Characterizing Product Properties: Perceptibility and Willingness

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The Miriam Hospital
A Lifespan Partner

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CONRAD
Leaders in Reproductive Health and HIV Prevention

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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

The need for interdisciplinary balance

*What if it turns out that **formulation properties ALSO govern user behavior**…? How could we figure this out…?*

- 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

  (a.k.a, Creating Desire)

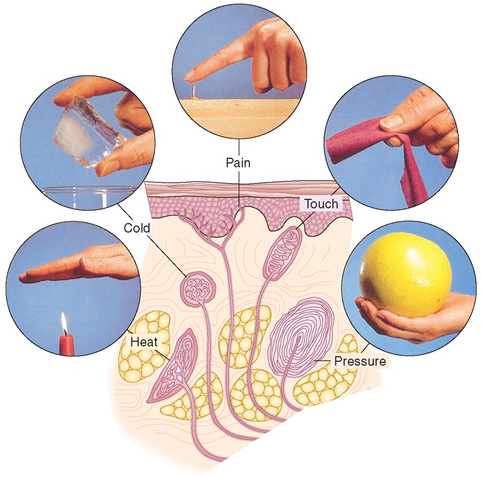
The Exploration… Perceptibility

- 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"
  - But… we believe, a precursor to both
  - Involving sensations

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
    - Rapidly adapting mechanoreceptors: perception of flutter and slip across the tissue
  - Thermoreceptors detect changes in temperature



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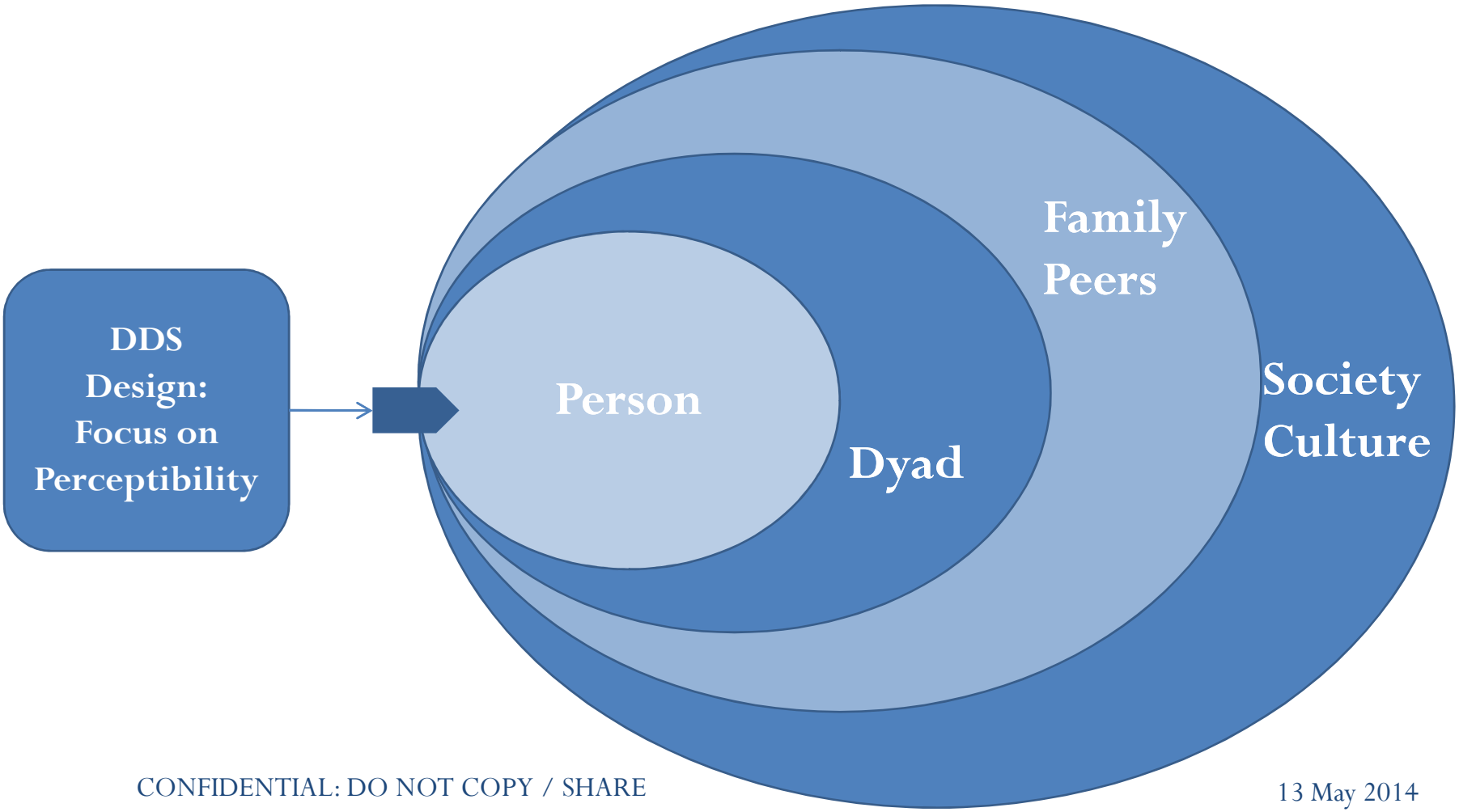
Scale Development

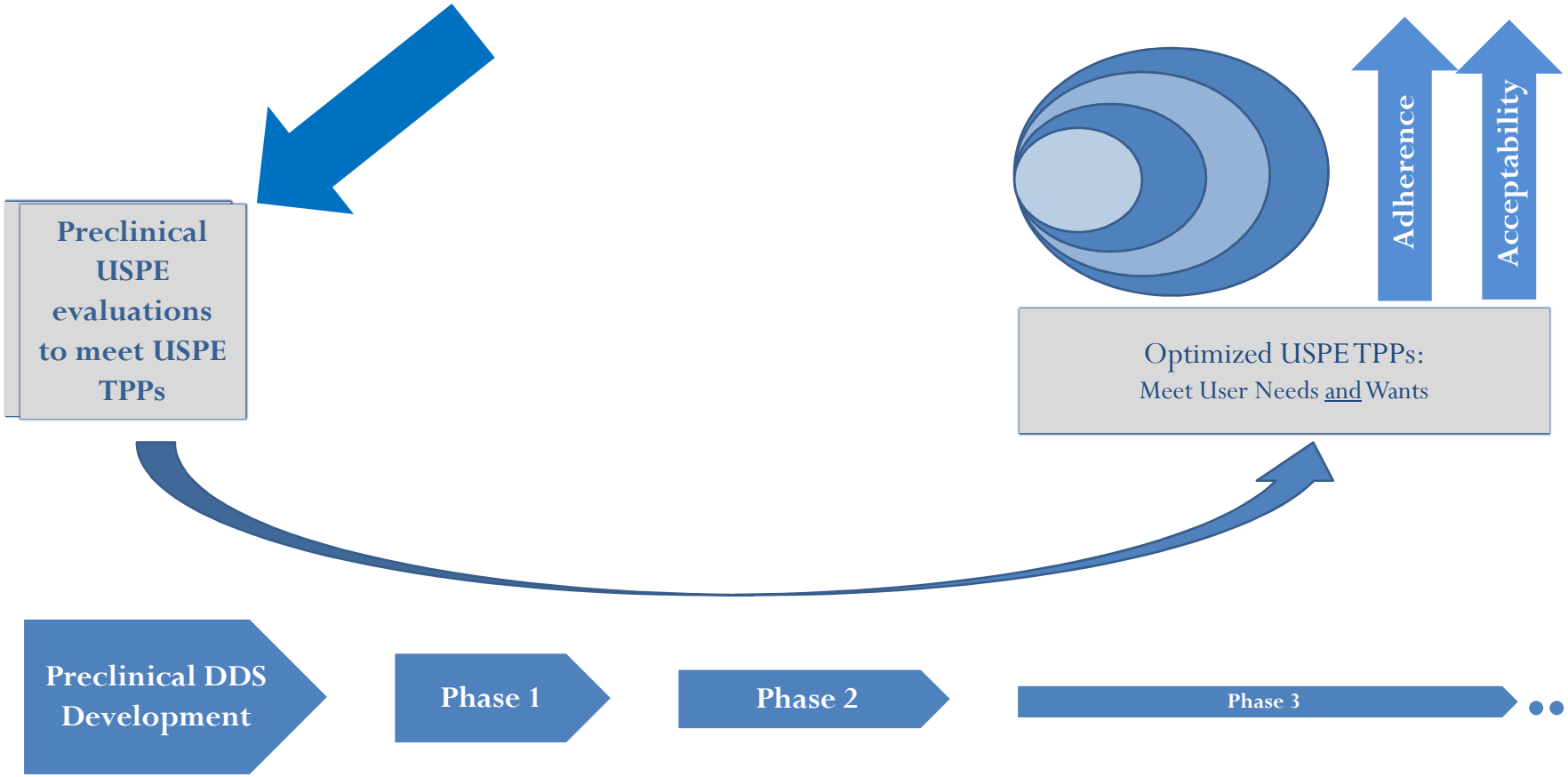
Goal is to develop psychometrically valid USPE scales that capture objective sensations – and can be used to:

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

Acceptability: contextual model



Conserving resources: rationale design



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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

"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

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

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

FIG. 3. Perceptibility Scales for Sexual Activity.

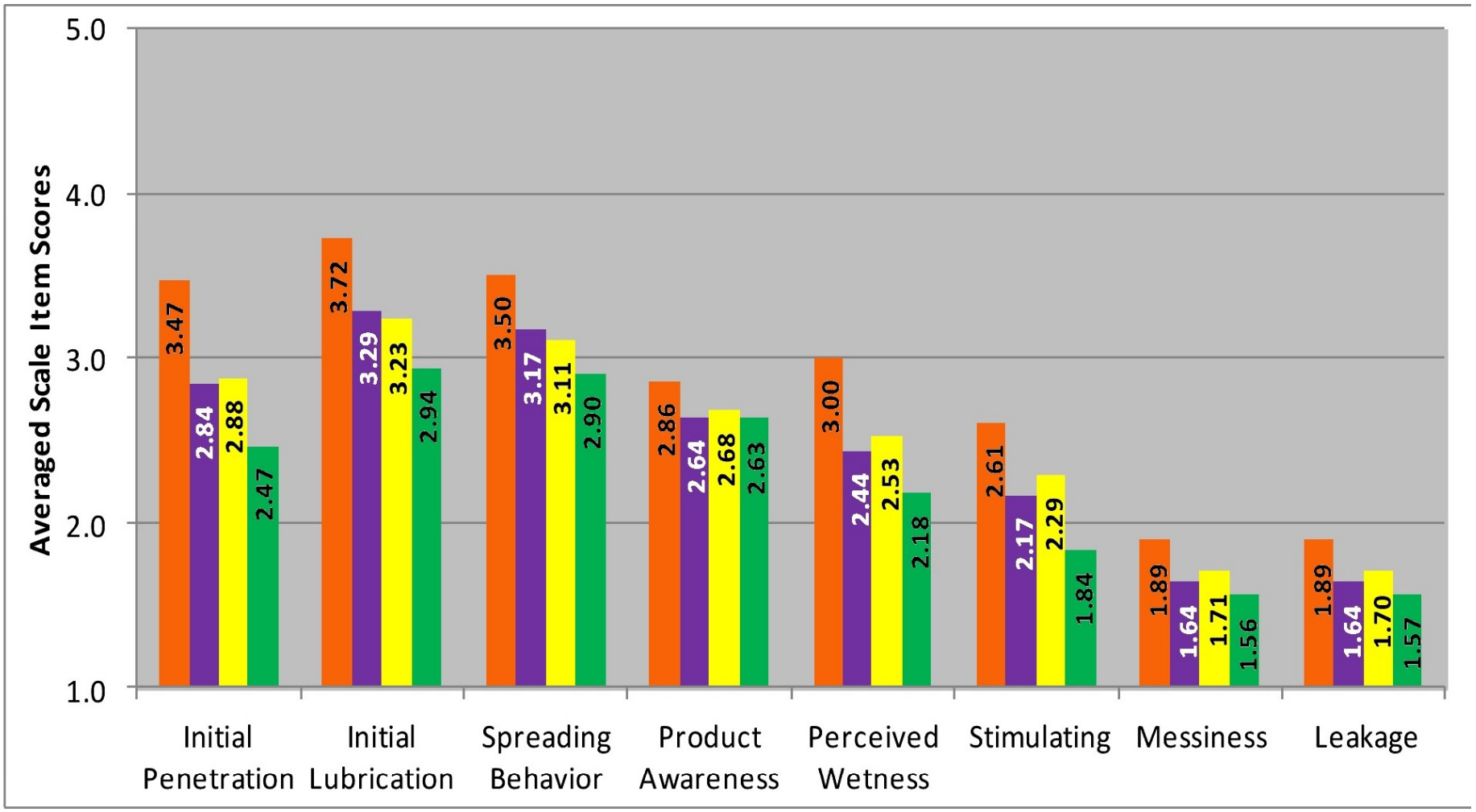
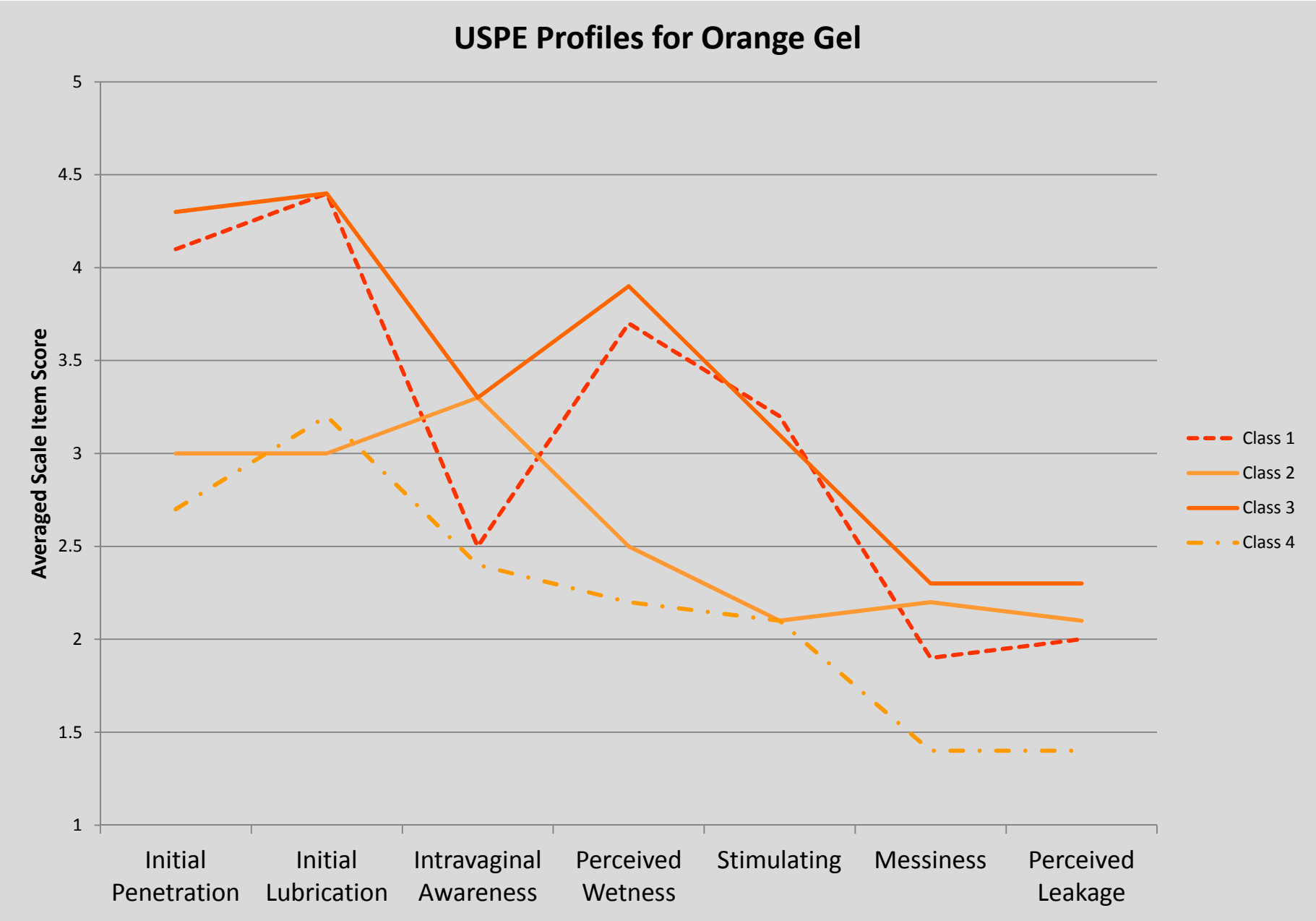
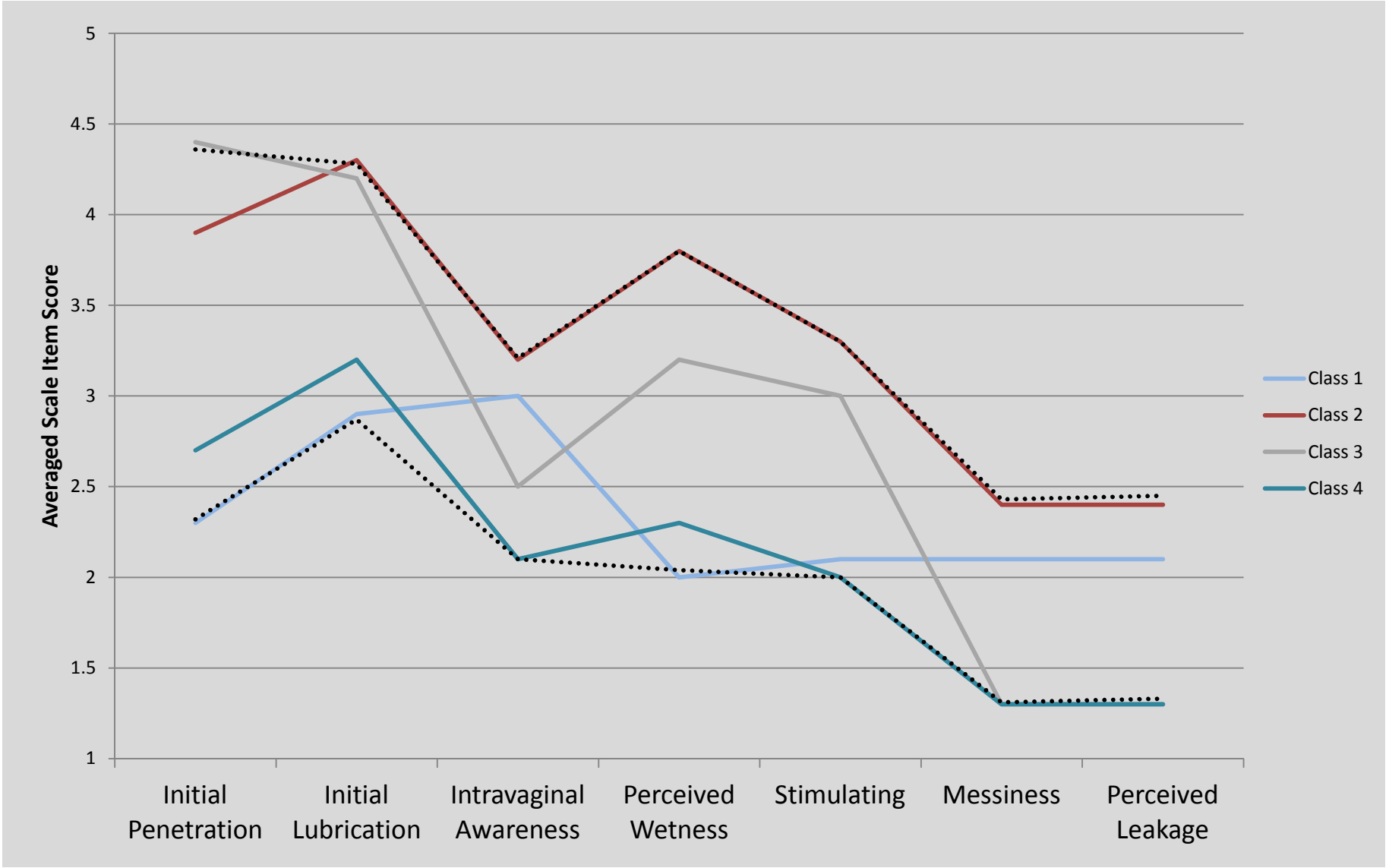


Figure 3. Averaged scale item scores for each Perceptibility Scale for Sexual Activity. 1=do not agree at all; 2=agree a little; 3=agree somewhat; 4= agree a lot; and 5= agree completely. Primary constituents for each gel were: 3% hydroxyethylcellulose (HEC) (orange); 1.25% carbopol (yellow); 2% HEC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


USPE Profiles for Orange Gel
Averaged Scale Item Score
5
4.5
4
3.5
3
2.5
2
1.5
1
Initial Penetration
Initial Lubrication
Intravaginal Awareness
Perceived Wetness
Stimulating
Messiness
Perceived Leakage
Class 1
Class 2
Class 3
Class 4

Choice-Experience Patterns



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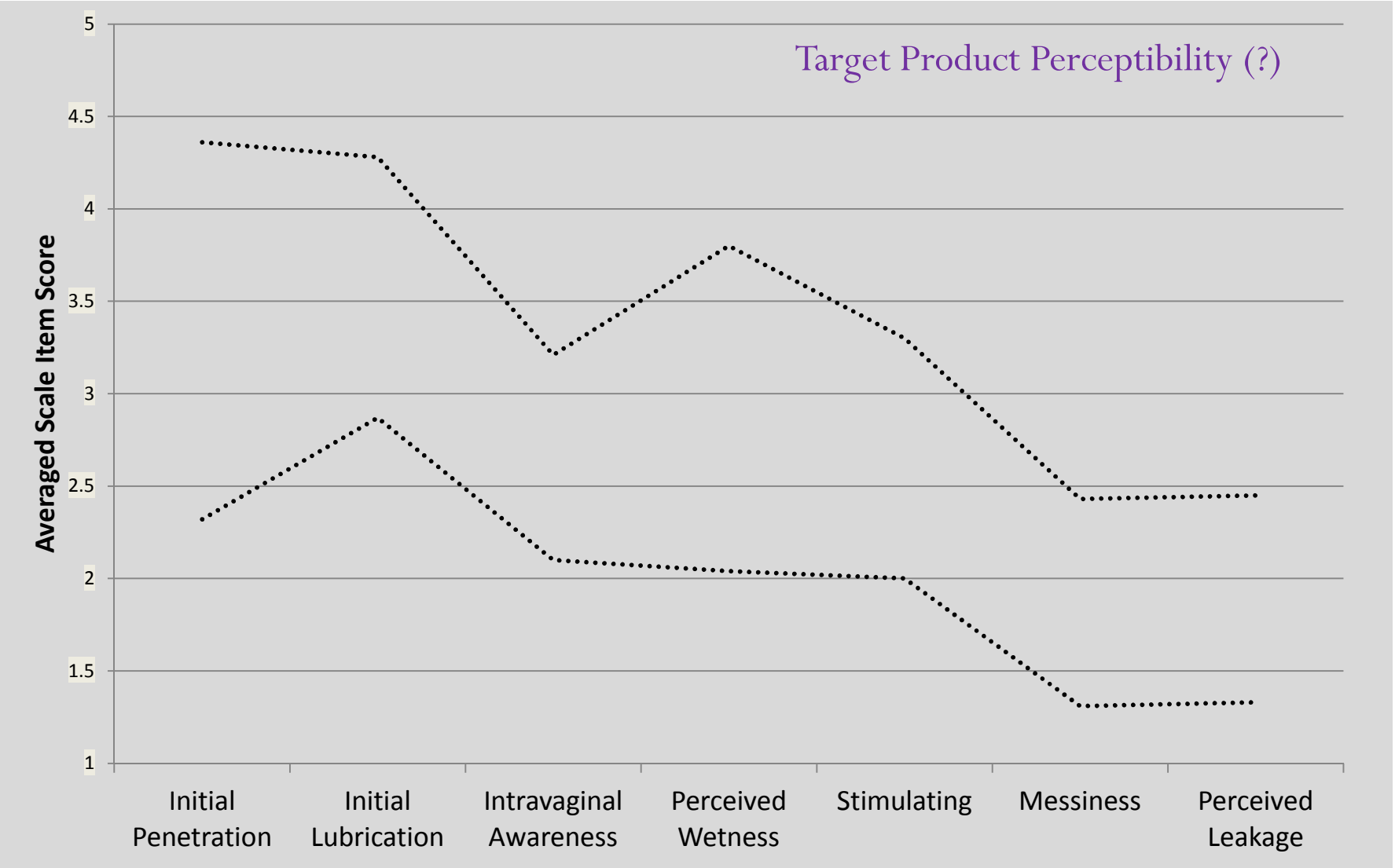
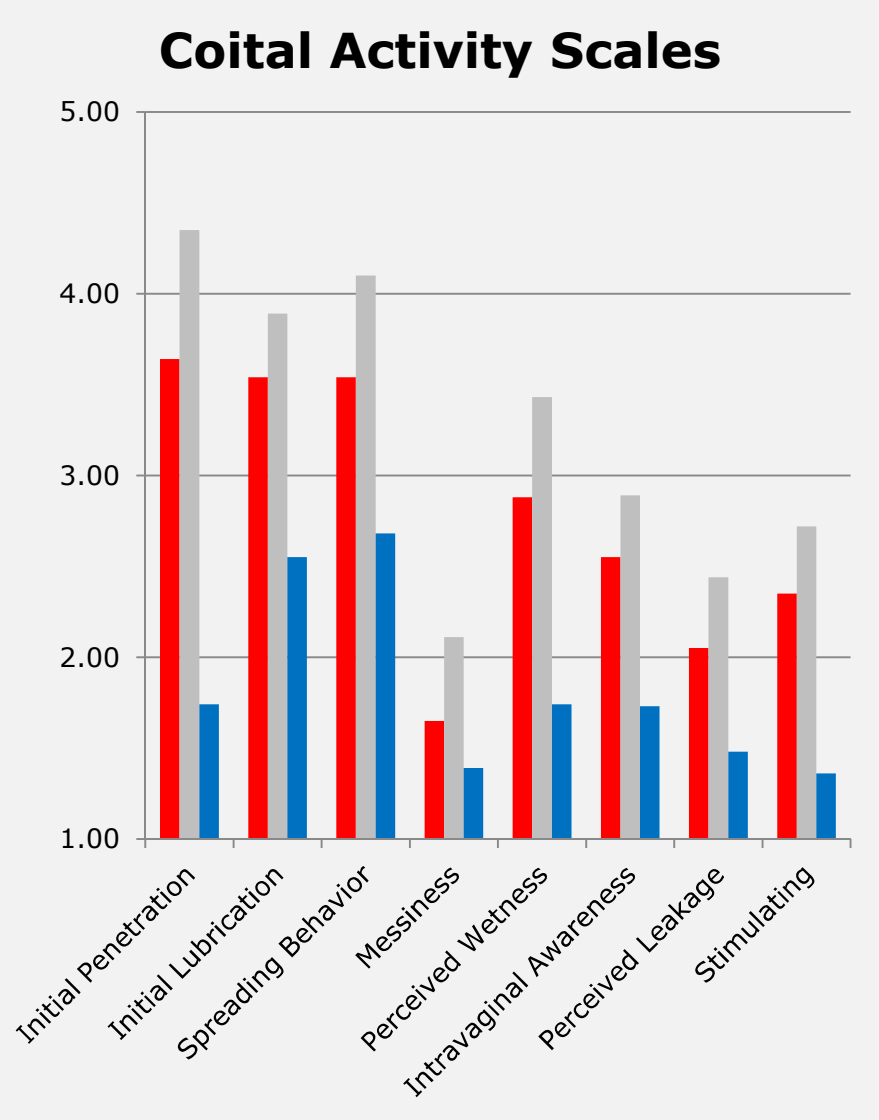
“The Sweet Spot”

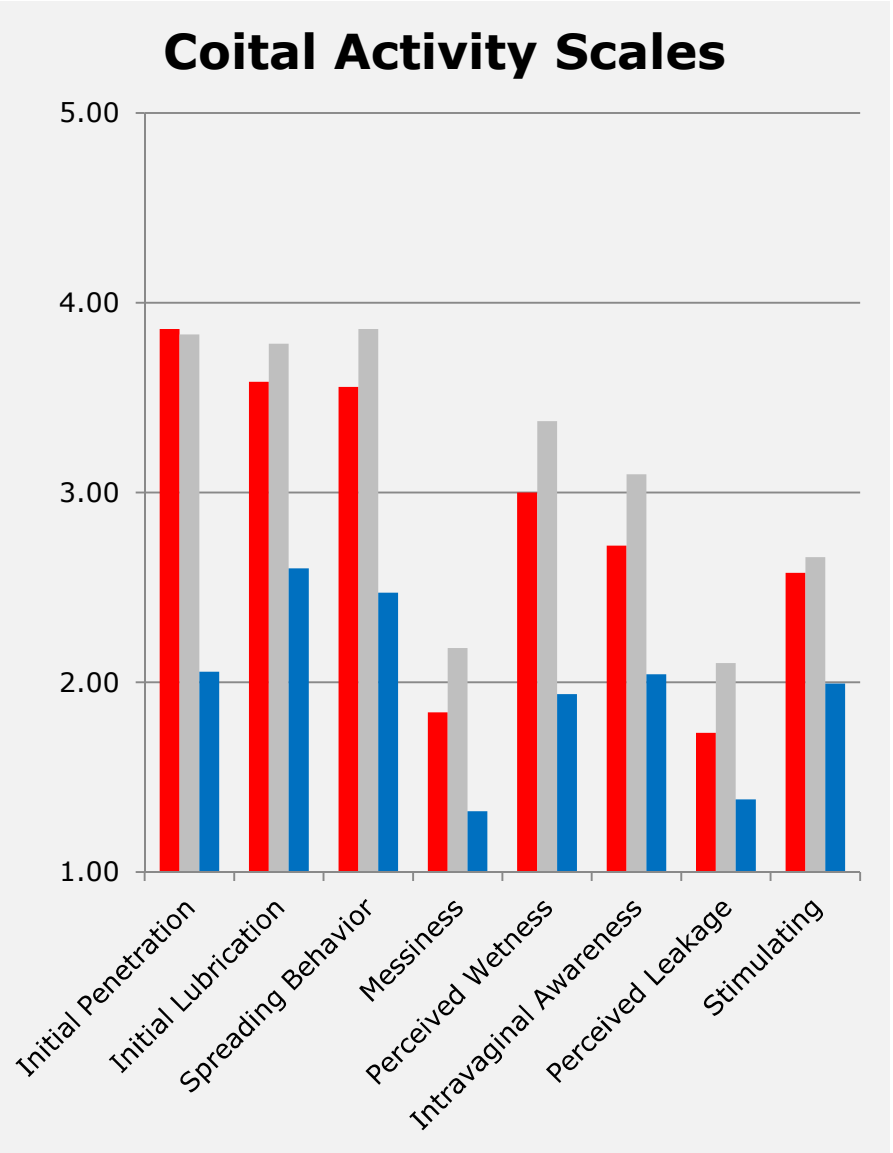


Project MIST

Female



Male



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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)

Can perceptibility science be helpful …?

- … such that new DDS balance optimization of efficacy and optimization of the user experience?
- … to the design of interventions (or educational or marketing programs) that increase uptake and use of biomedical prevention products?

- Can perceptibility science be useful in rectal prevention products, as well as vaginal prevention products? …

Project DRUM

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

- "Project 5" of U19 AI101961 (PI: Buckheit)

The Future of Perceptibility

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 that need to be tested and refined in broader circumstances, with more formulations, across larger use periods

Thank you!