Understanding Key Evidence Gaps in the Treatment of Anxiety Disorders in Children, Adolescents, and Young Adults:

A Stakeholder Workshop

July 26, 2017

pcori

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome & Housekeeping

- Today's meeting is open to the public and is being recorded
  - Members of the public are invited to listen to the teleconference and view the webinar
  - Meeting materials can be found on the PCORI website
- Visit www.pcori.org/events for more information
- We ask that in-person participants stand up their tent cards when they would like to speak and use the microphones
- Please remember to state your name when you speak

PCORI's Legislative Mandate

"The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis...

... and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services..."

--from PCORI's authorizing legislation

We Fund Comparative Clinical Effectiveness Research

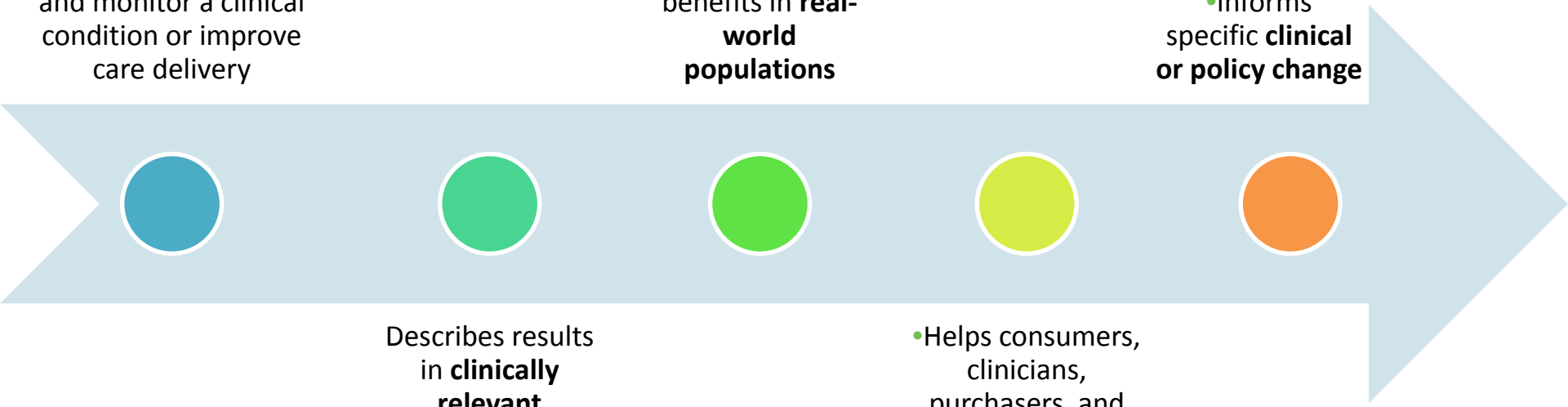
- Generates and synthesizes evidence comparing **benefits and harms of at least two different methods** to prevent, diagnose, treat, and monitor a clinical condition or improve care delivery

Describes results in **clinically relevant subpopulations**

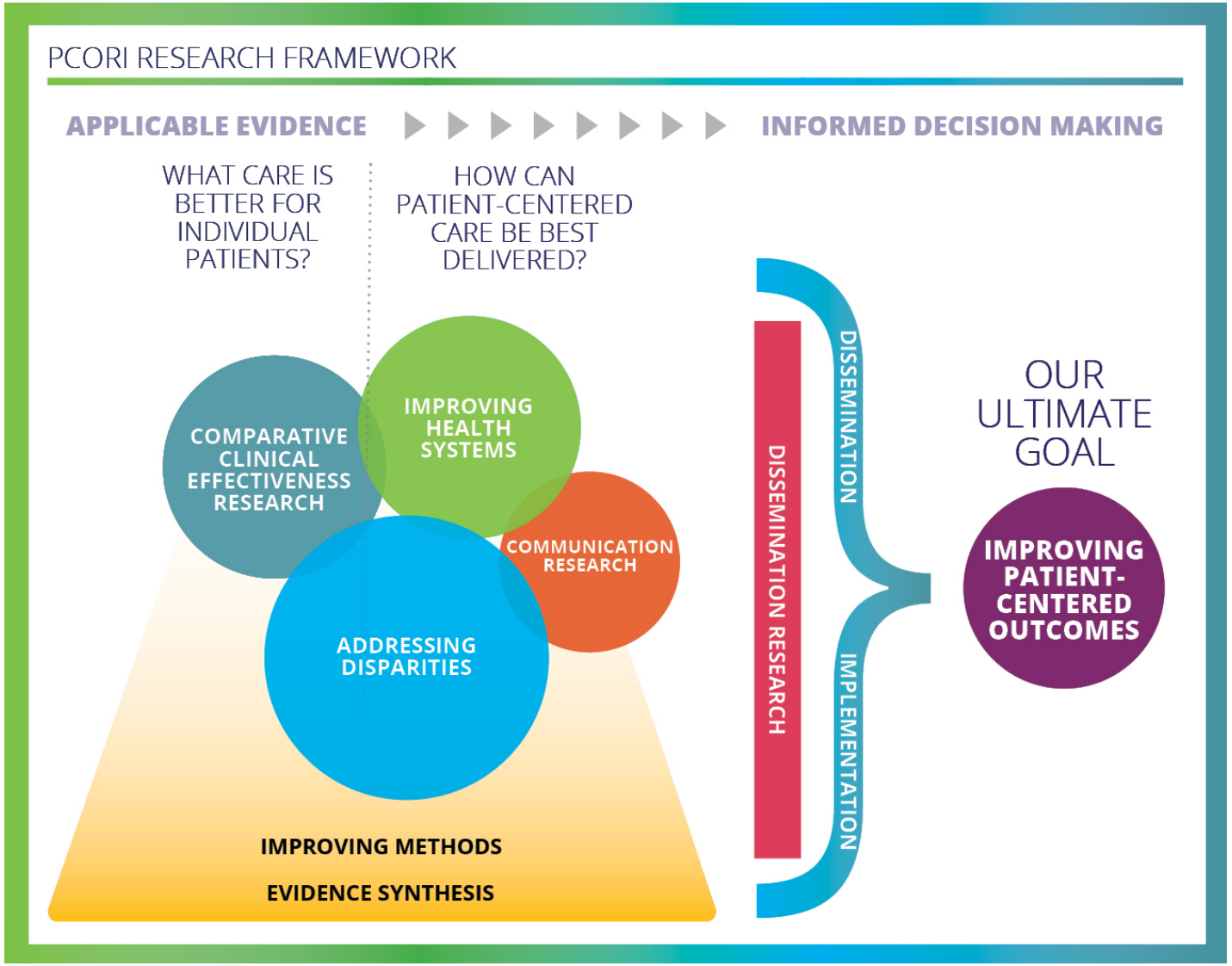
Measures benefits in **real-world populations**

- Helps consumers, clinicians, purchasers, and policy makers **make informed decisions** that will improve care for individuals and populations

- Informs specific **clinical or policy change**



Our Research Priorities and Framework

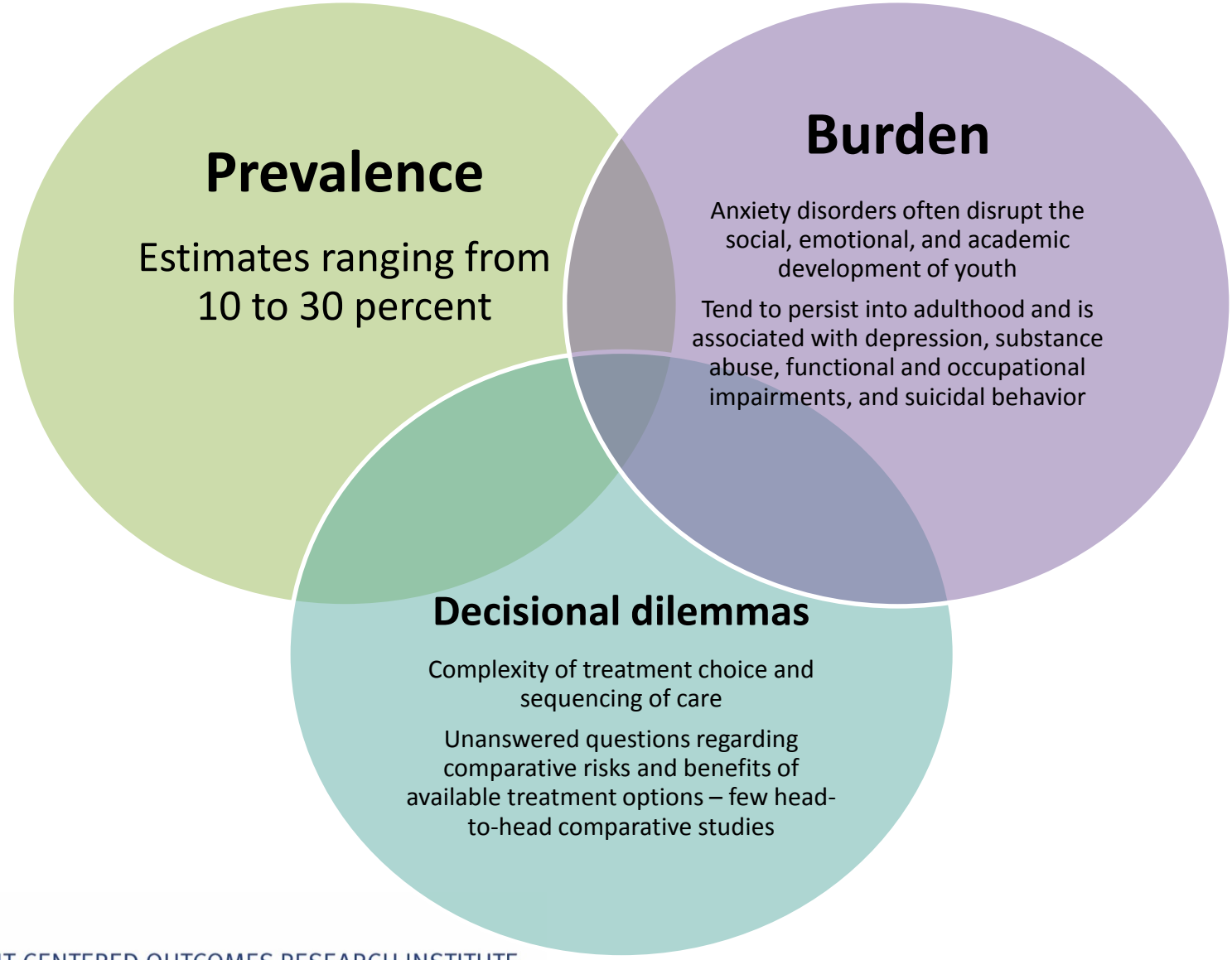


Topics Background and Workshop Goals

Purpose of this Workshop

- To discuss the critical issues and uncertainties faced by patients, caregivers, and clinicians in making treatment and other decisions for youth with anxiety disorders.
- To identify opportunities for PCORI to increase the actionable evidence base for management of anxiety disorders in youth in order to improve patient and caregiver outcomes
- To provide the broad range of expert consultation necessary for formulating a fruitful, applied research agenda in this area
  - Lived experience
  - Clinical and other occupational experience
  - Research knowledge/expertise

Anxiety Disorders in Youth – Why PCORI's Interested



Anxiety in the Media

STYLE

Prozac Nation Is Now the United States of Xanax

By ALEX WILLIAMS JUNE 10, 2017

#THIS IS #WHAT AN FEE

HEN Y
ATES Y

ARAH FADER
ICHELLE HAMMER

Matth Bennett
@MattBennett
Follow

iParty with Crippling Social Anxiety

6:26 AM - 17 Jul 2017

Answer Sheet

Facing down debilitating anxiety — a college freshman's story

By Valerie Strauss February 2, 2016

Girly Makeup
@girlymakeup
Follow

Now you can stay anxiety free 24/7 with an attachable fidget spinner! 🙏

SundayReview | CONTRIBUTING OP-ED WRITER

Fifty States of Anxiety

Seth Stephens-Davidowitz AUG. 6, 2016

Feeling worried? These days, much of America is.

Over the past eight years, Google search rates for anxiety have more than doubled. They are higher this year than they have been in any year since Google searches were first tracked in 2004.

So far, 2016 has been tops for searches for driving anxiety, travel anxiety, separation anxiety, anxiety at work, anxiety at school and anxiety at home.

anxiety
@lonestfeels
Follow

Having anxiety is the most silently painful experience. It makes no sense and you sit there alone and suffer for an unknown

On Parenting • Perspective

My son's anxiety is making him miss out on some of life's best moments

THE LEARNING NETWORK

Do You Think Anxiety Is A Serious Problem Among Young People?

Student Opinion

By SHANNON DOYNE JUNE 12, 2017

Anxiety Girl
@AnxietyGirlxo
Follow

Suddenly going into panic out of the blue, usually in the wrong place at the wrong time. #ThisIsWhatAnxietyFeelsLike

1:15 PM - 3 Jul 2017

Anxiety Disorders in Youth – PCORI's Work to Date

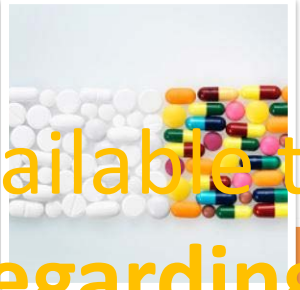
- Many stakeholders have expressed their interest in this topic, including **AAFP, ACP, AOA, SGIM, and NAPCRG**
- In May 2017, PCORI held **topic refinement discussions** with **AACAP, AAP, ADAA, and NIMH**
- In June 2017, PCORI released a **Special Area of Emphasis topic** in the Pragmatic Clinical Studies PCORI Funding Announcement on the **comparative effectiveness of digital applications of CBT**:
  - *Compare the effectiveness of one or more digital applications of CBT to an appropriate active control (e.g., face-to-face CBT) for the treatment of mild-to-moderate anxiety in children, adolescents, and/or young adults (through age 25).*

- Letters of intent due – July 25th, 2017
- Merit review – January 2018
- Anticipated announcement of awards – May 2018

Initial Feedback from Stakeholders

- Reported that **anxiety disorders in youth are underdiagnosed**
  - Anxiety may complicated or be misidentified by families, counselors, and primary care providers as other more commonly recognized disorders, such as ADHD, learning disorders, or depression
- Expressed **strong interest in a range of information needs, including CER, for both pharmacologic and psychological interventions** for children and adolescents with anxiety [ages 6+]
- Indicated need for research on the most appropriate **initial treatments, sequences of care**, including both pharmacologic and psychological approaches, **appropriate duration of care**, and **if/when to taper or discontinue medication**
  - *"Would allow us to better allocate resources to kids who need more help."*
- Consideration of family needs, communication needs, and how to navigate the healthcare system and better access care

Available Treatment Options for Anxiety Disorders in Youth



Despite the range of available treatments, **uncertainty remains regarding the most effective interventions and sequences of care.**

Psychological Interventions

- Cognitive behavioral therapy (CBT)
  - Short-term treatments that focus on teaching patients specific skills
  - Most widely studied ps intervention
  - Moderate strength of e for improving primary symptoms, function, cl and remission compare controls [AHRQ 2017]
- Non-CBT psychotherapie
  - -Considerably fewer st to CBT
  - -Moderate SOE compa [AHRQ 2017]

Ph ons

- Selective serotonin reuptake inhibitors (SSRIs)
- Serotonin-norepinephrine reuptake hibitors (SNRIs)
  - -For both SSRIs and SNRIs: Moderate SOE for improving primary nxiety symptoms and high SOE for mproving function compared to pill lacebo (AHRQ, 2017)
- cyclic antidepressants (TCAs)
- nzodiazepines
  - -Neither TCAs nor benzodiazepines howed statistically significant mprovement in primary anxiety ymptoms over pill placebo (AHRQ, 2017)

Access to CBT: Evidence for Digital Health Interventions (DHIs)

- **Access to face-to-face CBT is limited** by the insufficient supply of trained mental health practitioners, among other healthcare system factors

- DHIs (including computer-assisted therapy, smartphone apps, and wearable technologies) have the potential to increase the accessibility, efficiency, and clinical effectiveness of psychological interventions

- Meta-analyses and a systematic review by Hollis et al. (2017) **support a benefit of computerized CBT** (compared to wait-list and treatment-as-usual) for improving anxiety symptoms **in adolescents and young adults with mild-to-moderate symptomatology**
  - Non-CBT DHIs had mixed or uncertain effects on anxiety outcomes

Clinical Practice Guidelines Offer Conflicting Advice for Treating Childhood Anxiety Disorders

- Guidelines by NICE (2013), the British Columbia Medical Services Commission (BCMSC) (2010), and the AACAP (2007) offer **inconsistent advice regarding treatment for patients with moderate-to-severe symptomatology:**
  - NICE recommends individual or group CBT for all levels of symptom severity, and does *not* recommend any pharmacologic intervention for youth under age 18
  - BCMSC recommends starting with CBT, and adding SSRIs if CBT does not lead to an adequate response
  - AACAP recommends the consideration of SSRIs when youth present with moderate or severe symptoms initially, impairment makes participation in psychotherapy challenging, or psychotherapy results in a partial response
    - Medications other than SSRIs (i.e., TCAs, benzodiazepines, and buspirone) may also be considered

Numerous Evidence Gaps Remain

- Additional research is needed to assess:
  - The impact of comorbidities, family demographics, and stressors as treatment effect modifiers
  - The most beneficial components of CBT, and how this may vary by patient characteristics
  - The level and type of human support required for clinically effective DHIs, and whether DHIs improve access to and acceptability of care
- Evidence is significantly lacking for:
  - Head-to-head comparisons of individual medications
  - Comparisons of CBT versus medications
  - Comparisons of combination therapy (CBT + medication) versus monotherapy
  - Treatment sequencing approaches and the discontinuation of treatment
- Larger trials (>400 participants) with follow-up that exceeds 2-3 years are needed to address these evidence gaps

Breakout Sessions

To listen to the breakout session discussion:

1: Stepped therapy, including combination approaches and discontinuation of treatment

DIAL:

2. Addressing access to care, including format and delivery of CBT

DIAL:

Understanding Key Evidence Gaps in the Treatment of Anxiety Disorders in Children, Adolescents, and Young Adults

Breakout Group: Stepped Therapy/Sequencing Treatment

What are the most important areas of research focus?

- Understanding appropriate identification and support for variety of stages:
  - Population/prevention approaches
  - Early identification
  - Treatment choices and sequences, including appropriate treatment choice
  - Discontinuation strategies
  - Relapse and relapse prevention post-treatment

What are critical uncertainties faced by patients, caregivers, and clinicians in addressing the impact of anxiety?

- How do we provide access to support and treatments, given constraints in time, available professionals, cost, and stigma? Baseline severity, baseline functional impairment, culture/context.
- For medications, parents ask what are the side effects and how long does my child have to take it? For primary care, which medications are appropriate for which patients? For clinicians/systems/payers, what is the utility of pharmacogenomics in treatment selection?
- For clinicians, how and when do we discontinue therapy and how often should we follow patients to monitor for relapse?
- What should we do to prevent relapse?
- How to bring cultural issues around stigma, parenting, family structure appropriately into research design and care delivery?
- How to appropriately engage families as critical components in all phases of anxiety in children and youth?

What are the most important outcomes?

- Measures need to be translated and culturally appropriate.
- Measure developmental milestones within context (age, cultural, real-world)
- Reduction of symptoms does not translate to improved function
  - Independence and self-soothing
  - Ability to self-expose
  - Problem solving capabilities (age appropriate)
- Self-exposure to anxiety provoking situations
- Family burden (work days lost, etc)
- Relapse rates – ideal length of follow-up
- Generalizability/implementation of trial results →transition

Understanding Key Evidence Gaps in the Treatment of Anxiety Disorders in Children, Adolescents, and Young Adults

Breakout Group: Addressing access to care, including format and delivery of CBT

What are critical uncertainties faced by patients, caregivers, and clinicians in addressing the impact of anxiety?

- Lack of information on what anxiety is and how to treat it – both for families and clinicians
- How to efficiently and effectively identify children with anxiety – barriers to screening in primary care (time, resources, screening tools, what next?)
- How do we consider intervention in the context of a continuum of care from screening to assessment to appropriate referral to treatment and follow-up?
- How to get children the treatment that they need -> attending to contextual factors such as severity, availability of mental health providers is lacking, skill substitution/provider extenders, determining components of what is needed, setting, community resources, age.
- Public health perspective versus traditional approach: Is it preferable to aim for a small improvement in a large proportion of population vs. large improvement in a small/critically ill portion of population?
- How do we integrate quality conversation into the access discussion, and how is quality incentivized with respect to anxiety (vs. depression, which has quality metrics)?

What are the most important outcomes?

- Identification (a-typicality/typicality)
- Knowledge: That the public and clinicians have a better understanding of CBT & its components
- Functional outcomes of children (social and emotional: friends, sleep, engagement in events, school attendance, risk taking behavior→>substance abuse, IPV)
- Symptomology, including Family and child distress
- Family-based outcomes (family activities together, conflict, parents work, etc.)
- Secondary comorbidities
- Provider competence and fidelity
- Developmental milestones (opening a bank account)
- Satisfaction and engagement with treatment (burden of tx, fit with family needs)
- Process and utilization: Time and intensity of service delivery and referral, provider workflow

Thank you