Should We Be Using Self-Collection In The U.S.? (CON)

Philip E. Castle, PhD, MPH

Professor
Albert Einstein College of Medicine
Bronx, NY, USA

castle.philip@gmail.com

Disclosures

- I have received cervical screening tests and diagnostics for research at a reduced or no cost from Roche, Becton Dickinson, Cepheid, and Arbor Vita Corporation.

CON: Overview

I. Self-collection will never get US FDA approval.
II. Logistics/Infrastructure are not in place to support self-collection.
III. Cross-over: women who are participating in routine, clinic-based screening will also want to switch over to self-collection.
IV. Self-collection presents privacy issues.

I. Self-Collection Will Never Get FDA Approval

A. FDA still requires a Pre-Marketing Approval Trial (vs. 510(K) "Analytic Equivalence") = $$$,$$$,$$$

B. FDA will not allow specified sub-populations to be targeted (restricted use) = Must be made available to the general population (see III.).

C. FDA will require provider-collected specimens as the comparator = Target population (underserved women already not getting screened this way) will not participate.

I. Self-Collection Will Never Get FDA Approval (continued)

D. Laboratory Developed Testing (LDT) might be the work around (of the FDA) but each lab would have to establish it is own testing assay and validated protocol (to avoid something being classified as a "kit" and falling under FDA Regs) = variable performance (e.g., SurePath and HC2)

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II. Logistics/Infrastructure are not in place to support self-collection.

A. Success requires individual engagement = who is going to pay for that in this environment?

B. Testing ≠ Screening i.e., how are you going to get the HPV positives back for care?

C. Kits to women, samples to the lab, linkage to the women, etc. (see IV.)

Meta-Analysis: Participation Statistics

Scenario of invitation	#	Absolute participation		Relative participation	Participation difference
		Self- sampling % (95% CI)	Control % (95% CI)	(95% CI)	% (95% CI)
Per-protocol					
Mail-to-all	17/19†	19.2 (15.3-23.5)	11.1 (7.5-15.5)	1.78 (1.29-2.45)	7.8 (3.9-11.7)
Opt-in	4/6†	7.0 (2.4-13.6)	13.1 (11.1-15.2)	0.51 (0.31-0.85)	-5.3 (-11.6-1.0)
Community campaign	1	15.6 (12.4-19.5)	6.0 (4.2-8.7)	2.58 (1.67-3.99)	9.5 (5.4-13.7)
Door-to-door	4	94.2 (80.2-100)	53.3 (10.5-93.2)	1.99 (0.68-5.85)	39.7 (4.0-75.4)
Intention-to-treat*					
Mail-to-all	17/19†	24.0 (20.6-27.5)	11.1 (7.5-15.5)	2.25 (1.73-2.94)	12.1 (9.3-14.8)
Opt-in	4/6†	14.5 (10.1-19.6)	13.1 (11.1-15.2)	0.98 (0.71-1.35)	0.2 (-3.6-4.0)
Community campaign	1	15.6 (12.4-19.5)	6.0 (4.2-8.7)	2.58 (1.67-3.99)	9.5 (5.4-13.7)
Door-to-door	4	94.6 (83.0-99.9)	53.3 (10.5-93.2)	2.01 (0.66-6.15)	40.5 (3.0-78.0)

Certain studies reported that certain women, allocated to the self-sampling, had a Pap smear taken. The sum of the number of self-samples taken + Pap smears taken, were counted in the ITT analyses. In studies, where no such cases were reported, the number of events in the PP and ITT analyses were considered as equal.

†Rossi, 2011 & Rossi, 2015 had 2 control groups (one where a Pap smear was taken by a clinician and another where a sample for HPV testing was taken by a clinician).

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III. Cross-over: women who are participating in routine, clinic-based screening will want to switch over to self-collection.

A. What women would not want to do self-collection in the comfort of their home? = Financial Impact on Practices

B. What care will not be provided if women stay at home?

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Final Issues

A. Every good public health intervention has a rare, SAE---who is responsible, etc.?
B. Target population includes illegal aliens----immigration laws and fear of enforcement present formidable barriers.
C. Reimbursement, Reimbursement, Reimbursement—who is paying?