Grant Final Report

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Pharmaceutical Safety Tracking (PhaST): Managing Medications for Patient Safety

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Abstract

Purpose: To evaluate a novel system for monitoring drug safety among children who have been prescribed antipsychotics antidepressants.

Scope: Depression is an important and prevalent disorder among children. There is concern that antidepressants may exacerbate psychiatric symptoms.

Methods: Randomized clinical trial of an interactive voice response follow-up tool including 153 families of children aged 6-17 years who had been prescribed an antidepressant in the past week. Families were randomized to a PhaST or Treatment As Usual (TAU) condition. PhaST families received 7 IVR screening calls over three months.

Results: Of 76 PhaST children, we reached 74 (97%) at least once. For these children, the average number of completed calls was 6.6 (SD = 1.2), close to our target. The per-patient success rate for calling ranged from 0% to 89% (M = 43%). The reliability of the PhaST screening questions was Cronbach's alpha = .72. Of 493 screens administered, 8% reported non-adherence to medication (which is doubtlessly under reporting), and 30% of screens reported at least one psychiatric symptom. We counted the total number of contacts with families in patients' medical records, including visits, telephone calls, emails, letters, and reports of PhaST screens for the three follow-up months. PhaST children had almost five more contacts (M = 17.8 contacts, SD = 1.6) than TAU children (M = 12.9, SD = 1.8, $p < .001$). Conclusion: PhaST assisted clinicians in conducting follow-up monitoring of patients, when those patients needed close supervision and had difficulty making frequent office visits.

Key Words: None provided.

Final Report

Purpose

PhaST is a health information system that assists clinicians' management of medications in ambulatory settings. PhaST seeks to protect outpatients taking drugs that have recognized side effect risks even when those drugs are correctly prescribed. Existing clinical strategies for monitoring risky drugs rely on frequent office visits. Such strategies might succeed for families with access to a system that can supply the requisite visits. However, for many families, the financial or organizational burden of frequent visits is high. The result is that many patients are exposed to inadequate outpatient medication safety monitoring, with those having least access to health services likely to experience the least monitoring.

The PhaST system is an automated system for monitoring of medication adherence, side effects, and patient symptoms. PhaST uses research-based assessment procedures administered using interactive voice response (IVR) telephony. When a patient reports a problem with a medication on an IVR call, PhaST alerts a nurse trained to triage the problem, to counsel the patient or family, and when necessary to contact the patient's prescribing clinician or the hospital emergency services.

Our target medication is the pediatric use of anti-depressants. The growing use of psychoactive medications in children and adolescents has greatly increased the public health relevance of medication-related adverse events, including suicidality and manic activation. To compare PhaST and usual care, we conducted a randomized trial in a large urban specialty mental health system serving a primarily Medicaid population. We assessed the patients for adverse events during home visits at baseline and 1, 2, and 3 months.

The purpose of this study was evaluate PhaST as a novel system for monitoring drug safety among children who have been prescribed antipsychotics antidepressants. In this Final Report, we present analyses on our study sample of 153 families, on our success in gaining and maintaining telephone contact with the families, on the strong psychometric properties of the PhaST screen administered by the telephone robot, and on how PhaST increases the information about the child found in her medical record.

Scope

Background and Context

Newer antidepressants transformed the treatment of mental health concerns in children and adolescents. They provide child mental health practitioners with an important treatment option to be considered for youth with some of the most common and life-threatening psychiatric illnesses (Vitiello, 2007). In recent years, research has evaluated the effectiveness of this treatment option. Meta-analytic findings from the U.S. Food and Drug Administration (FDA) prompted a black box warning indicating antidepressant medication increases the risk of suicidal thoughts or

behaviors in children and adolescents (Hammad et al., 2006; U. S. Food and Drug Administration, 2004). An increased risk was also found in a subsequent meta-analytic review, although the benefits of antidepressants appeared to be much greater than the risk for suicidal ideation and behavior (Bridge et al., 2007). Given these potential benefits in light of the identified risks, authors concluded evidence "supports the cautious and well-monitored use of antidepressant medications as one of the first line treatment options (Bridge et al., 2007).

FDA Monitoring Recommendations. The FDA specified in its black box warning and subsequent revisions that "all patients treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality and unusual changes in behavior, especially during the initial months of a course of drug therapy, or at times of dose changes, either increases or decreases." (U.S. Food and Drug Administration, 2007). Inherent within these recommendations are several essential elements of monitoring approaches for antidepressant use in children and adolescents. These elements include the need for (1) clinically sufficient monitoring, (2) focus on potential side effects, (3) close contact during the initiation of medication treatment and dose changes, and (4) the provision of assessment and possible intervention when side effects are detected.

The first essential element of a monitoring approach involves the frequency with which monitoring is provided. Initial FDA monitoring guidelines stated provider contact should generally include weekly contact during the first four weeks of treatment with biweekly contact for the subsequent four weeks (U. S. Food and Drug Administration, 2005). Additional contact would be made at 12 weeks and as clinically indicated beyond that time frame (U. S. Food and Drug Administration, 2005). Though the label revisions issued in May 2007 do not prescribe this level of monitoring, current FDA recommendations continue to state that patients need to be "monitored appropriately and observed closely." (U.S. Food and Drug Administration, 2007). While professional consensus supports these current FDA guidelines (Morrato et al., 2008), questions regarding what constitutes *clinically sufficient monitoring* remain.

The second essential element of monitoring efforts defines the clinical focus of appropriate monitoring and close observation. The focus specified within the FDA guidelines includes "clinical worsening, suicidality and unusual changes in behavior." (U.S. Food and Drug Administration, 2007). These guidelines encompass clinical symptoms that have increased in intensity and/or frequency as well as those that have developed since beginning the medication. Recent and unusual changes in mood and behavior would also be assessed. Additionally, the date of onset and duration of symptoms could be noted. With a c*linical focus on potential side effects* of antidepressant use, the principal risk of suicidal ideation and behavior could be detected. The possibility of manic conversion (Martin et al., 2004) and side effects associated with medication nonadherence (Smith & Schuchman, 2005) may have a greater chance of being detected as well.

A third component essential to monitoring approaches involves the timing of these efforts during the course of antidepressant treatment. FDA guidelines suggest the most important times in which to monitor antidepressant use are "during the initial months of a course of drug therapy or at times of dose changes, either increases or decreases." (U.S. Food and Drug Administration, 2007). In developing and implementing monitoring approaches, it is important to design a system to intensively track symptoms during the first few months of antidepressant treatment. It is also important for the system to track medication adherence, noting any changes in type or dose of medication and being able to continue monitoring after the changes have occurred. The

FDA guidelines regarding the need for *close contact during initiation of medication treatment and potential dose changes* would clearly be a necessary condition of monitoring approaches.

An additional element inherent, though not specifically stated, in the FDA recommendations involves clinical safeguards for patients when risks are detected through active monitoring and close observation. These safeguards include the *provision of assessment and possible intervention when side effects are detected.* Professionals providing this assessment and possible intervention would further benefit from a standardized, research-based method of assessing possible side effects as well as established criteria for determining and addressing risk.

System and Family Resource Considerations

An additional essential element of any monitoring approach involves the need *to minimize further demands being placed on providers and families.* Existing clinical strategies for monitoring potential drug adverse events rely on frequent psychiatric, physician and/or other behavioral health professional contacts. However, additional monitoring appears nearly impossible given limited child and adolescent psychiatric resources (Kim, 2003). A lack of sufficient and access to psychiatric decision support as well as reimbursement issues may also affect the feasibility of increased primary care visits (Rushton et al.,2002). Utilizing other behavioral health professionals (e.g. registered nurses, community based clinicians) in monitoring efforts could prove challenging given staff recruiting and retention-related concerns (Stuart et al., 2009). Current caseload and waiting list sizes may impact monitoring as well.

In addition to limited system resources, families may also experience further challenges to increased monitoring efforts. Previous research findings have suggested youths may have difficulties obtaining additional professional monitoring due to transportation problems or inability to pay for treatment (Flisher et al., 1997). Families may also experience time and/or scheduling constraints that prevent attendance at additional office visits. In an effort to address both system and family resource challenges, it is essential necessary monitoring *minimizes further demands being placed on providers and families.*

Interactive Voice Response (IVR) Computer System

Traditional methods of clinical follow-up are nearly impossible with the demand on system and family resources. Therefore, researchers at Nationwide Children's Hospital (NCH) have incorporated the previously outlined components in the development of the Pharmaceutical and Safety Tracking (PhaST) system. PhaST is an interactive voice response (IVR) computer system designed to monitor children and adolescents between the ages of 6—17 years referred by their physicians following the prescription of an antidepressant medication.

Implementation of the PhaST system involves seven phone calls over the three months following a new prescription of an antidepressant. During the calls, respondents are asked eight screening questions that *focus on potential side effects* of their medication (see Table 1 for a list of the questions). The calls, *occurring during initiation of medication treatment and potential dose changes*, provide *clinically sufficient monitoring* in accordance with the initial FDA recommended monitoring guidelines. Parents/guardians respond to the questions if the youth is 12 years old or younger and youth older than 12 years old respond to the questions themselves. The eight screening questions take approximately two and half minutes to answer and screen for medication adherence, clinical worsening, suicidality and unusual changes in behavior. The

respondent answers the questions by pushing numbers on the phone. The respondent can also leave a message. If a concern is detected, safeguards involving the *provision of assessment and possible intervention when side effects are detected* an on-call PhaST Triage Staff (PTS) is paged to assess whether the matter requires further clinical attention. The role of the PTS is the *provision of assessment and possible intervention when side effects are detected.*

After the page is received, the PTS will log into her computer screen to access a web application (PhaSTWeb) designed to support her work. PhaSTWeb provides the PTS with the data from the screening call. The PTS can also listen to a message, if the respondent chose to leave one. In addition, for each concern reported by the respondent, PhaSTWeb displays a module of follow-up questions. The PTS uses the follow-up modules to guide a clinical interview designed to gather additional detail about the particular symptom (e.g. lethality assessment for those with suicidal ideation). As clinically indicated to further assess risk and ensure patient safety, the PTS may speak with a parent if the respondent is an adolescent or with an adolescent if his or her parent answers the screening questions. Following the completion of all indicated modules, the PTS will review all information gathered during the call and plans to address any risk detected. The PTS will then make a determination of the current level of risk and subsequent action steps to be reviewed with the family. Following each monitoring call, a report detailing the monitoring call is emailed to ongoing health care providers as applicable. The report contains information regarding the initial screening results and as applicable, the PTS triage risk assessment.

In providing an alternative to increased office visits, PhaST is able to *minimize further demands on providers and families.* Monitoring calls are utilized to screen for potential concerns and only when concerns are reported, an on-call clinician responds providing needed intervention until contact can be made with ongoing providers. Primary care physicians are also provided with an additional resource for monitoring youth on antidepressants including potential contact with behavioral health professionals regarding detected risks. In addition, families are able to schedule monitoring call times convenient for them with no additional transportation or treatment costs noted.

Settings

Nationwide Children’s Hospital is the largest provider of pediatric care in Central Ohio. Nationwide Children’s Hospital operates five community-based clinics providing mental health services, the great majority of our patients came from these clinics. A small number of patients were also referred by primary care doctors in the Columbus community.

Participants

The original design planned to recruit 800 children and adolescents under the age of 18 and older than 6 years old who have received a new prescription for an antidepressant through Nationwide Children's Hospital Behavioral Health and Counseling Services. We had expected, based on prior discussions with our IRB, to be able to contact patients directly following detection of a prescription in a computerized order entry system. This scheme, however, was rejected by the IRB, which ruled that we could recruit patients based only on referral from

physicians. This greatly limited our ability to recruit, so in the end we were able to study only 153 families.

The following table presents the demographics of our study population. The families were roughly representative of our community, and there were no significant differences between PhaST families and TAU families on any variable.

Table 1.

Variable	PhaST	Treatment as Usual	Total	p
Age	M = 13.0 years, SD = 3.0 years	M = 12.6 years, SD = 3.1 years	M = 12.8 years, SD = 3.0 years	.45
Sex: Male	42	36	51%	.29
Sex: Female	34	41	49%	
Race: Black	13	11	16%	.88
Race: White	56	60	76%	
Race: Other	7	6	8%	
Hispanic Ethnicity: Yes	2	1	2%	.55
Hispanic Ethnicity: No	74	76	98%	
Parent/Guardian Relationship: Biological Mother/Father	62	68	85%	.32
Parent/Guardian Relationship: Adoptive Mother/Father	5	3	5%	
Parent/Guardian Relationship: Grandparent	5	1	4%	
Parent/Guardian Relationship: Other	4	5	6%	
Parent Marital Status: Married, living with spouse	45	44	58%	.51
Parent Marital Status: Single, never married	10	11	14%	
Parent Marital Status: Divorced or Separated	16	18	23%	
Parent Marital Status: Other	5	4	5%	
Parent Education: Jr. High School or less	4	7	7%	.38
Parent Education: Some High School	19	21	26%	
Parent Education: High School	25	32	37%	
Parent Education: Some College	14	10	16%	
Parent Education: College	12	5	11%	
Parent Education: Missing	2	2	3%	
Total	76	77	100%	

Methods

Study Design

This was a randomized clinical trial. Families with a recently prescribed antidepressant were randomized into a PhaST condition, in which they received seven follow-up calls from the PhaST system over three months, or a Treatment As Usual (TAU) condition, in which they did not receive follow-up calls.

Data Sources/Collection

Participating families in both conditions made four visits to our research office, at baseline, and one, two, and three months following baseline. At these interviews, children and parents completed standard measures of depression and other relevant psychiatric disorders, and completed an extensive interview about medication side effects. After the final visit, we conducted a medical record review at the office of the treating clinician to determine what clinicians had recorded about the child's mental health status. In addition, for patients in the PhaST condition we had the data from the PhaST screens.

Recruitment

We approached psychiatrists at the NCH Behavioral Health Clinics and asked them to refer patients to the study. After prescribing an antidepressant to an eligible child, the physician presented the PhaST study to the family. If the family was interested, the physician faxed a referral form to the study. The research team then called the family and described the study on the phone. If the family was interested, the team scheduled a baseline visit where a signed informed consent process occurred.

We experimented with other methods of obtaining subjects, including placing forms that allowed parents to consent to be contacted into intake packets. None of these alternatives proved feasible.

Informed Consent

At the baseline visit, a research assistant explained the study to the family and obtained written informed consent from the subject's parent/guardian and assent from the youth. In addition, consent for release of information was obtained from the parent/guardian to communicate with the treating physician and other professionals involved in the youth's mental health care (if applicable) as well as to obtain medical records. Randomization to study condition was conducted by this RA and a description of the PhaST procedure was given to the families randomized into that condition. Information gathered from participants randomized into the PhaST condition included (1) a block of evening time and a telephone number where the adolescent or parent can be reached and (2) a four digit PIN that the parent or adolescent can use to confirm his or her identity.

Procedure

Once informed consent and assent was obtained, a second research assistant administered our assessment battery to the family. This RA served as an independent research evaluator and determined whether the patient had experienced an adverse event during the past month. This RA conducted all semi-structured interviews (e.g. suicidality assessment) that documented whether adverse events had occurred in the past month. This RA was blind to the patient's PhaST versus Usual Care status as the randomization was conducted prior to the semi-structured interview when the research evaluator was not present. The visits at months 1, 2, and 3 were

similar, except that they did not include consent or randomization procedures and only the RA acting as the independent research evaluator was present.

The PhaST Intervention

For youth within the PhaST condition, PhaST will monitor the patient through a series of brief telephone calls following the FDA's recommendations for frequency of visits. Our target was to make 7 calls over the same three-month period as the visits. The first four calls were weekly. The next two calls were every two weeks. The final call was one month later. The monitoring call presented the following seven questions in addition to a question about medication adherence:

Table 2.

Domain	Adolescent (≥ 13 years old) IVR Question	Parent IVR Question
Depression	"Since the last doctor visit or phone check up, have you had new or increased problems with sadness or depression? "Push 1 for Yes. "Push 0 for No." (same for all items)	"Since the last doctor visit or phone check up, has your child had new or increased problems with sadness or depression? "Push 1 for Yes. "Push 0 for No."
Anxiety	"Since the last doctor visit or phone check up, have you had new or increased problems with worry, fear, anxiety, or panic?	"Since the last doctor visit or phone check up, has your child had new or increased problems with worry, fear, anxiety, or panic?
Insomnia	"Since the last doctor visit or phone check up, have you had new or increased problems sleeping?	"Since the last doctor visit or phone check up, has your child had new or increased problems sleeping?
Agitation or Mania	"Since the last doctor visit or phone check up, have you had changes in mood, more energy than usual, or behavior that you or others don't like, or that worry you or others?	"Since the last doctor visit or phone check up, have you noticed any new problem behaviors, changes in mood, or more energy than usual in your child?
Aggression / Anger	"Since the last doctor visit or phone check up, have you been a lot more angry, irritable, or getting into fights or arguments with others?	"Since the last doctor visit or phone check up, has your child been a lot more angry, irritable, or prone to get into fights or arguments with others?
Open-Ended	"Since the last doctor visit or phone check up, have there been any other new or unusual changes in your feelings, behavior, or health that concern you?	"Since the last doctor visit or phone check up, have there been any other new or unusual changes in your child's feelings, behavior, or health that concern you?
Suicidality	"Since the last doctor visit or phone check up, have you had serious thoughts about ending your life?	"Since the last doctor visit or phone check up, has your child said or done anything suggesting that <insert 'he' or 'she'> might want to hurt <insert 'himself' or 'herself'>?

The 8-question PhaST screening assessment lasted an average of only 2 minutes and 12 seconds. To ensure that the health data were secure, the patients or parents identified themselves with PINs at the beginning of an automated call. Parents answer the questions for children 12 years old or younger and teenagers answer for themselves.

If a patient answered "no" to all the screening questions, the data were automatically stored and a report was routed to the patient's electronic health record and to the patient's clinician's electronic inbox. If a patient answered "yes" to any screening questions, the on-call PhaST nurse wass paged.

For any “yes” responses to a screening question, the PhaST nurse asked follow-up questions to triage the severity of the problem using a semi-structured clinical interview. The semi-structured interview included symptom-specific question modules corresponding to the seven symptom questions. There was one module for each of the screening questions. For example, the module tied to a “Yes” answer to the suicidality question determines whether the patient has suicidal ideation only, has a method, plan, or intent for committing suicide, engaged in preparatory acts or behavior, and/or has made an attempt.

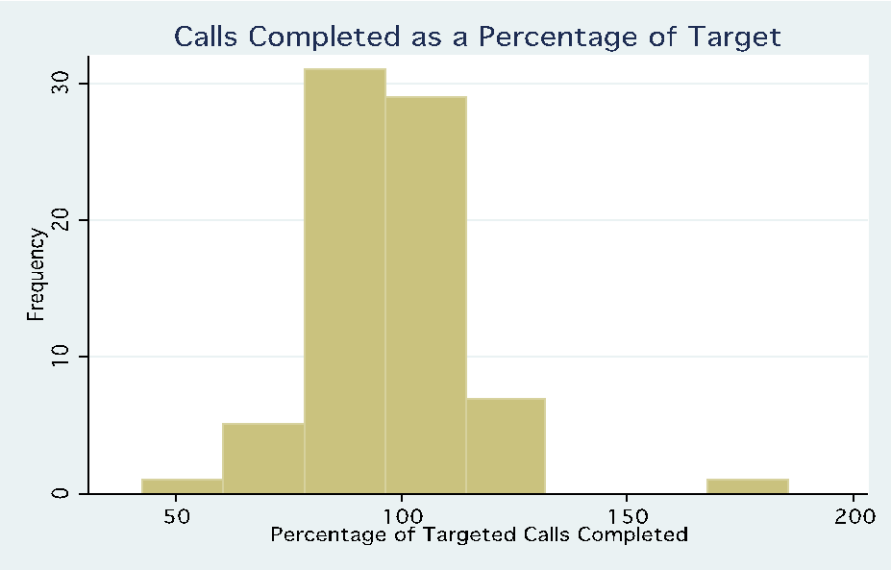
Based on the triage interview, the PhaST nurse decided whether action was warranted. If the screen was a false positive (meaning, no adverse event is occurring), the nurse logged the data to be included in a report sent to the patient's psychiatrist and clinician (if applicable). If she judged that the case required further attention, she spoke with the parent(s)/ guardian(s) and patient to develop a plan to address potential risk. If the nurse concluded that the case required immediate further assessment, she contacted the Nationwide Children’s Hospital Psychiatry Consultation Service.

Results

Analyses of Ability to Reach PhaST Participants

We tracked all call attempts and call completions in the PhaST condition (no calls were made, by design, in the Treatment as Usual condition). Overall, we succeeded in reaching participants for the targeted seven calls during the three month follow-up. Of the 76 PhaST children, we reached all but two (97%) at least once. Of the 74 who were able to call, the number of completed calls ranged from 3 to 13 (M = 6.6, SD = 1.2). Thus, the average number of successful calls was close to our target.

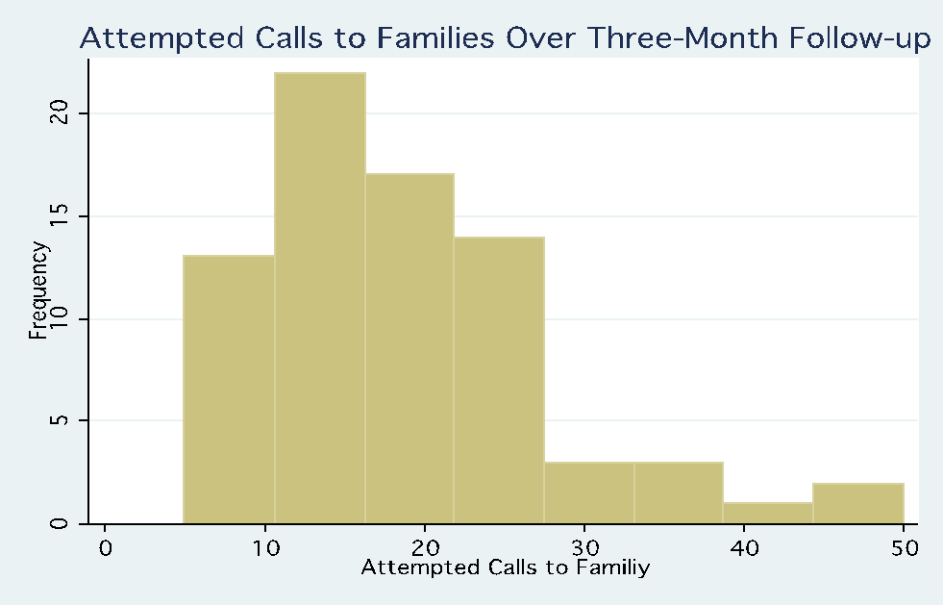
Figure 1. Calls completed as a percentage of target



Some patients were called more than the targeted seven times because it proved difficult to design an algorithm that would schedule calls that would achieve both the desired frequency of calls, the desired spacing between calls, families' preferences about when they would be called, and variation in the numbers of days between when the telephone robot initiated a call and when the child or parent actually answered. In making these tradeoffs we designed the algorithm with the notion that monitoring too frequently was better than not monitoring often enough.

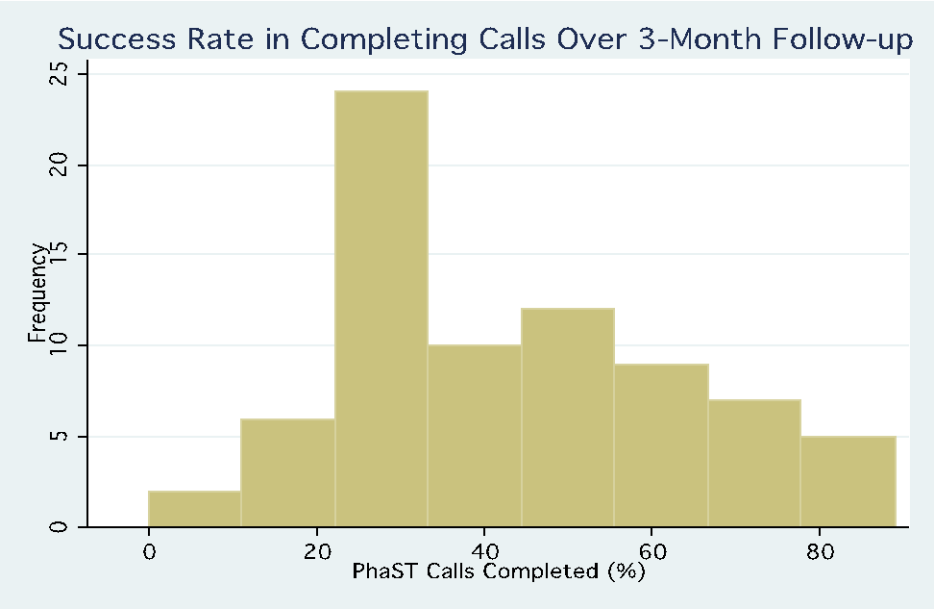
We also examined how many attempted calls were required to reach patients. The number of attempts over the three-month follow-up ranged from 5 to 50 (M = 18.4, SD = 9.1).

Figure 2. Attempted calls to families over three-month follow-up



As the chart suggests, it was relatively easy to reach most participants, although it was difficult to reach a few. The per-patient success rate of these attempts (that is, the number of completed calls divided by the number of attempted calls) ranged from 0% to 89% (M = 43%, SD = 21%).

Figure 3. Success rate in completing calls over 3-month follow-up



We have also examined factors that predicted success in contacting families. We had expected that our success rate in calling teens would be lower than our success in calling parents (who were the respondents for younger children). Surprisingly, the difference was quite small. We successfully reached a parent on 45% of attempted calls versus 42% of attempted calls to teens (a statistically non-significant difference). Similarly, we were slightly better at reaching the targeted number of calls to parents (99% of the targeted 7 calls) than with teens (92%), a difference that was not statistically significant.

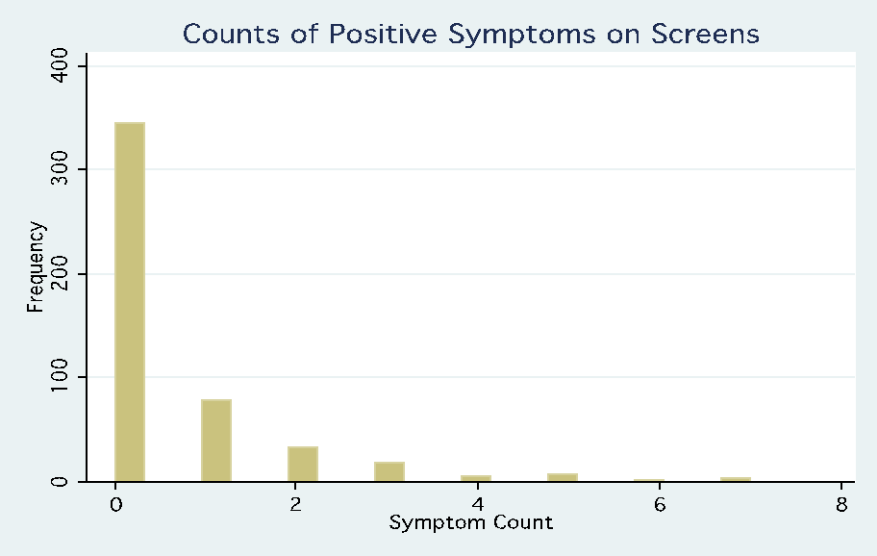
Analysis of PhaST Screen Response Data

Next we looked at the psychometric properties of the PhaST screen. The key questions were, first, does the PhaST screen have adequate internal consistency reliability?

493 screens were completed by 75 respondents in the PhaST condition. 30% of screens had a "Yes" response to at least one question. Cronbach's alpha estimate of scale reliability was .72. We also factor analyzed a tetrachoric correlation matrix of the items. All items loaded strongly together, except non-adherence. The first factor had an eigenvalue of 4.0 and explained 95% of the variance, all other eigenvalues were substantially less than one. All loadings on the first factor were positive and were greater than 0.67. A Rasch analysis found that reports of anger were the least severe symptom responses, and suicidality was the most severe symptom. The upshot is that there is psychometric evidence for the use of the symptom count as a measure of the child's psychiatric distress.

Of the 493 screens, 8% reported non-adherence to medication (which is doubtlessly but unsurprisingly under reporting). 30% of screens reported at least one psychiatric symptom. 66% reported medication adherence and no psychiatric symptoms, 4% reported nonadherence but no symptoms, 15% reported symptoms with adherence, and 15% reported non-adherence and at least one exacerbated symptom. The symptom counts on the screens are presented in the Figure.

Figure 4. Counts of positive symptoms on screens



Rates of responses on individual items are shown in the following table.

Table 3.

Item	Positive Responses	% (out of 493)
Depression	43	9%
Anxiety	38	8%
Sleep	48	10%
Mania / Agitation	65	13%
Anger / Aggression	58	12%
Open	27	5%
Suicidality	12	2%
Nonadherent	40	8%

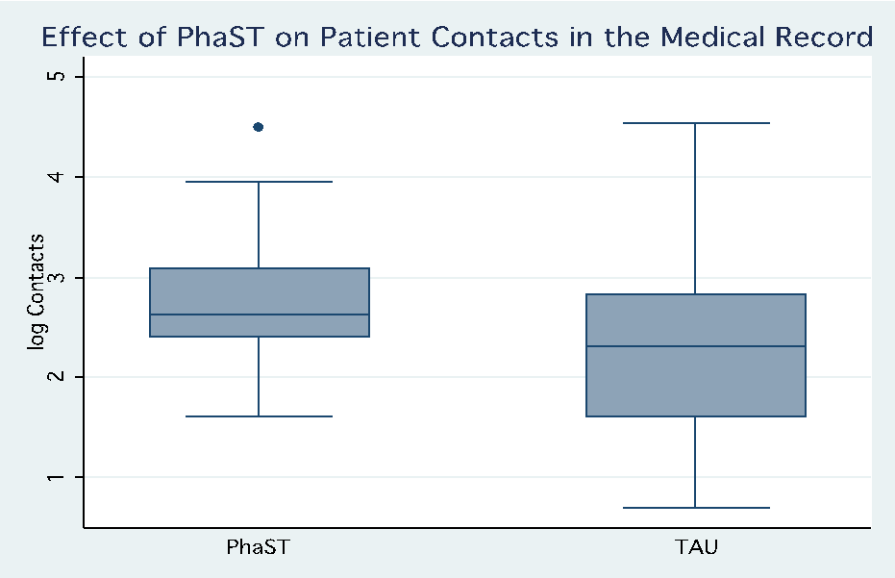
The Effect of PhaST on Patient Data Recorded in the Medical Record

We attempted to review the medical records of all patients in the study during the three months when the patients were followed. The practices were not – shockingly – able to locate the medical records of three of the participating families. However, we were able to review records for 75 PhaST children and 75 TAU children.

Because PhaST was designed to enhance the monitoring of children taking antidepressants, our first question was whether participating in PhaST increased the amount of data about children found in the medical record. So we counted the total number of contacts with families, including visits, telephone calls, emails, letters, and reports of PhaST screens in each child's record for the three months they were in the study. We found that children in the PhaST condition had almost five more contacts (M = 17.8 contacts, SD = 1.6) than did children in TAU (M = 12.9, SD = 1.8). Because the data were highly skewed (small numbers of patients had very high numbers of contacts), we log-transformed the number of contacts before analysis. The

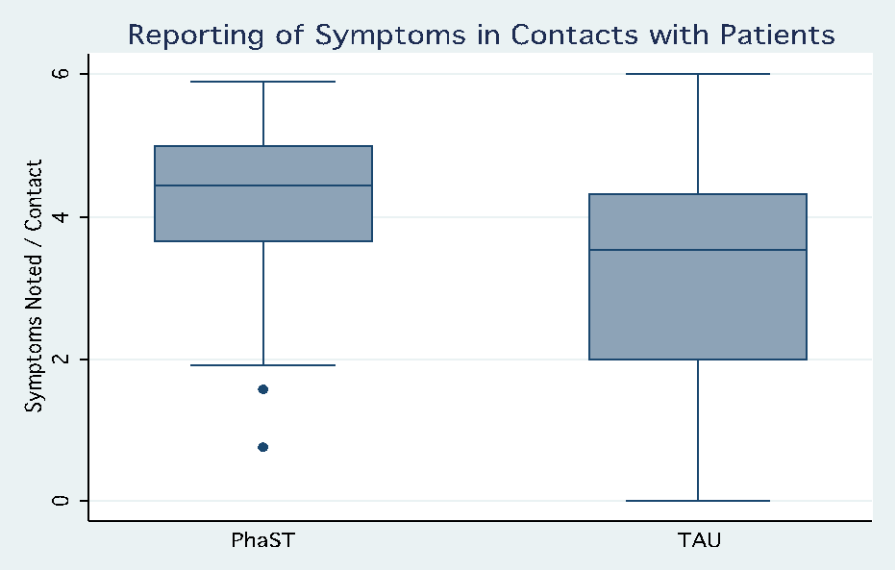
difference in the log-transformed data is statistically significant ($p < .001$; the difference is also significant in the non-transformed data ($p = .023$).

Figure 5. Effect of PhaST on patient contracts in the medical record



At each contact, we also asked whether the clinician noted the presence of depression, anxiety, sleep, mania, anger, or suicidality. These symptoms were noted at higher rates in the PhaST condition: there was a notation of the presence of an average of 4.3 conditions in the note concerning a contact (SD = 0.12), compared to 3.2 conditions in TAU (SD = 0.17; $p < .001$).

Figure 6. Reporting of symptoms in contacts with patients



Discussion

In summary, we have developed a software application to assist clinicians conduct follow-up monitoring of patients, when those patients need close supervision and have difficulty making frequent office visits. We have shown that the system is able maintain and establish contact with patients and it achieved its targeted rate of follow-up supervision. The screen has strong psychometric properties, and families used it to report significant rates of mental health problems. This information increased the amount of data on children's mental health condition available to clinicians, as shown through medical record reviews.

Conclusions, Significance, and Implications

Our preliminary analyses show that PhaST enables clinicians to have substantially increased information about patients, without burdening them with significant additional tasks.

Plans for Future Analyses

In future analyses, we will compare chart-documented adverse events against adverse events as determined by an examiner blind to the patient's randomization. We predict higher agreement between chart-documented adverse events and examiner-determined adverse events in the PhaST condition. We will also compare PhaST and usual care on measures of patient and provider satisfaction, patient outcomes, and measures of the quality of medication management such as rates of patient medication non-adherence.

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