# Pap Smear Collection With the Papette Brush: A Pragmatic Study

NCT05034614

5/20/2021

## General Study Information

Principal Investigator: Danielle O'Laughlin, PA-C, MS

Co-Investigators: [redacted]

Study Title: Pap smear collection with the Papette Brush: A Pragmatic Study

Protocol version number and date: Version 1; 5/20/2021

## Research Question and Aims

Hypothesis: The Papette brush used for cervical cancer screening is non-inferior to traditional spatula and cytobrush in obtaining a satisfactory endocervical sample for cytology.

Aims, purpose, or objectives:

1) Compare use of Papette brush to traditional spatula and cytobrush for cervical cancer screening.
2) Analyze rate of "inadequate endocervical cells" reported in cytology samples obtained by using Papette and traditional spatula and cytobrush.
3) Evaluate operator experience with Papette vs. traditional spatula and cytobrush in terms of ease of usage, time of collection, procedure related cervical bleeding and perceived pain.

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc.*):

The Papette brush, in contrast to the spatula-cytobrush, is a single device used for Pap smear collection that obtains the exocervix and endocervix sample simultaneously. Despite being available since the early 90's and a report that indicated adequate sampling with decreased bleeding associated with Papette use (ref), this device has not been extensively studied. A Cochrane report published in 2000 showed superiority of combined spatula-cytobrush to just spatula for cervical cells sampling in Pap smear. Despite simplicity in design, the Papette has also not been widely used in our institution. One main driver is cost – the Papette costs at least twice the cytobrush-spatula kit. The Papette has been reported to obtain a satisfactory sample in 91.4% of women and may provide increased patient and provider satisfaction due to ease of use as well as potentially decreased post-procedure cervical bleeding. This study will compare the Papette to the spatula-cytobrush for Pap smear sample collection.

Reference:

Ferenczy A, Robitaille J, Guralnick M, Shatz R. Cervical cytology with the Papette sampler. J Reprod Med. 1994. 39(4): 304-10. Accessed 4/26/21.

P Martin-Hirsch [1], G Jarvis, H Kitchener, R Lilford. Collection devices for obtaining cervical cytology samples: A Cochrane Database System Review. 2000; (2):CD001036.

## Study Design and Methods

**Methods:** *Describe in lay terms, completely detailing the research activities that will be conducted by Mayo Clinic staff under this protocol.*

The Papette and spatula/cytology brush for cervical cancer screening are currently both available for use in the primary care clinics (Community Internal Medicine and Family Medicine) and Obstetrics and Gynecology clinic at Mayo Rochester campus. However, providers in Community Internal Medicine would like additional data on the benefits of one collection method versus the other. Although, both methods of Pap smear collection are available this is not typically documented in the chart so a simple chart review study can not address the outcome.

Within Community Internal Medicine (CIM) we aim to complete 353 Pap smears using the Papette and 353 Pap smears using the traditional spatula/cytology brush from July 2021-June 2022. The total sample size will be 706 patients. Cluster sampling will be used: CIM practice in Rochester are located at Baldwin, NW, NE and SE clinics. The Baldwin practice is divided into 4 care teams: Ba5A, Ba5B, Ba6A and Ba6B. The Papette brush will be used to obtain Pap smear samples in women seen at CIM Ba5A, Ba5B and NW clinic while spatula/cytobrush will be used to obtain Pap smear samples at Ba6A, Ba6B, NE and SE clinics. Collection will be done until end of study date or until target sample size is met whichever comes first.

Outcome data to be collected:
-Demographics
-Cytology report on cellular adequacy: a retrospective review of subject medical record will be done to capture cytology report on completed Pap smear exam.
-Cervical bleeding with collection, ease of usage, time of collection, perceived pain, indication for pap smear, problem encountered: Provider who performed pap smear will be asked to complete a short questionnaire right after completion of exam.

Data will be stored in a secure database with only research members listed on the IRB having access to data.

## Subject Information

*Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.*

Target accrual: 706 Pap smear samples

Subject population (children, adults, groups): Adult women aged 21-64 years old eligible for pap smear exam; Providers performing Pap smear samples in CIM.

Inclusion Criteria: Adult women aged 21-64 years old who gave consent for medical records to be accessed and who will have a Pap smear exam in CIM from July 2021 through June 2022; Providers performing Pap smear samples in CIM.

Exclusion Criteria: Women <21 or >64; has vaginal spotting present during cervical sampling; did not give consent to have medical records accessed; Providers not part of CIM.

## Biospecimens

Collection of blood samples. When multiple groups are involved copy and paste the appropriate section below for example repeat section b when drawing blood from children and adults with cancer.

a. **From healthy, non-pregnant, adult subjects who weigh at least 110 pounds**. For a minimal risk application, the amount of blood drawn from these subjects may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _N/A____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _N/A_____

b. **From other adults and children considering age, weight, and health of subject.** For a minimal risk application, the amount of blood drawn from these subjects may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _N/A____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) __N/A_____

Prospective collection of biological specimens other than blood: _Pap smear sample_____

## Review of medical records, images, specimens

Check all that apply (data includes medical records, images, specimens).

☐ Only data that exists before the IRB submission date will be collected.

**Date Range for Specimens and/or Review of Medical Records:**
Examples: *01/01/1999 through 12/31/2015*, or all records through *mm/dd/yyyy*.

Note: The Date Range must include the period for collection of baseline data, as well as follow-up data, if applicable.

√☐ The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.
Examples

- The study plans to conduct a retrospective chart review and ask subjects to complete a questionnaire.
- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.

☐ The study will use data that have been collected under another IRB protocol. Include in the Methods section and enter the IRB number from which the research material will be obtained. *When appropriate, note when subjects have provided consent for future use of their data and/or specimens as described in this protocol.*

Enter one IRB number per line, add more lines as needed

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

## Data Analysis

*Power analyses may not be appropriate if this is a feasibility or pilot study, but end-point analysis plans are always appropriate even if only exploratory. Provide all information requested below or provide justification if not including all of the information.*

Power Statement:

A total sample size of 706 women (353 per cluster) is needed to detect a difference of 0.2 between the means of the brushes with 80% power, a two-sided significance level of 0.05, and an intraclass correlation was 0.1.

Data Analysis Plan:

Descriptive statistics will be reported for patient demographics by type of procedure. Chi-square tests will be used for categorical variables and Kruskal-Wallis test for continuous variables. For the primary analysis, a linear mixed model will be used to model the impact of procedure type on the rate of inadequate endocervical cells. The model will include a fixed procedure effect and a random cluster effect. As a sensitivity analysis, covariates such as age, previous bleeding history, and other factors will be adjusted for in the mixed model. The secondary outcome will be categorized as binary variable for whether the patient experienced procedure related bleeding. A logistic mixed model will be utilized to analyze any difference in bleeding between procedure types adjusting for the same variables as the primary analysis. Questionnaires filled out by the provider will be compared by procedure type to evaluate ease of use and other measures from a provider standpoint.

Endpoints:

Primary: Analyze rate of “inadequate endocervical cells” reported in cytology samples obtained by using Papette and traditional spatula and cytobrush.

Secondary: Evaluate procedure related bleeding experienced by using the Papette and traditional spatula and cytobrush.