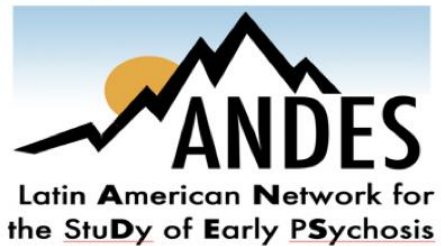




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Research Ethics Challenges in a First Episode of Psychosis Clinic in Latin America

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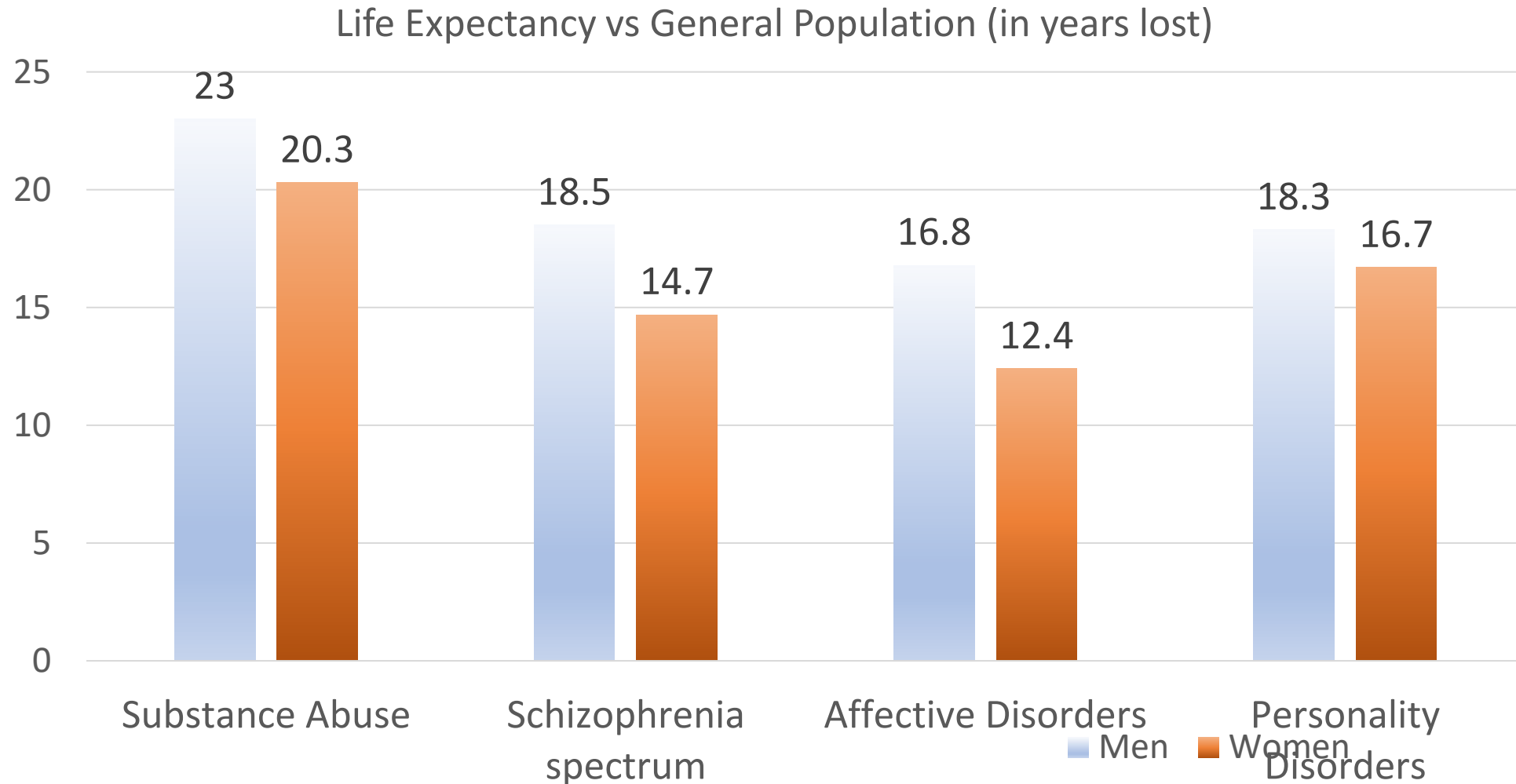
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Psychotic disorders produce substantial impact on mortality



Northern Metropolitan Health Service

- 8 Community mental health centers
- 2 hospitals with psychiatric wards
- 943.905 people (2015)

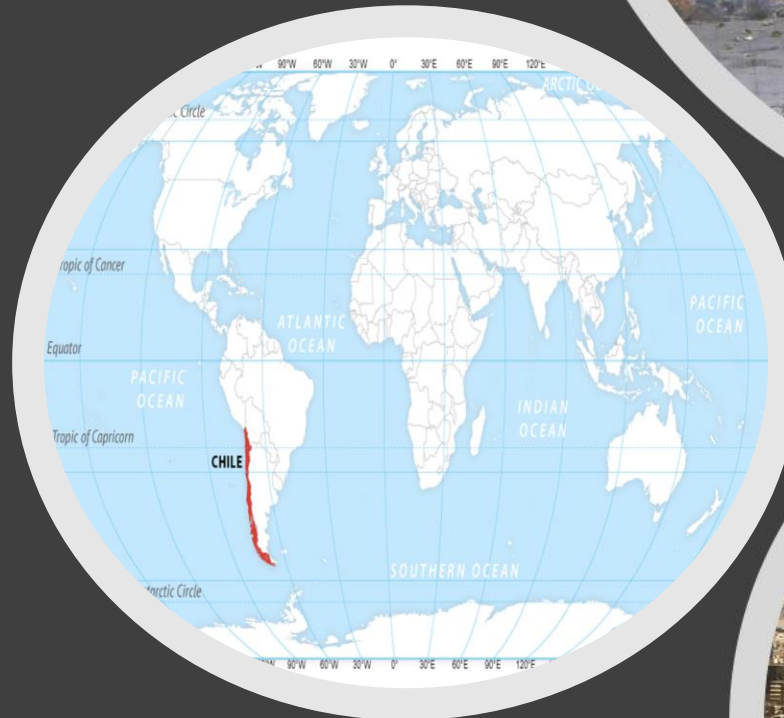
Incidence of FEP (2010-16)

15/100.000 person-years *

- Estimated FEP 140/y

Mixed Health System: 80% public 20% private

* Superintendencia de Salud de Chile, 2016.





Inpatient Treatment

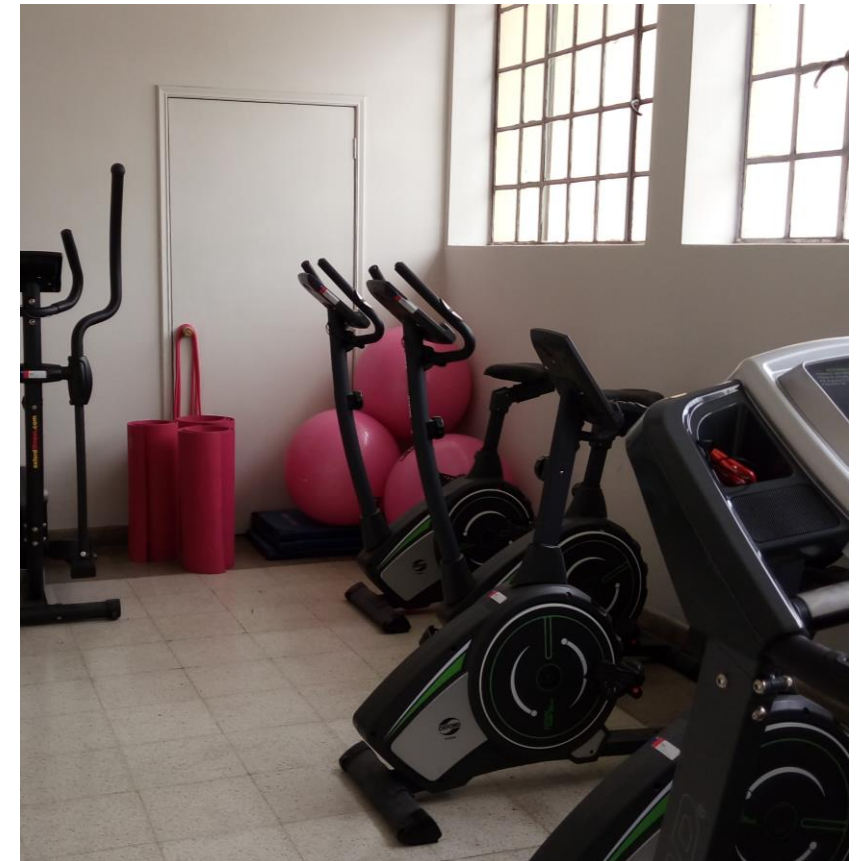
- Patients typically present with severe symptoms
 - Mean duration of untreated psychosis is 10.8 months
 - Mean days of hospitalization: 32
- Inpatients treated by multidisciplinary team of psychiatrists, psychologists, social workers, occupational therapists, and nurses
- Families participate through periodic meetings and a structured psychoeducation program



2014: Follow up cohort of First Episode of Psychosis patients

Public Funding for research

- Metabolic syndrome and healthy lifestyle Iruretagoyena et al. 2019
 - Neuroimaging Crossley et al. 2020
 - Treatment resistance Mena et al. 2018
 - Social determinants of mental health Crossley et al. 2018, Czepielewski et al. 2020, Castaneda et al. 2020
 - Epidemiology González-Valderrama et al. 2020
 - Public policies Aceituno et al. 2002
-
- MATRICS cognitive battery, physical exercise equipment, laboratory supplies, MRI



Autonomy and decisional capacity

Jeste et al. Schizophrenia Bulletin 2006
(n=12 studies)

Systematic review of studies with structured measures of decisional capacity

Results

Impaired decisional capacity:

Schizophrenia patients 10-52%

Controls 0-18%

Characteristics associated to impaired decisional capacity:

- hospitalized patients
- more negative symptoms
- more cognitive impairment

→ Substantial heterogeneity

→ Schizophrenia does not impair decisional capacity as a rule

Components of decision- making capacity

Hawkins et al. 2020

Important Note : Decisional capacity may vary over time:
Should be assessed relative to a specific decision at a particular time and context

1. **Understanding or comprehending** the meaning of the relevant information, including benefits and risks and alternatives
2. **Appreciation** of how the information applies and is relevant to one's own condition and situation.
3. **Reasoning** with the information provided or comparing options based on the person's values and beliefs. In other words, the ability to weigh risks and benefits and consequences of the decision.
4. **Evidencing or expressing** clearly a choice.
5. **Voluntary Choice**

Developing a consistent notion of decisional capacity

Grisso et al. 1995
Hawkins et al. 2020;
Rudnik 2002

Difficult in patients with some (but not all) mental capacities

- Protect those that cannot decide individually
- Avoid excluding subjects from decision making if possible
- Consider current values or preferences
- Define final decision-making authority

Standardized Instruments (MacCAT-T)

- Based on 4 components of decision making
- Criticism: insufficient, does not consider values, authenticity, emotions
- Depressed patients weight risks and benefits differently

What are we doing?



- Ask for consent to participate the days before discharge
- Treating physician decides when the patient has appropriate decisional capacity
 - Explains study to the patient and caregivers and asks for informed consent from both
- Pros
 - Permits a more comprehensive clinical and decisional capacity evaluation
 - Existence of a therapeutic relationship allows the patient and caregivers to ask questions openly in a protected and trustful environment.
- Cons
 - Less systematic evaluation
 - Risk of coercion

What are we doing?



- Why risk of coercion?
 - Patients are offered resources such as a cerebral MRI or cognitive evaluation otherwise unavailable
- How do we minimize risk?
 - Patients assured they would get treatment as usual according to Chilean laws independent from their decision
 - Always inform family and caregivers
 - No financial incentives to investigators or clinicians
 - May be influenced by personal or academic incentives

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Conclusions and recommendations

Patients cannot be declared incompetent based on their diagnosis

We should aim to protect a person's decisional capacity and assess it relative to a specific decision and context

We should aim to reduce behaviors that may undermine voluntariness, such as coercion.

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