Hello, my name is Emma Stallwood and I am a clinical research project assistant at the Hospital for Sick Children. Today, I will speak about an initiative that aims to develop a core outcome set to be used in clinical trials assessing treatments for major depressive disorder in adolescents, called IN-ROADS or the International Network for Research Outcomes in Adolescent Depression Studies.

Major Depressive Disorder or in short, MDD, is a significant disease burden worldwide. The life-time prevalence rate of MDD in adolescents is 11% and treatments to date have yielded suboptimal results in reducing the burden of this disease. Currently, there is a need for more research to identify the most effective treatments for adolescents with MDD.

In randomized clinical trials assessing treatments for adolescents with MDD, different researchers are measuring different “outcomes”. For example, one researcher may measure the outcomes school functioning, response to treatment, and family functioning, whereas another researcher may measure the outcomes depressive symptom severity, fatigue, and social functioning, to determine if a treatment is effective. If both randomized clinical trials found their treatment to be effective based on their measured outcomes, we cannot compare the effectiveness of these treatments because different outcomes were measured.

This variability in outcome selection makes it difficult to synthesize and interpret results through systematic reviews and meta-analyses, thereby making it difficult to determine which treatments are the most effective. To address this challenge, we would need a core outcome set. A core outcome set is a small list of outcomes that are agreed to be measured in all studies of a particular condition. It is important to note that a core outcome set
does not restrict researchers from measuring other outcomes, but it provides a list of outcomes that at minimum, a trial should measure.

Adopting a core outcome set for adolescents with MDD would minimize the differences in outcomes reported across adolescent MDD trials, improve the evidence synthesis process and translation to care through systematic reviews and meta-analyses, and ensure that reported outcomes are relevant to clinicians, families, and patients.

The objective of our IN-ROADS project is to develop a core outcome set for use in clinical research studies assessing outcomes in adolescents with major depressive disorder.

One of the first steps in the development of a core outcome set is conducting a systematic review to generate a list of categorized potential outcomes for inclusion in the core outcome set.

In 2018, we conducted a scoping review that identified all reported outcomes in clinical trials of adolescents with MDD. Across 42 articles included in this review, we found 86 unique outcomes with a lot of variability in definition and frequency of selection and reporting. These 86 outcomes were measured using 118 different outcome measurement instruments. Significant variability around which questionnaire, scale or tool was used to measure the same outcome was noted across studies.

Our next steps of this project will be to prioritize the candidate outcomes that were identified through our scoping review. Prioritization of candidate outcomes for inclusion in the IN-ROADS core outcome set will be done through an international web-based Delphi survey, which is an iterative multistage process that allows for group decisions to be made. This
Delphi survey will allow engagement of a diverse and international group of professional stakeholders.

We will also be conducting focus groups prior to the delphi component of our study with adolescents with lived experiences and caregivers so they can voice and identify which outcomes are most important to them. These patient driven outcomes will also be included in the delphi study along with the outcomes generated from our scoping review. Consensus regarding outcomes for inclusion in the core outcome set will be reached through structured rounds of surveys coupled with controlled feedback. After completion of the Delphi study, patient, caregiver, and professional stakeholder input will be brought together at an in-person consensus meeting, that will include healthcare professionals as well as patient and caregiver representatives, with the goal of establishing the final recommended core outcome set.

STEP 3: Knowledge translation and dissemination Our knowledge translation plan for IN-ROADS includes a strategy that targets each stakeholder group with the goal of identifying the type of change required as well as necessary specific endorsement and enforcement strategies. Publication of the core outcome set development work in appropriate journals and presentations at important international/national conferences will also ensure appropriate uptake around implementation of the new core outcome set at each stage of future adolescent MDD clinical trials. Our Progress to Date

Currently, we are in the planning and recruiting stages of the delphi survey and focus group activities. We submitted our protocol to the Journal of the American Academy of Child & Adolescent Psychiatry.
We feel that this core set of outcomes can be helpful to researchers in improving the quality and utility of future clinical research studies, and its implementation will help ensure that the results of clinical trials are useful and meaningful for clinicians and researchers, patients and families, and other important stakeholders.

If you would like to learn more about the IN-ROADS Initiative, please visit our website at www.in-roads.org.

On behalf of myself and the research team, we thank you for watching.