



Perceptions and Performance of Self-administered Rapid HIV Tests Conducted by Untrained Users in Real World Settings

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Background

- Men who have sex with men (MSM): majority of new infections
- 2012: FDA approved 1st rapid HIV home test
- Information is needed to document the use of rapid HIV home tests among populations for whom frequent testing is a high priority
- CDC Contract: “Evaluation of Rapid HIV Self-Testing among MSM in High Prevalence Settings” (eSTAMP)

eSTAMP Timeline



Objectives

- To characterize perceptions about rapid HIV home tests among internet-recruited MSM
- To evaluate how 2 rapid HIV tests perform when conducted by untrained MSM “at home”

Methods

HIV Tests

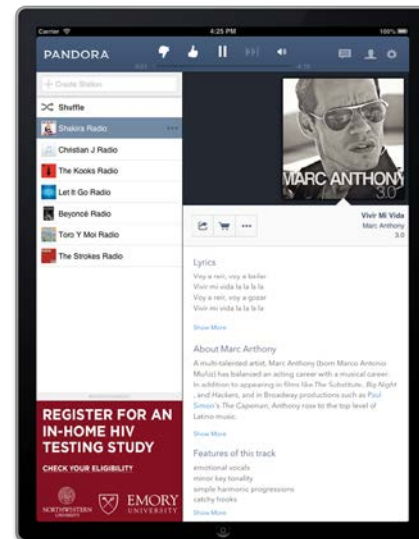
1. OraQuick In-Home HIV test (OQ)
2. Sure Check At-Home test (SC)
 - Sure Check HIV 1/ 2 Assay – under IDE
3. Dried Blood Spot Collection Kit
 - Mailed back and analyzed at CDC
 - Avioq HIV-1 Microelisa System
 - Western Blot
 - GS HIV Combo Ag/Ab EIA

Recruitment Goal

900 MSM

Identify 50 newly diagnosed HIV positive men

Online banner ad campaign



Eligibility Criteria

- Male at birth & id as male
- ≥ 18 years old
- Resident of the US
- HIV status: negative or unaware
- Report anal sex with a man, past 12 months
- Never participated in an HIV vaccine trial
- Never diagnosed with a bleeding disorder
- Not on antiretroviral medication to prevent HIV
- English proficient

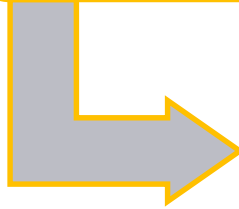
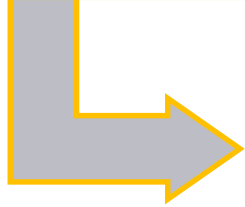
Participant activities

Eligible men
asked to
register by
providing:

- Shipping Address
- Phone Number
- Email Address

Baseline
Survey

Mailed a
study
package





1



OraQuick® In-Home HIV Test

2



DBS Specimen Collection Kit

3



Sure Check® HIV Home Test

Written and on-line video instructions

Testing Activities

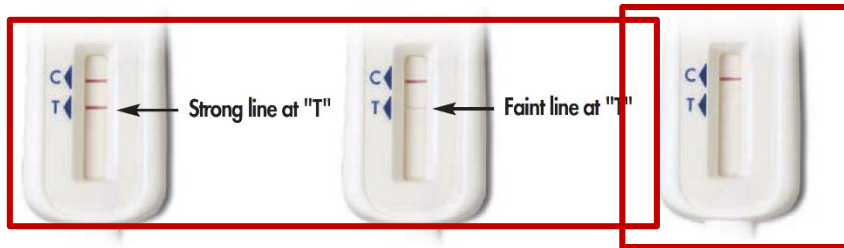
Complete 3 testing activities (1.5 - 2 hours)



Report rapid tests results on the study web site

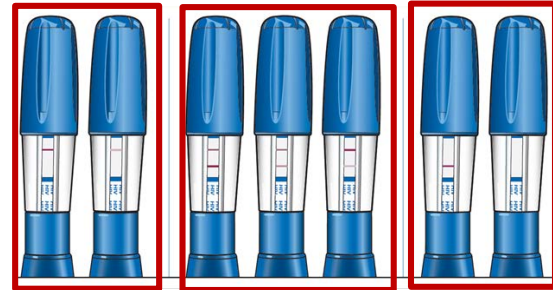
- Directly reporting result
- Select image that resembles result → **CONCORDANCE**

Please select the image that most looks like your Test Stick:



- Some lines, but my results do not look like the above examples
- No lines on the test stick

Please select the image that most looks like your test device:



Testing Activities

Complete 3 testing activities (1.5 - 2 hours)



Report rapid tests results on the study web site

- **Directly reporting result**
- **Select image that resembles result → CONCORDANCE**



Mail back the DBS card

- **CDC Lab inspected for quality and tested for HIV**



Complete post-testing surveys and receive \$60

Results

Baseline: Demographics (N=818)

- 64% aged 18-34
- 60% White, 22% Hispanic and 10% Black
- 86% ≥ some college
- 52% reported 4+ male anal sex partners, past 12 months
- Condomless anal sex, past 12 months:
 - With one partner: 37%
 - With 3+ partners: 37%

Baseline: Past experience with testing & testing history (N=818)

| | n | % |
|--------------------------------|-----|----|
| Ever worked in lab | 123 | 15 |
| Ever drawn blood | 98 | 12 |
| Ever used home diagnostic test | 162 | 20 |
| Ever tested for HIV | 671 | 82 |
| Never tested for HIV | 147 | 18 |

Baseline: Awareness/Use of Home HIV tests (N=818)

| | n | % |
|-----------------------------------|-----|----|
| Ever heard of home HIV tests | 656 | 80 |
| Used home HIV tests, past year | 79 | 12 |
| Not used home HIV test, past year | 575 | 87 |

- 95% OraQuick In-Home HIV Test
- Reason for using: Privacy (71%) and Convenience (63%)

Baseline: Main reason for not using home HIV test (N=579)

| | n | % |
|---|-----|------|
| Concerned about the cost of home HIV tests | 200 | 34.5 |
| Concerned about accuracy of home HIV tests | 102 | 17.6 |
| Already testing at clinic/doctor's office | 83 | 14.3 |
| Didn't know it was available or where to get it | 65 | 11.2 |
| Afraid of finding out that he has HIV | 48 | 8.3 |

Summary of Testing Activities (N=818)

| Reported OraQuick result | 622 | 76 |
|--------------------------|-----|----|
| Negative | 605 | 97 |
| Positive | 11 | 2 |
| Invalid | 6 | 1 |

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| | | |
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| Reported Sure Check result | 565 | 69 |
| Negative | 532 | 94 |
| Positive | 7 | 1 |
| Invalid | 26 | 5 |

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| Negative | 532 | 94 |
| Positive | 7 | 1 |
| Invalid | 26 | 5 |
| DBS cards processed | 548 | 67 |
| Negative | 538 | 98 |
| Positive | 9 | 2 |
| Indeterminate | 1 | 0.2 |

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Summary of Testing Activities (N=818)

| | n | % |
|---|-----|----|
| Participants with OQ, SC and DBS results | 515 | 63 |
| Participants with no SC, OQ nor DBS results | 174 | 21 |
| Participants missing at least one result | 129 | 6 |

Performance of OraQuick and Sure Check among participants with OQ, SC and DBS results (N=515)

| | Sensitivity (95% CI) | Specificity (95% CI) | Corrected Sensitivity (95% CI) | Corrected Specificity (95% CI) |
|------------|-------------------------|-------------------------|--------------------------------------|--------------------------------------|
| OraQuick | 81.8% (48.2, 97.7) | 100% (99.3, 100.0) | 88.89% (51.8, 99.7) | 100% (99.3, 100.0) |
| Sure Check | 80% (28.4, 99.5) | 99.8% (98.9, 100.0) | 100% (54.1, 100.0) | 100% (99.2, 100.0) |

Concordance: result reported and image selected (N=511)

| | OQ Negative n=500 | OQ Positive n=6 | OQ Invalid n=5 |
|----------------|----------------------|--------------------|-------------------|
| Negative Image | 98% | | |
| Positive Image | | 100% | |
| Invalid Image | | | 100% |

| | SC Negative n=484 | SC Positive n=4 | SC Invalid n=23 |
|----------------|----------------------|--------------------|--------------------|
| Negative Image | 99% | | |
| Positive Image | | 100% | |
| Invalid Image | | | 100% |

Concordance: result reported and image selected (N=511)

| | OQ Negative n=500 | OQ Positive n=6 | OQ Invalid n=5 |
|----------------|----------------------|--------------------|-------------------|
| Negative Image | 98% | | |
| Positive Image | 1.4% | 100% | |
| Invalid Image | 0.8% | | 100% |

| | SC Negative n=484 | SC Positive n=4 | SC Invalid n=23 |
|----------------|----------------------|--------------------|--------------------|
| Negative Image | 99% | | |
| Positive Image | 0.6% | 100% | |
| Invalid Image | 0.4% | | 100% |

Concordance: result reported and image selected (N=511)

| | OQ Negative n=500 | OQ Positive n=6 | OQ Invalid n=5 |
|----------------|------------------------------------|--------------------|-------------------|
| Negative Image | 98% <i>1 DBS +, SC +</i> | | |
| Positive Image | 1.4% | 100% | |
| Invalid Image | 0.8% | | 100% |

| | SC Negative n=484 | SC Positive n=4 | SC Invalid n=23 |
|----------------|----------------------|--------------------|--------------------|
| Negative Image | 99% | | |
| Positive Image | 0.6% | 100% | |
| Invalid Image | 0.4% | | 100% |

Summary of SC Invalid Test Results Reported

Sure Check Invalids = 26 Rate = 26/565 = 4.6%

| n | OraQuick Result | OraQuick Image selection | Sure Check result | Sure Check image selection | DBS Result |
|----|-----------------|--------------------------|-------------------|----------------------------|------------|
| 3 | Positive | Positive | <i>Invalid</i> | No lines | Positive |
| 20 | Negative | Negative | <i>Invalid</i> | No lines | Negative |
| 1 | missing | Negative | <i>Invalid</i> | No lines | Negative |
| 1 | Positive | Positive | <i>Invalid</i> | No lines | n/a |
| 1 | Negative | Negative | <i>Invalid</i> | No lines | n/a |

Frustration

"I received an invalid test result, despite following the instructions provided."

"Confusing to know how hard to push device into holder. Found out too late that I hadn't pushed it in hard enough. This was very upsetting and disappointing."

Successful interpretation

"I was relieved that the [invalid] result I got was an option in the pictures you gave."

"Test strip never turned pink after 1 minute, and no lines appeared after 15 minutes. Test was invalid."

Post-test Survey (N=537; response rate = 66%)

| | | n | % |
|----------------------------|---|-----|-----|
| Test yourself again | Finger-stick blood HIV test (Sure Check) | 180 | 34 |
| | Oral fluid HIV test (OraQuick) | 158 | 29 |
| | Depends upon the cost | 114 | 21 |
| | I would use both equally | 84 | 16 |
| | I would not use either of these tests | 1 | 0.2 |
| Recommend to others | Finger-stick blood HIV test (Sure Check) | 172 | 32 |
| | Oral fluid HIV test (OraQuick) | 144 | 27 |
| | I would recommend both equally | 218 | 41 |
| | I would not recommend either of these tests | 3 | 0.6 |

Post-test Survey (N=537; response rate = 66%)

| | | n | % |
|-----------------------|---|-----|-----|
| Easiest to use | Oral fluid HIV test (OraQuick) | 354 | 66 |
| | Finger-stick blood HIV test (Sure Check) | 85 | 16 |
| | Both were equally easy to use | 98 | 18 |
| Trust the most | Finger-stick blood HIV test (Sure Check) | 379 | 71 |
| | Oral fluid HIV test (OraQuick) | 33 | 6 |
| | I trust the results from both equally | 123 | 23 |
| | I do not trust results from either of these tests | 2 | 0.4 |

Limitations

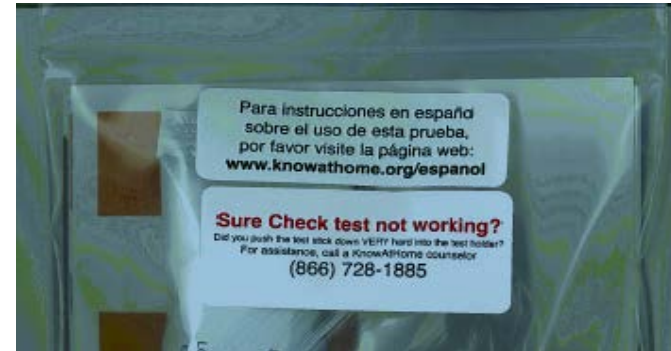
- Men recruited from select websites: limited generalizability
- Not all men reported their results; 21% no data
- Data reporting issues
- Sensitivity had large confidence intervals

Strengths

- Two-thirds completed all 3 testing activities and post testing survey
- 80% completed at least one testing activity
- Adequate quality of the returned DBS cards for HIV testing
- High concordance between reported results and images selected – successful interpretation

Conclusions

- Baseline: Cost and accuracy concerns
- Without prior in-person training, the majority of internet-recruited MSM who reported their results online successfully conducted 3 self-testing activities
- Specificity was high for both tests
- Participants had less trust in OQ than in SC despite easy to use
- Effort to reduce SC invalids



To be continued...

eSTAMP Part 4: RCT

| | Intervention Arm N=1600 | Control Arm N=1600 |
|--|---|--|
| Intervention | Free rapid HIV home tests <ul style="list-style-type: none">• Oraquick• Sure Check | |
| Online surveys | Baseline, 1, 3, 6, 9, 12 months | Baseline, 1, 3, 6, 9, 12 months |
| Performance Evaluation (12 month follow-up) | Provide SC and OQ results and mail back DBS card | Provide SC and OQ results and mail back DBS card |

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