

Receiving the HPV Vaccine

Please ensure to read this form as it contains important information regarding the vaccine.

1 Cervical cancer and human papillomavirus (HPV)

- (1) Cervical cancer is the growth of abnormal cells in the lining of the cervix uteri (the opening of the uterus). Its rate of incidence is currently increasing amongst those in the 20's and 30's, with approximately 11,000 women reportedly developing this cancer annually in Japan. The detection of cervical cancer is often delayed due to it having little to no noticeable symptoms in its early stages. Once the disease progresses, symptoms such as irregular vaginal bleeding and bleeding after sexual intercourse may appear.
- (2) Cervical cancer is caused by the contraction of the human papillomavirus (HPV).
- (3) In most cases, HPV infections are temporary and patients recover without treatment. However, a prolonged period of infection can lead to the on-set of cervical cancer.
- (4) HPV is a very common virus, with most sexually-active women contracting an HPV infection at least once in their lifetime.
- (5) Whilst there are over 200 strains of HPV, only 15 have been identified as carcinogenic. Approximately 50-70% of cervical cancer incidences are caused by two types of HPV –16 and 18.

2 HPV Vaccine Information

- (1) There are three varieties of HPV vaccine available: Cervarix®, GARDASIL®, and SILGARD®9

Cervarix®: prevents infection against HPV types 16 and 18.

GARDASIL®: prevents infection against types 6, 11, 16, and 18.

SILGARD®9: prevents infection against types 6, 11, 16, 18, 31, 33, 45, 52, and 58.

Notes:

HPV strains 16, 18, 31, 33, 45, 52, and 58 are the main types which cause cervical cancer.

HPV strains 6 and 11 are the main types which cause anogenital warts (condylomata acuminata)

- (2) Standard Vaccination Process

Cervarix®: The vaccine is administered via intramuscular injection to the upper arm, and the **second** and **third** doses are administered **one month** and **six months** after the initial dose respectively.

GARDASIL®: The vaccine is administered via intramuscular injection to the upper arm, and the **second** and **third** doses are administered **two months** and **six months** after the initial dose respectively.

SILGARD®9: The vaccine is administered via intramuscular injection to the upper arm, and the **second** and **third** doses are administered **two months** and **six months** after the initial dose respectively. If the first dose is administered when the patient is under 15 years of age, the course of vaccination can be completed with only one subsequent dose after 6 months. The effectiveness of this course of vaccination is relatively equal to three doses.

(3) Precautions

- i. HPV vaccines do not prevent all HPV infections.
- ii. HPV vaccines cannot treat existing HPV infections, nor can they treat or slow the development of existing cervical cancer or pre-cancerous lesions (abnormal cells which may develop into cancer).

3 The following individuals cannot receive the vaccination:

- (1) Those with an obvious fever (of 37.5°C or above).
- (2) Those suffering from a severe acute disease.
- (3) Those with a history of hypersensitivity to vaccine ingredients (including severe allergic reactions accompanied by difficulty breathing or generalized rash, usually appearing within 30 minutes after vaccination). Please speak to your physician for more details on ingredients.
- (4) Those who have been advised by a physician to not receive the vaccination.

4 The following individuals should consult their doctor before receiving the vaccination:

- (1) Those with a low platelet count or those susceptible to bleeding.
- (2) Those with preexisting conditions, such as cardiovascular disease, renal disease, hepatic disease, blood disorders, or developmental disorders.
- (3) Those who developed a fever within two days of receiving a vaccine in the past.
- (4) Those with a history of convulsions.
- (5) Those who have been diagnosed with an immune status abnormality, or have a family history of congenital immune deficiency.
- (6) Those who are pregnant or may be pregnant (during the three-dose vaccination period).
- (7) Those who are currently breastfeeding.
- (8) Those who have received other HPV vaccines.

5 Common Side Effects

- (1) Common side effects which are considered to be related to the vaccine are listed below.

Frequency of Incidence	Cervarix® Bivalent Vaccine	GARDASIL® Quadrivalent Vaccine	SILGARD®9 Nonavalent Vaccine
50% or more	Pain, redness, swelling, fatigue	Pain	Pain
10-49%	Itchiness, abdominal pain, muscle pain, joint pain, headaches	Erythema, swelling	Swelling, erythema, headaches
1-9%	Rash, dizziness, fever	Headaches, itchiness, fever	Dizziness, nausea, diarrhea, itchiness, fever, fatigue, internal bleeding

Less than 1%	Abnormal sensations at the site of injection, numbness, weakness throughout body	Diarrhea, abdominal pain, limb pain, musculoskeletal pain, skin hardening, bleeding, feelings of discomfort, fatigue	Nausea, stomach pain, muscle pain, joint pain, bleeding, hematoma, fatigue, skin hardening
Frequency Unknown	Limb pain, fainting, inflammation of lymph nodes	Fainting, nausea, joint pain, muscle pain, fatigue	Numbness, fainting, limb pain

- (2) In rare instances, one may experience a hypersensitive reactions; such as an anaphylactic reaction, or anaphylaxis- like reaction (difficulty breathing, swelling around the eyes or lips, tracheal spasm (episodic shortness of breath), rash), Guillain-Barre Syndrome (ascending paralysis of both legs), immune thrombocytopenic purpura (ITP) (purple spots, nose bleeds, bleeding of the gums), or acute disseminated encephalomyelitis (ADEM) (paralysis, sensory impairment, motor impairment). If you experience any of the above, please consult with your physician immediately.

6 Compensatory System for those Experiencing Health Complications related to Vaccination

- (1) Those who experience health complications that require medical treatment or develop an impairment affecting their daily life as a result of a routine vaccination can be compensated under the Preventive Vaccination Act.
- (2) Depending on the severity of the health complications experienced, compensation under law is provided for medical expenses, medical allowance, child-rearing pension for disabled children, disability pension, lump-sum death benefit, funeral expenses, and caregiving allowance. Apart from lump-sum death benefits and funeral expenses, these benefits will be paid until the conclusion of treatment for the illness or the period of treatment in the case of impairment.
- (3) However, to receive compensation, a national review committee composed of experts in fields such as vaccination and the treatment of infectious diseases, as well as legal experts, must determine if the health complications are experienced as a direct result of vaccination or if there are other attributing factors (such as infection contracted prior or following vaccination). If it can be proven that the health complications were caused by vaccinations, then you will be eligible to receive compensation.

※For queries regarding compensation applications, please contact the Public Health Promotion Division (053-453-6119) .

ヒトパピローマウイルス感染症予防接種予診票兼接種・非接種通知書
(受ける人が16歳未満で保護者が同伴する場合、受ける人が16歳以上の場合)

Vaccine Screening Questionnaire for Human Papilloma Virus Infection

(For the use if the child is accompanied by the guardian or is married)

Please fill in the blanks and circle the appropriate answer
(Especially the blanks in bold frames)

種類	シルガード9	ガーダシル	サーバリックス	回数	1回目	2回目	3回目	
	24	23	22		1	2	3	
Immunization Date 申込年月日	Year年	Month月	Day日					
Address 住所	Hamamatsu-shi			Temperature 診察前の体温		℃		
				Telephone 電話				
フリガナ				Gender 性別	Birth Date 生年月日	year 年	month 月	day 日
Name of the child 受ける人の氏名								
Name of the guardian※ 保護者の氏名				F 女	Age 年齢	years &		months old

Questions				Answers		Dr. Use
Did you read and undestand the explanation about the vaccination to be administered today? 今日受ける予防接種についての説明書を読み、理解しましたか				No	Yes	
Does the patient have any concerns about the child's health today?今日体に具合の悪いところがありますか If yes, describe the symptoms : 具体的な症状を書いてください ()				Yes	No	
Has the patient been ill within this past month? 最近1ヵ月以内に病気にかかりましたか If yes, describe the illness 病名 ()				Yes	No	
Has the patient received any immunization within the past month? (If yes, describe the date and circle the type) 最近1ヵ月以内に予防接種を受けたか(受けた場合には最後に接種した年月日とワクチンの種類に○を記入してください) Date 接種年月日 year年 month月 day日 ・Japanese encephalitis 日本脳炎 ・Diphtheria / Tetanus DT ・Cervical cancer vaccine子宮頸がん予防 ・Othersその他 ()				Yes	No	
Has the patient ever taken a vaccination of other Human Papilloma Virus Infection? これまでにヒトパピローマウイルス感染症予防接種を受けたことがありますか				Yes	No	
ある場合は接種したワクチンに○をして接種年月日を記載してください		1回目	(シルガード9・ガーダシル・サーバリックス) 年 月 日	種類・間隔		
		2回目	(シルガード9・ガーダシル・サーバリックス) 年 月 日			
Has the patient ever been treating of congenital abnormalities(diseases of heart,renal,liver,neurologic, immunodeficiency or other serious disease)from birth to now? Is the child consulting any physician now? 生まれてから今までに先天性異常、心臓、腎臓、肝臓、脳神経、免疫不全症、その他の病気にかかり、医師の診察を受けていますか If yes, describe the illness 病名 ()				Yes	No	
Did the doctor in charge for the treatment approved the immunization today? その病気を診てもらっている医師に今日の予防接種を受けてよいといわれましたか				No	Yes	
Has the patient ever had convulsions?ひきつけ(けいせん)を起こしたことがありますか If yes, at what age? () 歳頃				Yes	No	
Did the patient have a fever at the time? そのときに熱が出ましたか				Yes	No	
Has the patient ever had skin rash or felt ill after taking any medicine or food?薬や食品、ゴム製品、金属などで皮膚に発疹やじんましんが出たり、体の具合が悪くなったことがありますか If yes, what kind of medicine or food 薬・食品・製品名など ()				Yes	No	
Is there any close relatives with congenital immunodeficiency? 近親者に先天性免疫不全と診断されている方はいますか				Yes	No	
Has the patient ever felt ill after receiving a vaccination? これまでに予防接種を受けて具合が悪くなったことはありますか If yes, what type of vaccine? 予防接種の種類 ()				Yes	No	
Has any of your close relatives ever felt ill after receiving a vaccination?近親者に接種を受けて具合が悪くなった人はいますか				Yes	No	
For women: is there any possibility the patient might be pregnant (ex.: delayed period, etc.)? 女性の方へ:現在妊娠している可能性(生理が予定より遅れているなど)はありますか(注)妊娠または妊娠している可能性のある方への接種はのぞましくありません				Yes	No	
Do you have any questions regarding today's vaccination? 今日の予防接種について質問がありますか				Yes	No	
医師の記入欄 Doctor's Use	以上の問診及び診察の結果、今日の予防接種は According to the result , today's vaccination is: 保護者(接種を受ける者が16歳以上の場合は本人)に対して、予防接種の効果、副反応及び予防接種健康被害救済制度について、説明をしました。		3 可能 Possible	2 見合わせる Postponed	医師のサイン Physician's signature	
					(注)ワクチンの種類・有効期限を要確認	

Having received the doctor's examination and explanation and having understood the aims and effects of this immunization, the risk of severe side effects and the vaccine injury compensation program, do you consent the immunization?	Yes 同意します	No 同意しません	Guardian's signature 保護者自署 (接種を受ける者が16歳以上の場合は本人自署)
This questionnaire has the purpose to ensure the immunization's safety. I'm aware of that and agree with the submission of this questionnaire to the Hamamatsu city.			

使用ワクチン	接種量	実施場所 ・ 医師名 ・ 接種年月日		
ワクチン名	(筋肉内接種)	実施場所		
Lot No.	0.5	医師名		
(注)有効期限が切れていないか要確認	mL	接種年月日(非接種判定日) 年 月 日		

※It is not necessary to fill in the guardian's name if the vaccinee is married. 保護者の氏名は、接種する人が16歳以上の場合には記載の必要はありません。