

# *The role of the Health Care Providers during a mass psychogenic event in Colombia*

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*Bucharest, Romania May 14 – 16 2018*

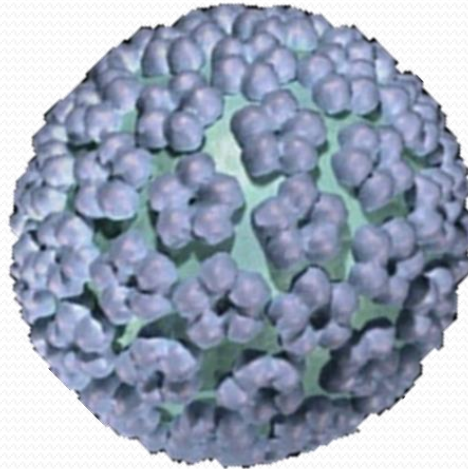


# *Cervical cancer in Colombia*



- *Total population: 49 millions*
- *No. of cases per year: 4660*
- *ASIR: 19.0 per 100,000*
- *No. of deaths p/year: 2,200*
- *ASMR: 8.0 per 100,000*
- *Second most common cause of death for cancer in women*

# *HPV Vaccination Program in Colombia*



# HPV Vaccination Program in Colombia

- **1985-2018: Key epidemiological studies on HPV and cervical cancer**
  - IARC pioneer case-control study in Cali and Spain,
  - Cohort study of HPV and CIN in women from Bogota,
  - ICO prevalence surveys of HPV types in cancer of the cervix, vulva, vagina, penis, in Cali and Bogota H&N
- **2000- Participation in phase III efficacy trials of HPV vaccines;**  
*2v-HPV , 4v- HPV, 9vHPV vaccines in Bogota, Cali and Medellin*  
**2006 – 2007: The 4v- HPV and the 2v-HPV vaccines licensed in Colombia**
- **2008- 2010 Acceptability studies of the HPV vaccine** among Health Care Providers, General Practitioners, Gynecologists & Pediatricians and among parents, school teachers and students by the NCI of Colombia
- **2011 : Cost-effectivity study of the HPV vaccine in Colombia** by the National University ; 4v-HPV vaccine selected
- **2011 – 2012 : Preparation for the introduction of the HPV vaccine in the Expanded program of Immunization**

# *HPV vaccine introduction at the local level in a developing country: attitudes and criteria among key actors :*

*Marion Piñeros , Carolina Wiesner, Claudia Cortés, Lina Trujillo, Instituto Nacional de Cancerología, Bogotá,*

- *Interview to top Health Care Providers of 4 Colombian cities: Bogota, Manizales, Cartagena & Arauca*
- *All interviewees readily agreed that cervical cancer is a major public health problem, but not all gave high priority to the HPV vaccine*
- *Most local decision makers who were firmly in favour of HPV vaccine introduction had reached their decision based more likely on pressure from local political figures and pharmaceutical companies than on sound scientific evidence*
- *Local decision and initiatives need to be strengthened technically and supported by national-level decisions, guidelines and follow-up.*

# *Knowledge, Acceptability and Attitudes Towards the HPV Vaccine among Colombian General Practitioners, Gynecologists and Pediatricians in Colombia*

Marion Piñeros<sup>1</sup>, Claudia Cortés<sup>1</sup>, Lina Trujillo<sup>1</sup>, Carolina Wiesner<sup>1</sup>

<sup>1</sup> Instituto Nacional de Cancerología, Bogotá, Colombia. Rev Colomb Cancerol 88 2009;13(2):88-98

## *Conclusions:*

- *Among Colombian physicians, especially among general practitioners, confusion exists concerning HPV, the different types of HPV vaccines, age at delivery and its long term efficacy, therefore,*
- *Educational and training courses, particularly for GP, on HPV, HPV vaccines, and screening should be widely available.*
- *Recommendations and The HPV vaccine and should be made available by the MOH through the National Immunization Program*



Aceptabilidad de la vacuna contra el Virus del Papiloma Humano en padres de adolescentes, en Colombia

*Human papillomavirus (HPV) vaccine acceptability amongst parents of adolescents in four Colombian areas*

- *196 parents (164 mothers – 32 fathers) of adolescents from 4 cities: Bogota, Manizales, Cartagena, Arauca*
- *Parents in private schools showed more resistance than parents in public schools*
- *Parents in Cartagena showed the highest resistance, considered that pregnancy in adolescents and sexual abuse were more important than cervical cancer*
- *Parents in Manizales were concerned with the age of vaccination*
- *Parents in Arauca were more concerned with genital warts*

# *Preparation for the Introduction of the HPV vaccine in the Colombian EPI Program*

- *The MoH provided education on HPV infection, cervical cancer and HPV vaccines ( Through Associations of gynecologists and Pediatricians). This was seconded by the pharmaceutical companies*
- *The MoH carried out an intense campaign directed to the general population by radio, TV, news media*
- *The MoH provided little information or education on the HPV Vaccine program to the local public health officers responsible for administering the vaccine*



# Launching the HPV vaccine program in Colombia- August 2012

*Girls on 4<sup>th</sup> grade of primary school- (9 years of age and older)*



Y QUE VIVAN SIN CÁNCER  
DE CUELLO UTERINO.

VACÚNATE



2013

girls in 4th to 11th grade  
(9-17 years old)

Schedule: 0,6,60 m



# HPV vaccination program in Colombia

**First Phase** : August 2012 – Feb. 2013

- ✓ All girls in 4th grade, 9 years & older
- ✓ 3 dose schedule: 0, 2, 6 months (4v-vaccine)



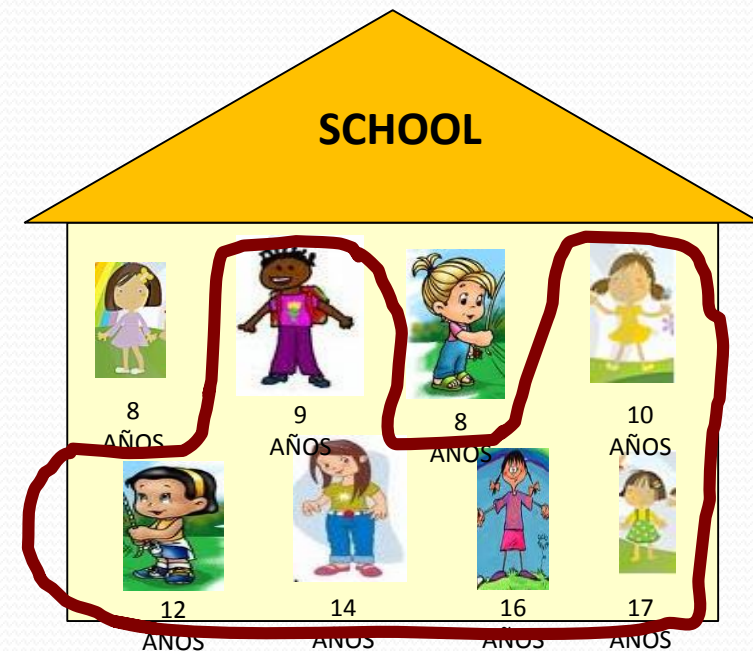
**MinSalud**  
Ministerio de Salud  
y Protección Social

**Second Phase:** 2013

- ✓ All girls 9 to 17 years of age
- ✓ Extended 3 dose schedule: 0, 6, 60 m

**Third Phase:** 2014 to present

- ✓ All girls 4<sup>th</sup> grade, 9 years and older
- ✓ 2 dose schedule: 0, 6 months



**Adverse effect event:** May to August 2014



# Carmen de Bolívar - Colombia



- Municipality with 75,151 inhabitants, 65% in urban area
- 21% of the population is 10 – 19 years old
- 85% of the population has been victim of violence or forced migration during the last 10 years
- 90% of the population is covered by the government social security (Subsidized Regimen)
- Illiteracy : 26% (~6% in Colombia)
- Unemployment: 41%
- Mental health problems:
  - Increase in suicide attempt (pesticides)

**May 29 – June 2 , 2014:**

**15 girls** 11 to 17 years old from the same school presenting:  
tachycardia, shortness of breath,  
chest pain, paresthesias & fainting

*Initial hypothesis: water, food, lead  
or pesticide poisoning : negative  
results*

*July 2014: HPV vaccine? 2th dose in  
March 2014*



*Outbreak study involving **517** subjects  
conducted by the INH of Colombia from  
August 25 to Oct 2014*

*Case definition: adolescents & young  
adults who have suffered from 2 or  
more of the initial symptoms from May  
29th to 15th October 2014*

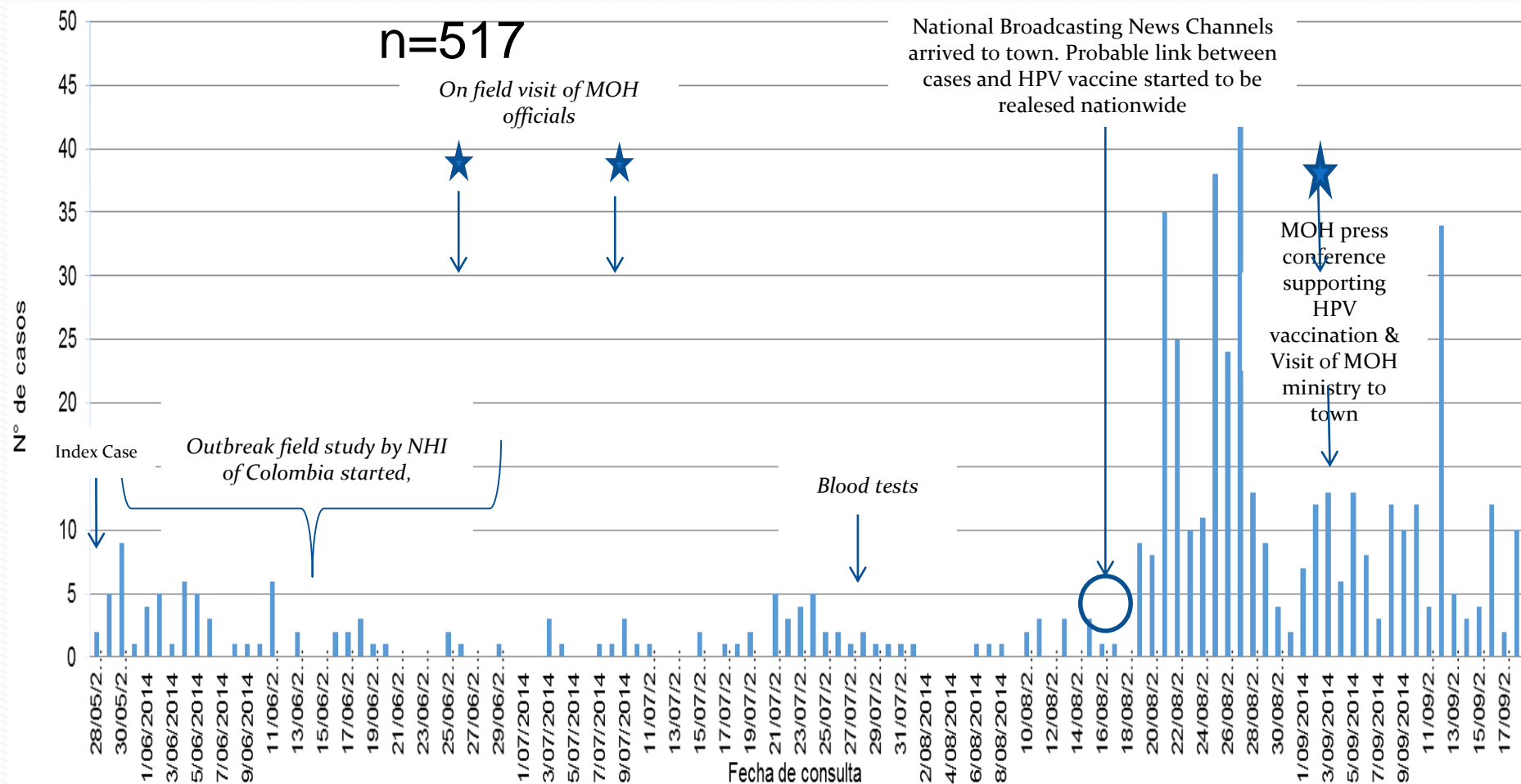
# ***Outbreak study in Carmen de Bolivar May –Oct. 2014***

- *517 girls 9 –19 years old presented 2 or more of the following symptoms: headache, paresthesia of lower or upper limbs, shortness of breath, chest pain , fainting.*
- *50% of cases were in the age group 13 – 15 years and 28% in the age group 16 – 19 years*
- *58% of cases came from 5 of the 19 schools*
- *Symptoms appeared 13.7 months after the 1<sup>st</sup> dose, and 6.7 months the 2<sup>nd</sup> dose of the vaccine*
- *11 cases (2.1%) presented similar symptoms before the vaccine*
- *14 cases( 2.7% ), 8 boys & 6 girls did not received the HPV vaccine*
- *Most cases resolved quickly without sequelae but ~44% consulted 2 or more times for similar symptoms*



# Cases treated at Local Health Centers

## Carmen de Bolivar, Colombia May – Sept 2014



Source: Colombian National Institute of Health

# Conclusion

- *The delayed onset of symptoms after vaccine administration, the shape of the epidemic curve and the lack of abnormalities at the physical and para-clinical examinations ruled out these events as vaccine related*
- *The most likely explanation is a mass psychogenic event caused by an exaggerated perception of potential adverse effects caused by the HPV vaccine and fueled by the media coverage*

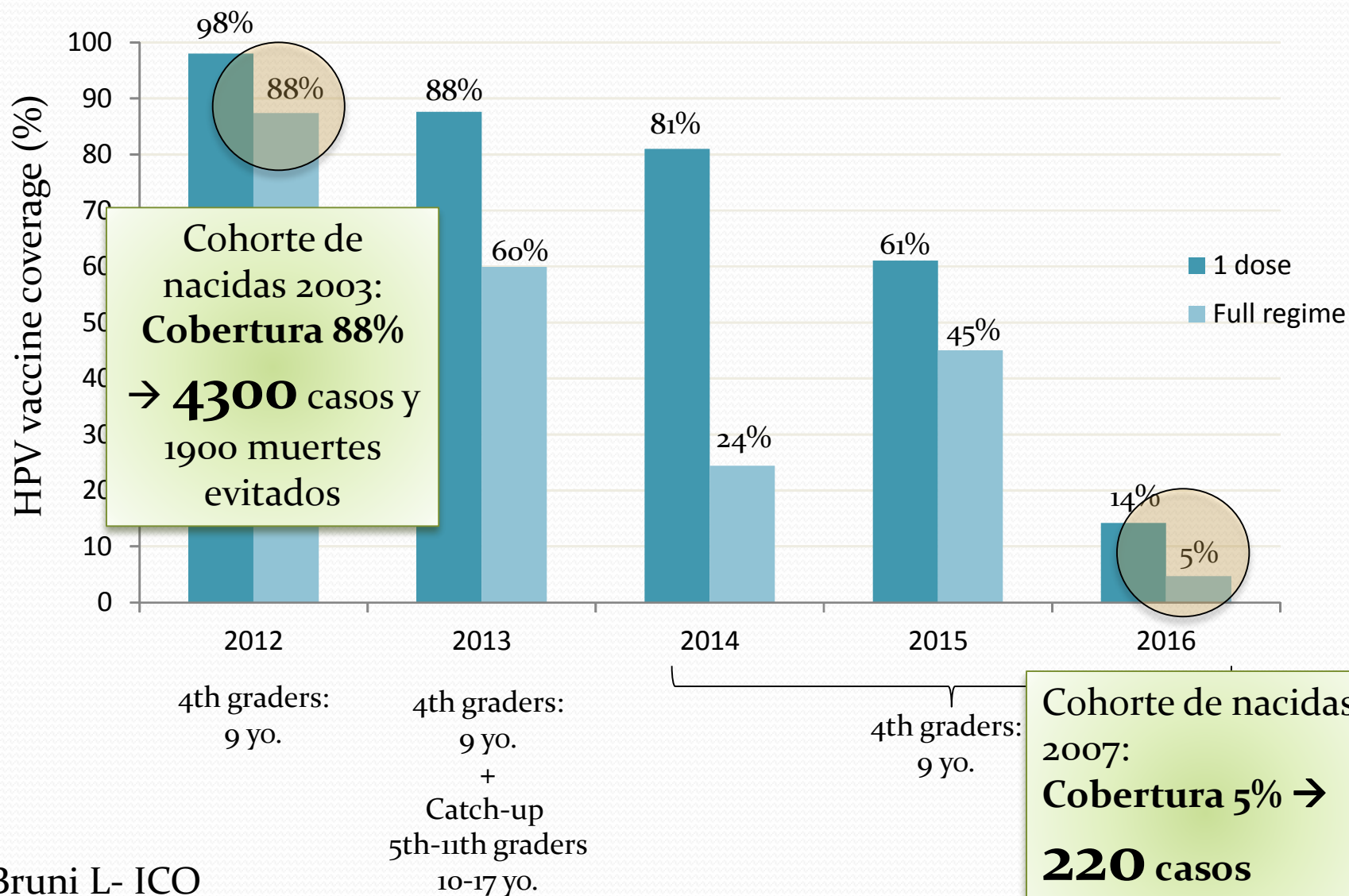
# *Problems in the management of the event in Carmen de Bolivar*

- *The health care providers in Carmen de Bolivar were not prepared to manage the crisis*
- *The high public health authorities reacted inadequately : - June 2014, a joint commission of MoH and the NIH was created to study the problem; toxicologist, epidemiologists*
- *- August 2014 the MoH and the President declared to the media that the event was probably due to “collective hysteria” non related to the HPV vaccine, while the parents of affected girls and their lawyers insisted that the HPV vaccine was the cause*
- *The news media and social media were the main source of information or “misinformation” and the event became a political issue*
- *Parents of affected girls were very upset because the results of the study carried out by the NIH of Colombia were first known by the community through the media, in January 2015*
- *Parents created an association of “padres de victimas de la vacuna VPH” vaccine” and the lawyer Monica Leon del Rio another “Reconstruyendo la Esperanza”*

# *Lessons learned*

- *The event in Carmen de Bolivar was underestimated*
- *Despite an excellent political will, the messages delivered by the Colombian health authorities were rather slow and too technical to reach adequately the Carmen de Bolivar population .*
- *Government and health officials messages lacked empathy*
- *The news media and social media on the contrary were very active, reacted quickly and transmitted emotional dramatic messages that became viral*

# HPV Vaccine Coverage in Colombia



# *Academia Nacional de Medicina*



*Letter of 14 March 2016 to the Minister of Health of Colombia*

*Request to modify the Protocol used in the National HPV Vaccination Program , specifically by:*

- *To perform a personalized analysis of each candidate for vaccination to identify those with autoimmune diseases or with a familiar history of these diseases*
- *To exclude from vaccination all those girls with autoimmune diseases or family history of them*
- *To vaccinate those eligible girls who provide informed consent*
- *To provide education on sexual and reproductive health*
- *at the same time of vaccination*



# *Debates in public health*

## *HPV vaccines: Scientific, ethic, and political features*

*Bogota,*      February 7/2018 (8 a.m. a 1 p.m)



• **8:00 – 8:10 am:** Opening.

Eduardo Rueda – Director Bioethics Institute, Pontificia Universidad Javeriana

**8:10 – 8:30 am:** Controversy on HPV vaccines.

Francisco J. Yepes – Professor, Instituto de Salud Pública – PUJ

**8:30 – 9:00 am:** Autoimmune disease.

Juan Manuel Anaya - Instituto CREA, Universidad del Rosario

**9:00 – 9:30 am:** Autoimmune/inflammatory syndrome induced by adjuvants.

Yehuda Shoenfeld - Zabłudowicz Center for Autoimmune Diseases. Israel

**9:30 – 9:50 am:** Cervical cancer: a global perspective.

Raúl Murillo - Centro Javeriano de Oncología

**9:50 – 10:10 am:** Coffee break

**10:10 – 10:40 am:** Efficacy and effectiveness of HPV vaccines.

Rolando Herrero - International Agency for Research on Cancer – IARC

**10:40 – 11:10 am:** HPV vaccine safety.

Patrick Zuber - Global Vaccine Safety, World Health Organization

**11.10 – 12:00 m:** Open forum. Chair: Eduardo Rueda

# *Main challenges in the reactivation of the HPV vaccine Program in Colombia*

- *There is a significant proportion of health care providers and academia in Colombia who not have confidence in the vaccine*
- *Parents, children and general population have been easily influenced by wrong messages in news media and social media and have lost confidence in the HPV vaccine*
- *In 2017 the Constitutional Court in Colombia ruled that the HPV vaccine was not obligatory and that informed consent prior to vaccination must be obtained,*
- *In 2017 a lawsuit against the Colombian government and Merck Sharp & Dohme was filed*

# *Strategies for the reactivation of the HPV vaccine Program in Colombia:*

## *Increase HPV Vaccine Advocacy*

- *Creation of a **Concertation Group**: (Liga Colombiana contra el Cancer , MOH, Clinical Societies ) aimed to improve cervical cancer control: by HPV vaccination and introduction of HPV testing as primary screening test*
- *An **e-course on HPV vaccine efficacy and safety** has been developed by the ICO and NCI of Colombia directed to Colombian physicians and health care workers*
- *Reactivation of school-based HPV vaccination has been focused in certain cities (**Cali and Pasto**)*
- *Colaboration has been established with the **HPV Prevention and Control Board**: Issue of the following Statement : Refutation of a proposal to screen all vaccine recipients before immunization in Dec. 2017*
- *A meeting of the **HPV Prevention and Control Board and the NCI of Colombia** is planned in November 2018*

# LA SEGURIDAD DE LA VACUNA DEL VPH

## ESTRUCTURA DEL CURSO

Los programas de monitorización continuada de los efectos adversos asociados a las vacunas son primordiales para asegurar la confianza y adherencia de la población.

Debido a que las vacunas son básicamente preventivas y no curativas, están sujetas a intensivos programas de seguimiento e inspección por parte de las instituciones públicas. Por otra parte la población habitualmente no es consciente de su eficacia y por tanto es más fácil focalizar en sus efectos adversos y no en sus beneficios.

La monitorización y comunicación adecuada sobre la seguridad de las vacunas son fundamentales porque el temor a los efectos adversos puede conducir a:

- Una disminución de la confianza en las vacunas, y
- Una reducción en la cobertura que puede comprometer el programa.

El **Instituto Catalán de Oncología, e-oncología** y el **Instituto Nacional de Cancerología** de Colombia han desarrollado este curso virtual, cuyo objetivo es transmitir a todos los profesionales implicados en la prevención del cáncer de cuello uterino, la última evidencia científica sobre la eficacia y seguridad de las vacunas contra el VPH.

### DURACIÓN

10 horas

### DESARROLLADO POR

### DIRIGIDO A

Médicos, enfermeras/matronas y en general todos los profesionales sanitarios implicados en la prevención primaria y secundaria del cáncer de cuello uterino.

# LA SEGURIDAD DE LA VACUNA DEL VPH

## PROGRAMA

## PROGRAMA

- 1 Introducción** Dr. F. Xavier Bosch Dra. Carolina Wiesner

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- 2 Impacto del VPH en América Latina y en Colombia** Dra. Laia Bruni Dr. Raúl Murillo

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- 3 Eficacia y efectividad vacunal** Dra. Silvia de Sanjose Dr. Joaquín Luna

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- 4 Seguridad vacunal. Participación de Colombia** Dr. F. Xavier Bosch Dra. Sandra Beltrán

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- 5 Episodio Carmen de Bolívar en Colombia y otros episodios** Dra. Carolina Wiesner Dra. Lina Trujillo Dra. Nubia Muñoz Dr. Antoni Trilla

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- 6 Conclusiones**

# EL TIEMPO

*EDITORIAL 12 de mayo 2018 ,*

## *Una vacuna segura*

- *Urge tomar en serio la investigación científica (Cochrane) que prueba que la vacuna contra el VPH no es dañina*
- Es urgente retomar la estrategia de vacunación para todas las mujeres entre los 9 y los 22 años, soportada en sólidos pilares de educación e información suficientes para toda la comunidad,
- Es un imperativo inaplazable si se quiere recuperar el terreno