

An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI)_†

Varicella Proof of Immunity - 2015 Update

PROTECTING CANADIANS FROM ILLNESS



Public Health
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**TO PROMOTE AND PROTECT THE HEALTH OF CANADIANS THROUGH LEADERSHIP, PARTNERSHIP,
INNOVATION AND ACTION IN PUBLIC HEALTH.**

—Public Health Agency of Canada

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PREAMBLE

The National Advisory Committee on Immunization (NACI) provides the Public Health Agency of Canada (hereafter referred to as the Agency) with ongoing and timely medical, scientific, and public health advice relating to immunization. The Agency acknowledges that the advice and recommendations set out in this statement are based upon the best current available scientific knowledge and is disseminating this document for information purposes. NACI members and liaison members conduct themselves within the context of the Agency's Policy on Conflict of Interest, including yearly declaration of potential conflict of interest.

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SUMMARY OF INFORMATION CONTAINED IN THIS NACI STATEMENT

The following summary provides key information for immunization providers. Please refer to the remainder of the Statement for details.

1. What

Varicella (chickenpox) is a viral disease that typically occurs in childhood. Immunization is recommended as a part of the routine childhood schedule.

2. Who

For the targeted populations listed, the following conditions are considered criteria for immunity to varicella:

1. **Pregnant women exposed to varicella and Immunocompromised patients:**
Documented evidence of immunization with two doses of a varicella-containing vaccine; or laboratory evidence of immunity, except for hematopoietic stem cell transplant (HSCT) recipients who are considered susceptible, until appropriately revaccinated after transplant.
2. **Health Care Workers**
- Currently employed or who have been employed in another Canadian healthcare setting: Self-reported history or diagnosis of varicella or herpes zoster by a health care provider, if the disease occurred before the year of a one-dose varicella vaccine program implementation; documented evidence of immunization with two doses of a varicella-containing vaccine; or previous laboratory evidence of varicella immunity.
3. **Health Care Workers**
- Newly hired into the Canadian healthcare system: Documented evidence of immunization with two doses of a varicella-containing vaccine; or previous laboratory evidence of varicella immunity.
4. **Healthy individuals:**
Self-reported history or diagnosis of varicella or herpes zoster by a health care provider, if the disease occurred before the year of varicella immunization program implementation; documented evidence of immunization with two doses of a varicella-containing vaccine; or previous laboratory evidence of varicella immunity.

3. How

Immunization should be offered to all susceptible individuals without contraindications to varicella vaccination. Pregnant women who are not immune to varicella should have vaccination offered post-partum.

New employment in a healthcare setting (i.e. Canadian HCW moving into a new facility within Canada) should be seen as an opportunity to assess immunity to varicella and to offer two doses of varicella vaccine when the status of immunity is in doubt.

4. Why

Identifying who is susceptible to varicella is important to allow for appropriate immunization strategies and post-exposure management.

I. INTRODUCTION

The National Advisory Committee on Immunization (NACI) currently recommends a 2-dose varicella vaccination schedule for all children aged 12 months to 12 years of age. Susceptible adolescents (12 to 17 years) and adults (18 years and older) should also be vaccinated. The Canadian Immunization Guide⁽¹⁾ enumerates criteria for proof of immunity.

In the United States, the Advisory Committee on Immunization Practices (ACIP)⁽²⁾ emphasizes limiting the number of false-positive reports of immunity by focusing on a diagnosis of varicella by a health-care provider, rather than self-reporting. In addition, because serologic evidence of varicella zoster virus (VZV) infection has been documented in 96%–97% of U.S.-born adults aged 20–29 years and in 97%–99% of adults aged ≥30 years tested during 1998–1999, birth in the United States before 1980 is considered evidence of immunity. This assumption does not apply to HCW, pregnant women, and immunocompromised persons. For these groups, certainty regarding immunity is necessary because of the possibility of nosocomial transmission to high-risk patients, transmission of the virus to the fetus, which might result in congenital varicella syndrome, and the possibility of severe disease.

The predictive value of self-reported disease was high in adults in the pre-vaccine era⁽³⁾⁻⁽⁵⁾. Since the introduction of universal vaccination programs in Canada, there has been a documented decrease in the prevalence of wild type varicella⁽¹⁾. This decreased prevalence will lead to lower positive predictive value of self-reported history of chickenpox, therefore requiring a re-examination of the criteria used for the determination of varicella immunity.

II. METHODS

Following a search of the literature and critical appraisal of 22 individual studies that examined the validity of self-reported history of chickenpox among children and adolescents, adults and healthcare workers, the NACI Varicella Working Group (VWG) presented the evidence and proposed recommendations to NACI. Following thorough review of the evidence and consultation at NACI meetings (June 4 and October 2, 2014), the committee voted on specific recommendations. The description of relevant considerations, rationale for specific decisions, and knowledge gaps are described in the text of this update.

III. EPIDEMIOLOGY

Varicella occurs worldwide and, in temperate countries without vaccination programs, it is mainly a disease of childhood, developing in 50% of children by the age of 5 years and 90% by the age of 12 years. In Canada, since the introduction of childhood varicella immunization programs, studies have found a decrease in the disease burden. However, assessing the effect of varicella immunization programs on the incidence of the disease is difficult as varicella infections are significantly under-reported, with less than 10% of the expected cases reported annually. Nationally limited surveillance information on varicella is available through Canadian Notifiable Disease Surveillance System (CNDSS) and the Immunization Monitoring Program, ACTIVE (IMPACT). More information about current varicella epidemiology in Canada is available on the Agency website: <http://www.phac-aspc.gc.ca/im/vpd-mev/varicella-eng.php>.

The predictive value of a reported history of varicella in determining natural immunity was assessed in 22 studies that looked at the seroprevalence and self-reported or parent-reported

history in various populations, including large samples of children, teenagers and adults and healthcare workers, from temperate and tropical countries. Tables 1-3 summarize the positive and negative predictive values for the various populations.

Table 1: Predictive value of reported history of varicella among children and youth (≤ 15 years)

Study Author(s)	Year of study	Country	Age range	Sample (N)	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)
Parella D ⁽⁶⁾	2004-2006	USA	1-14 years	730	90	85	85	90
Field N ⁽⁷⁾	2012	UK	11-15 years	181	94	20	68	65
Bricks LF ⁽⁸⁾	2003-2006	Brazil	1-5 years	204	90	93	80	97
Diez-Domingo J ⁽⁹⁾	2003	Spain	6-15 years	184	95	48	86	74
Heininger U ⁽¹⁰⁾	1999-2000	Switzerland	1-18 years	449	98	87	90	97
Koturoglu G ⁽¹¹⁾	2007-2008	Turkey	1-19 years	337	85	73	78	80
Mohanty S, Perella D, Jumaan A, et al. ⁽¹²⁾	2004-2006	USA	5-14 years	353	91	41	88	49
Kavaliotis J ⁽¹³⁾	1999-2001	Greece	1-14 years	632	88	89	81	93
Pooled				2136	92	81	84	91
Average					92	68	83	82

Table 2: Predictive value of reported history of varicella among youth and adults (≥15 years unless reported elsewhere) including HCWs

Study Author(s)	Year of Study	Country	Age range	Sample (N)	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)
Parella D⁽⁶⁾	2004-2006	USA	15-29 years	746	98.4	23.0	86.3	74.4
Alanen A⁽³⁾	2000		16-45 years	558	98.5	13.2	85.3	63.2
Artega A⁽¹⁴⁾	2006	Spain	18-26 years	226	86.2	25.0	64.3	53.7
Celikbas A⁽¹⁵⁾	2005	Turkey	17-52 years	363	100.0	2.5	23.9	100.0
Dashraath P⁽¹⁶⁾	2000-2005	Singapore	16-36 years	1987	87.2	83.2	94.3	67.1
Koturoglu G⁽¹¹⁾	2007-2008	Turkey	>20 years	200	91.6	8.3	71.2	28.6
Abbas M⁽¹⁷⁾	2006	Saudi Arabia	20-60 years	380	98.4	39.7	86.1	87.1
De Juanes JR⁽¹⁸⁾	After 2000	Spain	23-40 years	76	98.2	30.0	79.7	85.7
Alp E⁽⁵⁾	2010-2011	Turkey	19-60 years	1255	98.0	2.0	83.0	20.0
Trevisan A⁽¹⁹⁾	2003-2005	Italy	Mean 23 years	610	98.3	34.9	90.2	76.9
Almuneef M⁽⁴⁾	2002-2003	Saudi Arabia	20-60 years	231	89.0	21.7	57.4	62.5
Kanra G⁽²⁰⁾	1998	Turkey	20-23 years	180	100.0	5.3	59.1	100.0
MacMahon E⁽²¹⁾	2001-2002	UK	Mean 27.5 years	623	95.0	18.1	77.1	55.8
Singru S⁽²²⁾	After 2000	India	Mean 20 years	81	91.5	38.1	62.3	80.0
Mohanty S⁽¹²⁾	2004-2006	USA	15-19 years	183	98.8	6.3	91.7	33.3
Pooled				8493	93.3	33.4	77.7	66.5

Average	95.3	23.4	74.1	65.9
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Table 3: Predictive value of reported history of varicella among HCWs

Study Author(s)	Year of study	Country	Age range	Sample (N)	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)
Abbas M⁽¹⁷⁾	2006	Saudi Arabia	20 – 60 years	380	98	40	86	87
De Juanes JR⁽¹⁸⁾	2003	Spain	23 – 40 years	76	98	30	80	86
Alp E⁽⁵⁾	2010-2011	Turkey	19 – 60 years	1255	98	2	83	20
Trevisan A⁽¹⁹⁾	2003-2005	Italy	Mean 23 years	610	98	35	90	77
Almuneef M⁽⁴⁾	2002-2003	Saudi Arabi	20 – 60 years	1058	89	22	57	63
Kanra G⁽²⁰⁾	1998	Turkey	20-23 years	180	100	5	59	100
MacMahon E⁽²¹⁾	2001-2002	UK	Mean 27.5 years	623	95	18	77	56
Singru S⁽²²⁾	Not reported	India	Mean 20 years	81	91	38	62	80
Pooled				4263	95	23	73	68
Average					96	24	74	71

The positive predictive value (PPV) of self- or parental reported disease was consistent among all age groups. In the healthcare worker population, there is a high pooled PPV associated with self-report of varicella disease of 95% (range: 89 - 100%). The same has been seen in youth over 15 years of age and adults (pooled PPV: 93.3% [range 86.2-100%] and in children and adolescents (pooled PPV: 92% [range: 85-98%]. These values are, however, dependent on disease prevalence.

To overcome the impact of changing disease prevalence, likelihood ratios (LR) of a positive test (or LR+: the impact of self-reporting a varicella disease on the probability of being immune to varicella) can be used. A LR+ is considered significant when greater or equal to 10 and means that the pre-test probability is significantly affected by the factor or test that is being studied. For varicella, the LR+ are low across all age groups. For the healthcare worker population, the LR+ (i.e. reporting a history of varicella disease) was low at 2.28, suggesting that a self-reported history does not improve significantly the pre-test probability of having had varicella in the past; the high PPV reported is inherently due to the high baseline seroprevalence of varicella. Although this issue applies to the entire population, the impact of considering someone immune to varicella when they are susceptible has a greater impact in some populations, such as healthcare workers providing care to vulnerable patients.

IV. VACCINE PROGRAM IMPLEMENTATION

Table 4 provides information on the month and year of the one-dose varicella immunization program implementation in Canadian Provinces and Territories (P/T), after which reported history of varicella should not be considered as a proof of immunity, as its implementation had a marked impact on the prevalence of wild-type varicella disease.

Table 4: Implementation of one-dose varicella immunization programs in Canadian Provinces and Territories⁽²³⁾

Province or territory	Initial implementation of a varicella immunization program (month and year)
Prince Edward Island	April 2000
Alberta	March 2001
Northwest Territories	Sept. 2001
Nova Scotia	Jan . 2003
Nunavut	Sept. 2002
Ontario	Sept. 2004
New Brunswick	Sept. 2004
Manitoba	Oct. 2004
Newfoundland & Labrador	Jan. 2005
Saskatchewan	Jan. 2005
British Columbia	Jan. 2005
Quebec	Jan. 2006
Yukon	Jan. 2007

V. UPDATED RECOMMENDATIONS

In formulating recommendations, the following observations have been taken into account:

1. Due to the low incidence of disease following the implementation of immunization programs (one-dose program), self-reported history or clinical diagnosis by a health care provider is increasingly unreliable;
2. History of varicella is going to be increasingly difficult to establish, including the ability of health care providers to diagnose cases without laboratory testing.
3. Given the high baseline seroprevalence prior to the introduction of varicella programs, adults currently have a high likelihood of being immune to varicella;
4. History of varicella infection as reported by a parent is of uncertain reliability. Both Canadian Pediatric Society (CPS) and ACIP accept only health care provider diagnosis as indicative of past infection with varicella.
5. High-risk, susceptible individuals, including pregnant women, need to be protected from infection. Varicella during pregnancy can have adverse consequences for the mother and fetus, including congenital varicella syndrome.
6. The value of serology in the absence of natural disease is uncertain, due to poor sensitivity of commercial assays in detecting vaccine-induced immunity. In contrast, vaccination is reliable and cost-effective.
7. For the vast majority of vaccine-preventable diseases, NACI currently recommends that, when in doubt about previous disease or immunization status, an individual should be immunized.

It was also the shared opinion that the following principles should guide the determination of recommendations:

- For individuals at high risk for varicella complications, self-reported history cannot be considered as acceptable evidence of immunity;
- Because of the significant risk from varicella infection in immunocompromised individuals, it is important to ensure that HCWs are immune to varicella;
- Serological testing is not practical and not necessary in the general population;
- Immunizing individuals who lack adequate documentation is simple, safe, and effective.

Recommendation #1: For healthy individuals (including pregnant women without significant exposure* to VZV)

Individuals who have ANY of the following are considered immune to varicella:

- Self-reported history or diagnosis of varicella or herpes zoster by a health care provider, if the disease occurred before the year of implementation of a one-dose vaccine program (Grade B);
- Documented evidence of immunization with two doses of a varicella-containing vaccine (Grade A);
- Previous laboratory evidence of immunity** (Grade A);

Recommendation #2: For healthy pregnant women with significant exposure*to VZV and for immunocompromised individuals

* For the definition of significant exposure refer to the Varicella Vaccine Chapter in the Canadian Immunization Guide

** Laboratory testing should be conducted only once in a lifetime. If a person has been found to be seropositive, it is not necessary to test again.

Individuals who have ANY of the following are considered immune to varicella:

- Documented evidence of immunization with two doses of a varicella-containing vaccine (Grade A);
- Laboratory evidence of immunity** (Grade A);

Recipients of a hematopoietic stem cell transplant (HSCT) should be considered susceptible in the post-transplantation period regardless of a history of varicella disease or vaccination, or positive serologic test results, until appropriately revaccinated after HSCT.

Recommendation #3: For HCWs who are currently employed in or who have been employed in another Canadian healthcare setting

Individuals who have ANY of the following are considered immune to varicella:

- Self-reported history or diagnosis of varicella or herpes zoster by a health care provider, if the disease occurred before the year of implementation of a varicella vaccine program (one dose) (Grade B);
- Documented evidence of immunization with two doses of a varicella-containing vaccine (Grade A);
- Previous laboratory evidence of varicella immunity** (Grade A)

New employment in a healthcare setting (i.e. Canadian HCW moving into a new facility within Canada) should be seen as an opportunity to assess immunity to varicella and to offer two doses of varicella vaccine when the HCW has not been shown to be immune.

Following exposure to varicella within health care settings, verification of immunity, based on documented evidence of immunization with two doses of a varicella-containing vaccine or laboratory evidence of immunity, should be a part of post-exposure protocols.

Recommendation #4: For HCWs who are newly hired into the Canadian healthcare system

Individuals who have ANY of the following are considered immune to varicella:

- Documented evidence of immunization with two doses of a varicella-containing vaccine (Grade A);
- Previous laboratory evidence of varicella immunity** (Grade A).

Following exposure to varicella within health care settings, verification of immunity, based on documented evidence of immunization with two doses of a varicella-containing vaccine or laboratory evidence of immunity, should be a part of post-exposure protocols.

Recommendation #5: Immunization should be offered to all susceptible individuals without contraindications to varicella vaccination. Pregnant women who are not considered immune to varicella (as per Recommendation #1) should have vaccination offered post-partum (Grade A).

Detailed information about immunization in pregnancy and breastfeeding is available in the Canadian Immunization Guide.

Table 5. Levels of Evidence Based on Research Design

I	Evidence from randomized controlled trial(s).
II-1	Evidence from controlled trial(s) without randomization.
II-2	Evidence from cohort or case-control analytic studies, preferably from more than one centre or research group using clinical outcome measures of vaccine efficacy.
II-3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
III	Opinions of respected authorities, based on clinical experience, descriptive studies and case reports, or reports of expert committees.

Table 6. Quality (internal validity) Rating of Evidence

Good	A study (including meta-analyses or systematic reviews) that meets all design- specific criteria* well.
Fair	A study (including meta-analyses or systematic reviews) that does not meet (or it is not clear that it meets) at least one design-specific criterion* but has no known "fatal flaw".
Poor	A study (including meta-analyses or systematic reviews) that has at least one design-specific* "fatal flaw", or an accumulation of lesser flaws to the extent that the results of the study are not deemed able to inform recommendations.

* General design specific criteria are outlined in Harris RP, Helfand M, Woolf SH, et al. Current methods of the US Preventive Services Task Force: a review of the process. Am J Prev Med 2001;20:21-35.

Table 7. NACI Recommendation for Immunization -- Grades

A	NACI concludes that there is good evidence to recommend immunization.
B	NACI concludes that there is fair evidence to recommend immunization.
C	NACI concludes that the existing evidence is conflicting and does not allow making a recommendation for or against immunization; however other factors may influence decision-making.
D	NACI concludes that there is fair evidence to recommend against immunization.
E	NACI concludes that there is good evidence to recommend against immunization.
I	NACI concludes that there is insufficient evidence (in either quantity and/or quality) to make a recommendation, however other factors may influence decision-making.

LIST OF ABBREVIATIONS

<i>Abbreviation</i>	<i>Term</i>
ACIP	Advisory Committee on Immunization Practices
CPS	Canadian Pediatric Society
HSCT	Hematopoietic Stem Cell Transplant
MMRV	Measles, mumps, rubella and varicella
NACI	National Advisory Committee on Immunization
NPV	Negative Predictive Value
PPV	Positive Predictive Value
Var	Varicella
VZV	Varicella zoster virus

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