USE OF A SIMULATED MICROBICIDE IN TWO-WEEK TRIALS BY HIGH-RISK WOMEN IN HARTFORD, CONNECTICUT (U.S.A.)

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Sub-Study Objectives

- To determine if high-risk, primarily African American and Puerto Rican women in Hartford, Connecticut (United States) would successfully use a simulation microbicide with their primary, casual, and/or paying sex partners, and document their sexual experiences and product use.

- To explore factors affecting the acceptability and feasibility of these high-risk urban women using a microbicide with their primary, casual, and/or paying sex partners.

Microbicide

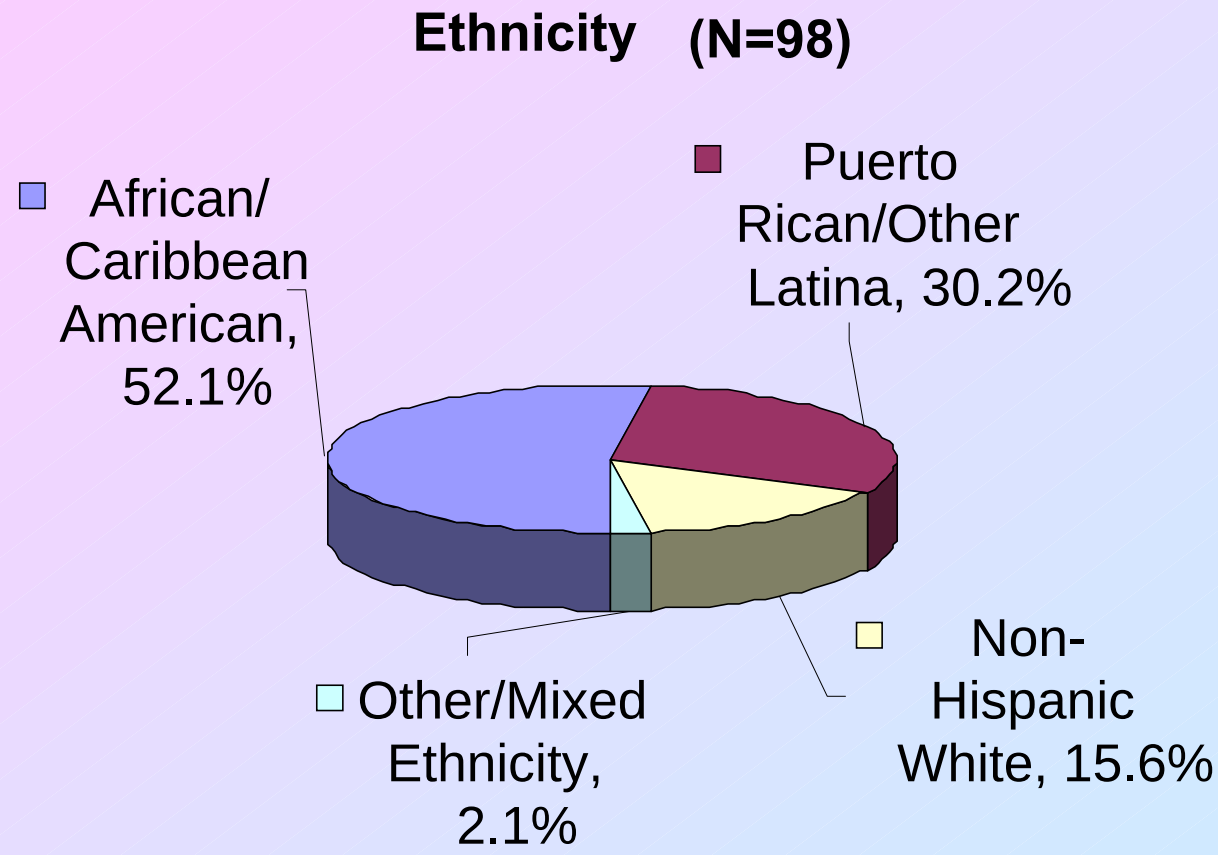
- Any substance that will decrease likelihood of mucosal transmission of HIV and/or other sexually transmitted pathogens

- First generation products will likely be topical gels that need to applied prior to sexual activity

Sub-Study Methods

- Completed Study
- Screened for Sub-Study
- Informed Consent
- Provided with Replens®, male and female condoms, coital logs
- Instructed on how to use product, deal with AEs, etc.
- Instructions given for documenting sexual activity
- Instructions given to use Replens® as microbicide simulation product every time they had vaginal intercourse and to *use a condom every time.*
- Follow-up interview scheduled
- Follow-up interview conducted/tabs & diaries collected
- Second trial offered

Data Analysis:
Study Sample Demographics



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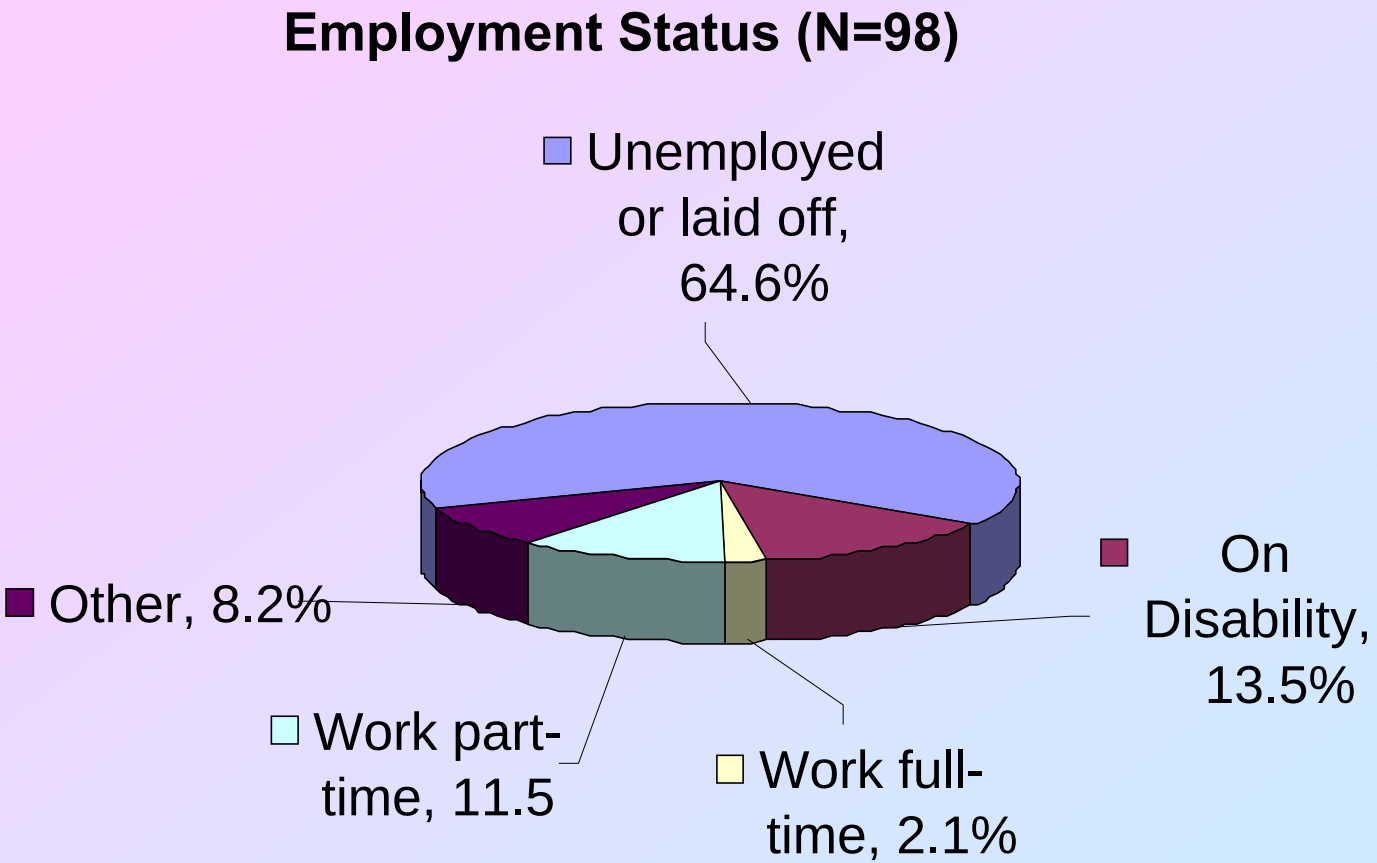

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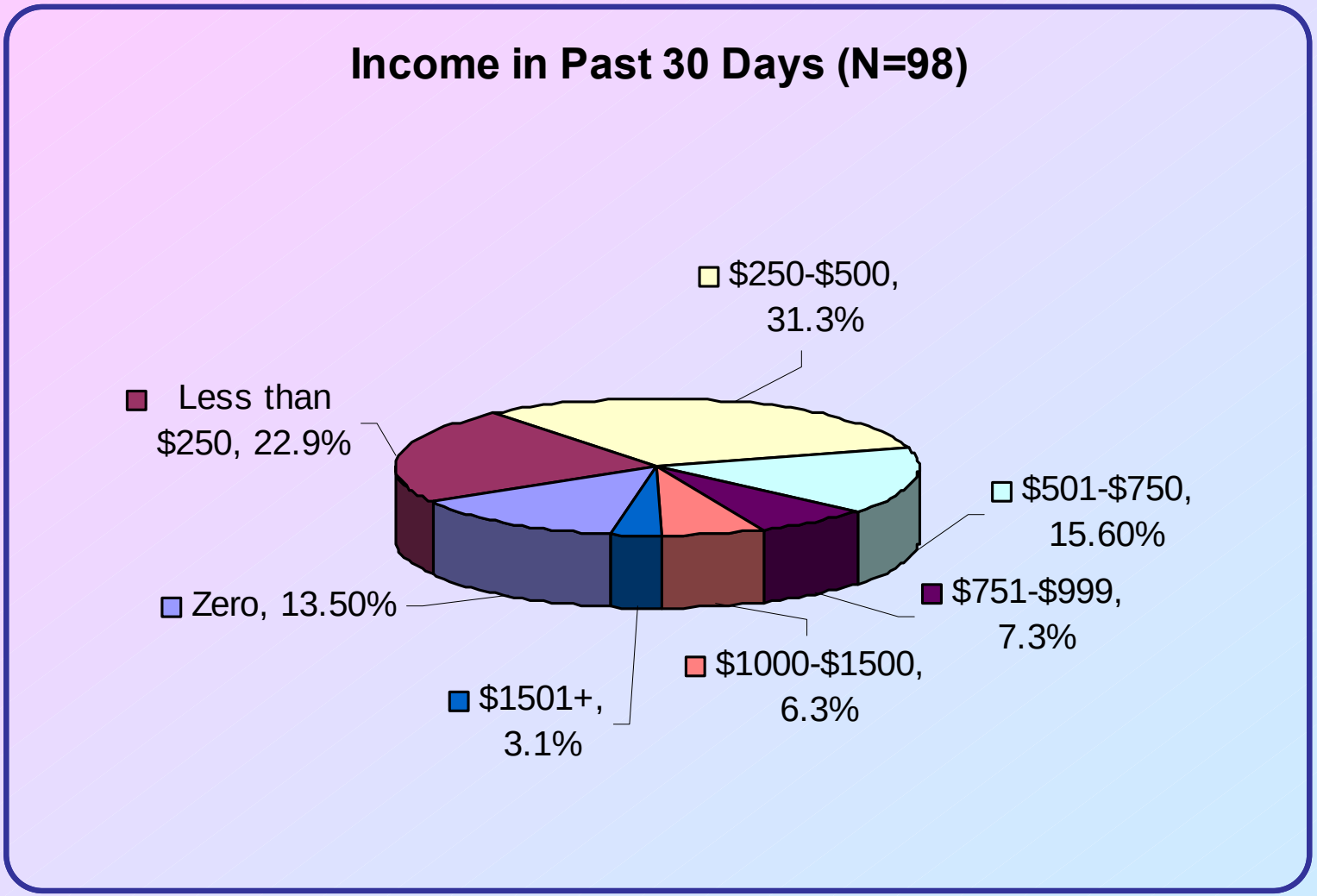

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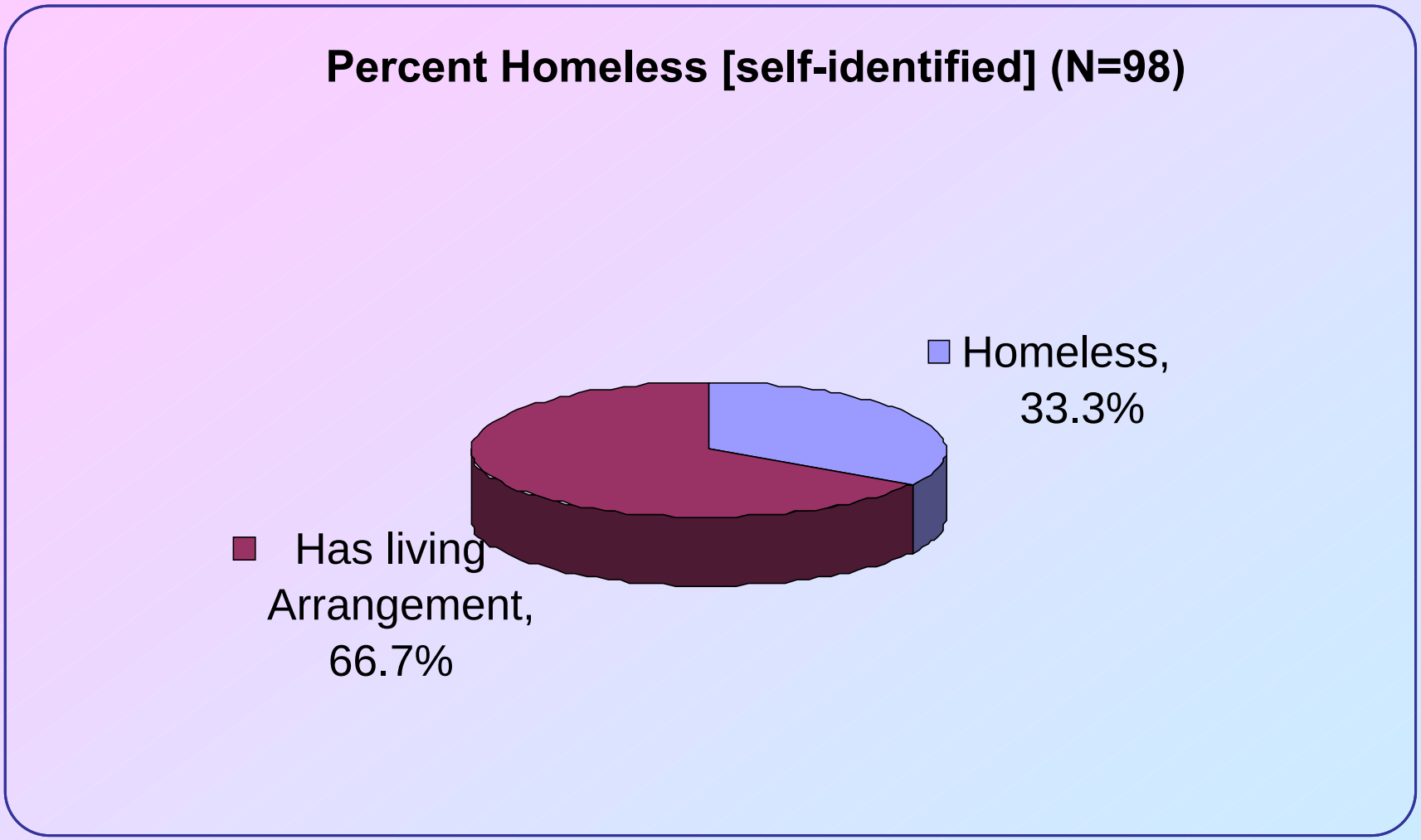

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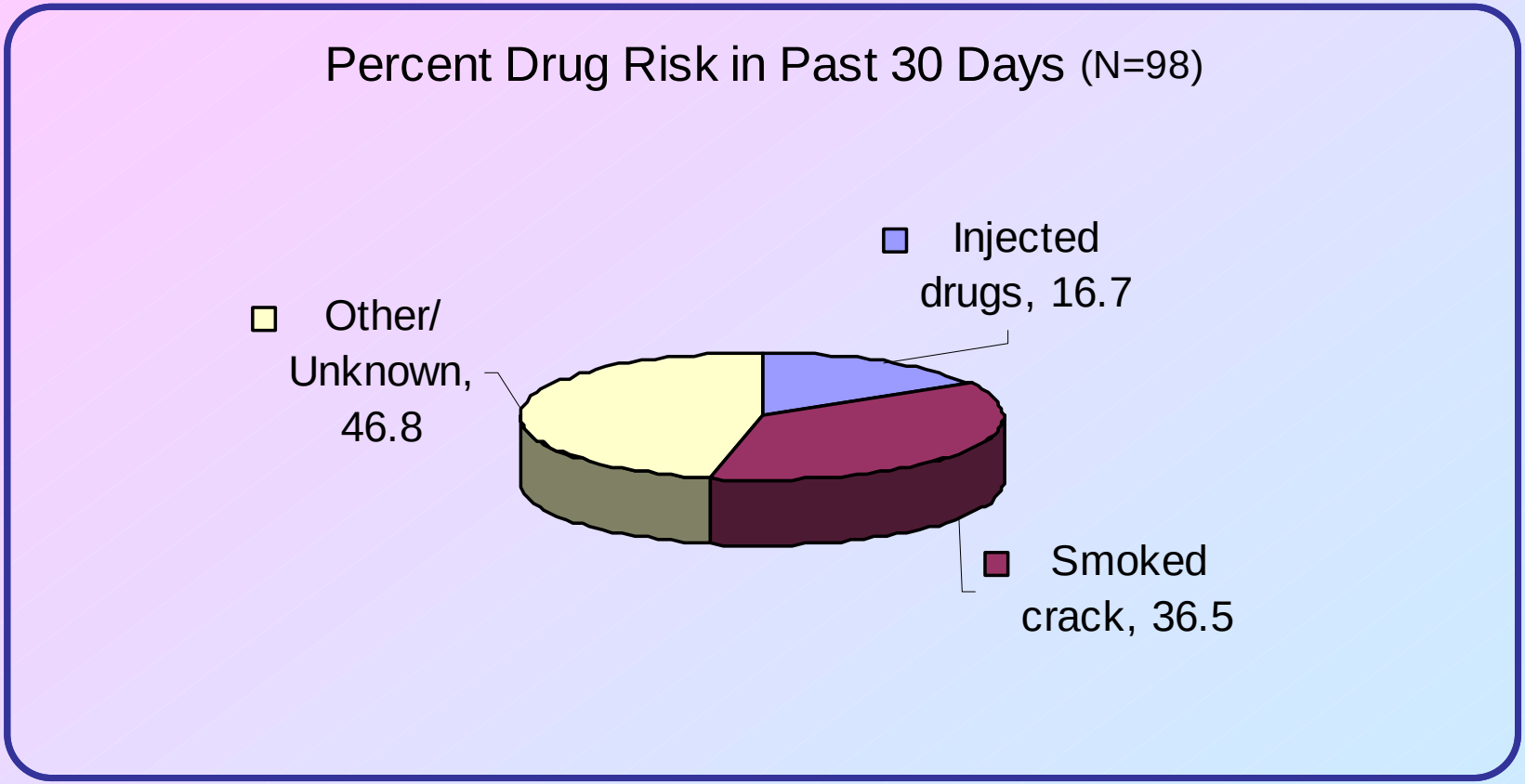

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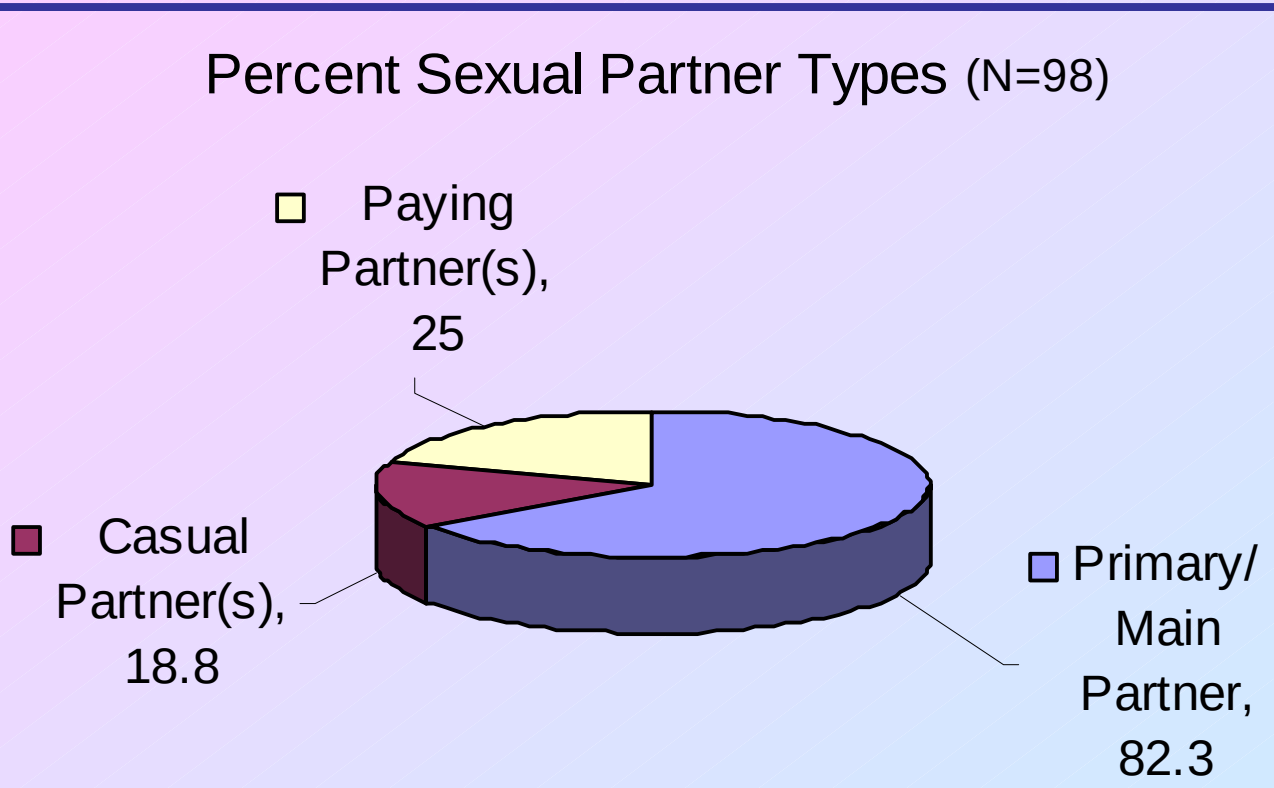
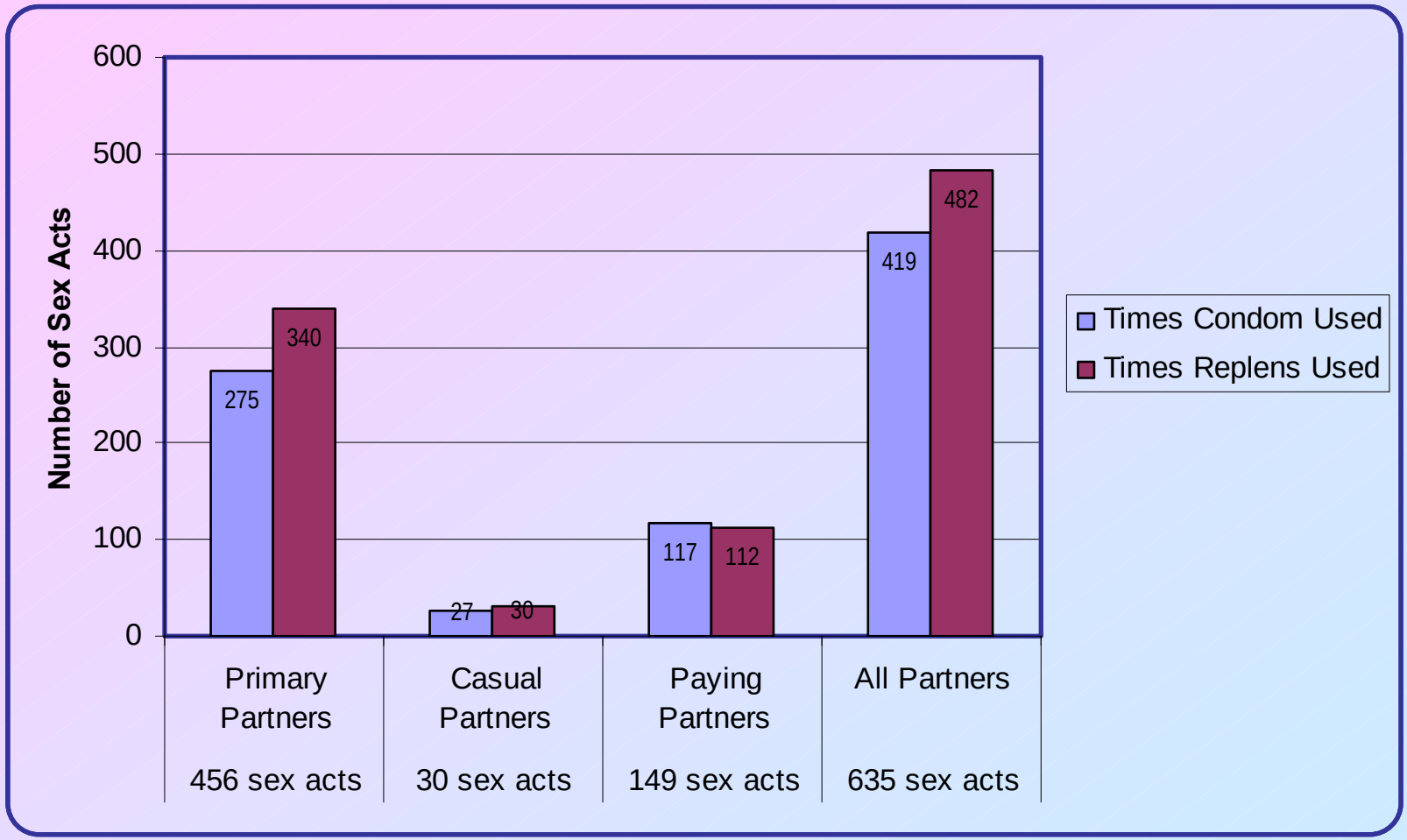
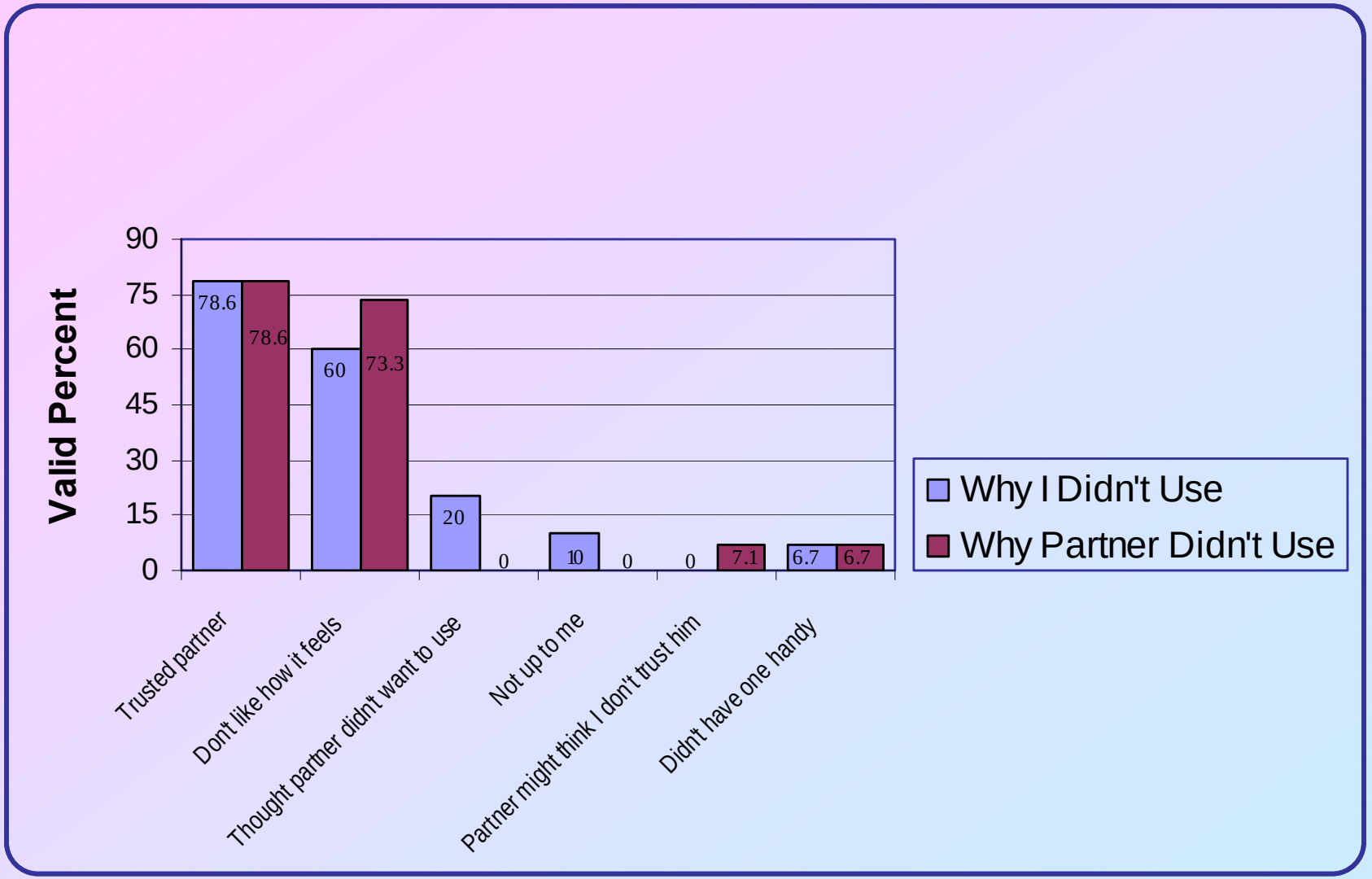


Findings

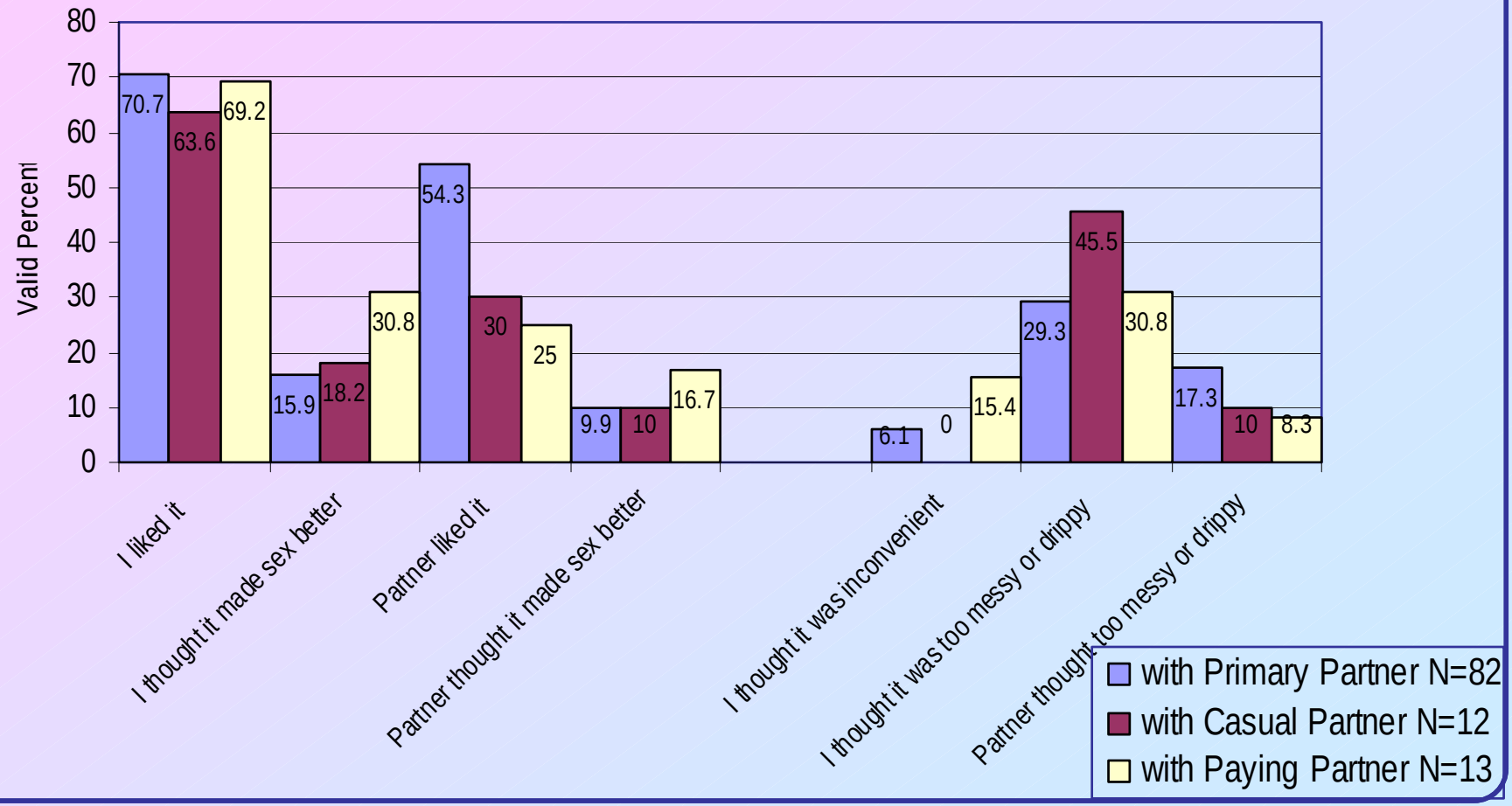
Simulation Product Use vs. Condom Use



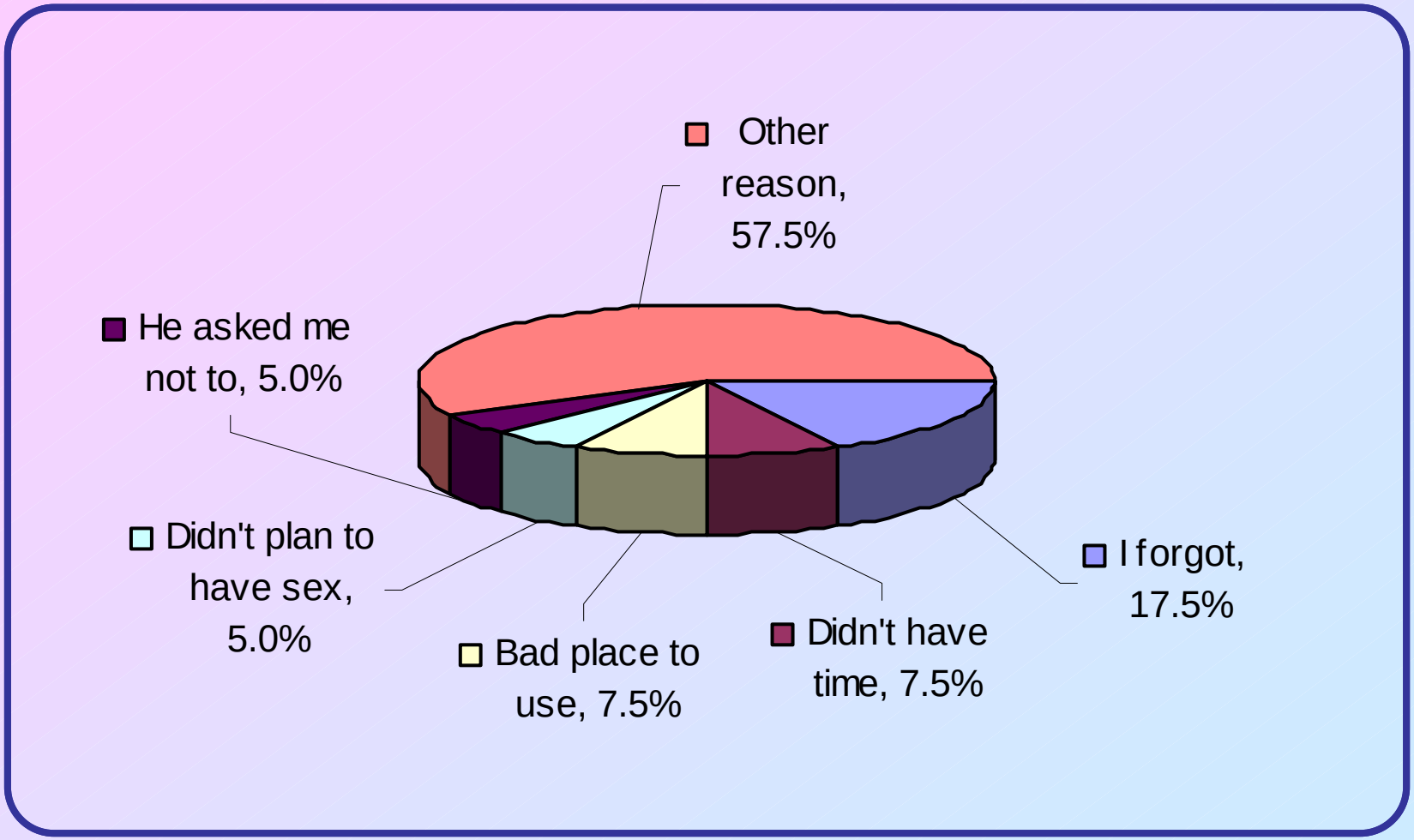
Top Reasons for NOT Using a Condom at Last Vaginal Intercourse N = 30



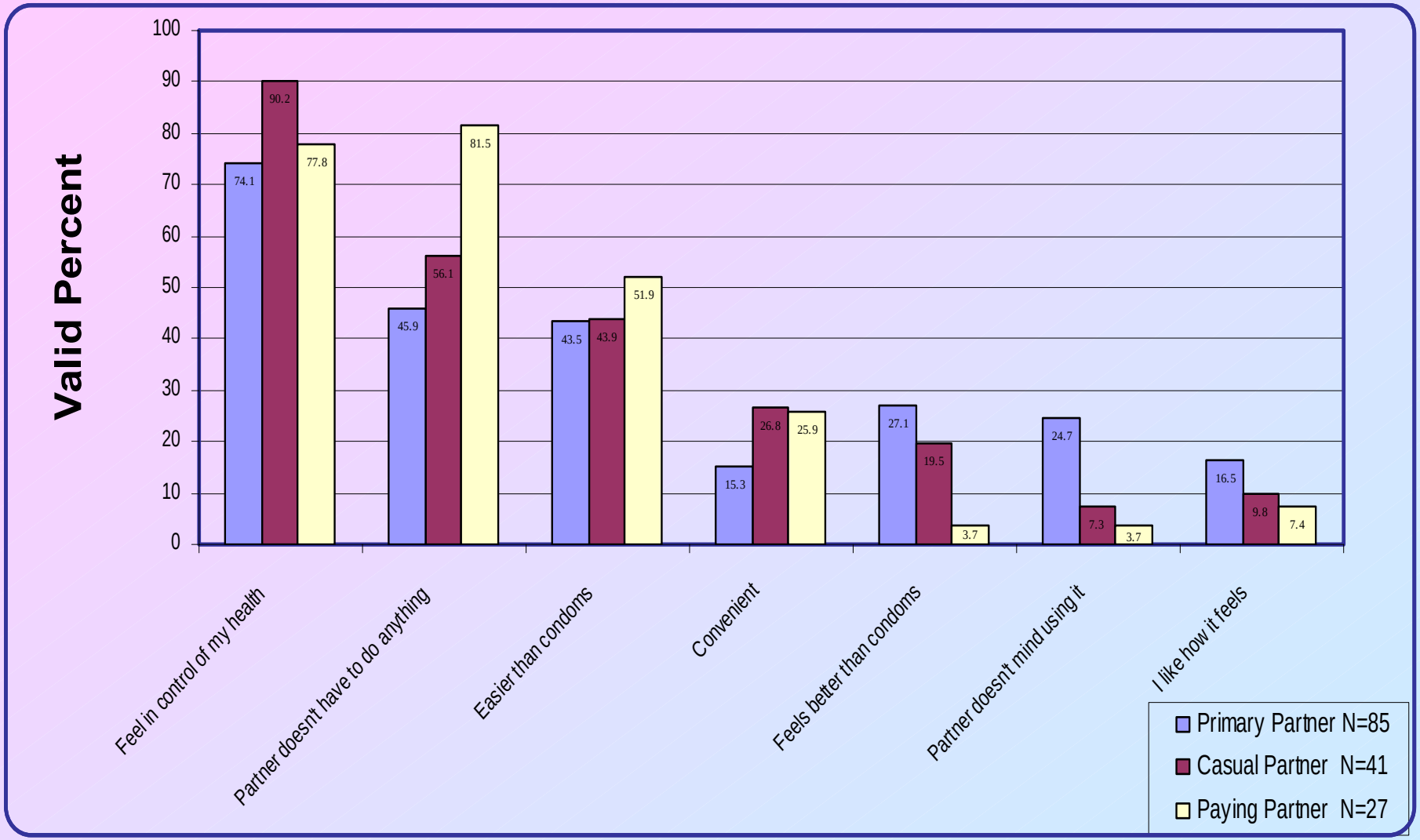
Experiences with Simulation Microbicide



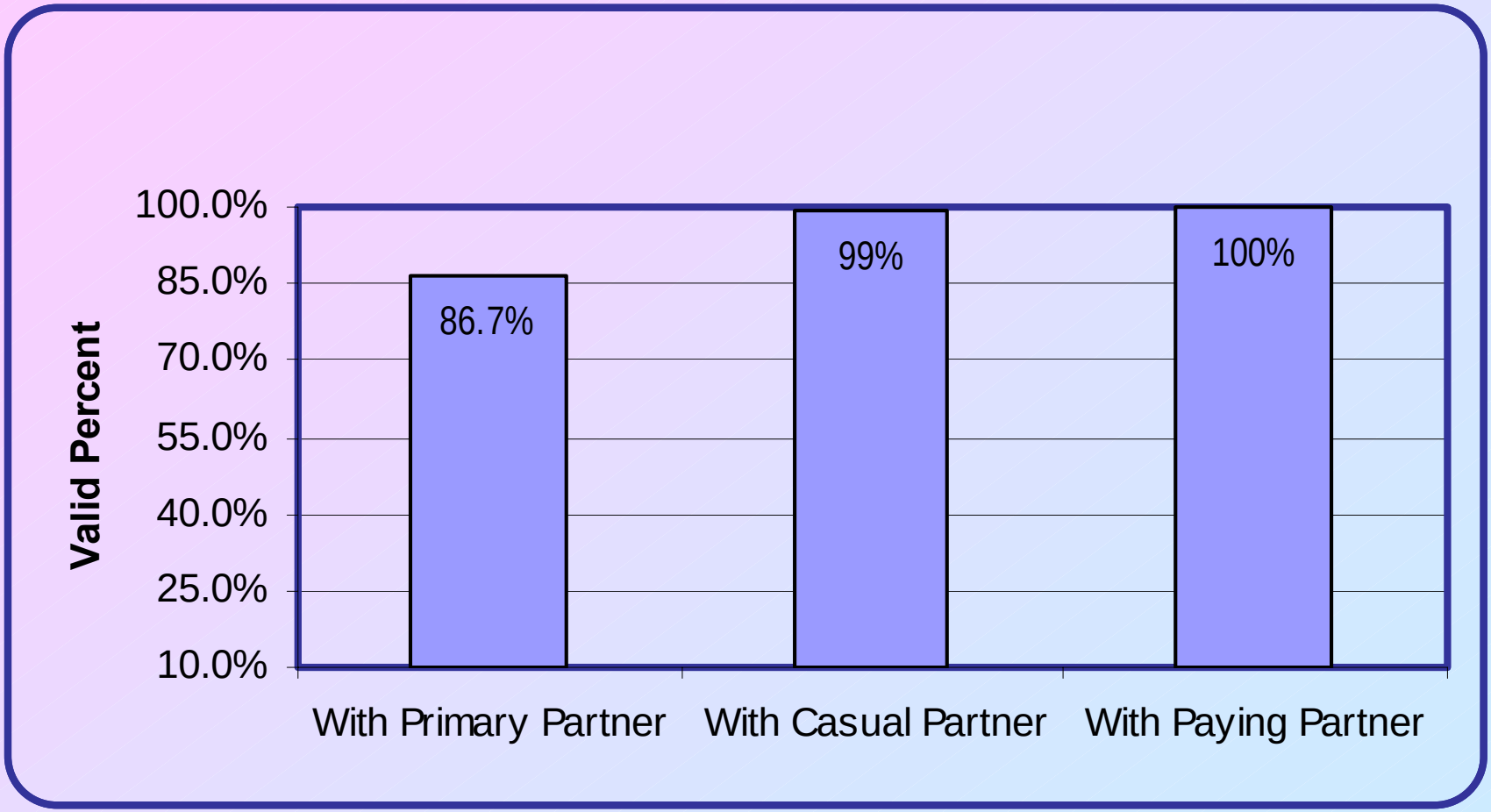
Why We Had Sex Without Using Replens During Last Sex Act Valid Percent N=40



What Women Liked About Using a Microbicide-Like Product



Willingness to Use a Microbicide



Key Findings

- High-risk urban women were willing and able to use a microbicide-like product

- Subjects were successful using the study product in a variety of settings with all types of sex partners

- Subjects used the product more frequently than they used condoms, especially in primary partnerships where condom use is particularly low

- Subjects successfully documented their sexual experiences and product and condom use

- Race, ethnicity, employment, and education did not affect product use

Significance

- An affordable, effective topical vaginal microbicide would be a viable and acceptable HIV prevention method for high-risk US urban women.

- Availability of a microbicide would likely increase the percentage of protected sex acts among high risk women.

Additional Findings

- No patterns emerged regarding who the “poor condom-good Replens users” were.
- Drug use was negatively correlated with condom use with primary partners, but not with other partners.
- Being high during sex had no correlation with condom use.
- Frequency of sharing needles or having injecting partners was not correlated with condom use.

Partner Sero-status and Condom Use

Partner SeroStatus and Condom Use	Test Score	P Value	Comment
HIV positive primary partner and condom use	R = .26	p<.01	Those with HIV positive primary partners were more likely to use condoms with any partner
HIV positive casual partner and condom use (negative correlation)	R = -.21	p<.05	Those with HIV positive casual partners were less likely to use condoms with any partner.
HIV positive paying partner and condom use (negative correlation)	R = -.22	p<.05	Those with HIV positive paying partners were less likely to use condoms with any partner.

STD Locus of Control and Condom Use

STD Locus of Control and Condom Use	Test Score	P Value	Comment
Belief "If it is meant to be I will get an STD" was negatively correlated with percentage of condom use with all partners	r = -.21	p<.05	Those who believed that getting an STD was up to chance were less likely to report using condoms
Belief "If it is meant to be I will get an STD" was negatively correlated with percentage of condom use with primary partners	r = -.24	p<.05	
Belief "If I take the right actions, I can keep from getting an STD positively correlated with condom use with primary partners	r = .33	p<.01	Those who believed their actions were protective were more likely to use condoms with their primary partners.

STD Locus of Control and Condom Use	Test Score	P Value	Comment
Belief "Having regular contact with a health care provider is the best way for me to avoid an STD was positively correlated with condom use with casual partners	r = .53	p<.05	Positive attitudes and beliefs about engagement were correlated with greater condom use.
Belief "My health care provider has a lot to do with my getting or avoiding an STD was positively correlated with percentage of condom use with all partners	r = .22	p<.05	
Belief "My partner has a lot do with my getting or avoiding an STD was positively correlated with condom use with paying partners.	r= .68	p<.01	
Belief "My partner has a lot to do with my getting or avoiding an STD was positively correlated with Replens use and paying partners.	r = .61	p<.05	

Locus of Control and Condom Use

Power Scale	Test Score	P Value
Positive power scores positively correlated with percentage of condom use with all partners	r = .61	p<.05
Positive power scores positively correlated with percentage of condom use with primary partners	r = .23	p<.05

Sexual Assertiveness and Condom Use

Sexual Assertiveness Scale	Test Score	P Value	Comment
SAS scores and percentage condom use	r = .59	p<01	
SAS scores and percentage condom use with primary partners	r = .63	p<.01	
SAS scores and percentage condom use with casual partners	r = 1.0		All individuals with high SAS scores used condoms with their casual partners
SAS and percentage Replens® use with primary partners	r = .24	p<.05	

Trial Participation and Behavior Change

Trial Participation and Behavior Change	Test Score	P Value	Increase in Mean Use
Percent of condom use increased from intake through Trial 1 for partners overall	t = 6.00	p<.01	45% to 73%
Percent of condom use increased from intake through Trial 1 for primary partners	t = -6.41	p<.01	32% to 67%
Percent of Replens use between Trial 1 and Trial 2 overall	t = -2.94	p<.01	82% to 91%
Percent of Replens use between Trial 1 and Trial 2 with primary partners	t = -3.09	p<.01	80%-90%

Acknowledgements

- Project Protect Team
  - Peg Weeks
  - Maryann Abbott
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  - Barbara Valdez
  - Mary Prince