

## Supplemental Information

### QUESTIONNAIRE A: PARENT SURVEY

#### Long-term Outcomes Associated With Extended-Interval Dosing of the 9vHPV Vaccine: A Prospective, Observational Cohort Study Supplementary to V503-069 Clinical Trial

##### Parent Survey

(Questionnaire A)

Version: v2.0

Date: March 8, 2021

Questionnaire A will be completed by one of the subject's parents (or other legal guardian) at or near the index date (ie, 1 month after the date of the administration of the second 9vHPV vaccine dose).

##### Introductory Statement

Thank you for allowing your child to participate in this research study and for taking the time to take this quick survey!

You will now be asked to answer 6 questions in relation to the HPV vaccine that your child recently received.

The survey will take <5 minutes to complete in total. Your answers are confidential and anonymous.

You can skip any question that you choose not to answer by clicking the "next" button. You can also use the "previous" button to return to a previous question and add or change an answer.

Once the survey is finished, please be sure to click the "submit" button at the end to save your answers. This makes it so that the link no longer opens the survey, and the information is secure.

Your Child's Study Subject ID Number: [Assigned by Study Staff]

Questions about your child's 9vHPV vaccine

Question 1: Why did your child not receive his/her second dose of the HPV vaccine per the vaccine schedule (ie, within 6–12 months after the first dose)?

Please check all that apply.

- ◆ I forgot about my child's appointment to receive the second dose.
- ◆ I was not aware that he/she was scheduled to receive a second dose.
- ◆ I could not find transportation to go with my child to the clinic/hospital.
- ◆ I was not able to schedule a convenient date and time for the appointment.
- ◆ My child had an unpleasant experience (eg, due to side effects) with the first dose.
- ◆ I was afraid of side-effects from the second vaccine dose.
- ◆ I could not afford the second vaccine dose (it was too expensive).
- ◆ I decided it was not needed because my child is not sexually active.

- ◆ I did not want my child to take the vaccine because I thought it would make him/her more sexually active and/or not practice safe sex.
- ◆ My child had an unexpected medical condition preventing him/her from receiving the second dose.
- ◆ I did not want my child to receive the second dose for other reasons, please specify: \_\_\_\_\_
- ◆ My child was unable to receive the second dose for other reasons, please specify: \_\_\_\_\_

Question 2: What would have helped you to make sure your child received the second vaccine dose in time (ie, within 6–12 months of the first vaccine dose)?

Please check all that apply.

- Reminders about the medical appointment.
- More information about HPV.
- More information about side effects from the vaccine.
- Financial aid (ie, that you did not have to pay for the vaccine yourself).
- Nothing, it was my decision that he/she should not take the second dose as intended.
- Other, please specify: \_\_\_\_\_

Background questions

Question 3: What is your age?

\_\_\_\_\_ years

Question 4: What is your sex?

- Female
- Male

Question 5: What is your highest level of education?

- Elementary school ( $\leq$  grade 5)
- Middle school (grade 6–8)
- High school diploma/General Educational Development (GED)
- Vocational-technical (trade) school degree
- Some college, but no degree
- College, associated degree (eg, AA and AS)
- University, bachelor's degree (eg, BA and BS)
- University, post-graduate degree (eg, MA, MS, and PhD)
- Professional degree (eg, MD and JD)
- Other, please specify \_\_\_\_\_

Question 6: What is your monthly household income?

Here we are asking about the total amount of money that is available each month for household spending and/or saving after taxes have been taken out.

- <\$1000  \$3000-\$3499  \$5500-\$5999  \$8000-\$8499
- \$1000-\$1499  \$3500-\$3999  \$6000-\$6499
- \$8500-\$8999  \$1500-\$1999  \$4000-\$4499
- \$6500-\$6999  \$9000-\$9499  \$2000-\$2499
- \$4500-\$4999  \$7000-\$7499  \$9500-\$9999
- \$2500-\$2999  \$5000-\$5499  \$7500-\$7999
- \$10 000 or more
- Prefer not to answer

## QUESTIONNAIRE B: ADOLESCENT SURVEY

### Long-term Outcomes Associated With Extended-Interval Dosing of the 9vHPV Vaccine: A Prospective, Observational Cohort Study Supplementary to V503-069 Clinical Trial

#### Adolescent Survey

(Questionnaire B)

Version: 2.0

Date: March 8, 2021

Questionnaire B will be completed by the subject annually across the prospective follow-up once he/she has turned 16 years of age.

#### Introductory Statement

Thank you for taking the time to participate in this research study!

You will now be asked to answer a number of questions related to risk factors for HPV, a common sexually transmitted infection for which you have been vaccinated. The vaccine has been shown to prevent common diseases caused by HPV. The questions concern your relationship status, sexual history and activity, and alcohol and drug use.

The questionnaire will take ~20 minutes to complete in total.

The survey is not a test. There are no right or wrong answers to any of the survey questions. We are interested in your experiences as you get older to help us learn more about HPV disease.

Your answers are confidential and anonymous. This means that only the study team at Kaiser will see them and that your name is not on the survey. We will not tell anyone else how you answered the questions, not even your parents if they ask.

We ask that you respond to each question and answer all the questions honestly. However, you can skip any question that you choose not to answer by clicking the “next” button. You can also use the “previous” button to return to a previous question and add or change an answer.

Once the survey is finished, please be sure to click the “submit” button at the end to save your answers. This makes it so that the link no longer opens the survey, and the information is secure.

Study Subject ID Number: [Assigned by Study Staff]

Relationship Status

Question 1: Are you currently in a sexual relationship?

Yes (go to Question 3)

No

Question 2: Have you been in a sexual relationship in the last 12 months?

Yes

No

Sexual Orientation/Identity, History, and Activity

Question 3: What is your sexual orientation/identity?

Heterosexual

Homosexual

Bisexual

Do not know

Other, please specify |\_\_\_\_\_|

Question 4: Have you ever had sex (eg, vaginal, oral, or anal intercourse)?

Yes

No (go to Question 12a)

Question 5: At what age did you have sex (eg, vaginal, oral, or anal intercourse) for the first time?

|\_\_\_\_| years of age

Question 6: Are you currently sexually active (ie, having sex at least once a month)?

With sex, we refer to, for example, vaginal, oral, or anal intercourse.

Yes (go to Question 8)

No

Question 7: Have you been sexually active (eg, had vaginal, oral, or anal intercourse) within the last 12 months?

Yes (go to Question 9)

No (go to Question 10)

Question 8: How many sexual partners do you currently have?

Please count all persons (eg, boyfriend/girlfriend, hook-ups, anonymous partners, and friends) you have been having sex with on a regular basis (ie, once a month, or more frequently) during the last 3 months.

|\_\_\_\_| partner(s)

Question 9: How many persons have you had sex with in total in the last 12 months?

|\_\_\_\_| person(s)

Question 10: How many persons have you had sex with in total in your lifetime?

|\_\_\_\_| person(s) (If female: go to Question 11a; if male: go to Question 11b)

Question 11a: Do you currently use birth control (eg, pills, mini pills, or condoms)? (female subjects only)

Yes (go to Question 11c)

No (go to Question 12a)

Question 11b: Do you use condoms when you are having sex? (male subjects only)

No, never (go to Question 12a)

Yes, less than half of all times (go to Question 12a)

Yes, approximately half of all times (go to Question 12a)

Yes, more than half of all times (go to Question 12a)

Yes, always (go to Question 12a)

Question 11c: What type of birth control do you use?

Please check all that apply.

Pills

Mini pills

- Patch
- Shot
- Vaginal ring
- Condoms (If checked, go to Question 11d; if not checked, go to Question 12a)
- Diaphragms
- Sponge
- Cervical cap
- Other, please specify \_\_\_\_\_

Question 11d: How often do you use condoms when you are having sex? (female subjects only)

- Less than half of all times
- Approximately half of all times
- More than half of all times
- Always

#### Alcohol, Tobacco, and Drug Use

Question 12a: During the last 12 months, how often did you have any kind of drink containing alcohol?

By a drink, we mean the equivalent amount of alcohol to a 12-ounce can or glass of beer or cooler, 1 glass of wine, or 1 shot of liquor.

- Every day
- 5 to 6 times a week
- 3 to 4 times a week
- Twice a week
- Once a week
- 2 to 3 times a month
- Once a month
- 3 to 11 times in the past year
- 1 or 2 times in the past year
- I did not drink any alcohol in the past year, but I did drink in the past (go to Question 13a)
- I have never drunk any alcohol in my life (go to Question 13a)

Question 12b: During the last 12 months, how many alcoholic drinks did you have on a typical day when you drank alcohol?

- 25 or more drinks
- 19 to 24 drinks
- 16 to 18 drinks
- 12 to 15 drinks
- 9 to 11 drinks
- 7 to 8 drinks
- 5 to 6 drinks
- 3 to 4 drinks
- 2 drinks
- 1 drink

Question 12c: During the last 12 months, what is the largest number of drinks containing alcohol that you drank within a 24-hour period?

- 36 or more drinks
- 25 to 35 drinks

- 19 to 24 drinks
- 16 to 18 drinks
- 12 to 15 drinks
- 9 to 11 drinks
- 7 to 8 drinks
- 5 to 6 drinks
- 3 to 4 drinks
- 2 drinks
- 1 drink

Question 13a: Do you currently smoke tobacco cigarettes or use e-cigarettes/vapes?

- Yes, daily (go to Question 13c)
- Yes, less than daily (go to Question 13d)
- No, not at all (go to Question 13b)

Question 13b: In the past, have you smoked tobacco cigarettes or used e-cigarettes/vapes?

- Yes, daily (go to Question 13f)
- Yes, less than daily (go to Question 13g)
- No, not at all (go to Question 14)

Question 13c: What is your average daily tobacco consumption?

\_\_\_\_\_ tobacco cigarettes per day (go to Question 14)

\_\_\_\_\_ times using e-cigarettes/vapes per day (go to Question 14)

Question 13d: On average, how many cigarettes do you smoke per week?

\_\_\_\_\_ tobacco cigarettes per week (go to Question 14)

If you use e-cigarettes/vapes, please check this box:  (go to Question 13e)

Question 13e: On average, how often do you use e-cigarettes/vapes?

- Almost daily (go to Question 14)
- A few times per week (go to Question 14)
- Approximately once a week (go to Question 14)
- Approximately every other week (go to Question 14)
- Approximately once a month (go to Question 14)

Question 13f: What was your average daily tobacco consumption?

\_\_\_\_\_ tobacco cigarettes per day (go to Question 14)

\_\_\_\_\_ times using e-cigarettes/vapes per day (go to Question 14)

Question 13g: On average, how many cigarettes did you smoke per week?

\_\_\_\_\_ tobacco cigarettes per week (go to Question 14)

If you used e-cigarettes/vapes, please check this box:  (go to Question 13h)

Question 13h: On average, how often did you use e-cigarettes/vapes?

- Almost daily
- A few times per week
- Approximately once a week
- Approximately every other week

Approximately once a month  
Question 14: During the last 12 months, have you smoked/eaten marijuana (weed)?

- Yes, daily on average
- Yes, almost daily on average
- Yes, a few times per week on average
- Yes, approximately once a week on average
- Yes, approximately every other week on average
- Yes, approximately once a month on average
- No

Question 15: During the last 12 months, have you used any illicit drugs (eg, MDMA<sup>a</sup>/ecstasy, heroin, or cocaine)?

Please check all that apply.

- Yes, daily on average.
- Please specify which illicit drug(s): \_\_\_\_\_|

- Yes, almost daily on average.
- Please specify which illicit drug(s): \_\_\_\_\_|
- Yes, a few times per week on average.
- Please specify which illicit drug(s): \_\_\_\_\_|
- Yes, approximately once a week on average.
- Please specify which illicit drug(s): \_\_\_\_\_|
- Yes, approximately every other week on average.
- Please specify which illicit drug(s): \_\_\_\_\_|
- Yes, approximately once a month on average.
- Please specify which illicit drug(s): \_\_\_\_\_|
- No<sup>a</sup>

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<sup>a</sup>3,4-Methylenedioxymethamphetamine; this was not defined in the survey as received by participants.

<b>SUPPLEMENTAL TABLE 7</b> HPV cLIA Seropositivity at Day 1 by Dose Interval Group (All Randomized Participants in Cohort 0)												
	12 to 24 mo (N = 57)			24 to 36 mo (N = 71)			36 to 54 mo (N = 18)			Total (N = 146)		
	Day 1 Serostatus			Day 1 Serostatus			Day 1 Serostatus			Day 1 Serostatus		
Assay (cLIA)	n	Positive, m (%)	95% CI (%)	n	Positive, m (%)	95% CI (%)	n	Positive, m (%)	95% CI (%)	n	Positive, m (%)	95% CI (%)
Anti-HPV 6	57	24 (42.1)	29.1–55.9	71	30 (42.3)	30.6–54.6	18	9 (50.0)	26.0–74.0	146	63 (43.2)	35.0–51.6
Anti-HPV 11	57	31 (54.4)	40.7–67.6	71	35 (49.3)	37.2–61.4	18	13 (72.2)	46.5–90.3	146	79 (54.1)	45.7–62.4
Anti-HPV 16	57	40 (70.2)	56.6–81.6	71	39 (54.9)	42.7–66.8	18	9 (50.0)	26.0–74.0	146	88 (60.3)	51.9–68.3
Anti-HPV 18	57	27 (47.4)	34.0–61.0	71	27 (38.0)	26.8–50.3	18	10 (55.6)	30.8–78.5	146	64 (43.8)	35.6–52.3
Anti-HPV 31	57	26 (45.6)	32.4–59.3	71	23 (32.4)	21.8–44.5	18	8 (44.4)	21.5–69.2	146	57 (39.0)	31.1–47.5
Anti-HPV 33	57	36 (63.2)	49.3–75.6	71	36 (50.7)	38.6–62.8	18	12 (66.7)	41.0–86.7	146	84 (57.5)	49.1–65.7
Anti-HPV 45	57	16 (28.1)	17.0–41.5	71	16 (22.5)	13.5–34.0	18	7 (38.9)	17.3–64.3	146	39 (26.7)	19.7–34.7
Anti-HPV 52	57	25 (43.9)	30.7–57.6	71	28 (39.4)	28.0–51.7	18	10 (55.6)	30.8–78.5	146	63 (43.2)	35.0–51.6
Anti-HPV 58	57	24 (42.1)	29.1–55.9	71	38 (53.5)	41.3–65.5	18	8 (44.4)	21.5–69.2	146	70 (47.9)	39.6–56.4

CI, confidence interval; m, number of participants who are serostatus positive at day 1; n, number of participants with non-missing day 1 anti-HPV cLIA results; N, number of participants randomized to the respective age group.  
Percentages are calculated as 100\*(m/n).

<b>SUPPLEMENTAL TABLE 8</b> Baseline Characteristics for the Subset of Observational Survey Participants	
	Participants (N = 99)
Sex, n (%)	
Male	57 (57.6)
Female	42 (42.4)
Age at first HPV dose, y, n (%)	
9	3 (3.0)
10	10 (10.1)
11	58 (58.6)
12	23 (23.2)
13	5 (5.1)
Race, n (%)	
White	44 (44.4)
Asian	23 (23.2)
Unknown/declined to state	19 (19.2)
Black	9 (9.1)
Hawaiian/Pacific islander	2 (2.0)
Native American	2 (2.0)
Ethnicity, n (%)	
Not Hispanic	71 (71.7)
Hispanic	28 (28.3)
Time interval between dose 1 and dose 2, days	
Mean (SD)	756.9 (269.7)
Median (range)	757 (365–1546)