


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

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Presented at the 27<sup>th</sup> Annual Meeting of the Society for Prevention Research, San Francisco, CA, May 31, 2019. This presentation was part of the grouped paper session, “Administrative Data Supporting Prevention Research from Planning to Outcomes.”



We gratefully acknowledge GGC4H study funders  
**National Center for Complementary and Integrative Health**  
**National Institute on Drug Abuse**  
**Office of Disease Prevention**  
**Office of Behavioral and Social Sciences Research**

Research reported in this publication was supported within the **National Institutes of Health (NIH) Health Care Systems Research Collaboratory** by cooperative agreement UG3AT009838 from the National Center for Complementary and Integrative Health, with co-funding from the National Institute on Drug Abuse, Office of Disease Prevention, and the Office of Behavioral and Social Sciences Research. This work also received logistical and technical support from the **NIH Collaboratory Coordinating Center** through cooperative agreement U24AT009676. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

# Objectives

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- 1) **Overview: Guiding Good Choice for Health (GGC4H)**
- 2) **Opportunities for Parent-focused Prevention in Primary Care**
- 3) **Questions, Challenges, and Lessons Learned**
  - ✓ **Design:** Could we achieve pragmatic implementation and valid statistical inference?
  - ✓ **Data:** Could we harness EHR data to address key study questions?
  - ✓ **Implementation:** Would Pediatrician Referral lead to higher intervention enrollment rates?



NIH Collaboratory

*Rethinking Clinical Trials*®

Health Care Systems Research Collaboratory

# Part of NIH Healthcare Systems Research Collaboratory

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- **Part of the NIH Common Fund**
- **Overall Objectives:**
  - 1) Strengthen the national capacity to implement cost-effective large-scale research studies that engage healthcare delivery organizations as research partners
  - 2) Support the design and rapid execution of pragmatic clinical trial Demonstration Projects that address questions of major public health importance
- **10 different NIH centers and institutes are involved**
- **16 multi-site Demonstration Projects funded in 3 rounds through U mechanism (2-phased cooperative agreement)**

# GGC4H: 5-Year UG3 /UH3 Cooperative Agreement

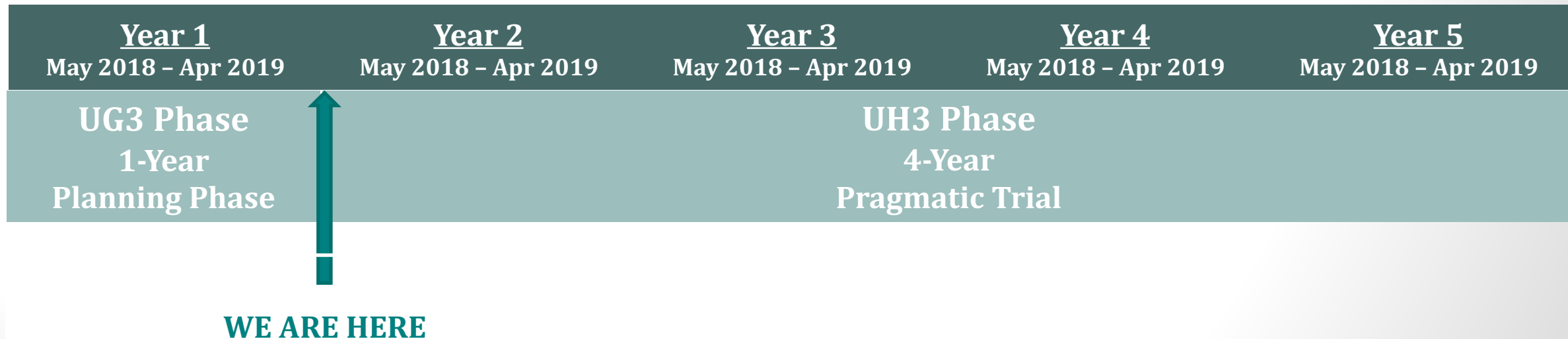
**Overall aim: Evaluate feasibility and effectiveness of implementing Guiding Good Choices in 3 large integrated healthcare systems:**

**Kaiser Permanente Northern California**

**Kaiser Permanente Colorado**

**Henry Ford Health System**

**working in partnership with University of Washington**



# GGC4H Multi-site Leadership Team

## Guiding Good Choices for Health (GGC4H)

### GGC4H Scientific Leadership

#### University of Washington

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Sabrina Oesterle, PhD  
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GGC Master Trainer

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### NIH Leadership

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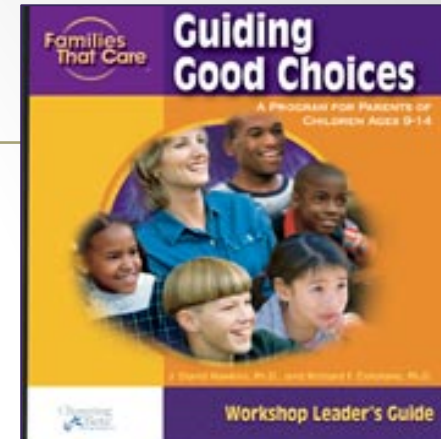
#### NIDA

Jacqueline Lloyd, PhD,  
Project Scientist

#### Ad Hoc Members

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

# Guiding Good Choices (GGC)



- **5- Session program for all parents of adolescents ages 11-14**
- **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.*

## GUIDING GOOD CHOICES SESSIONS

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



# GGC Helps Fill a Service Gap in Pediatric Primary Care

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- 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.*



# GGC4H: 4-Year Pragmatic Trial

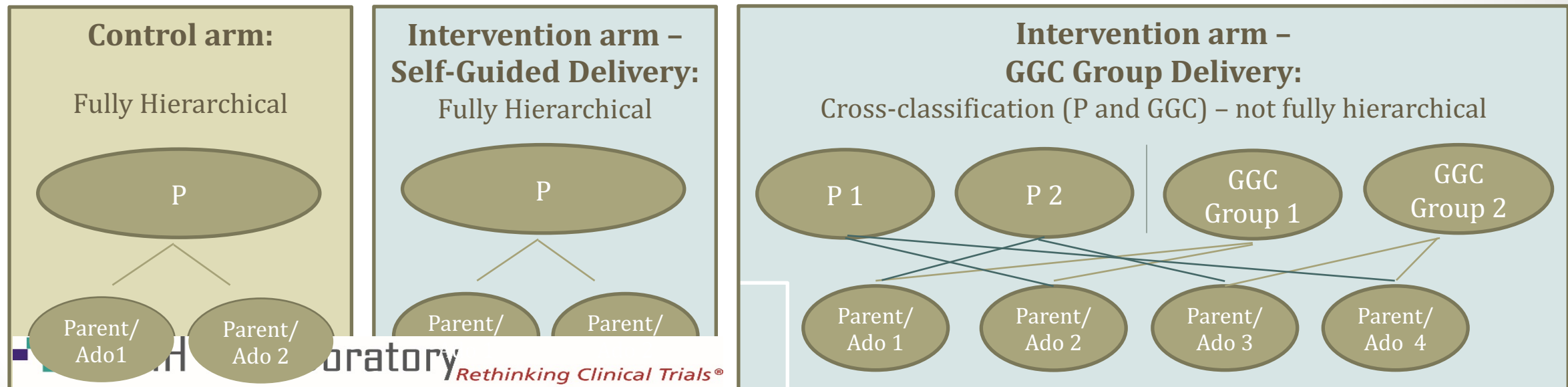
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- **Longitudinal cluster-randomized trial:**
  - ✓ Randomize pediatricians within clinic and HCS (24 per HCS), approximately **3,636 families** recruited to experimental or control arm
- **Implement GGC universally during two years (Y2, Y3 of study)**
  - ✓ 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 through Year 5 endpoint

*\*Reach, Effectiveness, Adoption, Implementation, Maintenance*

# (1) Design: Could we achieve pragmatic implementation and 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 intervention arm
- **If not modelled appropriately:** Threats to inference (bias), increased Type I error





# Innovative Modelling Approach from Biostatisticians

## Quesenberry and Sofrygin

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- 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:** P 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 P-level covariates, with focus on point and interval estimation of trial arm indicator regression coefficient

# Simulation Study: Power, Type I Error

## Results

- Primary outcomes: Log odds effect sizes for indicators of substance use initiation

Null hypothesis = 0.000

Tobacco use = 0.314

Marijuana use = 0.512

Alcohol use = 0.429

- Minimum power = .84
- Coverage of .93 or better
- Largest Type I error under Null = .06

- Input parameters

Healthcare systems 3

Pediatricians / HCS 24

Total sample / HCS 1,212 (3,636 parent-adolescent dyads)

Proportion GGC groups 30% of intervention participants

Parents per GGC group 15 (range: 6-15)

- ICC ranges

Pediatricians (P): 0.03, 0.05, 0.08, 0.10

GGC Groups: 0.03, 0.10

## (2) Data: Could we harness EHR data to address key study questions?

### Eligibility

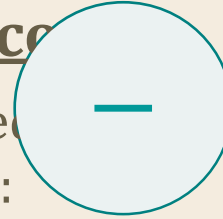


Identification of Intervention and Control Cohorts

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

# Would EHR data yield behavioral health outcomes?

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

## NO!

- Not measured or not measured consistently in EHRs of 3 HCS
- Developed **Adolescent Behavioral Health Survey** to collect data on behavioral health outcomes



### (3) Implementation: Would Pediatrician Referral lead to higher intervention enrollment rates?

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- **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





# Sample Scripts

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“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.”

# 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

# (3) Implementation: Would Pediatrician Referral lead to higher intervention enrollment rates?

## ■ 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



**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.


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Kaiser Permanente Oakland Pediatrics

## ■ 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

# Pilot Study Supported Feasibility of GGC

- **High fidelity delivery, high retention and satisfaction among parents**

- ✓ When groups started promptly, **~75% of enrolled parents attended at least 1 GGC session**
- ✓ **Modal attendance among attendees: 4 out of 5 sessions**
- ✓ **Overall satisfaction: 6.8 out of 7.0 (“very worthwhile”), and 100% would recommend GGC to other parents**



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

- **Self-guided GGC: 67% of those offered engaged, much positive feedback.**
- **Parents also want guidance about social media and screen time.**

# Early Lessons

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- Pediatric primary care may be a viable platform for scaling evidence-based parenting programs to achieve greater public health impact:
  - *GGC as a universal preventive intervention for parents of early adolescents seems to fill a service gap*
  - *Pediatrician recommendation may lead to higher enrollment*
  - *To be feasible, implementation / recommendation need to fit workflows of busy pediatric practices*
- Pragmatic implementation and valid statistical inference can both be achieved (with strong biostatisticians on board)
- EHR systems—even the VDW—are not likely to consistently contain data about children’s behavioral health outcomes of interest



**Thank You!**

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

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## 2 Critical GGC4H Goals

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

## Original study design

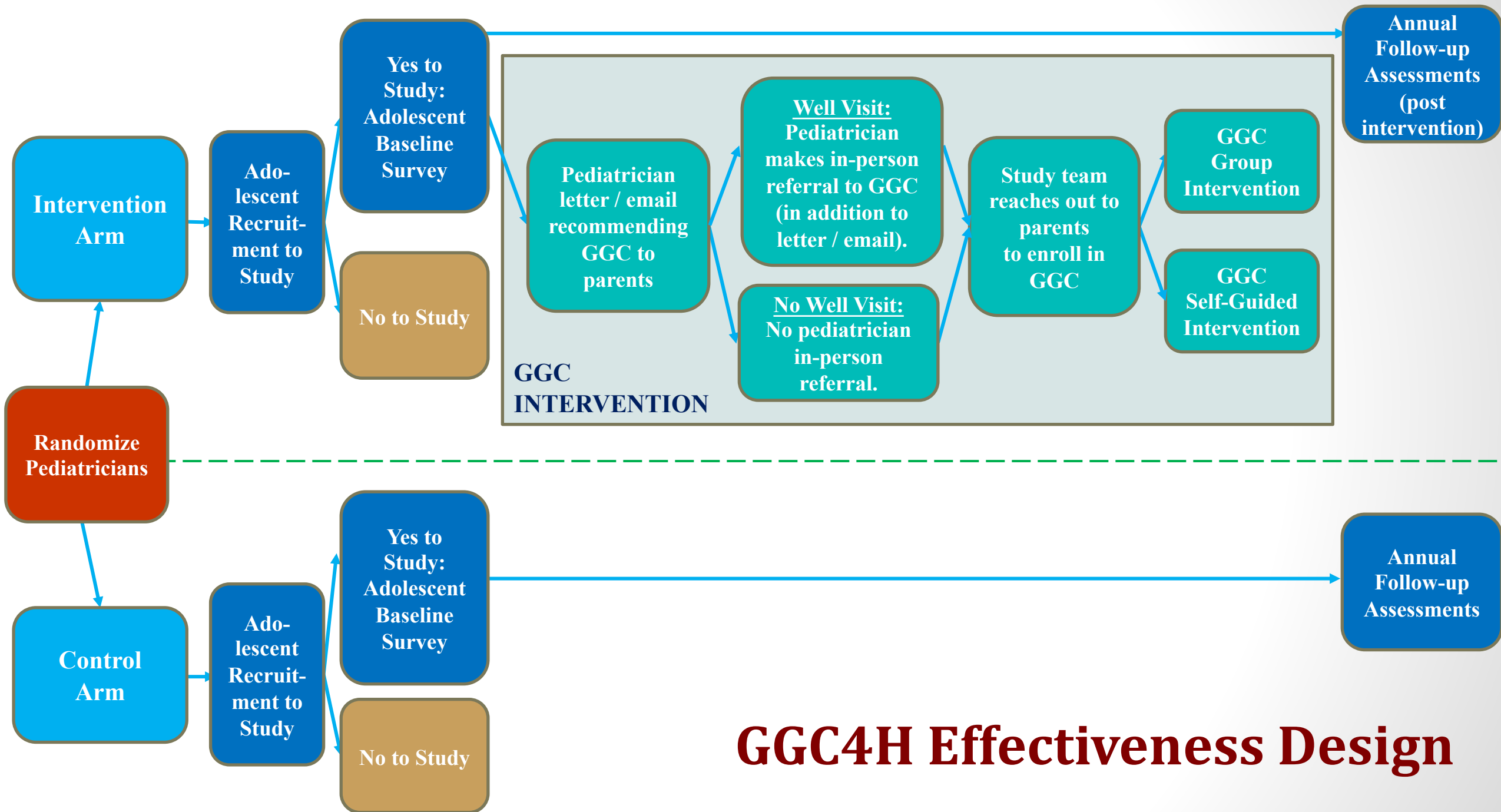
**Pragmatic:** Recruit participants to study after intervention to avoid contaminating intervention with study participation

**Problematic:** Selection bias, no pre-intervention baseline data

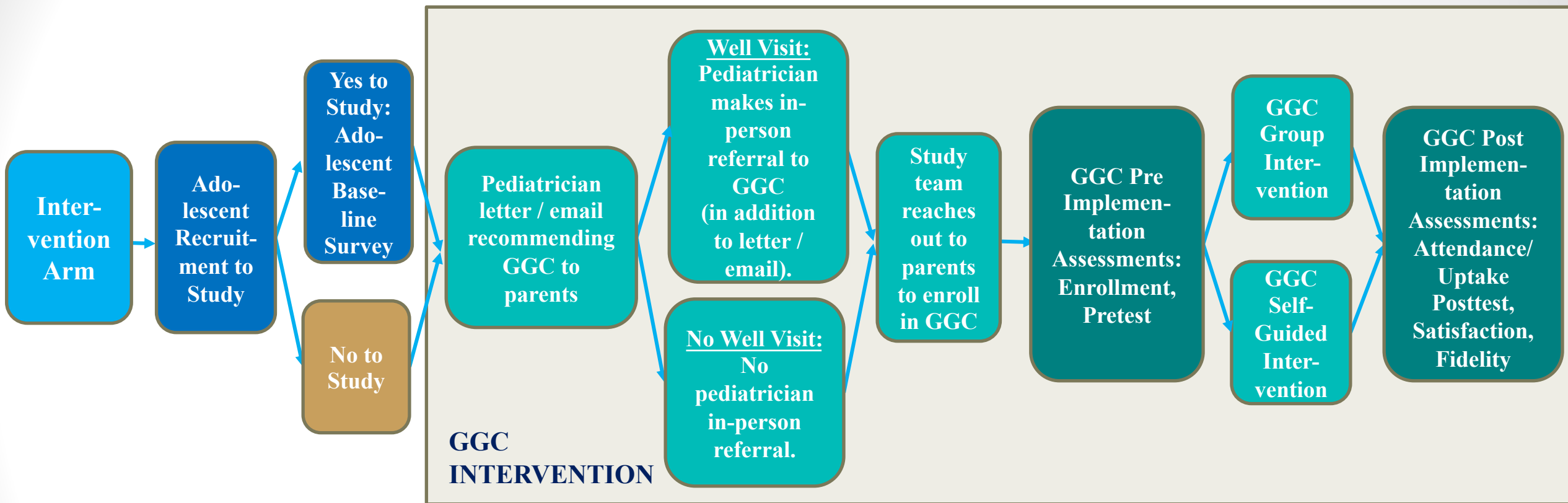
## Final study design

- 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

## GGC Group ICC = 0.10

Simulation analyses with 2000 virtual cohorts at 2 different study recruitment rates:

(1) 100% ( $n = 3,636$ )

(2) 90% ( $n = 3,272$ )

### Results:

- Minimum power = .84
- Coverage of .93 or better
- Largest Type I error under Null = .06

betaT = coefficient on treatment variable. ICC\_P = Pediatrician ICC.

Run	betaT	ICC_P	Power		Coverage	
			at Different Adolescent Recruitment Rates		at Different Adolescent Recruitment Rates	
			100%	90%	100%	90%
1	0.000	0.03	0.05	0.06	0.95	0.94
2	0.314	0.03	0.97	0.95	0.94	0.95
3	0.429	0.03	1.00	1.00	0.95	0.95
4	0.512	0.03	1.00	1.00	0.95	0.93
5	0.000	0.05	0.06	0.05	0.94	0.95
6	0.314	0.05	0.93	0.94	0.94	0.95
7	0.429	0.05	1.00	1.00	0.94	0.95
8	0.512	0.05	1.00	1.00	0.95	0.94
9	0.000	0.08	0.06	0.06	0.94	0.94
10	0.314	0.08	0.90	0.87	0.94	0.95
11	0.429	0.08	0.98	0.99	0.93	0.94
12	0.512	0.08	1.00	1.00	0.94	0.94
13	0.000	0.10	0.05	0.04	0.95	0.96
14	0.314	0.10	0.85	0.83	0.95	0.95
15	0.429	0.10	0.98	0.97	0.95	0.94
16	0.512	0.10	1.00	1.00	0.94	0.94