

*Cumulative Randomized Trial
Design for A Youth Suicide
Prevention Program*

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Outline

Limited evidence-base on community suicide prevention programs

Many states implementing suicide prevention programs

Special design challenges for low base rate behaviors (suicide) and ethical considerations for assigning communities to serve as controls.

Two ongoing randomized trials: Responding to Community / Scientific Needs

1. ***Georgia Gatekeeper Trial*** – Evaluate program as it is implemented system-wide;

From Trial 1, adopted a new Public Health Model for youth suicide prevention:

2. ***Sources of Strength Trial*** – Cumulative randomized trial to evaluate an evolving intervention across multiple randomized experiments

Support

**R34MH071189-01 (Wyman, Brown) NIMH
RCT of Gatekeeper Training for Suicide Prevention**

**SM57405-01 (Wyman, Brown) SAMHSA
Evaluating Success of a Gatekeeper Program in Linking Suicidal Students to Treatment**

**Supplement to SM57405-01 (Wyman, Brown) SAMHSA
Enhancing Youth and Community Engagement in Suicide Prevention**

**P20MH071897-01 (Caine) NIMH
Developing Center On Public Health and Population
Interventions For The Prevention Of Suicide**

**R01-MH40859 (Brown) NIMH NIDA CDC
Methodology for Mental Health/Substance Abuse Prevention & Early Intervention**

**SPAN-GA Developmental Support from the State of Georgia
Cobb County School District, Georgia**

**JDS Foundation (Brown, Wyman) Development of an Integrated Suicide Prevention
Program for Rural and Underserved Youth**

New York State-Office of Mental Health

Adolescent Suicidal Behavior

- 2-4% of teens acutely suicidal each year (YRBS)
- 10/100,000 deaths per year (CDC 2007)
- 3rd leading cause death ages 12-24
- 10-100 times more attempts (WHO 2004)
- Rural/tribal areas: **2 – 200** times higher suicide rates than national average

Limited Research-Base for Suicide Prevention

Many suicide prevention programs but few rigorously evaluated. Examples:

SOS – Aseltine & DeMartino 2004

Post-hospital -- Motto & Bostrom 2001

CBT for BPD – Linehan et al., 2006

Many programs are not currently ready for large-scale evaluation, but are being widely distributed.

How do we move the field forward?

Population-based approaches needed for suicide prevention

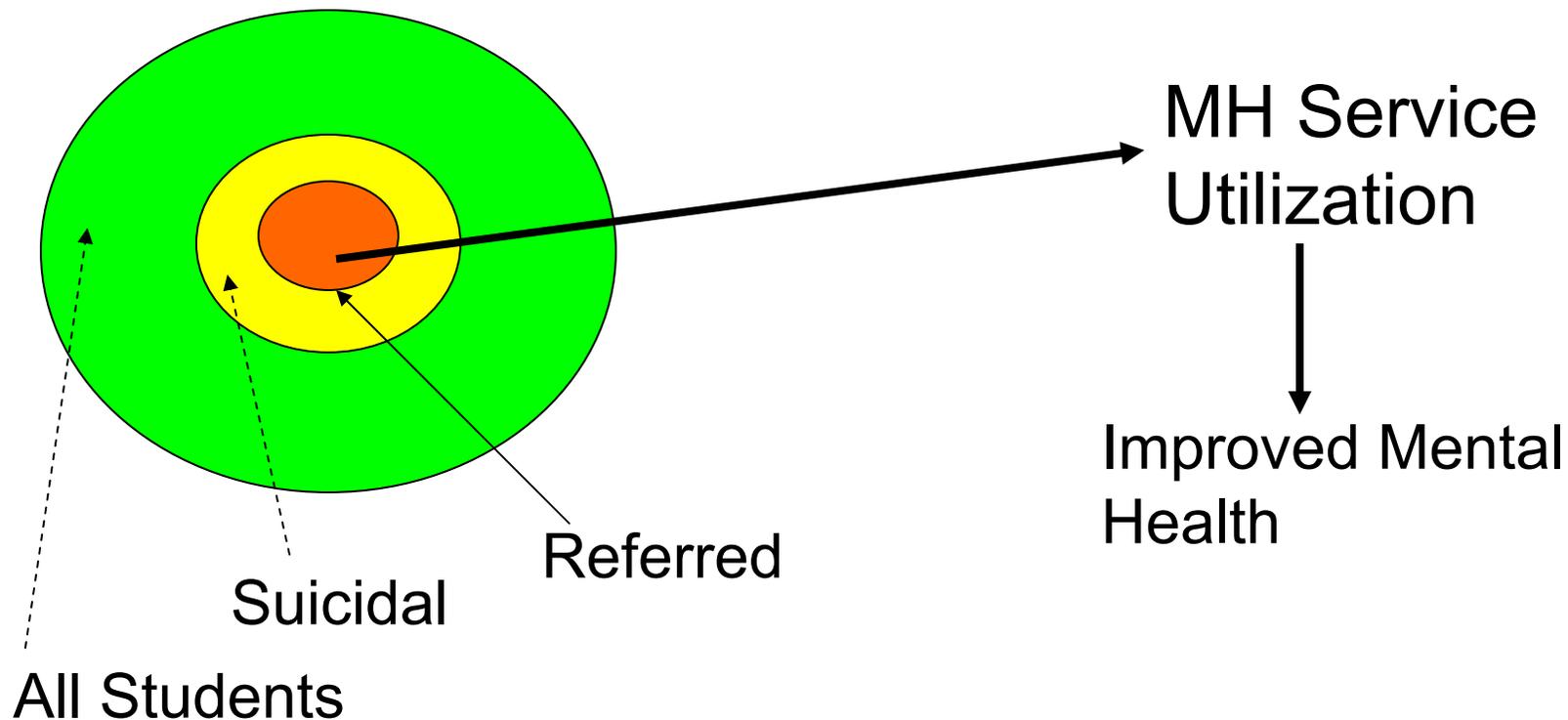
- No readily identified population group contains majority who die by suicide (Brown et al 2007)
- Few youth with mental health disorders in treatment (Gould & Kramer, 2001).
- “**Rose’s Theorem**” ... “*a large number of people at small risk may give rise to more cases of disease than a small number who are at high risk*”. (True of CVD, suicide)
- **Screening** and **gatekeeper training** – two widely used population strategies to identify suicidal youth/refer for treatment

Georgia Gatekeeper Project: Randomized Trial of QPR

- Large school district (Cobb County, GA) decided to use QPR to train all adult staff to recognize and refer youth for suicidality
 - 32 middle/high schools required to train all staff (over 4,000)
- QPR had never been evaluated on documented referrals/behaviors
- Predicated on ‘surveillance model’: increased knowledge of warning signs/referral protocols will increase detection (CDC, 1992)

Research Questions for Gatekeeper Model

1. Training impact (Who benefits?)
2. Increase detection/referral?
3. Reduce suicidality through MH Services?



Identifying and Referring Youth Who are Suicidal: Georgia Gatekeeper Trial (NIMH, SAMHSA)

Testing the QPR Gatekeeper Program (Quinnett, 2005)

Q – Question

P – Persuade

R -- Refer

50,000 Middle and High School Students in **32** schools
Training of > **3,000 school staff**

Schools Randomly Assigned to Immediate Staff Training
(16) or Wait-list for Later Training (16)

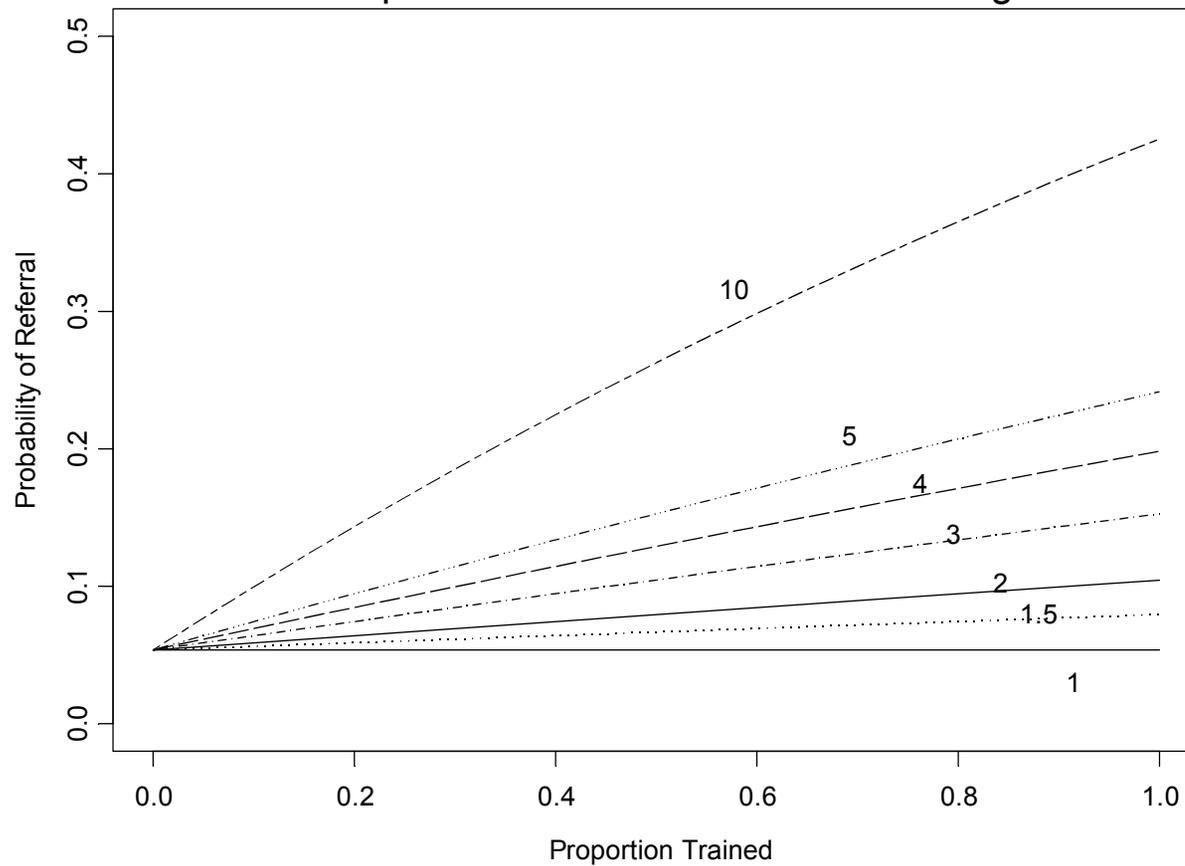
* Brown, Wyman et al. Clinical Trials, 2006

Suicidal Youth Unknown to Schools

- ~ 8% report attempt to kill themselves in the last year
- About 95% of these youth are unknown to the school.

Large Potential Impact of a Gatekeeper Training Program

Probability of Someone Referring Suicidal Child as Function of Proportion of Staff Trained and Training Effectiveness



Modified design from a standard wait-listed design to dynamic wait-listed design

Brown C.H., Wyman P. A., Guo J, and Peña J. (2006) Dynamic wait-listed designs for randomized trials: New designs for prevention of youth suicide. *Clinical Trials*, 3, 259-271

Brown CH, Wyman PA, Brinales J, & Gibbons RD. The role of randomized trials in testing interventions for the prevention of youth suicide. *International J Psychiatry*.

Brown, CH, Ten Have TR, Jo B, Dagne G, Wyman PA, Muthén BO, Gibbons RD. (2009). Adaptive Designs in Public Health. *Annual Review Public Health*, 30: 17.1-17.25. Downloaded from 10.1146/annurev.publhealth.031308.100223.

Dynamic Wait Listed Design As Intended

Year	Time Block	Wait-Listed Design		Dynamic Wait-Listed Design	
		Intervention	Wait-Listed	Intervention	Wait-Listed
1 and 2		16	16		
2 and 3	2			20	12
	3			24	8
	4			28	4
	5			32	0

Dynamic Wait Listed Design As Intended and Actual

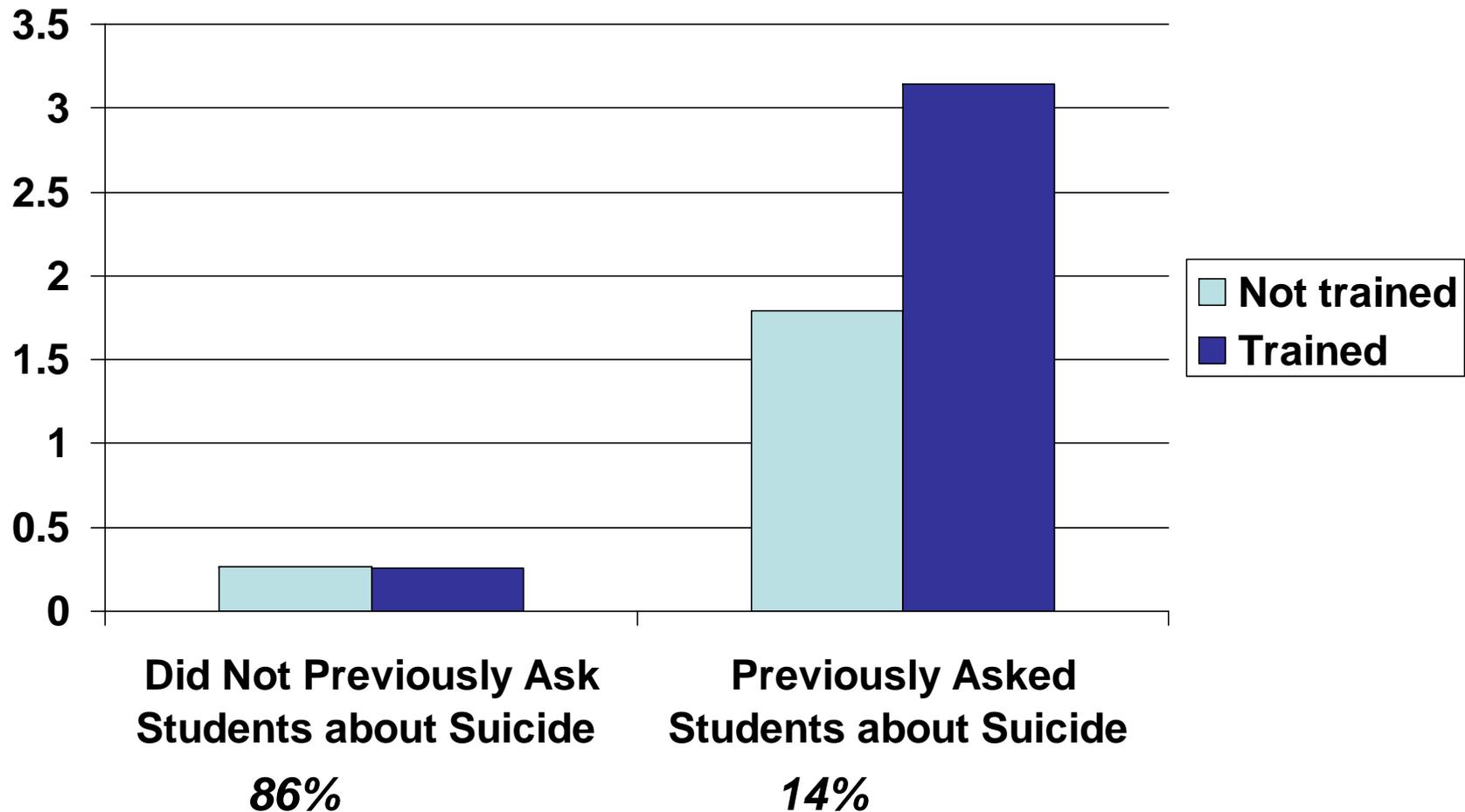
Year	Time Block	<u>Intended</u> Dynamic Wait-Listed Design		<u>Actual</u> Design	
Year	Time	Intervention	Wait-Listed	Intervention	Wait-Listed
1 and 2		16	16	16	16
	2	20	12	20	12
	3	24	8	24	8
	4	28	4	27	3
					1 not Trained
2 and 3		32	0	32	0

Evaluation of Staff Training

- Longitudinal assessments of diverse staff in 32 schools; 75% staff trained; 60% refresher
- Knowledge about warning signs does increase
- Self-efficacy and attitudes towards a gatekeeper role increase and are sustained over 1 year
- **Very minimal changes in self-reports of referral behavior/querying youth about suicide**

Wyman PA, Brown CH, Inman J, Cross W, Schmeelk-Cone K, Guo J, Peña J (2008). Randomized Trial of a Gatekeeper Training Program for Suicide Prevention: Impact on School Staff after One Year. *J Consulting and Clinical Psychology*, 76(1), 104-115.

'Asked Students about Suicide' increased only for staff already prepared



Results of GA Gatekeeper Trial on Referrals for Life Threatening Behavior

Poisson Mixed Effects Modeling:
426 Events

Fixed

Training
Grade
Gender
(new training)
Race/Ethnicity
Person-Days at Risk (offset)

Random

School (16)
Time Interval (46)

Robust (sandwich-type) estimates of variances

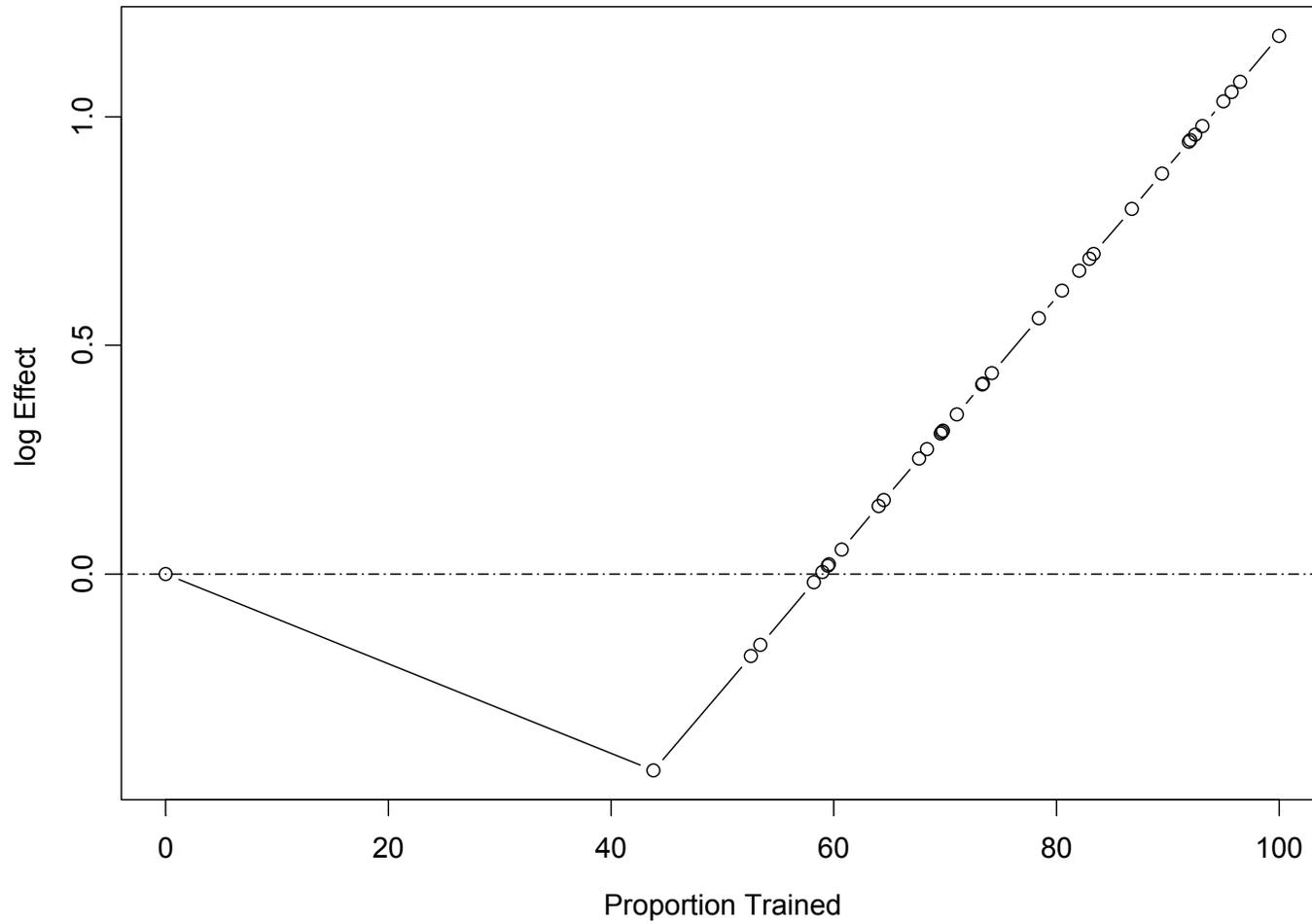
Intent to Treat (ITT) Analysis for Life Threatening Behavior Referrals by School Training Status : Poisson Random Effects Modeling

Effect	Coefficient	p-value
Middle School Trained	0.43	0.03
High School Trained	-0.37	0.10

No significant overall main effect of training on Life Threatening Behavior

Entirely Different Results by Middle/High School Stratification

Effect of Proportion Trained on Referral in Middle School



Teen help-seeking attitudes a barrier to success of gatekeeper training?

2,059 students surveyed in 32 Cobb County schools from 8th / 10th grades

7.3% reported a suicide attempt in past year

Fewer suicidal students willing to seek help from adults: low expectations for help and low perceived norms for help-seeking

“If overwhelmed by life ... “

‘Strongly agree’ or ‘agree’ with -->	<i>Would talk to adult or counselor</i>	<i>Believe counselor could help</i>	<i>Friends want me to talk to adult</i>	<i>Family want me to talk to adult</i>
Suicide attempt n=150	18%	22%	35%	35%
None N=1,909	38%	47%	45%	53%

Conclusions for Gatekeeper Training

1. Improved staff knowledge and attitudes about suicide prevention lasting up to 1 year
2. Overall, small to negligible effects on Life Threatening Behavior referrals; none in high schools
3. Middle Schools- modest increase in referrals after 60% of staff trained
4. **Unlikely to significantly reduce suicides in a population – perhaps contribute with other complementary strategies**
5. Randomizing over Places (schools) and time (multiply wait-listed) can be done in communities implementing suicide prevention programs.

Alternatives to 'Case Identification' Model?

1. Findings do not support model that gatekeeper training increases most adults' ability to 'detect and refer' [*health professionals also have low rates of recognition of youth MH problems* (Burns & Santos, 1995)]
2. 'Out of synch' developmentally with adolescents? – teens communicate with peers about distress
3. **MH disorders being only one of many factors that increase risk for suicide**
4. Treating very high risk youths will not prevent emergence of new 'cases'

Public Health Model for Reducing Teen Suicide

Well-Documented Social-ecology Risks for Suicide

- Low levels of social integration; connectedness with parents; bonding to school and community (e.g., Borowsky 1999)
- *Risk mechanisms include*: low 'belongingness'; support absent under crisis; influences for adaptive coping are low, limited access to formal help (CDC, 2007)

Targets for change

- Promote positive coping norms: help-seeking and competent communication about distress
- Connectedness between youth and capable adults in school and community
- Adults activate formal (services) **and** informal supports
- **Universal and Selective effects (at-risk youth)**

Role of Peer Networks in Modifying Teen Norms/Behaviors

- Primary influence on whether a teenager uses safe sex practices?

**Beliefs about what his/her friends
would do** (Bruckner, 2005)

- Many other health behaviors (smoking) are not made solely by isolated persons

**Behavior choices reflect collective norms
and pressures within niches of social
networks** (Christakis & Fowler, 2007, 2008).

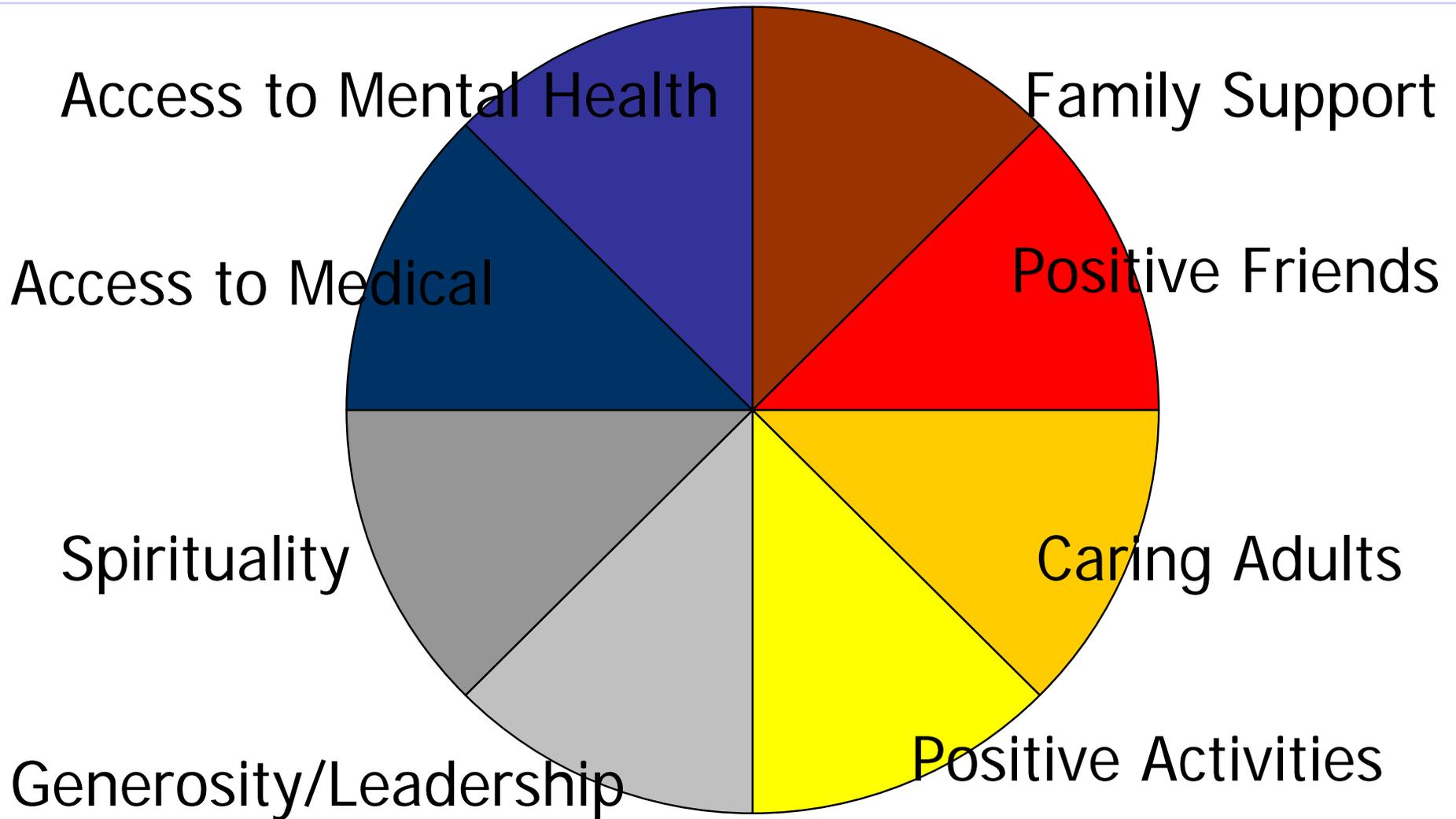
Phase 3. Sources of Strength

- National search to identify most promising intervention using teens as agents of change-
- public health approach increasing 'connectedness' in community
- Developer – Mark LoMurray, North Dakota
- 5,000 teen Peer Leaders trained
- 40% reduction in North Dakota youth suicide from 2000 – 2007 versus 10-year period in 1990s
- Limited prior formal evaluation

Training Peer Leaders

- **Select a group of diverse teens and adult advisors and provide four hour training with adult advisors**
- **Teens then follow with five action steps**
 - **STEP 1:** Peers name and contact their adults
 - **STEP 2:** Peers contact 5-10 friends, which will name their trusted adults; raise awareness across school
 - **STEP 3:** Peers to peer classroom messages
 - **STEP 4:** Peers provide Hope, Help, and Strength Messages for Positive Coping
 - **STEP 5:** Peers celebrate, receive recognition, message to parents

Sources of Strength





Who can *you* turn to?



A Cumulative Randomized Trial Design

Recognizing that

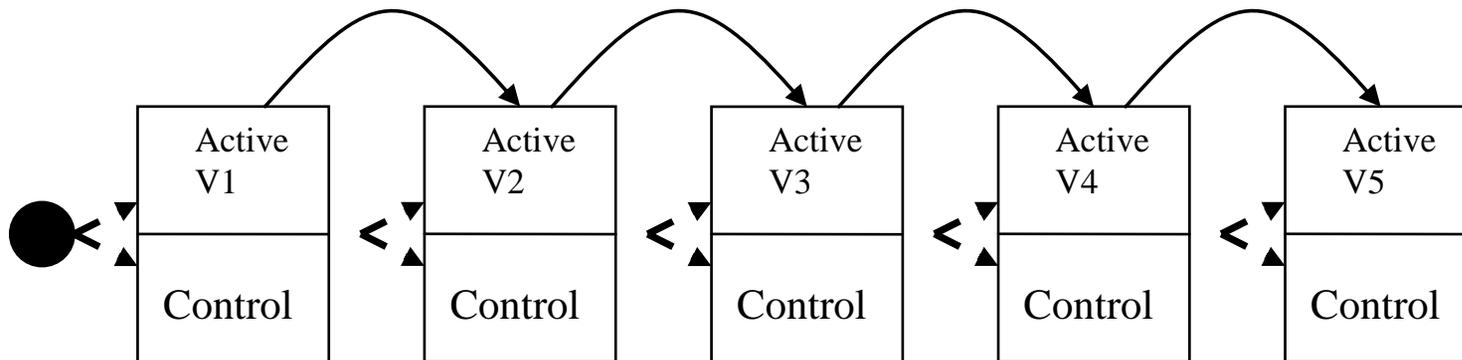
1. Promising interventions may need critical tuning
2. Interventions should evolve based on empirical findings
3. Early results should still be informative in overall evaluation
4. Funding of large trials predicated on
very strong preliminary results
very well articulated theory
5. Easier to obtain smaller blocks of funding
6. Smaller evaluations are logistically easier to handle
7. With multisite studies, permission to randomize is local

We propose a new design of a cumulative randomized trial that evaluates overall impact of an evolving intervention

Extending ideas of Adaptive Designs

Cumulative Trial Design

Randomize in a Number of Small Trials,
Recognizing that Active Intervention will
Continue to Evolve



There are Reasonable Tests for Overall Impact with Cumulative Designs

Different trials

$$t = 1, 2, \dots, T$$

K times the intervention is deliberately changed

$$T_1, T_2, \dots, T_K$$

Effect Size over Distinct Trials

$$\begin{array}{cccccccccccc} 1 & 2 & 3 & 4 & 5 & 6 & 7 & 8 & 9 & 10 & 11 \\ \bar{\delta}_1 & \bar{\delta}_1 & \bar{\delta}_2 & \bar{\delta}_2 & \bar{\delta}_2 & \bar{\delta}_3 & \bar{\delta}_4 & \bar{\delta}_4 & \bar{\delta}_5 & \bar{\delta}_6 & \bar{\delta}_7 \end{array}$$

First Assume $\bar{\delta}_1 \leq \bar{\delta}_2 \leq \bar{\delta}_3 \leq \bar{\delta}_4 \leq \bar{\delta}_5 \leq \bar{\delta}_6 \leq \bar{\delta}_7$

$H_0 : \bar{\delta}_7 = 0$

Alt: $\bar{\delta}_7 \neq 0$

Then the typical meta-analytic test based on the average intervention effect, adjusting for between trial variability, has reasonable statistical properties.

We can improve on this with ordinal regression modeling.

Primary Questions and Number of Schools Required

Does Sources of Strength

Improve Youth Connectedness with Adults?

~ 20 schools

Decrease Suicidal Ideation/Behaviors?

~ 32 schools

Decrease Suicides?

~ 100 schools

Current Cumulative Trials

(1) 6 Schools in Georgia completed 2007-8

(2) 8 Schools in New York 2008-2009

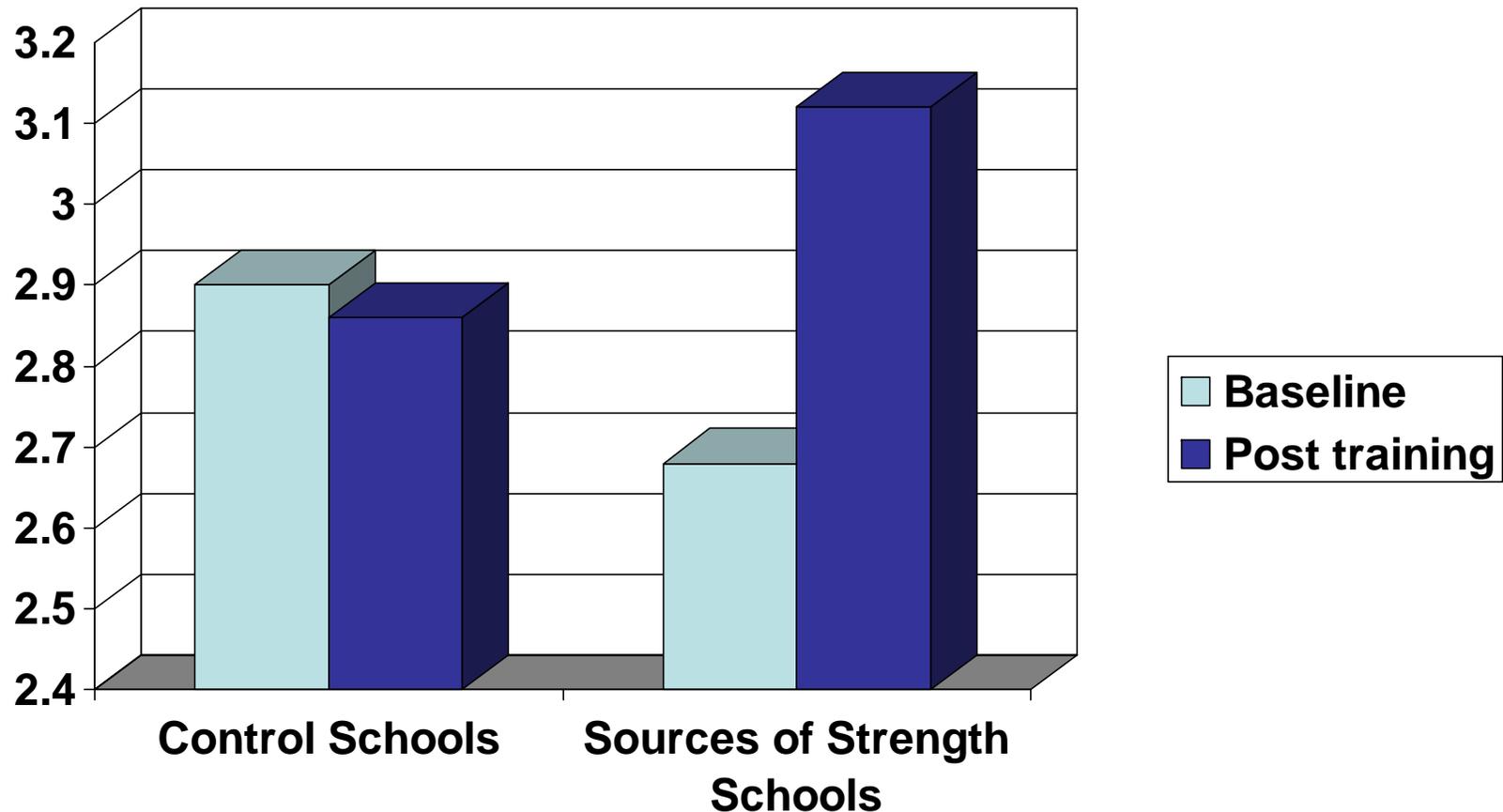
4 Schools in North Dakota 2008-2009

Changes: bi-weekly technical assistance during 'action step' phase, with increased rates of school saturation

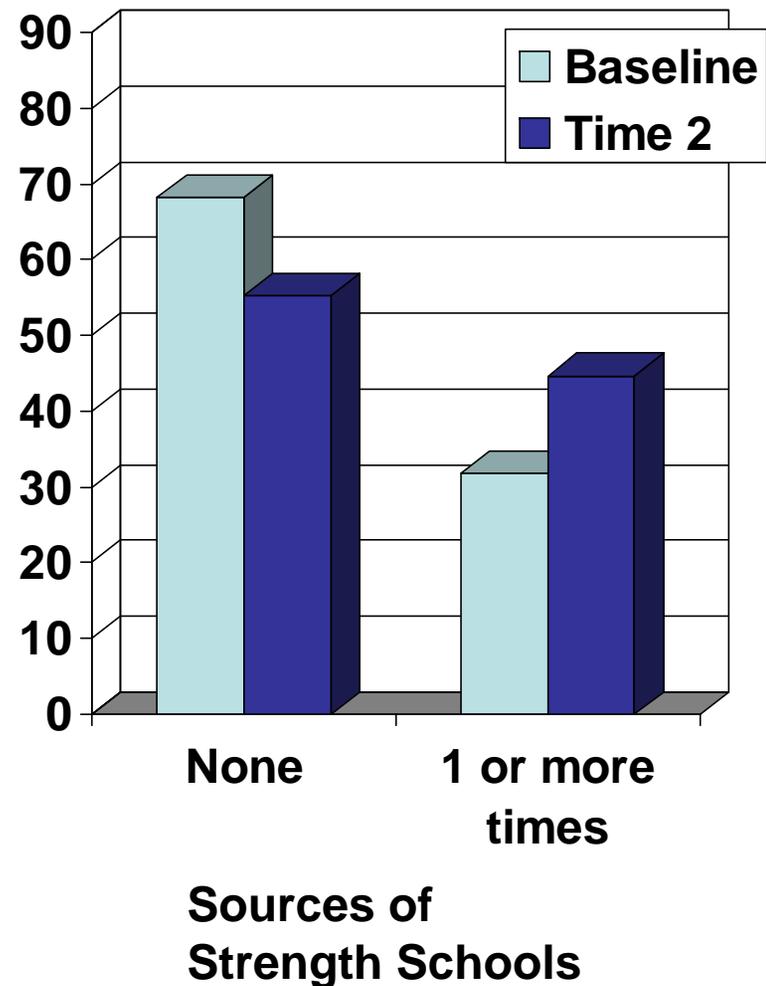
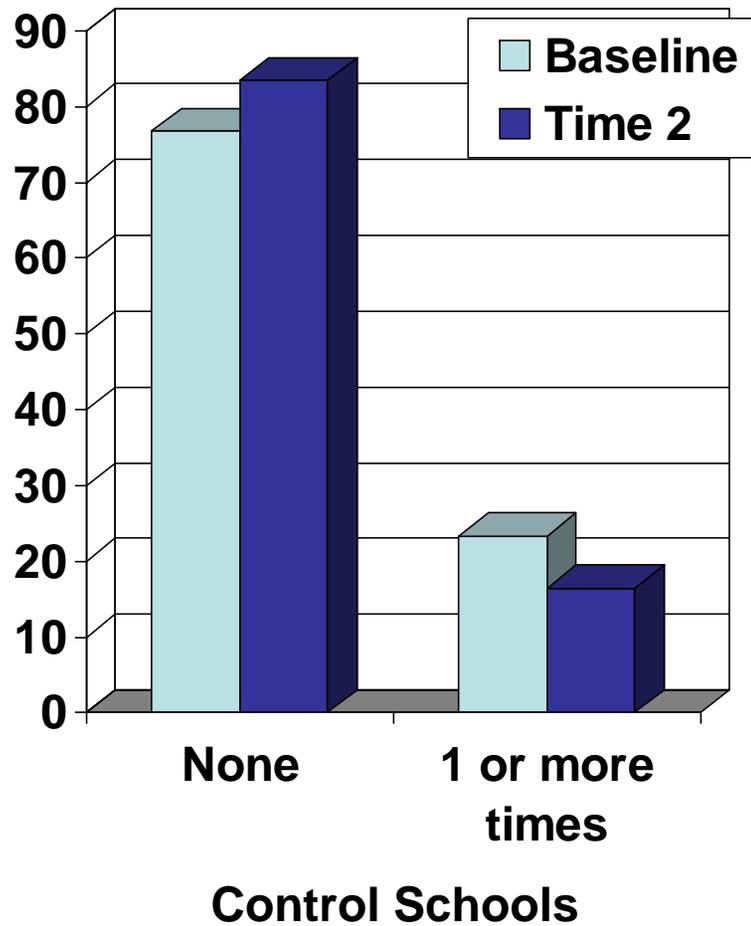
Impact of training on 176 Teen Peer Leaders in 6 Schools (GA)

- 6 high schools in Cobb County that already received staff gatekeeper training
- Randomized design – to immediate training or wait-list
- More than 50% of peer leaders aware of suicidal peers
- Positive training effect (at school-level (4 d.f.) on:
 - Help-seeking Norms $p < 0.05$
 - Coping Using Sources of Strength $p < 0.05$
 - Knowledge of helping Suicidal Peers $p < 0.01$
 - **Referral of Suicidal Peers to Adults $p < 0.05$**

Help-Seeking Norms of Peer Leaders increased ($p < .05$)



Referred a Suicidal Peer to Adults: 2-fold increase by training (p<.05)



Initial Conclusions for Peer Leader Training (Sources of Strength)

1. In high schools with adult staff training (QPR), peer leaders can be trained and implement 'peer to peer' messaging
2. Training increases Peer Leaders' positive help-seeking attitudes, reduces 'codes of silence'
3. Trained Peer Leaders refer more peers to adults for help, unlike adult training which did not increase referral behaviors in high schools

Conclusions about Designs

1 Designs come out of and evolve through Community –
Research Partnerships

2. Effectiveness as program is rolled out

Dynamic Wait-Listed Design

Randomize across Place and Time

3. Cumulative Design Uses Multiple, Small Trials to
Improve Intervention and Evaluate Impact