Meeting the Challenges of Correctional Mental Health Research

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- **Agenda**

1. **Robert Trestman**
   research and collaboration needs
2. **Joel Silberberg**
   ethical considerations
3. **Philip Candilis**
   oversight & accreditation
4. **Humberto Temporini**
   pragmatic issues

Mental Health Research in Jails and Prisons: Why and How to Play in a DOC Sandbox

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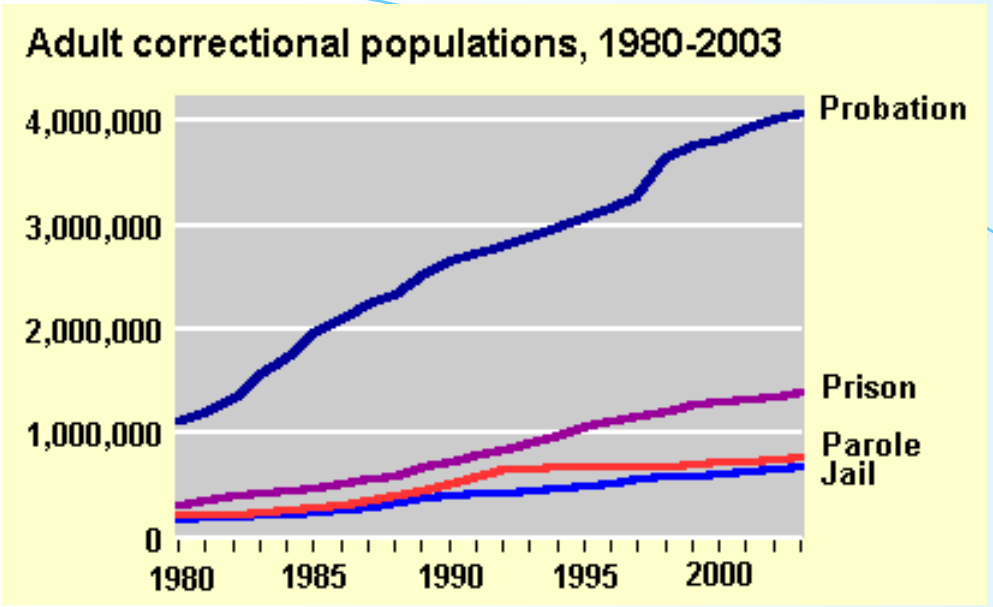

In 2003, 6.9 million people were on probation, in jail or prison, or on parole:

3.2% of all U.S. adult residents or 1 in every 32 adults.

•State and Federal prison authorities had under their jurisdiction 1,470,045 inmates at yearend 2003: 1,296,986 under State jurisdiction and 173,059 under Federal jurisdiction.

•Local jails held or supervised 762,672 persons awaiting trial or serving a sentence at midyear 2003. About 71,400 of these were persons serving their sentence in the community.

Bureau of Justice Statistics, 2005

Treatment in State Prisons

On June 30, 2000:

- 150,900 State inmates were in mental health therapy/counseling programs
- 114,400 inmates were receiving psychotropic medications
- 18,900 were in 24-hour care (infirmary).
- 1 in 10 State inmates received psychotropic medications
- 1 in 8 in mental health therapy or counseling

BJS, *Mental Health Treatment in State Prisons 2000*

Mental Illness in Custody

- About as prevalent as hospital and community clinic psychiatric samples

  Substance abuse is pandemic

Diamond et al 2001;Trestman et al, in review

Mental Illness in Custody

- Inmates with Mental Illness are:
  - Have been and will be seen in community clinics
  - Among the more difficult to manage due to emotional instability, impulsivity, and / or psychosis
  - Likely to receive disciplinary reports, administrative segregation time and consume disproportionate staff energy
  - Likely to be on multiple medications, with associated risks and costs

Traumatic / Acquired Brain Injury

- Behavior and emotion dyscontrol (Sarapata et al., 1998).
- Prevalence rates of between 38% and 86% in prisons (Barnfield and Leathem, 1998; Turkstra, Jones and Toler, 2003; Sarapata et al., 1998; Brewer-Smith, Burgess and Shults, 2004; Walker, Hiller et al., 2003).
- Significantly higher rate of TBI among those convicted of violent vs non-violent crimes (56% versus 38%) (Brewer-Smith, Burgess and Shults, 2004).

Key Issues in Custody

- ☑ Safety
  - Decreased movement
  - No Keep on Person meds
  - Decreased aggression
  - Decreased suicidal behavior and completed suicides

Key Issues in Custody

- ☑ Cost
  - Direct
    - Dispensing, product recovery
    - Med Lines
    - Pill acquisition and packaging
  - Indirect
    - General population vs. specialized housing
    - Disciplinary Reports / process
    - CET - Cell Extraction Teams

Research Needs

- Data Management Capacity
- Epidemiology
- Natural History
- Treatment Interventions
  - Psychotherapy
  - Psychopharmacology
- Economics
- Community Transition

Collaboration

- Ask not what DOC can do for you. . .
- What is in it for DOC?
- Understanding the needs of DOC
  - Reducing safety risks
  - Reducing behavioral problems
  - Reducing their population
  - Reducing recidivism
  - Risk averse: litigation and bad publicity

Meeting the Challenges of Correctional Mental Health Research – Ethical Considerations

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Overview

- Significant number of inmates are mentally ill
- Legal and ethical issues in regard to research in the correctional setting
- Regulatory restrictions limit subject research in correctional setting
- Is it ethical not to do mental health research in the correctional environment ?

Basic Demographics

- 1,931,859 persons in U.S. prisons and jails at mid-year 2000
  - 56% increase since 1990
  - 92,688 women (6.7% of all prisoners)
- 283,800 mentally ill offenders at mid-year 1998
  - e.g. Cermak Health Services of Cook County largest public health provider in Illinois

Bureau of Justice statistics

Medical Ethics

- Claude Bernard 1865:

  “Never perform an experiment which might be harmful to the patient even though highly advantageous to science or the health of others”

Medical Ethics

- *Patient autonomy* (respecting the decision making capacity of an autonomous person)
- *Beneficience* (providing benefits to patients)
- *Nonmalefecience* (avoiding harm to patients)
- *Justice* (fairly attributing costs, benefits and risks to others-Beauchamp and Childress 1989)
- *Simultaneous application of these principles* leads to conflicts, and physicians (and researchers) attempt to balance the principles, or to apply other principles or authority, to resolve the conflict

Wettstein RM, 1992

Correctional Psychiatry Research Has Many Unique Ethical Dilemmas and Issues

- Should research be allowed in prison settings based on the history of significant ethical problems in the past and the fact that prisoners inherently have less free will while incarcerated ?
- The history of significant ethical problems has frequently involved minority groups
- In USA, African Americans and Hispanics constitute a disproportionately large percentage of the incarcerated population
- Prisoners with mental illness are the “most vulnerable of the vulnerable”

Correctional Research

- Every person of adult years and sound mind has a right to determine what shall be done with his body

  Justice Benjamin Cardozo, 1914

- Tension between autonomy and paternalism is heightened in research because experimental treatment is rarely intended for the participant's direct benefit

  Melton, 1997

These two statements demand extra attention in Corrections

Correctional Research:
Best predictor of future behavior is past behavior ?

Coercion

- Newgate Prison, 1718:

  George I offers free pardon to any inmate of Newgate Prison who agrees to be inoculated with infectious Smallpox in variolation experiment

  Vaccine v. death/intense suffering ?

  Welcome offer to escape from "bottomless pit of violence" v. coercion ?

- Kaimowitz v. DMH, 1973: "The inherently coercive atmosphere to which the involuntarily detained mental patient is subjected has bearing on the voluntariness of his consent…. They are not able to voluntarily give informed consent because of the inherent inequality of their position."

Coercion

- 1919-1922 : Testicular transplant experiments on 500 prisoners at San Quentin
- 1944-1946: Malaria experiment on 400 prisoners in Illinois
- 1950 :Viral hepatitis experiments on 200 women prisoners in Pennsylvania
- Final report of Tuskegee Syphilis Study; “Society can no longer afford to leave the balancing of individual rights against scientific progress to the scientific community”

Correctional Research:
Best predictor of future behavior is past behavior ?
Not so if we continue to make changes

History

- Nuremburg Code of 1949:

  The 10 point Code begins with “The voluntary consent of the human subject is absolutely essential”
- Declaration of Helsinki, 1964:

  “The interests of science and society should never take precedence over the well being of the subject”

History

- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (NCPHSBBR), 1976
- Code of Federal Regulations, 1978
  - Human subjects in general
  - Prisoners in particular

Federal Regulations on Medical Research in Correctional Setting

- Four Categories of Permitted Research
  - Possible causes, effects, and processes of incarceration and criminal behavior
  - Prisons as institutional structures or prisoners as incarcerated persons
  - Conditions affecting prisoners as a class
  - Practices to improve health or well-being of subject

45 CFR 46, Subpart C (Revised October 1, 1994)

Special Provisions for Correctional Research

- Specially organized IRB with prison advocate present
- Consideration of the following:
  - Avoid incarceration-related enticements
  - Risks commensurate with risks to non-incarcerated volunteers
  - Selection of subjects without interference
  - No influence on parole

45 CFR 46, Subpart C (Revised October 1, 1994)

Subsection C misunderstood

- Minimal human research takes because conditions appear too rigorous
- Need clearer understanding of “coercion and informed consent in research involving prisoners”
- HIV Education Prison Project at Brown University
  - Lowered threshold for implementation of clinical trials

Consent to participate in research

-*Capacity*: ability to understand the relevant information and to appreciate those consequences of his or her decision to participate in the research that might reasonably be foreseen

-*Voluntary*: inmate's right to come to a decision freely, without force, coercion or manipulation

-*Informed*: medical condition, nature and effect of participation in research, risks, availability of follow up treatment etc.

Informed Consent

- A process by which one individual agrees to allow another individual to intrude upon their bodily integrity or other rights, where the agreeing party is competent to consent, and the consent is given voluntarily and with a reasonable degree of knowledge of the factual situation

Correctional Research Informed Consent

- Nature and purpose of research
- Risks and potential benefits
- Alternative treatments
- Limits of confidentiality
- *Compensation and treatment for injury*
- *Whom to contact with questions*
- *Participation is voluntary*
- *Subject may withdraw at any time*

Voluntariness ?

Free of coercion, subtle or overt

Kaimovitz v.Michigan Department of Mental Health

- Mental Disability Law reporter 147 (1976):

  Residents of “total institutions” such as prisons are in inherently coercive environments which severely limits their capacity to give true voluntary consent

Voluntariness

- Many inmates are in the process of appealing their convictions or hoping for parole, it is reasonable to assume that they may feel, possibly realistically, that if they do not cooperate with treatment procedures they will be punished further and lose opportunities for release (Stone, 1984)

Coercion and Consent in Research Involving Prisoners

- Study designed to assess decisional capacity and susceptibility to coercion in 30 mentally ill prisoners and 30 healthy controls
- All controls and all but one of the prisoners demonstrated adequate capacity to consent to the hypothetical drug trial

Moser, Arndt et.al 2004

Coercion and Consent in Research Involving Prisoners (Cont)

- Prisoners scored lower on quantitative measure of decisional capacity
- Regarding possible coercion, prisoners main reasons for participation in research included avoiding boredom, meeting someone new, appearing cooperative in hopes of being treated better, and helping society.
- Despite serious past incidents, ethicists will need to consider the possibility that prisoners have become an overprotected population

Moser, Arndt et.al 2004

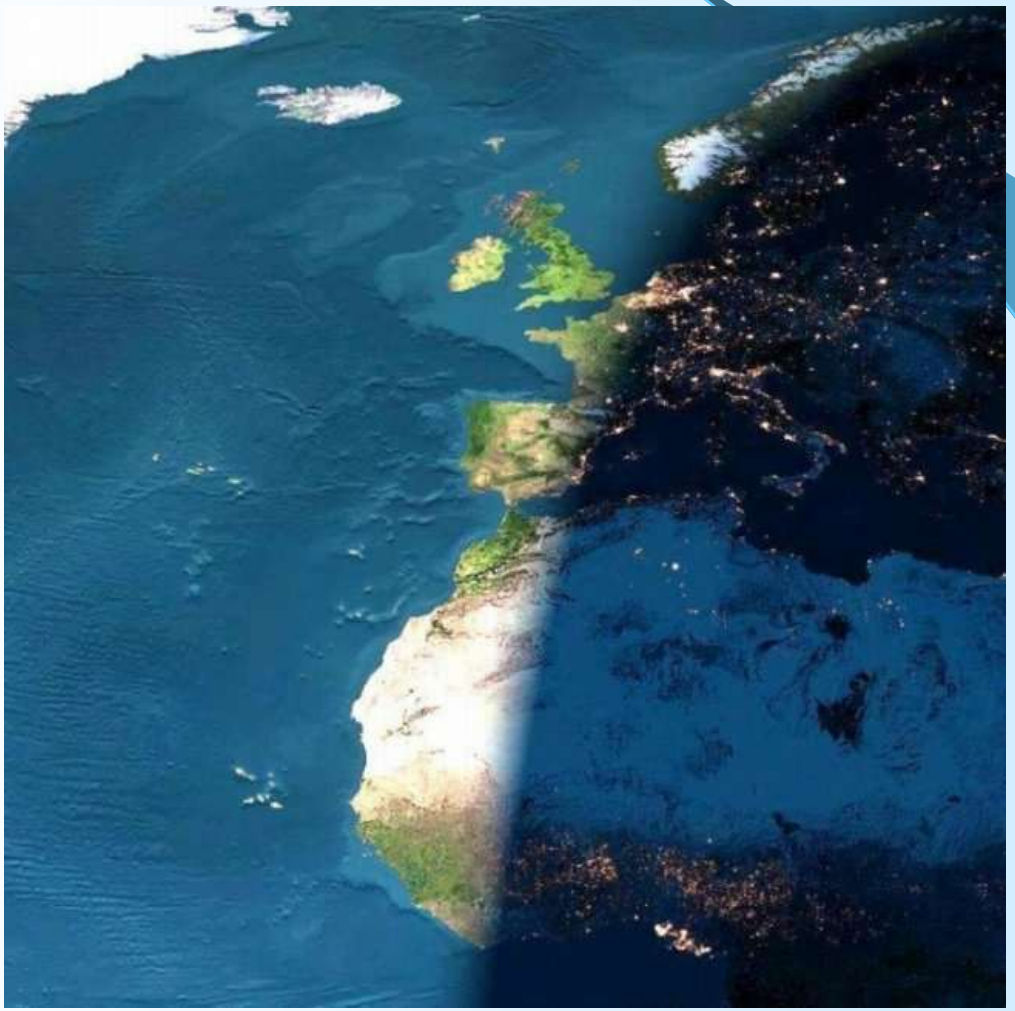
Boredom

MacArthur Competence Assessment Tools for Treatment and Clinical Research

- MacCAT-T and MacCAT-CR
- Designed to permit efficient structured assessment of decisional capacity that is nonetheless individualized to the particular situation of each patient or research subject
- Cognitive impairment, as measured by neuropsychological tests, displays substantially greater predictive power of impairment of capacity than psychiatric symptoms

Appelbaum, 2004

Coercion and Consent in Research Involving Prisoners



Identification and Prioritization of Research Needs of Correctional System

- Survey all stakeholders
- Focus groups
- The amount of coercion experienced in treatment or in participation in research is strongly associated with "procedural justice"

  -dignity, respect, listening, communication, participation

Example: Ethical Arguments and Research Findings in Regard to Outpatient Commitment

- Goals:
  - Balance liberty interests with health interests
  - Intervene earlier in the process before the need for even-more-restrictive hospitalization
  - Ensure due process

Rights-Based

- Positive rights *e.g., free public education*
- Negative rights *e.g., freedom from interference*
- Great value on individual freedom

Beneficence

- Unawareness of illness has a neurobiological basis
- Rights based arguments appear to give way to beneficence - parens patriae powers of the state

-Substituted judgment (allows greater autonomy)

-Best interest standard (for more chronic patients)

(M. Munetz et. Al., 2003)

Utilitarianism

- Greatest good for the greatest number
  - Delay of treatment
  - Lifetime suicide rate
  - Medical neglect
  - Frequency of violence:

As perpetrator or victim

Outcomes of Outpatient Commitment

Outpatient commitment can improve treatment outcomes when the court order is sustained and combined with relatively intensive community treatment. A court order alone cannot substitute for effective treatment in improving outcomes.

Swartz MS et al, *Psychiatric Services* 52:325-329, 2001

Favorable Outcome Depends On

- Early involvement of community staff
- Length of court order and renewability
- Single point of entry
- Adequate funding
  - Medicaid-funded case management
  - Housing
  - Transportation

Advances in Ethics Affecting Forensic Research

Philip Candilis, MD

UMass Medical School

Coercion

- Cases
  - Newgate Prison, 1722: Smallpox vaccine or death: welcome offer or coercion?
  - Kaimowitz v. DMH, 1973: “The inherently coercive atmosphere to which the involuntarily detained mental patient is subjected has bearing on the voluntariness of his consent…. They are not able to voluntarily give informed consent because of the inherent inequality of their position.”
  - National Commission, 1976: Although prisoners may not regard consent as coercive, research must be prohibited because adequate monitoring of the consent process is impossible.

Coercion (cont.)

- Definitions
  - Whether ordinary person finds an offer irresistible (Beauchamp and Faden)
  - Whether offer is inherently unfair and “moral baseline” is illegitimate (Appelbaum)
  - Whether there is a threat of severe negative sanction (Gert, Nozick)
  - Whether individual need can be balanced against social value: e.g., compensation v. inducement v. coercion

Coercion (cont.)

- Research (MacArthur Network)
- Absence of perceived coercion
  - Being included in decision-making
  - Nature of others' intentions
  - Absence of deceit
  - Receiving respect
  - More relevant than threats, physical force, legal status
- What is ethical determinant: Individual or community perception?

Equipoise

- Definition
  - Normative and descriptive
  - An honest disagreement among experts
  - Required for justification of research trial
  - Individual v. clinical (physician v. community)
  - Toward a broader view of community equipoise:
    - Not merely professional consensus
    - What is community that designs research?
    - The role of patients/subjects
    - Collaborative decision-making
    - Valid v. valuable science
- Relevance to forensic research

Voluntarism

- The ability to act in accord with one's authentic sense of what is good, right, and best in light of one's situation, values, and prior history (Roberts 2002)

- Four domains
  - Developmental factors
  - Illness-related considerations
  - Psychological issues, religious/cultural values
  - External features, pressures

The New Research Ethic

- Controversy and Scandal
  - ACHRE, 1995 (lack of informed consent, widespread ethics lapses)
  - GAO, 1996 (IRB overload, lack of resources)
  - US DHHS, 1998 (commercialization, IRB-shopping, private boards)
  - OHRP suspends research at over 12 centers, 1990s to date
  - Ellen Roche, Jesse Gelsinger

The New Research Ethic: Increased Scrutiny

- OHRP: QA, QI, CQI program
- NCQA: VA system, creation of HRPP
- PRIMR: accreditation standards
- IOM: endorses HRPPPs
- AAHRPP: accreditation, self-assessment
- Themes
  - Broader institutional responsibility (HRPPPs)
  - Accreditation
  - Standardization of review (CQI standards)
  - Ongoing research monitoring
  - Commitment of greater resources

The New Research Ethic: Costs

- UT San Antonio 1979: $100,000
- VA 2003: $1.2 million
  - Hi-volume IRB (300-350 protocols/yr)
  - 8 support staff, FT admin, FT AA, database analyst, .05 FTE/member x 9, 0.5 FTE for Chair
- UMass Med School: $280,000
- Mass. DMH: <$100,000
- Mass. DOC: no budget

Can Forensic Research Survive the New Research Ethic?

The practical aspects of correctional research

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THE FIRST STEP

Develop an idea

THREE MAIN ISSUES

1- Funding it

2- Getting it done

3- Disseminating the findings

PAYING FOR IT

- Where to look for Funding
  - **NIJ**
  - **NIMH**
  - **DOJ**
  - **SAMHSA**
  - **NIDA**
  - **NIAAA**

PAYING FOR IT

- NIJ
  - In 2003 $211M in research grants awarded to 372 projects
  - Topics related to Criminal Justice
  - Of interest to correctional research
    - Sexual victimization in corrections
    - Evaluation of community corrections
    - Development of screening instruments

PAYING FOR IT

- NIMH
  - Multiple types of grants
  - Both individual and institutional
  - Five divisions
  - Correctional research through the Division of Services and Intervention Research
  - Of interest to corrections:
    - Research infrastructure grants

PAYING FOR IT

- Department of Justice (DOJ)
  - In FY2003, DOJ spent 6.9B in grants
  - All grants related to criminal justice
  - Variety of topics via:
    - Bureau of Justice Assistance
    - National Institute of Justice
    - Office for Victims of Crime
  - Examples:
    - Bullet proof vests for local PD
    - Serious and Violent Offender Re-entry initiative

PAYING FOR IT

- Substance Abuse and Mental Health Services Administration (SAMHSA)
  - Through **Division of Criminal and Juvenile Justice**
  - FY 2004 $8.25M available in grant funds
  - Multiple interests:
    - Alternatives to seclusion and restraints
    - Reentry services to Juveniles and Adults returning to the community after incarceration

Getting it done

A long and winding road

Getting it done – First Steps

- Success depends on good relationships
- Make people aware of what you want to do or are doing, be open and expect lengthy and somewhat laborious meetings
- Remember that DOC is an inherently paranoid environment

Getting it done – Before starting

- Maintain open communication channels
- With Commissioners, Wardens and individual facility staff (HSAs, MDs, RNs)
- DOC staff often willing to help once they are included and feel respected

Getting it done

- Remember internal and external controls
  - Your institution's IRB
  - The DOC's own IRB
  - Any state office of protection and research
  - Your State's Attorney General
- Each may have deadlines, special requests and requirements
- It is essential to know what the requirements are

Getting it done – Once started

- Avoid generating any extra burden on the facility staff
- Always keep the custody component “in the loop” (counts, movements)
- Keep in mind that you/your staff may have to arrange for tasks such as blood drawings, obtaining and returning medical charts, etc

REMEMBER

WE ARE GUESTS IN CUSTODY'S HOME

Once you are done

Showing the results

Showing the results

- Do's
  - Inform custody chain (eg, Commissioners, Wardens, etc) **FIRST**
  - Discuss your findings with AG's office if necessary
  - Present your findings at the institutions where the protocols were tested
  - Accept that DOC may not like your results
- Don't
  - "Rush to publish" Remember that your findings involving DOC will be scrutinized, analyzed by local radio hosts and several monitoring panels
  - Talk to anyone outside DOC without DOC's permission (unless you have to)