

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



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

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

University of Washington

Richard Catalano,
MPI

Margaret Kuklinski,
MPI

Kaiser Permanente Northern CA

Stacy Sterling,
MPI

Rahel Negusse,
Site PD

Kaiser Permanente Colorado

Arne Beck,
Site PI

Jennifer Boggs,
Site PD

Henry Ford Health System

Jordan Braciszewski,
Site PI

Amy Loree,
Site PD

NIH

NCCIH

Robin Boineau, MD, Project
Officer

NIDA

Jacqueline Lloyd, PhD,
Project Scientist

Ad Hoc Members

Qilu Yu, PhD, NCCIH
Elizabeth Nielsen, PhD,
ODP
Erica Spotts, PhD, OBSSR



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

3) Key accomplishments and learning from current pilot study

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**

*Surgeon General's Report, *Facing Addiction in America*, 2016

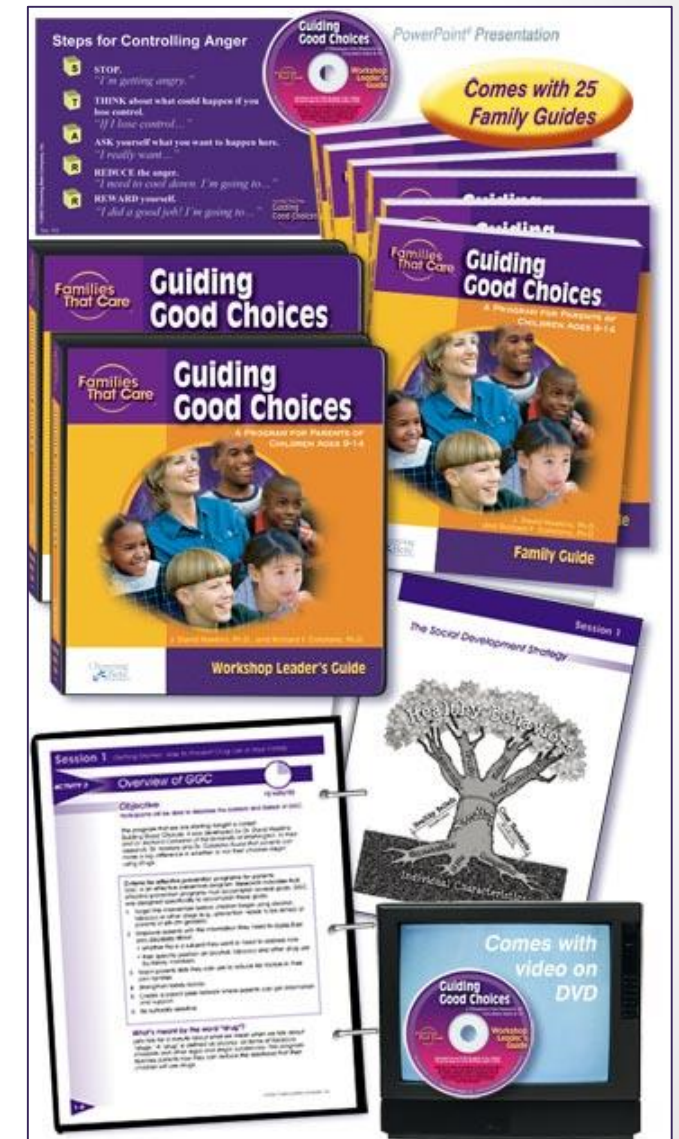


Why Implement Evidence-based Parenting Programs?

- 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

GUIDING GOOD CHOICES SESSIONS

Session 1	Getting Started: How to Prevent Drug Use in Your Family
Session 2	Setting Guidelines: How to Develop Healthy Beliefs and Clear Standards
Session 3	Avoiding Trouble: How to Say No to Drugs (with children in attendance)
Session 4	Managing Conflict: How to Control and Express Your Anger Constructively
Session 5	Involving Everyone: How to Strengthen Family Bonds

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

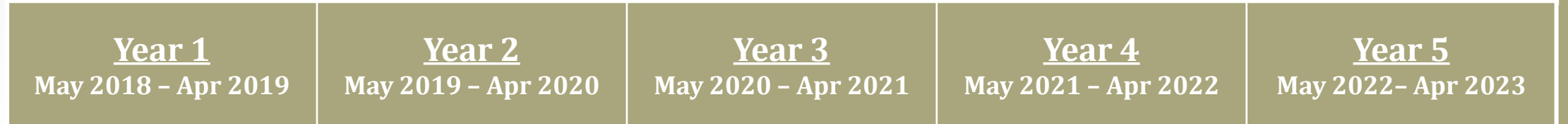
Kaiser Permanente of Northern California

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.

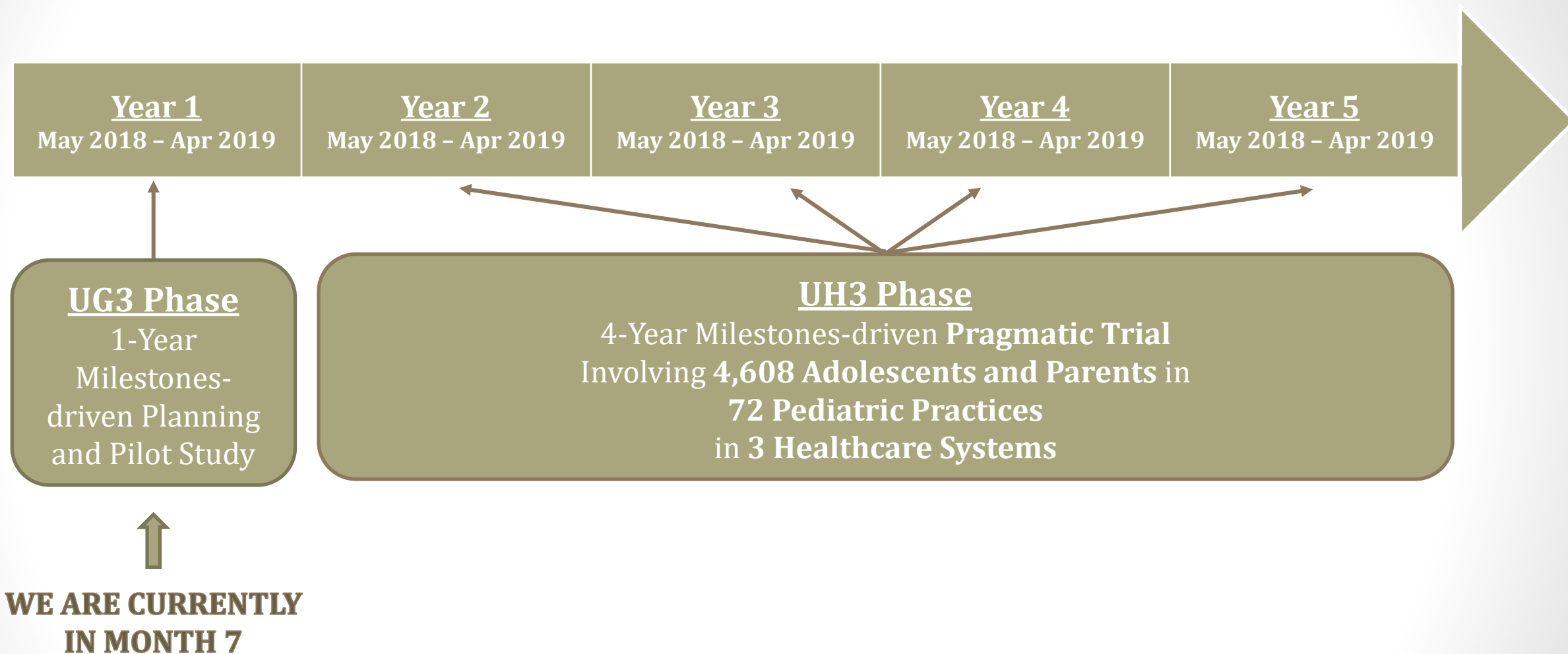
UG3/UH3 Cooperative Funding Mechanism



UG3/UH3 Cooperative Funding Mechanism



UG3/UH3 Cooperative Funding Mechanism



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

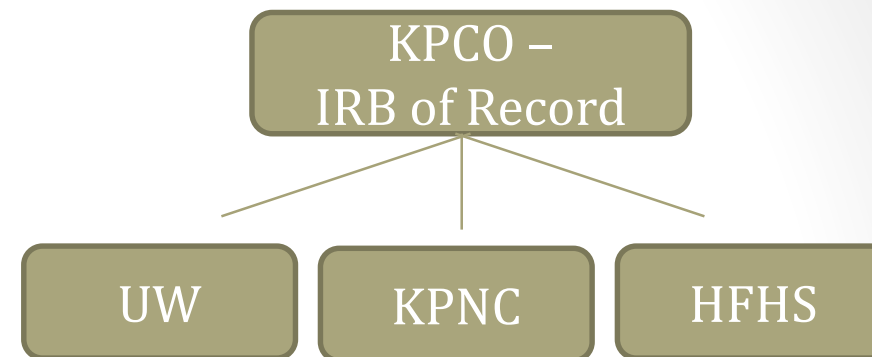
- 
- 1) Why offer evidence-based parenting programs in pediatric primary care
 - 2) Guiding Good Choices for Health (GGC4H): a novel opportunity for improving adolescent health
 - 3) Key accomplishments and learning from current pilot study**
 - 4) Next steps

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:

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 **GGC as a new service** being offered by some clinics in the HCS **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

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

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

Prescription Pads



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 wellbeing 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

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 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

Informant	Construct	Method	Y2	Y3	Y4	Y5
Pediatricians, HCS leaders	Adoption of GGC	Qualitative interviews with 5 informants per HCS	✓	✓		
Interventionists	GGC Intervention Fidelity	Session Fidelity Forms	✓	✓		
Parents <i>(will not be identifiable or linked to adolescent data)</i>	GGC Knowledge, Attitudes, Skills, Behaviors shown to prevent behavioral health problems, strengthen/maintain family bonds	GGC Pretest/Posttest Surveys	✓	✓		
	GGC usefulness/satisfaction	GGC Satisfaction Surveys	✓	✓		
Adolescents	Parent and family processes Primary outcomes: Substance use initiation Secondary outcomes: Depressive symptoms and antisocial behavior Exploratory outcomes: Anxiety symptoms, healthcare utilization, screen time, social media usage, sexting	Adolescent Behavioral Health Survey, EHR	✓	✓	✓	✓

Evaluating Effects on Adolescent Behavioral Health: Youth Survey

DOMAINS ASSESSED IN YOUTH SURVEY			
Primary Outcomes	Secondary Outcomes	Exploratory Outcomes	Mechanisms to Impact
Substance Use Age of Initiation Lifetime Frequency Past-Year, Past 30-day Use Past 30-day Use Amount Substances Examined Alcohol, Marijuana, Cigarettes, E-Cigarettes, Inhalants, Opioids, Other Drugs	Mental Health Depression (PHQ-9) Antisocial Behavior Ever Past-Year	Anxiety (GAD-7) Screen & Social Media Time Sexting	Parent and Family Risk & Protective Factors (RPFs) Individual RPFs Peer RPFs School RPFs

- 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

Richard F. Catalano, PhD, rico@uw.edu

Margaret R. Kuklinski, PhD, mrk63@uw.edu

Stacy A. Sterling, DrPH, Stacy.A.Sterling@kp.org