HPV Prevention and Control Board

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COALITION to STRENGTHEN the HPV IMMUNIZATION COMMUNITY

THE INCLEN TRUST INTERNATIONAL

HPV vaccine roll-out
Lessons learned from planning process: Sri Lanka

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Sri Lanka

South Asia Regional Meeting
HPV Prevention and Control Landscape and the way forward
13th , 14th and 15th - Dec 2022 – New Delhi, India.

Outline of Presentation

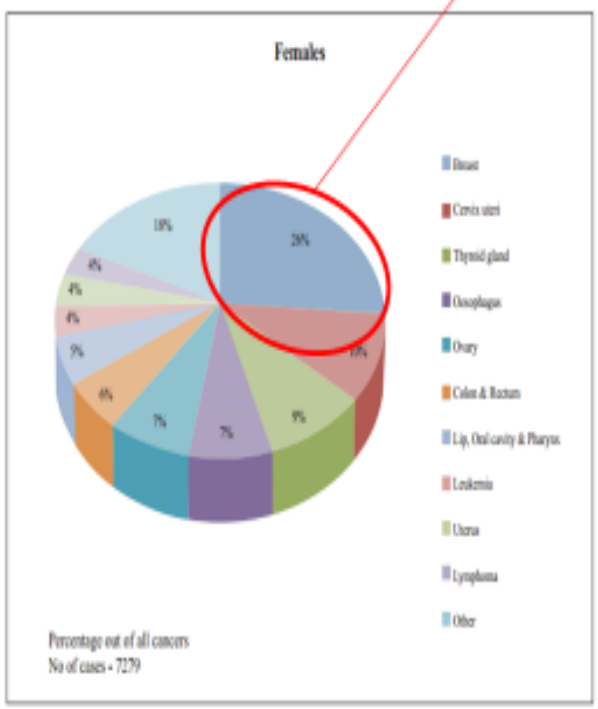
- ❑ Evidence generation for HPV vaccine introduction
  - Cervical cancer burden
  - HPV burden assessment- prevalence, genotypes
  - HPV risk attribution in cervical cancer development
- ❑ Existing preventive strategies for cervical cancer prevention
- ❑ Evidence-based decision-making procedure for HPV vaccine introduction into NIP
- ❑ Implementation of HPV vaccination programme

Cervical cancer/HPV disease burden

cervical cancer burden using routine data;

- Indoor mortality & morbidity data
- Population-based cancer registry data
- National Cancer Control Programme data

2nd commonest female cancers – 10% of all female cancers are cervical cancer (2008)



This translates to nearly 850-950 cervical cancer cases annually (hospital data)

Estimate for Sri Lanka : almost 12% of all female cancers are cervical cancers

http://globocan.iarc.fr/old/FactSheets/cancers/cervix-new.asp

National Cancer Control Programme, Cancer Incidence data

HPV prevalence in cervical cancer cases : other Sri Lankan studies

- Among Invasive cervical cancers :2013 (n=98)
  - Any genotype of HPV positive : 84.7% ([95% CI: 76.0%–91.2%]
  - HPV-16 : 67.3% [95% CI: 57.1–76.5] (66/98)
  - HPV-18 : 9.2% [95% CI: 4.3–16.7]

Karunaratne et. al. BMC Cancer 2014, 14:116 http://www.biomedcentral.com/1471-2407/14/116

- Among invasive carcinoma specimens: 2006-2007 (n=108)
  - Any genotype of HPV positive 93%
  - HPV genotypes 16 & 18 together: 83.4%

Samarawickrama NA, Tabrizi SN, Hewavisenthi J, Leong T, Galand SM. Int J Gynaecolo Obstet, 2011 Nov:115 (2), 180-2.

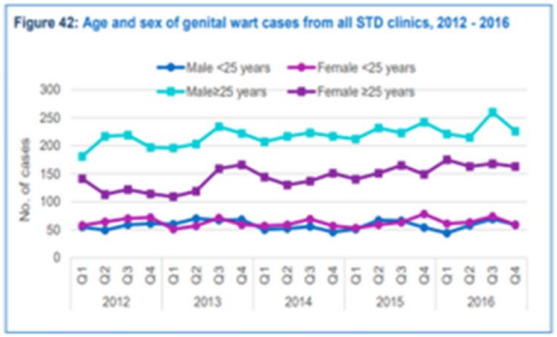
- Among cervical cancer specimens :2006 (n=15)
  - HPV genotype 16 positive : 73%
  - HPV genotype 18 : 20%

De Silva et. al ,*Ceylon Medical Journal*, 2006 , vol. 51, no.3, pp.114-117.

HPV-related genital warts:

2012	2013	2014	2015
1792	1911	1872	2005

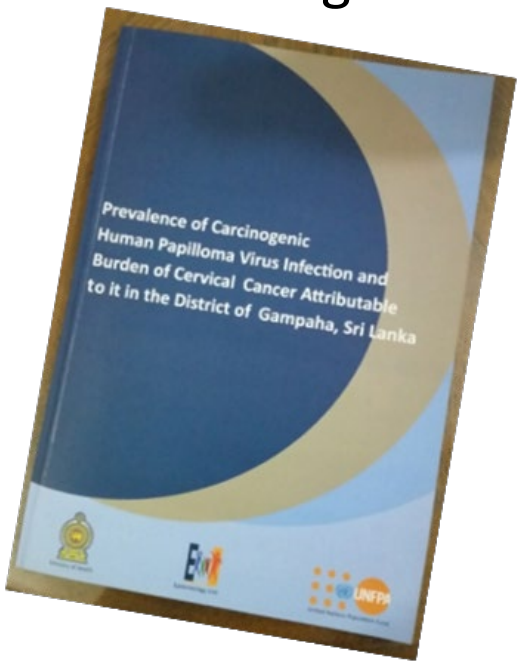
Source: National STD/AIDS control programme, Sri Lanka Annual Report 2016



HPV vaccine introduction: Evidence for decision making

Large scale community-based burden study conducted to identify country-specific burden (2009):

- HPV prevalence and specific genotype among clinically normal women,
- HPV prevalence and genotype among cervical cancer patients,
- HPV genotype risk attribution in developing cervical cancers,
- Cost estimation for cervical cancer screening: existing national Pap smear screening programme,
- Cervical cancer management cost incurred to the government at each stage of cervical cancer.



Gamage Deepa., Rajapaksa L, Abeysinghe M.R.N., and De Silva A.,
Prevalence of carcinogenic Human Papilloma Virus infection and burden of cervical cancer attributable to it in the district of Gampaha, Sri Lanka, 2012UNFPA, Epidemiology Unit, ISBN 978-955-8375-06-8

HPV Community prevalence study Sri Lanka

Gamage et al (2009)

HPV Community Prevalence study

- Clinically normal women in the district of Gampaha
- Community-based descriptive cross-sectional study,
- Sample size: 2000 married women (Age group 20-59 years)

HPV prevalence: Clinically normal women	
Overall HPV prevalence	HPV Genotype 16 & 18 prevalence
3.3% (95% CI 3.2-3.4)	1.2% (95% CI 1.15 – 1.25)

Genotype	16	18	31	33	35	45	51	56	73
Number	22	2	1	1	2	1	1	4	2

Of the total positives : major proportion were genotype 16 & 18 (42%)

HPV prevalence among cervical cancers and risk attribution of HPV for cervical cancer : *Gamage et al*

Hospital based case-control study (2009)

HPV status	Cases	Controls	
Positive	32(80%)	6(3.8%)	$\chi 2 = 116.6$, $df=1$, $p<0.001$, $OR=102.67$
Negative	8(20%)	154(96.2%)	
Total	40(100%)	160(100%)	*(29.84 – 302.20)*

HPV genotype	Cases	Controls	
Type 16	29(90.6%)	4(66.7%)	HR-VP
Type 18	2(6.3%)	0(0%)	HR-VP
Type 31	1(3.1%)	0(0%)	HR
Type 42	0(0%)	2(33.3%)	LR
Total	32(100%)	6(100%)	

	Adjusted Odds Ratio for HPV infection (by logistic regression)	Population Attributable Risk (PAR) %
All HPV genotypes	172	85%
Genotype 16 & 18	190.30	69%

Costing study for Assessment

Gamage et al

- Cost incurred by the government in pre-cancer detection and cervical cancer management evaluated in different scenarios: based on baseline findings of costing study
- Cervical cancer screening cost for:
  - Single screening
  - At call - recall method screening (at least twice in lifetime)
  - Maximum expected recall of 5 yearly screening
- Cervical cancer management costs at each stage of the disease in government institutions were assessed
- Cost and the number needed to be vaccinated for the prevention of one cervical cancer case per year
- Additional vaccine and vaccination cost to the National Immunization Programme (NIP) to vaccinate one and multiple cohorts.

Costing study for Assessment.. continued

Gamage et al

- Cost estimation done for different vaccination options
  - Below 13 years vs Above 13 years
  - Campaign mode vs Routine vaccination
  - School based vs Community-based

	yes	No	Do not know
Awareness/knew availability of HPV vaccine	390 (87%)	57 (13%)	-
Opinion on introduction of HPV vaccine in addition to Pap screening in cervical cancer prevention	424 (94%)	3 (1%)	23 (5%)
If introduce opinion of addition of HPV vaccine to EPI	433 (96%)	6 (1%)	11 (3%)
Opinion of parents' agreeability to vaccinate girls	327 (73%)	39 (9%)	84 (19%)
Feasibility of convincing to vaccinate only girls	399 (89%)	24 (5%)	27 (6%)

Main implementation strategy	Schools	410 (91%)	Clinics/hospitals	40 (9%)
If think schools:	Yes	No	Do not know	
Opinion of extra burden to duties	19 (4%)	379 (84%)	52 (13%)	
Opinion of any possibility of disturbance to existing School Medical Inspection	19 (4%)	428 (95%)	3 (1%)	
Possibility to get down any missed children to Community clinics	411 (91%)	12 (3%)	27 (6%)	
Desire to assist or implement services for HPV vaccination if selected school vaccination as the main strategy	429 (95%)	6 (1%)	15 (3%)	

Costing – Island wide

- Target Population *(One female age Cohort between 13-20 years)* - **175,000**
- Cost per dose is 4.5 USD
- Vaccine wastage is 5%, First year 6 months buffer stock
  - HPV vaccine costing scenarios.xlsx

Schedule	Coverage (First, Second & third doses)	Cost in First year (including Buffer) USD	Cost per year (Second year onward) USD
2 doses	90% and 80%	2,170, 547	**1, 447, 031**
	60% and 50%	1, 364, 344	**909, 563**
3 doses	90%, 85% and 80%	3, 162, 797	**2, 108, 531**
	60%, 55% and 50%	2,046, 516	**1,364, 344**

- Reviewed other country experiences globally, and in the region
- Field-level healthcare workers' opinions taken through a survey (n=450)

Decision-making process for HPV vaccine introduction

2010: Review of the evidence of HPV vaccine at the National Immunization Summit

HPV was not considered as a country priority due to the high vaccine price

2015: a further review of evidence at the National Immunization Summit

An expert working group was appointed to review the feasibility of HPV vaccine implementation

- 2015: Decision was taken to form an Expert working group
- Expert group discussed existing evidence and the country's situation on HPV vaccine and cervical cancer prevention
- Concept paper developed and submitted to Advisory Committee on Communicable Diseases (ACCD)
- ACCD decided to include HPV vaccination in the National Immunization Programme.

Task was handed over to the Epidemiology Unit, Ministry of Health to proceed with the HPV vaccine introduction and implementation

Different Options considered for implementation

- School based vs Clinic (MOH/ Hospital) based
- **School based**
  - is good for monitoring; fewer dropouts, high coverage maintenance
  - Communication may be a challenge, particularly in mixed schools
  - Safety concerns (Available evidence reveals mostly anxiety related reactions are reported following HPV vaccination)
  - What is the best grade?
    - Grade 7: ongoing SMI/aTd
    - Grades 8-9
    - Grade 6
  - At present, SMIs are handled by PHIs. Who is going to take responsibility of HPV vaccination? PHI or PHM or both?
- **Clinic based**
  - Dropouts may be high and high coverage maintenance may be a challenge

Different Options considered for implementation…. continued

- **Island-wide or Phase based?** (In a selected district/Province first and then to expand within the country)
- **Phase based**
  - Good to identify any program implementation issues,
  - Initial cost is low & more affordable,
  - Need to justify why not the entire country

- Prior to the introduction of the HPV vaccine - National, district, and divisional-level cold chain capacity assessment was done. Was found to be Adequate.

- Immunization services are integrated into the PHC delivery system since its inception. As a result, new vaccine introductions do not incur a massive operational cost.

Road map in the decision for HPV vaccine introduction

After the decision on vaccine introduction, the Expert group further decided on the vaccine, schedule, and implementation strategies:

Quadrivalent vaccine	2 dose schedule at 0 & 6 months	Nation wide introduction
Target population: girls in Grade 6 (10-11 years)	Mode of introduction as a school based programme and to follow up any drop-outs at community clinics	HPV vaccination initiated in October 2017

HPV vaccination coverage Same cohort FU coverage 2017-2018 (by Dec 2019)	Garde 6, Age 10-11 year girl cohort	1st dose coverage	2nd dose coverage
	2017	77%,	70%
	2018	95%	93%

Vaccine implementation preparatory activities

- Ensured the Government's commitment to financial sustainability for the introduction of HPV vaccine into the National Immunization Programme,
- Had close communication with the Education sector throughout the preparatory phase,
- Partner organizations supported the preparatory work - GAVI, UNICEF, WHO,
- All preparatory work including advocacy and training of health staff organized and conducted by the National Immunization Programme, Ministry of Health, in line with the programme requirements.

Key areas addressed during the advocacy for staff & public

- ❑ Need good advocacy
  - Why are only girls vaccinated?
  - Why is the vaccine needed during the teenage years? Why not at other ages?

- ❑ Addressing known Anxiety related adverse events following HPV vaccination,

- ❑ Importance and necessity of screening programme, despite the vaccine introduction,

- ❑ Address misinformation and disinformation

Enabling factors for the successful introduction of the HPV vaccine to the NIP

- Existence of well established public health infrastructure,
- Integration of immunization programme into PHC service delivery system,
- Existence of well-established inbuilt routine monitoring and evaluation mechanism for NIP,
- Availability of free healthcare delivery system,
- High literacy rate & public trust in immunization,
- Existence of a well-organized school health programme,
- Good partnership between the health and education sectors.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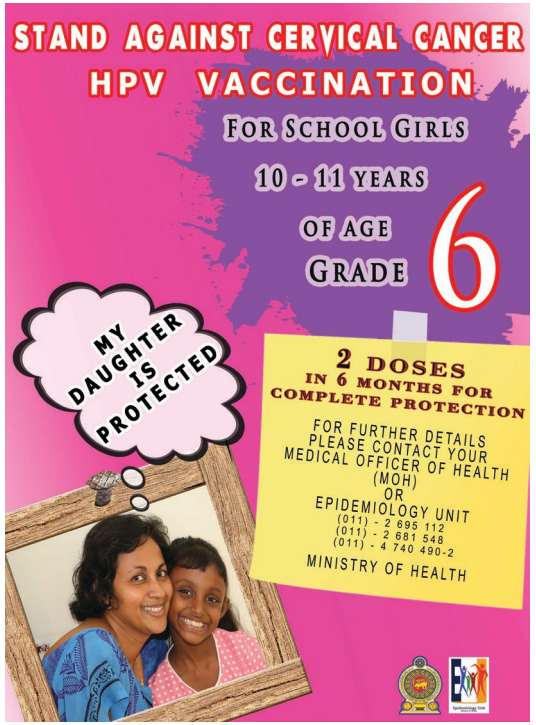
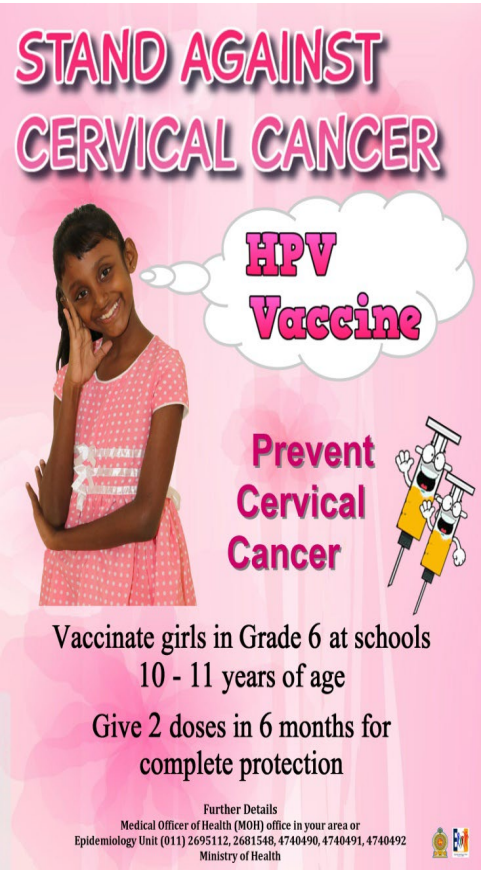
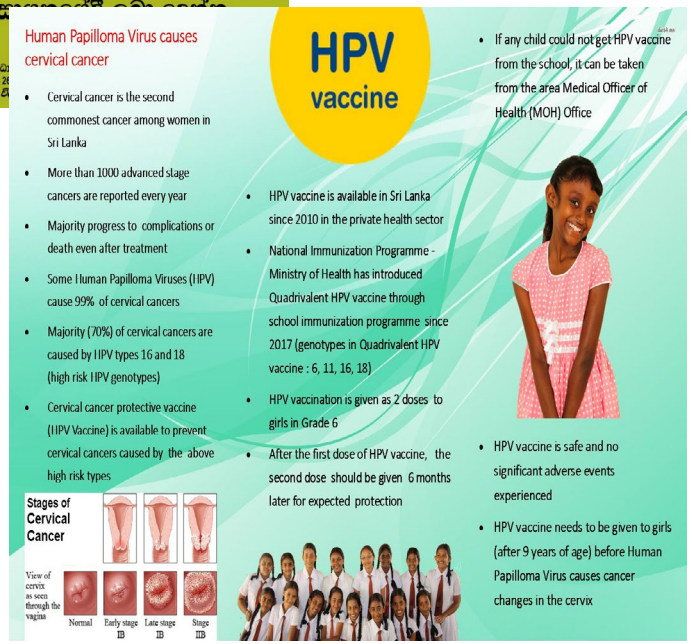

STAND AGAINST CERVICAL CANCER
HPV VACCINATION
FOR SCHOOL GIRLS
10 - 11 YEARS
OF AGE
GRADE 6
MY DAUGHTER IS PROTECTED
2 DOSES
IN 6 MONTHS FOR
COMPLETE PROTECTION
FOR FURTHER DETAILS
PLEASE CONTACT YOUR
MEDICAL OFFICER OF HEALTH
(MOH)
OR
EPIDEMIOLOGY UNIT
(011) - 2 695 112
(011) - 2 681 548
(011) - 4 740 490-2
MINISTRY OF HEALTH


கருப்பைக் கழுத்துப்
புற்றுநோயை
எதிர்ப்போம்
HPV (எச் பீ வீ) தடுப்பூசி
கருப்பைக் கழுத்து
புற்றுநோயிலிருந்து எம்மைப்
பாதுகாக்கும்
பாடசாலைகளில் ஆறாம் ஆண்டில் பயிலும்
மாணவிகளுக்குத் தடுப்பூசி வழங்குக
(வயது 10–11)
பூரண பாதுகாப்பிற்கு ஆறு மாத கால இடைவெளியில்
இரண்டு தடவைகள் ஏற்றப்பட வேண்டும்
மேலதிக விபரங்களுக்கு
சுகாதார வைத்திய அதிகாரி (MOH) அலுவலகம்
தொற்றுநோய் விஞ்ஞான அலகு (011) 2695112, 2681548, 4740490, 4740491, 4740492
சுகாதார அமைச்சு


STAND AGAINST
CERVICAL CANCER
HPV
Vaccine
Prevent
Cervical
Cancer
Vaccinate girls in Grade 6 at schools
10 - 11 years of age
Give 2 doses in 6 months for
complete protection
Further Details
Medical Officer of Health (MOH) office in your area or
Epidemiology Unit (011) 2695112, 2681548, 4740490, 4740491, 4740492
Ministry of Health


Human Papilloma Virus causes
cervical cancer
HPV
vaccine
Cervical cancer is the second commonest cancer among women in Sri Lanka
More than 1000 advanced stage cancers are reported every year
Majority progress to complications or death even after treatment
Some Human Papilloma Viruses (HPV) cause 99% of cervical cancers
Majority (70%) of cervical cancers are caused by HPV types 16 and 18 (high risk HPV genotypes)
Cervical cancer protective vaccine (HPV Vaccine) is available to prevent cervical cancers caused by the above high risk types
HPV vaccine is available in Sri Lanka since 2010 in the private health sector
National Immunization Programme - Ministry of Health has introduced Quadrivalent HPV vaccine through school immunization programme since 2017 (genotypes in Quadrivalent HPV vaccine : 6, 11, 16, 18)
HPV vaccination is given as 2 doses to girls in Grade 6
After the first dose of HPV vaccine, the second dose should be given 6 months later for expected protection
If any child could not get HPV vaccine from the school, it can be taken from the area Medical Officer of Health (MOH) Office
HPV vaccine is safe and no significant adverse events experienced
HPV vaccine needs to be given to girls (after 9 years of age) before Human Papilloma Virus causes cancer changes in the cervix
Stages of Cervical Cancer
View of cervix as seen through the vagina
Normal
Early stage IB
Late stage IB
Stage IIB


Vaccinate your daughter today with HPV vaccine to protect her life in future from cervical cancer
HPV vaccination and cervical cancer screening gives full protection from cervical cancers
Comprehensive prevention of cervical cancer helps to live generations together ... !
2 doses in 6 months for complete protection
FOR FURTHER INFORMATION
Medical Officer of Health of your area
Epidemiology Unit
Ministry of Health - Sri Lanka
Stand Against
Cervical Cancer
with
HPV
VACCINATION


2
6
HPV தடுப்பு
மருந்தேற்றல்
மூலம்
கருப்பைக் கழுத்துப்
புற்றுநோயிலிருந்து
பாதுகாப்புப் பெறுவோம்
Epidemiology Unit
Ministry of Health - Sri Lanka