



**Follow-Up 15
Vaginal Swab Enrollment,
Swab after Collection,
Epithelial Markers, Vaginal Maturation
Index and Vaginal Health Microbiome**

CODEBOOK

ARCHIVED DATASET 2019

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DOCUMENTATION FOR THE PUBLIC-USE SWAN VISIT 15 VAGINAL SWAB DATASET

1. Who is included in the public use dataset:

The dataset contains follow-up visit 15 information for the subset of the original cohort still participating in the SWAN longitudinal study from the seven clinical sites. The sites include Boston, MA, Pittsburgh, PA, Oakland and Los Angeles, CA, Detroit, MI, Newark, NJ, and Chicago, IL.

2. How this codebook is constructed:

Following this documentation section are copies of vaginal swab forms that were used at visit 15. A list of additional variables is also provided. The questionnaires include the variables available for public use next to the question in bold red uppercase underlined letters. Those variables not available for public use have a # before the variable and are in blue. Any special notes are indicated with footnotes at the bottom of the page.

The assigned participant ID has been replaced with a randomly generated ARCHID in order to protect participant privacy. The *baseline* interview date is denoted as day 0 and is used as the basis for all other dates. All other questionnaires or data collected that have a date attached have been converted to the number of days from the baseline interview. For example, if the Visit 15 Vaginal Swab Enrollment Form was collected 15 years after the baseline interview, the day for the Vaginal Swab Enrollment Form Completion date would be day 3,650 and the Baseline Interview would be day 0.

All variables for visit 15 have a 15 at the end of the variable name.

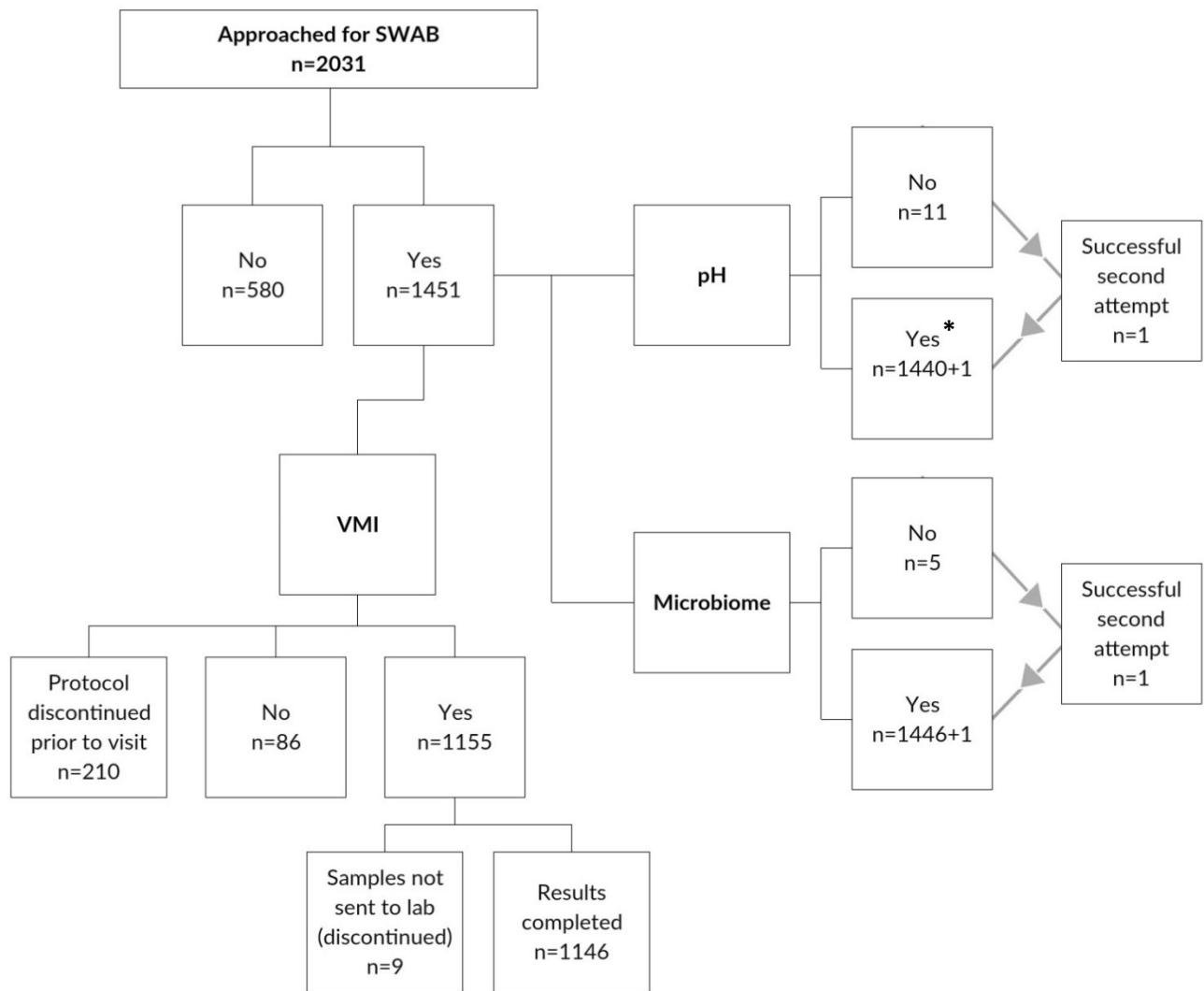
3. Missing data coding:

Original missing codes (-1: not applicable, -7: refused, -8: don't know, -9: missing) have been recoded to SAS missing codes (.B: not applicable, .D: refused, .C: don't know, and .A: missing).

4. Ways this data can be used and additional notes

The data in this dataset is a combination of the following datasets:

- Enrollment: The enrollment form documents the women who participated in the vaginal swab protocol as part of follow-up visit 15.
- Vaginal Maturation Index (VMI): Of the 1451 vaginal swab participants, 1241 women were approached to include VMI sampling as part of the vaginal swab. 210 were not approached as VMI was discontinued prior to their visit. Of the 1241 approached, 1155 women agreed to participate in vaginal sampling for VMI. 9 of these women had samples collected, but not submitted to the cytology lab at the time of the VMI protocol suspension.
- pH results: This data includes participation and results for a vaginal pH reading.
- Microbiome: Results of the microbiome samples are attached.



Swab After Collection Form:

The following variable was created to categorize the 'other' category:

OVSPCAT15 (Coded "Other Products" field) was created to categorize responses to the specify field for "Within the last 72 hours...Used any other product," text responses were evaluated and categorized as powder, lotion, oil, steroid, antibiotic, lubricant, wipe, over-the-counter product, pad, estrogen, or other, based on feedback from the SWAN vaginal health (VUSH) committee. Analysts may choose to combine these categories with variables from form sections B2 and B3 as described below. This was not changed in the dataset itself to stay consistent with original participant responses.

OVSPCAT15 Category	Relevant Form Variable
1: Powder	New category
2: Lotion	New category
3: Oil	New category
4: Steroid	New category
5: Antibiotic	VAGMED7215 (B3. g.) Vaginal medication
6: Lubricant/Moisturizer	VMOIST7215 (B2. c.) Lubricant/Moisturizer
7: Wipe	FEMWPE7215 (B3. f.) Feminine hygiene spray/wipe
8: Over the counter	FEMWPE7215 (B3. f.) Feminine hygiene spray/wipe
9: Pad	VAGPAD7215 (B3. i.) Pad
10: Estrogen	ECREAM7215 (B2. a.) Estrogen cream or tablet
11: Other	

Epithelial Markers Data:

Variables for standardized values of each marker have been created in this dataset.

Epithelial Marker Standardization

The markers included in this dataset are tight junction proteins, inflammatory markers, estrogen receptors and housekeeping genes:

- Tight junction proteins: TJP1, TJP2, TJP3, Claudin1, Claudin2, Occludin
- Estrogen receptors: ER-alpha, ER-beta, G-coupled protein
- Inflammatory markers: RANTES, IL-beta, IL-6, IL-8
- Housekeeping genes: Glyceraldehyde 3-phosphate dehydrogenase, 18S ribosomal RNA, Beta-actin

Variables for the raw values of these markers represent the number of PCR cycles (Ct) required to produce fluorescence at a standardized level of .04. The lower the number (i.e. the fewer cycles required) the higher the level of gene expression. These values are between 10 and 40 if expression was detected.

Because the values of the genes of interest reflect the total amount of expression in the sample, not taking into consideration the actual amount of sample, these values were standardized against housekeeping genes GADPH, 18S, and B-actin. A housekeeping index variable (HKI15) was created by averaging values for the three housekeeping genes. Expression for each gene of interest was standardized by subtracting the housekeeping index off of the raw marker value. If a raw marker had no value, the standardized value was set to 30, representing no gene expression detected after 40 PCR cycles. Participants (n=15) who had a missing value for one or more of the housekeeping genes had all standardized values set to missing.

Standardized values (n=7) were also set to missing if they were calculated to be outside the range of -20 to +20 for tight junction proteins or -20 to +25 for inflammatory markers and estrogen receptors. Raw Ct values were not changed.

Determination of the relative expression of the gene of interest

- Relative Expression of (Gene X) = Standardized Gene X (Sample 2) – Standardized Gene X (Sample 1)
- This value is then linearized for presentation using the formula $2^{\text{Expression}}$ due to the nature of PCR.

Example: Z01	Raw Ct	HKI	Standardized Ct	Relative Expression Sample 1 vs Sample 2	Linearization
Sample 1	24	19.67	4.33	3.00	8.00
Sample 2	26	18.67	7.33		

This indicates that sample 1 has 8 times the amount of ZO1 as sample 2

Vaginal Maturation Index Dataset:

Please note it is recommended to check the Maturation Index Limitations variable (MILIM15) and explanatory variables (items B3a. and B3b.) when deciding which samples to include in analysis.

Study Leadership decided to discontinue VMI Sampling on June 10, 2016.

Sample Collection Procedures:

As part of visit 15, women were asked to complete a vaginal swab protocol. If a participant agreed, and the visit was prior to the June 10, 2016 suspension of the VMI portion, she was asked to collect 3 samples from her vagina including the VMI swab. Participants were approached in a private location, provided with instructions, and given access to a private space for sample collection.

Collection material for the VMI sample included 1 Copan Flocked Swab (wrapped) and a closed ThinPrep container with 20 milliliters solution. Samples were kept at room temperature and shipped to the UPMC Cytology Lab within the 6-week sample expiration period.

Cytology Lab Procedures:

Results for the Vaginal Maturation Index (proportions of parabasal, intermediate, and superficial cells from vaginal swab) and overall interpretation (normal or abnormal; reason for abnormal responses) are provided by the Magee-Womens Hospital of UPMC Cytology Lab following procedures outlined here:

- 1) Slide Preparation: sample material is transferred to slides via ThinPrep®-3000 (T-3).
- 2) Staining: prepared slides are stained via Pap stain procedure using Sakura Slide Stainer with quality control (QC) completed and documented on every run. QC checks include confirming that cells are well stained and transparent with distinct chromatin, stain is even over entire slide, and that results are reproducible as well as consistent.
- 3) Imaging: Primary screening for presence of abnormal cells in cervical samples is completed with digital imaging via Hologic ThinPrep Imager Duo. Image data is processed into 22 individual fields of interest based on cellular features and nuclear darkness.
- 4) Screening: A cytotechnician views imaged results via Imager scope. If all 22 fields are negative, Vaginal Maturation Index tests are performed and interpretations noted. If there is a positive determination of abnormality, both the initial and a second cytotechnician complete a full manual review and interpretation. Cases determined by this process to be reactive/reparative or above are then passed to pathologist for final review.

Microbiome Data

A sponge tipped swab was placed in a test tube and sent to the microbiome lab at Oakland, CA. The samples were then processed by the lab to assess the types of normal bacteria found in the vagina.

Brief description of the data: The data includes 193 commonly found bacteria classified into CST (Community State Type Classification) and SUBCST (Sub-Community State Type Classification) categories via the Community State Type (CST) classification method detailed in the following two slides.

Description of Laboratory methods:

The data was processed by the lab using the criteria (minimum 500 reads for samples, and for bacterial taxa, their presence at $> 10^{-5}$ study wide). Samples were set to missing for those which we obtained less than 500 reads, i.e., amplification or sequencing failure and that after repeating the assay.

The main CSTs are defined as below:

- CST I - dominated by *Lactobacillus crispatus*,
- CST II - dominated by *Lactobacillus gasseri*,
- CST III - dominated by *Lactobacillus iners*,
- CST IV - represented by a diverse set of strict and facultative anaerobes, and lacks any significant amount of *Lactobacillus*
- CST V - dominated by *Lactobacillus jensenii*.

The sub CST are subcategories within each main CST

- CST IA, dominated with close to 100% *Lactobacillus crispatus*
- CST IB, comprises a majority of *Lactobacillus crispatus* and other anaerobic bacteria
- CST IIIA, dominated with close to 100% *Lactobacillus iners*
- CST IIIB, comprises a majority of *Lactobacillus iners* and other anaerobic bacteria
- CST IVA, comprises a diverse set of strict and facultative anaerobes, with a significant amount of BVAB 1 (BV-Associated Bacteria 1), and lacks any significant amount of *Lactobacillus*
- CST IVB, comprises a diverse set of strict and facultative anaerobes, with a significant amount of *Gardnerella vaginalis*, and to a lesser extent *Atopobium vaginae*, and lacks any significant amount of *Lactobacillus*
- CST IVC, comprises of a diverse array of strict and facultative anaerobes, including *Prevotella*, *Enterococcus*, *Staphylococcus*, *Streptococcus* and *Bifidobacterium*, these could be in significant amount, and lacks any significant amount of *Lactobacillus*,
- CST IVC-0, comprises a homogenous set of strict and facultative anaerobes, and can contain *Prevotella* in higher amount
- CST IVC-1, comprises of a diverse array of strict and facultative anaerobes, and is dominated by *Streptococcus* species
- CST IVC-2, comprises of a diverse array of strict and facultative anaerobes, and is dominated by *Bifidobacterium* species
- CST IVC-3, comprises of a diverse array of strict and facultative anaerobes, and is dominated by *Enterococcus* species
- CST IVC-4, comprises of a diverse array of strict and facultative anaerobes, and is dominated by *Staphylococcus* species

VAGINAL SWAB ENROLLMENT FORM*Study of Women's Health Across the Nation***SECTION A. GENERAL INFORMATION**

A1. RESPONDENT ID: AFFIX ID LABEL HERE **ARCHID~**

A2. SWAN STUDY VISIT # 15 **VISIT**

A3. FORM VERSION: 04/11/2015 **#FORM_V**

A4. DATE FORM COMPLETED: / / **SWABEDAY15†**
M M / D D / Y Y Y Y

A5. INTERVIEWER'S INITIALS: _____ **#INITS**

A6. RESPONDENT'S DOB: / / 1 9 **#DOB**
M M D D Y Y Y Y

VERIFY WITH RESPONDENT

A7. DID THE PARTICIPANT AGREE TO PARTICIPATE IN THE VAGINAL SWAB PROTOCOL?

NO **SWABPART15** 1

YES 2 **B1**

A7.1 REASON WHY THE PARTICIPANT DID NOT AGREE **#NOSWAB15**

NOT APPROACHED/DID NOT ATTEND IN CLINIC VISIT 1 **END**

NOT APPROACHED/ENROLLMENT CLOSED..... 2 **END**

UNABLE TO COMPLY WITH PROTOCOL..... 3 **END**

INELIGIBLE 4 **END**

OTHER 5 **END**

IF OTHER, SPECIFY _____ **#NOSWABS15**

REFUSED -7 **END**

~ A randomly generated ID will be provided that is different from the original ID

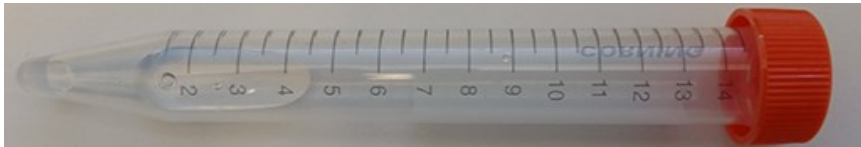
† This date is given in days since the initial baseline interview, which is day zero.

SECTION B. PROTOCOL COMPLETION

AFTER EXPLAINING THE PROTOCOL TO THE PARTICIPANT, PROVIDE THE SAMPLE KITS: BROWN PAPER BAG, INSTRUCTIONS AND OTHER MATERIALS. WHEN THE PARTICIPANT HAS COMPLETED THE SAMPLE COLLECTION, COMPLETE THE FOLLOWING (ASKING THE PARTICIPANT THE QUESTIONS AS INDICATED).

IF THE PARTICIPANT WAS UNABLE TO COMPLETE A COLLECTION BECAUSE SHE DID NOT UNDERSTAND THE DIRECTIONS OR SHE HAD PROBLEMS WITH THE COLLECTION MATERIALS, ASK IF SHE WOULD BE WILLING TO TRY AGAIN. IF YES, PROVIDE HER WITH A NEW PAPER BROWN BAG AND THE APPROPRIATE KIT(S). RECORD WHETHER A SECOND COLLECTION WAS COMPLETED. IF NOT, NO FURTHER COLLECTION ATTEMPTS SHOULD BE MADE.

KIT #1: MICROBIOME COLLECTION TUBE



B1. Did you complete the microbiome collection (placed swab in orange top tube)? **BIOME15**
 NO 1
 YES 2 **B2**

B1.1. If NO, why did you not complete the orange top tube collection? **#NOBIOME15**

CHANGED MIND / DID NOT WANT TO 1 **B2**
 DID NOT UNDERSTAND DIRECTIONS..... 2
 PROBLEM WITH COLLECTION MATERIALS..... 3
 OTHER..... 4 **B2**
 IF OTHER, SPECIFY _____ **#NOBIOMES15**

B1.2. DID THE PARTICIPANT COMPLETE A SECOND COLLECTION? **BIOME215**

NO 1
 YES 2

KIT #2: VMI COLLECTION CONTAINER



B2. Did you complete the collection with the ThinPrep container? **VMI15**

NO 1
 YES 2 **B3**

B2.1. If NO, why did you not complete the ThinPrep collection? #NOVMI15

CHANGED MIND / DID NOT WANT TO 1 **B3**

DID NOT UNDERSTAND DIRECTIONS.....2

PROBLEM WITH COLLECTION MATERIALS.....3

OTHER.....4 **B3**

IF OTHER, SPECIFY _____ #NOVMIS15

B2.2. DID THE PARTICIPANT COMPLETE A SECOND COLLECTION? VMI215

NO 1

YES2

KIT #3: VAGINAL PH

B3. Did you complete the PH card? PHCARD15

NO 1

YES2 **SECTION C**

B3.1. If NO, why did you not complete the PH card? #NOPHCARD15

CHANGED MIND / DID NOT WANT TO 1 **SECTION C**

DID NOT UNDERSTAND DIRECTIONS.....2

PROBLEM WITH COLLECTION MATERIALS3

OTHER.....4 **SECTION C**

IF OTHER, SPECIFY _____ #PHCARDS15

B3.2. DID THE PARTICIPANT COMPLETE A SECOND COLLECTION? PHCARD215

NO 1

YES2

SECTION C. SAMPLE PROCESSING

PROVIDE THE PARTICIPANT WITH THE **VAGINAL SWAB AFTER COLLECTION FORM**. WHILE THE PARTICIPANT COMPLETES THE FORM, RETRIEVE THE BROWN PAPER BAG AND DO THE FOLLOWING:

KIT #1: MICROBIOME COLLECTION TUBE



IF THE PARTICIPANT COMPLETED THE MICROBIOME COLLECTION, RETRIEVE THE MICROBIOME TUBE FROM THE BROWN PAPER BAG AND COMPLETE C1.

C1. DOES THE TUBE CONTAIN A SWAB? BIOMSWAB15

NO 1 **DISCARD, C3**

YES2

C2. LABEL THE COLLECTION TUBE WITH ONE OF THE “UCDAVIS” LABELS AND PLACE THE MATCHING “UCDAVIS” LABEL HERE:

#BIOMEBAR15

PLACE THE COLLECTION TUBE IN THE REFRIGERATOR.

KIT #2: VMI COLLECTION CONTAINER



IF THE PARTICIPANT COMPLETED THE VMI COLLECTION, RETRIEVE THE VMI CONTAINER FROM THE BROWN PAPER BAG AND COMPLETE C3.

C3. LABEL THE COLLECTION CONTAINER WITH ONE OF THE “UPMC” LABELS AND PLACE THE MATCHING “UPMC” LABEL HERE:

#VMIBAR15

PLACE THE CONTAINER IN THE DESIGNATED BOX AND MAINTAIN AT ROOM TEMPERATURE.

KIT #3: VAGINAL PH

IF THE PARTICIPANT COMPLETED THE PH COLLECTION, RETRIEVE THE PH CARD FROM THE BROWN PAPER BAG AND COMPLETE C5.

C4. DID PARTICIPANT CIRCLE A NUMBER ON PH CARD? **CIRCLEPH15**
NO 1 [END]
YES 2

C5. NUMBER CIRCLED ON PH CARD: **PHNUM15**

4.5 5.0 5.5 6.0
6.5 7.0 7.5 8.0 8.5

DISCARD THE PH CARD AFTER COMPLETING C5. ABOVE

SWAB AFTER COLLECTION FORM**ANNUAL FOLLOW-UP***Study of Women's Health Across the Nation***SECTION A. GENERAL INFORMATION****AFFIX ID LABEL HERE**

- A1. RESPONDENT ID: **ARCHID~**
- A2. SWAN STUDY VISIT # _____ **VISIT**
- A3. FORM VERSION: 03/18/2015 **#FORM_V**
- A4. DATE FORM COMPLETED: / / **SWABDAY15+**
- A5. INTERVIEWER'S INITIALS: _____ **#INITS**
- A6. RESPONDENT'S DOB: / / **#DOB**

VERIFY WITH RESPONDENT

-
- A7. COMPLETED IN: **#LOCATIO15**
- RESPONDENT'S HOME 1
- CLINIC/OFFICE 2
- RESPONDENT'S HOME W/ PROXY 3
- CLINIC/ OFFICE W/ PROXY 4
- A8. INTERVIEW LANGUAGE: **#LANGUAG15**
- ENGLISH 1
- SPANISH 2
- CANTONESE 3
- JAPANESE 4
- A9. INTERVIEWER-ADMINISTERED? **#INTADMIN15**
- NO 1
- YES 2

~ A randomly generated ID will be provided that is different from the original ID *

This date is given in days since the initial baseline interview, which is day zero.

Section B. For Vaginal Swab Participants: To be completed AFTER swab collection.**# Variable Excluded from Public Use Data File**

To better understand the information about the normal vagina in peri and post-menopausal women from the vaginal swabs, we would appreciate your responses to the following questions. Please note that each set of questions is asking about a different time frame. (Circle one number for each question.)

B1. In the past 3 months,				B2. In the last 72 hours (3 days),			
have you...		NO	YES	have you...		NO	YES
a.	Used estrogen cream or tablets in your vagina at least once a week? <u>ECREAM3M15</u>	1	2	a.	Used estrogen cream or tablets in your vagina? <u>ECREAM7215</u>	1	2
b.	Used an estrogen-containing vaginal ring (such as Estring)? <u>VRING3M15</u>	1	2	b.	Used an estrogen-containing vaginal ring (such as Estring)? <u>VRING7215</u>	1	2
c.	Used vaginal moisturizers (such as, Replens) at least once a week? <u>VMOIST3M15</u>	1	2	c.	Used a vaginal moisturizer or sexual lubricant (for example, brands like Replens, Vagisil, Astroglide)? <u>VMOIST7215</u>	1	2
d.	Taken an antibiotic by mouth for any reason? <u>ANTIBI3M15</u>	1	2	d.	Taken an antibiotic by mouth for any reason? <u>ANTIBI7215</u>	1	2

B3. In the last 72 hours (3 days),	have you...	NO	YES
a.	Sat in a hot tub or swam in a pool? <u>HOTTUB7215</u>	1	2
b.	Taken a bubble bath? <u>BUBATH7215</u>	1	2
c.	Douched? <u>DOUCHE7215</u>	1	2
d.	Had sexual intercourse (penetration with sexual activity)? <u>SEXINT7215</u>	1	2
e.	Used soap to wash the vulva/opening of vagina? <u>SOAPWS7215</u>	1	2
f.	Used any feminine hygiene spray or wipe? <u>FEMWPE7215</u>	1	2
g.	Used any vaginal medications for a vaginal or vulva infection (for example, products like Monistat or Metrogel)? <u>VAGMED7215</u>	1	2
h.	Used any other product: (powder, oil, cream, gel, ointment, tablet) on or in the vaginal area? (<u>not</u> reported above in B1, B2, or B3h) <u>OTHVAG7215</u>	1	2
	i.1. If YES, What product? <u>#OVAG72SP15</u>	(IF NO, GO TO B3.i)	
i.	Used a pad (e.g.: for urine leakage or vaginal discharge)? <u>VAGPAD7215</u>	1	2

B4. In the last 24 hours (1 day),	have you...	NO	YES
a.	Had any vaginal discharge that bothered you? <u>VAGDIS2415</u>	1	2
b.	Had any irritation/itching inside or around your vagina? <u>VITCH2415</u>	1	2
c.	Had any pain inside or around your vagina? <u>VPAIN2415</u>	1	2

**Thank you for helping us with this important research study.
Please place the completed questionnaire in the envelope provided, seal it, and give it**

VMI Results**Study of Women's Health Across the Nation****SECTION A. GENERAL INFORMATION**

- A1. BARCODE: _____ **#BARCODE**
- A2. SWAN STUDY VISIT # 15 **VISIT**
- A3. FORM VERSION: 10/20/2015 **#FORM_V**
- A4. SAMPLE DATE: _____ / _____ / _____ **VMIDAY15[†]**
M M D D Y Y Y Y
- A5. SIGN OUT DATE: _____ / _____ / _____ **#SIGNDATE**
M M D D Y Y Y Y
- A6. LAB TECH INITIALS: _____ **#LABINIT15**
- A7. SITE ID : _____ **#SITE**

SECTION B. RESULTS**B1. ADEQUACY STATEMENT**

- Satisfactory..... 1 **ADEQUACY15**
- Limited..... 2
- Unsatisfactory..... 3 **GOTO B5**

~ A randomly generated ID will be provided that is different from the original ID [†]
This date is given in days since the initial baseline interview, which is day zero.

IF ADEQUACY STATEMENT IS SATISFACTORY OR LIMITED:

VAGINAL MATURATION INDEX

B2. CELLS (MUST ADD UP TO 100)

% Parabasal Cells : _____ **PARABASL15**
 % Intermediate Cells: _____ **INTERMED15**
 % Superficial Cells: _____ **SUPERFIC15**

B3. MATURATION INDEX LIMITATIONS? **MILIM15**

No 1 **GOTO B4**
 Yes 2

B3a. IF YES, INDICATE MI LIMITATIONS (CIRCLE NO OR YES FOR EACH)

	No	Yes	
Inflammatory/Infectious Processes	1	2	<u>INFL15</u>
Presence of Glandular Cells	1	2	<u>GLNDCELL15</u>
Presence of Atypical Cells	1	2	<u>ATYPCELL15</u>
Other	1	2	<u>MIOTH15</u>

If Other, Specify **#MIOTHS15** _____

B3b. IF YES TO INFLAMMATORY/INFECTIOUS PROCESSES, CIRCLE NO OR YES FOR EACH ITEM

	No	Yes	
Fungal Organisms	1	2	<u>INFLFO15</u>
Reactive/Reparative Changes	1	2	<u>INFLRR15</u>
Hyperkeratosis	1	2	<u>INFLHK15</u>
Heavy Inflammation	1	2	<u>INFLHI15</u>
Other	1	2	<u>INFLO15</u>

If Other, Specify **#INFLOS15** _____

OVERALL INTERPRETATION

B4. IS OVERALL INTERPRETATION NORMAL? **OI15**

No 1 **GOTO B4b**
 Yes 2

B4a. **IF YES (NORMAL), CIRCLE NO OR YES FOR EACH ITEM**

	No	Yes	
Fungal Organisms	1	2	<u>OIFO15</u>
Reactive/Reparative Changes	1	2	<u>OIRR15</u>
Hyperkeratosis	1	2	<u>OIHK15</u>
Inflammatory Cell Changes	1	2	<u>OICC15</u>
Moderate Inflammation	1	2	<u>OIMODI15</u>
Heavy Inflammation	1	2	<u>OIHEAVI15</u>
Other	1	2	<u>OINOTH15</u>

If Other, Specify **#OINOTHS15** _____

B4b. **IF NO (NOT NORMAL), CIRCLE NO OR YES FOR EACH ITEM**

	No	Yes	
Low Grade Squamous Intraepithelial Lesion (LGSIL)	1	2	<u>LGSIL15</u>
High Grade Squamous Intraepithelial Lesion (HGSIL)	1	2	<u>HGSIL15</u>
Atypical Squamous Cells, Undetermined significance (ASC-US)	1	2	<u>ASCUS15</u>
Atypical Squamous Cells, Cannot Exclude HGSIL (ASC-H)	1	2	<u>ASCH15</u>
Atypical Glandular Cells (AGC)	1	2	<u>AGC15</u>
Other	1	2	<u>OIAOTH15</u>

If Other, Specify **#OIAOTHS** _____

B4c. **IF NO (NOT NORMAL), DID THE PATHOLOGIST PROVIDE RECOMMENDATIONS?**

PATHR15

No 1
 Yes 2

B3c.1 IF PATHOLOGIST PROVIDED RECOMMENDATIONS, CIRCLE NO OR YES FOR EACH ITEM

	No	Yes	
Diagnostic Colposcopy	1	2	<u>DIAGCOLP15</u>
Endocervical Sampling	1	2	<u>ENDOCERV15</u>
Endometrial Sampling	1	2	<u>ENDOMET15</u>
Elective DNA Testing	1	2	<u>ELECTDNA15</u>
Other	1	2	<u>PATHRO15</u>

If Other, Specify #PATHROS15

IF ADEQUACY STATEMENT IS SATISFACTORY, END FORM.

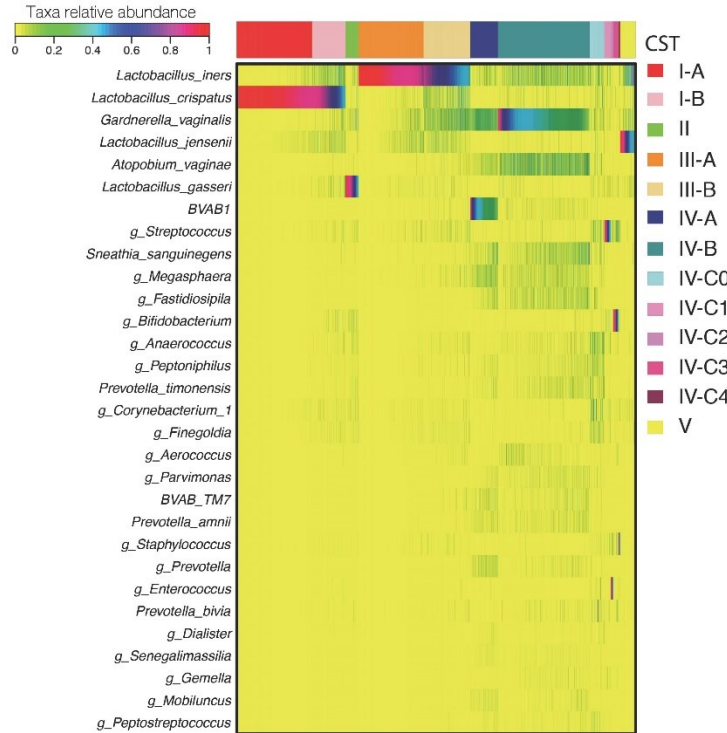
IF ADEQUACY STATEMENT IS LIMITED OR UNSATISFACTORY:

B5. REASONS FOR INDETERMINATE READING (CIRCLE NO OR YES FOR EACH ITEM)

	No	Yes	
Scant Cellularity	1	2	<u>SCANT15</u>
Inflammation	1	2	<u>INFLAM15</u>
Blood	1	2	<u>BLOOD15</u>
Transformation	1	2	<u>TRANSF15</u>
Other	1	2	<u>IROTH15</u>

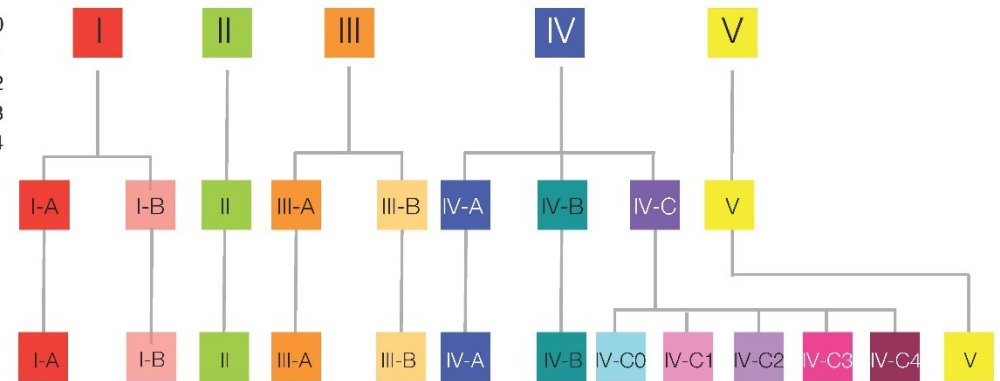
If Other, Specify #IROTHS15

Vaginal community composition and structure



- Community state type classification based on over 12,000 samples (16S rRNA gene V3-V4 regions)

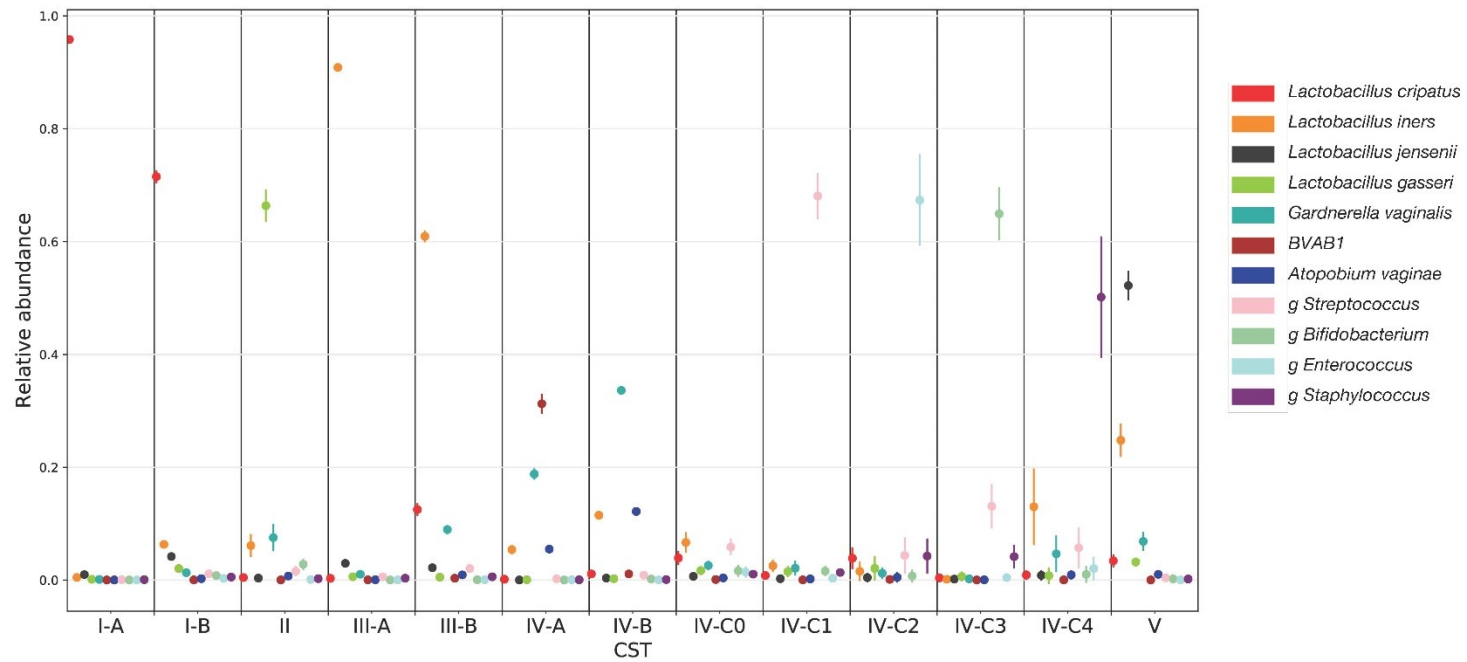
- Expanded classification - CST hierarchy



Robinson C, France M et al. unpublished

Improved community state type assignments

- Consistent classification using distance to centroid of CST and Random Forest algorithm



Robinson C, France M et al. unpublished