

Recovery After an Initial  
Schizophrenia Episode (RAISE)  
– Impact Evaluation Study

# Background

- A gap in our knowledge of system integration strategies was identified that led to the need to conduct a study of **how to integrate an early intervention program into an existing service system.**
- Study emphasis is not an effectiveness evaluation of the intervention, but an **Impact Evaluation Study (IES).**
- The IES will use the intervention model developed to identify strategies to facilitate the implementation of team-based care for first episode psychosis (FEP) within the U.S. healthcare system.

## RAISE-IES Specific Aims (1):

- To adapt and evaluate the *impact* of a comprehensive and integrated treatment intervention for FEP to be delivered in real-world practice settings to promote symptomatic recovery, minimize disability, and maximize social, academic, and vocational functioning.

# RAISE-IES Specific Aims (2):

- To gather information on how well the early intervention program works within participating sites, e.g.,
  - the success of referral networks and recruitment activities;
  - the extent to which providers accept specialized training and supervision;
  - whether administrative support of program activities are maintained over time

## RAISE-IES Specific Aims (3):

- To delineate and develop the manuals, checklists and quality indicators necessary to establish first episode psychosis treatment programs within real-world service systems, as well as determine effective strategies for the engagement and retention of individuals with FEP into long-term treatment.

# Deliverables Overview

- Specific Aims
  - The treatment package itself
    - has been delivered to NIMH.
  - Experiences of Implementation
    - Case Study Reports (“What we did”)
  - Tools necessary to “embed the multi-component intervention within real-world delivery systems” (“What we learned”)
    - Turn-key manuals
    - Barriers
    - Financing

# Sources of “Data”

- Recruitment/Outreach Database: NY and MD recruitment staff collected detailed data on all calls and inquiries
- Impact Study (Quantitative Data): Participant interviews were conducted at Baseline, 3, 6, 12, 18 and 24 months
- Qualitative Study: Interviews of participants, family members, clinicians, administrative staff, and referrers
- Clinical Materials/Manuals

# Assessment and Follow-up Rates

Schedule	Total Anticipated	Total Completed	Number Missed	Not in Window or Being Scheduled	% Follow Up
Baseline	60	60	0	0	100% (60/60)
3-Month	59	55	1	3	98% (55/56)
6-Month	58	49	2	7	96% (49/51)
12-Month	54	21	6	27	78% (21/27)
18-Month	51	6	2	43	75% (6/8)
24-Month	23	0	2	21	0% (0/2)



# Statistical Analysis Plan for RAISE Connection Program

# Overview

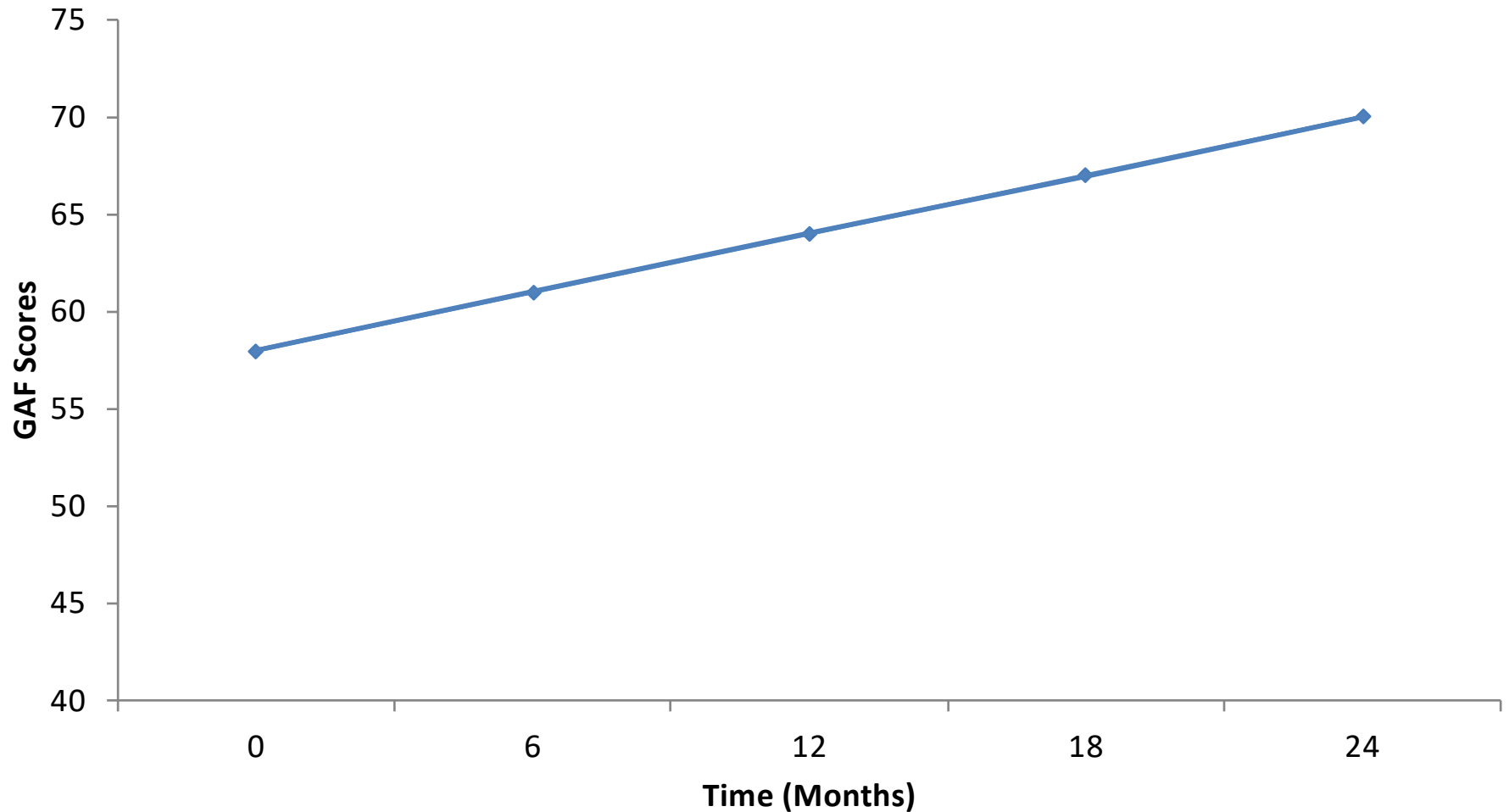
- “Quantitative” data and collection schedule
- Preliminary analysis
  - Data quality check; Descriptive statistics; Checking distributional and linearity assumptions
- Primary outcome data analysis
  - Longitudinal data analysis to assess improvement over time
- Service utilization and engagement
- Secondary data analyses
  - Secondary outcome measures
  - Moderator and mediator
    - Fidelity data

# Primary Outcome Data Analyses

- Primary outcomes
  - MIRECC GAF scores
  - PANSS scores
  - Total months of remission
- Longitudinal analysis using all interim data
  - Five assessments (baseline, 6 month, 1 year, 18 month, 2 year)

# Primary Outcome Data Analyses

## Expected Change Over Time of MIRECC GAF



# Service Utilization and Engagement

- Frequency distributions of services received
  - RAISE services report for each participant quarterly (chart review)
  - Non-RAISE services from self-report
- Hospitalization and ER visits from self report
  - Total number of hospitalizations
  - Total number of ER visits

# Secondary Outcome Measures

- Clinical Global Improvement (CGI)
- Participation in the work force
- Education
- Other

# Secondary Data Analyses: Moderator

- Hypothesized moderators (baseline pre-treatment measures)
  - Duration of psychosis
  - Age
  - Premorbid adjustment scale
  - Baseline cognitive battery
  - Prior hospitalization
  - Family interaction
  - Negative symptom subscale from PANSS
- Moderator analysis: test for time by moderator interaction

# Secondary Data Analyses: Mediator

- Hypothesized mediators (post-treatment measures)
  - Fidelity (overall and specific component)
  - Engagement
    - Service utilization
    - Client satisfaction
    - Service-related recovery
- Mediator analysis
  - Test for significant indirect treatment effect through a candidate mediator



# Fidelity as Mediator

- Fidelity components
  - Core Fidelity (e.g., staffing over time)
  - Psychopharmacology Intervention Fidelity (e.g., % on antipsychotic over time)
  - IPS Fidelity (e.g., % employed or in school over time)
  - Family Intervention Fidelity (e.g., family groups over time)
  - Team Recovery Coach Fidelity (e.g., substance use sessions over time)

# Proposed Engagement Measures: Service Utilization

Engagement as treatment participation (low threshold)

- Individuals with at least one visit in each three-month interval will be considered engaged during that interval.

Engagement as treatment participation (higher threshold)

- Individuals with at least one visit in each one -month interval will be considered engaged during that interval.

Engagement as treatment participation with team (low threshold)

- Individuals with at least one visit in each three-month interval to at least three of four team members will be considered engaged with the team during that interval

Engagement as treatment participation with team (higher threshold)

- Individuals with at least one visit in each one-month interval to at least three of four team members will be considered engaged with the team during that interval

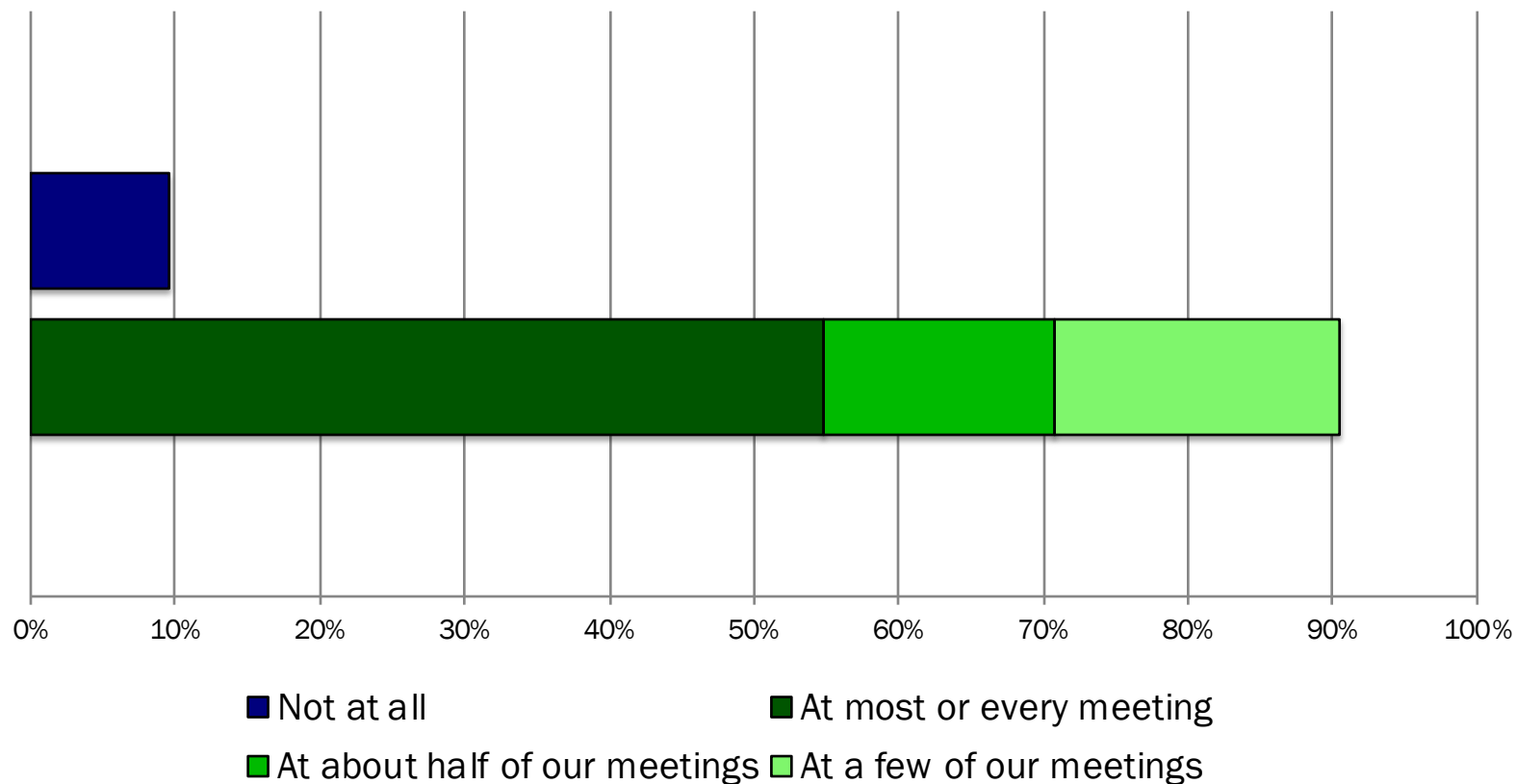
# Proposed Engagement Measures: Other

- Overall satisfaction with services
- Recovery orientation of services
- Given the potential importance of medication in preventing relapse, medication adherence could be viewed as a proxy for engagement.

# Engagement and Fidelity Measure Examples

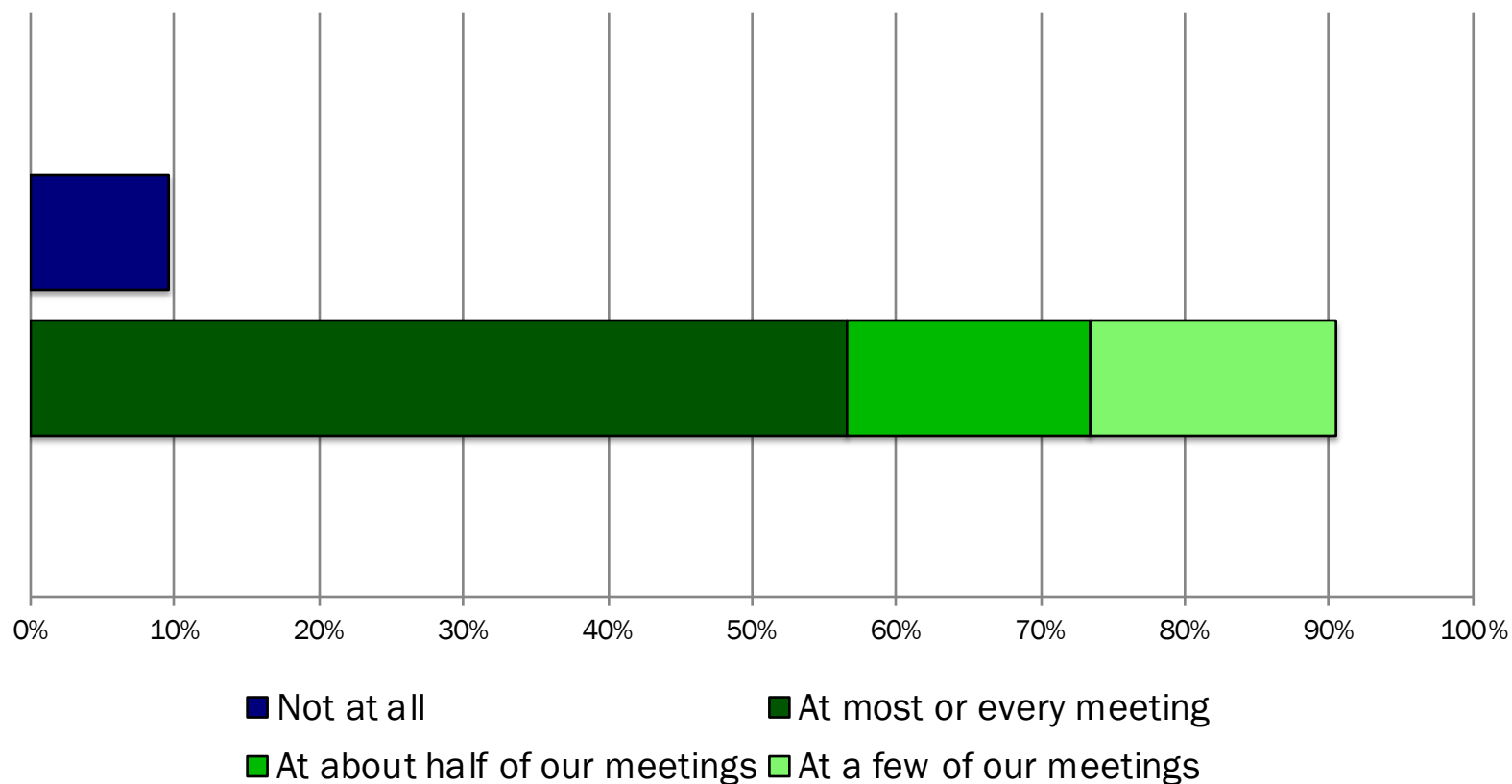
## When you meet with your Connection Team psychiatrist...

**...how often does the topic of medication side effects come up?**

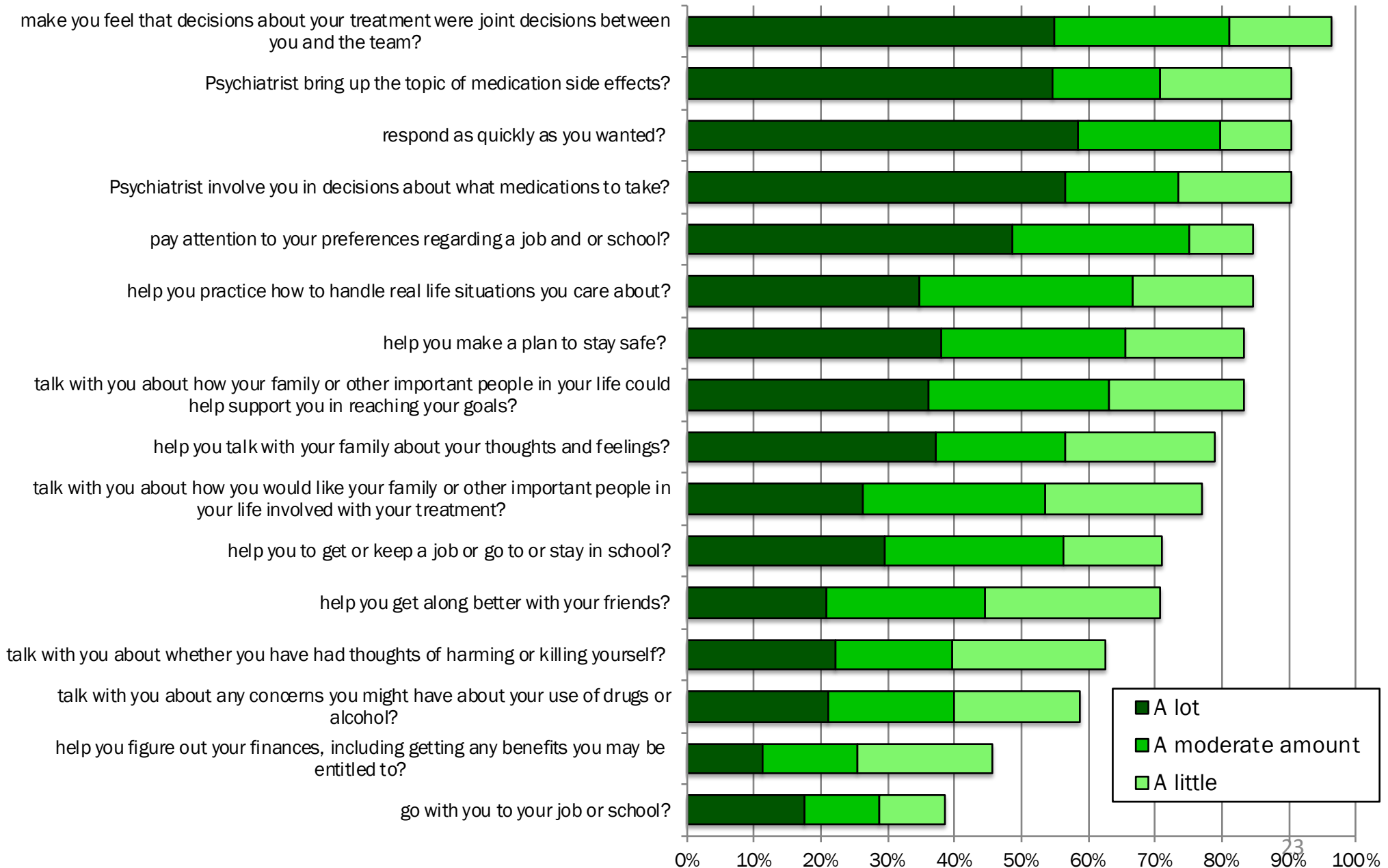


## When you meet with your Connection Team psychiatrist...

**...how often does your psychiatrist involve you in decisions about what medications to take?**



# In the past month, how much did your Connection Team...



# In the past month, how much did your Connection Team...

