

MyBodyMytest: A Self-Sampling Approach to Address Cervical Cancer Disparities in North Carolina

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My Body!  *My Test!*

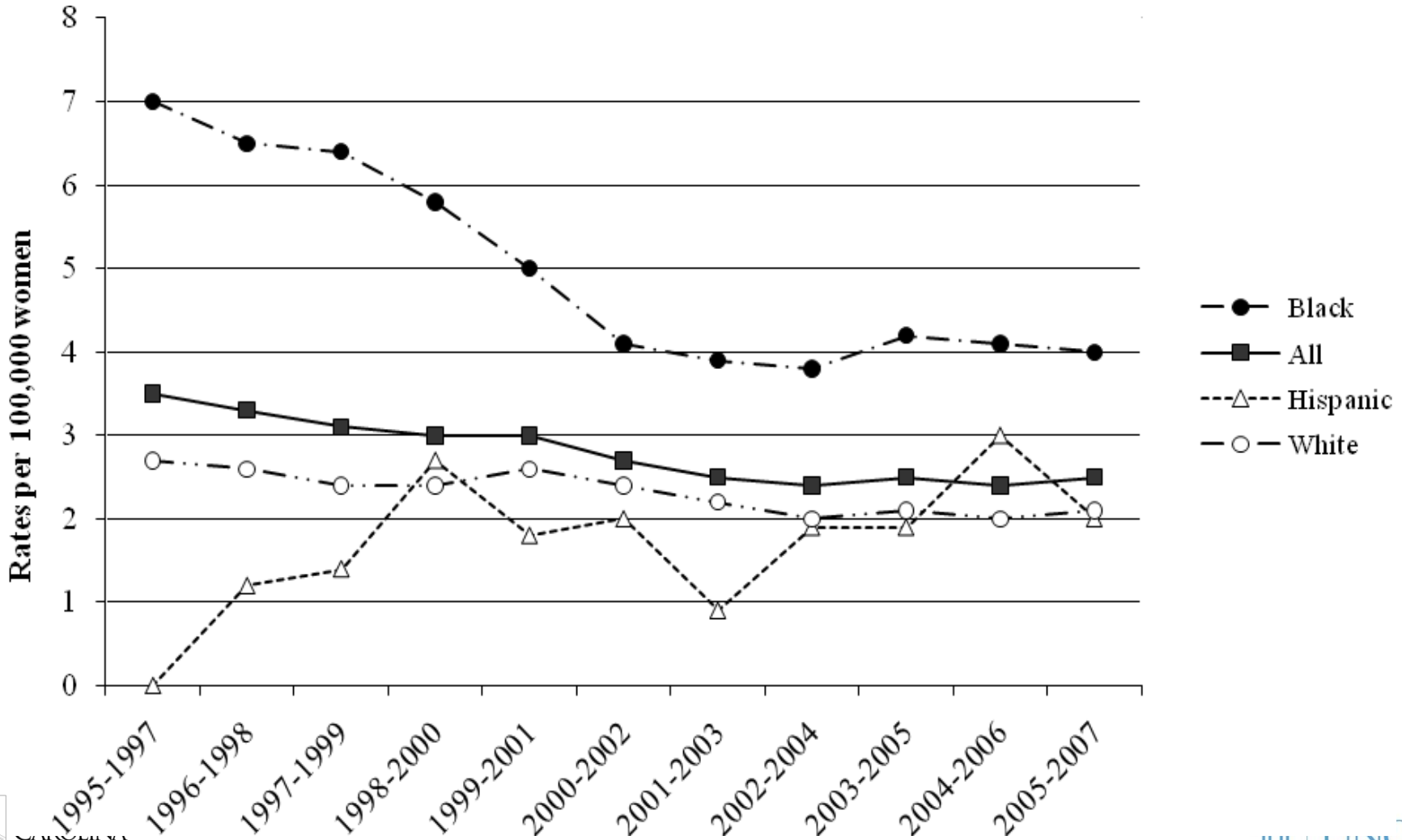


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CAROLINA
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UNC
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Cervical cancer mortality rates remain higher in black women in NC



Carolina Framework for Action against Cervical Cancer

4 causes of cervical cancer, largely preventable

~100% HPV infection

54% Not screening

29% Screening errors based on cytology alone

12% Not completing treatment

Study Objectives

- Determine feasibility and acceptability of home-based self-collection for HPV testing in a high-risk population
 - Unscreened for cervical cancer in 4+ years, low-income, uninsured or on Medicaid/Medicare; aged 30-64
- Assess validity of home self-collected samples by comparing
 - Home self-collection (self-home)
 - to
 - Clinic self-collection (self-clinic)
 - and
 - Physician collection (clinician)

Study Objective

- Determine **validity of home self-collection** compared to clinic self-collection and physician-collection (Pap) in 150 high-risk women

Study Design

- Population-based recruitment of low-income women overdue for cervical cancer screening
- Kits mailed to participant's home to self-collect vaginal sample and return by mail
- Clinic appointment to collect i) second self-collected vaginal sample and ii) clinician-collected endocervical sample
- Tested for hrHPV
- Liquid-based Cytology on clinician-collected samples
- Referral to colposcopy and treatment per standard indication

Study sites



Methods

- Self-collected vaginal sample using Rovers Viba brush, preserved in Aptima sample transport media (STM) (Hologic-Genprobe)
- Physician-collected samples collected and imaged via ThinPrep, aliquot into Aptima STM for HPV testing
- Aptima assays (Hologic-GenProbe)
 - Human papillomavirus: 14 high-risk strains + type specific for 16 and 18/45



How to Collect Your Sample

Do not collect a sample if you are pregnant or during your period. If you are on your period, please wait until you have stopped bleeding for at least one day. If you are pregnant, you should not collect a sample.

1. Wash your hands or use the hand wipe to clean your hands. Put on the glove if you choose.



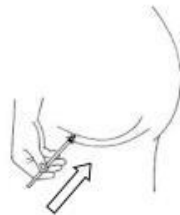
2. You should have a brush with a blue handle and a sample container with liquid in it. Open the sample container by twisting off the lid. Save the lid. **Do not pour out the liquid.** Put the open container on a stable counter or table.

3. Open the envelope with the brush in it. **Please be careful not to touch the white brush tip with your hands.**



4. Stand, sit, or lie down in a comfortable position. Some women find it helpful to squat with their legs apart.

5. Relax and then gently push the brush into your vagina until it will not go any farther or until you feel resistance. It's kind of like putting in a tampon.



6. Turn the brush around 5 times while it is inside your vagina.



7. Slowly pull out the brush. **Do not touch the white brush tip.**

8. Notice that there is clear plastic on the handle near the white brush tip. Hold the brush tip inside of the sample container.

Hold the blue brush handle with one hand.

Use your other hand to gently push the clear plastic toward the white brush.

The white brush tip will fall off into the sample container.



9. Put the lid back on the container and screw the lid on tightly.



10. You are done with the collection!

Put the container in the plastic bag and close the bag.

Put the plastic bag, contact info sheet, the signed consent form, and the signed HIPAA form in the padded envelope. Close and mail the envelope. You do **not** need to add any stamps.

Thank you!

Study completion

Received self-collection kit

193



Returned self-collection kit

161 (83%)

Inadequate mailed
samples
9 (5.6%)



Completed clinic appointment

151 (78%)

94% of those who returned kits completed appointment

HPV positivity and agreement (n=132)

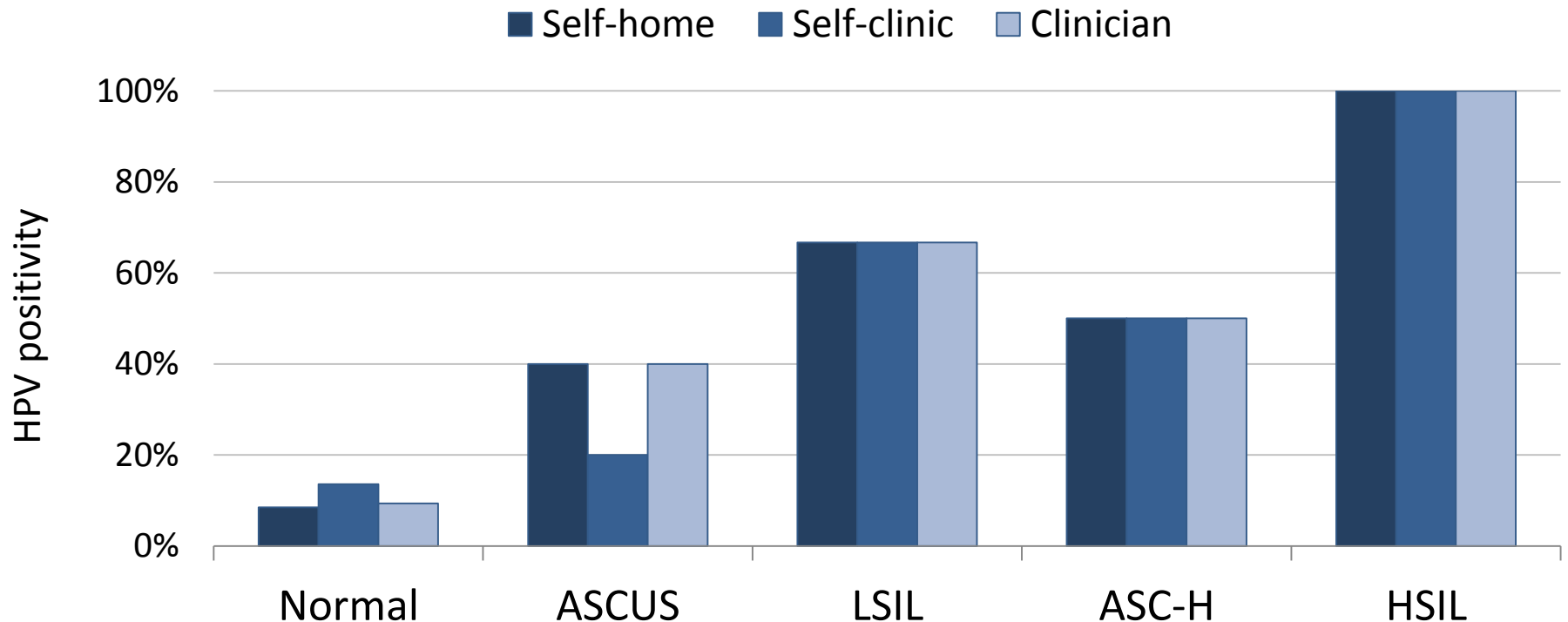
Sample type	HPV positive
Home self-collected	17 (13.1%)
Clinic self-collected	22 (16.9%)
Clinician collected	18 (13.9%)

- Kappa home self-collected and clinician: 0.70 (95% CI 0.53, 0.87)
- 100% agreement between home self-collected and clinician in cases of CIN2+: all positive

Cytology and histology results

Normal	88.8%
ASCUS	4.9%
LSIL	2.1%
ASC-H	2.8%
HSIL	1.4%
All abnormalities	11.2%
Histologically confirmed CIN2+	2.8%

HPV positivity by sample type and cytology result



- Confirmed CIN2+ in 4 of 7 completed colposcopies: 3% of study population
- 100% positivity in home self-collected and clinician sample in all cases of CIN2+

Acceptability (n=147)

Overall, are your thoughts about the self-test...

Mostly positive	71%
Neutral	24%
Mostly negative	5%

Would you be willing to use the self-test again?

Yes	96%
No	3%
Don't know	1%

Conclusions

- Home self-collected and clinician-collected samples
 - Substantial agreement for high-risk HPV infection
- HPV detected all in high-grade lesions by all sample methods
- Majority of women regarded the experience positively

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Thank you!

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