Study Protocol

Official Title: Screening Wizard, Component 1 of iCHART (Integrated Care to Help At-Risk Teens)- Feasibility/Pilot Phase

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Scientific Background

Depression is the single most important contributor to suicidal ideation, attempt, and death by suicide among adolescents. Consequently, the United States Preventive Services Task Force (USPSTF) recommends that all adolescents be screened annually for major depression when formal procedures are in place to follow-up on a positive test. These recommendations have been implemented at Children's Community Pediatric (CCP) practices where adolescents who present for routine care are requested to complete the PHQ-9 depression screen on a tablet computer handed to them as a part of routine care, and embedded mental health services are present. Embedded mental health services refers to mental health services that occur within the pediatric primary care office (referring to a therapist or other mental health provider being housed within the same facility as medical providers). All practices within CCP from which this project will recruit have embedded mental health providers available, on-site. However, remaining challenges are that pediatric primary care providers (PCPs) are uncertain about how to: (1) interpret the results of screens and, (2) assess and integrate information about patient beliefs, preferences and barriers to guide their management decisions as recommended by the latest Guidelines for Adolescent Depression in Primary Care (GLAD-PC). These challenges may account for making referrals that are a less-than-ideal fit for the patient and may partially account for low rates of treatment adherence in patients who screen positive for depression. Screening Wizard aims to design and test an automated decision-support system that will provide PCPs with this information and facilitate "formal procedures to follow-up on a positive test" as recommended by the USPSTF.

Study Objectives

Screening Wizard seeks to increase the rates of personalized referrals by PCPs among adolescents who screen positive on the PHQ-9 for depression and/or suicidal ideation at community pediatric practices by providing PCPs with decision-support recommendations that are personalized to: 1) the adolescent's symptom acuity, suicidal ideation, and comorbidities as well as 2) the adolescents' and their parents' treatment preferences, readiness for treatment, and potential barriers to following through on PCP recommendations (e.g., negative attitudes toward treatment). The goal is to provide PCPs with an opportunity to address these barriers and thereby increase the likelihood that adolescents and parents feel that their needs were met. We will collaborate with NuRelm and the Methods Core to create and rapidly iterate Screening Wizard's computerized adaptive screen, user interface, and presentation of treatment recommendations among a sample of PCPs, adolescents and their parents. NuRelm has experience with the development of behavioral health applications. Afterwards we will test the effectiveness of supplementing the PHQ-9 already administered at community pediatric practices with our tool.

Aim 1b (Phase 1b, Feasibility). To examine the feasibility of Screening Wizard in pediatric primary care clinics using a stepped wedge design. In order to enhance uptake of SW by community pediatric clinics, we will conduct the proposed work within the RE-AIM framework.

Aim 2: To examine the cost-effectiveness of Screening Wizard vs. TAU determined through service utilization of healthcare and social services.

In relation to economic analysis, we will conduct incremental cost-effectiveness analyses (CEA) to test the hypothesis that the cost per outcome achieved will be lower for adolescents exposed to ETUDES interventions (Screening Wizard is 1 of 3 interventions within the ETUDES Center) versus our treatment as usual (TAU) control condition. We will adopt a societal perspective assessing the cost of all usual health services, costs of services in other sectors (e.g., school), and costs to the families (e.g., out-of-pocket costs, missed time from work). This perspective will provide the type of data relevant to health care managers and health policy makers who would make decisions about whether or not to adopt our interventions.

We will pilot Screening Wizard in two community pediatric practices using a stepped wedge design (n=2 clinics, 50 adolescents).

Hypothesis 1b: Screening Wizard will increase the rate of personalized referrals, compared to TAU. We will perform multilevel modeling to explore time effects and intervention-level factors associated with Screening Wizard. We will first conduct t-tests for continuous variables and chi-square tests for categorical variables to examine for baseline differences in demographic and clinical variables. We will use generalized linear mixed models (nesting for site) to examine for between-intervention differences in personalized referral rate. Baseline characteristics distinguishing groups will be included as covariates in models examining treatment effects. Criterion for success: 75% of PCP recommendations partially or completely match Screening Wizard personalized referral and there is a 50% increase in number of parents and adolescents who feel their needs were met after the PCP visit during the Screening Wizard phase compared to TAU.

Study Design & Methods

The information that will go into Screening Wizard will be clinical severity as determined by the patient reported PHQ-9 and Y-CAT adaptive screens for suicidal risk, anxiety and mania, screen for trauma risk and substance use history as per routine screen already performed at practices, parent perception of adolescent functioning, both parent and patient readiness for treatment, treatment preferences (antidepressants and psychotherapy), depression literacy, and adolescent and parent perceived barriers to treatment, with an estimated total time for screening of 4 minutes or less, including the PHQ-9 and adaptive screen for suicide risk. The PHQ-9 report of functional impairment and total score, and the screens for suicidal risk, anxiety, mania, and substance use provide information about acuity and the need for specialty vs. primary care location for treatment, and the attitudinal measures will shape recommendations that reflect personal preferences, readiness to engage in treatment, depression knowledge, and perceived barriers.

During TAU, PCPs will receive a PHQ-9 score and results of the suicide item. When the clinics

implement Screening Wizard, PCPs will receive reports of screening results with accompanying decision support. A one-page results sheet will be wirelessly sent to an in-office printer for the PCP to examine prior to the visit as well as integrated into the EHR. In addition, the PCP will receive psychoeducation material personalized to the parent and adolescents' preferences and concerns identified by the assessment which can be printed or electronically sent to patients and parents. For example, a PCP may receive a one-page document that lists: the patient's name and date of birth; their mental health screening results (e.g. MENTAL HEALTH SCREENING RESULTS: Depression Score (PHQ-9) = 14 – Consider Depressive Disorder, Moderate Severity, Mild functional impairment; ED Stars Suicidality Concerns: Low, Anxiety: Consider Generalized Anxiety Disorder, Mild Severity; Mania: Negative Screen; Substance Use: Negative Screen), Functioning Score (Parent Report): Moderate Problems with Functioning; a Values Results Table which categories the following: readiness for treatment, treatment preference, depression knowledge, identified barriers in both the adolescent and parent (e.g. adolescent and/or parent prefer therapy; adolescent identifies barriers of stigma and school/activities conflict and parent identifies barriers of stigma and insurance coverage/cost), noting any differences between the two – as issues of high concern, some concern, or no concern. In this example, all categories may be of some concern to both the adolescent and parent but the adolescent's depression knowledge is high while the parent's is medium and there, a difference is noted. Then the personalized referral recommendation will be provided based on the decision support algorithm. In this example, the PCP will be instructed to "consider referral for psychotherapy by a embedded mental health specialist and ask patient to schedule a PCP follow-up appointment to reassess if after reviewing materials, they change their mind regarding treatment preferences or have further questions." Additionally, personalized psychoeducation materials obtained from a menu of mental health resources matched to the patients' value results will be listed and printed. These resources were gathered and approved by an expert committee including Dr. Radovic through the Youth Providers 2.0 initiative funded by the Agency for Healthcare Research and Quality. In this example, these include: 1) Parental Education on Depression in Children; 2) Stigma Handout for Adolescent; for Parent; 3) Parent Guidance re: Insurance for Mental Health; 4) Adolescent-Parent Guidance on Asking for School Accommodations for Mental Health Concern. Screening Wizard helps to target the selection of materials in such a way as to potentially promote treatment initiation. In this example, the parent may realize that the patient has a conflict between attending a treatment appointment and school activities. Screening Wizard would recognize this discrepancy and provide the parent with materials about school accommodations, which might increase likelihood that the adolescent would attend treatment and the parent would be satisfied with visit.

Screening Wizard will be developed with iterative feedback from end-users (both families and PCPs) using principles of user-centered design with the assistance of the ETUDES Methods Core in conducting qualitative studies described below. A decision tree based on available evidence and expert consensus will determine personalized treatment recommendations with input from the measures as described above. The flowchart for the decision tree will be refined during the usability (phase 1a) and feasibility (phase 1b) phases of the study and will include an immediate referral to a suicidality intervention provided by the primary care clinic staff if high suicidality is identified by PHQ-9 item 9 and the adaptive suicide assessment. The decision tree will prioritize decisions as to how quickly patients should be seen, and in what sector based on suicidality, depression severity, parent perception of adolescent functioning, and presence of

comorbidities. The default treatment recommendations made based on depression severity will then be modified based on: 1) readiness for treatment and 2) treatment preference considering A) congruence between the adolescent and parent, B) depression knowledge, and C) identified barriers. We will also inquire about family history of bipolar illness. The NuRelm team and Methods Core will support integration with the Epic EHR at this stage.

In the Phase 1b, Feasibility, we will test the feasibility of using
Screening Wizard in two community pediatric practices (n=50) using a stepped wedge design. We hypothesize that participants, parents, and clinicians will find the intervention usable and feasible to deploy.

To operationalize the main outcome, we will review the EHR for the treatment recommendation made by the PCP and categorize it as: 1) PCP recommendations matches Screening Wizard referral; 2) PCP recommendation partially matches Screening Wizard referral; or 3) PCP recommendation does not match Screening Wizard referral.

For example, if the Screening Wizard recommendation would be to "consider referral for psychotherapy by a embedded mental health specialist and ask patient to schedule a PCP follow-up appointment to reassess if after reviewing materials, they change their mind regarding treatment preferences or have further questions." If the PCP treatment plan is to refer to embedded mental health specialist AND schedule a PCP follow-up appointment, this would be a match outcome; if the PCP treatment plan is to ONLY refer to embedded mental health specialist this would be a partial match outcome; if the PCP treatment plan is to start an antidepressant, this would be a does not match outcome. Additionally, we will cross-validate the Screening Wizard results in a random sample of 20% of referrals made via Screening Wizard by comparing the Screening Wizard recommendation with the recommendation made by two experts (Drs. Brent and Goldstein) in depression treatment.

Eligibility Criteria

Youth Inclusion Criteria:
-Youth aged 12-26 yo
-Biological or adoptive parent is willing to provide informed consent for teen to participate
-Youth speaks and understands English

Youth Exclusion Criteria:
-Non English speaking
-No parent willing to provide informed consent
-Is currently experiencing acute mania or psychosis, evidence of an intellectual or developmental

disorder (IDD), life threatening medical condition that requires immediate treatment, or other cognitive or medical condition preventing youth from understanding study and/or participating.

Statistical Considerations

A stepped wedge design was selected for both ethical considerations and feasibility. A stepped wedge cluster randomized trial design involves the sequential random rollout of an intervention over multiple time periods following a "baseline" period when no cluster has been exposed. The crossover is typically in one direction, from control to intervention, and continues until all of the clusters receive the intervention with observations taken from every cluster and at each time period. All 3 studies in the ETUDES Center, and specifically, Screening Wizard, will utilize this design. Prior to study start, each CCP study practice will be randomly assigned to switch from Treatment As Usual (TAU) to the intervention.

In the proposed stepped wedge design, all practices start with TAU (i.e.,PCP referral to embedded MH care) and are randomized to transition to implement Screening Wizard at different times. All clinics will be initially monitored for at least 2 months during TAU, followed by a staggered adoption of Screening Wizard. During each time period, a new clinic will begin to use Screening Wizard (order determined by block randomization. A web-based system will randomly assign the next clinic to begin.

Hypothesis 1b: Screening Wizard will increase the rate of personalized referrals, compared to TAU. We will perform multilevel modeling to explore time effects and intervention-level factors associated with Screening Wizard. We will first conduct t-tests for continuous variables and chi-square tests for categorical variables to examine for baseline differences in demographic and clinical variables. We will use generalized linear mixed models (nesting for site) to examine for between-intervention differences in personalized referral rate. Baseline characteristics distinguishing groups will be included as covariates in models examining treatment effects. Criterion for success: 75% of PCP recommendations partially or completely match Screening Wizard personalized referral and there is a 50% increase in number of parents and adolescents who feel their needs were met after the PCP visit during the Screening Wizard phase compared to TAU.

Due to the pilot nature of this study, sample size and power considerations center around the precision of confidence interval (CI) width estimation for feasibility outcomes. In the Development Phase (Aim 1), a sample size of 50 affords us a 95% CI width of no more than 0.28.