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CAMS Relational Agent System (CAMS-RAS) for Suicide Prevention

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Study Title: CAMS Relational Agent System (CAMS-RAS) for Suicide Prevention
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Principal Investigators: Linda Dimeff, PhD & David Jobes, PhD, ABPP
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PROJECT ABSTRACT / INTRODUCTION

Every 13 minutes, someone in the United States (US) chooses to end his or her life, resulting in over 40,000 suicides in the US each year. The economic cost of suicide in the US was $34.6 billion annually in 2005; when adjusted for present day inflation, the economic toll rises to $42.2 billion[1]. The combined cost of medical and work loss is estimated at $34.6 billion annually[2]. In 2011, 487,700 people were treated in emergency departments (EDs) for self-inflicted injuries [3]. Beginning in 1999 with the Surgeon General's Call to Action to Prevent Suicide[4], millions have been devoted annually – both publicly (approximately $40 million from NIH) and privately (approximately $20 million from American Foundation for Suicide Prevention) – to prevent suicide[5]. Yet despite this significant and sustained effort, there is no evidence of a decrease in suicides or suicide attempts in the US[5].

Our overarching goal is to create a tool that could reduce suicide rates, increase delivery of efficacious suicide interventions, and decrease overall costs associated with suicidal behaviors. With this in mind, we intend to: (1) develop and scientifically validate a relational agent for suicidal patients that delivers Collaborative Assessment and Management of Suicidality (CAMS), an efficacious and cost-effective intervention developed by David Jobes, PhD, ABPP; and (2) to create an integrated software system (CAMS Relational Agent System; CAMS-RAS) that assists medical personnel by synthesizing the CAMS intervention findings into an easy-to-interpret report and providing empirically-derived clinical decision support; integrates into the health care system's electronic health record (EHR); enhances the patient's coping capability by including psychoeducational skills training modules for use during and after hospitalization; and automates the delivery of caring contacts, an efficacious and brief suicide prevention intervention provided after discharge. Our initial target will be EDs, as they are often the initial point of contact and where personnel must make the decision whether to hospitalize or discharge the suicidal patient. We will also conduct testing in other medical and outpatient mental health settings to ensure public health impact and commercial success.

SPECIFIC AIMS:

The concept for this project emerged from an invited NIMH/AHRQ-sponsored workshop, *Mental Health and Health IT: The Way Forward* (April 26-27, 2010) that sought to promote the use of innovative technologies to advance mental health treatments and to improve treatment accessibility, utilization and outcomes for those suffering from mental illness. There, Brian Jack, MD presented Project RED (Reengineered Discharge) and "Louise," a discharge planning nurse relational agent (avatar) designed to reduce hospital readmissions by improving discharge planning. Use of "Louise" reduced hospital readmissions by 30%. Importantly, 74% of patients who used "Louise" preferred her over a human nurse or physician. We wondered whether a relational agent like "Louise" could be used in EDs to facilitate a suicide risk assessment and intervention for the nearly half-million suicidal patients admitted annually to EDs, as well as other medical and clinic settings. Given the limited training in evidence-based suicide assessment, intervention, and risk management among ED and other medical personnel, such a tool, if effective, could significantly increase the proportion of suicidal patients who receive a cost-effective, evidence-based suicide intervention

Project Vision: Our overarching goal is to create a tool that could reduce suicide rates, increase delivery of efficacious suicide interventions, and decrease overall costs associated with suicidal behaviors. With this in mind, we intend to: (1) develop and scientifically validate a relational agent for suicidal patients that delivers Collaborative Assessment and Management of Suicidality (CAMS), an efficacious and cost-effective intervention developed by David Jobes, PhD, ABPP; and (2) to create an integrated software system (CAMS Relational Agent System; CAMS-RAS) that *assists* medical personnel by synthesizing the CAMS intervention findings into an easy-to-interpret report and providing empirically-derived clinical decision support; *integrates* into the health care system's electronic health record (EHR); *enhances the patient's coping capability* by including psychoeducational skills training modules for use during and after hospitalization; and *automates the delivery* of caring contacts[6-10], an efficacious and brief suicide prevention intervention provided after discharge. Our primary target will be EDs, as they are often the initial point of contact and where personnel must make the decision whether to hospitalize or discharge the suicidal patient. To ensure the broadest possible public health and commercialization impact, we will simultaneously conduct testing in psychiatric inpatient settings, on medical floors where patients are receiving medical treatment for injuries sustained during a suicide attempt, and in outpatient mental health clinics.

Phase 1 study aims include:

- **Aim 1:** Create a CAMS-RAS Advisory Board to advise team in its development and to ensure it aligns well with the needs and system requirements of hospitals and outpatient clinics treating suicidal patients and optimizes workflow to achieve successful commercialization and public health impact.
- **Aim 2**: Iteratively design and develop "Dr. Dave" (named and modeled after CAMS treatment developer, David Jobes, PhD), a socially and emotionally intelligent relational agent that can successfully perform the CAMS in the ED and other hospital departments; also design and develop prototypes of all other features planned for Phase II including: clinical decision support, optional risk management assessments, and non-demanding caring contacts.
- **Aim 3**: Conduct feasibility tests (usability, acceptability, and satisfaction) of CAMS-RAS (including "Dr. Dave") with primary target end-users including: *suicidal patients admitted to the ED, inpatient psychiatry, or medical floors (n=8, resulting from five onsite days at a local hospital)*, as well as hospital-based administrators (n=8), medical personnel (n=12), and peer advocates (n=7); *outpatient suicidal clients (n=20)* and outpatient administrators & clinicians (n=10).

BACKGROUND & SIGNIFICANCE

Suicide Remains a Significant Public Health Problem. Suicide is currently the tenth leading cause of death among Americans of all ages[2]. Over 40,600 suicides occurred in the US in 2012 – one suicide every 13 minutes[3] – and more than a million adults in the U.S. reported suicide attempts[3]. In 2012, 483,596 people were treated in EDs for self-inflicted injuries (primarily suicide attempts), of whom 332,833 people were hospitalized [3]. In 2012, the lifetime cost of self-inflicted injuries in the U.S. was $33 billion[11], including $1 billion for medical treatment and $32 billion in lost productivity[11]. The estimated annual cost of completed suicide was $34.6 billion, with each completed suicide costing over $1M[2]. A third of those who suicide test positive for alcohol, and nearly a quarter test positive for opiates[12]. The depression and despair leading an individual to consider suicide are profound, characterized by hopelessness about alternatives to end emotional pain. Family, friends, and co-workers also experience uniquely painful consequences following a loved one's suicide[13-16] and are often plagued by stigma[17,18]. Despite numerous public health initiatives and billions spent to combat suicide[11,19,20], the annual national suicide rate in the US continues to rise[1].

Further, most clinicians and ED personnel are unprepared or unwilling to treat suicidal patients[21-24]. For example, only 40% of psychology training programs[21,22, 111] and a third to half of psychiatry residency programs[25,26] provide training on suicide risk assessment and management. Unwillingness to treat arises from concern about making decisions that have life and death consequences, distress associated with the prospect of losing a patient, and/or fear of malpractice litigation[21,24]. Within the ED, while medical personnel are often confident in their ability to screen for suicidality, they are significantly less confident in their ability to assess severity of risk, counsel patients, and generate safety plans. Numerous studies also highlight that negative biases about suicidal patients exist among ED medical personnel[111] which may decrease the willingness of suicidal patients to openly communicate about their reasons for wanting to die and their intentions[111].

Treatments to Reduce Suicide Attempts and Suicides Do Exist. Linehan[27] recently summarized published findings from all available suicide-specific randomized controlled trials (N=43). Overall, outpatient psychosocial interventions show considerably more promise compared to inpatient hospitalization or pharmacotherapy[7,9,27-32]. Brief caring contacts via mail or phone were highly successful brief interventions that prevented death by suicide[6-10]. Specifically, those who receive a caring note from the hospital following discharge were nearly 10 times less likely to attempt suicide compared to controls in one study[6]; in others, those who received caring contact were nearly half as likely to attempt or complete suicide in the future[7-10].

CAMS is an Efficacious, Cost-Effective and Easy-to-Transport Intervention. CAMS was developed by David Jobes, PhD, ABPP for use by clinicians in engaging, assessing, and treating suicidal patients[33,34]. CAMS uses a chart-ready documentation tool called the "Suicide Status Form" (SSF) to serve as a clinical roadmap guiding assessment, treatment planning, and ongoing tracking of risk and outcome/disposition of care. The assessment information gathered via the SSF then informs a suicide-specific and problem-solving focused treatment plan including stabilizing the patient and identifying and treating the drivers of suicidality. Subsequent sessions begin with updating the SSF, and addressing the suicide-related issues and drivers. Each session ends with updating the CAMS treatment plan and crisis plan.

Seven non-randomized trials[35-41] and one RCT[42] across multiple treatment settings provide evidence that CAMS reduces suicidality. For example, two within-subjects pilot studies demonstrated rapid reductions of suicidal ideation on repeated measures of suicidal patients[37,38]. In one, Arkov et al.[38] reported significant improvements on the SSF for 27 community mental health participants. In the other, Ellis et al.[37] reported large effect sizes on a range of outcome variables, including hopelessness and psychological pain, as well as a 50%

drop on self-perceived risk of suicide among an inpatient sample. In a quasi-experimental comparison group clinical trial with 56 suicidal US Air Force personnel, Jobes et al.[41] found that patients receiving CAMS resolved suicidal ideation in significantly fewer sessions (M = 7.3) compared to care-as-usual (CAU) patients (M = 11.4). Moreover, CAMS patients had significantly fewer, and spent less time in, ED visits and primary care medical appointments compared to CAU patients by the six month assessment. Recently, Comtois and her colleagues[42] conducted an RCT that investigated the feasibility of CAMS within a "Next-Day Appointment" outpatient treatment setting. Suicidal patients (N=32) were randomly assigned to CAMS or a CAU control condition. While patients in both conditions improved overall, CAMS patients had significantly larger and sustained decreases in suicidal ideation, as well as significantly greater gains in overall symptoms and hope. Furthermore, CAMS subjects reported significantly higher satisfaction at the 12-month follow up.

Innovative Technologies Can Facilitate the Dissemination and Delivery of CAMS to Improve Reach and Public Health Outcomes. A substantial and growing body of research has emerged on the use of innovative technologies (IT) to improve mental health outcomes[43-45] using mobile technology[46-50], computerized CBT[45,47,51,52], and computer-assisted therapy[53]. Advances in computer science have allowed researchers to build relational agents who can deliver dialog based health and mental health interventions directly to patients[54,55]. While their use is novel, findings are promising. When agents give humans social cues, humans react as they would to a human[56]; they can be as engaging as humans[57]. In the area of mental health, users both accept and like agents, which enhance patient interactions with health interventions[58,59]. In EDs, a virtual discharge nurse ("Louise") was well accepted and liked, and significantly reduced hospital readmissions[60,61]. One relational agent is currently being investigated as a non-threatening provider of psychoeducation and referrals for veterans with PTSD or depression[54].

RESEARCH & DESIGN METHODS

The CAMS Relational Agent System is highly innovative in *what* it seeks to do and *how* it seeks to do it. We know no other project of its kind – one that uses a relational agent with highly vulnerable and distressed patients to perform an exquisitely sensitive clinical intervention. If we are able to build a relational agent that acutely suicidal patients find acceptable in delivering CAMS during a suicidal crisis and in the context of an ED, we will significantly add to the research literature on what is possible to achieve with relational agents in mental health. More importantly, we will be one step closer to solving a significant public health problem through increased access to an efficacious, cost-effective suicide prevention intervention.

CAMS-RAS "Transports" Dr. Jobes to the Suicidal Patient & Medical Providers 24/7. Rather than training all hospital medical personnel and outpatient clinic providers who treat suicidal patients to become proficient in suicide assessment and management procedures, and adherent in delivery of CAMS, CAMS-RAS will ensure the reliable and consistent delivery of CAMS to suicidal patients. Health professionals will receive clinical decision support consistent with best-practice and the latest research findings on predictors of suicide risk will aid personnel in deciding whether to hospitalize a patient.

The CAMS-RAS Platform will be Designed to Maximize Public Health Impact. First, we will design and build the platform and all CAMS-RAS features for ease of expansion to other settings and for other languages (a Spanish version of CAMS-RAS is planned for Phase III), and cultures (building a team of culturally diverse avatars to join "Dr. Dave"). Second, CAMS-RAS will be designed to incorporate other empirically-supported suicide prevention interventions, like use of non-demanding caring contacts in this project. Third, we will design it to integrate within the setting's ***workflow*** and to ***integrate into EHRs*** (versus as a stand-alone "silo"). Both aspects are imperative to increase the probability that large systems will adopt its use. Finally, CAMS-RAS will be offered as an additional product within our WILLOW product line of treatment delivery tools designed for use in health maintenance organizations and their EHRs (www.willow.technology). Our building of commercial partners, as well as development of the marketing and sales strategy for WILLOW, will speed successful commercialization of CAMS-RAS and thereby its public health impact.

CAMS-RAS Directly Addresses the NIMH Strategic Plan by Strengthening Public Health Impact of NIMH-Supported Research (Objective 4): To ensure that efficacious interventions generated through NIMH and other funding are "used by patients, families, healthcare providers, and the wider community involved in mental health care"[62], CAMS-RAS addresses all elements of NIMH Objective 4: It is an innovative method to facilitate the dissemination and implementation of an evidence-based practices (Strategy 4.1); and we will thoroughly (in Phase II and III) evaluate this new technology for information dissemination (Strategy 4.2). Finally, we will expand our network of meaningful relationships with key stakeholder organizations (Strategy 4.3) to include HealthPartners/Regions Hospital and Harborview Medical Center. (Current organizations partnering with EBPI in developing the Willow product line include Allina Healthcare, Group Health Cooperative, and Oregon State Hospital).

Overview. Our overarching goal is to develop a socially and emotionally intelligent relational agent ("Dr. Dave") and software system for suicidal patients and their treatment providers that: (1) facilitates the delivery of an evidence-based approach to suicide assessment and management, (2) integrates naturally treatment providers' workflow, and (3) streamlines the clinical assessment, intervention, and care of suicidal patients in diverse settings. Our primary Phase I target are EDs, as they are the initial point of contact for suicidal patients and face the important decision of whether to hospitalize or discharge the patient. To ensure the broadest possible public health and commercialization impact, we will simultaneously conduct testing in psychiatric inpatient settings, on medical floors where patients are receiving medical treatment for injuries sustained during a suicide attempt, and in outpatient mental health clinics.

In Phase I, we propose to develop and test key elements of the CAMS Relational Agent System (CAMS-RAS), including "Dr. Dave" who will engage suicidal patients in a 15-minute suicide risk assessment using a portion of the CAMS Suicide Status Form (SSF). We also will develop and test the basic designs for all other features planned for Phase II including: clinical decision support (content and graphical layout); optional suicide risk assessment modules; non-demanding caring contacts (*a brief intervention for post-discharge)*; and *brief skills-based behavioral interventions to decrease acute distress (e.g., paced breathing, progressive muscle relaxation, distraction strategies, etc)*. CAMS content will be developed in close collaboration with treatment developer Dr. Jobes, and CAMS research collaborator, Katherine Comtois, PhD, MPH. "Dr. Dave" will be built by Christine Lissetti, PhD in her Affective Social Computing Laboratory in The School of Computing and Information Sciences at Florida International University. Consistent with the novelty and complexity of this project, Phase I outcomes will include: usability (e.g., Can target end-users easily use all elements of the system?); satisfaction (e.g., Do suicidal patients like "Dr. Dave" and wish to engage with him; are the caring contacts messages from Dr. Dave viewed positively?); and acceptability (e.g., Do suicidal patients, treatment providers, and administrators find CAMS-RAS acceptable?). In the event of a successful Phase I, we will proceed to Phase II to complete all elements of CAMS-RAS, *including necessary training (for providers) and systems implementation materials (for administrators) to ensure the successful use of CAMS-RAS*. We will then conduct a RCT comparing CAMS-RAS to care-as-usual in hospitalized and outpatient suicidal patients. In addition to use of Phase I outcome variables, Phase II client outcome variables will include: decreases in suicidal ideation, suicidal attempts, and hopelessness; and increase in perceived reasons to live. Provider outcomes variables will include: increased self-efficacy in intervening with suicidal patients; system-level outcomes will include cost-effectiveness.

Rationale for Phase I Scope. While the CAMS-RAS has the potential for significant public health impact, there are a number of unknowns. For example, will suicidal patients respond favorably to "Dr. Dave"? Will they like him enough to welcome and benefit from caring contact *brief interventions* delivered from him at a later date? Table 1 provides a summary of many of our questions. After much consideration, we decided to focus Phase I on the most basic questions: Can we successfully build a relational agent that acutely suicidal patients will find acceptable for purposes of performing a suicide risk assessment and intervention? Furthermore, can we link it to a broader system that will meet the needs of medical personnel and their administrators?

Product Description. The CAMS-RAS, when Phase I and II are completed, will consist of the following components: "Dr. Dave" (the relational agent); clinical decision support to help medical personnel determine the patient's suicide risk and whether hospitalization is indicated; non-demanding brief intervention caring contacts; optional modules for more in-depth assessment of behavioral risk factors for suicide (drug/alcohol abuse[12]; intimate partner violence[63], etc.), psychoeducational coping skills training, including evidence-based behavioral skills for assisting patients in regulating their emotions and tolerating distress (e.g., diaphragmatic breathing, paced breathing, progressive muscle relaxation, etc.); training tools to teach personnel how to use CAMS-RAS; and a systems architecture design document illustrating a step-wise approach to integrating CAMS-RAS within systems' EHRs. This document will illustrate how information provided by the patient to "Dr. Dave" will flow into the EHR so medical personnel can readily access it. The design document will also illustrate where the clinical decision support will reside. Table 2 provides a provisional description of several key CAMS-RAS features for Phase I and Phase II.

The centerpiece of the CAMS-RAS system is "Dr. Dave", a relational agent, or avatar, that will deliver the SSF to assess the user's suicide risk; "Dr. Dave" will communicate using Text-to-Speech while the patient answers by typing in free responses or selecting from multiple-choice items. "Dr. Dave" will respond empathically, with verbal and non-verbal expressions. The computer codes the user's responses to quantitative items and collates qualitative responses into a clinically useful summary that includes intervention recommendations for review by the clinical team.

Formative Evaluation: Usability, Satisfaction, and Acceptability Studies. Because the success of any system rests on whether end-users like, can easily use, and find it acceptable, we will solicit extensive input

from target end-users and stakeholders throughout the Phase I process. Often referred to as user-centered design[64,65], we use a rigorous iterative process of development in which end-users join each development cycle, using and giving feedback on prototypes, to ensure product design successfully meets their needs. We will iterate on all CAMS-RAS features as often as necessary to ensure usability, satisfaction, and acceptance, and to optimize workflow among medical personnel who use CAMS-RAS. Each iterative phase of development will involve testing with no less than five individuals, allowing the development team to validate hypotheses and themes, and to guard against outliers.

Participants, Settings, and Recruitment. Primary target end-users include: 1) suicidal patients currently admitted to EDs, psychiatric inpatient units, and medical floors (n=8; gathered during a total of five onsite days at a local hospital); 2) hospital medical personnel who treat suicidal patients (n=12); 3) hospital administrators (n=8); 4) hospital-based peer advocates (n=7); 5) outpatient mental health clinicians and administrators (n=10); and 6) suicidal individuals currently receiving outpatient mental health services (n=20). All research participants will be 18 years or older. Hospitalized suicidal patients will be initially invited to participate in the study by the ED's Chief, onsite coordinator, or their designee ("onsite contact"); outpatient suicidal clients will be invited to participate by their outpatient clinician. To ensure external validity, Phase I exclusion criteria will be limited to the following criteria: (1) acutely psychotic and thus unable to provide informed consent; (2) severely agitated (as deemed by physician, nurse, or outpatient therapist); and (3) not fluent in English as the initial "Dr. Dave" will be English-speaking. (We will create a Spanish-speaking "Dr. Dave" in Phase III). Prospective medical personnel, outpatient clinicians, administrators, and stakeholders who wish to participate as subjects will learn about the project from their onsite coordinator. Inclusion criteria for non-patient participants will include English fluency. Those interested in participating will be referred to the research team for consenting. Hospital patients will be recruited from Harborview Medical Center (Seattle, WA). Hospital medical personnel, administrators, and other stakeholders will be recruited from Harborview and Health Partners/Regions Hospital (St. Paul, MN). Outpatient mental health clinic administrators and therapists will be recruited from Portland DBT Institute (PDBTI; Portland, OR), DBT Center of Michigan (Holt, MI), and Mid-Valley Behavioral Care Network (Portland, OR). Suicidal outpatients will be recruited from PDBTI.

No less than 50% of hospital clients and medical personnel will be recruited from Harborview's ED because the ED is the initial point of entry for many suicidal patients admitted to a hospital. Additionally, EDs face the weighty decision of whether to hospitalize or discharge the patient (e.g., stigmatization of the patient, high healthcare costs associated with psychiatric hospitalization, risks of a completed suicide). Finally, the acute nature of the suicidal crisis when patients are in the ED allows us to design CAMS-RAS to appropriately incorporate the complexity of the tasks ED staff face as we build "Dr. Dave" and to determine the research procedures that will be required for a successful Phase II trial.

Procedures. Patient Participants**:** For efficiency and safety in recruiting, consenting, and testing hospitalized and outpatient suicidal patients, we will establish specific dates in which Drs. Dimeff or Koerner (both licensed clinical psychologists with expertise in treating suicidal patients) will be onsite to conduct testing. Hospital onsite visits (five days total) will coincide with the work schedule of our onsite contacts to ensure that eligible suicidal clients are informed of the study and, if interested, directly introduced to study staff. We will then conduct the informed consent process. PDBTI suicidal outpatients will learn about the study from their clinician. Those wishing to participate will contact study research assistant (RA) via the phone for purposes of screening and informed consent. The RA will describe the study, answer questions, and conduct informed consent. After providing consent, an appointment with Dr. Dimeff or Dr. Koerner will then be arranged at PDBTI. Before conducting the user-testing, Dr. Dimeff or Dr. Koerner will administer the demographics measures; following the testing, participants will be asked to complete a usability measure and a brief semi-structured interview. Measures may be completed verbally, using paper/pencil or an online method as directed by the onsite contact to ensure patient safety. Expected duration of the study session after informed consent (e.g., user-testing, brief measures completion, and semi-structured interview) is 45 to 90 minutes, depending on the task, extent of participant feedback, and capacity of participant. Subjects will be compensated $50 for their time. Non-Patient Participants: After learning of the study from the onsite contact, those interested in participating will contact our offices via phone or email to schedule a brief screening interview with the RA. Those meeting study criteria will then be sent (via email or fax) the informed consent form for review during the telephone call. The RA will review informed consent; those providing verbal consent will return the signed informed consent via fax, scan, or standard mail. An appointment with study staff will be scheduled at a mutually convenient time, either remotely or in-person, depending on what is most efficient and the content being reviewed. Remote sessions will occur via the telephone and Join.Me, a free online screen-sharing service. All assessments will be conducted online. Expected testing length is 45 to 90 minutes; subjects will be compensated $50. During Phase I, use of "Dr. Dave" will be under the guidance and instruction of study staff. Thus Phase I participants will require no training in the use of "Dr. Dave."

End-User Testing. Patient-Participants. Special attention will be paid to their reactions to "Dr. Dave's" emotive and communicative expressions, as well as the helpfulness and genuineness of the non-demanding caring contacts messages. In addition to usability and acceptability, considerable emphasis will be placed on users' interest in "engaging" with "Dr. Dave", the extent to which they feel connected to and understood by him, and their degree of interest in receiving non-demanding caring contacts from him. Early on in the process of product development, feedback will primarily be derived by showing subjects low-fidelity representations of "Dr. Dave" and conducting a semi-structured interview done by Dr. Dimeff or Dr. Koerner. The interview will be guided by questions like those in Table 2. The intent of this interview is to understand the user's likes, dislikes, and preferences. Once the first "Dr. Dave" prototype is built, to aid in our understanding of design problems that interfere with intended use we will begin a "talk out loud" process where users will verbalize their thoughts and actions in real-time as they interact with the software system. We will conduct the semi-structured interview after this process to better understand their comments and preferences. Service Professional & Stakeholder Participants. The testing process is identical to the patient testing method described above with the following exceptions: considerably less emphasis will be placed on "Dr. Dave" and content of the caring contacts; emphasis will instead be placed on workflow integration, the content and layout of the clinical decision support, and risk management considerations (for administrators). These subjects may be asked to provide input and guidance on more than one occasion during the developmental process. (They will be compensated $50 for each point of contact).

Assessment Instruments-Patients. The Demographic Questionnaire-Brief (DDQ-B)[66] obtains limited, essential demographic data. The Patient Health Questionnaire-9 (PHQ-9)[67] is a brief nine-item multiple-choice, self-report measure[68] used as a screening and diagnostic tool. **Non-Patients:** The Demographics Questionnaire (DQ)[69] obtains a wide range of demographic data about healthcare providers. The Usability, Satisfaction and Acceptability Questionnaire (USAQ) is a brief face-valid, self-report measure that the PI derived from the System Usability Scale[70,71] and has successfully used in previous studies. Items are rated on a five-point Likert scale (1 = poor; 3 = good; 5=excellent). The USAQ will include open-ended questions to better understand what was most/least helpful with respect to each category as well as additional items to measure users' acceptance of the avatar.

Data Management Procedures. Participants will be assigned a participant identification number which will be used to label all data collected. A single list of participant names linked with ID numbers will exist in a password-protected electronic file stored securely and accessible only to study staff. Research staff must use their names and passwords to access the storage site itself. Signed copies of participant consent forms will be stored in a locked file cabinet in a locked office at the EBPI site, accessible only to the PIs and research team or electronically on a secure, password protected site with maximum protections. Participant ID numbers will not appear on consent forms.

Data Analysis. Qualitative data will include written feedback from participants and annotations from investigators noting: likes, dislikes, confusion, suggestions for improvement, misunderstandings, and potential unintended consequences. Qualitative data will be analyzed using a grounded theory approach (a data-reduction method for qualitative data used to generate and test hypotheses from the ground up)[72]. Data from the USAQ will determine feasibility: USAQ scores below a 3.5 on a five-point Likert scale will indicate a need for improvement. An aggregated mean score of 3.5 or higher will support feasibility.

PROTECTION OF HUMAN SUBJECTS

Because our patient participants will be currently acutely suicidal and/or recently hospitalized because of suicidality, there is a higher probability than usual for the study procedures to cause emotional distress. (It is equally possible that engagement with Dr. Dimeff or Koerner and turning their mind to another topic will serve as a distress tolerance/coping strategy, and in the moment of their participation, reduce their anguish). Even with this sensitive population, we believe the risk to be low for several reasons. First, the department chair or a designee will determine who is sufficiently stable to engage in the interview process. They will rule out those patients they believe to be at considerable imminent risk and/or so agitated that engagement in the study protocol could cause harm to them or the interviewers. Second, both Dr. Dimeff and Koerner are highly experienced in interacting with acutely suicidal patients and as such, will be able to gauge whether to reduce the length/scope of the interview, discontinue the testing, and/or teach these patients distress tolerance strategies (e.g., paced breathing, distraction techniques). Third, it is likely that for the majority of individuals, engagement doing the research trial will function as a distraction from either the events resulting in their suicidality and/or from unpleasant elements of their hospitalization.

The most distressing portion of the testing for patients may be at the beginning, when asked to complete the PHQ-9 to assess their psychological distress. Importantly, items from both of this measure are similar to those commonly and routinely asked of suicidal clients upon admission. The Suicide Short Form (SSF) also involves the individual reflecting on the "drivers" for suicide as well as their "reasons for living".

Other potential risks common to participants are minimal. Some participants may feel discomfort as they provide feedback on the relational tool and answer the questionnaires because they are hesitant to criticize the tool that we have developed. Because patients will be referred to the study by a service professional that they have received treatment from, they may feel some pressure to participate. Non-patient participants may also feel a similar pressure to participate as they will receive the recruitment materials from their supervisors/administrators. There is also the potential risk of loss of confidentiality.

There is no known physical, social, economic, or legal risk from participating for patients and non-patients. There are no known alternative procedures to assess this information.

The primary alternative to participating in the research is to elect not to participate in the research. Patient refusal to participation will not affect their treatment and provider refusal to participate will not affect their employment. Participants will be informed that they have the right to refuse to participate or to discontinue participation at any time.

Protections against Risk:
The primary risk to participants is relevant only to client participants and involves the potential for the study procedures to engender emotional distress or further increase their suicidality. As mentioned earlier, these risks are minimized by the design of the study: clients will be referred by our onsite contacts who know each patient's clinical presentation, we will have limited contact with the client (45-90 minutes), the primary focus of and assessment and user testing will be the relational agent, and the patient will be receiving treatment at the time of the user test. Additionally, Drs. Dimeff and Koerner, who will be conducting the user tests, are experts in treating suicidal patients. In the event that they determine that the study procedures are causing or increasing distress or suicidal ideation in a particular client they will stop the user immediately and inform the patient's care team. Drs. Dimeff and Koerner will collaborate closely with co-I Dr. Kate Comtois throughout the study to ensure proper management of high-risk situations. Dr. Comtois has been conducting assessment and clinical trial research with suicidal individuals for more than 15 years and has taught over 25 research assistants to conduct these interviews and assess and manage risk during suicide risk assessments. She has been a member of the NIMH Data Safety Monitoring Board (DSMB) since 2001 as well as serving on two other DSMBs for clinical trials with high-risk participants. As overall PI for study, Dr. Jobes will be consulted for concurrence with plan on imminent risk situations as well.

To protect patient participants from loss of confidentiality, the following procedures will be employed. Each client participant will be given an ID number and no identifying information will be written or documented on any data collected from the participant. Only the PIs, Co-I, and research staff trained in procedures for conduct of ethical human subjects research will have access to audio-visual recordings of user test sessions and to study data exported from SurveyMonkey. The identity of participants will be kept separate from records of their data. As noted below, data will be identified by a participant code only. The master list that links subject names and code numbers will be stored in a password-protected computer file that is stored on the computer of one of the PIs and one member of the research team. Audio-visual recordings of user testing data will be stored in password-protected, encrypted files on a password-protected computer. For service providers and stakeholders, these data are not considered to be sensitive or health-related, because participants are providing information about their experience of the CAMS-RAS, not sensitive information about themselves. For patients, this data is considered sensitive, given that participants will be identified as being mental health clients. Therefore, as described above, the identity of all participants will be kept separate from records of their testing data.

Participants will also be asked to complete the aforementioned self-report questionnaires on SurveyMonkey. To complete the questionnaires, participants will enter their unique participant code rather than identifying demographic information into SurveyMonkey. Data gathered via SurveyMonkey will be securely transmitted and stored according to SurveyMonkey's data security policy, accessible only to the PIs, Co-Is, and research

staff via a password secured account. Study RAs will download the data from SurveyMonkey and place it into a local database that is password protected and does not include any identifying information beyond the participant code.

User testing data will be recorded and stored on EBPI secure computer systems. Data will be securely stored on password protected EBPI computers, accessible only by research staff who have completed training in ethical conduct of human subjects research. User testing data will be destroyed after 5 years. We will safeguard service providers and stakeholders from perceiving pressure from their supervisors/administrators to participate in several ways. First, we will instruct supervisors/ administrators to invite but not pressure their employees to participate. Second, supervisors will invite their employees to participate, but will not participate in the consent process. Instead, service providers will contact the study RA to initiate the consent process. Finally, supervisors will not be informed of their staffs' decision to participate in the study.

We will safeguard patients from perceiving pressure from their treatment provider to participate in several ways. First, we will instruct service providers to invite but not pressure clients to participate. Second, clinicians will recruit and invite their patients to participate, but will not participate in the consent process. Instead, patients will contact the study RA to initiate the consent process. Finally, service providers will not be informed of clients' decision to participate in the study. Dr. Koerner will be available to talk with any clinician or study participant who experiences discomfort related to the study procedures. Her contact information will be included on the consent form and all participants will be made aware of this resource in the event that it is needed.

Management of Adverse Events. Participants will be provided with information about how to report Potential Adverse Events (patients will report to the chair of their department or the onsite coordinator; non-patients will be directed to a study website). In addition, client participants will be encouraged to report any Potential Adverse Events directly to their medical personnel who is in charge of their care. Potential Adverse Event reports will be monitored daily by study staff. Because the risks to participation are low, the likelihood of Adverse Events related to the proposed research is judged to be low. In the event that a Potential Adverse Event is reported, the departmental chair and a PI/Co-Investigator will be notified by the system immediately. The chair and/or Co-PI/Co-Investigator will then assess the situation and determine an appropriate clinical and ethical course of action, including report of an Adverse Event to the PI, EBPI's IRB (BHRC) and the Data Safety Monitoring Board.

Potential Benefits of the Proposed Research to Human Subjects and Others
Patient participants may benefit from improved care as a result of their interaction with the relational agent. Findings from this study will be used to develop a product that is intended to increase quality of care for patients who recently made a suicide attempt or are struggling with suicidal ideation.

IMPORTANCE OF THE KNOWLEDGE TO BE GAINED
The proposed research contributes to the goal of improving quality of care for suicidal patients, particularly in EDs where there is often a lack of sufficient mental health resources. Developing a successful relational agent based on CAMS means that suicidal patients will receive evidence-based assessment and treatment delivered in a more timely, effective, and efficient manner than is typical in EDs and other settings.

PLANNED ENROLLMENT

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	0	0	0	0	**0**
Asian	3	1	0	0	**4**
Native Hawaiian or Other Pacific Islander	0	0	0	0	**0**
Black or African American	6	5	2	0	**13**
White	21	16	5	3	**45**
More than One Race	2	1	0	0	**3**
Total	**32**	**23**	**7**	**3**	**65**

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