

Appendix. Supplementary Tables

Table 1. Overall Pregnancy Outcome Summary (Protocol 016)

	HPV 6/11/16/18 Vaccine
Number of women who became pregnant	11
Total number of pregnancies	11
Total number of pregnancies with known outcome	8
Live births	
Number of live births/number of pregnancies with known outcome	6/8 (75)
Normal	6/6 (100)
Method of delivery	
Vaginal	6/6 (100)
Fetal loss	2/8 (25)
Type of loss	
Spontaneous abortion	1/2 (50)
Elective abortion	1/2 (50)
Fetal outcome	
Unknown	2/2 (100)

Data are n/N (%) unless otherwise specified.

Garland SM, Ault KA, Gall SA, Paavonen J, Sings HL, Ciperro KL et al. Pregnancy and infant outcomes in the clinical trials of a human papillomavirus type 6/11/16/18 vaccine: a combined analysis of five randomized controlled trials. *Obstet Gynecol* 2009;114.

Table 2. Overall Pregnancy Outcome Summary (Protocol 018)

	HPV6/11/16/18 Vaccine	Placebo
Number of women who became pregnant	6	2
Total number of pregnancies	6	2
Total number of pregnancies with known outcome	4	2
Live births		
Number of live births/number of pregnancies with known outcome	0/4 (0)	1/2 (50)
Normal	0	1/1 (100)
Method of delivery		
Vaginal	0	1/1 (100)
Fetal loss		
Number of fetal losses/number of pregnancies with known outcome	4/4 (100)	1/2 (50)
Type of loss		
Spontaneous abortion	1/4 (25)	0
Elective abortion	3/4 (75)	1/1 (100)
Fetal outcome		
Unknown	4/4 (100)	1/1 (100)

Data are n/N (%) unless otherwise specified.

Garland SM, Ault KA, Gall SA, Paavonen J, Sings HL, Ciperro KL et al. Pregnancy and infant outcomes in the clinical trials of a human papillomavirus type 6/11/16/18 vaccine: a combined analysis of five randomized controlled trials. *Obstet Gynecol* 2009;114.

Table 3. Overall Pregnancy Outcome Summary (Protocol 013)

	HPV6/11/16/18 Vaccine	Placebo
Number of women who became pregnant	548	531
Total number of pregnancies	632	612
Total number of pregnancies with known outcome	618	609
Live births		
Number of live births/number of pregnancies with known outcome	444/618 (71.8)	427/609 (70.1)
Normal	411/444 (92.6)	394/427 (92.3)
Abnormal*	30/444 (6.8)	31/427 (7.3)
Congenital or other anomaly	8/444 (1.8)	9/427 (2.1)
Other medical condition	24/444 (5.4)	22/427 (5.2)
Unknown	3/444 (0.7)	2/427 (0.5)
Method of delivery		
Cesarean	160/444 (36.0)	137/609 (32.1)
Vaginal	283/444 (63.7)	290/609 (67.9)
Unknown	1/444 (0.2)	0 (0)
Fetal loss		
Number of fetal losses/number of pregnancies with known outcome	174/618 (28.2)	182/609 (29.9)
Type of loss		
Spontaneous abortion	120/174 (69.0)	122/182 (67.0)
Late fetal death	3/174 (1.7)	5/182 (2.7)
Elective abortion	51/174 (29.3)	55/182 (30.2)
Fetal outcome		
Normal	14/174 (8.0)	12/182 (6.6)
Abnormal [†]	5/174 (2.9)	6/182 (3.3)
Congenital or other anomaly	0/174 (0)	0/182 (0)
Other medical conditions	4/174 (2.3)	6/182 (3.3)
Unknown	155/174 (89.1)	164/182 (90.1)

Data are n/N (%) unless otherwise specified.

*Two infants in the vaccine group appear in both categories "congenital or other anomaly" and "other medical condition."

[†]One vaccine recipient reported an abnormal fetal outcome with no further information.

Garland SM, Ault KA, Gall SA, Paavonen J, Sings HL, Ciperro KL et al. Pregnancy and infant outcomes in the clinical trials of a human papillomavirus type 6/11/16/18 vaccine: a combined analysis of five randomized controlled trials. *Obstet Gynecol* 2009;114.

Table 4. Overall Pregnancy Outcome Summary (Protocol 015)

	HPV6/11/16/18	Placebo
Number of women who became pregnant	1,092	1,125
Total number of pregnancies	1,284	1,331
Total number of pregnancies with known outcome	1,255	1,283
Live births		
Number of live births/number of pregnancies with known outcome	908/1255 (72.4)	903/1283 (70.4)
Normal	855/908 (94.2)	871/903 (96.5)
Abnormal*	52/908 (5.7)	30/903 (3.3)
Congenital or other anomaly	21/908 (2.3)	9/903 (1.0)
Other medical condition	33/908 (3.6)	21/903 (2.3)
Unknown	1/908 (0.1)	2/903 (0.2)
Method of delivery		
Cesarean	212/908 (23.3)	214/903 (23.7)
Vaginal	696/908 (76.7)	688/903 (76.2)
Unknown	0 (0)	1/903 (0.1)
Fetal loss		
Number of fetal losses/number of pregnancies with known outcome	347/1255 (27.6)	380/1283 (29.6)
Type of loss		
Spontaneous abortion	217/347 (62.5)	241/380 (63.4)
Late fetal death	14/347 (4.0)	9/380 (2.4)
Elective abortion	115/347 (33.1)	130/380 (34.2)
Unknown	1/347 (0.3)	0 (0)
Fetal outcome		
Normal	16/347 (4.6)	12/380 (3.2)
Abnormal [†]	7/347 (2.0)	13/380 (3.4)
Congenital or other anomaly	1/347 (0.3)	3/380 (0.8)
Other medical conditions	6/347 (1.7)	7/380 (1.8)
Unknown	324/347 (93.4)	355/380 (93.4)

Data are n/N (%) unless otherwise specified.

*Three infants in the vaccine group appear in both categories "congenital or other anomaly" and "other medical condition."

[†]One placebo recipient reported two fetal losses with no further information. A second placebo recipient reported an abnormal fetal outcome with no further information.

Garland SM, Ault KA, Gall SA, Paavonen J, Sings HL, Cipraro KL et al. Pregnancy and infant outcomes in the clinical trials of a human papillomavirus type 6/11/16/18 vaccine: a combined analysis of five randomized controlled trials. *Obstet Gynecol* 2009;114.

Table 5. Overall Pregnancy Outcome Summary (Protocol 019)

	HPV 6/11/16/18	Placebo
Total number of pregnancies	152	176
Total number of pregnancies with known outcome	123	135
Live births		
Number of live births /number of pregnancies with known outcome	89/123 (72.4)	93/135 (68.8)
Normal	83/89 (93.3)	88/93 (94.6)
Abnormal*	6/89 (6.7)	5/93 (5.4)
Congenital or other anomaly	2/89 (2.2)	2/93 (2.2)
Other medical condition	5/89 (5.6)	3/93 (3.2)
Method of delivery		
Cesarean	31/89 (34.8)	28/93 (30.1)
Vaginal	58/89 (65.2)	65/93 (69.9)
Fetal loss		
Number of fetal losses/number of pregnancies with known outcome	34/123 (27.6)	42/135 (31.1)
Type of loss		
Spontaneous abortion	27/123 (21.9)	32/135 (23.7)
Late fetal death	0	1/135 (0.7)
Elective abortion	5/123 (4.1)	5/135 (3.7)
Ectopic pregnancy	2/123 (1.6)	3/135 (2.3)
Unknown	0	1/135 (0.7)
Fetal outcome[†]		
Normal	1/32 (3.1)	3/39 (7.7)
Abnormal	1/32 (3.1)	3/39 (7.7)
Congenital or other anomaly	1/32 (3.1)	0
Other medical conditions	0	3/39 (7.7)
Unknown	30/32 (93.7)	33/39 (84.6)

Data are n/N (%) unless otherwise specified.

*One infant in the vaccine group appear in both categories "congenital or other anomaly" and "other medical condition".

[†]Excludes ectopic pregnancies.

Garland SM, Ault KA, Gall SA, Paavonen J, Sings HL, Ciprero KL et al. Pregnancy and infant outcomes in the clinical trials of a human papillomavirus type 6/11/16/18 vaccine: a combined analysis of five randomized controlled trials. *Obstet Gynecol* 2009;114.

Table 6. Pregnancies With Estimated Date of Conception Within 30 Days of Any Vaccination* for Women Enrolled in Phase III Trials of Quadrivalent HPV Vaccine: Merck V501-013 (FUTURE I), 015 (FUTURE II), 016, 018 and 019

	Protocol 013, 015, 016, and 018 (Data From Reference 3)		Protocol 019	
	Quadrivalent Vaccine	Placebo	Quadrivalent Vaccine	Placebo
Number of pregnancies	114	114	14	24
Number of pregnancies with known outcome	112	115	14	23
Live births				
Number of live births/number of pregnancies with known outcome	70/112 (62.5)	66/115 (57.4)	9/14 (64.3)	18/23 (78.3)
Normal	56/70 (80.0)	59/66 (89.4)	9/9 (100)	15/18 (83.3)
Abnormal	14/70 (20.0)	6/66 (9.1)	0 (0)	3/18 (16.7)
Congenital or other anomaly	5/70 (7.1)	0/66 (0)	0 (0)	1/18 (5.6)
Other medical conditions	9/70 (12.9)	6/66 (9.1)	0 (0)	2/18 (11.1)
Unknown	0/70 (0.0)	1/66 (1.5)	0 (0)	0 (0)
Method of delivery				
Cesarean	22/70 (31.4)	18/66 (27.3)	2 (22.2)	4 (22.2)
Vaginal	48/70 (68.6)	47/66 (71.2)	7 (77.8)	14 (77.8)
Unknown	0 (0)	1/66 (1.5)	0 (0)	0 (0)
Fetal loss				
Number of fetal losses/number of pregnancies with known outcome	42/112 (37.5)	49/115 (42.6)	5/14 (35.7)	5/23 (22.7)
Type of loss				
Spontaneous abortion	19/42 (45.2)	26/49 (53.1)	4/5 (80)	3/5 (60)
Late fetal death	2/42 (4.7)	0 (0)	0 (0)	0 (0)
Elective abortion	21/42 (0.5)	23/49 (46.9)	1/5 (20)	0 (0)
Ectopic pregnancy	0 (0)	0 (0)	0 (0)	2/23 (8.7)
Fetal outcome [†]				
Normal	2/42 (4.8)	0/49 (0)	0 (0)	0 (0)

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Abnormal	0/42 (0)	1/49 (2.0)	0 (0)	0 (0)
Congenital anomaly	0/42 (0)	0/49 (0)	0 (0)	0 (0)
Other medical conditions	0/42 (0)	1/49 (2.0)	0 (0)	0 (0)
Unknown	40/42 (95.2)	48/49 (98.0)	5/5 (100)	3/3 (100)

FUTURE, Females United to Unilaterally Reduce Endo/Ectocervical Disease.

Data are n/N (%) unless otherwise specified.

*Includes three women whose estimated dates of conception were 36, 43, and 48 days prior to dose 1.

†Excludes ectopic pregnancies.

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