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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 July 2, 2018	PROPOSED ACTIONS July 2, 2018	CURRENT STATUS As of August 30, 2019
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**: ○ Kaiser Permanente Northern California ○ Henry Ford Health System ○ Kaiser Permanente Colorado		Changes to Demonstration Project since July 2018: • **Study design:** This is a cluster-randomized, pragmatic trial, with randomization at the pediatrician level and observation of intervention effects at the adolescent patient level. Using a constrained randomization approach, the study team will randomize 72 pediatricians, 24 in each healthcare system (36 intervention, 36 control), to either intervention (GGC) or control arms. Constraints (pediatrician panel size, pediatrician gender, and a

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

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	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 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.		pediatrician panel-level indicator of socioeconomic status) will ensure balance across intervention and control arms after randomization, reduce potential variability in effect sizes among pediatricians, and increase power. Patients and families are not aware of their pediatrician's assignment. • **Primary outcome:** Incidence of adolescent substance use initiation (alcohol, cigarettes, e-cigarettes, and/or marijuana) through last follow-up. • **Recruitment:** Prior to the initiation of the intervention, adolescents will be recruited to the study, which we are calling the "Promoting Adolescent Wellness Study" (PAWS). Eligible adolescents are born between 6.1.2007 and 5.31.2009 and are empaneled with the 72 pediatricians. Parent and adolescent exclusions include having a cognitive or intellectual impairment documented in the EHR that would prohibit them from understanding the purpose of the study and measures, or, for those in the intervention arm, the GGC curriculum. Adolescents will participate in the study if their parent/legal guardian consents and they assent. Adolescents will be recruited in two cohorts. Cohort 1 includes adolescents born between 6.1.2007 and 5.31.2008; parents

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	○ **Primary outcomes:** Substance use initiation and prevalence ○ **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. ○ Parents can participate in GGC program without participating in the study.		of adolescents in the intervention arm will be offered GGC in study year 2. Cohort 2 includes adolescents born between 6.1.2008 and 5.31.2009; parents of adolescents in the intervention arm will be offered GGC in study year 3. • **Baseline survey:** After study recruitment, adolescent participants will complete a behavioral health survey (the PAWS Survey). The study team developed this survey because the study's primary outcome, secondary outcomes (e.g., depressive symptom count, prevalence of antisocial behavior, emergency department utilization), and family process mediators of impact (e.g., parent-adolescent bonding, communication, guidelines for behavior) were not consistently available in the EHRs of the three health care system partner sites. • **Survey follow-up:** Following baseline administration, the PAWS Survey will also be administered 6-, 18-, and 30-months (cohort 1 only) post intervention. The consent/assent process includes information about study follow-up. • **PAWS study website:** The PAWS study name is being used to distinguish the study from the GGC intervention and help ensure the study blind. A PAWS study website will provide parents with key information,

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	○ 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. 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.		including links to consent forms at each site. The website is expected to go live in September 2019 (pawstudy.org). • **GGC Intervention:** Following study recruitment, GGC will be recommended to all parents/legal guardians of adolescents in the intervention arm, regardless of whether their adolescent participates in the study. This will allow the team to understand GGC enrollment rates among parents regardless of whether they are enrolled in a research study. Parents will receive this recommendation via letter, email, and/or in-person from their child's pediatrician during their adolescent's well visit. • The study protocol attempts to maintain blinding to the GGC intervention among study arm parents by (a) using a study name (PAWS) that does not include the intervention name (Guiding Good Choices), (b) providing study participants with general information about study's purpose (e.g., "PAWS researchers and physicians will use survey answers to guide programs and services offered to adolescents and their families. The study team will check in with participants annually for up to 3 years to continue to understand their health needs and offer relevant programs and services to meet them.), and (c) having a

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			gap between study recruitment and GGC intervention enrollment (among intervention arm parents). However, some parents may connect the GGC intervention to the survey study. We are currently developing talking points to address this possibility. In general terms, the talking points will indicate that GGC is a program that is being tested within the "Promoting Adolescent Wellness Study" (PAWS).
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.		• The minutes from the last meeting erroneously state that the IRB of record is the University of Colorado. Kaiser Permanente Colorado (KPCO) is the IRB of record for all participating institutions (Kaiser Northern California, Henry Ford Health System, University of Washington and KPCO). • We received approval from the KPCO IRB for the UH3 study on August 7, 2019. Approval includes study recruitment, intervention enrollment, and baseline and follow-up survey administration. Since approval was received, we have submitted minor modifications including those pertaining to website language, and consent via website (see Consent section below)

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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 duress for adolescents; there are privacy/confidentiality concerns; and it is possible stigmatized behaviors could be identified. There was acknowledgement 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.		The KPCO IRB determined that the study is 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.		• **PAWS study:** We will contact parents of eligible 11- to 12-year-old children via phone, email, letter, and/or text to invite their child to participate in a survey study. The contact method will depend on what is allowable and feasible within each health care system. Parents will provide oral consent on the phone (or via a web-based consent process pending IRB approval). The child then completes an oral (or web-based, pending IRB approval) assent process prior to completing the survey. The survey will be completed via phone (or web-based, pending IRB approval). • Parents are not asked to provide consent when they are approached about GGC

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			group participation. We do not collect any identifiable outcomes from parents, nor do we connect parent/child outcomes other than to note whether the parent of a child participated in GGC. • The study team holds in-person meetings at each participating clinic to orient pediatricians to the study. Their potential role (i.e., if randomized to the intervention arm) in recommending that parents enroll in GGC is part of the orientation. Pediatricians are also told that they can opt out of participating in the study by contacting study staff. Key information about the study and opt out process are summarized in an information sheet containing contact information for study staff.
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.		We have a more robust plan now. See the attached document, "Guiding Good Choices for Health (GGC4H) Data and Safety Monitoring," which summarizes the approach approved by NCCIH.

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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.	The parent consent form now indicates that we have a certificate of confidentiality through NIH.

Guiding Good Choices for Health (GGC4H) Data and Safety Monitoring

We have finalized our plans for data and safety monitoring since the last report out to the Ethics and Regulatory Committee. While this study is minimal risk and the intervention being studied is a low-risk behavioral intervention, we further protect our study participants through a Data and Safety Monitoring Plan and an Independent Monitoring Committee (IMC). The role of the IMC will be to: (1) monitor and evaluate the safety of study participants; (2) monitor the performance of the study; and (3) assure that the data and safety monitoring plan—including the reporting of any adverse events (AEs) and serious adverse events (SAEs)—is adhered to. In order for the IMC to fulfill their role, the study team will send a report 10 days in advance of the IMC meeting documenting any AEs or SAEs by site and participant code. The report will include a description of how the study team responded to the AE or SAE. The IMC will then determine whether the response was sufficient and recommend further action if needed.

The IMC members do not have any personal involvement or professional interest in the outcome of the trial. They have not collaborated or co-published with the MPIs/PIs in the past three years. They are qualified to review the patient safety data generated by this study because of their unique expertise.

- Catherine Lee, PhD, a biostatistician and research scientist at the Kaiser Permanente Northern California Division of Research will serve as the IMC's PhD level biostatistician expert.
- Robert J. McMahon, PhD, Professor of Psychology, Simon Fraser University, Vancouver, British Columbia, Canada. Dr. McMahon will serve as the IMC's parenting intervention expert.
- Elizabeth Sanders, PhD, Associate Professor, University of Washington, Seattle, WA. Dr. Sanders will serve as the IMC's cluster randomized trials expert.
- Stephen Sidney, MD MPH, Director of Research Clinics, Division of Research, Kaiser Permanente Medical Care Program, Oakland, CA. Dr. Sidney will serve as the IMC's medical and clinical trials expert.

The IMC will monitor the study twice annually and will consult closely with the MPIs/PIs as needed. Because the intervention being tested is a low-risk behavioral intervention, we do not anticipate safety findings that would precipitate halting the study. However, if any of the following were to occur, it would trigger a safety review by the IMC, which would then recommend any further steps for the study team to take:

- A study-related SAE occurring at any study site.
- Two or more AEs consisting of extreme distress reactions to the intervention curriculum across three study sites.