Updates to the Human Papillomavirus Nonavalent (GARDASIL®9/HPV9) Immunization Program Q&A for Immunization Providers – July 2025

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1. What are the changes to the eligibility criteria for the publicly funded HPV9 immunization program in BC?

Table 1. Summary of changes to BC's HPV9 immunization program*

As of July 31, 2025, BC's HPV9 immunization program has **expanded** to include the following individuals (changes are indicated in **bold**):

- All individuals up to 26 years of age (inclusive)**
- Individuals living with HIV between 27-45 of age (inclusive)***
- Individuals 27-45 years of age (inclusive) who self-identify as belonging to the gay, bisexual, and other men who have sex with men community, including Two-Spirit, transgender, and/or nonbinary people (including those who are not yet sexually active and/or are questioning their sexual orientation)***
- Individuals who have received post-colposcopy treatment for cervical dysplasia on or after July 31, 2025
- Information drawn from the BC Immunization Manual

**Those who have already turned or will be turning 27 in 2025 (i.e., birth cohort 1998) can initiate a publicly funded HPV vaccine series until the end of 2025. They must complete their publicly funded series by December 31, 2026.
***Select eligible groups who have already turned or will be turning 46 in 2025 (i.e., birth cohort 1979) can initiate a publicly funded HPV vaccine series until the end of 2025. They must complete their publicly funded series by December 31, 2026.

For further details, see Part 4 — Biological Products, HPV Vaccine, in the BC Immunization Manual.

2. What are the changes to the schedule for the HPV9 immunization program?

Changes to BC's HPV9 immunization program include a 1-dose schedule for those under 21 years of age and a 2-dose schedule for those 21 years of age and older. Individuals who are immunocompromised remain on a 3-dose schedule. See Table 2 below and <u>Part 4 — Biological Products, HPV Vaccine</u> for details.

	Table 2. Schedule*	
	Prior to July 31, 2025	On or after July 31, 2025
Immunocompetent individuals	 <u>9-14 years of age (inclusive)</u>: 2 doses separated by at least 6 months <u>Individuals 15 years of age and</u> <u>older:</u> 3 doses given at 0, 2, and 6 	 <u>9-20 years of age (inclusive)</u>: 1 dose <u>21-45 years of age (inclusive)</u>: 2 doses given at 0 and 6 months
Immunocompromised individuals	 <u>Individuals 9 and older</u>: 3 doses given at 0, 2, and 6 months 	 Immunocompromised individuals, including individuals living with HIV, 9-45 years of age (inclusive): 3 doses given at 0, 2, and 6 months
Post-colposcopy treatment for cervical dysplasia	N/A	• 3 doses given at 0, 2, and 6 months

*Information drawn from the BC Immunization Manual

3. Why have the number of doses in the HPV9 vaccine series decreased and how has BC's HPV9 immunization program evolved over time?

Changes to the number of doses in the HPV9 vaccine series in BC's HPV9 immunization program are aligned with the National Advisory Committee on Immunization's (NACI) <u>Updated Recommendations on</u> <u>Human Papillomavirus (HPV) Vaccines</u>. In July 2024, NACI updated their guidance on HPV vaccines to include a strong recommendation that individuals 9 to 20 years of age should receive one dose, and individuals 21 to 26 years of age should receive two doses of HPV vaccine.¹

In 2007, HPV vaccines were first introduced in Canada with a 3-dose schedule for adolescents and young adults. Following research showing that two doses provided the same immune protection, NACI provided updated guidance for a 2-dose schedule in immunocompetent youth aged 9 to 14 years.¹

Over the last decade, several clinical trials and studies in females have shown that one dose of HPV vaccine can provide comparable protection against HPV infection and disease among 9- to 20-year-olds. Infectious disease vaccine modelling has shown that under reasonable assumptions, a 1-dose schedule in Canada is expected to have similar health outcomes over the short and long term compared to a 2-dose schedule. Evidence is currently limited to studies in females, with current follow-up extending to 11 years following vaccination.¹

NACI will continue to monitor evidence of 1-dose HPV vaccine schedules as evidence becomes available from clinical trials, Canadian data, and other countries where similar schedules are adopted (e.g., United Kingdom and Australia).¹

4. Have any other immunization programs outside of BC implemented a 1-dose HPV9 vaccine schedule?

In December 2022, the World Health Organization (WHO) published <u>updated recommendations</u> on HPV vaccine schedules, noting that a single-dose schedule, referred to as an alternative, off-label single-dose schedule, can provide comparable efficacy and durability of protection to a 2-dose regimen for individuals aged 9 to 20 years, and recommended a 1- or 2-dose schedule in this age group.¹

Since then, several countries have implemented a 1-dose HPV vaccine schedule. This includes several G20 countries, such as the United Kingdom and Australia, where existing multi-dose HPV immunization programs were switched to 1-dose programs.¹ A 1-dose schedule has also been implemented in Quebec and Yukon.

5. What are the minimum intervals between doses of a 2- or 3-dose HPV vaccine series?

Table 3. Minimum intervals between doses of a 2- or 3-dose HPV series (including any combination of HPV2, HPV4, HPV9 and/or HPV unknown)*		
2-dose series	 For two doses given prior to July 31, 2025, the minimum interval is 150 days (or 5 months) For two doses given on or after July 31, 2025, the minimum interval is 24 weeks 	
3-dose series	 dose 2 given ≥ 4 weeks after dose 1 dose 3 given ≥ 12 weeks after dose 2 and ≥ 24 weeks after dose 1 	

See Table 3 below for the minimum intervals between doses of a 2- or 3- dose HPV series.

*Information drawn from the BC Immunization Manual

6. How do I know whether an individual's HPV vaccine series is considered complete?

Whether an individual's HPV series is considered complete depends on several factors, including:

- Age
- Immunocompetence and/or HIV status
- HPV immunization history and minimum intervals between doses
- Receipt of post-colposcopy treatment for cervical dysplasia (see Question 11)

See Table 4 below for populations considered fully immunized based on immunization history.

Table 4. Populations considered fully immunized based on immunization history*	
Population	Immunization history
1. Immunocompetent individuals	 Received one dose HPV9 under 21 years of age, regardless of interval from a dose of HPV2, HPV4, or HPV unknown
	<u>OR</u>
	 Valid 2- or 3-dose HPV series**
2. Immunocompromised individuals (<i>except</i> people	 Received a valid 3-dose HPV series**
living with HIV, and HSCT and CART therapy recipients)	Note: Those who received an age-appropriate HPV series** while immunocompetent are considered complete. Those who started but did not complete an age-appropriate HPV series while immunocompetent and became immunocompromised should receive a total of up to three doses of HPV vaccine.
3. Individuals living with HIV	Received a valid 3-dose series of <u>HPV9</u>

*Information drawn from the BC Immunization Manual

**'HPV series' refers to a complete HPV series of any type (including any combination of HPV2, HPV4, HPV9 or HPV unknown).

Eligible HSCT and CART therapy recipients require re-immunization after treatment. Visit <u>Part 2</u> — <u>Immunization of Special Populations, Specific immunocompromising conditions, HSCT and CART Therapy</u> for details.

See 'Special considerations' in <u>Part 4 — Biological Products, HPV Vaccine</u> for HPV9 eligibility based on previous HPV immunization history.

7. What is the recommendation for individuals who have completed an HPV2 or HPV4 vaccine series, are <u>not</u> eligible for publicly funded HPV9 vaccine, and wish to receive it?

NACI advises that while not recommended at a population level, in discussion with their health care provider, individuals who have completed a valid HPV2 or HPV4 series and are at ongoing risk of HPV exposure, may benefit from one additional dose of the HPV9 vaccine to receive protection offered by the additional types included in the HPV9 vaccine.¹ In BC, if the client is not eligible for publicly funded HPV9 vaccine, this dose would need to be purchased.

8. What are the recommendations for individuals 27 years of age and older who are not eligible for publicly funded HPV9 vaccine?

NACI recommends that individuals 27 years of age and older may receive the HPV vaccine with shared decision making and discussion with a health care provider. For more information, read NACI's <u>Updated</u> recommendations on Human Papillomavirus (HPV) vaccines.

In BC, only those for whom HPV vaccine is indicated as noted in <u>Part 4 — Biological Products, HPV</u> <u>Vaccine</u> are eligible for publicly funded HPV vaccine. See 'Doses and schedule' for dosing and schedule considerations.

9. How has the eligibility for HPV9 vaccine changed for individuals living with HIV, and why?

As of July 31, 2025, individuals 9-45 years of age (inclusive) living with HIV are eligible for up to a total of 3 doses of HPV9 irrespective of HPV2, HPV4, or HPV unknown immunization history. Previously received doses of HPV9 are counted towards 3-dose HPV9 series completion.

Individuals living with HIV are at higher risk of HPV infection and HPV-related diseases, including cancer.² As HIV infection is associated with infection with more types of HPV, the HPV9 vaccine provides greater protection.³

10. Why has eligibility for HPV9 vaccine been expanded to individuals who have received post-colposcopy treatment for cervical dysplasia?

See <u>glossary</u> for definitions of cervical intraepithelial neoplasia (CIN) classification systems, colposcopy, and treatment for CIN2+.

Emerging evidence have demonstrated that individuals who had confirmed cervical intraepithelial neoplasia (CIN) and received **post-colposcopy excisional treatment** benefit from receipt of the HPV vaccine. Specifically, HPV vaccination has been shown to significantly reduce the odds of recurrence of CIN2+ (CIN2 and CIN3).^{4–6}

Vaccine recipients should be advised that the HPV vaccine is a preventive vaccine and does not have any therapeutic effect on existing cervical lesions (i.e., vaccine does not prevent the consequences of current HPV infection). In addition, it cannot be guaranteed that HPV vaccination post-cervical treatment will prevent recurrence and patients require continued surveillance.

Glossary

Table 5. Glossary and background for post-colposcopy treatment for cervical dysplasia*		
	Many classification systems are used in different parts of the world to	
Cervical intraepithelial	classify and name precancerous conditions of the cervix based on cytology	
neoplasia (CIN)	(examination of individual cells) and histology (examination of whole tissue	
classification system	sections). The CIN classification system is used to describe the severity of	
	the abnormal changes in the squamous cells of the cervix, based on a tissue	
	biopsy (histology) and ranges from CIN1 (mild dysplasia), CIN2 (moderate	
	dysplasia), and CIN3 (severe dysplasia/carcinoma in situ). With CIN1,	
	cervical dysplasia is mild, with changes to the cells looking only slightly	
	different from normal cells. With CIN2 and CIN3, changes to cells are	
	deeper in the cervical lining, and the cells are considered more abnormal.	
	The higher the grade, the higher the risk of progression to cervical cancer.	
	CIN2 is the threshold for treatment of dysplasia in BC and in many other	
	jurisdictions.	
	Colposcopy is used as a follow-up test to evaluate abnormal cervical cancer	
Colposcopy	screening tests (cytology and/or abnormal findings on gross examination of	
	the cervix, vagina or vulva). A colposcopy is a diagnostic procedure in which	
	a colposcope (a dissecting microscope with various magnification lenses) is	
	used to provide an illuminated, magnified view of the cervix, vagina, or	
	vulva. The primary goal of colposcopy is to identify precancerous and	
	cancerous lesions so that they may be treated early.	
	This refers to the treatment required after abnormal colposcopic findings,	
Treatment for CIN2+	such as histologically proven CIN2 or greater. Following abnormal	
	colposcopy findings, treatment options include ablation (i.e., cryotherapy or	
	laser) or diagnostic excision (e.g., loop electrosurgical excision procedure	
	[LEEP] or cold knife conization).	

*Information drawn from multiple sources7-10

11. For how many doses of HPV9 vaccine are individuals who have received postcolposcopy treatment for cervical dysplasia eligible?

Individuals who have received post-colposcopy treatment for cervical dysplasia who have not previously received any doses of HPV vaccine are eligible for a 3-dose series given as 0.5 mL **IM** at 0, 2, and 6 months.

Individuals who have completed an age-appropriate HPV vaccine series (including HPV2, HPV4, HPV9, and/or HPV unknown) prior to post-colposcopy treatment for cervical dysplasia are not eligible for further doses of HPV9.

Individuals who have received an incomplete HPV vaccine series are eligible for up to a 3-dose HPV series. If given according to minimum intervals, previously received doses of HPV2, HPV4, HPV9, and/or HPV unknown are counted towards 3-dose HPV vaccine series completion.

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12. Why are individuals who have received post-colposcopy treatment for cervical dysplasia offered a 3-dose schedule (instead of a schedule based on immunocompetence/age)?

To date, the benefit of HPV vaccination after post-colposcopy treatment for cervical dysplasia have primarily been evaluated with a 3-dose schedule.⁵

13. When should an individual initiate or complete their HPV series after receiving post-colposcopy treatment for cervical dysplasia?

While a 3-dose HPV vaccination series should ideally be initiated or completed as soon as possible after treatment, there is no minimum or maximum timeframe within which it must either be initiated or completed.

14. Which individuals are eligible for publicly funded HPV vaccine after receiving postcolposcopy treatment for cervical dysplasia?

See Table 6 below for HPV9 vaccine eligibility considerations for recipients of post-colposcopy treatment for cervical dysplasia.

Table 6. HPV vaccine eligibility for recipients of post-colposcopy treatment for cervical dysplasia	
Program start	Only BC residents who have had treatment to their cervix (e.g., LEEP or cold knife conization) on or after July 31, 2025 (whether within or outside of BC),
	are eligible for publicly funded HPV vaccine.
Age	Individuals of any age who have received treatment to the cervix will be eligible for publicly funded HPV vaccine based on previous HPV immunization history (see Table 4 in Question 6).
	Note: Although HPV9 vaccine is approved by Health Canada for use in individuals 9 to 45 years of age, NACI indicates that HPV vaccine may be considered for individuals older than 45 years of age based on risk. Therefore, individuals of any age who have received post-colposcopy treatment for cervical dysplasia, including individuals over the age of 45, are eligible for publicly funded HPV9.

15. Do individuals need to provide proof that they received post-colposcopy treatment for cervical dysplasia to be eligible for publicly funded HPV9 vaccine?

No. Individuals can self-identify as having received treatment for cervical dysplasia identified during colposcopy.

16. Have the recommendations for the receipt of HPV vaccine in pregnancy been revised?

Yes. Prior to July 31, 2025, a 'Precaution' was listed in <u>Part 4 — Biological Products, HPV vaccine</u>, indicating that HPV vaccine is not recommended in pregnancy.

As per NACI's <u>Updated recommendations on Human Papillomavirus (HPV) vaccines</u>, HPV vaccine can be administered in pregnancy. The HPV vaccine is expected to provide a benefit to anyone who is at ongoing risk of HPV infection, including during pregnancy. Therefore, the pregnancy-related 'Precaution' has been removed from <u>Part 4 — Biological Products</u>, HPV vaccine.¹¹

Available evidence specific to the safety of HPV9 vaccination during or around pregnancy indicates no increased risk of adverse pregnancy or fetal outcomes associated with HPV9 vaccine during or around pregnancy, and any adverse outcomes appear to occur at similar rates as observed in the general population.¹¹

For additional considerations on HPV vaccine in pregnancy, read NACI's <u>Updated Recommendations on</u> <u>Human Papillomavirus (HPV) vaccines</u>.

17. Why has the age of HPV vaccine eligibility been expanded to 45 for individuals who self-identify as belonging to the gay, bisexual, and other men who have sex with men community, including Two-Spirit, transgender, and/or non-binary people?

In a 2012 statement, NACI advised that there is good evidence to recommend the use of Gardasil[®]9 in men who have sex with men (MSM). Compared to the general population, MSM have a disproportionately high burden of HPV infection, particularly vaccine-preventable high-risk types 16 and 18. Infection with high-risk HPV types in particular, increases the risk of anal intraepithelial neoplasia (abnormal cells in the lining of the anus) and is associated with cancer of the anus, particularly among MSM who are HIV-positive.¹¹

Gay, bisexual, and other men who have sex with men (GBMSM) also face barriers to cancer care and HPV immunization uptake. These barriers include fear—or the experience of discrimination by health care professionals and having a previous negative experience with the medical system due to their sexual orientation/practices, among others.^{12,13}

Evidence is also emerging that transgender, and gender diverse* (TGD) people are more affected by HPV types that can cause cancer at high rates. TGD people face additional barriers to cancer care, including deadnaming (i.e., the harmful, accidental, or intentional dismissal, denial, or rejection of a person's gender identity by use of a name other than their Lived Name¹⁴), misgendering, and a lack of provider knowledge about gender affirming care, among other systemic and structural barriers. As well, health care professionals generally have a lack of knowledge about TGD-specific cancer care. Knowing about HPV, how it can affect their health, and how to prevent it can help TGD people make informed decisions about their sexual health.¹²

The inclusion of "Two-Spirit, transgender and/or non-binary people", recognizes those who do not identify as men while belonging to or sexually engaging with the MSM community; and acknowledges the historic and ongoing erasure of transgender, non-binary and/or Two-Spirit people from organizational policies and practices.¹⁵

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NOTE: Medical language used to describe certain groups does not always reflect how people experience, perceive, or describe their gender identity, sexual practices, or sexual orientation.¹⁶ The language used in the HPV eligibility criteria is not intended to exclude those who describe their gender identity, sexual orientation, or sexual practices differently.

*For the purposes of this Q&A, the term 'transgender and gender diverse people' was used to reflect the language used in the referenced literature.

See Table 7 below for health care provider resources on providing care to 2S/LGBTQIA+ populations.

Table 7. Health care provider resources on providing care to 2S/LGBTQIA+ populations	
TransCareBC	TransCareBC's course on <u>Gender-Affirming Sexual Health Care</u> is a primer for supporting gender diverse clients with concerns related to their sexual health and wellbeing. This course focuses on integrating key relational practices with gender-affirming care considerations relevant to sexual health.
	Visit <u>TransCareBC</u> for more information on providing gender-affirming care, and
	how to approach discussions about gender identity.
Canadian	Visit CAEP to take a course on 2SLGBTQIA+ Health and Cultural Humility in
Association of	Emergency Medicine. The content of this course is applicable to many health
Emergency	professions.
Physicians (CAEP)	
Community-Based	Visit <u>CBRC</u> 's ' <u>Reports and Publications</u> ' page for resources on providing care to
Research Centre	gay, bisexual, transgender, Two-Spirit, and non-binary people with cultural
(CBRC)	humility, including the <u>Quick Reference Guide: Taking a GBT2Q-affirming sexual</u>
	<u>history</u> .

18. For individuals newly eligible under the age expansion, is there a benefit to getting the HPV vaccine at an older age?

Yes. While HPV vaccine is most effective when given at a younger age (i.e., before exposure to HPV), HPV vaccination is also expected to benefit those already exposed to some HPV types, as it provides protection against all the HPV types included in the vaccine.¹

In the absence of vaccination, it is estimated that 75% of sexually active Canadians will have a sexually transmitted HPV infection at some point in their lives. Even if a person is already infected with one or more vaccine HPV type(s), the vaccine will provide protection against the other HPV type(s) contained in

the HPV9 vaccine. This includes protection against several high-risk cancer-causing types and genital warts. $^{\rm 1}$

In Canada, immunization against HPV types 16 and 18 (included in all HPV vaccines) can prevent approximately 70% of anogenital cancers and 60% of high-risk precancerous cervical lesions. Immunization with HPV9 vaccine can prevent up to an additional 14% of anogenital cancers and up to 30% of high-risk precancerous cervical lesions caused by the additional five HPV types (31, 33, 45, 52 and 58) against which the vaccine protects.¹¹

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