A NEW PRAGMATIC TRIAL:

PARENTS, PEDIATRICIANS, AND PREVENTION:
PATHWAYS TO ADOLESCENT HEALTH

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Many Behavioral 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:


- Many effective parenting programs are among these tested and effective prevention programs.

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)
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.
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**
- 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

**Use Ongoing Findings & Feedback**
- From all HCS stakeholders to improve model

**Partner** with them to finalize plans for pragmatic trial.

**Disseminate Model & Findings**
- To HCS & non-HCS research, practice, and policy stakeholders
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*

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

* 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

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Level of Difficulty*</th>
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<tbody>
<tr>
<td>Enrollment and engagement of patients/subjects</td>
<td>✓</td>
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<tr>
<td>Engagement of clinicians and health systems</td>
<td>✓</td>
</tr>
<tr>
<td>Data collection and merging datasets</td>
<td>✓</td>
</tr>
<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td>✓</td>
</tr>
<tr>
<td>Stability of control intervention</td>
<td>✓</td>
</tr>
<tr>
<td>Implementing/delivering intervention across healthcare organizations</td>
<td>✓</td>
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</table>

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

*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

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

**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
# Estimated Sample Size

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<thead>
<tr>
<th></th>
<th>KPNC</th>
<th>HCS Site</th>
<th>KPCO</th>
<th>Total Across HCS Sites</th>
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<tr>
<td><strong>PCPs</strong></td>
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<tr>
<td>Intervention</td>
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<tr>
<td>Control</td>
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<tr>
<td>Total PCPs</td>
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<td>24</td>
<td>24</td>
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<tr>
<td><strong>FAMILIES</strong></td>
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<tr>
<td>Control</td>
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<td>384</td>
<td>1152</td>
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<tr>
<td>Intervention</td>
<td>384</td>
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<td>1152</td>
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<tr>
<td>Delivery mode</td>
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<tr>
<td>GGC groups</td>
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<td>GGC self-study</td>
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<tr>
<td><strong>Total</strong></td>
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<td>768</td>
<td>768</td>
<td>2304</td>
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<tr>
<td><strong>Total Families</strong></td>
<td>1536</td>
<td>1536</td>
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## Adolescent Assessment Schedule

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<thead>
<tr>
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<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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<tr>
<td><strong>Cohort 1 (n=2304)</strong></td>
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<tr>
<td>Intervention (n=1152)</td>
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<td>3</td>
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<tr>
<td>Control (n=1152)</td>
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<tr>
<td>Adolescent age</td>
<td>11-12</td>
<td>12-13</td>
<td>13-14</td>
<td>14-15</td>
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<tr>
<td><strong>Cohort 2 (n=2304)</strong></td>
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<td>Intervention (n=1152)</td>
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<td>Control (n=1152)</td>
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<td>11-12</td>
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