

Real-life challenges in implementing public strategies for HPV vaccination in developing countries, and strategies to increase immunization coverage

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CONFLICTS OF INTEREST

X No, nothing to display Yes, please specify:

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AGENDA

• What are the facts about HPV?

What lessons we are still learning about the HPV vaccination

• What are the challenges for the present and future?

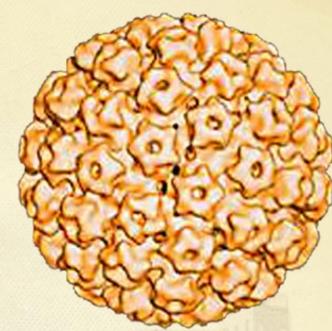




What are the facts about HPV?

- Human papillomaviruses are viruses belonging to the family *Papillomaviridae*, capable to induce lesions of the skin and mucosa.
- The main HPV-related diseases in women are genital warts, cancer of the vulva, vagina, cervix, and anal cancer
- As in women, HPV Infections are common in men:
- -Genital Warts
- -Anal Cancer (MSM) / Penile Cancer
- -Oropharyngeal and oral cavity cancers
- -Recurrent respiratory papillomatosis







• What are the facts about HPV?

15 million Are infected with the HPV virus, which can be considered an epidemic in Brazil.

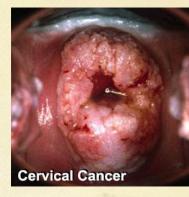
1 million Cases of genital warts each year

20,000 New cases of cervical cancer each year – 5,000 deaths

2nd second leading cause of death by cancer in women











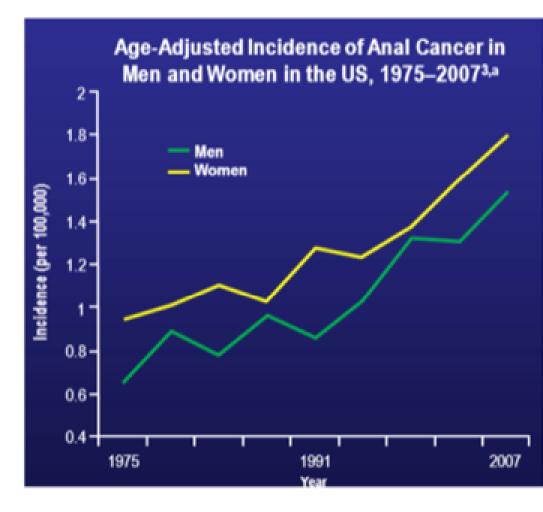


"In ten years in Brazil, The Anal Cancer increased by 36% in women and 96% in men (especially in men who have sex with men)"

National Institute of Cancer – INCA, Brazil, 2014

Epidemiology of Anal Cancer: US

- In 2012 in the US, there were ~6,230 new cases of anal cancer.
- The incidence of anal cancer is increasing by 2% per year.

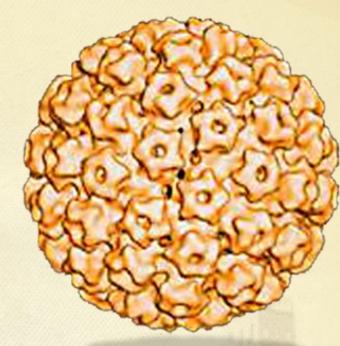


American Cancer Society. Cancer Facts and Figures 2012. http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents. SEER Stat Fact Sheets: Anal Cancer seer.cancer.gov/statfacts/html/anus.html. SEER Fast Stats. Seer.cancer.gov/faststats/selections.php?#Output

• What are the facts about HPV?

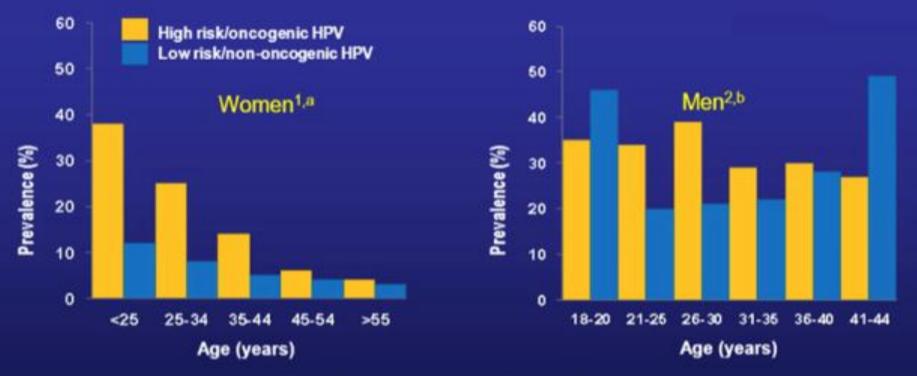
- There are over 100 HPV types (30 types infect the genital tract).
- There are four main types:
 6 and 11 (90% of genital warts);
 16 and 18 (70% of cases of cervical cancer).
- The Most HPV infections are asymptomatic.
- The majority of infections are cleared spontaneously.
- It is not a sign of promiscuity, because not all forms of transmission are through sexual intercourse







Prevalence of HPV Infection



Although most HPV infections clear on their own, persistence of certain HPV types can lead to clinically significant diseases.³

HPV = human papillomavirus. *Prevalence of cervical HPV intection among 2,356 study participants who complete at least 1 clinical visit. *Prevalence of genital HPV infection among men age 18-44 years in Tucson, Arizona (N = 290).

Goodman MT et al. Cancer Res. 2008;68:8813–8824, Adapted and reprinted by permission from the American Association for Cancer Research. Goodman MT et al, Prevalence, acquisition, and clearance of cervical human papillomavirus infection among women with normal cytology. Hawaii Human Papillomavirus Cohort Study. Cancer Res, 2008, vol 68, issue 21, 8813–8824.
 Giuliano AR et al. J Infect Dis. 2008;198:827–835. Giuliano AR et al, Age-specific prevalence, incidence, and duration of HPV infections in a cohort of 290 US men, J Infect Dis, 2008, vol. 198, 827–836, by permission of the Infectious Diseases. Society of America. 3. Centers for Disease Control and Prevention (CDC). Epidemiology and Prevention of Vaccine-Preventable Diseases. 12th ed. Chapter 10: Human papillomavirus. odc.gov/vaccines/publipini/book/downloads/hpv.pdf. Accessed January 3, 2013.





• What are the facts about HPV?

Primary Prevention of HPV - prevents contamination by HPV.

- 1. sexual abstinence¹
- 2. Condom use protects up to 70%, does not provide total protection against contagion¹
- 3. HPV vacination²

GARDASILTM [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine]

GARDASIL"

Quadrivalent vaccine – (HPV types 6, 11, 16 18) •99% efficacy against genital warts •high efficacy against cancer (cervical, vulva vagina and anus) •Schedule 0, 2, 6 months Bivalent vaccine – (HPV types 16,18)
95-100% efficacy against cervical intraepithelial neoplasia (CIN) and cervical cancer
Schedule – 0, 1, 6 months

1.Instituto do HPV. Guia do HPV. Disponível em: http://incthpv.org.br/upl/fckUploads/file/Guia do HPV Julho 2013_2.pdf.Acessado em fevereiro de 2014. 2. World Health Organization. Executive summary: the state of world health. Disponível em: http://www.who.int/whr/1995/media_centre/executive_summary1/en/index.html. Acessado em fevereiro de 2014.

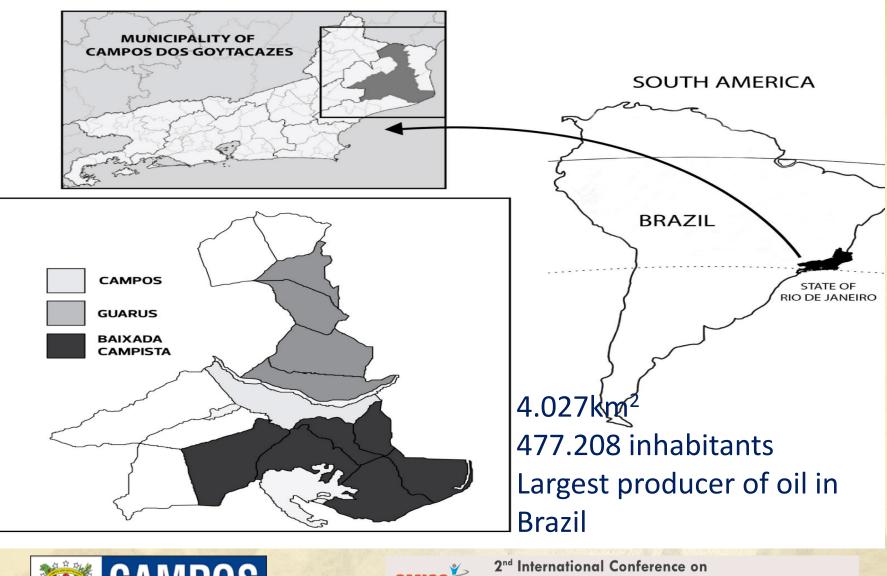
What lessons we are still learning about the HPV vaccination

- More than 140 countries have now licensed HPV vaccines, many of them in public vaccination programs
- The Australians have shown that immunization of females elicits a herd immunity effect, but in 2013 introduced the quadrivalent vaccine for boys of 11-13 years (because of the Increased incidence of HPV in men who have sex with men
- Vaccination in school plays an important role to increase vaccination coverage
- The pediatrician continues to be effective in the process of convincing parents regarding vaccination





What lessons we are still learning about the HPV vaccination





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DS. & STIS



Ceremony to launch the HPV vaccine for girls 11 to 15 years in september 2010



Implementation of the quadrivalent vaccine against HPV in the Municipality of Campos dos Goytacazes, Brazil – A combination of strategies to increase immunization coverage and early reduction of genital warts $^{\star,\pm\pm}$

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ABSTRACT

Introduction: Among the more than 100 types of human papillomavirus (HPV), about 90% of genital warts are caused by HPV types 6 and 11; types 16 and 18 cause 70% of cases of cervical cancer. Tracking through Pap associated with condom use are strategies in preventing this condition. Vaccination against HPV has been added to the portfolio of protection. In September 13, 2010, the quadrivalent vaccine against HPV was made available for resident girls between 11 and 15 years of age in the municipality of Campos dos Goytaczes, Rio de Janeiro, Brazil using a hybrid strategy of vaccination.

Objectives: Assess vaccination coverage in that municipality after adopting several strategies for active search and missed opportunities for vaccination against HPV. Evaluate acceptance for the vaccine and reasons for refusal the HPV vaccine. Evaluate the frequency and occurrence of adverse events to that vaccine. A survey of reduction of genital warts was also conducted.

Methods: A survey of vaccination coverage for the chosen age group was carried out. By previous appointment, schools received vaccination on site; two "D-Days" for municipal vaccination were set along side with the creation of the project "Holidays HPV-free". The vaccine was also offered in two public permanent sites on a daily basis; Vaccine adverse events were assessed in 1000 adolescents after 96 h of vaccine administration A survey on reduction of genital warts was studied 3 years before and 2 years after introduction of vaccine. *Results*: The 1st vaccine dose reached about 53%, 90.1% and 87.9% of coverage, respectively in 2010, 2011 and 2012. By using the same model, the complete scheme with 3rd dose reached 0%, 65.1% and 66.2% of coverage status. There were observed a total of 430 local and systemic events in 360 subjects (36% of 1000 girls), stratified by each dose received. No serious adverse events or any hospitalization were reported; We also observed a reduction of about 55% in the incidence of genital warts in women under 21 years old. *Conclusion*: A hybrid strategy for HPy proved to be effective in vaccinating adolescents in this municipality.

HPV vaccine was safe and effective in reducing genital warts, as demonstrated by international studies. © 2013 The Authors. Published by Elsevier Ltd. All rights reserved.

 $^\circ$ This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited. $^\circ\circ$ This is the first study of a public Municipal Immunization Program carried out in

Brazil through a survey on HPV vaccination coverage and also an efficient hybrid vaccination strategy in Campos dos Goytacazes. Data of the National System of Notification (SINAN) of Brazillan Ministry of Health considered that there was a significant reduction in the incidence of genital warts in the Municipality of Campos dos Goytacazes, with a reduction of about 55% in women under 21 years of age after 2 years of vaccination.

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- Trials in Vaccinology
- August, 2013.

Main Topics

- We conducted a survey of vaccination coverage for chosen age group from 2010 – 2012. (girls 11-15)
- We used strategies to increase vaccination coverage – A hybrid strategy was used
- 3. We analysed Reasons for refuse the HPV vaccination
- 4. We verified Reduction in genital Warts in women.
- We conducted a survey to Evaluate of adverse events to HPV vaccination
- 6. More than 80.000 of HPV vaccine doses distributed

Introduction

The human papillomavirus (HPV) is a sexually transmitted virus with a high outcome of morbidity and mortality of cervical cancer [1], accounting for about 275,000 deaths annually in women worldwide [1].

In Brazil, a high percentage of the population is infected with HPV, with an estimate of about 9–10 million of individuals infected, producing an annual incidence of 17,540 new cases of cervical cancer, responsible for 4000 deaths per year in the country [2].

HPV belongs to a heterogeneous family of more than 100 different genotypes. Among these genotypes, 40 of them can infect the anogenital region [3]. They are classified in high-risk and





Vacinação contra HPV prossegue em escolas públicas e particulares



Schools – 65% of the vaccine coverage







Permanent sites (vaccination rooms) – 35% of the vaccine coverage





Vaccination Coverage – 2010 - 2012

Table 1 - Quadrivalent HPV vaccine coverage among adolescents by dose and year of vaccination,Campos dos Goytacazes, Brazil.

2010	11 years (vg/pop=vc)	12 years	13 years	14 years	15 years		Total VC (%)
1st dose	1583/4083 = 38,7%	1695/3923=43,2%	2321/3969=58,4%	1930/4031=47,8%	3219/4280=75,2%		52,90%
3st dose*	0	0	C	0		0	0
2011	11 years (vg/pop=vc)	12 years	13 years	14 years	15 years		Total VC (%)
1st dose	3756/4122 = 91,1%	3121/3960=78,8%	3948/4007=98,5%	3210/4069=78,8%	4231/4321=97,9%		89,02%
3st dose	2650/4122 = 64,2%	2054/3960=51,8%	3218/4007=80,3%	2430/4069=59,7%	2980/4321=68,9%		65,10%
2012	11 years (vg/pop=vc)	12 years	13 years	14 years	15 years		Total VC (%)
1st dose	3680/4159 = 88,4%	3054/3996=76,4%	3890/4042=96,2%	3460/4105=84,2%	4087/4359=93,7%		87,90%
3st dose	2423/4159 = 58,2%	3112/3996=77,8%	2980/4042=73,70%	2646/4105=64,4%	2530/4359=58%		66,20%

Abbreviations: vg = vaccines given

pop = adolescent population in the years 2010, 2011 and 2012

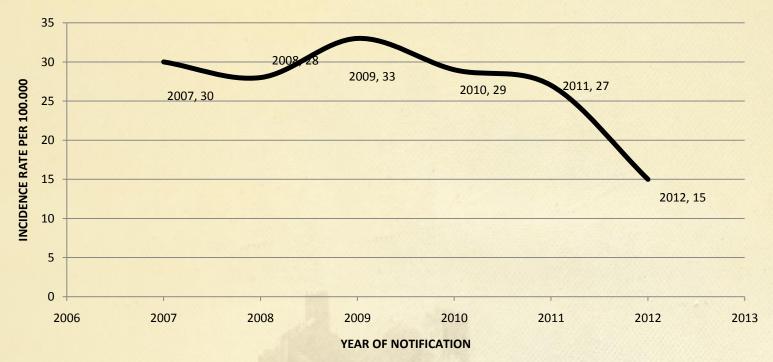
vc = vaccination coverage

* In 2010 there was not given the 3rd dose in any teen, because the implementation

of the quadrivalent vaccine started in september, 2010.

RESULTS

INCIDENCE OF GENITAL WARTS IN WOMEN < 21 YEARS IN THE MUNICIPALITY OF CAMPOS DOS GOYTACAZES, BRAZIL







Main reasons for refusal of the HPV vaccine in 13% of the 300 parents interviewed

33% My daughter is virgin and don't need the vaccine My daughter is too young to need the vaccine 23% 15% The priest / Shepherd said not to take the vaccine Vaccination against HPV will make my girl sexually active 15% My daughter has so many healthy problems 5% The Pediatrician of my girl advised not to vaccinate 5% Don't Believe That the vaccine is effective 5% 0% 5% 10% 15% 20% 25% 30%





35%



TECHNICAL REPORT ON THE VACCINE AGAINST HPV IN PRIMARY CARE MINISTRY OF HEALTH, BRAZIL. NOVEMBER, 2013



INFORME TÉCNICO SOBRE A VACINA CONTRA O PAPILOMAVÍRUS HUMANO (HPV) NA ATENÇÃO BÁSICA

- HPV vaccination started in Brazil in march, 2014 only for girls
- The Chosen Age group was: 11-13 years in 2014 / 9-11 in 2015 / 9 years in 2016
- Quadrivalent HPV vaccine

HPV Schedule in Brazil in 2014

Dose	Scheme (months)	Month Recommended	Strategy			
FIRST	0	March	Vac. Rooms and Schools			
SECOND	6	September	Vac. Rooms and Schools			
THIRD	60	March	Vac. Rooms and Schools			



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2nd International Conference on

Brasilia Novembro, 2013

What lessons we are still learning about the HPV vaccination



Ceremony to launch the HPV vaccine for boys 11 to 13 years in March, 2014, by using our own municipal resources





What lessons we are still learning about the HPV vaccination

Other recommendations of HPV vaccine in Campos dos Goytacazes



- Recurrent genital warts and difficult to treat
- Recurrent respiratory papillomatosis

2nd International Conference on

Victims of sexual abuse

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HIV positive - men and Women under 27 years Studies are being conducted to evaluate effectiveness of HPV vaccine in HIV positive women



Challenge 1 - Ensure high HPV vaccination coverage

- Try all alternatives to get your teen to vaccinate
- Continuously evaluate the coverage and the reasons for refusal to vaccinate
- develop strategies for health education
- Strengthen medical education







Vaccination bus









2nd International Conference on HIV/AIDS, STDS, & STIS Accelerating Scientific Discovery Accelerating Scientific Dis

PREFEITURA - NOTÍCIAS - MUL

SERVICOS FALE COM A GENTI

Estudantes no Encontro de Atenção à Saúde do Homem no HGG





Lectures in Schools





Challenge 2 - How to deal with parents to ensure HPV vaccine is safe and necessary?

- All of the medical plays a key role in convincing parents
- Ensure that the HPV vaccine is safe and effective
- Talk about sexuality, but being careful not to link the HPV vaccination as related to the onset of sexual activity
- Make clear that the vaccine does not protect against other sexually transmitted diseases. Thus, sex education, condom use and Pap smear screening should continue

Safety Profile^{1,2}



Good safety and tolerability profile^{1,2}



Organisation mondiale de la Santé

Weekly epidemiological record Relevé épidémiologique hebdomadaire

10 APRIL 2009, 84th YEAR / 10 AVRIL 2009, 84* ANNÉE No. 15, 2009, 84, 117–132 http://www.who.int/wer

VAERS – Vaccine Adverse Event Reporting System do CDC/FDA •More than 57 million doses in the United States until March 2013¹ •Serious adverse events were not higher than expected incidence for the general population¹

World Health Organization (WHO)

- More than 180 million doses distributed worldwide²
- Good safety profile².
- No reports of systemic events related to the vaccine².





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1. Centers for Disease Control and Prevention. Human Papillomavirus (HPV) Vaccine. Disponível em http://www.cdc.gov/vaccinesafety/vaccines/HPV/Index.html. Acessado em 22/02/2014. 2. GACVS Safety update on HPV Vaccines. Disponível em http://www.who.int/vaccine_safety/vaccinesafety/vaccines/HPV/Index.html. Acessado em 22/02/2014. 2. GACVS Safety update on HPV Vaccines. Disponível em http://www.who.int/vaccine_safety/committee/topics/hpv/en/index.html. Acessado em 22/02/2014.

When talking with parents about immunization, parents want to know three things:

- 1) Does it work?
- 2) Is it safe?
- 3) What is your recommendation?







People don't make decisions on the basis of fact People make decisions on the bases of emotion and experience







- Do not use statistics with parents
- Our messages to parents may need to be less scientific and more personnel and emotional
- We need to tell compelling stories





- First Approach My favorite
- Has anyone that care about had cancer?
- What was it like for them? For you?
- •We can reduce the chances of your son our daughter
- having a cancer experience?
- Do you want to reduce your child's risk of cancer





- Second Approach use caution when approaching
- HPV stands for human papillomavirus
- HPV causes genital warts and cervical cancer
- HPV is a sexually-transmitted disease
- Many adolescents become sexually active by age 13
- do you want this vaccine for your teen aged 11 year old?





Conclusions – What we cannot forget?

- 1. Vaccination is the most cost effective strategy for prevention
- 2. The HPV vaccine proved to be safe and effective in reducing genital warts and cancers
- 3. School plays an important role in health education, increasing coverage rates for HPV vaccine
- 4. The doctor has a central role in convincing the parents to allow the vaccination against HPV
- 5. The public health authorities should be continually strengthening the monitoring of adverse events and providing information to the population





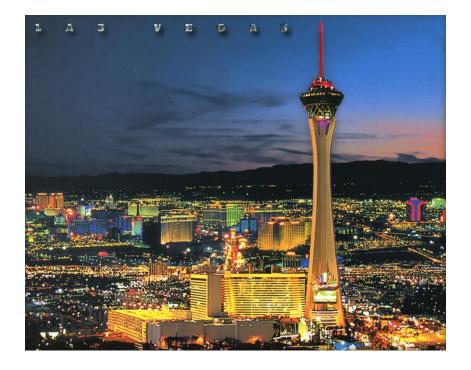






THANK YOU!

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