Current Suicide Risk Assessment

Grand Rounds
Rogers Memorial Hospital
13 March 2014

John Greist, MD
Disclosures

John Greist, MD: Past two years

Grant/Research Support: AstraZeneca, Forest, Janssen, Lilly, Otsuka, Takeda, Transcept, UCB

Consultant: GSK, Lilly, Novo Nordisk, Pfizer

Pharmaceutical Stocks: None

Principal: Healthcare Technology Systems

Shareholder: Waypoint Health Innovations
If suicidal ideation and behavior cannot be properly identified, they cannot be properly understood, managed or treated.

Use and role of computer interviews in suicide risk assessment.
Suicide Risk Signal Detection

- Any signal is likely to be small
- Signal accuracy requires reliability
- Small signals need greater reliability
- Computer interviews are perfectly reliable
  - Faithfully present each question
  - Document processing of interview algorithm
- Greater suicidality candor with computer interview
The identification and monitoring of at-risk patients is an important step in protecting these individuals.

Scope:
Psychiatric and General Hospital patients with emotional or behavioral care components:
- Identification of at-risk patients
- Monitoring these patients while under care
- Ongoing monitoring following discharge

The Joint Commission has issued guidelines NPSG 15.01.01: Find out which patients are most likely to try to commit suicide

Rationale:
The identification and monitoring of at-risk patients is an important step in protecting these individuals.
Joint Commission Program Requirements

• Conduct a **prospective** risk assessment to identify specific patient characteristics that may indicate suicide risk

• Adopt a structured screening process for the ER, clinics and 24hr care settings

• Adopt a standardized tool for consistent, routine application:
  • Accepted by the field, based on current evidence and practice
  • Producing a patient risk rating
Draft FDA Guidance 2010 and 2012

- Prospective assessment of suicidal ideation and behavior
  - Identify patients at risk
  - Collect complete, timely data
- The C-SSRS is an “acceptable” prospective assessment
- Administration by ‘phone and computer’ are acceptable
- Identifies predictive value of lifetime eC-SSRS study data
- Specifically cites “The eC-SSRS … is an alternative approach to obtaining data on suicidal ideation and behavior.”
Columbia-Suicide Severity Rating Scale

Clinician Interview or Patient Self-Report?

Best both!
Key Elements for C-SSRS and eC-SSRS

**IDEATION**

- **Passive**
  1. Wish to be dead, sleep and not wake up
- **Active**
  2. Thoughts of killing self
  3. Contemplation of method
  4. Method + intention to act
  5. Method + intent and plan

**INTENSITY**
*(only for most severe ideation)*

- Frequency
- Duration
- Controllability
- Deterrents
- Reasons

**BEHAVIOR**

- Suicide Attempts (Intent/Desire to Die)
- Self-injurious Behavior. Non-suicidal
- Interrupted Attempts
- Aborted Attempts
- Preparatory Actions

**LETHALITY**

- Injury Severity
- Potential Lethality

**REPORT**

**CLINICIAN**

Positive Finding
Suicidal Ideation and Behavior – Classifications

Data classification C-CASA categories are specifically defined [App A]
Assessments producing responses in these categories render further classification steps unnecessary. [177-79]

<table>
<thead>
<tr>
<th>Suicidal Ideation</th>
<th>Suicidal Behavior</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Passive</td>
<td>1. Completed suicide</td>
</tr>
<tr>
<td>2. Active: Nonspecific, no method, intent, or plan</td>
<td>2. Suicide attempt</td>
</tr>
<tr>
<td>3. Active: Method, but no intent or plan</td>
<td>3. Interrupted attempt</td>
</tr>
<tr>
<td>4. Active: Method and intent, but no plan</td>
<td>4. Aborted attempt</td>
</tr>
<tr>
<td>5. Active: Method, intent, and plan</td>
<td>5. Preparatory actions toward imminent suicidal behaviors</td>
</tr>
</tbody>
</table>

- **Done correctly** C-SSRS and eC-SSRS do this classification directly

[137-151] [FDA Draft Guidance Document Line Numbers]
Assessment variability
Rater Variability

Scoring Variability
17 item HamD
Item Level Analyses

Rater Variability

Distribution of disagreements by rater experience and training

- Experienced Calibrated Raters: 7%
- Experienced Non Calibrated Raters: 9%
- No Experience Raters: 11%

Agreement: 73%
“Differences in how follow-up questions were phrased and differences in which follow-up questions were asked were the most common type of information variance.”
Challenges with Suicidality Interviews

- Time consuming for clinicians to adequately interview patients
- Patients are less candid when asked by a physician than by a computer
- Interviewers paraphrase questions and interpret responses differently, affecting reliability and validity
- Staff burden for training and retraining
eC-SSRS Overview

- A fully structured self-report electronic C-SSRS interview
  - Developed in 2008 in collaboration between ERT, HTS and Dr. Kelly Posner
  - Three delivery options: IVR phone, Tablet, Web
  - “Procedurally invariant,” ensuring each question is
    - asked correctly
    - answered
    - documented
  - Shortest path 8 questions; longest path 19 questions

C-SSRS vs. eC-SSRS Interviews

C-SSRS Clinician Interview

Starts with:
- Two pages of semi-structured prompts
- A free form interview

Results in:
- A handwritten report
- Responses interpreted and appropriate boxes checked
- Free form text description of positive findings

eC-SSRS Self-Rated Interview

Starts with:
- A fully structured consistent interview
- Proper questions, follow-ups and branching logic
- The patient enters responses
- Average length is 3.8 minutes

Results in:
- An immediate eC-SSRS Report
- Staff alerts for positive findings
- Consistent, complete data for referrals and analyses
Challenges with Paper Documentation

- Free text data issues
- Potential for discordant data
- Follow up questions documention
- Data transcription (time & errors)
Attempt Probing:

- At any time in your life, have you made a suicide attempt?
  - If **negative** branch to “intentional self harm” question
  - If **positive**
- Enter the number of suicide attempts
- When you made your most recent attempt, were you trying to end your life?
- Did you think it was possible that you could have died from what you did?
- So then,
  - Did you want to die, even a little, when you did this? Or
  - Did you do it purely for other reasons, without ANY intention of killing yourself, like to relieve stress, feel better, get sympathy, or get something else to happen to you?
Is the Self Rated eC-SSRS Better Than The Clinician?

- **No**, they’re complementary and are better together than either is alone
  - Computer interview standardization
  - Greater disclosure to computer
  - Clinician knowledge, experience, intuition and data integration

- Most eC-SSRS reports are negative, needing only brief clinician review

- Positive eC-SSRS reports organize and guide the clinician review
eC-SSRS Operational Overview
The Self Rated eC-SSRS Process

Findings are transferred to the ERT data repository and reports are sent immediately to staff.

If Positive
ERT Alerts Staff

If Negative
Staff Reviews Report

Follows up Per Policy
## eC-SSRS Findings Report

### Columbia Suicide Severity Rating Scale – eC-SSRS

#### Lifetime Assessment

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Lifetime</th>
<th>Recent</th>
</tr>
</thead>
<tbody>
<tr>
<td>ponsor: ERT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject: 2006</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol: SITEPRO_VIAPHONE EC-SSRS EQUIVALENCY STUDY</td>
<td>Site ID: 001</td>
<td></td>
</tr>
<tr>
<td>Collection Date/Time: 04-MAR-2014 14:40:40 CST</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Ideation

<table>
<thead>
<tr>
<th>Level</th>
<th>Lifetime</th>
<th>In the last 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Wish to be dead or not wake up</td>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>2. Non-specific thoughts</td>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>3. Specific thoughts off method</td>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>4. Some intent to act, no plan</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>5. Specific plan and intent</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Most severe level of ideation:

- S. Specific plan and intent

### Behaviors

<table>
<thead>
<tr>
<th>Actual Suicide Attempts</th>
<th>Lifetime</th>
<th>In the last 24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Interrupted Attempts</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Aborted Attempts</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Preparatory Actions</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Non-suicidal Self-injurious Behaviors</td>
<td>No</td>
<td>0</td>
</tr>
</tbody>
</table>

### Lethality of Suicide Attempts

- Most Recent Attempt
- Most Serious Attempt
- First Attempt

- Could have died without medical treatment or permanent physical damage [4]
- Could have died without medical treatment or permanent physical damage [4]
- Could have died without medical treatment or permanent physical damage [4]

### Potential Lethality of Suicide Attempts

- Most Recent Attempt
- Most Serious Attempt
- First Attempt

- N/A
- N/A
- N/A

### Alerts

- POSITIVE FINDING: LIFETIME SUICIDE IDEATION - SOME INTENT TO ACT, NO PLAN
- POSITIVE FINDING: RECENT LIFETIME SUICIDE BEHAVIOR - ACTUAL ATTEMPTS
- POSITIVE FINDING: RECENT LIFETIME SUICIDE BEHAVIOR - ABORTED ATTEMPTS
- POSITIVE FINDING: RECENT LIFETIME SUICIDE BEHAVIOR - PREPARATORY ACTIONS
- POSITIVE FINDING: RECENT LIFETIME SUICIDE IDEATION - SPECIFIC PLAN AND INTENT

### Site Personnel

- Signature: __________________________
- Date: __________________________

Disclaimer: This computer-automated assessment is designed to aid comprehensive assessment of suicide risk. Clinicians responsible for the safety of patients should verify the information provided. Additional assessment of suicidal ideation and/or behaviors may be required. Determination of the relative absence or presence of patient risk is dependent upon sound clinical judgment.

eC-SSRS ERT based upon C-SSRS® Research Foundation for Mental Hygiene.

Generated on: 04-Mar-2014 16:02:31 (US/Eastern)  ERT Confidential  Page 1 of 1
Suicide Risk Monitoring Schedule

- First assessment is *Lifetime* – “Have you ever…”
- Next, the *recency* of positive findings
  - “Was this ideation in the past month?”
  - “Was this behavior in the past 6 months?”
- During hospitalization, for subsequent admissions or post hospital care
  - “*Since your last assessment*, on mm/dd, xx days ago, have you…”
- Rogers policy determines scheduling of the eC-SSRS
- Rogers policy determines appropriate follow up for positive findings - like any other safety finding (i.e. labs or ECGs)
eC-SSRS System Experience

• More than 70 studies in 29 disorders
• More than 160K assessments

35K study findings (Depression, Epilepsy, Fibromyalgia, Insomnia, PTSD)

• Completion rate: 99.89%
• Assessments after baseline (Lifetime)
  • Negative 98.3% (completion time 3.5 min.)
  • Positive 1.7% (completion time 7.7 min.)

Odds Ratios within Participant Classification Groups

*Lifetime* assessment prediction of *short-term* behaviors

75,000 Assessments

(Psychiatric Patients)  
N = 6760

(Non-Psychiatric Patients)  
N = 2077

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**Baseline SCCs**

- None (N = 4967)  
  - Odds Ratio: 4.7
- Ideation Only (N = 156)  
  - Odds Ratio: 5.7
- Behavior Only (N = 861)  
  - Odds Ratio: 9.3
- Both (N = 776)  
  - Odds Ratio: 12.5

**Baseline SCCs**

- None (N = 1983)  
  - Odds Ratio: 17.1
- Ideation Only  
- Behavior Only (N = 47)  
  - Odds Ratio: 12.5
- Both (N = 35)  

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**Post baseline F/U**

- w/ Suicidal Behav  
  - 72 days: 1.29%
  - 98 days: 0.15%
**Short-term suicidal behaviors based on Lifetime SI**

Increased odds of prospectively reporting a *suicidal behavior* associated with most severe *lifetime suicidal ideation* reported at baseline:

<table>
<thead>
<tr>
<th>Baseling Ideation</th>
<th>Patients not prospectively reporting suicidal behavior</th>
<th>Patients prospectively reporting suicidal behavior</th>
<th>Odds ratio of prospective suicidal behavior report (95% CI; p-values &lt; .001)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N =3575</td>
<td>N =201</td>
<td></td>
</tr>
<tr>
<td>No Ideation Reported</td>
<td>1757 (99.0%)</td>
<td>17 (1.0%)</td>
<td>--</td>
</tr>
<tr>
<td>Passive</td>
<td>737 (95.2 %)</td>
<td>37 (4.8%)</td>
<td><strong>5.19 (2.90 – 9.27)</strong>***</td>
</tr>
<tr>
<td>Active, no method</td>
<td>288 (92.9 %)</td>
<td>22 (7.1 %)</td>
<td><strong>7.90 (4.14 – 15.05)</strong>***</td>
</tr>
<tr>
<td>Active, method, no intention</td>
<td>375 (91.0 %)</td>
<td>37 (9.0 %)</td>
<td><strong>10.20 (5.68 – 18.30)</strong>***</td>
</tr>
<tr>
<td>Active, <em>Intention</em>, &amp; Method</td>
<td>240 (83.0 %)</td>
<td>49 (17.0 %)</td>
<td><strong>21.10 (11.96 – 37.24)</strong>***</td>
</tr>
<tr>
<td>Active, <em>Intention</em>, &amp; Plan</td>
<td>178 (82.0 %)</td>
<td>39 (18.0 %)</td>
<td><strong>22.65 (12.55 – 40.86)</strong>***</td>
</tr>
</tbody>
</table>
Each *lifetime* suicidal behavior at baseline prospectively predicts suicidal behavior during trial

<table>
<thead>
<tr>
<th>Baseline Reports</th>
<th>Patients not prospectively reporting suicidal behavior</th>
<th>Patients prospectively reporting suicidal behavior</th>
<th>Odds ratio of prospective suicidal behavior report</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 3577</td>
<td>N = 201</td>
<td><strong>p &lt; .001</strong></td>
</tr>
<tr>
<td>Actual Attempt</td>
<td>522 (85.6 %)</td>
<td>88 (14.4 %)</td>
<td>4.56 (3.40 – 6.11)***</td>
</tr>
<tr>
<td>BL Interrupted Attempt</td>
<td>349 (82.7 %)</td>
<td>73 (17.3 %)</td>
<td>5.28 (3.88 – 7.18)***</td>
</tr>
<tr>
<td>BL Aborted Attempt</td>
<td>461 (84.7 %)</td>
<td>83 (15.3 %)</td>
<td>4.75 (3.53 – 6.40)***</td>
</tr>
<tr>
<td>BL Preparatory Behavior</td>
<td>177 (81.2 %)</td>
<td>41 (18.8 %)</td>
<td>4.92 (3.38 – 7.16)***</td>
</tr>
</tbody>
</table>

A person reporting any one of the lifetime behaviors at baseline is ~ 4.5 to 5 times more likely to prospectively report a behavior during subsequent follow-up
Number of different lifetime suicidal behaviors predicts suicidal behavior during trial

<table>
<thead>
<tr>
<th></th>
<th>Patients not prospectively reporting suicidal behavior</th>
<th>Patients prospectively reporting suicidal behavior</th>
<th>Odds ratio of prospective suicidal behavior report</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N =3577</td>
<td>N =201</td>
<td>*** p&lt;.001</td>
</tr>
<tr>
<td>No Behaviors</td>
<td>2791 (97.3%)</td>
<td>76 (2.7%)</td>
<td>4.56 (3.40 – 6.11)***</td>
</tr>
<tr>
<td>Reported at BL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One Behavior</td>
<td>345 (91.5 %)</td>
<td>32 (8.5%)</td>
<td>3.41 (2.22 – 5.23)***</td>
</tr>
<tr>
<td>Two Behaviors</td>
<td>214 (84.3 %)</td>
<td>40 (15.7%)</td>
<td>6.86 (4.57 – 10.32)***</td>
</tr>
<tr>
<td>Three Behaviors</td>
<td>172 (81.5 %)</td>
<td>39 (18.5 %)</td>
<td>8.33 (5.50 – 12.62)***</td>
</tr>
<tr>
<td>Four Behavior</td>
<td>55 (79.7 %)</td>
<td>14 (20.3 %)</td>
<td>9.35 (4.98 – 17.54)***</td>
</tr>
</tbody>
</table>

Any type of lifetime behavior increases likelihood of behavior during trial by ~ 3.4 times; likelihood increases proportionally with increased number of different behaviors reported.
Each eC-SSRS *lifetime* ideation and behavior question predicts *short-term* suicidal behaviors.

e-CSSRS ensures all questions are asked correctly... answered... and documented.
Sensitive Subjects

• Sexual functioning
• Substance use
• HIV risk factors
  and… Suicidal ideation and behaviors

• Fewer false negatives (Type II error) with computer
  …than clinician interview
Patients preferred the computer interview to talking to a physician … the computer was more accurate than clinicians in predicting suicide attempts.

A Computer Interview for Suicide-Risk Prediction

BY JOHN H. GREIST, M.D., DAVID H. GUSTAFSON, PH.D., FRED F. STAUSS, M.S., GLEN L. ROWSE, M.S., THOMAS P. LAUGHREN, M.D., AND JOHN A. CHILES, M.D.
“Severity of self-rated suicide ideation and depressive symptoms predicted emergence of suicidality …

… self-rated instruments of suicidality and depression are more sensitive in detecting suicidal risk than rating scales scored by the clinician (ie, CDRS-R).”

ASERT – Study Population

- N = 208
- Average age 41.2
- Mean duration of epilepsy 20.4 years
- Mean seizures/month 18.7
- Unemployed 25.0%; On disability 23.1%
- More than one anti epileptic drug 75.5%
- Epilepsy surgery 25.5%
- Vagus nerve stimulator 15.4%

Assessment of Suicidality in Epilepsy

ASERT – Study Findings (N = 208)

- **Lifetime Suicide Attempt Rates**
  - C-SSRS 10.2%
  - eC-SSRS 13.1%

- **Lifetime Suicidal Behavior* Rates**
  - C-SSRS 15.5%
  - eC-SSRS 21.1%

- **Behaviors reported only to C-SSRS or eC-SSRS**
  - C-SSRS 6.3%
  - eC-SSRS 38.1%

*Behaviors: Interrupted/aborted attempts, preparatory actas

ASERT - Study Conclusions

- False negative reports always possible
- 6 times more likely in face-to-face assessments
- To reduce risk and increase safety
  - Administer self-rated eC-SSRS,
  - Conduct eC-SSRS findings review
  - Then add appropriate face-to-face contact

eC-SSRS Benefits

Enhances Patient Safety

• Increased patient candor
• Immediate suicide risk notification
• Lifetime and recent patient experience

Increases Quality Data

• Reliability in content and delivery
• Reduced effect of assessment variability
• Accurate documentation and reporting
• Reduced inconsistencies, more accurate referrals
eC-SSRS Benefits

Reduces Staff Burden

- Reduces training burden
- Minimizes the assessment language barrier between patient and staff
- Reduces one-on-one nursing requirements

Fulfils Regulatory Focus / Reduces Risk and Liability

- Ensures compliance with the safety recommendations of both The Joint Commission and FDA
- Utilizes a standardized, validated, and accepted scale
- Protects the liability and reputation of the facility by avoiding negative publicity of attempts
How might Rogers use the eC-SSRS?

• **Possibly**
  - At first admission *Lifetime* and *Recency*
  - Thereafter *Since last assessment* (SLA)
    - As ordered during admission
    - At discharge
    - At readmission
    - After discharge as appropriate

• **Certainly**
  - According to any protocol Rogers decides
Surgical Safety Check List

• 8 international hospitals, wide range of SES
• 19 checklist elements
• Improvements
  • Death rate 1.5% ⇒ 0.8%
  • Inpatient complications 11% ⇒ 7% (p < .001)
  • Appropriate antibiotic use 56% ⇒ 83%
• Checklist steps ↑ from 34–57% (p < .001) but…
  “omission of individual steps was still frequent.”

I’m firmly convinced that behind every great man or great woman is a great computer.
Discussion
Trainability of Human Raters

• US multicenter trial: 31 raters at 15 sites
  • First, didactic training with test
  • Then live interview coaching and rating

• Rater Applied Performance Scale (RAPS) Range 4 – 16
  • Excellent = 14.5 – 16
  • Good = 10.5 – 14.4 (had to score > 10.4 to qualify)
  • Fair = 6.5 – 10.4
  • Poor = < 6.5

• 57% “Qualified” 1st time; 93% by 3rd try

• Baseline mean score 12.2

Sustainability of Rater Training

• Same raters reassessed 12 months later
  • Baseline 12.2 dropped to 10.7 (Good = 10.5 - 14.4)
  • Only 58% still qualified
  • Unqualified 42% mean score 7.8 (Fair = 6.5 - 10.4)

• Retraining “requalified” all raters by 3rd try

• Performance in the previous and next 12 months?