Suicide in a Natural History Study: Boundaries of Research Obligations*

Rumi Kato Price, PhD, MPE
Washington University School of Medicine
St. Louis MO, USA
E-mail price@rkp.wustl.edu

Acknowledgments*

- National Institute on Drug Abuse (K02DA00221, R01DA09281).
- Longer Life Foundations, Washington University School of Medicine and the Reinsurance Group of America.
- National Institute of Mental Health (R01MH60691).

* No financial conflicts exist with any of the above funding agencies; No consulting relationships; No stock equity over $10,000; No involvement in a Speaker’s Bureau.
Suicide in a Natural History Study

- Background.
- 25-Year Follow-up study.
- How one suicide changed the course of a natural history study?
- How to balance science and clinical care in a natural history study.
- Using ethical guidelines to help fill the gaps in epidemiologic research of suicidality.
1971- Thousands of American soldiers returning from Vietnam were addicted to narcotics. The White House initiated a study conducted by Washington University in 1972 and 1974.
1993- Washington University began a follow-up study...

Washington University School of Medicine

Vietnam Era Study (VES)
VES Samples (Total Target N = 1,226)

1972
N = 898
- D+ Vet: 484
- D- Vet: 414
- Nonvet: 1972
- Deceased: 7

1974
N = 855
- D+ Vet: 308
- D- Vet: 263
- Nonvet: 284
- Deceased: 7
**VES Samples (N=1,227): Demographic Characteristics**

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Veterans</th>
<th>Non-veterans</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug +</strong></td>
<td><strong>Drug -</strong></td>
<td><strong>(N = 511)</strong></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Age in 1972 (SD)</td>
<td>22.5 (3.2)</td>
<td>24.2 (4.9)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whites</td>
<td>59.9</td>
<td>81.7</td>
</tr>
<tr>
<td>Blacks</td>
<td>34.1</td>
<td>11.6</td>
</tr>
<tr>
<td>Hispanics</td>
<td>5.7</td>
<td>4.9</td>
</tr>
<tr>
<td><strong>Employment Status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active duty in 1972</td>
<td>16.0^1</td>
<td>16.1^1</td>
</tr>
<tr>
<td>Not employed</td>
<td>31.3^1</td>
<td>15.7^1</td>
</tr>
</tbody>
</table>

1. 1972 status; among the interviewed. 2. 1974 status, the unemployed includes “laid-off.”
# Opiate Addiction before, in and after Vietnam

## Table 1.—Drug Use Before, In, and After Vietnam*

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Before Vietnam, %</th>
<th>In Vietnam, %</th>
<th>Since Vietnam, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marijuana, any</td>
<td>41</td>
<td>69†</td>
<td>45</td>
</tr>
<tr>
<td>Any drug: narcotics, amphetamines, barbiturates</td>
<td>30</td>
<td>45</td>
<td>23</td>
</tr>
<tr>
<td>Narcotics</td>
<td>11</td>
<td>43</td>
<td>10</td>
</tr>
<tr>
<td>Addiction to narcotics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>By self-report</td>
<td>0.2</td>
<td>20</td>
<td>0.7</td>
</tr>
<tr>
<td>By symptoms of dependence ‡</td>
<td>0.4</td>
<td>21</td>
<td>1</td>
</tr>
<tr>
<td>Amphetamines</td>
<td>24</td>
<td>25</td>
<td>19</td>
</tr>
<tr>
<td>Barbiturates</td>
<td>14</td>
<td>23</td>
<td>12</td>
</tr>
<tr>
<td>Combinations of drug types</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All 3: narcotics, amphetamines, barbiturates</td>
<td>4</td>
<td>18</td>
<td>6</td>
</tr>
<tr>
<td>Amphetamines &amp; barbiturates</td>
<td>5</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Narcotics &amp; amphetamines</td>
<td>3</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Narcotics &amp; barbiturates</td>
<td>2</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Narcotics only</td>
<td>2</td>
<td>15</td>
<td>1</td>
</tr>
<tr>
<td>Amphetamines only</td>
<td>11</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>Barbiturates only</td>
<td>2</td>
<td>...§</td>
<td>2</td>
</tr>
</tbody>
</table>

* Data from the interviewed general sample (N = 451).
† Estimate based on assumption that those who used marijuana before continued in Vietnam.
‡ Criteria given on p 957.
§ Less than 0.5%.

25-Year Follow-Up

Washington University Vietnam Era Study - Phase III

- Adult course of drug abuse.
- Long-term consequences of drug abuse in adult life.
- Relationships among drug abuse, war trauma, PTSD and other psychopathology over time.
- Impact of substance abuse and trauma on health care utilization.
VES Samples (Total Target N = 1,226)

1974
N=855

D+ Vet: 308
D- Vet: 263
Nonvet: 284
Deceased: 7

1996-7
N=841

D+ Vet: 323
D- Vet: 320
Nonvet: 198
Deceased: 115
Washington University Vietnam Era Study (VES): 1971-1997*

**Time Line**
- **Veterans' Induction**: Sept. - Dec. 1972
- **Arrival in Vietnam**: Oct. - Jan. 1974-75

**Mean Age (years)**
- Pre-S: 19.7
- In-S: 21.3
- In-V: 22.4
- Post-V: 23.5
- 1972 Interview Data: 25.4
- Post-V 1972-74: 44.3
- Post-V 1974: 48.5

**Fieldwork**
- Target Sampling
- Baseline Interview
- First Followup Interview
- Location Study
- 2nd Followup Interview

**Measures**
- **Veterans**
  - Pre-S
  - In-S
  - In-V
  - Post-V
  - 1972 Interview Data
  - 1974 Interview Data
  - Mortality Assessment 1974-93
  - Post-V 1974-96

- **Nonveterans**
  - Pre-S
  - In-S
  - In-V
  - Post-V
  - Interim
  - 1972-74 Interview Data
  - 1974 Interview Data

*Pre-S (Pre-Service), In-S (In-Service), In-V (In-Vietnam), and Post-V (Post-Vietnam) up to the 1972 interview. Measures from the in-service period for veterans prior to their arrival in Vietnam were not used in the subsequent analyses.*
Survival Curves for Drug-Positive Veterans, Drug-Negative Veterans and Nonveterans, 1972-1996 (N = 1,227)*

1974 - 1996 †

1971 - 1974 ‡

* Mortality information was available for the period of 1974-1996 for all three groups; for the period of 1971-1974, for the veterans only.
‡ The log-rank test between two groups for 1971-1974. D+ veterans vs. D- veterans: $X^2 = .60$, $p = .44$. 
### Most Significant Early Risk Factors of Mortality: 1972-1996*

<table>
<thead>
<tr>
<th>Veterans Interviewed in 1972 (n = 896) §</th>
<th>Conditional Risk Ratio</th>
<th>(95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (each year)</td>
<td>1.07</td>
<td>(1.02-1.11)</td>
</tr>
<tr>
<td>African-American</td>
<td>1.59</td>
<td>(1.06-2.40)</td>
</tr>
<tr>
<td>Pre-Service</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Believed drank too much</td>
<td>2.91</td>
<td>(1.72-4.91)</td>
</tr>
<tr>
<td>In-Vietnam</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DEROs-positive status</td>
<td>2.57</td>
<td>(1.58-4.18)</td>
</tr>
<tr>
<td>Started drinking more</td>
<td>1.90</td>
<td>(1.21-2.96)</td>
</tr>
<tr>
<td>Post-Vietnam</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disobeyed orders still in service</td>
<td>2.29</td>
<td>(1.13-4.65)</td>
</tr>
<tr>
<td>Knows where to buy opiates</td>
<td>1.86</td>
<td>(1.21-2.84)</td>
</tr>
<tr>
<td>Feelings of depression</td>
<td>1.51</td>
<td>(1.02-2.24)</td>
</tr>
</tbody>
</table>

-2 Log L = 74.78, d.f. = 8, P < .0001

Table continued on next slide
### Most Significant Early Risk Factors of Mortality: 1972-1996* (con’t)

<table>
<thead>
<tr>
<th>Veterans and Nonveterans Interviewed in 1974 (n = 854)§</th>
<th>Conditional Risk Ratio</th>
<th>(95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>African-American</td>
<td>1.96</td>
<td>(1.17-3.27)</td>
</tr>
<tr>
<td><strong>Pre-Service</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injected opiates</td>
<td>2.79</td>
<td>(1.24-6.24)</td>
</tr>
<tr>
<td><strong>Interim</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Significant opiate withdrawal symptoms</td>
<td>3.09</td>
<td>(1.77-5.38)</td>
</tr>
<tr>
<td><strong>1972-1974</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not married in 1974</td>
<td>2.05</td>
<td>(1.24-3.39)</td>
</tr>
<tr>
<td>Depression with thought of death</td>
<td>2.14</td>
<td>(1.16-3.96)</td>
</tr>
<tr>
<td>Craving for opiates</td>
<td>2.34</td>
<td>(1.17-4.67)</td>
</tr>
</tbody>
</table>

-2 Log L = 74.78, d.f. = 8, P < .0001

* Significant predictors were chosen on the basis of the backward elimination criterion at the P = .05 level. The sample size for each Cox regression excludes missing cases.

§ 28 variables chosen as significant predictors of each time period using logistic regressions were entered to the final Cox regression.
Patterns and Predictors of Cumulative Mortality until Middle Age

- Drugs kill.
- A more malignant picture of the long-term impact of heroin use starting in Vietnam.
- Alcoholism and depression additional significant risk factors for premature death up to mid-40’s.
- Even a short-term intensive drug use appears to signal premature death.

25-Year Follow-Up

Washington University Vietnam Era Study - Phase III

- Long-term consequences of drug abuse in adult life.
VES III. Drug Use: 1972 to 1996

Heroin Users
35%
In Vietnam

Last 10 Years
51.5%
(6.3*)

Last 3 Months
27.7%
(6.2*)

Marijuana
29.4%
(4.7*)

Cocaine
10.2%
(6.9*)

Opiates
13.2%
(6.5*)

4.6%
(4.8*)

Dead
16.1%
(5.2*)

1. The weighted percentage of heroin users in Vietnam represents Sept. ‘71 returnees. Drug use outcomes are unweighted encompassing up to 1996-7. Odds ratios are in comparison to nonveterans, adjusted for age and race; *, significant. N=839.
Health Problems in Past Year (1996-7)\textsuperscript{1}

Heroin Users

35%

2 or More

20.8% (2.6*)

HBP

23.4% (1.9*)

Arthritis

21.3% (1.7*)

Diabetes

8.6% (2.4*)

Hepatitis\textsuperscript{2}

5.8% (4.2*)

1. The weighted percentage of heroin users in Vietnam represents Sept. ‘71 returnees. Health problem outcomes are unweighted encompassing up to 1996-7. Odds ratios are in comparison to nonveterans, adjusted for age and race; *, significant. N=839. 2. Includes hepatitis due to both viral and alcohol use.
Marriage and Employment: 1972-1996

Heroin Users 35%

First 10 Years

30.5% (1.7*)

13.5% (7.9*)

7.9% (4.4*)

Last 10 Years

23.6% (1.5)

7.6% (2.4)

7.9% (3.7*)

Divorced at least once

Unemployed for 2+ out of 10 years

Fired at least once

1. The weighted percentage of heroin users in Vietnam represents Sept. ‘71 returnees. The outcomes are unweighted encompassing up to 1996-7. Odds ratios are in comparison to nonveterans, adjusted for age and race; *, significant. N=839.
How One Suicide Changed the Course of a Natural History Study?

- Reports to the NIDA director’s office.
- Collaborators’ demand to stop the fieldwork immediately.
- Epidemiologic interview triggers suicidality!
- St. Louis VA hearing.
- Intervention implementations with a request of IRB.
- Lengthy process of identifying who are at increased risk.
- Costs over-run.
How One Suicide Changed the Course of a Natural History Study?

- Relationships among drug abuse, war trauma, PTSD and other psychopathology over time.
VES-III. Post-traumatic Stress Disorder (PTSD) up to 1996

Heroin Users
35%
In Vietnam

24.8%
(1.6*)
Originated in Vietnam

21.3%
(1.9*)
Originated Since 1972

Heroin Users in Vietnam

How One Suicide Gave a Birth to New Studies?

- Drug abuse, PTSD and suicidality.
- Generality of suicidality findings in the VES cohort.
- Using clinical data to inform a new study design and to ask new questions.
- Inquiries into resiliency factors in middle aged men at risk for suicide.
- Integrating human aspects to science questions.
How One Suicide Gave a Birth to New Studies?

- Drug abuse, PTSD and suicidality.
VES-III. Suicidality: from Vietnam to 1996 (%, OR)$^1$

- **Heroin Users**
  - **35%**
  - In Vietnam

- **Completed Suicide**
  - 1.4% ($\infty)^2$

- **Attempt**
  - 9.9% (9.6*)
  - 12.4% (6.8*)

- **Plan**
  - 18.8% (3.6*)
  - Frequent Thought

1. The weighted percentage of heroin users in Vietnam represents Sept. ‘71 returnees. The outcomes are unweighted encompassing up to 1996-7. Odds ratios are in comparison to nonveterans, adjusted for age and race; *, significant. N=839. 2. No completed suicides were observed among nonveterans.

Length of Suicidal Ideation Stratified by Concurrent PTSD (n=120)

Length of Suicidal Ideation Stratified by Drug Dependence (n=120)

Logrank: p=.17
Wilcoxon: p=.04

# PTSD, Substance Abuse and Other Psychopathology on Suicide Ideation: 1972-1996 (n=637)

<table>
<thead>
<tr>
<th></th>
<th>Hazard ratio</th>
<th>P</th>
<th>Risk limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol dependence</td>
<td>1.18</td>
<td>.343</td>
<td>.84 - 1.68</td>
</tr>
<tr>
<td>Major depression</td>
<td>3.21</td>
<td>&lt;.001</td>
<td>1.93 - 5.34</td>
</tr>
<tr>
<td>Adult antisocial personality</td>
<td>1.88</td>
<td>.002</td>
<td>1.25 - 2.81</td>
</tr>
<tr>
<td>PTSD</td>
<td>1.51</td>
<td>.339</td>
<td>.65 - 3.48</td>
</tr>
<tr>
<td>Drug dependence</td>
<td>2.06</td>
<td>.002</td>
<td>1.31 - 3.24</td>
</tr>
<tr>
<td>PTSD x log (time)</td>
<td>1.31</td>
<td>.049</td>
<td>1.00 - 1.70</td>
</tr>
</tbody>
</table>

Source: Price et al., Drug & Alc Dependence, 2004 (in press). 1. Time-dependent Cox regression analysis allowing for recurrence of suicidal ideation. A robust sandwich estimator applied to adjust the variances (data points n = 15,925). Age, race, enlistment status and education adjusted as covariates. 2. Depression measure excludes questions of suicidality. 3. Other interaction terms with log (time)^2 were not significant.
PTSD, Drug Dependence and Suicidal Ideation: Path Analysis Model


- Paths with coefficient < .1 (approximately $p < .05$).
- Paths with coefficient > .1 ($p < .001$).
PTSD, Drugs and Suicidality

- PTSD most stable over time; drug dependence declines, but suicidal behavior increases over time to midlife.
- Associations become stronger over time.
- Alcohol dependence and antisocial personality not as strong as predictors of suicidal ideation over time.
- Drug dependence exacerbates PTSD and suicidal ideation; once the course is set, self-medication kicks in.

How One Suicide Gave Birth to New Studies?

- Generality of suicidality findings in the VES cohort.
How One Suicide Gave Birth to New Studies?

- Using clinical data to inform a new study design and to ask new questions.
How One Suicide Gave a Birth to New Studies?

- Inquiries into resiliency factors in middle aged men with at risk for suicide.
VES-IV: “Suicide” Study

- Quasi case-control design to take advantage of the existence of a large number of suicidals.
- Episode-based interview to capture protective factors mitigating suicide risk.
- Quantitative-qualitative integration to examine the patterns of interactions between risk and protective factors.
VES-IV Sampling Design

In Target Sample (N=418)

Higher-Risk (N=168)

Projected = 49

Observed = 119

Medium Risk (N=223)

Not in Target Sample (N=224)

Lower-Risk (N=250)
Location of VES-IV Target Sample Members

Higher-Risk (N=168) ▲
Lower Risk (N=250) ◇
VES Samples (Total Target N = 1,226)

1996-7
N=841

323 D+ Vet
320 D- Vet
198 Nonvet
115 Deceased

2002-4
(n=346, in field)

151 D+ Vet
195 D- Vet
38 Nonvet
38 Deceased
Maximizing predictability vs. flexibility to handle uncertainty in the field.

Balancing “etic” and “emic” approaches to control data quality but get most out of participants.

Tension between maximizing scientific yield and humanity considerations.

Safety, safety, safety....

And of course, budget constraints!!

VES-IV Instrumentation

Scientific, Clinical and Practical Considerations
Institutional Barriers to a Study of Suicidality

- The Study Section said...
  "Clinical intervention is not a science aim."

- The WU IRB intervened...
  "This man is too dangerous! Do not recruit him to the study component."
  (Didn’t we interviewed him last time?)

- The VA IRB disapproved a media interview request...
  "Interviews may not be the best interest of veterans, if not well controlled."
Institutional Barriers to a Study of Suicidality

- **Serious Adverse Events (SAE) definition (21 CFR 312):**
  - Death, any life threatening event, or unanticipated event.

- **WU IRB SAE reporting criteria:**
  - Death.
  - Hospitalization unless preplanned.
  - Unanticipated or life-threatening drug reactions.
  - Congenital anomaly in the offspring of a drug study.
  - Higher risk experienced than described in protocol.
  - Prolonged stay in a health care facility.
  - Significant, physical or psychological, persistent or permanent harm or disability.
  - Breach of confidentiality.
How to Balance Science and Clinical Care in a Natural History Study??

- Personnel: clinicians or seasoned interviewers?
- How to “diagnose” imminent risk?
- When to deviate from the standard instrumentation?
- When and how to move from epidemiology to clinical intervention?
- When to let go participants?
- How to cover the research from liabilities?
How to balance science and clinical care in a natural history study??

- **Personnel: clinicians or seasoned interviewers?**
  - Difficult to train clinical skills to survey interviewers.
  - Difficult to train clinicians to take their clinical hat off while doing a research interview.

- **Personnel: Need for debriefing within and by professionals.**
How to “Diagnose” Imminent Risk?

ST-SUP1. SUICIDE RISK ASSESSMENT - IMMEDIATE STOP

1. TIMING OF SUICIDE PLAN  IF ST7a = 04 (PLAN TO ATTEMPT < 24 HOURS), R IS AT IMMINENT RISK.

2A. TIMING OF SUICIDE PLAN  IF ST7a = 03, (ATTEMPT > 24 HOURS & WITHIN A WEEK)

2B. DETAILS OF PLAN  GO TO ST5 TO ST7. CHECK BOXES BELOW

<table>
<thead>
<tr>
<th>Method/how well thought out</th>
<th>Location known or planned</th>
<th>Intervention not possible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has means or method now; or used in past</td>
<td>If 2 or more boxes checked.</td>
<td></td>
</tr>
</tbody>
</table>

2C. IF BOXES ARE CHECKED FOR BOTH 2A AND 2B, R IS AT HIGH RISK.

3. ARE THERE OTHER INDICATIONS OF HIGH RISK SUCH AS FLORID EXPRESSION OF ANGER WITH ACUTE DEPRESSION, HOMICIDAL IDEATION, REPEATED REFERENCE TO SUICIDE WITH NO TIME FRAMEWORK?

INTERVIEWER: IF A BOX FOR IMMINENT RISK OR HIGH RISK IS CHECKED, STOP THE INTERVIEW AND GO TO SECTION RT.
How to “Diagnose” Imminent Risk?

Start

Does the Respondent Have a Plan to Attempt Suicide in the Next 24 Hours?

Yes

Classify as Imminent Risk

No

Does the Respondent Have a Plan to Attempt within the Week, and Has Two or More Details for a Future Attempt?

Yes

Classify as High Risk

No

Interviewer Judges Respondent to be High Risk (e.g. because of florid expression of anger with acute depression, homicidal ideation, repeated reference to suicide with no time frame, etc.)

No

Proceed with Interview

Yes

Proceed with Triage and Referral.
When to Deviate from the Standard Instrumentation?

If the Respondent has had a suicidal episode or ideation within the last month, or if the Respondent continues to talk about suicidal events or thoughts, skip to Section ST, Suicidal Thought/Plan; others, go to Section EE.

If Sections EE, Extraordinary Experiences, to Ho, hopelessness were skipped, go back to Section EE; others, go to Section HC: Health Care.

Complete SR-SUP1 and SR-SUP2, ascertain risk status.

Complete the Start of the Interview through the Lifechart.

Complete Section ST.

Complete Section EE through Ho.

If Section ST has already been completed skip to Section HC. Health Care; others, continue to ST. Suicidal Thought.

Triage and Referel.

Complete healthcare and rest of interview.

If Box #1 or #2 checked on SR-SUP2, assign Respondent to Medium Risk.

Followup.
When to Deviate from the Standard Instrumentation?: An Example

<table>
<thead>
<tr>
<th>YEAR</th>
<th>RESIDENCES (Address)</th>
<th>MOVE MONTH</th>
<th>EMPLOYMENT (Job)</th>
<th>STATUS MONTH</th>
<th>RELATIONSHIPS (Name)</th>
<th>STATUS MONTH</th>
<th>MEMORABLE EVENTS (2 events per year)</th>
<th>EFFECT MONTH</th>
<th>OTHER EPISODE</th>
<th>MONTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996</td>
<td>BEF. LAST INT.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1997</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1998</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1999</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ID #
When to Deviate from the Standard Instrumentation?: An Example

<table>
<thead>
<tr>
<th>IF TWO OR MORE EVENTS WITH NEGATIVE EFFECTS ARE LISTED SINCE (DATE OF LAST INTERVIEW), GO TO THE INSTRUCTIONS AFTER THE TOP OF THE NEXT COLUMN.</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC19 If R has not listed two events with a negative effect, go to LC19.</td>
</tr>
<tr>
<td>IF NO: GO TO THE INSTRUCTIONS AFTER LC24.</td>
</tr>
<tr>
<td>IF YES: GO TO LC20.</td>
</tr>
<tr>
<td>LC20 Tell me about the event. What year did it happen?</td>
</tr>
<tr>
<td>RECORD EVENT UNDER &quot;MEMORABLE EVENTS&quot; COLUMN BESIDE APPROPRIATE YEAR.</td>
</tr>
<tr>
<td>LC21 In what month did the event happen?</td>
</tr>
<tr>
<td>RECORD MONTH IN APPROPRIATE MONTH/YEAR COLUMN.</td>
</tr>
<tr>
<td>ENTER CODE 02 UNDER MEMORABLE EVENTS &quot;EFFECT&quot; COLUMN BESIDE APPROPRIATE EVENT/YEAR/MONTH.</td>
</tr>
<tr>
<td>LC22 Can you recall any other time since your last interview on (DATE LAST INTERVIEW) when something happened that upset you strongly or made you feel stressed, depressed, anxious, or angry for a period of time?</td>
</tr>
<tr>
<td>IF NO: GO TO THE INSTRUCTIONS AFTER LC24.</td>
</tr>
<tr>
<td>IF YES: GO TO LC23.</td>
</tr>
<tr>
<td>LC23 Tell me about the event. What year did it happen?</td>
</tr>
<tr>
<td>RECORD EVENT UNDER &quot;MEMORABLE EVENTS&quot; COLUMN BESIDE APPROPRIATE YEAR.</td>
</tr>
<tr>
<td>LC24 In what month did the event happen?</td>
</tr>
<tr>
<td>RECORD MONTH IN APPROPRIATE MONTH/YEAR COLUMN.</td>
</tr>
<tr>
<td>ENTER CODE 02 UNDER MEMORABLE EVENTS &quot;EFFECT&quot; COLUMN BESIDE APPROPRIATE EVENT/YEAR/MONTH.</td>
</tr>
</tbody>
</table>

---

DO NOT MENTION THE INFORMATION OF SUICIDAL IDEATION IN 1996/7, IF AVAILABLE, UNLESS RESPONDENT VOLUNTARILY DISCLOSES AT ANY POINT IN THE LC SECTION.

RECORD SUICIDAL EPISODE ONLY IF VOLUNTEERED. DESCRIBE BRIEFLY IN "OTHER EPISODE" COLUMN BESIDE APPROPRIATE YEAR AND MONTH.

IF THE RESPONDENT HAS HAD A SUICIDAL EPISODE OR IDEATION WITHIN THE LAST MONTH, OR IF THE RESPONDENT CONTINUES TO TALK ABOUT SUICIDAL EVENTS OR THOUGHTS, SKIP TO SECTION ST. SUICIDAL THOUGHT/PLAN. OTHERS, GO TO SECTION EE.

COMPLETE AFTER INTERVIEW: GO TO SR-SUP1, BOX "LC. LIFE CHART." BASED ON THE INFORMATION ON LC-SUP1, LIFE CHART, EMPLOYMENT, RELATIONSHIPS, AND MEMORABLE EVENTS COLUMN, CHECK APPROPRIATE ITEMS FOR "RECENT JOBS/PERSONAL LOSS," "RECENT LOSS OF RELATIONSHIP," AND "RECENT PHYSICAL HEALTH LOSS."
When and How to Move from Epidemiology to Clinical Intervention?

RISK ASSESSMENT FORM - FLOW CHART FOR MEDIUM OR LOWER RISK

Start

Has the Respondent had a Suicidal Attempt Since the Last Interview?

Did the Respondent have Difficulty with Feelings/ Negative Mood/Concerns with Safety?

Compute Prior Risk Score (0-2)

Compute Recent Loss (0-2)

Compute PTSD Score (0-1)

Compute Substance Abuse (0-2)

Compute Psychiatric/Substance Abuse Care (0-4)

What is the Total Risk Score (0-17)?

Compute Hopelessness Score (0-2)

Compute Worthlessness Score (0-1)

Compute Current Suicidal Thought (0-1)

Compute Current Depression (0-2)

ID#

(12-17) Classify as Medium Risk

(5-11) Classify as Low Risk

(0-5) Classify as No Risk

No Risk Low Risk Medium Risk

MARK THE FINAL RISK STATUS HERE
Intervention/Referral Flow Chart

Start Interview

Does the Respondent Require Intervention?

Yes: Is Risk of Suicide Imminent?

Yes: Insure Hospitalization or Contact with Local Authorities

No: Finish Remaining Sections, Provide Voucher, Provide Contact Number

No: ST-SUP1 Risk Assessment Form

ST-SUP1 Risk Assessment Form

Finish Remaining Sections, Provide Voucher, Provide Contact Number

Insure Hospitalization or Contact with Local Authorities

Yes: Interviewer Contacts Specified Local Agency or Life Crisis Center if Local Agency is Unavailable

No: Insure Hospitalization or Contact with Local Authorities

Yes: Finish Remaining Sections, Provide Voucher, Provide Contact Number, Inform Respondents of Available Local Services

No: Insure Hospitalization or Contact with Local Authorities

Yes: Provide Voucher, Provide Contact Number

No: Inform Respondents of Available Local Services

Is the Respondent in Treatment?

Yes: Does the Respondent Need to Be Dropped?

Yes: Insure Hospitalization or Contact with Local Authorities

No: Provide Voucher, Provide Contact Number

No: Inform Respondents of Available Local Services

Is Risk of Suicide Imminent?

Yes: Provide Voucher, Provide Contact Number

No: Inform Respondents of Available Local Services

Is Risk of Suicide Imminent?

No: Finish Remaining Sections, Provide Voucher, Provide Contact Number

Yes: Interviewer Contacts P.I.

P.I. and Consultants Develop Follow-up Plan.

Follow-up: Is Risk Decreased?

Yes: Provide Voucher, Provide Contact Number

No: Inform Respondents of Available Local Services

Does the Respondent Need to Be Dropped?

Yes: Insure Hospitalization or Contact with Local Authorities

No: Provide Voucher, Provide Contact Number

Inform Respondents of Available Local Services

End

Medium Risk: Referral and Follow-up

No/Low Risk: Referral and Follow-up
How to balance science and clinical care in a natural history study??

- How to cover the research from liabilities?
  
  - Life-crisis vouchers for 24/7 coverage for one year (respondent must initiate).
  - Project psychiatrist on call for high-risk respondent interviews.
  - PI on-call for “flagged” cases.
  - PI and project coordinator review clinical vignettes after interviews, for selected high-risk cases.
  - “After care” through VA outpatient-arm national networks (VET Centers).
  - SAE report backed up by project psychiatrist’s independent assessment using the audio-taped interview.
Using Ethical Guidelines to Fill Gaps in Epidemiologic Research of Suicidality

- Treat suicide (or suicide attempt) as an anticipated outcome.
- Stop treating suicidals as an exclusion criteria.
- Uniform guidelines for subject protection and measures collection.
- Large-scale epidemiologic studies as well as smaller R01 studies should collect death certificates and follow up suicidals - But anonymity a big issue!
- A better mechanism for data sharing.
# VES-III & IV Collaborators

<table>
<thead>
<tr>
<th>Organization</th>
<th>Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>WU Medicine</td>
<td>Rumi Kato Price, Lee Robins, Edward Spitznagel, George Murphy, Collins Lewis</td>
</tr>
<tr>
<td>WU Social Work</td>
<td>Enola Proctor, Sally Haywood</td>
</tr>
<tr>
<td>St. Louis VA</td>
<td>Katherine Virgo, Seth Eisen</td>
</tr>
<tr>
<td>Readjustment Counseling Services (Vet Center)</td>
<td>Gary Collins, Rodney Haug, Robert Mathes</td>
</tr>
<tr>
<td>St. Louis Crisis Services Center</td>
<td>G. Lee Judy</td>
</tr>
<tr>
<td>Consultants</td>
<td>Bruce Goldberger, Gery Ryan</td>
</tr>
<tr>
<td>Contract Work</td>
<td>Research Triangle Institute, Psychemedics</td>
</tr>
</tbody>
</table>