

HPV Vaccine Effectiveness And Potential Manufacturing Collaboration In Thailand

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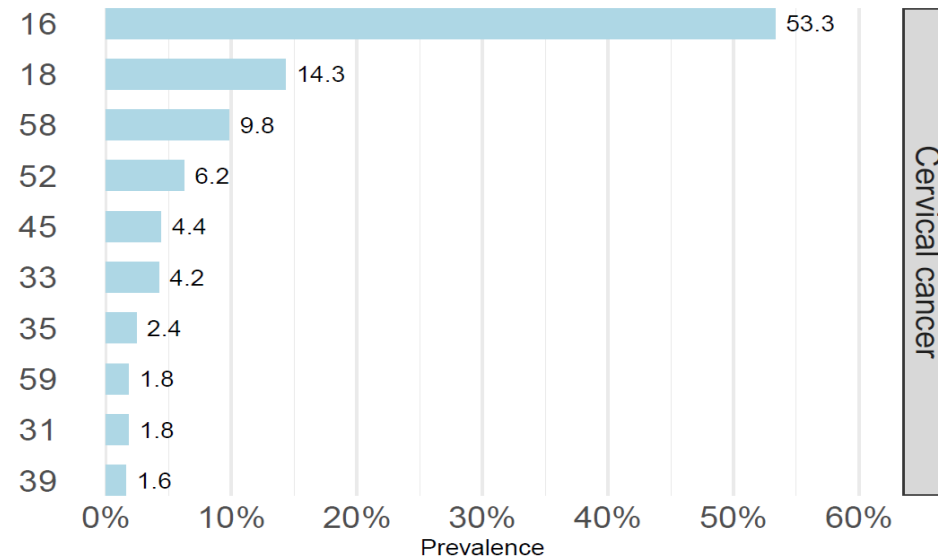


Human Papillomavirus and Related Cancers in Thailand



- Approximately **8,622** women **were diagnosed** with cervical cancer every year
- Approximately **5,015** women **died** from the disease in each year
- Cervical cancer ranks as the **3rd** common cancer among women in Thailand and the **2nd** common cancer among women between 15-44 years of age.
- **67.6%** of cervical cancer cases were caused by **HPV types 16 and 18**

Comparison of the ten HPV frequent oncogenic types in Thailand



HPV vaccine introduction in Thailand



HPV vaccine

Nation wide
introduction in 2017

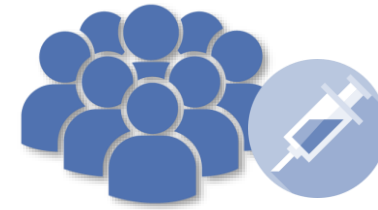


HPV vaccination coverage (%)

HPV coverage-first dose (estimation year 2019)	76
HPV coverage-last dose (estimation year 2019)	66
HPV coverage-first dose (estimation year 2020)	-*
HPV coverage-last dose (estimation year 2020)	-*

*Global HPV vaccine constrains have an impact on Thailand's HPV immunization program.

Thailand' response to global HPV vaccine shortage



Participation in the single-dose HPV vaccination study
(To assist in increasing HPV vaccine coverage)



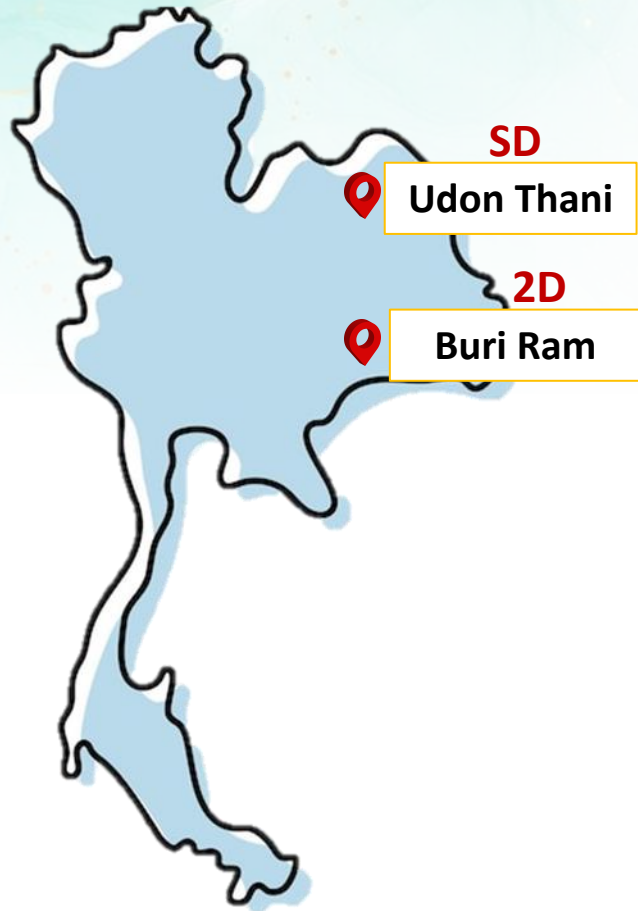
Seeking for collaboration of technology transfer partnership
for the HPV vaccine production
(to create a vaccine self-reliance)



HPV vaccine effectiveness study
in Thailand



HPV vaccine effectiveness study in Thailand



- In 2018, IVI (supported by the Bill & Melinda Gates Foundation) launched a Human papillomavirus (HPV) vaccine single-dose impact study in Thailand.
- The study will measure the effectiveness of a single-dose of HPV vaccine administered to young women in Thailand, by comparing with 2-dose regimen, generating data on single dose effectiveness to inform global public health policy.
- This study will track and analyze the level of HPV vaccine protection in females vaccinated with a single dose of the vaccine for a period of 5 years.

BILL & MELINDA
GATES *foundation*

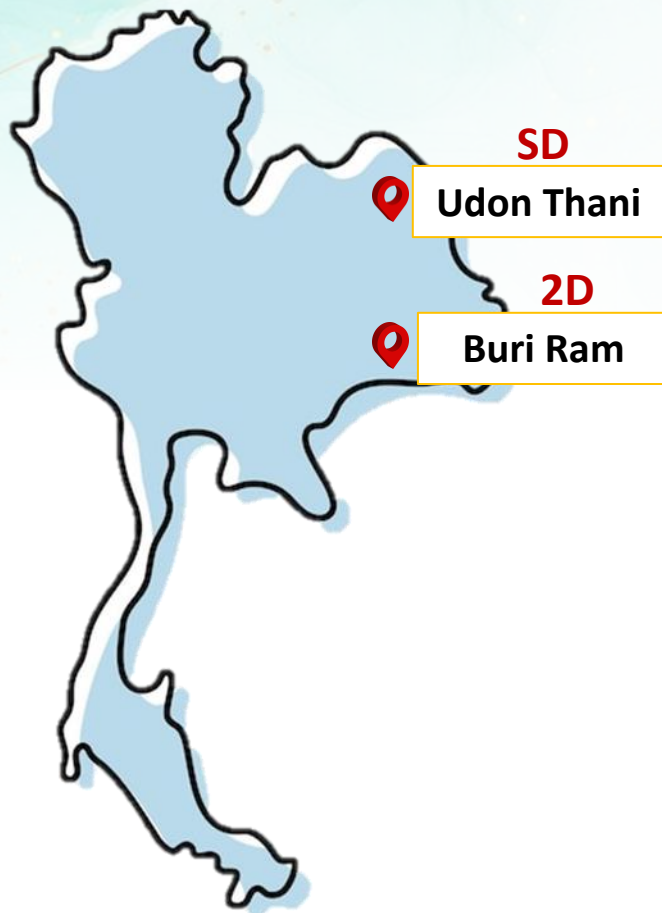


Chula
Chulalongkorn University

HPV vaccine single dose study in Thailand (1)

Thailand Impact Study

- Observational study of 1 dose and 2 doses of 2vHPV given to Grade 8 girls (age <15 years) in two similar Thai provinces (Udon Thani & Buri Ram)
- Primary objectives:
 - Demonstrate HPV vaccine effectiveness of 1 dose and 2 doses Year 2 and Year 4 post vaccination
 - Effectiveness by reduction in vaccine-type HPV prevalence (HPV 16 & 18) compared to prevalence among unvaccinated same grade female students collected in baseline survey
- Evaluate if HPV vaccine effectiveness of 1 dose is non-inferior to 2 doses by comparing reductions in vaccine-type prevalence
 - Year 4 post vaccination



HPV vaccine single dose study in Thailand (2)



Study Design : an observational community effectiveness study of SD or 2D of CERVARIX

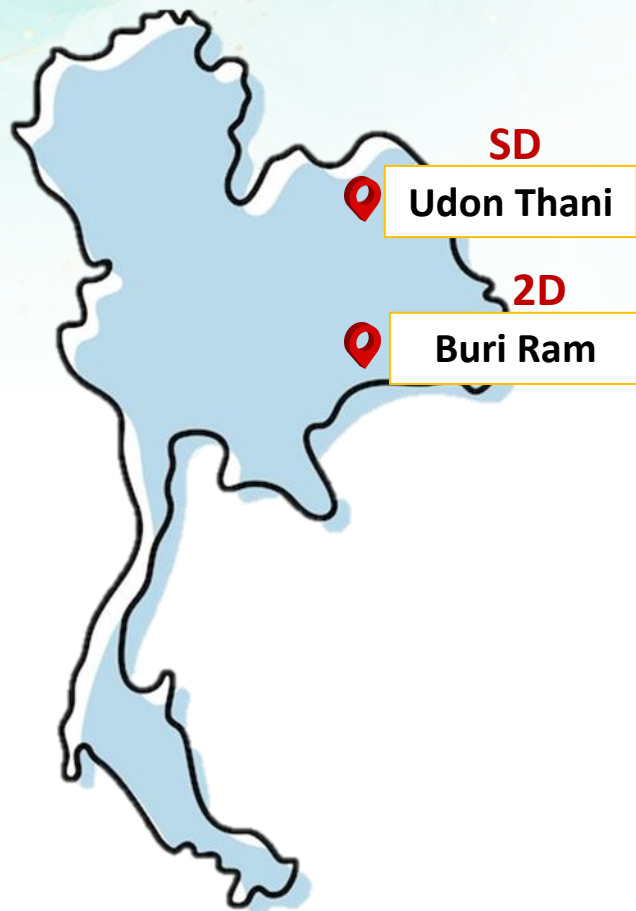
Study Component	Timeline	Sample Size	Intervention/Activity
Part A: Vaccination	2018 Dec-2019 Feb	All eligible 8,000~9,000* schoolgirls (<15 years old) in Grade 8 per province	Udon Thani: single-dose HPV vaccine regimen Buri Ram: two-dose HPV vaccine regimen 6 months apart
		N = 1,500 for SBQ	
		N = 200 (pre-vaccine serology)	
Part B: Baseline CSS	2018 Dec-2019 Feb	G10/V1: N = 2,600 schoolgirls per province	SBQ and HPV urine prevalence
		G12/V3: N = 2,000 schoolgirls per province	
Part C: Year 2 CSS	2020 Dec-2021 Feb	G10/V1: N = 2,600 schoolgirls per province	SBQ and HPV urine prevalence
		N = 200 (serology)	
Part D: Year 4 CSS	2022 Dec-2023 Feb	G12/V3: N = 2,000 schoolgirls per province	SBQ and HPV urine prevalence
		N = 200 (serology)	

* Approximate number of Grade 8 schoolgirls that will be eligible and offered vaccination

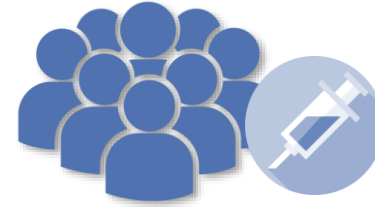
Vaccine effectiveness will be assessed as the reduction in vaccine HPV-type infection measured in a CSS two and four years after vaccination, compared to the Baseline CSS.

SBQ = sexual behavior questionnaire CSS = cross-sectional survey

HPV vaccine single dose study in Thailand (3)

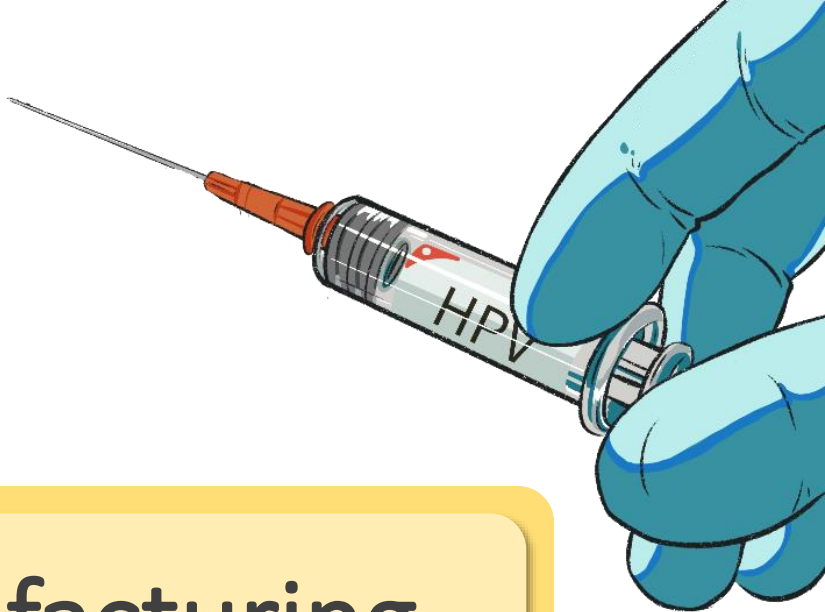


Year 2 effectiveness estimates:



- Both a single dose and two doses of HPV vaccine significantly decreased the prevalence of HPV in the two provinces. **(Preliminary results-unpublished)**
- The results of this survey were part of a global data package that provided substantial evidence to support the benefits of a single-dose HPV regimen which was then submitted to the SAGE.
- After reviewing all evidences, SAGE recommends a one- or two-dose schedule for girls and young women 9-20 years old.

Year 4 effectiveness is ongoing.



HPV vaccine potential manufacturing
collaboration in Thailand



Global HPV Vaccine Product Available (2013-2019)



Bi
valent



GSK:



Cervarix



WHO PQ



Quadri
valent



MSD:



Gardasil



WHO PQ



Nona
valent



MSD:



Gardasil9



WHO PQ



Note:

- There were just 2 manufacturers who supplied NIP with HPV vaccines between 2013 and 2019.
- Since 2019, the supply of HPV vaccines has not been sufficient to fulfill the growing demand.

PATH
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INNOVAX
万泰疫苗

KFW

BILL & MELINDA
GATES foundation

PATH, Inovax, KfW, and the Bill & Melinda Gates Foundation are partnering to expand options for human papillomavirus (HPV) vaccines in the countries that need them most.



Cecolin: A bivalent HPV Vaccine was developed.

To create a vaccine self-reliance in Thailand



NVI (a government agency) was established.

A non-profit organization under the supervision of the Minister of Public Health governed by **National Vaccine Security Act of B.E.2561 (2018)**. NVI collaborates with the Ministry of Public Health' departments, as well as academic institutions and vaccine manufacturers to support national vaccine security.



- Evaluate, analyze, and develop a draft national vaccine policy and action plan
- Govern and direct national vaccine policy and strategic planning



- **Strengthen and promote infrastructure for national vaccine supply, expected to be used in both normal and emergency scenarios**



- Function as an information and integrated vaccine knowledge management center



- **Create and strengthen network of vaccine partners, national and international**
- Promote, support, and develop a vaccine and activities related HRD training course

Potential manufacturing collaboration in Thailand



2017

NVI sought for a technology transfer collaboration for HPV vaccine production in order to promote vaccine self-sufficiency in the country.



2018

Collaboration has started.

- MOU between NVI and INNOVAX has been signed for Downstream production-bivalent HPV vaccine tech-transfer.
- GPO-MBP (Currently, Global Biotech Products), a local manufacturer, was chosen by INNOVAX to receive tech-transfer.
- Collaboration started before NMPA grant vaccine license in China (December 30, 2019) and before WHO confirmed that Cecolin® has been accepted by WHO for Prequalification (October 14, 2021).



2019-2022

- Collaboration was interrupted by some technical issues and COVID-19 pandemic.
- 2021, MOU has been update → Tripartite MOU (NVI, INNOVAX and, GPO-MBP)
 - for bivalent HPV vaccine technology transfer and multivalent in the future

Current Global HPV Vaccine Product Available (As of Jan 2023)



Bi
valent



GSK:

Cervarix

INNOVAX:

Cecolin*

Walvax:

Unknown**

WHO PQ

NMPA



Quadri
valent



MSD:

Gardasil

SII:

Cervavac***

WHO PQ

DCGI



Nona
valent



MSD:

Gardasil9

WHO PQ


















The global HPV vaccine market situation has changed.

By 2024, sufficient increases in production capacity will result in a healthy HPV supply situation.

*WHO PQ since October 2021

Only for local market (China) since March 2022, *Only for local market (India) since July 2022

Thailand's Current Vaccine Capabilities

Viral vector	Nucleic acid	Inactivated EGG BASED & CELL	Subunit	Common Infrastructure	Upstream research & Research utilization
					
<p>R&D</p> 	<p>R&D → Clinical trial</p> 	<p>Clinical trial ↓ Production</p>	<p>R&D ↓ Clinical trial</p>	<p>Animal testing center</p> 	<p>Other vaccine R&D</p>
<p>Production</p> 	<p>R&D → Clinical trial Production</p> 			<p>Pilot plant</p>  <p>Manufacturer</p> 	<p>Pandemic Flu vaccine</p>  <p>Botulinum antitoxin</p> 

Way Forward



NVI is actively looking for potential collaborations on;

- Clinical trial of vaccine to provide crucial information for global
- Vaccine R&D to production to ensure adequate supply.

HPV vaccine effectiveness and Potential Manufacturing Collaboration in Thailand

**The HPV Vaccine
Saves Lives**



**Thank you
for your attention**