



Ethical Issues Related to Pragmatic Design
Trials in Mental Health: The At Home/Chez
Soi Project

Diego S. Silva, Ethics Consultant
At Home/Chez Soi Project,
Mental Health Commission of Canada



Overview

- AHCS – Goals, Values, and Background
- Modifications to traditional rules in research ethics
 - Knowledge gap in research ethics
 - Withdrawing from project
 - Critical incidents and safety committees
- Recommendations and Conclusions



AT HOME/CHEZ SOI – GOALS,
VALUES, AND BACKGROUND



At Home/Chez Soi - Goals

- At Home/Chez Soi (AHCS)
 - ❖ “To provide policy relevant evidence [i.e. effectiveness data] about what services and system interventions best achieve housing stability and improved health and well-being for those who are homeless and mentally ill”
 - Mental Health Commission of Canada. *Request for Applications: MHCC Research Demonstration Projects in Mental Health and Homelessness*. Ottawa, Canada: Mental Health Commission of Canada, 2009 (internal document).



At Home/Chez Soi - Values

- Empowerment of individuals with mental illnesses
 - ❖ Traditional value within mental healthcare
- “The project is all about choice”
 - ❖ AHCS website - <http://www.mentalhealthcommission.ca/English/Pages/homelessness.aspx>
- Primary (not sole) guiding principle is autonomy
 - ❖ In the context of mental health?
 - ❖ At the very least, mental illness ≠ absence of autonomy



At Home/Chez Soi - Background

- Explanatory trials
 - Test efficacy of intervention
 - Under ideal conditions
 - Narrowly defined group of participants
 - E.g. traditional randomized control trial of drug X
 - Key Question: Can the intervention work?
- Pragmatic trials
 - Test effectiveness of intervention
 - Under non-ideal conditions
 - Broadly defined group of participants
 - Key Question: Does the intervention work?



At Home/Chez Soi - Background

- AHCS
 - Pragmatic trial [i.e. test effectiveness] of complex intervention
 - Providing housing + supports for persons mental illnesses

- Two previous projects that informed AHCS
 1. Pathways to Housing – New York, NY
 2. Streets to Homes – Toronto, ON



At Home/Chez Soi – Background (Methods)

- Five Canadian Cities
 - Vancouver, Winnipeg, Toronto, Montreal, and Moncton

- Study population
 - 18+
 - Absolutely homeless or precariously housed
 - Serious mental illness
 - With or without coexisting addiction

- Potential participants identified via local service providers



At Home/ Chez Soi – Background (Methods)

- Participants are randomized to one of three arms
 1. Intervention arm – housing + supports
 - E.g. rent subsidies; ACT or ICM
 2. Treatment as usual – care participant would normally receive from local agency
 3. Local arm – care tailored to local context (e.g. Aboriginal care in Winnipeg)

- Service providers are partners with researchers
 - Provide service portion of project

- Therefore, need to consider needs of
 1. Participants
 2. Researchers
 3. Service providers
 4. Public



MODIFICATION TO TRADITIONAL RULES IN RESEARCH ETHICS



Traditional Research Ethics Values

- Tri-council Policy Statement
 - ❖ Respect for Human Dignity
 - ▣ Respect for persons
 - ▣ Concern for welfare
 - ▣ Justice
 - ❖ The gist
 - ▣ Respect participants' autonomy
 - ▣ Protect participants from harm
 - ▣ Treat people fairly and equitably
 - ▣ Bonus: sound scientifically



Knowledge Gap

- Research ethics literature speaks to
 - ❖ Assertive community treatment
 - ❖ Conducting studies with persons with violent pasts/behaviors
 - ❖ Community-based participatory research
 - ❖ Clinical research with persons with mental illnesses



Knowledge Gap

- Research ethics literature doesn't speak to
 - ❖ Pragmatic trial designs
 - ❖ Discussion of culture outside social sciences
 - I.e. Culture in delivery of healthcare services
 - ❖ How to conduct research with consumers
 - ❖ Specific questions/challenges
 - E.g. Sustainability of housing and supports after project; sharing of information between team members; power imbalance and undue influence; etc.



Filling the Knowledge Gap

- Modifying traditional research ethics procedures to meet traditional research ethics values
 - ❖ Autonomy, welfare, justice
- Substantive and procedural issues
- 'Learning as we go'



Withdrawing from AHCS Project

- In traditional clinical trials
 - ❖ When a participant withdraws, they return to regular course of treatment
- What happens when a participant withdraws from AHCS?
 - ❖ They have option to retain housing subsidies
 - ❖ No longer included in study data
 - ❖ Must abide by service provider contracts



Withdrawing from AHCS Project

- Two reasons for retaining housing
 1. Withdrawing housing is return to homelessness
 - Would run counter for value of welfare
 2. Possibility of undue influence or coercion
 - Def: when X influences Y in a manner Y would not normally act and want to act
 - Participant may not want to receive psychosocial treatment but may want to keep housing



Critical Incidents and Safety Committees

- Need to ensure safety as best as possible
 - ❖ Of participants
 - Data collected in participants' homes
 - High rates of morbidity and mortality
 - Project is intertwined with life of participants
 - ❖ Of staff and public
 - Participants might have violent histories
 - Need to protect staff and public while including participants with broad ranges of past behavior
 - NB: persons with MI more likely to victim of violence than perpetrator



Critical Incidents and Safety Committees

- Traditional clinical trial
 - ❖ Adverse event
 - "Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.... [including] any unfavorable and unintended sign... symptom, or disease temporally associated with the use of a medicinal... product, whether or not related to the medicinal... product"
 - Health Canada, ICH Guidance: Good Clinical Practice
 - ❖ Goals in indentifying adverse event
 - Protect subjects from harm
 - To distinguish a negative event that occurs because of underlying condition from that of intervention



Critical Incidents and Safety Committees

- Definition of 'adverse events' doesn't work for AHCS project
 - ❖ Persons besides participants could be harmed
 - ❖ Narrowly medical definition
 - ❖ Distress commonly associated to mental illness
 - ❖ Need a definition that goes beyond realm of research

- Differences likely stem from pragmatic design



Critical Incidents and Safety Committees

- Critical incident
 - ❖ Any event that results in serious physical, material, psychological, or legal harm to the participant, member of frontline staff, researcher, or member of the public and is associated with involvement in the study
 - Language of service providers
 - How to define 'serious'?
 - Would event or incident X affect how the project is conducted?
 - Would event or incident X have implications for how the AHCS project should proceed in the future?



Critical Incidents and Safety Committees

- Data Safety and Monitoring Boards (DSMB)
 - ❖ Est. in 1960s "to monitor interim data in clinical trials in order to ensure the safety of participating subjects" and scientific integrity
– Slutsky & Lavery, NEJM, 2004;35(11):1143-47.
 - ❖ Looking for patterns of abnormal trends in the data
 - Positive of negative; stopping rules

- Composed of scientists, clinicians and statisticians external to study
 - ❖ Meet at mid-way point of study

- Multisite, long-duration, 'vulnerable' or marginalized population



Critical Incidents and Safety Committees

- Limitations to DSMBs
 - ❖ Critical incidents need to be followed regularly to identify patterns and institute changes, if necessary
 - ❖ Safety of all stakeholders to rely on more than data from the project
 - ❖ Some insight about the project itself is necessary
 - I.e. cannot all be external persons
 - ❖ Need ongoing education and dissemination of safety information across all sites



Critical Incidents and Safety Committees

- AHCS Safety Committee
 - ❖ Keep track of all critical incidents through reporting from local sites
 - Critical incident reports
 - ❖ Issues resolved at local level; safety committee to look for patterns in real-time
 - ❖ Meet at least four times per year (or when necessary)
 - ❖ Serves as educational resource to broader project
 - ❖ Mix of persons internal and external to project
 - Including local consumer reps



RECOMMENDATIONS AND CONCLUSIONS



Recommendations

- Ethics education prior to start of study
 - ❖ Brainstorming with all stakeholders (including participants)
- Creation of safety committees with diverse representation
- Hire ethicist or work with local ethics resources
- Always remember the *raison d'être* of research ethics and use it as an ongoing guide
 - ❖ Autonomy, welfare, justice



Conclusions

- AHCS project will continue to present new challenges
 - ❖ 'Learning as we go'
- Research designs becoming more complex
 - ❖ Heterogeneous study populations
 - ❖ E.g. pragmatic trials ethics – no literature currently exists
- Research ethics questions will become more complex, as well
- Future research ethics procedures
 - ❖ Context specific
 - ❖ Nimble
 - ❖ Dynamic



Silva DS, Goering PN, Jacobson N, Streiner DL. (2011) Off the Beaten Path: Conducting Ethical Pragmatic Trials with Marginalized Populations. *IRB: Ethics & Human Research*, 33(3): ??



BY DIEGO S. SILVA, PAULA N. GOERING, NORA JACOBSON, AND DAVID L. STREINER

Off the Beaten Path: Conducting Ethical Pragmatic Trials with Marginalized Populations

In October 2009, the Mental Health Commission of Canada (MHCC) began recruiting participants for its *Je Home/Chao Sol* (AHCS) project. The AHCS project is designed as a pragmatic trial intended to provide policy relevant evidence (i.e., effectiveness data) about what services and system interventions best achieve housing stability and improved health and well-being for those who are homeless and mentally ill.¹ Explanatory trials (e.g., traditional randomized control trials of a drug) test the efficacy or benefits of a treatment or intervention under ideal conditions with narrowly defined participants (i.e., Can the intervention work?), while pragmatic trials test the effectiveness or benefits of a treatment or intervention under routine

about research ethics did not meet the project's needs. Finally, we use two examples—one substantive and the other procedural—to show how we modified existing research ethics thinking and practices to better serve project stakeholders.

AHCS Project Goals, Values, and Knowledge Gaps
 The AHCS project is a pragmatic trial of a complex intervention intended to test the effectiveness of providing persons who are homeless and mentally ill with housing and supports for their mental illnesses. The project is based on two previously successful programs: first, studies suggest that the Pathways to Housing program, which combines subsidized housing



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