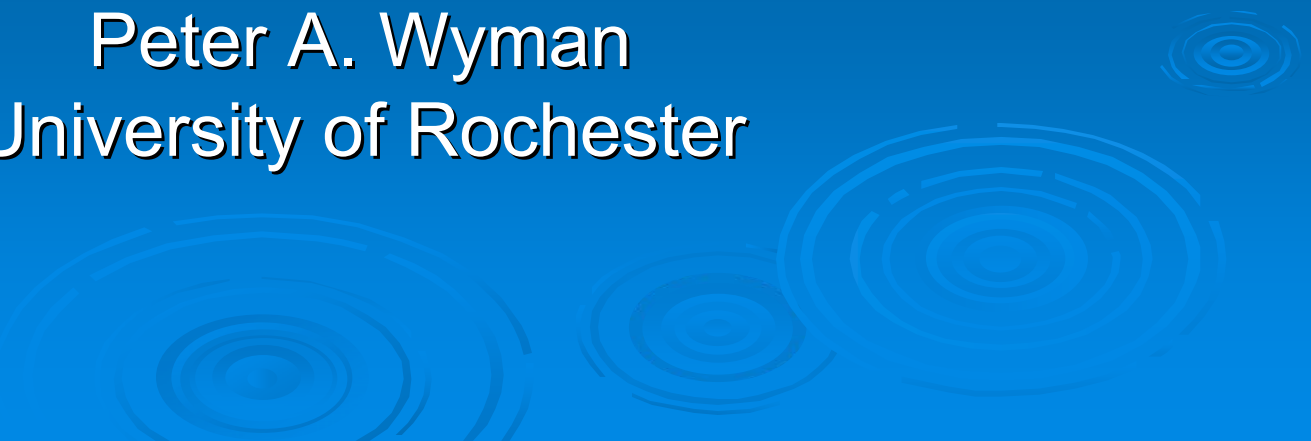


Science-Based Approaches for Prevention of Suicide

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Support

R01-MH40859 (Brown)

Designs & Analyses for Mental Health Preventive Trials
NIMH and NIDA

3R01MH040859-15S1 (Brown)

Methodology for Population-Based Approaches to the Prevention of Suicide
NIMH Office of Rare Diseases
CDC Injury Prevention Center

R34MH071189-01 (Wyman)

RCT of Gatekeeper Training for Suicide Prevention
NIMH

P20MH071897-01 (Caine)

**Developing Center On Public Health and Population
Interventions For The Prevention Of Suicide**
NIMH

What we will cover

What is the role of scientific evaluation of suicide prevention strategies?

How can good science be done in complement to community needs, interests, and values?

Design and early data on the Georgia Gatekeeper Training Study

A Trial of Gatekeeper Training for Suicide Prevention

Georgia Gatekeeper Trial

Peter Wyman, Hendricks Brown

Brown, Wyman, Guo, Peña (under review).

Dynamic wait-listed designs for randomized trials: New designs for prevention of youth suicide

QPR Gatekeeper Training

QPR: (Quinnett, 1995): Integrated “system” of gatekeepers and mental health professionals

- Citizen Gatekeeper training (1.5 hour) basic training; all teachers/school staff; warning signs, 3 steps to take; focus on youth
- Suicide Triage training (8 hours) for “first responders”, skills for initial assessment and more advanced referral skills. 1 counselor in each middle/high school.
- Instructor Training course (8+ hours) certified to provide training, triage skills, knowledge of supplemental modules (e.g., youth QPR); Prevention-Intervention Center Staff.

What is the role of scientific evaluation of suicide prevention strategies?

Rigorous design and evaluation to address specific questions

Can a prevention program be implemented?

Does this program work?

Who benefits, who is harmed?

For whom?

How long?

Under what conditions?

Why we need science

“The path to hell is paved by good intentions”

Our families and communities deserve program that work, and are in a constant state of improvement

Research – Community Partnership

Research has to serve the goals of a community

State of Georgia Legislature, SPAN Georgia, Public School District, County Mental Health System

- Researchers invited in to the school district
- QPR Training already chosen
- QPR Training had to be given to ALL staff
- Research had to be conducted ethically and serve the needs of the youth
- School District Not Identified Until it Approves

NIMH research grant Co-directed by researchers and Superintendent of Schools

General Scientific Method

1. Clearly specify study objectives

Hypotheses

2. Provide a rationale for what you intend to achieve based on prior work

Theory of Intervention

3. Provide a detailed plan of action

4. Measure key “variables” throughout

5. Examine hypotheses with statistical analyses

6. Form conclusions based on the results of these analyses

Georgia Gatekeeper Training Program

Hypothesis – QPR training of school staff increases **referral** of suicidal youth in a particular school district

NOTE: Does not directly answer whether reduction in suicide would occur

Theory of Intervention

- Suicidal youth typically tell someone
- Adults do not recognize suicidal warning signs

Randomized Field Trial

Randomized – choice of who gets what intervention is determined by a chance process

Randomized at the SCHOOL level the TIMING of Training of Each School

Field – done in the community, rather than an artificial laboratory, so that real-life uncontrolled situations are allowed to happen

Trial – A design specifically set up to allow for an evaluation of one or more distinct intervention conditions.

Themes in Modern Randomized Field Trials

1. The “Gold Standard” - Empirical Tradition
2. A Fair Unbiased Comparison
Randomization, Blindness
3. Ethical Standards / Opportunities for Trials
4. Highly Regimented Procedures and Organization for Trial Conduct

History of Clinical Trials – Ian Chalmers

http://www.rcpe.ac.uk/controlled_trials/

Randomized Trials as Scientifically Rigorous

Grades of Evidence (Canadian, US Preventive Task Forces '92)

Multiple, repeated randomized clinical trials

Single randomized clinical trial

Non-randomized experiment

Pre-post design w/o control

Expert opinion

First Published Trial?

Prove thy servants, I beseech thee, ten days, and let us pulse [*herbs*] to eat and water to drink. ... let the children that eat of the portion of the king's meat, and as thou seest, deal with thou servants. So he consented to them in this manner, and proved them ten days. And at the end of ten days their countenances appeared fairer and fatter in flesh than all the children which did not eat the portion of the king's meat.

-- The Book of Daniel, 12 – 15.

Randomized Trial as A Fair Comparison

First Proposal in Health for equal comparison groups

1662 Van Helmont

Let us take out of the hospitals...200 or 500 poor people, that have fevers, pleurisies. Let us divide them into halves, let us cast lots, that one halfe of them may fall to my share, and the other to yours; I will cure them without bloodletting and sensible evacuation; but you do, as ye know...We shall see how many funerals both of us shall have.

Measures

Each Referral in Each School

Previous and Current Suicidality and Other Risk Factors

Report by Mental Health Professional at Initial Assessment

All Middle and High School Youth

Youth Suicidality and Risk Factors from Anonymous Surveys

Staff

Degree of Training Completed in Each School

Surveys on Knowledge, Attitudes, Self Assessment of Ability to Refer

Analysis

Compare Rate of Referral in Schools Given Intervention versus those Without Intervention

Fictitious Data: 90 vs 75

How **surprised** are we by this difference?

Assume intervention has no effect, just by chance how likely is this difference to occur?

Size of Study and Quality of Study Design

- Bigger studies give more precision
- The more infrequent the outcome, the larger the study that is needed
- To attribute observed differences to the intervention, need equivalent schools in intervention and control conditions

Using Science for Evaluating Suicide Prevention Programs (Fictitious Data)

	QPR Provided Intervention Schools	QPR Not Provided Control Schools
Number of Referrals	90	75

Interpreting Statistical Results as True Intervention Effects

Intervention and Control Schools
“Equivalent” in everything except
intervention status

**Balance -- same number of middle and
high schools**

**Randomization (after balancing)
-- protect against unmeasured
differences**

Monitoring Safety of Children

School District Review of Protocol

Institutional Review at USF, U Rochester

Peer Scientific Review at NIH

NIMH Advisory Board Review

Ongoing Data Safety and Monitoring
Committee (DSMC) Review

Data Safety and Monitoring Committee

Why Interim Monitoring?

- Identify safety problem
 - Much better position than IRB for adverse events monitoring
- Identify logistic problems
 - Too many dropouts
 - Not enough recruitment
 - Low adherence
- See if trial objectives have been met
 - Early stopping of a trial

Data Safety and Monitoring Committee: Why Independent

- No member has any basis for preferring any outcome of the trial
 - Investigators do have interests
- Typically members approved by study sponsor

Data Safety and Monitoring Committee: Why a Committee

- Ensure that regular and systematic monitoring happens
- Objective assessment of the data
- Protect confidentiality of interim treatment comparisons

Clinical Medicine

Biostatistics

Biomedical Ethics

Pharmacy, Epidemiol, Law, Patient Advocates

Universities whose research has been Shut Down by OPHR

- UCLA (West LA VA Center)
- Duke University
- University of Illinois at Chicago
- University of Pennsylvania
- Johns Hopkins Medical Center
- Five other medical centers

Design of The Georgia Gatekeeper Trial

Testing a Gatekeeper Training Program aimed at school staff improving the rate of referrals for suicide

60,000 Middle and High School Students in 32 schools

Schools Randomly Assigned to “Wait-Listed” Design

Timeline

- May 2003 Invited to schools
- Sept 2003 Submitted R34 through RAPID system
- January 2004 Date trial and training began
- April 2004 Received funding
- June 2004 DSMC first meeting
- April 2005 Complete training in 16 schools
- August 2005 Began training of remaining 16 schools

Georgia Gatekeeper Project
Protection of Human Participants

- Adverse Events: Student Deaths by Suicide
 - Distinguish between **expected** and **unexpected** rates of suicide among students in the District based on analysis of suicide rates from 1988 - 2002.
 - **Unexpected rates of suicide warrant shutting down the trial.**

Number of Youth Suicide Deaths from 1988 to 2002 in County



Two criteria to define unexpected rate of suicide

(1) Number of deaths in either intervention condition exceeds 7.

Potential for suicide 'clusters'.

(2) Number of deaths by suicide in either intervention condition significantly different from the other

Prevalence of Suicidal Behavior in Middle and High School

14% of Middle and High School Children Reported Seriously Thinking About Killing Themselves Last Year

6% of Middle and High School Children Reported Attempting to Kill Themselves Last Year

Proportion of Suicidal Attempters Identified by School System

6%

Probability that a Single Staff Member Would be able to Identify and Refer a Suicidal Child

0.03%

Can Staff be Effective? – Staff Surveys

- Know signs about youth suicide
42% Nothing or very little
- Know referral sources
44% None or very few
- What questions to ask regarding suicide risk
54% None or very few
- What to say or not say to a youth
54% None or very little
- Believe they can elicit a commitment not to commit suicide
51% None or very little

Can Staff be Effective? – Staff Surveys

Students talk to me about thoughts and feelings

12% Never or seldom

33% Often or always

Students come to me for advice

23% Never or seldom

27% Often or always

Students turn to me when concerned about another student

23% Never or seldom

29% Often or always

Training Summary

Trained 75% of the Staff in Schools

QPR Training

Improved Staff

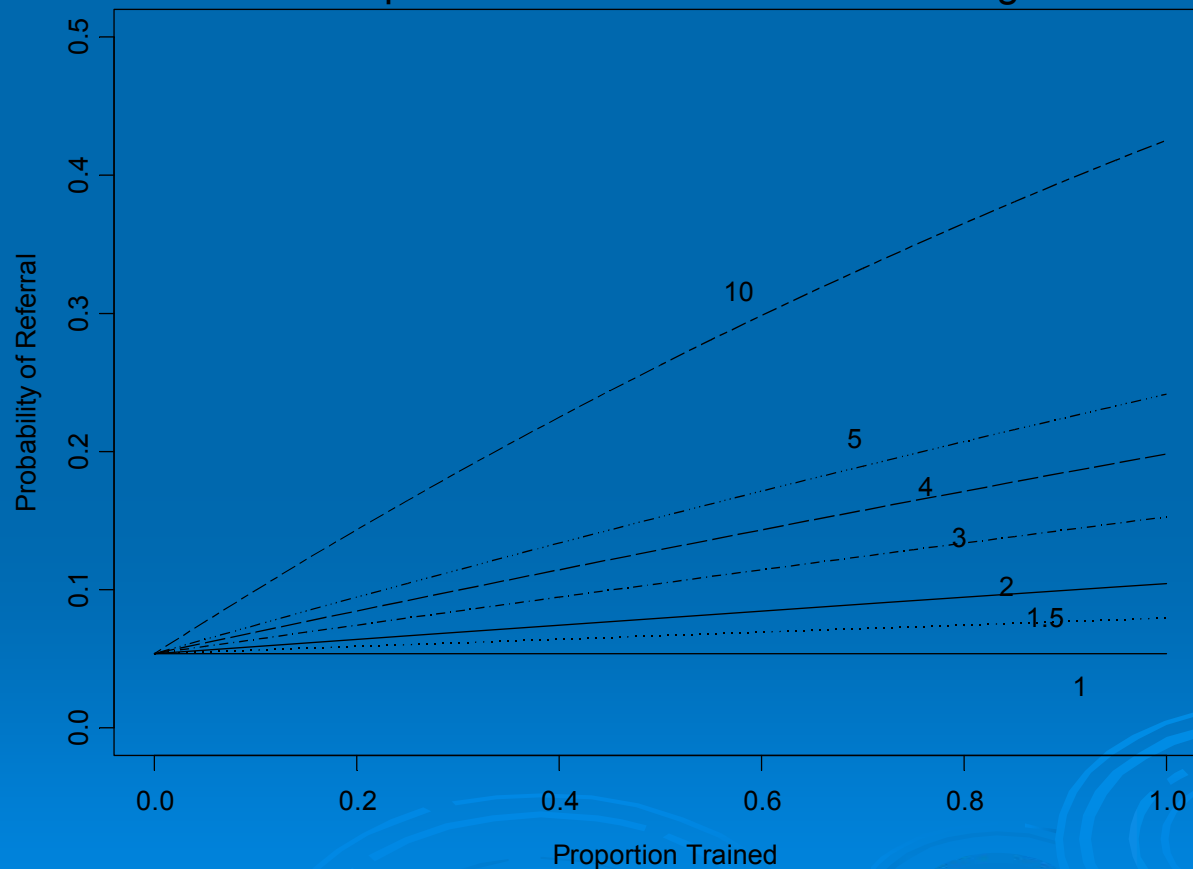
Knowledge about Suicidal Risk Factors

How to refer in your school

Self-reported ability to refer youth

Large Potential Impact of a Gatekeeper Training Program

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



Wait Listed Design

Random Half of the Schools Receive Intervention Training Immediately (1/04-5/05)

Remaining Half Receive Training in Second Phase (8/05-5/06) -- These are also randomized into 4 different times

Advantages

Everyone gets intervention just as quickly as it would take the school district to complete all training

The randomized time of intervention allows rigorous comparison of intervention versus control

Summary

Good Science Can be Done to Determine
What Programs Work and For Whom

Strong Partnership between Communities
and Researchers

Funding to Support Rigorous Research