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Challenges in Research on Suicide Prevention

C E. Coffey

Brian K. Ahmedani

Henry Ford Health System, bahmeda1@hfhs.org

M J. Coffey

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term *abortion* appeared sufficient; nevertheless, some disclosures may have been missed. Whether the low proportion of hospitals that did not cite health care restrictions reflects a lack of transparency or nonadherence to the directives is unknown. In addition, some of the hospitals that cited the directives may provide reproductive services. How often patients consult hospital websites for such information is also unknown.

Greater transparency about religious affiliation and care restrictions may allow patients to make more informed choices.¹ In the state of Washington, hospitals must provide their reproductive health and end-of-life care policies on publicly available websites.⁶ Further research on the effect of this initiative on patient satisfaction and health care choices is warranted.

Joelle Takahashi, BA
Abigail Cher, BA
Jeanelle Sheeder, PhD
Stephanie Teal, MD, MPH
Maryam Guiahi, MD, MSc

Author Affiliations: University of Colorado School of Medicine, Aurora (Takahashi, Cher); Department of Obstetrics and Gynecology, University of Colorado School of Medicine, Aurora (Sheeder, Teal, Guiahi).

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Corresponding Author: Maryam Guiahi, MD, MSc, Department of Obstetrics and Gynecology, University of Colorado School of Medicine, University of Colorado Anschutz Medical Center, 12631 E 17th Ave, Mailstop B192-2, Aurora, CO 80045 (maryam.guiahi@ucdenver.edu).

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Drafting of the manuscript: Takahashi, Sheeder, Guiahi.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Takahashi, Sheeder, Guiahi.

Administrative, technical, or material support: Takahashi, Cher, Guiahi.

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COMMENT & RESPONSE

Challenges in Research on Suicide Prevention

To the Editor In a Viewpoint, Drs Sisti and Joffe¹ expressed concern that interventions to reduce suicide have not been well studied in clinical trials and proposed inclusion of actively suicidal individuals in trials. The US Food and Drug Administration (FDA) provides regulatory advice on clinical trials for psychiatric drug development. We wish to comment on several issues in the article.

In the recent FDA draft guidance to industry on antidepressant drug development,² inclusion of patients with suicidal ideation and behavior in clinical trials was encouraged. Other conditions with increased risk of suicidal ideation and behavior, including bipolar disorder and schizophrenia, were not mentioned because separate guidances are pending; however, the FDA agrees with the inclusion of such patients in trials. To the extent possible, study populations should reflect the full severity range of patients encountered in clinical practice.

However, we do not believe that including patients with suicidal ideation or behavior in clinical trials obviates the need to provide standard-of-care treatment for acutely suicidal patients. In a previous FDA guidance,³ it was recommended that patients with suicidal ideation (ie, Columbia-Suicide Severity Rating Scale⁴ score ≥ 4) should be excluded or discontinued from most clinical trials so that they can receive immediate psychiatric intervention. We have additional concerns about including patients with suicidal ideation or behavior in trials for nonpsychiatric indications because psychiatric monitoring is limited in these settings. Nevertheless, such inclusion may be possible with appropriate precautions.

In recent years, some drug development programs have proposed reduction of suicidal ideation or behavior as a treatment indication. Such studies are ethically supportable if patients receive standard-of-care interventions based on severity of suicidal ideation or behavior, although they may require inpatient settings. Unlike the authors, we believe that adverse events related to suicidal ideation or behavior should be reported as adverse events in these studies, but only if the events are more severe than at baseline. This recommendation would permit appropriate safety monitoring while avoiding overreporting. Moreover, events reported as adverse events could still be included in the efficacy analyses.

As the authors noted, death due to suicide is not a practicable primary end point for trials of interventions to reduce suicidal ideation or behavior. The FDA is open to considering surrogate end points to support indications for treatment of suicidal ideation or behavior. We agree that data on suicidal behavior and deaths should be collected with suicidal ideation because the relationship between them is not yet fully characterized.

Jean Kim, MD, MA
Michael Davis, MD, PhD
Tiffany Farchione, MD

Author Affiliations: Division of Psychiatry Products, US Food and Drug Administration, Silver Spring, Maryland.

Corresponding Author: Jean Kim, MD, MA, Division of Psychiatry Products, Office of Drug Evaluation I: Office of New Drugs, Center for Drug Evaluation and Research, US Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993 (jean.kim@fda.hhs.gov).

Conflict of Interest Disclosures: None reported.

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To the Editor Drs Sisti and Joffe¹ described challenges in conducting research on suicide. We agree that such research should include individuals with suicidal behavior and that suicide attempts and death are appropriate outcomes for trials. We also agree that conceptualizing the outcome of suicide as an adverse event might trigger objections by regulatory bodies that jeopardize the feasibility of such investigations.

We disagree, however, that the zero suicide model might “paradoxically constrain” research.¹ As previously described,^{2,3} the zero suicide model is a comprehensive quality improvement approach that organizations can use to improve health care delivery. The zero suicide model consists of 3 essential components: a conviction that ideal health care is attainable, a road map to achieve that vision, and requisite expertise in systems engineering to rapidly achieve zero suicides.

Following its introduction in 1966,⁴ the concept of zero defects spread to industries throughout the world, and recently, innovating to zero was called 1 of 10 megatrends for innovation.⁵ High-reliability organizations aggressively pursue perfection, an approach that has driven commercial aviation to achieve remarkable levels of safety. Twenty years ago, the Henry Ford Health System adopted this approach, setting goals for mental health care and achieving an 80% reduction in suicides, which was maintained over a decade.³

In our view, the success of the zero suicide model depends on a just culture, one that views errors or near misses as system failures from which to learn and rapidly improve. In response to defects, a just culture asks “What happened and how?” not “Who did it?” A just culture seeks recovery, restoration, and improvement, not blame, punishment, or retribution.

Thus, we disagree that a corollary of the zero suicide model “is that every suicide represents a culpable failure on the part of health professionals.”¹ Quite the contrary, the zero suicide model views a suicide as a system defect that provides an essential opportunity for learning and rapid improvement. This approach is constructive and productive and will not only improve care but enable clinical research. The Substance Abuse and Mental Health Services Administration and the National Institute of Mental Health have recently provided funding to study the effectiveness of the zero suicide model.

C. Edward Coffey, MD
Brian K. Ahmedani, PhD
M. Justin Coffey, MD

Author Affiliations: Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina, Charleston (C. E. Coffey); Department of Psychiatry, Henry Ford Health System, Detroit, Michigan (Ahmedani); Department of Psychiatry and Behavioral Sciences, Baylor College of Medicine, Houston, Texas (M. J. Coffey).

Corresponding Author: C. Edward Coffey, MD, Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina, 67 President St, MSC 861, Charleston, SC 29425 (coffeyc@musc.edu).

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In Reply We are gratified to know that the FDA is developing guidance that supports inclusion of individuals with suicidal ideation or behavior associated with serious mental illnesses, including schizophrenia and bipolar disorder, in clinical trials. We agree that trial participants with acute suicidal ideation or behavior, including those in the control groups of clinical trials evaluating suicidal ideation or behavior as an end point, be provided with standard-of-care (including emergency) interventions or with investigational approaches hypothesized to be as good as or better than the standard of care. However, mandating participant exclusion when suicidal ideation or behavior passes a predetermined threshold is a step backward: drawing conclusions about new treatments for the population most at risk would be impossible.

The question of whether worsening of suicidal ideation or behavior should be reported as an adverse event merits further discussion for at least 2 reasons: (1) the importance of distinguishing between lack of efficacy of an intervention and its toxicity and (2) the risk that sponsors, data and safety monitoring committees, or institutional review boards will take actions because of unjustified concerns about toxicity that undermine ongoing trials.

The issue of nonpsychiatric research involving suicidal participants is an important one but is beyond the scope of our argument.

We appreciate the clarification offered by Dr Coffey and colleagues, who provide additional details about the aims and mission of the zero suicide model and the importance of a just culture in ensuring safety. As we noted in our article, the zero suicide model is a laudable goal in clinical settings.¹ Furthermore, we strongly agree that a just culture and a nonpunitive approach are essential to understanding root causes and preventing sentinel events in clinical care.

Our concern is that the zero suicide model might be inappropriately applied in research settings in which the aim is to identify evidence-based suicide reduction interventions that can bring the zero suicide vision closer. Engaging in such research entails a forthright acknowledgment that some participants will attempt suicide and that despite investigators' best efforts, some of those attempts may be successful. It is important to clarify that such events, assuming adherence to protocol and standards of care, do not represent culpable failures on behalf of investigators or institutions.

Dominic A. Sisti, PhD
Steven Joffe, MD, MPH

Author Affiliations: Department of Medical Ethics and Health Policy, Perelman School of Medicine at the University of Pennsylvania, Philadelphia.

Corresponding Author: Dominic A. Sisti, PhD, Division of Medical Ethics, Department of Medical Ethics and Health Policy, Perelman School of Medicine at the University of Pennsylvania, 423 Guardian Dr, Blockley Hall, Philadelphia, PA 19104 (sistid@upenn.edu).

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Reducing the Burden of Fellowship Interviews

To the Editor The Viewpoint by Dr Melcher and colleagues¹ raised concerns regarding time expenditures, incurred costs, and loss of clinical coverage caused by interviewing for surgical fellowships and proposed an interview match as a way to decrease the overall amount of interviews. They referenced a survey of pediatric surgery program directors that showed the median rank at which programs matched was less than 4.² There is a flaw in this justification: one cannot assume that the top 4 candidates on a rank list were all applicants who would have been granted interviews through an interview match.

I echo the authors' concerns that such a system would unfairly favor candidates who look good on paper and conversely could be detrimental to candidates who excel in personal interviews. Likewise, it would not allow for the serendipitous connection between an applicant and representatives from a program.

Technology may provide an alternative strategy to decrease the time and expense of interviews. Telephone interviews have been used in other disciplines as a less expensive alternative to the traditional interview process. After an application is received, telephone interviews might be used as an additional screening prior to or in place of the interview process. This would allow for a true interaction between an applicant and representatives from a program in an efficient, less costly manner.

Niel F. Miele, MD

Author Affiliation: Robert Wood Johnson Medical School, Rutgers University, New Brunswick, New Jersey.

Corresponding Author: Niel F. Miele, MD, Robert Wood Johnson Medical School, Rutgers University, One Robert Wood Johnson Pl, MEB-342, New Brunswick, NJ 08901 (mielenf@rwjms.rutgers.edu).

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To the Editor Dr Melcher and colleagues¹ accurately described the challenges of the current surgical fellowship application system and proposed a match within the match solution. The essence of their proposal centers on limiting the number of interviews that an applicant can participate in and that programs can conduct.

Before adopting the interview match system proposed by the authors, other approaches should be considered. Industrial organizational psychology (the science of human behavior related to work) may suggest a solution. Industrial organizational psychologists conduct research on employee behaviors and attitudes and how these can be improved through hiring practices and training programs. Other high-risk professions and most Fortune 500 companies use industrial organizational psychologists to improve personnel selection by their organizations.²

Industrial organizational psychology suggests that there are 2 problems with the current surgical training selection process. First, applicants lack information that can help them determine their fit into a program and candidacy for selection. Second, programs lack tools that credibly separate one candidate from another.³ As a result, applicants cast a wide net to improve their chances of selection, and programs conduct many interviews to try to obtain more information. Industrial organizational psychology would suggest that candidates complete prescreening assessments (situational judgment tests, personality profiles, integrity tests, etc) that evaluate competencies identified to be required for success in the position. The results would then be used by programs to determine who to invite to interview.

Some surgery programs have worked with industrial organizational psychologists to address the problems associated with interviewing for fellowships. Preliminary studies have shown improved efficiency, a reduction in interview numbers, improved candidate satisfaction, and improvement in the diversity of candidates considered.^{4,5}

Brian J. Dunkin, MD
Aimee K. Gardner, PhD

Author Affiliations: Houston Methodist Hospital, Houston, Texas (Dunkin); Baylor College of Medicine, Houston, Texas (Gardner).

Corresponding Author: Brian J. Dunkin, MD, Department of Surgery, Houston Methodist Hospital, 6550 Fannin St, SM 1661A, Houston, TX 77030 (bjdunkin@houstonmethodist.org).

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