Integrating delirium measurement into your research

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Outline

- Selection of an appropriate measure
- Training of delirium assessors
- Ongoing oversight and quality control
- Non-exhaustive compendium of measures
- Case Studies

Delirium Measurement in Research Studies

- One size does NOT fit all
- Considerations:
  - What kind of assessment to use?
  - How to determine delirium presence, severity?
  - Who should perform the assessments?
  - How often to perform the assessments?
- Answer may differ from study to study

How are the data being used?

- Example 1: Large epidemiology study to identify risk factors for delirium
  - High reproducibility, Balance sensitivity/specificity
- Example 2: Delirium screening for quality improvement project—nursing care
  - High sensitivity—maximize benefit
- Example 3: Delirium screening for Phase I treatment trial—toxic drug
  - High specificity, Clinical diagnosis

Bedside assessment in Epi Studies

- Not making a clinical diagnosis
- Making a research assignment of delirium presence or absence
- Goals:
  - High validity: concordance with external standard
  - High reliability: concordance with each other

How do we do it?

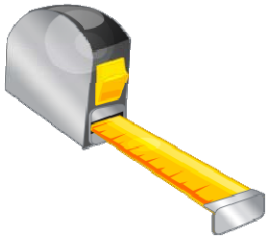
- Standardized delirium assessment
- Extensive training of assessors
- Close oversight and quality control

Standardized Delirium Assessment

Key Components

- Cognitive testing
  - Including formal testing of attention
- Observations of symptoms
  - Altered level of consciousness
  - Psychomotor agitation/retardation
- Presence/acuity of mental status change
  - Fluctuations during assessment
  - Ask patient, proxies (nurses, family)

Delirium Measurement



- Presence or absence:
  - CAM diagnostic algorithm
  - DSM diagnosis—harder to operationalize
  - Cutoff on a sum scale—appropriate?
- Delirium severity: validated measure
  - DRS-98, MDAS, CAM-S most commonly used
- Repeat measure at least once daily
  - more often in VERY high risk groups
  - Daily misses cases in middle of night

Assessor Training

Who do we hire?

- Usually bachelor's degree in nursing, psychology or cognitive neuroscience
- Some have Masters degrees
- At least 2 years clinical research experience
- Experience in clinical (hospital) setting
- Demonstrated interest and ability to work with older adults

Didactic (classroom) training

- Basic training in delirium
  - Needed even for clinicians (even moreso)
- Training in mental status evaluation
  - General principles: hearing, vision, comfort, distractions, proxies, etc.
  - Evaluation begins when entering room, ends when leaving the room
- Training in delivering the assessment
  - Practice delivering to each other

Training Videos

- Used at the conclusion of didactic training
- Enables all learners to code assessment
- Review and discuss coding
  - Illustrates how to integrate cognitive testing and observations during interview
  - Ensures everyone is able to recognize key features of delirium

Field Training

- Observed interviews by senior staff
  - Start with senior volunteers
  - Move on to real patients
- Review interviews, coding immediately upon completion—provide feedback
- Inter-rater training—do 2 assessors agree?
  - Usually pair learner with seasoned assessor
  - Try to assess at least 5 delirious patients

Common Issues in Training

- Focus exclusively on answers to questions, not observations
- Making excuses for patient
  - Very old—what do you expect?
  - Is really sick
  - Just took a pain medication
- Difficulty translating incorrect answers, observations into delirium symptoms

Oversight, Quality Control

Weekly Team Meetings

- Review:
  - Interesting Cases
  - Specific coding questions
- Cross-check coding of assessments
  - All reviewed before submitted for data entry

Quality Control

- Ongoing inter-rater reliability checks
  - At least 5% of all assessments
  - Experienced/less experienced pairs
- Senior review of selected assessments
- Periodic re-training of specific elements
- Cross-check with medical record review

Challenge: Multi-site Studies

- How to replicate “local” training?
- Convene all sites for “kick-off” meeting
- Have standardized training followed by “certification” of assessors
- Periodic tele/video conferences
- Centralized quality review

Bedside Delirium Measures

A (Non-exhaustive)
Compendium of Approaches

DSM5

- Requires detailed clinician evaluation
  - Patient assessment, cognitive testing
  - Interviews with family, care providers
  - Medical record review
  - Perhaps laboratory, radiology studies
- Requires clinical expertise, time, cost
- The “gold standard”, but rarely used except in validation studies

Long CAM

- All 10 Features in the original CAM
- Each feature: not present, mild, marked
- Flexible cognitive testing—MMSE, MoCA, SPMSQ, SBT, etc.
- Can operationalize:
  - Delirium diagnosis: CAM diagnostic algorithm
  - Delirium severity: CAM-S long form (0-19)

Short CAM

- 4 Features in CAM diagnostic algorithm
- Each feature: not present, mild, marked
- Flexible cognitive testing—MMSE, MoCA, SPMSQ, SBT, etc.
- Can operationalize:
  - Delirium diagnosis: CAM diagnostic algorithm
  - Delirium severity: CAM-S short form (0-7)

3D-CAM

- 4 Features in CAM diagnostic algorithm
- Fixed cognitive testing, observations
- Each feature: present/absent based on answers to questions
- Can operationalize:
  - Delirium diagnosis: CAM diagnostic algorithm
  - Delirium severity: 3D-CAM-S (0-7)

CAM-ICU

- 4 Features in CAM diagnostic algorithm
- Fixed cognitive testing, designed for non-verbal (intubated) patients
- Each feature: present/absent based on answers to questions
- Can operationalize:
  - Delirium diagnosis: CAM diagnostic algorithm
  - Current no CAM-ICU severity measure
- B-CAM: adaptation for verbal patients

4AT

- Not CAM-based
- Fixed cognitive testing, observations
- Points based on answers, observations
- Add up points:
  - Delirium diagnosis: cutoff score
  - Delirium severity: sum of points

NEECHAM, DOS, etc.

- Not CAM-based
- Observation items based on routine care
- Points based on observations
- Add up points:
  - Delirium diagnosis: cutoff score
  - Delirium severity: sum of points

Delirium Severity

DRS-98

- Rates 14 features of delirium
- Each feature: mild, moderate, severe
- Add up scores for each feature to get total severity score
- Usually performed after fairly detailed cognitive testing and patient interview
- Designed for clinicians—ratings require some sophistication

MDAS

- Rates 10 features of delirium
- Each feature: mild, moderate, severe
- Add up scores for each feature to get total severity score
- Usually performed after cognitive testing
  - Works particularly well with the MMSE
  - Severity scoring based on performance on testing, making it easier for non-clinicians than the DRS-98

Most severity measures

- Tend to “overweight” hyperactive sxs
- Thus, interventions that convert delirium from hyperactive to hypoactive could be seen as reducing severity
- Treatment trials: important to examine other clinically relevant outcomes

Other Approaches

FAM-CAM

- Family members, not patients
- 4 Features in CAM diagnostic algorithm
- Each feature assessed by questions to family members observing the patient
- Can operationalize:
  - Delirium diagnosis: CAM diagnostic algorithm
  - No severity scale currently

Chart Review

- Review: ALL notes from ALL disciplines
- ANY text relevant to MS change extracted
- Reviewed by at least 2 experts
- Delirium coded as:
  - unlikely, possible, probable, likely, definite
- Delirium: at least 2 “probable” or higher
- Disagreements: adjudication, 3rd reviewer
- Cannot score severity
- Combine with interviews to ↑ sensitivity

Administrative Data

- ICD-9, 10
  - Delirium has numerous codes, use all
  - Poor sensitivity,
  - Likely high specificity
  - Useful in situations where prevalence is low, high specificity is most important

Case Studies

What measure would you use?

Study 1

Phase I trial of a new toxic treatment for hyperactive delirium

2 Measures:

- Eligibility for trial
- Outcome measure for trial

Study 2

Post-marketing surveillance of a drug in over 10 million hospital medical records for possible association with delirium

Study 3

Randomized trial of 2 types of anesthesia approaches for hip fracture in 2000 patients over 50 sites. Delirium is one of several outcomes.

Study 4

Mechanistic study of 100 participants at 2 sites incorporating MRI imaging, CSF, and plasma collection for biomarker studies

Study 5

Quality improvement study within nursing department to reduce use of restraints in hyperactive delirium

Study 6

Retrospective study in 300 patients to derive and validate a clinical prediction rule for delirium in patients admitted with CHF

Summary/Conclusions

- Delirium Measurement:
  - Choice of approach: depends on study
  - Different type of staff needed depending on what method will be used
- Key Elements:
  - Standardized assessment
  - Extensive training of assessors
  - Close oversight and quality control

Questions?