Neurocognitive & Cultural Factors Influencing Informed Consent in HIV+ & At-Risk Populations

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Overview

- Neuropsychology
- Neurocognitive Effects of:
  - HIV/AIDS
  - Substance Use (SU)
- Sociocultural Factors:
  - HIV & SU Research in Latino/a Communities
- Informed Consent for Research
  - Requirements
- The Reality & Challenges
- Strategies
Neuropsychology (NP)

- Study of brain and behavior
- Assess brain functioning via cognitive tests
- Rely on NP test results for information about the integrity of the brain/function
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Break outs & Discussion
Why Discuss NeuroAIDS at an HIV Prevention Research Ethics Training?

1) Many of you already work w/ PLWHA
   - Directly
   - Discordant couples
   - HIV testing; seroconverters

2) Those who haven’t are probably at “high risk” to do so in future

3) The Neuro aspect of HIV/AIDS - poorly understood by most:
   - Consumers
   - Providers
   - Researchers?
How does HIV affect the brain?

- HIV has a **HIGH** affinity for the CNS

- Crosses Blood-Brain Barrier and infects neuronal support system

- Neurochemical changes

- Structural Damage
  - to brain cells
  - connections between brain cells

- HIV Encephalitis (inflammation of the brain)
NeuAIDS: HIV & the Brain

- Neurologic syndromes
  - Peripheral Neuropathy
  - Polyradiculopathy, myelopathies, etc.

- High rates of NP impairment for:
  - Symptomatic & Asymptomatic patients (30 – 50%)

- HIV-Associated Neurocognitive Disorders
  - Asymptomatic Neurocognitive Impairment
  - Mild Neurocognitive Impairment
  - HIV-Associated Dementia

1 Antinori et al., 2007
Neurocognitive Effects of HIV/AIDS

- Pattern of NP Deficits
  - Early - Mild & diffuse
  - Later – Greater deficits observed
  - Fronto-striatal pattern

- NP Deficits In:
  - Attention/WM
  - Processing Speed
  - Executive Function
  - Learning
  - Memory*
  - Motor Functioning

- Temporal sequence = Variable
Prevalence of NP Impairment in the Pre-CART and Post-CART Eras

Slide courtesy R. Heaton

Pre-CART: HIV- < Non-AIDS < AIDS

Post-CART: HIV- < Non-AIDS, AIDS
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- Break outs & Discussion
Substance Use & Comorbidity

- Substance abuse and HIV closely linked epidemics
- Substance use = A primary co-morbid factor in NeuroAIDS research
- Substances of abuse have demonstrated neuroimmunomodulatory effects, which could interact with HIV infection in the CNS
<table>
<thead>
<tr>
<th>Substance</th>
<th>Neurocog. Domain</th>
<th>Average Effect Sizes</th>
<th>Residual Impact w/ Abstinence</th>
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<tbody>
<tr>
<td>Cannabis</td>
<td>Learning, Memory</td>
<td>Small</td>
<td>No</td>
</tr>
<tr>
<td>Cocaine</td>
<td>Attention, Working memory, Executive</td>
<td>Medium</td>
<td>Yes (worse than opiates)</td>
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<td></td>
<td></td>
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<td></td>
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<tr>
<td>Benzodiazepines/Sedatives</td>
<td>Global Neuropsychological Functioning</td>
<td>Medium-large</td>
<td>Yes</td>
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<tr>
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<td>Visuospatial, Executive Functioning,</td>
<td>Varied</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Working memory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opiates/MMT</td>
<td>EF, Attention/Working Memory, Memory,</td>
<td>Varied</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Motor speed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>Verbal memory, EF, Attention, Motor</td>
<td>Varied</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Note. EF = Executive Functioning

*Slide courtesy D. Byrd*
Neurocognitive Impairment & Substance Use

- Cognitive domains most commonly affected in studies of substance abuse:
  - Executive Functioning
  - WM - Working memory
  - Speeded information processing
### HIV + Substance Use: An overview of the NP literature

#### Effect of HIV w/in SU
- Pakesch (1992)
- Concha (1992)
- Selnes (1997)
- Farinpour (2000)
- Gonzalez (2005)
- Chang (2008)

#### Effects of SU w/in HIV
- Bornstein (1993)
- Richardson (2001)
- Chana (2006)
- Levine (2007)

#### Effects of HIV and SU
- Margolin (2002)
- Rippeth (2004)
- Sassoon (2007)

*Slide courtesy D. Byrd*
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Break outs & Discussion
Why Focus on Latinos?

- Largest Racial/Ethnic Minority Group
- Fastest growing
  - By 2050 = 24% of the U.S. population
- Diverse Diaspora
- Disproportionate impact of health & social risk factors
Latinos & SES Disparities

- Compared to non-Hispanic whites, U.S. Latinos have:
  - Lower education & literacy
  - Higher poverty rates
Latinos & SES Disparities

- Compared to non-Hispanic whites, U.S. Latinos have:
  - Limited healthcare access & utilization
    - Financial, cultural, & linguistic barriers
    - Patient factors, provider factors, institutional factors, system

- Can contribute to disparities in:
  - Health outcomes
  - Disease burden
Latinos & HIV Health Disparities

- Disproportionate Impact
  - ~14% of U.S. population
  - 20% of Reported AIDS cases
  - Rate of NEW AIDS Diagnoses:
    - 2x’s Rate for non-Hispanic Whites
Latinos & HIV Health Disparities

- Compared to non-Hispanic whites, U.S. Latinos are:
  - Less likely to receive combination antiretroviral therapy (CART)
  - More likely to have peripheral neuropathy*
  - Higher mortality rate
  - More likely to die at younger age

CHARTER STUDY

% NC Impairment by Site/Ethnicity

- Hispanic
- non-Hispanic white
- African-Am.

- MSSM
- UCSD
- UTMB
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Break outs & Discussion
Informed Consent for Research

- 3 Primary Purposes¹:
  1) To Promote individual autonomy
  2) To Encourage rational decision-making
  3) To Protect the research pt.’s safety & well-being

¹Berg et al., 2001
Informed Consent for Research

- APA (2010 Amendments) Principal E:
  - Respect for People’s Rights & Dignity by ensuring valid informed consent. ¹

- Valid Informed Consent ~ 3 Elements¹,²:
  1) Appropriate Disclosure → Informed?
     - Sufficient info/time to make reasoned choice
     - Language & language level
  2) A Competent Patient/Participant → Rational?
     - Able to understand/appreciate info presented?
  3) Consent Voluntarily Given → Truly Voluntary?
     - No penalty for declining/withdrawing

¹Fisher, 2012; ²Berg et al., 2001
Basic Elements of Informed Consent (DHHS)

1. An explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject; and

8. Participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
Informed Consent for Research

Requirements –I (APA, 2010*; Standard 8.02):

(a) When obtaining informed consent as required in Standard 3.10, Informed Consent, psychologists inform participants about:

(1) the purpose of the research, expected duration, and procedures;

(2) their right to decline to participate and to withdraw from the research once participation has begun;

(3) the foreseeable consequences of declining or withdrawing;

(4) reasonably foreseeable factors that may be expected to influence their willingness to participate such as potential risks, discomfort, or adverse effects;

(5) any prospective research benefits;

(6) limits of confidentiality;

(7) incentives for participation;

(8) whom to contact for questions about the research and research participants' rights.
(b) Psychologists conducting intervention research involving the use of experimental treatments clarify to participants at the outset of the research:

1. the experimental nature of the treatment;
2. the services that will or will not be available to the control group(s) if appropriate;
3. the means by which assignment to treatment and control groups will be made;
4. available treatment alternatives if an individual does not wish to participate in the research or wishes to withdraw once a study has begun;
5. compensation for or monetary costs of participating including, if appropriate, whether reimbursement from the participant or a third-party payor will be sought.
The Take Away [So Far]

- HIV infection and substance use (SU) are independently associated with significant cognitive, functional, neurologic and neuropathologic complications. (Brown et al., 1992; Heaton et al., 1995)

- However, the literature on the combined effects of SU and HIV on the CNS has produced conflicting results. (Gonzalez & Cherner, 2007)

- Latinos/as are disproportionately impacted by both HIV/AIDS epidemic and substance use.

- Comprehensive understanding of informed consent is critical for ethically conducting research with vulnerable populations such as ours.
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Break outs & Discussion!
Informed Consent for Research Reality & Challenges

Medical /Psych. Comorbidities
- HIV/AIDS
- Substance Abuse
- Psychiatric Dxs

Sociocultural Factors
- Education
- SES
- Culture

Neurobeh. Outcomes

Informed Consent

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Challenges & Insights from Working in Spanish [East] Harlem

- Comorbidities
  - Substance Use
  - Psychiatric illness
- Low/Poor education quality
- Closed head injury

- Lack of appropriate referential data
IC Research Challenges

1) Sociocultural Issues
   1) Literacy
   2) Language
   3) Others?

2) Power Asymmetry

1) Mistrust/Disclosure Fears
Informed Consent Considerations

1) Sociocultural Issues?
   *Ensuring consent is informed

2) Power Asymmetry?
   *Ensuring consent is informed & voluntary

3) Mistrust/Disclosure?
   *Ensuring consent is informed & voluntary

4) Capacity to Consent?
   *Ensuring consent is rational

5) Institutional Barriers?
1) Sociocultural Considerations

- Different ways of:
  - being (e.g., time orientation)
  - thinking (e.g., field independence vs. dependence)
  - problem-solving (approaches)**
Informed Consent Considerations & Strategies

**Sociocultural Considerations**

- **Sociohistorical Context?**
  - Country of Origin
  - Immigration Issues?? [La Migra? Torture?]
  - Time in U.S.
  - Geography
  - Region of country
    - Urban v. Suburban v. Rural?

Informed Consent Considerations & Strategies

- Sociocultural Considerations → Strategies
  - Race/Ethnicity (as a proxy for?)
    - Yrs. of Education ≠ Literacy
    - Literacy* → Reading consent to all pts.
    - Language* → Bilingual staff
      - Avoid using interpreters when you can
      - Only use professional, trained interpreters
  - Access/Quality of Healthcare → Referrals
  - Culture? → Measuring Acculturation
    **Abbreviated multidimensional acculturation scale (Zea et al., ‘03)
  - Cultural attitudes towards healthcare; Rx; Tx?

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-Arnold et al., 1994; Kenneson et al., 1999; Lorente, 2003; Manly et al., 1998; Rivera Mindt, 2008; Ryan et al., 2008
Informed Consent Considerations & Strategies

Sociocultural Considerations → Strategies

- Culturally Appropriate Communication
  - Multiculturally aware & competent staff
- Respeto
  - Respect, including targeted communication based on age, gender...
- Personalismo
  - Formal friendliness, warm, personal relationship
  - Show interest in the pt's life at each visit (eg, starting the visit with a brief conversation about their life)
  - Provide a business card
  - La doctora meets with everybody!**
  - Warming up the waiting area - This place is for you!**
2) Power Asymmetry

- Considerations:
  - SES & Coming from Disenfranchised Backgrounds

- Strategies:
  - Consent process begins in the waiting room\(^1\)
  - Respect & Dignity ~ Autonomy
    - We do not know more about our pt’s lived experience than they do!
  - Breakfast & Dignity
  - Being OF, IN, and FOR the community

*Community Engagement

1. Rivera Mindt et al, 2010
3) Mistrust/Disclosure

- Considerations:
  - Urine Toxicology
  - Disclosure

- Strategies:
  - Know your hustle & be upfront with it.
  - Know your pts.
  - Understand & Proactively Address Concerns through Consent Process – Sliding scale approach (CF)
Considerations for Questionable CtC:

- Rational decision-making impacted by:
  - Varying levels of HIV-related impairment (up to 50% impaired)
  - Substance related cog. Alterations (withdrawal, acute intox) \(^1\)
- Typically don’t have guardians or legal representatives
- Can’t summarily exclude those with Questionable CtC

\(^1\)Fisher, 2012
Informed Consent Considerations & Strategies

- Research on Capacity to Consent (CtC)\(^1\):
  a) Persons with more serious mental illness/cog. dx’s perform worse on structured CtC measures.

b) However, considerable heterogeneity in abilities.

IMPORTANT:

- c) Impaired competency more strongly related to Cog. Deficits than Psych. Symptoms\(^2\)

\(^{1}\text{Melton et al., 2007; }^{2}\text{Carpenter et al., 2000}\)
Informed Consent Considerations & Strategies

- Strategies to Address Questionable CtC:

  #1) Evaluation of Competency

  - *MacArthur Competence Assessment Tool for Clinical Research* (MacCAT-CR)¹, ², ³

  - Measures multiple competency abilities¹,⁴:
    - Ability to express choice
    - Understanding
    - Appreciation
    - Reasoning

  - “Constructed” based on research project

  - Brief (15 – 20 minutes)

  - Document informed consent process/abilities above

¹Applebaum & Grisso, 2001; ²Dunn et al., (2006); ³Melton et al., 2007; ⁴Fisher, 2012
### MacCATT RECORD FORM

<table>
<thead>
<tr>
<th>Disclosure</th>
<th>Patient Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 Diagnosis</td>
<td>Rating</td>
</tr>
<tr>
<td>#2 Feature of Disorder</td>
<td>Rating</td>
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<tr>
<td>#3 Feature of Disorder</td>
<td>Rating</td>
</tr>
<tr>
<td>#4 Feature of Disorder</td>
<td>Rating</td>
</tr>
<tr>
<td>#5 Course of Disorder</td>
<td>Rating</td>
</tr>
<tr>
<td>Other</td>
<td>Rating</td>
</tr>
</tbody>
</table>

**UNDERSTANDING-DISORDER**

*Disclose:* “Now please explain in your own words what I’ve said about your condition.”

*Probe (if necessary):* Re-Disclose and Re-Inquire if necessary.

- **Agrees**
- **Disagrees**
- **Ambivalent**

**APPRECIATION-DISORDER**

*Inquire:* “Now that is what we think is the problem in your case. If you have any reason to doubt that, I’d like you to tell me so. What do you think?”

- Agrees
- Disagrees
- Ambivalent

*Probe:* If patient disagrees or is ambivalent, description of disagreement and patient’s explanation.

**UNDERSTANDING-TREATMENT**

*Disclose:* “Now please explain in your own words what I’ve said about this treatment.”

*Probe (if necessary):* Re-Disclose and Re-Inquire if necessary.

<table>
<thead>
<tr>
<th>Disclosure</th>
<th>Patient Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 Name of Treatment</td>
<td>Rating</td>
</tr>
<tr>
<td>#2 Feature of Treatment</td>
<td>Rating</td>
</tr>
<tr>
<td>#3 Feature of Treatment</td>
<td>Rating</td>
</tr>
<tr>
<td>#4 Feature of Treatment</td>
<td>Rating</td>
</tr>
<tr>
<td>Other</td>
<td>Rating</td>
</tr>
</tbody>
</table>

MacCATT: MacArthur Competency Assessment Tool for Treatment (MacCAT-T)
Copyright © 1998 by The Mount Sinai School of Medicine
Developed with support from the John D. and Catherine T. MacArthur Foundation

Fordham University/The Mount Sinai School of Medicine
THE MacCAT-TR

UNDERSTANDING-BENEFITS/RISKS

Disclosure: “Now please explain in your own words what I’ve said about benefits and risks of this treatment.”

Probe (if necessary): Re-Disclose and Re-Inquire (if necessary).

<table>
<thead>
<tr>
<th>Disclosure</th>
<th>Patient Response</th>
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<tbody>
<tr>
<td>#1 Benefit</td>
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</tr>
<tr>
<td>#2 Benefit</td>
<td></td>
</tr>
<tr>
<td>#3 Risk</td>
<td></td>
</tr>
<tr>
<td>#4 Risk</td>
<td></td>
</tr>
</tbody>
</table>

Understanding-Benefits/Risks (Sum)

APPRECIATION-TREATMENT

Inquire: “You might or might not decide that this is the treatment you want - we’ll talk about it later. But do you think it’s possible that this treatment might be of some benefit to you?”

- [ ] Agrees
- [ ] Disagrees
- [ ] Ambivalent

Probe: “So you feel that it isn’t possible for that treatment to be of some help for your condition. Can you explain that to me? What makes it seem that the treatment would/wouldn’t be of possible benefit to you?”

ALTERNATIVE TREATMENTS

See Alternative Treatment (AT) Forms, one for each Alternative Treatment.

FIRST CHOICE AND REASONING

Choice: “Now let’s review the choices that you have. First, second, and so on (name each treatment option reviewed earlier, including no-treatment option). Which of these seems best for you? Which do you think you are most likely to want?”

Choice

Inquire: “You think that (state patient’s choice) might be best. Tell me what it is that makes that seem better than the others?”

Probe: Discuss explanation to explore reasoning process.

Explanation

Consequential Comparative
The MacCAT-TR

GENERATE CONSEQUENCES

**Inquire-1:** “I told you about some of the possible benefits and risks or discomforts of (name the patient’s preferred treatment option). What are some ways that these might influence your everyday activities at home or at work?”

Consequences-1

**Inquire-2:** “Now let’s consider (name of any other treatment or the no-treatment option). What are some ways that the outcomes of that option might influence your everyday activities at home or at work?”

Consequences-2

FINAL CHOICE

**Inquire:** “When we started this discussion you favored (insert ‘First Choice’ from earlier inquiry, or note that the patient seemed to be having difficulty deciding). What do you think now that we have discussed everything? Which do you want to do?”

Choice

LOGICAL CONSISTENCY OF CHOICE

Examiner’s Explanation

Logical Consistency

---

**MacCAT-T RATING SUMMARY**

<table>
<thead>
<tr>
<th>Sum of Ratings</th>
<th>Number of Items</th>
<th>Subtotal Rating</th>
</tr>
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<tbody>
<tr>
<td>UNDERSTANDING</td>
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<tr>
<td>Disorder</td>
<td>______ ÷ ______ = ______</td>
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<tr>
<td>Treatment</td>
<td>______ ÷ ______ = ______</td>
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<tr>
<td>Benefits/Risks</td>
<td>______ ÷ ______ = ______</td>
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Understanding Summary Rating (0-6)

<table>
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<td>Disorder</td>
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<td>Treatment</td>
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Appreciation Summary Rating (0-6)

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<tr>
<td>Generate Consequences</td>
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</tr>
<tr>
<td>Logical Consistency</td>
<td></td>
</tr>
</tbody>
</table>

Reasoning Summary Rating (0-8)

Expressing A Choice Summary Rating (0-2)

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OPTIONAL: Summary scores for Understanding of each alternative treatment

Alternative 1: Alternative 3:

Alternative 2: Alternative 4:
Strategy #2 to Address Questionable CtC

2) Interventions to Improve Competency

- Initially poor CtC performance can be remediated by educational interventions that: ¹, ², ³, ⁴, ⁵
  
a) reiterate information
  
b) instruct on information initially poorly understood
    * re-read parts of consent at 1st post-test

- If such efforts can be demonstrated to be successful, subjects can be permitted to make their own decisions about the research project.” ⁵

¹ Carpenter et al., 2000; ², ³ Wirshing et al. 1998 & 2005; ⁴ Moser et al., 2006; ⁵ Applebaum, 1998
Informed Consent Considerations & Strategies

5) Institutional Barriers

- How do institutional req’s = barriers to valid consent?
  - Overly long, legalistic informed consent boilerplates
  - Poor fit with cognitively impaired participants
  - Lack of flexibility

- Strategies
  - ???
Muchas Gracias!

谢谢!
Merci!
Danke!
ありがとう!
Grazie!
Thank you!
References


References


