

## ***Partners In Health/Zanmi Lasante***

### **Results from a school-based pilot HPV vaccine intervention in Haiti's Central Plateau**

#### ***Executive Summary***

*Zanmi Lasante*, in partnership with the Haitian Ministry of Health, identified 3,806 girls aged 10-12 years in Haiti's Central Plateau who were eligible for vaccination with Gardasil® HPV vaccine. Administration of the first dose took place at 162 schools across three communities during November 2009. Despite major strains on the health system caused by the earthquake in Port-au-Prince in January 2010, 3,302 (86.8%) of the girls received their second dose. The overall three-dose completion rate was 75.8%. This rate compares favorably with completion rates in developed countries, and provides evidence for the feasibility of scaling up HPV vaccine delivery in Haiti and other resource-poor settings.

#### ***1. Overview of PIH in Haiti***

*Zanmi Lasante* (ZL – “Partners In Health” in Haitian Kreyol) is Partners In Health's sister organization in Haiti. The organization began as a small community clinic in the village of Cange in Haiti's Central Plateau in 1985. Cange is now home to the ZL Sociomedical Complex, which includes a 104-bed, full-service hospital with two operating rooms, adult and pediatric inpatient wards, an infectious disease center, an outpatient clinic, a women's health clinic, ophthalmology and general medicine clinics, a laboratory, a pharmaceutical warehouse, a blood bank, radiographic services, and a dozen schools. ZL has also expanded its operations to 15 public facilities. Today, ZL is the largest health care provider in central Haiti – serving a catchment area of 1.2 million across the Central Plateau and the Lower Artibonite. ZL employs approximately 5,000 people, almost all of them Haitians, including doctors, nurses and community health workers. In 2008, ZL recorded more than 2.6 million patient visits at clinical sites.

#### ***2. Introduction – Gardasil® HPV Vaccine***

Haiti suffers more under the burden of cervical cancer than arguably any country in the world. According to the International Agency for Research on Cancer (IARC), Haiti has among the world's highest incidence of cervical cancer at a rate of 87.3 per 100,000 women. In comparison, the cervical cancer incidence in North America is 7.7 per 100,000. Deaths from cervical cancer are also alarming high. At 48 deaths per 100,000 women, Haiti's mortality rate from cervical cancer is surpassed only by Tanzania and Lesotho. Accounting for 64 percent of all female cancer deaths,

cervical cancer is the leading cause of cancer death among women and among the total Haitian population.<sup>i</sup>

Gardasil® is a quadrivalent vaccine proven to prevent infection from four of the most common strains of human papillomavirus (HPV), including the two types that cause 70% of all cervical cancer cases. Clinical trials of Gardasil® concluded that, when administered before the onset of sexual activity, the drug prevented 100% of infections caused by these HPV strains (types 16 and 18). The recommended age of vaccination is 10-12 years. Gardasil® is given in three doses: the second dose two months after the first, and the final dose six months after the initial vaccination.<sup>ii</sup>

In 2009, ZL and the Haitian Ministry of Health (MSPP) formed a partnership with Axios International, a consulting firm designated to manage the disbursement of approximately three million doses of Gardasil® donated by Merck, the vaccine manufacturer. Given the urgency of the cervical cancer burden in Haiti and the particular vulnerability of the country's poorest women, ZL selected three underserved communes in the Central Department to receive the pilot vaccination: Lascahobas, Mirebalais and Boucan Carre. The total population of these villages and their surrounding communities is approximately 200,000. The vaccines were administered to patients in primary schools across the participating communes, utilizing the delivery platform and human resources of the MSPP.

Gardasil® was disbursed to Haiti in two separate shipments, the first of which contained 8,000 doses. After observing the attrition rate between the first and second rounds of administration, ZL and MSPP requested an additional 3,200 doses, for a total of 11,200. ZL funded the remainder of the implementation and administrative costs of the project – approximately \$30,000 – from the operational budget of ZL's *Proje Sante Fanm* ("Women's Health Project" in Haitian Kreyol).

### ***3. Methodology & Implementation***

Prior to the start of vaccination delivery, a steering committee was formed to oversee the logistics of implementation. The committee was formed at the Departmental level and included nurses and physicians from various ZL sites in the Central Plateau. The support of the director of the MSPP of the Central Department was integral to the implementation process. He wrote letters to school directors, which gave ZL access to schools and helped gain the support of the community health nurses in each commune, who were specially trained in community and population health. The nurses had specific experience running MSPP vaccination programs, management of vaccinators and training. ZL also received approval for the intervention from the director general of MSPP and was granted permission to import Gardasil® into the country

ZL and MSPP also implemented a broad community information campaign to inform the target population and their families about the risks of cervical cancer and the efficacy of Gardasil®. The campaign was carried out using various forms of mass media, including radio advertisements, posters and leaflets delivered to students and community groups in the vicinity of the target schools. It was assumed that all inhabitants of the catchment area received information regarding Gardasil and were therefore aware of the vaccination efforts taking place in the area. From each commune, 20 health care workers (60 in total) were trained for the purposes of vaccine administration, data collection and relevant health promotion.

Direct beneficiaries of the project were the 3,800 girls who were targeted to receive the vaccine. Girls aged 10-12 were identified from 162 schools across Lascahobas, Mirebalais and Boucan Carre. Schools were recruited based on their willingness to participate, and enrollment continued until 3,800 girls were registered. In participating schools, 100% of the girls in the targeted age range were enrolled in the program. School directors informed parents of the vaccination intervention, and the parents were given the opportunity to opt out of the program if they did not want their daughter to be vaccinated.

#### 4. Results

A total of 3,806 girls were given their first dose of the vaccine during the last week of November 2009. Table 1 describes the distribution of the girls by age and village. Mirebalais was the village with the largest share of participants (52.2%), followed by Lascahobas (26.4%) and Boucan Carre (21.4%).

**Table 1. Participant characteristics and compliance by village**

	Lascahobas	Mirebalais	Boucan Carre	Total
<b>Number of schools</b>	33	92	37	162
<b>Number of girls by age</b>				
10 years	397	735	316	1,448
11 years	266	508	231	1,005
12 years	343	744	266	1,353
All ages	<b>1,006 (26.4%)</b>	<b>1,987 (52.2%)</b>	<b>813 (21.4%)</b>	<b>3,806 (100%)</b>
<b>Compliance with vaccinations</b>				
Dose 1	1,006 (100%)	1,987 (100%)	813 (100%)	3,806 (100%)
Dose 2	903 (89.8%)	1,654 (83.2%)	745 (91.6%)	3,302 (86.8%)
Dose 3	857 (85.2%)	1,309 (65.9%)	718 (88.3%)	2,884 (75.8%)
<b>Lost to follow-up</b>				
After dose 1	103 (10.2%)	333 (16.8%)	68 (8.4%)	504 (13.2%)
After dose 2	46 (4.6%)	345 (17.4%)	27 (3.3%)	418 (11.0%)

A devastating earthquake struck the Haitian capital, Port-au-Prince, on January 12, 2010. The second dose was to be administered during the last week of January, but

was delayed due to the chaos brought about by the quake. Still, only 504 (13.2%) of the girls vaccinated with the first dose were lost to follow-up. Extensive efforts were made to locate many of the girls in their homes to deliver the second dose, which resulted in a total compliance rate of 86.8%. Compliance for Lascahobas and Boucan Carre were approximately 90%; the rate for Mirebalais (83.2%) may have been lower due to its close proximity to Port-au-Prince.

The third and final dose was delivered during the second week of June 2010. For both Lascahobas and Boucan Carre, the rate of compliance dropped only slightly (decreases of 4.6% and 3.3%, respectively), while the decrease in Mirebalais was more significant (17.3%). Overall, 2,884 of the original 3,806 girls received all three doses of the vaccine (75.8%).

## ***5. Challenges***

The national turmoil that resulted from the earthquake was the most significant challenge to the success of the intervention. ZL and MSPP were forced to quickly allocate resources to urgent care issues in Port-au-Prince, which diverted attention from the project. Many schools in the central plateau also closed during the immediate aftermath of the quake, which complicated efforts for follow-up and administration of the second dose. Despite this challenge, however, the second dose compliance rate of 86.8% is truly remarkable.

Another significant challenge of the campaign was that it was largely limited to schools. Girls that were not enrolled in primary education were not eligible to receive the vaccine. As noted earlier, this was done partly because of the ease with which eligible girls could be found, and to maximize potential for compliance with the second and third doses. The intervention was also planned this way to minimize costs and time. However, given the region's low primary school enrollment rate – only 33.4% among girls in the Central Department<sup>iii</sup> (the lowest in Haiti) – a more effective strategy to reach the most impoverished might involve registering girls outside of the school system. Haiti does have a community-based vaccine delivery program for younger age groups living in rural sites, but the school-based approach was preferred in this case in order to reach more girls, and because of the more complicated three-dose regimen associated with HPV vaccines.

Other challenges include the need to scale up vaccine coverage in order to achieve a broader population-level impact. While the doses of this campaign were provided at no cost to the recipients, future HPV vaccines would need to be highly subsidized or given at no cost in order to attain widespread uptake. This may prove difficult given the state of crisis in which Haiti currently finds itself, coupled with the fact that the preventive impact of the vaccine will not be realized until many years into the future. Unless an HPV vaccine is provided to eligible girls free of charge, it will continue to be a lesser priority compared to other basic health needs.

## **6. Lessons Learned**

It is important to consider the fact that the HPV vaccine was entirely new to the country – HPV was virtually unknown among the target population and even some medical providers. Cervical cancer remains a disease without a name, and under-diagnosis continues to be a major problem. Targeting this age group of girls was also challenging as public health campaigns aimed at adolescent girls or boys are currently sparse. The challenges of gaining acceptance from the government were also significant as Gardasil® was a completely new vaccine with different delivery procedures. Despite these obstacles, however, we are optimistic about the future of widespread use of an HPV vaccine in Haiti, particularly in light of the high completion rate observed in this pilot project.

This project highlights an effective approach with high levels of adherence, despite the preponderance of impoverished rural communities and an unprecedented natural disaster. The overall three-dose completion rate of 75.8% is impressive – not only considering the difficult logistics of Haiti but also compared to developed countries. Evidence from peer-reviewed studies of HPV vaccine adherence in the United States demonstrates that the three-dose completion rate in the general population is on the order of 40%.<sup>iv,v</sup> These rates were concluded from observational studies of females in the same general age group (9-17 years) who had received the first dose and were actively followed-up for regimen completion. Among vulnerable populations, including minority patients and those enrolled in public insurance programs, the three-dose completion rates were even lower.

As discussed, this project also targeted an age group generally neglected with respect to health prevention and vaccination. Given the exceptionally high degree of acceptance (of the original 3,800 identified prior to the first dose, only one girl's family refused to participate), there is a strong indication that the program would be feasible at a much larger scale. Much of this success is directly attributable to ZL's active partnership with the MSPP, its longstanding ties with the communities in which it works, and the strategic efforts of the steering committee to emphasize widespread sensitization and government support.

## **7. Future steps**

Given the extraordinary burden of cervical cancer in Haiti and ZL's demonstration that the vaccine can be administered even in the midst of one of the worst natural disasters of our time, the imperative to marshal public and private funds to implement this intervention is even greater than before. This intervention provides concrete evidence that the capability of the MSPP to deliver vaccines – even against the backdrop of an unprecedented crisis – is comparable to public health systems with far greater resources. With increased support from public and private donors, ZL and MSPP could effectively scale-up the use of an HPV vaccine to other regions of

Haiti. This will ultimately contribute to a significant reduction in the rate of cervical cancer on a national level.

## **References**

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- <sup>i</sup> **WHO/ICO Information Centre on Human Papilloma Virus (HPV) and Cervical Cancer**  
[<http://www.who.int/hpvcentre/statistics/en/>]
- <sup>ii</sup> **Nation Cancer Institute (NCI) Factsheet – HPV Vaccines**  
[<http://www.cancer.gov/cancertopics/factsheet/risk/HPV-vaccine>]
- <sup>iii</sup> Cayemittes M, Placide MF, Mariko S, Barrère B, Sévère B, Alexandre C: **Enquête Mortalité, Morbidité et Utilisation des Services, Haïti, 2005-2006**. Calverton, Maryland, USA: Ministère de la Santé Publique et de la Population, Institut Haïtien de l’Enfance et Macro International Inc.; 2007.
- <sup>iv</sup> Chao C, Velicer C, Slezak J, Jacobsen SJ: **Correlates for Completion of 3- Dose Regimen of HPV Vaccine in Female Members of a Managed Care Organization**. *Mayo Clinic Proceedings* 2009, **84**(10):864-870.
- <sup>v</sup> Staras S, Haderxhanaj L, Shenkman E: **Completion of HPV vaccine series among Florida low-income adolescents**. *APHA 138th Annual Meeting & Expo*. Denver, Colorado, USA; 2010.

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