Guiding Good Choices for Health (GGC4H): Testing the Feasibility and Effectiveness of Implementing Guiding Good Choices in Three Healthcare Systems

Richard Catalano, PhD, MPI
Margaret Kuklinski, PhD, MPI
Stacy Sterling, DrPH, MPI

NIH Collaboratory Grand Rounds, December 14, 2018
Thank you to our NIH Funders and Partners

- National Center for Complementary and Integrative Health
- National Institute on Drug Abuse
- Office of Behavioral and Social Sciences Research
- Office of Disease Prevention
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Thank you also to the NIH Collaboratory and Collaboratory Cores for support and guidance
# GGC4H Team

## Guiding Good Choices for Health (GGC4H) Executive Committee

### GGC4H Leadership

<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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### NIH

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<thead>
<tr>
<th>NCCIH</th>
<th>NIDA</th>
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<tr>
<td>Robin Boineau, MD, Project Officer</td>
<td>Jacqueline Lloyd, PhD, Project Scientist</td>
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<td>Ad Hoc Members</td>
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<td></td>
<td>Qilu Yu, PhD, NCCIH</td>
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<td>Elizabeth Nielsen, PhD, ODP</td>
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<td>Erica Spotts, PhD, OBSSR</td>
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Objectives

1) Why offer evidence-based parenting programs in pediatric primary care

2) Guiding Good Choices for Health (GGC4H): a novel opportunity for improving adolescent health

3) Key accomplishments and learning from current pilot study

4) Next steps
1) Why offer evidence-based parenting programs in pediatric primary care

2) Guiding Good Choices for Health (GGC4H): a novel opportunity for improving adolescent health

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4) Next steps
Many Behavioral Health Problems Begin Or Rise Sharply During Adolescence

By the time they leave high school

- 50% of adolescents will have used some form of illicit drugs.
- 20-25% will have met diagnostic criteria for depression.
- Many will engage in delinquency or violence.
- Other common behavioral health problems: Sexual risk behavior, other mental health problems, academic and school problems.

➔ Behavioral health problems in adolescence influence later health.
➔ Annual costs of substance misuse $442B v. diabetes $245B*

Why Implement Evidence-based Parenting Programs?

1) Parents want their children to be successful.
2) Children want to discuss important issues with their parents throughout development.
3) Many risk and protective factors for behavior problems can be affected by family action.
4) Parenting programs have shown impact on risk and protective factors, increased positive behavior and reduced behavioral health problems in controlled trials.
Guiding Good Choices (GGC)

- Parenting program for parents of early adolescents ages 11-14
- Theoretically grounded in the Social Development Model
- Evaluated in two RCTs
  - Affects **Parenting Behavior** regardless of family risk (Spoth et al., 1998)
  - Reduced Growth in **Substance Use** (Mason et al., 2003)
  - Reduced Growth in **Delinquency** (Mason et al., 2003)
  - Reduced **Depressive symptoms** (Mason et al., 2007)
  - **Cost-beneficial**: Benefit-Cost Ratio: $2.77 (WSIPP, 2018)
GGC: Five 2.5 Hour Sessions, 1 with Adolescents

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<thead>
<tr>
<th>GUIDING GOOD CHOICES SESSIONS</th>
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<tbody>
<tr>
<td><strong>Session 1</strong></td>
<td>Getting Started: How to Prevent Drug Use in Your Family</td>
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<tr>
<td><strong>Session 2</strong></td>
<td>Setting Guidelines: How to Develop Healthy Beliefs and Clear Standards</td>
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<tr>
<td><strong>Session 3</strong></td>
<td>Avoiding Trouble: How to Say No to Drugs (with children in attendance)</td>
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<td><strong>Session 4</strong></td>
<td>Managing Conflict: How to Control and Express Your Anger Constructively</td>
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<tr>
<td><strong>Session 5</strong></td>
<td>Involving Everyone: How to Strengthen Family Bonds</td>
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**Sessions emphasize parenting skills**
- Build family bonding
- Establish and reinforce clear and consistent guidelines for children’s behavior
- Teach children skills to resist peer influence
- Improve family management practices
- Reduce family conflict

→ **GGC is organized around substance use prevention, but skills generalize to other parenting concerns.**
Advantages to Providing Parenting Programs in Primary Care

- **Pediatricians have high credibility** and are trusted by parents. Therefore, are good agents for validating good parenting practices.
- Pediatric primary care is more **universally available and relatively affordable** with new health insurance coverage.
- Care provided in a **pediatric setting is non-stigmatizing** because most families go to a pediatrician or family physician, not just those with health problems.
- **AAP Recommends pediatricians provide anticipatory guidance to parents**
- These advantages **may create high recruitment and retention rates** for family-focused prevention programs.
1) Why offer evidence-based parenting programs in pediatric primary care

2) Guiding Good Choices for Health (GGC4H): a novel opportunity for improving adolescent health

3) Key accomplishments and learning from current pilot study

4) Next steps
GGC4H: Multisite Partnership between GGC Developers and 3 Large Integrated Healthcare Systems

- Social Development Research Group, School of Social Work, University of Washington
  Richard Catalano, PhD, MPI – developed GGC with David Hawkins
  Margaret Kuklinski, PhD, MPI

- Kaiser Permanente of Northern California
  Stacy Sterling, DrPH, MPI

- Henry Ford Health System
  Jordan Braciszewski, PhD, Site PI

- Kaiser Permanente of Colorado
  Arne Beck, PhD, Site PI
3 Large, Learning Healthcare Systems

Kaiser Permanente of Northern California
Henry Ford Health System
Kaiser Permanente of Colorado

- All are affiliated with the NIDA Clinical Trials Network and the Healthcare Systems Research Network (HCSRN: 18 systems), and within HCSRN, the Mental Health Research Network (MHRN) and Addiction Research Network (ARN).

- As such, have strong avenues for disseminating study results and evidence-based best practices across a wide variety of large health systems, community-based health centers, Federally Qualified Health Centers, and patient-engaged research centers.

- Strong experience conducting HCS-embedded research studies.
## UG3/UH3 Cooperative Funding Mechanism

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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## UG3/UH3 Cooperative Funding Mechanism

<table>
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<tr>
<th>Year</th>
<th>Duration</th>
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<tbody>
<tr>
<td>Year 1</td>
<td>May 2018 – Apr 2019</td>
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<tr>
<td>Year 2</td>
<td>May 2019 – Apr 2020</td>
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<tr>
<td>Year 3</td>
<td>May 2020 – Apr 2021</td>
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<tr>
<td>Year 4</td>
<td>May 2021 – Apr 2022</td>
</tr>
<tr>
<td>Year 5</td>
<td>May 2022 – Apr 2023</td>
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**UG3 Phase**
- 1-Year Milestones-driven Planning and Pilot Study

**WE ARE CURRENTLY IN MONTH 7**
UG3/UH3 Cooperative Funding Mechanism

- **UG3 Phase**
  - 1-Year Milestones-driven Planning and Pilot Study

- **UH3 Phase**
  - 4-Year Milestones-driven Pragmatic Trial
    - Involving 4,608 Adolescents and Parents
    - In 72 Pediatric Practices
    - In 3 Healthcare Systems

**Year 1**
May 2018 – Apr 2019

**Year 2**
May 2018 – Apr 2019

**Year 3**
May 2018 – Apr 2019

**Year 4**
May 2018 – Apr 2019

**Year 5**
May 2018 – Apr 2019

WE ARE CURRENTLY IN MONTH 7
UH3 Pragmatic Trial Design

- Longitudinal cluster-randomized trial
  - Randomization pediatrician practices within clinic and HCS (24 per HCS), approximately 4600 families recruited to experimental or control arm

- RE-AIM* framework used to evaluate implementation and effectiveness outcomes

- Implement GGC in Study Years 2 and 3
  - 2 cohorts of adolescents and families
  - 2 GGC delivery modalities: Group and self-guided

- Evaluate sustained impact on adolescent behavioral health and other outcomes through Study Year 5

*Reach, Effectiveness, Adoption, Implementation, Maintenance
Effectiveness: Hypothesized Adolescent Health Impacts

- **Primary – Substance use initiation with 3 indicators**
  - Alcohol use
  - Marijuana use
  - Tobacco use

- **Secondary – Other impacts from prior trials**
  - Mood symptoms
  - Antisocial behavior

- **Exploratory – Not previously evaluated but plausibly linked to GGC, including:**
  - EHR: Health service utilization
  - PRO: Anxiety symptoms, screen time, social media use, sexting
1) Why offer evidence-based parenting programs in pediatric primary care

2) Guiding Good Choices for Health (GGC4H): a novel opportunity for improving adolescent health

3) **Key accomplishments and learning from current pilot study**

4) Next steps
UG3 Major Goals & Accomplishments

1) Gain IRB approval for the study
2) Engage HCS stakeholders
3) Orient pediatricians to “warm hand-off” referral to GGC
4) Prepare to deliver GGC
5) Publicize GGC, enroll parents, and implement GGC
6) Finalize pragmatic trial design and protocol

→ Monitor lessons learned and use to refine approach
1) Human Subjects and IRB Approach

- KPCO is single IRB of record:
  UW, KPNC, HFHS IRBs all agreed to cede oversight to KPCO IRB

- Key pragmatic research question:
  \textit{What is the level of interest in enrolling in GGC – unencumbered by the artificiality of also enrolling in a research study?}

- IRB approach – led by Jennifer Boggs, PhC, MSW, KPCO Project Mgr
  ✓ Enroll families in \textbf{GGC as a new service} being offered by some clinics in the HCS \textbf{without first enrolling them in a research study}
  ✓ Recruit adolescents to the study after parents complete GGC (EHR, PRO data)
  ✓ Justification for this approach:
    (1) GGC is a minimal risk intervention, and
    (2) GGC is already established as an evidence-based intervention
2) Engage HCS Stakeholders

- **3-step process**
  1. Site PIs met with *pediatrics /adolescent medicine chiefs* to discuss study and gain their support
  2. After gaining high-level support, repeated process with *heads of clinics* targeted for pilot
  3. Then introduced study to *pediatricians* – over lunch or during regular meeting

- All sites approached agreed to participate → diverse HCS and clinics are involved in pilot
  - **KPCO:** Oakland Pediatrics Clinic
  - **HFHS:** Ford Road Clinic
  - **KPCO:** Highlands Ranch, Ken Caryl, East, and Centerpoint Clinics
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**Lessons learned**

- Stakeholders at all levels were interested in and supportive of our study – filling a service gap!
- Embedded research experience of HCS partners has been key to engagement.
3) Orient Pediatricians to “Warm Handoff” Referral to GGC

- Guiding framework – pediatrician role
  - Pediatrician’s **recommendations carry weight** with parents
  - Role needs to be **brief** to fit normal workflow
  - Also needs to be **flexible** to account for different pediatrician styles
  - **Provide tools** to support the role

- Developed pediatrician “scripts” organized around key messages
  - Parenting adolescents can be challenging
  - Just like becoming a new parent is a big transition, so is becoming the parent of a teenager
  - Your adolescent is becoming more independent
  - Parents want to keep their children safe and their families close
  - Exploring risky behavior is common during this time
  - We’ve got your back: GGC4H will help strengthen family bonds and help you help your child through this period

- Created GGC4H “prescription” pads that pediatricians could give to parents
Guiding Good Choices: prescription for success

We know good parents like you often have a lot of questions about the teen years. You’re looking for ways to help your kids avoid some of the risky behaviors that come with that age. You also want to know how to talk with your kids about challenging issues and keep your relationship strong.

We are offering a free class for parents called Guiding Good Choices that does just that. This proven-effective program provides you with tools to help your child steer clear of risky behaviors, communicate effectively, and maintain strong family bonds. It has helped many families like yours navigate adolescence. And it’s now available to you.

Guiding Good Choices - A prescription for good health and well-being for young adolescents.

Instructions:
- Contact us: 510-910-1328
- Hear from us: We'll call you in 1-2 weeks.
- Attend our groups with food!

Prescriber:

Kaiser Permanente
Kaiser Permanente Oakland Pediatrics
4) Prepare to Deliver GGC – 2 Major Tasks

- **Develop self-guided version of GGC – guiding principles**
  - Offer flexibility and choice for parents
  - Maintain GGC core components: theoretical foundation, learning objectives, tools, skills
  - Provide 10 weeks of telephone and email support to parents in this mode

- **Train interventionists & provide ongoing technical support**
  - 3-day in-person training with Master GGC Trainer Kevin Haggerty, PhD, MSW
  - Manualized training approach leading to GGC certification: Didactic and interactive (role plays, exercises, **practice, practice, practice**) 
  - Also trained to provide self-guided support
  - Weekly support throughout implementation by GGC expert Mary Casey-Goldstein, MEd
5) Enrollment and Implementation Status

- Enrollment complete at KPNC and HFHS, continuing at KPCO
  - KPCO is expanding pilot clinic sites, enrollment strategies

- Implementation
  - 2 groups underway at KPNC, will finish before Christmas
  - 2 groups will begin at HFHS, KPCO in January
  - Self-guided implementation underway at all sites
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  - KPCO is expanding pilot clinic sites, enrollment strategies

- Implementation
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  - 2 groups will begin at HFHS in January
  - Self-guided implementation underway at all sites

Early lessons

- Enrollment rates are higher when families receive pediatrician’s warm handoff.
- Reasons for declining: (a) Parents and/or children too busy, (b) my child is doing fine, (c) we’ve been through adolescence before, don’t need GGC, (d) not interested.
- Families are hard to reach by phone, even with HCS support.
- Families of 11-12 year olds are concerned about social media use; there is a need for education around the importance of preventing substance use – and why this is an ideal age for prevention.
6) Finalize Pragmatic Trial Design and Protocol

- Many aspects to this!

- Today’s focus
  1) Novel analytic approach
  2) Data collection
**Novel Analytic Approach**

**Design:** Cluster randomized trial with partial cross-nesting in intervention arm

- **Pragmatic enrollment approach:** Parents from the same pediatrician enroll in different groups, parents from different pediatricians enroll in the same group → **cross nesting**

- **Cross nesting:** Threats to inference, increased Type I error

- **GGC4H Lead Biostatistician Quesenberry** developed appropriate modelling approach based on Luo et al. 2015 to resolve these issues.

- **GGC4H Biostatistician Sofrygin** running simulation study to assess study power to detect intervention effects on primary substance use initiation outcomes.
## Data Collection: Multiple Informants Used to Assess GGC Implementation Feasibility and Effectiveness

<table>
<thead>
<tr>
<th>Informant</th>
<th>Construct</th>
<th>Method</th>
<th>Y2</th>
<th>Y3</th>
<th>Y4</th>
<th>Y5</th>
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<tbody>
<tr>
<td><strong>Pediatricians, HCS leaders</strong></td>
<td>Adoption of GGC</td>
<td>Qualitative interviews with 5 informants per HCS</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td><strong>Interventionists</strong></td>
<td>GGC Intervention Fidelity</td>
<td>Session Fidelity Forms</td>
<td>✓</td>
<td>✓</td>
<td></td>
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<tr>
<td><strong>Parents</strong></td>
<td>GGC Knowledge, Attitudes, Skills, Behaviors shown to prevent behavioral health problems, strengthen/maintain family bonds</td>
<td>GGC Pretest/Posttest Surveys</td>
<td>✓</td>
<td>✓</td>
<td></td>
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<tr>
<td></td>
<td>GGC usefulness/satisfaction</td>
<td>GGC Satisfaction Surveys</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td><strong>Adolescents</strong></td>
<td>Parent and family processes</td>
<td>Adolescent Behavioral Health Survey, EHR</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td></td>
<td>Primary outcomes: Substance use initiation</td>
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<td>Secondary outcomes: Depressive symptoms and antisocial behavior</td>
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<tr>
<td></td>
<td>Exploratory outcomes: Anxiety symptoms, healthcare utilization, screen time, social media usage, sexting</td>
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**Evaluating Effects on Adolescent Behavioral Health: Youth Survey**

<table>
<thead>
<tr>
<th>Primary Outcomes</th>
<th>Secondary Outcomes</th>
<th>Exploratory Outcomes</th>
<th>Mechanisms to Impact</th>
</tr>
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<tbody>
<tr>
<td><strong>Substance Use</strong></td>
<td>Mental Health</td>
<td>Anxiety (GAD-7)</td>
<td>Parent and Family Risk &amp; Protective Factors (RPFs)</td>
</tr>
<tr>
<td>Age of Initiation</td>
<td>Depression (PHQ-9)</td>
<td>Screen &amp; Social Media</td>
<td>Individual RPFs</td>
</tr>
<tr>
<td>Lifetime Frequency</td>
<td>Antisocial Behavior</td>
<td>Time Sexting</td>
<td>Peer RPFs</td>
</tr>
<tr>
<td>Past-Year, Past 30-day Use</td>
<td>Ever Past-Year</td>
<td></td>
<td>School RPFs</td>
</tr>
<tr>
<td>Past 30-day Use Amount</td>
<td></td>
<td></td>
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<tr>
<td><strong>Substances Examined</strong></td>
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<td></td>
</tr>
<tr>
<td>Alcohol, Marijuana, Cigarettes, E-Cigarettes, Inhalants, Opioids, Other Drugs</td>
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- Developed and currently testing an **Adolescent Behavioral Health Survey** to collect data on key adolescent outcomes.
- Necessary because EHR data did not include all outcomes and/or were not consistently available across site.
- Baseline administration by telephone; subsequently mobile/internet administration to add flexibility and reduce costs.
EHR Data: 3 Purposes

**Eligibility**
Identification of Intervention and Control Cohorts
Identification of 11- and 12-year old well-child visits
Pediatrician reminders about upcoming well-visits with eligible adolescents

**Adolescent Outcomes**
Patient data collected during routine clinical care:
- Substance use
- Mental health symptoms, diagnoses
- Medical diagnoses
- Utilization – ED, inpatient, outpatient

**GGC Cost-Effectiveness**
Cost decision-support systems integrate utilization data and general accounting ledgers
Clinical encounters: Activities-based costing → service unit cost
Services provided at non-HCS facilities but paid for by HCS are also available

2 sources of EHR data
1) **Clarity**: Relational database refreshed in real time or daily, used to identify well-child visits
2) **Virtual Data Warehouse**:
   - Extensive EHR data source developed over 20 years to support multisite HCS research
   - Data elements are harmonized, standardized across member sites, continually updated
   - Organizes data on enrollment, demographics, encounters, diagnoses, pharmacy, laboratory, PRO, claims
   - Code will be developed, programmed by HFHS and distributed to run on VDW, saving time, cost
1) Why offer evidence-based parenting programs in pediatric primary care

2) Guiding Good Choices for Health (GGC4H): a novel opportunity for improving adolescent health

3) Key accomplishments and learning from current pilot study

4) Next steps
GGC4H Next Steps

- Complete **Pilot Study** at all sites
- Complete **Simulation Study** and evaluate study power
- Use findings to **refine approach for GGC4H Trial**
- Complete all **Transition Request** requirements so that we can receive funding for the UH3 phase
- Apply for supplemental funding to develop an **eHealth version of GGC** – to increase choice and offer greater flexibility for parents
  - Internet and mobile ready
  - Increase access to lower SES families who may not have computers
  - Overcome barriers, pree
  - Allow intervention to be accessed “on the go” by busy parents
Summary and Conclusions

- Test of anticipatory guidance through parent education
- High levels of support and partnership from all three healthcare systems
- We have made good progress
- We have learned important lessons for the full trial
- We are developing new statistical approaches for evaluating hypotheses in the pragmatic trial
Thank you to our GGC4H Funders and Partners

National Center for Complementary and Integrative Health
National Institute on Drug Abuse
Office of Behavioral and Social Sciences Research
Office of Disease Prevention
NIH Health Care Systems Research Collaboratory

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