Guiding Good Choices for Health (GGC4H): Update and Lessons From the UG3 Phase

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Presentation to NIH Collaboratory Annual Meeting. May 1, 2019.
# GGC4H Multi-site Pragmatic Trial - Leadership Team

## Guiding Good Choices for Health (GGC4H)

<table>
<thead>
<tr>
<th>University of Washington</th>
<th>Kaiser Permanente Northern CA</th>
<th>Kaiser Permanente Colorado</th>
<th>Henry Ford Health System</th>
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<tbody>
<tr>
<td>Richard Catalano, MPI</td>
<td>Stacy Sterling, MPI</td>
<td>Arne Beck, Site PI</td>
<td>Jordan Braciszewski, Site PI</td>
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<td>Margaret Kuklinski, MPI</td>
<td>Rahel Negusse, Site PD</td>
<td>Jennifer Boggs, Site PD</td>
<td>Amy Loree, Site PD</td>
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<td>Sabrina Oesterle, PhD Methodologist</td>
<td>Charles Quesenberry, PhD, Lead Biostatistician</td>
<td>Matt Daley, MD Physician Leader</td>
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<td>Kevin Haggerty, PhD GGC Master Trainer</td>
<td>Oleg Sofrygin, PhD, Biostatistician</td>
<td>Constance Weisner, PhD, Senior Leader</td>
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<td>Kathryn McCollister, PhD</td>
<td>Hendricks Brown, PhD</td>
<td>Lauren Hartman, MD, Physician Leader</td>
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<td>Ellen Perrin, MD</td>
<td>John Graham, PhD</td>
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**Consultants**

- Hendricks Brown, PhD
- John Graham, PhD
- Kathryn McCollister, PhD
- Ellen Perrin, MD

**Kaiser Permanente Colorado**

- Arne Beck, Site PI
- Jennifer Boggs, Site PD
- Matt Daley, MD Physician Leader

**Henry Ford Health System**

- Jordan Braciszewski, Site PI
- Amy Loree, Site PD

**NIH Leadership**

- **NCCIH**
  - Robin Boineau, MD, Project Officer

- **NIDA**
  - Jacqueline Lloyd, PhD, Project Scientist

- **Ad Hoc Members**
  - Qifu Yu, PhD, NCCIH
  - Elizabeth Nielsen, PhD, ODP
  - Erica Spotts, PhD, OBSSR

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National Center for Complementary and Integrative Health, National Institute on Drug Abuse, Office of Disease Prevention, and Office of Behavioral and Social Sciences Research.
Guiding Good Choices (GGC)

- 5- Session program for all parents of adolescents ages 11-14
- Evaluated in two 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)

**Sessions emphasize**
- Build family bonding
- Establish and reinforce clear and consistent guidelines; monitor children’s behavior
- Teach children skills to resist peer influence
- Improve family management practices
- Reduce family conflict

**GGC is organized around substance use prevention delivered universally, but skills generalize to other parenting concerns.**

<table>
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<tr>
<th>GUIDING GOOD CHOICES SESSIONS</th>
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<tr>
<td>Session 1</td>
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<td>Session 2</td>
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<td>Session 4</td>
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<td>Session 5</td>
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GHC Helps Fill a Service Gap in Pediatric Primary Care

- AAP recommends pediatricians provide anticipatory guidance to parents – but there are barriers to doing this.

- Instead: Have pediatricians refer parents to GGC for delivery by behavioral health specialists within each HCS.
  - Pediatricians have high credibility and parents’ trust. They are good agents for validating positive parenting practices.
  - Care provided in a pediatric primary care setting is non-stigmatizing.

➔ Advantages may create higher recruitment and retention rates in primary care compared to community settings.

➔ This pragmatic trial, set in the context of real-world health systems, will allow us to examine recruitment and retention outcomes as well as adolescent behavioral health impacts.
GGC4H: 4-Year Pragmatic Trial

- **Longitudinal cluster-randomized trial in 3 HCS:**
  - Kaiser Permanente Northern California, Kaiser Permanente Colorado, Henry Ford Health System
  - Randomize pediatricians within clinic and HCS (24 per HCS), approximately 3,636 families recruited to experimental or control arm

- **Implement GGC universally during two years (Y2, Y3 of study)**
  - Intervention arm pediatricians refer all parents of adolescents ages 12 during well-child visit
  - 2 GGC delivery modalities: Group and self-guided

- **RE-AIM* framework** used to evaluate implementation and effectiveness outcomes through Y5
  - **Implementation**: Reach, adoption, fidelity, participant engagement and skills
  - **Effectiveness**: Evaluate GGC’s impact on adolescent substance use initiation at Year 5 endpoint

*Reach, Effectiveness, Adoption, Implementation, Maintenance*
## Project Status: A Very Busy UG3 Year!

### INTERVENTION
- Develop, finalize self-guided intervention
- Intervention available – all sites
- Implementation and recruitment tools

### DATA COLLECTION/EHR
- Design finalized
- Develop, finalize data collection methods
- Finalize plans for ascertaining primary endpoint

### SITE IMPLEMENTATION
- Develop, finalize recruitment methods
- Engage HCS practitioners
- Train all personnel
- Finalize sub-contracts

### OVERSIGHT
- Develop Governance Plan
- Establish study-related committees
- Finalize design, analysis plan
- DSMB approval
- IRB approval

### ADMINISTRATIVE
- Protocol to NIH for initial review
- Protocol to PRC
- Transition Request to NIH

- **Completed an ambitious set of milestones**
- **Pilot Study conducted at all sites (5 clinics)**
- **Transition Request made, 3 NCCIH reviews, 2 PRC meetings**
- **Awaiting UH3 funding decision**
Challenge 1: Study Design

**Goal: Answer 2 critical study questions**
1) Assess GGC effectiveness
2) Understand GGC uptake in naturalistic setting

**Original study design**
Pragmatic but problematic: Selection bias, no pre-intervention baseline data.

**Final study design**
1) Design challenges solved with input from Biostats core, PRC, and our own creative thinking
2) Allows us to address GGC effectiveness and uptake questions
GGC4H Effectiveness Design

**Intervention Arm**
- Adolescent Recruitment to Study
  - Yes to Study: Adolescent Baseline Survey
    - Pediatrician letter/email recommending GGC to parents
  - No to Study

**Control Arm**
- Adolescent Recruitment to Study
  - Yes to Study: Adolescent Baseline Survey
  - No to Study

**Randomize Pediatricians**

**GGC INTERVENTION**
- Well Visit: Pediatrician makes in person referral to GGC (in addition to letter/email).
  - Study team reaches out to parents to enroll in GGC
  - GGC Group Intervention
  - GGC Self Guided Intervention
- No Well Visit: No pediatrician in person referral.

**Annual Follow up Assessments**
GGC INTERVENTION

Yes to Study: Adolescent Recruitment to Study

Pediatrician letter / email recommending GGC to parents

Well Visit: Pediatrician makes in person referral to GGC (in addition to letter / email).

Study team reaches out to parents to enroll in GGC

GGC Pre Implementation Assessments: Enrollment, Pretest

GGC Group Intervention

GGC Self Guided Intervention

GGC Post Implementation Assessments: Attendance/ Uptake, Posttest, Satisfaction, Fidelity

No Well Visit: No pediatrician in person referral.

GGC4H Implementation Design
Challenge 2: Valid Statistical Inference

- **2 GGC delivery modalities**: Group and Self-guided
- **Pragmatic enrollment approach**: Parents from the same pediatrician (P) enroll in different groups, parents from different pediatricians (P) enroll in the same group → cross-classification
- **Result**: Cluster-randomized trial with partial cross-classification in the intervention arm
- **If not modelled appropriately**: Threats to inference (bias), increased Type I error
Solution: Include Strong Study Biostatisticians on the Team

- **Lead Biostatistician Quesenberry → Innovative statistical approach**
  - Extended Luo et al. (2015) for a generalized linear model with binary outcomes
  - Key: *Appropriate modelling of random effects* in control (pediatrician), self-guided GGC (pediatrician), and group GGC (pediatrician, GGC group)
  - Analysis focus: Point and interval estimation of trial arm indicator regression coefficient

- **Biostatistician Oleg Sofrygin conducted simulation study**
  - **Goal:** Evaluate power for assessing primary outcomes, alpha levels, coverage
  - **Varied:** Sample size, ICC for GGC groups and pediatricians, effect sizes for binary outcomes (based on prior GGC trials), group size
  - **Result – 2000 virtual cohorts:** Strong power, nominal alpha levels, adequate coverage at 100%, 90% of expected adolescent recruitment levels
GGC4H Data Sharing Plan

- **Internal Data Sharing Plan**
  - Remove all 18 Protected Health Identifiers.
  - Therefore do not need to execute data sharing agreements among 4 site partners.

- **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.
# GGC4H Barriers Scorecard

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<tr>
<th>Barrier</th>
<th>Level of Difficulty*</th>
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<tr>
<td>Enrollment and engagement of patients/subjects</td>
<td>1</td>
</tr>
<tr>
<td>Engagement of clinicians and health systems</td>
<td>2</td>
</tr>
<tr>
<td>Data collection and merging datasets</td>
<td>3</td>
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<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td>4</td>
</tr>
<tr>
<td>Stability of control intervention</td>
<td>5</td>
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<tr>
<td>Implementing/delivering intervention across healthcare organizations</td>
<td>X</td>
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*Your best guess!
1 = little difficulty
5 = extreme difficulty
Many “Barriers” weren’t because of Team Skills, Experience

- Challenge was accomplishing so much so quickly!
- Great breadth and depth in skills, experience of team members
  - IRB: *Boggs*
  - HCS-embedded research and relationships, data sharing: *Sterling, Beck, Braciszewski, Hartman, Daley, Perrin*
  - GGC intervention: *Catalano, Haggerty, Kuklinski, Casey-Goldstein*
  - GGC intervention delivery: *Negusse, Jones, Williams, Barela, Kazan, Elsiss*
  - Cluster-randomized trials in real-world settings: *Catalano, Sterling, Kuklinski, Beck, Braciszewski, Brown*
  - Biostatistics/methodology: *Quesenberry, Sofrygin, Oesterle, Brown*
Summary and Conclusions

- GGC4H: A pragmatic test of anticipatory guidance for parents of adolescents in primary care
- High levels of support and partnership from all three healthcare systems
- Excellent progress in UG3 phase—aided by Collaboratory input. Experience will benefit UH3 trial
- Simulation study showed statistical innovations provide more than adequate power to evaluate primary outcome at study endpoint
- We have a strong study team. We are enthusiastic and well-prepared for the larger trial.
Thank You!

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