Pediatric Treatment Resistant Depression Center of Excellence: Program Design PHASE II REPORT

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MEADOWS MENTAL HEALTH POLICY INSTITUTE



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EXECUTIVE SUMMARY

The Need for a Pediatric Treatment Resistant Depression Center of Excellence

Treatment resistant depression is a growing problem for children in Texas and more widely in the United States. While depression typically first manifests in adulthood, its impact on children and youth is devastating and growing, with 20% of children experiencing a major depressive disorder before adulthood¹ and rates of reported depression symptoms among children and youth growing to over 40% during the pandemic (and receding in the years since only to 30%).² Unfortunately, only about one third of these children receive needed care, and as many as 40% receive no treatment at all,³ leading to poor clinical outcomes.⁴ Research demonstrates that untreated depression is the largest driver of suicide,⁵ which is the second and third leading cause of death in youth ages 10–14 and 15–24 in the United States, respectively.⁶,⁷

While we can treat most cases successfully with standard routine and specialty care, up to 20% of children and youth with major depressive disorder do not respond to initial or secondary evidence-based psychotherapy and medication treatments.⁸ The children whose depressive symptoms are not alleviated by first and second-line treatments are often described as suffering from "treatment resistant depression" (or TRD). Though there is no universally recognized definition for pediatric treatment resistant depression (P-TRD), the most commonly referenced definition describes children who have not responded to at least one evidence-based psychotherapy trial (of adequate duration) and at least two selective serotonin reuptake inhibitor (SSRI) medication trials (both of adequate dose and duration).⁹ Among children ages six to 12, the Meadows Mental Health Policy Institute (Meadows Institute) estimates that approximately 3,400 in Dallas County, 10,000 in the Dallas-Fort Worth Metroplex, 37,500 across Texas, and 370,000 nationwide meet criteria for P-TRD.

The Meadows Institute estimates the operation costs of a P-TRD center for excellence (CoE) to be approximately \$3 million per year with a capacity to serve 150 children (and their families), equating to about \$20,000 per patient for the first year of care, and a proportion of that for each year thereafter. Additionally, a CoE can expect self-pay revenue for its services to be above those costs (over \$29,000 per patient per year calculated at 143% of Medicare). Fortunately, for children and families with adequate insurance coverage, a CoE should be able to be reimbursed for a portion of its services directly from the carrier.

⁷Centers for Disease Control and Prevention (n.d.). 10 Leading Causes of Death, United States. National Center for Injury Prevention and Control. Web-based Injury Statistics Query and Reporting System (WISQARS). Retrieved September 27, 2023, from <u>https://wisqars.cdc.gov/data/lcd/home</u>

⁸Dwyer, J. B., Stringaris, A., Brent, D. A., & Bloch, M. H. (2020). Previously cited.





¹Dwyer, J. B., Stringaris, A., Brent, D. A., & Bloch, M. H. (2020). Annual research review: Defining and treating pediatric treatment-resistant depression. *Journal of Child Psychology* and Psychiatry, and Allied Disciplines, 61(3), 312–332. <u>https://doi.org/10.1111/jcpp.13202</u>

²National Center for Health Statistics. (2023). Household pulse survey: 2020–2023, *anxiety and depression*. <u>http://www.cdc.gov/nchs/covid19/pulse/mental-health.htm</u> ³Avenevoli, S., Swendsen, J., He, J. P., Burstein, M., & Merikangas, K. R. (2015). Major depression in the national comorbidity survey-adolescent supplement: Prevalence, correlates, and treatment. *Journal of the American Academy of Child & Adolescent Psychiatry*, 54(1), 37–44.e2. <u>https://doi.org/10.1016/j.jaac.2014.10.010</u>

Arraus, C., Kadriu, B., Lanzenberger, R., Zarate Jr., C. A., & Kasper, S. (2019). Prognosis and improved outcomes in major depression: A review. *Translational Psychiatry*, 9(1), 1–17. http://doi.org/10.1038/s41398-019-0460-3

⁵Dwyer, J. B., Stringaris, A., Brent, D. A., & Bloch, M. H. (2020). Previously cited.

⁶Center for Disease Control and Prevention (2023). Facts About Suicide. Suicide Prevention. <u>https://www.cdc.gov/suicide/facts/index.html</u>.

Despite the many children and families struggling with P-TRD, there is no national CoE focused exclusively on P-TRD and few known medical centers offering specialized care of any type for P-TRD, leaving children and their families without access to critical, often lifesaving, support. In short, there is a clear and growing need for specialized treatment nationally and regionally to support children and their families living with P-TRD.

Essential Design Elements for a P-TRD CoE

Building upon our Phase I efforts, during this extended Phase II program design phase the Meadows Institute developed an ideal framework for a P-TRD CoE (depicted in Chart 1). To ensure that the framework is grounded in the latest evidencebased practices, a multidisciplinary Meadows Institute team crafted it based on multiple rounds of discussions with experts (Appendix 1) and an exhaustive examination of peer-reviewed journals (Appendix 7). Through this multifaceted approach, our team created a comprehensive blueprint encapsulating the most effective strategies for addressing treatment-resistant depression in pediatric populations, outlining the program elements necessary to implement a P-TRD CoE able to provide state-of-the-art services and set the standard of care for children ages 12 and younger.

Chart 1: Pediatric Treatment Resistant Depression Center of Excellence Framework

Core Elements		
Comprehensive interdisciplinary evaluation	Specialized Intervention	s Implementation Site
Family involvement and support Case management and navigation Address social determinants of health	Diagnostic expertise Psychopharmacology Individual and group therapies Family therapy School psychology Social work Outpatient programs Inpatient care	Strong existing infrastructure Inpatient unit Availability of interventional psychiatry Academic institution Research capabilities Growth capacity

The criteria we established within the framework allow us to rigorously assess a site's capacity to deliver the specialized care and support required to implement the envisioned CoE with a transparent basis for decision-making.



INTRODUCTION

With this report, made possible by generous support from the Bette Rathjen Foundation for Emotional Health, the Meadows Institute lays out the programmatic elements necessary to implement a P-TRD CoE, including in-depth examination of services, staffing, and related expenses. We grounded this analysis in the establishment of a standardized definition of P-TRD, coupled with a thorough evaluation of its occurrence and need. The needs-based component of this report focuses on Dallas, as it was our initial target community. Furthermore, it provides a typical illustration of the needs in a given major urban community, and we can update the community-specific analysis for any metropolitan region looking to craft such a program.

DEFINING PEDIATRIC TREATMENT RESISTANT DEPRESSION

Currently, there is no consensus on diagnostic criteria or optimal treatment for TRD for any age group, including P-TRD. In the absence of a universally accepted definition, the guiding definition of P-TRD we adopted for this project was based on an extensive literature review and is characterized by a progression of phases in clinical treatment. We consider children presenting with symptoms of depression to have P-TRD at Stage 5 in the following widely used state-based model of pediatric depression symptoms (see Table 1).

Table 1: Pediatric Depression Treatment Progression¹⁰

Pediatric Depression Treatment Progression		
Stage	Definition	Phase
0	No previous depression treatment	
1	Previous counseling for depression (modality or evidence support for modality unclear)	
2	2 Previous evidence-based psychotherapy for depression of adequate duration Initial treatment trials	
3	3 One trial of	
4	A second	
5	Additional medication and psychotherapy trials with consideration for augmentation	Treatment resistant depression

PEDIATRIC TREATMENT RESISTANT DEPRESSION PREVALENCE

A successful center of excellence (CoE), in any community, needs to reflect the community it serves, and we used Dallas and the Dallas-Fort Worth Metroplex to model the potential needs that might be met by such a program and as a model for a potential market for the CoE. This section provides an overview of the prevalence of P-TRD both in North Texas and nationally, helping to quantify the need for a CoE.

Because prevalence studies break down ages in ways that did not align precisely with our population of interest (ages 12 and under), we synthesized data from multiple P-TRD prevalence estimates in order to project the number of children suffering from P-TRD in a given year. Among children six to 12 years of age, we estimate that approximately 3,400 in Dallas County, 10,000 in the Dallas-Fort Worth Metroplex, 37,500 across Texas, and 370,000 nationwide meet criteria for P-TRD. For additional information on client population estimates by region and age groups, see Table 2.

¹⁰Adapted from Dwyer, J. B., Stringaris, A., Brent, D. A., & Bloch, M. H. (2020). Previously cited.

^{*}Fluoxetine is FDA approved for children ages 8 and older with MDD; Escitalopram is FDA approved for youth ages 12 and older with MDD; Fluvoxamine is FDA approved for children ages eight and older with OCD, but not MDD; Sertraline is FDA approved for children ages six and older with OCD, but not MDD.

^{**}Duloxetine is FDA approved for children ages seven and older with GAD, but not for MDD.

P-TRD Estimated Client Population by Region and Age Group			
Ages 6–11	Ages 6–12	Age 12	Ages 12–15
	Dallas	County	
2,600 (2,000–3,200)	3400 (2,700-4,200)	800 (700–1,000)	3,700 (3,000-4,400)
Dallas-Fort Worth Metroplex			
7,600 (5,900–9,400)	10,000 (7,800-12,300)	2,400 (1,900–2,800)	11,200 (9,200-13,300)
	Te	xas	
28,500 (22,100-35,500)	37,400 (29,300-46,100)	8,800 (7,200–10,600)	41,700 (34,400-49,500)
United States			
281,600 (217,900-350,500)	369,700 (289,900-456,000)	88,200 (72,000–105,500)	419,700 (346,200-498,000)

Table 2: Estimated Client Population per Year by Region and Age Group (2021)

THE CENTER OF EXCELLENCE ESSENTIAL DESIGN ELEMENTS

Caring effectively for pediatric treatment resistant depression (P-TRD) requires a coordinated and comprehensive array of treatment modalities, most of which have been inadequately studied in children and youth. This dilemma is generally true for the practice of child and adolescent psychiatry (and other branches of medicine), necessitating "off-label" adult practices to be frequently applied to children. In designing a P-TRD CoE with the best care continuum possible, we began by incorporating the relevant evidence base for children and then extrapolated best practices from adult care or adolescent care to fill gaps.

Our framework for the P-TRD CoE is a model of coordinated comprehensive care that includes medical evaluation and treatment, individual and family skill building, family educational supports, and care coordination, with family navigation as the central and guiding element as seen in Chart 2.¹¹

¹¹When developing our framework for a P-TRD CoE, we drew inspiration from the Coordinated Specialty Care (CSC) model, an evidence-based practice known for its comprehensive approach to treating first-episode psychosis. For more information on a coordinated care for P-TRD model see Appendix 2.





Chart 2: Coordinated Comprehensive Care for Pediatric Treatment Resistant Depression

The core range of services we considered included: comprehensive, multi-disciplinary diagnostic assessments (including both psychiatric and all other related health needs), the complete array of evidence-based outpatient treatment modalities, digital and virtual supports, partial hospitalization and intensive outpatient options, inpatient care, and residential treatment for children with longer-term functional impairments. The optimal CoE would encompass this entire spectrum of care for managing both initial and subsequent episodes of P-TRD, along with the necessary follow-up care.

Comprehensive Interdisciplinary Evaluation

Every child's care should start with a comprehensive interdisciplinary evaluation that includes the child suffering from P-TRD along with their family.¹² Unfortunately, too often families do not get such an evaluation, even after months or years of treatment, but when treatment outcomes are not being realized, it becomes even more essential. **Receiving an evaluation able to yield a clear problem statement, diagnosis (or multiple diagnoses), and plan for care over the short and longer term is the cornerstone of our proposed CoE model, and it would ideally take place face-to-face within the CoE facility, though the CoE may conduct most of the activities virtually via telehealth for children and families unable to meet in person. A core team, including at minimum a child psychiatrist, a pediatric psychologist, a neuropsychologist, and a family therapist, would perform the comprehensive evaluation, coordinating closely on the assessment to come to consensus with each other and with the family on the nature of the child's and family's needs, their key drivers, and the most effective available treatments to address them in the short and longer term. As needed, the CoE**

¹²In this report, we use the definition of family as two or more persons related in any way - biologically, legally, or emotionally.

would also maintain a network of local and national referral partners able to provide other diagnostic and medical services, including brain imaging, electroencephalogram (EEG), neurological evaluation, or other specialty evaluation and diagnostic services. A psychiatric social worker would also ideally be part of the team to compile prior treatments and information on their respective outcomes, as well as information on school and community functioning.

The comprehensive evaluation would provide the best possible diagnosis to guide ongoing care, along with a detailed, personalized, and family-focused treatment plan that is culturally and linguistically appropriate. Each of these points is critical. The evaluation would bring together **details from a multi-disciplinary team**, details that most assessments cannot include, as they lack the range of experts necessary to assemble them. Each clinical team member offers a unique perspective based on their skill, expertise, and clinical experience. For example, a neuropsychological assessment offers insight into a child's cognitive functioning, including any learning disabilities that may be contributing to academic challenges. A child psychiatrist offers diagnostic expertise, considering all biological, psychological, and social factors contributing to the clinical presentation. A pediatric psychologist offers expertise in developmental assessment and evidence-based therapies that are critical to developing a treatment plan. A family therapist offers insight into family functioning, including strengths, challenges, and growth opportunities.

Additionally, as we further describe later in this report, these details **would be personalized with data from the entire family and from the full range of functional activities in which the child participates**. The evaluation would also be **family-focused**, **recognizing that the adults raising the child are typically the people most able to affect outcomes and inform treatment through their observations and concern**. Once the team reaches consensus on the diagnosis, longer-term strategy, and initial treatment plan, the care team would meet with the child and family and incorporate their perspectives and preferences into the care plan to ensure that it makes sense to them and reflects their best sense of how to help their child.

Once completed, there will be two primary paths forward from the comprehensive evaluation:

- Optimally, the CoE would take the lead in providing care for the child and their family. This is possible both for children who live locally, as well as for those for whom virtual care is appropriate.
- The other path involves sending written documentation of the complete evaluation back to the child's referring clinician if they already have a sufficient clinical team with which they are working. This is especially likely to be necessary if the family does not reside routinely in the same community as the CoE and requires (or otherwise prefers) in-person care (rather than virtual care through the CoE).

In either scenario, the team would ensure direct coordination of care with the referring clinician, the clinical team who will provide follow-up care, and the child's pediatrician.

The initial treatment plan would focus on the most pressing needs, with provisions for monitoring progress closely and updating the plan regularly as treatment progresses. Ideally, ongoing care would continue until symptoms and functioning improve to a point at which care can transition to a recovery or maintenance phase. Given that treatment will often need to continue for years at some level – and that many of the most effective treatments for TRD such as electroconvulsive therapy (ECT), transcranial magnetic simulation (TMS), and ketamine, are not viable options until the child is older (ages 13 and above, at minimum and varies based on state regulations) – there will also likely be episodes where the CoE is lead on care and times when other community partners can take the lead on care. At these points in time (partial or full remission, maintenance, or times of watchful waiting between episodes of more intensive care), the CoE would refer the child to outpatient partners with whom the CoE has an established referral relationship (or who the family otherwise prefers), with provisions to return for additional evaluation and treatment over time. In addition to being most efficient for the child and family, time-limiting the care to the complex components that require the expertise of the CoE and allowing other trusted clinicians (including the primary care provider) to do their parts, the CoE can also serve more children and their families.

Cultural Competency

Cultural competency is another critical component of the interdisciplinary evaluation, and it involves the psychiatric social worker conducting a cultural assessment to gain deeper insights into the child, family, and their perspectives on development, values, preferences, and beliefs about mental health treatment. It is essential that the CoE deliver culturally competent mental health care to each child and their family to ensure treatment engagement, adherence, and optimal outcomes aligned with the values and beliefs of the family. This goal requires tailoring interventions to align with diverse cultural values, reducing barriers to access, and fostering trust through effective communication. The CoE would build strong therapeutic alliances by recognizing and leveraging cultural strengths and contributing to prevention and early intervention strategies. By addressing unique cultural needs and promoting equity, the CoE would create an inclusive and effective treatment environment that meets the unique needs of each child and family.

Inclusion / Exclusion Criteria

Identifying children who can and cannot participate in the CoE's programming array is essential for three reasons: (1) providing the appropriate type of evidence-based care to the operationally defined P-TRD population, (2) reducing the risk of harm to children and their families secondary to providing inappropriate interventions or costly supports to them, and (3) protecting vulnerable children from being inappropriately enrolled in the CoE, thus wasting valuable time that could have been spent providing appropriate care. As outlined in Table 1, all children ages 12 and younger with Stage 5 P-TRD would be eligible for treatment at the CoE. In addition, a child meets exclusion criteria from CoE programming if the child presents with a current or past diagnosis of psychosis, bipolar disorder, or substance use disorder. After the care team conducts the evaluation, they will determine exclusion criteria.

Addressing Comorbidities

There is longstanding and considerable consensus that childhood trauma is significantly associated with the development of depression.¹³,¹⁴ Since an estimated 45% of children living in the United States have experienced one or more forms of trauma,¹⁵ it bears to reason that a comprehensive interdisciplinary evaluation through the CoE will serve to distinguish between depressive symptomatology originating from adverse childhood experiences versus more unidimensional childhood TRD. Similarly, anxiety and depression are two of the most highly comorbid childhood diagnoses¹⁶ with their entanglement only exacerbated by the COVID-19 public health crisis.¹⁷ The CoE's interdisciplinary evaluation would additionally serve to differentiate between the common occurrence of anxiety preceding depressive presentations in children¹⁸ as opposed to a more traditional display of childhood TRD appropriate for the CoE. There is evidence that additional pediatric diagnoses confound a clear diagnosis of TRD¹⁹ and the interdisciplinary evaluation will serve to best clarify these ambiguous presentations. Ultimately, the CoE's targeted approach toward differentiating between childhood TRD and symptomatology comorbidities obscure at the initial evaluation stage will inform a child's comprehensive treatment plan and associated inclusion / exclusion in the CoE's programming.

In addition to evaluation of potential behavioral health comorbidities, it is also important to enhance the comprehensive evaluation by incorporating a thorough pediatric evaluation which will include assessment of developmental milestones, nutrition, and general medical considerations. By including a comprehensive pediatric evaluation, clinicians can delve into

¹³Flory, J. D., & Yehuda, R. (2015). Comorbidity between post-traumatic stress disorder and major depressive disorder: alternative explanations and treatment considerations. *Dialogues in Clinical Neuroscience*, 17(2), 141–150. <u>https://doi.org/10.31887/DCNS.2015.17.2/iflory</u>

¹⁴Vitriol, V., Cancino, A., Leiva-Bianchi, M., Serrano, C., Ballesteros, S., Asenjo, A., Cáceres, C., Potthoff, S., Salgado, C., Orellana, F., & Ormazábal, M. (2017). Childhood trauma and psychiatric comorbidities in patients with depressive disorder in primary care in Chile. *Journal of trauma & dissociation: the official journal of the International Society for the Study of Dissociation* (ISSD), 18(2), 189–205. <u>https://doi.org/10.1080/15299732.2016.1212449</u>

¹⁵Sacks, V., Murphey, D., & Moore, K. (2014). Adverse childhood experiences: National and state-level prevalence (research brief No. 2014–28). Child Trends. <u>http://www.childtrends.org/wp-content/uploads/2014/07/Brief-adverse-childhoodexperiences_FINAL.pdf</u>

¹⁶Melton, T. H., Croakin, P. E., Strawn, J. R., & Mcclintock, S. M. (2016). Comorbid anxiety and depressive symptoms in children and adolescents. *Journal of Psychiatric Practice*, 22(2), 84–98.

¹⁷Racine, N., McArthur, B. A., Cooke, J. E., Eirich, R., Zhu, J., & Madigan, S. (2021). Global Prevalence of Depressive and Anxiety Symptoms in Children and Adolescents During COVID-19: A Meta-analysis. *JAMA Pediatrics*, 175(11), 1142–1150. <u>https://doi.org/10.1001/jamapediatrics.2021.2482</u>

¹⁸Kim-Cohen, J., Caspi, A., Moffitt, T. E., Harrington, H., Milne, B. J., & Poulton, R. (2003). Prior Juvenile Diagnoses in Adults With Mental Disorder: Developmental Follow-Back of a Prospective-Longitudinal Cohort. Arch Gen Psychiatry, 60(7), 709–717. https://doi.org/10.1001/archpsyc.60.7.709

¹⁹Rao, U., & Chen, L. A. (2009). Characteristics, correlates, and outcomes of childhood and adolescent depressive disorders. *Dialogues in Clinical Neuroscience*, 11(1), 45–62. <u>https://doi.org/10.31887/DCNS.2009.11.1/urao</u>

the holistic well-being of the patient, exploring potential contributors to P-TRD beyond the psychiatric realm. Evaluating developmental milestones provides insights into any underlying neurodevelopmental issues that may influence the course of depression, while a focus on nutrition allows for the identification of dietary factors that could impact mental health. Collaboration with the primary care physician ensures a seamless integration of medical considerations into the overall evaluation, helping to rule out physical illnesses or other biological factors that may contribute to or exacerbate P-TRD. This multifaceted approach not only broadens the scope of understanding regarding the origins of treatment resistance but also lays the foundation for a more comprehensive and individualized treatment plan tailored to the specific needs of the child.

Family Involvement and Support

As presence of a strong support network is a critical component of treatment, increasing attendance,²⁰ retention, and the success of treatment,²¹ family support and encouragement is pivotal to patient success and vital to the CoE.²² In this report, we use the definition of family as "two or more persons related in any way – biologically, legally, or emotionally."²³

Standard treatment modalities do not always include families as crucial participants, which can lead to challenges in treatment success and outcomes. Families of children with a mental illness report that a lack of knowledge and understanding of their child's treatment and diagnosis leaves them unable to support their child throughout the care process.²⁴ Including families in the treatment process reduces feelings of isolation, giving families a sense of responsibility in ensuring their child receives adequate care.²⁵ An improved understanding of what supports and services a child and their family needs to increase treatment engagement and retention will enable them to access the appropriate care, improving their mental health outcomes. Treatments for P-TRD often require more than emotional and social support; they often depend on the logistical involvement of a child's family. We highlight additional details on the family's vital role in Appendix 3.

Recognizing family engagement as a pivotal component of P-TRD treatment, we extend beyond one-dimensional psychiatric approaches to amplify the enduring positive impact of family and community involvement, fostering comprehensive engagement. The objective is to alleviate the challenges families may encounter in participating in treatment planning and to integrate family support as an indispensable facet of effective treatment. This CoE should use Family Systems Theory and Patient and Family Engagement, evidenced-based models, to successfully engage families and amplify clinical outcomes. See Appendix 4 for additional details about these models.

The CoE's philosophy of care should have three core tenets:

- Education: Provide families with comprehensive knowledge about treatment methodologies, medication administration, and their pivotal role in supporting their child. Education should also address cultural and faith-based mental health stigmas to foster robust family engagement.
- Inclusion: Actively involve children and families in their treatment journey, maintaining transparent communication through various mediums the CoE tailors to specific treatment modality.
- **Empowerment:** Recognize the invaluable expertise patients and families derive from their lived experiences. The CoE should intentionally involve families in the decision-making process, leveraging their insights from past treatment outcomes and cultivating an environment conducive to candid discussions regarding wellbeing, symptom progression, and satisfaction with the care the CoE provides.



²⁰Haine-Schlagel, R., & Walsh, N. E. (2015). A review of parent participation engagement in child and family mental health treatment. *Clinical Child and Family Psychology Review*, 18(2), 133–150.

²¹Robst, J., Rohrer, L., Armstrong, M., Dollard, N., Sharrock, P., Batsche, C., & Reader, S. (2013). Family involvement and changes in child behavior during residential mental health treatment. *Child & Youth Care Forum*, 42(3), 225–238. https://doi.org/10.1007/s10566-013-9201-6

²²Dowell, K. A., & Ogles, B. M. (2010). The effects of parent participation on child psychotherapy outcome: A meta-analytic review. Journal of Clinical Child & Adolescent Psychology, 39(2), 151–162. https://doi.org/10.1080/15374410903532585

²³Institute for Family-Centered Care. (2010). Frequently asked questions. <u>http://www.familycenteredcare.org/faq.html</u>

²⁴Andershed, B., Ewertzon, M., Johansson, A. (2017). An isolated involvement in mental health care—Experiences of parents of young adults. *Journal of Clinical Nursing*, 26(7-8), 1053–1065. <u>https://doi.org/10.1111/jocn.13560</u>

²⁵Andershed, B., Ewertzon, M., Johansson, A. (2017). Previously cited.

Aside from incorporating the family into the continuum of care and decision-making processes, it is also crucial to support families. The CoE would integrate family psychoeducation, support groups like NAMI's Back to Basics and Family-to-Family, and wellness activities for the entire family. Maintaining good mental health throughout the family is an important part of supporting both those in treatment and those caring for them.

Coordination with Schools

All stakeholders stressed the significance of school coordination within the CoE. This unanimous agreement among experts underscores the pivotal role of schools in the comprehensive care of children with P-TRD. Coordination of care with educational institutions ensures a holistic approach, aligning the efforts of healthcare professionals with the school environment. This collaboration extends to assessments focused on identifying any learning disabilities or academic challenges that may contribute to the complexity of P-TRD. Recognizing the interconnectedness of mental health and academic success, the CoE should emphasize the importance of providing educational support tailored to the unique needs of each child. By integrating school coordination into the CoE, providers will create a supportive and cohesive environment that addresses the multifaceted challenges faced by children with P-TRD, fostering both mental well-being and academic achievement.

Social Determinants of Health

Traditionally, communities have looked at health care, including mental health care, as a function of the resources available to provide care. Although those resources are critically important, the social determinants of health (SDOH) and the community context in which people live also have an impact on health, development, and morbidity. The SDOH are "the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks."²⁶

Acknowledging and attending to SDOH within the CoE is vital. These determinants encompass a range of non-medical factors, including socioeconomic status, education, employment, access to healthcare, housing, and community resources. This comprehensive awareness provides a deeper understanding of a child's overall well-being and the potential underlying causes of their mental health diagnoses. It enables tailoring interventions to address specific circumstances, such as providing financial counseling for those facing economic stressors. Furthermore, recognizing these determinants allows for proactive measures to prevent and / or provide early intervention. By addressing SDOH, the CoE could reduce disparities, ensuring equitable access to effective care in the community it serves. Acknowledging SDOH as a critical piece to providing excellent care, as we learned from stakeholders in Phase I; it is also vitally important to consider SDOH selecting the CoE's location. Access to care and services in a physical location or community will impact the care provided. See Table 7 in Appendix 5 for more on SDOH.

Inpatient Programming

While our goal is always to provide care in the least restrictive environment, we recognize that some children may require acute inpatient treatment for imminent safety concerns and crisis stabilization. The P-TRD CoE should have access to an inpatient program that is affiliated with the chosen medical center to ensure strong clinical communication and continuity of care. It would employ a comprehensive, multidisciplinary approach to effectively address refractory depressive symptoms and reduce functional impairments. The program should offer personalized treatment plans based on each child's clinical condition that coordinate care with the child's CoE providers.

The P-TRD CoE would reserve the inpatient program for crisis stabilization of acute symptoms requiring inpatient care, focusing on patient and family safety. The P-TRD inpatient program should encompass evidence-based treatments, including medication evaluation and management, individual, group, and family therapy, psychoeducation, and supportive therapies. Linkage to outpatient supportive services begins at admission, focusing on discharge planning, sustainability, and safety, with an emphasis on transitioning children to lower levels of care while preventing future readmissions.



²⁶Office of Disease Prevention and Health Promotion. (n.d.). Social Determinants of Health. <u>https://health.gov/healthypeople/priority-areas/social-determinants-health</u>

Intensive Outpatient and Partial Hospitalization Programs

Intensive outpatient programs (IOP) and partial hospitalization programs (PHP) are an important part of the continuum of care and can serve as alternatives to inpatient hospitalization. In a PHP, the child resides at home but commutes to a treatment center five days a week, usually for a full day of treatment with time incorporated for educational support. Likewise, an IOP allows the child to remain in the community while attending treatment three to four days per week for several hours each day. Both treatment modalities utilize group therapy and can have a specific focus on family support and therapy. The CoE could utilize PHPs or IOPs as alternatives to inpatient hospitalization and as a step-down intervention for children transitioning out of an inpatient level of care or as a step-up intervention for children in outpatient treatment who need a higher level of care.

Intensive outpatient programming should be a clinical track of the chosen academic medical center for coordination and continuity of care with CoE providers. The IOP and PHP affiliated with the CoE will prioritize tailoring interventions to meet the unique needs of each child and will share a common goal of providing individualized, structured care with an emphasis on maintaining continuity within the child's family and community.

Affiliated Clinicians

The CoE should provide certification and membership for affiliates, creating a referral network initially locally but extending regionally and then nationally. It could affiliate with organizations such as the National Network of Depression Centers, a national organization comprised of leading academic centers of excellence focused on advancing scientific discovery and reducing the burden of depression by improving access to evidence-based care, to establish this network. Creating this type of specialized referral network has several important benefits, including the ability to share innovative, effective, and evidence-based strategies in treating P-TRD across various regions, thereby improving access to this vital care. It also creates opportunities for improved care coordination, ensuring that care transitions are patientcentered and seamless. Finally, it ensures that the CoE is at the cutting edge of clinical research in the field of P-TRD.

Research Opportunities

The CoE will additionally expand its innovative approach to research initiatives, with a special focus on refining the definition and best practice treatment of P-TRD. This involves forging collaborations with academic institutions and research organizations to drive progress and deepen understanding in this pivotal area. Potential P-TRD CoE research endeavors include:

- Leverage existing associations such as the National Network of Depression Centers²⁷ to coordinate and amplify research efforts.
- Embed the P-TRD CoE into an existing academic medical center to bi-directionally inform clinical and research efforts, including consideration of interventional treatments or novel psychopharmacologic treatments.
- Coordinate efforts with CoE personnel who have acquired support through federal institutions such as the National Institutes of Mental Health or Substance Abuse and Mental Health Services Administration via research grants (R series), career awards (K series), fellowships and training grants (F and T series), or research program project and center grants (P series).

TRANSFORMING SUPPORTIVE SERVICES IN P-TRD TREATMENT

While specialized treatments for P-TRD are available in communities nationwide, the providers delivering care often have limited awareness of and coordination in treatment planning. Additionally, family members are frequently excluded from

²⁷National Network of Depression Centers. (n.d). Programs and services: what we do. <u>https://nndc.org</u>

the decision-making process, leaving loved ones to manage the long-term, often traumatic, experience of care provision on their own, while also navigating an overly complex healthcare system without proper guidance or support.

This CoE should bridge the gaps in services, providing comprehensive support for both children receiving treatment and their families as they navigate the healthcare system. It would bring together evidenced-based treatments and associated systemic supports in a unified holistic environment, setting itself apart from the traditionally siloed systems of care. In this section, we describe the key systemic supports and philosophies required to provide innovative person-centered care in a P-TRD CoE.

Severe Depression and Recommended Treatments Across Development

Identifying treatment resistant depression in children remains a challenge due to lack of an agreed upon definition and varied screening practices and comfort levels of treating depression in a primary care setting. Although depression can present at any time in life, it is increasingly common for people to experience their initial major depressive disorder (MDD) episode during childhood.²⁸ In the current system of care, detection often occurs after symptoms have already manifested prominently, if not resulted in a crisis. In contrast, early screening and intervention presents several opportunities. By proactively identifying signs of depression in children, we enable tailored support, ultimately fostering healthier emotional development and mitigating long-term repercussions. Furthermore, early intervention enables the swift utilization of specialized interventions, facilitating targeted treatments and improving the likelihood of successful outcomes by addressing depression at its onset. See Chart 3 for our model of depression treatment across development.



Chart 3: Severe Depression and Recommended Treatments Across Development Severe Depression and Recommended Treatments Across Time

Care Settings

• **Primary Care:** The primary care medical home can effectively meet most of the physical and mental health needs of children and families generally prefer to have their behavioral health needs addressed within primary care rather than specialty care.²⁹ Before the age of 12, screening for depression should be considered if a child presents with a behavioral health concern. The U.S. Preventive Services Task Force recommends depression screening within primary care starting at the age of 12. Routine screening allows for early intervention and initial treatment for children and youth can generally be facilitated by a primary care physician, sometimes with child psychiatry consultation.

²⁹Dunn, J. A., Chokron Garneau, H., Filipowicz, H., Mahoney, M., Seay-Morrison, T., Dent, K., & McGovern, M. (2021). What are patient preferences for integrated behavioral health in primary care? *Journal of Primary Care, Jan-Dec*(12). <u>http://doi.org/10.1177/21501327211049053</u>



²⁸Williams, S. B., O'Connor, E., Eder, M., & Whitlock, E. P. (2009). Screening for child and adolescent depression in primary care settings: A systematic evidence review for the U.S. Preventive Services Task Force. Agency for Healthcare Research and Quality. <u>https://www.ncbi.nlm.nih.gov/books/NBK35129/</u>

• **Specialist:** In early childhood, the complexity of mental health conditions often requires a specialist, such as a child psychiatrist or pediatric psychologist, to assist in both diagnosis and treatment. For children and youth, if initial treatment in primary care is not effective, a referral to a specialist should be considered.

- Multidisciplinary Team: Psychotherapy is the primary modality of treatment for depression in early childhood. Best practice involves a multidisciplinary team, consisting of a licensed therapist, child psychiatrist, and pediatrician, at minimum, and should allow for coordination with schools and other community partners, as indicated.
- **Coordinated Comprehensive Care:** For children who present with treatment-resistant depression, a coordinated comprehensive care approach offers the best chance at treatment response and remission. It combines evidence-based psychotherapy and medication treatments in a holistic, coordinated approach to the treatment of depression.

Specialized Interventions

To provide a wide variety of treatments that meet the complex needs of children with P-TRD, the CoE should possess expertise in specific specialized interventions to effectively treat the scope of P-TRD symptoms in one centralized location. All care the CoE provides should incorporate established measures to document treatment response, maintain quality of care, and create a rapid feedback and improvement system. We will define these measures as we finalize the scope of programming.

P-TRD		
Intervention	Description	Providers
Diagnostic Expertise	Interdisciplinary comprehensive evaluation	MD, PhD,
	Neuropsychological testing	PhD
Psychopharmacology	Ongoing	MD, PharmD
Individual and Group	Cognitive Behavioral Therapy ³⁰	PhD
Therapies	Dialectical Behavioral Therapy ³¹	PhD
	Mindfulness ³²	PhD
	Supportive Therapy ³³	PhD
	Art and Expressive Therapies ³⁴	PhD

Table 3: P-TRD CoE Specialized Interventions

³⁰David-Ferdon, C. & Kaslow, N. J. (2008). Evidence-based psychosocial treatments for child and adolescent depression. Journal of clinical child and adolescent psychology, 37(1), 62–104. https://doi.org/10.1080/15374410701817865

³¹Perepletchikova, F., Nathanson, D., Axelrod, S. R., Merrill, C., Walker, A., Grossman, M., Rebeta, J., Scahill, L., Kaufman, J., Flye, B., Mauer, E., & Walkup, J. (2017). Randomized clinical trial of dialectical behavior therapy for preadolescent children with disruptive mood dysregulation disorder: Feasibility and outcomes. *Journal of the American Academy of Child & Adolescent Psychiatry*, 56(10), 832–840. https://doi.org/10.1016/j.jaac.2017.07.789

³²Perry-Parrish, C., Copeland-Linder, N., Webb, L., & Sibinga, E. M. S. (2016). Mindfulness-Based Approaches for Children and Youth. *Integrative Pediatric in Medicine*, 46(6), 172–178. <u>https://doi.org/10.1016/j.cppeds.2015.12.006</u>

 ³³Tompson, M. C., Sugar, C. A., Langer, D. A., & Asarnow, J. R. (2017). A randomized clinical trial comparing family-focused treatment and individual supportive therapy for depression in childhood and early adolescence. *Journal of the American Academy of Child & Adolescent Psychiatry*, 56(6), 515–523. <u>https://doi.org/10.1016/j.jaac.2017.03.018</u>
 ³⁴Blomdahl, C., Gunnarsson, A. B., Guregård, S., & Björklund, A. (2013). A realist review of art therapy for clients with depression. *The Arts in Psychotherapy*, 40(3), 322–330. <u>https://doi.org/10.1016/j.aip.2013.05.009</u>

Family Therapies	Family-Focused Therapy ³⁵	LCSW
	Family Psychoeducation ³⁶	LCSW
	Strategic Family Therapy (SFT) ³⁷ LCSW, PhD	
	Internal Family Systems (IFS) ³⁸ LCSW, PhD	
	Fast Training ³⁹	LCSW, PhD
	Enhanced Triple-P ⁴⁰	LCSW, PhD
	Incredible Years ⁴¹	LCSW, PhD
School Psychology	Individual education plans	PhD
	Communication with schools	PhD
Social Work	Centralized link between patients, families, and care plan	LCSW
	Address psychological needs of patient and family	LCSW
Case Management Navigation	Centralized point of contact for care navigation and support	RN
	Facilitation of appointments and resources	RN
Outpatient Programs	Intensive Outpatient Program	MD, PhD, LCSW, RN
	Partial Hospitalization Program	MD, PhD, LCSW, RN
Inpatient Care	Crisis stabilization services	MD, PhD, LCSW, RN

Specialized Services Available in Adolescence

If a child continues to have unremitting, severe depression that has not responded to the CoE's comprehensive treatment, the CoE could consider neuromodulation treatments and novel pharmacologic treatments for youth ages 13 and older. While electroconvulsive therapy (ECT) continues be the most effective treatment for treatment-resistant depression across the lifespan,⁴² it is not widely available for children or youth based on regulatory standards across states. Novel neuromodulation treatments such as transcranial magnetic stimulation (TMS), including intermittent theta-burst stimulation (iTMS) and the Stanford neuromodulation therapy (SNT) protocol have been shown to be safe and variably effective in major clinical trials, though the FDA has not approved of these interventions for the pediatric population. Ketamine has been shown in studies to rapidly reduce depressive symptoms and suicidality in adolescents; however, additional studies are needed to assess the durability and specificity of ketamine's effects on depressive symptoms.⁴³,⁴⁴,⁴⁵,⁴⁶ While the latter two treatments do not have proven research regarding safety and efficacy for children 12 and under, the CoE could consider them for youth (ages 13 and older) or if future research identifies protocols for providing this type of care at earlier ages.

³⁵Ginsburg, G. S., & Schlossberg, M. C. (2002). Family-based treatment of childhood anxiety disorders. *International Review of Psychiatry*, 14(2), 143–154. <u>http://doi.org/10.1080/09540260220132662</u>

³⁶United Nations Office on Drugs and Crime. (2009). Compilation of evidence-based family skills training programmes. United Nations Office on Drugs and Crime. <u>http://css.</u> <u>unodc.org/documents/prevention/family-compilation.pdf</u>

³⁷Szapocznik, J., Muir, J. A., Duff, J. H., Schwartz, S. J., & Brown, C. H. (2015). Brief Strategic Family Therapy: Implementing evidence-based models in community settings. Psychotherapy Research, 25(1), 121-133. <u>https://doi.org/10.1080/10503307.2013.856044</u>

³⁸Schwartz, R. C., & Sweezy, M. (2020). Internal family systems therapy: Second edition. The Guilford Press.

³⁹Seattle Children's Hospital. (n.d.). Fast program training - seattle children's. Seattle Children's Hospital. <u>https://www.seattlechildrens.org/healthcare-professionals/community-providers/fast/fast-programs/</u>

⁴⁰United Nations Office on Drugs and Crime. (2009). Previously cited.

⁴¹United Nations Office on Drugs and Crime. (2009). Previously cited.

⁴²McDonald, W. M., Meeks, T. W., Carpenter, L. L., McCall, V. W., & Zorumski, C. F. (2017). Electroconvulsive therapy and other neuromodulation therapies. The American Psychiatric Association Publishing Textbook of Pharmacology (Fifth Edition). American Psychiatric Association Publishing. <u>https://doi.org/10.1176/appi.books.97816153716</u>

⁴³Dwyer, J. B., Landeros-Weisenberger A., Johnson, J. A., Londono Tobon, A., Flores, J. M., Nasir, M., Couloures, K., Sanacora, G., & Bloch, M. H. (2021). Efficacy of intravenous ketamine in adolescent treatment-resistant depression: A randomized midazolam-controlled trial. *American Journal of Psychiatry*, 178(4), 352–362. <u>https://ajp.psychiatryonline.org/doi/pdf/10.1176/appi.ajp.2020.20010018</u>

⁴⁴Meshkat, S., Rosenblat, J. D., Ho, R. C., Rhee, T. G., Cao, B., Ceban, F., Danayan, K., Chisamore, N., Di Vincenzo, J. D., & McIntyre, R. S. (2022). Ketamine use in pediatric depression: A systematic review. *ScienceDirect*, 317, 1–7. <u>https://www.sciencedirect.com/science/article/abs/pii/S01651781220</u>

⁴⁵Kim, S., Rush, B. S., & Rice, T. R. (2021). A systematic review of therapeutic ketamine use in children and adolescents with treatment-resistant mood disorders. *European Child & Adolescent Psychiatry*, 30, 1485–1501. https://doi.org/10.1007/s00787-020-01542-3

⁴⁶Parikh, T., & Walkup, J. T. (2021). The future of ketamine in the treatment of teen depression. *American Journal of Psychiatry*, 178(4), 288–289. <u>https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2020.21020172</u>

CARE MANAGEMENT AND NAVIGATION

The health care system in the United States has become increasingly complex and challenging to navigate, particularly for patients with complex care needs, multiple providers, and specialists. In short, the demand on patients and families to access needed care is burdensome. When caring for children with complex care needs, such as P-TRD, it is often difficult and time-consuming to identify and navigate available services and programs. Patients, in addition to their families, experience many care transitions over their lifespan and are vulnerable to gaps in care that can occur during these transitions.⁴⁷ Additionally, as families are seemingly expected to know how to communicate their questions and / or concerns in a manner that providers can adequately answer their question, there can be a gap in communication style that can affect a family's ability to make well-informed decisions. Not all families are able to overcome these types of hurdles, leading to confusion, futile and stressful searches, uncertainty, and discontinued health care engagement until the patient requires costly acute stabilization. Studies indicate that the complexities of health care system navigation particularly affect people with low health literacy.⁴⁸

Children with complex care needs and their families experience better health outcomes if they have access to a personcentered system that is achieved through the comprehensive delivery of quality services across the lifespan, designed according to the multidimensional needs of the individual, and delivered by a coordinated team of providers working across disciplines, settings, levels of care, and sectors.⁴⁹ Providing access to a centralized CoE for children with P-TRD helps streamline services, making it easier for families to access care in one place. Appendix 6 provides additional details on specific care management and navigation services.

STAFFING MODELS, SERVICES, AND FINANCIAL PROJECTIONS

Initially, the P-TRD CoE will offer comprehensive, multi-disciplinary outpatient evaluations for children and their families with longitudinal follow-up. Once established and operational, the CoE may offer additional services, including intensive outpatient programs, partial hospitalization programs, and inpatient care.

STAFFING MODEL AND ESTIMATED ANNUAL BUDGET

A core team, including a child psychiatrist, a pediatric psychologist, a neuropsychologist, and a family therapist, would conduct the comprehensive interdisciplinary evaluation at the CoE. Intensive outpatient follow-up will include psychopharmacology management, individual evidence-based psychotherapies, family therapy, case management, and educational and care navigation support. All services the CoE delivers should be evidence based and tailored to meet the needs of individual patients and their families. The CoE would provide complex care navigation to ensure that children and their families are aware of treatment dates, times, and locations. The CoE could also offer telehealth services to increase treatment accessibility.

Our analysis of core services to be offered at the CoE highlighted the barriers associated with reimbursement for essential services for children with P-TRD. An estimated 60% of services that are crucial components of the CoE are not routinely reimbursed in a fee-for-service environment. In order to be able to provide the highest quality of evidence-based clinical care, specialty services, and holistic family centered care and to demonstrate the importance of these services in improving clinical outcomes, our initial proposed financial model is a direct pay model. Once we have demonstrated success of the model, we will work with commercial payors and Medicaid to ensure that this model of care is more widely available.

⁴⁷Doucet, S., Luke, A., Splane, J., & Azar, R. (2019). Patient navigation as an approach to improve the integration of care: The case of NaviCare/SoinsNavi. International Journal of Integrated Care, 19(4), 7. http://doi.org/10.5334/ijic.4648

⁴⁸Griese, L., Berens, E. M., Nowak, P., Pelikan, J. M., & Schaeffer, D. (2020). Challenges in navigating the health care system: Development of an instrument measuring navigation health literacy. *International Journal of Environmental Research and Public Health*, 17(16), 5731. <u>https://doi.org/10.3390/ijerph17165731</u>

⁴⁹Doucet, S., Luke, A., Splane, J., & Azar, R. (2019). Previously cited.

Based on our financial projections, we estimate that the annual CoE program costs per patient would be approximately \$20,000 in the Dallas-Fort Worth area. The annual program cost per patient was calculated using provider salaries from the United States Bureau of Labor Statistics for Dallas with added benefits as well as administrative overhead costs. Our financial projections are based on an average patient panel of 150 at full operational capacity. The expected annual self-pay revenue per patient would be approximately \$29,000. The self-pay revenue per patient was estimated using Medicare's reimbursement rates for Dallas with an additional applied 143%.⁵⁰ This rate accounts for the average rate a commercial payer would reimburse at a private practice.

In analyses incorporating U.S. Census data, we estimate that there is sufficient clinical demand among families with the ability to self-pay in the Dallas-Fort Worth area. Despite regional differences in demand for services and ability to self-pay, we expect that results would be similar for other major metropolitan areas throughout the country. Our model can be tailored to estimate based on individual institution's reimbursement rates and other regional parameters such as average salaries.

PHASE III - NEXT STEPS

In talking to specialists at academic medical centers, we identified strong existing infrastructure, robust research capabilities, a keen educational emphasis, a culture of collaboration, and substantial potential for sustained growth as key attributes that would make for a successful implementation site for a P-TRD CoE.

In addition to applying the CoE framework, other considerations when evaluating potential implementation sites included access and regulations on specialized interventions for treatment-resistant depression. Given the emerging evidence regarding the safety and efficacy of transcranial magnetic stimulation (TMS) and Ketamine for youth, a site that has these treatments available for youth would be ideal.

The presence or absence of state regulations and age limits pertaining to electroconvulsive therapy (ECT) for youth can influence the accessibility and practice of ECT in various ways. In states with well-defined policies and regulations, there is a structured framework that guides the use of ECT in youth, potentially ensuring a standardized and safer application of the therapy. These regulations may include criteria for determining the appropriateness and necessity of ECT, offering oversight to safeguard the well-being of younger patients.

Conversely, the lack of specific state regulations or guidelines may provide more flexibility and potentially increase access to ECT for youth. The absence of stringent criteria can grant healthcare providers greater discretion in deciding when to administer ECT, potentially allowing for more individualized decision-making based on clinical judgment and patient needs. However, this lack of specificity may lead to variations in practice, raising concerns about consistency and appropriateness in the use of ECT for youth.

The impact of access to ECT is complex, as the absence of specific regulations might be seen as advantageous for prompt decision-making based on clinical assessments. Nevertheless, it also underscores the importance of careful consideration of ethical and safety considerations in the absence of standardized guidelines. The discussion around state regulations for ECT in adolescents involves balancing the benefits of individualized decision-making with the potential risks and the need for consistent standards to ensure the well-being of young patients. In table 4, we outline differences in state ECT regulation requirements.

⁵⁰Neuman, T., Jacobson, G., & Levitt, L. (2020). *How much more than Medicare do private insurers pay*? Kaiser Family Foundation. <u>https://www.kff.org/medicare/issue-brief/how-much-more-than-medicare-do-private-insurers-pay-a-review-of-the-literature/</u>



Table 4: ECT State Regulations

ECT State Regu	lations
State	ECT Regulations
Illinois	<18 years old with parent/legal guardian consent
	Needs approval by court
	Тwo
Washington	No specific legislation
Pennsylvania	No specific legislation
Texas	<16 years old
	>16 years old with parent/legal guardian consent
	>65 years old 2 licensed psychiatrists must evaluate and agree with need for ECT

Implementation Roadmap

The roadmap below outlines the implementation steps as short (one to three months), medium (three to six months), or long-term (six to 12 months) activities. Each of these steps requires the development of detailed project plans, in coordination with the selected implementation site, service providers, and people with lived experience. This is intended to serve as a high-level roadmap for initial planning and program conceptualization.

Table 5: Implementation Roadmap

Implementation Steps	Short Term	Mid Term	Long Term
Assess need and build the case for P-TRD CoE			
Identify and partner with implementation site			
Implement comprehensive outpatient, team-based evaluation, treatment, and follow-up for P-TRD			
Identify referral pathways:			
Inpatient hospital partnerships			
Affiliate clinicians			
Intensive outpatient program development			
Partial hospitalization program development			
Inpatient treatment program development			
Develop capacity to conduct research to develop and disseminate P-TRD best practices			

CONCLUSION

The establishment of the Pediatric Treatment Resistant Depression Center of Excellence would be a pivotal step in addressing the pressing need for specialized pediatric depression treatment. This center would emerge as a beacon of clinical best practice, optimized family system care coordination, and research for children aged 12 and under with treatment resistant depression. By prioritizing multi-disciplinary evaluation, comprehensive family support, the care continuum, and wrap-around services, a P-TRD CoE is poised to not only bridge existing health inequities but to also set a national precedent for excellence in pediatric mental health care.

APPENDICES

Appendix 1: Key Informant Interviews Table 6: Key Informant Interviews

Organization	Name	Title
Children's Hospital of Philadelphia	Jason Lewis, PhD	Section Director, Mood, Anxiety, and Trauma Disorders
(CHOP)	Kathy Mu, DO	Attending Psychiatrist, Department of
Children's National Medical Center	Adelaide Robb, MD	Division Chair, Child Psychiatry
	Faith Renee Kelley, MD	Child and Adolescent Psychiatrist, Medical Director
		– Mood Disorders Clinic
Cincinnati Children's Hospital Medical Center	Melissa DelBello, MD	Department Chair, Psychiatry and Behavioral Neuroscience
Cleveland Clinic	David Streem, MD	Chief Medical Officer
	Brian Barnett, MD	Psychiatrist
Dell Medical School	Greg Fonzo, PhD	Psychologist
	Roshni Koli, MD	Former Medical Director, Pediatric Mental Health; Assistant
		Professor; Department of Psychiatry and Behavioral Sciences
Dr. Katz, Inc	Nathaniel Hundt	Founder of Dr. Katz
Lurie Children's Hospital	Tapan Parikh, MD	Psychiatrist, The Pritzker Department of Psychiatry and Behavioral Health
Stanford Medical School / Magnus Medical	Scott Ashworth	Chief Marketing Officer, Chief Commercial Officer
Massachusetts General Hospital	Maurizio Fava, MD	Chair of Psychiatry
University of California, Irvine Health	Rimal Bera, MD	Clinical Professor of Psychiatry, Psychiatry & Human Behavior School of Medicine
University of Texas Health Houston	Salih Selek, MD	Director of Refractory Mood Disorders Program / ECT Clinic
University of Texas, Medical Branch	Karen Wagner, MD	Professor and Chair, Department of Psychiatry and Behavioral Sciences
Texas Children's Hospital	Kirti Saxena, MD	Associate Professor of Psychiatry and Behavioral Sciences, Baylor College of Medicine; Section Chief for Psychiatry, Texas Children's Hospital
University of Texas Southwestern,	Sasha Alick Lindstrom, MD	Assistant Professor of Neurology
Peter O'Donnell Jr. Brain Institute	Kala Bailey, MD	Chief of Psychiatry

Appendix 2: Coordinated Specialty Care

When developing the framework for a P-TRD CoE (see Chart 5), the Meadows Institute drew inspiration from the Coordinated Specialty Care (CSC) model (Chart 4), an evidence-based practice known for its comprehensive approach to treating first-episode psychosis, including an emphasis on intensive wraparound services. Chart 4, based on the NIMH-Recommended Evidence-Based CSC Service Component,⁵¹ outlines the different facets of CSC for Schizophrenia.

Chart 4: Coordinated Specialty Care for Schizophrenia⁵²,⁵³



In CSC, a multidisciplinary team of mental health professionals, including psychiatrists, therapists, substance use disorder counselors, employment specialists, and peer specialists, collaborates to deliver personalized care. Recognizing the significance of early detection, CSC intervenes promptly, as people experiencing psychosis often face delays of up to five years before receiving treatment.⁵⁴ Moreover, the CSC model actively involves families in supporting the recovery process, fostering a holistic approach to care and supporting a family throughout a child's illness journey.

CSC offers a range of effective treatments, including medication management, individual therapy, and illness management, alongside lesser-known evidence-based approaches like supported education and supported employment. CSC aims to initiate treatment and support early in the illness trajectory, promoting a healthy developmental path for people with psychosis.

Similarly, our objective in establishing a P-TRD CoE mirrors the goals and impact of CSC, intervening early and providing comprehensive care, incorporating all necessary treatments and support services to guide children towards a healthy developmental trajectory. In leveraging the principles of CSC, we similarly aim to address P-TRD in its earliest stages, fostering resilience and promoting recovery in children.

Chart 5: Coordinated Comprehensive Care for Pediatric Treatment Resistant Depression



⁵¹Substance Abuse and Mental Health Services Administration. (2023). *Coordinated Specialty Care for first episode psychosis: Costs and financing strategies* (HHS Publication No. PEP23-01-00-003). Rockville, MD: Substance Abuse and Mental Health Services Administration.

⁵²Torous, J. (2016, November 17). Coordinated Specialty Care for Schizophrenia [Twitter/X]. <u>https://twitter.com/JohnTorousMD/status/799296074267627520</u>

⁵³Dixon, L. (2017). What it will take to make Coordinated Specialty Care available to anyone experiencing early schizophrenia: Getting over the hump. JAMA Psychiatry, 74(1). http://doi.org/10.1001/jamapsychiatry.2016.2665.

⁵⁴Wang, P. S., Berglund, P. A., Olfson, M., & Kessler, R. C. (2004). Delays in initial treatment contact after first onset of a mental disorder. *Health Serv Res*, 39(2), 393-415. <u>http://doi:10.1111/j.1475-6773.2004.00234</u>

Appendix 3: Role of the Family Informed Consent

Informed consent is an important aspect of providing patient-centered care, promoting autonomy and joint decision-making between providers and patients. It is a crucial part of the treatment process in which the provider informs the patient and family about the potential clinical risks, benefits, and outcomes of treatment.⁵⁵ Not only does the law require informed consent, but it also opens the door for collaboration between the clinical team, patient, and family. Discussing the care plan prior to treatment provides an opportunity for both the child and their family to ask questions, clarify doubts, and make an informed decision before consenting to treatment. Culturally and linguistically appropriate services allow for increased equitable access across diverse patient and family populations.⁵⁶ As minors are unable to legally consent to treatment,⁵⁷ families and caregivers play a key role in understanding the recommended treatment and ensuring that it meets the needs of their child. The CoE should utilize informed consent as an opportunity to encourage patients and their families to ask questions, make certain they understand the risks and benefits of treatment, and facilitate joint decision-making prior to initiating care. While they cannot legally consent, the CoE can receive children's assent indicating their agreement to care prior to treatment.

Appointment Reminders

In addition to transportation, regular appointment reminders from family members allow patients to stay on track in their treatment. Research demonstrates that appointment reminders significantly increase medical appointment attendance.^{58,59} Family members can communicate with their child more easily compared to virtual reminders such as phone calls, texts, or emails, which the child may not have access to. This makes family involvement even more important, as it can ensure the patient receives necessary support and care. Families providing transportation for their child's medical appointments can benefit from regular reminders prior to the date of service, helping increase appointment attendance that they may have missed due to oversight or a lack of motivation to attend. By providing these reminders, healthcare providers can ensure that patients receive the necessary care and treatment, while also supporting and reinforcing the role of parents or guardians in their child's mental health treatment.

Patient Monitoring

Family members have a unique perspective, accompanying children throughout the lifecycle of treatment. While children may not always be able to articulate their therapeutic successes and challenges, family members can observe physical and behavioral changes that may differ from the patient's baseline. Compared to clinicians, family members have a better understanding of their child's baseline behavior prior to treatment. This context allows for the monitoring of potential side effects that may arise because of treatment. Direct communication from treatment staff not only increases understanding of the process, but also increases safety in providing information on side effects, including observed changes in mood, behavior, and appearance.

Appendix 4: Evidenced-Based Family Engagement Models Family Systems Theory

Family systems theory is a basis for understanding family engagement and examines the family as an interconnected unit where the actions and needs of each individual member impact the cohesion and wellbeing of the family unit as a whole.⁶⁰ Family systems theory explains human behavior through the lens of a larger family ecosystem and emphasizes the importance of understanding the dynamics and interactions within the system in order to improve mental health outcomes. This theory also looks at the impact of additional environmental factors such as cultural expectations and belief

 ⁵⁵Shah, P., Thornton, I., Turrin, D., & Hipskind, J. E. (2023). Informed consent. In *StatPearls*. StatPearls Publishing. <u>https://www.ncbi.nlm.nih.gov/books/NBK430827/</u>
 ⁵⁶U.S. Department of Health and Human Services, Office of Minority Health. (n.d.). What is CLAS?. <u>https://thinkculturalhealth.hhs.gov/clas/what-is-clas</u>
 ³⁷Shah, P., Thornton, I., Turrin, D., & Hipskind, J. E. (2023). Previously cited.

⁵⁸Hasvold, P. E., & Wootton, R. (2011). Use of telephone and SMS reminders to improve attendance at hospital appointments: A systematic review. Journal of Telemedicine and Telecare, 17(7), 358–364. <u>https://doi.org/10.1258/jtt.2011.110707</u>

⁵⁹ McLean, S. M., Booth, A., Gee, M., Salway, S., Cobb, M., Bhanbhro, S., & Nancarrow, S. A. (2016). Appointment reminder systems are effective but not optimal: results of a

systematic review and evidence synthesis employing realist principles. Patient preference and adherence, 10, 479–499. https://doi.org/10.2147/PPA.593046

⁶⁰The Bowen Center for the Study of the Family. (n.d.). *Learn about Bowen theory*. <u>https://www.thebowencenter.org/core-concepts-diagrams</u>

systems. Engaging family members through the lens of family systems theory creates an opportunity for buy-in from family members and increases their ability to understand their impact on the behavior of their child. An important aspect of family involvement is to increase understanding of the role that family members can play in improving the well-being of their loved one.

Patient and Family Engagement

Patient and family engagement (PFE) is a model that centers patients and families as crucial members of a treatment team, prioritizing partnerships among patients, families, and health care providers with the goal of improving healthcare delivery and health outcomes.⁶¹ PFE recognizes the importance of involving patients and their families in their healthcare decision-making and treatment process and acknowledges that patients and families are experts in their own care.⁶² Additionally PFE has demonstrated improved health outcomes, communication satisfaction, and family cohesion.⁶³

We recommend a treatment process that engages family from inception to transition into relapse prevention. By engaging the family in treatment, the CoE would recognize the importance of the family unit and the impact that family dynamics can have on a child's behavior and well-being.

Appendix 5: Social Determinants of Health Table 7: Social Determinants of Health

Social Determinants of Health			
SDOH	Definition	Interconnectivity	
Economic stability	Economic stability includes a family's joint income, financial resources, and employment which directly impact the ability to access quality housing, medical and mental health treatment, nutritious foods, and quality education.	Lack of economic stability creates barriers to quality mental health treatment services including specialty services for children with complex mental health needs	
Educational access and quality	Financial resources impact where people	Working children and youth have less time to focus on K-12 education which also impacts their ability to cultivate meaningful interpersonal relationships.	
Health care access and quality	Health care access and includes having insurance to cover the cost of basic services such as visits to a primary care provider. Beyond the coverage of basic services, geographic location, transportation, and the ability to take time off from work pose barriers to accessing quality healthcare. Health care quality includes cultural competence, prevention focus, appropriate follow-ups, continuity of care, and patient navigation.	A lack of health care access and quality can lead to a delay in seeking care, potentially resulting in health complications.	



⁶¹Cené, C. W., Johnson, B. H., Wells, N., Baker, B., Davis, R., & Turchi, R. (2016). A Narrative Review of Patient and Family Engagement: The "Foundation" of the Medical "Home." Medical Care, 54(7), 697–705. https://doi.org/10.1097/MLR.00000000000548

⁶²Carman, K. L., Dardess, P., Maurer, M., Sofaer, S., Adams, K., Bechtel, C., & Sweeney, J. (2013). Patient and family engagement: A framework for understanding the elements and developing interventions and policies. *Health Affairs*, 32(2), 223–231. <u>https://doi.org/10.1377/hlthaff.2012.1133</u>

⁶³ Cené, C. W., Johnson, B. H., Wells, N., Baker, B., Davis, R., & Turchi, R. (2016). Previously cited.

Neighborhood and built environment	Access to quality affordable housing in neighborhoods without pollution / environmental toxins, access to clean water, green spaces to play, and adequate public transportation are all a part of a quality neighborhood and environmental conditions. High levels of crime also impact the built environment in which people live.	The quality of one's living environment plays a crucial role in determining overall health and well-being. Access to clean air and water, safe neighborhoods, green spaces, affordable housing, and transportation options all contribute to creating an environment that supports and promotes good health. Conversely, living in environments with environmental hazards, high crime rates, and limited resources can increase health risks and lead to poorer health outcomes over time.
Social and community context	Social and community context includes interpersonal relationships with family, neighbors, and the community at large. Social relations are shaped by the basic needs of the community being met and are impacted by housing security, community safety, and interaction with the criminal justice system.	Positive social and community factors contribute to better health outcomes, while challenges in these areas can lead to increased health risks and potential health issues.

Appendix 6: Care Management and Navigation Services Patient and Family Navigation

Patient and family navigation improves both access to and use of mental health services. A navigator is a person on the patient's care team who provides support to patients and their families with the goal of establishing and maintaining health care. They assist with care coordination and address practical, social, and psychological barriers to care, while also aiding in empowering, educating, and bridging the communication gap between providers and families.⁶⁴

Research demonstrates that caregivers' perceived barriers are an important predictor of mental health service engagement and are related to the stigma caregivers feel about having a child with a mental health disorder, their beliefs about the potential effectiveness of treatment, and their trust in mental health professionals. Caregiver skills and knowledge about navigating the mental health system also impact treatment engagement.⁶⁵

At the CoE, patient and family navigation should be a core treatment element. Ensuring patients and their families understand their care, feel comfortable with treatments the CoE offers, and trust the treatment team are essential to successful patient engagement. Mental health treatment engagement often includes problem recognition, appointment attendance (initial and ongoing), and adherence to the treatment plan. A navigator will work with children, families, and the treatment team to remove barriers to care.

Patient and Family Navigation Elements ⁶⁶	
Service Area	Activity
Informal and educational support	Teaching families about child development or mental illness
Instructional and skill development support	Instruction on parenting strategies or crisis management
Emotional and affirmational support	Ensuring communication between families and providers and promoting caregiver well-being
Instrumental support	Providing resources for respite care and transportation
Advocacy support	Informing caregivers about rights and negotiation strategies

Table 8: Patient and Family Navigation Elements

⁶⁴Godoy, L., Hodgkinson, S., Robertson, H. A., Sham, E., Druskin, L., Wambach, C. G., Savio Beers, L. S., & Long, M. (2019). Increasing mental health engagement from primary care: The potential role of family navigation. *Pediatrics*, 143(4). <u>http://doi.org/10.1542/peds.2018-2418</u>

⁶⁵Godoy, L., Hodgkinson, S., Robertson, H. A., Sham, E., Druskin, L., Wambach, C. G., Savio Beers, L. S., & Long, M. (2019). Previously cited.

⁶⁶ Godoy, L., Hodgkinson, S., Robertson, H. A., Sham, E., Druskin, L., Wambach, C. G., Savio Beers, L. S., & Long, M. (2019). Previously cited.

Community Education and Referrals

An effective referral system promotes high-quality treatment by ensuring that there are ongoing close relationships between community providers, crisis services, and other levels of care.⁶⁷ The CoE should leverage expertise and innovative treatments to manage acute or refractory depressive symptoms, while also making certain that children remain connected to community providers for ongoing follow-up and maintenance care. Both reaching the appropriate children and easing their transition back to the community should be important areas of focus.

The CoE should also focus on effective outreach and engagement with the community to identify potential children in need of treatment, as well as educate the community about the availability of CoE treatment resistant depression services. This involves raising awareness about P-TRD, encouraging families and children with treatment resistant depression symptoms to seek help, and providing mental health triage services, thus reducing unnecessary hospital admissions. The clinical workflow should include crisis intervention (mental health triage) to ensure timely care for children in mental health crisis while minimizing harm, linking patients to appropriate resources and treatment, partnering with local community organizations to reach a wider audience, creating educational materials to raise awareness about P-TRD, and training community members to identify and refer children experiencing symptoms. Collectively, these efforts aim to expedite access to treatment and support for children in need.

Managing Transitions of Care

Successful transitions from differing levels of care are critical for children with complex mental health disorders and their treatment providers. Smooth care transitions are essential for reducing the risk of recidivism and improving outcomes for patients.⁶⁸ They support patient safety, ensure quality of care, decrease costs, and provide a positive experience for patients and families.⁶⁹ Additionally, a comprehensive transition plan is necessary for children and their families to understand the next treatment steps. Outlining the necessary steps for effective communication and transition of care is vital to successful patient outcomes and quality of life for both those entering and exiting the CoE.

Table 9: Transitions of Care Best Practices

Transitions of Care Best Practices ⁷⁰	
Prior to Discharge	
Develop relationships, protocol, and procedures for safe and rapid referrals	Begin discharge planning upon admission
	Develop collaborative protocol with outpatient providers
	Partner with outpatient providers
	Share essential medical records electronically
Involve family member and other natural supports	Encourage family participation
	Include peer specialist
	Engage with school and community supports

⁶⁷Seyed-Nezhad, M., Ahmadi, B., & Akbari-Sari, A. (2021). Factors affecting the successful implementation of the referral system: A scoping review. Journal of family medicine and primary care, 10(12), 4364–4375. http://doi.org/10.4103/jfmpc.jfmpc_514_21

⁶⁸Velligan, D. I., Roberts, D., Martinez, M., Fredrick, M., Hillner, K., & Luber, P. (2015). Following AACP guidelines for transitions in care: the transitional care clinic. *Psychiatry Serv*, 67, 259-261. <u>http://doi.org/10.1176/appi.ps.201500435</u>

⁶⁹ Jabbarpour, Y. M., & Raney, L. E. (2017). Bridging transitions of care from hospital to community on the foundation of integrated and collaborative care. Focus (*American Psychiatric Publishing*), 15(3), 306–315. <u>https://doi.org/10.1176/appi.focus.20170017</u>

⁷⁰National Action Alliance of Suicide Prevention. (n.d.) Best practices in care transitions for individuals with suicide risk. <u>https://theactionalliance.org/sites/default/files/report</u> - <u>best practices in care transitions final.pdf</u>

Connect with outpatient provider	Schedule an outpatient appointment
	Offer step-down care
	Partner with outpatient provider
	Initiate personal contact between the patient and the outpatient provider
	Consider innovative approaches for connecting patient with the
	outpatient provider
After Discharge	
Follow up with patient and outpatient provider	Provide essential records to the outpatient provider at time of discharge
	Make a discharge follow up call to the patient
	Provide ongoing caring contacts to the patient

Transportation

Transportation is understandably key to accessing health care, as well as an important social determinant of health that disproportionately impacts people with chronic health conditions.⁷¹ Approximately 3.6 million Americans delay or miss medical care due to a transportation barrier each year.⁷² This barrier may lead to rescheduled or missed appointments, delayed care, and missed or delayed medication use. Transportation remains a barrier to healthcare access due to a multitude of issues, including funding limitations, distance or time burden, conflicting work obligations, limited social supports, and lack of reliable public transit. Understanding interventions that can improve access to transportation is essential to providing quality wraparound services in a CoE.

Research consistently demonstrates that Medicaid beneficiaries who use non-emergency medical transportation services are significantly more likely to make the recommended number of visits than those who do not use the services.⁷³ Other common transportation solutions are providing bus passes or transport vouchers (e.g., taxi). When patients receive transport vouchers combined with education, individual counseling, and referral to care, 83% of patients access their care.⁷⁴ However, these interventions do not mitigate transportation-related barriers to treatment in all cases. For example, some TRD treatments (e.g., electroconvulsive therapy) require transportation with a friend or family member for monitoring and safety. Additionally, working with the pediatric patient population further complicates transportation, as one must also consider the needs of a parent or guardian.

While access to independent transportation is ideal, it is not always feasible. There is a unique opportunity with the advancement of ride share applications in the health care sector to help fill the gap in transportation. Companies like Uber have launched a health care platform that aims to improve access to care. This solution would allow parents and / or guardians to be present for transportation and care to meet the necessary safety protocols after treatment. Another option for improving access is having the CoE run or contract with an independent transportation service. The CoE clinical staff could reserve this service to schedule round trip transportation for children and families who are unable to access transportation to treatment independently.



⁷Starbird, L. E., DiMaina, C., Sun, C. A., & Han, H. R. (2019). A systematic review of interventions to minimize transportation barriers among people with chronic diseases. *Journal of community health*, 44(2), 400–411. <u>https://doi.org/10.1007/s10900-018-0572-3</u>

⁷²Wallace, R., Hughes-Cromwick, P., Mull, H., & Khasnabis, S. (2005). Access to health care and nonemergency medical transportation: Two missing links. *Transportation Research Record*, 1924(1), 76–84. <u>https://doi.org/10.1177/0361198105192400110</u>

⁷³Wallace, R., Hughes-Cromwick, P., Mull, H., & Khasnabis, S. (2005). Previously cited.

⁷⁴Wallace, R., Hughes-Cromwick, P., Mull, H., & Khasnabis, S. (2005). Previously cited.

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