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The Incubator Treatment Development Model: The SAFETY Treatment for Suicidal/Self-Harming Youth

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Youths who make suicide attempts or engage in repetitive self-harm are at risk for future suicide attempts and death by suicide or self-harm. This treatment development report focuses on the Safe Alternatives for Teens and Youth (SAFETY) treatment. SAFETY is a 12-week outpatient child and family-centered cognitive-behavioral treatment, informed by dialectical-behavior therapy, and designed to promote safety following a suicide attempt or repeated episodes of self-harm. Previous reports have described results of small open and randomized treatment development trials. Here, we describe our "incubator" treatment development model. Combining scientific rigor with attention to the community context in which treatment is delivered, the incubator model emphasizes laboratory-based treatment development trials and quantitative and qualitative data generated through partnerships with community treatment sites and youth and parent consumers of care. Aims of this approach are to: (1) integrate information from our partners throughout the treatment development process; (2) create a more feasible and easily transportable "youth" and "family" centered treatment; and (3) accelerate the pace with which laboratory-based treatment advances can be incorporated into improvements in community care. We describe our incubator treatment development model and how data generated through our treatment development process and interactions between the laboratory and community teams contributed to the development of the SAFETY treatment.

Despite extensive scientific advances, suicide and suicide attempts continue to occur at unacceptable rates. In the United States (U.S.), the age-adjusted suicide rate increased 33% from 1999 to 2017 (Hedegaard et al., 2018), suicide is currently the second leading cause of death among youth ages 10-24, and rates of suicide deaths exceed those for any single medical illness (Kochanek et al., 2019).

Suicidal ideation and behavior frequently have their first onsets during adolescence and lead to increased suicide and suicide attempt risk across lifetimes. While we have treatments for suicidal and self-harming youth that have yielded reduced suicide attempt rates in open and single randomized controlled trials (RCTs), some promising results have failed to replicate. There are two independent trials supporting the efficacy of dialectical behavior therapy (DBT) for reducing self-harm, a composite variable that includes suicide attempts, nonsuicidal self-injurious behavior (NSSI), and self-harm with unclear intent (McCauley et al., 2018; Mehlum et al., 2014). However, these results mostly reflect decreased NSSI due to the higher frequency of NSSI compared to suicide attempts. While the second DBT trial (McCauley et al., 2018) found a DBT advantage for reducing suicide attempts at post-treatment, we still have no treatments with demonstrated efficacy for reducing suicide attempts in both original and replication RCTs (Asarnow & Mehlum, 2019; Brent, 2011; Iyengar et al., 2018; Ougrin et al., 2015). Current research also indicates problems with continuity of care after suicidal episodes with too many youth receiving inadequate (or no) follow-up mental health treatment, as well as few detectable

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benefits of community treatment, perhaps partly due to inadequate treatment dose (Asarnow, Baraff, et al., 2011; Bridge et al., 2012; Hughes et al., 2017; Rowe et al., 2014).

To address the critical need for an effective treatment for this population, we developed the SAFETY treatment. Our treatment development process carefully attended to the need to develop a treatment that would be both acceptable to and valued by the targeted population of youth and families presenting with suicidality, while also being acceptable and feasible in routine community settings. Our prior reports have described results of an initial open trial, a small randomized controlled trial, and predictors of treatment response; these results support the initial efficacy of the SAFETY treatment for reducing suicide attempt risk and improving clinical outcomes and functioning (Asarnow et al., 2015, 2017; Babeva et al., 2019).

This article describes our treatment development model, how this model compares with alternative models, and how our model guided and informed the development of the SAFETY treatment. Throughout, we focus on practical clinical issues and the potential of our treatment development model for accelerating the pace with which laboratory-based advances can be translated into improvements in community care.

Incubator Treatment Development Model

Similar to the business incubator model, our "incubator model" emphasizes the use of controlled environments to accelerate the success and growth of the developed treatment and combines rigorous testing within the lab and outreach to community partners delivering services and youth and parent consumers of treatment. This approach aimed to: (a) integrate information from our partners throughout the treatment development process; (b) create a more feasible, acceptable, and transportable "youth"- and "family"-centered treatment; and (c) accelerate the often-cited 17-year gap between the demonstration of treatment efficacy in research trials and availability in routine community treatment settings (Institute of Medicine [U.S.] Committee on Quality of Health Care in America, 2001; Morris et al., 2011).

As shown in Figure 1, our approach included work in the lab (top row) with development of a preliminary treatment manual, followed by initial pilot testing, and more extensive testing to evaluate treatment efficacy and safety (Asarnow et al., 2017, 2015; Babeva et al., 2019). Input from community partners and youth and parent consumers of care (lower row of Figure 1) was also obtained from the very beginning as we developed our initial treatment manual. This work began with consultation with community providers and leaders of clinical organizations regarding the needs of community settings and potential constraints and barriers that could impact treatment feasibility, extended to clinician surveys and qualitative interviews with youth and parent consumers of care, and examined feasibility issues through pilot testing within community treatment sites. As described in more detail in later sections of this article, input from community partners informed our laboratory treatment development work through all phases of our work. This community input was obtained through individual consultations, survey and interview procedures, and a formal Advisory Board meeting conducted during early pilot testing in the lab. We also assessed readiness of community partners to implement the treatment approach in their settings. When the leadership teams at the community sites felt that the lab-based data on feasibility and efficacy was sufficient to justify extension of the approach to their settings, community sites were supported in using the approach within their settings with "clinical supervision as usual" within the site to ensure that treatment was delivered consistent with site policies and procedures. While we are referring to this as "pilot testing in the community," it is important to note that care was delivered as usual by the site clinicians, with access to the SAFETY manual and consultation by the laboratory "treatment development clinicians" to enhance understanding of the treatment principles and approach. Feedback from our community partners on the value and effectiveness of the SAFETY approach in their sites was then fed back into the treatment development process. This approach creates a two-way street with innovation and development occurring from the lab to practice, and from practice to the lab.

Our approach and goal of accelerating the pace with which treatment improvements lead to improved community care was fueled by our prior research pointing to weak effects of community follow-up "treatment as usual' (TAU) for youth who had presented to the ED with suicide attempts and/or suicidal ideation, with no detectable benefits on clinical outcomes for youth who received outpatient community follow-up TAU versus those who never linked to follow-up treatment in their communities (Asarnow, Baraff, et al., 2011). Consistent with the Deployment Focused Model developed by Weisz and colleagues, which considers the patients, clinicians, and treatment contexts for which the treatment is intended early in the treatment development process with the aim of identifying and including treatment characteristics needed for success (Weisz et al., 2015), the "incubator" approach attends to practice setting variables from the start while also recogniz-

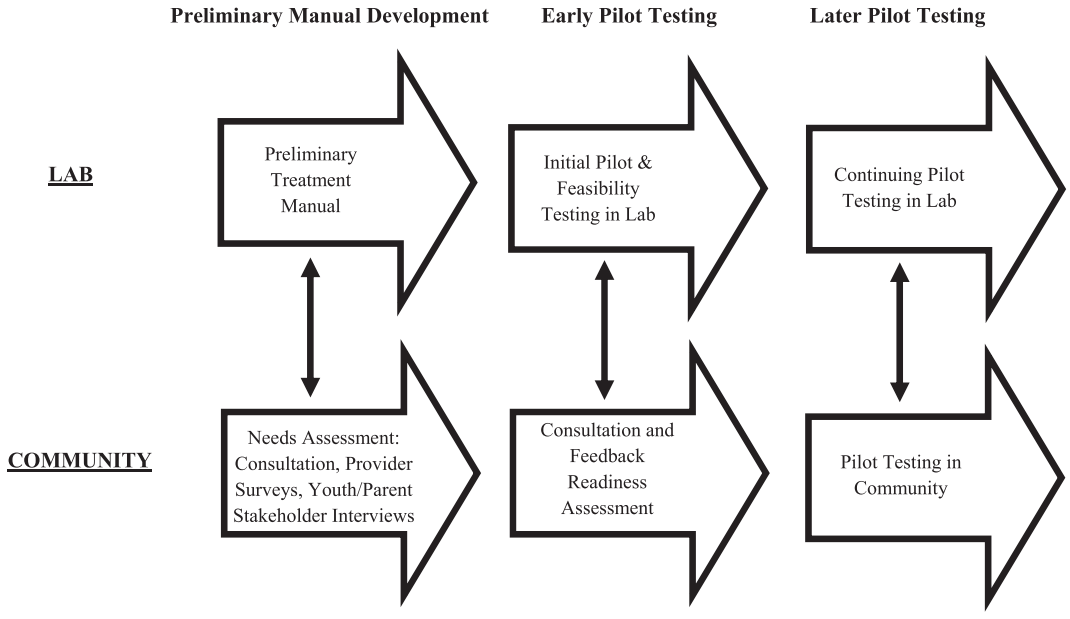

Figure 1. The "Incubator" Treatment Development Model. © Joan R. Asarnow, Ph.D

ing the importance of controlled laboratory-based evaluation of efficacy. By facilitating early identification of barriers to use in community treatment settings, the "incubator" model aims to develop optimal strategies for delivering the treatment under "usual treatment" conditions, resulting in a more feasible and easily transportable product ready for testing in community effectiveness trials. Indeed, our incubator model could be viewed as an example of the deployment-focused model which emphasizes integration of rigorous testing within the lab, piloting within community partner sites, shared knowledge, and collaborative learning among the laboratory and community-based teams.

Alternative Treatment Development Models

Considering alternative treatment development models helps set the context for our incubator model. Until relatively recently, the dominant treatment development model has been the traditional medical or pharmaceutical model. This model is used by the U. S. Food and Drug Administration (2018) and serves as the basis for the National Institute of Health/Mental Health (NIH/NIMH) definition of clinical trials. The medical model begins with Phase 1 trials aimed at evaluating the safety and side effects/potential adverse sequelae and dosage of a new treatment with a relatively small number of volunteers (samples of 20 to 100) for a limited time period (e.g., several months). Following this limited demonstration that a treatment is not harmful, larger Phase 2 trials with samples ranging up to several hundred with the disease or condition are used to evaluate efficacy and side effects over several months to 2 years. Larger "Phase 3" trials are then used to evaluate whether a new treatment shows any benefits relative to a comparator "placebo" treatment. These adequately powered randomized controlled trials test the efficacy of the new treatment under rigorously controlled conditions while also monitoring for adverse reactions. Treatments that have demonstrated safety and efficacy during Phases 1 through 3 are then testing in "Phase 4" effectiveness or pragmatic trials, which test the treatment under routine community care conditions to determine whether the treatment will continue to show benefits relative to a comparator condition (often treatment as usual) in routine practice settings. This rigorous sequential process has proven very useful in pharmaceutical treatment development where there is a concern regarding the potential harm of new medicines. However, this process is lengthy, limits the speed with which new treatments can become available to patients in need within the community settings where they receive care, and contributes to the often cited 17-year science-to-practice gap or lag between the development of new treatments in the lab and their availability in practice.

An alternative "community partnership" model has been increasingly utilized. This approach uses Community-Partnered Participatory Research methods to build trust and two-way knowledge exchange between community partners and researchers. Community and academic partners work collaboratively and have co-equal say both on the treatment approach

and the evaluation strategy and tools. This approach is exemplified by the Community Partners in Care program (Chung et al., 2010; Wells et al., 2013), which involved a partnership within Los Angeles County to improve community care for depression in an underresourced community. In this project, a council of academic and community members used partnered working groups and community forums to gather broad input from community and academic partners (additional description available at https://hss.semel.ucla.edu/cpprn/). Within this community, the strong partnership and use of community engagement activities to nurture participation, trust, and equality in decision-making held particular promise for addressing barriers to care associated with perceived stigma and distrust of the medical establishment.

Within this context, our incubator model as an exemplar of the deployment-focused approach (Weisz et al., 2003) can be viewed as falling in the middle between the traditional medical and full community partnership models. In considering our "incubator model," it is important to note that a treatment must have some demonstrated safety and evidence that the treatment does not cause "harm" prior to exporting to community sites. While the integrated SAFETY treatment is novel, the SAFETY treatment approach is grounded in established cognitive-behavioral and DBT principles. SAFETY also uses measurement-based care with patient response and outcomes closely monitored during treatment and treatment adjusted to address patient and family needs, offering some protection against adverse effects. Therefore, unlike a novel medication, the SAFETY treatment was not viewed as "experimental" with potentially "harmful" effects relative to TAU by our partner agencies and clinicians, perceptions that were supported by our early pilot data (Asarnow et al., 2015). These characteristics of the treatment enabled earlier deployment and pretesting in clinical settings, compared to alternative treatments which if viewed as more experimental with potential for doing harm require more safety testing prior to deployment.

Initial Roots and Development of SAFETY Treatment

SAFETY was originally designed as a brief treatment that could be incorporated as part of an emergency response to a suicide attempt. This approach grew out of recognition that poor continuity of care is a significant problem for youth after a suicide attempt, and that the period after ED or hospital discharge is associated with elevated suicide attempt risk. Indeed, increasing continuity of care after ED/hospital discharge has been a consistent objective within the U.S. *National Strategy for Suicide Prevention*: in 2001, Objective 7.1 was to "increase the proportion of patients treated for self-destructive behavior in hospital emergency departments that pursue the proposed mental health follow-up plan"; and in 2012, Objective 8.4 was to "promote continuity of care and the safety and well-being of all patients treated for suicide risk in emergency departments or hospital inpatient units" (U.S. Department of Health and Human Services, 2001, 2012). Goals of SAFETY, therefore, were to increase rates of care and reduce suicide attempt risk during this high-risk period. Further, our earlier data indicating that linking to community treatment as usual after ED/hospital discharge appeared to have few if any benefits on youth suicidality or other clinical outcomes, indicated that additional treatment/services work was needed if we were to address the clinical needs of these youth, including reducing suicide attempt risk (Asarnow, Baraff, et al., 2011; Asarnow, Porta, et al., 2011).

While we began our work in the laboratory, our approach was informed by guidance from community partners and our clinical experiences. This involved several key decisions in developing the initial treatment concept. First, in designing the treatment it was essential that we consider what was feasible in crisis services, as most youth with serious suicide attempts are eligible for crisis care. At the time we began developing SAFETY, our community partners advised that 12 weeks of intensive community-based services were being authorized within crisis programs. Consequently, SAFETY was designed as a 12-week treatment for the high-risk period after ED/hospital discharge.

Second, a major concern in our targeted population based on prior research is low rates of care. Rates and dose of care tend to be higher with home-based treatments, and crisis programs at our county sites had some home-based services, although home visits were challenging for other community sites. With input from our community partners, we decided to allow but not require home-based treatment in the SAFETY treatment, and encouraged an initial home visit (unless the family declined/preferred a clinic visit) and used in-home sessions when problems emerged with treatment adherence. The initial in-home session plus an option to include in-home sessions allowed both initial evaluation of the youth's family and social ecological context and a strategy for enhancing treatment dose/adherence. This also offered a level of flexibility which we believed would enhance the likelihood that community sites with different service structures could implement the intervention.

Third, youth who make suicide attempts are characterized by high levels of heterogeneity and may require

somewhat different treatment strategies. To maintain a tight focus during the early treatment development phase, we decided to restrict heterogeneity in our sample and limit youth in our trials to those with suicide attempts during the preceding 3-month period, and to limit diagnostic heterogeneity by excluding youth with psychosis, mania, or severe obsessive-compulsive disorder. These diagnostic exclusions were based on our belief that medication or other disorder-specific interventions would be needed for these youths and our desire to focus primarily on psychosocial treatment components at this initial phase in the treatment development process. While we recognized that restricting heterogeneity could create challenges for community sites, in consultation with our community partners, we decided to defer consideration of what might be needed to address the needs of a more expanded group of youth to a later treatment development phase.

Even with these restricted treatment eligibility criteria, the heterogeneity of youth who attempt suicide and the complexity and range of problems faced by many of these youth and their families contributed to two other treatment development decisions. First, to balance the need for adequate specification of the treatment model with the need to be responsive to the unique needs of youth and families, core principles were developed to guide the assessment and treatment process. These core principles emphasize a focus on safety, multiple systems in each youth's social ecology, individual tailoring of treatment to each youth's strengths and suicide/SH risk and protective processes, and general cognitive-behavioral principles (Table 1). Second, we use a modular approach to treatment, with specific treatment modules selected and sequenced based on the working case conceptualization, referred to as the cognitive-behavioral fit analysis. Consistent with multisystemic therapy, the cognitive-behavioral fit analysis identifies cognitive-behavioral processes and reactions that contribute to increased suicide attempt risk, and explain the youth's suicidal/self-harm behavior within the context of his/her broader social systems including family, peers, school, and community (Henggeler et al., 2002). Guided by this cognitive-behavioral fit analysis, modules were presented as part of a SAFETY pyramid with an emphasis on ensuring safe settings and environments through restricting access to dangerous self-harm methods at the base of the pyramid. Building on the essential foundation of the safe and protective environment needed

Table 1
SAFETY Treatment Principles

1. The primary purpose of assessment is to understand the "fit" between suicide attempts, their broader systemic context, and cognitive-behavioral processes.
2. The primary purpose of treatment is to enhance SAFETY and reduce suicide attempt (SA) risk; sessions focus on factors/processes identified in the cognitive-behavioral fit analysis as contributing to or reducing SA risk and targeted in the treatment plan.
3. Interventions are designed to promote SAFE settings/environments, relationships and contacts with SAFE people, and SAFE vs. UNSAFE actions/behavior/activities, thoughts, and stress reactions. (See SAFETY Pyramid).
4. Assessment is continuous and linked with treatment; information on the youths and their systemic context emerges throughout the treatment period and is used to refine the cognitive-behavioral fit analysis and treatment plan.
5. Treatment contacts build on strengths as levers of change and emphasize strengths
6. Treatment is present focused, action oriented, and requires consistent (daily or weekly) effort by the youth and family members to promote youth SAFETY and reduce SA risk.
7. Treatment targets sequences of behaviors within and between multiple systems that maintain or reduce SA risk.
8. Treatment is developmentally appropriate and culturally sensitive, fitting the developmental needs of the youth and cultural context of the youth and family.
9. Treatment outcomes are evaluated continuously from multiple perspectives (e.g. youth, family, clinician); therapists assume accountability for overcoming barriers to successful outcomes.
10. Attention is directed to promoting treatment generalization and persistence from the start; the role of caregivers (e.g. parents, teachers, health care providers, other family members) across multiple systemic contexts is emphasized.

Note. Adapted from MST, Henggeler et al. (2002).

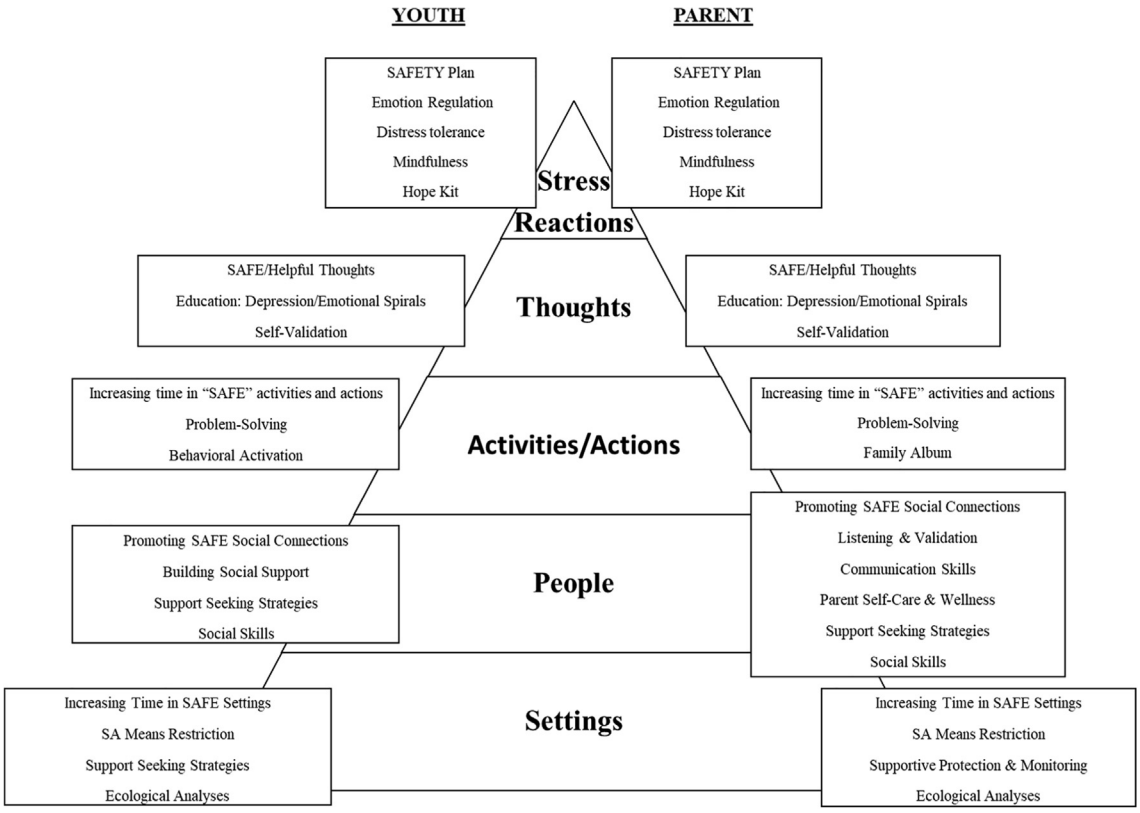

Figure 2. SAFETY Pyramid: Conceptual Model and youth and parent intervention modules and foci. © Joan R. Asarnow, Ph.D

to prevent potentially lethal suicidal and self-harm behavior, other levels of the pyramid emphasized safe people and social connections, safe activities and actions, safe thoughts, and safe stress reactions. See Figure 2 for SAFETY pyramid, and illustrative modules.

Fourth, our treatment development process was evidence-informed and rooted in knowledge regarding the developmental needs of youth. At the time we began developing SAFETY, however, there were no treatments for youth who made suicide attempts with demonstrated efficacy. Consequently, we considered available evidence on youth and adults. This included: youth research demonstrating benefits of multisystemic therapy for reducing suicide attempts and self-harm, relative to inpatient hospitalization, for youth presenting with mental health crises (Huey et al., 2004), and in-home family treatment which had shown benefits in reducing suicidal ideation among youth presenting with self-poisoning without major depression (Harrington et al., 1998); and adult research demonstrating the promise of cognitive therapy for suicide prevention (Brown et al., 2005) and DBT (Linehan et al., 2006). To promote evidence-informed care, we used measurement-based care throughout treatment, with suicidal behavior and self-harm, depressed mood and/or other key targets, monitored at each session and tracked in relation to delivered treatment components using a clinical dashboard (Figure 3). Information on the clinical dashboard was used throughout treatment to refine the working case conceptualization and treatment plan, and recognize when shifts in treatment strategy were needed.

Integrating Information From Partners/ Stakeholders

During the preliminary manual development phase, we consulted with community partners early and gained additional information from clinician surveys and qualitative interviews with parent and youth consumers of care (some coding and analysis of qualitative interviews continued into the first year of the early pilot testing phase). The SAFETY treatment was also strongly influenced by our emergency treatment for suicidal youth; the Family Intervention for Suicide Prevention (FISP, also known as SAFETY-Acute), which has been shown to be effective in improving continuity of care after an ED visit for suicide attempts or suicidal ideation, relative to usual ED care in three separate EDs (Asarnow, Baraff, et al., 2011; Rotheram-Borus et al., 2000; for review, Zullo et al., 2020). Indeed,

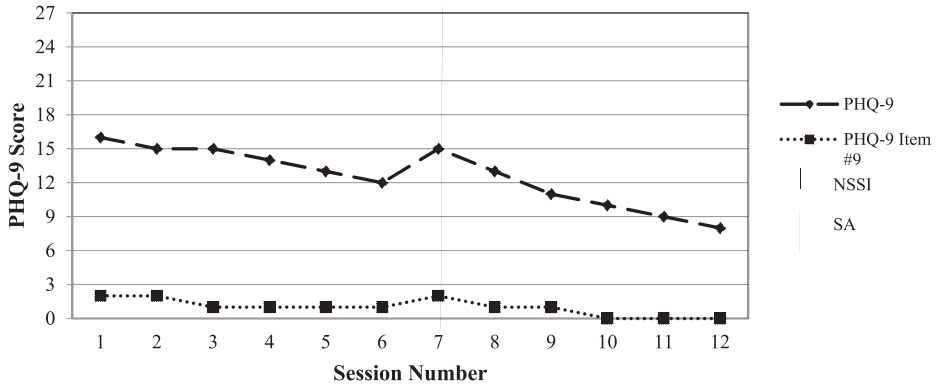

Figure 3. Clinical Dashboard: Patient progress during SAFETY treatment. ***Note.*** PHQ-9 = Patient Health Questionnaire, range 0-27, Total ≥ 11 Positive Score; Item #9, thoughts of death or suicide, range 0-3, >0= several days or more; NSSI = non-suicidal self-injury; SA = suicide attempt. Patient had one episode of NSSI and no SAs during treatment. PHQ=9 ranged from 16 to 8. © Joan R. Asarnow, Ph.D

the first session of the SAFETY treatment is a slightly modified version of our emergency treatment designed to be delivered in the home. It merits note that the broader focus on youth with suicide attempts or suicidal ideation was adopted for the ED intervention based on feedback from our ED partners that targeting a broader population of "suicidal youth" would be more acceptable and enhance feasibility within ED settings. While we considered this approach for SAFETY, we decided to limit heterogeneity as described above during the initial treatment development phase. Below we describe data collected from community partners and parent and youth consumers of care, followed by discussion of how this feedback contributed to the development of the SAFETY treatment.

Provider Perspective: Clinician Survey

With a community partner, a large child and adolescent mental health agency serving over 4,000 youth each year, we conducted an anonymous agency-wide needs assessment survey to inform our work. The response rate was near 100%, underscoring our success in achieving a working partnership with the agency leaders and providers. A major question addressed concerned feasibility and whether there were enough youth with recent suicide attempts within the community programs who would qualify for SAFETY as originally designed, or whether there was a need to expand the treatment eligibility criteria. Results indicated that 61% of clinicians had at least one client at the agency that had attempted suicide while on their caseload. Across the agency, 11% of youth had histories of suicide attempts and 21% had histories of NSSI. These data underscored the need for clinicians to have tools for successfully treating youth who engage in NSSI as well as those making suicide attempts, and too narrow a treatment target was judged to be unfeasible within community treatment settings.

Patient-Oriented Treatment Development: Youth and Family Perspectives

To obtain information on youth and parent perspectives on treatment after a SA, we conducted qualitative interviews with families and youth with participants drawn from two diverse settings: (a) a large agency serving Safety Treatment and families in the Los Angeles area, and (b) our University of California, Los Angeles program. Criteria for inclusion in the sample included: history of suicide attempt in past 5 years; current youth age 14–25 years; youth stable, no report of current suicidal ideation or behavior at time of contact; youth spoke English; parent spoke English or Spanish. The sample included 23 families: 13 families where the youth and one parent were interviewed; 9 families where one parent was interviewed (n = 1, interview in Spanish); and one family where both parents were interviewed. This yielded a sample of 37 interviews. The parent sample was predominantly mothers (94%), and 50% endorsed minority racial or ethnic group (17% Hispanic, 11% Multi-ethnic/racial, 6% African American, 16% Pacific Islander/Asian/Other). Interview questions focused on three broad questions: What helped after the suicide attempt? What did not help? What did participants want in the recovery process after a suicide attempt?

Interviews were transcribed, coded, and analyzed using the grounded theory approach (Strauss & Corbin, 1990). Quotes were analyzed using the "cutting and sorting" technique outlined by Ryan and Bernard (2003). A team led by study author (DC) reviewed

Table 2
Common Interview Themes

Theme	Frequency (N = 37)	%
Family Involvement	35	94.6%
Restrictive Treatment Environment	34	91.9%
Caring Providers	31	83.8%

the quotes, collaboratively sorted them into groups with similar content, and identified themes based on the content of quotes within each group. After the themes were established, five research assistants independently coded selected quotes based on the established themes to reach a group consensus. Intercoder reliability ranged from 72% to 86%. The most common themes to emerge are listed in Table 2. Illustrative quotes are provided below.

Family Involvement

The importance of family involvement was emphasized by youth and parents, often in the context of the challenges of separation due to hospitalization and out of home placements. The following quotes illustrate the desire by youth and families for greater parent and family involvement in the treatment process. In addition, some quotes emphasize the point that youth and parents may find hospitalization and out-of-home placements to limit or impede family involvement, which can be a barrier to recovery if it adversely impacts the youth's mood and level of suicide attempt risk.

Youth Quotes:

"*My parents. . . I had a few visits with them, but other than that I wasn't really involved with them very much and I guess that was what got me really deep and down and in my depressed state and after I had gotten in my depressed state I attempted suicide.*"

"*Well, maybe talk to the family more or whatever the problem was, like if the problem was a family member, try to get that person in and talk to them.*"

Parent Quotes:

"*We couldn't get through to the house where he was staying. No one answered the phones.*"

"*A program with parent education and support. A program involving the family not just the child.*"

While the first youth quote emphasizes the adverse impact of separation from the family on the youth's mood, the first parent quote highlights the fact that treatments where youth are placed outside of the home (hospital or other residential care) can lead to reduced ability to fill parent roles, such as knowing what is happening with your child—a key component of parent protective monitoring and supervision. Responding to probes regarding what participants wanted in the recovery process, the second youth and parent quotes emphasize a desire for family involvement in treatment. The second parent quote also notes the belief that it was important to include intervention components that directly support and involve parents.

Reactions to Inpatient or Residential Treatment Settings

Parents had mixed reactions to restrictive inpatient or residential treatment environments. The quotes below illustrate how some parents believed that hospitalization could increase safety by increasing protective monitoring. Others, however, questioned the benefits and safety of out of home placement. The relative brevity of inpatient stays was also viewed as a problem by some parents.

Parent Quotes:

"*We wanted him to be observed 24 hours … and in the hospital they can do that, but then it was only for a short term.*"

"*The most unsafe positions he has been in were outside of the house. . .I don't feel like there was any gain made with the time he was out of the house.*"

"*The hospital is useless, absolutely useless … they make no changes. Every time he was in the hospital they made no changes at all in his regimen.*"

Youth quotes highlighted the possibility that, for some youth, crisis intervention and hospitalization can lead to less willingness to openly report on suicidal urges in the future.

Youth Quotes:

"*If you tell someone. . .you're going to end up getting even more depressed. They're going to send you to some hospital for months. . .you can't tell anybody, you just can't tell anybody.*"

"*If you tell your therapist, they'll call the PET team. They call PET team and they'll come and pick you up and take you to the hospital, almost no questions asked. . .. . . there you really know you're isolated and if you go, if your parents visit, you're stuck in like a room with mirrored glass windows. . . It's terrible. . . It's no hope and it's even farther away from our home.*"

Caring Providers

Parents and youths highlighted the importance of caring providers, indicating that they found significant value in having providers whom they felt were genuinely invested in their recovery and well-being. The quotes below underscore the significance of the quality of the therapeutic alliance and are representative of

parent and youth responses to questions about their best experiences with mental health care.

Parent Quotes:

"*Individuals, their personalities that came into it, that were responsive. Individuals that went above and beyond, that really listened, that really responded. But that was an issue of character, of personality. It was not an issue of training or programming or anything else.*"

"*It's people who cared.*"

Youth Quotes:

"*All of them were really different and they all just had something really special about them and I think they really did care and it wasn't like a job for them, I felt they were fulfilling something for themselves being there, you can just feel it, it felt good for them to help you and that's a great feeling.*"

Piloting in Community Treatment Sites

To pretest the protocol within community treatment settings, we applied the treatment in two diverse community clinics with two community cases. Challenges noted included: (a) difficulties allocating two therapists to each youth and family; (b) case finding challenges due to relatively low rates of youth with recent suicide attempts in routine outpatient settings; (c) the large number of youth whose self-harm was NSSI; (d) family conflicts that necessitated involvement of adults other than parents to support youth (e.g., grandparent); and (e) challenges in scheduling home visits at one clinic, where home visits were not part of routine practice. The other clinic incorporated SAFETY within home-based services. Aspects of the treatment that were relatively easy to incorporate included: a focus on building skills which was consistent with CBT and DBT models; a primary treatment goal of increasing safety and decreasing suicide attempt/self-harm risk; attention to youth and family issues; and a modular approach that selected specific treatment modules based on the working cognitive-behavioral fit analysis.

How Information From Partners/ Stakeholders Impacted Development of SAFETY Treatment

Table 3 summarizes how community partner/stakeholder feedback contributed to changes in the SAFETY treatment as originally conceptualized. First, the clinician surveys, pilot testing in community sites, and our own recruitment experience highlighted the high prevalence of NSSI and need for treatments for youth presenting with NSSI as well as suicide attempts. When considered in conjunction with research indicating that NSSI is a strong predictor of future suicide attempts (Asarnow, Porta, et al., 2011; Wilkinson et al., 2011) and that overall self-harm (including suicide attempts, ambiguous self-harm behavior, and NSSI; Crosby et al., 2011) is the strongest predictor of suicide deaths in adolescents (Hawton et al., 2015), we decided to extend our treatment target to the broader category of self-harm in our later pilot testing and included youth presenting with repeated self-harm in our randomized controlled trial (Asarnow et al., 2017).

Second, youth and parent qualitative interviews underscored the importance of family involvement and understanding and addressing the needs of parents as well as their children. This led to decisions to (a) use a two-therapist model, with one therapist primarily focused on the youth and the other focused primarily on the parent, and (b) to structure sessions so that the youth therapist met with the youth, while the parent therapist met with the parent(s), and the youth and parent therapists came together at the end to work to strengthen support within the family, practice skills that would enhance safety as a family (e.g., youth going to parent when feeling acute distress or suicidal urges, and parent responding in a way that youth found helpful), and address issues and problems that required the family together (e.g., problem-solving around school issues that the youth could not address on his/her own). This had the advantages of allowing the needs of youth and parents to be addressed, while reducing threats to youth confidentiality and the therapeutic alliance that could occur if the same therapist met individually with both the youth and parent. The SAFETY approach also attended to the need to enhance communication and support within the family by including specific time with the youth and parents together, while supported by their individual therapists. Some families may prefer less involvement, and parents who valued family involvement may have been more likely to participate in the qualitative interviews than parents who were less interested in parent involvement. However, the SAFETY treatment allows for flexibility. When the cognitive-behavioral fit analysis/case conceptualization suggests advantages of another approach (e.g., fewer family sessions, involvement of another responsible adult), the approach was adjusted.

Incorporating information from our piloting in community sites, we reduced home visits to an initial session or when patients repeatedly missed sessions (as described above). This resulted in a primarily in-clinic treatment. Recognizing that adults other than parents were often helpful for supporting and protecting the youth, we also extended work beyond the parents to other adults with whom the parents and youth

Table 3
Description of Development of SAFETY Treatment and Changes Made Based on Feedback From Community Partners and Stakeholders

	Original Decision	Change Based on Feedback
Clinician Survey	Developed to be incorporated within emergency services to meet the needs of youth and parents after a suicide attempt	Larger number of youth with NSSI relative to those with suicide attempts in clinician's caseloads, contributed to decision to expand SAFETY to include youth with either a suicide attempt in the past 3-months or ≥3 self-harm episodes (including suicide attempts or NSSI)
Youth & Parent Qualitative Interviews	Originally developed with single therapist model	Underscored importance of family involvement and addressing both youth and family needs; contributed to decision to use a 2-therapist model with one therapist serving as the primary youth-therapist, and the other the primary parent/family therapist.
Piloting at Community Sites	Developed to include only youth with recent suicide attempts and in-home sessions	Low rates of youth with recent suicide attempts in routine outpatient settings and the large number of youth whose self-harm had no suicidal intent or unclear intent, contributed to decision to expand SAFETY to include youth with ≥ 3 self-harm episodes. Due to challenges implementing in-home sessions in some practice settings, home visits were limited to the initial session or when patients repeatedly missed sessions. Recognizing that adults other than parents could aid in supporting and protecting youth, included option to reach out beyond parents to other adults with whom the parents and youth were comfortable.

were comfortable. For instance, in one case the grandmother attended some of the family sessions. Although we noted challenges of the two-therapist approach in our community piloting, a decision to retain the two-therapist model was made based on: (a) the belief that work with parents/adult caregivers was critical for ensuring safety; (b) concerns that having the same therapist for youth and parent would present a barrier to disclosing information about suicidality, self-harm, and other sensitive issues, impeding therapists' abilities to obtain full and accurate information and address these important issues; and (c) the belief that treatment adherence would be improved by increasing parent motivation to attend and bring the youth to sessions.

Discussion

The increasing rate of suicide deaths and suicide attempts in youth underscores the critical need to develop effective treatments for youth at elevated risk of fatal and nonfatal suicide attempts, and to bring these treatments into the community settings where youth receive care. Our incubator treatment development model offers one approach to creating a feasible and transportable "youth"- and "family"-centered treatment that can be used within community practice settings, with the ultimate goal of accelerating the pace with which laboratory-based treatment advances can yield improved community care. Our process yielded a treatment shaped by information from families, youth, and community partners in combination with rigorous treatment development trials within the laboratory.

The incubator treatment development model focuses attention on the needs of community settings during all phases of the treatment development process (Figure 1). This resulted in identification of implementation challenges throughout the treatment development process. Some of these challenges could be addressed through adjustments during the treatment development process (Table 3). However, we also identified tensions between the needs of youth present-

ing with suicide attempts and self-harm behavior, and usual practices within routine clinical settings. For instance, after much consideration of feedback from our community partners and youth and parents who had recovered from suicidal episodes, we made a decision to retain the use of a two-therapist model, with one therapist focusing on the child and the other the parents. While we recognize that this two-therapist approach is a potential barrier to implementation of SAFETY in some settings, results of systematic reviews and meta-analyses point to treatments with strong family components as those most likely to benefit suicidal and self-harming youth (Glenn et al., 2019; Iyengar et al., 2018; Ougrin et al., 2015). Further, our pilot/treatment development trials support the value of our approach for decreasing suicide attempt risk (Asarnow et al., 2015, 2017; Babeva et al., 2019), and a two-therapist model was used in one of the other treatments with demonstrated benefits for reducing suicide attempts in randomized controlled trials (Esposito-Smythers et al., 2011). Dialectical behavior therapy (DBT), the other treatment with demonstrated efficacy for reducing suicide attempts in a randomized controlled trial, compared to individual and group supportive therapy, used one therapist for the youth, and an additional therapist for weekly multifamily group therapy and parent phone coaching (McCauley et al., 2018). Similar to SAFETY, the DBT approach provides individual therapeutic support for youth and parents by different therapists, offering some separation and reducing threats to the therapeutic alliance with the youth stemming from confidentiality concerns, although some family therapy sessions (with the youth present) are held by the youth therapist. DBT is also more intensive and costly than SAFETY, with 3 treatment hours per week (1 hour individual, 2 hours per group with 2 therapists in each group) and 6 months of DBT in the one trial showing a DBT advantage on suicide attempts (McCauley et al., 2018). This relatively high treatment dosage has the additional disadvantage of reducing time for nontreatment activities important for development, such as homework, extracurricular activities, and time with friends. Currently, we are examining ways in which barriers to the two-therapist model can be addressed, such as developing algorithms for assigning two therapists when need is greatest and using multifamily skills groups as done in DBT for adolescents (McCauley et al., 2018; Mehlum et al., 2014; Miller et al., 2007). It could be, however, that a two-therapist model is necessary or advantageous for acute treatment of suicidal and self-harm behavior, and our science can also guide policy and clinical service development.

Our experience working with community partners also underscores the value of the diverse perspectives offered by community clinicians and administrators of clinical programs, youth and parent consumers of care, and research scientists. Through mobilizing these collective perspectives and creating collaborative learning among laboratory and community teams, the hope is that our "incubator" model can lead to a more rapid transition from efficacy to effectiveness trials in community settings and accelerate the pace with which SAFETY, or other treatments with demonstrated effectiveness, can be incorporated within the settings where children and families receive care in their communities. While the future will tell whether the incubator treatment development model can accelerate the pace with which laboratory-based treatment advances are incorporated into community care, the incubator model did yield a treatment that was informed by the needs of the service settings, clinicians providing care, and youth and parent consumers of care. Moreover, as we have learned with the shift to telehealth services during this time of the COVID-19 pandemic and public health emergency, these needs vary over time, requiring that we continue our treatment development and adaptation process to meet the challenges of providing optimal care for youth and families (Hughes & Asarnow, this volume).

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