Guiding Good Choices for Health (GGC4H): Lessons from a Pragmatic Trial in Three Large Healthcare Systems

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Objectives

- Overview: Guiding Good Choice for Health (GGC4H)
- Opportunities for Parent-focused Prevention in Primary Care
- Challenges and Opportunities (or… the only constant in life is change…)
  - Balancing pragmatic implementation and rigorous design
  - Could we harness EHR data to address key study questions?
  - Implementation during the pandemic

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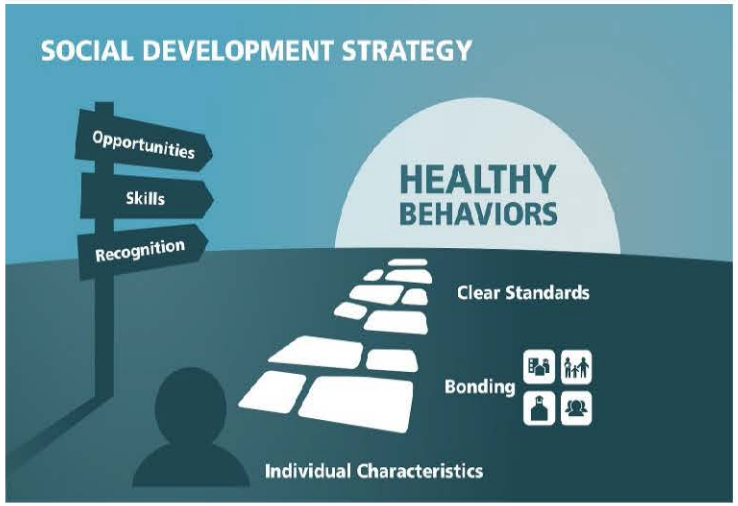
Guiding Good Choices

Anticipatory guidance curriculum, consistent with AAP guidelines

- Theoretical foundation: Social Development Strategy
- Five 2-hour sessions teach specific skills*
  - Getting Started: How to Promote Health and Wellbeing During the Teen Years
  - Setting Guidelines: How to Develop Healthy and Clear Standards
  - Managing Conflict: How to Deal with Anger in a Positive Way
  - Avoiding Trouble: How to Say No, Keep Your Friends, and Still Have Fun *(with adolescents)*
  - Involving Everyone: How to Strengthen Family Bonds



- Evidence-based – 2 prior RCTs
  - Reduced alcohol, marijuana, cigarette use; depression symptoms; antisocial behavior -- for 4-6 years after middle-school baseline
  - Strengthened families: Better communication, closer relationships, less family conflict

An Introductory Session is added when GGC is delivered virtually.

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Guiding Good Choices (GGC)

- 2 prior 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)
- Session goals – Social Development Model
  - 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.

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GGC Helps Fill a Service Gap in Pediatric Primary Care

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

- Have pediatricians refer parents to GGC for delivery by embedded 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.

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Outcomes: RE-AIM Framework

Effectiveness - Adolescent Health Outcomes

- Primary – Substance use initiation with 4 indicators
  - Alcohol, Marijuana, e-Cigarette, Tobacco Use
- Secondary – Other impacts from prior trials
  - Depression symptoms, Antisocial behavior
- Exploratory – Available in EHR, not previously evaluated but plausibly linked to GGC
  - Anxiety symptoms, Health service utilization (inpatient, ED)

Implementation Outcomes

- Reach, Adoption, Implementation, Maintenance
- Includes health economic evaluation: Cost, cost-effectiveness

Protocol Paper: Scheuer, Kuklinski, Sterling, Catalano, et al.
(2022, *Contemporary Clinical Trials)*

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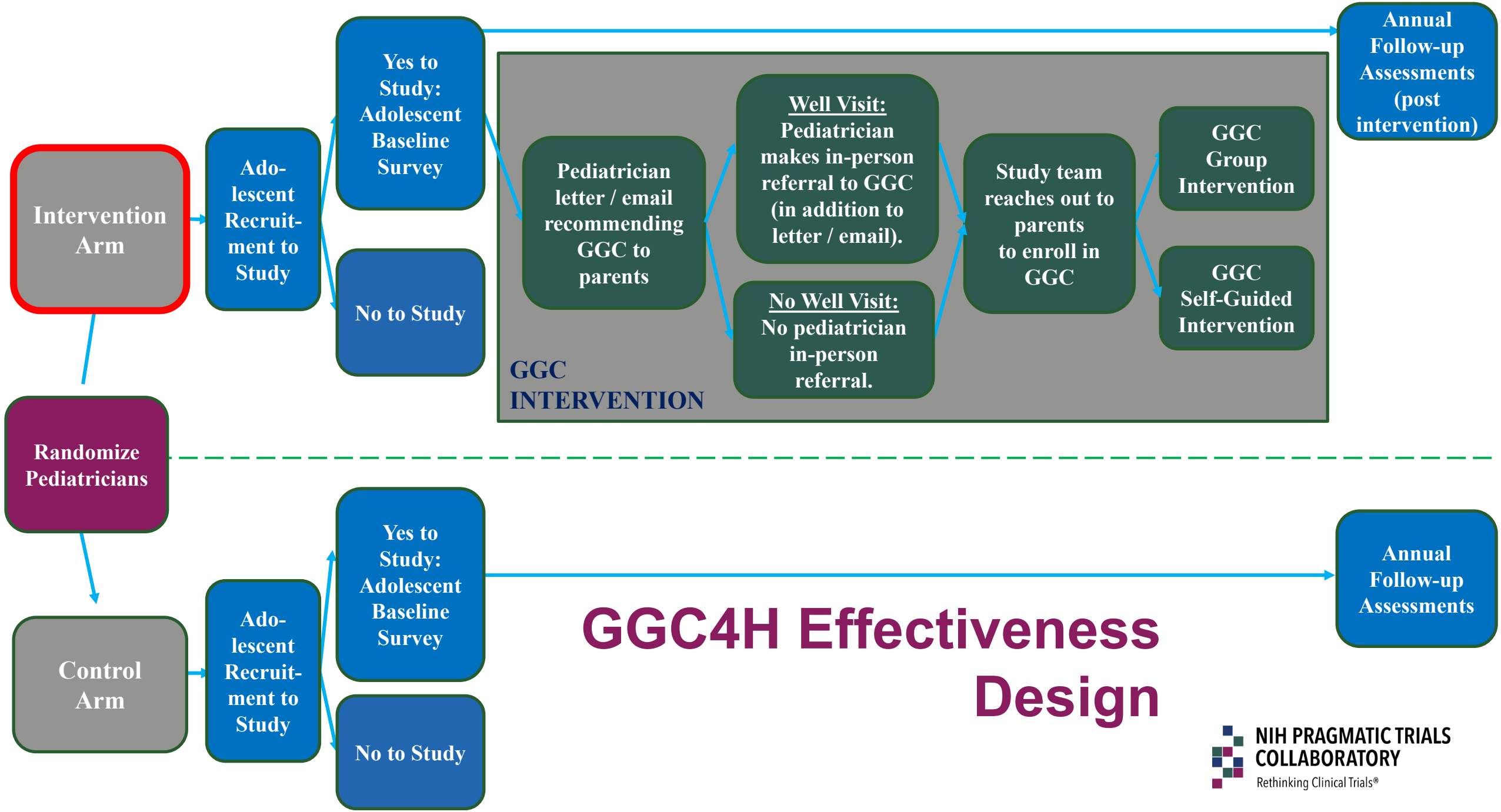
PRE-COVID 19 TIMELINE

Year 1 May 2018 – Apr 2019	Year 2 May 2019 – Apr 2020	Year 3 May 2020 – Apr 2021	Year 4 May 2021 – Apr 2022	Year 5 May 2022 – Apr 2023
• Milestones-driven planning phase • Pilot study	• Recruit **Cohort 1** into study • Implement GGC with Cohort 1	• Recruit **Cohort 2** into study • Implement GGC with Cohort 2 • Cohort 1 Follow-up 1	• Cohort 1 Follow-up 2 • Cohort 2 Follow-up 1	• Cohort 1 Follow-up 3 • Cohort 2 Follow-up 2

COVID-19

ACTUAL TIMELINE

Year 2 May 2019 – Apr 2020	Year 3 May 2020 – Apr 2021	Year 4 May 2021 – Apr 2022	Year 5 May 2022 – Apr 2023	Year 6 NCE May 2023-Apr 2024
• Develop Virtual GGC	• Retrain for Virtual GGC • Cohort 1 Mini-baseline • Implement GGC with Cohort 1	• Recruit Cohort 2 into study • Implement GGC with Cohort 2 • Cohort 1 Follow-up 1	• Cohort 1 Follow-up 2 • Cohort 2 Follow-up 1	• Cohort 2 Follow-up 2



GGC4H Effectiveness Design

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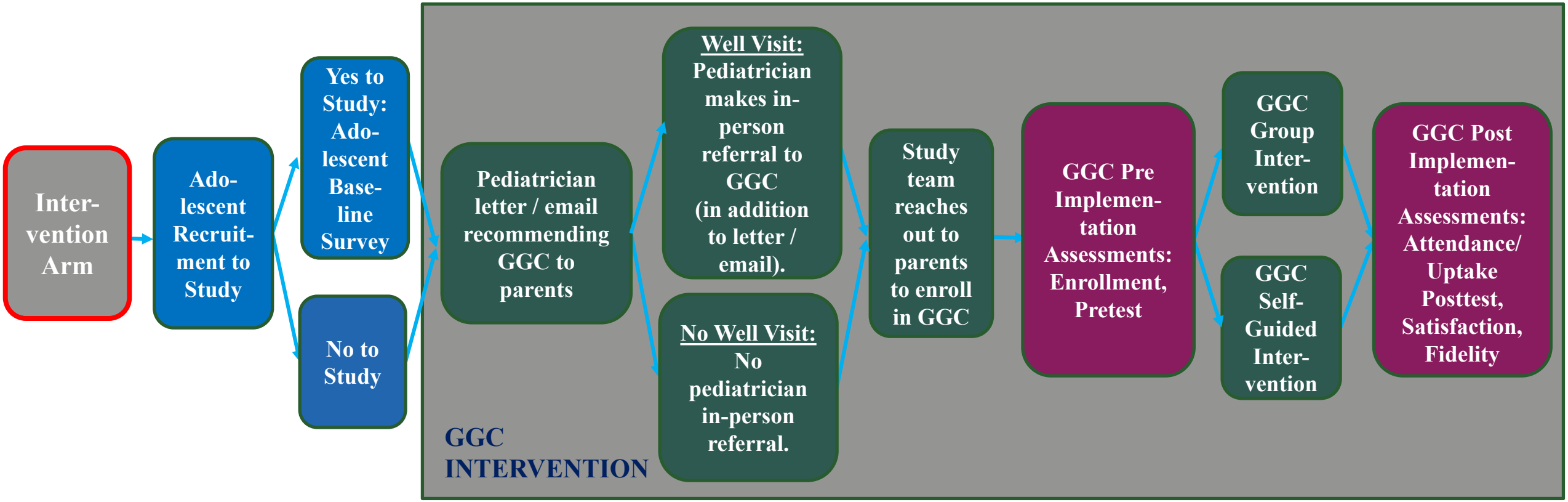

GGC4H Implementation Design

We realized we could offer intervention to all parents of eligible adolescents empaneled with intervention arm pediatricians.

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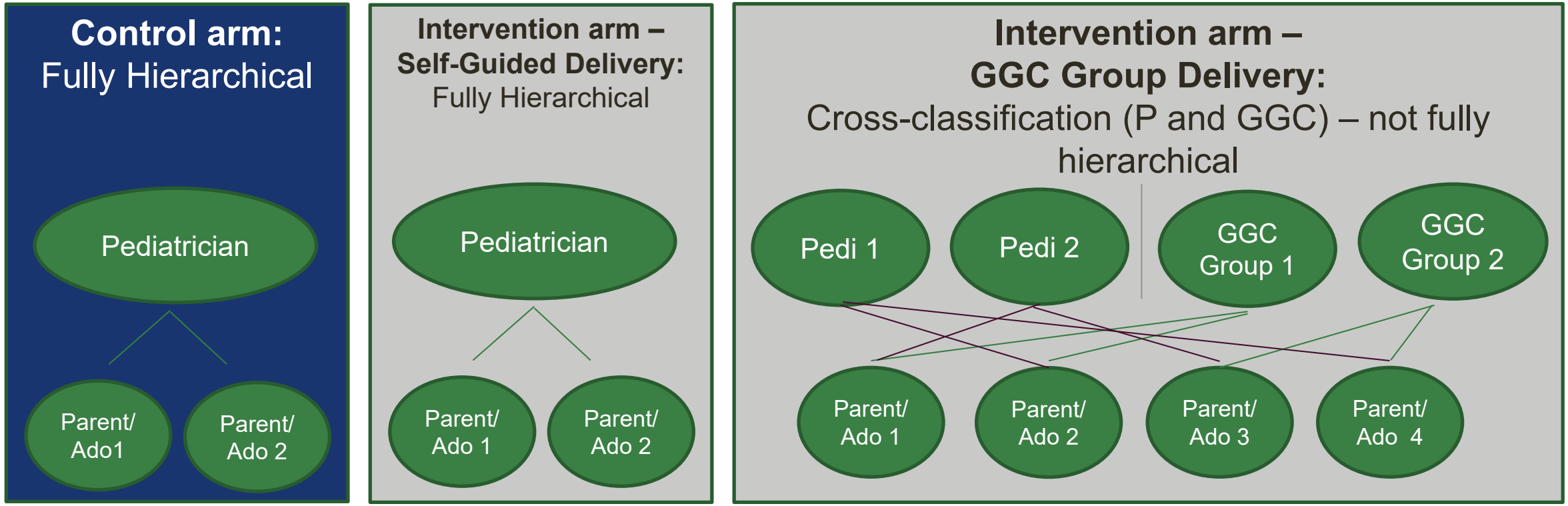
(1) Design: Could we achieve pragmatic implementation and valid statistical inference? Yes



Cluster-randomized trial with partial cross-classification in intervention arm

If not modelled appropriately: Threats to inference (bias), increased Type I error

Valid statistical inference in the face of a complex but pragmatic implementation approach.

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Innovative Modelling Approach from Biostatisticians Quesenberry and Sofrygin

- Extend Luo et al.'s (2015) linear model to generalized linear model for binary outcomes (logistic mixed effects regression)

- Appropriately model random effects – with 2 different subsets in intervention arm
  - **Self-guided subset:** Pediatrician is the only random effect, same as in the **control arm**

  - **Group GGC:** Both P and GGC group are random effects

- Fixed parent/adolescent-level and Pediatrician-level covariates, with focus on point and interval estimation of trial arm indicator regression coefficient

(2) Data: Could we use EHR data to address key study questions? Yes and No

Eligibility ✓

Identification of

Intervention and Control Cohorts

Identification of 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

EHR data sources:

1) **Clarity:** Relational database refreshed in real time or daily, used to identify well-child visits

2) **Virtual Data Warehouse:** Database developed over 20 years to support multisite HCS research
   - Coverage: Enrollment, demographics, encounters, diagnoses, pharmacy, laboratory, PRO, claims
   - Data are harmonized, standardized across member sites, continually updated

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Would EHR data yield behavioral health outcomes? No!

GGC4H YOUTH OUTCOMES			
Primary Outcomes	**Secondary Outcomes**	**Exploratory Outcomes**	**Mechanisms to Impact**
Substance Use Age of Initiation **Substances Examined** Alcohol, Marijuana, Cigarettes, E-Cigarettes, Inhalants, Opioids, Other Drugs	**Mental Health** Depression (PHQ-9) **Antisocial Behavior** Ever Past-Year **Substance Use** Lifetime Frequency Past-Year, Past 30-day Use Past 30-day Use Amount	**Anxiety (GAD-7)** **Screen & Social Media Time** **Sexting**	**Parent and Family Risk & Protective Factors (RPFs)** **Individual RPFs** **Peer RPFs** **School RPFs**

- Not measured consistently or documented systematically in EHRs across the 3 HCS
- Developed **Adolescent Behavioral Health Survey** to collect data on behavioral health outcomes; **widely used, validated measures**
- **Administered online or by telephone with trained interviewers**

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(3) Implementation: Would Pediatrician Referral lead to higher intervention enrollment rates? Yes, but…

- Pragmatic referral process at well child visit
  - Role needs to be brief to fit normal workflow
  - Needs to be flexible to account for different pediatrician styles
  - Provide tools to support the role:
    Flexible scripts and prescription pads

- Trial logistics
  - Naturalistic experiment with two modes of recruitment

Pediatrician Referral	Enrollment Rate
In-person	31% (range: 28%-71%)
Via letter / email	25% (range: 18% - 29%)

- Both modes: Higher enrollment than in community settings
  - Some preliminary evidence that “in-person” pediatrician referral resulted in stronger enrollment

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Sample Referral Scripts

"We have a new free program called Guiding Good Choices for Health and I'm encouraging all parents of my 11-12 year old patients to attend this free program."

"The reason I'm recommending this class is that there is research showing that it is effective in helping parents talk to their kids about the importance of avoiding risky behaviors, while also supporting strong parent-child relationships."

"We're offering a new free class called Guiding Good Choices. It's for parents of children your son's/daughter's age in my practice, to provide you with tools to help your child avoid risky behaviors during the challenging teen years while keeping your relationship strong."

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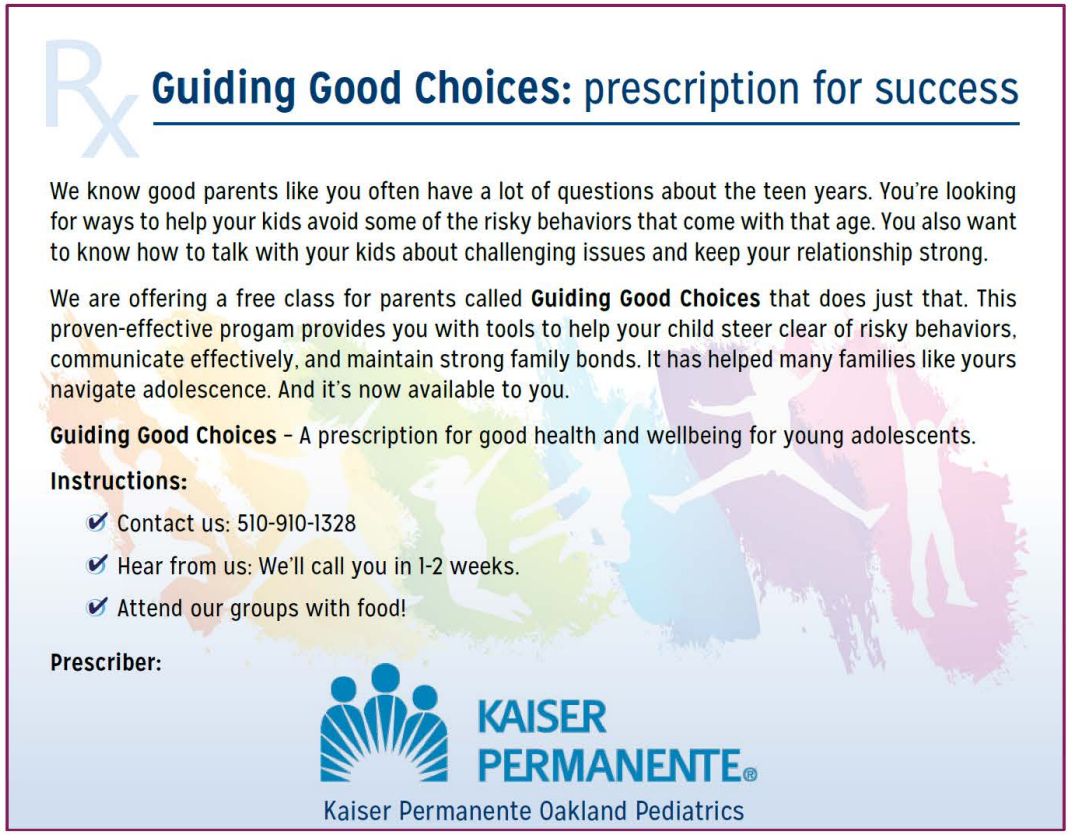
Prescription pads



Rx **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 progam 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:

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Kaiser Permanente Oakland Pediatrics

(3) Implementation: Would Pediatrician Referral lead to higher intervention enrollment rates? Yes, but…

Virtual GGC – Adaptation, implementation, satisfaction

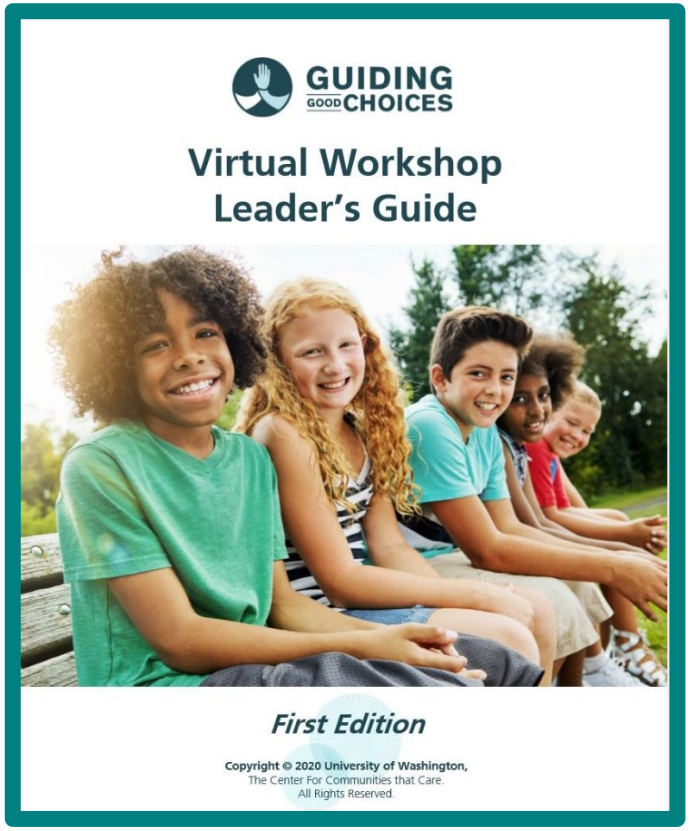
Preliminary step: Focus groups, qualitative interviews with parents – Summer 2020

Goals of developing Virtual GGC

- Maintain fidelity and efficacy
- Engage parents in virtual environment → strong exposure
- Added Introductory session & “Tech Check”
- Adjusted activities to work better in virtual environment

Questions

- Would parents enroll?
- Was adapted GGC feasible, acceptable, satisfying?



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Preliminary Findings

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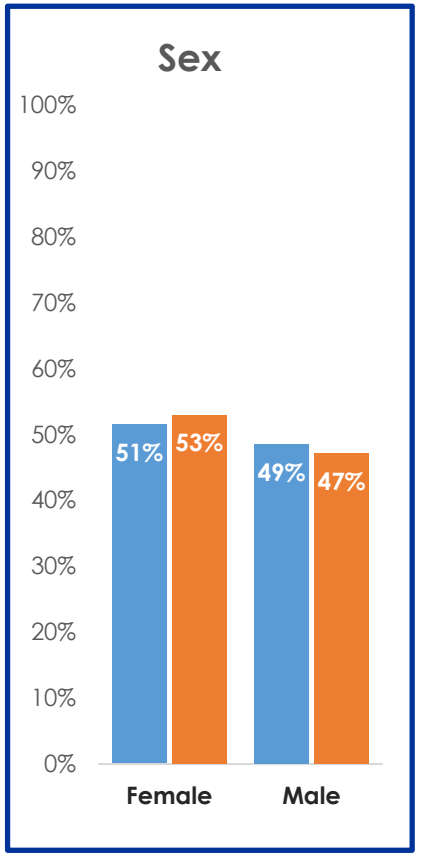
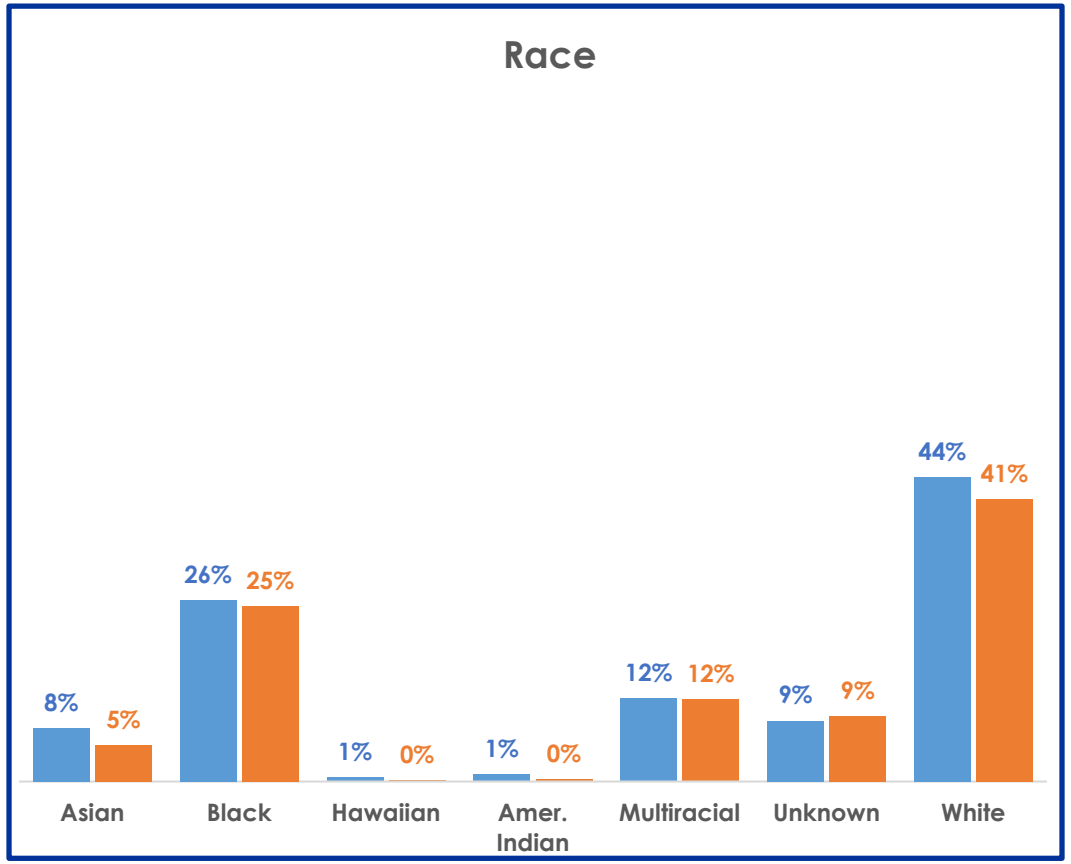
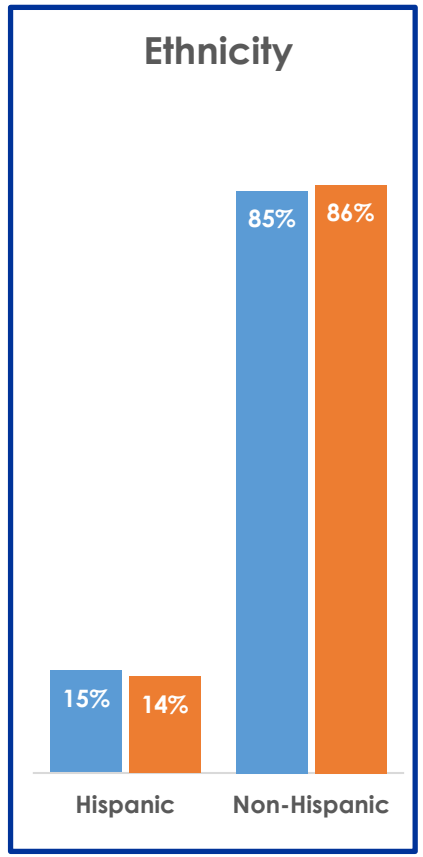
Cohort 1 Demographics

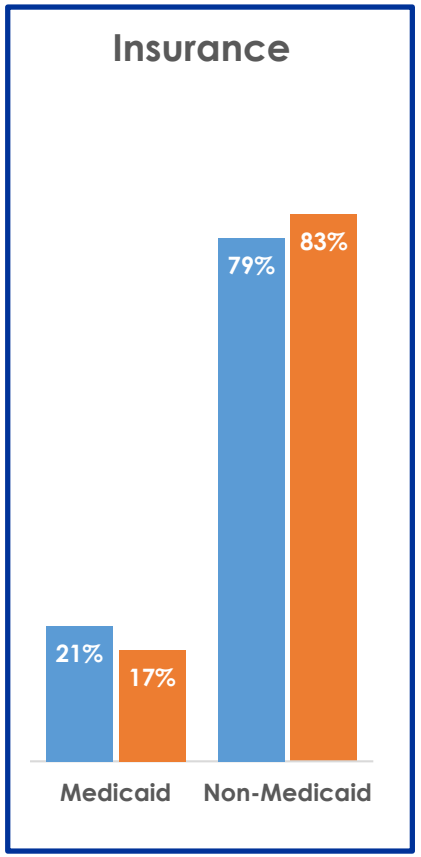
965 Adolescents,
75 Pediatricians

GGC (*n* = 468) Control (*n* = 497)









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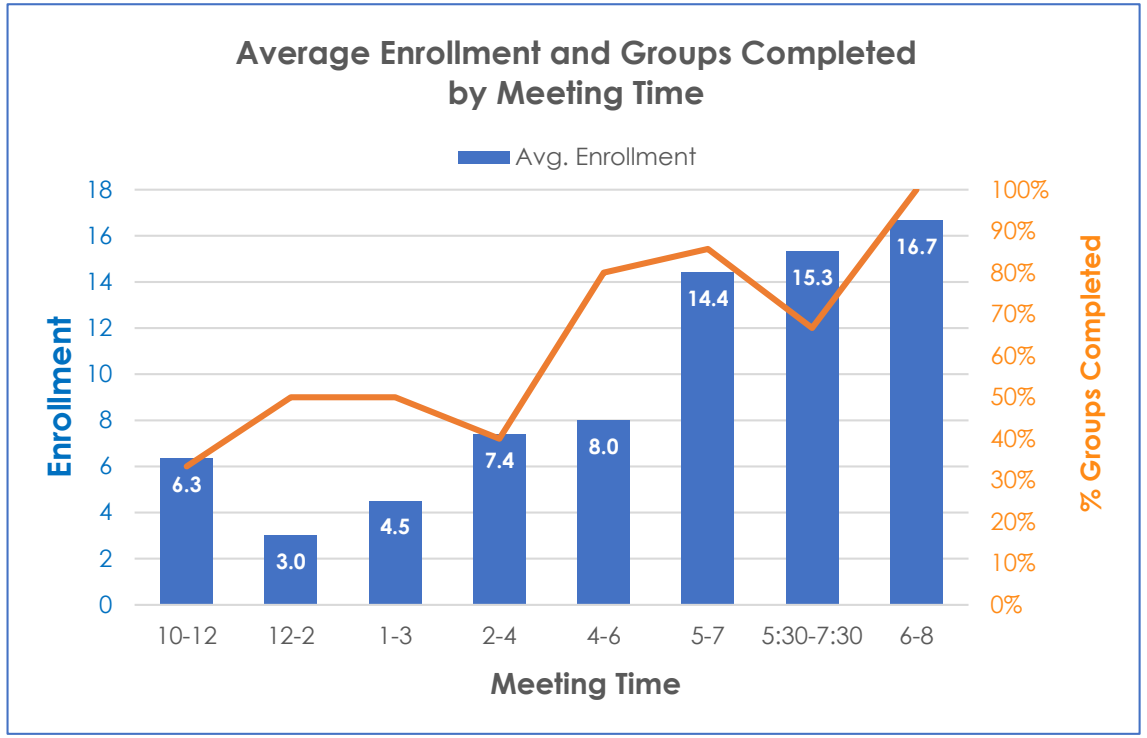
Cohort 1: Virtual GGC Enrollment

- Offered 5 Cycles of GGC from November 2020 – June 2021
  - Plan: 2 groups/site per cycle → 30 groups total (10 per site)
  - Launched: 26 groups (7-10 per site)
- Enrolled 308 families – 11.8 per group
  - 27% among PAWS families, 16% among broader set of families GGC offered to
  - Evening groups had better enrollment and retention
  - Fall, winter, early spring -- better enrollment than late spring, summer



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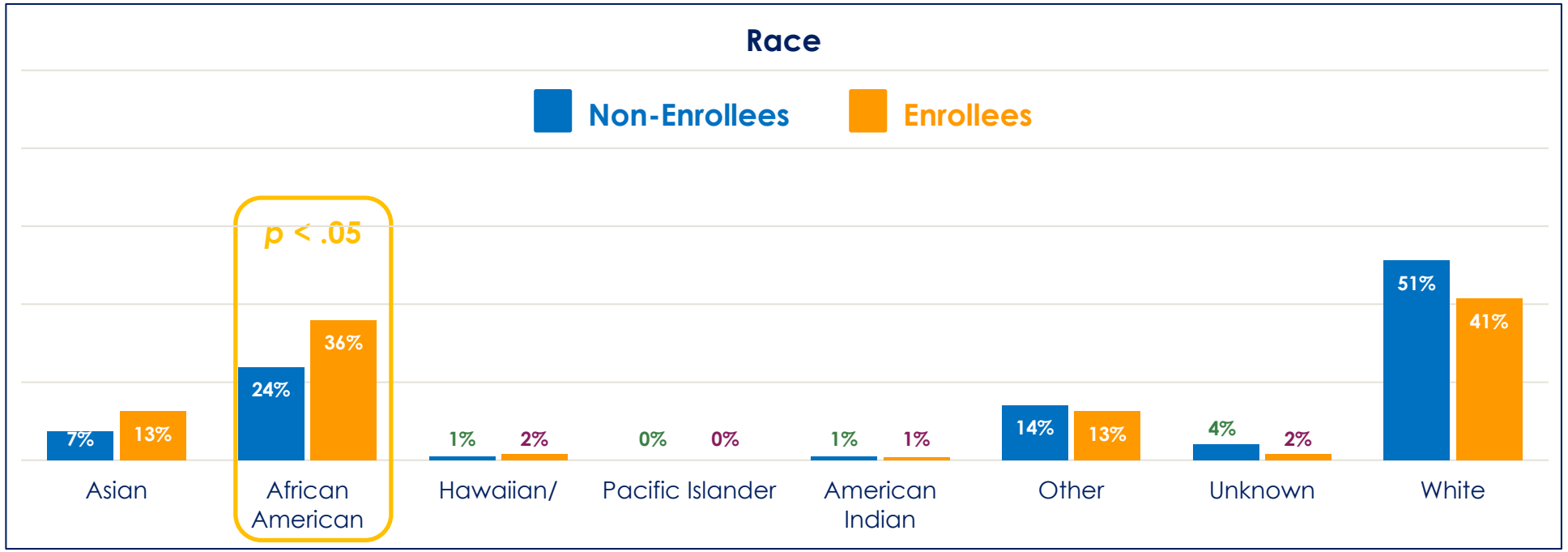
27% of study families enrolled in GGC

- **~10% higher than in community settings**
  - Few well visits → few in-person pediatrician recommendations due to COVID

- **Enrollees compared to non-enrollees***
  - Sex, ethnicity, insurance were similar
  - Some differences in race: More African Americans enrolled



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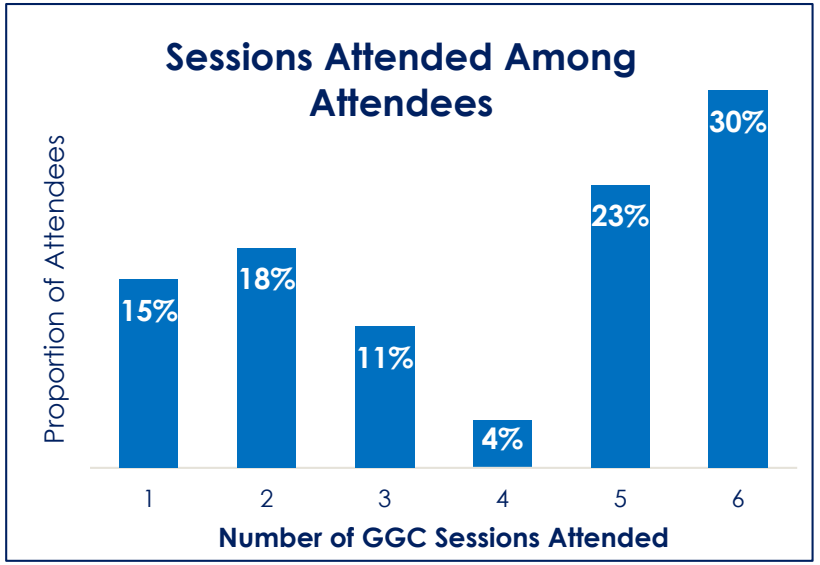
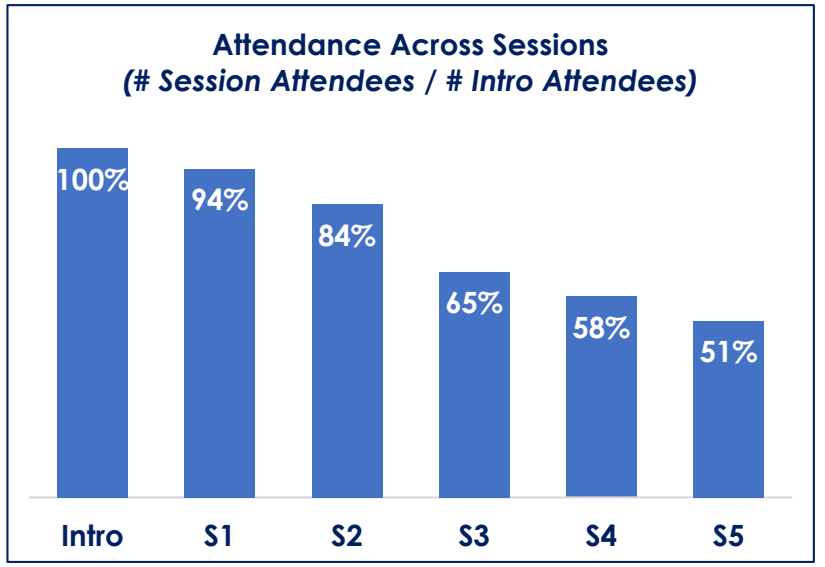
*Adolescent demographics

Attendance

- 63% of enrollees attended at least one session
- Attendees compared to non-enrollees*
  - Sex, ethnicity were similar
  - More likely to identify as Asian, less likely to be insured through Medicaid
- Among attendees, attendance was strong
  - Over 50% attended 5 or 6 sessions
  - *M* = 3.9 sessions, Median = 5 sessions, Mode = 6 sessions
- Some attrition after sessions – especially Session 2 (Guidelines) to Session 3 (Anger Management)





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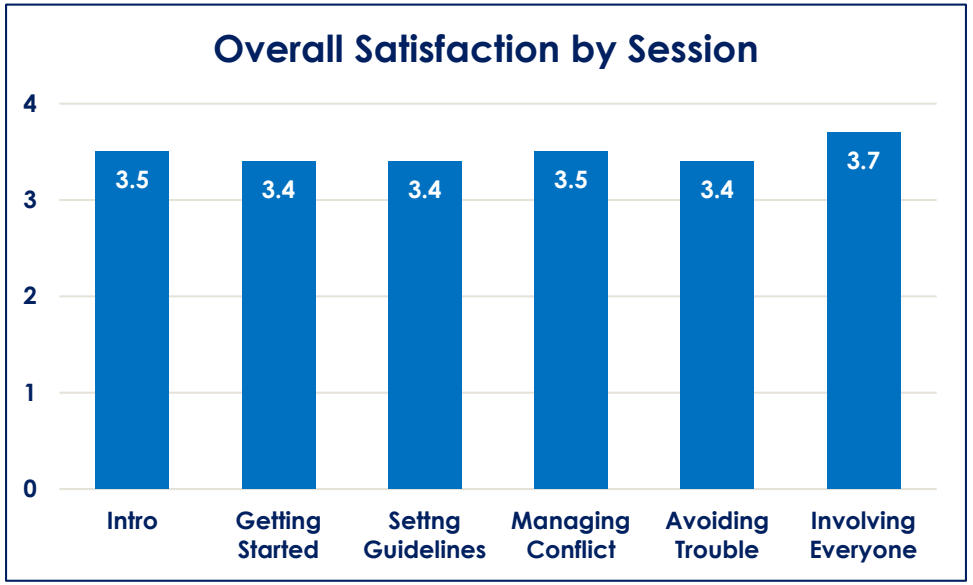
*Adolescent demographics

Satisfaction with Virtual GGC

How satisfied were you with each of the following aspects of the session?
(parent post-session surveys completed voluntarily, n = 120)

- Overall Session
- Video Segments
- Activities/ Exercises
- Family Guide
- Workshop process

1	Not Satisfied
2	Somewhat Satisfied
3	Satisfied
4	Very Satisfied



What Parents are Saying

"I feel empowered to **better deal with family conflicts** and my own contribution to them. Thank you!"

"The topic of this session [Session 2 - **guidelines, monitoring, consequences] could be the topic of the entire program**. Much of our **children's emotional health is in reaction to the choices made regarding substance abuse** and/or other excessive behaviors."

"The **small group discussions were awesome**. They gave us a chance to **connect with and learn from other parents**."

"I appreciated these sessions and that they **started conversations that can be difficult for parents to have with their children.** This course would be **extremely beneficial to most families."**

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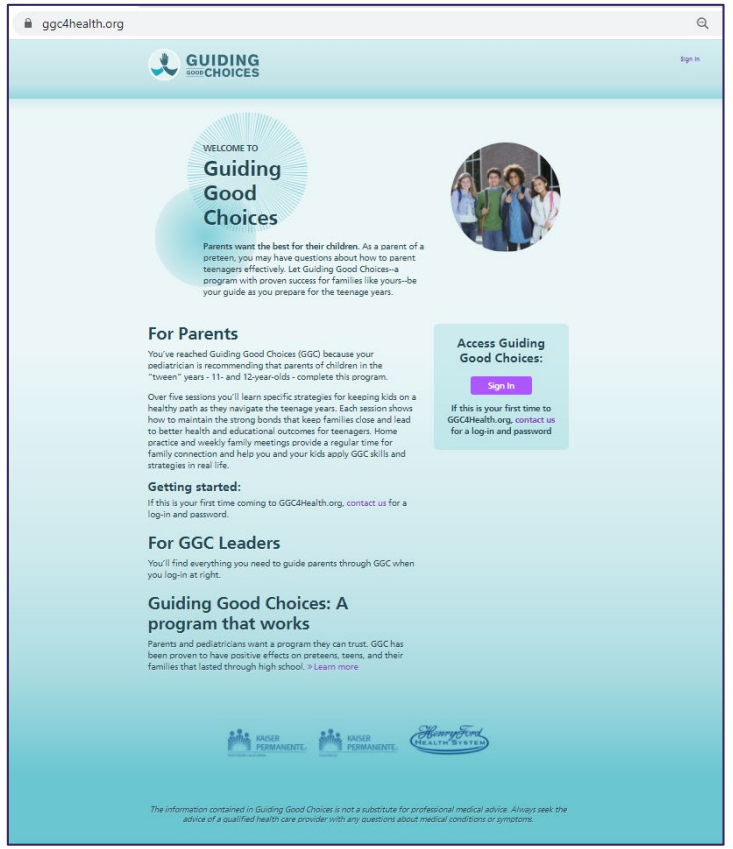
eGGC – Self-Guided Option

- Little engagement
  - Vast majority of eGGC participants never log in to website!
  - Outreach calls have not boosted engagement
- Hard-to-engage population
  - Declined option to enroll in GGC groups
  - Stopped attending GGC groups
  - Did not respond to enrollment outreach (calls, emails, texts)
- Offer more modest outreach
  - “Nudge” through emails, text messages
  - Offer calls to those who engage
  - Respond to any requests for support



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Next Steps

- Complete Cohort 2 recruitment and implementation
- Complete stakeholder interviews at each site to understand support for prevention
- Analyze Spanish language implementation (KPNC supplement & TPMG EID supplement)
- Continue analyses
  - Examine baseline levels of risk, protection, outcomes – pre-COVID and during the pandemic
  - Assess implementation fidelity
  - Assess parent knowledge, attitudes, skills prior to GGC
  - Patient Outcomes
- Manuscript Development

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Thank You!

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