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A NEW PRAGMATIC TRIAL:

PARENTS, PEDIATRICIANS, AND PREVENTION: PATHWAYS TO ADOLESCENT HEALTH

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Many Behavorial Health Problems Begin Or Rise Sharply During Adolescence

By the time they leave high school

- **50% of adolescents** will have used some form of **illicit drugs.**
- **20-25%** will have met diagnostic criteria for **depression.**
- Many will engage in **delinquency or violence.**
- **Other common behavioral health problems:** Sexual risk behavior, other mental health problems, academic and school problems.

➔ ***Behavioral health problems in adolescence influence later health.***

40 Years Of Prevention Science Research Advances

Over 70 effective policies and programs proven to prevent behavioral health problems are now available:

- **Effective programs: www.blueprintsprograms.com**; O'Connell, Boat & Warner, 2009, Surgeon General, 2016.
- **Many effective parenting programs are among these tested and effective prevention programs.**
- **Effective prevention saves money: www.wsipp.wa.gov** Washington State Institute for Public Policy Benefit-Cost Results, May 2017.

Why Implement Evidence-based Parenting Programs?

1) Parents want their children to be successful.

2) Children want to discuss important issues with their parents throughout development.

3) Many risk and protective factors for behavior problems can be affected by family action.

4) Parenting programs have shown impact on risk and protective factors, increased positive and reduced behavioral health problems in controlled trials.

Many Advantages to Providing Parenting Programs In Pediatric Primary Care

- **Pediatricians have high credibility** and are trusted by parents.
- Pediatric primary care is **universal and relatively affordable**.
- Care provided in **a pediatric setting is non-stigmatizing and preventive** as almost everyone with a child goes to a pediatrician or family physician.
- Universal programs can fulfill Bright Futures guideline of providing **anticipatory guidance to all parents** – currently a challenge.

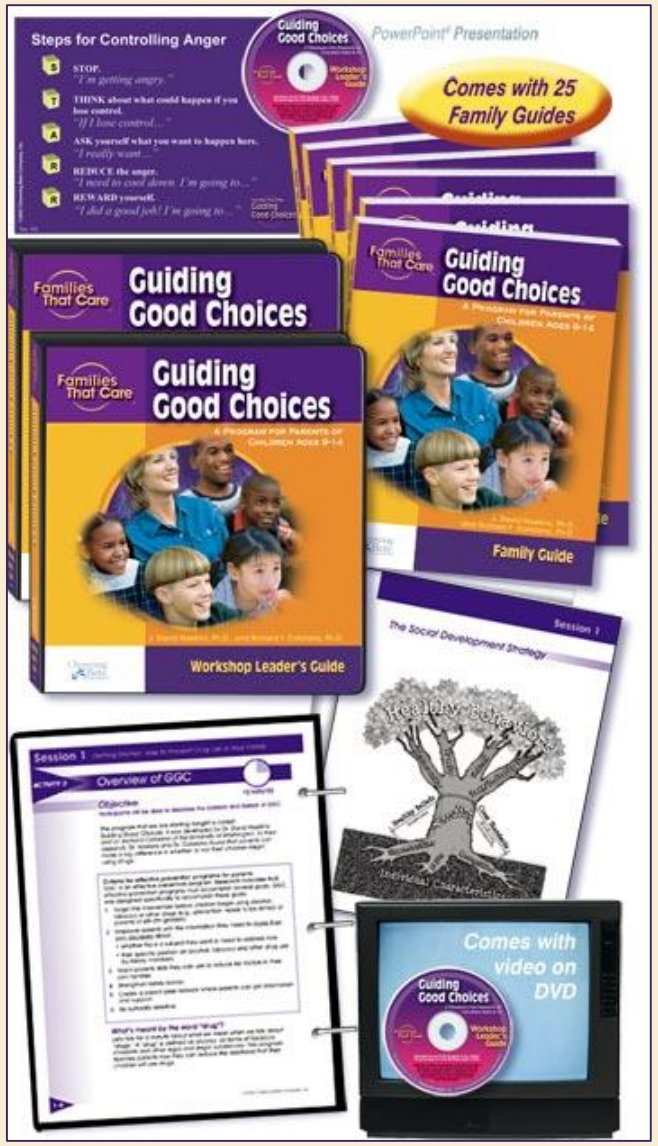
➔ ***These advantages may create high recruitment and retention rates for parenting programs and achieve public health impact.***

Recruitment to Effective Parenting Programs is a Critical Research Question

- **School-based trials** of parenting programs have produced **population wide effects despite low recruitment rates:** 17% in PROSPER study.
- What population level effect might be achieved if **40% or more of eligible families** were reached with an **effective preventive intervention?**
- **Can a non-stigmatizing, credible primary care provider obtain this level of parenting program exposure?**

Guiding Good Choices

- Universal prevention program for **parents of early adolescents** ages 11-14
- Theoretically grounded: **Social Development Model**
- **Five 2-hour sessions** emphasize **bonding, parenting skills, healthy communication**
- **2 RCTs demonstrated behavioral health impact:**
  - ✓ Affects **Parenting Behavior** regardless of family risk (Spoth et al., 1998)
  - ✓ Reduced Growth in **Substance Use** (Mason et al., 2003)
  - ✓ Reduced Growth in **Delinquency** (Mason et al., 2003)
  - ✓ Reduced **Depressive symptoms** (Mason et al., 2007)
  - ✓ **Cost-beneficial: Benefit-Cost Ratio: $2.77** (WSIPP, 2018)



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- 4.2 million members, with **1 million pediatric members**
  - ✓ 45% of all commercially insured Northern Californians;
  - ✓ 52% female, 17% Hispanic, 20% Asian, and 7.5% African American.
  - ✓ Members insured through employer-based plans, Medicare, Medicaid, and health insurance exchanges.
- Approximately **43% of adolescents ages 11-15** have **annual well-check.**
- Implementation site: **KPNC Oakland Pediatrics Department**
  - ✓ SES and racial/ethnic diversity in members
  - ✓ Physicians' demonstrated interest in partnering in research studies
  - ✓ 45 PCPs, all board certified in Pediatrics or Family Medicine, 59% female and 49% non-white.

- A leading non-profit health care system serving **over 1 million people** in **Metropolitan Detroit.**
  - ✓ Diverse membership: 33% African American, 54% White, 3% Asian, 1% Hispanic
  - ✓ Patients are insured through a number of health plans, including the HFHS-owned Health Alliance Plan.

- **72% of young people** have annual primary care visit, **often with well-check.**

- Candidate clinics chosen for **racial and socio-economic diversity** and **clinicians' support for and enthusiasm about participation in research:**
  - ✓ **New Center One Clinic,** Midtown Detroit: Urban, high concentration of African-American families
  - ✓ **Ford Road Clinic,** Dearborn: Largest Arab-American population in the world outside of Middle East
  - ✓ **Sterling Heights Clinic:** Predominately working to middle class families, sizeable rural catchment area
  - ✓ **Farmington Road Clinic:** Suburban, higher SES families.

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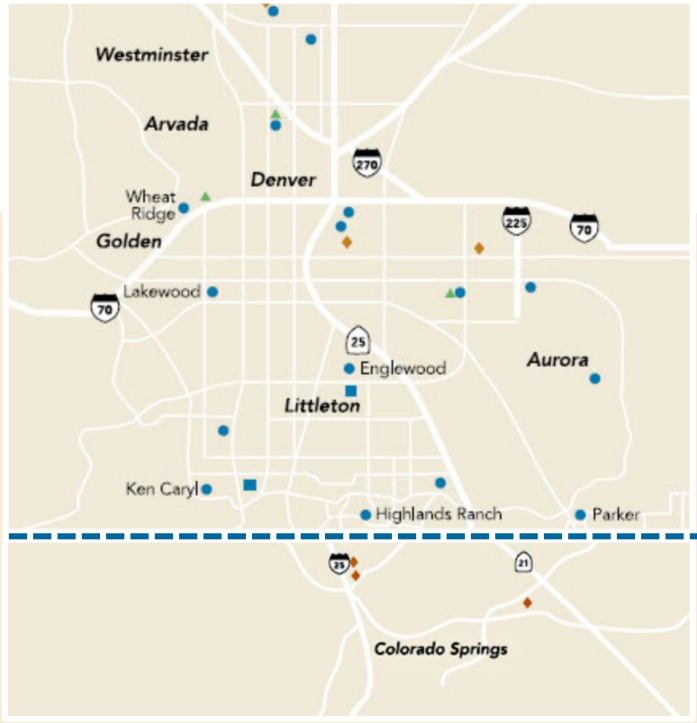

- **625,000 members** in Denver, Boulder, Southern CO and Northern CO.
  - ✓ 70% White, 3% Asian, 4% African American, 22% mixed racial background, 22% report Hispanic ethnicity.
  - ✓ Provides health insurance for approximately 20% of the Denver metropolitan population.
- Over **70% of members ages 11-15 in candidate clinics** received a **well-check** in prior year.
- Candidate clinics represent **urban and rural Coloradans** (select up to 4):
  - ✓ Denver/Boulder metro area clinics: **East, Skyline, Smoky Hill**
  - ✓ Eastern plains clinics: **Greeley, Pueblo**
  - ✓ Rocky Mountain clinics: **Frisco, Edwards**

Model of Anticipatory Guidance

Engage & Maintain Support

of stakeholders in KPNC, KPCO, and HFHS.

Partner with them to finalize plans for pragmatic trial.

Engage & Enroll Parents In GGC

IDENTIFY eligible families who have an adolescent age 11-12.

PUBLICIZE GGC with flyers from HCS & PCP endorsement letter.

PRESCRIBE GGC at well-check: PCP offers "warm hand off."

1 FOLLOW-UP CALL to enroll parents

GGC Group Intervention or **Workbook Self-Study** for non-group enrollees.

Deliver GGC in 3 HCS

DELIVER GGC parent groups & support **self-study** parents

ACHIEVE PROXIMAL IMPACT on target parenting behaviors, skills, and parent-adolescent relationship quality.

IMPROVE ADOLESCENT BEHAVIORAL HEALTH:
Substance use initiation (alcohol, marijuana, and tobacco), secondary, and exploratory outcomes

DISSEM-INATE MODEL & FINDINGS TO HCS & NON-HCS RESEARCH, PRACTICE, AND POLICY STAKE-HOLDERS

USE ONGOING FINDINGS & FEEDBACK
FROM ALL HCS STAKEHOLDERS TO IMPROVE MODEL

Study Design – UH3 Phase

- **Cluster-randomized controlled trial (C-RCT): Randomization of pediatricians within healthcare systems (HCS)**
  - ✓ 3 HCS
  - ✓ 24 pediatricians per HCS (N = 72 total)
- **Pediatricians recommend that parents enroll in GGC at their child's age 11-12 wellness visit**
  - ✓ Group intervention
  - ✓ Self-study with outreach/support for those who do not choose group
- **2 cohorts of families — estimated sample size: 4,608 families**
  - ✓ Cohort 1: Intervention in Y2, follow-up in Y3 – Y5
  - ✓ Cohort 2: Intervention in Y3, follow-up in Y4 – Y5

Adolescent Behavioral Health Outcomes

- **Primary – Substance use initiation with 3 indicators**
  - ✓ Alcohol use
  - ✓ Marijuana use
  - ✓ Tobacco use
- **Secondary – Other impacts from prior trials**
  - ✓ Depressive symptoms
  - ✓ Antisocial behavior
- **Exploratory – Available in EHR, not previously evaluated but plausibly linked to GGC**
  - ✓ Anxiety symptoms
  - ✓ Health service utilization

Some RE-AIM Hypotheses & Measures*

CONSTRUCT	HYPOTHESES	MEASURES
REACH	• Parent enrollment in GGC will be higher than in non-HCS settings.	EHR data, Enrollment call sheets
ADOPTION	• HCS partners will remain engaged and find the model feasible and useful. • Parents will be engaged in GGC and find it useful.	Stakeholder meeting notes, Qualitative Interviews, GGC Attendance Records, GGC Satisfaction Surveys, Project Self-Study Call Sheets
IMPLEMEN-TATION	• Engagement, enrollment, and program delivery will be consistent with protocols.	Enrollment call sheets, GGC Fidelity Forms
MAINTEN-ANCE	• Results will be maintained or strengthened over time. • Results will generalize across HCS, and participant gender, race/ethnicity, health insurance status, and primary language.	Measures used for other constructs

** Data sources: HCS Stakeholders, pediatricians, parents, adolescents, and EHR records*

Data Sharing UG3

- **Waiver of informed consent**
  - ✓ A major study aim is to assess whether parents will enroll in a parenting intervention.
  - ✓ Therefore we will consent post intervention delivery for the research study and get a waiver of informed consent at enrollment.
  - ✓ We will obtain consent from parents and assent from adolescents prior to collecting data.
  - ✓ We have not obtained IRB approval yet.
- **Current Data Sharing Plan: 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.

Barriers Scorecard

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

We assumed 3 = difficulty typical of a complex RCT and would be experienced in completing most items.

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

Key Takeaways

1) **Good parenting is prevention.**

2) **Implementation of Guiding Good Choices** in **pediatric primary care** provides an **opportunity to study** whether we can **reach large numbers of parents** and achieve **public health impact.**

3) **Our healthcare systems partners** are well-positioned to **disseminate** model and findings to other **large healthcare systems, Federally Qualified Health Centers, and community-based health centers.**

Thank you for supporting this study!

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Additional Material

P4TH: MULTISITE PARTNERSHIP TO IMPLEMENT GUIDING GOOD CHOICES, IN 3 HEALTHCARE SYSTEMS

- **Social Development Research Group, School of Social Work, University of Washington**, developers of Guiding Good Choices
- **3 large "learning" healthcare systems:**
  Kaiser Permanente Northern California
  Henry Ford Health System
  Kaiser Permanente Colorado
- **Evaluate implementation and effectiveness outcomes using RE-AIM framework**

FIVE 2-HOUR SESSIONS, ONE INCLUDING ADOLESCENTS

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

Sessions emphasize parenting skills

- Build family bonding
- Establish and reinforce clear and consistent guidelines for children's behavior
- Teach children skills to resist peer influence
- Improve family management practices
- Reduce family conflict

ESTIMATED SAMPLE SIZE

	HCS Site KPNC		HCS Site HFHS		HCS Site KPCO		TOTAL ACROSS HCS SITES		
PCPs									
Intervention	12		12		12				**36**
Control	12		12		12				**36**
Total PCPs	24		24		24				**72**
FAMILIES	Cohort 1	Cohort 2	Cohort 1	Cohort 2	Cohort 1	Cohort 2	Cohort 1	Cohort 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**		

ADOLESCENT ASSESSMENT SCHEDULE

	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*