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Health Care Systems Research Collaboratory

Regulatory/Ethics Consultation Call:

Pragmatic Trial of Parent-Focused Prevention in Pediatric Primary Care: Implementation and Adolescent Health Outcomes in Three Health Systems (GGC4H: Guiding Good Choices for Health)[1]

July 2, 2018
Meeting Participants

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AGENDA ITEMS	DISCUSSION	ACTION ITEMS
Review of Demonstration Project	• Study Co-Principal Investigator Margaret Kuklinski provided an overview of the GGC4H study. The study will apply the RE-AIM[2] framework to evaluate the feasibility and effectiveness of offering the GGC4H intervention to parents of adolescent children aged 11-12 years in primary health care settings. • **Collaborative network partners**: o Kaiser Permanente Northern California o Henry Ford Health System o Kaiser Permanente Colorado The Social Development Research Group, School of Social Work, University of Washington, developed Guiding Good Choices and are partners in this study. • **NIH Institute:** National Center for Complementary and Integrative Health (NCCIH) • **Study design:** GGC4H comprises a 5-session intervention (~2 hours/week) focused on building resistance skills for problematic behavior among children including substance	

[1] Formerly Parents, Pediatricians, and Prevention: Pathways to Adolescent Health (P4TH)
[2] http://www.re-aim.org/

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	abuse. The intervention is ideally delivered to groups of 8-12 parents. Children attend one of these sessions. The Guiding Good Choices (GGC) program has been implemented multiple times and evaluated in 2 randomized controlled trials (RCTs). The program is primarily designed to strengthen parent/child bonds, focusing on fostering consistently reasonable consequences for problematic behavior and building skills for expressing anger in constructive ways. Skills developed through the program are broadly applicable, not just for substance abuse but also for other risky/antisocial behavior and depressive symptoms. o **Primary outcomes:** Substance use initiation and prevalence o **Secondary outcomes:** Depression symptoms; antisocial behavior • GGC4H will recruit 24 pediatric primary care pediatric providers from each of the 3 participating health care systems (either from one large clinic or 4 smaller clinics). Randomization will take place at the pediatrician level. Approximately 1,540 families per health care system will be enrolled over a 2-year period. GGC4H will be piloted in its first year and implement the intervention in years 2 and 3. Adolescents receiving the GGC4H intervention will be followed for 2-3 years. • Parents are not asked to provide research consent prior to enrolling in the intervention. Pediatricians receive an information sheet about the study that provides a mechanism for them to opt out. NB: the GGC4H intervention is an established, evidence-based intervention and its efficacy is not the primary focus of this study. o Parents can participate in GGC program without participating in the study. o Pediatricians are randomized to GGC intervention, who offer it to parents. Those randomized to control do not offer the program. • While the GGC program is known to be effective in a school/community setting, it is not known whether it can be extended to the clinical care setting and maintain its effectiveness. • Data are being acquired from EHRs, but several items are not part of standard clinical EHR information. Screeners for risky behavior are typically administered as part of wellness visits, but recording of that information varies across health systems. Therefore, EHR data will be supplemented by additional questionnaires/phone surveys.	

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	Answers to questions using these approaches will remain confidential except for those that suggest harm to self/others, threat to safety, or abuse/neglect, which may be shared with parents and/or providers as warranted.	
Status of IRB approval	• The IRB application is being submitted today (July 2nd) to the University of Colorado IRB (IRB of record for the study). Other sites are being asked to cede to it.	
Risk classification	• The study PIs anticipate that this study will be classified as minimal risk. The only potential risks seem to be that the questions asked could potentially cause emotional stress for adolescents; there are privacy/confidentiality concerns; and it is possible stigmatized behaviors could be identified. There was acknowledgment that such issues needed to be handled carefully, but the understanding among call participants was that data being collected were typically captured in usual clinical care and that the study was therefore appropriately classified as minimal risk.	
Consent	• After the GGC4H intervention is complete, **parents** will be asked to provide oral permission for the study team to contact children. **Children** are asked to provide assent. **Pediatricians** participating in the study are given an option to opt-out (see details included in study design overview for details of permission/consent/assent process). • The study team has requested alteration of informed consent from the IRB.	
Privacy/HIPAA	• HIPAA authorization is required for the release of the child's medical record; this authorization has been incorporated into the parental permission form (which allows the study team to contact the child). Permission and HIPAA authorization are emailed to the parent; assent is oral.	
Monitoring and oversight	• An institutional monitoring committee of experts will meet twice yearly to review, which is consistent with the requirements of the funding institute.	
Issues beyond the study	• A certificate of confidentiality will be automatically provided per new NIH policy. This certificate adds provisions for future research uses and confidentiality obligations for future data sharing.	• May need to include certificate of confidentiality in consent; includes suggested consent language.

Overview of *Parents, Pediatricians, and Prevention: Pathways to Adolescent Health*

Study description (one sentence):
This study uses the RE-AIM framework to evaluate the feasibility and effectiveness of implementing Guiding Good Choices, a universal, evidence-based anticipatory guidance curriculum for parents of early adolescents, in three large, integrated healthcare systems serving socioeconomically diverse families.

Settings and Partners:
Kaiser Permanente Northern California
Henry Ford Health System
Kaiser Permanente Colorado

The Social Development Research Group, School of Social Work, University of Washington, developed Guiding Good Choices and are partners in this study.

Intervention:
Guiding Good Choices (GGC) is a 5-session, universal preventive intervention for parents of early adolescents ages 9-14. Each session lasts approximately 2 hours, and one session involves both parents and the target child. Grounded in the Social Development Model, the primary objectives of the intervention are to strengthen parent-adolescent bonding, establish and reinforce clear and consistent guidelines for children's behavior, teach children skills to resist peer influence, improve family management practices, and reduce family conflict.

Two rigorous RCTs conducted with normative populations of parents of 6th graders in the Midwest provided evidence that GGC led to sustained reductions in adolescent behavioral health problems from grades 7 through 12 and proximal and sustained impact on strengthening parenting practices. GGC's impacts on adolescent health-risking behaviors included lower rates of initiation and growth in alcohol, marijuana, and tobacco use; lower current substance use; and lower growth in depressive symptoms and general delinquency. Effects were first observed 1-2 years following intervention and were sustained through grade 12. GGC also had and a direct, proximal intervention effect, d=.45, on parenting behaviors targeted by the intervention (e.g., increased opportunities for children's positive involvement in the family, clear communication of family rules, rewards for compliance, helping children express anger constructively), and on more global indicators of positive parenting affect and effective family management practices (e.g., parent monitoring, consistent discipline). Though formal mediation analyses were not conducted, this work suggests GGC's effects on parenting as the mechanism leading to adolescent health impact.

An independent meta-analysis highlighted GGC's sustained impacts on population level alcohol use (ES = .26), marijuana use (ES = .31 GGC), cigarette smoking (ES = .19 GGC), and depressive symptoms (ES = .24 GGC) in high school, based on results from the two RCTs.

Outcomes:
The main objective of the study is to improve adolescent behavioral health through the delivery of GGC. Because GGC targets common risk and protective factors (RPFs) for problem behaviors, we expect impacts on multiple outcomes. We have, however, designated primary, secondary, and exploratory outcomes to examine in the trial:

(1) Primary outcomes reflect GGC's status as an evidence-based substance use prevention program and findings from prior RCTs: Substance use initiation (with three indicators: alcohol, marijuana, and tobacco use). We hypothesize that, compared to control arm adolescents, GGC arm adolescents will report lower rates of substance use initiation.

(2) Secondary outcomes reflect additional significant impacts found in the prior RCTs: Reductions in depressive symptoms and antisocial behavior. We hypothesize that, compared to control arm adolescents, GGC arm adolescents will report lower rates of depressive symptoms and delinquency.

(3) Exploratory analyses will examine additional impacts not previously explored in trials that are available in the EHR and plausibly linked to GGC (e.g., anxiety symptoms, externalizing symptoms, conduct problems and aggressive behavior, health service utilization).

Design:

(1) **E**ffectiveness with respect to adolescent behavioral health will be evaluated using a cluster randomized controlled trial (with additional partial nesting in the intervention condition); **Table 1** summarizes our expected sample size. **Table 2** summarizes the schedule for collecting data from adolescents. **Table 3** summarizes our measures.

- Pediatricians within each healthcare system will be randomized to the intervention or control condition.
- Parents whose 11- or 12-year-old children receive a well-check from a pediatrician in the intervention condition will be referred by their pediatrician to the intervention.
- Parents will then choose whether to enroll in the group intervention or to receive self-study materials.
- To avoid cross-nesting, GGC groups will be comprised of parents from the same PCP.
- The C-RCT with additional partial nesting reflects that (1) Intervention and control parent-adolescent dyads are clustered within primary care PCPs, and (2) only Intervention parents are clustered within GGC groups, hence the additional partial nesting.
- Impacts on adolescent behavioral health will be evaluated using an intent-to-treat approach, regardless of actual intervention dose or delivery mode. Data will be collected annually from the EHR and via telephone survey with adolescents. Cohort 1 baseline is in Y2 with follow-up at Y3, Y4, Y5. Cohort 2 baseline is Y3 with follow-up in Y4, Y5.

Table 1: Sample Sizes: HCS, PCPs, and Families

	HCS Site						TOTAL ACROSS HCS SITES		
	KPNC		HFHS		KPCO				
PCPs									
Intervention	12		12		12		36		
Control	12		12		12		36		
Total PCPs	**24**		**24**		**24**		**72**		
Families	1	2	1	2	1	2	1	2	TOTAL
Control	384	384	384	384	384	384	1152	1152	2304
Intervention	384	384	384	384	384	384	1152	1152	2304
Delivery mode									
GGC groups	128	128	128	128	128	128	384	384	768
GGC self-study	256	256	256	256	256	256	768	768	1536
Total	768	768	768	768	768	768	2304	2304	**4608**
Total Families	**1536**		**1536**		**1536**		**4608**		

Table 2. Data Collection: Adolescents

	YEAR 2	YEAR 3	YEAR 4	YEAR 5
Cohort 1 (n=2304)	**Baseline**	**Follow-up**	**Follow-up**	**Follow-up**
Intervention (n=1152)	x	1	2	3
Control (n=1152)	x	1	2	3
Adolescent age	*11-12*	*12-13*	*13-14*	*14-15*
Cohort 2 (n=2304)		**Baseline**	**Follow-up**	**Follow-up**
Intervention (n=1152)		x	1	2
Control (n=1152)		x	1	2
Adolescent age		*11-12*	*12-13*	*13-14*

(2) Implementation feasibility outcomes--**R**each, **A**doption, and **I**mplementation--pertain only to the intervention condition. In general, analyses will evaluate whether trial outcomes are at least as strong as benchmarks established in the UG3 phase with input from HCS stakeholders or found in the GGC efficacy trial (e.g., 3.9 GGC group sessions attended).

- Analyses will rely on tests of non-inferiority, which are based on rejecting the null hypothesis that the outcome being evaluated is significantly ($p < .025$) less than the benchmark.
- Rejection of the null hypothesis will indicate strong evidence that the benchmark was met. Data collection schedule depends on the outcome; see **Table 4**.

Table 3. GGC Effectiveness: Measurement of Adolescent Behavioral Health Outcomes *(Intervention and Control Arms)*

Construct	Key Variables	Measure[a]	Source[b]	YEAR 2	3	4	5
Primary Behavioral Health Outcomes (and related SU questions)							
Substance Use	• Alcohol, tobacco, marijuana: • Ever and past year use (y/n); • Initiation or onset of use; • Past year, past month, or past two week frequency use consequences, symptoms, disorder (e.g., do family or friends tell you, you should cut down on your drinking; have you ever gotten into trouble while you were using alcohol or drugs	AST, ABHS (S2BI)	EHR, ADO	✓	✓	✓	✓
Secondary Behavioral Health Outcomes							
Mental Health	• Mood symptoms (past 2 weeks) • Suicidality (past 2 weeks) • Anxiety symptoms (past 2 weeks) • Mood of Anxiety diagnosis	AST (PHQ-2, Suicidality), ABHS (PHQ-9, GAD-7)	EHR, ADO	✓	✓	✓	✓
Legal/Delinquency	• Stole something worth > $5, stolen something from a store, damaged or destroyed property, been arrested, attacked someone with idea of hurting them, beaten up someone so badly they needed to see a doctor or a nurse, carried a handgun	ABHS (MTF)	EHR, ADO	✓	✓	✓	✓
Exploratory Behavioral Health Outcomes							
Medical	• SU, MH, Behavioral symptoms, diagnosis • ED and Inpatient Service Utilization • Prescriptions	EHR	--	✓	✓	✓	✓
Risk Behaviors	• Riding with driver under the influence, friends' ATOD use, sexual activity, excessive screen time, etc.	AST	EHR, ADO	✓	✓	✓	✓
School	• Grades	AST	EHR, ADO	✓	✓	✓	✓
Parenting and Family Outcomes							
Perceptions of Parenting and Family Processes *(primary outcome)*	• Parent proactive communication, parent-adolescent relationship quality, family management	ABHS	EHR, ADO	✓	✓	✓	✓
Covariates							
Demographics - Adolescent	• Sex, race/ethnicity, insurance coverage, health concerns and diagnoses at baseline	EHR	--	✓	✓	✓	✓

[a] **Measures:** EHR = Electronic health record. AST = Adolescent Screening Tool administered at wellness visit. ABHS = Supplemental Adolescent Behavioral Health Survey. S2BI = Substance Screening and Brief Intervention.[164] PHQ-2, PHQ-9 = Public Health Questionnaire, 2-item/9-item.[165] GAD-7 = Generalized Anxiety Disorder, 7-item.[166] MTF = Monitoring the Future.[167] PPTS- Standard pretest/posttest measures for GGC.

[b] **Source:** EHR = Electronic health record. PAR = Parent. ADO = Adolescent. PCP = Primary care physician. CLN = Clinic staff. INT = Interventionist. ADM = Project administrative records.

Table 4. Implementation Feasibility Constructs, Measures, and Data Collection Schedule

Construct	Key Variables	Measure[a]	Source[b]	YEAR 2	3	4	5
Reach							
Eligibility	• # families with adolescent age 11-12 served by study provider*	EHR	--	✓	✓		
Exclusion	• % eligible families for whom English, Spanish are not primary language	EHR	--				
Enrollment	• % eligible parents who enroll in GGC group • % eligibility parents who report use of self-study materials • Demographic comparability among enrollees, non-enrollees	Enrollment Call Sheets	PAR	✓	✓		
Demographics - Parent	• Sex, race/ethnicity, primary language, insurance coverage	EHR	--				
Adoption							
HCS/PCP Adoption and Engagement	• Model feasibility, ongoing engagement with and support for trial and model of anticipatory guidance, emergent concerns, barriers to and facilitators of model implementation, support for evidence-based behavioral intervention and embedded service delivery	Workgroup Meeting Notes, Qualitative Interviews	HCS, PCP, CLN	✓	✓	✓	✓
GGC Group Attendance[c]	• # sessions attended	GGC Session Attendance Records	INT	✓	✓		
GGC Group Satisfaction and Usefulness[c]	• Effectiveness of the workshop content, workshop process, workshop leaders; • Usefulness of the overall session, video segments, activities and exercises, family activity book	GGC Session Satisfaction Surveys	PAR	✓	✓		
Self-Study Utilization[d]	• % parents who received GGC materials, • % parents who used workbook, accessed online content, or both • % workbook modules completed through self-study	Project Self-Study Call Sheets	PAR	✓	✓		
Implementation							
Engagement/ Enrollment Fidelity[e]	• % eligible parents receiving prescription from PCP	Enrollment Call Sheets	PAR	✓	✓		
GGC Session Fidelity	• Adherence, Dosage, Participant Responsiveness, Overall Quality Levels • Summary of Adaptations, Omissions, Deletions	GGC Session Fidelity Forms	INT	✓	✓		
Maintenance and Generalizability							
Maintenance	• Repeated assessments of Reach, Effectiveness, Adoption, Implementation constructs – across cohorts, two intervention years, or, for adolescent outcomes through year 5	Measures described above	All sources	✓	✓	✓	✓
Generalizability	• Comparability of Reach, Effectiveness, Adoption, and Implementation constructs across HCS, adolescents (sex, race/ethnicity), parents (race/ethnicity, primary language English v. Spanish, insurance status)	Measures described above	All sources	✓	✓	✓	✓

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[b] Source: EHR = Electronic health record. PAR = Parent. ADO = Adolescent. PCP = Primary care physician. CLN = Clinic staff. INT = Interventionist. ADM = Project administrative records.

[c] Measured only in parents in the GGC group delivery mode.

[d] Measured only in parents in the GGC self-study delivery mode.

[e] Measured in all parents in the intervention arm.