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

Nubia Muñoz MD MPH
Emeritus Professor at the National Cancer Institute of Colombia
Former Unit Chief at the International Agency for Research on Cancer, Lyon, France

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Cervical cancer in Colombia

- Total population: 49 millions
- No. of cases per year: 4,660
- 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
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- **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, H&N in Cali and Bogota

- **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-effectiveness 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.

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
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 4th grade of primary school - (9 years of age and older)
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)

**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 4th grade, 9 years and older
- 2 dose schedule: 0, 6 months

**Adverse effect event**: May to August 2014
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
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 1st dose, and 6.7 months the 2nd 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.

Report of the Colombian National Institutes of Health
January 2015  www.ins.gov.co
Cases treated at Local Health Centers
Carmen de Bolivar, Colombia  May – Sept 2014

n=517

On field visit of MOH officials

National Broadcasting News Channels arrived to town. Probable link between cases and HPV vaccine started to be released nationwide

Outbreak field study by NHI of Colombia started,

Blood tests

Index Case

MOH press conference supporting HPV vaccination & Visit of MOH ministry to town

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

- **Cohorte de nacidas 2003:**
  - **Cobertura 88%**
  - **4300** casos y **1900** muertes evitados

- **Cohorte de nacidas 2007:**
  - **Cobertura 5%**
  - **220** casos evitados

Bruni L- ICO
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 - Zabludowicz Center for Autoimmune Diseases. Israel

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 do 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**).

- Collaboration 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.
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 Cancérología 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.
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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