

*Assessment of Social and Instrumental
Functioning in Schizophrenia:
Balancing Reliability and Validity*

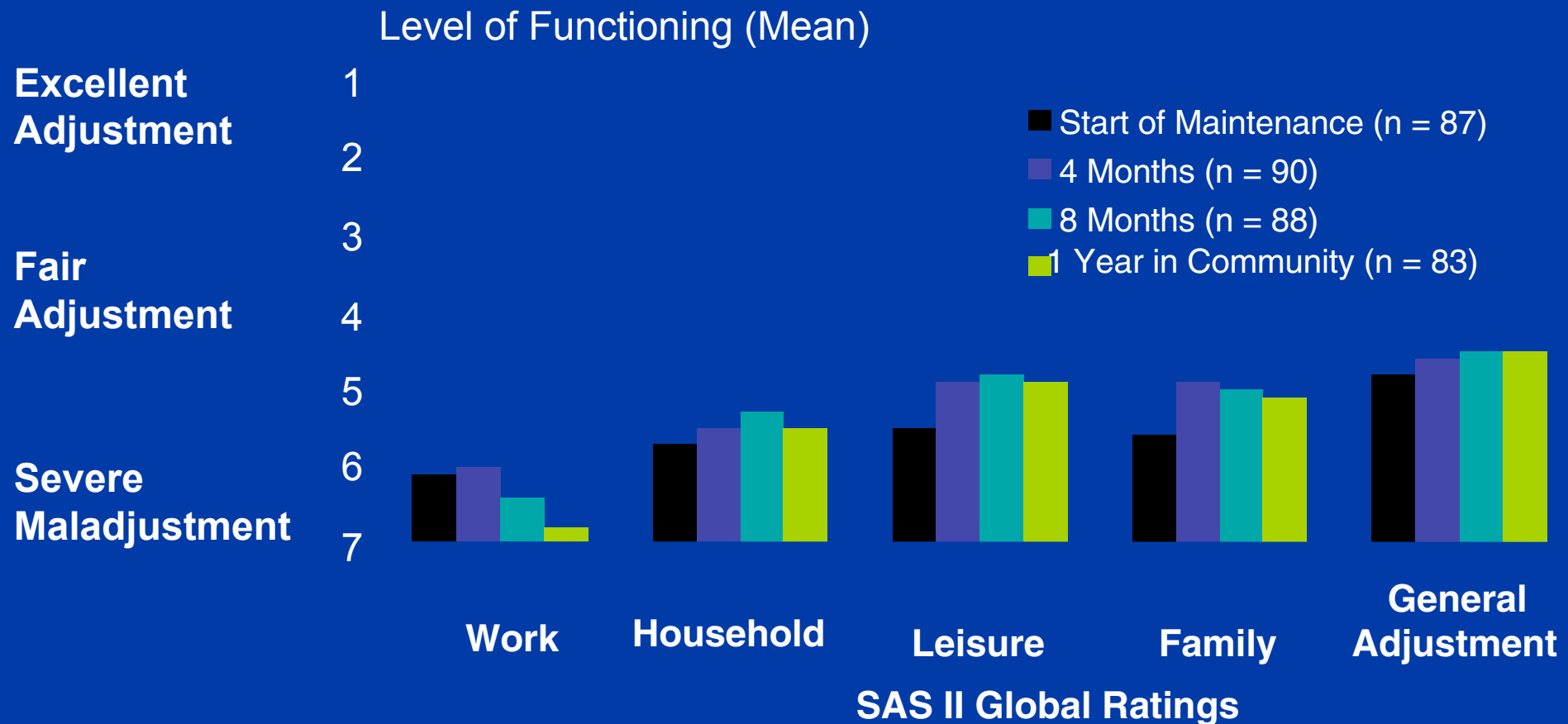
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Disclosure of Commercial Interest

| Name | Type of Affiliation | Commercial Entity |
|-------------------|---------------------------|---|
| Schooler, Nina R. | Grant/Research Support | Astra Zeneca Bristol Meyers Squibb Eli Lilly and Company Janssen Pharmaceutica Pfizer Inc |
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Ratings of Social Adjustment Over 1 Year

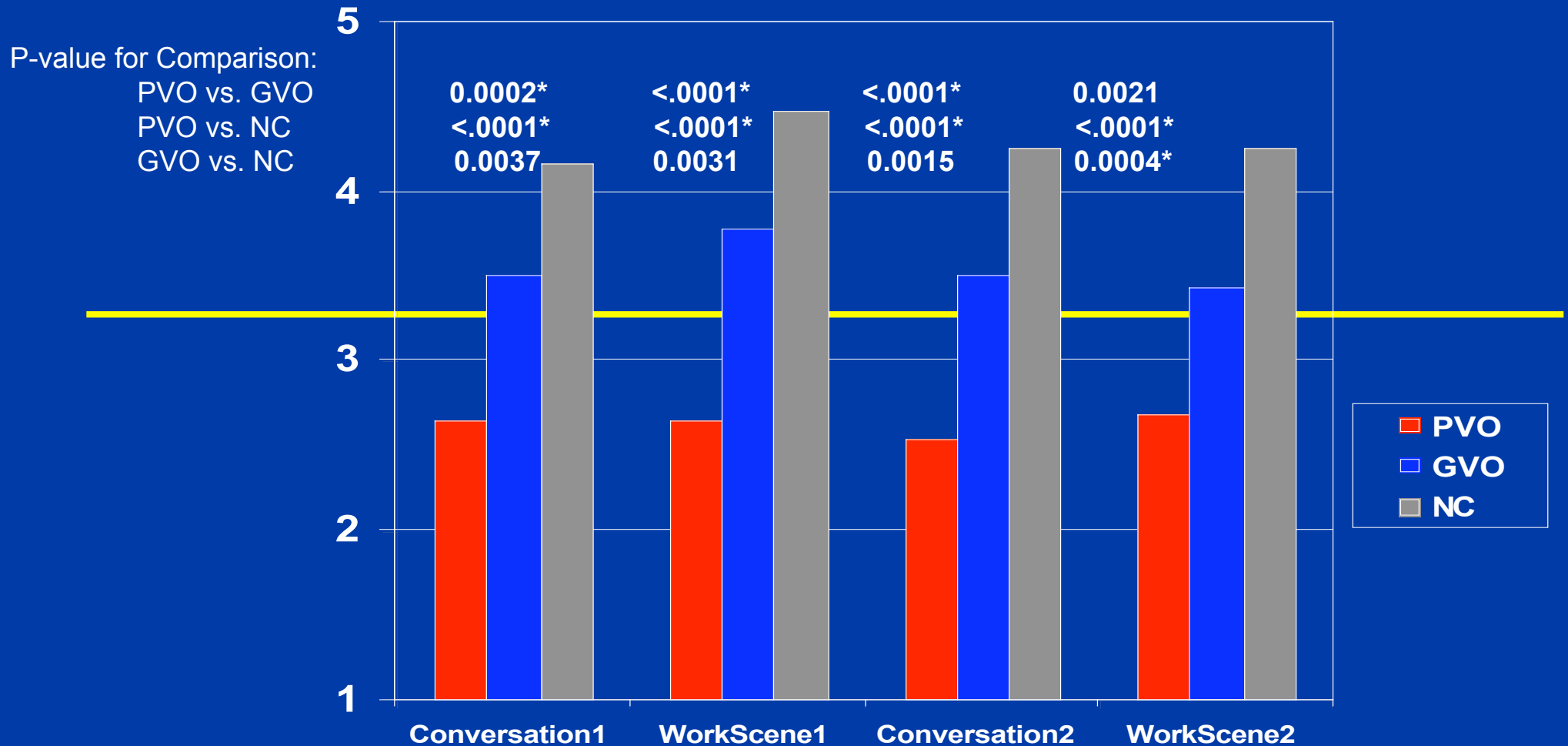
Non relapsed patients receiving oral or depot medication



What do these data tell us?

- Ratings based on semi-structured patient interview
- Absence of clinical relapse does not translate into improved functioning
- Overall level of functioning is very poor
 - Maybe better with newer agents?
- Work functioning looks even lower than other areas
- Measures all show test-retest reliability
- No information about *actual* functioning

Social Skill of Patients with Good and Poor Vocational Outcomes



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What do these data tell us?

- Groups are defined by objective indices of vocational status
- Social skills are correlated with vocational outcome
- Correlation is *not* causation
 - Will change in social skills translate to change in work?
- Overall skill level even for good vocational outcome is below that of controls

Key Domains of Functional Outcome

- Work - objective measures
- Housing – objective measures
- Social interaction – report or observation
 - Friends/peers
 - Family
- Financial Management – objective measures
- Happiness and life satisfaction - self report

Information Sources for Domains of Functional Outcomes

| Domain | External Data Source | Simulation | Informant Report | Self Report |
|--------------------|----------------------|------------|------------------|-------------|
| Work | Gold stand | Available | Available | Available |
| Housing | Gold stand | NA | Available | Available |
| Social Interaction | NA | Gold stand | Available | Available |
| Finances | Gold stand | Available | Available | Available |
| Satisfaction | NA | NA | NA | Gold stand |

Time Frame for Functional Outcomes: Likelihood of Detecting Change

| Domain | 12 weeks | 6 months | 12 months | More than 1 year |
|--------------------|----------|----------|-----------|------------------|
| Work | No | Unlikely | Possible | Probable |
| Housing | No | Possible | Probable | Probable |
| Social Interaction | Possible | Probable | Probable | Probable |
| Finances | No | Unlikely | Possible | Probable |
| Satisfaction | Probable | Probable | Probable | Probable |

The ideal measure in the ideal trial

- Integrates sources of information based on “gold standard”
 - Employment and housing records
 - Simulated situations
 - Informant information
 - Self report
- Trial duration is adequate to allow detection of changes in functioning
- Relapse prevention trials provide appropriate model

Plausible measures in plausible trials

- Integrates sources of information based on heuristics
 - Simulations
 - Informant report
 - Self report
- Trial duration defined by hypothesized change in other measures
 - Changes in functioning hypothesized to follow
 - Analagous to prodromal signs of relapse

Conclusions

- Changing functional outcomes in schizophrenia requires specific interventions beyond prevention of relapse
- Detecting such changes will require longer clinical trials
- Ideal measures of outcome will integrate multiple sources of information
- Shorter trials may benefit from use of proxy measures such as simulations