Impact of Managed Problem Solving Antiretroviral Adherence Intervention on HIV Copy-Years

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Disclosure

• Federal support
  – NIMH: R01 MH067498
  – NIAID/AHRQ/NINR
• Foundation
  – DDCRF
• Industry
  – BMS
  – Abbott
Problem Solving for Adherence

- Depression is major adherence barrier
- Multifactorial nature of both depression and non-adherence
- Problem solving already adapted
  - Cancer and HIV respite care
  - Obesity
Problem Solving Therapy vs. Treatment

• Therapy requires training
  – Many sessions
  – Patients need motivation
  – Added burden of homework

• Treatment
  – Goal is just solving problems
  – Problem solver is part of team
Conceptual Framework

**Adherence and Implementation Feedback**

- **Clinician**
- **Interventionist**
- **Patient**

**Tools:** medical information, facilitating routines, memory aids, social supports enhancement, mental health resources, toxicity management
Defining the Problem
Brainstorm
Decision re: Plan
Implement Plan
Assessment and Modification

Plan → Assessment Cycle → Analyze → Improve → Assess → Plan
MAPS Study Design

- Train interventionists to deliver MAPS
  - College graduate
  - Familiar/comfortable with HIV topics
  - Health background not necessary

- Randomize 1:1 to MAPS vs. Usual Care (UC)
Eligibility Criteria

- HIV-1 infection
- Age $\geq 18$ years
- HIV VL $\geq 10^3$ copies/ml
- Any CD4 count
- Not living in care facility
- Able to consent
- Initiating an active regimen
Baseline Screening

• **Assessment of adherence barriers**
  – Knowledge of regimen
  – Knowledge of desirable adherence
  – Plans if doses missed
  – Depression
  – Substance Use
Delivery of Intervention

• Initial visit
  – Duration 60-90 min

• 3 monthly follow-up visits with adherence feedback via MEMS
  – Duration 45-60 min

• Weekly phone calls for 3 mo
  – Duration 5-20 min

• Monthly refill calls for 1 yr
  – Duration 1-5 min
Outcomes

• **Primary: adherence**
  - Measured continuously using MEMS
  - Summarized quarterly: % doses taken

• **Secondary: HIV VL**
  - Measured quarterly
  - VL<75 copies/ml
  - HIV copy-years = average viral load over each quarter x 3 months, and summed over the year
ITT vs. AT

• Intent to Treat
  – Primary analysis approach
  – Strategy trial—all subjects evaluated

• As Treated
  – Secondary analysis approach
  – Provides useful data on patients remaining in care
Assessed for eligibility (n=218)

Excluded (n=38)
- Not meeting inclusion criteria (n=21: 14 inappropriate regimen, 7 viral load < 1000 copies/ml)
- Declined to participate (n=10)
- Enrolled in another study with adherence intervention (n=7)

Enrolled (n=180)

Allocated to MAPS (n=91)

- Lost to follow-up (n=33)
  - No longer willing to follow protocol (n=8)
  - Lost to clinical care (n=11)
  - Moved away from study center (n=8)
  - Death (n=1)
  - Other (incarcerated, stopped rx) (n=5)

Allocated to UC (n=89)

- Lost to follow-up (n=23)
  - Not willing to follow protocol (n=2)
  - Lost to clinical care (n=13)
  - Moved away from study center (n=1)
  - Death (n=1)
  - Other (incarcerated, stopped rx) (n=6)
<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>MAPS (n=91)</th>
<th>UC (n=89)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age (range), yrs</td>
<td>43 (20-65)</td>
<td>42 (19-60)</td>
</tr>
<tr>
<td>Male sex</td>
<td>52 (57%)</td>
<td>56 (63%)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>80 (88%)</td>
<td>73 (82%)</td>
</tr>
<tr>
<td>White</td>
<td>9 (10%)</td>
<td>15 (17%)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (2%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Treatment naïve</td>
<td>40 (44%)</td>
<td>32 (36%)</td>
</tr>
<tr>
<td>Baseline VL (log\textsubscript{10} copies/ml)-Q25,75</td>
<td>3.24 (2.46, 4.32)</td>
<td>3.47 (2.35, 4.40)</td>
</tr>
<tr>
<td>Baseline CD4 count cells/mm\textsubscript{3}- Q25,75</td>
<td>287 (146, 370)</td>
<td>244 (116, 379)</td>
</tr>
</tbody>
</table>
Adherence Results

• MAPS associated with higher adherence
  – ITT: Odds of being in a higher category of adherence $1.78 \ (1.07\text{-}2.96)$ for MAPS vs. UC
  – AT: Odds of being in a higher category of adherence $2.33 \ (1.35\text{-}4.05)$ for MAPS vs. UC
VL Results

- **MAPS** - higher odds of UDVL
  - ITT: Odds of UDVL = 1.48 (0.94-2.31) favoring MAPS
  - AT: Odds of UDVL = 1.98 (1.15-3.41) favoring MAPS

- **MAPS** - lower HIV copy-years
  - ITT: MAPS: 1.54 vs. UC: 2.02 log copy-years, p=0.046
  - AT: MAPS: 1.36 vs. UC: 1.87 log copy-years, p=0.027
Limitations

• Generalizability
  – Specialty clinic population
  – Use of MEMS for feedback

• Evidence for effect
  – Mixed conclusion on virologic effect

• Bias
  – Unclear how dropouts affected true impact of intervention
Conclusions and Next Steps

- MAPS effective at improving adherence and virological outcome
  - Refine and disseminate
- Adapt to VA System
  - MAPS-EXTRA
  - Use pharmacy refill system
- Modify approach to use for retention
  - PREPARE
Acknowledgements

- **Research Faculty**
  - Brian Strom MD MPH
  - James Coyne PhD
  - Steven Palmer PhD
  - Thomas Ten Have PhD (deceased)
  - Scarlett Bellamy ScD
  - Peter Houts PhD

- **Clinical/Pharmacy Faculty**
  - Janet Hines MD
  - Susan Hansen-Flaschen CRNP
  - Eileen Hollen CRNP
  - Ian Frank MD
  - Pablo Tebas MD
  - Jay Kostman MD
  - Phil Green MD
  - Amy Graziani PharmD
  - Rose O’Flynn PharmD

- **Research Staff**
  - Jennifer Chapman MPH
  - Jacqueline O’Duor MSW
  - Christina Psaros PhD
  - Randy Shine BA
  - Lori Kishel MSW
  - Sherry Han MS
  - Alice Liao
  - Michelle Legaspi-Sanchez
  - Courtney McCuen

- **Research Volunteers**
  - Alyssa Huegel
  - Aman Shah
  - Becca Platoff
  - Hauchie Pang
  - Jing Ren
  - Katie Brown
  - Liz Kern
  - Luv Patel
  - Nithin Paul
  - Sarah Barenbaum
  - Tony Rizzo
  - Wan Jun Lim
Thank you to:
NIMH, referring providers and study participants!