

# From the Booty's Point of View: Using Perceptibility Data to Inform Rectal Microbicide Development

Kate Morrow, PhD

Senior Research Scientist, The Miriam Hospital

Associate Professor:

Psychiatry & Human Behavior, Brown Medical School

Behavioral & Social Sciences, Brown School of Public Health

Thank you, IRMA!



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# Acknowledgements

## NIH Microbicide Innovation Program

<b>Project LINK</b> <b>PI: Morrow</b>	<b>Project MIST</b> <b>PI: Buckheit, ImQuest BioSciences</b> <b>Project Lead: Morrow</b>
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The Project LINK Team	The Project MIST Team



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# Objectives:

- Introduce “perceptibility science”
- Illustrate how perceptibility developed using vaginal formulation studies
- Make the case for perceptibility work in the development of rectal microbicides
- Ask for help



# The challenge

- Microbicides – or *any* biomedical prevention products – need to be used to be effective.
- **Effectiveness** is dependent on both biologic efficacy and user behavior
- Biologic **efficacy** is dependent on active pharmaceutical ingredients, and - drug delivery to, and retention in, target tissues
- **Drug delivery** is dependent on rheological and other biophysical properties of DDS formulations (in the case of semi-solids)  
... and **user behavior** to initiate (and/or sustain) the delivery process

*What if it turns out that formulation properties ALSO govern user behavior...?*

- A non-optimized user experience will ultimately negate an optimized API and its delivery (or lack thereof)
- Balance optimization of drug delivery with optimization of the user experience

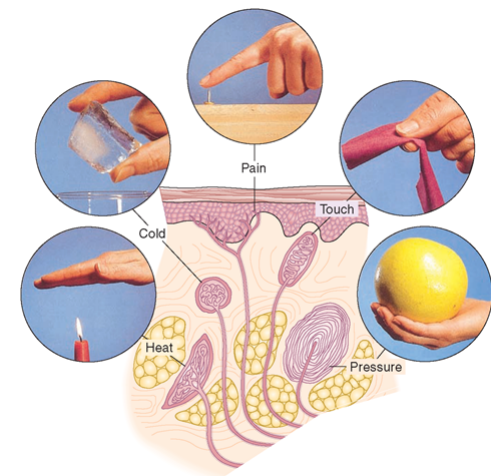


# The Exploration... Perceptibility

- **The objective measurement of user sensory perceptions and experiences (USPE) of formulation and/or device characteristics and their performance during use**
- Distinct from conventional “acceptability” and “tolerability”
  - Involves sensations and sensory experiences (and, ultimately, what people *think* of those experiences)
  - Can be evaluated early in the product development process
    - preclinically

# Perceptibility is Basic Behavioral Science

- The somatosensory system, or the sense of touch, allows the human body to experience pressure and texture, temperature and pain, and perceive position and movement
  - Mechanoreceptors respond to pressure and distortion:
    - Slowly adapting mechanoreceptors: perception of form and roughness/texture
    - Rapidly adapting mechanoreceptors: perception of flutter and slip across the tissue
  - Thermoreceptors detect changes in temperature





# Scale Development

Goal is to develop psychometrically valid USPE scales that capture objective sensations – and can be used to:

1. Screen potential formulations and devices during early preclinical development
2. Explore impact of USPEs, during clinical trials, on:
  - ... the meanings users make of those sensations, which are secondary in initial measurement, but very important thereafter
    - Regardless of the “accuracy” of those meanings
    - Willingness to try biomedical prevention products once, and/or more than once
    - Willingness to use such products over time
    - Ultimately... adherence, both during clinical trials and in subsequent uptake and maintained use

# Measuring *what...?*

- Sensations:
  - lubrication, smooth, tacky, dry, slick, oily, sticky, wet, moist, viscosity... etc.
- Pressure and movement:
  - physical awareness, fullness, “foreign object,” messiness, leakage
- Changes in USPE over time:
  - at initial penetration, early intercourse, end of intercourse, “average” over time
    - Changes in viscosity over time

# Project LINK

- LINK: 3 stages
  - Formative, qualitative (narrative) data: users describing their sensations and experiences of gel “behavior”
  - Scale development: item generation, refinement and testing
  - Scale validation for vaginal gel USPEs
    - 4 gel formulations
    - Each participant evaluated each gel (random order)

ORIGINAL PAPER

## User-Identified Gel Characteristics: A Qualitative Exploration of Perceived Product Efficacy of

Kathleen M. Morrow · Kristen Underhill · Jacob J. Sara Vargas · Rochelle K. Rosen · David F. Katz

AIDS Behav  
DOI 10.1007/s10461-013-0652-4

ORIGINAL PAPER

Project MAPLE



## “Set it and Forget it”: Women’s Perceptions and Opinions of Long-Acting Topical Vaginal Gels

Jacob J. van den Berg · Rochelle K. Rosen · Dana E. Bregman · Lara A. Thompson · Kathleen M. Jensen · Patrick F. Kiser · David F. Katz · Karen Buckheit · Robert W. Buckheit Jr. · Kathleen M. Morrow

AIDS RESEARCH AND HUMAN RETROVIRUSES  
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DOI: 10.1089/aid.2013.0099

PRECLINICAL STUDIES/DRUG DEVELOPMENT

## Designing Preclinical Perceptibility Measures to Evaluate Topical Vaginal Gel Formulations: Relating User Sensory Perceptions and Experiences to Formulation Properties

Kathleen M. Morrow,<sup>1,2</sup> Joseph L. Fava,<sup>1</sup> Rochelle K. Rosen,<sup>1,3</sup> Sara Vargas,<sup>1,2</sup> Julia G. Shaw,<sup>1</sup> E. Milu Kojic,<sup>4,5</sup> Patrick F. Kiser,<sup>6</sup> David R. Friend,<sup>7</sup> David F. Katz,<sup>8</sup> and The Project LINK Study Team

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FIG. 3. Perceptibility Scales for Sexual Activity.

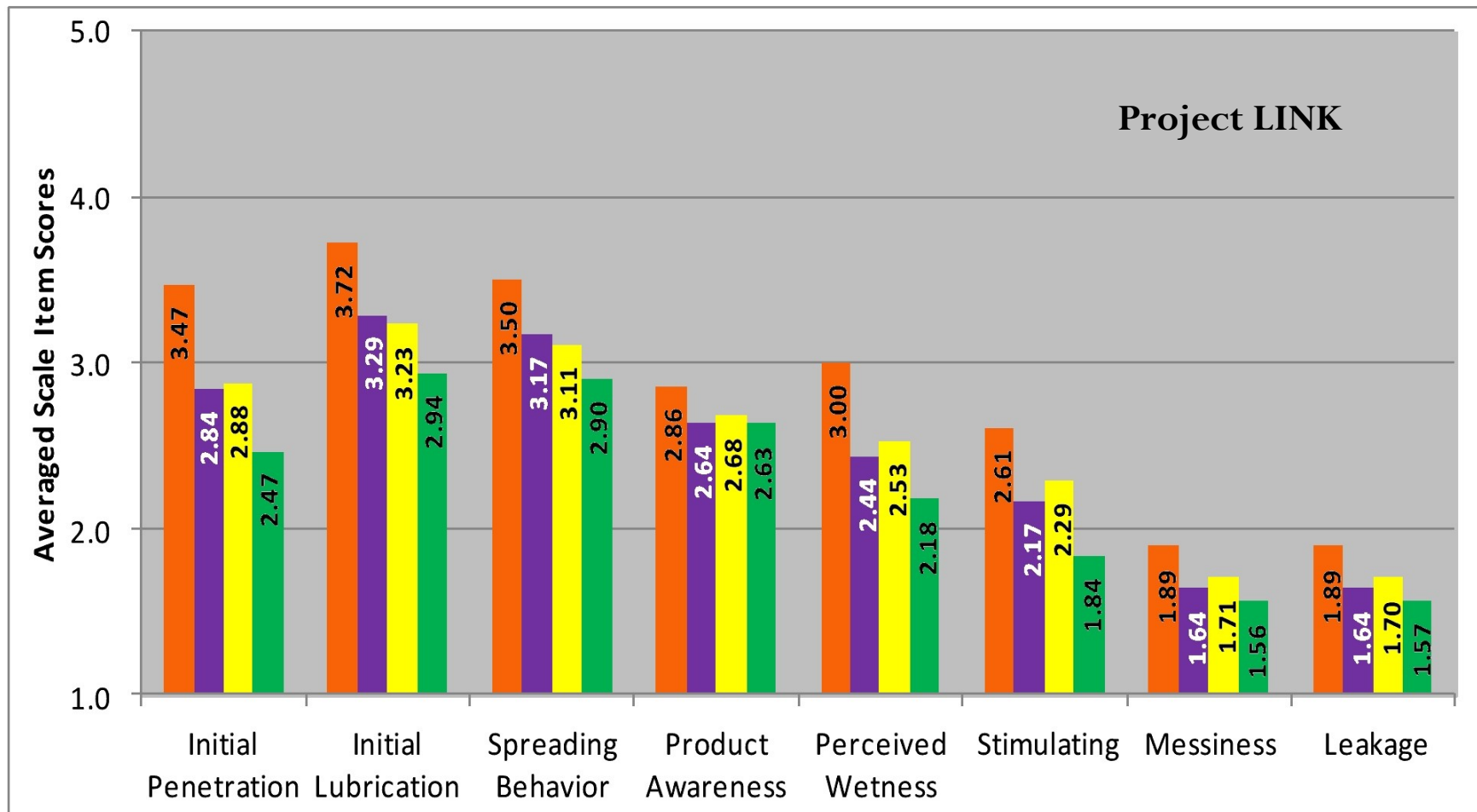
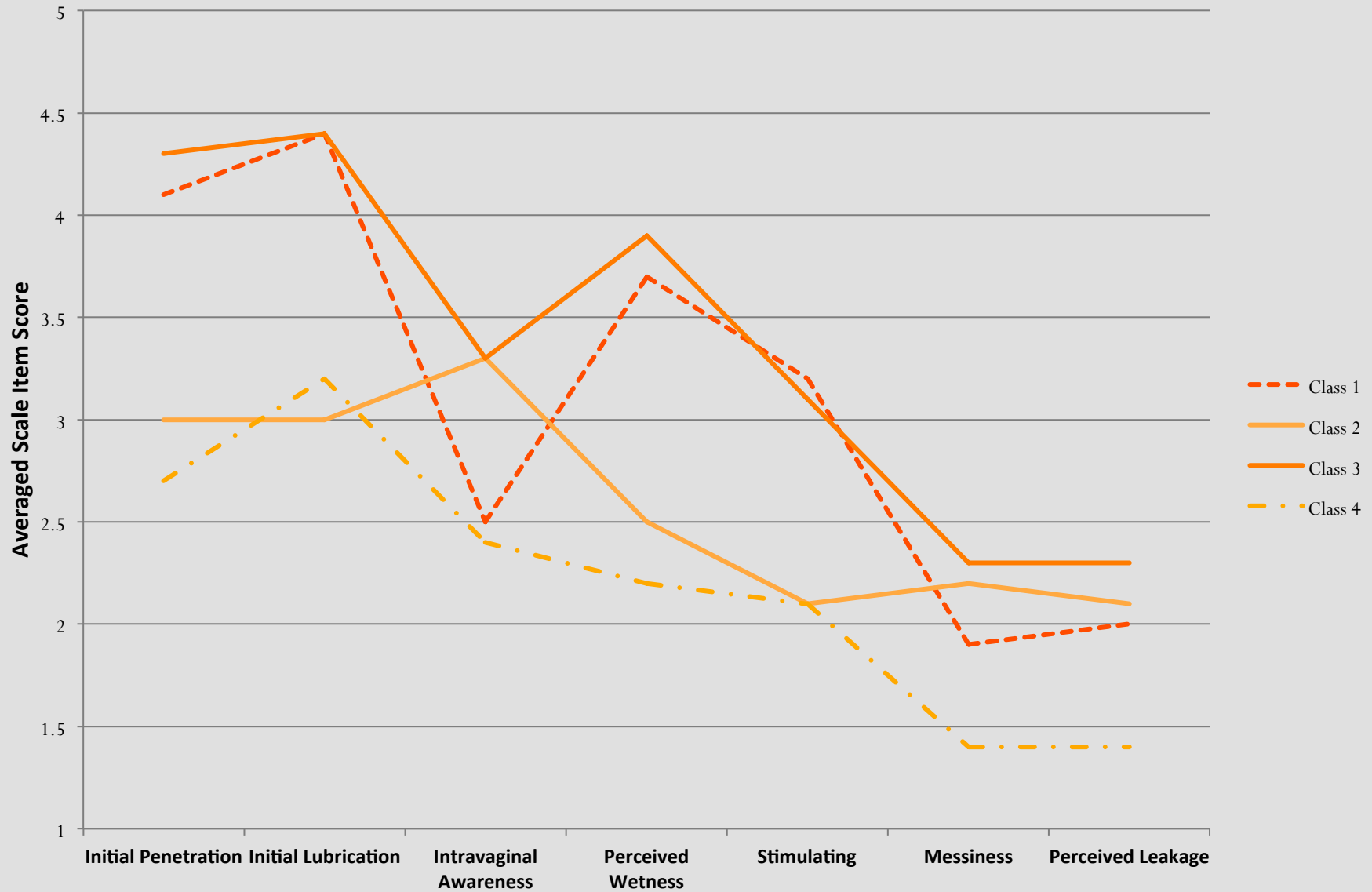


Figure 3. Averaged scale item scores for each Perceptibility Scale for Sexual Activity. 1=do not agree at all; 2=agree a little; 3=agree somewhat; 4= agree a lot; and 5= agree completely. Primary constituents for each gel were: 3% hydroxyethylcellulose (HEC) (orange); 1.25% carbopol (yellow); 2% HEC and 1.73% carbopol (purple); and 3% HEC and 2.5% carbopol (green). Pair-wise comparisons are presented in Table 6.

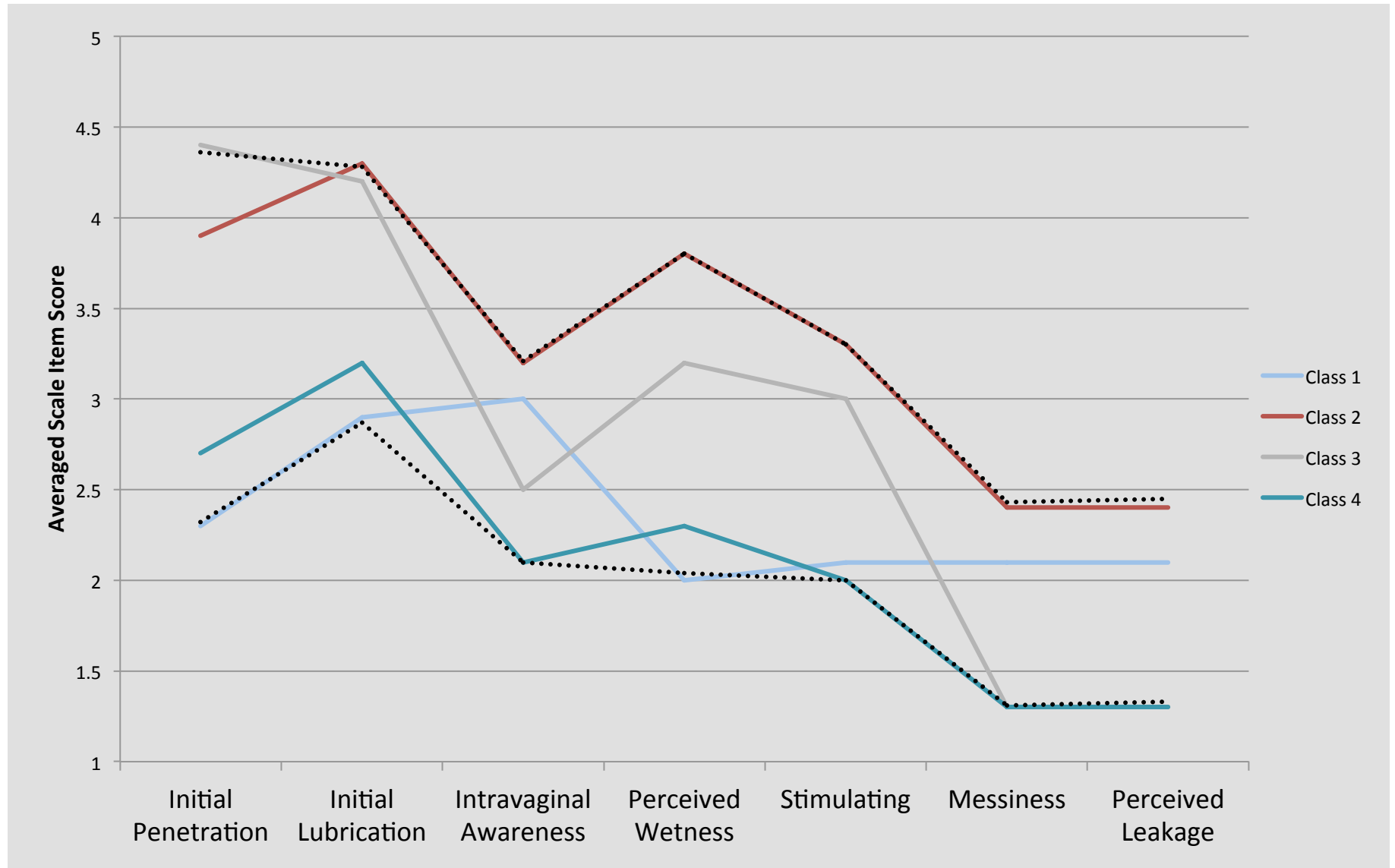
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## USPE Profiles for Orange Gel

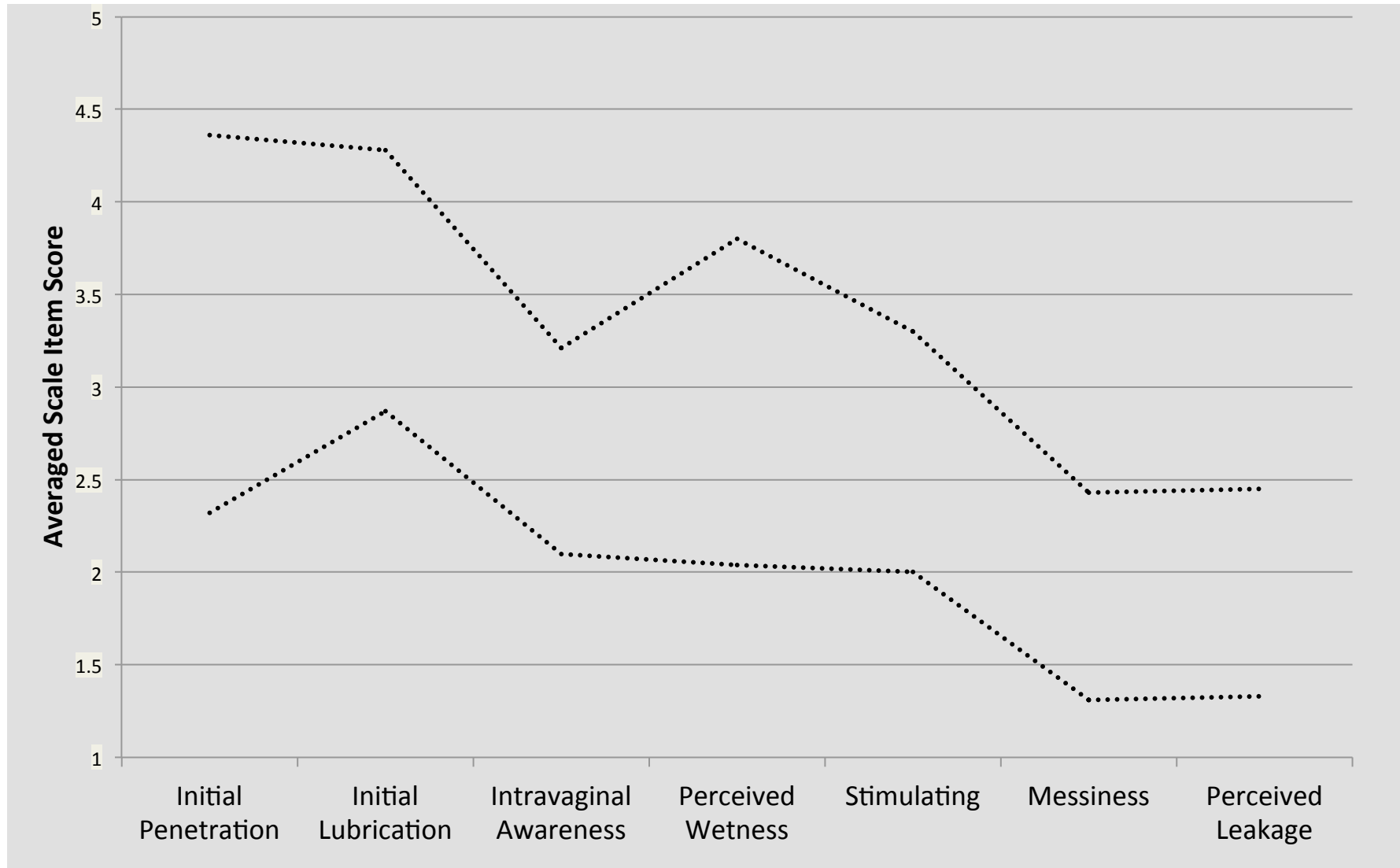


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# Choice-Experience Patterns



# “The Sweet Spot”





# But what about couples...?

- Project MIST (heterosexual vaginal sex):
  - Add film USPEs
  - Calibrate for volume
  - Add male partner USPEs
- Enrolled monogamous heterosexual couples
  - Evaluated 3 formulations: high volume, low volume, film (random order)
  - Separate USPE evaluations and in-depth interviews

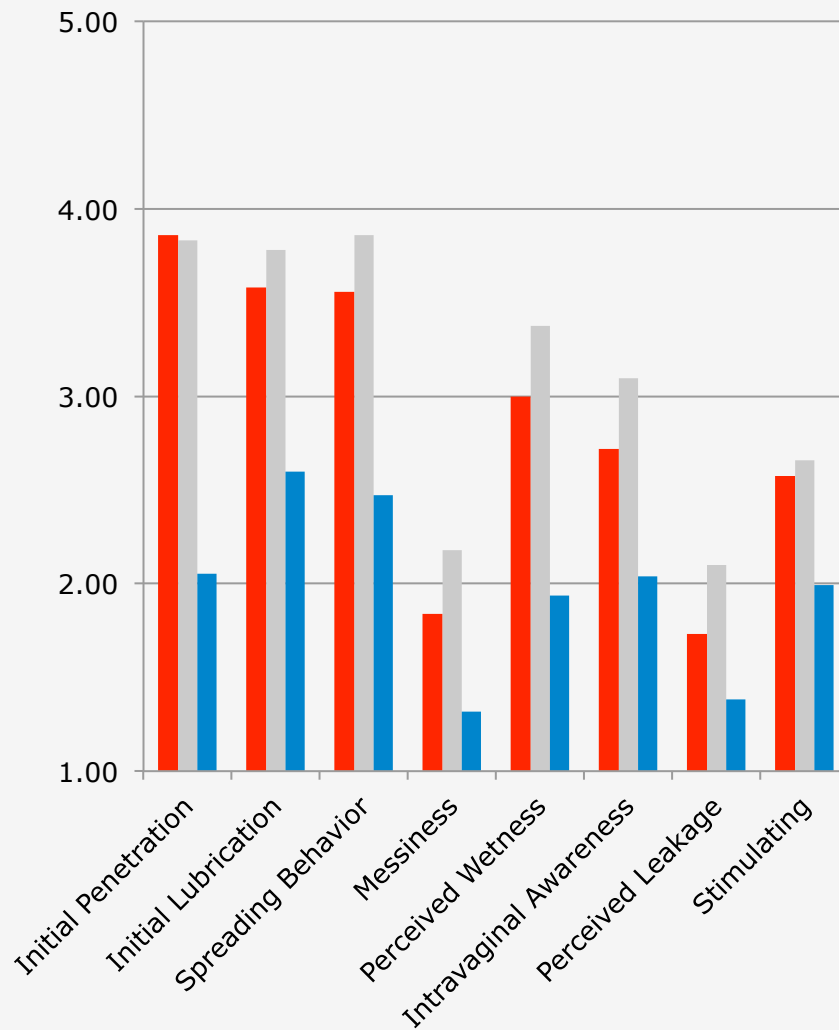
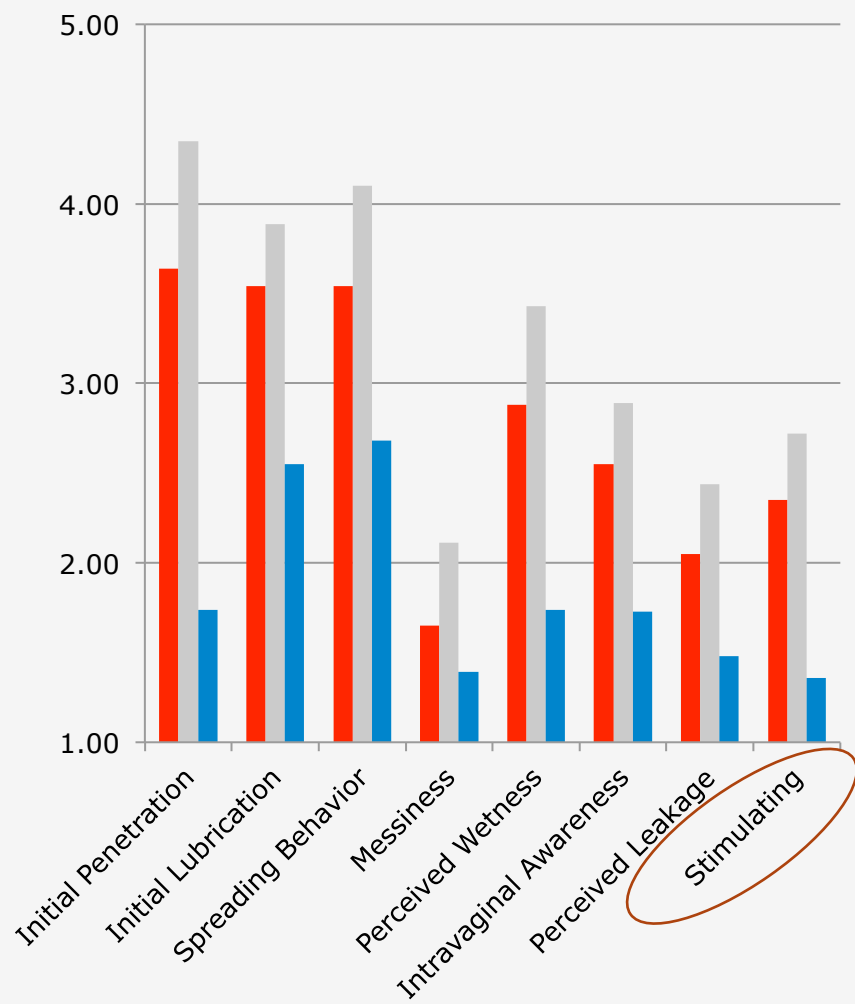
# Project MIST

Female

Male

## Coital Activity Scales

## Coital Activity Scales



# What have we learned...?

- Project LINK:
  - *in mano* scales (1) educate users re: USPE measures, and (2) may serve as screening tools in early formulation development, to identify “red flags” in prototype formulations
  - Application and Ambulation scales capture USPE during critical early “try” experiences
  - Coital scales capture USPEs that analyses show play a role in “willingness to use”
- Project MIST:
  - Both female and male users can respond to USPEs in vaginal sex
  - Psychometrics hold well in both female and male users, and when new formulations are evaluated (with new USPEs emerging)

# Perceptibility science can be helpful

1. In preclinical development of drug delivery systems
  2. In prediction of acceptability and adherence in late stage clinical trials and market use
- Still a nascent science, a novel set of tools
    - needs to be tested and refined in broader circumstances,
    - with more formulations,
    - across larger use periods, and
    - with varying populations, including transgendered individuals
  - But wait...!
  - A vagina is a vagina is a vagina...

# What about the **BOOTY**?!!!!



# Project DRUM

- Adapting vaginal USPE items to the anorectal environment
- Adding new USPE items identified in in-depth interviews and refined in cognitive interviews that are relevant to RAS
- Psychometrically validating that combined item pool into rectal USPE scales for MSM, gay men, and women who have receptive anal sex

“Project 5” of U19 AI101961 (PI: Buckheit)

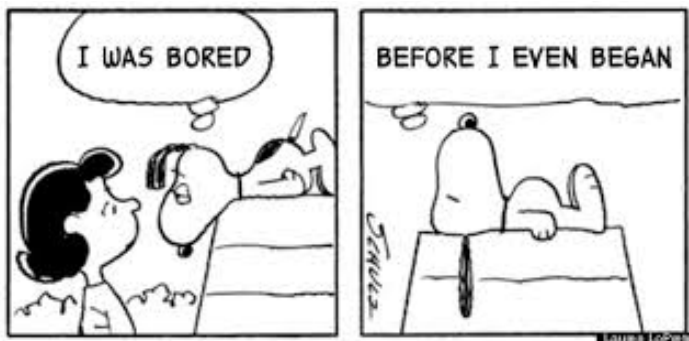
Snapshots

www.CartoonStock.com



"You don't sniff my butt anymore."

We want it safe,  
We want it effective,  
and  
We want it sexy!!



Using perceptibility evaluations to  
develop user-centered products  
can make a difference !

We can get to the bottom  
of the HIV epidemic!

17 July 2014



If you are, or know someone, in the Providence ,RI, area who has receptive anal sex – male or female –

If you know a willing bottom...

Call or email the **Project DRUM** team:

**(401) 793-8143**

**reprohealthteam@lifespan.org**



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## Project DRUM



*Project DRUM* is a research study conducted by The Miriam Hospital to assess men's and women's opinions about different products. Your opinions will help scientists create new products that men and women can use to prevent HIV and other sexually transmitted diseases.

Do your part in the fight against HIV!

Share your opinions about products to be used by men and women.

You might be eligible to participate if:

- You are a man or woman age 18 and older
- You want to share your opinions about products to be used during sex

PLEASE CALL OR EMAIL PROJECT DRUM

(401)-793-8143

reprohealthteam@lifespan.org

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Questions...?

Thank you!