THE LANCET Oncology

Supplementary webappendix

This webappendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Kreimer AR, González P, Katki HA, et al for the CVT Vaccine Group. Efficacy of a bivalent HPV 16/18 vaccine against anal HPV 16/18 infection among young women: a nested analysis within the Costa Rica Vaccine Trial. *Lancet Oncol* 2011; published online Aug 23. DOI:10.1016/S1470-2045(11)70213-3.

Supplementary Table. Estimated vaccine efficacy against anal and cervical HPV 31, 33, or 45 infections individually.

Cohort	HPV type	Anatomic Site	Arm	# Women	# of HPV Infections	HPV Prevalence (95%CI)	HPV Vaccine Efficacy (95%CI)
Full ¹	31	Anus	HPV	2103	30	1.4% (1.0% to 2.0%)	54.5% (30.3% to 70.8%)
			Control	2107	66	3.1% (2.5% to 3.9%)	
		Cervix	HPV	2103	35	1.7% (1.2% to 2.3%)	54.5% (32.4% to 69.8%)
			Control	2107	77	3.7% (2.9% to 4.5%)	
Restricted ²	31	Anus	HPV	1678	18	1.15 (0.7% to 1.7%)	62.3% (36.0% to 78.5%)
			Control	1724	49	2.8% (2.1% to 3.7%)	
		Cervix	HPV	1678	22	1.3% (0.8% to 1.9%)	- 63.5% (41.3% to 78.0%)
			Control	1724	62	3.6% (2.8% to 4.6%)	
Full ¹		Anus	HPV	2103	18	0.9% (0.5% to 1.3%)	-6.1% (-108% to 45.8%)
			Control	2107	17	0.8% (0.5% to 1.3%)	
		Cervix	HPV	2103	22	1.0% (0.7% to 1.6%)	4.2% (-73% to 47.0%)
			Control	2107	23	1.1% (0.7% to 1.6%)	
Restricted ²	33	Anus	HPV	1717	13	0.8% (0.4% to 1.3%)	21.3% (-62.8% to 62.7%)
			Control	1767	17	1.0% (0.6% to 1.5%)	
		Cervix	HPV	1717	14	0.8% (0.4% to 1.3%)	24.2% (-51.7% to 62.8%)
			Control	1767	19	1.1% (0.7% to 1.6%)	
Full ¹	45	Anus	HPV	2103	13	0.6% (0.3% to 1.0%)	- 60.5% (26.0% to 79.9%)
			Control	2107	33	1.6% (1.1% to 1.2%)	
		Cervix	HPV	2103	22	1.0% (0.7% to 1.6%)	54.1% (24.5% to 72.7%)
			Control	2107	48	2.3% (1.7% to 3.0%)	

Restricted ²		Anus	HPV	1704	9	0.5% (0.3% to 1.0%)	62.8% (21.9% to 83.5%)
			Control	1761	25	1.4% (0.9% to 2.1%)	
		Cervix	HPV	1704	17	1.0% (0.6% to 1.6%)	52.5% (16.4% to 73.9%)
			Control	1761	37	2.1% (1.5% to 2.9%)	

¹Full analysis cohort included all women who accepted anal specimen.

²Restricted cohort included women from the full cohort with no evidence of prevalent cervical HPV 31, 33, or 45 infection (depending on analytic type in question) prior to vaccination, and who received three doses of the HPV or control vaccine.

Acknowledgements.

We would like to extend a special thanks to the women of Guanacaste and Puntarenas, Costa Rica, who gave of themselves in participating in this effort. We also acknowledge the tremendous effort and dedication of the staff in Costa Rica involved in this project, including Bernardo Blanco and his team (census), Ricardo Cerdas and Ana Hernández (blood processing), José Miguel González, Osman López, Johnny Matamoros, Manuel Sánchez, Rafael Thompson and Jorge Umaña (field activity coordinators), Su Yen Araya, Hazel Barquero, Hayleen Campos, Muriel Grijalba, Ana Cristina Monge, Ana Peraza, Diana Robles, María Fernanda Sáenz, Dorita Vargas, and Jessica Vindas (clinic coordinators), Paola Alvarez, Dinia Angulo, Ana Live Arias, Betzaida Barrantes, Marianela Bonilla, Mary José Calvo, Loretto Carvajal, Jessenia Chinchilla, Blanca Cruz, Marianela Herrera, Andrea Interiano, Fabiola Jiménez, Erick Lagos, Viviana Loría, Andrea Messeguer, Rebeca Ocampo, Silvia Padilla, Angie Ramírez, Libia Rivas, Daniela Romero, Byron Romero, Jessenia Ruiz, Daniela Ruiz, Genie Saborío, Sofía Ssoto, Malena Salas, Adriana Torrez, Natalia Ugalde, Ana Cristina Ugalde, Adriana Vallejos, Yesenia Vázquez, Maricela Villegas (clinicians), Marta Alvarado, Ana Cristina Arroyo, Gloriana Barrientos, Diana Díaz, Marlen Jara, Maureen Matarrita, María Ester Molina, Elida Ordóñez, Gina Sánchez, and Zihara Villegas (nurses), Arianne Castrillo and Vivian López (education and outreach effort coordinators), Karla Coronado (appointment coordinator), Ricardo Alfaro (quality control coordinator), Charles Sánchez and Livia Romero (document center coordinators), Cristian Montero (quality assurance, regulatory) and Carlos Avila and Eric Alpízar (IT coordinators). Special recognition is also extended to Sofía Elizondo, Executive Director of Fundación INCIENSA and her staff for their administrative support. In the United States we would like to extend our appreciation to the team from Information Management Services (IMS) responsible for the development and maintenance of the data system used in the trial and who serve as the data management center for this effort. We would like to specifically acknowledge the invaluable contributions made by Jean Cyr, Julie Buckland, Laurie Rich, Brian Befano and Dennis Buckman. We acknowledge the contributions made by individuals at Westat, Inc., who provided project development and/or monitoring support, including Kerry Grace Morrisey, Kirk Midkiff, Susan Truitt, Sonia Stoszek, Maribel Gomez, and Isabel Trejos. We acknowledge the assistance provided by Carla Chorley, Troy Moore, Kathi Shea, and Heather Siefers in the establishment of a specimen and vaccine repository for our trial and in their continued assistance with the handling and shipment of

specimens. From GSK Biologicals, we would like to acknowledge Gary Dubin, Anne Schuind, Frank Struyf, Kelechi Lawrence, Darrick Fu, and Bruce Innis for their contribution to discussions regarding trial conduct and Francis Dessy and Catherine Bougelet for HPV-16/18 antibody testing. We would like to thank members of the Data and Safety Monitoring Board charged with protecting the safety and interest of participants in our trial (Steve Self, Chair, Adriana Benavides, Luis Diego Calzada, Ruth Karron, Ritu Nayar, and Nancy Roach) and members of the external Scientific HPV Working Group who have contributed to the success of our efforts over the years (Joanna Cain, Chair, Diane Davey, David DeMets, Francisco Fuster, Ann Gershon, Elizabeth Holly, Silvia Lara, Henriette Raventós, Wasima Rida, Luis Rosero-Bixby, Kristen Suthers, Sarah Thomas and Raphael Viscidi). We thank Annet Westbroek and Yvonne Zomerdijk from DDL for their help in testing the anal specimens, John Schussler from IMS for his help with the analysis, and Nora Macklin from NCI for her support in preparing the manuscript for submission.