Current Suicide Risk Assessment

Grand Rounds
Rogers Memorial Hospital
13 March 2014

John Greist, MD

Disclosures

John Greist, MD: Past two years

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

Consultant: **GSK, Lilly, Novo Nordisk, Pfizer**

Pharmaceutical Stocks: **None**

Principal: **Healthcare Technology Systems**

Shareholder: **Waypoint Health Innovations**

If suicidal ideation and behavior cannot be properly identified, they cannot be properly understood, managed or treated

Use and role of computer interviews in suicide risk assessment

Suicide Risk Signal Detection

- Any signal is likely to be small
- Signal accuracy requires reliability
- Small signals need greater reliability
- Computer interviews are perfectly reliable
  - Faithfully present each question
  - Document processing of interview algorithm
- Greater suicidality candor with computer interview

Joint Commission – National Patient Safety Goals

The The Joint Commission has issued guidelines

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

Rationale:

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

Scope:

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

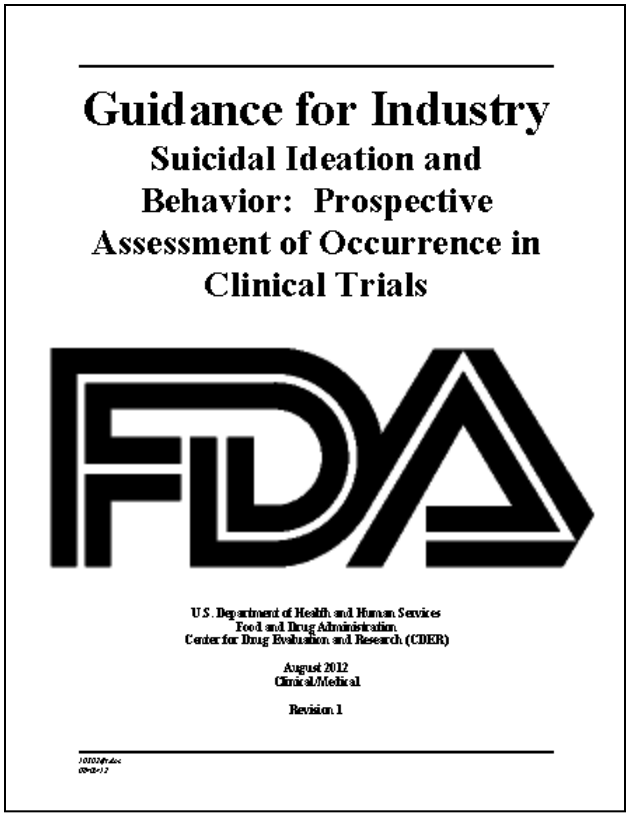
- Identification of at-risk patients
- Monitoring these patients while under care
- Ongoing monitoring following discharge

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

Draft FDA Guidance 2010 and 2012

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



Guidance for Industry

Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials

FDA

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

August 2012
Clinical/Medical

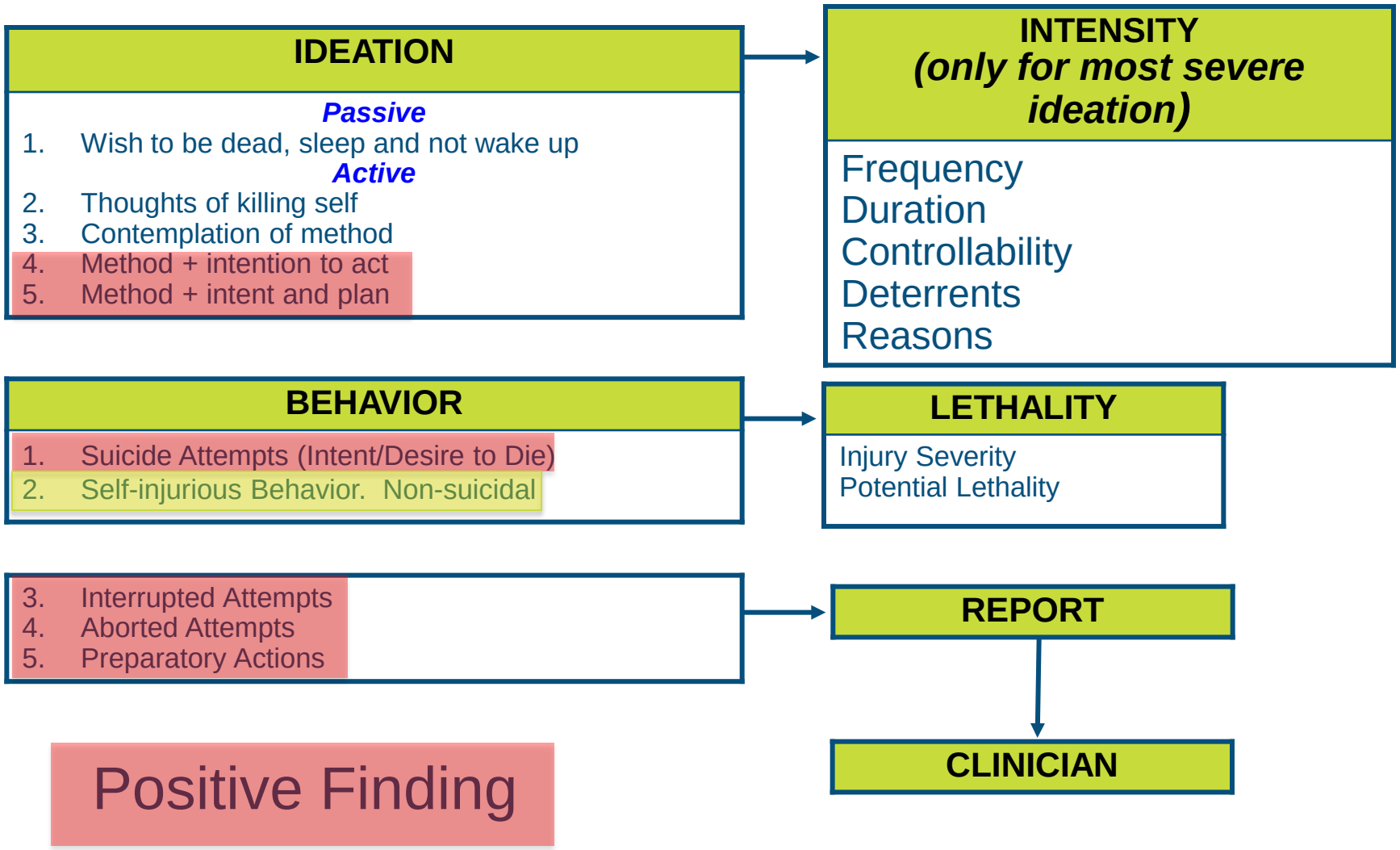
Revision 1

Columbia-Suicide Severity Rating Scale

Clinician Interview or Patient Self-Report?

Best both!

Key Elements for C-SSRS and eC-SSRS



Suicidal Ideation and Behavior – Classifications

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

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 [137-151]

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

[FDA Draft Guidance Document Line Numbers]

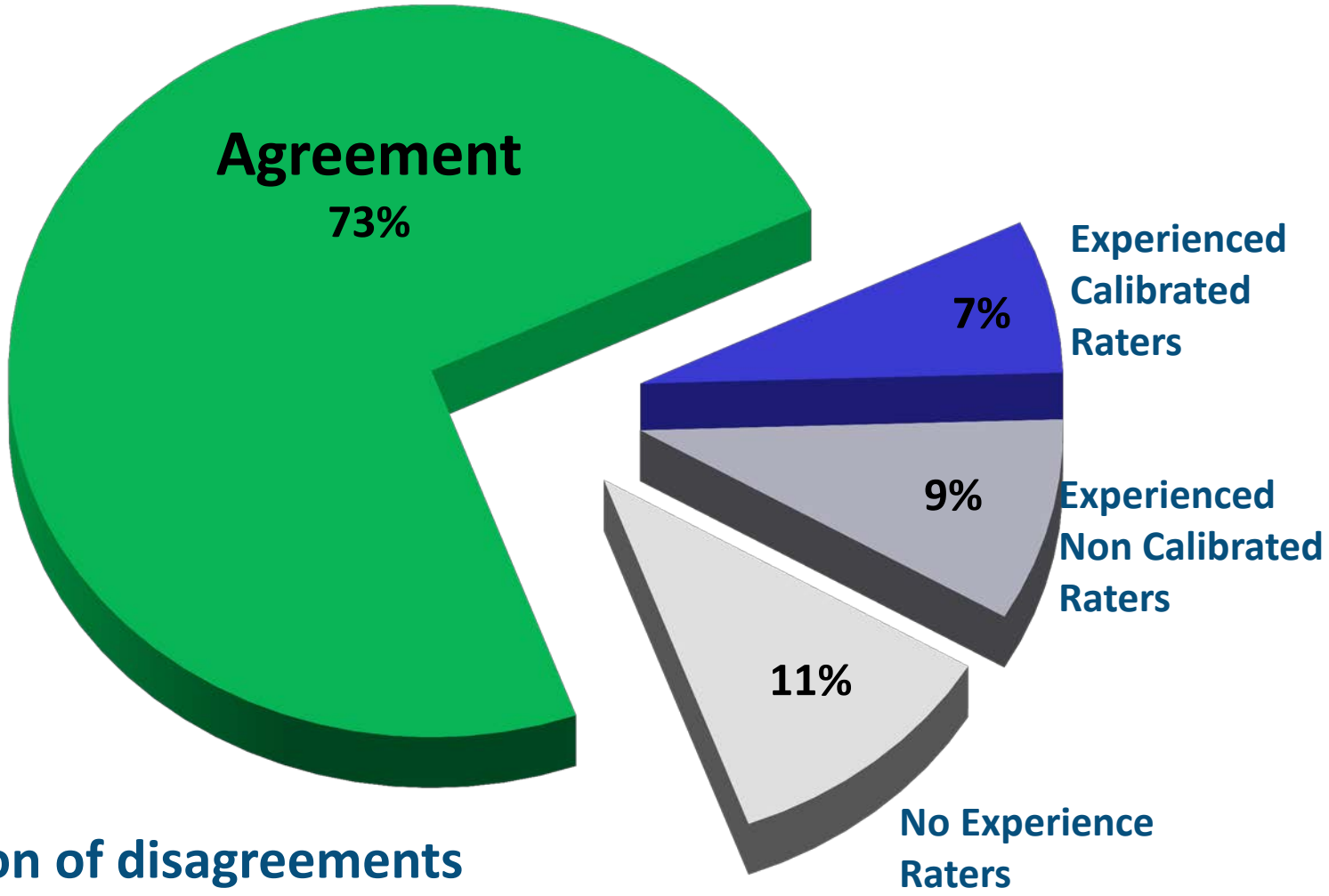
Assessment variability

Rater Variability

Scoring Variability
17 item HamD
Item Level Analyses

Kobak et al. J Clin Psychopharmacol. 2009 Feb;29(1):82-85.

Rater Variability



Distribution of disagreements by rater experience and training

Rater Variability

Experienced & Calibrated Raters

Experienced & Not Calibrated Raters

No Experience Raters

Variance Source

Interpretation	(35%)
Information	(27%)
Criterion	(25%)
Observation	(4%)
Subject	(8%)
Recording	(1%)

"Differences in how follow-up questions were phrased and differences in which follow-up questions were asked were the most common type of information variance."

Challenges with Suicidality Interviews

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

eC-SSRS Overview

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

- Validation paper: Mundt JC et al. J Psych Res 2010;44:1224-8.

C-SSRS vs. eC-SSRS Interviews

C-SSRS Clinician Interview

Starts with:

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

Results in:

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

eC-SSRS Self-Rated Interview

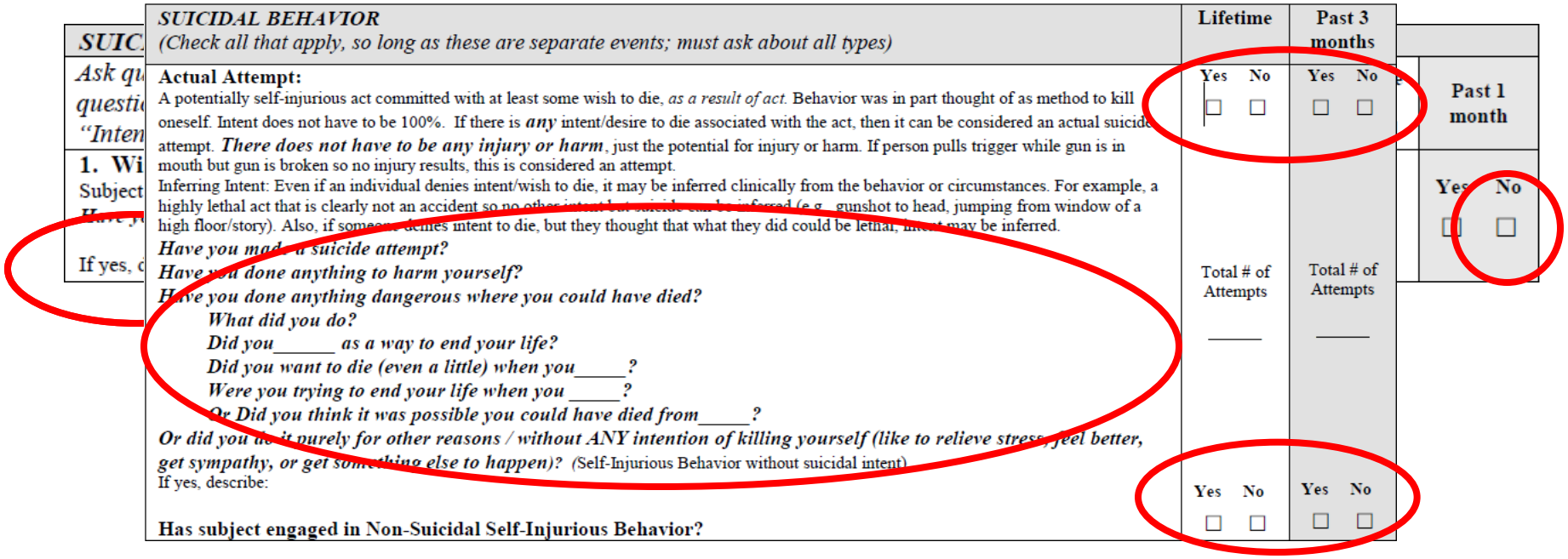
Starts with:

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

Results in:

- An immediate eC-SSRS Report
- Staff alerts for positive findings
- Consistent, complete data for referrals and analyses

Challenges with Paper Documentation

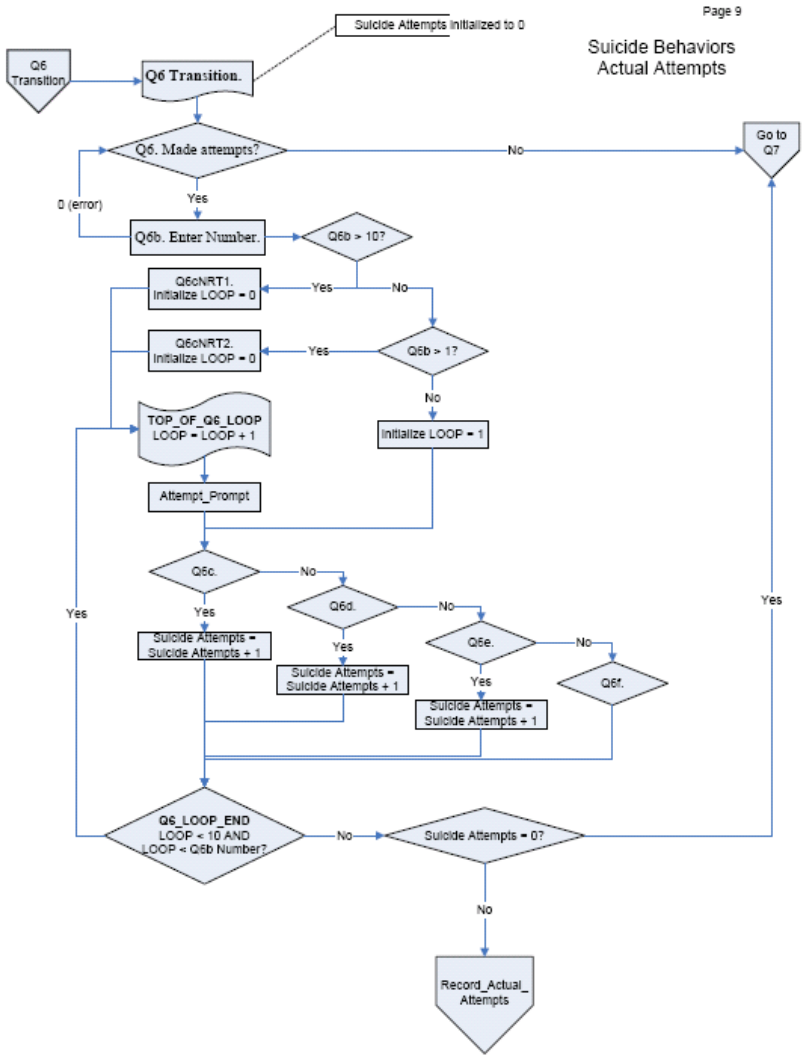


SUICIDAL BEHAVIOR
(Check all that apply, so long as these are separate events; must ask about all types)

	Lifetime	Past 3 months	Past 1 month
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.	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
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)	Total # of Attempts _____	Total # of Attempts _____	
If yes, describe:			
Has subject engaged in Non-Suicidal Self-Injurious Behavior?	Yes ☐ No ☐	Yes ☐ No ☐	

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

eC-SSRS Fully Structured Probing



Attempt Probing:

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

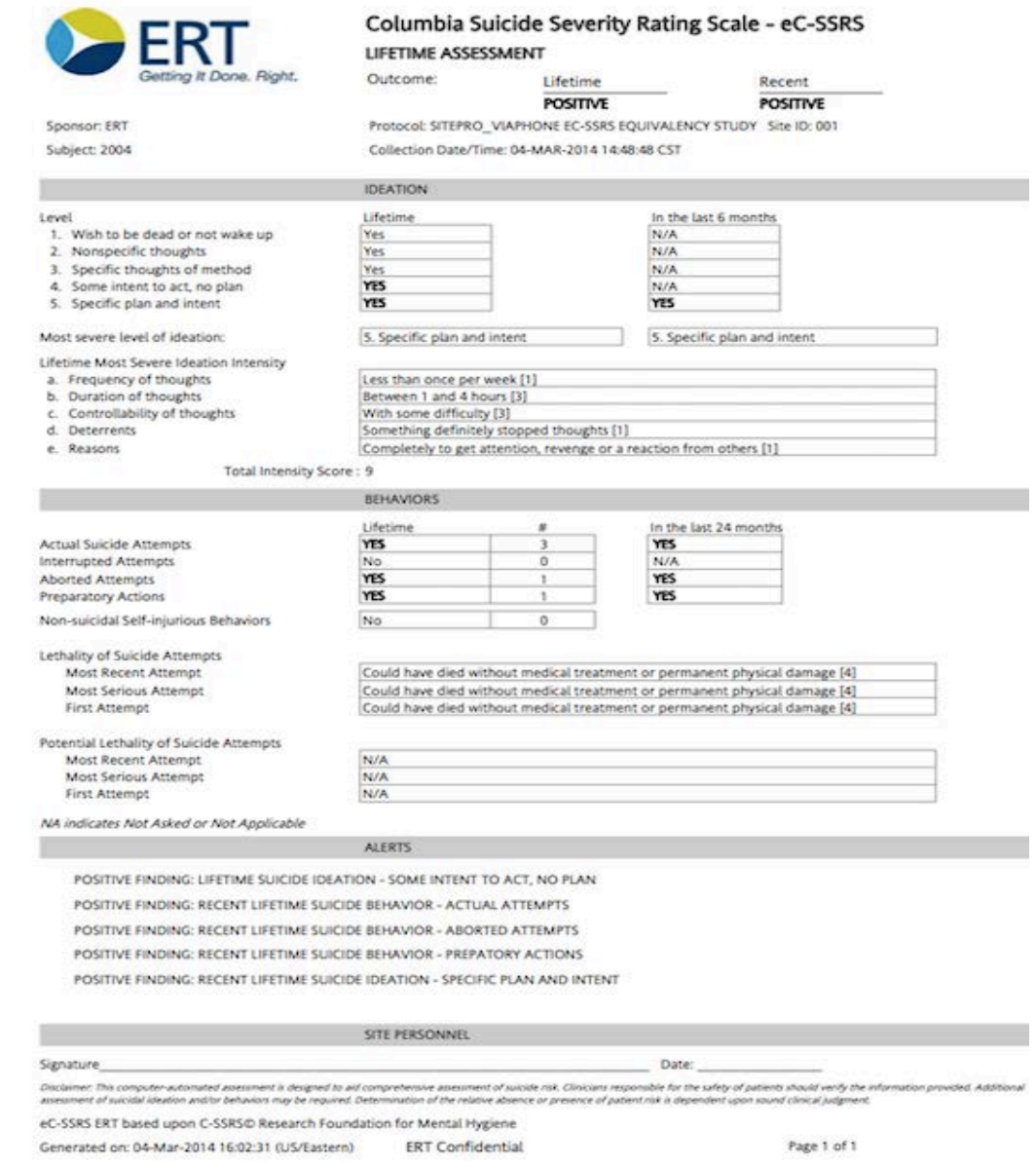
Is the Self Rated eC-SSRS Better Than The Clinician?

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

eC-SSRS Operational Overview

The Self Rated eC-SSRS Process

eC-SSRS Findings Report



ERT
Getting It Done. Right.

Columbia Suicide Severity Rating Scale – eC-SSRS

LIFETIME ASSESSMENT

Outcome:	Lifetime	Recent
	POSITIVE	**POSITIVE**

Sponsor: ERT
Subject: 2004
Protocol: SITEPRO_VIAPHONE EC-SSRS EQUIVALENCY STUDY Site ID: 001
Collection Date/Time: 04-MAR-2014 14:48:48 CST

IDEATION

Level	Lifetime	In the last 6 months
1. Wish to be dead or not wake up	Yes	N/A
2. Nonspecific thoughts	Yes	N/A
3. Specific thoughts of method	Yes	N/A
4. Some intent to act, no plan	**YES**	N/A
5. Specific plan and intent	**YES**	**YES**
Most severe level of ideation:	5. Specific plan and intent	5. Specific plan and intent

Lifetime Most Severe Ideation Intensity

a. Frequency of thoughts	Less than once per week [1]
b. Duration of thoughts	Between 1 and 4 hours [3]
c. Controllability of thoughts	With some difficulty [3]
d. Deterrents	Something definitely stopped thoughts [1]
e. Reasons	Completely to get attention, revenge or a reaction from others [1]

Total Intensity Score : 9

BEHAVIORS

	Lifetime	#	In the last 24 months
Actual Suicide Attempts	**YES**	3	**YES**
Interrupted Attempts	No	0	N/A
Aborted Attempts	**YES**	1	**YES**
Preparatory Actions	**YES**	1	**YES**
Non-suicidal Self-injurious Behaviors	No	0	

Lethality of Suicide Attempts

Most Recent Attempt	Could have died without medical treatment or permanent physical damage [4]
Most Serious Attempt	Could have died without medical treatment or permanent physical damage [4]
First Attempt	Could have died without medical treatment or permanent physical damage [4]

Potential Lethality of Suicide Attempts

Most Recent Attempt	N/A
Most Serious Attempt	N/A
First Attempt	N/A

NA indicates Not Asked or Not Applicable

ALERTS

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

SITE PERSONNEL

Signature_____ Date: _____

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

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

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

Suicide Risk Monitoring Schedule

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

eC-SSRS System Experience

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

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

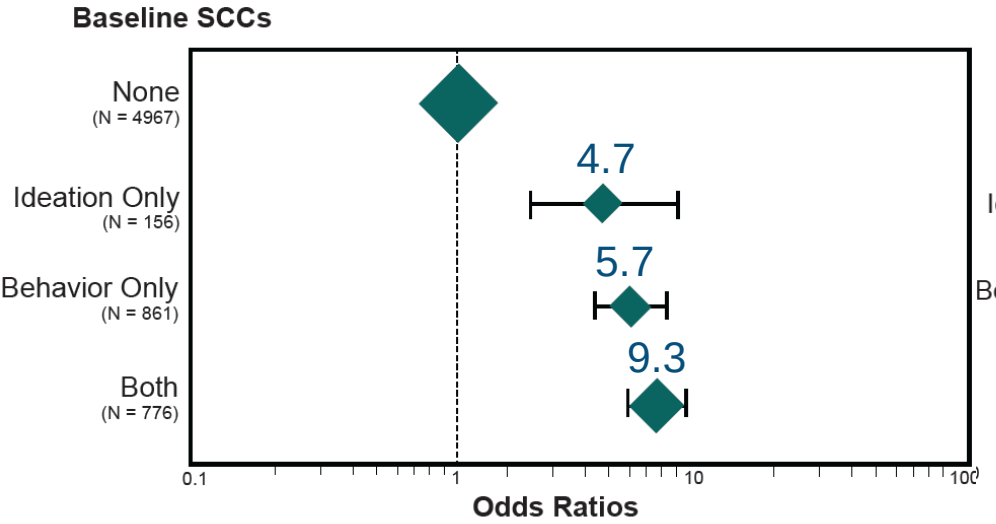
  - Completion rate: 99.89%
  - Assessments after baseline (*Lifetime*)
    - Negative 98.3% (completion time 3.5 min.)
    - Positive 1.7% (completion time 7.7min.)

- Predictions paper: Mundt JC et al. J Clin Psychiat 2013;774:887-93.

Odds Ratios within Participant Classification Groups
Lifetime assessment prediction of *short-term* behaviors

75,000 Assessments

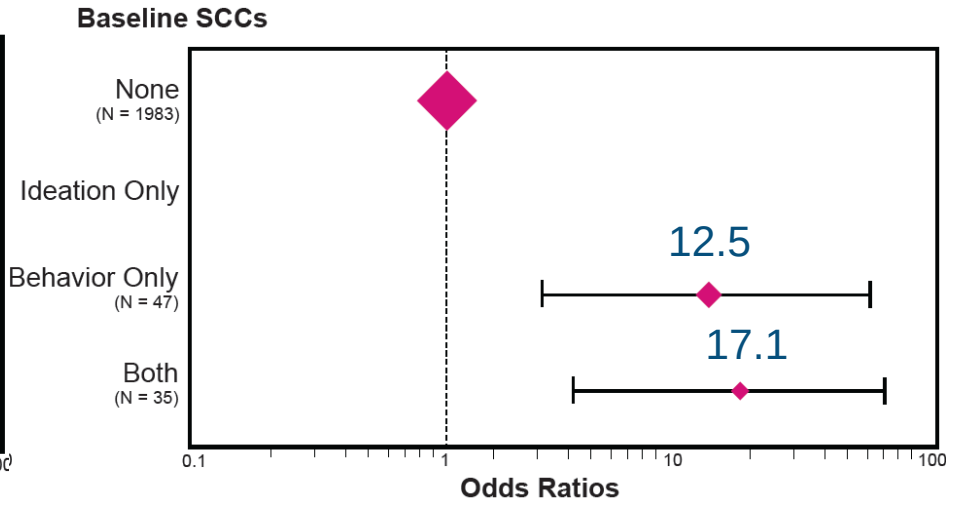
(Psychiatric Patients)
N = 6760



Post baseline F/U
72 days

w/ Suicidal Behav
1.29%

(Non-Psychiatric Patients)
N = 2077



Post baseline F/U
98 days

w/ Suicidal Behav
0.15%

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Short-term suicidal behaviors based on *Lifetime* SI

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

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

Each *lifetime* suicidal behavior at baseline prospectively predicts suicidal behavior during trial

Baseline Reports	Patients not prospectively reporting suicidal behavior N =3577	Patients prospectively reporting suicidal behavior N =201	Odds ratio of prospective suicidal behavior report *** p<.001
Actual Attempt	522 (85.6 %)	88 (14.4 %)	4.56 (3.40 – 6.11)***
BL Interupted Attempt	349 (82.7 %)	73 (17.3 %)	5.28 (3.88 – 7.18)***
BL Aborted 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

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Number of different lifetime suicidal behaviors predicts 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 *** p<.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; likelihood increases proportionally with increased number of different behaviors reported.

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Each eC-SSRS ***lifetime*** ideation and behavior question predicts ***short-term*** suicidal behaviors.

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

Sensitive Subjects

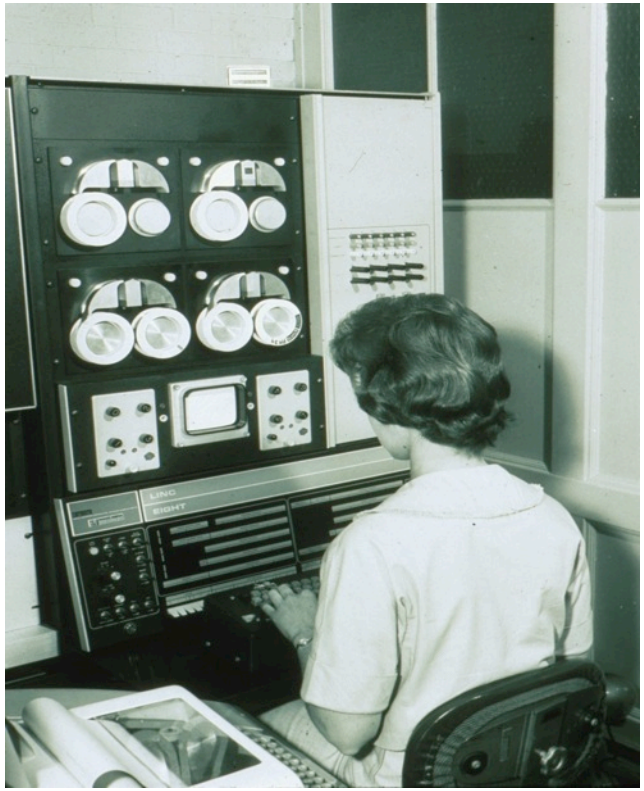
- Sexual functioning
- Substance use
- HIV risk factors

  and… Suicidal ideation and behaviors

- Fewer false negatives (Type II error) with computer

  …than clinician interview

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

Treatment of Adolescents Depression 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 (ie, CDRS-R)."

Vitiello, et al., J Clin Psychiatry 2009;70:741-7

ASERT – Study Population

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

Hesdorffer et al. Epilepsia 2013 Feb 28. doi: 10.1111/epi.12128 [Epub ahead of print]

Assessment of Suicidality in Epilepsy

ASERT – Study Findings (N = 208)

- Lifetime Suicide *Attempt* Rates
  - C-SSRS 10.2%
  - eC-SSRS 13.1%
- Lifetime Suicidal *Behavior** Rates
  - C-SSRS 15.5%
  - eC-SSRS 21.1%
- Behaviors reported only to C-SSRS or eC-SSRS
  - C-SSRS 6.3%
  - eC-SSRS 38.1%

*Behaviors: Interrupted/aborted attempts, preparatory actas

Hesdorffer et al. Epilepsia 2013 Feb 28. doi: 10.1111/epi.12128 [Epub ahead of print]

ASERT - Study Conclusions

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

Hesdorffer et al. Epilepsia 2013 Feb 28. doi: 10.1111/epi.12128 [Epub ahead of print]

eC-SSRS Benefits

Enhances Patient Safety

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

Increases Quality Data

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

eC-SSRS Benefits

Reduces Staff Burden

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

Fulfils Regulatory Focus / Reduces Risk and Liability

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

How might Rogers use the eC-SSRS?

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

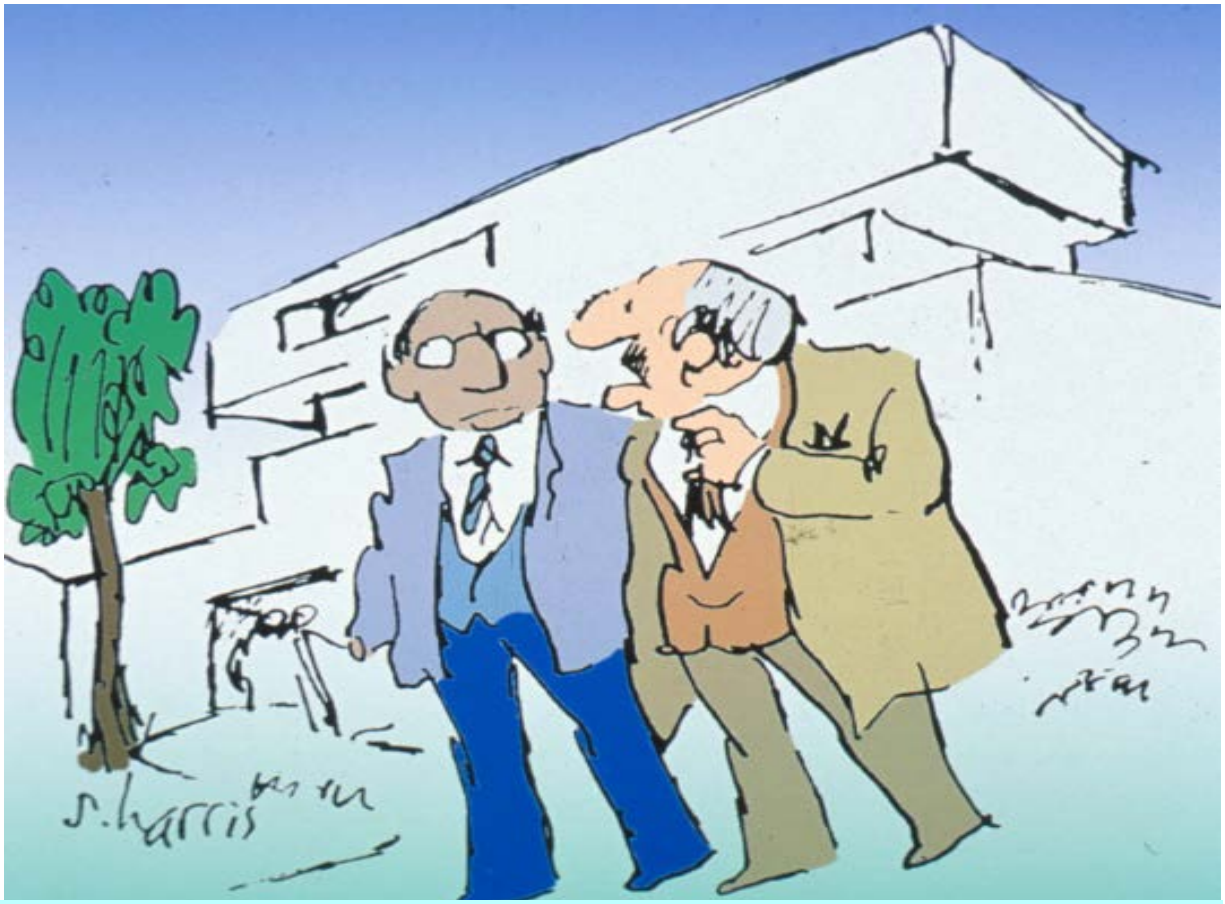
- **Certainly**
  - According to any protocol Rogers decides

Surgical Safety Check List

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

Haynes et al. NEJM 2009;360:491-9.

What more is there to say?



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

Discussion

Trainability of Human Raters

- US multicenter trial: 31 raters at 15 sites
  - First, didactic training with test
  - Then live interview coaching and rating
- Rater Applied Performance Scale (RAPS) Range 4 – 16
  - Excellent = 14.5 – 16
  - Good = 10.5 – 14.4 (had to score > 10.4 to qualify)
  - Fair = 6.5 – 10.4
  - Poor = < 6.5
- 57% "Qualified" 1st time; 93% by 3rd try
- Baseline mean score 12.2

Kobak et al. J Clin Psychopharmacol. 2007;27(5):534-5.

Sustainability of Rater Training

- Same raters reassessed 12 months later
  - Baseline 12.2 dropped to 10.7 (Good = 10.5 - 14.4)
  - Only 58% still qualified
  - Unqualified 42% mean score 7.8 (Fair = 6.5 - 10.4)
- Retraining “requalified” all raters by 3rd try
- Performance in the previous and next 12 months?

Kobak et al. J Clin Psychopharmacol. 2007;27(5):534-5.