focused on stories which suggested that there was insufficient evidence about the vaccine to initiate school-based programs (MacLean's story on "guinea pigs"), a lack of urgency to initiate the program and low perceived health risk.

In Ontario, there was a lower uptake of the HPV program after the first dose (53%) than in some other provinces (e.g. Nova Scotia 80-85%) although this pattern is similar to the experience in early phases of the implementation of other vaccine programs.

The Ontario Council of Catholic Bishops position led to an initial refusal by two Ontario Catholic School Boards to offer the school-based vaccine program.

The HPV program requires substantial public resources and systematic program evaluation as it is not yet proven that it will prevent cervical cancer. Optimizing screening to reach the 30% of women who are seldom or never screened is crucial. Establishing comprehensive and integrated cancer information systems to optimize benefits of screening and vaccination (recruitment, recall and follow-up, and program evaluation) is essential.

Implementation of the Manitoba Human Papillomavirus (HPV) Immunization Program: Four Main Program Elements

S. Stopera

The HPV vaccine program consists of four main elements including:

- Manitoba HPV Immunization Program;
- Enhancements to Cervical Cancer Reduction Strategy;
- HPV Vaccine Program Evaluation including HPV Vaccine Surveillance; and
- Integration of the HPV Immunization Program with Healthy Sexuality/Reproductive Health Programs.

Manitoba HPV Immunization Program

To determine the best model for allocation of the federal funding related to the HPV vaccine program, an economist was hired to determine cost estimates for HPV immunization delivery in Manitoba. The Manitoba model included costing assumptions on uptake, wastage, single cohort and school setting. HPV per dose funding costs over three years was established for first dose as well as second and third doses. Manitoba Health and Healthy Living (MHHL) is providing a guaranteed per dose funding to all regional health authorities and a remoteness allowance in addition to one-time start up costs for fixed costs consistent throughout the regions.

The immunization program is targeted at grade six females (cohort size is 7504) and is delivered by Public Health Nurses in the schools beginning 2008-2009. There is a three dose vaccine schedule with first dose start dates in late September-early October. The HPV vaccine will be integrated with other routine school-based vaccine programs over time. Parents received Consent Forms (print and electronic) and HPV Fact Sheets (print and electronic form www.gov.mb.ca/health/hpv/) and were invited to HPV Educational Sessions in some regions. HPV Questions and Answers for Public Health Nurses and HPV Questions and Answers for the Public were also available for further educational information.

A vaccine registry, Manitoba Immunization Monitoring System (MIMS) was introduced in 1988 to include immunizations of children born after Jan. 1, 1980. It has been expanded in 2000 to include all immunizations of Manitoba's adults and from 2003 onward, has been used for annual coverage reports. MIMS is the best source of individuals vaccinated with HPV in school-based programs. The proposed database linkage may include MIMS, Medical Claims, Drug Program Information Network, Discharge Abstracts and the Manitoba Health

Population Registry along with Cancer Care's Cervical Screening Registry and the Cancer Registry.

Enhancements to Cervical Cancer Reduction Strategy

Manitoba is currently drafting an overall cervical cancer reduction strategy with Cancer Care Manitoba (CCMB) and MHHL Public Health Division. CCMB will lead a new consortium for development of the cervical cancer reduction strategy with input from stakeholders. The overarching strategy is to advise on enhancements to primary, secondary and tertiary prevention to identify gaps and opportunities at the provincial level.

The Manitoba Diagnostic Consortium led by Cadham Provincial Laboratory (CPL) has been assembled with partners to develop a business plan for laboratory technology improvements.

Future laboratory capacity is projected at a minimum of 300,000 specimens/ year in Manitoba. HPV typing offers definite cost savings relative to colposcopy referrals. Side by side assessment of new molecular diagnostics can be performed at CPL. Key issues have been identified.

HPV Vaccine Program Evaluation including HPV Vaccine Surveillance

The surveillance objectives have been formulated through partnership between CCMB and MHHL Public Health Division for both pre-vaccine and post-vaccine areas. There has been an expert consultation/review of the components of the vaccine program evaluation plan. A new data sharing agreement between Public Health and CCMB will facilitate the disclosure of data for the purposes of HPV evaluation and surveillance. Meetings are in progress with the HPV Evaluation and Surveillance Subcommittee. A work plan for HPV vaccine program evaluation including HPV surveillance has been drafted and is awaiting feedback and costing from CCMB.

The proposed components of the HPV vaccine program evaluation work plan include (a) pre-vaccine and post-vaccine uptake rates in Manitoba, (b) post-vaccine uptake rates in Manitoba's First Nations, (c) HPV vaccine safety, (d) impact of the vaccine on cervical cancer screening, (e) impact of the vaccine on anogenital warts, (f) impact of vaccine on cervical dysplasia and (g) impact of the vaccine on cervical cancer risk.

Manitoba is host to numerous population-based linkable data bases. The benefits to linking information systems include optimizing the evaluation of the vaccine program, providing a sustainable infrastructure, increasing the research capacity of the province, providing timely feedback of information for quality improvement and facilitating evidence best practice.

Integration of the HPV Immunization Program with Healthy Sexuality/Reproductive Health Programs

Initiatives include: (a) MHHL has partnered with Cancer Care on the 'Tell Every Woman' Campaign to promote public awareness of cervical screening and the vaccine, (b) MHHL will participate in a workshop on Aboriginal Women and HPV hosted by International Centre for Infectious Disease, (c) MHHL will facilitate new initiatives with the Manitoba Dept. of Education on sexual health promotion using HPV as a platform and (d) MHHL will consult with community organizations (SERC, Klinic, Nine Circles) for potential partnerships.

Modeling as a Framework for Integrated Decision-Making Regarding Primary and Secondary Cervical Cancer Interventions

C. Bauch

Both primary and secondary cervical cancer interventions can have a major impact on disease burden. However, assessments of primary and secondary interventions tend to use different expertise, and types of data and models. Types of models include:

- *Cohort models* which track events occurring to individuals in a given cohort, over some time horizon. They are often used to assess screening and vaccination programs but do not capture herd immunity effects. Incidence of infection is a model *input*.
- *Dynamic models* which describe how infection is transmitted in the population and how primary interventions work. They can capture herd immunity effects and are often used to assess vaccination programs. Incidence of infection is the model *output*.
- *Hybrid models* where the output of a dynamic model is used as input for a cohort model. Parameters and communication between models need to be consistent.
- *Integrated dynamic models* where there is only one set of parameters and both infection transmission and disease history/screening aspects are integrated under the same framework. An "integrated" dynamic model of HPV vaccination and screening is currently being developed by Bauch and co-investigators to investigate screening strategies in the era of HPV vaccination.

For the purposes of this talk, an illustrative hybrid model is presented consisting of:

- An agent-based simulation of the network of sexual partnerships (under development) through which HPV transmission occurs; and
- A previous Markov cervical cancer cohort model which describes disease history and screening in a Canadian female birth cohort.

The cohort model simulates lifetime events in a female Canadian birth cohort, recruited infection-free at age 13. The cycle length is 6 months and the model is calibrated to data along 3 segments of the disease pathway: infection, precancerous lesions and cervical cancer. Infection assumptions are that susceptible individuals can be infected with high risk (HR) or low risk (LR) HPV types with some probability per cycle, infections are either transient or persistent and, after spontaneous clearance of HR/LR types, partial immunity to HR/LR types can be acquired.

The cohort model also makes assumptions related to:

- Screening: individuals undergo Pap test at specific intervals and there is follow-up for abnormal outcomes including HPV triage and colposcopy, according to factors such as age (e.g. <30, >30) and type of outcome (e.g. ASCUS versus LSIL);
- Cancer: where diagnosis through symptom detection or routine screening and treated cases is tracked for 5 years due to higher risk of related mortality during this period; and
- Mortality due to other causes, with hysterectomy included.

The network model that is currently being developed is a heterosexual partnership network simulation model where each network node is a male or female and each link is a sexual partnership. Links can form and break up and HPV infection spreads through links. The age structure by group include ages : 13-19, 20-24, 25-34, 35-44, 45-54, 55-64, 65-79. At present, the model describes transmission of high risk (HR) types only.

In the network model, partnership types are classified into steady and casual, and individuals can vary in their sexual activity level. Furthermore, there is a probability of HPV transmission per unit time in a susceptible-infectious partnership dependent upon male-to-female versus female-to-male transmission, and frequency of sexual activity (dependent on age, partnership type, and condom usage).

Individuals remain infectious for a specified duration of time *as per* the cohort model. If an individual spontaneously clears an infection, the individual has partial immunity to re-infection by HR types *as per* the cohort model. Duration of immunity from vaccine needs to be assessed through sensitivity analysis. The HPV transmission rate is obtained by fitting modeled prevalence to empirical prevalence data. Partnership formation rate and duration are obtained by fitting modeled sexual behaviour to sexual behaviour data.

In conclusion, modeling can provide a systematic and evidence-based framework for assessing vaccination and screening strategies. For cervical cancer interventions, models can provide:

- A way to sharpen thinking about assumptions and inter-relationships; and
- Credible projections of future health and cost outcomes under various vaccination and screening strategies.

Key Note Speakers – Day 2

Nunavut/PHAC HPV Surveillance Initiative

I. Sobol & S. Totten

There are many changes in health and public health in Nunavut (NU) and inequities and disparities in health in Aboriginal communities. In a 1999 study of 19 communities, representing 80% of the NU population (Healy et al, 2003), residual Liquid Based Cytology (LBC) cervical specimens were tested for 13 oncogenic HPV types. In this earlier study, HPV was more prevalent in younger age groups; there was a 26% prevalence of oncogenic HPV and 6.9% prevalence of Squamous Intraepithelial Lesions (SIL). Preliminary, unpublished data from this study indicated that the predominant circulating HPV types in Nunavut may be different from those most prevalent in other Canadian studies.

There is a crucial need to provide information for Nunavut Health & Social Services for decision-making on HPV immunization, to contribute to national surveillance baseline of HPV prevalence and type distribution, to examine the correlation between HPV types and cytological outcomes and to determine potential differences in HPV type distribution in Aboriginal and non-Aboriginal women.

Objectives for this study are to:

- Provide Information for Nunavut Health & Social Services for decision-making on HPV immunization;
- Contribute to national surveillance baseline of HPV prevalence and type distribution;
- Examine the correlation between HPV types and cytological outcomes; and
- Further examine potential differences in HPV type distribution in Aboriginal and non-Aboriginal women.

Results will contribute to a national HPV surveillance program that is being undertaken by PHAC along with provincial, territorial and external partners.

The current protocol includes:

- Routine Pap screening at all Nunavut community health clinics;
- Cytology performed at Dynalife Dx, Edmonton (usual practice);
- Residual LBC specimens are sent to NML for HPV typing; and
- Non-nominal results are linked by unique ID.

HPV detection was performed by the National Microbiology Laboratory using an in-house Luminex method that compares favourably to the Roche LinearArray genotyping method. Analysis was performed in terms of overall HPV and type specific prevalence, prevalence of abnormal Pap results, correlation between HPV types and Pap results and, in future, Inuit/non-Inuit breakdown. Results were based on a merged data set (cytology and HPV results; n=1116). Mean age was 31.7 (range 13-77) and 90% of the participants were Inuit. Epidemiological classification of HPV types was based on Munoz et al, 2003.

- High risk (oncogenic): 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82; and
- Low risk (non-oncogenic): 6, 11, 40, 42, 43, 44, 54, 61, 70, 72, 81.

Preliminary overall HPV prevalence of any type was 34%; prevalence of women positive for a at least one oncogenic HPV type was 24% and for women infected with 2+ HPV types was 12%. Of the oncogenic HPV types, HPV 16 was the most prevalent (7.3%) and HPV 31 was 4.3%. HPV 18 was the fourth most prevalent type at 2.1%.

Of the non-oncologic HPV types, HPV 6 and 11 were detected in 1.6% and 0.7% of women respectively, although other types (HPV 81 and HPV 42) were each present in approximately 2% of the population. From cervical cytology, approximately 4% of women had a low grade or high grade lesion (LSIL 3.1%; HSIL 1.1%). In comparing Pap tests with HPV prevalence results, 100% of high grade lesions and 83% of low grade lesions were infected with oncogenic HPV.

Approximately 1/3 of women were positive for any HPV; 1/4 were positive for oncogenic HPV. There was a high prevalence of "vaccine types" but other types were also important (e.g. HPV31). Prevalence of oncogenic HPV increased with higher grade lesions. HPV16 was present in 60% of HSIL specimens. Surveillance will continue into 2009 and, with a larger number of participants, there will be increased power to correlate HPV types with Pap cytology. There is also the potential for electronic cytology reports that will facilitate future data merging and analysis.

Program Evaluation/Research Priorities – Update/ Report Successes to Date

S. Dobson

The HPV Vaccine Research Workshop (2005) in Quebec City, Canada met to develop research priorities for HPV Vaccine use in Canada. Eligible participants voted using electronic pad using a 5 point likert scale ranking on:

- Importance: Is the question important for decision-making on HPV vaccine in Canada?
- Feasibility: Is it feasible (technology and infrastructure to design a study)?

The 10 highest ranked research questions were:

Research questions

Rank	Q	Label	Importance N=41	Feasibility N=40	Importance & Feasibility N=41
1	C1	How to deliver HPV vaccine program and optimal age	4.86	4.14	9
2	C8	KAB in recipients, providers, parents	4.54	4.41	8.95
3	C6	Vaccine delivery costs	4.84	4.09	8.92
4	B2	Immunogenicity of 2 dose schedule	4.64	4.24	8.88
5	B19	Impact on screening programs	4.85	4	8.85
6	C9	How to promote vaccine	4.64	4.14	8.78
7	B7	Co-administration with other vaccines	4.66	4.11	8.76
8	A11	Economic burden of HPV diseases	4.51	4.21	8.72
9	B1	Effectiveness of a 2 dose schedule	4.53	3.97	8.5
10	C3	Vaccine programs affect on screening	4.58	3.86	8.44

The 10 highest ranked infrastructure gaps included accessibility of data for modeling, CIC HPV working groups, networking of disciplines, conflict of interest levels, acceptability studies, articulation of goals of the program, collaboration between Cancer/NACI, capacity of epi/eco modeling, NACI equivalent in cancer screening, and Canadian Institutes for Health Research Request For Proposals that focus on multi-disciplines.

Many of these issues have either been achieved or are on the way to being achieved. The recommendations were that there needed to be a clear articulation of national goals for HPV vaccination program, and the introduction of the HPV vaccine must not come at the expense of cervical cancer screening programs. The challenge was that research questions pertaining to program delivery were highly ranked but most difficult to fund.

There was then a series of 4 Master's classes on vaccines, modeling, screening and program evaluation. The goals were to foster collaborations between researchers and educators from the differing fields of cervical cancer screening, vaccines and public health. The objectives were to develop practical research strategies, build a pool of experts through collaborative research and the public, and develop demonstration projects.

In considering the future, there are a series of dichotomies that need to be addressed:

- Research versus Evaluation;
- Privacy versus Public Health;
- Academic Institutes versus Networks;
- Grant funding versus Industry funding;
- Research/Evaluation is peer reviewed versus Public Health standard practice;
- Altruism (i.e. Can we answer questions for the rest of the world?) versus Provincial and National self interest;
- Entrepreneurial attitudes to research (the Canadian health care system offering opportunities on a par with Scandinavia for population based research) versus standard cancer control evaluation; and
- Uniformity of programs versus Provincial Diversity.

An idea to be developed is demonstration zones by studying and comparing differences. This is the equivalent for public health of the research lab for the immunologists. This could provide and opportunity to build on the unique capacities found in given regions by using monitoring tools that are not in general use because of costs or availability.

Discussion from Conference Groups

Cervical Cancer Screening Group

Recommendations

This group amalgamated 9 top priority recommendations and prioritized these to the top 3 that included:

Furthering existing guidelines for acceptable cervical screening addressing:
1. Screening tests and intervals;
    - Determining the appropriate age to commence cervical screening;
    - Management of abnormal tests; and
    - Management of disease, treatment and follow-up.
2. Engaging in economic modeling and analyses of organized versus opportunistic screening.
3. Developing a balanced scorecard to be published nationally to encourage program development and support.

Other recommendations including; (a) strengthening links to primary care services, (b) establishing key program components (i.e. recruitment, results, recall), (c) minimizing unnecessary screening, (d) creating a repository and mechanism for sharing standards and guidelines across Canada and (e) developing performance indicators for laboratories were considered important but of a less urgent nature at this time.

Actionable Next Steps

<u>Guidelines for Organized Cervical Screening</u>

Rationale
Furthering the development of acceptable organized cervical screening guidelines during a time of technological transition where multiple options exist was identified as the highest priority initiative. This priority needs to be addressed from a national perspective to minimize duplication and repetition of efforts as well as squandering of resources. Leadership for this initiative could be established through a newly reconstituted Screening Action Group/Committee (i.e. in collaboration with Canadian Partnership Against Cancer Screening Action Committee) that would be the vehicle for affecting this priority and working with the reconstituted Canadian Preventive Services task force or another similar body using a contracted services model.

Timelines
Timelines for this initiative will vary between groups and provinces but it was generally decided that the goal would be to secure funding by April 1, 2009 so that the guidelines could be completed over the 2009/2010 fiscal year.

Economic Modeling

Rationale
The next step would be to address practical issues (e.g. program development) related to the translation of acceptable cervical screening guidelines into practice. The Screening Action Group would develop an uncomplicated business plan to undertake economic analysis to delineate various options in screening program and support their establishment. This plan would focus on; (a) organized versus opportunistic cervical screening, (b) options for recruitment and recall of individuals and (c) organization of laboratory services to address issues of quality and price.

Timelines
The economic modeling exercise could be taken on by the Canadian Partnership Against Cancer screening action group in collaboration with the newly created Screening Action Group/ Committee. The business plan development could go hand-in-hand with the development of the acceptable guidelines initiative described in the first priority.

Balanced Scorecard

Rationale
A balanced scorecard would encourage program development and support for cervical cancer screening. An empowered committee, *The Implementation Committee*, would take responsibility for consolidating initiatives moving forward. Responsibilities would be to explore funding possibilities and initiate discussions with national organizations including Canadian Partnership Against Cancer and the Public Health Agency of Canada (PHAC), as well as provincial and territorial programs, to clarify roles on leadership, governance and decision-making capacity that each will play in supporting the Cervical Screening Implementation Committee and its projects.

Timelines
There is an urgent need to establish the Implementation Committee to provide leadership in 2009. Funding possibilities will be explored and initial discussions will be held with national organizations in November- December, 2008. An Annual Report will be produced in 2009 that would include: (a) baseline indicators from recently published guidelines (e.g. Guidelines for Monitoring Cervical Cancer Screening), (b) data collection over the first 6 months of 2009 and (c) a full report would be completed prior to the end of 2009.

Primary Prevention with HPV Vaccine Group

Recommendations

This group focused on key surveillance and monitoring issues within the era of HPV vaccine availability in Canada. From this perspective, they identified 2 top priority recommendations in relation to monitoring, surveying and evaluating outcomes including:

1. Tracking the incidence, prevalence and distribution of HPV genotypes associated with cervical, anogenital and oral precancerous and cancerous lesions by:
   - Developing and linking of data bases and registries (e.g. caner, cervical screening, HPV genotype and Vaccine); and
   - Sentinel surveillance sites (involving active surveillance for specific circumstances for particular jurisdictions).
2. Articulating vaccine uptake challenges and opportunities elucidating explanations for why some geographic areas have either higher or lower vaccine uptake. An opportunity would be targeting professional education and training, knowledge dissemination as well as education for parents and teenagers.

Actionable Next Steps

<u>Incidence, prevalence and distribution of HPV genotypes</u>

Rationale
There is a long list of potential organizations/ groups that would be appropriate to involve in determining the incidence, prevalence and distribution of HPV genotypes including cancer and immunization registries, Canadian Partnership Against Cancer, public health and privacy legislative bodies, public and Non Governmental Organizations and professional bodies as well as funding agencies (e.g. Canadian Institutes of Health Research and Canadian Institute of Health Information). The ideal organization would have; (a) a current role relation to action, (b) existing partnerships with essential stakeholders and (c) potential for taking a leadership or co-coordinating role. Given these criteria, two potential candidates would be the Cervical Cancer Screening Agencies & Programs (e.g. Cervical Cancer Prevention and Control Network or from Public Health Agencies).

Timing
After selection of an agency for the leadership/ co-coordinating role, there are three next steps that need to start now including; (a) active sentinel surveillance, (b) linkages of pre-existing databases (over the next 3 years) and (c) establishing registries where they do not currently exist. Many jurisdictions have begun this process and it will be important to learn lessons from them.

Vaccine uptake challenges and opportunities.

Rationale

There is a long list of potential organizations and groups that would be appropriate to involve in exploring vaccine uptake and identifying challenges and opportunities. These include Departments of Education & school boards, primary care health providers, the Canadian Cancer Society and provincial cancer agencies, Ministries of Health, Nongovernmental Organizations that represent high risk groups, professional working groups and pharmaceutical industries. However, it would be essential to ensure the Public Health organizations, professional bodies (e.g. Society of Obstetricians and Gynecologists of Canada [SOGC], College of Family Physicians of Canada [CFPC], Gynecologic Oncology Group [GOG], Canadian Pediatric Society [CPS]) and Information Technology expertise to promote data linkages amongst participants as key stakeholders in the co-coordinating group. Those with expertise in systematic review of the literature on uptake decision making also need to participate to ensure that empirically validated decision-making models on uptake are being considered.

Timing

For all activities, the timeframe needs to be ongoing with annual updates. Actionable next steps include; (a) writing to professional bodies to promote HPV specific training at all levels from students to health professionals across the provincial-national scope, (b) using the existing structure and mechanism, and survey methodology to better understand the rational for low or high uptake, incorporating qualitative questions regarding attitudes and beliefs about vaccines and (c) implementing training and education days at schools for students and teachers.

Integration of Screening and Immunization Group

Recommendations

There is current overlap of the conceptualization between the groups. This overlap provides opportunities for moving towards integration and collaboration. A key question in terms of integration is whether we are referring to integration of programs (e.g. delivery or services) or integration of information systems (e.g. monitoring and evaluation). Ultimately, if our goal is to move towards maximizing the benefits of cervical cancer prevention, there needs to be an organized integrated approach to cervical screening and HPV immunization.

The top 3 priority recommendations include:

1. Establishing national leadership around development of strategies to integrate screening/ immunization formation systems;
2. Supporting the national leadership to developing strategies for integrating screening and immunization into STI information systems;
3. Assisting the national leadership in integrating key messaging to promote immunization and screening.

There is definite benefit for working on all three priorities collectively and simultaneously

Actionable Next Steps

<u>Population based cervical screening information systems</u>

Rationale
This priority was seen as the key first step. Key groups that need to be involved would include (a) provincial/ territorial screening and immunization programs and (b) public health organizations including the Public Health Agency of Canada, Health Infoway, Health Canada, clinical and laboratory based health professionals, Canadian Partnership Against Canada, International Centre for Infectious Diseases.

Timing
A meeting in January 2009 is organized for strategic planning (hosted by Canadian Partnership Against Cancer) to identify which groups need to come together to address population based cervical screening information systems. Over the next fiscal year (2009/2010), this group would identify milestones required to meet the objective by 2015 (when young women who are now being immunized would first reach the time for cervical cancer screening).
There would also be a second forum by the end of March 2010 to evaluate progress.

Harmonized core messaging

Rationale
Harmonized and effective messaging will promote prevention, screening and immunization. The same key groups as delineated above would be considered for the population based cervical screening information systems.

Timing
The same timelines as discussed in the population based cervical screening information systems would be expected, except tighter. There would be a similar meeting to develop the strategic plan by the end of January 2009 (hosted by Canadian Partnership Against Cancer). The second step would be to identify milestones required to meet the objectives by 2010.
A forum by the end of March 2010 would be supported to evaluate progress and determine if objectives have been met.

National venues

Rationale
National venues would support the integration of screening and immunization. Similar key groups as for the above two initiatives would be considered for inclusion in this initiative.

Timing
The same timelines as discussed in the harmonizing core messaging initiative would be expected. There would be a meeting to develop the strategic plan by the end of January 2009 for identifying milestones to meet the objectives by 2015. There would also need to be a reconvening of this forum by the end of March 2010 to evaluate progress and determine if objectives have been met.

Additional points to consider that overlap with the recommendations of other groups include HPV surveillance and reaching the high risk populations. The integrated systems that are discussed will reach most of the populations. However, there will always those that are high risk and hard to reach, and in these cases, we need to make special efforts if we are going to successfully integrate cervical cancer screening and HPV immunization initiatives.

Program Evaluation/ Research Priorities Group

In this group, the focus was to integrate the recommendations of the other 3 group. To achieve this goal, a series of relevant questions are proposed including:

What are the best solutions to move evaluation/research forward in Canada?

First, there needs to be recognition that evaluation and research are not one and the same; there are specific and generic needs for both. A key point of difference is that monitoring and evaluation are ongoing functions while research is more finite. Furthermore, the needs of research may be very specific to the research question but are frequently tied to the context and therefore we need to be sensitive to all of these issues and cognizant of them. The NETWORK approach was considered the best way to meet these needs; an example being the Clinical Diseases Network in Australia developed to meet the needs of evaluation and research as they arise and change.

What organizations can provide these solutions?

The list that was identified includes the following (may not be exhaustive or complete):

- Canadian Institutes of Health Research: A key to providing funding for evaluation and research in the areas of; (a) prevention science and (b) dissemination science (focusing on "breakthrough to follow through");
- Public Health Agency of Canada: In relation to chronic diseases, STI, immunization and National Microbiology Laboratory; also with a mandate to assist in the issues that are important to this forum;
- Canadian Partnership Against Cancer: In relation to primary prevention, screening, surveillance and research action groups;
- Modeling groups to provide modeling expertise for designing interventions and evaluation;
- International Centre for Infectious Diseases: A Non-profit NGO with a national mandate;
- Public Health Networks: In relation to influencing Ministry of Health's decision making relevant to the evidence;
- Canadian Health Services Research Foundation: In relation to interaction between screening and immunization service envelopes as well as many more disciplines and collaboration;
- Bridging to Provider/ Professionals organizations such as Society of Gynocologic Oncologists of Canada and Canadian Association for Immunization, Research and Evaluation.

What do organizations need to provide these solutions?

First and foremost, a champion is needed at key organizations such as CIHR to stimulate new opportunities. HPV and cervical cancer issues have not been a high priority and the new HPV vaccine experience can be used as a catalyst to intervention.
Second, both a top down approach to solidify strategic direction and a bottom-up format for those in the field to influence those at the top is needed. Clarity and advocacy are also essential in regards to legislation on privacy, linkages and to address barriers.
Finally, a broker to bring constituents to the table would be helpful. A model to examine and replicate may be the BC model which is viewed as collaborative, cohesive, supported and efficient.

Although there were no specific organizations that were identified as needing to have a coordination role, there are many who are well qualified. Each will play a specific role but there will be constraints and sensitivities to attend to. There is a need to be sensitive to the likelihood of success within the context of organizational constraints (e.g. conflicts of interest).

Timeframe

There is an urgent need to move forward quickly. A meeting to create a national strategic plan involving Canadian Partnership Against Cancer, Public Health Agency of Canada and International Centre for Infectious Diseases in January 2009 would be ideal. It would also be important to bring to the table initiatives that are already in progress that would be relevant to the strategic direction. The short term deliverable is the high level national strategic group meeting (January, 2009). The longer term deliverable is effectiveness where linkages of registries will be crucial for evaluation of effectiveness.

Conclusions

Within this forum, there has been an abundance of material presented, suggestions for moving forward, momentum and energy. It is essential to preserve and enhance this diligence and enthusiasm.

There is a real sense of urgency and a definite window of opportunity **NOW** with the introduction of the HPV vaccine. If this window is missed, we may not be able to retrieve the opportunity again – therefore, it is important to move to action immediately.

Moving ahead requires moving together collectively and strategically building on successes, strengths, accomplishments and the existing research; using this as a foundation for the future.

Knowledge translation - moving from practice to research and back to practice is a key component of success and needs to be enhanced.

There is an opportunity to situate this group appropriately ensuring that cervical cancer screening programs are highly functional and efficient and then using the time from HPV vaccination to first screening as a window of opportunity.

There have been landmark documents in Canada including key reports, guidelines, systematic reviews and consensus documents that need to be used for the development and sustainability of the integration of screening and immunization programs. Other international initiatives (e.g. European guidelines) also need to be recognized and referenced.

A collective effort needs to be established and sustained. From this forum, we require a comprehensive plan with common goals, outcomes and timelines from the 4 discussion groups to move forward. Planning, partnerships, and budgets all need to move forward quickly to realize substantial gains in 2009/2010. There is a strong desire to reconvene this forum in one year's time to evaluate and plan for the future.

The tendency to focus on barriers needs to be resisted as does developing research on barriers (which is rarely translated back into practice). Alternately, program and practice issues need to be highlighted and evaluated appropriately.

The ultimate goal is to enhance women's health and provide all levels of prevention to minimize cervical cancer and decrease mortality rates.

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