Statistical Analytic Plan v1.2

Official title: SEARCH: Short Message Service (SMS) Electronic Adolescent Reminders for Completion of HPV Vaccination - Uganda: Pilot

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Aim: To pilot assess the impact and feasibility of vaccine reminders on HPV vaccination

Primary Analysis
The outcome will be timeliness of vaccination (time to event). Time will be from start of main message series to receipt of the next needed dose. For those who did not receive the dose, time will be right censored at 6 months The primary analysis will be intention-to-treat (ITT), whether or not further messages were declined or undeliverable.

Timeliness of vaccine receipt will be compared using Kaplan-Meier curves using a stratified log rank test. In addition, in order to gain effect sizes needed for a future large-scale intervention, comparisons will also be stratified assessing those due for the first dose (initiation) and second dose (completion). It will also be assessed using chi square analyses.

A secondary per protocol analysis will only include those who received the entire set of reminders.

Outcome Variables
1) Receipt of by 24 weeks for dose 1 for uninitiated
    a. Yes, if Day enrollment to HPV dose 1 is < 168 days
    b. No, if Day enrollment to HPV dose 1 is >= 168 days
    c. No, if never received

2) Receipt of by 24 weeks for dose 2 for initiated
    a. Yes, if Day enrollment to HPV dose 2 is < 168 days
    b. No, if Day enrollment to HPV dose 2 is >= 168 days
    c. No, if never received

3) Receipt of by 24 weeks combined
    d. Yes, if Day enrollment to next needed dose (1st or 2nd depending on if initiated or uninitiated) is < 168 days

a. No, if Day enrollment to next needed dose (1st or 2nd depending on if initiated or uninitiated) is >= 168 days
b. No, if never received

Analyses:

1. Chi square of randomization group by 24 week variables

2. Calculate relative "risk"

3. Check for interaction term by language and by site for randomization (separately)

4. Calculate number needed to treat for one additional vaccination by 24 weeks for dose 1, dose 2 or either (combined variable)

5. Run Kaplan-Meier curve. Outcomes are the 24 week variables.