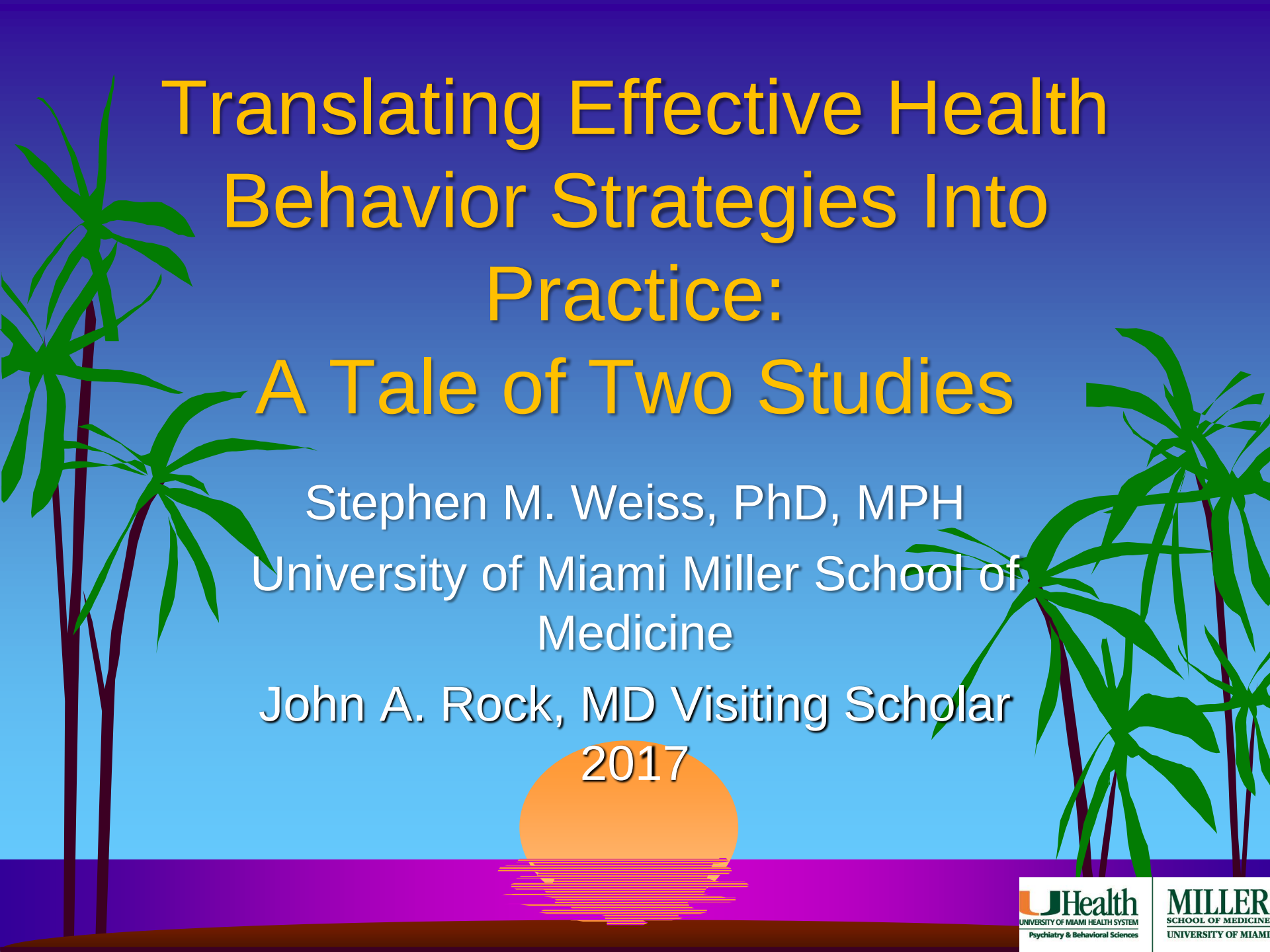
Translating Effective Health Behavior Strategies Into Practice: A Tale of Two Studies

Stephen M. Weiss, PhD, MPH

University of Miami Miller School of Medicine

John A. Rock, MD Visiting Scholar 2017



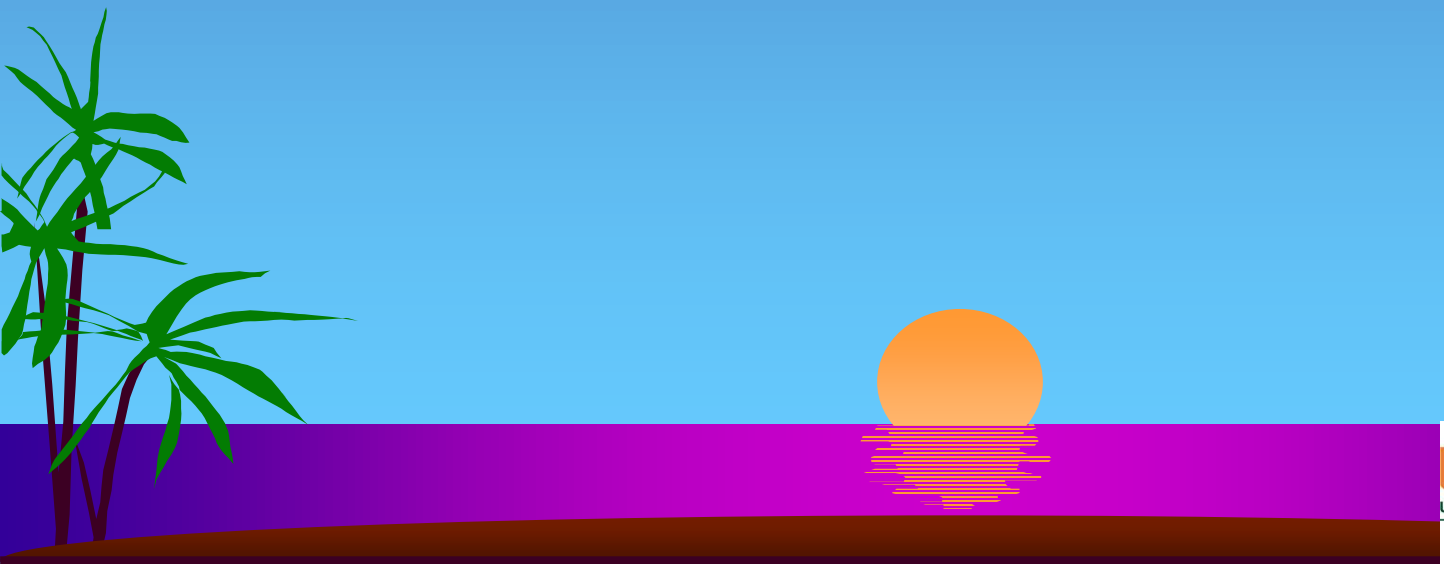
Relevance of Translational (D&I) Science

- Increasingly recognized in academia, clinical practice and health policy as a key component to determining allocation of limited health resources
- Provides a pathway for Evidence-based Interventions (EBIs) to enter the health care system
- Necessary to determine impact of interventions on population health

What is implementation science?

- Research on implementation addresses the process by which innovative, evidence-based health interventions can be tested within real-world public health and clinical service systems.
- Implementation science is the study of methods to promote the integration of evidence-based research findings into healthcare policy and practice.

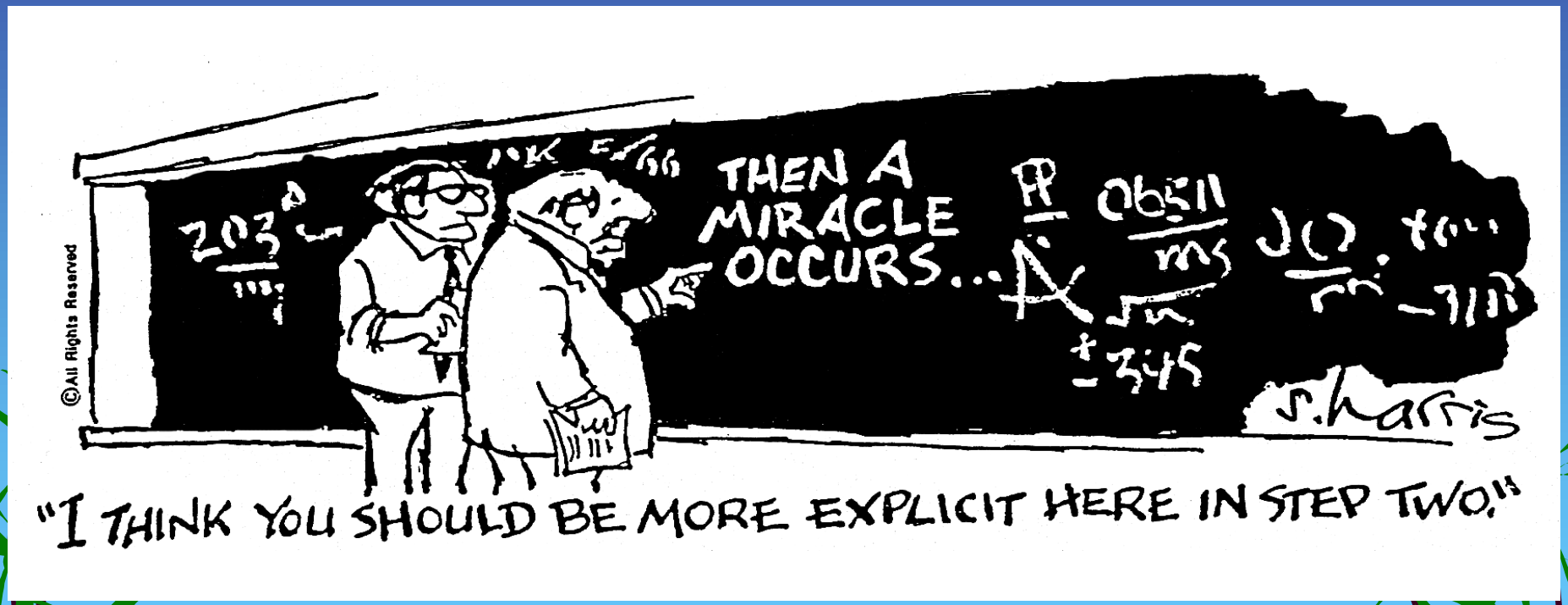
When can we consider an intervention to be "evidence-based"?



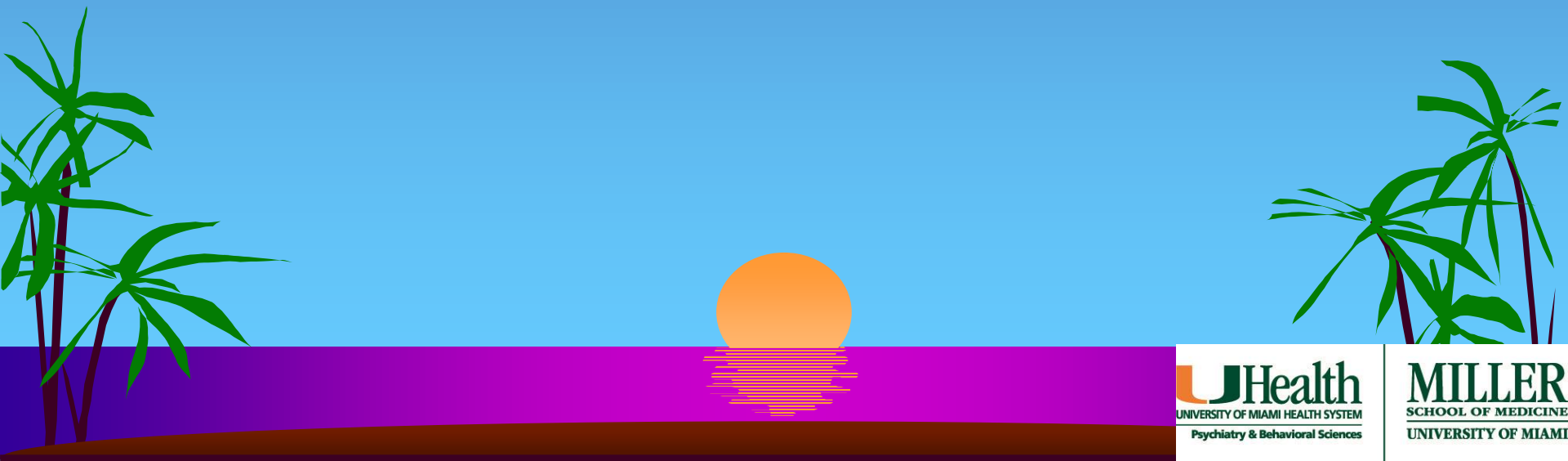
UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM
Psychiatry & Behavioral Sciences

MILLER
SCHOOL OF MEDICINE
UNIVERSITY OF MIAMI

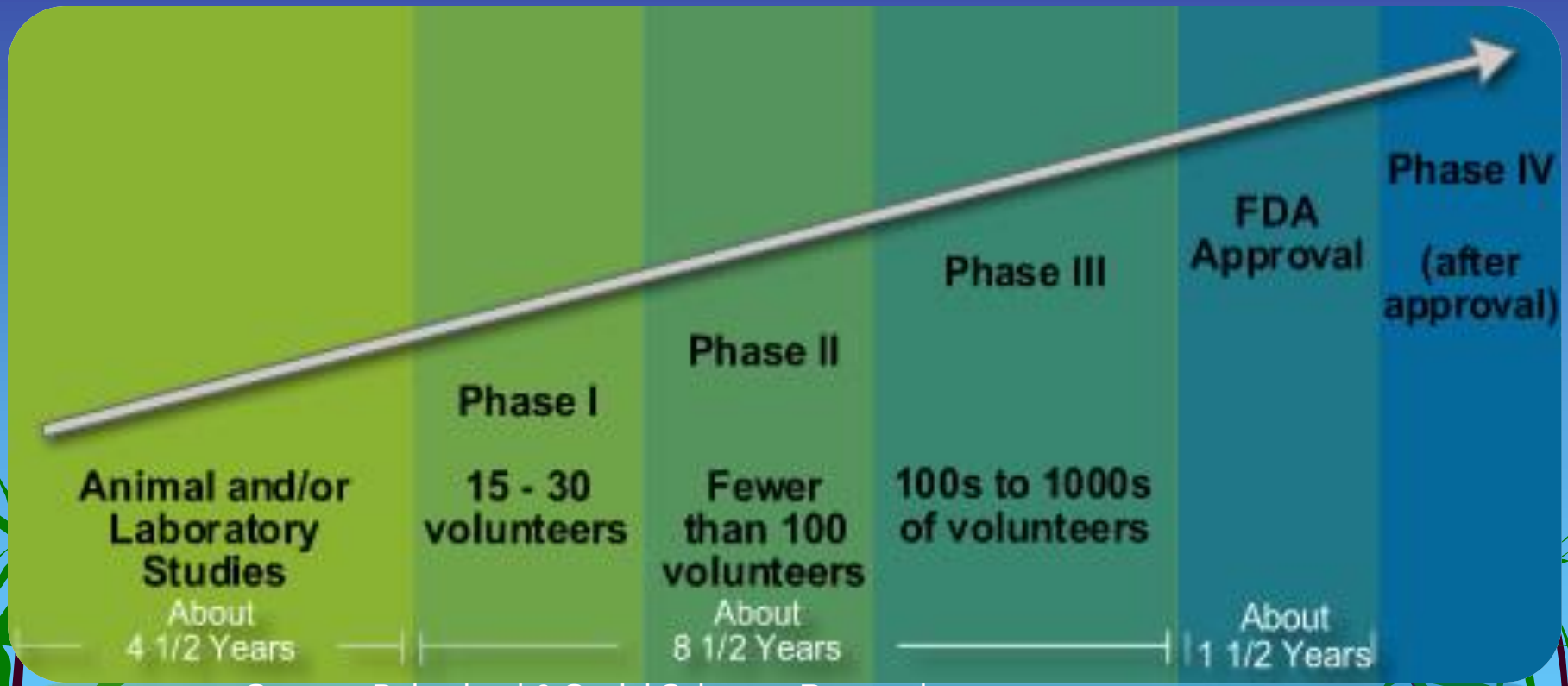
Unraveling the "Black Box"



For drugs and devices, we rely on the FDA to provide guidelines and standards for Randomized Clinical Trials (RCTs)



FDA Clinical Trial Phases



Source: Behavioral & Social Sciences Research (http://www.esourceresearch.org/)

UHealth University of Miami Health System
Psychiatry & Behavioral Sciences

MILLER School of Medicine
University of Miami

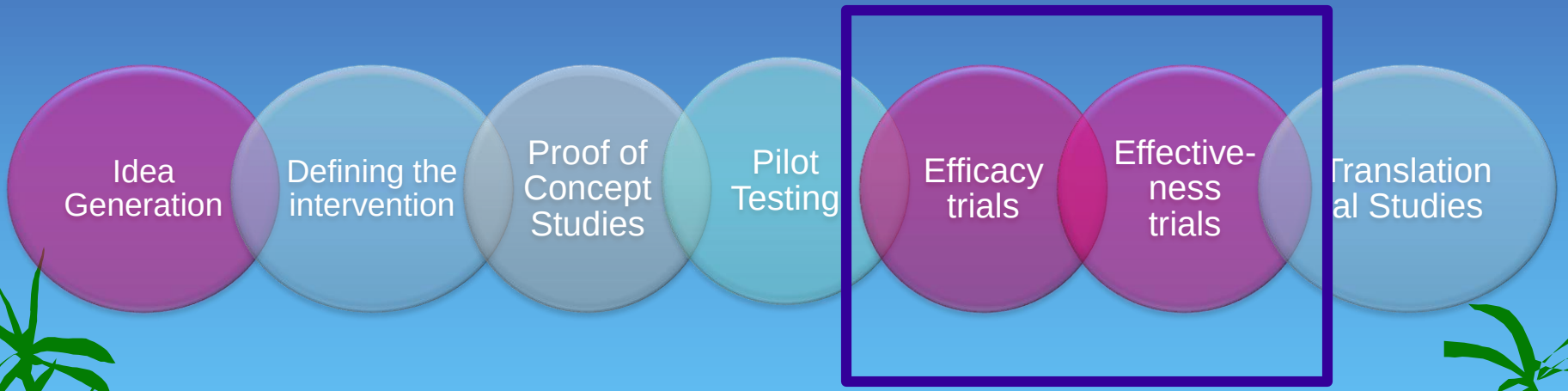
But what about the other areas of science, such as the kinds of behavioral, biobehavioral, and public health interventions we test?

How are they developed?

Sources of Interventions

- Observational studies
- Meta-analyses
- Independent scientific reviews (e.g., Cochrane Reviews, NAS)
- Peer review (NIH, CDC, AHRQ et al.)
- Scientific journals
- RCTs

Establishing an Evidence Based Intervention (EBI)



Efficacy-Effectiveness Continuum

EFFICACY	EFFECTIVENESS
• Research setting	• "Real world" settings
• "Ideal" circumstances	• Typical circumstances
• Stricter eligibility → narrow population	• Looser eligibility → more representative population
• Manualized interventions delivered by research staff	• Feasible interventions – delivered by regular staff
• High adherence	• Variable adherence
• Outcomes of physiologic or clinical interest	• Outcomes of clinical or public-health relevance
• Maximizes internal validity	• Maximizes external validity

Internal Validity & External Validity

- **Internal Validity** – can we infer a causal relationship? … "in this study, the intervention made a difference in the outcome".

- **External Validity** – are the findings applicable beyond the controlled limits of the study? "To what populations, settings, treatment variables and measurement variables can this effect be generalized?"

Campbell DT, Stanley JC. Experimental and quasi-experimental designs for Research. Chicago, IL: Rand McNally. 1966.

Establishing a Common Nomenclature

- **Dissemination** - active approach of spreading EBIs to the targeted audience via established channels using specific and planned strategies
- **Adoption-** decision of the organization or a community to commit to and initiate an evidence based intervention
- **Implementation** - use of strategies to adapt and integrate evidence-based health interventions and change practice patterns within specific settings

Establishing a Common Nomenclature

- **Sustainability (the Achilles Heel of D&I)**
  - Acceptability
    - Is EBI integrated within the chosen setting?
    - Is the EBI acceptable to the target group(s) of interest?
  - Capacity building
    - Has the D&I research group institutionalized activities (e.g., training) that enable the setting to continue to deliver the EBI after external support has been terminated?

Rabin, Brownson, Haire-Joshu, Kreuter, Weaver, 2008

So what are the potential EBIs for HIV prevention?

- Delayed sexual debut
- Reduced number of partners/ monogamy
- Correct and consistent male and female condom use
- **Voluntary male medical circumcision**
- Medication adherence
- Prophylactic antiretroviral therapy (PrEP, TxP, PMTCT)
- Treatment of sexually transmitted infections
- Future: vaccine
- Future: microbicides

Evidence Base for VMMC as an HIV Prevention Strategy

- Over 40 observational studies reviewed
- Three large RCTs were conducted in South Africa (N = 3,274), Uganda (N = 4,996) and Kenya (N = 2,784), 2002 - 2006. All three trials were stopped early due to utility at study midpoint.
- 58-73% reduction in risk of acquiring HIV

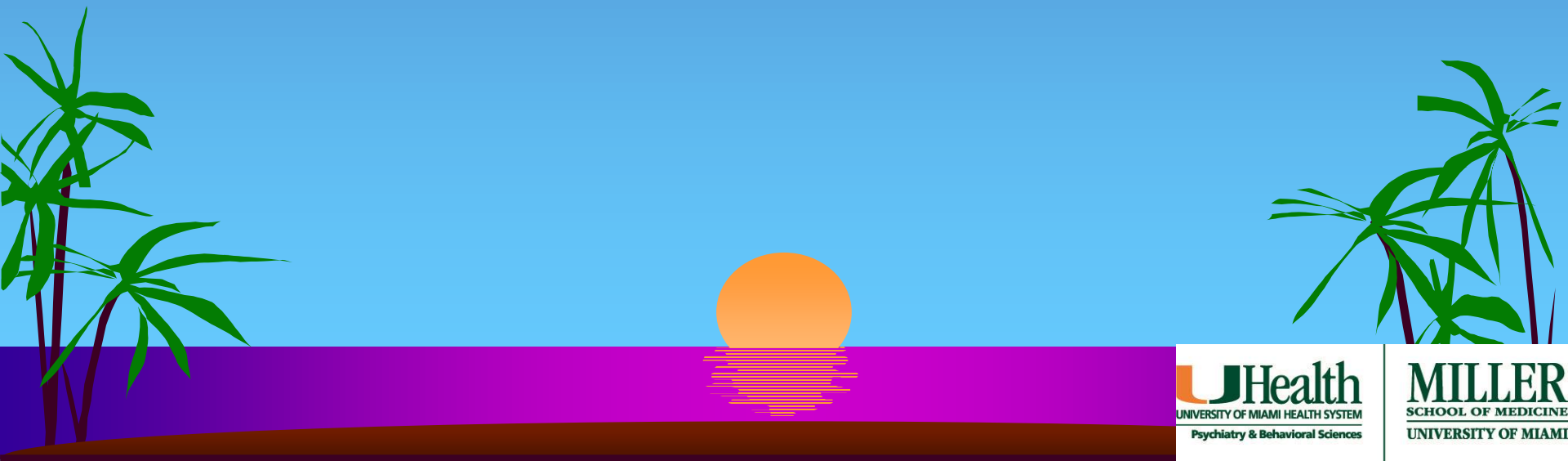
Additional benefits

- ⬇ Penile Cancer
- ⬇ HR-HPV ➡ ⬆ Cervical Cancer
- ⬇ Syphilis (and other Chancroid STDs)
- ⬇ HIV transmission to women
- ⬆ Penile Hygiene and appearance

Cost Effectiveness Analysis

- To reach 80% of goal of 20.3 million VMMCs in sub-Saharan Africa would cost US $1.52 billion
- VMMC would save US $16.5 billion by preventing 3.4 million infections through 2025 (5-6 MCs = 1 HIV infection averted)

From a health behavior perspective, what is particularly unique about this issue?



Zambia

Population

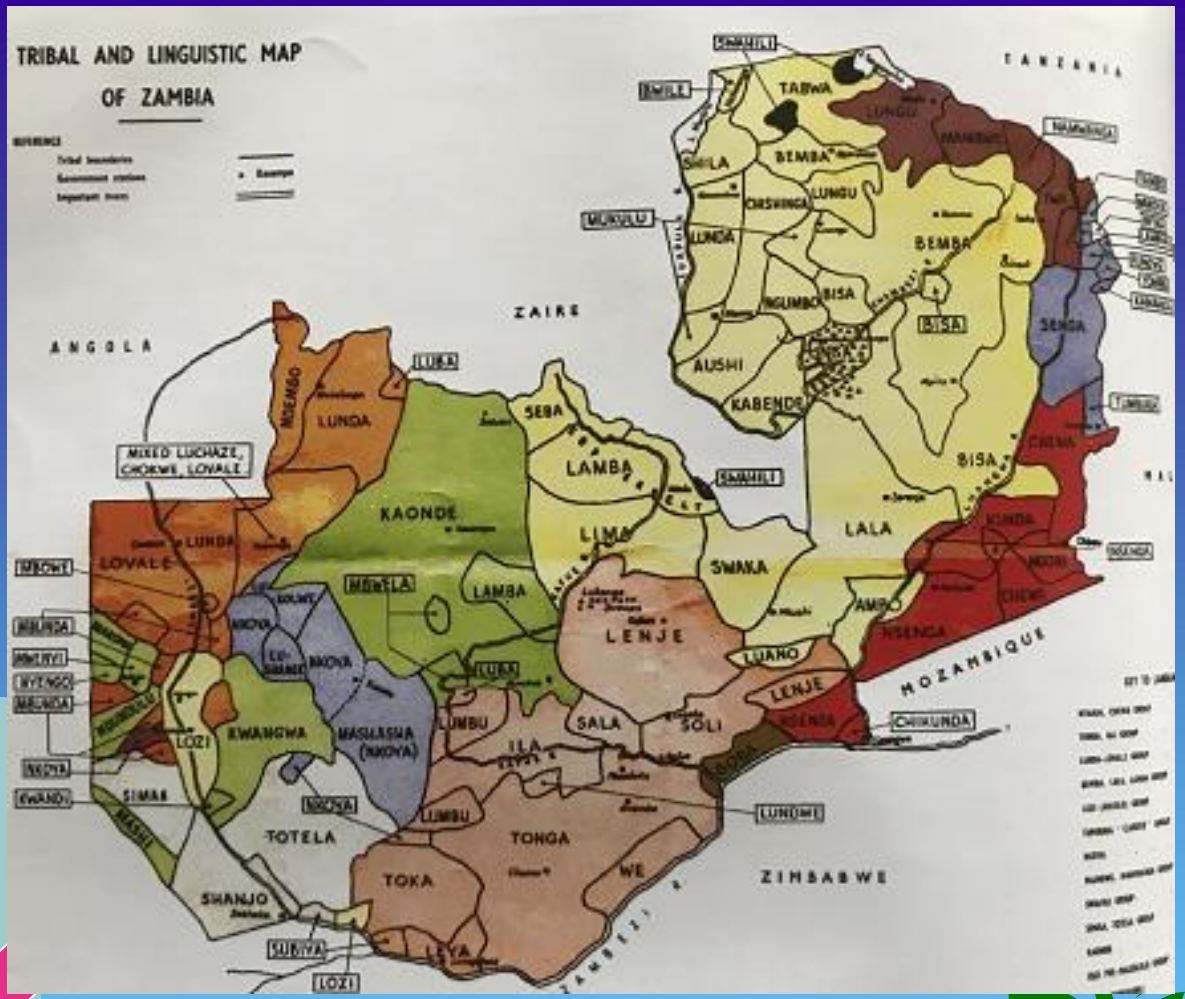
~17.4 million

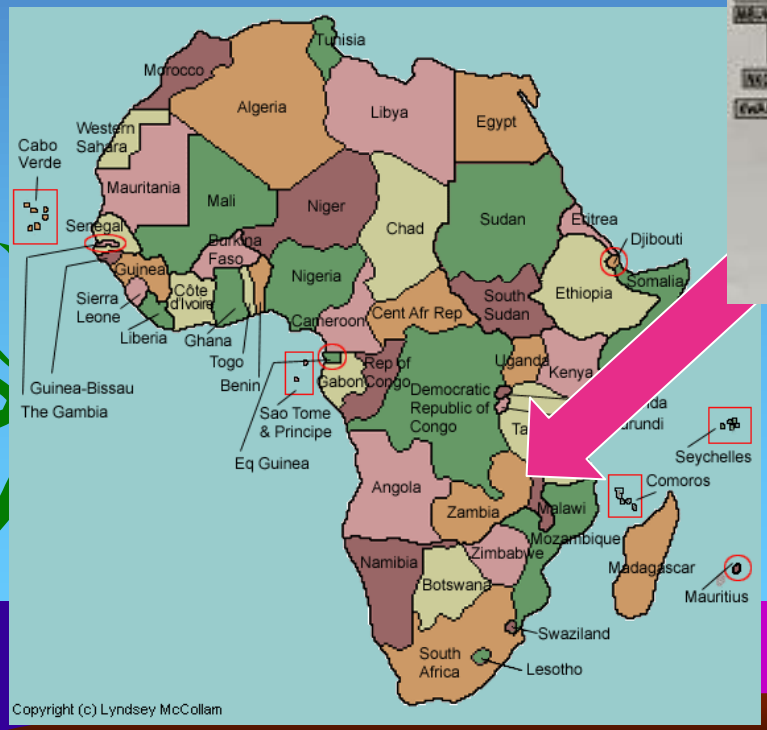
Life expectancy 1996

42 years

Life expectancy 2015

61 years





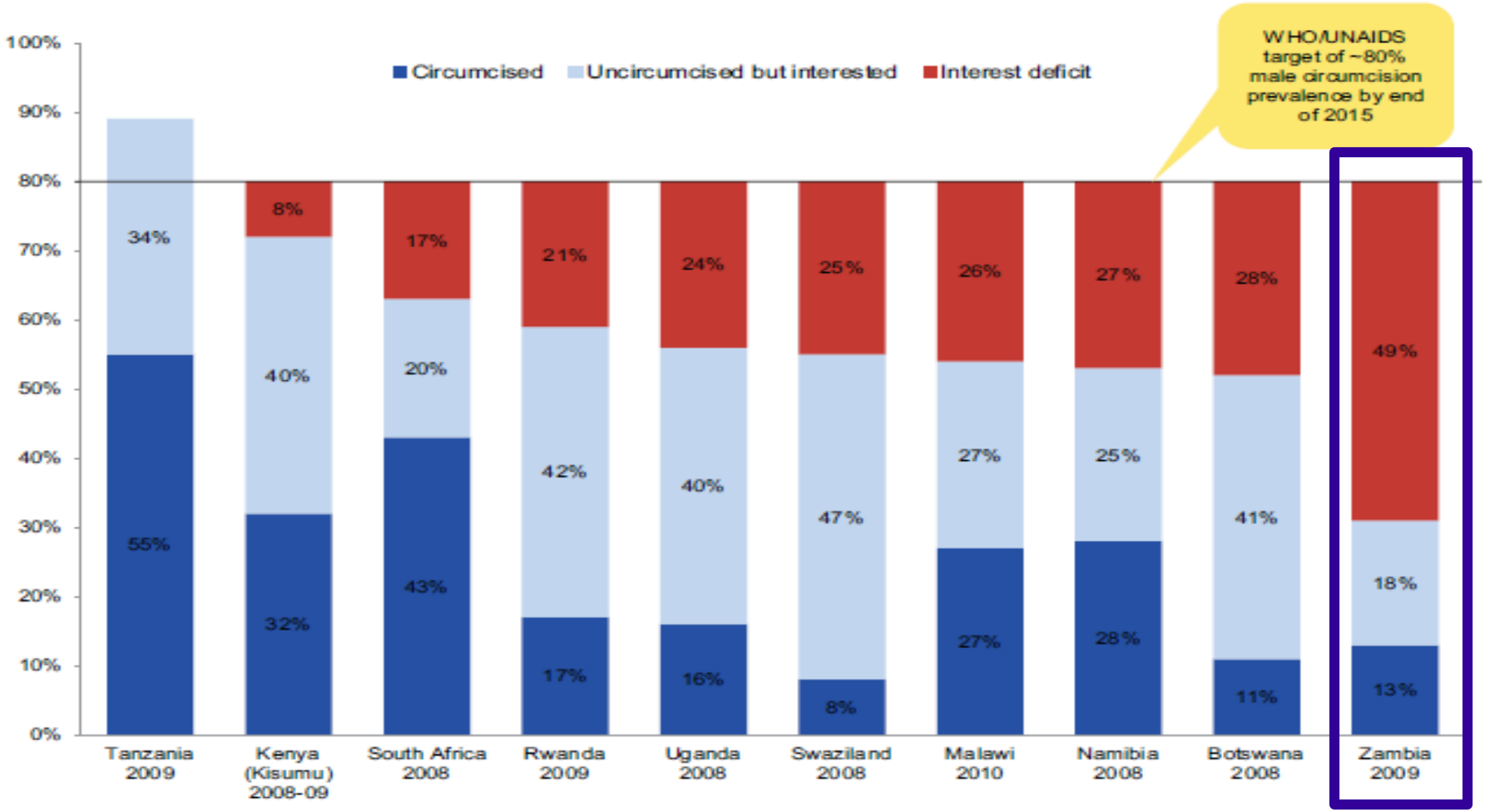
UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM
Psychiatry & Behavioral Sciences

MILLER
SCHOOL OF MEDICINE
UNIVERSITY OF MIAMI

VMMC as an HIV Prevention Strategy - GRZ

- Goal : 1.9M circumcisions by 2015 (80% of eligible men)
- 2015 status ~ 900,000 MMCs performed (<50% of goal)
- 2015 goal has been extended to 2020

FIGURE 6. The "Interest Deficit" for Voluntary Medical Male Circumcision (VMMC) in Selected VMMC Priority Countries of Eastern and Southern Africa



Data (and age range) based on country studies: Tanzania (ages 18–44),[79] Kenya (ages 15–49),[80] South Africa (ages 15–49),[81] Rwanda (ages 15–59),[82] Uganda (ages 18–80),[83] Swaziland (ages 15–29),[84] Malawi (ages 15 and older),[85] Namibia (ages 15–29),[84] Botswana (ages 15–29),[84] Zambia (ages 15–59).[86]

Country Operational Plan for the Scale-up of Voluntary Medical Male Circumcision In Zambia

"Without a focused strategy that is successful in creating demand among large numbers of males in the target age range to seek VMMC services, investments in VMMC infrastructure and human resources will not have the intended impact. As such, demand generation is not only a key priority … but will also be emphasized throughout the program, so that demand for the service remains high and targets can be met. Significant emphasis will be placed on linking service delivery with demand."

Increasing the Availability and Acceptability of Voluntary Medical Male Circumcision (VMMC) in Zambia

Stephen M Weiss PhD MPH,
Robert Zulu MD, Ndashi Chitalu MD MPH,
Deborah Jones PhD

Supported by NIH/NIMH R01MH095539 and
NIH/NIAID CFAR P30AI073961

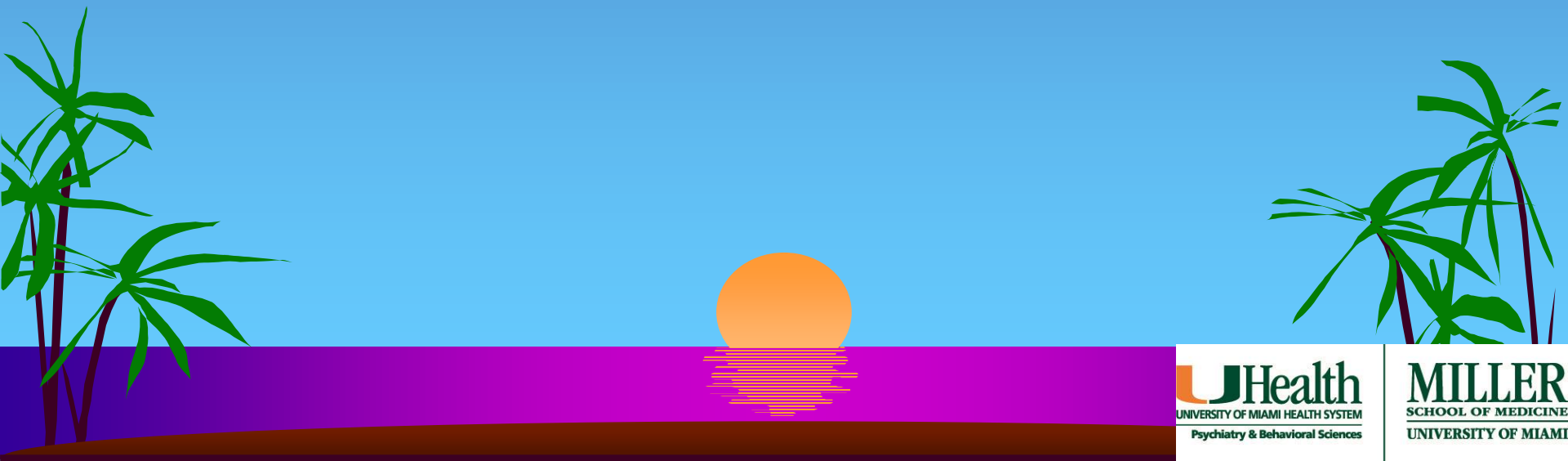
UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM
Psychiatry & Behavioral Sciences
MILLER
SCHOOL OF MEDICINE
UNIVERSITY OF MIAMI

Program Objective

- To establish a “biobehavioral” partnership between biomedical and behavioral scientists and health care providers to balance the **availability** of male circumcision services (supply) with **acceptability** (demand) of circumcision in a limited resource setting for “at risk” Zambian men and their female partners

The Challenges

- Lack of trained VMMC providers
- 70+% of adult males uncircumcised
- 80% of uncircumcised men have expressed NO interest in VMMC



Spear & Shield I

- **Specific Aim 1**: to determine if participants in the Spear & Shield comprehensive risk reduction intervention (experimental condition) will be more likely to undergo circumcision, in comparison with participants having the same VMMC services available plus usual care (attention control condition). [N.B. Observation condition: VMMC training only]

Spear & Shield I

- **Specific Aim 2**: to determine whether VMMC will significantly affect the maintenance of safer sexual practices (i.e., no “behavioral disinhibition”) in the experimental group as compared to the attention control group.

Spear & Shield I

- **Specific Aim 3:** to determine the influence of female partner preferences on the willingness of men to undergo circumcision

Design

- Sites: 13 Community Health Centers in Lusaka Province were matched (by size) and randomized to one of three conditions
  - Experimental (5)
  - Control (5)
  - Observation Only (3)
  - 3 health care providers from each CHC received VMMC training at all sites.
  - HCT staff were trained to conduct the Spear and Shield Intervention at Experimental sites

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM
Psychiatry & Behavioral Sciences

MILLER
SCHOOL OF MEDICINE
UNIVERSITY OF MIAMI

Design (cont'd)

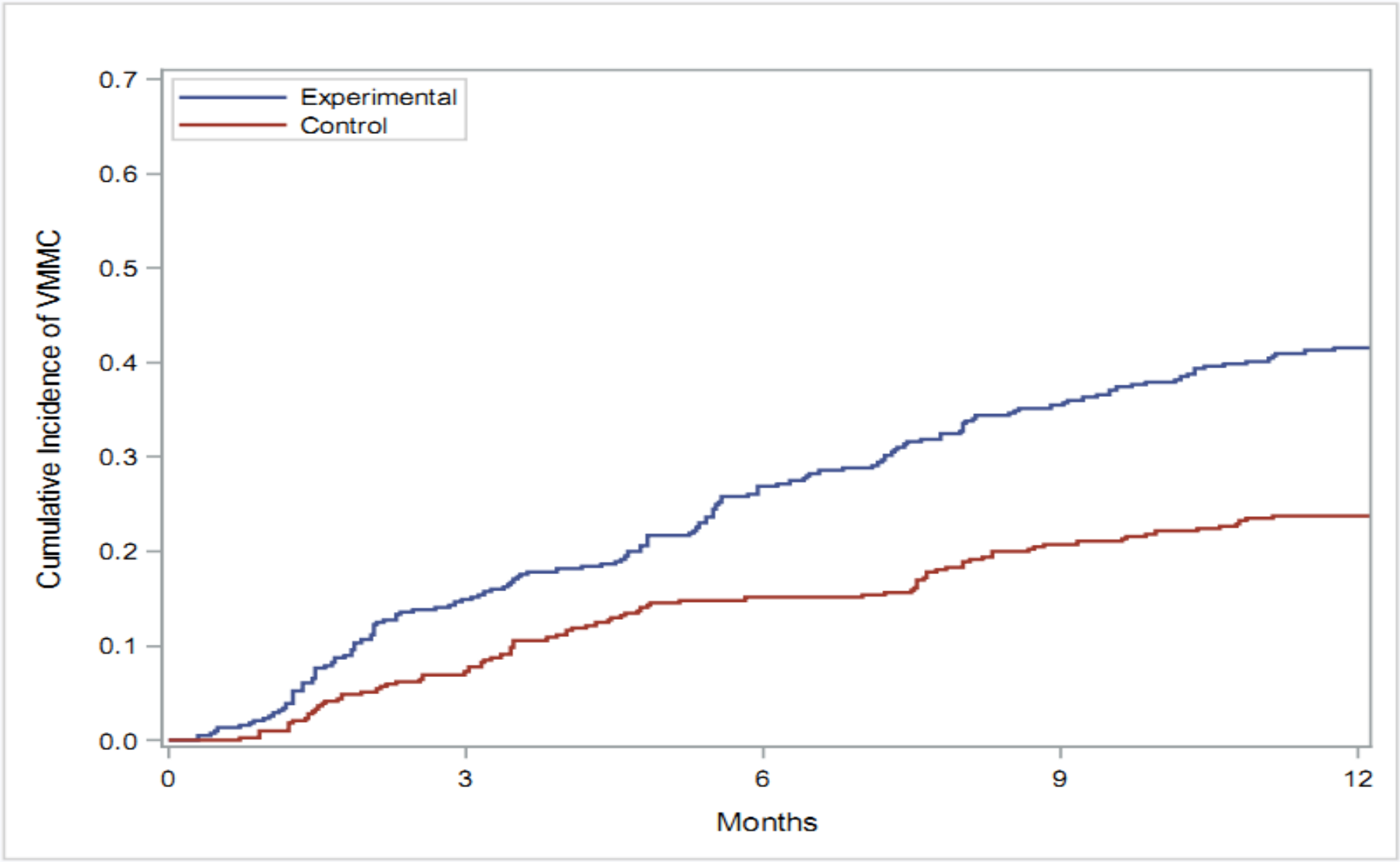
- Participant Eligibility (n=800 men)
  - Participated in HCT
  - HIV-
  - Uncircumcised
  - **No interest in undergoing circumcision**
- Female participants (n=668)
  - Primary sexual partners of study participants
  - Willing to participate in a similar group for women

Intervention

- Experimental condition
  - Four weekly 90 minute group sessions (8-10 participants per group) plus usual care
  - Topics include information about HIV/AIDS, sexual risk reduction strategies, sexual communication, PMTCT, with special emphasis on VMMC, including discussion with a post-VMMC patient, and presentation /Q & A by a VMMC provider
- Control condition
  - Time equivalent group sessions on endemic disease prevention (e.g., TB, malaria, diabetes) plus usual care

Results

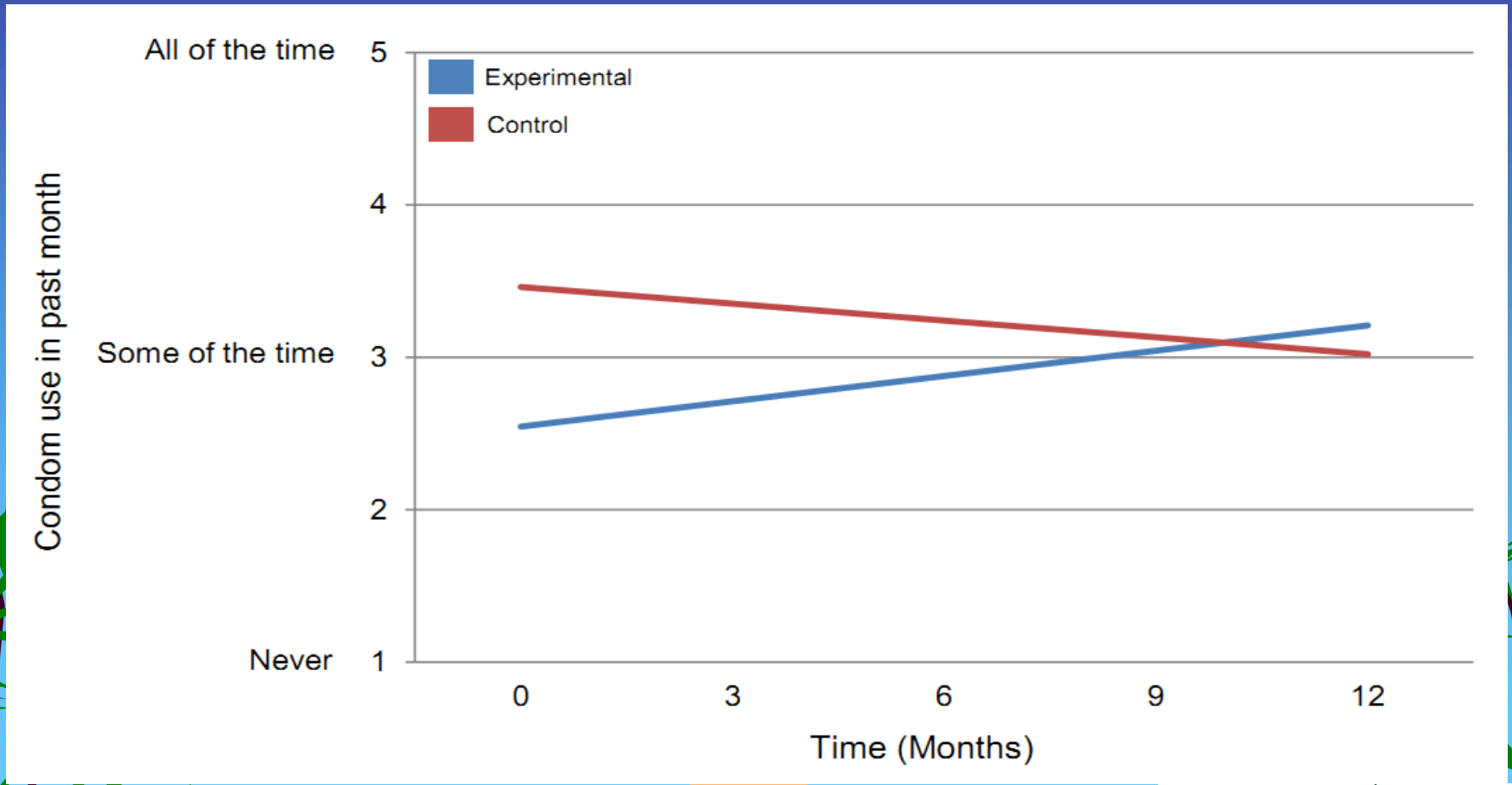
Kaplan-Meier Cumulative Incidence of VMMC



Results

No Behavioral Disinhibition

Condom use among participants undergoing VMMC



Significant pre-post increase among Experimental condition participants (p = .027), no change among Controls (p = .198)

UHealth University of Miami Health System Psychiatry & Behavioral Sciences

Miller School of Medicine University of Miami

Results
Women's Influence

Women's VMMC acceptance mediated men's readiness for VMMC…

…such that a ~6% increase in the likelihood of undergoing VMMC was attributable to increased women's acceptance following the intervention

Results
Satisfaction with VMMC

- Men rated their overall mean level of satisfaction at 8.4 (sd=2.7) (0 = not at all satisfied; 10 =extremely satisfied)
- Men (96%) and women (94%) would recommend VMMC to a friend
- 72% of men & 86% of women reported increased or unchanged sexual satisfaction
- 68% of couples agreed that sex was better or unchanged…only 8% indicated that satisfaction decreased.
- 99% of couples noted improved penile appearance and hygiene

“Spillover” effect

Total VMMC and HCT after 36 months

Clinic	VMMC	HCT	Percent undergoing VMMC
Experimental	3,543	30,430	**11.64%**
Control	3,392	42,810	**7.92%**
Observation only	801	17,848	**4.49%**

Odds Ratios:
Experimental vs. Observation only: 2.80
Control vs. Observation only: 1.83
Experimental vs. Control: 1.53
These data did not include study participants

Spear & Shield II

Based upon the successful outcomes of S&S I, this “dissemination and implementation” study is scaling up the S&S program to 96 CHCs in four Zambian Provinces with high HIV prevalence and low rates of VMMC, and will -

- train ~ 200 qualified CHC health care providers to perform VMMCs
- train ~200 CHC HCT staff to conduct the behavioral intervention

over a 5 year period (initiated in 2016)

Design

- Participants

  - Nearly 100 staff members from 24 CHCs and hospitals in each of the 4 study Provinces

- Quantitative Data
  - S&S + VMMC Program Uptake, Barriers to EBI Uptake, Practitioner Attitudes and Organizational Barriers, Clinic Burden, Burnout, Readiness for Organizational Change, Organizational Social Context
  - Variables mapped to the CFIR Matrix
- Qualitative Data
  - Semi-structured qualitative interviews
  - Transcripts coded to the CFIR Matrix

Consolidated Framework for Implementation Research (CFIR)

- The CFIR is a platform that can be used to identify areas of strength, weakness, and areas needing improvement as a continuous measure of intervention effectiveness.
- The CFIR Matrix is comprised of
  - 5 domains containing 41 constructs that influence implementation

CFIR Domains and Constructs

I. Intervention Characteristics

- A Intervention Source
- B Evidence Strength & Quality
- C Relative Advantage
- D Adaptability
- E Trialability
- F Complexity
- G Design Quality & Packaging
- H Cost

II. Outer Setting

- A Patient Needs & Resources
- B Sophistication
- C Peer Pressure
- D External Policy & Incentives

III. Inner Setting

- A Structural Characteristics
- B Networks & Communications
- C Culture
- D Implementation Climate
  - 1 Tension for Change
  - 2 Compatibility
  - 3 Relative Priority
  - 4 Organizational Incentives & Rewards
  - 5 Goals and Feedback
  - 6 Learning Climate
- E Readiness for Implementation
  - 1 Leadership Engagement
  - 2 Available Resources
  - 3 Access to Knowledge & Information

IV. Characteristics of Individuals

- A Knowledge & Beliefs about the Intervention
- B Self-efficacy
- C Individual Stage of Change
- D Individual Identification with Organization
- E Other Personal Attributes

V. Process

- A Planning
- B Engaging
  - 1 Opinion Leaders
  - 2 Internal Leaders
  - 3 Champions
  - 4 External Change Agents
  - 5 Key Stakeholders
  - 6 Innovation Participants
- C Executing
- D Reflecting & Evaluating

Interim Data Analyses

- Interim data analyses examined the organizational, logistic, managerial, interpersonal and structural variables, comparing more successful with less successful CHC S&S Program implementers.
- Findings guide S&S implementation strategies and strengthening less successful S&S sites to improve performance and enhance program sustainability

Health Facility S&S by Intervention Uptake

Male and female session contacts by health facility

Clinic	Group 1		Group 2		Group 3		Group 4		Group 5		Total M/F					
	M	F	M	F	M	F	M	F	M	F	M	F	Total	% M	% F	Rank
Kafue Est	38	27	34	44	29	29	25	29	30	42	156	171	327	48%	52%	1
Kalingalinga	21	42	29	32	28	34	36	32	26	23	140	163	303	46%	54%	2
Kanyama	33	30	26	34	27	37	48	38	0	0	134	139	273	49%	51%	3
Matero Ref	35	29	30	25	33	33	26	28	0	0	124	115	239	52%	48%	4
Chaisa	29	34	23	35	27	37	0	41	0	0	79	147	226	35%	65%	5
Kafue Hosp	20	26	29	32	29	44	0	31	0	0	78	133	211	37%	63%	6
Chipata	19	20	23	41	24	26	23	28	0	0	89	115	204	44%	56%	7
Ngombe	25	19	26	32	28	26	0	24	0	13	79	114	193	41%	59%	8
Chilenje	28	28	25	34	20	26	0	0	0	0	73	88	161	45%	55%	9
Chainda	27	33	13	40	0	32	0	0	0	0	40	105	145	28%	72%	10
Chazanga	31	35	29	27	0	9	0	0	0	0	60	71	131	46%	54%	11
UNZA	32	17	37	27	0	0	0	0	0	0	69	44	113	61%	39%	12

Session contacts were ranked as “bottom 4” vs. “top 4” performers.

Results – Clinic Staff

Comparison of Most vs. Least Successful Clinics

	All (n = 32)	Bottom 4 (n = 16)	Top 4 (n = 16)	p
Time at Facility				0.723
Less than 5 years	15(46.9%)	8(50.0%)	7(43.8%)	
More than 5 years	17(53.1%)	8(50.0%)	9(56.3%)	
Job Title				0.154
Sister in Charge or Professional Nurse	18(56.3%)	7(43.8%)	11(68.8%)	
Assistant nurse, lay health worker, counselor	14(43.8%)	9(56.3%)	5(31.3%)	
Time in Position				0.446
Less than 5 years	10(31.3%)	6(37.5%)	4(25.0%)	
More than 5 years	22(68.8%)	10(62.5%)	12(75.0%)	
Gender				0.710
Male	11(34.4%)	6(37.5%)	5(31.3%)	
Female	21(65.6%)	10(62.5%)	11(68.8%)	
Age	37.66(7.51)	37.38(8.41)	37.38(6.75)	0.836
Education				0.144
Up to grade 12	2(6.3%)	2(12.5%)	0(0.0%)	
Diploma, certificate, masters, doctorate	30(93.8%)	14(87.5%)	16(100.0%)	
Income				0.088
0 to 3400	11(34.4%)	4(25.0%)	7(43.8%)	
3401 to 5000	16(50.0%)	11(68.8%)	5(31.3%)	
More than 5000	5(15.6%)	1(6.3%)	4(25.0%)	

Results - Inner Setting

	All Mean	Bottom 4 Mean (n = 13)	Top 4 Mean (n = 14)	p
Inner Setting (all constructs combined)	2.704	3.077	2.357	0.735
Structural Characteristics	-0.111	-0.154	-0.071	0.915
Networks & Communications	1.630	1.692	1.571	0.902
Culture	0.148	0.077	0.214	0.345
Implementation Climate	0.111	0.462	-0.214	*0.087*
Tension for Change	0.074	0.000	0.143	0.335
Compatibility	0.333	0.077	0.571	0.076
Relative Priority	0.185	0.077	0.286	0.705
Organizational Incentives & Rewards	0.000	0.154	-0.143	0.269
Goals and Feedback	1.000	0.846	1.143	0.111
Learning Climate	0.259	0.154	0.357	0.209
Readiness for Implementation	0.185	0.231	0.143	0.973
Leadership Engagement	0.296	0.308	0.286	0.569
Available Resources	-1.667	-1.000	-2.286	0.222
Access to Knowledge & Information	1.037	1.077	1.000	0.604

Results – Outer Setting

	All Mean	Bottom 4 Mean (n = 13)	Top 4 Mean (n = 14)	p
Outer Setting (all constructs combined)	0.556	0.308	0.786	0.507
Patient Needs & Resources	0.000	0.077	-0.071	0.547
Cosmopolitanism	0.370	0.308	0.429	0.693
Peer Pressure	0.000	0.000	0.000	1.000
External Policy & Incentives	-0.111	-0.077	-0.143	0.484

Results - Intervention

	All Mean	Bottom 4 Mean (n = 13)	Top 4 Mean (n = 14)	p
Intervention Characteristics (all constructs combined)	1.519	1.385	1.643	0.807
Intervention Source	0.074	0.154	0.000	0.299
Evidence Strength & Quality	0.593	0.615	0.571	0.841
Relative Advantage	0.222	0.231	0.214	0.641
Adaptability	0.333	0.385	0.286	0.705
Trialability	0.037	0.077	0.000	0.299
Complexity	0.000	0.000	0.000	1.000
Design Quality & Packaging	0.074	0.000	0.143	0.335
Cost	-0.111	0.000	-0.214	0.563

Results -Individuals

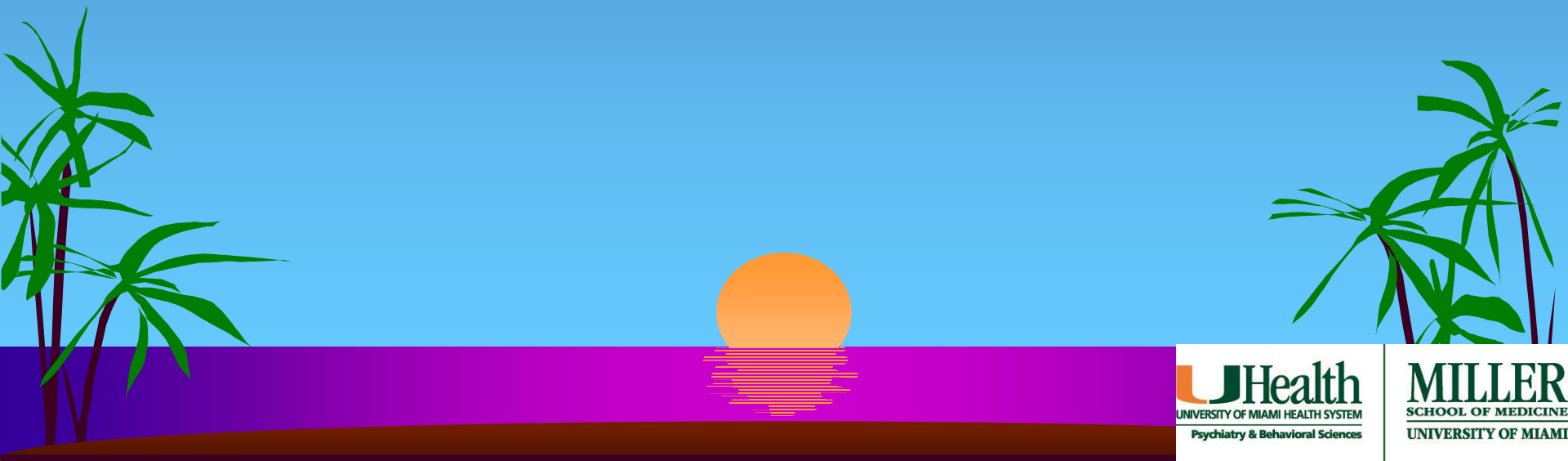
	All Mean	Bottom 4 Mean (n = 13)	Top 4 Mean (n = 14)	*p*
Characteristics of Individuals (all constructs combined)	2.259	2.615	1.929	0.395
Knowledge & Beliefs about the Intervention	0.556	0.769	0.357	0.674
Self-efficacy	0.148	0.308	0.000	0.132
Individual Stage of Change	0.370	0.231	0.500	0.705
Individual Identification with Organization	0.519	0.154	0.857	**0.020**
Other Personal Attributes	0.259	0.154	0.357	0.563

Results – Project Staff

	All (n = 32)	Bottom 4 (n = 16)	Top 4 (n = 16)	p
Staff				**0.005**
Staff Member 1 (Matero Ref, Kalingalinga)	8(25.0%)	0(0.0%)	8(50.0%)	
Staff Member 2 (Chainda, Chazanga, Kafue Estates)	12(37.5%)	**8(50.0%)**	**4(25.0%)**	
Other Staff (Kanyama, UNZA)	12(37.5%)	8(50.0%)	4(25.0%)	
Staff Member 2 vs Staff Member 1				**< 0.001**
Staff Member 2 (Chainda, Chazanga)	12(60.0%)	8(100.0%)	4(33.3%)	
Staff Member 1 (Kalingalinga, Matero Ref)	8(40.0%)	0(0.0%)	8(66.7%)	
Staff				0.144
Other Clinics + Staff Member 1	20(62.5%)	8(50.0%)	12(75.0%)	
Staff Member 2	12(37.5%)	8(50.0%)	4(25.0%)	

Principal Finding

- Poor project staff performance was associated with poor health facility performance.



Study Implications

- Findings from Spear & Shield I indicate
  - *Successful dissemination and implementation of the Spear and Shield II Program could increase the numbers of men undergoing VMMC by a factor of 2.5 to 8.5, making a substantive contribution to the GRZ national circumcision/HIV prevention objectives.*