



## SCEPTER-III

# Clinical Trials to Evaluate Patient-Centered Outcomes of Sedation in Mechanically Ventilated Patients in the Adult ICU

March 28-29, 2019

Washington, DC

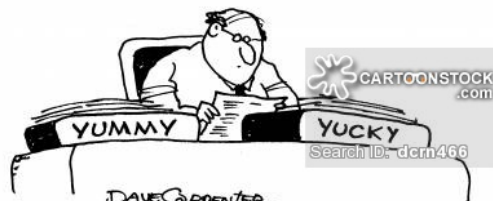
Compound Discovery



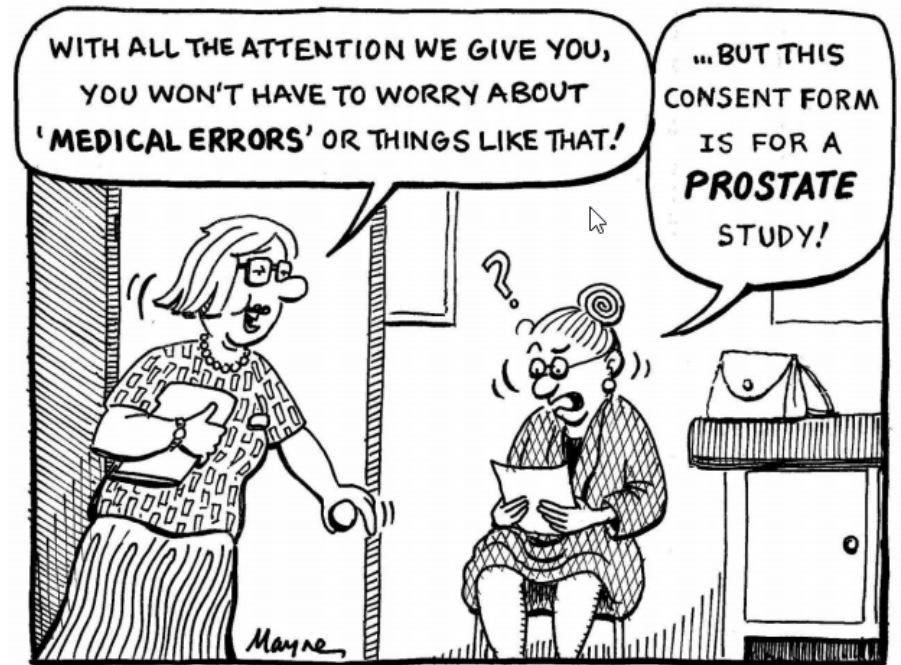
Phase 4 post marketing clinical trials



FOOD AND DRUG ADMINISTRATION

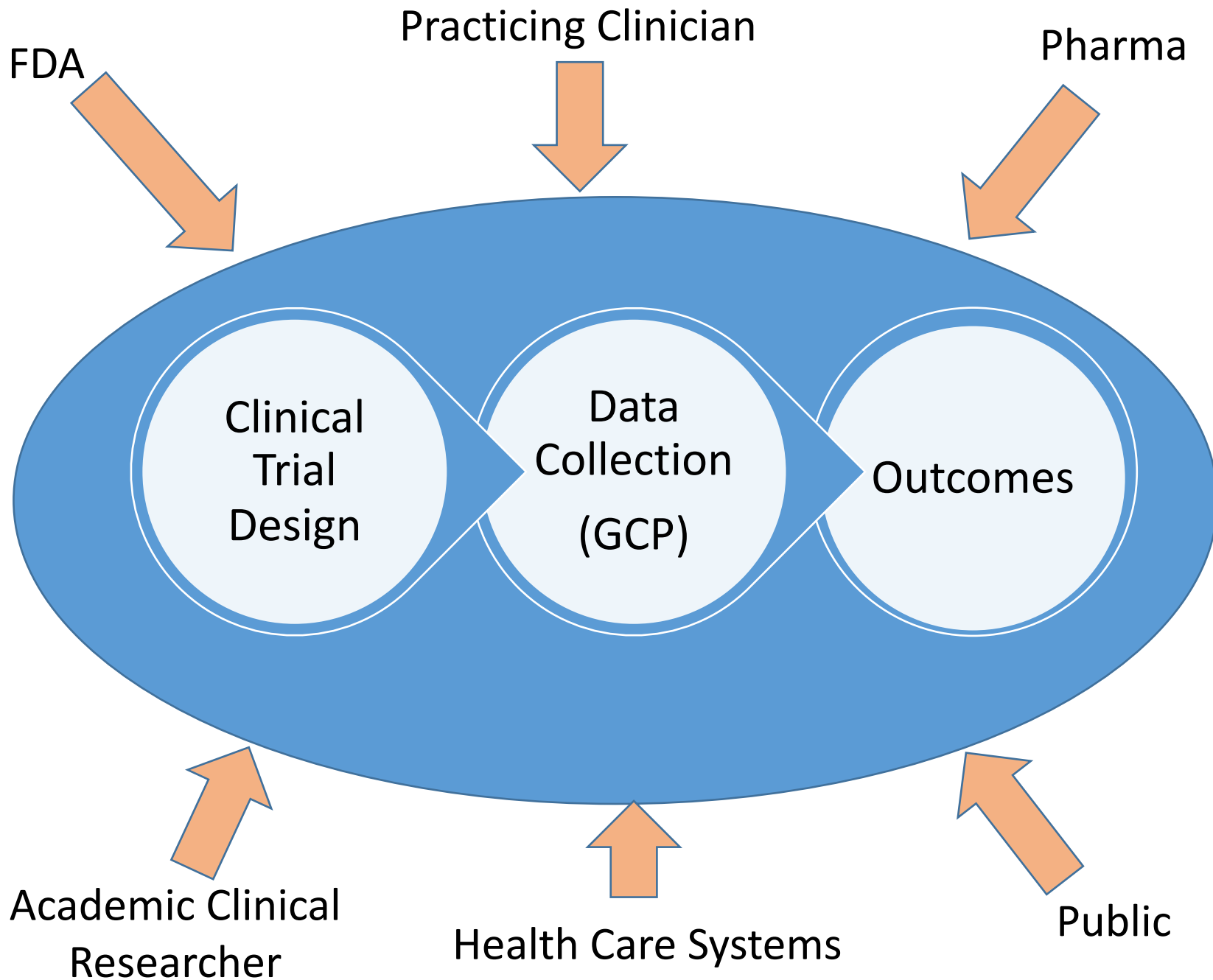


FDA Approval



Phase 1 -3 clinical trials





# **Sedation Consortium on Endpoints and Procedures for Treatment, Education, and Research (SCEPTER)**

- Two systematic reviews on Procedural Sedation (adult and pediatric) published
- Two consensus recommendations published on Procedural Sedation (Efficacy and Safety)
- Consensus conference on sedation for Adult ICU patients in March
- Future conference on sedation for Pediatric ICU patients

(Anesth Analg 2017;124:821–30)

■ SPECIAL ARTICLE

# **Evaluating Patient-Centered Outcomes in Clinical Trials of Procedural Sedation, Part 1 Efficacy: Sedation Consortium on Endpoints and Procedures for Treatment, Education, and Research Recommendations**

Mark R. Williams, MBBS, BSc,\* Denham S. Ward, MD, PhD,†‡ Douglas Carlson, MD,§||

# Who Should Provide Investigators With Direction on How to Conduct Clinical Trials of Procedural Sedation?

John F. Butterworth, IV, MD

## Recommendations for Procedural Sedation Clinical Trials

### To the Editor

We thank Butterworth<sup>1</sup> for his editorial that accompanies our recent article<sup>2</sup> and helps define the different processes that are used to produce published reviews that clarify and summarize difficult clinical problems. When these reviews contain recommendations and come from regulatory or accrediting agencies (eg, Food and Drug Administration [FDA], the Joint Commission) or a professional society (eg, American Society of Anesthesiologists), they may even be considered “standards” that mandate certain clinical practices. At the other extreme are recommendations by a group of “experts,” based on evidence available in the literature, to guide clinical research investigations, including clinical trials, but not to mandate clinical practice. Our recent article, along with a related systematic review,<sup>3</sup> falls in this latter category.

and other stake holders? Do either ACTION or Williams et al<sup>1</sup> have standing to speak for the FDA regarding what outcomes and procedures will be accepted for regulatory approval of new chemical entities? Do either ACTION or Williams et al<sup>1</sup> speak for the pharmaceutical industry? Do either ACTION or Williams et al<sup>1</sup> speak for any recognized specialty or scientific organization? Alternatively, should we regard these recommendations as well-intended advice from a group of interested investigators and consultants?

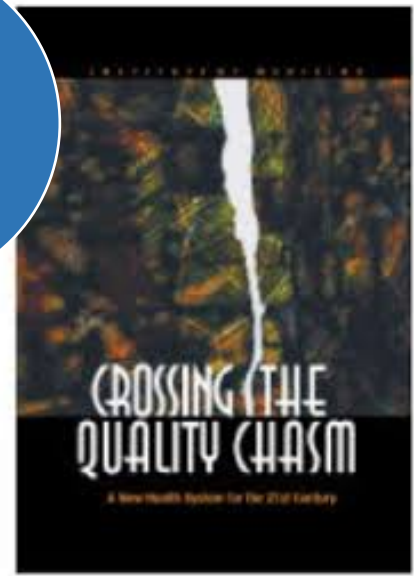
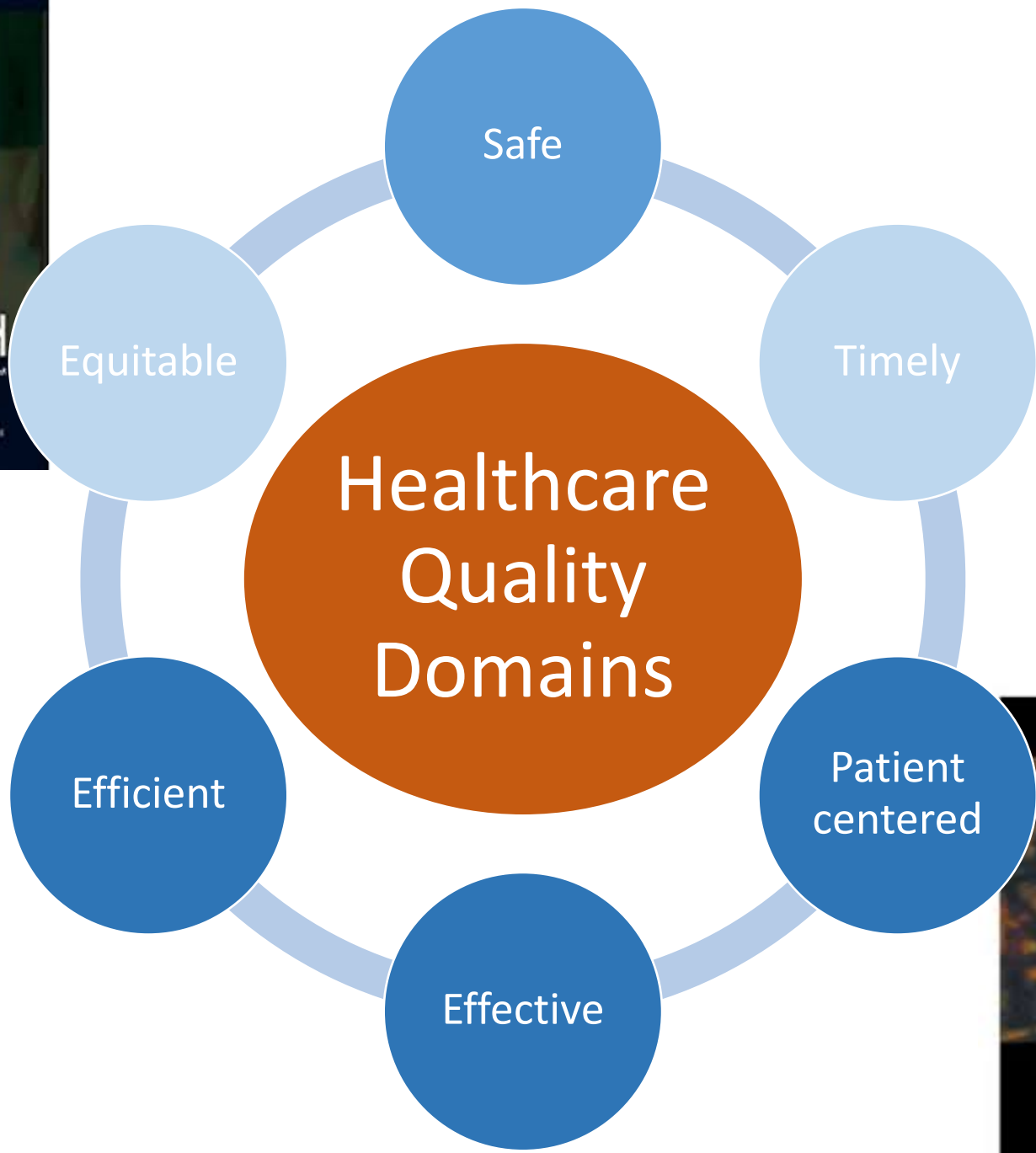
■ SPECIAL ARTICLE

(Anesth Analg 2018;127:1146–54)

# **Evaluating Patient-Centered Outcomes in Clinical Trials of Procedural Sedation, Part 2 Safety: Sedation Consortium on Endpoints and Procedures for Treatment, Education, and Research Recommendations**

Denham S. Ward, MD, PhD,\*† Mark R. Williams, MBBS, BSc,‡ John W. Berkenbosch, MD,§

<https://www.openanesthesia.org/article-of-the-month/>



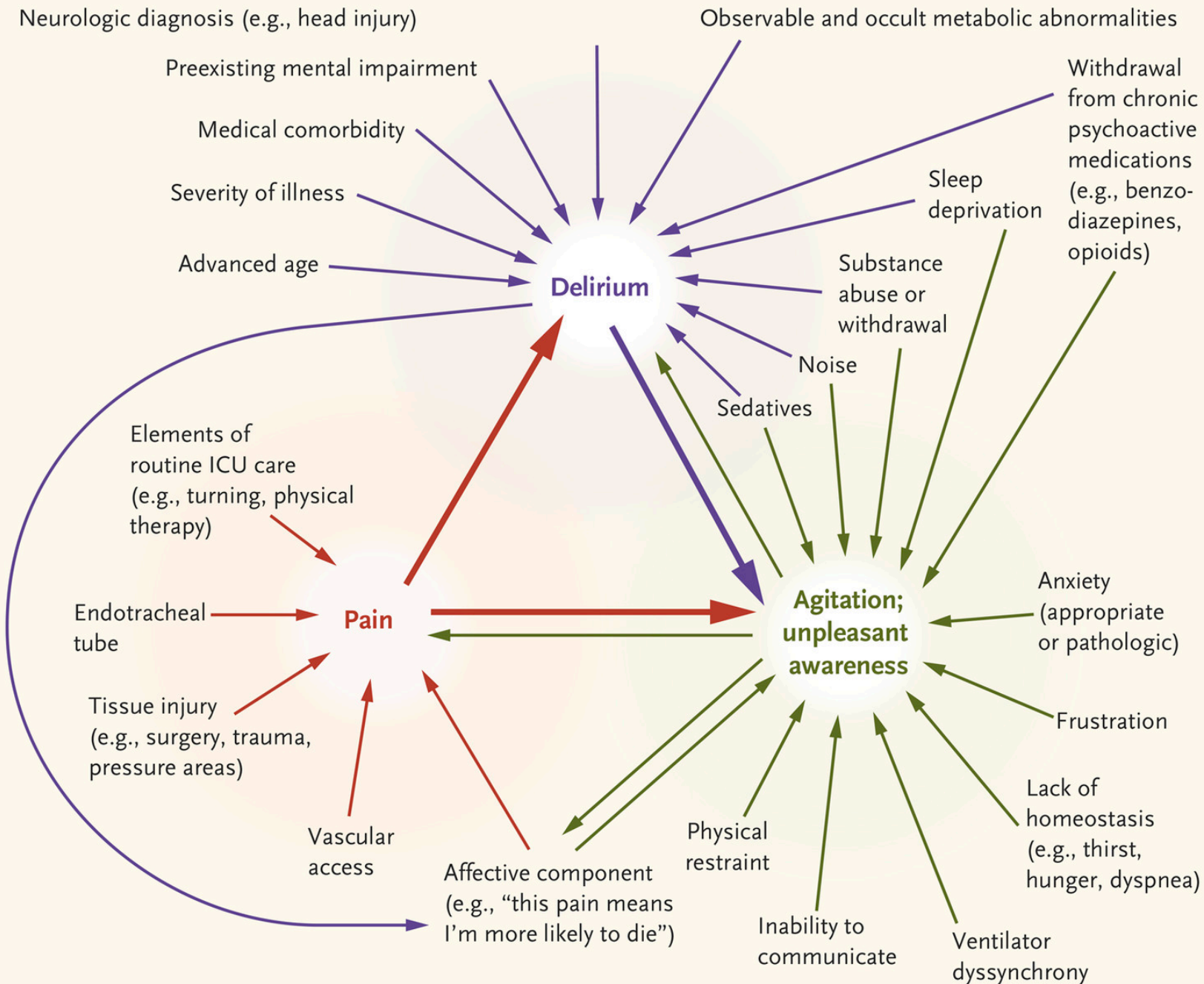


## Patient

- Comfortable
- No anxiety
- No unpleasant recall
- Prompt return to baseline
- No side effects (e.g. PONV)

## Clinician

- Rapid recovery & D/C
- Optimal procedure outcome
- No airway intervention or CV instability
- Ease of sedation
- Consistent sedation
- Ease of procedure
- Ideal conditions for procedure





Online Special Article

# **Clinical Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult Patients in the ICU**

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Céline Gélinas, RN, PhD<sup>5</sup>; Dale M. Needham, MD, PhD<sup>6</sup>; Arjen J. C. Slooter, MD, PhD<sup>7</sup>;  
Pratik P. Pandharipande, MD, MSCI, FCCM<sup>8</sup>; Paula L. Watson, MD<sup>9</sup>; Gerald L. Weinhouse, MD<sup>10</sup>;