Guiding Good Choices for Health (GGC4H)

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Brief Overview

- **6- Session virtual Universal Prevention program for all parents of adolescents ages 11-14**
- **Evaluated in previous RCTs**
  - ✓ Affects **Parenting Behavior** regardless of family risk (Spoth et al., 1998)
  - ✓ Reduced Growth in **Substance Use, Delinquency; Depressive Symptoms** (Mason et al., 2003, 2007)
  - ✓ **Cost-beneficial:** Benefit-Cost Ratio: $2.77 (WSIPP, 2018)

SOCIAL DEVELOPMENT RESEARCH GROUP, University of Washington

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Current Status

1. Recruitment. Two cohorts of eligible adolescents born between 6/1/2007 and 5/31/2008 (Cohort 1) or 6/1/2008 and 5/31/2009 (Cohort 2), were 1,975 adolescents recruited and assented, and whose parents consented (n=1,975; 24% of those eligible). 75 pediatricians across 3 sites.
2. Follow-ups. 12-mo – 64% RR (78% - 49% across sites); 24-mo – 66% RR (70% - 58% across sites). Starting on 24-mo for Cohort 2
3. Data cleaning, analysis
4. Manuscript preparation (1 paper published; 1 under review; 9 in process; 14 planned); other dissemination (13 conference presentations, 2 accepted)
5. Examining implementation outcomes

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Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects				X	
Engagement of clinicians and health systems	X				
Data collection and merging datasets			X		
Regulatory issues (IRBs and consent)		X			
Stability of control intervention	X				
Implementing/delivering intervention across healthcare organizations			X		

*Your best guess! 1 = little difficulty 5 = extreme difficulty

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Top Challenges

1. Pandemic (*of course!*) and all its sequelae: drastic decrease in in-person Pediatrics visits; adaptation of GGC from in-person to virtual modality
2. Resources and staffing
3. Recruitment: prevention is a hard sell, busy parents, pandemic overwhelm and then fatigue, then societal reopening
4. Considering future adoption and implementation
5. Cross-site variations in workflows, technologies, data

Recent Generalizable Lessons Learned

- Telehealth behavioral health programs are acceptable to families and feasible within the health system context. They do not appear to exacerbate disparities and may, in fact, increase access for under-served populations.
- Balancing methodological rigor and real-world clinical workflows is possible, but can be challenging: e.g., GGC4H partial cross-classification in intervention arm required considerable collaborative between study team and Methods Core to develop a suitable approach.
- Do not assume you can rely solely on EHR data, even in a pragmatic trial; you may need to conduct primary data collection

Current Data Sharing Plan & Obstacles

- **Internal Data Sharing Plan**
  - ✓ Executed data sharing agreements among 4 site partners, to account for various types of data with different levels of potential identifiers (EHR, Survey, Qualitative Interviews, Focus Groups).
  - ✓ Sharing cleaned, combined datasets between sites.

- **External Data Sharing Plan: Supervised Data Archive with Monitored data sharing**
  - ✓ Protect against deductive disclosure.
  - ✓ De-identified individual data.
  - ✓ Requests must be of high scientific merit.
  - ✓ Co-authorship of at least one study PI or MPI.

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Rules for External Data Sharing

- **Compliance with GGC4H Data Use Agreements.** Approved requests for data must be compliant with the existing data sharing agreements between the four participating sites.

- **Fair Use Agreement.** Researchers approved to use data will be required to sign a Fair Use Agreement prior to receiving data. This agreement affirms the commitment of all parties to avoiding deductive disclosure and protecting the privacy and confidentiality of participants and proprietary information of the four study sites.

- **Documentation.** Data documentation will clearly describe each variable in the dataset, which instrument supplied that variable, and what each code for each variable represents.

Rules for External Data Sharing cont.

- **Resources Not Reported in Published Studies.** In the case of resources not yet reported in the published literature, the GGC4H team reserves primary right to examine and publish on them. Other researchers will be able to use these with permission, but on a more restricted basis, and with the explicit understanding of collaborative use with the GGC4H team, and future co-authorship with members of the team.

- **Data.** Researchers outside of the HCS Collaboratory and GGC4H team may use data from GGC4H in accordance with all principles outlined in the Resource and Data Sharing Plan, including but not limited to measures to ensure the confidentiality and privacy of participants and proprietary information for any involved institutions.

- **Authorship.** Any manuscripts, publications, presentations, reports, and the like will include co-authorship with one or more Parent Study Team members (e.g., at least one PI on the project for which the data were collected) and acknowledgement of the HCS Collaboratory and study funder.

Data We're Planning to Share

- A final, de-identified research dataset upon which the accepted primary pragmatic trial publication or other manuscripts are based

Thank You!

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