

Core Outcomes Sets for Delirium Trials

Presenter: Louise Rose, RN, PhD

Time	Section
01:24	<u>Introduction of Louise Rose</u>
05:09	<u>Definitions</u> <ul style="list-style-type: none"> • Core Outcome Set (COS): consensus driven standardized set of outcomes • Core Outcome Measurement Set (COMS): outcomes + measures + measurement characteristics • First establish outcomes (WHAT to measure), then establish measurement parameters (HOW to measure)
06:34	<u>Why generate COS & COMS?</u> <ul style="list-style-type: none"> • Promote consistency in reporting among studies <ul style="list-style-type: none"> ○ Evaluating similar interventions in similar populations ○ Can be used in clinical audit & QI projects • Improves ability to aggregate data across trials thereby informing guidelines and clinical decision making to ultimately improve patient outcomes • A core outcome set can be seen as a minimum core outcomes set (other outcomes can be added, but core outcome set should always be in there for consistency) • Struggles in systematic reviews in trying to aggregate data because the use of different outcomes and measures
08:02	<u>Del-CORs project</u> <ul style="list-style-type: none"> • A COS was needed in the field of delirium research since there was none at the time • Aim: to develop international consensus among key stakeholders for core outcome sets for future trials of interventions to prevent and/or treat delirium in adults <ul style="list-style-type: none"> ○ 4 patient groups: Critically ill adults, acute hospitalization without ICU admission, Palliative care, and older adults in long-term care (decided against including pediatrics—needs to be a separate project) • Item generation phase: <ul style="list-style-type: none"> ○ Systematic reviews extracting outcomes & measures ○ Semi-structured interviews with survivors/family members to identify relevant outcomes (Palliative and LTC COS also interviewed clinicians) • Item reduction & consensus phase <ul style="list-style-type: none"> ○ Modified 2 round e-Delphis surveys (3 stakeholder groups—patients/family, clinicians, researchers)—ranked on 9-point Likert scale for how important each outcome is to be included in the COS <ul style="list-style-type: none"> ▪ Trying to narrow down to 6-10 outcomes ○ Consensus meetings (in person and virtual)
16:52	<u>First Core Outcome Set</u> <ul style="list-style-type: none"> • Outcome set for intensive care • First item generation phase with a systematic review (identified 195 studies, 141 had completed recruitment of 74,632 participants) • Looked at outcomes specific to delirium: most common ones across these studies were delirium incidence, delirium duration, and use of antipsychotic medications. But many others too emphasizing the heterogeneity • Also found 95 non-delirium specific outcomes (most common: ICU length of stay, hospital length of stay, mortality, ventilation duration)
19:10	<u>Interview phase</u> <ul style="list-style-type: none"> • Interviewed just over 20 ICU survivors and family members • When coming outcomes from systematic reviews and the interviews, found only 6 within the interview set that were different from the systematic review

	<ul style="list-style-type: none"> • For the first round of Delphi, presented 32 outcomes to the participants, they presented 3 more so ended up with 35 outcomes ranked for importance. 17/35 went to the consensus meeting • Final Del-ICU COS had 7 outcomes: <ul style="list-style-type: none"> ○ Delirium occurrence (incidence or prevalence) ○ Emotional distress (mental health) ○ Delirium severity (degree of inattention, disorganized thinking) ○ Time to delirium resolution ○ Cognition ○ Mortality ○ Health-related quality of life
23:07	<p><u>Intensive Care COS finished within the Del-CorS timeframe</u></p> <ul style="list-style-type: none"> • Consensus meeting for what the measurement parameters would be for those core outcomes • 18 participants to talk about outcome measures with good representation from survivors, family members, and professions that deal with a lot of delirium • Only gained consensus on 4 tools for the 7 outcomes • For delirium occurrence, had 100% consensus that this should be measured using CAM-ICU or delirium checklist which mirrors the guidelines of how delirium should be screened in intensive care <ul style="list-style-type: none"> ○ No consensus on when to start looking for delirium occurrence <ul style="list-style-type: none"> ▪ Most common is at ICU admission or within the first 24 hours of ICU admission ▪ Almost full consensus to stop at ICU discharge, but discussion on the fact that delirium is not necessarily discontinued once patients are discharged from the ICU; often still experience delirium in the hospital and occasionally still at home ○ Consensus on when to check for delirium occurrence: mirror a typical nursing shift (8 or 12-hour shift) • Not close to consensus for a delirium severity measurement, but did reach consensus to start measuring severity when delirium is detected and stop when delirium is no longer detected • For time to delirium resolution, there was 100% consensus to keep checking screening for delirium with either the CAM-ICU or the delirium checklist, but no consensus on when to stop looking • 100% consensus for mortality being confirmation of death, but did not get consensus that mortality should be measured up to 60 days and a lot of discussion about how long the follow-up should be in terms of mortality • Nearly got consensus on using the EQ5D5L for health-related quality of life (has gotten consensus in other core outcome sets related to critically ill patient population). Up to 6 months was the closest consensus in regards to the measurement parameters • Consensus that hospital anxiety distress scale should be used for anxiety and depression measurement, but did not get consensus on which measure to use for PTSD. Also no consensus for a measure on delirium-related distress <ul style="list-style-type: none"> ○ Longer term outcomes was very important for this patient population (12 month time frame)
28:57	<p><u>Second Core Outcome Set</u></p> <ul style="list-style-type: none"> • Outcome set for acute hospitalization without ICU admission • Started off with systematic review work (identified 183 studies, recruiting over 61,000 participants) • Adults only, big portion of these studies only being conducted on older adults (higher risk profile in this population) • Found a range of prevention or treatment (or both) and pharmacological or non-pharmacological interventions • Identified 79 potential core outcomes from systematic review work and 18 interviews that were conducted • Reduced that down to 31 outcomes for the first round of e-Delphi, and then resulted in 39 outcomes with additions from participants

	<ul style="list-style-type: none"> • Through the consensus building whittled that down through nominal group technique to the final core outcomes set • 6 outcomes in final outcomes set: <ul style="list-style-type: none"> ○ Delirium occurrence (incidence or prevalence) ○ Emotional distress (mental health) ○ Delirium severity (degree of inattention, disorganized thinking) ○ Delirium duration ○ Cognition ○ Health-related quality of life • Completely independent process with completely different participants and there is a lot of similarity • Starting to see some consistency in the pattern of outcomes that a large volume of experts in the field, including patients and survivors, think are important to have in the core outcome set • Haven't done a core measurement set within this timeframe
32:23	<p><u>Third Core Outcome Set</u></p> <ul style="list-style-type: none"> • Outcome set for palliative care • Systematic review work only 13 studies recruiting 2,863 participants • Interviewed 18 family members/clinicians which overall results in 71 potential outcomes • Reduced down to 40 which went into the first Delphi survey round • 4 final outcomes in the core outcomes set: <ul style="list-style-type: none"> ○ Delirium occurrence (incidence or prevalence) ○ Delirium duration until resolution (no further delirium or death) ○ Overall delirium symptom profile ○ Distress due to delirium (patient, family member, carer)
35:40	<p><u>Fourth Core Outcome Set</u></p> <ul style="list-style-type: none"> • Outcome set for older adults in long-term care • Systematic review work identified 18 studies recruiting 5,639 participants • Same process as for the other outcome sets, 18 interviews, identified 54 potential outcomes, item deduction and then Delphi survey rounds, consensus meetings • 6 final outcomes in the core outcomes set: <ul style="list-style-type: none"> ○ Delirium occurrence (incidence or prevalence) ○ Delirium related distress ○ Delirium severity ○ Cognition including memory ○ Admission to hospital ○ Mortality
38:07	<p><u>The 4 Delirium COS</u></p> <ul style="list-style-type: none"> • The final four outcome sets turned out to be very similar (comparison table in slides)
38:43	<p><u>Conclusions:</u></p> <ul style="list-style-type: none"> • The Del-CORs project addressed call from delirium research community to produce COS for delirium research • The four COS developed have similar elements despite substantial differences in the patient populations <ul style="list-style-type: none"> ○ Delirium occurrence ○ Delirium related distress/emotional distress ○ Delirium severity/symptom profile • The ICU COMS provides some guidance on measurement • Further work needed on other COMS and promoting adoption of the COS into future research
40:38	<p><u>Questions and Answers</u></p>