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Expanding the Evidence Base for HPV Vaccination in Developing Countries:
A Global Perspective featuring GARDASIL Access Program Participants

9:00 – 10:30 am EST

October 31, 2011

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Webinar Agenda

9:00 – 9:30 am	**Introduction** **Lessons learned analysis: eight projects** *Mike Chirenje, Chair, GARDASIL Access Program Advisory Board, and Professor, Department of Obstetrics and Gynaecology, College of Health Sciences, University of Zimbabwe*
9:30 – 9:45 am	**Bolivia lessons learned presentation** *Martin Gutiérrez M.A, Communications Director* *Centro de Investigación, Educación y Servicios (CIES)*
9:45 – 10:00 am	**Lesotho lessons learned presentation** *Florence Mohai, Head of Family Health Division* *Lesotho Ministry of Health and Social Welfare*
10:00 – 10:15 am	**Nepal lessons learned presentation** *Dr. Surendra B. Bade, President,* *Nepal Network for Cancer Treatment & Research (NNCTR)*
10:15 – 10:30 am	**Q&A** *All*

We encourage you to ask questions throughout the webinar through the chat feature in the lower left hand corner of your screen. ***Please note who your question is intended for.***

About The GARDASIL Access Program

- Through the GARDASIL Access Program, Merck & Co., Inc. has pledged up to three million doses of GARDASIL for use in approved HPV vaccination projects in developing countries
- The GARDASIL Access Program **enables organizations and institutions in eligible lowest income countries to gain operational experience designing and implementing human papillomavirus (HPV) vaccination projects**, with the goal of supporting the development of successful child and adolescent immunization models
- **The operational experiences and lessons learned by participants in the program are widely disseminated** to contribute to the public knowledge base on HPV vaccine access
- The program is managed by Axios Healthcare Development (AHD), a US non-profit organization, with strategic guidance provided by the independent GARDASIL Access Program Advisory Board comprised of international public health experts

More information available on http://www.gardasilaccessprogram.org

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GARDASIL Access Program
Progress to Date

To date, **828,800 doses of GARDASIL have shipped to 19 participants in 17 countries**, enough to vaccinate more than **275,200 eligible girls.**

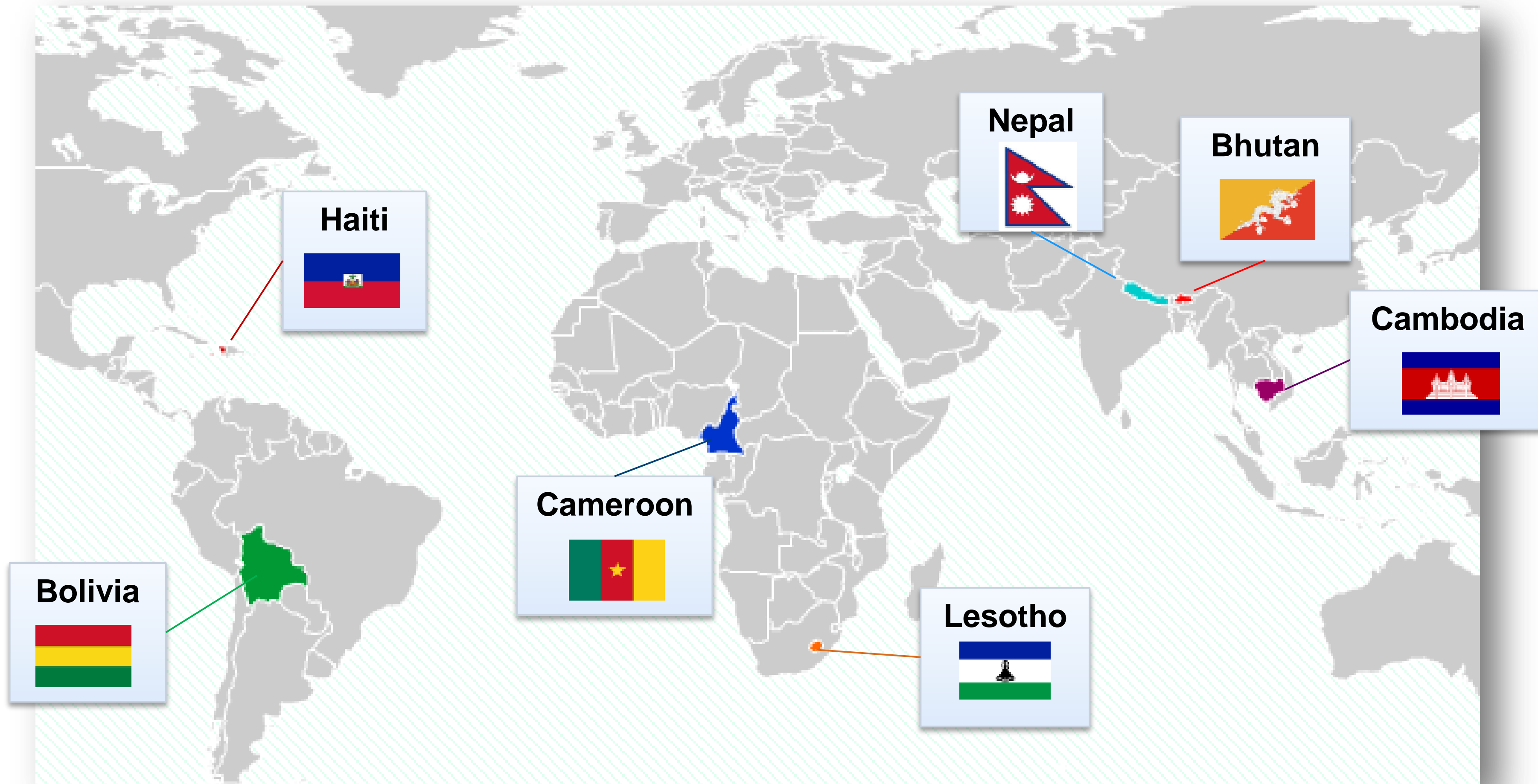
Lessons Learned Analysis

Eight GARDASIL Access Program Projects

Prepared by Axios

Map of Project Countries

*An Interim Analysis of Eight Projects**



** Please note that this is an interim analysis of eight GARDASIL Access Program projects. The projects analyzed do not represent all currently approved GARDASIL Access Program projects.*

Baseline Characteristics of Projects

Based on Numbers Gathered in April 2011

	Participant Status	# of vaccination distribution sites	# of girls targeted	# of girls who received full course (3 doses)
Bolivia 1	NGO	57	3,480	3,739
Bolivia 2	NGO	258	30,900	27,597
Bhutan	MoH	9	3,200	2,721
Cambodia *(1st project only)*	MoH	1	2,000	2,027
Cameroon*	NGO	20	1,600	1,033
Haiti	NGO	7	3,300	2,884
Lesotho *(1st project only)*	MoH	47	40,100	33,818
Nepal *(1ST project only)*	NGO	24	3,000	3,164

**Cameroon has yet to fully vaccinate their cohort*

Vaccine Delivery Models Used

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Points of Vaccine Administration			
	School	Clinic	Mixed Models
Bolivia 1	✓	–	–
Bolivia 2	–	–	✓
Bhutan	✓	–	–
Cambodia	–	✓	–
Cameroon	–	✓	–
Haiti	✓	–	–
Lesotho	–	–	✓
Nepal	–	–	✓

3 Models

- School: 3 programs
- Clinic: 2 programs
- Mixed: 3 programs

Project Performance
Definition and Results to Date

« Project performance » has two factors or indicators:

1. Definition of « Project Reach » (PR)

$$PR = \frac{\text{\# of girls receiving a full course (3 doses) of the vaccine}}{\text{\# of girls the project originally targeted}}$$

Mean PR= 87.8%

2. Definition of « Adherence » (Ad)

$$Ad = \frac{\text{\# of girls receiving a full course (3 doses) of the vaccine}}{\text{\# of girls who received the 1st dose of the vaccine}}$$

Mean Ad=90.9%

Key Observations & Lessons Learned

- **School models were the best** in reaching girls within WHO age recommendation (9-13 years)
- Interim evidence indicates that **mixed models (including schools, clinics, mobile clinics) allow for better performance, followed by school models**
- **Project should conform to local norms** for other routine vaccinations (i.e. signed consent vs. opt-out)
- **When school-based projects extended beyond the academic year, or when natural disaster struck, clinic and/or door-to-door follow up enabled administration of the full 3-dose vaccination series (Haiti, Bolivia, Nepal, Lesotho)**
- When **contextual circumstances forced school or mixed model projects to conduct follow-up vaccination on dates outside of the regular school calendar**, it became exponentially difficult to prevent girls lost to follow up (Bhutan, Lesotho, Nepal)
- **Humanitarian response to sudden natural/social disasters detracts from preventive care measures including vaccination, requiring contingency planning** to manage disruption to the 3-dose HPV vaccination series at months 0/2/6 (Haiti, Lesotho)
- **Specific resources should be allocated to sensitize and train school teachers to assist in recruitment and follow up** of girls during the vaccination campaign

The positive trends shown in this interim analysis will require further validation as additional participants complete their HPV vaccination projects and submit formal progress reports in the coming months.
-- PUBLICATION OF FULL RESULTS IS FORTHCOMING --

From Evidence to Impact…

As we work to bring women's cancers and HPV vaccination to the forefront of the global public health agenda,
the success stories from HPV vaccination projects give us the tools to:

- Demonstrate that HPV vaccination is feasible in resource-constrained settings
- Emphasize the value of operational experience in establishing effective HPV vaccination programs
- Contribute to the development of successful child and adolescent immunization models in lowest income countries

BOLIVIA

GARDASIL Access Program
Lessons Learned

Presented by Martin Gutiérrez M.A.
Communications Director,
Centro de Investigación, Educación y Servicios (CIES)

October 31, 2011

Ministerio de Salud
y Deportes

Project Design

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SALUD SEXUAL
SALUD REPRODUCTIVA

Target population:

- 5th grade girls (9-13 years of age)

Partners (local and international):

- Ministry of Health and Sports (implementer)
- SEDES and SEDUCA (implementer)
- International Planned Parenthood Federation (IPPF/WHR) (technical assistance and coordination)

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Recruitment Methods & Administration Sites

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- **Recruitment Methods**
  - Schools
  - Community through Mobile Health Units
  - CIES and Ministry of Health clinics

- **Administration Sites**
  - Public schools by MOH with CIES support
  - CIES clinics
  - Health establishments

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Implementation Strategies

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SALUD REPRODUCTIVA

Urban Areas:

- Schools: teams mobilized to schools
- Selected health clinics and CIES clinics: opportunity for follow-up for missed doses

Rural Areas:

- Mobile Health Units in rural and remote areas

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Communications Activities

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- A solid media and social campaign was created
- Availability of IEC materials to support the campaign
- All materials were specifically designed to our target public

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Implementation Phases

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1. Coordination and Planning
2. Sensitization, Information and training
3. Vaccination
4. Follow-up
5. Systematization

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Progress to Date

Year	Number of Girls Who Received Third Dose	Reach/Rate of Follow-Up	N° of Municipalities
2009	3,739	99%	10/325
2010	27,597	98%	14/325
2011	50,000 (2011 goal)	95.9% (2011 goal)	26/325
Total	81,336	97.7%	8%

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Progress to Date

- **Improvements in community, parent, teacher, government buy-in**
  - Increase in PAP screening in all CIES clinics
  - Social demand increased for the HPV vaccine in selected communities

- **Progress in securing potential future government/national support**
  - Through the project, we were able to bring national attention to the issue of cervical cancer
  - The current cervical cancer prevention plan is aimed at vaccinating all girls in the 5th grade
  - MoH official expressed that HPV vaccine will be incorporated in the 2013 national vaccination schedule, subject to reduction in its price

- **Additional measures of success**
  - Involvement of the Ministry of Education in cervical cancer prevention
  - MOH indicated a comprehensive approach training providers on VIAA and equipment

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Lessons Learned

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Importance of securing stakeholder support

- Joint planning and programming among CIES, MoH and SEDES was key to achieving results
- Participation of MSD, SEDES, municipalities and users gives legitimacy to the process and project
- It is necessary to have an active scientific committee to support the project and share responsibilities

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Lessons Learned

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- **Proper planning of vaccination timing based on administration site choice:** School-based vaccination campaigns need to be aware of the school calendar to avoid vaccine abandonment with the girls moving or away for vacation or holidays

- **The power of media**: A well-rounded media campaign is key for community information

- **Need for ongoing training**: Ongoing training in the implementation and development of the EPI enables proper management of protocols and standards

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Overcoming Key Challenges

CHALLENGE	SOLUTION
Lack of government commitment to HPV vaccination	Sensitization and informational meetings
Faith-based organizations organized campaign against the vaccine	Design and launch strong media campaign
Lack of systems to monitor vaccination	Strengthen data systems
HPV vaccine is not yet in the national vaccination calendar	Continue advocacy with EPI for coordination of vaccination schedule
Delay by the MOH in sending results of the vaccination campaigns	CIES regional clinics and EPI supported the process as needed
Lack of supplies to implement HPV vaccination	Advocate for support needed to fund HPV vaccination supplies

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Conclusions

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- The model is effective through a donation from the Gardasil Access Program as acknowledged by the Ministry of Health
- The model is feasible and technically viable
- The program has high reach/rate of follow-up.
- The HPV vaccine is socially accepted among the group targeted
- The Bolivian government's commitment to cervical cancer prevention and treatment is expressed in its National Plan

HPV vaccination is part of the government agenda.

LESOTHO

GARDASIL Access Program Lessons Learned

Presented by Florence Mohai

Head of Family Health Division

Ministry of Health and Social Welfare

October 31, 2011

About Lesotho

- Lesotho is surrounded by RSA and it has the population of 1.88 million & Total Fertility Rate of 3.3 (LDHS: 2009)
- Lesotho has terrain that is mostly highlands with plateaus, hills and mountains with more than 1,800m above sea level
- The country is divided into ten administrative districts which differ in terms of size, topography, climate and stage of development
- The Age Standardised Incident Rate is 66.7/100,000 women (2006: MOHSW)
- Climate: Hot summers with heavy rainfall, extremely cold winters with snow & temperatures below-15 degrees Celsius in the mountain areas

Program Design

- **Target Population:**
  - In 2009, target population was females aged 9-18
  - In 2011, target became 9-13 yrs. based on WHO guidelines

- **Partners:**
  - Other partners were Lesotho Boston Health Alliance, UNFPA (*United Nations Population Fund* - transport & t-shirts), WHO (transport & leaflets) while UNICEF, EGPAF (*Elizabeth Glaser Pediatric AIDS Foundation)*, ICAP (*International Center for Aids Care and Treatment Programs*) & PIH (*Partners in Health*) provided transport

- **Donation:**
  - 126,400 doses of GARDASIL were approved in 2008 for Phase 1 and 120,000 additional doses were approved in 2010 for Phase 2
  - Total approved = 246,400 doses
  - Total shipped to date = 206,400 doses (remaining 40,000 to be shipped in Nov. 2011)
  - MOHSW worked with Axios to coordinate the vaccine donation and manage the program

Program Design Cont.

- **Recruitment of girls and vaccine administration done through schools**
  - Makes it easier to reach targeted children and ensure follow-ups
- **Government involvement**
  - Has increased budget for EPI Programme from $483,871 to $2,741,935 in 2011 & other funds were put aside for procurement of cold chain equipment etc.
- **Community involvement**:
  - Religious leaders, chiefs, CHWs and teachers were involved in informing targeted children about vaccination dates, while parents provided consent for their children to be vaccinated

Program Design Cont.

- **Communication Activities:**
  - **Posters: Distributed to health centers/hospitals and targeted to health workers**
    - 1st poster with indications, contraindication, dosage, storage, side effects / 2nd poster with immunization schedule with intervals
  - **T-shirts: Worn by vaccinators on vaccination day**
  - **Stickers: Distributed to medical facilities to be handed out to children during vaccination days**
    - Stickers were placed in medical booklets marking when the child was vaccinated
  - **Media: Local newspapers, television and local radio stations**
    - Statement made by the Honorable Minister in the parliament on the prevention of cervical cancer was captured by media
    - One-on-one interviews with government representatives and district public health nurses

Progress To Date

- **Lesotho introduced the vaccine in March 2009,** targeting 9-18 yrs. females in two pilot districts:
  - 1st Round Reach: 90.5%
  - 2nd Round Reach: 94.6%
  - 3rd Round Reach : 93.5%
- At the end of 2010, Lesotho re-applied and got 120,000 doses of GARDASIL
- **Lesotho started implementation of the 2nd phase of the vaccination program in the same two pilot districts in Feb. 2011** targeting 9-13 yrs. females based on WHO guidelines
  - 1st dose given to 19,915 females
  - 2nd dose given to 19,800 females (115 children were missed due to heavy rainfall)
  - 3rd dose given to 19,200 females
- **Improvement on Cold-Chain Management:**
  - Government is fully supporting the program, budget increased from $483,871 to $2,741,935 in 2011
  - Cold room site has been identified for increasing capacity storage for 2012, additional 100 refrigerators will be procured this year to cater for the future

Addressing Key Challenges

- **Plan for Climate : Unfavourable climate conditions affected the 3rd round immunization** campaigns, and as a result, some children were missed
- **Plan for Timing: Examination time affected the 3rd round –** use school calendar for planning vaccination sessions
- **Pregnancy**: Some of the females became pregnant and did not get 2nd nor 3rd doses (e.g. 33 children in different schools became pregnant)
- **Addressing Misconceptions: Use influential people like the parliamentarians & continuous health education to address misinformation** found online or transmitted through some health professionals

Lessons Learned

- **Resource mobilization is required for sustaining the program,** hence why it is important to sensitize parliamentarians as a means of making it easier to secure financial support.
- **IEC plans should include continuous social mobilization** via radio, television and print before and during implementation. Churches are a strong way to reach many people in the community.
- **Parents need to be informed ahead of time** to solicit their support and to obtain their consent for vaccinating their children
- **Teachers were encouraged by parents who had been educated** on the benefits and risks of vaccination during community gatherings.
- **Implementation is easier when integrated with the EPI,** as existing structures for cold chain management can be used. Implementation costs also decrease after the first year.
- **Networking with development partners facilitates provision** of continued support

Conclusions

- **The MOHSW alone cannot prevent cervical cancer,** and there is need for multi-sectoral collaboration. Political will is required for sustainability of the program
- **Awareness creation is of importance to dispel myths and misconceptions** among the communities and among the targeted children
- **Networking with donors is of importance, as well as informing them about new Ministry initiatives** for the purpose of soliciting their support in prevention of cervical cancer and other cancers that affect the reproductive organs

The Ministry acknowledges the support of Axios and Merck for their donation of GARDASIL. Unity is strength and we can all be achievers in prevention of cervical cancer.

NEPAL
GARDASIL Access Program
Lessons Learned

Presented by Dr. Surendra B. Bade Shrestha
President
Nepal Network for Cancer Treatment & Research (NNCTR)
Nepal Australian Cervical Cancer Foundation (NACCF)

October 31, 2011

Program Design

Target Population

- 5th to 7th grades girl students between 11-13 years of age
- Total population of 11-13 year old girls in Nepal is about 820,000
- Every year around 300,000 girls are added to this demographic
- There are 75 districts in Nepal and this vaccination project is taking place in 7 districts

Program Design
Partners

Partners were key to driving support for the project and aiding in implementation:

Government Involvement
- Vaccine program approval was granted by the Ministry of Health and Population (MoHP)
- Monitoring of district level program implementation was done by Family Health Division (FHD)

Local Partners
- Government District Health Offices (DHO):
  - Makwanpur district to deliver vaccines to 2,000+ school girls in the district
  - Kapilbastu District to deliver vaccines to 2,500+ school girls in the district
- BPKM Cancer Hospital (Government Cancer Hospital) to deliver vaccines to 2,000+ school girls in the district of Chitwan
- NGOs at Kaski, Kathmandu, Bhaktapur and Kavre districts to deliver vaccines to 3,500 school girls
- Private Pharmaceuticle Co. (Yetichem) at Kathmandu to provide main cold chain management needs at no cost
- Other district level Government agencies and NGOs

International Partners
- Australian Cervical Cancer Foundation (ACCF) Brisbane provided financial and institutional support for local management
- Axios-managed Gardasil Access Program provided Gardasil through a pledge from Merck and Co.

Program Design
Recruitment Methods

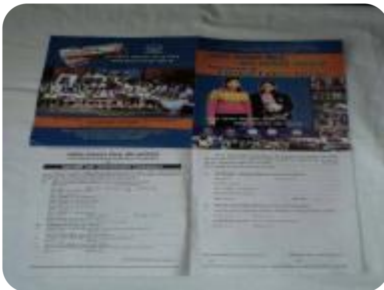
- Family Health Division (FHD) communicated official program information to the district level government agencies to encourage support
- Contact was made with public, community, private schools and their associations to reach girls, parents/guardians
- Community meetings provided an interactive environment for school administrators to teach girls and their parents about the cervix, cervical cancer and the vaccine (25-200 in attendance)
- Girls were then asked to bring back signed consent forms to school prior to the day of first vaccination.

Program Design

Administration Sites

- 20 schools and 4 clinic sites were chosen
- Schools were selected as the key administration site because:
  - The maximum numbers of girls are accessible through schools
  - Schools provide a convenient way to run vaccine awareness programs for students, teachers and parents
  - Schools provide better chance for higher reach/rate of follow-up
- A coordinator for the vaccine project was nominated by the school administration in each school
- From June 2010 to February 2011, 63 orientation center and 54 vaccine centers were organized in schools

Program Design
Communications Activities



- Prior to launching the vaccination project, a press conference was organized for local media, leading to media coverage in a number of national newspapers
- Person-to-person/mouth-to-mouth strategy was used to pass on the information to all stakeholders
- Key messages used in communications materials included basic information on the morbidity of cervical cancer and HPV vaccination as a primary preventive measure
- Communications materials (leaftlets) were developed in the local language for teachers, parents and girls
- Copies of vaccine project approval letters from the MoHP and FHD, WHO age recommendations for vaccination and other official documents, along with an information brochure, were shared with school administrations, girls and their parents to educate all parties on HPV vaccine, benefits, management of side effects

Progress to Date

Project 1: Completed on December 2008		
	Number of Girls Vaccinated	Reach/Rate of Follow-Up
1st Dose	3,206	106.9%
2nd Dose	3,196	99.7%
3rd Dose	3,164	98.69%

Project 2: September 2011-Ongoing

- Ongoing vaccination project for 10,000 girls
- 6,528 girls have already received a 1st dose of Gardasil

Lessons Learned

- **Need for early sensitization and stakeholder support**
  - The awareness of cervical cancer morbidity is still very low in urban areas and almost none in rural areas
  - People are pressed with the immediate health problems and prevention is not prevalent among Nepalese people
  - School administrations are often hesitant to have vaccine program in their schools due to:
    - Concerns about who will be responsible for any adverse reactions that may arise
    - Limited knowledge of the HPV vaccine, including benefits and safety profile
    - Concerns over not having enough time to conduct the program
  - Skepticism as to why the vaccine was provided free of cost
  - Concern on HPV vaccination as "new" and 'experimental'

- **Importance of project timing**
  - In rural areas, farming season often prevented girls from attending school, so ongoing coordination with the school was essential

Lessons Learned

- **Follow-up**
  - Follow-up for second and third doses became challenging without active cooperation of the school administration
  - For that reason, schools were encouraged to keep detailed follow-up information in a computerized database at NNCTR in Banepa following each vaccination round

- **Importance of Early Government Support in Encouraging National Programs**
  - Despite initial support for implementation, the government declined to be further involved in the initial phase of the project
  - However, positive community support, demand for the vaccine and associated media coverage prompted MoHP officials to create a small liaison and monitoring unit under the Family Health Division (FHD) for exploring the possibility of introducing the HPV vaccine at the national level
  - The Nepal Government and the MoHP gave official permission to NACCF/NNCTR to collaborate with two District Health Offices (DHO), however, it will likely still be a few years before the Government considers a national vaccination program due to:
    - limited resources
    - low priority placed on HPV vaccination (among other routine vaccinations)
    - government is also interested to monitor the pros and cons of vaccination program.

Overcoming Challenges

Potential suggestions for overcoming challenges faced in Nepal:

- Encourage a public statement from the government in support of the HPV vaccination to resolve potential skepticism among different stakeholders
- A WHO position paper on the HPV vaccination could help to clear misinformation on vaccine projects as 'new' and 'experimental'
- Push for ongoing, active cooperation from the school administration, along with more education through national and local media
- Nepal does not have National Cancer Registration and only a few major hospitals have combined their cancer incidences data to provide some basis for assumption. Cancer disease burden is still not available, and as a result. this has limited our ability to demonstrate the need for the vaccine – we hope our program will be one step in formalizing this much needed information

Questions & Answers

Please submit your questions via the chat feature on your webinar dashboard.

Please note who your question is intended for.

Questions & Answers

Please submit your questions via the chat feature on the lower left hand side of your screen in the webinar dashboard.

Please note who your question is intended for.

- **Mike Chirenje,** Chair, GARDASIL Access Program Advisory Board, and Professor, Department of Obstetrics and Gynaecology, College of Health Sciences, University of Zimbabwe
- **Lisa Tapert**, Vice President of Global Access Programs, Axios International
- **Martin Gutiérrez,** Communications Director, Centro de Investigación, Educación y Servicios (CIES)
- **Florence Mohai,** Head of Family Health Division, Lesotho Ministry of Health and Social Welfare
- **Dr. Surendra B. Bade**, President, Nepal Network for Cancer Treatment & Research (NNCTR)

We will address questions on a first come, first serve basis. If we do not get to your question, please email your question to GARDASILaccess@axiosint.com.

Thank You Very Much For Your Time.

For More Information on the
GARDASIL Access Program,
visit www.gardasilaccessprogram.org.