

# RA1SE

## Recovery After an Initial Schizophrenia Episode

A Research Project of the NIMH

Robert Heinssen, Ph.D., ABPP  
Acting Director, Division of Services and Interventions Research  
National Institute of Mental Health

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**NIMH**  
National Institute of Mental Health

# Background

- The current paradigm for treating schizophrenia in the United States focuses on managing established illness and entrenched disability
- RAISE will test whether early, aggressive, and pre-emptive intervention can slow or halt clinical and functional deterioration in schizophrenia
- Improved functioning among individuals with schizophrenia may translate into significant cost savings for society

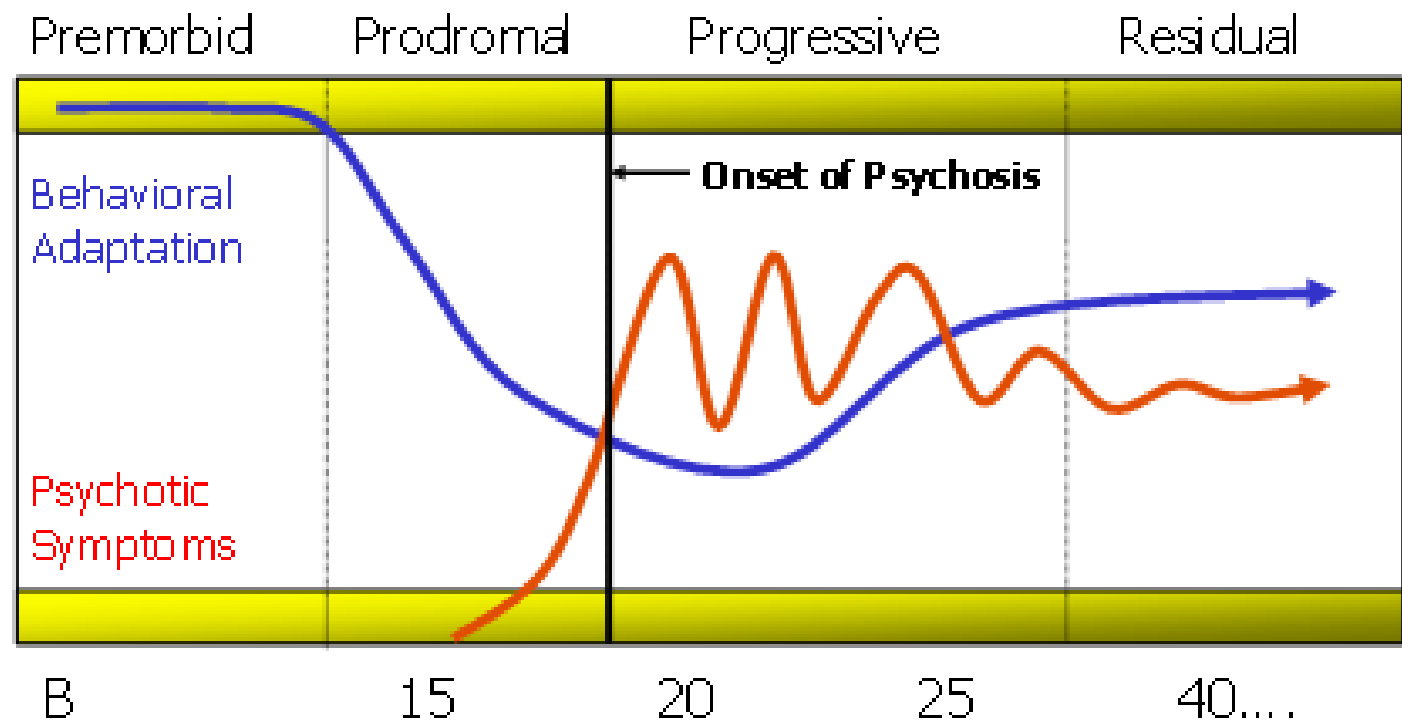


# Schizophrenia Facts

- Onset in late adolescence, early adulthood
- Psychotic symptoms, cognitive deficits, and social impairments contribute to disability
- Lifetime risk for suicide is ~5%
- ~2.5 million adults in U.S. are affected
- Economic cost of \$62.7 billion in 2002



# Clinical Course of Sz

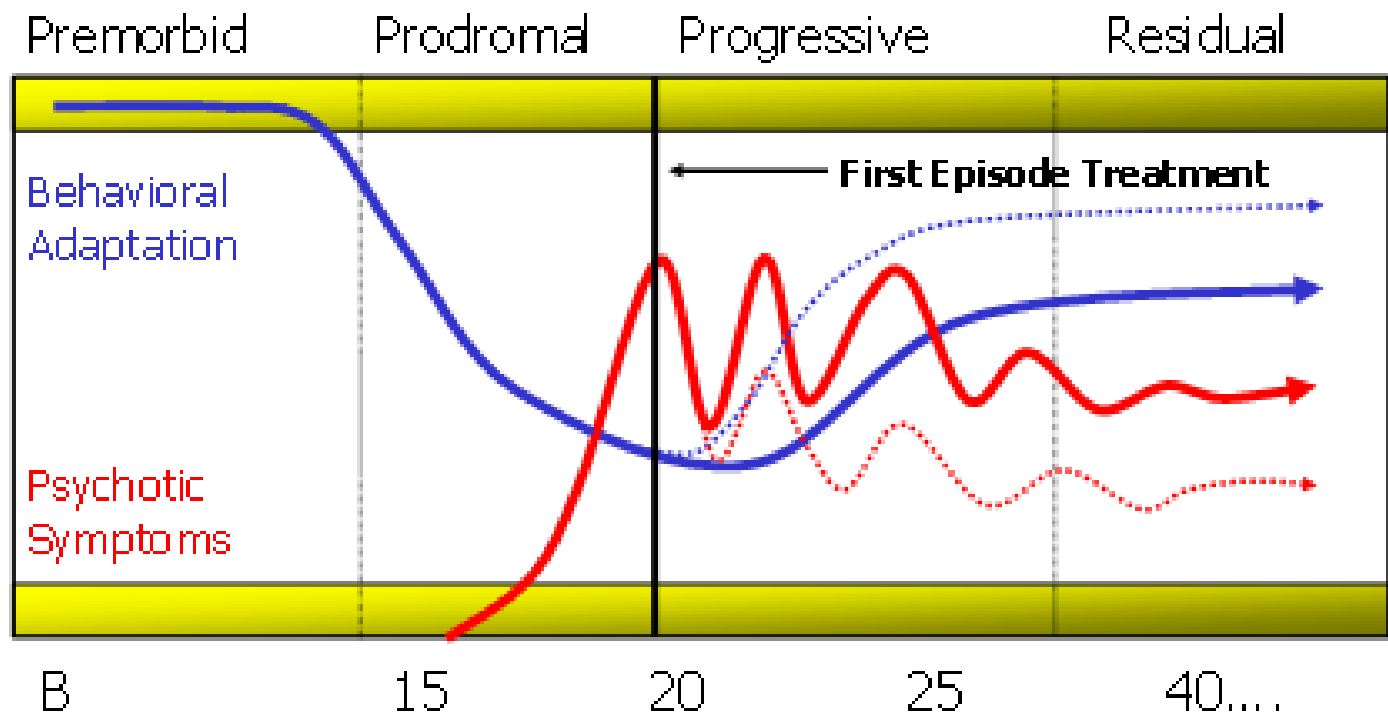


# Improved Outcomes for 1<sup>st</sup> Episode Psychosis

- Earlier treatment produces better outcomes:
  - Better response to antipsychotic medications
  - Better outcomes for social and vocational rehabilitation
  - Greater impact for psychological therapies that target residual symptoms, behavioral adaptation, and quality of life



# Early Intervention Is Key



# Projected Cost Savings

| Outcome                     | Degree of Improvement | Annual Cost Savings |
|-----------------------------|-----------------------|---------------------|
| Reduced Unemployment        | 10%                   | \$2.5 billion       |
|                             | 25%                   | \$6.3 billion       |
| Reduced Caregiver Burden    | 10%                   | \$0.9 billion       |
|                             | 25%                   | \$2.3 billion       |
| Reduced Justice Involvement | 10%                   | \$0.3 billion       |
|                             | 25%                   | \$0.8 billion       |
| Reduced Homelessness        | 10%                   | \$0.7 billion       |
|                             | 25%                   | \$1.9 billion       |

Leslie, D.L., The economic burden of schizophrenia in the United States: A report prepared for the National Institute of Mental Health, 2007.



# RAISE Objectives

- Design and test effective interventions for early phase schizophrenia that can be implemented on a population-level basis
- Engineer rapid adoption and implementation of effective treatment packages by engaging “end users” at the start of intervention development
- Assess clinical, functional, and economic outcomes
- Generate information relevant to key stakeholders, including health care policy makers



# Structure of Contracts

## Three Phase Project:

- Phase 1: Intervention development and refinement
  - *July 16, 2009 – Winter 2010*
- Phase 2: Feasibility testing of intervention
- Phase 3: Large scale practical clinical trial



# Project Teams

## **Feinstein Institute for Medical Research (FIMR)**

PI: John Kane, MD

- Zucker Hillside Hospital
- SUNY Downstate Medical Center
- University of Calgary
- University of Pittsburgh
- University of California, Los Angeles
- Univ of Medical and Dental of NJ
- Univ of North Carolina, Chapel Hill
- Yale University
- Univ of Texas SW Medical Center
- Weill Cornell Medical College
- Dartmouth University
- Nathan Klein Institute
- Burrell Behavioral Health

## **Research Foundation for Mental Hygiene (RFMH)**

PI: Jeffrey Lieberman, MD

- Columbia University
- University of Maryland, Baltimore
- Westat, Inc.
- Dartmouth University
- University of California, Los Angeles
- Duke University
- Univ of North Carolina, Chapel Hill
- University of California, Davis
- Beth Israel Deaconess Medical Ctr
- Sheppard Pratt



# Similarities

- Multi-modal, evidenced-based treatment
- Integrated treatment teams
- Personalized care
- Emphasis on engagement and recovery
- Client/family members involved in decisions regarding treatment choices



# Differences

- Financing structure for interventions
- Specific components of services offered
  - Medication algorithm
  - Domains addressed
- Approaches to treatment decision making
- Aspects of Phase 3 practical clinical trial design



# Trial Designs

|                      | <b>FIMR</b>                                       | <b>RFMH</b>  |
|----------------------|---|--|
| <b>Sample Size</b>   | 400   | 330  |
| <b>Ages</b>          | 16 – 40 years                                     | 15 – 35 years  |
| <b>Control Group</b> | Treatment as Usual (TAU)                          | TAU plus Case Management   |
| <b>Randomization</b> | Site (20 – 30)                                    | Individual   |
| <b>Financing</b>     | Reimbursement through public or private insurance | Reimbursement through public or private insurance; for noninsured, funding from state mental health authorities (NY, MD) |



# Stakeholders' Meeting

July 16-17, 2009

- “The aim is to incorporate feedback from key stakeholders outside of the investigative team to achieve broad-based consensus regarding the public health importance of the intervention and the scientific merit of the study design.”
  - Consumers and family members
  - Clinicians and mental health service administrators
  - Federal Agencies
  - Scientific community



# Consumers & Relatives

- Address language issues
  - Employ language consumers themselves use to describe the illness
- Importance of outreach to community settings to enhance recruitment
  - Churches, schools, primary care settings, emergency departments
- Achieve diversity among RAISE project staff



# Community Stakeholders

- Emphasis on the importance of cost and policy implications
- Need to look to the future shape of the healthcare system
- Consider implications for diverse clinical settings (e.g., rural locations)
- Incorporate technology to increase reach (e.g., Internet, telemedicine)



# Scientific Consultants

- Identify areas to crosswalk studies
  - Inclusion criteria
  - Outcome measures
  - Economic analysis
- Consider additional intervention elements (e.g., peer support, cognitive remediation)
- Identify ‘active ingredient’ within treatment package



# Federal Partners

- Costs
  - Determine useful outcomes for agencies
  - Document the reimbursement process
  - Document savings, spending, cost benefit, cost-effectiveness
- Educate consumers about initiative
- Continue Federal Involvement
  - DHHS Assistant Secretary for Planning and Evaluation, Office of Disability, Aging and Long-Term Care Policy



# Next Steps

- Data harmonization meeting, Fall 2009
- ASPE DALTCP review of financing mechanisms for early psychosis treatment, Fall 2009
- Phase 2 to start Winter 2010
- Phase 3 to start Winter 2011

