

# **Randomized Controlled Trial of HIV Counseling with Rapid and Standard HIV Tests (RESPECT-2)**

## ***Preliminary results***

Carol Metcalf<sup>1</sup>, Helene Cross<sup>2</sup>, Beth Dillon<sup>1</sup>, John Douglas<sup>3</sup>,  
C Kevin Malotte<sup>4</sup>, Paul Young<sup>5</sup>, Catherine Lindsey<sup>1</sup>, Tom  
Peterman<sup>1</sup>, for the RESPECT-2 Study Group

<sup>1</sup>CDC, <sup>2</sup>NJ Dept. Health and Senior Services, <sup>3</sup>Denver Public Health,  
<sup>4</sup>CA State University Long Beach, <sup>5</sup>NOVA Research Company



# RESPECT-2 Study Group

**Centers for Disease Control and Prevention:** Carol Metcalf, Bob Byers, Beth Dillon, Heather Frederick, Michael Iatesta, Mary Kamb, Catherine Lindsey, Vel McKleroy, Tom Peterman, Laura Selman, Beena Varghese

**Long Beach Site:** C. Kevin Malotte, David Souleles, Suzanne Padilla, Nettie DeAugustine, Judy Hollingshead

**Denver Site:** John Douglas, Lesley Brooks, Ken Miller, Cornelis “Kees” Rietmeijer

**Newark Site:** Sindy Paul, Helene Cross, LaVerne Parish, Lena Raveneau,

**NOVA Research Company:** Paul Young, Bob Francis, Chris Gordon, Carmita Signes

**Center for AIDS Intervention Research:** Seth Kalichman





## Background

- STD clinics important providers of HIV CTR services.
- Project RESPECT: HIV testing with 2 brief (~20 minute) prevention counseling sessions more effective at preventing STDs than HIV testing with information alone.
- Influenced policy and practice of prevention counseling in US.
- BUT, low return rates for HIV test result and 2nd counseling session.



## Background – Rapid HIV tests

- Enable preliminary HIV test result to be available within 30 minutes
- Negative results do not require confirmation
- Much higher proportion of clients receive their HIV result than with standard HIV tests
- Efficacy of completing prevention counseling in 1 visit compared to 2 visits unknown.



## Objective

To compare **rapid HIV testing** and all counseling in 1 visit with **standard HIV testing** and 2 counseling sessions a week apart for efficacy at preventing STDs in STD clinic patients.



## Methods

- Randomized Controlled Trial in 3 STD clinics
- Randomized:
  - Rapid or standard HIV test at enrollment
  - “Booster” (relapse prevention) counseling or no booster at 6 months
- Follow-up at 3, 6, 9, and 12 months
- Intention-to-treat analysis



## Eligibility

- HIV-negative clients attending STD clinic for an STD examination
- Age: 15 - 39 yrs (18 - 39 yrs Newark)
- Required to consent, speak English, be available for 1 year follow-up, and have had sex in the past 3 months
- Enrollment: February 1999 - December 2000



## Counseling Interventions

- Based on Project RESPECT / CDC model
- 2 sessions of ~20 minutes each at baseline
- HIV result given at start of 2nd session
- Approach and content similar in both groups
- Timing of the 2nd session:  
Rapid test - Same visit (after STD exam)  
Standard test - 1 week later
- Reminder letter and calls to maximize return for 2nd session (standard test group)



# Outcome Measurement

## STD

- Baseline and every 3 months: gonorrhea and *Chlamydia* (NAATs of urine), and *Trichomonas* (culture vaginal swab F, urine sediment M )
- Baseline and 12-months: HIV and syphilis

## Behavioral

- Audio Computer-Assisted Self Interview (ACASI) at baseline and every 3 months





## Participant Demographics (n = 3293)

- **Sex:** 46 % female
- **Race / ethnicity:** 51 % African-American  
22 % White  
18 % Hispanic  
9 % Other
- **Median / mean age:** Females 23 / 25 yrs;  
Males 25 / 26 yrs
- **Site:** Denver 38%, Long Beach 29%,  
Newark 33%



# Baseline Risk Characteristics by HIV Test Type

Characteristic	Standard (n = 1648)	Rapid (n = 1645)
>1 partner last 3 mo	54 %	55 %
New partner last 3 mo	66 %	69 % (72 %)
MSM last 3 mo (of M)	9 %	10 %
STD at baseline	24 % (22 %)	26 % (27 %)

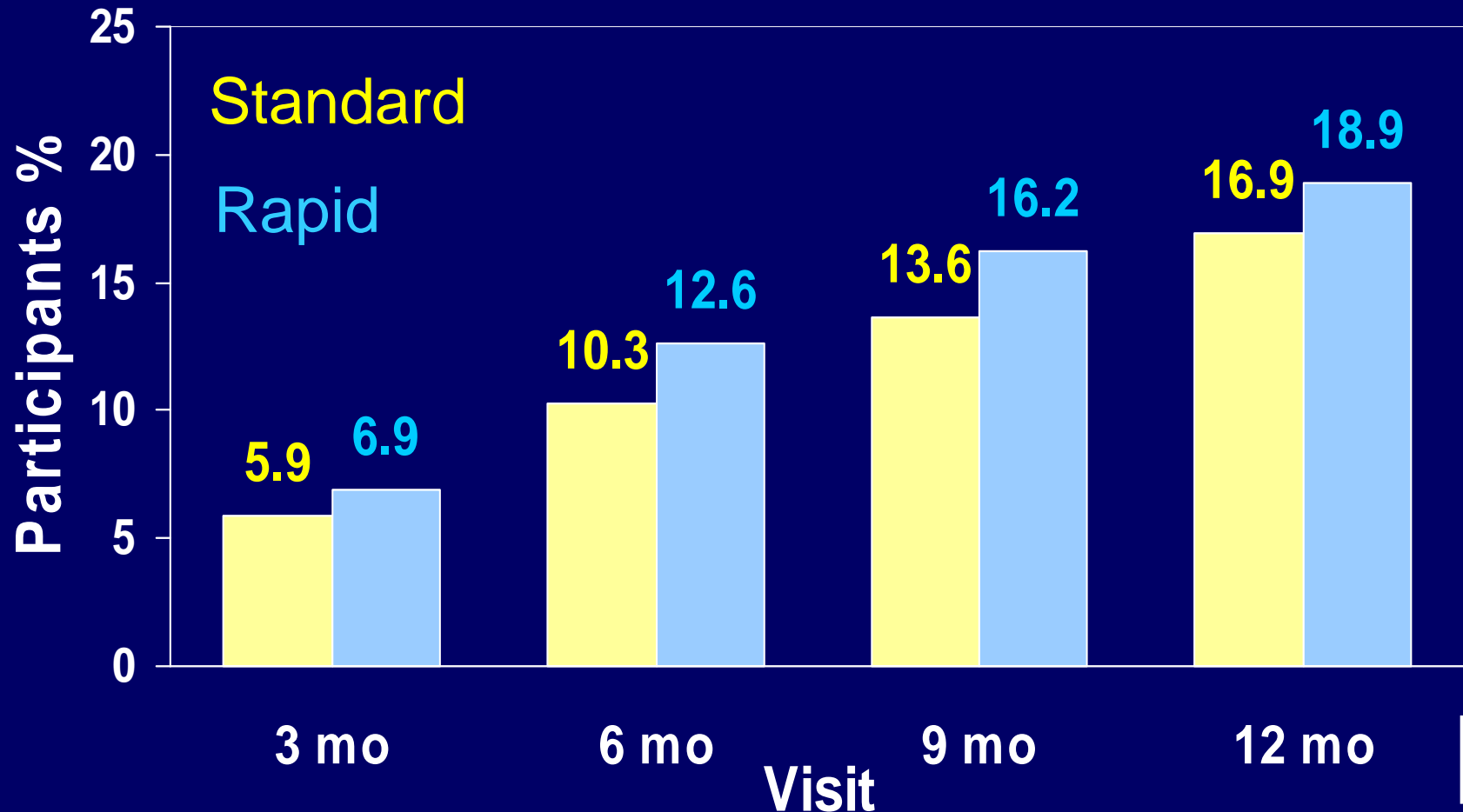


## Completion of Baseline Counseling and follow-up by HIV Test Type

- Completed counseling (%)
  - Standard 72
  - Rapid 99
- Follow-up (% at 3, 6, 9, and 12 months)
  - Standard 71 – 71 – 73 -- 73
  - Rapid 72 – 72 – 71 -- 72



## Cumulative Incidence of One or More STDs During Follow-up by HIV Test Type





# Cumulative Incidence of One or More STDs During Follow-up

## Rapid Test Group vs. Standard Test Group

Up to...	Risk Ratio (95% CI)	P-value
3 mo visit	1.17 (0.90-1.52)	0.25
6 mo visit	1.23 (1.01-1.49)	0.04
9 mo visit	1.19 (1.01-1.40)	0.04
12 mo visit	1.12 (0.97-1.30)	0.13



# Relative Risk of STDs During Follow-up: Rapid Test Group Compared to Standard Test Group by Site

Up to...	Denver Risk Ratio (95% CI)	Long Beach Risk Ratio (95% CI)	Newark Risk Ratio (95% CI)
3 mo visit	1.28 (0.84-1.97)	1.00 (0.57-1.76)	1.16 (0.77-1.75)
6 mo visit	1.25 (0.92-1.69)	0.93 (0.60-1.43)	1.39* (1.03-1.88)
9 mo visit	1.25 (0.97-1.61)	0.95 (0.65-1.37)	1.28 (0.98-1.67)
12 mo visit	1.13 (0.97-1.42)	0.96 (0.69-1.33)	1.21 (0.96-1.53)



## Conclusion

- Results preliminary
- Substantially more patients received their HIV test result using a rapid HIV test than a standard HIV test.
- Overall standard 2-visit counseling was associated with fewer new STDs.
- Differences in STD rates between groups decreased over time.

Please visit the RESPECT-2 website:

[www.cdc.gov/hiv/projects/respect-2](http://www.cdc.gov/hiv/projects/respect-2)

