

On the Road to Prevention:

Using the Columbia Suicide Severity Rating Scale in the Military

Increasing Precision and Redirecting Scarce Resources

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Suicide is a Major Public Health Crisis

- Suicide is one of the world's greatest public health epidemics
- Leading cause of death across the world and across ages
- 2nd leading cause of death in children
- 3rd leading cause of death in youth 15-19
 - Suicide **doubled** for African American males 1980-1996
- 4th leading cause of death for adults 18 - 65 in US
- **Every 15 minutes** a person dies by suicide in US

“The under-recognized public health crisis of suicide” -
Thomas Insel, Director of NIMH

Suicide is a preventable public health problem

Scope of Suicide Among College Students

- Estimated to be 2nd leading cause of death
- 1100 suicides per year; 75% male
- 1.5% report suicide attempt in past year
- 10% report suicidal ideation in past year
- 50% of college students report suicidal ideation at some time in life
- **< 20% of college students who die by suicide received campus-based services**
- Suicide rates higher among seniors and graduate students

Suicide Rates on the Rise in the U.S. Military...

- Suicide is the 2nd most common cause of death in the U.S. military - accounts for 20% of suicides each year
- Overall suicide rate across the Army is up more than 24%
- Suicide rates amongst active duty military *and* veterans have risen over the past 4 years (JAMA, 2009)
- Suicides doubled in 2010 among army reservists and national guardsmen
- More than 1/2 of those who died by suicide were at home in the US and never deployed to a war zone
- Air Force: approx first 15 days of 2012 – 9 suicides

Suicide in the Police Force

Overall Picture

- 1st or 2nd leading cause of death of policemen alongside car accidents
- In 2011, almost three times as many died by suicide as are killed in the line of duty
- The rate of police suicide is comparable to the rate of suicides in the US Army
- The NYC, the rate of officers dying by suicide is almost three times that of suicides in the gen. population

Suicide in U.S. Correctional Facilities

Overall Picture

- Suicide is the most common cause of death in correctional facilities
- In US prisons, rate of suicide close to 2x that of general pop.
- In US jails, rate of suicide 9x that of general pop.
- Nearly 30% of inmates who die by suicide have no psychiatric illness and no clear warning signs
- Incarcerated youth: 31% report a suicide attempt. Significantly higher rates of suicidal behavior than the general adolescent population

Consistent profile for incarcerated suicides:

- Young
- White
- Single
- First-time
- Non-violent offenders
- ***Death within the first 24 hours of arrest.***

Youth Suicidal Ideation and Behavior

IN HIGH SCHOOLERS

- Ideation: 20%
 - With a plan: 17%
- **Attempt: 10%**
 - Attempt requiring medical attention: 3%

DEPRESSED TEENS

- Ideation: 60%
- Attempt: 30%

IN COLLEGE STUDENTS

- Ideation (Lifetime): 50%
- Ideation (Past Year): 10%
- Attempt: 1.5%

Public Health Burden.....

- 2 million adolescents attempt suicide annually, resulting in 700,000 ER visits
- Attempters constitute high proportion of all emergency referrals to child, adolescent, and adult psychiatric services and subsequently command disproportionate level of resources

Economic Burden of Suicide

- Worldwide, suicide accounts for:
 - **\$26.7 billion** in combined medical and work-loss damages yearly
 - Majority of violence-related injury deaths (64%)
 - US (2005): \$5 billion/year *Centers for Disease Control and Prevention 2011*
- Within corporate family consisting of 100,000 employees (average of 4 blood relatives per employee):
 - **Every 7 days**, one employee or family member will die by suicide
 - Every day, 3 attempts resulting in significant medical injury and disability, which directly impacts health care costs, particularly for self-insured companies. *Centers for Disease Control and Prevention 2011*
- **\$1.2 million** potentially saved for every suicide (36,909 in 2009) prevented in the U.S.
 - Nonfatal injuries, occupational productivity, medical care, years of life lost
 - Psychological pain and suffering of survivors

Scope of the Problem: Depression

- World Health Organization predicts that depression will be second most burdensome disease by the year 2020 (Murray & Lopez, 1997)

Unfortunately...

- 90% of individuals who die by suicide have untreated mental illness, 60% depression.
- Under-treatment of mental illness is pervasive
 - 50-75% of those in need receive no treatment or inadequate treatment (Alonso et al., 2007; Wang et al., 2005)
 - 50% of African Americans don't seek treatment
 - 50-75% of children with depression go undiagnosed and untreated
- < 20% of adolescent suicides receive any consistent treatment prior to their death.

**Suicide prevention efforts
depend upon appropriate
identification & screening**

The Problem...

- Field of medicine challenged by lack of conceptual clarity about suicidal behavior and corresponding lack of well-defined terminology
 - In both research and clinical descriptions of suicidal acts
- Variability of terms referring to same behaviors, e.g., threat, gesture. Often negative and based on incorrect notions about seriousness and lethality in methods e.g., manipulative, non-serious

Consequences....

- Negative implications on appropriate management of suicide and research
 - If suicidal behavior and ideation cannot be properly identified, it cannot be properly understood, managed or treated in any population or diagnosis

****Furthermore, comparison across epidemiological or drug safety data sets is compromised, decreasing confidence in rates of suicide attempts, and limiting comparisons across counties, states, and countries...***

Consequences...

- Difficulty in interpreting the meaning of suicidal occurrences and hampers precise communication on individual or population basis
 - Occurrences that should be called suicidal may be missed
 - Occurrences may be inappropriately called suicidal

The Need for Consistent Definitions & Data Elements

- “ Research on suicide is plagued by many methodological problems...
Definitions lack uniformity,...reporting of suicide is inaccurate...”
Reducing Suicide Institute of Medicine
2002

Alex Crosby, CDC

General Chiarelli

(retired US Army general who served as the 32nd Vice Chief of Staff of the U.S. Army, forefront of suicide prevention efforts)

Emphasizes the need for

"reliable diagnostic tools to screen for behavioral health issues."

Examples of The Problem

<u>Original Label</u>	<u>Text</u>
Personality Disorder	10 y.o. male exhibited symptoms of PD of moderate severity and was discontinued, one day later pt. attempted to hang himself w/ a rope after dispute w/ his father. Investigator did not consider this an SAE but rather part of the PD.
Accidental Overdose AND Neurosis	The overdose of 6 capsules of study medication was in fact intentional and in response to an argument with the subject's mother.
Medication Error	The patient took 11 tablets impulsively and then went to school...the patient denied that it was a suicide attempt.
Hostility	Age 10: Before his mother's call to the site and again after arguing with his stepfather, he wrapped a cord from the miniblinds around his neck, threatening to kill himself.

More Examples of Difficulties in Event Labeling

<u>Original Label</u>	<u>Narratives</u>
Emotional Lab./ Suicide Attempt	The patient is reported to have engaged in an episode of "automutilation" where she slapped herself in the face.
Suicide Attempt	Pt. had thoughts of killing self but had no intention of acting on them.
Abdominal hernia	41-year old Caucasian male experienced a mild abdominal hernia that led to hospitalization and surgery 1 week later and the patient recovered. The patient experienced eventration after a laparotomy due to an abdominal wound caused by a self-inflicted gun shot .
Trauma	The patient made an attempt to stab himself in the abdomen on day 49 which resulted in minor injury only. This was not considered a true suicide attempt by the investigator and no action was taken...Hence it was not considered to be clinically significant.
Suicide Attempt	Hitting his head on the wall... The patient explained it is like my thoughts are about to explode.

**** Note severity goes both ways- labels more severe than₁₉ they should be as well as less severe than warranted****

"Suicide"

- "...The patient, involved in the federal witness protection program for having testified against mobsters, died by apparent suicide. He made a call to a lawyer and said 'please help, I'm going to die'. According to primary care physician and Investigator, the patient did not exhibit any signs of depression. There was no sign of despondency or hopelessness. The autopsy report stated the following: 'cause of death: intra-oral gunshot wound of the head; how injury occurred: shot self; manner of death: suicide'..."

Reason to question labels!

More Consequences...Why Standardization is Important

- Use of Columbia's standardized classification algorithm led to a *50% reduction in suicide attempts and more precise and lower risk estimates* (Posner et al., 2007, *AJP*)
- Consistent with previous findings that misclassification leads to overestimation of true risk (Jurek et al., 2005)

Limitations of the Data: *Lessons Learned from Research and Clinical Practice*

ASSOCIATION \neq CAUSALITY

- Not designed to answer the question / adequately assess suicide risk
- **ASCERTAINMENT BIAS**
 - Not systematically elicited - FDA risk analyses relied on spontaneously generated AEs



- May account for differential between drug vs placebo
- May be 'false' or misleading results / reasons other than causality
- Many data sets show systematic screening does not confirm risk

NEED BETTER, SYSTEMATIC ASSESSMENT

Clinician Screen Inadequate

- “Structured Interview May Better Detect Adolescent Suicidality: Simpler 2-Question Screening Approach by Trained Clinicians Falls Short” (Medscape Medical News, 2008)
- Screening method (without a measure) over-detected suicidal ideation & under-detected suicidal acts

MSNBC Article 5.7.2008

- "We know that whether or not these drugs actually cause suicidal thought or action is ***a question we have to answer***, but up until now, none of the clinical trials for the drugs were set up to address the question," says Posner. "Either way we have to get the right answers. It's critical to know about drugs that pose risk, but ***debunking false notions of risk is equally important to the public health.***"
- "...the FDA hopes that by using Posner's methods, they may be able to find categories of people who might be at risk for suicide on a particular drug...and in whom it can safely be prescribed" says T. Laughren.

Furthermore, Expect to See It Across All Medical Disorders and Beyond...

- Suicidal behavior and ideation prevalent across all medical disorders
 - 25.5% have ideation
 - 8.9% make an attempt

Druss and Pincus, 2000.

So need to get it right.....

How to Fix the Problem...

Columbia - Suicide Severity Rating Scale

- Systematic administration of tool designed to track suicidal adverse events and change across a treatment trial
 - In context of multi-site NIMH trial (Treatment of Adolescent Suicide Attempter Study),
 - In response to need for a measure of suicide behavior/ideation severity and change
- ***"Prospective counterpart"*** of the FDA-commissioned system (indicated in C-CASA article, Posner et al., 2007, *AJP*); C-CASA is retrospective C-SSRS
- Way to get better safety monitoring and avoid inconclusive results
- This is why FDA and other regulatory authorities are often recommending or asking for C-SSRS in ongoing or future studies.

Columbia-Suicide Severity Rating Scale (C-SSRS)

- Developed by leading experts
 - collaboration with Beck's group
- Evidence-based and supported
- Feasible, low-burden – short administration time (average is a few minutes)
- Assesses *both* behavior and ideation: uniquely addressing the need for a summary measure
- *Comprehensive measure that includes only the most necessary suicidal characteristics (i.e., the most essential, evidence-based items needed in a thorough assessment)*

C-SSRS Requests/Uses

- JCAHO Best Practices Library
- World Health Organization-Europe: *100 Best Practices for Adolescent Suicide Prevention*
- AMA Best Practices Adolescent Suicide
- U.S. Army, U.S. Navy, U.S. Air Force, U.S. Marines, and National Guard
- Health Canada
- Hospitals and Community Clinic Settings
 - Inpatient and ERs; general medical and psychiatric, Crisis services, Special Needs Clinics, VA's
- A county-wide Suicide cluster in New York
- Japanese National Institute of Mental Health and Neurology
- Israeli Defense Force and Israeli National Suicide Prevention Program
- Korean Association for Suicide Prevention
- Planned statewide dissemination in Victoria, Australia – Health and Law Enforcement agencies
- International Mission Organizations
- Drug and Alcohol Addiction Centers
- National Institute on Alcohol Abuse and Alcoholism: NIAAA
- Commissioned by VA to do online training for clinical trials
- Center of Excellence for Research on Returning War Veterans
- Fire Departments
- Police Departments
- Judges/legal/police – to help reduce unnecessary hospitalization
- Primary care
- Worker's Compensation Administration
- Surveillance Efforts; CDC Definitions are Columbia Definitions
- Prisons / juvenile justice
- Suicide Section of **SCID**
- Clinical Practice, nationally and internationally
- Schools (Middle Schools, High Schools, and College Campuses)
- Homeless populations
- Claims/HMOs
- Clergy (ex: Hindu priests)
- EAPs

Counties...States...Countries

Linking Systems

Inpt → Bridge → Outpt

Enables quicker
response to those who
need it due to precision
of communication

"F.D.A. Requiring Suicide Studies in Drug Trials " New York Times (1.24.2008)

- ***Most Profound Change in Drug Development Regulation in 16 Years***

New England Psychologist (April 2008)

- Benjamin Toll (Yale) goes onto say "***The community-at-large benefits*** from this type of screening when its citizens are appropriately and adequately treated"
- "***We give the scale at every session as part of best practice,***" Toll says. "We are not predicting that they are suicidal, but if they are, we will attend to it. I'm pleased to say we've not found anyone suicidal."

“[Using the C-SSRS] may actually be able to **make a dent in the rates of suicide** that have existed in our population and have remained constant over time...that would be an enormous achievement in terms of public health care and preventing loss of life.” - Jeffrey Lieberman, M.D., President Elect of American Psychiatric Association (APA)

**Predicting Suicide Attempts:
Major National Goal of Action Alliance**

NIMH:

Widely Used Screening Tool Shown to Successfully Predict Suicide Attempts

ABC:

Suicide Prevention Tool Useful in Teens, Adults

L.A. Times, U.S. News, MSN:

Suicide Attempts Can Be Predicted, Researchers Say

CBS:

Can Suicide be Really Predicted? Study Says Yes

Health Canal:

Landmark Study Finds Columbia Suicide Severity Rating Scale Predicts Suicide Attempt

Crain's:

Columbia Suicide Scale zeroes in on At-Risk Patients

“Having a proven method to assess suicide risk is a **huge step forward in our efforts to save lives**...have established the validity of the C-SSRS. This is a critical step in putting this tool in the hands of health care providers and others in a position to take steps for safety” -Michael Hogan, New York State Office of Mental Health Commissioner

“...the feeling is that **the C-SSRS has separated the wheat from the chaff; it focuses attention where it needs to be**. This easy to use instrument allows our clinicians to move ahead with confidence and we are similarly confident that we are providing them with the **best technology available**.” –

OMH, NY

State-Wide Dissemination

The logo for the Providence Journal, featuring the word "PROVIDENCE" in a small, all-caps serif font above the word "Journal" in a large, stylized, blackletter-style serif font. The background of the logo is a dark teal color with a faint, light-colored cloud pattern.

BREAKING NEWS

Suicide screening tool to be rolled out in RI

March 12, 2012 11:06 am By News Staff

PROVIDENCE, R.I. (Associated Press) -- A widely used screening tool designed to help health care providers determine who is most at risk of attempting suicide is **being rolled out in Rhode Island**.

The Providence Center, a **behavior health center** serving people with psychiatric illnesses and substance abuse problems, says it began using the screening tool this month.

It's also being used in the **emergency rooms** at Roger Williams and Fatima **hospitals** and will be rolled out at the center's **community-based mental health programs**. The tool is known as the **Columbia Suicide Severity Rating Scale**.

Providence Center CEO Dale Klatzker says the scale **will help providers direct resources where they're needed most**. Rhode Island leads the country in the percentage of residents who attempt suicide.

“New Suicide Prevention Initiatives in Rhode Island”

Released: March 20, 2012

“The use of this scale can be **transformative for Rhode Island** because it will improve care and **allow us to focus resources where they most help people**,” -Dale K. Klatzker, President/ CEO of The Providence Center.

“The scale is an **easy way to save lives**...Our staff have been trained by Dr. Posner, the creator of the C-SSRS, and have found it **easy to use and effective**. **By tying it to our electronic health records**, it becomes that much more **streamlined into every day care**.”

State-Wide Dissemination

georgia.gov™



Georgia Department of

BEHAVIORAL HEALTH and DEVELOPMENTAL DISABILITIES

- Georgia Crisis and Access Line (GCAL) through Behavioral Health Link (BHL)
 - Mobile Crisis Response Teams
 - Community Hospitals providing designated beds
 - Crisis Stabilization Units (CSU) provide walk-in psychiatric and counseling services in a center that is clinically staffed 24 hours per day, 7 days per week, to receive individuals in crisis.
 - Crisis Apartments (in development) that provide an alternative to crisis stabilization units and hospitalization
 - Assertive Community Treatment teams (ACT) that operate with fidelity to the Dartmouth ACT model.
 - Intensive Case Management teams, comprising 10 full-time case managers per team, which coordinate treatment and support services and assist individuals with accessing community resources.
 - Peer support Services
- *Anticipated large majority of hospitalizations can be avoided**
- Forensic services
 - Case Management service providers that coordinate treatment and support services and help maintain services and supports already in place.
 - Supported housing services
 - Supported employment services
 - Core services provided through core providers
 - Physician Assessment & Care
 - Diagnostic Assessment
 - Behavioral Health Assessment
 - Group Counseling/Training
 - Family Counseling/Training
 - Community Support
 - Service Plan Development
 - Crisis Intervention
 - Individual Counseling
 - Psychological Testing
 - Nursing Assessment & Care
 - Medication Administration
 - Prevention Services such as Suicide Prevention

Top-Down: New Jersey Youth

Traumatic Loss Coalitions for Youth Program

“Rating scale opens the door for precision in intervention and prevention of suicide among wide spectrum of populations including youth, teens, and young adults”

“To continue their mission of combating suicide in NJ, the Traumatic Loss Coalitions for Youth Program (TLC) from the University of Medicine and Dentistry of NJ – University Behavioral HealthCare aim to raise awareness about the **Columbia Suicide Severity Rating Scale and put it in the hands of those that work with youth and young adults in...**

- schools
- social service agencies
- juvenile justice facilities
- religious organizations
- military facilities
- primary care offices
- and colleges and universities across the state...”

County-Wide Dissemination

One Example: Lapeer County, Michigan

**“Complete
Top-Down
Dissemination”**



- Court workers
 - Mental health workers
 - K-12 school staff: teachers, bus drivers, cafeteria workers, etc.
 - Clergy
 - Law enforcement
 - ER staff
 - Child welfare workers
 - Police Officers, Sheriff, Road Patrol, Village & State Troopers
- * All first responders:** *EMT, Fire Department, Police Officers, etc.*

Hope at last to break suicide's silence

March 25, 2012

Kelly Posner, Ph.D., principal investigator for Columbia's Center for Suicide Risk Assessment earlier this month brought this information to Middle Tennessee, in a meeting of health professionals at Nashville's Oasis Center for troubled teens, and a separate briefing with authorities at Fort Campbell."

Other methods that use imprecise terminology and have variable concepts of what constitutes suicidal behavior... **often hinder communication about an individual that could prevent suicide.**"

The new system is gradually being implemented by the **Army, Navy, Air Force and National Guard; by police and fire departments; drug and alcohol addiction centers; and public schools and colleges.**

Commentary on Article:

- "A leading cause of death"? I have my doubts about that assertion." "Maybe in some third-world, oppressed countries - or among some teenagers, but certainly not in the US."
- "Hope at last to break suicide's silence. I was not aware there was any." -Retired Mental Health Editor
- "*Suicide is very much preventable. I applaud the development of an instrument to help identify those in need of help...*"

**... systematically
assessing using the
C-SSRS decreases
burden**

Decreases False Positives

PHQ-9 (commonly used depression screening tool)

Suicide Item: Thoughts that you would be ***better off dead*** or of ***hurting yourself*** in some way

...Calls instances suicidal that shouldn't be and misses every type of ideation and behavior that need to be identified

Data confirm that when item followed by C-SSRS, cases that should not have been called suicidal are eliminated

**C-SSRS reduces false positives
and avoids false negatives**

Hospital Screening: Cleveland Clinic

Improved Identification with Decreased False Positives

Outpatient Psychiatry Pilot – Self Report Computer Version (523 Encounters)

- 7.4% positive screen on C-SSRS

vs.

- 22.3% endorsed item #9 of PHQ9

Most, but not all, of the positive Columbia screen patients endorsed #9 of PHQ9 (e.g. cases were missed)

C-SSRS Findings: Obesity Patients

Comparison of Retrospective and Prospective Data

Trial Phase ²	Retrospective Double-blind	Prospective C-SSRS Extension
Number of Patients ³	8600	~ 5600
Suicidal Ideation	452	12*
Suicidal Behavior	6	4

¹ Stemmed from positive responses on PHQ-9

² Double-blind phase ranged from 12 to 104 weeks; Extension phase was 52 weeks

³ Maximum number of patients entering the extension phase of the trials

* Markedly lower rates of suicidal behavior/ideation with systematic monitoring

Advantages....Operationalized Criteria for Next Steps or Referral for Management

- Specify parameters for triggering referrals to mental health professionals
 - e.g., 4 or 5 on ideation item to indicate need for immediate referral
 - Decreases unnecessary referrals, interventions, etc.

In the past, people didn't know what to manage, so they would hear **any answer and intervene...*

Clinical Monitoring Guidance: Threshold for Next Steps

SUICIDAL IDEATION	
<p>Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes," ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.</p>	Lifetime: Time He/She Felt Most Suicidal
<p>1. Wish to be Dead Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up. <i>Have you wished you were dead or wished you could go to sleep and not wake up?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>
<p>2. Non-Specific Active Suicidal Thoughts General, non-specific thoughts of wanting to end one's life/commit suicide (e.g. "I've thought about killing myself") without thoughts of ways to kill oneself/associated methods, intent, or plan. <i>Have you actually had any thoughts of killing yourself?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>
<p>3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g. thought of method to kill self but not a specific plan). Includes person who would say, "I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it.....and I would never go through with it". <i>Have you been thinking about how you might do this?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>
<p>4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan Active suicidal thoughts of killing oneself and subject reports having <u>some intent to act on such thoughts</u>, as opposed to "I have the thoughts but I definitely will not do anything about them". <i>Have you had these thoughts and had some intention of acting on them?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>
<p>5. Active Suicidal Ideation with Specific Plan and Intent Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out. <i>Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>

Indicates
Need
for
Next Step

One Example: FDA Correspondence, How C-SSRS Is Used

Endocrinology-

- C-SSRS to be administered at baseline, then at each visit throughout the duration of the trial
- Baseline:
 - A subject should be excluded from the trial if he/she has any suicidal ideation of type 4 or 5 on the C-SSRS in the last month.
- During Study Conduct:
 - A subject **should be referred to a Mental Health Professional** (MHP) if he/she has any suicidal ideation of **type 4 or 5 on the C-SSRS.**

**See later slides for more details*

POLICY:

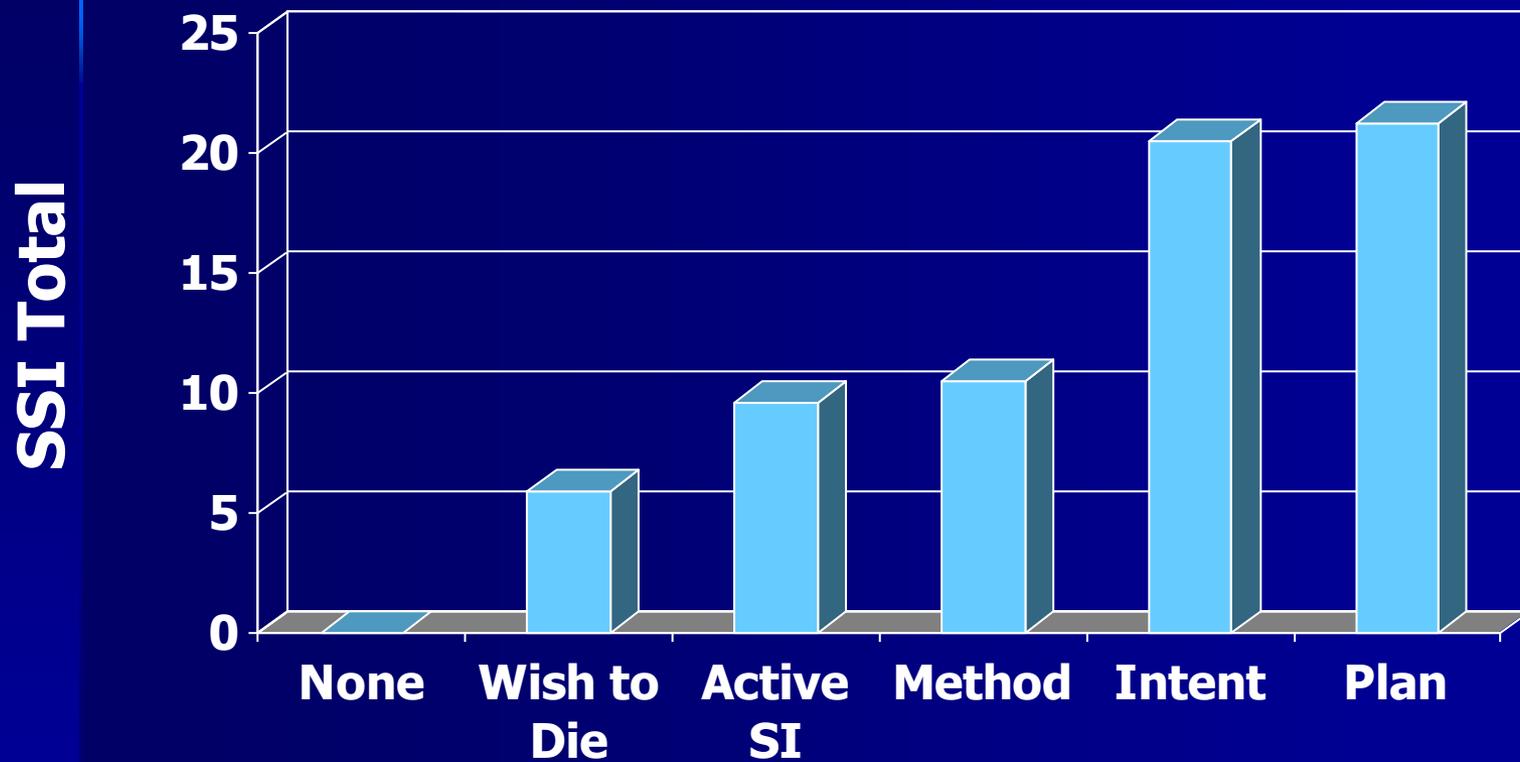
1. All patients admitted to the hospital will be screened for their risk of self-harm using the Columbia Suicide Severity Rating Screen (C-SSRS). Flow chart attached.
2. A progress note is generated from the C-SSRS tool and placed on the patient's chart to summarize the findings of the screening.
3. All adult patients who are admitted as a result of a suicide attempt will be maintained on a 1:1 level of observation and have a psychiatric evaluation.
4. Patients requiring suicide precautions will be transferred to the Spruce Pavilion or another psychiatric facility, unless there is a compelling reason to remain on a non-psychiatric unit. This decision will be a collaborative effort between the attending physician and consulting psychiatrist.
5. The C-SSRS assigns a level of risk to the patient. Patients identified as risk level 3, 4 or 5 (corresponding to a positive response to questions 3, 4 or 5) will have patient safety measures implemented as defined in the response process.

PROCEDURE:

Question	Trigger
Level 4/5 Yes to question 4 or 5	<ul style="list-style-type: none">• Nursing Order to call MD for Psych Consult• Nursing Interventions (print on Kardex):• Pt Safety Monitor – 1:1 Observation• Pt Safety Monitor – Within arm's reach at all times• Complete Self Harm Safety Assessment every shift• Affix Suicide Risk Magnet to door• Revise Diet order to Safe tray• Alerts to ATC, Nutrition Services, Environmental Services and Security• Progress note for chart
Level 3 Yes to question 3 (and no to question 4 and 5)	<ul style="list-style-type: none">• Consult to Care Team• Nursing Interventions (prints on kardex):• Pt Safety Monitor – 1:1 Observation• Pt Safety Monitor – Within arm's reach at all times• Complete Self Harm Safety Assessment every shift• Affix Suicide Risk Magnet to door• Revise Diet order to Safe Tray• Alerts to ATC, Nutrition Services, Environmental Services, Spruce Facilitator and Security• Progress note for chart

Example:
**Hospital
Policies**

SSI Total Score by Highest Level of Ideation on the C-SSRS



American Foundation
for Suicide Prevention

$F(5,185) = 14.35, p < 0.001$

Currier, Brown & Stanley (2009)

Data Confirmation...

4 and 5 Predicts Attempts in National Attempter Study

(Posner et al., *AJP* December 2011)

- C-SSRS Lifetime Ideation at baseline, types 4 and 5, predicted suicide attempts in adolescent suicide attempters, followed over a year
 - OR = 3.26, 95% CI: 1.02-10.45, $p = 0.047$
 - Beck SSI NOT predictive
- C-SSRS Lifetime Ideation, types 4 and 5, predicted actual, interrupted or aborted attempts on CSHF
 - OR = 2.76, 95% CI: 1.07-7.12, $p = 0.036$

Prediction in Non-Suicidal Adults and Adolescents

- Confirmed By e-CSSRS data: 35,007 (3776 subjects) across depression, epilepsy, insomnia, fibromyalgia
 - Patients with baseline prior ideation of 4 or 5 or prior behavior are 4-5x more likely to report suicidal behavior at follow up than patients with negative baseline report.
 - Patients with both are 8x more likely to report suicidal behavior
- Prediction in adolescent emergency department follow-up study (King et al)
 - Duration predictive
 - Attempt and lifetime attempt not predictive, reinforcing ideation assessment
 - NSSI not predictive

Lifetime Different Suicidal Behaviors Predict Suicidal Behavior During Trial

<u>Baseline Reports</u>	Patients not prospectively reporting suicidal behavior N = 3577	Patients prospectively reporting suicidal behavior N = 201	Odds ratio of prospective suicidal behavior report (95% CI; <i>p-values</i> < .001) *** <i>p</i> < .001
Actual Attempt	522 (85.6 %)	88 (14.4 %)	4.56 (3.40 – 6.11)***
BL Interrupted Attempt	349 (82.7 %)	73 (17.3 %)	5.28 (3.88 – 7.18)***
BL Aborted/Self-Interrupted Attempt	461 (84.7 %)	83 (15.3 %)	4.75 (3.53 – 6.40)***
BL Preparatory Behavior	177 (81.2 %)	41 (18.8 %)	4.92 (3.38 – 7.16)***

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 Predict Suicidal Behavior During Trial

	Patients not prospectively reporting suicidal behavior N = 3577	Patients prospectively reporting suicidal behavior N = 201	Odds ratio of prospective suicidal behavior report (95% CI; <i>p-values</i> < .001) *** <i>p</i> < .001
No Behaviors Reported at BL	2791 (97.3%)	76 (2.7%)	4.56 (3.40 – 6.11)***
One Behavior	345 (91.5 %)	32 (8.5%)	3.41 (2.22 – 5.23)***
Two Behaviors	214 (84.3 %)	40 (15.7%)	6.86 (4.57 – 10.32)***
Three Behaviors	172 (81.5 %)	39 (18.5 %)	8.33 (5.50 – 12.62)***
Four Behavior	55 (79.7 %)	14 (20.3 %)	9.35 (4.98 – 17.54)***

Any type of Lifetime behavior increases likelihood of behavior during trial by ~ 3.4 times; increases proportionally with increased number of different behaviors reported

Each question is needed
to provide maximum
protection

Decreased Burden

■ ■ ■ SUICIDE SCREENING in a General Hospital Setting: Initial Results

Presented by: Debra Haas Stavarski, RN, MS; Director, Nursing Research

The Reading Hospital and Medical Center, West Reading, Pennsylvania

PURPOSE

A major barrier to effective suicide screening in the acute care hospital setting has been lack of a brief, valid, reliable, and universally acceptable tool that addresses ideation and behavior, and provides clear operational definitions of both. An abbreviated version of the Columbia-Suicide Severity Rating Scale (C-SSRS) screen was developed as part of a hospital suicide screening protocol. This study evaluated the psychometric properties of the abbreviated C-SSRS screen, protocol performance, and impact on selected outcome indicators.

THEORETICAL FRAMEWORK

The Johnson Behavioral Systems Model was used as the framework for the study. Johnson's model addresses the integration of patient behavior for prevention of illness and injury, as well as influences on behavior of both patient and caregiver.

RESEARCH TEAM

- ▶ Debra Stavarski, RN, MS; Director of Nursing Research, The Reading Hospital and Medical Center
- ▶ Udemia Millsaps, MEd; Research and Continuing Education Coordinator, Department of Psychiatry, The Reading Hospital and Medical Center
- ▶ Andres J. Pumariega, MD; Chair of Psychiatry, Cooper University Hospital, Camden, N.J.
- ▶ Kelly Posner, PhD; Associate Professor of Psychiatry and Director, Center for Suicide Risk Assessment, Columbia University Medical Center, New York, N.Y.
- ▶ Barbara Romig, RN, MSN; Director of Education/Professional Development, The Reading Hospital and Medical Center
- ▶ Robert Rice, BSN, RN-BC; Clinical Practice Educator, Inpatient Psychiatry, The Reading Hospital and Medical Center
- ▶ Heather Close, BS; Former Research Assistant, The Reading Hospital and Medical Center
- ▶ Mary Jo Castellucci, BS; Systems Analyst, The Reading Hospital and Medical Center



METHODS

Descriptive Study Design

- ▶ Instrument ratings
- ▶ Inter-rater reliability

Naturalistic Setting

- ▶ >500-bed community hospital
- ▶ Eastern Pennsylvania

Convenience Sample: Adult Inpatients

- ▶ Admitted January – June 2010

INSTRUMENT: ABBREVIATED C-SSRS

- ▶ C-SSRS: gold standard for suicide assessment
- ▶ Brief, valid, reliable tool desired for routine screening
- ▶ Abbreviated C-SSRS (2009)
- ▶ Triage algorithm for The Reading Hospital and Medical Center response to C-SSRS levels developed by Posner, Pumariega, Millsaps (2009)

CAREGIVER EDUCATION

- ▶ DVD Training on C-SSRS Tool
- ▶ Introduction to abbreviated C-SSRS Tool
- ▶ Caregiver reflection on attitudes toward suicide assessment
- ▶ Vignette training

CLINICAL SUICIDE SCREENING PROTOCOL

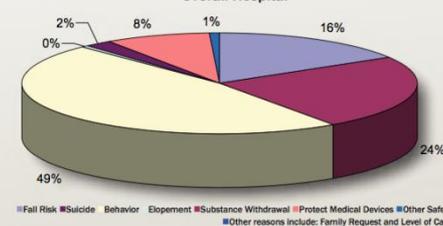
- ▶ Screening C-SSRS incorporated into admission assessment for all medical-surgical patients
- ▶ Automated risk stratification
- ▶ Prevention protocol triggered for identified risk
- ▶ Safety interventions implemented specific for risk levels 1 - 5

NURSE INTER-RATER RELIABILITY

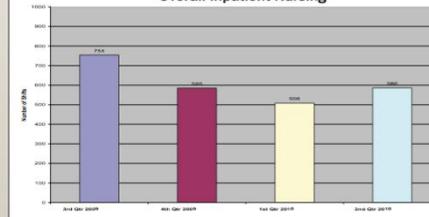
	Intra-rater Reliability Broken Down by Experience					
	Consistency			Absolute Agreement		
	No Raters	Single Measure	Average Measure	Single Measure	Average Measure	Cronbach's Alpha
Experience Unknown	32	0.643	0.983	0.633	0.982	0.983
Experience 0 to 10 years	406	0.658	0.999	0.657	0.999	0.999
Experience 11 years and above	315	0.618	0.998	0.617	0.998	0.998
Experience 0 to 10 years	562	0.675	0.999	0.673	0.999	0.999
Experience 11 years and above	219	0.643	0.997	0.643	0.997	0.999

PATIENT SAFETY MONITOR UTILIZATION

Utilization Reason, 2nd Quarter 2010
Overall Hospital



Patient Safety Monitor Utilization for Suicides
Overall Inpatient Nursing



IMPLICATIONS FOR PRACTICE

The abbreviated C-SSRS has been successfully incorporated into a clinical suicide screening protocol that is a component of assessment for all patients admitted to the acute care hospital setting, regardless of psychiatric history. This practice, implemented in early 2010, complies with Joint Commission recommendations published in a November 2010 Sentinel Event Alert.

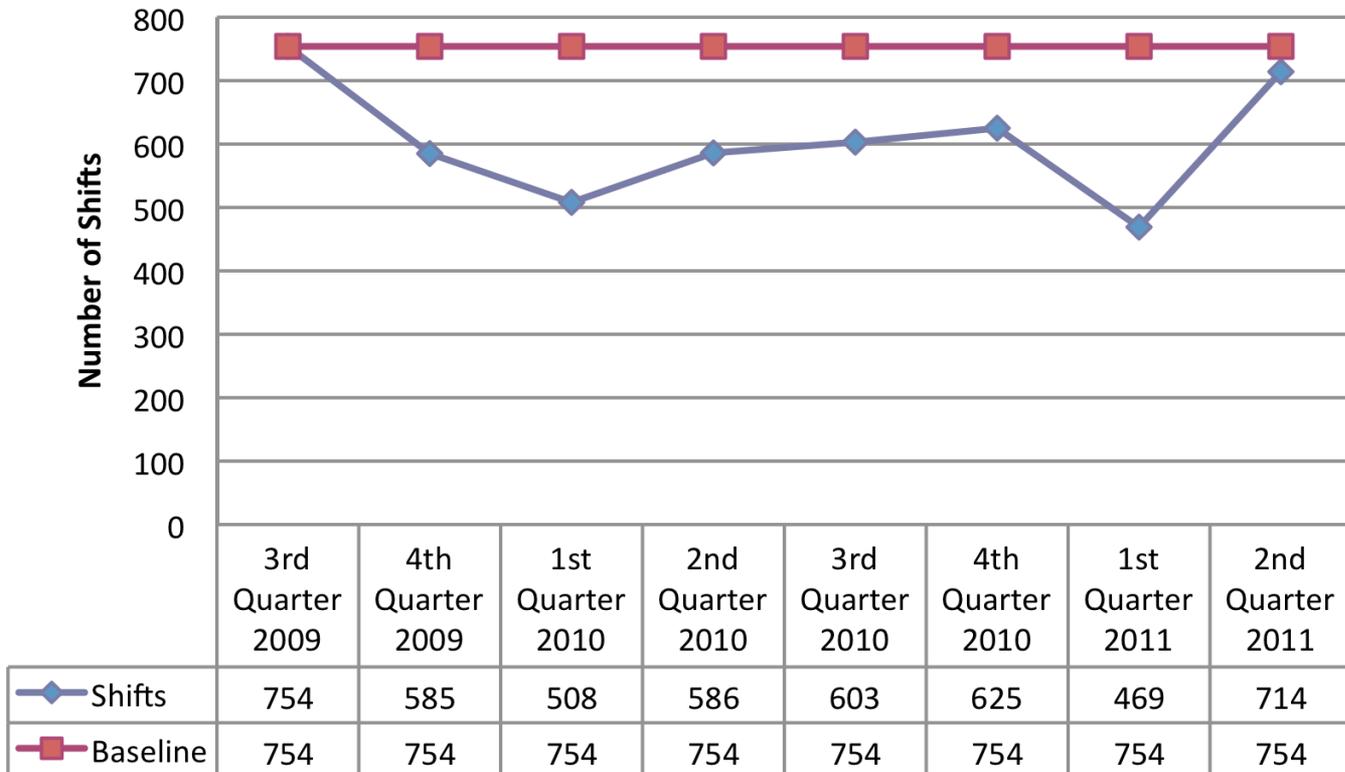


The Reading Hospital and Medical Center
www.readinghospital.org

Patient Care Monitor Shift Utilization

July, 2009 to June, 2011

Patient Safety Monitor Shifts For Suicide Precaution



Reduction in Unnecessary Interventions/ Redirecting Scarce Resources

■ Policy:

- Discussed during the Rhode Island **Senate Commission Hearing** to **address ER overuse and ER diversion**. Senators aim to have frontline responders use scale - specifically EMS and community police

■ Hospital system: steadily decreased one-to-ones (27,000 screened)

- Reading Hospital - "allowed us to identify those at risk and **better direct limited resources in terms of psychiatric consultation services and patient monitoring** and it has also given us the **unexpected benefit of identification of mental illness in the general hospital population** which allows us to better serve our patients and our community."

■ Corrections:

- California corrections department spent approx. **\$20 million in 2010** on a suicide-watch program, which they believe **could be cut in half by these methods**

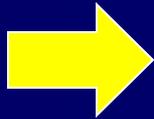
Rhode Island Senate Commission Hearing Report for State Wide Implementation:

Recommendation:

- *"Support the **state wide coordination and implementation** of an evidence based suicide/mental health assessment tool and training for Rhode Island healthcare providers and first responders for determination of placement in emergency department or alternative settings."*
- *"...this recommendation would be critical in assisting those in the field with an additional tool for **everyday use**."*
 - Testimony by a Pawtucket police officer: "...the officer highlighted the important and timely decisions that law enforcement must make...the limited training that law enforcement often receives outside of the police academy was discussed and the importance of providing our first responders with the appropriate tools to assess an individual was identified as a necessary tool." 54

Reduction in Unnecessary Interventions/ Redirecting Scarce Resources

NYC
Problem



- New York City middle schools/nurses: Identified all these kids that would have otherwise been missed while dramatically reducing unnecessary referrals. One district **~60-90% of the referrals are unnecessary.**
- “The great majority of children & teens referred by schools for psych ER evaluation are not hospitalized & **do not require the level of containment, cost & care** entailed in ER evaluation.”
- “Evaluation in hospital-based psych ER’s is **costly, traumatic** to children & families, and may be **less effective** in routing children & families into ongoing care.”

Potential Liability Protection

“If a practitioner asked the questions... It would provide some legal protection”

—Bruce Hillowe, mental health attorney specializing in malpractice litigation
(Crain’s NY, 11/8/11)

Implemented by national risk managers of *The Doctor’s Company*, a medical malpractice insurance company to be used by physician members

“I believe it sets the standard...we take a proactive position in patient safety” – Patient Safety Risk Manager

- Policies now place more burden on universities to implement interventions to protect students from self-harm (Franke, 2004; Lake et al., 2002)
- Schools implementing programs to enable students to receive appropriate treatment & remain in school; Americans with Disabilities Act protects students’ rights to remain in school

Simply.....

- 1-5 rating for suicidal ideation, of increasing severity (from a wish to die to an active thought of killing oneself with plan and intent)
 - Can be two questions:
 - *Have you wished you were dead or wished you could go to sleep and not wake up?*
 - *Have you actually had any thoughts of killing yourself?*

If answer is "No" to both, no more questions on ideation

- Four behaviors assessed, few questions required
- All items include **definitions** for each term and **standardized questions for each category** are included to guide the interviewer for facilitating improved identification

Research Supported Items/Criteria

■ Preparatory Behavior

- Those with recent preparatory behavior (e.g., collecting pills, razors, or loaded weapon) **8x** more likely to die by suicide (Brown & Beck, unpublished)
- Those who reported at worst point **10x** more likely to die suicide (Brown & Beck, unpublished)
- Preparatory Behavior on SSI predicted death by suicide and history of suicide attempts (Joiner et al., 2003)

■ Interrupted Suicide Attempts

- **3x** more likely to die by suicide (Steer, Beck & Lester, 1988)
- No difference in levels of intent

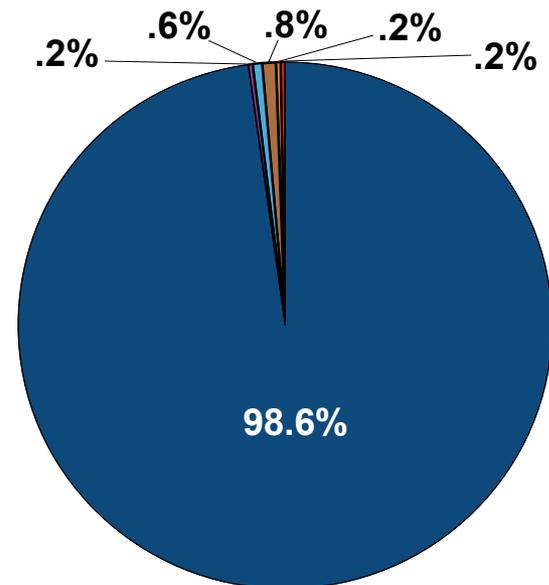
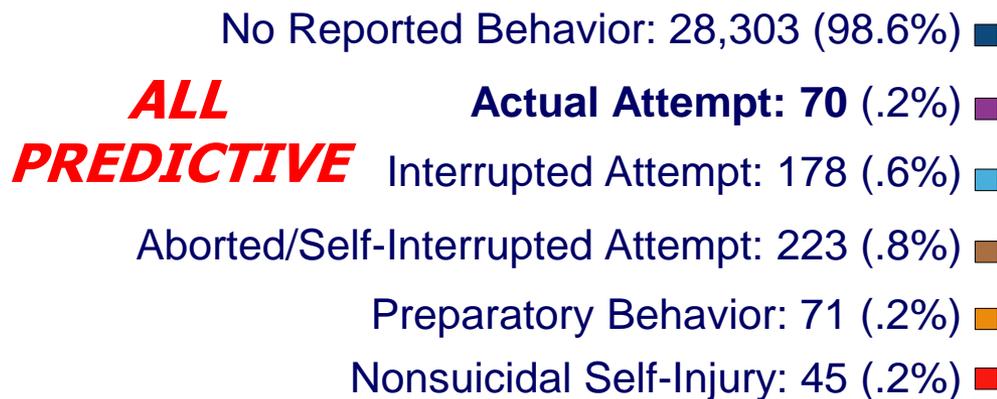
■ Aborted/Self-Interrupted Suicide Attempts

- 29-50% of samples report aborted attempts (Marzuk et al., 1997; Barber et al., 1998)
 - Evidencing this as common suicidal behavior
- Subjects who made aborted attempts **2x** as likely to have made a suicide attempt (Barber et al., 1998)
- Intent scores similar with suicide attempters

eC-SSRS..Depressed Subjects...*ALL* of These Behaviors Are Prevalent (only 13% of behaviors are attempts)

% OF REPORTED SUICIDAL BEHAVIOR

n = 28,699 administrations



***Only 1.7% had any worrisome answer**
***Only .9% with ~50,000 administrations**

472 Interrupted, Aborted/Self-Interrupted, Preparatory
vs. 70 Actual Attempts

Suicide Attempt Definition

A self-injurious act committed with at least some intent to die, as a result of the act

- There does not have to be any injury or harm, just the ***potential*** for injury or harm (e.g., gun failing to fire)
- Any “non-zero” intent to die – Does not have to be 100%
- Intent and behavior must be linked
- Intent can sometimes be inferred clinically from the behavior or circumstances
 - For example, if someone denies intent to die, but they thought that what they did could be lethal, intent can be inferred
 - “Clinically impressive” circumstances; highly lethal act where no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story, setting self on fire, or taking 200 pills)

As Opposed To *Non-suicidal Self-injurious Behavior*

- Engaging in behavior PURELY (100%) for reasons other than to end one's life:
 - Either to affect:
 - Internal state (feel better, relieve pain etc.) - "self-mutilation"
 - **And/Or** -
 - External circumstances (get sympathy, attention, make angry, etc.)

Suicide Attempt? Yes or No

1. The patient wanted to escape from her mother's home. She researched lethal doses of ibuprofen. She took 6 ibuprofen pills and said she felt certain from her research that this amount was not enough to kill her. She stated she did not want to die, only to escape from her mother's home. She was taken to the emergency room where her stomach was pumped and she was admitted to a psychiatric ward. _____
2. Young woman, following a fight with her boyfriend, felt like she wanted to die, impulsively took a kitchen knife and made a superficial scratch to her wrist; before she actually punctured the skin or bled, however, she changed her mind and stopped. _____
3. Patient was feeling ignored. She went into the family kitchen where mother and sister were talking. She took a knife out of the drawer and made a cut on her arm. She denied that she wanted to die at all ("not even a little") but just wanted them to pay attention to her. _____
4. The patient cut her wrists after an argument with her boyfriend. _____
5. Had a big fight with her ex-husband about her stepson. Took 15-20 imipramine tablets and went to bed. Slept all night and until 4-5 pm the next day. States she couldn't stand up or walk. Called EMS – taken to the ER – drank charcoal and admitted to hospital. Unable to verbalize clear intent, but states she was well aware of the dangers of TCA overdose and the potential for death. _____

Suicidal Behavior

SUICIDAL BEHAVIOR

(Check all that apply, so long as these are separate events; must ask about all types)

Actual Attempt:

A potentially self-injurious act committed with at least some wish to die, *as a result of act*. Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is *any* intent/desire to die associated with the act, then it can be considered an actual suicide attempt. **There does not have to be any injury or harm**, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt.

Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g. gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred.

Have you made a suicide attempt?

Have you done anything to harm yourself?

Have you done anything dangerous where you could have died?

What did you do?

Did you _____ as a way to end your life?

Did you want to die (even a little) when you _____?

Were you trying to end your life when you _____?

Or did you think it was possible you could have died from _____?

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)? (Self-Injurious Behavior without suicidal intent)

If yes, describe:

Has subject engaged in Non-Suicidal Self-Injurious Behavior?

Since Last Visit

Yes No

Total # of Attempts

Yes No

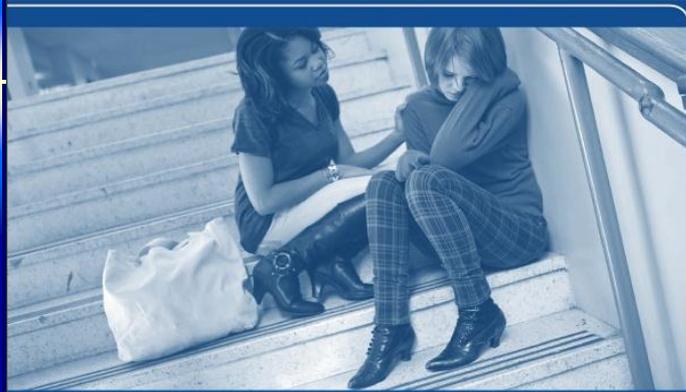
May help to infer intent

Important: Shows you did the appropriate assessment and decided it should not be called suicidal

CDC Self-Directed Violence: Uniform Definitions

Adopted Columbia Definitions

(link to C-SSRS in CDC document)



SELF-DIRECTED VIOLENCE SURVEILLANCE

UNIFORM DEFINITIONS AND
RECOMMENDED DATA ELEMENTS

National Center for Injury Prevention and Control
Division of Violence Prevention



Uniform Definitions

Definitions

Self-directed violence (analogous to self-injurious behavior)

Behavior that is self-directed and deliberately results in injury or the potential for injury to oneself.

This does not include behaviors such as parachuting, gambling, substance abuse, tobacco use or other risk taking activities, such as excessive speeding in motor vehicles. These are complex behaviors some of which are risk factors for SDV but are defined as behavior that while likely to be life-threatening is not recognized by the individual as behavior intended to destroy or injure the self. (Farberow, N. L. (Ed.) (1980). *The Many Faces of Suicide*. New York: McGraw-Hill Book Company). These behaviors may have a high probability of injury or death as an outcome but the injury or death is usually considered unintentional. Hanzlick R, Hunsaker JC, Davis GJ. *Guide for Manner of Death Classification*. National Association of Medical Examiners. Available at: <http://www.charlydmiller.com/LIB03/2002NAMEmannerofdeath.pdf>. Accessed 1 Sept 2009.

Self-directed violence is categorized into the following:

Non-suicidal (as defined below)

Suicidal (as defined below).

Non-suicidal self-directed violence

Behavior that is self-directed and deliberately results in injury or the potential for injury to oneself.

There is no evidence, whether implicit or explicit, of suicidal intent. Please see appendix for definition of implicit and explicit.

Suicidal self-directed violence

Behavior that is self-directed and deliberately results in injury or the potential for injury to oneself.

There is evidence, whether implicit or explicit, of suicidal intent.

Undetermined self-directed violence

Behavior that is self-directed and deliberately results in injury or the potential for injury to oneself.

Suicidal intent is unclear based on the available evidence.

Suicide attempt

A non-fatal self-directed potentially injurious behavior with any intent to die as a result of the behavior.

A suicide attempt may or may not result in injury.

Interrupted self-directed violence – by self or by other

By other - A person takes steps to injure self but is stopped by another person prior to fatal injury. The interruption can occur at any point during the act such as after the initial thought or after onset of behavior.

By self (in other documents may be termed "aborted" suicidal behavior) - A person takes steps to injure self but is stopped by self prior to fatal injury.

Source: Posner K, Oquendo MA, Gould M, Stanley B, Davies M. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. *Am J Psychiatry*. 2007; 164:1035-1043. <http://cssrs.columbia.edu/>

Source: Posner K, Oquendo MA, Gould M, Stanley B, Davies M. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. *Am J Psychiatry*. 2007; 164:1035-1043. <http://cssrs.columbia.edu/>

CDC: Columbia definitions for other suicidal behaviors

(link to C-SSRS in CDC document)

<http://www.cdc.gov/violenceprevention/pdf/Self-Directed-Violence-a.pdf>

Interrupted suicide attempt*	A person takes steps to injure self but is stopped by another person from starting the self-injurious act, before the potential for harm has begun.
Aborted/Self-Interrupted suicide attempt*	A person takes steps to injure self but is stopped by self from starting the self-injurious act, before the potential for harm has begun.
Suicide attempt*	A potentially self-injurious act committed with at least some wish to die, as a result of act.
Other preparatory suicidal behavior*	Acts or preparation towards imminently making a suicide attempt, but before potential for harm has begun. This can include anything beyond a verbalization or thought, such as assembling a method (e.g., buying a gun, collecting pills) or preparing for one's death by suicide (e.g., writing a suicide note, giving things away).

Source: Posner K, Oquendo MA, Gould M, Stanley B, Davies M. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. Am J Psychiatry. 2007; 164:1035-1043.

<http://cssrs.columbia.edu/>

Also from CDC:

Glossary items of “unacceptable terms”

- Attempted suicide
- Completed suicide
- Complete suicide
- Failed attempt
- Failed completion
- Fatal suicide attempt
- Parasuicide
- Nonfatal suicide
- Suicide victim
- Nonfatal suicide attempt
- *Suicide gesture*
- Manipulative act
- Past suicide
- *Suicide threat*



PERSONNEL AND
READINESS

OFFICE OF THE UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

OCT 11 2011

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE

SUBJECT: Standardized Suicide Nomenclature (Self-Directed Violence Classification System) Policy

This memorandum implements the use of the Self-Directed Violence Classification System developed by the Centers for Disease Control and Prevention (CDC) (Attachments 1 and 2) for future data collection, reporting, and/or system-wide comparisons between the Department of Defense (DoD) and the Department of Veterans Affairs (VA). Requests for information on suicides, suicide attempts, and suicide risk factors from the Services, DoD, and VA have historically resulted in a variety of reports that appear inconsistent, or even contradictory. To resolve these inconsistencies, the 2009 DoD-VA Health Executive Council's Joint Strategic Plan required DoD and VA to adopt a standardized system of nomenclature for clinical events related to suicide.

A working group led by the Suicide Prevention and Risk Reduction Committee, in collaboration with the VA National Suicide Prevention Office, the Mortality Surveillance Division of the Armed Forces Medical Examiner, and CDC developed recommendations for common DoD/VA suicide nomenclature, definitions, and comparable suicide data. The working group agreed to use the Self-Directed Violence Classification System developed by CDC.

The Services will report suicide data using this standardized nomenclature within 60 days from the date of this memorandum. The long-term goal is to include this policy as well as the DoD Suicide Event Report in the DoD Instruction that is currently being prepared.

Department of
Defense and the
Department of
Veterans Affairs
Requires the
CDC-adopted
Columbia
Definitions

C-SSRS: Lifetime / Recent

- Worst point found to be the **most clinically meaningful**
- Assessment of suicidal ideation at its worst point is **more predictive of suicide than current ideation** (Beck, 1999)
- Reporting lifetime suicidal ideation on C-SSRS at screening associated with increased chance of reporting suicidal behavior, Fisher's exact test [$p = 0.0008$, during the trial (TASA)]

SUICIDAL IDEATION		Lifetime: Time He/She Felt Most Suicidal		Past 1 month	
<p>Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.</p>					
<p>1. Wish to be Dead Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up. <i>Have you wished you were dead or wished you could go to sleep and not wake up?</i></p> <p>If yes, describe:</p>		Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<p>2. Non-Specific Active Suicidal Thoughts General non-specific thoughts of wanting to end one's life/commit suicide (e.g., "I've thought about killing myself") without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period. <i>Have you actually had any thoughts of killing yourself?</i></p> <p>If yes, describe:</p>		Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<p>3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, "I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it...and I would never go through with it." <i>Have you been thinking about how you might do this?</i></p> <p>If yes, describe:</p>		Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<p>4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan Active suicidal thoughts of killing oneself and subject reports having <u>some intent to act on such thoughts</u>, as opposed to "I have the thoughts but I definitely will not do anything about them." <i>Have you had these thoughts and had some intention of acting on them?</i></p> <p>If yes, describe:</p>		Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<p>5. Active Suicidal Ideation with Specific Plan and Intent Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out. <i>Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?</i></p> <p>If yes, describe:</p>		Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Since Last Visit

Capture all events and types of thoughts since last assessment: "Since I last saw you have you done anything.....had thoughts of..."

SUICIDAL IDEATION		Since Last Visit
<p><i>Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes," ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.</i></p>		
<p>1. Wish to be Dead Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up. <i>Have you wished you were dead or wished you could go to sleep and not wake up?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	
<p>2. Non-Specific Active Suicidal Thoughts General, non-specific thoughts of wanting to end one's life/commit suicide (e.g. "I've thought about killing myself") without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period. <i>Have you actually had any thoughts of killing yourself?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	
<p>3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g. thought of method to kill self but not a specific plan). Includes person who would say, "I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it.....and I would never go through with it". <i>Have you been thinking about how you might do this?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	
<p>4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan Active suicidal thoughts of killing oneself and subject reports having <u>some intent to act on such thoughts</u>, as opposed to "I have the thoughts but I definitely will not do anything about them". <i>Have you had these thoughts and had some intention of acting on them?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	
<p>5. Active Suicidal Ideation with Specific Plan and Intent Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out. <i>Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	

Screening 2012 Version

COLUMBIA-SUICIDE SEVERITY RATING SCALE

Posner, Brent, Lucas, Gould, Stanley, Brown, Fisher, Zelazny, Burke, Oquendo, & Mann
Screen Version

SUICIDE IDEATION DEFINITIONS AND PROMPTS:		Past month	
Ask questions that are in bolded and underlined. The rest of the information at each question is for staff information only.		Yes	NO
Ask Questions 1 and 2			
1) Wish to be Dead: Person endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up? <u><i>Have you wished you were dead or wished you could go to sleep and not wake up?</i></u>			
2) Suicidal Thoughts: General non-specific thoughts of wanting to end one's life/commit suicide, "I've thought about killing myself" without general thoughts of ways to kill oneself/associated methods, intent, or plan." <u><i>Have you actually had any thoughts of killing yourself?</i></u>			
If YES to 2, ask questions 3, 4, 5, and 6. If NO to 2, go directly to question 6.			
3) Suicidal Thoughts with Method (without Specific Plan or Intent to Act): Person endorses thoughts of suicide and has thought of a least one method during the assessment period. This is different than a specific plan with time, place or method details worked out. "I thought about taking an overdose but I never made a specific plan as to when where or how I would actually do it...and I would never go through with it." <u><i>Have you been thinking about how you might kill yourself?</i></u>			
4) Suicidal Intent (without Specific Plan): Active suicidal thoughts of killing oneself and patient reports having <u>some intent to act on such thoughts</u> , as oppose to "I have the thoughts but I definitely will not do anything about them." <u><i>Have you had these thoughts and had some intention of acting on them?</i></u>			
5) Suicide Intent with Specific Plan: Thoughts of killing oneself with details of plan fully or partially worked out and person has some intent to carry it out. <u><i>Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?</i></u>			
6) Suicide Behavior Question <u><i>"Have you ever done anything, started to do anything, or prepared to do anything to end your life?"</i></u> Examples: Collected pills, obtained a gun, gave away valuables, wrote a will or suicide note, took out pills but didn't swallow any, held a gun but changed your mind or it was grabbed from your hand, went to the roof but didn't jump; or actually took pills, tried to shoot yourself, cut yourself, tried to hang yourself, etc.			
If YES, ask: <u>How long ago did you do any of these?</u> <input type="checkbox"/> Over a year ago? <input type="checkbox"/> Between three months and a year ago? <input type="checkbox"/> Within the last three months?			

Screening 2012 with Triage Points (Reading Hospital)

SUICIDE IDEATION DEFINITIONS AND PROMPTS:

Ask questions that are bolded and underlined. The remaining information is for staff only.

Yes	No
-----	----

6) Suicide Behavior Question:

Have you ever done anything, started to do anything, or prepared to do anything with any intent to die?

Examples: Attempt: Took pills, shot self, cut self, jumped from a tall place; Preparation: Collecting pills, getting a gun, giving valuables away, writing a suicide or goodbye note, etc.)

If YES, ask: **How long ago did you do any of these?**

- More than a year ago? Between a week and a year ago? Within the last week?

II. TRHMC Response Protocol to C-SSRS Screening (Linked to last item answered YES)

Item 1 - Mental Health Referral at Discharge

Item 2 - Mental Health Referral at Discharge

Item 3 - Care Team Consult (Psychiatric Nurse) and Patient Safety Monitor/Procedures

Item 4 - Psychiatric Consultation and Patient Safety Monitor/Procedures

Item 5 - Psychiatric Consultation and Patient Safety Monitor/Procedures

Item 6 - If more than a year ago, Mental Health Referral at discharge

If between 1 week and 1 year ago - Care Team Consult (Psychiatric Nurse) and Patient Safety Monitor

If one week ago or less - Psychiatric Consultation and Patient Safety Monitor

Disposition: Mental Health Referral at discharge

Care Team Consult (Psychiatric Nurse) and Patient Safety monitor/Procedures

Psychiatric Consultation and Patient Safety Monitor/Procedures

If reassessment, please identify the stressors since initial C-SSRS assessment. If none, please write NONE in box.

Signature of Nurse/Person Completing Form _____

Date _____

Time _____

Printed Name of Nurse/Person Completing Form _____

PT #:



**COLUMBIA-SUICIDE SEVERITY
RATING SCREEN VERSION**

Feasibility...

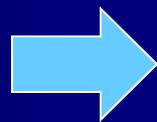
- Iatrogenic
 - **“Dare to ask”**: study shows asking doesn’t cause distress or suicidal ideation (Gould et al., JAMA 2005)
- Good Acceptance in Practice
 - 1,000 sites across the country (nurses, coordinators, physicians) – overwhelming majority said “easy to incorporate”, “has improved safety”, “is beneficial”

Feasibility / No Mental Health Training Required

- **No mental health training required** (nurses, coordinators, etc.)
 - **99% reliability independent of mental health training and education**
 - 812 health care professionals at Reading Hospital trained on the C-SSRS
- **Ease of training:** very scalable
 - **Online training via website** or DVD
 - 30 minutes
 - Training DVDs available in many languages (scale – 103 languages)
 - Trainingcampus.net: used by NIH for neurological assessment training

Columbia-Suicide Severity Rating Scale Feasibility

- Millions of administrations
- Many thousands of settings
- 103 languages
- No mental health training required
- Healthcare workers to frontline responders
- Developing an app for phones/ipads, etc.



Various Uses within Clinical and Institutional Settings

- Screening upon entry to a service
- Monitoring of outcome and safety
- Component of comprehensive Suicide Risk Assessment
- Treatment benefit outcomes
- Monitoring during treatment during pharmacological (or psychosocial) treatment
 - Measuring worsening and improvement
- Collection of epidemiological data

C-SSRS Uses in Research

In Clinical Trials

- Well over a million administrations
- Trials in Phases I-IV
- Drug/placebo; active controls; open maintenance
- Thousands of sites internationally, psychiatry and non-psychiatry
- 103 languages
- Measuring worsening and improvement
- Range of interventions: pharmacologic, device, psychotherapy, ECT

Within A Study

- Treatment benefit outcomes
- Safety outcomes
- Clinical safety monitoring
- Coordinated efficiently with other measures
- Epidemiological
- Establishment of inclusion/exclusion criteria
 - Past exclusion arbitrary e.g. "serious risk"??
[criteria can be operationalized and assessed by C-SSRS
e.g. 4 or 5 on C-SSRS in past X months depending on phase/indication]

Tailored for Population Specific Data Collection

- For Example - Huntington's Disease, Bereavement, Epilepsy, Suicide Clusters

SUICIDAL IDEATION				
<p>Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes," ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.</p>	Since Last Visit		Postictal	
	Yes	No	Yes	No
<p>1. Wish to be Dead Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up. <i>Have you wished you were dead or wished you could go to sleep and not wake up?</i></p> <p>If yes, describe:</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>2. Non-Specific Active Suicidal Thoughts General non-specific thoughts of wanting to end one's life/commit suicide (e.g. "I've thought about killing myself") without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period. <i>Have you actually had any thoughts of killing yourself?</i></p> <p>If yes, describe:</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g. thought of method to kill self but not a specific plan). Includes person who would say, "I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it.....and I would never go through with it". <i>Have you been thinking about how you might do this?</i></p> <p>If yes, describe:</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Pediatric C-SSRS / Cognitively Impaired

SUICIDAL BEHAVIOR <i>(Check all that apply, so long as these are separate events; must ask about all types)</i>	Lifetime
<p>Actual Attempt: A potentially self-injurious act committed with at least some wish to die, <i>as a result of act</i>. Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is <i>any</i> intent/desire to die associated with the act, then it can be considered an actual suicide attempt. <i>There does not have to be any injury or harm</i>, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g. gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. <i>Did you hurt yourself on purpose? Why did you do that?</i> <i>Have you made a suicide attempt?</i> <i>Have you done anything to harm yourself?</i> <i>Have you done anything dangerous where you could have died?</i> <i>What did you do?</i> <i>Did you _____ as a way to end your life?</i> <i>Did you want to die (even a little) when you _____?</i> <i>Were you trying to end your life when you _____?</i> <i>Or did you think it was possible you could have died from _____?</i> <i>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)?</i> (Self-Injurious Behavior without suicidal intent) If yes, describe:</p> <p>Has subject engaged in Non-Suicidal Self-Injurious Behavior?</p> <p>Has subject engaged in Non-Suicidal Self-Injurious Behavior, intent unknown?</p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p> <p>Total # of Attempts _____</p> <p>Yes No <input type="checkbox"/> <input type="checkbox"/></p> <p>Yes No <input type="checkbox"/> <input type="checkbox"/></p>
<p>Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act (<i>if not for that, actual attempt would have occurred</i>). Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. <i>Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?</i> If yes, describe:</p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p> <p>Total # of interrupted _____</p>
<p>Aborted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. <i>Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?</i> If yes, describe:</p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p> <p>Total # of aborted _____</p>
<p>Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g. buying pills, purchasing a gun) or preparing for one's death by suicide (e.g. giving things away, writing a suicide note). <i>Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?</i> If yes, describe:</p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p>
<p>Suicidal Behavior: Suicidal behavior was present during the assessment period?</p>	<p>Yes No <input type="checkbox"/> <input type="checkbox"/></p>

Suicide Cluster - Schenectady County

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes," ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

1. Wish to be Dead

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts

General non-specific thoughts of wanting to end one's life/commit suicide (e.g. "I've thought about killing myself") without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g. thought of method to kill self but not a specific plan). Includes person who would say, "I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it....and I would never go through with it".

Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to "I have the thoughts but I definitely will not do anything about them".

Lifetime

Recent

Situation/
Stressor*

Yes No

Military Version

Tailored for Population Specific Data Collection

<i>Additional Questions</i>		Yes	No
<p><u>Legal Troubles</u> <i>Are you currently facing any legal troubles?</i> *Within military structure or outside</p> <p><i>If yes, how have these circumstances impacted you/your family?</i></p> <p>Additional Information:</p>		<input type="checkbox"/>	<input type="checkbox"/>
<p><u>Financial Troubles</u> <i>Are you experiencing any financial troubles?</i> If yes:</p> <p><i>Do these concerns feel overwhelming or unmanageable?</i></p> <p><i>Sometimes a person can feel that others close to them (e.g., family) would be better off financially if the person were no longer alive. Have you experienced this?</i></p> <p><i>Is this financial stress or hardship the worst crisis you have ever experienced?</i></p>		<input type="checkbox"/>	<input type="checkbox"/>
<p><u>State of Service</u> (pre-deployment, post-deployment, etc) Pre-deployment ___ Post-deployment ___ Multiple deployments ___</p> <p><i>Are the thoughts/behaviors we talked about related to your _____?</i> (e.g., pending deployment)</p>		<input type="checkbox"/>	<input type="checkbox"/>
<p><u>Marital or Relationship Stress</u> <i>Are you having any marital or relationship stress or problems?</i> *Ask about domestic violence.</p>		<input type="checkbox"/>	<input type="checkbox"/>
<p><u>Drug or Alcohol Use</u> <i>Do you use drugs or alcohol?</i></p> <p><i>Do you have a history of drug or alcohol abuse?</i></p> <p>Additional Information:</p>		<input type="checkbox"/>	<input type="checkbox"/>
<p><u>Pain</u> <i>Are you experiencing pain – chronic or intermittent?</i></p> <p>Additional Information:</p>		<input type="checkbox"/>	<input type="checkbox"/>

Child and Family Assistance Center
(CAFAC Version)

Developed and implemented at Fort Carson, Colorado

Military Family Member Version C-SSRS Suicide Risk Assessment

	<u>Yes</u>	<u>No</u>
<p>1. Legal Troubles <i>Are you, or is anyone in the family, facing any legal troubles (military or civilian)?</i></p> <p><i>If yes, how have these circumstances impacted you/your family?</i></p>		
<p>2. Financial Troubles <i>Are you or your immediate family members experiencing any financial troubles?</i></p> <p><i>Do these concerns feel overwhelming or unmanageable?</i></p> <p><i>Sometimes a person can feel that others close to them (e.g., family) would be better off financially if the person were no longer alive. Have you or anyone in the family experienced this?</i></p> <p><i>Is this financial stress or hardship the worst crisis you, or your family, have ever experienced?</i></p>		
<p>3. State of Service (Deployment Cycle) Service Member is:</p> <p>___ deployed</p> <p>___ <u>predeployment</u> (within 3 months)</p> <p>___ <u>postdeployment</u> (within 3 months)</p> <p>___ Other</p> <p>___ # of deployments</p> <p><i>Are the thoughts/behaviors we talked about related to SM's deployment?</i></p>		

VA
Version

**COLUMBIA-SUICIDE SEVERITY
RATING SCALE
(C-SSRS)**

U.S. Department of Veterans Affairs Version

Version 1/14/09

*Posner, K.; Brent, D.; Lucas, C.; Gould, M.; Stanley, B.; Brown, G.; Fisher, P.; Zelazny, J.;
Burke, A.; Oquendo, M.; Mann, J.*

Disclaimer:

This scale is intended to be used by individuals who have received training in its administration. The questions contained in the Columbia-Suicide Severity Rating Scale are suggested probes. Ultimately, the determination of the presence of suicidal ideation or behavior depends on the judgment of the individual administering the scale.

Definitions of behavioral suicidal events in this scale are based on those used in The Columbia Suicide History Form, developed by John Mann, MD and Maria Oquendo, MD, Conte Center for the Neuroscience of Mental Disorders (CCNMD), New York State Psychiatric Institute, 1051 Riverside Drive, New York, NY, 10032. (Oquendo M. A., Halberstam B. & Mann J. J., Risk factors for suicidal behavior: utility and limitations of research instruments. In M.B. First [Ed.] Standardized Evaluation in Clinical Practice, pp. 103 -130, 2003.)

For reprints of the C-SSRS contact Kelly Posner, Ph.D., New York State Psychiatric Institute, 1051 Riverside Drive, New York, New York, 10032; inquiries and training requirements contact posnerk@nyspi.columbia.edu

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Implementation by First Responders

Examples of Police Force utilization:

- Laminated cards
- Metal key chains
- Apps on phone

C-SSRS used in Government, Industry, & Foundation sponsored intervention studies

Psychiatric

- MDD
- Major Depressive Episode Associated with Bipolar I Disorder
- Refractory Depression
- Bipolar Disorder
- GAD
- OCD
- ADHD (w/ and w/o Dyslexia)
- Schizophrenia
- Personality Disorders
- Alcohol Dependence
- Tardive Dyskinesia
- Bereavement
- Apathy
- Tourette's Syndrome
- Psychedelic drug therapy
- Seasonal Affective Disorder

* *Basically All Psychiatric Disorders*

Non-Psychiatric

- Healthy Volunteers
- Overweight patients
- Obesity
- Diabetes
- Interstitial Cystitis/ Painful Bladder Syndrome
- Eczema
- Smoking Cessation (w/ and w/o Schizophrenia/Schizoaffective Disorder)
- Cancer Survivors
- Insomnia
- Cardiovascular Disease
- Non-alcoholic Steatohepatitis
- Overweight with Type 2 Diabetes
- **Group Intervention for OEF/OIF**
- **TBI Survivors and Families**
- Opioid induced constipation
- Cough
- Spinal Muscular Atrophy
- Nasal and Ocular Allergies
- Metabolic disorders
- **Traumatic Brain Injury**
- Alzheimer's Disease
- Dementia
- Huntington Study Group
- Fibromyalgia
- Epilepsy
- Epileptic patients with renal impairment
- Chronic Headaches
- Neuropathic Pain due to Multiple Sclerosis
- Diabetic Peripheral Neuropathic Pain
- Peripheral Neuropathic pain
- Osteoarthritis pain
- Lower Back Pain
- Restless Leg Syndrome
- Homeless populations
- Autoimmune Illnesses (Lupus, Multiple Sclerosis)

National Implementation Efforts in the Military: National Guard, Air Force, Navy, Marines, VA

- **To be implemented throughout The National Guard Psychological Health Program**
 - Consists of 56 Directors of Psychological Health (DPHs), provides a range of behavioral health services to Service Members and their families.
 - Chief among these services is behavioral health assessment and referral to appropriate treatment providers.
- **C-SSRS incorporated into Air Force Guide for the Management of Suicidal Behaviors**
 - Currently being updated at Uniformed Services University of the Health Sciences - a decision has been made to include the C-SSRS to help behavioral health providers in the correct classification of suicide ideation and behaviors.
 - The updated guide is hoped to be disseminated to the AF community in 2013 upon final approval by AF leadership.
- **Navy – Training for use throughout all Primary Care**
- **Marine Corps: intended use in support workers**
 - family advocacy workers, substance abuse specialists, victim advocates, attorneys, and chaplains

C-SSRS Uses in the Military/VA

C-SSRS used among active military personnel and veterans for a myriad of populations and interventions:

PTSD
MDD
Treatment Resistant MDD
TBI
Alcohol/Substance Abuse
Bipolar disorder
Schizophrenia

Suicide
Suicide risk tracking,
prevention & treatment
Group Intervention for
OEF/OIF TBI Survivors &
Families

- **Over 40,000** active and veteran military personnel will be enrolled in studies using the C-SSRS for various indications
- Self-Injury component of the Army Study to Assess Risk and Resilience in Service Members (Army STARRS)
 - Epidemiologic study of mental health, psychological resilience, suicide risk, suicide-related behaviors, and suicide deaths in the U.S. Army
 - Largest study of suicide and mental health among military personnel ever undertaken
 - One of a series of efforts by the Army aimed at reducing the rate of suicide among its soldiers
 - The Army STARRS study includes soldiers from all phases of Army service

C-SSRS and the VA

- VA Version of the C-SSRS developed in collaboration with the VA – streamlined & coordinated within current systems
- Already requested or being used in 30-40 VA hospitals
- Engaged in a collaborative empirical process while supporting simultaneous national implementation

Requests from an Array of Domestic and International US Military/VA Facilities

▪ *Some Examples:*

- West Point
- Naval Hospital in Okinawa, Japan
- New York State Veterans Initiative
- VA Greater Los Angeles Healthcare System
- New Mexico Veterans Administration Health Care System
- San Luis Obispo & Santa Maria Community Based Outpatient VA Clinics
- Ramstein Air Base, Germany
- Fort Campbell

"C-SSRS USE BY MARYLAND NATIONAL GUARD CHAPLAINS"

Maryland National Guard publication, February 2011

- Continuing tragedy of military suicides calls for substantial prevention efforts
- Clergy use C-SSRS in ministering to National Guard members and families
- Screening is critical part of prevention in military and in general population
- The Partners in Care Clergy personnel- representing 49 local congregations from across the state -used training as they minister to referred Maryland National Guard members and families, as well as their own congregants, and surrounding communities.
- Partners in Care is administered by the Joint Force Headquarters Chaplain's Office.



Dr. Posner at C-SSRS training with Partners In Care Chaplains; Maryland National Guard Adjunct General was instrumental in bringing the training to Guard Chaplains.

C-SSRS Uses in the Military/VA

- **Walter Reed National Military Medical Center:**
 - “This scale is so helpful, especially in the military, when providers have to make very quick judgments.”
 - “Assessors find the tool *easy to use and helpful in correctly classifying the suicidal behaviors* [and] find the information collected via the CSSRS *helpful in their case conceptualizations and treatment approach with the patient.*”
- **Navy Medical Center, San Diego:**
 - “I am very impressed with how comprehensive and how well-conceptualized the scale is designed.”
- **John D. Dingell VA Medical Center:**
 - “I am *impressed* with the *increased quality of the C-SSRS in assessing this area in patients and feel it would serve our Veteran better in this area.*”
 - “*to tease out those who have serious suicidal ideations from those who say they are suicidal...*”

ESSENTRIS Military Electronic Health Records:

- **Retrospective chart review: 1500 cases admitted for suicide-related events**

C-SSRS Used in Education

Elementary → High School Education

- School Districts
- School Clergy
- Autism, Intellectually Disabled, BOCES
- School-based Wellness Centers
- Suicide Clusters



Nurses
Counselors
Social Workers
One-to-One Aides
Physicians
Coaches
Teachers

Higher Education

- College Campuses and Counseling Centers
- Center of Collegiate Mental Health
 - ~700 colleges/university
- Graduate Schools
- Medical Schools
- International Universities – *e.g.*
 - *University of Victoria, South Africa,*
 - *National University of Ireland*
- Nursing Schools



RAs
Gatekeepers
Incoming Student Screening
Physicians
Counselors

Research

- As Intervention and to Assess Outcome
 - *E.g. Turnaround for Children, SAMSA, Garret Lee Smith Grant*

What are we seeing?

Events in 35,224 eCSSRS administrations

(MDD, PTSD, insomnia, epilepsy and fibromyalgia)

Most Serious Ideation **Since Last Call:**

NONE	24634 (86.1%)
Q1 Passive Ideation	20929 (10.2%)
Q2 Active Ideation	487 (1.7%)
Q3 Method?	321 (1.1%)
Q4 Intent?	202 (0.7%)
Q5 Plan and Intent?	23 (0.1%)

~1.7% required any practitioner follow-up; **NONE** in non-psychiatric conditions

Events in Pain and Fibromyalgia Patients

	Pain Trial	Fibromyalgia Trial
Wish to be dead	0.72%	0.64%
Suicidal Thoughts	0.34%	0.21%
Ideation w/out Intent	0.12%	0.16%
Ideation w/out plan	0.06%	0.11%
Ideation plan intent	0.03%	0.05%
Actual	0%	0%
Nonsuicidal	0%	0%
Interrupted	0%	0%
Aborted	0%	0%
Prep acts	0%	0%
Behavior	0.03%	0.05%
Suicide	0%	0%
Total	<u>1.3%</u>	<u>1.22%</u>
Total at baseline:		<u>22.98%</u>

The eC-SSRS Approach in Practice



Patient contacts the system



The site reviews the Report

ERT
Getting it Done. Right.
Suicide Severity Rating Scale
Since Last Call: 11-JUN-2009
NEGATIVE

Sponsor: HTS Protocol: Columbia Subject ID: 0100006
Site: Date: 16-JUN-2009 Time: 14:30:44

***** Patient *****
Patient: [redacted]
1. 1. With to be dead or not wake up: Yes No NA

Active

2. 1. Non-suicidal thoughts	Yes	No	NA
2. 2. Specific thoughts of period			X
3. 3. Some more to go, no plan			X
3. 4. Specific plan and intent			X

Intensity

3. 1. Intensity of thoughts	0	1	2	3	4	5	NA
3. 2. Frequency of thoughts							X
3. 3. Duration of thoughts							X
3. 4. Controllability of thoughts							X
3. 5. Thoughts							X
3. 6. Reasons							X

Total Score = 0

***** Intensity *****

Since your last call, have you done anything to intentionally harm yourself? Yes No # NA

3. 7. Suicide Attempts			X				
3. 8. Non-suicidal Self-harm							X

Severity of Injury

3. 9. Lethality of Suicide Attempts	0	1	2	3	4	NA
3. 10. Most Serious Attempt						X
3. 11. Potential Lethality	0	1	2	NA		
3. 12. Most Serious Attempt				X		

3. 13. Interrupted Attempts	Yes	No	#
3. 14. Altered Attempts			X
3. 15. Preparatory Actions			X

Signature: _____ Date: _____

Disclaimer: This computer-assisted 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 behavior may be required. Determination of the relative salience of presence of present risk is dependent upon sound clinical judgment.
SSRS-IV: ©research@tulane.edu; see: hand upon
SSRS-C: Emily Proven, Columbia University

The system immediately emails a findings report to the site

eC-SSRS Benefits

***FDA Best Practices Meeting for Meta-analyses – optimal solution for minimizing bias*

- **Reliability in content and delivery**
 - Reduced effect of clinician variability, reduced queries
- Data Collection:
 - Coordinated data – like pilot, surgeon and anesthesiologist **checklists**
 - **Cleaned, locked database**
- **Self-rated (computerized) instruments of suicidal behavior and depression are more sensitive in detecting risk – Increased Patient Candor** (*TADS study, 2009; Griest 1973*)
 - Sensitive subject matter (sexual functioning, HIV risk factors, suicidal ideation and behavior, etc)
- **Immediate suicide risk notification**
 - Positive finding → active alert → site follows up per protocol
- **Computers and clinicians are complementary**
 - Most eC-SSRS reports are negative, needing only brief clinician review
 - Positive eC-SSRS reports organize and guide clinician review
- Reduced site burden
- Scalability

Science and Public Health

Demand Uniformity

(Gibbons, NCDEU 2010)

- Moving away from a single instrument inherently degrades the precision of the signal (compounding existing imprecision across sites and raters)
- The impact of *imprecision grows when incidence rates are low* (e.g., if incidence rate is 30%, imprecision is less meaningful, but when incidence rate is 5%, imprecision has greater costs for safety analyses)
 - Cannot tolerate imprecision with low frequency events
- 1% v. 3% - misclassification of 1 or 2 cases can have a profound impact, affect ratios, and substantially alter conclusions
- Even assuming two equally valid measures, adding another component of variability; more measurement variability adds to noise
 - Huge impact when trying to combine studies

Take away: Multiple measures increase noise, decreases precision, and weakens rigor of data

Finally.

Some Answers...?

***Centralized Data
Repository***

For questions and other inquiries,
email Dr. Kelly Posner at:
posnerk@nyspi.columbia.edu

Website address for more information
on the C-SSRS:
<http://www.cssrs.columbia.edu/>

Assessment Periods / Time Frames

FLEXIBLE, AMENABLE TO CLINICAL OR STUDY NEED

- Baseline / Lifetime History
 - Worst point found to be the most clinically meaningful
 - Assessment of suicidal ideation at its worst point is more predictive of suicide than current ideation (Beck, 1999)
 - Reporting lifetime suicidal ideation on C-SSRS at screening associated with increased chance of reporting suicidal behavior, Fisher's exact test [$p = 0.0008$, during the trial (TASA)]
- Screening: Recent / Last Week / Past Month / 6 Months
- Since Last Assessment

C-SSRS used in International Agencies

- National Suicide Prevention Program, Israel
- Health Canada
- Israel Health Ministry
- Korean Association for Suicide Prevention
- Japanese National Institute of Mental Health and Neurology
- FDA
- European Medicines Agency (EMA)
- MHRA
- VA/Maryland Army National Guard
- Israeli Defense Force

Suicidal Ideation in War Veterans

of Operations Enduring Freedom and Iraqi Freedom

- PTSD/TBI
- Depression
- Alcohol problems

Higher scores on measures of

- combat exposure
- psychosocial difficulties
- stigma
- barriers to care

Lower scores on measures of

- resilience
- unit support
- postdeployment social support

Suicide in the U.S. Military

Overall Picture

- Of the 30,000 suicides a year in the U.S., 20% are veterans.
- An estimated 30% of soldiers who took their own lives in 2008 did so while on deployment.

Conclusions from *AJP* on “Occupational Risk”

“Occupation influences suicide method. Access to and opportunity to use lethal means in the workplace are distinct but related occupation-specific suicide risk factors in the military and in other at-risk professions. In professions where access to lethal means is inevitable, moderating opportunity for suicide is crucially important. In regular-duty military personnel, a medical downgrading, combined with risk factors established in civilians such as younger age, male gender, psychiatric illness, and past self-harm, increases the risk of suicide.”

Advantages of Self-Report: Reporting Sensitive Subject Matter

- Sexual functioning
- Substance use
- HIV risk factors

and... Suicidal ideation and behaviors

- Fewer false negatives with computer than clinician interview

**A word about screening...
also critical to prevention**

Primary care: opportunity for prevention

- Majority of suicides see their doctor prior to their death
 - 45% in the month prior to their death
 - 80% in the year prior
- Excellent opportunity for prevention!

**Treatment is
Critical....The Story about
Medications
(the one providers and
families don't have!)**

**Beginning with FDA
data...so many
misunderstandings....
such limited data**

Summary of FDA Findings

- Event Data
 - Risk ratios for pooled analyses were significant (range from 1.7 to 2.2)
 - Signals seen predominantly in MDD patients
 - Inconsistencies remain in risk:
 - Across trials within programs
 - Across programs
 - Nevertheless, a reasonably consistent signal:
 - Evidence for suicide risk in 7 of 9 programs
 - No events in bupronion and nefazodone programs
 - Risk difference overall about 2% to 3%
 - **No suicides in any of 24 trials**

How Should These Findings Be Interpreted?

- May be increased risk for suicidal behavior/ideation during short-term treatment with all drugs in the antidepressant class
- Signal most compelling in MDD population, but may not be limited to this population
- Many possible explanations for variation in signal within and across programs

Overall relative risks (RR) of suicidal behavior or ideation (codes 1, 2, & 6) by drug

Drug	Relative Risk (95% CI), MDD trials	Relative Risk (95% CI), all trials, all indications
Citalopram	1.37 (0.53, 3.50)	1.37 (0.53, 3.50)
Fluvoxamine	No MDD trials	5.52 (0.27, 112.55)
Paroxetine	2.15 (0.71, 6.52)	2.65 (1.00, 7.02)
Fluoxetine *	1.53 (0.74, 3.16)	1.52 (0.75, 3.09)
Sertraline	2.16 (0.48, 9.62)	1.48 (0.42, 5.24)
Venlafaxine	8.84 (1.12, 69.51)	4.97 (1.09, 22.72)
Mirtazapine	1.58 (0.06, 38.37)	1.58 (0.06, 38.37)
Nefazodone	No events	No events
Bupropion	No MDD trials	No events

* Note that TADS data are added to Prozac

Fixed Effect Results on Suicidal Behavior/Ideation (1,2,6), Suicidal Behavior (1,2),
and Suicidal Ideation (6)
By Drug in MDD Trials (Seven Programs)

Drug Program (# of trials)	RR (95% CI) for 1,2,6 (Sui Behav/Ideation)	RR (95% CI) for 1,2 (Sui Behav)	RR (95% CI) for 6 (Sui Ideation)
Citalopram (2)	1.37 (0.53,3.50)	2.23 (0.59,8.46)	0.75 (0.19,2.95)
Venlafaxine (2)	8.84 (1.12,69.51)*	2.77 (0.11,67.10)	7.89 (0.99,62.59)
Paroxetine (3)	2.15 (0.71,6.52)	2.30 (0.67,7.93)	1.09 (0.24,5.01)
Fluoxetine (3 + 1)	1.53 (0.74,3.16)	2.15 (0.50,9.26)	1.30 (0.59,2.87)
Mirtazapine (1)	1.58 (0.06,38.37)	No Events	1.58 (0.06,38.37)
Nefazodone (2)	No Events	No Events	No Events
Sertraline (2)	2.16 (0.48,9.62)	0.98 (0.17,5.68)	3.88 (0.44,34.54)

Oh the Testimony.....

- "I am one of the many victims of the SSRI antidepressant era. I took 6-13 bullets in the heart area at my high school when [Columbine student] Eric Harris, who was on Luvox, fired at me. They almost amputated my leg and arm. My heart was missed by 1 mm...antidepressants are dangerous for those who take them and those they associate with...If antidepressants are effective, why didn't they help Eric Harris? He said they helped him feel suicidal. He reported having psychotic reactions to the drug and was taken off.

As soon as they put him back on, he was suicidal again...these drugs help increase the rage in people and cause them to do things they wouldn't anyways...**you need to take action immediately before more innocent people like me and you get hurt or die horrible deaths...[as Americans] we have the right to feel safe and if you were doing your jobs we would be safe.** "

“Why are we worrying about terrorists in other countries when pharmaceutical companies are our biggest terrorists by releasing these drugs on an unsuspecting public? How are we supposed to feel safe if we cannot trust the FDA to do what we are paying you to do? Where were you when I got shot? We should consider antidepressants accomplices to the murder.”

Mother: “Both Mark and I know that had Eric Harris not been given the antidepressants Zoloft and Luvox, the nightmare at Columbine never would have happened...”

- "...the most damaging thing...would be to impair one's ability to metabolize serotonin, yet that is exactly how SSRI's work...this produces nightmares, migraines, heart and chest pain, anxiety, depression, suicide (esp. very violent suicide and repeated attempts) hostility, violent crime, arson, substance abuse, psychosis, mania, autism, brain disease, anorexia, reckless driving, Alzheimer's, etc. How did anyone think it would be therapeutic to induce these reactions? ***Remember 20 years ago, when depressed people would slip away quietly to kill themselves, rather than themselves and everyone one around them?"***

– author of *Prozac: Panacea or Pandora*, who went on to note a study of violent 'mutant mice' as a parallel to people treated with SSRI's and likened the advent of SSRI drugs to a "national holocaust"

- [from the mother of this man] “These drugs change kind, gentle children into monsters.”

“As a psychiatrist, I am very ashamed of how poorly we have served the nation in terms of educating about the dangers of side effects of antidepressants...I personally apologize to anybody whose children have been affected adversely by antidepressants.”

Oh the Media.....

- Washington Post: *FDA Confirms Risk Antidepressants Raise Children's Suicide Risk*
- Video Games and pictures of deceased children

The vote.....

FDA Adult Analysis of Risk

- Overall, no significant risk in adults
- When combined with pediatric findings, results demonstrated an age-effect
 - Risk of suicide was apparent in those up to 25 years in the antidepressant group;
 - No effect was found for adults 25-64 (no difference between placebo and drug);
 - While an expected or protective effect was found in those 65 years and older.
 - For psychiatric disorder subgroup
 - Sertraline significant for protective effect OR 0.25 (0.07-0.90) $p=0.03$
 - Paroxetine significant for risk OR 2.76 (1.16-6.60) $p=0.02$ ¹²¹

FDA Adult Analysis of Risk

- As a result of this finding, the Psychopharmacological Drugs Advisory Committee recommended that the FDA update the Black Box warning to include young adults
- Concern expressed about the declining prescription rates since the introduction of the pediatric black box warning
- Label stated depression biggest cause of suicide

***Antidepressants & Suicide:
What does the evidence really
tell us?***

**Antidepressants Reduce
Suicide and Suicidal Behavior**

Antidepressants May Prevent Suicide

- Studies show suicide rate has fallen steadily since the introduction of SSRI antidepressants
 - Across age groups
 - In many countries (Rihmer et al., 2005)
 - Denmark (Erlangsen et al., 2008)
 - Hungary (Rihmer et al., 2000)
 - Sweden (Carlsten et al., 2001)
 - Italy (Barbui et al., 1999)
 - Japan (Nakagawa et al., 2007)
 - USA (Olfson et al., 2003; Gibbons et al., 2005)
 - Australia (Hall et al., 2003)
 - Even after controlling for unemployment & alcoholism (Grunebaum et al., 2004)
 - Antidepressants associated with reduction in suicide attempts (Gibbons et al., 2007)

Evidence Suggests That it is Untreated Depression That Kills

- Autopsy studies show suicide associated with no treatment or non-compliance in children and adolescents
 - Of 49 suicides, 24% had been prescribed an antidepressant and NONE had any SSRIs in system at time of death (Utah Youth Suicide Study Gray et al., 2003)
 - 66 suicides under 18, no Paxil found and only 3 had any antidepressant
 - Study of 36 youth (<18 years old) suicides in New York City from 1999-2002 found metabolic traces of antidepressants in the blood of only one—a homeless 16-year-old who died of an intentional drug overdose (Leon et al., 2006)

Antidepressants in Adult Suicides in NYC: 2001-2004 (Leon et al., 2007)

- Medical examiner surveillance study of all NYC suicides, 18 years and older
 - N=1,419 suicides
 - Antidepressants detected in 23.1% (267/1158).
 - Antidepressants least prevalent in 18-24 year olds (13.9%).

Sex Effect Really About Treatment??

Gibbons 2010, Personal Communication

Lower Antidepressant Treatment Rates in Males than in Females

- Only 17% of male suicide completers tested positive for antidepressants versus 44% in females
- Violent suicide death rates are much higher in males
- The rate of violent suicide death is much higher in those not taking antidepressants

Evidence That SSRIs May Prevent Suicide

- Studies show suicide rate steadily increased *prior to SSRIs* and has fallen steadily since their introduction
 - Across age groups
 - In many countries
- Areas of the US with the biggest increases in SSRI prescriptions are associated with the biggest declines in youth suicide rates (Olfson et al., 2003).

Gibbons et al., 2007

VA Data

- Antidepressants & Suicide in a Veterans' Health Dataset
 - N=226,866 with MDD with 6 month follow-up.
 - Attempt Rate: SSRI (364/100,000) < No SSRI (1057/100,000), $p < 0.001$.
 - Attempt Rate: SSRI only (123/100,000) < No treatment (335/100,000), $p < 0.0001$.
 - Attempt Rate: Before SSRI (221/100,000) > After SSRI treatment (123/100,000), $p < 0.0001$.

Undoing the Myth...

Watch patients closely at the beginning of treatment because anti-depressants can cause suicidal behavior (activate or energize)

Traced back to a line in a 1960s textbook

“Activation Complex”

FDA Time to Event Analysis

- = prior to 20 days!
- Subjects on drug at most risk between 20-60 day period; slightly elevated but not meaningful
- At 80 days the rr between drug and placebo drops to below 1, thus placebo at greatest risk
- Similar message to many other studies: if one goes untreated, more likely to have an event

Risk of Attempts Highest Month Before SSRI: Pattern of Risk Same as Psychotherapy (Simon et al., 2006,2007)

- Suicide risk was highest in the month before commencing treatment and declined steadily after starting treatment
- Risk of suicide attempt in depressed patients
 - 1,124/100,000 Antidepressant from Psychiatrist
 - 778/100,000 Psychotherapy
 - 301/100,000 Antidepressant from Primary Care Physician
- Pattern of attempts over time was the same in all three treatment groups – highest in the month before treatment, next highest in first month of treatment before declining thereafter.

***The Bad News.....
Unintended
Consequences***

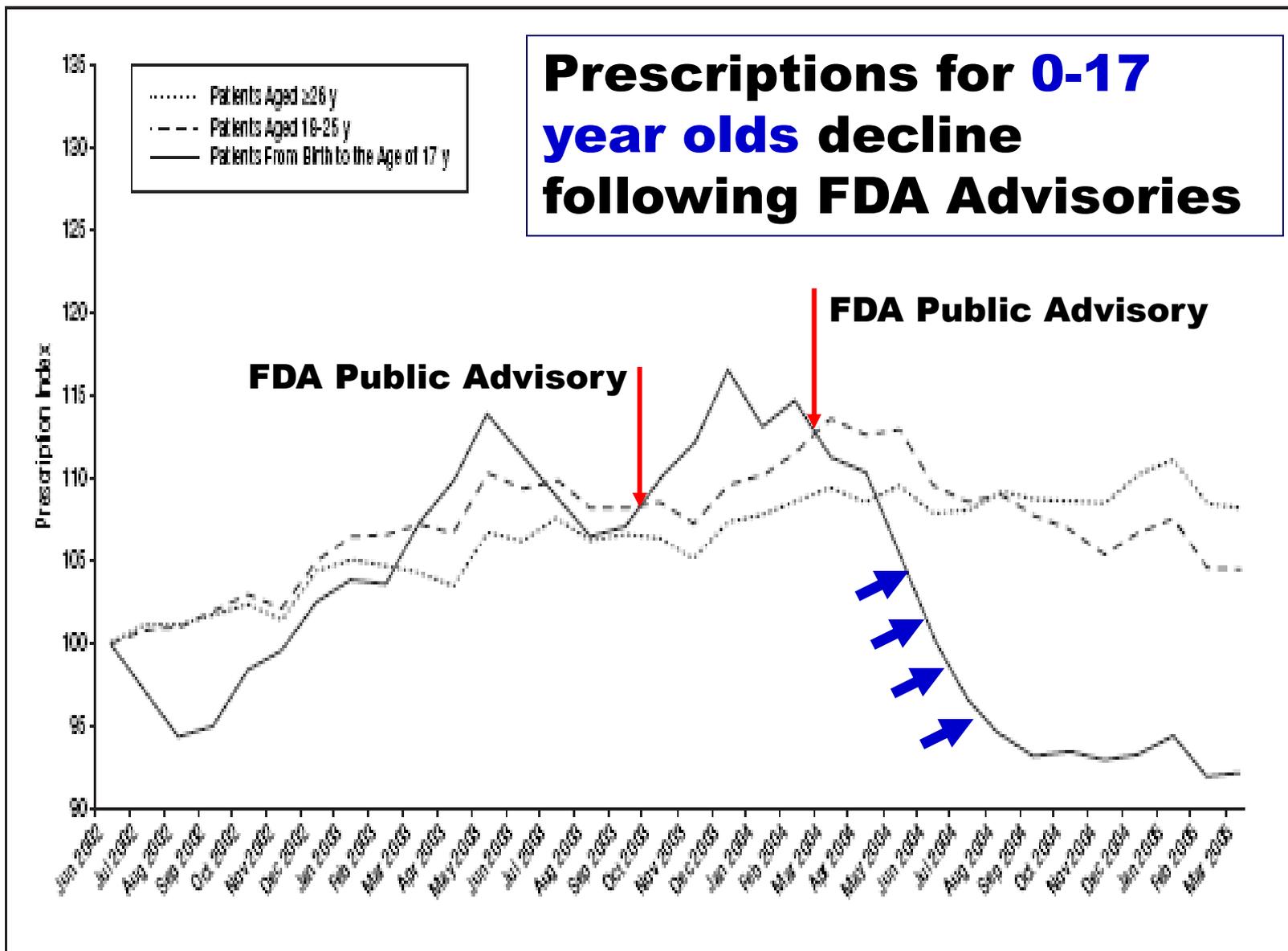


Figure 2. Prescription volume Indexed to normalize the difference in prescription volume between the age groups. June 2002 = 100, and subsequent data points are relative to this baseline value. Antidepressant total prescriptions by age.⁴ In May 2003, there was a Food and Drug Administration (FDA) data request; In October 2003 and March 2004, there were FDA public health advisories; and in September 2004, there was an FDA advisory panel meeting.

Impact on Antidepressant Prescribing

- Libby et al., 2007
 - SSRIs prescription fills were **58% lower** than predicted by the pre-FDA advisory prescribing trend.
 - The proportion of pediatric antidepressant cases receiving no antidepressant increased to 3x the rate predicted by the pre-advisory trend
- American Academy of Child & Adolescent Psychiatry Survey
 - When asked what they were doing about black box warning, over **1/3 psychiatrists said changing to atypical antipsychotics**
- Bhatia et al., 2008
 - Clinicians in Nebraska decrease prescriptions of antidepressants to pediatric patients
 - **Over 20% of clinicians reported a caregiver or patient had refused** antidepressant medication treatment due to the FDA's black box warning¹³⁵

International Impact

- Australia: Recent data show a decline in pediatric antidepressant prescriptions (2003/04 – 2005/06):
 - 0-14 years: 26.6%
 - 15-20 years: 13.7%
- Recent data of suicide rate not yet available.

(Medicare, Australia 2007)

Suicide Epidemic.....?

- Gibbons et al., *AJP*, 2007
 - Netherlands: Since warnings, 22% drop in prescriptions and 49% increase in youth suicide 2003 to 2005
 - USA: Since warnings, 22% drop in prescriptions and 12% increase in youth (5-19 years) dying by suicide 2003 to 2004
 - USA: Single largest year-to-year increase in suicide within this age group since CDC began systematic data collection in 1979
 - Canada: Suicide rates among children and adolescents increased significantly after the Health Canada issued a warning

Trouble in a 'Black Box'

Did an effort to reduce teen suicides backfire?

By Tony Dokoupil
Newsweek

July 16, 2007 issue - Seventeen-year-old Michael didn't want to end up crazed and suicidal like the Columbine killers. The Massachusetts teen had read that Eric Harris and Dylan Klebold were taking antidepressants when they rampaged murderously through their Colorado high school in 1999, and he didn't want to snap as they had. "He'd say it was like there was an evil guy on his left shoulder and a good guy on his right, but the evil guy just kept winning," Michael's mother, Lorraine, recalls. Despite his pain, Michael feared that antidepressants would "put him over the edge." Lorraine wasn't so sure. After consulting a specialist, she persuaded Michael in January to try Prozac, one of a family of drugs known as selective serotonin reuptake inhibitors, or SSRIs. By spring, the "good guy" was winning: Michael made the honor roll for the first time.



The FDA has already taken steps to modify the box in reaction to reports that its message was being misunderstood. "Our goal was to inform people of a risk, not halt treatment," says Dr. Thomas Laughren, head of psychiatry products, the division responsible for the warning. "But it's still only one year of data," he cautions. In May, his office mandated revisions "to reflect the apparent beneficial effect of antidepressants" and remind people that mood disorders are "the most important cause" of suicide.

The next test for the FDA will come this December, when the CDC releases suicide figures for 2005. "If the rates are up again, it's likely we'll go back to the board of advisers," says Laughren. The agency has repealed only one black box in its history, on the acid-reflux medication Prilosec, pulled in 2003. "But I wouldn't rule it out," Laughren adds. "The evidence is very compelling."

Suicide Epidemic.....All data point in the same direction

- Bridge JAMA, 2008
 - Estimated the expected suicide rates in 2004 and 2005 based upon previous trends between 1996 and 2003
 - 2004 and 2005 suicide rates significantly greater than expected rates with an estimated 326 excess suicide deaths among youth aged 10 to 19 years in 2004 and 292 excess deaths in 2005

More consequences...

- Impact on depression identification
- Diagnosis of depression in youth and young adults dropped to levels not seen in 10 years in the US (Libby et al 2007)

Decreased Diagnosis and Treatment of Depression in Both Children and Adults

- Libby et al., 2009
 - National diagnosis rates of depression decreased to 1999 levels for adolescents and to pre-2004 levels for adults
 - SSRI prescriptions decreased for adolescents and adults
 - No increase in the provision of psychotherapy for adolescents
 - “Substitute care did not compensate in pediatric and young adult groups, and spillover to adults continued, suggesting that unintended effects are non-transitory, substantial, and diffuse in a large national population.”

- Take home message: The FDA advisories on antidepressants and suicide had a clear "chilling effect" on the diagnosis and treatment of pediatric MDD; this effect spilled over to the adult population as well.

Suicidal Concerns in Other Drugs: Antiepileptic Medications

- FDA conducted a meta-analysis of data from 199 placebo-controlled trials
 - 11 antiepileptic drugs used to treat epilepsy, bipolar disorder, migraine headaches, and other conditions
 - Carbamazepine, Divalproex sodium, Felbamate, Gabapentin, Lamotrigine, Levetiracetam, Oxcarbazepine, Pregabalin, Tiagabine, Topiramate, Zonisamide
 - 27,863 patients in drug arms and 16,029 patients in placebo arms

Suicide Concerns: Antiepileptic Medications

- Overall odds ratio of suicidal behavior or ideation in drug versus placebo 1.80 (95% CI: 1.24-2.66)
 - Epilepsy Indication – 3.53 (95% CI: 1.28-12.10)
 - Psychiatric Indication – 1.51 (95% CI: 0.95-2.45)
 - Other Indication – 1.87 (95% CI: 0.81-4.76)
- Relative risk lower than antidepressants
- FDA recommends clinicians notify patients and their caregivers of the potential for an increase in the risk of suicidal thoughts or behaviors

Problems with the Analyses

- Two-thirds of the trials had no suicidal events
- Majority of the suicidal events were observed in only 2 of the 11 antiepileptics (lamotrigine and topiramate) and these medications already had suicide warnings on their labels

AED Advisory Meeting

- FDA Public Health Advisory Panel votes against black box warning

“Elevated Rate of Teen Suicide Stirs Concern” WSJ 9.3.08

- “The FDA in 2007 called for an update to the boxed warning, adding that depression and certain other serious psychiatric disorders are themselves the most important causes of suicide.”
- Newly published research (Bridge et al., 2008) “could rekindle controversy over the FDA's decision to require the “black box” warnings...The warnings, along with the agency's concerns about antidepressants, contributed to a drop in prescriptions...Are concerns about antidepressants scaring people away from medicines that could help them?”

“Suicide risks studied in drugs for physical ills ” The Associated Press

8.31.2008

- Federal drug regulators are investigating the mental and emotional side effects of medications prescribed to relieve physical symptoms.
- “Douglas Briggs, 54, was a family doctor who injured his back in a car crash. Three surgeries over the years failed to completely resolve his problem. In February 2004, he began taking Neurontin, an epilepsy drug also prescribed for nerve-related pain and used for chronic back trouble. On Christmas Day in 2004, Briggs wanted to be alone. He urged his family to go see a movie. ***When they returned, they found he had hanged himself in the foyer of their home.***”

Suicidal Concerns: Chantix

- Varenicline (Chantix) – Nicotine receptor partial agonist
- Smoking responsible for 1 in 5 deaths; most effective smoking cessation drug
- Post marketing cases
 - Do not tell you about causal link to a drug
 - Further complicated when underlying condition is associated with high risk

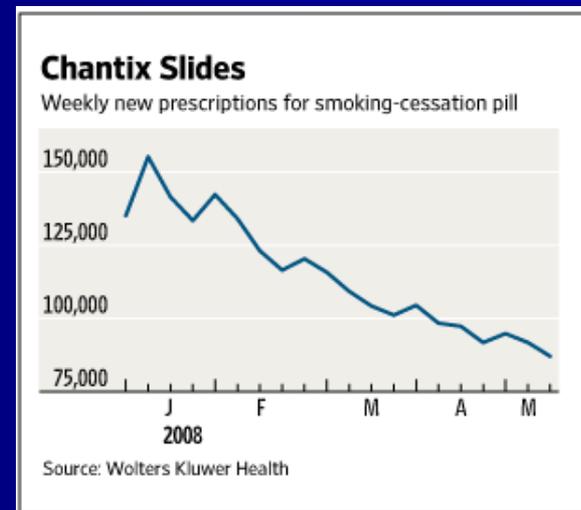
Smoking big risk factor for suicide

Headlines...

- “This is my brain on Chantix ”
New York Magazine 2.10.08
- “VA testing drugs on war veterans:
Experiments raise ethical questions” Washington Times 6.18.08
 - United States Department of Veterans Affairs testing Chantix on war veterans with PTSD without properly warning them of the side effects
 - Vet almost killed during psychotic episode and threatened police officers

“F.A.A. Bans Antismoking Drug, Citing Side Effects ” The New York Times 5.22.08

- “The Federal Aviation Administration said Wednesday it would no longer permit pilots or air traffic controllers to use the smoking cessation drug Chantix, citing potential side effects that could pose a threat to the safe operation of aircraft”



More Drugs Involved: Singulair

- “The mystery of medications linked to suicide ”
MSNBC 5.7.08
- Cody Miller, 15, began using Singulair for his allergies in the summer of 2007. When he became moody and anxious, his parents were surprised. He had no history of emotional problems. About two weeks after he started taking his new medication, he hanged himself in an upstairs closet of the family home.

C-CASA Singulair: 1/13/09 FDA Update

Company	Merck		Astra Zeneca		Cornerstone Therapeutics	
Medication	Montelukast		Cornerstone Therapeutics		Zileuton	
# Placebo Cntrld Trials	41		45		11	
	Active	Placebo	Active	Placebo	Active	Placebo
# Px	9929	7780	7540	4659	1745	1063
Suicidal Ideation Events	1	0	0	1	0	0
Suicidal Behaviors	0	0	0	1	0	0
Deaths by Suicides	0	0	0	0	0	0
Total	1 (0.01%)	0	0	2 (0.04%)	0	0

For questions and other inquiries,
email Dr. Kelly Posner at:
posnerk@nyspi.columbia.edu

Website address for more information
on the C-SSRS:
<http://www.cssrs.columbia.edu/>

Conclusions

- Intervention trials using prospective and systematic measurement of suicidal behavior/ideation would more clearly delineate the relationship between suicidal adverse events and medication treatment
- Consistent and systematic assessment (e.g. C-SSRS) can provide more meaningful data within a study, as well as across studies, improving pooled analyses
- Decreasing false positives and debunking false notions of risk are as important as knowing about risks that exist
- Suicidal subjects should be included in trials: increases generalizability and avoids unnecessary exclusions

For questions and other inquiries,
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Columbia-Suicide Severity Rating Scale (C-SSRS)

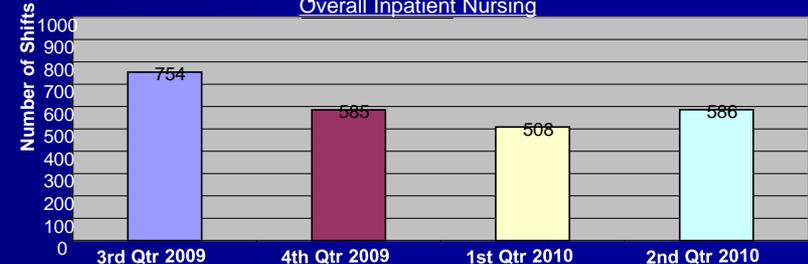
Posner, K.; Brent, D.; Lucas, C.; Gould, M.; Stanley, B.; Brown, G.; Zelazny, J.; Fisher, P.; Burke, A.; Oquendo, M.; Mann, J.

- Developed in NIMH attempter trial to uniquely address need for summary measures – 1st scale to assess full range of ideation and behavior
- Developed by many leading experts - collaboration with Beck's group
- *OPERATIONALIZED THRESHOLDS FOR NEXT STEPS RESULTING IN SIGNIFICANT REDUCTION OF UNNECESSARY INTERVENTIONS AND BURDEN*
- Extensively international use across research, clinical and institutional settings
- Several million administrations
- Available in 103 languages
- Average administration time 1-2 minutes
- *Data confirm that 4 or 5 on ideation predict suicide attempts in national attempter study (Posner et al., AJP Dec 2011); further confirmed by eC-SSRS: 35,007 administrations, those at baseline with 4 or 5 in prior ideation and/or behavior are 4x – 8x more likely to report subsequent suicidal behavior*

REDUCED BURDEN & COST IN HOSPITAL SETTING

REDIRECTING SCARCE RESOURCES WHILE IDENTIFYING THOSE AT GREATEST RISK
JCAHO BEST PRACTICES LIST

Reading Hospital: IMPROVED IDENTIFICATION WHILE REDUCING UNNECESSARY ONE-TO-ONES
Patient Safety Monitor Utilization For Suicides
Overall Inpatient Nursing



- Excellent feasibility – no mental health training required to administer (812 nurses, 99% reliability independent of MH training or education)
- Systematic use of C-SSRS shown to decrease burden compared to other methods or doing nothing
- Extremely sensitive and specific
- CDC has adopted – link to C-SSRS in CDC document

Columbia-Suicide Severity Rating Scale (C-SSRS)

Posner, K.; Brent, D.; Lucas, C.; Gould, M.; Stanley, B.; Brown, G.; Zelazny, J.; Fisher, P.; Burke, A.; Oquendo, M.; Mann, J.

USES/RECOMMENDATIONS INCLUDE:

- General medical and psychiatric emergency departments / Hospital systems
- Primary care
- Schools / college campuses
- US Army/National Guard/VAs/Navy and Air Force settings
- Frontline responders (police, fire department, EMTs)
- Substance abuse treatment centers
- Prisons/jails/juvenile justice systems/ judges to reduce unnecessary hospitalizations
- FDA, WHO, JCAHO Best Practices Library
- AMA Best Practices Adolescent Suicide, Health Canada, Israeli Defense Force, Japanese National Institute of Mental Health

“If a practitioner asked the questions... It would provide some legal protection” —Bruce Hillowe, mental health attorney specializing in malpractice litigation

California corrections department spends \$20 million on a suicide-watch program, which they believe could be cut in half by these methods

“[Using the C-SSRS] may actually be able to make a dent in the rates of suicide that have existed in our population and have remained constant over time...that would be an enormous achievement in terms of public health care and preventing loss of life.” - Jeffrey Lieberman, M.D., chairman of Columbia University’s Dept of Psychiatry and director of the New York State Psychiatric Institute

Additional eC-SSRS slides

eC-SSRS: Behavior Findings

Lifetime calls (35,224):

Suicidal Behaviors:

- Actual Attempts 1,084 (3.1%)
- Interrupted/Aborted Attempts & Preparatory Behavior 1,293 (3.7%)

Since Last Contact Calls (28,701)

Suicidal Behaviors:

- Actual Attempts 70 (0.2%)
- Interrupted/Aborted Attempts & Preparatory Behavior 331 (1.2%)

eC-SSRS: SLC Behavior Findings

Suicidal Behaviors: **Since Last Call** calls (28,701):

- 1 attempt 70 (0.2%)
- Interrupted Attempt 331 (0.9%)
- Aborted Attempt
- Preparatory Behavior

eC-SSRS: Behavior Findings

Lifetime calls (35,224):

Suicidal Behaviors:

- Actual Attempts 1,084 (3.1%)
- Interrupted/Aborted Attempts & Preparatory Behavior 1,293 (3.7%)

Since Last Contact Calls (28,701)

Suicidal Behaviors:

- Actual Attempts 70 (0.2%)
- Interrupted/Aborted Attempts & Preparatory Behavior 331 (1.2%)

Results: Lifetime Rates of Suicidal Behavior

■ Actual Attempts:

- 1,084 (62.5%) of the 1734 Positive Baseline Reports reported an Actual Attempt at some time in past
- 650 (37.5%) did not report an Actual Attempt

■ Interrupted or Aborted Attempts, or Preparatory Behaviors (IAA/PB):

- 1,293 (74.6%) of the 1734 reported a prior IAA/PB at some time in past.
- 441 (25.4%) did not report a prior IAA/PB

Results: Lifetime Rates of Ideation for Reports of Suicidal Behavior

- Most Severe Suicidal Ideation Reported:
 - 106 (6.1%) = No Ideation
 - 245 (14.1%) = Passive Ideation
 - 188 (10.8%) = Active Nonspecific
 - 300 (17.3%) = Active w/Method
 - 505 (29.0%) = Active w/Intent
 - 393 (22.7%) = Active w/Intent & Plan

eC-SSRS/IVR

- **>35,000 administrations in MDD, PTSD, insomnia, epilepsy and fibromyalgia**
- **Integrated approach – if needed, the clinician is able to administer the C-SSRS to clarify and add additional and/or supplemental information after reviewing the eC-SSRS report**
- **Data from first 16,000 administrations: ~1.7% required follow-up by a clinician to clarify and/or supplement information collected via the eC-SSRS**

Relationship Between Follow-Up Reports of Suicidal Behaviors and Follow-Up Observations

	No reported behaviors N = 3593	One or more reported behaviors N = 189	Student's t-test
Number of follow-up observations	Mean = 5.88 SD = 2.48	Mean = 6.23 SD = 2.03	t(3780) = -1.90 p. = .06
Number of days since baseline	Mean = 63.7 SD = 51.2	Mean = 63.3 SD = 45.9	t(3780) = 0.10 p. = .92

- These data suggest that “positive” baseline reports – reflecting
 - self-reported ideation of 4 or 5
 - or prior behavior
 - or bothare associated with a higher likelihood of reporting suicidal behavior during a follow-up eC-SSRS while participating in the trial

Data Collection

- Coordinated data – like pilot, surgeon and anesthesiologist *checklists*
 - Self-reported data – eC-SSRS
 - Site collected data – C-SSRS
 - Follow-up on positive reports
 - Ad hoc data
 - Clinician findings “trump” self-report findings
- Cleaned, locked database

eC-SSRS Benefits

- Reliability in content and delivery
- Accurate documentation and reporting
- Immediate suicide risk notification
- Reduced effect of clinician variability
- Reduced queries
- Increased patient candor
- Combined computer and clinician assessment
- Reduced site burden
- Scalability

Meta-analyses & large database studies

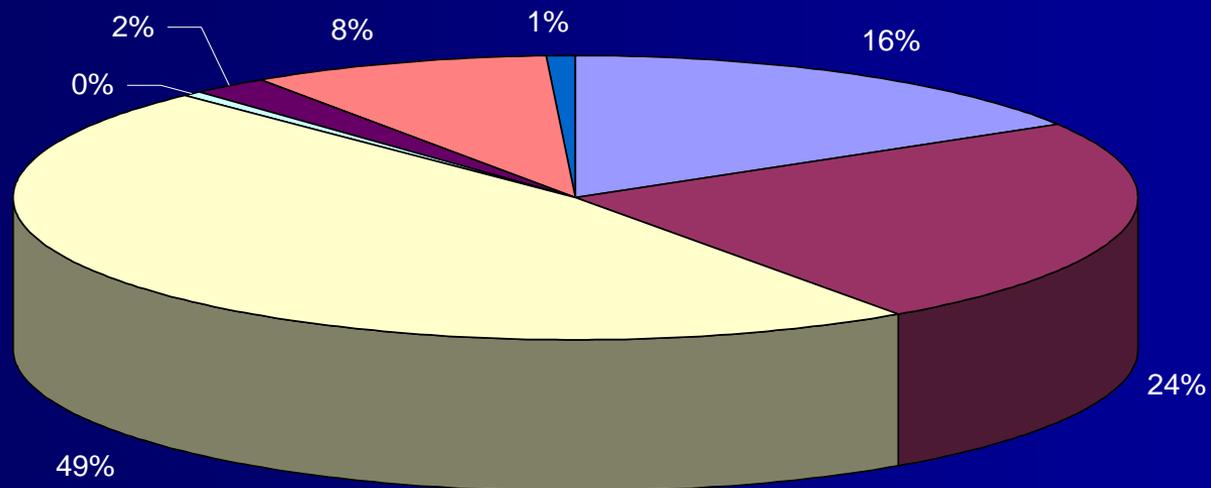
- No evidence of association between antidepressants and risk of suicidality/suicide
 - Beasley et al. (1991)
 - Khan et al. (2003)
 - Gunnell et al. 2005
 - Jick et al. (2004)
 - Valuck et al. (2004) (adolescents)
 - Fergusson et al. (2005) (adolescents) attempt, but not suicide
 - Martinez et al. (2005) (adolescents) self-harm but not suicide

Continued...

- Wightman et al., 2010
- Tourian et al., 2010
- Mulder et al., 2008
- Kasper et al., 2010
- Machado et al., 2011 (desvenlafaxine in epilepsy)
- Barbui et al., 2009 (safe for adults)
- Seemüller et al., 2009

Utilization of 1:1

Utilization Reason
2nd Quarter 2010
Overall Hospital



Fall Risk Suicide Behavior Elopement Substance Withdrawal Protect Medical Devices Other Safety

Other reasons include: Family Request and Level of Care

Various Uses of C-SSRS Within a Study

- Treatment benefit outcomes
- Safety outcomes
- Clinical safety monitoring
- Coordinated efficiently with other measures
- Epidemiological
- Inclusion/exclusion

C-SSRS in Clinical Trials

- Trials in Phases I-IV
- Few thousand sites internationally, psychiatry and non-psychiatry
- Over 100 different languages for all versions
- Drug/placebo; active controls; open maintenance
- Range of interventions: pharmacologic, device, psychotherapy, ECT

C-SSRS Uses In The Military

- The C-SSRS is being used among active military personnel and veterans for a myriad of populations and interventions:
 - PTSD
 - MDD, Treatment Resistant Major Depression
 - Alcohol/substance abuse
 - Suicide/Suicide risk tracking, prevention and treatment
 - Bipolar disorder
 - Schizophrenia
 - TBI
 - Group Intervention for Operation Enduring Freedom /Operation Iraqi Freedom TBI Survivors and Families
- Over 40,000 active and veteran military personnel will be enrolled in studies using the C-SSRS for the indications listed above

C-SSRS Uses In The Military

- Self-Injury component of the Army Study to Assess Risk and Resilience in Service Members (Army STARRS)
 - Epidemiologic study of mental health, psychological resilience, suicide risk, suicide-related behaviors, and suicide deaths in the U.S. Army
 - Largest study of suicide and mental health among military personnel ever undertaken
 - One of a series of efforts by the Army aimed at reducing the rate of suicide among its soldiers
 - The Army STARRS study includes soldiers from all phases of Army service

Time Frames: Baseline / Lifetime

- Behavior is “ever”
 - Capture all lifetime occurrences (e.g. total number of attempts ever)
- For Ideation and Intensity of Ideation, time he/she was feeling the most suicidal (as opposed to average across life)
 - “The time in your life you were feeling the most suicidal, did you wish you were dead, have thoughts of actually killing yourself...” etc

C-SSRS: Baseline / Screening

SUICIDAL IDEATION		
<i>Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes," ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.</i>	Lifetime: Time He/She Felt Most Suicidal	Recent
<p>1. Wish to be Dead Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up. <i>Have you wished you were dead or wished you could go to sleep and not wake up?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>
<p>2. Non-Specific Active Suicidal Thoughts General non-specific thoughts of wanting to end one's life/commit suicide (e.g. "I've thought about killing myself") without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period. <i>Have you actually had any thoughts of killing yourself?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>
<p>3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g. thought of method to kill self but not a specific plan). Includes person who would say, "I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it.....and I would never go through with it". <i>Have you been thinking about how you might do this?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>
<p>4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan Active suicidal thoughts of killing oneself and subject reports having <u>some intent to act on such thoughts</u>, as opposed to "I have the thoughts but I definitely will not do anything about them". <i>Have you had these thoughts and had some intention of acting on them?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>
<p>5. Active Suicidal Ideation with Specific Plan and Intent Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out. <i>Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>

eC-SSRS/IVR

- **35,224 administrations in MDD, PTSD, insomnia, epilepsy and fibromyalgia**
- **Integrated approach – if needed, the clinician is able to administer the C-SSRS to clarify and add additional and/or supplemental information after reviewing the eC-SSRS report**
- **~1.7% required follow-up by a clinician to clarify and/or supplement information collected via the eC-SSRS**

Screening Programs are Successful!!

- High-school screening programs associated with 2x in detection of at-risk individuals (Scott et al., 2004)
- Meta-analysis concluded that **screening results in lower suicide rates in adults** (Mann et al., 2006)
- Columbia Teen-Screen demonstrated 88% sensitivity and 76% specificity
- College Screening Project - data suggests that screening brings high-risk students into treatment
 - Only 1 suicide in 4 years post-screening vs. 3 suicides in 4 years pre-screening program (Haas et al., 2008)
- Adult primary care screenings - **47% increase in rates of detection and diagnosis of depression**

Gatekeepers: opportunities for prevention

- Majority of people who die by suicide see their primary care doctor prior to their death
 - 45% in the month prior to their death
 - 80% in the year prior
- Other gatekeepers:
 - Teachers
 - Coaches
 - Dormitory staff
- No mental health training required for C-SSRS

SUICIDALITY IN "NORMAL" TEENS

- **Thinking about suicide: 20%**
 - **With a plan 17%**
- **Making a suicide attempt: 10%**
 - **Attempt requiring medical attention 3%**
- **Committing suicide: .006%**

TEEN SUICIDALITY IN DEPRESSION

— 15 STUDIES, 12,141 SUBJECTS —

Shaffer, 2005

Ideation	60%
Attempt	30%
Completion	0.05%

Public Health Burden.....

- 2 million adolescents attempt suicide annually, resulting in 700,000 ER visits
- Attempters constitute high proportion of all emergency referrals to child and adolescent psychiatric services and subsequently command disproportionate level of resources

What we are seeing.....

- MDD: adults approx. 10%
- GAD: 3%
- Non-Alcoholic Chronic Liver Disease: < 1% (liver disease associated with depression & suicidality; no referrals triggered)
- ADHD: ages 6-12, 0% ideations & behaviors
- Approximately 20,000 subjects:
 - Cardiovascular: 1-2% (no referrals triggered)
 - Obesity: <1% (no referrals triggered)
- Obesity with Depressed Patients: 1.25% ideation or behavior

eC-SSRS/IVR

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- **Integrated approach – if needed, the clinician is able to administer the C-SSRS to clarify and add additional and/or supplemental information after reviewing the eC-SSRS report**
- **~1.7% required any practitioner follow-up / NONE in non-psychiatric conditions**

C-SSRS Current Uses

In Clinical Trials

- Well over a million administrations
- Trials in Phases I-IV
- Thousands of sites internationally, psychiatry and non-psychiatry
- 103 languages
- Millions of administrations
- Drug/placebo; active controls; open maintenance
- Range of interventions: pharmacologic, device, psychotherapy, ECT

Within A Study

- Treatment benefit outcomes
- Safety outcomes
- Clinical safety monitoring
- Coordinated efficiently with other measures
- Epidemiological
- Establishment of inclusion/exclusion criteria
 - In past exclusion arbitrary e.g. "serious risk"??
[criteria can be operationalized and assessed by C-SSRS
e.g. 4 or 5 on C-SSRS in past X months depending on phase/indication]

Various Uses of C-SSRS Within a Service

- Screening upon entry to a service
- Monitoring of outcome and safety
- Component of comprehensive Suicide Risk Assessment
- Measuring improvement and worsening
- Monitoring of Suicidal Adverse Events during pharmacological (or psychosocial) treatment
- Collection of epidemiological data

Assessment Periods/Time Frames

Flexible, amenable to study or clinical need

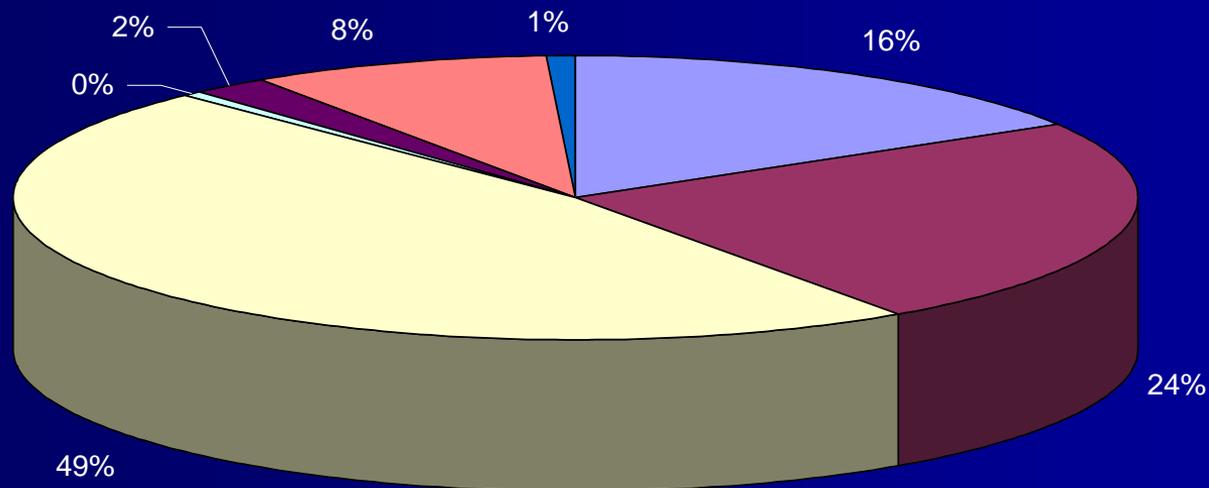
- Baseline/lifetime history
- Screening: Recent/Last Week/Past Month/6 months
- Since last assessment (whatever time period that may be)

Baseline –Worst Point Time Period

- Worst point found to be the most clinically meaningful
- Assessment of suicidal ideation at its worst point 14x more predictive of suicide than current ideation (Beck, 1999)
- Reporting lifetime suicidal ideation on C-SSRS at screening associated with increased chance of reporting suicidal behavior, Fisher's exact test $p = 0.0008$, during the trial (TASA)

Utilization of 1:1

Utilization Reason
2nd Quarter 2010
Overall Hospital



Legend: ■ Fall Risk ■ Suicide ■ Behavior ■ Elopement ■ Substance Withdrawal ■ Protect Medical Devices ■ Other Safety

■ Other reasons include: Family Request and Level of Care

Extremely Feasible and Low-Burden

- Who can administer the C-SSRS?
 - Need to be trained
 - Do not have to be a Mental Health Professional to administer this scale; thousands of health professionals have been trained
 - Examples: Any type of physician, psychologist, clinical social worker, mental health counselor, nurse, coordinator

Can be computer-administered, self-report via phone

Inter-Rater Reliability

- 812 health care professionals at Reading Hospital trained on the C-SSRS
- Cronbach's Alpha and the Inter-rater reliability show high agreement
→ ***The average person trained on the C-SSRS will rate cases correctly***
- ***No significant difference*** in successful rating of cases irrespective of gender, highest level of education, years of experience, mental health experience, or prior formal suicide assessment training.

Two-Way Random Inter-Rater Reliability					
	Cronbach's Alpha	Single Measure	Average measure	Number of Raters	Number of Vignettes
Consistency	0.999	.655	.999	812	14
Absolute Agreement	0.999	.653	.999	812	14

Inter-Rater Reliability / Feasibility

- No mental health training required (nurses, coordinators, etc.)
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Two-Way Random Intra-Rater Reliability					
	Cronbach's Alpha	Single Measure	Average measure	Number of Raters	Number of Vignettes
Consistency	0.999	.655	.999	812	14
Absolute Agreement	0.999	.653	.999	812	14

Public Health Burden.....

- Attempters constitute high proportion of all emergency referrals to psychiatric services and subsequently command disproportionate level of resources

eC-SSRS – Very Few “Serious” or Referrals

- Low positive response rates:
 - Most Serious Ideation **Baseline:**
 - Q4 Intent? 175 (7.6%)
 - Q5 Plan and Intent? 144 (6.2%)
 - Most Serious Ideation **Since Last Call:**
 - Q4 Intent? 57 (0.7%)
 - Q5 Plan and Intent? 7 (0.1%)
 - Suicidal Behaviors: **Since Last Call** calls (8342):
 - 1 attempt 8
 - 2 attempts 3
 - 3 or more attempts 1
 - Interrupted Attempt 36 (0.4%)
 - Aborted Attempt 45 (0.5%)
 - Preparatory Behavior 19 (0.2%)

Excellent Psychometrics for Adults & Adolescents

- Convergent validity
- Predictive validity
- Discriminant validity
- Inter-rater reliability
- Internal consistency
- Sensitivity to change

Advantages of Self-Report

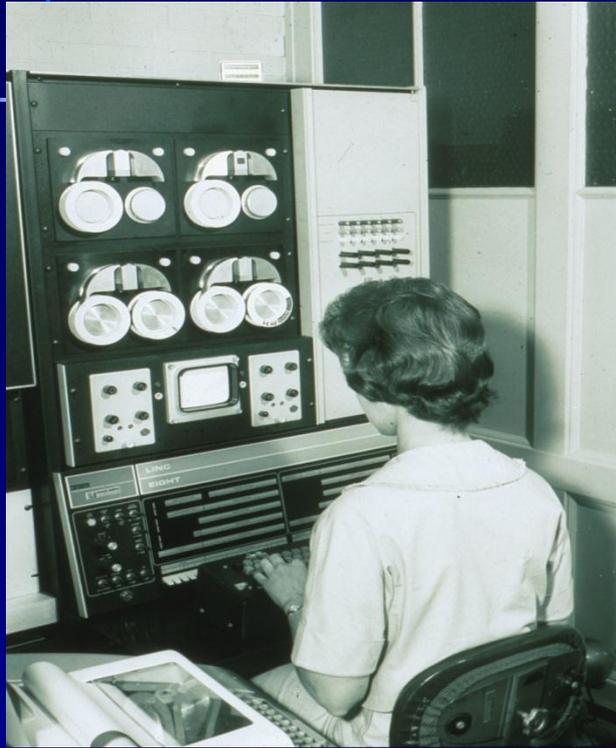
Reporting Sensitive Subject Matter

- Sexual functioning
- Substance use
- HIV risk factors

and... Suicidal ideation and behaviors

- Fewer false negatives with computer than clinician interview

History - 1973



**Computer-automated
assessment
of suicidality**

Circa 1973

“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.

Am J Psychiatry 130:12, December 1973

Recently - 2009

Adolescents in TADS Study

- “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 (i.e., C-DRSR).”

Is The Computer Better Than the Clinician?

- No, they're complementary, better together than either is alone.
- Most eC-SSRS reports are negative, needing only brief clinician review.
- Positive eC-SSRS reports organize and guide clinician review.

Notification Alerting

- Positive Findings
- Active Alerting
 - Call to Site
 - Speak to Clinician
- Site follows up as defined in protocol



C-SSRS: Baseline / Screening

SUICIDAL IDEATION		
<i>Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes," ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.</i>	Lifetime: Time He/She Felt Most Suicidal	Recent
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Data Confirmation...

4 and 5 Predicts Attempts in National Attempter Study

(Posner et al., *AJP* December 2011)

- C-SSRS Lifetime Ideation at baseline, types 4 and 5, predicted suicide attempts in adolescent suicide attempters, followed over a year
 - OR = 3.26, 95% CI: 1.02-10.45, $p = .047$
- C-SSRS Lifetime Ideation, types 4 and 5, predicted actual, interrupted or aborted attempts on CSHF
 - OR = 2.76, 95% CI: 1.07-7.12, $p = .036$
- Confirmed By e-CSSRS data: 35,000 across depression, epilepsy, insomnia, fibromyalgia
 - Patients with baseline **prior ideation of 4 or 5** or **prior behavior** are 4-5x more likely to report suicidal behavior at follow up than patients with negative baseline report.
 - Patients with **both** are 8x more likely to report suicidal behavior

Lessons Learned: Prior **Research and Clinical Practice**

- All previous antidepressant, anticonvulsant and other non-psychiatric trials were not set-up to adequately assess suicidal behavior and ideation
- Association does not mean causality
- FDA risk analyses for suicidal risk relied on spontaneously generated AEs
 - Maybe clinicians had more contact with subjects on active meds, and thus more opportunity to hear about suicidal occurrences
- May be 'false' or misleading results/Reasons other than causality
- Need to do better, systematic assessment

Inter-Rater Reliability / Feasibility

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- **99% reliability independent of mental health training and education**
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 - No significant difference in successful rating of cases irrespective of gender, highest level of education, years of experience, mental health experience, or prior formal suicide assessment training.

Finally.

Some Answers...?

***Centralized Data
Repository***

Baseline –Worst Point Time Period

- Worst point found to be the most clinically meaningful
- Assessment of suicidal ideation at its worst point 14x more predictive of suicide than current ideation (Beck, 1999)
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Feasibility

Iatrogenic

- Asking about suicidality does not cause distress or suicidality (Gould et al., JAMA 2005)

National Guard

SUICIDAL IDEATION		Lifetime: Time He/She Felt Most Suicidal	Past 1 month
<p>Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.</p>			
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<p><i>"Now, I'd like you to think about the time in your life when you were feeling the most suicidal. During that time..."</i></p>			
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C-SSRS Current Uses

In Clinical Trials

- Well over a million administrations
- Trials in Phases I-IV
- Drug/placebo; active controls; open maintenance
- Thousands of sites internationally, psychiatry and non-psychiatry
- 103 languages
- Measuring worsening and improvement
- Range of interventions: pharmacologic, device, psychotherapy, ECT

Within A Study

- Treatment benefit outcomes
- Safety outcomes
- Clinical safety monitoring
- Coordinated efficiently with other measures
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- Establishment of inclusion/exclusion criteria
 - Past exclusion arbitrary e.g. “serious risk”??
[criteria can be operationalized and assessed by C-SSRS
e.g. 4 or 5 on C-SSRS in past X months depending on phase/indication]

Various Uses of C-SSRS within Clinical and Institutional Settings

- Screening upon entry to a service
- Monitoring of outcome and safety
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SAFE VET Demonstration Project

- SAFE VET Executive Committee: Kerry Knox, Gregory Brown, Glenn Currier, Barbara Stanley
- Building on the success of the VA Suicide Prevention Coordinator Initiative, SAFE VET seeks to enhance the VA infrastructure by providing more support and guidance for identifying high risk veterans in community EDs, VA EDS and Urgent Care Units
- In place in five VAs: Manhattan, Philadelphia, Denver, Buffalo, Portland
- Uses Safety Planning and Follow-up with a specialized clinician to help suicidal patients discharged from the ED cope with future suicidal feelings and get engaged in recommended treatment

Risk Assessment

C-SSRS Suicide Risk Assessment Version (Excerpt)

Instructions: Check all risk and protective factors that apply. To be completed following the patient interview, review of medical record(s) and/or consultation with family members and/or other professionals.			
Suicidal and Self-Injury Behavior (Past week)*		Clinical Status (Recent)	
<input type="checkbox"/>	Actual suicide attempt	<input type="checkbox"/>	Lifetime
<input type="checkbox"/>	Interrupted attempt	<input type="checkbox"/>	Lifetime
<input type="checkbox"/>	Aborted attempt	<input type="checkbox"/>	Lifetime
<input type="checkbox"/>	Other preparatory acts to kill self	<input type="checkbox"/>	Lifetime
<input type="checkbox"/>	Self-injury behavior w/o suicide intent	<input type="checkbox"/>	Lifetime
Suicide Ideation (Most Severe in Past Week)*		<input type="checkbox"/>	Hopelessness
<input type="checkbox"/>	Wish to be dead	<input type="checkbox"/>	Major depressive episode
<input type="checkbox"/>	Suicidal thoughts	<input type="checkbox"/>	Mixed affective episode
<input type="checkbox"/>	Suicidal thoughts with method (but without specific plan or intent to act)	<input type="checkbox"/>	Command hallucinations to hurt self
<input type="checkbox"/>	Suicidal intent (without specific plan)	<input type="checkbox"/>	Highly impulsive behavior
<input type="checkbox"/>	Suicidal intent with specific plan	<input type="checkbox"/>	Substance abuse or dependence
Activating Events (Recent)		<input type="checkbox"/>	Agitation or severe anxiety
<input type="checkbox"/>	Recent loss or other significant negative event	<input type="checkbox"/>	Perceived burden on family or others
	Describe:	<input type="checkbox"/>	Chronic physical pain or other acute medical problem (AIDS, COPD, cancer, etc.)
		<input type="checkbox"/>	Homicidal ideation
<input type="checkbox"/>	Pending incarceration or homelessness	<input type="checkbox"/>	Aggressive behavior towards others
<input type="checkbox"/>	Current or pending isolation or feeling alone	<input type="checkbox"/>	Method for suicide available (gun, pills, etc.)
Treatment History		<input type="checkbox"/>	Refuses or feels unable to agree to safety plan
<input type="checkbox"/>	Previous psychiatric diagnoses and treatments	<input type="checkbox"/>	Sexual abuse (lifetime)
<input type="checkbox"/>	Hopeless or dissatisfied with treatment	<input type="checkbox"/>	Family history of suicide (lifetime)
<input type="checkbox"/>	Noncompliant with treatment	Protective Factors (Recent)	
<input type="checkbox"/>	Not receiving treatment	<input type="checkbox"/>	Identifies reasons for living
Other Risk Factors:		<input type="checkbox"/>	Responsibility to family or others; living with family
		<input type="checkbox"/>	Supportive social network or family
		<input type="checkbox"/>	Fear of death or dying due to pain and suffering
		<input type="checkbox"/>	Belief that suicide is immoral, high spirituality
		<input type="checkbox"/>	Engaged in work or school
Other Protective Factors:			

Risk Factors

- Risk assessment should include a review of risk and protective factors
- Risk factors typically carry more influence than protective factors
- Risk and protective factors are summarized

Risk Factors

- Two most important risk factors
 - Previous Suicide Attempt
 - Major Depressive Disorder

Psychiatric Disorder

- Psychiatric disorder is a risk factor for suicide
- 90% of people who die by suicide will have a psychiatric disorder
- Disorders of greatest risk
 - Depressive Disorders (greatest risk)
 - Bipolar Disorder (depressed or mixed phase)
 - Alcohol & Substance Use Disorders (high risk)
 - Schizophrenia/Psychosis
 - Borderline Personality Disorder
 - Anxiety Disorder
- Risk assessment should include an assessment of psychiatric disorder focusing on the disorders higher risk disorders but should not be limited to these disorders.

Additional Important Risk Factors

- Suicidal ideation
- Non-suicidal self-harming behavior
- Family history of suicide
- Hopelessness
- Recent stressful life event- e.g., relationship break-up, loss of job, legal problems.
- Divorced, widowed, or separated, particularly in males
- Unemployment
- Abuse (particularly childhood sexual or physical)
- Chronic Illness (epilepsy, MS, AIDS, stroke, MI)

Recent Activating Events

- Divorce, separation or other interpersonal loss
- Death of spouse/partner, family member, close friend
- Legal problems
- Financial difficulties, unemployment or change in job status
- Pending incarceration or homelessness
- Other loss or other significant negative event

Clinical Status

- Major depressive episode
- Mixed affective episode
- Substance abuse or dependence*
- Axis II Cluster B Personality Disorder
- Hopelessness, especially stable hopelessness
- Agitation or severe anxiety
- Social isolation or loneliness

Clinical Status

- Problem solving deficits
- Perceived burden on family or others
- Abrupt change in clinical status (improvement or deterioration)
- Highly impulsive behavior
- Homicidal ideation
- Aggressive behavior towards others

Clinical Status

- Chronic physical pain or other acute (or newly diagnosed) medical problem (AIDS, COPD, cancer, etc.)
- Method for suicide available (gun, pills, etc.)
- Physical or sexual abuse (lifetime)
- Family history of suicide (lifetime)
- Other traumatic experience (lifetime)

Psychiatric and Addiction Treatment History

- Previous psychiatric diagnoses and treatments
- Hopeless or dissatisfied with treatment
- Noncompliant with treatment
- Not receiving treatment
- Refuses or feels unable to agree to use a safety plan

C-SSRS Feasibility & Use

- Well over a million administrations
- Many thousands of settings
- 103 languages
- Measuring worsening and improvement
- Treatment benefit outcomes
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- Clinical safety monitoring
- Epidemiological

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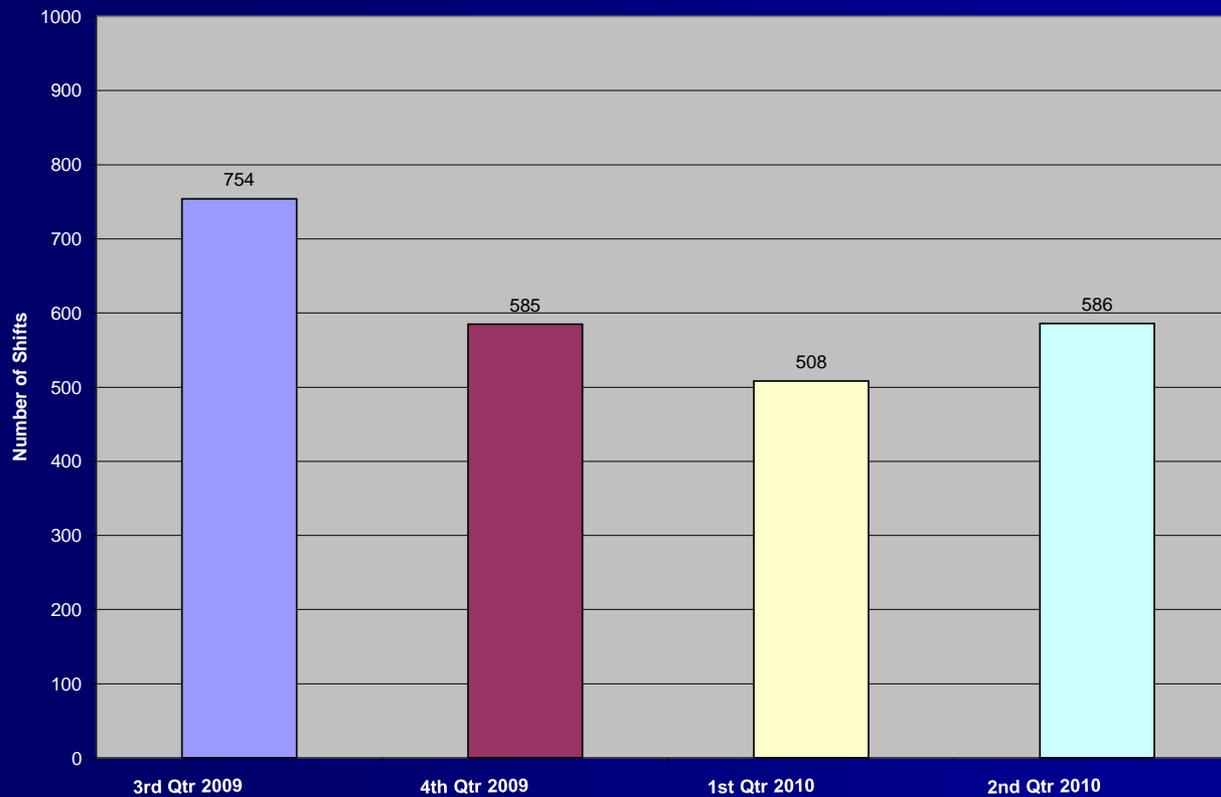
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“F.D.A. Requiring Suicide Studies in Drug Trials ” New York Times 1.24.08

- Most Profound Change in Drug Development Regulation in 16 Years
- “Researchers at Columbia University have developed a questionnaire to help systematically assess suicidal thoughts and behavior. The Food and Drug Administration is now requiring that drug companies adopt the methodology in their clinical trial.”

Decreasing Burden

Patient Safety Monitor Utilization For Suicides
Overall Inpatient Nursing



Most Common Diagnoses in Teen Suicides

	Male (N=213)	Female (N=46)
Depression	50%	69%
Antisocial	43%	24%
Substance Abuse	38%	17%
Anxiety	19%	48%

**66% of 16- to 19-Year-Old Male Suicides
Have Substance/Alcohol Abuse**

Suicide Attempt? Yes or No

The patient wanted to escape from her mother's home. She researched lethal doses of ibuprofen. She took 6 ibuprofen pills and said she felt certain from her research that this amount was not enough to kill her. She stated she did not want to die, only to escape from her mother's home. She was taken to the emergency room where her stomach was pumped and she was admitted to a psychiatric ward.

1. Yes
2. No
3. Not enough information

Decreases False Positives

PHQ-9

Thoughts that you would be **better off dead** or of **hurting yourself** in some way

HAM-D

3. Suicide

0 = Absent

1 = **Feels life is not worth living**

2 = Wishes he were dead or any thoughts of possible death to self

3 = Suicidal ideas or gestures

4 = Attempts at suicide (any serious attempt rates 4)

MADRS

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicide attempts should not in themselves influence the rating.

0 = Enjoys life or takes it as it comes.

2 = **Weary of life**. Only fleeting suicidal thoughts.

4 = **Probably better off dead**. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.

6 = Explicit plans for suicide when there is an opportunity. Active preparations for suicide.

Data confirm that when item followed by C-SSRS, eliminate cases that should not have been called suicidal

Thus C-SSRS reduced false positives

Potential Liability Protection

“If a practitioner asked the questions...
It would provide some legal protection”

—Bruce Hillowe, mental health attorney specializing in malpractice litigation

Time Frames: Lifetime

- Behavior is “ever”
 - Capture all lifetime occurrences (e.g. total number of attempts ever)
- For Ideation and Intensity of Ideation, time he/she was feeling the most suicidal (as opposed to average across life)
 - “The time in your life you were feeling the most suicidal, did you wish you were dead, have thoughts of actually killing yourself...” etc

Feasibility / No Mental Health Training Required

- **No mental health training required** (nurses, coordinators, etc.)
- **99% reliability independent of mental health training and education**
- 812 health care professionals at Reading Hospital trained on the C-SSRS
 - The Cronbach's Alpha and the Intra-rater reliability demonstrate that the average person trained on the C-SSRS will rate cases correctly
 - No significant difference in successful rating of cases irrespective of gender, highest level of education, years of experience, mental health experience, or prior formal suicide assessment training.

Correspondence from the EMEA to the London Times

- "European legislation for both clinical trials and marketing authorization of medicines has established clear procedures to report and evaluate any suicidal event. **The use of the Columbia University Questionnaire to systematically assess suicidal thoughts and behaviors has been required for a number of ongoing developments in the context of the EMEA Scientific Advice procedure.** In addition, the issue of suicidality is regularly addressed during pre-authorization evaluation of new medicines (centralized procedure and also referrals in the context of mutual recognition and decentralized authorization procedures), usually at the time of the initial assessment report (Day 80) of the Agency's Committee for Medicinal Product for Human Use (CHMP) and when specific questions are issued to the Applicant at Day 120. **Suicidality may be addressed by reports, as mentioned above, but also during the evaluation of new medicinal products based on: a Central mechanism of action; for example a Central Nervous System active substance like a new anti-epileptic,** a target population, like patients suffering from major depression, bipolar disorder, or frequent concomitant conditions in the target population, like depression/anxiety during smoking cessation.

Conclusions

- Intervention trials using prospective and systematic measurement of suicidal behavior/ideation would more clearly delineate the relationship between suicidal adverse events and medication treatment
- Consistent and systematic assessment (e.g. C-SSRS) can provide more meaningful data within a study, as well as across studies, improving pooled analyses
- Decreasing false positives and debunking false notions of risk are as important as knowing about risks that exist

**So we identified....What
next?**

Safety Planning with Suicidal Individuals: A Quick Therapeutic Intervention

The Safety Planning Intervention
(Stanley & Brown, 2008)

Intervention with Suicidal Individuals

- Majority of suicidal individuals who commit suicide do so on their first attempt
- Only a small percentage of suicide attempts are seen in the emergency room
- The most frequent professional contact prior to suicide is the primary care physician, not a mental health professional
- High risk period---3 months following an attempt

- Rudd et al. (1996) found that suicidal patients are very difficult to engage in treatment.
- 11% to 50% of attempters refuse outpatient treatment or drop out of outpatient therapy quickly (Kurz & Moller, 1984).
- Up to 60% of suicide attempters do not even attend more than one week of treatment post-discharge from the ED (O'Brien et al., 1987; Granboulan, et al., 2001; King et al., 1997; Piacentini et al., 1995; Trautman et al., 1993; Spirito et al., 1989; Taylor & Stansfield, 1984; Kurz & Moller, 1984; Litt et al., 1983).
- Of those who do attend treatment, 3 months after hospitalization for an attempt, 38% have stopped outpatient treatment (Monti et al., 2003)
- After a year, 73% of attempters will no longer be in any treatment (Kruee & Hales 1988).

Brief Interventions for Suicidal Patients

- Current specialized psychotherapies (e.g. CT, DBT) for suicidal patients are labor intensive and require extensive training, and, as such, may not be feasible to use for all clinicians assessing and treating suicidal patients
- Simple, straightforward strategies that include immediate intervention ought to be considered for suicidal patients
- Crisis contact may be the ONLY contact the suicidal individual has with the mental health system; many patients refuse further treatment or drop out after one or two sessions
- If the crisis contact is seen by patients as helpful, they may be more willing to seek ongoing treatment

Safety Plan: What is it?

- Prioritized written list of coping strategies and resources for use during a suicidal crisis.
- Helps provide a sense of control.
- Uses a brief, easy-to-read format that uses the patients' own words.
- Enhances commitment to treatment.

Safety Planning Intervention

Safety Planning Intervention, that incorporates elements of four evidence-based suicide risk reduction strategies:

1. Means restriction
2. Teaching brief problem solving and coping skills (including distraction)
3. Enhancing social support and identifying emergency contacts
4. Motivational enhancement

Safety Plan: What it's not

- Safety Plans are not “no-suicide contracts”
- No-suicide contracts ask patients to promise to stay alive without telling them how to stay alive
- May serve to “protect” the institution or therapist more than the patient
- Virtually no empirical evidence to support effectiveness of no-suicide contracts

Safety Plan: Why do it?

- Development and implementation of a safety plan IS treatment
- Should be the first intervention with a suicidal patient
- Helps to immediately enhance patients' sense of control over suicidal urges and thoughts and conveys a feeling that they can "survive" suicidal feelings
- Similar to fire drill or rehearsal

SAFE VET Approach

Use the emergency visit as an opportunity to intervene:

1. To mitigate suicide risk to help patients identify their personal obstacles
2. To enhance motivation to attend treatment regularly and to problem solve to remove obstacles

Provide follow-up contact to:

1. Enhance safety
2. Encourage ongoing treatment attendance

Treatment is Critical

- Treatment of the underlying disorder reduces the risk of suicide
- 90% of the individuals who commit suicide have an untreated mental illness, mostly depression
- Under treatment of mental illness is pervasive
 - Alonso et al. (2007) reported that 48% of those in need were not receiving treatment

Potential “Activation” Syndrome

**Defined as Treatment-Emergent
Hostility or Agitation**

Overall relative risks of treatment-emergent agitation or hostility by drug in MDD trials

Drug	Relative Risk (95% CI), MDD trials
Citalopram	1.87 (0.34, 10.13)
Paroxetine	7.69 (1.80, 32.99)
Fluoxetine *	1.01 (0.40, 2.55)
Sertraline	2.92 (0.31, 27.83)
Venlafaxine	2.86 (0.78, 10.44)
Mirtazapine	0.52 (0.03, 8.27)
Nefazodone	1.09 (0.53, 2.25)
All drugs	1.79 (1.16, 2.76)

* Note that TADS data are NOT added to Prozac

- Bhatia et al., 2008

- Clinicians in Nebraska decrease prescriptions of antidepressants to pediatric patients
- Over 20% of clinicians reported a caregiver or patient had refused antidepressant medication treatment due to the FDA's black box warning

American Academy of Child & Adolescent Psychiatry Survey

- When asked what they were doing about black box warning, over 1/3 psychiatrists said changing to atypical antipsychotics

The Columbia Suicide Severity Rating Scale in the Age of Budget Cuts:

Increasing Precision and Redirecting Scarce Resources

and What We Really Know about Suicide and Medications: Practice Implications

Kelly Posner, Ph.D.

Principal Investigator Columbia/FDA Classification Project for Drug Safety Analyses

Principal Investigator Center for Suicide Risk Assessment Columbia University

Suicide Risk Assessment and the Columbia-Suicide Severity Rating Scale (C-SSRS)

Improved Precision With Reduced Burden

***Posner, K.; Brent, D.; Lucas, C.; Gould, M.; Stanley, B.; Brown, G.; Zelazny, J.;
Fisher, P.; Burke, A.; Oquendo, M.; Mann, J.***

Kelly Posner, Ph.D.

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***Principal Investigator Center for Suicide Risk Assessment Columbia
University***

Conclusions

- Suicide is a preventable public health problem
- Systematically assessing using the C-SSRS *decreases* burden
- C-SSRS is extremely feasible and low-burden
- Decreasing false positives and debunking false notions of risk are as important as knowing about risks that exist

On the Road to Prevention:
**Using the Columbia-Suicide Severity
Rating Scale to Increase Precision
and Redirect Scarce Resources**

*Posner, K.; Brent, D.; Lucas, C.; Gould, M.; Stanley, B.; Brown, G.; Zelazny, J.;
Fisher, P.; Burke, A.; Oquendo, M.; Mann, J.*

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University***

Various Uses of C-SSRS Within a Service

- Screening upon entry to a service
- Monitoring of outcome and safety
- Component of comprehensive Suicide Risk Assessment
- Measuring improvement and worsening
- Monitoring of Suicidal Adverse Events during pharmacological (or psychosocial) treatment
- Collection of epidemiological data

Scope of the Problem: Depression

- World Health Organization Predicts that depression will be second most burdensome disease by the year 2020 (Murray & Lopez, 1997)

Suicide Among War Veterans

- Every day, 18 veterans die by suicide, 5 of whom are in the VA system
- 1000 Veterans attempt suicide every month
- Women veterans are 2x more likely to die by suicide than non-veterans.
- Of Oregon veterans who died by suicide, >50% had contact with Portland VA Medical Center 30 days before they died. All had some contact with VA health system in the year before they died
- The suicide rate among veterans aged 20-24 was 22.9 per 100,000 in 2007—four times higher than non-veterans in the same age bracket.

PTSD and Suicidal Ideation in War Veterans

- PTSD significantly associated with suicidal ideation after accounting for age, depression and substance abuse
- PTSD veterans over 4X more likely to report suicidal ideation than veterans without PTSD
- The likelihood for suicidal ideation is 5.7X greater in vets with PTSD and 2+ comorbidities
 - OIF/OEF veterans diagnosed with a mental disorder, 27% have 3+ different mental health diagnoses

Systematic vs. Spontaneous Data: Different Results

- FDA pediatric antidepressant analyses systematic item data – no signal
- Many other analyses point in an inconsistent direction...
 - Large data sets from sponsors, item data show no risk
 - Always same direction, if AE shows nothing, item data show improvement of suicidal behavior/ideation
- TADS: AE data showed risk, systematic suicide assessment did not.
- 5-year pediatric SSRI (escitalopram) study using C-SSRS (*Emslie et al., AACAP; 2008*)

Prediction in Adolescents

“Using the C-SSRS to Assess Adolescents in Psychiatric Emergency Settings”

(King et al., 2012)

Severity at index visit is **significant predictor of subsequent suicide attempt** (broadly defined to include aborted and interrupted); $p = 0.035$

	Suicide Attempt* ($n = 10$) M (<i>SD</i>)	No Suicide Attempt ($n = 77$) M (<i>SD</i>)
Frequency	3.30 (1.57)	2.88 (1.42)
Duration**	3.10 (1.20)	2.09 (1.13)
Controllability	2.70 (1.89)	2.74 (1.43)
Deterrents	1.81 (1.29)	1.40 (1.58)
Reasons for Ideation	3.90 (0.74)	3.19 (1.32)
Total Score	14.40 (4.25)	12.18 (5.45)

*Suicide Attempt is broadly defined to include interrupted and aborted attempts

** = $p < .01$

Note: Logistic Regression full model $p < .01$

N=289 psychiatrically hospitalized suicidal adolescents (ages 12-17 years) followed up one year later

Prediction in Adolescents

“Using the C-SSRS to Assess Adolescents in Psychiatric Emergency Settings”
(Cont’d)

(King et al., 2012)

- Neither past week nor lifetime history of suicide attempt at index visit predict suicide attempt during follow-up (defined with and without aborted and interrupted attempts).
- Nonsuicidal Self-injurious behavior at index visit does not predict suicide attempt during follow-up.
- Nonsuicidal Self-injurious behavior at baseline does predict return visits for psychiatric services ($p = .029$)
 - Among adolescents reporting self-injurious behavior at index visit, 44.6% returned to emergency services within eight months (versus 28.3%)

eC-SSRS Assessments of Lifetime Ideation and Behavior are Predictive of Suicidal Behaviors Occurring During Trial Participation

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Abstract

Introduction: Safety concerns regarding suicidality in clinical trials resulted in the release of FDA draft guidance in September, 2010. Prospective assessment of suicidal ideation and behavior in clinical trials was recommended, and the Columbia Suicide Severity Rating Scale (C-SSRS) was identified as an acceptable instrument. Alternative administration methods, such as interactive voice response (IVR) technology, were also acceptable. The feasibility, reliability, and validity of the eC-SSRS have been demonstrated and it has been incorporated into many clinical trials. This poster examines the importance of lifetime suicidal ideation and behavior assessed at baseline in relation to prospective risk for suicidal behavior occurring during trial participation.

Methods: 35,224 eC-SSRS records from ongoing and completed studies were extracted from a centralized database in May 2011. Data from 14 studies (7 Major Depression, 3 Insomnia, 2 Epilepsy, 1 Post-Traumatic Stress Disorder, and 1 Fibromyalgia study) were merged and 217 records (0.6%) were excluded due to incompleteness, an early system implementation error, and under-representation of **Fibromyalgia** subjects. Each record included study, site, and subject IDs, date/time stamps for start and end of each assessment, and subject responses to the eC-SSRS queries.

Results: Each eC-SSRS assessment (6,308 baseline/lifetime; 28,699 prospective follow-ups) was scored with respect to reported suicidal ideation and/or behavior. Lifetime ideation with an intention to act was reported at baseline by 14.1% of subjects; 27.3% reported prior suicide-related behavior. A baseline and one or more prospective follow-ups were provided by 3,776 subjects (Mean of 6.3 visits and 63.7 days of follow-up). The percentages of subjects prospectively reporting suicidal behaviors during study participation, related to lifetime ideation and behavior are shown below. These data show that subjects who report lifetime suicidal ideation that includes a method or plan with intent and/or prior suicidal behavior at baseline are four to eight times more likely to prospectively report a suicidal behavior during study participation than subjects without lifetime ideation or behavior.

Baseline Report & Lifetime Ideation (+); Behavior (-)	N	Prospectively Reported Suicidal Behavior	Relative Risk
Ideation (+); Behavior (-)	2,792 (73.9%)	2.4%	1.00
Ideation (+); Behavior (+)	75 (2.0%)	12.9%	5.00
Ideation (-); Behavior (-)	478 (12.7%)	8.6%	4.01
Ideation (-); Behavior (+)	431 (11.4%)	18.3%	7.64

Conclusion: Improved precision for suicide monitoring in clinical trials is critically important. The eC-SSRS is an efficient and effective tool for prospectively monitoring treatment safety and benefit. Subjects reporting lifetime suicidal ideation with intent to act, prior suicidal behavior, or both, at baseline assessments, are at greater risk of prospectively reporting suicidal behavior during trial participation.

Introduction

Questions concerning suicidal ideation and behavior have been raised in randomized clinical trials involving both pediatric and adult patients. The FDA drafted industry guidance in September 2010 entitled "Suicidality: Prospective Assessment of Occurrence in Clinical Trials."

The C-SSRS and the eC-SSRS, a validated computer-administered version of the interview, are acceptable to the FDA for prospectively monitoring suicidal ideation and behavior in clinical trials and have been used in many studies.

The drafted guidance represented current thinking with respect to assessing suicidal ideation and behavior in clinical trials, and recommended prospective assessment and active querying of patients at baseline and at each subsequent visit. The prospective counterpart to the Columbia Classification Algorithm of Suicide Assessment (C-CASA) is the Columbia Suicide Severity Rating Scale (C-SSRS), which assesses the severity and frequency of suicidal ideation, different types of suicidal behavior, and the lethality of suicide attempts.

The primary objectives of the Guidance were to (1) ensure timely recognition and treatment of patients experiencing suicidal ideation and behavior during study participation, and (2) promote more timely, complete, and systematic collection of suicidal ideation and behavior data to improve detection of change should such occur.

Public comments in response to the FDA draft guidance raised some concern about the relevance of lifetime severity of suicidal ideation and behavior assessed at baseline on patient risk for subsequently engaging in suicidal behavior during study participation. The infrequent occurrence of suicidal behavior in clinical trials makes it difficult to address such concerns on a study-by-study basis. However, electronically stored eC-SSRS data permit relatively easy aggregation of records across multiple studies to address such issues.

As indicated in the FDA Guidance, using the prospective C-SSRS means no further mapping should be done to the retrospective C-CASA adverse event classification system.

Methods

All 35,224 eC-SSRS assessments administered to clinical research participants between September 2009 and May 2011 were extracted from a central database for analysis.

Records from 14 clinical studies (7 MDD, 3 Insomnia, 2 Epilepsy, 1 PTSD, and 1 Fibromyalgia) were extracted.

Each record included an ID number for the study, site, and subject, a date/time stamp for the start and end of each assessment, and the subjects' responses to each eC-SSRS question. No demographic, treatment, and/or personally identifying information were available.

217 records were excluded from the analysis; these included the 6 baseline assessments from the recently started Fibromyalgia study, 10 assessments from an early programming error that predated system correction, and 201 incomplete assessment records.

- 161 of the incomplete eC-SSRS records were later followed by a completed assessment for that subject the same day

The remaining eC-SSRS records (35,007) were scored with respect to the presence or absence of suicidal ideation and/or behavior.

- The most severe suicidal ideation reported during the assessment was scored along the 5-point severity sub scale of the C-SSRS.
- Reported suicidal behaviors identified by the C-SSRS behavior subscale were also documented.

Results

35,007 eC-SSRS records were evaluated

- 6,308 Baseline Calls
- 28,699 Follow-up Calls

Each eC-SSRS report categorized as "Positive" or "Negative"

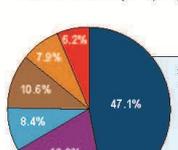
- Positive reports (N = 2,220): Suicidal ideation severity of 4/5, OR actual, aborted, or interrupted suicide attempts or preparatory behavior
- Negative reports (N = 52,787): All cases not meeting these criteria

Assessment burden

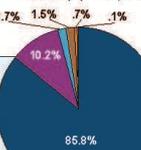
- On average, eC-SSRS assessments took 3.8 minutes and 10.3 responses to queries to complete
- Positive eC-SSRS assessments took an average of 7.7 minutes and 22.7 responses to complete
- Negative eC-SSRS assessments took an average of 3.0 minutes and 9.4 responses to complete

Most Severe Suicidal Ideation

Baseline Lifetime (n = 6,308)

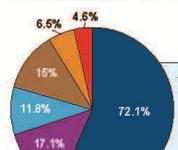


Follow-up (n = 28,699)

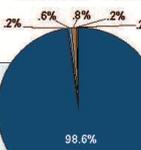


Suicidal Behavior

Baseline Lifetime (n = 6,308)



Follow-up (n = 28,699)



Descriptive statistics across all eC-SSRS follow-up assessments for each clinical population

	Total assessments	Total follow-up assessments	Mean number of follow-ups	Mean days of follow-up	Mean days between follow-ups	Negative reports	Positive reports
MDD	4713	27,524 (96.3%)	6.4	68.0	12.1	27,122	403
PTSD	132	7811 (79.3)	6.0	67.0	12.1	7,619	192
Insomnia	180	2,261 (93%)	1.3	51.3	40.9	2,260	0
Epilepsy	28	41 (1.4%)	2.0	99.4	91.8	47	0
TOTAL	5052	28,699	5.7	84.4	14.9	28,205	494

Conclusions

Suicidal behavior is rare, even in clinical trials that involve 'high-risk' patients, but the risk is real and the need to protect patients and improve data quality are of paramount importance.

The eC-SSRS is efficient and effective for collecting lifetime reports of suicidal ideation and behavior at baseline, and for prospectively monitoring ideation and behavior at subsequent visits.

eC-SSRS assessment methods with electronic data capture and immediate feedback of results address the objectives of the FDA guidance for monitoring suicide ideation and behavior in clinical trials.

Subjects with Positive baseline reports due to either lifetime ideation with intent to act or prior suicidal behavior are 4 to 8 times more likely to report suicidal behavior during study participation than patients with Negative baseline reports. Subjects Positive for both at baseline are nearly 8 times more likely to report suicidal behavior during the trial.

Prospective Reports of Suicidal Behavior during Study Participation

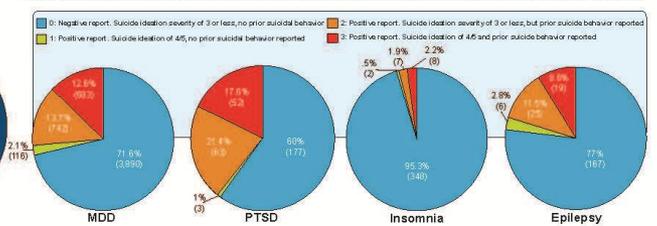
3,776 subjects provided a baseline and one or more follow-up eC-SSRS assessments

18,513 follow-up assessments were completed; 296 (1.6%) were prospective reports of a suicidal behavior since last contact

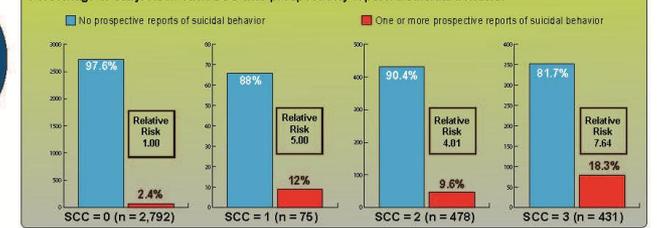
201 of the 3,776 subjects prospectively reported a suicide attempt, interrupted or aborted attempt, or preparatory behavior

- 197 were MDD subjects
- 4 were PTSD subjects
- 48 subjects reported suicidal behavior at multiple visits

Safety Concern Codes (SCC): Baseline Assessments of Lifetime Suicidal Ideation and Behavior



Percentage of subjects in each SCC who prospectively reported suicidal behavior



Study Limitations

These data are predominantly from depressed patients, with many fewer assessments of patients with PTSD, Insomnia, and Epilepsy.

These data do not address whether the recency of lifetime ideation and behavior reported at baseline, relative to the time at which the baseline report was obtained, influences the likelihood of suicidal behavior occurring during study participation.

The analyses do not address the extent to which the prospective reports of suicidal behavior obtained were confirmed by clinical follow-up, or the extent to which feeding back the eC-SSRS results influenced subsequent clinical care provided to the subject.

The data extracted for these analyses cannot address potential differences between treatment conditions.

Conflict of Interest Statement:

ERT provided electronic patient reported outcome services to industry-sponsored clinical trials, including eC-SSRS assessments. University funds are provided to the Research Foundation for Mental Hygiene and Healthcare Technology Systems for delivery of eC-SSRS™ assessments.
 Dr. Greist is a consultant to Healthcare Technology Systems and ERT and has minor stock holdings in each company.
 Dr. Greist is a principal stock shareholder of Healthcare Technology Systems.
 Dr. Posner is Director of the Center for Suicide Risk Assessment at the Research Foundation for Mental Hygiene. Dr. Posner received funding from the eC-SSRS and he center, the Columbia Center for Suicide Risk Assessment, receives research support from pharmaceutical companies.

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Additional Features Assessed

- Lethality of Attempts; Compilation of Beck Medical Lethality Rating Scale
- Other Features of Ideation: Intensity
 - Frequency
 - Duration
 - Controllability
 - Reasons for Ideation
 - Deterrents

****All these items significantly predictive of death by suicide (on SSI)/minimum amount of info needed for tracking and severity***

C-SSRS Format and Administration

- Allows for utilization of *multiple sources* of information
 - Any source of information that gets you the most clinically meaningful response (subject, family members/caregivers, records)
- Semi-structured – flexible format
 - Questions are provided as helpful tools – it's not required to ask any or all questions - just enough to get the appropriate answer

C-SSRS: Baseline / Screening

"Past X months"

Depending on exclusion criteria: (Screening: Recent / Last Week / Past Month / 6 Months)

SUICIDAL IDEATION			
<i>Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes," ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.</i>	Lifetime: Time He/She Felt Most Suicidal	Recent	
<p>1. Wish to be Dead Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up. <i>Have you wished you were dead or wished you could go to sleep and not wake up?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	
<p>2. Non-Specific Active Suicidal Thoughts General non-specific thoughts of wanting to end one's life/commit suicide (e.g. "I've thought about killing myself") without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period. <i>Have you actually had any thoughts of killing yourself?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	
<p>3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g. thought of method to kill self but not a specific plan). Includes person who would say, "I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it.....and I would never go through with it". <i>Have you been thinking about how you might do this?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	
<p>4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan Active suicidal thoughts of killing oneself and subject reports having <u>some intent to act on such thoughts</u>, as opposed to "I have the thoughts but I definitely will not do anything about them". <i>Have you had these thoughts and had some intention of acting on them?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	
<p>5. Active Suicidal Ideation with Specific Plan and Intent Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out. <i>Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?</i></p> <p>If yes, describe:</p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>Yes No</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	

Hospital Screening/ Triage (Reading Hospital)

SUICIDE IDEATION DEFINITIONS AND PROMPTS:

Ask questions that are **bolded and underlined**. The remaining information is for staff only.

Yes	No
-----	----

Ask questions 1 and 2

1) Wish to be Dead:

Person endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
In the past week, have you wished you were dead, or wished you could go to sleep and not wake up?

2) Suicidal Thoughts:

General non-specific thoughts of wanting to end one's life/commit suicide, "I've thought about killing myself" without general thoughts of ways to kill oneself/associated methods, intent or plan.
In the past week, have you had any actual thoughts of killing yourself?

If YES to 2: Ask Question 3.

3) Suicidal Thoughts with method (without Specific Plan or Intent to Act):

Person endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place, or method details worked out. "I thought about taking an overdose but I never made a specific plan as to when, where, or how I would actually do it...and I would never go through with it."
In the past week, have you been thinking about how you might do this?

If NO to 2 or NO to 3, skip to Question 6 and stop there

If YES to Question 3, ask Question 4 and 5, Do NOT ask Question 6

4) Suicidal Intent (without specific plan):

Active suicidal thoughts of killing oneself and patient reports having some intent to act on such thoughts, as opposed to "I have the thoughts but I definitely will not do anything about them."
In the past week, have you had these thoughts and had some intention of acting on them?

5) Suicidal Intent With Specific Plan:

Thoughts of killing oneself with details of plan fully or partially worked out, and person has some intent to carry it out.
In the past week, have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

PT #:



A80580

**COLUMBIA-SUICIDE SEVERITY
RATING SCREEN VERSION**

Hospital Screening/ Triage (Reading Hospital)

SUICIDE IDEATION DEFINITIONS AND PROMPTS:

Ask questions that are bolded and underlined. The remaining information is for staff only.

Yes	No

6) Suicide Behavior Question:

Have you ever done anything, started to do anything, or prepared to do anything with any intent to die?

Examples: Attempt: Took pills, shot self, cut self, jumped from a tall place; Preparation: Collecting pills, getting a gun, giving valuables away, writing a suicide or goodbye note, etc.)

If YES, ask: **How long ago did you do any of these?**

- More than a year ago? Between a week and a year ago? Within the last week?

II. TRHMC Response Protocol to C-SSRS Screening (Linked to last item answered YES)

Item 1 - Mental Health Referral at Discharge

Item 2 - Mental Health Referral at Discharge

Item 3 - Care Team Consult (Psychiatric Nurse) and Patient Safety Monitor/Procedures

Item 4 - Psychiatric Consultation and Patient Safety Monitor/Procedures

Item 5 - Psychiatric Consultation and Patient Safety Monitor/Procedures

Item 6 - If more than a year ago, Mental Health Referral at discharge

If between 1 week and 1 year ago - Care Team Consult (Psychiatric Nurse) and Patient Safety Monitor

If one week ago or less - Psychiatric Consultation and Patient Safety Monitor

Disposition: Mental Health Referral at discharge

Care Team Consult (Psychiatric Nurse) and Patient Safety monitor/Procedures

Psychiatric Consultation and Patient Safety Monitor/Procedures

If reassessment, please identify the stressors since initial C-SSRS assessment. If none, please write NONE in box.

Signature of Nurse/Person Completing Form _____

Date _____

Time _____

Printed Name of Nurse/Person Completing Form _____

PT #:



AS0580

**COLUMBIA-SUICIDE SEVERITY
RATING SCREEN VERSION**

C-SSRS Suicide Risk Assessment Version (Excerpt)

Instructions: Check all risk and protective factors that apply. To be completed following the patient interview, review of medical record(s) and/or consultation with family members and/or other professionals.			
Suicidal and Self-Injury Behavior (Past week)*		Clinical Status (Recent)	
<input type="checkbox"/>	Actual suicide attempt	<input type="checkbox"/>	Lifetime
<input type="checkbox"/>	Interrupted attempt	<input type="checkbox"/>	Lifetime
<input type="checkbox"/>	Aborted attempt	<input type="checkbox"/>	Lifetime
<input type="checkbox"/>	Other preparatory acts to kill self	<input type="checkbox"/>	Lifetime
<input type="checkbox"/>	Self-injury behavior w/o suicide intent	<input type="checkbox"/>	Lifetime
Suicide Ideation (Most Severe in Past Week)*		<input type="checkbox"/> Hopelessness	
<input type="checkbox"/>	Wish to be dead	<input type="checkbox"/>	Major depressive episode
<input type="checkbox"/>	Suicidal thoughts	<input type="checkbox"/>	Mixed affective episode
<input type="checkbox"/>	Suicidal thoughts with method (but without specific plan or intent to act)	<input type="checkbox"/>	Command hallucinations to hurt self
<input type="checkbox"/>	Suicidal intent (without specific plan)	<input type="checkbox"/>	Highly impulsive behavior
<input type="checkbox"/>	Suicidal intent with specific plan	<input type="checkbox"/>	Substance abuse or dependence
Activating Events (Recent)		<input type="checkbox"/>	Agitation or severe anxiety
<input type="checkbox"/>	Recent loss or other significant negative event	<input type="checkbox"/>	Perceived burden on family or others
	Describe:	<input type="checkbox"/>	Chronic physical pain or other acute medical problem (AIDS, COPD, cancer, etc.)
		<input type="checkbox"/>	Homicidal ideation
		<input type="checkbox"/>	Aggressive behavior towards others
<input type="checkbox"/>	Pending incarceration or homelessness	<input type="checkbox"/>	Method for suicide available (gun, pills, etc.)
<input type="checkbox"/>	Current or pending isolation or feeling alone	<input type="checkbox"/>	Refuses or feels unable to agree to safety plan
Treatment History		<input type="checkbox"/>	Sexual abuse (lifetime)
<input type="checkbox"/>	Previous psychiatric diagnoses and treatments	<input type="checkbox"/>	Family history of suicide (lifetime)
<input type="checkbox"/>	Hopeless or dissatisfied with treatment	Protective Factors (Recent)	
<input type="checkbox"/>	Noncompliant with treatment	<input type="checkbox"/>	Identifies reasons for living
<input type="checkbox"/>	Not receiving treatment	<input type="checkbox"/>	Responsibility to family or others; living with family
Other Risk Factors:		<input type="checkbox"/>	Supportive social network or family
		<input type="checkbox"/>	Fear of death or dying due to pain and suffering
		<input type="checkbox"/>	Belief that suicide is immoral, high spirituality
		<input type="checkbox"/>	Engaged in work or school
		Other Protective Factors:	

Risk Factors for Active Duty

- Medical downgrading (*AJP*, 2005)
- Access to weapons (*AJP*, 2005)
- Enlisted Rank (*Military Suicide Risk Assessment*, 2003)
- Re-entry after deployment or new assignment (*Military Suicide Risk Assessment*, 2003)
- Pending separation retirement
- Exposure to violence, exposure to war, being wounded, trauma, and depression (Bryan et al., 2010)

Military Culture

- “Manning up”
 - “Fault” or weakness (their problem)
- Not a help-seeking culture

Child and Family Assistance Center Version (continued)

<p>4. Marital, Relationship, or Family Stress</p> <p><i>Are you having marital, relationship, or family stress or problems?</i></p> <p>*Ask about domestic violence</p>		
<p>5. Drug or Alcohol Use</p> <p><i>Do you, or does anyone in the family, use drugs or alcohol?</i></p> <p><i>Do you, or does anyone in the family, have a history of drug or alcohol abuse?</i></p> <p>Additional Information:</p>		
<p>6. Pain</p> <p><i>Are you, or is anyone in the family, experiencing pain – chronic or intermittent?</i></p> <p>Additional Information:</p>		

Multisite National Trials

- International Study to Predict Optimized Treatment - in Depression (iSPOT-D)
- Collaborative Lithium Trials (COLT) under NICHD contract
- ED-SAFE
- RAISE schizophrenia study
- NIAAA - testing medications for alcoholism treatment
- NIMH funded ED study with youth - Cincinnati Children's Hospital
- Multisite NIH trial
- Registry study (natural history database of HD-affected, family members, and controls)
- NIH AED trials
- NIDA-funded clinical trial of bupropion for adolescent methamphetamine abusers
- NIH-funded trial for bipolar depression
- Preschool ADHD Treatment Study

International Agencies

- National Suicide Prevention Program, Israel
- Health Canada
- Israel Health Ministry
- Korean Association for Suicide Prevention
- Japanese National Institute of Mental Health and Neurology
- FDA
- European Medicines Agency (EMA)
- MHRA
- VA/Maryland Army National Guard
- Israeli Defense Force

A word about screening... also critical to prevention

- Primary Care: Opportunity for Prevention
 - Majority of suicides see their doctor prior to their death
 - 45% in the month prior to their death
 - 80% in the year prior
 - Excellent opportunity for prevention!
 - A significant proportion of adolescent attempters in the ER did not present for psychiatric reasons

NEED TO SCREEN!

Screening Programs are Successful!!

- High-school screening programs associated with 2x detection of at-risk individuals (Scott et al., 2004)
- Meta-analysis concluded that **screening results in lower suicide rates in adults** (Mann et al., 2006)
- Columbia Teen-Screen demonstrated 88% sensitivity and 76% specificity
- College Screening Project - data suggest screening brings high-risk students into treatment
 - Only 1 suicide in 4 years post-screening vs. 3 suicides in 4 years pre-screening program (Haas et al., 2008)
- Adult primary care screenings - **47% increase in rates of detection and diagnosis of depression**