Prescription Drug Abuse: It's Not What the Doctor Ordered

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13th RCMI International Symposium on Health Disparities
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Acting Deputy Director
National Institute on Drug Abuse

Prescription drugs used non-medically are the second most commonly used drug among current users of an illicit drug in 2011

<table>
<thead>
<tr>
<th>Drug</th>
<th>Number of Past Month Users, Aged 12 or Older (Million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Illicit Drug</td>
<td>22.5</td>
</tr>
<tr>
<td>Marijuana</td>
<td>18.1</td>
</tr>
<tr>
<td>Psychotherapeutics*</td>
<td>6.1</td>
</tr>
<tr>
<td>Cocaine (incl. Crack)</td>
<td>1.4</td>
</tr>
<tr>
<td>Crack</td>
<td>0.4</td>
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<tr>
<td>Inhalants</td>
<td>0.4</td>
</tr>
<tr>
<td>Inhalant</td>
<td>0.5</td>
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<tr>
<td>Methamphetamine</td>
<td>0.4</td>
</tr>
<tr>
<td>Heroin</td>
<td>0.3</td>
</tr>
<tr>
<td>LSD</td>
<td>0.2</td>
</tr>
</tbody>
</table>

*Nonmedical use

Source: SAMHSA, 2011 National Survey on Drug Use and Health (September 2012).
Past Month Use For Illicit Drugs, Non-medical Use of Psychotherapeutics, Non-medical Use of Pain Relievers, and Cigarettes Among Ethnic Groups (Persons 18 Or Older)

Source: SAMHSA, Center for Behavioral Health Statistics and Quality (formerly the Office of Applied Studies), National Survey on Drug Use and Health, 2008, 2009 and 2010

Current Non-Medical Use of Prescription Drugs By Age Group, 2002 – 2011

Note: Percentages for filled symbols are significantly higher compared to 2011.

New Users in the Past Year of Specific Illicit Drugs Among Persons Aged 12 or Older, 2011

Note: The specific drug refers to the drug that was used for the first time in the past year, regardless of whether it was the first drug ever used or not.

Source: SAMHSA, 2011 National Survey on Drug Use and Health (September 2012).

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Pain Relievers Account for the Largest Portion of Non-medical Use of Prescription Drugs

Past Month Users, Ages 12 or Older (Thousands)

- Pain Relievers: 6,119
- Sedatives: 231
- Stimulants: 571
- Tranquilizers: 1,292

In 2011, 73% of current non-medical use of prescription drugs involved pain relievers.

Number of Opioid Prescriptions Dispensed by U.S. Retail Pharmacies, Years 1991-2011

- Opioids: 1991-2011
- Oxycodone: 1991-2011

IMS’s Source Prescription Audit (SPA) & Vector One®: National (VONA)

Maternal Opiate Use and Neonatal Abstinence Syndrome (NAS)

Stimulant Prescription Drugs
Medical & Ethical Consideration of Prescription Stimulants as Cognitive Enhancers: Some of the Issues

- What tasks are these good for and what tasks are they not good for?
- May elicit harms to children not apparent in adults (e.g., reduced growth rate)
- The potential for abuse/addiction particularly if snorted or smoked
- Drug–drug interactions; the presence of contraindications may grow
- Concerns of people being coerced (e.g., shift workers, incentive for best performers)
- Greater inequality, if access is dependent on wealth or SES
- "Quick fix;" may ignore weaknesses in education (e.g., large class size, limited resources)

Adapted from Sahakian BJ, Morein-Zamir S. J Psychopharmacol. 2011

Why Do People Abuse Prescription Drugs?

These prescription drugs, like other drugs of abuse (cocaine, opioids, marijuana) raise brain dopamine levels

Dopamine Neurotransmission

BUT dopamine is also elevated by natural reinforcers
Illicit & Prescription Psychostimulant Drugs

Stimulants

Example: Ritalin

How They Work...
Enhance brain activity by increasing the activity of brain excitatory chemical messengers, such as norepinephrine and dopamine, leading to mental stimulation

Stimulants Are Generally Prescribed For:
- ADHD
- Narcolepsy
- Depression that does not respond to other treatments
- Asthma that does not respond to other treatment

Opioids

Examples: OxyContin, Vicodin

How They Work...
Attach to opioid receptors in the brain and spinal cord, blocking the transmission of pain messages but also cause an increase in the activity of dopamine

Opioids are Generally Prescribed for:
- Postsurgical pain relief
- Management of acute or chronic pain
- Relief of cough and diarrhea
When Used Therapeutically Drugs are Given Orally which Results in Slow Brain Uptake When Abused Drugs are Snorted or Injected which Results in Fast Brain Uptake

Pharmacokinetics in Human Brain

What is the Difference Between Therapeutic Use and Abuse?

- Dose and Frequency of Dosing
  - Lower, fixed regimes vs higher, escalating use
- Route of Administration
  - Oral vs injection, smoking, snorting
- Expectation of Drug Effects
  - Expectation of clinical benefits vs euphoria “high”
- Context of Administration
  - School, clinic, home vs bar, discotheque
- Perceived Risk
  - A medication’s “perceived risk” can be low leading to abuse

Cocaine clears quickly from the brain which can account for binge pattern of abuse

Lower, fixed regimes vs higher, escalating use
Oral vs injection, smoking, snorting
Expectation of clinical benefits vs euphoria “high”
School, clinic, home vs bar, discotheque
A medication’s “perceived risk” can be low leading to abuse
Treatment for Prescription Medication Abuse

Four-Fold Substance Use Disorder TX Admissions
Pain Relievers: 1998-2008

Source: SAMHSA Treatment Episode Data Set (TEDS), 1998 and 2008.

Buprenorphine for the Treatment of Addiction to Opioid Medication

Subutex® -- Monotherapy product
Suboxone® -- Buprenorphine/Naloxone

- Related to morphine (partial agonist)
- Uses same receptors as morphine but does not produce the same high
- Can be abused, but combining with naloxone decreases abuse potential
- Long-lasting, less likely to cause respiratory depression
In 2007 an estimated 22.3 million Americans were dependent on or abused any illicit drugs or alcohol. But... only 3.9 million (17%) of these individuals had received some type of treatment in the past year. Although treatments for addiction are available, they are not being widely used by those who need them. But... only 3.9 million (17%) of these individuals had received some type of treatment in the past year. Although treatments for addiction are available, they are not being widely used by those who need them. But... only 3.9 million (17%) of these individuals had received some type of treatment in the past year. Although treatments for addiction are available, they are not being widely used by those who need them.

Race/Ethnicity of Patients Receiving Substance Abuse Treatment in US (2010)

All Substance Abuse Admissions By Patient Gender, Age And Race/Ethnicity (2010)
How to Minimize the Diversion and Abuse of Prescription Medications

Engage the Healthcare System

Prevention Strategies – Training & Education

- Enhance clinical training for physicians, nurses, dentists and pharmacists in the areas of pain management, opioid pharmacology and abuse and addiction

  NIH Pain Consortium
  Centers of Excellence in Pain Education

- In 2012, NIH selected 12 Centers of Excellence in Pain Education (CoEPes), which will act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing and pharmacy schools.
Prevention Strategies – Public Education

- Increase patient, lay public, and policy makers’ awareness of the potential risks for abuse inherent in all opioid analgesics

Need for New Medications

- Develop medications with lower abuse potential including drugs that don’t cross BBB (i.e., CbR2 agonist)
- Develop slow release formulations (low dose and long duration) including depot formulations
- Develop novel formulations to reduce abuse liability including mixture formulations (e.g., naloxone and buprenorphine)
Take Back Programs

DEA Model
- Take-Back Days
  - Working with State, Local, and Tribal Law Enforcement Partners
  - Over 5,000 drop off locations 2-3 times a year
  - September 2012
    - 488,395 pounds (244 tons) of prescription medications collected from public
  - DEA's previous four Take-Back events, over 2 million pounds (1,018 tons) of prescription medications were removed from circulation

Prescription Drug Monitoring Programs

- Statewide electronic database collects data on substances dispensed in the state.
- Through the database, physicians and pharmacies can identify patients who are seeking multiple prescriptions.
- As of the summer of 2010, 34 states had operational programs.
Interactive Videoconferencing for Outreach and Disease Prevention

Robert Dottin1, Julianne Imperato-McGinley2, Don Tobias4, Carlos Lijeron5, Raúl Morales1, Jeff Zhu2, Karen Pierre3 and Ulrich Rauch3

Hunter College, CUNY
Weill Cornell Medical College
University of Trinidad and Tobago
Cornell University Cooperative Extension

A Novel e-Platform for Community Health by Interactive Multipoint VideoConferencing

Physicians, Nutritionists, Psychiatrists

Hunter College, Manhattan, NY
Brooklyn, NY
Hardware Codecs
Unconnected: Clinics, Doctors offices, DVD, TV

Connected: Faith based groups, Community groups

*Christakis, N. and Fowler, : Connected: The Surprising Power of Social Networks

Format for Videoconferencing

- Workshops with community health Professionals or other experts
- Short informal presentations
- Questions and Answers
- Audience participation from disparate locations

The Obesity Epidemic

- 66% of Americans are overweight or obese
- From 1990 to 2000, the percentage of obese people in the LISA increased from 21% to 33%

Green Node: normal
Yellow Node: obese (size of circle is proportional to BMI)

1975
1995
Objective: to provide evidence-based health information through interactive videoconferencing workshops with experts and disparate communities.

Aim: To promote spreading (contagion) of lessons learned within communities.

Long term goal: To prevent illness, to save lives and money.

Contagion of Influence

Three Month Follow-up Survey of 100 New York City Churches

- 91% recall the event
- 59% passed information to friends
- 40% made lasting lifestyle changes.
- 29% of those have made lifestyle changes, indicating spreading.

Impact

Contagion

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H3Africa: Human Heredity and Health
NIH & Wellcome Trust Funded Genomics and Health Project

Interactive Videoconferencing for H3Africa Projects

Thank You
Disproportionate representation of African-American children in the child welfare system is well documented. “Racial disproportionality” refers to the disproportionate number of African-American children in the child welfare system relative to their presence in the overall child population.
In 2005, African-American accounted for only 14.8% of the U.S. child population under 18 years of age (U.S. Census Bureau, 2005) and 32% of the children in foster care (AFCARS, 2005). Comparatively, Caucasian children accounted for 68.5% of the U.S. child population under 18 years of age (U.S. Census Bureau, 2005) and 41% of the children in foster care within the same year (AFCARS, 2005).

Racial disproportionality in child protective services occurs when there are a disproportionate number of racialized children within CPS relative to the group's existence in the general population (Chapin Hall Center for Children, 2008). Whereas, racial disparity refers to the presence of a specific racial group within CPS as compared to another racial group within CPS.

With the exception of the use of NSCAW and AFCARS, few studies have utilized national, case-level data to provide statistical estimates of the degree of disparate access to mental health treatment services. Existing evidence is based on small community-derived samples. The current study examined the association between African-American racial identity and access to mental health services while controlling for child, caregiver, household and abuse characteristics.
We conducted secondary analyses of the 2010 National Child Abuse and Neglect Data System (NCANDS) based on investigated reports of child abuse and neglect that received a maltreatment disposition in the reporting year, 2010 (Oct 1, 2009-Sept 30, 2010).

NCANDS 2010 Child File reflects case-level data based on the submissions of 51 states and the District of Columbia and commonwealth of Puerto Rico resulting in 3.3 million referrals.

This disproportionality of African-American children is evident at all CPS decision points including:

- Reports of child abuse and neglect
- CPS investigations
- CPS service delivery
- Out-of-home placement
- Court involvement

When compared with Caucasian children, African-American children are less likely to receive CPS referred services such as mental health treatment.

- African-American children have fewer contacts with case managers
- African-American children have fewer developmental or psychological assessments
- Among families served by CPS, the availability and utilization of mental health assessments and interventions has an impact on family reunification.
STUDY OBJECTIVE
● To examine the association between racial identity and mental health services employing secondary data analysis of a large national child welfare data set.

RESEARCH QUESTION
● Is racial identity associated with mental health services when controlling for child, caregiver, and household characteristics?

STUDY HYPOTHESIS
● Hypothesis:
   ● While controlling for child, caregiver, and household characteristics, African-American racial identity is associated with mental health services.
The mental health services construct was derived from the variable, “mental health services,” item 81 in the NCANDS 2010 child file (NCANDS User Guide & Codebook, 2010).

Based on case-level data submitted by CPS agencies in 51 U.S. states, D.C. and Puerto Rico.

NCANDS 2010 child file reflects case-level data resulting in an overall sample of 3.3 million referrals.

This study’s sample was restricted to suspected or substantiated primary maltreatment investigations in the reporting year 2010.

Investigations involving duplicate report IDs and child IDs were removed.

Study sample = 408,063 investigations.

Bivariate analysis (chi-square) and multivariate analysis (logistic regression) were used to determine the factors that contributed to mental health services among children for whom primary maltreatment was suspected or substantiated.

Pearson chi-square analysis was conducted to test for group differences among child, caregiver, and household characteristics and racial identity in the proportion of investigations leading to mental health services.
A 4-block logit model (binary logistic regression) was used to examine the association between racial identity and mental health services. Blocks were compared to determine their independent contribution and inclusion in the target group, mental health services. Adjusted odds ratios were reported with 95% confidence intervals.

Child characteristics:
- Investigations involving children who had emotional problems had higher odds of referral to mental health services (OR=2.09).

Caregiver characteristics:
- Investigations involving children of caregivers who had problems with alcohol, drugs, and violence had higher odds of referral to mental health services (OR= 1.48, 2.22, 1.43).
MULTIVARIATE FINDINGS

Household characteristics
- Investigations involving children from families with financial problems had 66% higher odds of referral to mental health services (OR=1.66)

Racial identity:
- Investigations involving children of African-American racial identity had 84% higher odds of referral to mental health services when compared with children of non-African-American racial identity (OR=1.84)

CPS referral to mental health services is a factor of racial identity
- African-American children had 84% higher odds (OR=1.88) of CPS referral to mental health services when compared with non-African-American children
- Investigations involving children from families with financial problems had 66% higher odds of referral to mental health services (OR=1.66)
- Investigations involving children of caregivers who had problems with alcohol, drugs, and violence had higher odds of referral to mental health services (OR=1.48, 2.22, 1.43)
- Investigations involving children who had emotional problems had higher odds of referral to mental health services (OR=2.09)
Nagelkerke R - only 4.1% of the variance explained
Obesity, Binge Eating, & Health Disparities among Hispanic Persons

- Hispanic adults, especially women, have higher prevalence of obesity than whites and the prevalence is increasing faster in Hispanics. (Flegal et al. JAMA 2010)
  - 43% hispanic vs. 33% white women have BMI > 30
- Hispanic adults have higher prevalence of obesity-related medical co-morbidity, such as MetSyn (Jin et al. Circulation 2005) and type-II diabetes (NHANES, 2002)
- Hispanics have elevated prevalence rates of binge-eating and BED as observed in the National Latino & Asian American Study. (Alegria et al. Int J Eat Disord 2007)
  - Significant correlates of BED include severe obesity (OR=5.8) and low education (OR=5.0)

Hispanics and Health Disparities

- Hispanics are under-represented in Rx studies for both obesity and BED. (Franko et al. JCCP 2012)
- Hispanics with limited English proficiency have greater health-care disparities & longer duration of untreated problems, especially mental health. (Staer, Med Care 2010)
- NIMH Collaborative Psychiatric Epidemiol Study found higher lifetime prevalence of BED in Hispanics than whites, but...Hispanics had lower mental health utilization (Marques et al. Int J Eat Disord 2010)

Binge Eating Disorder

- Recurrent episodes of binge-eating (without weight compensatory behaviors) with marked distress.
- BED associated with obesity and psychosocial impairment.
- Treatment Issues:
  - ?? different treatment needs (obesity vs ED)
  - ?? negative prognosis for obesity Rx outcomes
- Overall, CBT>BWL for reducing binge-eating whereas BWL>CBT for acute weight loss although...BWL for BED tends to result in minimal and less weight loss than typically reported for BWL in obesity trials. (Olsz et al., JCCP 2011; Wilson et al. AGP 2010)
Pharmacotherapy combined with BWL or CBT for weight loss in BED

- Specific pharmRx (orlistat, topiramate) enhanced ("modestly") weight-loss with CBT and BWL.
  - Grilo et al. Biol Psychiatry 2005
  - Golay et al. Obesity 2005

- Antidepressants did not enhance weight losses in either CBT or BWL (5 studies)
  - Reas & Grilo. Obesity 2008

Aims

This effectiveness treatment study...

- Randomized placebo-controlled trial of orlistat (anti-obesity med) with culturally-adapted BWL in obese Hispanic adults with BED versus without BED.
- To determine acute-treatment outcomes (4 months) and maintenance (durability) of changes over 6-month f/u after completion of Rx.
- To test BED status as a moderator of Rx outcomes.
- To examine specific outcomes within BED.

Design

- Community mental health center serving monolingual Hispanic adults who are educationally- and economically-disadvantaged and have mental health needs.
- Randomized assignment stratified by BED status
- Double-blind placebo-control
  - orlistat (120 mg tid) vs. placebo (tid) by bi-lingual MD
- BWL (16 weeks) individual weekly sessions
  - culturally-adapted BWL version of Diabetes Prevention Program (DPP; Diabetes Care 2002; West et al. Obesity 2008)
  - fully bi-lingual clinicians deliver BWL, delivery informed by latino cultural constructs to enhance therapeutic alliance (West et al. Obesity 2008)
- Repeated assessments (monthly, post-Rx, 6-month f/u)
Subjects (N = 79) Obese Latino/as

- BMI: 37
- Age: 46 yr
- Female: 82%
- < HS Educ: 62%

- Axis I dx: 85%
- # psych meds: 2
- % antidepr: 75%

(within BED subgroup)
- Binge/mo: 16
- Age onset: 27

Baseline Diagnostic and Repeated (monthly) Assessments

- Spanish Structured Clinical Interview for DSM-IV Axis I Psychiatric Disorders
- Spanish Eating Disorder Examination Interview
  - IRR rho: 0.98 (OBE), 0.79-0.96 (EDE scales) (Grilo et al. 2005)
  - IRR rho: 0.85 (OBE), 0.82-0.99 (EDE scales) (N=20 cases)
- Spanish Beck Depression Inventory
- BMI (measured weight and height)

Participant Flow Through Study

- 139 screened
- 90 evaluated
- 79 randomized
- 40 BED vs. 39 NBO

Data Collection Rates

- at postRx: 95% BED vs. 92% NBO
- at 6-month f/u: 93% BED vs. 96% NBO

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Results: Treatment Variables

**Rx Completion Rates**
- 73% BED vs. 85% NBO (75% orlistat+BWL vs. 82% placebo+BWL)

**Medication Compliance** (at 75% level)
- 68% BED vs. 74% NBO (70% orlistat+BWL vs. 72% placebo+BWL)

**Post-Rx: Significant Improvements**

- Percent Change - Post treatment

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<thead>
<tr>
<th></th>
<th>NBO</th>
<th>BED</th>
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<tbody>
<tr>
<td>OBE</td>
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<td>EDE Global</td>
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<tr>
<td>BDI</td>
<td></td>
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<tr>
<td>BMI</td>
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</table>

**Treatment Outcomes**

<table>
<thead>
<tr>
<th></th>
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<th>time</th>
<th>Med</th>
<th>BED</th>
<th>med-by-BED</th>
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</thead>
<tbody>
<tr>
<td>BMI</td>
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<td>Eat concern</td>
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- Mixed models analyses revealed sig. improvements & sig. effects for time.
- Medication was not associated significantly with any outcome, except for a marginal effect on BMI.
- BED was associated with sig. worse EDE & BDI outcomes, but not BMI.
- Med-by-BED interaction effects were found for BMI and EDE shape/weight concerns (indicating BED moderated those outcomes).
**% BMI Loss by BED Across Rx Groups**

<table>
<thead>
<tr>
<th>% BMI Loss at Post-treatment</th>
<th>Placebo</th>
<th>Orlistat</th>
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</thead>
<tbody>
<tr>
<td>NBO</td>
<td>BED</td>
<td>NBO</td>
</tr>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>6</td>
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**B**ED moderated orlistat effects on weight loss (interaction effect p=.027)

Orlistat+BWL had greater weight loss than placebo+BWL in the non-BED group, but not among BED patients.

**6-month follow-up: Good maintenance of the significant improvements**

Percent Change from baseline - 6 month follow up

**BED significant predictor & moderator of increased BDI and Eating Concerns from post-Rx to 6-month f/u**

**Bed predicted greater increases in BDI post-Rx to 6-month f/u.**

(F=8.8, p<.02)

**Bed moderated course of BDI (F=4.9), p=.03.**

BED patients who received placebo had BDI increases whereas NBO patients receiving orlistat did not.
**BED Group: Binge Eating Outcomes**

Remission from binge-eating:
- At post-Rx: 60% orlistat vs. 70% placebo
- At 6-month f/u: 50% orlistat vs. 50% placebo

**RCT Conclusions**

In this controlled “effectiveness” RCT for obesity and BED, performed at a community mental health center serving educationally- & economically-disadvantaged Spanish-speaking Hispanics with co-morbid psychiatric needs:

- **We observed comparable outcomes for BWL orlistat/placebo as reported in the literature for efficacy trials with restrictive criteria.**
- **BWL produced significant improvements in binge-eating, ED features, & BDI, and significant – albeit “modest” – BMI reductions, which were well-maintained through 6-month f/u.**
- **Adding orlistat to BWL produced greater weight-loss among obese patients without BED, but not among those with BED.**
- **Although 50% of BED patients maintained remission from binge-eating 6-months following treatment, BED was a negative prognostic indicator for obesity treatments.**
SEPA II: An HIV Prevention Intervention for Reducing Health Disparities among Hispanic Women

N. Peragallo, DrPH; RM. Gonzalez-Guarda, PhD; R. Cianelli, PhD; N. Villegas, PhD

13th RCMI International Symposium on Health Disparities

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Introduction

• It is estimated that globally 34 million people live with HIV, with an estimated 2.5 million new cases and 1.7 million AIDS related deaths in 2011 (UNAIDS, 2012).

• In the U.S., the incidence of HIV is increasing more rapidly among racial and ethnic minorities, representing over 72% of new HIV cases and 65% of those currently living with HIV (CDC, 2012; Kaiser Family Foundation, 2008).

• HIV rates for Hispanics are 3.5 times as high as those of Caucasians and among minorities, women are the most affected by the epidemic (CDC, 2010).
Introduction

- Women are disproportionately at risk for the acquisition of HIV infection due to a combination of biological, social and environmental factors that may present challenges to safer sexual practices.
- Various factors increase HIV risk and health disparities among Hispanic women such as high rates of poverty and unemployment, immigration, acculturation stress and cultural values. These and other risk factors create a unique configuration for HIV risk among Hispanic women.

US Census Bureau, 2012; CDC, 2011; Guzmán et al., 2012; Pérez, Díaz, y Grajales, 2008; Pérez y Vélez, 2000; Pérez et al., 2012.

Introduction

- The feminization of HIV infection and the ethnic diversification of women in the U.S. have led to a call for the development and evaluation of gender- and culturally-specific HIV prevention strategies (Dworkin & Ehrhardt, 2007; UNESCO, 2002, Peragallo et al., 2012).
- SEPA has been shown to be effective for reducing HIV risk behaviors among Hispanic women (CDC, 2011; Pérez et al., 2005; Pérez et al., 2012; Gonzalez-Guarda, Pérez, Urrutia, & Vasquez, 2008; Gonzalez-Guarda, Urrutia, Villarruel, & Pérez, 2011).

Objective

To evaluate the efficacy of SEPA II, a culturally adapted intervention designed to reduce HIV risk and improving health disparities among Hispanic Women in South Florida.
SEPA
Salud (Health)
Educación (Education)
Prevención (Prevention)
Autocuidado (Self-Care)

SEPA is a culturally-specific HIV risk reduction intervention.

Methods
Design
SEPA II is a randomized controlled trial.

Sample
- 548 Hispanic women residing in South Florida between 18 and 50 years old and sexually active in the last 3 months participated in the study:
  - 274 were assigned to the intervention group
  - 274 to the delayed-intervention control group

Methods
General Characteristics of the Intervention
- SEPA has five group sessions of two hours each. Each group had approximately 8-10 participants, a facilitator and co-facilitator. There were Spanish and English groups.

<table>
<thead>
<tr>
<th>SEPA Sessions</th>
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<tbody>
<tr>
<td>1. Situación: HIV y AIDS en tu comunidad</td>
</tr>
<tr>
<td>2. Entendiendo Sexualmente Transmisiones de Enfermedades Infecciosas incluyendo HIV/AIDS</td>
</tr>
<tr>
<td>3. Cómo prevenir el VIH/AIDS</td>
</tr>
<tr>
<td>4. Hablar de comportamiento sexual y comunicarse con tu pareja</td>
</tr>
<tr>
<td>5. Prevención y manejo de violencia intrafamiliar</td>
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</tbody>
</table>

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Methods

Data Collection

- Participants were recruited from: personal contact at public places such as community centers, fliers, and referrals from women in the study.
- Participants were assessed by female bilingual interviewers using a structured questionnaire at baseline and 3-months, 6-months, and 12-months post-baseline.
- The interviews were conducted in offices at or near a community service agency. Assessments were collected with the assistance of a web-based research management software system (e-Velos).

Methods: Measures

Behavioral

- Condom use
- Intimate Partner Violence (Revised Conflict Tactic Scale short form) \( \alpha = 0.87 \)
- DRINK

Social Cognitive and Community Prevention

- Partner communication (Catania, 1995) \( \alpha = 0.89 \)
- Perceived HIV risk
- Self efficacy for HIV/AIDS \( \alpha = 0.72 \)
- HIV related Knowledge (Heckman et al., 1998) \( \alpha = 0.75 \)
- Safer sex peer norms (Sikkema et al., 1996) \( \alpha = 0.80 \)
- Perceived Barriers to condom use (Sikkema et al., 1996) \( \alpha = 0.58 \)
- Behavioral Intentions to use condoms (Sikkema et al., 1996) \( \alpha = 0.87 \)
- Community Prevention (Peragallo et al., 2005)
- Depression (CES-D) \( \alpha = 0.94 \)
- Bilingual Accumulation Scale (Marin & Gamba, 1996), \( \alpha = 0.80 \) and \( 0.95 \) for Hispanicism and Americanism subscales respectively.

Data Analysis

- Data were analyzed using:
  - Descriptive Statistics
  - Outcome hypothesis were tested in a separate intent-to-treat (ITT) Generalized Estimating Equations (GEE).
  - The software PASW17.0 was used to analyze the data.

Ethical Aspects

- This study was approved by the University of Miami and the Florida Department of Health IRBs.
## Sample Characteristics

<table>
<thead>
<tr>
<th>Descriptive Variables</th>
<th>Control (n = 274)</th>
<th>SEPA (n = 274)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
</tr>
<tr>
<td>Age (years)</td>
<td>38.22</td>
<td>8.73</td>
</tr>
<tr>
<td>Education (years)</td>
<td>13.11</td>
<td>3.51</td>
</tr>
<tr>
<td>Years living in the U.S.</td>
<td>10.99</td>
<td>9.88</td>
</tr>
<tr>
<td>Acculturation (Americanism)</td>
<td>2.32</td>
<td>0.80</td>
</tr>
<tr>
<td>Acculturation (Hispanic Values)</td>
<td>3.55</td>
<td>0.44</td>
</tr>
<tr>
<td>Number of sexual partners (Last 3 months)</td>
<td>1.08</td>
<td>0.45</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Descriptive Variables</th>
<th>Control (n = 274)</th>
<th>SEPA (n = 274)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>%</td>
</tr>
<tr>
<td>Employed</td>
<td>218</td>
<td>79</td>
</tr>
<tr>
<td>Monthly income &lt; $2000/month</td>
<td>253</td>
<td>92</td>
</tr>
<tr>
<td>Born outside of U.S.</td>
<td>251</td>
<td>92</td>
</tr>
<tr>
<td>Living with partner</td>
<td>199</td>
<td>73</td>
</tr>
<tr>
<td>Has health insurance</td>
<td>114</td>
<td>42</td>
</tr>
</tbody>
</table>

### Country of Origin

<table>
<thead>
<tr>
<th>Country</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central/Caribbean</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Costa Rica</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Cuba</td>
<td>70</td>
<td>13</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>31</td>
<td>6</td>
</tr>
<tr>
<td>El Salvador</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>Guatemala</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Haiti</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Mexico</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td>Nicaragua</td>
<td>29</td>
<td>5</td>
</tr>
<tr>
<td>Panama</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>28</td>
<td>5</td>
</tr>
<tr>
<td>South America</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Argentina</td>
<td>14</td>
<td>3</td>
</tr>
<tr>
<td>Bolivia</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Bolivia</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Colombia</td>
<td>180</td>
<td>34</td>
</tr>
<tr>
<td>Ecuador</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Paraguay</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Peru</td>
<td>45</td>
<td>8</td>
</tr>
<tr>
<td>Uruguay</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Venezuela</td>
<td>21</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>546</td>
<td>100</td>
</tr>
</tbody>
</table>
Results
Magnitude (OR) of Difference in Outcomes at Every Assessment for Women in the Control and SEPA Conditions

<table>
<thead>
<tr>
<th>Time</th>
<th>Control</th>
<th>SEPA</th>
<th>Control</th>
<th>SEPA</th>
<th>Control</th>
<th>SEPA</th>
<th>Control</th>
<th>SEPA</th>
<th>Control</th>
<th>SEPA</th>
<th>Control</th>
<th>SEPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Baseline</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
</tr>
<tr>
<td>6 months</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
</tr>
<tr>
<td>12 months</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
<td>21</td>
<td>61</td>
</tr>
</tbody>
</table>

*p < .05, **p < .01, ***p < .001.

Estimated trajectory of Condom Use (any) from GEE intent-to-treat analysis comparing intervention and control group

Baseline 3 months 6 months 9 months 12 months

R = 0.18, SE = 0.06, p < .001, 95% CI [0.08, 0.19]
Estimated trajectory of Partner Violence from GEE intent-to-treat analysis comparing intervention and control group

Baseline 3 months 6 months 9 months 12 months

Estimated trajectory of Got Drunk from GEE intent-to-treat analysis comparing intervention and control group

Baseline 3 months 6 months 9 months 12 months

Estimated trajectory of Communication with Partner from GEE intent-to-treat analysis comparing intervention and control group

Baseline 3 months 6 months 9 months 12 months
Conclusions & Implications

• SEPA was effective in reducing HIV risk among Hispanic women and its results should be disseminated to community-based organizations for wide-scale use.

• This study provided evidence that HIV/AIDS prevention interventions must be developed in the community and culturally tailored to the targeted population of the intended program.

• SEPA addressed multiple and interrelated health disparities experienced by Hispanic women, which potentiates the public health significance of this intervention.
Recommendations Based on SEPA

- Interventions should be theoretically, community based, and culturally-tailored.
- Strong referral system established (e.g. mental health, domestic violence, housing).
- Sustained contact and booster sessions.
- Critical to address violence, discrimination, lack of access to healthcare.

SEPA Intervention Adaptation

- Project SEPA has been tested in various settings and implemented successfully in other HIV prevention initiatives:
  - In Chicago with Mexican and Puerto Rican women.
  - Mano a Mano, initiative for women and men in Chile (R01 TW-03-00776-5; R01 007574-5) and HIV and STI prevention intervention for young Chilean women using technology (I-STI).
  - "VIDA" and "DYVA" projects used mixed methods to further refine and adapt SEPA.
  - SEPA II (NIH/MCHMD P60 MD002266).
  - SEPA-O: HIV prevention for women 50 years and older.

Next Step in HIV Prevention among Hispanic Women

SEPA III: The Effectiveness Trial

- The need for HIV prevention strategies is clear; however, the ability to effectively incorporate and implement evidence-based practices “within the real world” settings is rarely reported (Salmon et al., 2010).
- SEPA III examines the readiness and capacity for practice improvement as it incorporates the SEPA intervention into Miami-Dade Health Department sites that serve Hispanic women in Miami Dade County, Florida.
Questions & Answers

Thank you for participating!