

00:00 Hello, my name is Emma Stallwood and I am a clinical research project assistant at the

00:05 Hospital for Sick Children. Today, I will speak about an initiative that aims to develop

00:10 a core outcome set to be used in clinical trials assessing treatments for major depressive

00:16 disorder in adolescents, called IN-ROADS or the International Network for Research Outcomes

00:23 in Adolescent Depression Studies.

00:25 Major Depressive Disorder or in short, MDD, is a significant disease burden worldwide.

00:31 The life-time prevalence rate of MDD in adolescents is 11% and treatments to date have yielded

00:37 suboptimal results in reducing the burden of this disease. Currently, there is a need

00:42 for more research to identify the most effective treatments for adolescents with MDD.

00:48 In randomized clinical trials assessing treatments for adolescents with MDD, different researchers

00:54 are measuring different “outcomes”. For example, one researcher may measure the outcomes

00:59 school functioning, response to treatment, and family functioning, whereas another researcher

01:05 may measure the outcomes depressive symptom severity, fatigue, and social functioning,

01:11 to determine if a treatment is effective. If both randomized clinical trials found their

01:16 treatment to be effective based on their measured outcomes, we cannot compare the effectiveness

01:21 of these treatments because different outcomes were measured.

01:25 This variability in outcome selection makes it difficult to synthesize and interpret results

01:31 through systematic reviews and meta-analyses, thereby making it difficult to determine which

01:36 treatments are the most effective. To address this challenge, we would need a core outcome

01:42 set. A core outcome set is a small list of outcomes that are agreed to be measured in

01:47 all studies of a particular condition. It is important to note that a core outcome set

01:53 does not restrict researchers from measuring other outcomes, but it provides a list of

01:58 outcomes that at minimum, a trial should measure.

02:01 Adopting a core outcome set for adolescents with MDD would minimize the differences in

02:06 outcomes reported across adolescent MDD trials, improve the evidence synthesis process and

02:13 translation to care through systematic reviews and meta-analyses, and ensure that reported

02:18 outcomes are relevant to clinicians, families, and patients.

02:22 The objective of our IN-ROADS project is to develop a core outcome set for use in clinical

02:28 research studies assessing outcomes in adolescents with major depressive disorder.

02:34 One of the first steps in the development of a core outcome set is conducting a systematic

02:38 review to generate a list of categorized potential outcomes for inclusion in the core outcome

02:43 set.

02:45 In 2018, we conducted a scoping review that identified all reported outcomes in clinical

02:51 trials of adolescents with MDD. Across 42 articles included in this review,

02:57 we found 86 unique outcomes with a lot of variability in definition and frequency of

03:02 selection and reporting. These 86 outcomes were measured using 118 different outcome

03:09 measurement instruments. Significant variability around which questionnaire, scale or tool

03:15 was used to measure the same outcome was noted across studies.

03:20 Our next steps of this project will be to prioritize the candidate outcomes that were

03:25 identified through our scoping review. Prioritization of candidate outcomes for inclusion in the

03:30 IN-ROADS core outcome set will be done through an international web-based Delphi survey,

03:35 which is an iterative multistage process that allows for group decisions to be made. This

03:41 Delphi survey will allow engagement of a diverse and international group of professional stakeholders.

03:48 We will also be conducting focus groups prior to the delphi component of our study with

03:53 adolescents with lived experiences and caregivers so they can voice and identify which outcomes

03:59 are most important to them. These patient driven outcomes will also be included in the

04:04 delphi study along with the outcomes generated from our scoping review. Consensus regarding

04:09 outcomes for inclusion in the core outcome set will be reached through structured rounds

04:14 of surveys coupled with controlled feedback. After completion of the Delphi study, patient,

04:21 caregiver, and professional stakeholder input will be brought together at an in-person consensus

04:26 meeting, that will include healthcare professionals as well as patient and caregiver representatives,

04:33 with the goal of establishing the final recommended core outcome set.

04:36 STEP 3: Knowledge translation and dissemination Our knowledge translation plan for IN-ROADS

04:41 includes a strategy that targets each stakeholder group with the goal of identifying the type

04:46 of change required as well as necessary specific endorsement and enforcement strategies.

Publication

04:52 of the core outcome set development work in appropriate journals and presentations at

04:57 important international/national conferences will also ensure appropriate uptake around

05:02 implementation of the new core outcome set at each stage of future adolescent MDD clinical

05:08 trials. Our Progress to Date

05:09 Currently, we are in the planning and recruiting stages of the delphi survey and focus group

05:14 activities. We submitted our protocol to the Journal of the American Academy of Child & Adolescent

05:20 Psychiatry.

05:21 We feel that this core set of outcomes can be helpful to researchers in improving the

05:26 quality and utility of future clinical research studies, and its implementation will help

05:31 ensure that the results of clinical trials are useful and meaningful for clinicians and

05:36 researchers, patients and families, and other important stakeholders.

05:40 If you would like to learn more about the IN-ROADS Initiative, please visit our website

05:44 at www.in-roads.org.

05:49 On behalf of myself and the research team, we thank you for watching.