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Proceedings of the National Varicella Consensus Conference

Montreal, Quebec
May 5-7, 1999

Health Canada
Health Protection Branch
Laboratory Centre for Disease Control
Bureau of Infectious Diseases
Division of Immunization

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Introduction

The National Varicella Consensus Conference was sponsored by the Laboratory Centre for Disease Control (LCDC), Health Canada, and held from May 5-7, 1999, in Montreal, Quebec. The first varicella vaccine in Canada, a live attenuated Oka strain vaccine, was licensed in December 1998 and is recommended by the National Advisory Committee on Immunization (NACI) for primary immunization of healthy persons aged ≥ 12 months[1].

While varicella is often considered to be a fairly benign disease among otherwise healthy children aged up to 12 years, available epidemiologic data show that cases in that age group account for a substantial public health burden: approximately 90% of all varicella cases, 80% to 85% of varicella-associated physician visits, 85% to 90% of hospitalizations, nearly 50% of fatal cases, and the majority of annual costs, most of which are related to productivity losses by caregivers[1]. In children aged < 10 years, varicella is now the main cause of death due to diseases potentially preventable by routine childhood vaccination in Canada.

Primary varicella is a more severe disease in adults, with a case fatality rate 10 to 30 times higher than in children. Moreover, in both adults and children, the majority who die of varicella have no identifiable risk factor for severe disease.

Currently, varicella vaccine is not universally accepted by all health care professionals or the public. Multiple competing priorities for public health resource allocation at the provincial/territorial or local level increase the likelihood that the timing of implementation of varicella vaccination programs will differ widely among provinces and territories. In addition, a number of logistic challenges to the implementation of routine vaccination programs exist with the currently licensed freezer-stable vaccine, which is the most heat-sensitive of all vaccine products currently available. The primary challenges are the cost of the vaccine, and the storage and handling requirements (specific issues include inadequate freezer capacity, cost of freezer space for both public health delivery and physicians offices, and potential difficulties with the cold chain maintenance in the delivery of the vaccine to remote areas).

Modeling data suggest that unless high coverage with varicella vaccine is uniformly achieved in all jurisdictions, there is a danger of causing a shift in the epidemiology of varicella to the adult population with a resulting increase in morbidity. Thus, more than for any routinely used vaccine, the urgent need for national consensus on the potential benefits of routine varicella vaccination and the strategy for implementing routine vaccination programs was recognized.

The goal of the conference was to present a forum for federal, provincial, and territorial public health representatives, clinical experts, and other professional stakeholders to discuss and exchange ideas on issues related to the varicella vaccine, including implementation of population-based vaccination programs, provider and public acceptance of the vaccine, and ways to maximize the benefits of the vaccine for the Canadian population.

The specific objectives of the conference were to discuss and exchange ideas on

- national goals for the control of varicella and herpes zoster
- a coordinated approach to implementation of varicella vaccination programs in all provinces and territories

- post-marketing research needs for varicella-zoster virus (VZV)-related disease and varicella vaccine

The conference included broad participation from all major stakeholders identified: the Laboratory Centre for Disease Control, the Bureau of Biologics and Radiopharmaceuticals, Medical Services Branch, provinces and territories (chief medical officers of health, provincial/territorial epidemiologists, and local representatives), the Advisory Committee on Population Health, the Canadian Occupational Health Nurses Association, the Canadian Association of Medical Microbiologists, the Community Hospital Infection Control Association Canada, the Canadian Infectious Disease Society, the Canadian Nurses Association, the Canadian Paediatric Society, the Canadian Public Health Association, the College of Family Physicians of Canada, the National Advisory Committee on Immunization, the Society of Obstetricians and Gynaecologists of Canada, the Toronto Fetal Centre, the U.S. Centers for Disease Control and Prevention, and a consumer advocate.

As well, representatives of two vaccine manufacturing companies were invited to attend the conference as observers and to present the most current technical and scientific information on their respective products: Merck Frosst Canada s VARIVAX® (the only vaccine currently licensed in Canada) and SmithKline Beecham s Varilrix (*not* currently licensed in Canada). A representative of the American Red Cross also participated as an observer.

Although representation was invited from the Canadian Blood Services and HémaQuébec, neither organization was able to send a representative to the conference. Manufacturer representatives were invited to sit in on all plenary sessions, but they did not participate in the plenary debate or in working group discussions, nor did they provide funding for the event. A request to exclude manufacturers from the plenary sessions was defeated by majority vote. A detailed list of participants is provided in Appendix A.

Conference Format and Process

The meeting began with a series of scientific presentations to the plenary group by invited experts from Canada and the United States (the invited speaker for the European perspective was unable to attend; however, written material was provided to participants). This was followed by 2 days of discussion in five concurrent working groups on specific public health issues and presentation of working group summaries to the plenary for discussion.

Current scientific information was presented on the following topics:

- Virology, clinical syndromes and immune response to VZV (Dr. Anne Gershon)
- Epidemiology of VZV in Canada (Dr. Barbara Law, Dr. Yves Robert, and Dr. Danuta Skowronski)
- Varicella seroprevalence in Canadian populations (Dr. Sam Ratnam)
- Risk and incidence of Group A beta hemolytic streptococcal infections in varicella (Dr. H. Dele Davies)
- Epidemiology and surveillance of VZV in the United States (Dr. Jane Seward)
- Epidemiologic modeling of varicella in Canada (Dr. Gaston de Serres, Mr. Marc Brisson)
- Surveillance needs for VZV and varicella vaccine in Canada (Dr. Monique Douville-Fradet)
- Infection control for VZV (Dr. Anne Matlow)
- Varicella vaccine experience in the United States (Dr. Jane Seward)
- Preventing varicella in special risk populations (Dr. Myron Levin)
- Economic analysis of varicella vaccine use in Canada (Dr. Jaime Caro)
- VARIVAX® (Dr. Didier Reymond)
- Varilrix (Dr. Alan Kimura)

To create a balance of perspectives and professional diversity, participants were assigned to one of five concurrent working groups. Participants were assured that divergent opinions were not only welcome but absolutely necessary to the process of consensus building. Each working group comprised 9 to 12 participants as well as a pre-assigned group chair and rapporteur (Appendix B). The five working groups discussed issues in the following content areas: (1) Public health goals and objectives for varicella control and vaccine coverage; (2) Development and implementation of varicella vaccination programs; (3) Varicella

vaccine use in special populations; (4) Promotion of varicella vaccination programs; and (5) Surveillance needs (disease and vaccine related).

Working group participants were asked to deliberate on specific questions relating to their content area and to propose recommendations based on those questions. The proposed recommendations from each group were presented to the plenary for discussion in a process of consensus building, to arrive at final recommendations. Consensus was defined as agreement that a given recommendation under discussion was acceptable to participants. It was recognized that consensus did not require unanimity, although it would require more than a simple majority of voting participants in favour of a recommendation. Electronic key pads were used to record votes on each recommendation to ensure consistency, reliability, and voter confidentiality. The specific criteria used for reaching consensus on recommendations were:

- A vote of 90% to 100% in favour of a motion was considered as consensus on a given recommendation.
- A vote of 75% to 89% in favour of a motion was considered as consensus if there were no major objections expressed by participants; if an objection was raised, the recommendation was opened to further discussion.
- A vote of < 75% in favour of a motion resulted in further discussion of the recommendation and repeat voting.

The following section of this report presents the summary of the plenary discussions for each working group s proposals and the final consensus recommendations. The recommendations took into account current scientific knowledge presented at the conference as well as information presented to participants as background reading material before the meeting (Appendix C). Although the majority of participants were invited after being identified by various stakeholder groups, they did not necessarily express the views of the groups they belong to and may have expressed their personal views on some issues. In his opening remarks, Dr. Paul Gully, Deputy Director General, LCDC, noted that it would be important to evaluate the process of consensus by measuring the acceptance and implementation of the recommendations and guidelines from the consensus conference across the country.

Conference General Recommendation

A definition of health care workers was recommended, based on the national *Infection Control Guidelines for Occupational Health in Health Care Facilities*[2].

General Recommendation

The definition of health care worker should include all individuals, including trainees, in health care settings (e.g. hospitals, ambulatory care settings, long-term care facilities) who may have the potential for acquiring or transmitting infectious agents during the course of their work. Volunteers who have direct patient contact should be considered as health care workers.

Public Health Goals and Objectives for Varicella Control and Vaccine Coverage

Public health goals for varicella control were deliberated within the context of the logistics of program implementation with the currently licensed freezer-stable vaccine. Participants noted that a highly expensive vaccine combined with vaccine delivery costs could divert funds from other public health priorities, thus making the immediate implementation of a varicella vaccination program less attractive. However, a lower price might make a freezer-stable vaccine more acceptable.

Although it is desirable to eliminate VZV in Canada, participants agreed that it is even more important to establish goals for implementation of vaccination programs as an intermediate step towards the reduction of VZV-associated morbidity and mortality. Given the diversity of vaccine program implementation in the provinces/territories, it was considered more feasible to establish realistic targets for disease reduction in 2005, by which time programs should be in place. It was felt that by the year 2005, the logistic difficulties with the currently licensed vaccine should have been overcome, irrespective of whether a refrigerator-stable vaccine is available in Canada. It was also emphasized that a goal of reducing hospitalizations will not be realized until all the major priority groups (by age and risk) identified at the conference have been vaccinated.

Criteria were developed for introducing routine varicella vaccination. Among other issues these took into consideration the technical feasibility of vaccine delivery (e.g. existence of an adequate freezer capacity) and the universal availability of the vaccine for all members of a target population. A number of the recommendations regarding varicella vaccination were targeted to susceptible persons in specified groups, defined as those persons without a history of varicella or vaccination. Once a routine childhood program is in place, the reasonable expectation is that coverage levels similar to current levels for measles vaccination can be reached; hence the coverage targets for varicella vaccination of susceptible children were linked to those for measles.

Several recommendations arising from the conference reinforced existing or ongoing public health initiatives and activities by other groups, such as the creation of a national immunization registry. The need to have a mechanism to prioritize vaccines within the broader discussion of public health funding was discussed extensively. Cost-sharing between the federal and provincial/territorial governments was proposed for further deliberation at the national level, for example, the possibility of federal funding of catch-up varicella immunization with provincial/territorial responsibility for the ongoing costs of varicella immunization.

Recommendation 1.1

The criteria for embarking on a routine varicella vaccination program should be as follows:

- Primary decisions: the vaccine is safe, effective and beneficial to the individual; and the burden of disease justifies program consideration.
- Absolute criterion: feasibility to deliver the vaccine to > 90% of the targeted population in each province/territory.
- Relative criteria: availability of a refrigerator-stable vaccine product;

availability of a combination product; vaccine cost comparable to existing routine childhood vaccines; and 100% accessibility to a vaccination program.

With these absolute and relative criteria taken into consideration, all provinces/territories should have a routine childhood varicella immunization program by 2005.

Recommendation 1.2

Consideration having been given to the criteria for embarking on a routine varicella vaccination program, where the public health infrastructure can support childhood varicella vaccination this should proceed. Pending this, the following priorities for program implementation with the currently licensed freezer-stable varicella vaccine are suggested. Priorities must be reviewed with changes in vaccine formulation. Vaccination should be offered to susceptible persons in the following groups, in descending order of priority:

- health care workers and other special groups (as defined in the recommendations under *Varicella Vaccine Use in Special Populations*)
- selected immunocompromised groups (as defined in the recommendations under *Special Populations*), including those eligible for research protocols, and families and close contacts of these persons
- preteens at the time of other vaccination programs
- children at 1 year of age
- catch-up of children aged 1 year to preteens
- other adults

Recommendation 1.3

By 2005, a federal/provincial/territorial forum should establish reduction goals for VZV-associated morbidity.

Recommendation 1.4

By 2003, 100% of health care workers (as defined in the *General Recommendation*) should have known positive varicella serology, or a reliable history of disease, or documentation of varicella vaccination, or an acceptable medical contraindication to varicella vaccination.

Recommendation 1.5

By 2003, provincial and territorial immunization registries and a national immunization registry network should be developed, as per the ongoing registry initiative.

Recommendation 1.6

By the year 2010, varicella vaccination coverage targets should be tied to measles vaccination coverage targets to be achieved by the second birthday and by the seventh birthday[1].

Recommendation 1.7

The Advisory Committee on Population Health should propose to the Federal/Provincial/Territorial Deputy Ministers a formula for adequate federal funding of new immunization programs.

Recommendation 1.8

The Advisory Committee on Population Health should develop a mechanism to prioritize and introduce new vaccines with a view to harmonizing programs across the country.

1 The coverage targets voted on were 95% and 97% by the second and the seventh birthday respectively. However, the discussion was to link the varicella coverage targets to those for measles, which are 97% and 99% respectively[3]. The actual measles targets should be taken into consideration in program implementation and evaluation.

Development and Implementation of Varicella Vaccination Programs

Strategies for vaccine delivery in a routine immunization program were discussed on the basis of separate assumptions that (1) the only vaccine available would be the currently licensed freezer-stable product, or (2) a refrigerator-stable vaccine would be available. Recommendations regarding program implementation were proposed that took into account the desire to achieve high coverage rates as quickly as possible. However, participants acknowledged that specific strategies and decisions regarding actual program implementation would have to be made by provincial/territorial authorities.

Concerns about the capacity to deliver a freezer-stable vaccine effectively pertain to Health Canada s Medical Services Branch and other jurisdictions responsible for vaccination programs, as well as to provincial/territorial public health departments. Participants were hesitant to recommend costly cold chain improvements that might quickly become redundant if a refrigerator-stable product soon became available in Canada. Furthermore, introduction of a full freezer cold chain for varicella vaccine could adversely affect other immunization programs as a result of the costs. Direct distribution by the manufacturer to clinics was discouraged because of inherent drawbacks: the difficulty of inducing clinics to provide records to provincial/territorial public health departments; the lack of provincial/territorial public health control of administrative aspects of program delivery, including funding and cold chain maintenance; and the ethical issues associated with providing lists of vaccinators in any jurisdiction to a specific manufacturing company. It was also noted that for the purpose of public purchase, it would be useful to obtain the actual cost of the vaccine (i.e., after the transportation and storage costs factored into the current price have been subtracted).

Participants reiterated that universal vaccination of young children with the freezer-stable vaccine is not feasible at this time, but that in the meanwhile an interim strategy should be adopted to make the vaccine accessible to preteens and to selected risk groups as defined in the recommendations under *Special Populations*. The importance of using a phased approach, to allow time for consideration of a variety of outstanding issues, was stressed. The best option for universal vaccination of young children is to implement a program within 2 years of the introduction of a refrigerator-stable vaccine, to be followed by a 5-year catch-up program for susceptible preteens. Options to be considered for a catch-up program include mass vaccination (ideal but costly), immunization of preteens linked with school-based hepatitis B vaccination, vaccination at school entry, or a combination of these. No specific age limits were defined for catch-up programs in order to provide flexibility in provincial/territorial implementation strategies, which will differ according to existing public health systems. However, implementation of catch-up programs should allow for coverage of all age cohorts up to the age targeted for pre-adolescent immunization.

Recommendation 2.1

A universal immunization program for young children should be implemented within 2 years of the availability of a refrigerator-stable vaccine.

Recommendation 2.2

Systematic immunization should begin as soon as possible for susceptible preteens < 13 years of age with whatever vaccine is available, preferably through a school-based program. Immunization of prioritized at-risk persons, as defined in the recommendations under *Special Populations*, should be initiated at the same time.

Recommendation 2.3

As soon as a universal program is in place, a catch-up program for susceptible persons < 13 years of age should be initiated and completed within 5 years.

Recommendation 2.4

Primary immunization of children < 13 years of age should be done with one dose. Surveillance must be planned in order to permit reassessment of this policy.

Recommendation 2.5

There should be no booster dose planned in the vaccination program. Research is required to measure the need for booster vaccination to prevent varicella and herpes zoster, and for timing of boosters if needed.

Recommendation 2.6

Vaccine should be administered to children as early as recommended (by the manufacturer) for a given vaccine. When possible, it should be linked with a vaccination visit already in place.

Recommendation 2.7

Before the use of a freezer-stable vaccine is contemplated, the following critical conditions must be met: appropriate freezers must be in place to maintain vaccine at ***minus*** 15° C; there should be an appropriate monitoring system for maintenance of the cold chain; an appropriate system of vaccine delivery to maintain vaccine at ***minus*** 15° C must be in place; all vaccine handlers must be trained on proper vaccine storage and handling requirements; there should be a system in place to monitor vaccine wastage; and availability of dry ice must be ensured.

Varicella Vaccine Use in Special Populations

Emphasis was placed on all susceptible healthy adults as the main target for varicella vaccination. However, a number of populations were identified for active targeting, including health care workers and household contacts of immunocompromised individuals.

Recommendations regarding vaccination of health care workers refer *both* to occupational exposure to VZV and to the possibility that health care workers might transmit the virus to patients (see definition of health care workers in the *General Recommendation*). The principle that health care workers must be immunized against those diseases that they are capable of transmitting to individuals was considered to be important, reasonable, and realistic. Nonetheless, this was also recognized as a potential area of controversy. There was debate on the management of vaccinated health care workers exposed to wild type VZV. It was noted that in up to 20% of immunized adults exposed to varicella a breakthrough rash may develop.

Regardless of age, a history of varicella is a highly reliable and valid way to determine an individual s immune status to varicella[1]. Screening for the specified high-priority populations should be a two-step process, beginning with enquiry about a history of varicella and followed by serologic tests only for persons who have an uncertain or a negative history. Ideally, serologic tests to determine the need for immunization should be conducted only when they are considered to be cost-beneficial.

Once high vaccination coverage rates have been achieved and maintained, controlling potential pockets of infection will be the key to controlling the disease, and outbreak intervention programs will become more important. During this control phase, the need for early detection of varicella cases among special population groups at high risk of infection may warrant more intense screening for immunization. Such groups may include immigrants (adults and children) and individuals in institutions such as penal institutions (where the closed setting, ease of transmission, and high percentage of high-risk populations such as HIV-positive individuals increase the risk of infection). History taking may be adequate, but information on immigrant seroprevalence was identified as a research need.

In health care settings, post-exposure prophylaxis should be considered within 72 hours and up to 5 days after exposure for non-pregnant, susceptible staff and for susceptible inpatients, in consultation with infectious disease experts. However, post-exposure prophylaxis should not be substituted for immunization programs. In the control phase, post-exposure prophylaxis may need to be considered for the special situations or groups that follow: for susceptible persons following varicella exposure within 72 hours and up to 5 days of a point source exposure in daycare centres, in household settings, and in homeless shelters where there are lots of children. It is recommended that all susceptible persons be vaccinated at the same time.

Providers in travel clinics may remind susceptible persons of the availability of the varicella vaccine, although there is no increased risk of acquiring the disease through travel.

Recommendation 3.1

All healthy, susceptible non-pregnant adults should be targeted for vaccination. However, priority for active targeting should be given to health care workers; household contacts of immunocompromised individuals; child care workers; and primary and secondary school teachers.

Recommendation 3.2

Active targeting plan: All jurisdictions and employers with an existing responsibility (such as Occupational Health, Public Health, obstetric care workers, primary care physicians, etc.) are to direct campaigns of screening (history of varicella with or without serology) and offer vaccine to the active targets.

Health care workers

Recommendation 3.3

Susceptible health care workers should be immune prior to employment or should be immunized according to a two-dose schedule to be completed within 2 months, to minimize outbreaks and loss of time due to varicella in health care settings. All susceptible health care workers currently in the system should be immunized. Initial priority should be given to immunizing health care workers on wards or in patient care settings that contain susceptible high-risk patients (e.g. settings with immunocompromised patients, intensive care units, and emergency rooms).

Recommendation 3.4

Identifying susceptibles: Before an employee begins employment, a varicella history should be obtained. If there is any doubt about previous disease or vaccination, or the history is negative or unknown, serologic testing should be performed. If the result is negative, the employee should be immunized. If the individual receives the vaccine, (s)he should be furloughed or reassigned only if there is a varicella-like rash.

Recommendation 3.5

Post-exposure management: Significant exposure for health care workers should be defined as 15 minutes face-to-face or 1 hour in a patient room. Immunized and exposed health care workers whose antibody status is not known should be watched vigilantly for a varicella-like rash, with or without serologic testing. If a health care worker has a rash, it should be reported to occupational health. The worker should be granted furlough or reassigned for the duration of the rash.

Immunocompromised individuals

Recommendation 3.6

Live, attenuated vaccine should not be routinely given for immunocompromising diseases (e.g. lymphoma, congenital or acquired immunodeficiency) or treatments associated with T-cell abnormalities (e.g. intensive chemotherapy, high dose steroids, cyclosporine, azathioprine, methotrexate, tacrolimus).

Recommendation 3.7

Immunization should be discussed with an infectious disease expert in the following cases:

- patients with congenital transient hypogammaglobulinemia
- HIV-infected persons with normal immune status
- solid organ transplant recipients (vaccine should be given a minimum of 4 to 6 weeks prior to transplantation).

Recommendation 3.8

The following persons may be safely immunized:

- if they are not on immunosuppressive medications, patients with nephrotic syndrome or those undergoing hemodialysis and peritoneal dialysis
- patients on low dose steroid therapy: < 2 mg/kg and a maximum of < 20 mg/day
- patients on inhaled steroids

Screening of susceptible persons

Recommendation 3.9

Prior to vaccination, screening (history with/without serology) is recommended for the following special groups: health care workers, teachers, daycare staff, and persons in institutions of health education (e.g. nursing schools, medical schools). A reliable history of varicella is satisfactory to establish immunity. If there is no known history or the history is uncertain, serology should be performed.

Recommendation 3.10

Obstetric care providers should identify the varicella status of women during pregnancy, and immunize postpartum those who are susceptible prior to discharge. Varicella screening should be added to obstetric prenatal chart/laboratory requisitions to be checked separately for potential identification of susceptible women. Primary care providers should identify the varicella status of women of reproductive age and immunize them if necessary.

Promotion of Varicella Vaccination Programs

As with any newly licensed vaccine, in order to maximize vaccine coverage, it will be very important that varicella vaccination programs include educational activities targeting policy makers, health care professionals, and the general public. Participants examined the challenges to the successful implementation of routine varicella vaccination programs arising from lack of information, misinformation or misconceptions about the disease or the efficacy and safety of the vaccine. The need to provide consistent, up-to-date information about the associated benefits and risks was stressed. Educational activities should include expert and academic input, which tend to be credible sources of information for health care providers in particular, as well as parental advocacy, which proved a successful component of the strategy to introduce the hepatitis B vaccine in British Columbia, and subsequently across the country.

Promotional activities targeted at policy makers should focus on the possible severe consequences of the disease and prevention through vaccination. To promote routine varicella vaccination among health care providers, provincial/territorial funding for both promotion and delivery should be provided to public health units, since it is unrealistic to introduce an immunization program without providing additional funding to pay for staffing. Health care providers in the non-public health sector, such as pharmacists, should be provided with adequate information to motivate them to promote the vaccine. Specific attention will be required to deal with the anti-vaccine lobby with the objective of providing accurate and clear information to help the public make fact-based decisions. Strategies identified include presenting current, factual information to counter anti-vaccine messages, having references available, and involving credible experts.

National bodies such as Health Canada and the Canadian Immunization Awareness Program have a coordinating role to play in gathering and providing educational materials, but it was recognized that decisions on distributing the material should remain with provincial/territorial authorities and other jurisdictions responsible for vaccination programs, which can link promotional activities with routine vaccination programs once those are implemented. In jurisdictions that lack a system to distribute promotional material effectively, groups such as the Canadian Paediatric Society should be approached for help.

Recommendation 4.1

Information regarding varicella (including the burden of illness and complications; health care costs; vaccine efficacy and safety; the NACI recommendations for vaccine use; and the National Varicella Consensus Conference recommendations) should be presented at the upcoming meeting of the Deputy Ministers of Health, and this information should be made available for presentation to other key policy makers.

Recommendation 4.2

The Canadian Immunization Awareness Program should make available to provincial/territorial authorities and other jurisdictions responsible for vaccination programs information packages, for distribution to health care providers (public health, non-public health,

pharmacists) at the appropriate time. The packages should include the NACI statement on varicella; the National Varicella Consensus Conference recommendations; a Q&A format indicating incidence and complications of varicella disease and the benefits and risks of vaccine; information available on Health Canada s web site; a bibliography; and other web site links.

Recommendation 4.3

The Canadian Infectious Disease Society, the Canadian Medical Association, the Canadian Nurses Association, the Canadian Paediatric Society, the Canadian Public Health Association, and other professional associations should raise the profile of varicella disease/vaccine through the inclusion of (1) articles in their professional publications and (2) presentations at professional meetings (CEU/CME credits).

Recommendation 4.4

The Canadian Paediatric Society should take a lead role in coordinating the promotion of varicella vaccination by (1) providing a speaker list regarding varicella vaccination, for continuing education events and media interviews; (2) developing an educational package (slides, hand-outs) for use in presentations at the local level; and (3) incorporating information on varicella vaccine in *Your Child s Best Shot* and other educational materials.

Recommendation 4.5

The promotion of varicella vaccination to the general public should be done at the provincial/territorial and local level, by providing information regarding the disease, the vaccine and the local program through the use of (1) media, including press conferences and public service announcements; (2) partnerships with non-governmental organizations, service clubs, and the private sector; and (3) advocacy by individuals affected by the disease.

Recommendation 4.6

Health Canada and provincial/territorial public health authorities should monitor and exchange information on varicella vaccine that is disseminated by persons and organizations opposed to immunization, together with accurate, referenced material regarding the issues raised.

Recommendation 4.7

Health Canada should monitor varicella vaccine acceptance by including relevant questions in surveys such as the National Population Health Survey and repeating the 1999 survey on the use of varicella vaccine in Canada in 1 to 2 years.

Recommendation 4.8

Provincial/territorial authorities or Health Canada should provide a 1-800 telephone number to ensure standardization of information and registry of information.

Surveillance Needs

Participants agreed that there is a need for a baseline estimate of disease incidence before program implementation; some data already exist and need to be collated and, in some cases, validated. Recommendations for improved/additional data needs were proposed to address the current information gaps identified. In addition, it was recommended that all provinces/territories should have a surveillance system for varicella in place, although the systems do not necessarily need to be the same at the onset of immunization programs.

The surveillance system should attain seven goals: (1) allow descriptive analysis of varicella incidence; (2) detect changes in severe varicella disease; (3) monitor changes in the epidemiology of herpes zoster; (4) measure vaccine coverage; (5) monitor vaccine safety; (6) provide estimates of vaccine effectiveness in the field; and (7) enhance the capacity of the laboratory for varicella testing to support surveillance.

The surveillance methods used to estimate incidence must be flexible and dynamic so that as incidence drops, the reporting method may change, for example from aggregate reporting during the implementation phase (which includes the period before and during actual program implementation) to case-by-case reporting during a control phase . The definition of the control phase was identified as a research need. Further research is also required to standardize the definition of susceptibility ; this includes determining the levels of antibodies that correlate with protection against infection, establishing test reliability for various commercial test kits, and determining clearly what are positive and negative test results.

Once varicella control has been achieved, surveillance strategies for the elimination phase will need to be established, such as intensified outbreak control, contact tracing, and continued laboratory confirmation of cases and differentiation of wild versus vaccine virus strains.

Additional/improved data needs

Recommendation 5.1

All provinces should have a surveillance system that can provide information on the number and age distribution of cases of both varicella and herpes zoster.

Recommendation 5.2

Canadian data should be gathered on the epidemiology and burden of illness in pregnancy. This should include gestational varicella and herpes zoster; perinatal varicella (maternal and infant); and congenital varicella syndrome (add to the Canadian Paediatric Surveillance Program as active surveillance).

Recommendation 5.3

National population-based data should be gathered on the incidence of severe disease, particularly in adults, including hospitalizations and deaths.

Recommendation 5.4

Varicella and herpes zoster should be added to the Vital Statistics List of Rare and Infrequent Causes of Death.

Surveillance goals

Recommendation 5.5

A goal should be adopted to detect changes in the age-specific incidence of varicella.

The specific strategies/methods to achieve the specified goal are as follows:

- **Implementation phase:** aggregate reporting, using sources such as schools, nurseries, daycare centres, emergency departments, walk-in clinics, sentinel physicians, and health claims data
- **Control phase:** case-by-case reporting, including enhanced sentinel surveillance and outbreak investigation and control (with laboratory confirmation of cases, differentiation of wild versus vaccine virus strains, and serologic testing)

Recommendation 5.6

A goal should be adopted to describe changes in frequency and risk factors for severe varicella disease (defined as hospitalization or death due to varicella or an associated complication).

The specific strategies/methods to achieve the specified goal are as follows:

- A sentinel hospital-based system, including the following components
  - pediatric: use revised IMPACT surveillance
  - adult: use existing systems (e.g. Canadian Hospital Epidemiology Committee, Canadian Infectious Disease Society, Community Hospital Infection Control Association Canada) to identify patients and collect data
  - report cases to provincial/territorial epidemiologists
  - collate data at a national level
- Laboratory differentiation of VZV strains (wild type versus vaccine strain)
- For deaths, a review of the vital statistics database

Recommendation 5.7

A goal should be adopted to monitor changes in the epidemiology of herpes zoster.

The specific strategies/methods to achieve the specified goal are as follows:

- **Implementation phase:** to continue baseline monitoring and, for childhood herpes zoster, establish case-by-case reporting (through the Canadian Paediatric Surveillance Program) and laboratory differentiation of wild type versus vaccine virus strains
- **Control phase:** to continue baseline monitoring and initiate case-by-case reporting for adults aged 20 to 50 years through sentinel physicians and hospital-based reporting

Recommendation 5.8

A goal should be adopted to measure vaccine coverage in targeted populations.

The specific strategies/methods to achieve the specified goal are as follows:

- to add varicella vaccine to the annual National Vaccine Coverage Survey
- to utilize existing registries such as the provincial immunization registries and the national network of registries
- to adjust coverage estimates for prior disease (which would result in falsely low coverage) if indicated, based on vaccine target population

Recommendation 5.9

A goal should be adopted to monitor vaccine safety.

The specific strategies/methods to achieve the specified goal are as follows:

- to use existing systems to monitor vaccine-associated adverse events
- to monitor childhood herpes zoster post-vaccination (see Recommendation 5.7)
- to monitor transmission of vaccine virus to contacts; if disease is severe, case-by-case investigation should be carried out (see Recommendation 5.6)
- to report inadvertent vaccination of pregnant women to existing pregnancy registries (e.g. manufacturer-based registries, Motherisk)
- to monitor the inadvertent vaccination of pregnant women by adding a question

regarding prior vaccine exposure to the prenatal form

Recommendation 5.10

A goal should be adopted to measure vaccine effectiveness in the field.

The specific strategies/methods to achieve the specified goal are as follows:

- **Implementation phase:** selected outbreak investigation among vaccinated populations
- **Implementation phase:** special studies (seroepidemiology among immunized populations, immunogenicity under field conditions)
- **Control phase:** investigation of disease in vaccinated individuals

Recommendation 5.11

A goal should be adopted to ensure laboratory capacity for VZV testing to support surveillance.

The specific strategies/methods to achieve the specified goal are as follows:

- to have in place a readily available laboratory capacity (i.e. a provincial laboratory or a reference laboratory) to confirm the diagnosis of VZV infection as needed, and to determine susceptibility to VZV as needed
- to establish a national reference laboratory to perform strain characterization and to ensure quality assurance

Recommendation 5.12

A goal should be adopted to disseminate surveillance data.

The specific strategies/methods to achieve the specified goal are as follows:

- each province/territory should have a system in place for regular, timely dissemination of surveillance data
- to compile surveillance data at the national level as part of the annual immunization report
- to add varicella updates to LCDC s web site during the implementation phase

Recommendation 5.13

The surveillance methods should be evaluated:

- Ongoing evaluations of the surveillance systems should be built in by those responsible for the systems.
- Periodic special studies should be conducted to ensure the validity of the data.
- Regular surveys of users of surveillance systems should be conducted to evaluate ease of use of the system and the suitability and utility of the data.
- The systems should be modified or new systems developed as gaps are identified by users and expert groups.

Research Needs

Participants identified a number of research needs and priorities related to varicella, outlined below. It was also recommended that these priorities be brought to the attention of appropriate funding bodies so that research funds can be made available to address them.

- General immunization issues, such as the need for booster doses and waning immunity, should be addressed.
- Studies should be done to assess the molecular epidemiology of VZV strains in Canada.
- Mechanisms of and susceptibility to VZV embryopathy should be defined.
- Models should be used to predict when surveillance systems should shift from aggregate to case-by-case reporting and when special studies should be done for case investigation. Surveillance data should be periodically fed back into the models to improve their predictive capacity.
- Appropriate and safe immunization strategies should be determined for immunocompromised patients, including HIV-infected persons; cancer patients in remission; solid organ transplant recipients; bone marrow transplant recipients; patients with hypogammaglobulinemia; leukemia patients (e.g. whether to immunize 3 months after treatment, and the role of acyclovir); persons with chronic lung disease (e.g. cystic fibrosis); and other immunocompromised individuals, such as those receiving cyclosporine treatment.
- Studies should be done to determine the potential for early use of vaccine in anatomically compromised individuals (e.g. persons with pulmonary conditions or skin disease); persons with chronic heart disease; and pre-operative cases (for elective surgeries).
- History and serologic status of health care workers should be investigated to establish (1) a Canadian profile among the age groups in this population; (2) the benefits of booster vaccine, if any; and (3) the potential need to revise the definition of health care worker with respect to potential work exposure.
- Epidemiologic studies should be undertaken to determine whether any of the following groups are at higher risk and should be identified as priorities for specific immunization strategies: aboriginal persons (e.g. whether aboriginal children are at higher risk of complications from varicella, whether invasive group A streptococcal infections are more common, whether children are at risk for missed vaccination opportunities because of relocation); homeless persons; and immigrants (e.g. seroprevalence information to determine endemicity from country of origin).
- Special studies in pregnant women should be carried out to determine how many times a pregnant woman should be screened; the loss of immunity; and prospective (anonymous) varicella prevalence among pregnant women or babies.

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Appendix B

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Appendix C

Background Reference Materials

Overview of VZV Infections/General Epidemiology

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