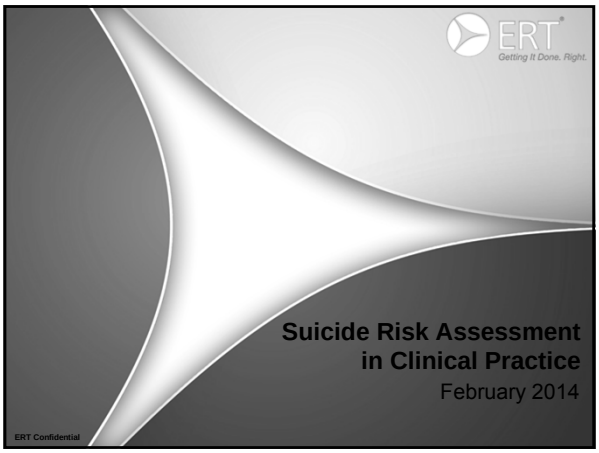


Disclosure

- I DO have an interest in this technology, program, product and/or service
- The development of this electronic, self-rated Suicide Risk Assessment program described in this session was funded by ERT

Our Goal

To take Best Practice from

Clinical Research to Clinical Practice

- Incorporate Patient Reported Outcomes (PROs) into clinical practice
- Enhance behavioral health assessments in primary care screening
- Enhance evidence based medicine in behavioral health

Using the eC-SSRS: Practical / Operational / Data Considerations

Objectives

1) Understanding the potential of a consistent, scalable, electronic application

2) Seeing the value of a complete assessment at screening

3) Using a routine self-rated prescreen assessment

Agenda

ERT Overview and Introductions

Suicide Risk Assessment (SRA)

- Why is it Important Now?
- What are the Challenges?
- What are Best Practices?

One Approach

- Columbia-Suicide Severity Rating Scale
- Benefits
- Clinical practice
- Experience / Findings
- Details, Questions, Suggestions

Who is ERT and what do we do?

EXPERT® Technology Platform

Cardiac Safety Solutions
TQT | First in Man to Phase IV | 12-Lead | Holter | ABPM

Respiratory Solutions
Centralized Spirometry | Peak Flow | DLCO | eNO

Clinical Outcome Assessments (COA)
Patient Reported Outcomes (PROs) | Clinician Reported Outcomes (ClinROs) | Observer Reported Outcomes (ObsROs)

Suicide Risk Assessment
Initial assessment | Ongoing assessment | Columbia-Suicide Severity Rating Scale

Global Coverage

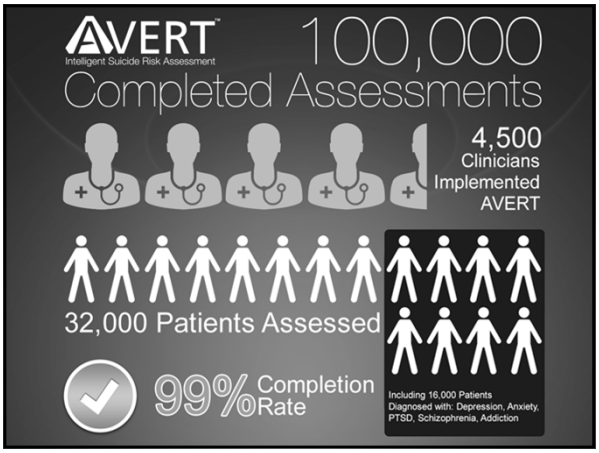
US: HQ Philadelphia, PA | Pittsburgh, PA | Bridgewater, NJ | Scotts Valley, CA

Europe: Höchberg, DE | Peterborough, UK

Asia: Tokyo, JP

Patient Data Collection

- 40+ Years
- 7,200+ Studies
- 2,210,000+ Patients
- 108,000+ Site Deployments (70,000+ Patient Care Sites)
- 117 Languages
- 10,000,000+ ECGs
- 14,000,000+ Flow Volume Loops
- 100,000,000+ eCOA Sessions



Agenda

ERT Overview & Introductions

Suicide Risk Assessment (SRA)

- Why is it Important Now?
- What are the Challenges?
- What are Best Practices?

AVERT™

- Columbia-Suicide Severity Rating Scale
- Benefits of the AVERT approach
- AVERT in practice
- Our Experience
- Details, Questions, Suggestions

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- Incorporate Patient Reported Outcomes (PROs) into clinical practice
- Enhance behavioral health assessments in primary care screening
- Enhance evidence based medicine in behavioral health

Suicide Risk in Healthcare

- 2011: Number of inpatient suicides reached an all time high[1]
- Overall rate of suicide exceeds deaths from motor vehicle accidents and homicides[2]
- 45% of victims had contact with primary care providers within 30 days of suicide
- The Joint Commission
  - Suicide among the top five sentinel events investigated
  - Suicide risk was not adequately assessed in 60% of inpatient suicides
  - Suicide Prevention is part of their National Patient Safety Goals

1 Joint Commission Sentinal Event Data at http://www.jointcommission.org/assets/1/18/Event_Type_by_Year_1995_4Q2012.pdf, December 2012. Web. 29 August 2013.

2 Centers for Disease Control and Prevention, National Center for Injury Prevention abd Control. National Vital Statistics Reports, accessed on August 29, 2013. Site available from http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_04.pdf

Proactive Risk Assessment

Assessment must move beyond ad-hoc reporting to proactively:

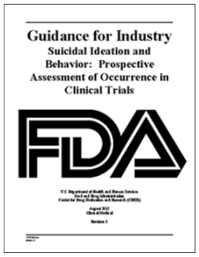
- Identify patients at risk
- Routinely assess at-risk patients
- Reduce suicidal behaviors

The FDA and The Joint Commission have issued guidelines to ensure:

- Consistent probing of lifetime and recent suicidal ideation and behavior
- Proactive assessment and documentation of patient responses

Suicidal Ideation & Behavior – Draft FDA Guidance 2010 and 2012

- Prospective assessment of suicidal ideation and behavior
  - Identify patients at risk
  - Collect complete, timely data
  - Perform in every phase, in every trial, at every visit
    - In all psychiatric indications
    - In all neurology compounds
    - For all other drugs pharmacologically similar to drugs about which there has been concern
- The C-SSRS is an 'acceptable' prospective assessment
- Administration by 'phone and computer' are acceptable



Joint Commission – National Patient Safety Goals

The Joint Commission

NPSG 15.01.01: Find out which patients are most likely to try to commit suicide

Rationale:

The identification and monitoring of at-risk patients is an important step in protecting these individuals.

Scope:

Psychiatric and General Hospital patients with emotional or behavioral care components:

- Identification of at-risk patients
- Monitoring these patients while under care
- Ongoing monitoring following discharge

Joint Commission Program Requirements

- Conduct a prospective, risk assessment to identify specific patient characteristics that may indicate suicide risk
- Adopt a structured screening process for the ER, clinics and 24hr care settings
- Adopt a standardized tool for consistent, routine application:
  - Accepted by the field, based on current evidence and practice
  - Producing a patient risk rating
- Provide suicide prevention information following discharge to at-risk patients

Challenges in Risk Assessment

- Suicidal ideation and behavior is an uncomfortable topic
- Interviews are inconsistent, providing unreliable findings
- Proper probing is required to differentiate suicidal and non-suicidal thoughts and actions
- Inconsistent findings consume valuable mental health resources
- Implementing a policy on a broad scale requires broad staff training and creates an assessment burden

Best Practices for Routine Suicide Risk Assessment

Establish an assessment policy and recommend monitoring frequency e.g.

- Lifetime Negative – low risk; little or infrequent assessment needed
- Lifetime Positive – higher risk; more routine assessment necessary
- Recent Positive – high risk; active mental health treatment required

Follow a simple, consistent assessment methodology

Document and archive patient data to support evidence-based practice

Adopt a low burden method to assess patients between visits

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- Clinical practice
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- Details, Questions, Suggestions

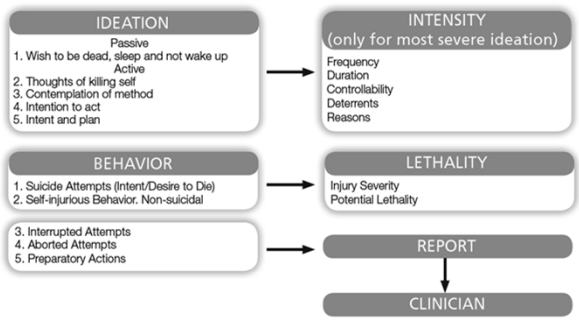
Consequences of Inconsistent Assessment

- If suicidal behavior and ideation cannot be properly identified, they cannot be properly understood, managed or treated in any population or diagnosis
- Misclassification leads to overestimation risk and more referrals to behavioral health (Jurek et al., 2005)
- In a clinical trial, the Columbia standardized assessment led to a *50% reduction in false positives* (Posner et al., *AJP,* 2007)

The Columbia - Suicide Severity Rating Scale (C-SSRS)

- Extensive use in *mental health indications;* now in non-mental health indications under FDA Guidance
- Clinician Rated, Semi-structured interview
- Handwritten report of findings and free form text descriptions
- Assesses both behavior and ideation: uniquely addressing the need for a summary measure of suicide risk
- Provides a 1-5 rating for suicidal ideation - from a wish to die to an active thought of killing oneself with plan and intent
- Classifies four distinct suicidal behaviors
- Distinguishes non-suicidal self injurious behavior

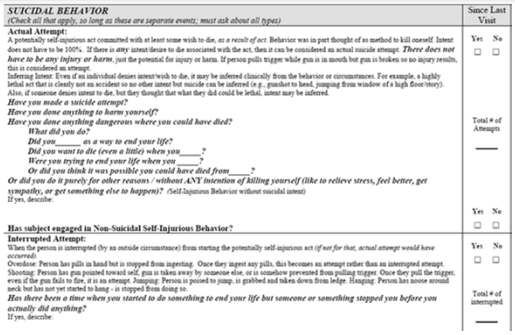
Key Elements for C-SSRS and eC-SSRS



Suicide Risk Monitoring at Patient Visits

- Assessed at each visit
  - First assessment is "Lifetime" – "Have you ever…"
  - Next, the recency of positive findings
    - "was this ideation in the past month?"
    - "was this behavior in the past 6 months?"
  - Subsequent Visits
    - "Since your last contact, on mm/dd, xx days ago, have you…"
- Facility policy describes the application of the eC-SSRS
- Policy must outline appropriate follow up for positive findings - like any other safety finding (i.e. labs or ECGs)

C-SSRS A Semi-Structured Interview



SUICIDAL BEHAVIOR (Check all that apply, so long as these are separate events; must ask about all types)	Since Last Visit
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:	Yes No ☐ ☐ Total # of Attempts ____ Yes No ☐ ☐
Has subject engaged in Non-Suicidal Self-Injurious Behavior?	
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred)*. 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. ***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?*** If yes, describe:	Yes No ☐ ☐ Total # of interrupted ____

Suicidal Ideation and Behavior – Classifications

Suicidal Ideation

1. Passive
2. Active: Nonspecific, no method, intent, or plan
3. Active: Method, but no intent or plan
4. Active: Method and intent, but no plan
5. Active: Method, intent, and plan

Suicidal Behavior

1. Completed suicide
2. Suicide attempt
3. Interrupted attempt
4. Aborted attempt
5. Preparatory actions toward imminent suicidal behaviors

Self-injurious behavior, no suicidal intent

One Approach – Electronic Suicide Risk Assessment

A computer assisted, self-reported suicide risk assessment

- AVERT: Electronic administration
- eC-SSRS
- Developed with the authors, suicide risk experts and patient reported outcomes experts
- Multiple validation studies completed and published
- FDA draft guidance has endorsed the use and has cited the results

One Approach in Clinical Practice

Sample Positive Report

ERT
Getting It Done. Right

Columbia Suicide Severity Rating Scale - eC-SSRS
SINCE LAST CONTACT 26-DEC-2012
Outcome: POSITIVE
Protocol: ERT_EC-SSRS 2.0 (C_B) Site ID: 001
Collection Date/Time: 26-DEC-2012 11:24:23 EST
Sponsor: eRBD_UAT
Subject: 85213

IDEATION

Level	Since Last Contact
1. Wish to be dead or not wake up	No
2. Nonspecific thoughts	No
3. Specific thoughts of method	N/A
4. Some intent to act, no plan	N/A
5. Specific plan and intent	N/A

Most severe level of ideation: No Ideation

Most Severe Ideation Intensity

a. Frequency of thoughts	N/A
b. Duration of thoughts	N/A
c. Controllability of thoughts	N/A
d. Deterrents	N/A
e. Reasons	N/A

Total Intensity Score : N/A

BEHAVIORS

	Since Last Contact	#
Actual Suicide Attempts	YES	2
Interrupted Attempts	No	0
Aborted Attempts	No	0
Preparatory Actions	No	0
Non-suicidal Self-injurious Behaviors	No	0

Lethality of Suicide Attempts
Most Serious Attempt: Could have died without medical treatment or permanent physical damage [4]

Potential Lethality of Suicide Attempts
Most Serious Attempt: N/A

NA indicates Not Asked or Not Applicable

ALERTS

POSITIVE FINDING: SINCE LAST CONTACT SUICIDE BEHAVIOR/ACTUAL ATTEMPTS

Example Staff Review - per prescribed policy

- Use report in review with patient
- Review negatives and sign
- Review of positive findings
- Review recent positive findings
  - Ideation in the past "I" months
  - Behavior in the past "B" months
- Follow-up
  - Mental Health referral
  - Care and safety monitoring
  - Psychiatric consultation

System Experience

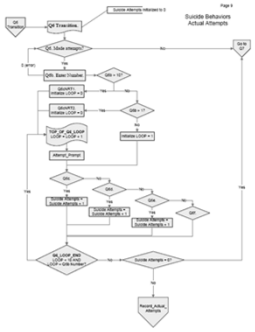
Widely Deployed and Proven to be Low Burden for Patients and Clinical Staff

- 100,000+ applications of 32,000+ patients
- 4,500+ patient care sites
- 99%+ completion rate
- Assessments after baseline
  - Negatives 98.3% (completion time 3.5 min.)
  - Positives 1.7% (completion time 7.7min.)
- 3.8 minute average completion time

Enhanced C-SSRS with the eC-SSRS

- C-SSRS is a major improvement over retrospective chart review.
- eC-SSRS is a fully structured self-rated pre-screen.
- eC-SSRS further reduces:
  - Assessment burden
  - Assessment variability
  - Risk of Type II error (False Negatives)
  - Data queries

eC-SSRS Fully Structured Probing



Attempt Probing:

- At any time in your life, have you made a suicide attempt?
- Enter the number of suicide attempts
- When you made your most recent attempt, were you trying to end your life?
- Did you think it was possible that you could have died from what you did?
- So then,
  - Did you want to die, even a little, when you did this? Or
  - Did you do it purely for other reasons, without ANY intention of killing yourself, like to relieve stress, feel better, get sympathy, or get something else to happen to you?

C-SSRS vs. eC-SSRS Interviews

C-SSRS Clinician Interview

Starts with:

- Two pages of semi-structured prompts
- A free form interview

Results in:

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

eC-SSRS Self-Rated Interview

Starts with:

- A patient enters the system
- A fully structured "perfect" interview
- Proper questions, follow-ups and branching logic
- Average length is 3.8 minutes

Results in:

- An eC-SSRS Report is generated immediately
- Staff alerts for positive findings
- Consistent, complete data for referrals

Benefits

Enhances Patient Safety

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

Increases Quality Data

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

Benefits

Reduces Staff Burden

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

Fulfils Regulatory Focus / Reduces Risk and Liability

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

ERT
Getting It Done. Right.

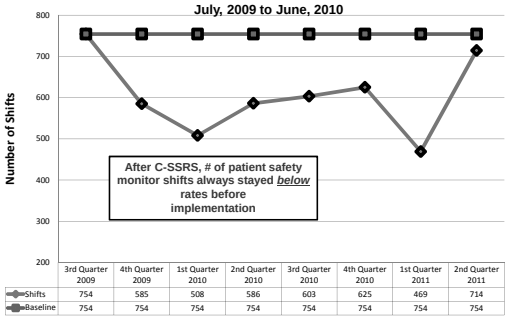
Questions / Discussion

Consequences of Inconsistent Assessment

- If suicidal behavior and ideation cannot be properly identified, they cannot be properly understood, managed or treated in any population or diagnosis
- Misclassification leads to overestimation risk and more referrals to behavioral health (Jurek et al., 2005)
- In a clinical trial, the Columbia standardized assessment led to a *50% reduction in false positives* (Posner et al., *AJP,* 2007)

Patient Safety Monitor Shift Utilization

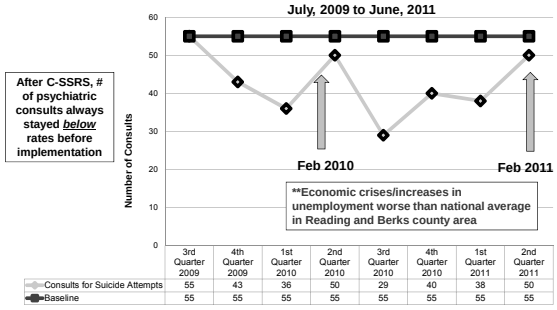
Stavarski D, Millsaps U, Pumariega A, Posner K, Romig B, Rice R, Close H, Castellucci M. Suicide Screening in a General Hospital Setting: Initial Results. Presented and ammended from: The Reading Hospital and Medical Center; 2010; West Reading, Pennsylvania



	3rd Quarter 2009	4th Quarter 2009	1st Quarter 2010	2nd Quarter 2010	3rd Quarter 2010	4th Quarter 2010	1st Quarter 2011	2nd Quarter 2011
Shifts	754	585	508	586	603	625	469	714
Baseline	754	754	754	754	754	754	754	754

Psychiatric Consultations for Suicide Attempts

Stavarski D, Millsaps U, Pumariega A, Posner K, Romig B, Rice R, Close H, Castellucci M. Suicide Screening in a General Hospital Setting: Initial Results. Presented and ammended from The Reading Hospital and Medical Center; 2010; West Reading, Pennsylvania



	3rd Quarter 2009	4th Quarter 2009	1st Quarter 2010	2nd Quarter 2010	3rd Quarter 2010	4th Quarter 2010	1st Quarter 2011	2nd Quarter 2011
Consults for Suicide Attempts	55	43	36	50	29	40	38	50
Baseline	55	55	55	55	55	55	55	55

Best Practices for Routine Suicide Risk Assessment

Establish an assessment policy and recommend monitoring frequency. For example:

- Lifetime Negative – low risk; little or infrequent assessment needed
- Lifetime Positive – higher risk; more routine assessment necessary
- Recent Positive – high risk; active mental health treatment required

Follow a simple, consistent assessment methodology

Document and archive patient data to support evidence-based practice

Adopt a low burden method to assess patients between visits

Identify Patients at Risk through Past History and Recent Behavior

The most reliable predictors of patient risk are:

- A past history of suicidal behavior
- The severity of lifetime suicidal ideation
- Fawcett's 6 symptoms/signs

Fawcett's Outpatient Suicide Risk Factors[1]

Acute risk factors – within one year

- Severe anxiety
- Panic attacks
- Global insomnia
- Recent alcohol abuse
- Severe anhedonia
- Difficulty concentrating

Chronic risk factors – 2 to 10 years

- Suicidal ideation – risk of method too
- Prior suicide attempt – severity too
- Hopelessness

[1]Fawcett et al. Am J Psychiatry. 1990;147:1189-94.

Reliable Predictors of Future Risk

Patients with lifetime suicidal ideation or behavior

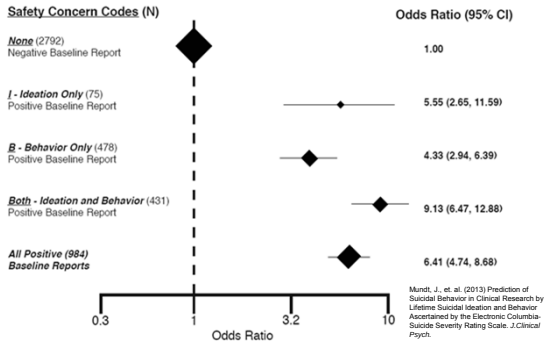
- 4 to 5 times more likely to report suicidal behavior

Patients with lifetime positive for both

- 9 times more likely to report suicidal behavior
- Similar risks were identified for:
  - Ideation Level - 5x – 20x
  - Ideation Intensity - 6x – 34x
  - Behavior type - Any type of lifetime behavior 5x
  - Number of Behaviors - 3x – 9x

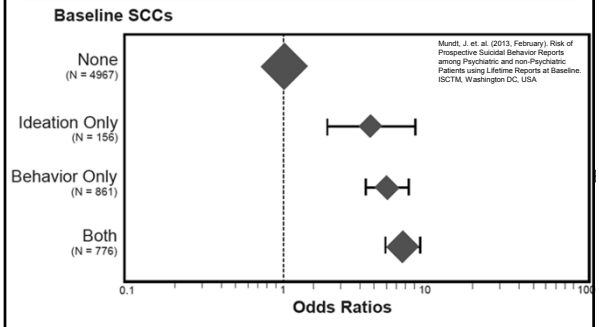
Mundt, J., Greist, J., Jefferson, J., Federico, M., Mann, J., Posner, K. (2013) Prediction of Suicidal Behavior in Clinical Research by Lifetime Suicidal Ideation and Behavior Ascertained by the Electronic Columbia-Suicide Severity Rating Scale. *Journal of Clinical Psychiatry*, 16 July 2013

Patients with Lifetime Suicidal Ideation or Behavior (35k Assessments)



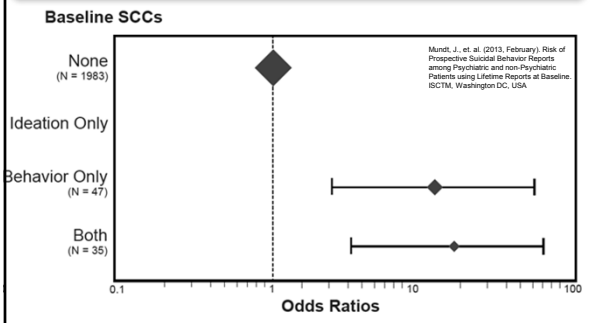
Mundt, J., et. al. (2013) Prediction of Suicidal Behavior in Clinical Research by Lifetime Suicidal Ideation and Behavior Ascertained by the Electronic Columbia-Suicide Severity Rating Scale. *J.Clinical Psych.*

Odds Ratios for Psychiatric Patients (75k Assessments)



Mundt, J. et. al. (2013, February). Risk of Prospective Suicidal Behavior Reports among Psychiatric and non-Psychiatric Patients using Lifetime Reports at Baseline. ISCTM, Washington DC, USA

Odds Ratios for Non-Psychiatric Patients (75k Assessments)



All Types of Lifetime Behaviors are Predictive

Any behavior indicates a ~ 4.6 to 5.3 times higher probability of reporting a behavior during subsequent follow-up

Lifetime Report	Odds Ratio of Suicidal Behavior ***p<.001
Actual Attempt	4.56 (3.40 – 6.11)***
Interrupted Attempt	5.28 (3.88 – 7.18)***
Aborted Attempt	4.75 (3.53 – 6.40)***
Preparatory Behavior	4.92 (3.38 – 7.16)***

Mundt, J., et. Al. (2013) Prediction of Suicidal Behavior in Clinical Research by Lifetime Suicidal Ideation and Behavior Ascertained by the Electronic Columbia-Suicide Severity Rating Scale. *J.Clinical Psych*

Number of Types of Behaviors Reported in Lifetime

Likelihood of a suicidal event increases proportionally as additional types of lifetime events are observed.

Number of Types of Behaviors Reported in Lifetime	Odds Ratio of Suicidal Behavior ***p<.001
One Type of Past Behavior	3.41 (2.22 – 5.23)***
Two Types of Past Behaviors	6.86 (4.57 – 10.32)***
Three Types of Past Behaviors	8.33 (5.50 – 12.62)***
Four Types of Past Behaviors	9.35 (4.98 – 17.54)***

Mundt, J., et. Al. (2013) Prediction of Suicidal Behavior in Clinical Research by Lifetime Suicidal Ideation and Behavior Ascertained by the Electronic Columbia-Suicide Severity Rating Scale. *J.Clinical Psych*

Reporting Sensitive Subject Matter

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

Fewer false negatives (Type II error) with computer
…than clinician interview

Computer 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

In 2011

"…suicidal thoughts and plans were more likely to be endorsed by patients than clinicians, and clinicians were less likely to use the more extreme rating ("strongly agree").

These results suggest the possibility that some patients may be more willing to endorse suicidal ideation on self-report assessments or that some clinicians may be reluctant to record suicidal ideation."

And in 2012 ➡

Trivedi et al. 2011 J. Clin. Psychiatry. 72:757-764.

Assessment of Suicidality in Epilepsy – Rating Tools (ASERT)

- Assessments compared
  - C-SSRS
  - eC-SSRS
- C-SSRS done face-to-face
- eC-SSRS administered by interactive voice response (IVR) computer interview

The Epilepsy Study Consortium; Assessment of Suicidality in Epilepsy - Rating Tools (ASERT). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2012- [cited 2013 August 29]. Available from: http://clinicaltrials.gov/ct2/show/NCT01085461.

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ASERT – Study Findings

Lifetime Suicide *Attempt* Rates

- C-SSRS 10.2%
- eC-SSRS 13.1%

Lifetime Suicidal *Behavior** Rates

- C-SSRS 15.5%
- eC-SSRS 21.1%

Behaviors reported only to C-SSRS or eC-SSRS

- C-SSRS 6.3%
- eC-SSRS 38.1%

*Behaviors: Interrupted/aborted attempts, preparatory acts

The Epilepsy Study Consortium; Assessment of Suicidality in Epilepsy - Rating Tools (ASERT). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2012- [cited 2013 August 29]. Available from: http://clinicaltrials.gov/ct2/show/NCT01085461 Identifier: NCT 01085461.

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ASERT - Study Conclusions

- False negative reports always possible
- More so with face-to-face assessments
- To reduce risk and increase safety
  - Administer self-rated eC-SSRS,
  - Conduct eC-SSRS findings review
  - Then appropriate face-to-face contact

The Epilepsy Study Consortium; Assessment of Suicidality in Epilepsy - Rating Tools (ASERT). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2012- [cited 2013 August 29]. Available from: http://clinicaltrials.gov/ct2/show/NCT01085461

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Is the Self Rated eC-SSRS - Better Than The Clinician?

- No, they're complementary and are better together than either is alone
  - Computer interview standardization
  - Greater disclosure to computer
  - Clinician intuition
- Most eC-SSRS reports are negative, needing only brief clinician review
- Positive eC-SSRS reports organize and guide the clinician review

I'm firmly convinced that behind every great man or great woman is a great computer.