

Official Title: Placement Success Predictor: Using Site-Customized Machine Learning Models to Predict the Best Level of Care Placement for Each Child's Behavioral Health Needs

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PURPOSE

The purpose of this study is to test the efficacy and effectiveness of a new clinical-decision support tool, Placement Success Predictor. PSP will make level-of-care recommendations with machine learning algorithms that predict the likelihood of an adolescent having a good outcome in a particular placement type. We have preliminary evidence supporting the feasibility of developing these models from work supported by The Duke Endowment (TDE) and an SBIR Phase I project (Trudeau et al., 2023): Placement recommendations based on these machine learning models distinguished between youth who did well in residential care versus non-residential care (e.g., 80% of those who received care in the recommended setting with the highest predicted likelihood of success had above average risk-adjusted outcomes).

BACKGROUND

In 2017, a total of 669,799 children were confirmed victims of maltreatment in the United States; of the 442,733 children in foster care, 34% have been in more than one placement and 11% are in a group home or institution (The Annie E. Casey Foundation, KIDS COUNT Data Center, 2020). Stakes are extremely high for making the best out-of-home placement choice per child because some placement types and multiple placements are associated with poor outcomes (e.g., Rubin et al., 2007). In the past few years, legislation has been created to guide placement decisions for children. Federal law 42 U.S. Code 675 requires that children in the care of the state are placed “in a safe setting that is the least restrictive (most family like).” In addition, the Family First Prevention Services Act signed into law (see Title VII in the Bipartisan Budget Act of 2018; U.S. Congress, 2018) includes measures to reduce the number of children in long-term residential settings.

Current child welfare decision-making includes well-documented biases, such as differential placement by race and ethnicity (e.g., Lee et al., 2015). Structured decision making (SDM; NCCD, n.d.) has been used to guide decisions about risk but SDM is limited by the use of a smaller group of factors to make recommendations (Teixeira & Boyar, 2017). There is also a well-documented lack of inter-rater reliability for non-technical solutions to support decision-making: Clinician-determined placement decisions for the same profiles using standard level-of-care criteria were near zero ($r = .007$) between clinicians (Bickman et al., 1997). This study is an effort to develop and test a science-based clinical decision support tool using behavioral health data collected through standard clinical practice.

RATIONALE FOR REQUEST FOR WAIVER OF INFORMED CONSENT

We are requesting a waiver of informed consent from the Institutional Review Board under the Common Rule (45 code of federal regulations [CFR] 46.116(d); excerpt from <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html> below):

1. the research involves no more than minimal risk to the subjects;
 - *testing of a minimal risk intervention (i.e., site-placement prediction scores per client for staff to consider during the level of care decision-making process).*
 - *analysis of behavioral health data collected through standard clinical practice at Children's Hope Alliance (CHA) and Iowa Department of Human Services (DHS)*
2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. the research could not practicably be carried out without the waiver or alteration; and,
4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Seeking a waiver of informed consent is consistent with other RCTs of clinical decision support tools for use with pediatric cases (e.g., Downs et al., 2018 – autism screening plus recommendations; Kharbanda et al., 2021 – appendicitis risk assessment plus recommendations).

STUDY PROTOCOL

1. RISKS TO HUMAN SUBJECTS

a. Human Subjects Involvement, Characteristics, and Design

CLINICAL PARTNER 1

We plan to conduct an RCT to assess efficacy of the use of Placement Success Predictor on improved well-being outcomes and reduced healthcare costs in child welfare.

Sample. The Placement Success Predictor will provide site-placement prediction scores per client for staff to consider during the level of care decision-making process. Inclusion criteria: client at Iowa DHS who takes a TOP. There are no exclusion criteria. In the past year, 1,617 unique clients at Iowa DHS took a TOP. Given that the study requires only completion of

standard clinical measures that are used in practice at Iowa DHS, we expect there will be more than enough power to find even a small effect size. No participant compensation will be provided as the TOP itself is a standard part of care delivered in Iowa and its completion is required by the state.

Randomization. A random number generator or a digit in the client's record number (e.g., the second-to-last digit) will be used to determine group assignment (experimental = access to Placement Success Predictor results versus control = no access) for each client.

Methods. Iowa DHS will have the opportunity to use this new tool with clients assigned to the experimental condition. Use of TOP is part of Iowa DHS's federally mandated strategy to comply with Family First legislation. We will work Iowa DHS to ensure Placement Success Predictor output and recommendations are easily visible to decision makers when the client is randomly included in the experimental group.

Intervention Condition. Placement Success Predictor results [client's likelihood of success per placement based on machine learning models] will be shared with the caseworkers via ORI's WellnessCheck platform. In addition, monthly aggregate reports will be shared with administrators with Placement Success Predictor results per client.

Control Condition. Placement Success Predictor results [client's likelihood of success per placement based on machine learning models] will NOT be shared with the caseworkers via ORI's WellnessCheck platform.

CLINICAL PARTNER 2

We plan to conduct a quasi-experimental effectiveness and quality improvement study to assess and improve the usage of Placement Success Predictor in a behavioral health setting.

Sample. Children's Hope Alliance (CHA) serves approximately 2,000 unique clients per year (2,069 took a TOP in the past year). Inclusion criteria: client at CHA. There are no exclusion criteria.

Methods. Placement Success Predictor will be introduced to all clinicians at CHA and the tool will be available for use with all clients (i.e., there are no exclusion criteria). It will make placement recommendations per client for placement types that have at least 100 clients for supervised machine learning model development: i.e., 'Child ACTT', 'Day Treatment', 'Foster Care', 'Intensive In-Home', 'Outpatient', 'Physicians Group', 'School Based Therapy', and 'TASK [Treatment for Sexualized Kids].' This will enable us to conduct a naturalistic study of usage by behavioral health clinicians and make changes in the system to increase usage per CHA user and collect ongoing administrative feedback. We hypothesize that following the Placement Success Predictor recommendations will be associated with better client outcomes (i.e., better than those predicted by the Risk-Adjusted algorithms) versus not following the Placement Success Predictor recommendations. This effectiveness study will ensure we build a solid product that can be easily adapted into almost any segment of the market (e.g., child welfare, behavioral health).

Intervention. Placement Success Predictor results [client's likelihood of success per placement based on machine learning models] will be shared with the caseworkers via ORI's WellnessCheck platform for clients. In addition, monthly aggregate reports will be shared with administrators with Placement Success Predictor results per client.

MEASURE AND OUTCOMES. The Treatment Outcome Package (TOP) is used in standard clinical practice at both CHA and Iowa DHS. The TOP includes three forms: the Consumer Registration form, the Case-mix form, and the Clinical Scale. The TOP Consumer Registration form (TOP-CR) consists of eleven items regarding demographic characteristics (e.g., race, education). The TOP Case-Mix form (TOP-CM) includes 54 items about stressful life events, physical health, and medication use in the past 12 months and the past 30 days. The Adolescent TOP Clinical Scale (TOP-CS) is a 58-item scale for adolescents who are

between the ages of 11 – 21. The TOP assesses the client's past 2-week experience on 12 domains including Depression, Attention Problems, Conduct Disorders, and Suicidality, and provides a total well-being score. Participants indicate "All" to "None of the Time" for each item on a 6-point Likert scale. Several studies have indicated the reliability and validity of the TOP (e.g., Baxter et al., 2016; Boswell et al., 2009; Kraus et al., 2010; Kraus et al., 2005). The TOP CS is completed via self-report, as well as from the perspective of other raters who know the adolescent well.

TOP assessments will be automatically administered via email or text message to the caseworker, client, or a significant rater identified by the caseworker every 40-60 days. All study data are collected and stored at Outcome Referrals, Inc. (ORI, Study Site).

POTENTIAL RISK. There is minimal risk associated with participating in this study as clients will be managed closely during care and behavioral health outcome data for this study will be collected as part of the site's standard clinical protocol to assess each client's treatment progress and clinical needs.

2. ADEQUACY OF PROTECTION AGAINST RISKS

- a. *Potential risks.* Only standard clinical assessments currently used in practice at CHA and Iowa DHS will be used in this study; no additional assessments will be required. Therefore, we are requesting a waiver of informed consent from the Institutional Review Board under the Common Rule (45 code of federal regulations [CFR] 46.116). Seeking a waiver of informed consent is consistent with other RCTs of clinical decision support tools for use with pediatric cases (e.g., Downs et al., 2018; Kharbanda et al., 2021).

There is the potential for machine learning models to be used for profiling and perpetuating existing social biases in our culture such as racism (Glaberson, 2019).

- b. *Protection against risks.* ORI has strict protocols in place to secure clinical and research data. See Data and Storage Confidentiality section below.

If race becomes an important predictor in any model, we will evaluate the potential benefit of including this data in the model compared to the risk of perpetuating racial disparities. Unless we can find a good, evidence-based rationale for including race, it will be eliminated.

Data Storage and Confidentiality

Below is a description of the key IT Security measures which the joint ORI IT team applies on an ongoing basis to protect the security of WellnessCheck.net and other ORI assets. NOTE: TOP data are available through our secured network to the client's clinical team for treatment.

1. Network:

- Network Infrastructure Architecture
- Web Server deployed in DMZ
- Hardware Firewall operating between Web Server and back end Application, Database and Report Servers
- Secure Multiprotocol Switches operating between systems behind Hardware Network Firewalls
- Network appliances regularly updated reasonably near latest revisions, including security patches

- Enterprise-wide Hardware Network Firewalls continually operate 24x7 with: Active and Passive Intrusion Detection/Intrusion Prevention (IDS/IPS)
- Monitoring of network traffic signatures
- Automated priority alert notification on event detection to internal IT Security personnel
- Web Filtering, Anti-Spam, Anti-Virus/Anti-Malware, Anti-Phishing Protection
- Daily/hourly/per minute updates to Active and Passive IDS/IPS, Anti-Spam, Anti-Virus/AntiMalware, Anti-Phishing Signature databases
- Unified Threat Management (UTM) appliances deployed and configured for primary network gateway protection
- Data encrypted at rest and in transit
- 2. System:
 - Operating systems and relevant packages regularly updated reasonably near latest revisions, including security patches
 - Double encryption of backups
- 3. Application:
 - Userid/Password Authenticated Application Sessions
 - PII exclusion from logging
 - Primary application components (Web, Application and Report Servers) regularly updated reasonably near latest revisions, including security patches
- 4. Database:
 - Access credentials persisted with hashing, not clear text
 - Client/Patient information made anonymous (Behavioral Health/WellnessCheck 1.0)
 - Database table spaces containing PII are double-encrypted at rest
 - Primary Database Server components regularly updated reasonably near latest revisions, including security patches
 - All database backups are encrypted with two different encryption keys and are stored at a Tier 1 datacenter within the Continental United States
- 5. Source Revision Control:
 - All source repositories resident and maintained in-house behind a Hardware Firewall
 - No outsourcing of Software Engineering processes
- 6. Cloud Services:
 - No Cloud Services used for production runtime environment
 - No Cloud Services utilized for data storage
- 7. Compliance Testing:
 - Full gray box penetration test conducted in August of 2022. All systems passed with no critical or high vulnerabilities discovered.

c. Populations that are vulnerable to coercion or undue influence and pregnant women, fetuses and neonates, if relevant to your study. The Placement Success Predictor will be developed with data from children and adolescents to inform placement decisions of children in child welfare. To test the efficacy of this clinical-decision making tool on caseworker's placement decisions, it is necessary to look at the behavioral health outcomes of clients who were placed with or without the caseworker having access to the recommendation from this innovative resource.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO RESEARCH PARTICIPANTS AND OTHERS

Clinical data collected from the behavioral health outcome assessments will be available to and actionable by each client's treatment team to improve care.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

If there is evidence-based support for the efficacy and effectiveness of the Placement Success Predictor tool then it will be an excellent resource for placement staff and administrators to help improve care for children, lessen the friction between payers and providers, and potentially save hundreds of millions in healthcare costs.

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