SOCIAL DEVELOPMENT RESEARCH GROUP, University of Washington

KAISER PERMANENTE Northern California

Henry Ford Health System

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Guiding Good Choices for Health (GGC4H): Update and Lessons From the UG3 Phase

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Presentation to NIH Collaboratory Annual Meeting. May 1, 2019.

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GGC4H Multi-site Pragmatic Trial - Leadership Team

Guiding Good Choices for Health (GGC4H)

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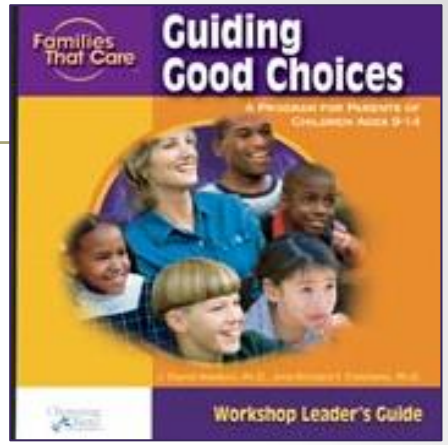
Guiding Good Choices (GGC)



- **5- Session program for all parents of adolescents ages 11-14**
- **Evaluated in two 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)
- **Sessions emphasize**
  - ✓ 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 <u>universally</u>, but skills generalize to other parenting concerns.*

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**

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.**

- **Instead: Have pediatricians refer parents to GGC for delivery by 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.***

GGC4H: 4-Year Pragmatic Trial

- **Longitudinal cluster-randomized trial in 3 HCS:**
  - ✓ *Kaiser Permanente Northern California, Kaiser Permanente Colorado, Henry Ford Health System*
  - ✓ *Randomize pediatricians within clinic and HCS (24 per HCS), approximately **3,636 families** recruited to experimental or control arm*
- **Implement GGC universally during two years (Y2, Y3 of study)**
  - ✓ *Intervention arm pediatricians refer all parents of adolescents ages 12 during well-child visit*
  - ✓ *2 GGC delivery modalities: Group and self-guided*
- **RE-AIM* framework** used to evaluate implementation and effectiveness outcomes through Y5
  - ✓ ***Implementation:*** *Reach, adoption, fidelity, participant engagement and skills*
  - ✓ ***Effectiveness:*** *Evaluate GGC's impact on adolescent substance use initiation at Year 5 endpoint*

Reach, **Effectiveness, **A**doption, **I**mplementation, **M**aintenance*

Project Status: A Very Busy UG3 Year!

INTERVENTION	DATA COLLECTION/ EHR	SITE IMPLEMENTATION	OVERSIGHT	ADMINISTRATIVE
• Develop, finalize self-guided intervention • Intervention available – all sites • Implementation and recruitment tools	• Design finalized • Develop, finalize data collection methods • Finalize plans for ascertaining primary endpoint	• Develop, finalize recruitment methods • Engage HCS practitioners • Train all personnel • Finalize sub-contracts	• Develop Governance Plan • Establish study-related committees • Finalize design, analysis plan • DSMB approval • IRB approval	• Protocol to NIH for initial review • Protocol to PRC • Transition Request to NIH

- Completed an ambitious set of milestones
- Pilot Study conducted at all sites (5 clinics)
- Transition Request made, 3 NCCIH reviews, 2 PRC meetings
- Awaiting UH3 funding decision

Challenge 1: Study Design

Goal: Answer 2 critical study questions

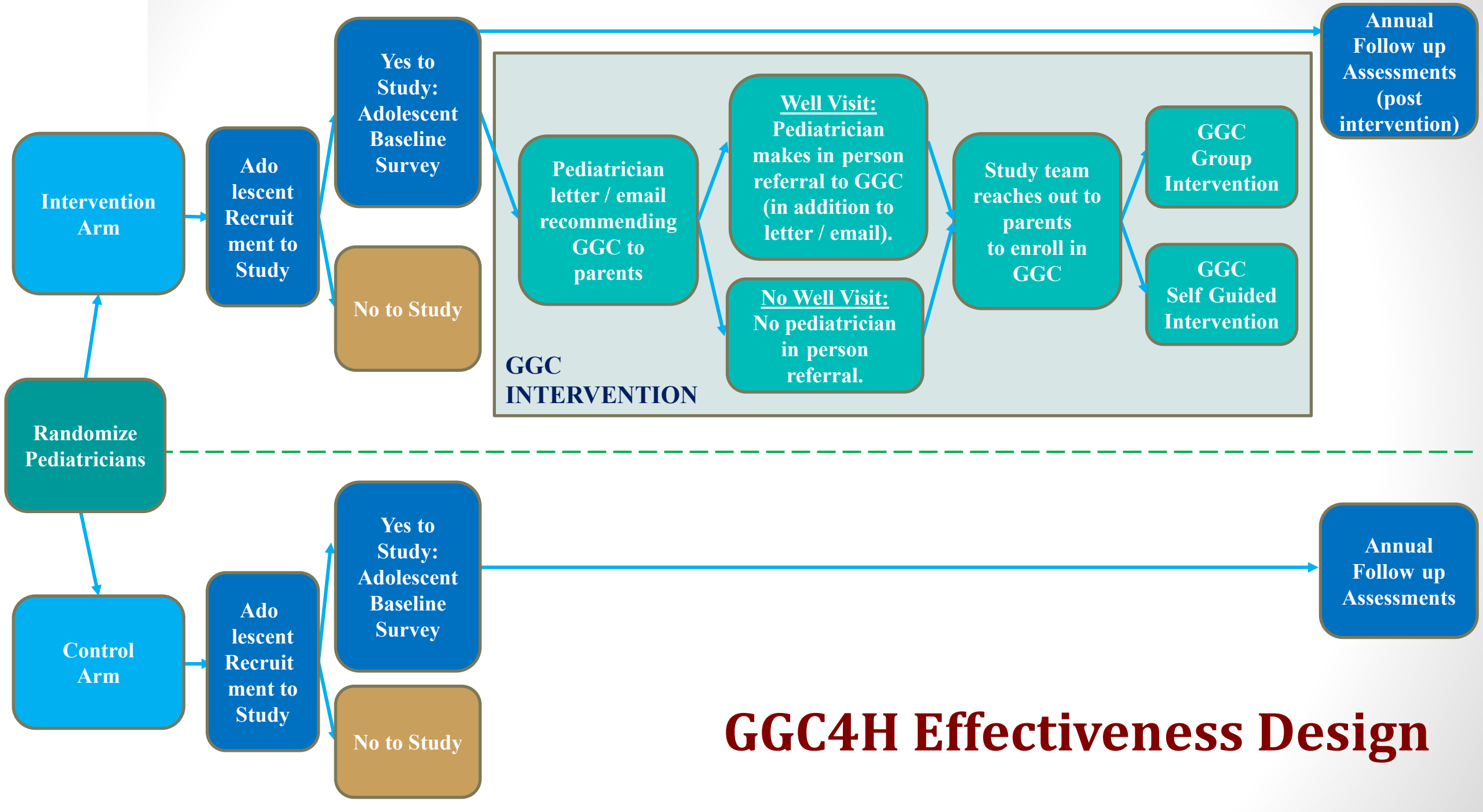
1) Assess GGC effectiveness
2) Understand GGC uptake in naturalistic setting

Original study design

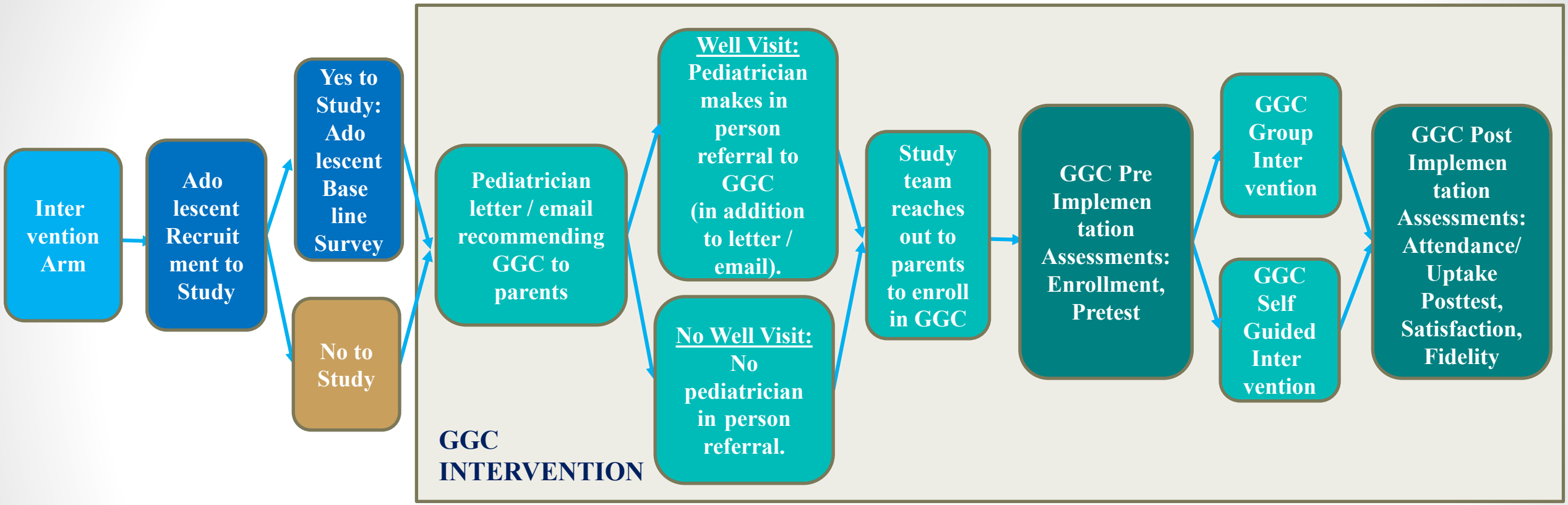
Pragmatic but problematic: Selection bias, no pre-intervention baseline data.

Final study design

1) Design challenges solved with input from Biostats core, PRC, and our own creative thinking
2) Allows us to address GGC effectiveness and uptake questions



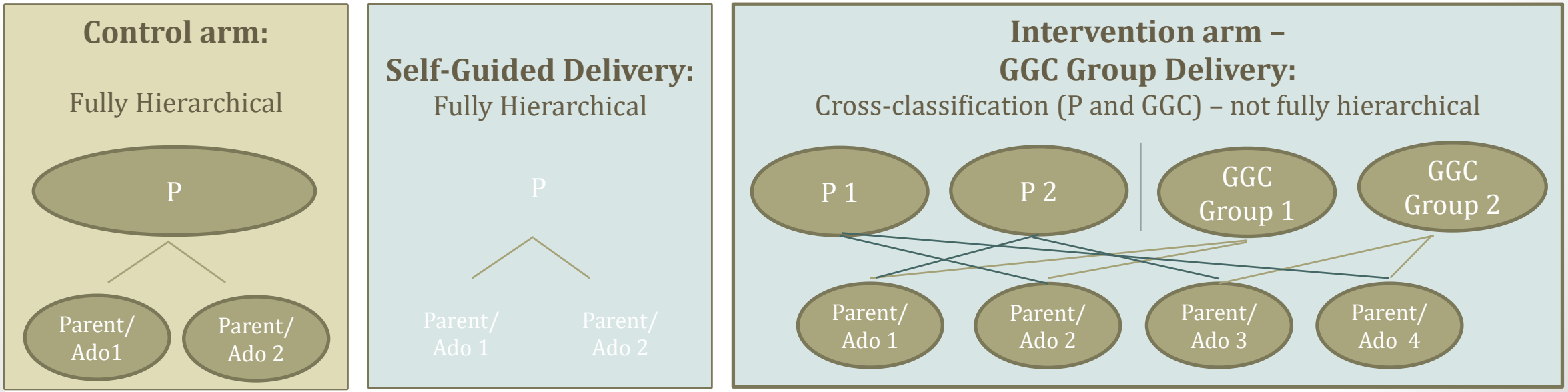
GGC4H Effectiveness Design



GGC4H Implementation Design

Challenge 2: Valid Statistical Inference

- **2 GGC delivery modalities:** Group and Self-guided
- **Pragmatic enrollment approach:** Parents from the same pediatrician (P) enroll in different groups, parents from different pediatricians (P) enroll in the same group → **cross-classification**
- **Result:** Cluster-randomized trial with partial cross-classification in the intervention arm
- **If not modelled appropriately:** Threats to inference (bias), increased Type I error



Solution: Include Strong Study Biostatisticians on the Team

- **Lead Biostatistician Quesenberry → Innovative statistical approach**
  - ✓ **Extended Luo et al. (2015)** for a generalized linear model with binary outcomes
  - ✓ Key: **Appropriate modelling of random effects** in control (pediatrician), self-guided GGC (pediatrician), and group GGC (pediatrician, GGC group)
  - ✓ Analysis focus: Point and interval estimation of trial arm indicator regression coefficient
- **Biostatistician Oleg Sofrygin conducted simulation study**
  - ✓ **Goal:** Evaluate power for assessing primary outcomes, alpha levels, coverage
  - ✓ **Varied:** Sample size, ICC for GGC groups and pediatricians, effect sizes for binary outcomes (based on prior GGC trials), group size
  - ✓ **Result – 2000 virtual cohorts: Strong power, nominal alpha levels, adequate coverage at 100%, 90% of expected adolescent recruitment levels**

GGC4H Data Sharing Plan

- **Internal Data Sharing Plan**
  - ✓ Remove all 18 Protected Health Identifiers.
  - ✓ Therefore do not need to execute data sharing agreements among 4 site partners.
- **External Data Sharing Plan: Supervised Data Archive with Monitored data sharing**
  - ✓ Protect against deductive disclosure.
  - ✓ De-identified individual data.
  - ✓ Requests must be of high scientific merit.
  - ✓ Co-authorship of at least one study PI or MPI.

GGC4H Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects			x		
Engagement of clinicians and health systems	x				
Data collection and merging datasets			x		
Regulatory issues (IRBs and consent)		x			
Stability of control intervention	x				
Implementing/delivering intervention across healthcare organizations			x		

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*Your best guess!
1 = little difficulty
5 = extreme difficulty

Many "Barriers" weren't because of Team Skills, Experience

- **Challenge was accomplishing so much so quickly!**
- **Great breadth and depth in skills, experience of team members**
  - IRB: ***Boggs***
  - HCS-embedded research and relationships, data sharing: ***Sterling, Beck, Braciszewski, Hartman, Daley, Perrin***
  - GGC intervention: ***Catalano, Haggerty, Kuklinski, Casey-Goldstein***
  - GGC intervention delivery: ***Negusse, Jones, Williams, Barela, Kazan, Elsiss***
  - Cluster-randomized trials in real-world settings: ***Catalano, Sterling, Kuklinski, Beck, Braciszewski, Brown***
  - Biostatistics/methodology: ***Quesenberry, Sofrygin, Oesterle, Brown***

GGC master trainer Kevin Haggerty and interventionists Rahel Negusse, Bre Barela, Amie Williams, Farah Elsiss, Rowyda Kazan, and Ashley Jones

Summary and Conclusions

- GGC4H: A pragmatic test of anticipatory guidance for parents of adolescents in primary care
- High levels of support and partnership from all three healthcare systems
- Excellent progress in UG3 phase—aided by Collaboratory input. Experience will benefit UH3 trial
- Simulation study showed statistical innovations provide more than adequate power to evaluate primary outcome at study endpoint
- We have a strong study team. We are enthusiastic and well-prepared for the larger trial.

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Thank You!

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