TOWARDS THE DEVELOPMENT OF A CORE OUTCOME SET IN PEDIATRIC POST-OPERATIVE PAIN TRIALS

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Why Study Pediatric Post-operative Pain?

- Pain assessment is an important aspect of post-operative patient care (Poobalan 2003)
- Accurate assessment drives pain management decisions such as whether analgesic dose changes are needed or whether changes to the management plan are warranted (Chou 2008)
- Evaluating it in the most consistent way possible across a continuum of care is an important therapeutic goal

Development of Core Outcomes

- Core outcomes are the minimum set of outcomes that patients and professionals agree should be measured in all trials of a certain condition (Williamson et. al.)
- Core outcome sets provide a way of stabilizing outcome domains that can be used in post-operative pain trials
- Aim to facilitate comparison of results across trials and synthesis of results in meta-analyses
- There has been no systematic evaluation of outcomes reported in pediatric post-operative pain trials to provide a foundation for the future development of a core outcome set.
- Key issues to consider in the development of a core outcome set include its scope, the stakeholder groups to involve, choice of consensus method and the achievement of a consensus (Williamson 2012)

Outcome Reporting Bias

- “the results-based selection for publication of a subset of the original measured outcome variables” (Kirkham 2010)
- A high degree of outcome reporting bias has been noted in the literature (Williamson 2014)
- To avoid outcome reporting bias we chose to systematically evaluate the outcomes reported in the trial registry clinicaltrials.gov.

Methods

- Collaborated with a research librarian to gather initial set of trial registries
- Search thread→Trials investigating pain management of post operative pain in pediatric patients.
- Four authors individually screened and validated the preliminary set of gathered trials for eligibility, any discrepancies/duplicates were adjudicated by discussion between the authors
- We consulted several sources when developing the abstraction manual (Page et al., McNair et al.). Results were then coded onto Google Doc.

Methods

- Once abstraction manual was developed the authors extracted the following elements from the registries:

Procedure type	Phase of trail	Study type
Study Design	Sample size	Primary or secondary outcomes
Measurement device	Metric	Method of aggregation

- Two pairs of authors coded the initial set, while subsequently validating the other authors results for accuracy.
- After discrepancies were resolved amongst different coders, AR and JY jointly reviewed all abstracted data from all authors a third time together to ensure the accuracy and integrity of the data for this study

Methods

- Final outcomes were then standardized to improve the consistency of naming→Many outcomes from different studies measured the same thing but worded each outcome differently.
- After the outcomes had been standardized, we placed them into one of twelve broader domains that were developed in conjunction with a board certified anesthesiologist, Dr. Amy Stafford MD

Post-operative Analgesia	Pain Assessment	Unexpected Events	Anesthetics
Quality Measures	Vital Signs	Pharmacological	Recovery
Post-operative time	Morbidity	Intra-operative	Other

Methods

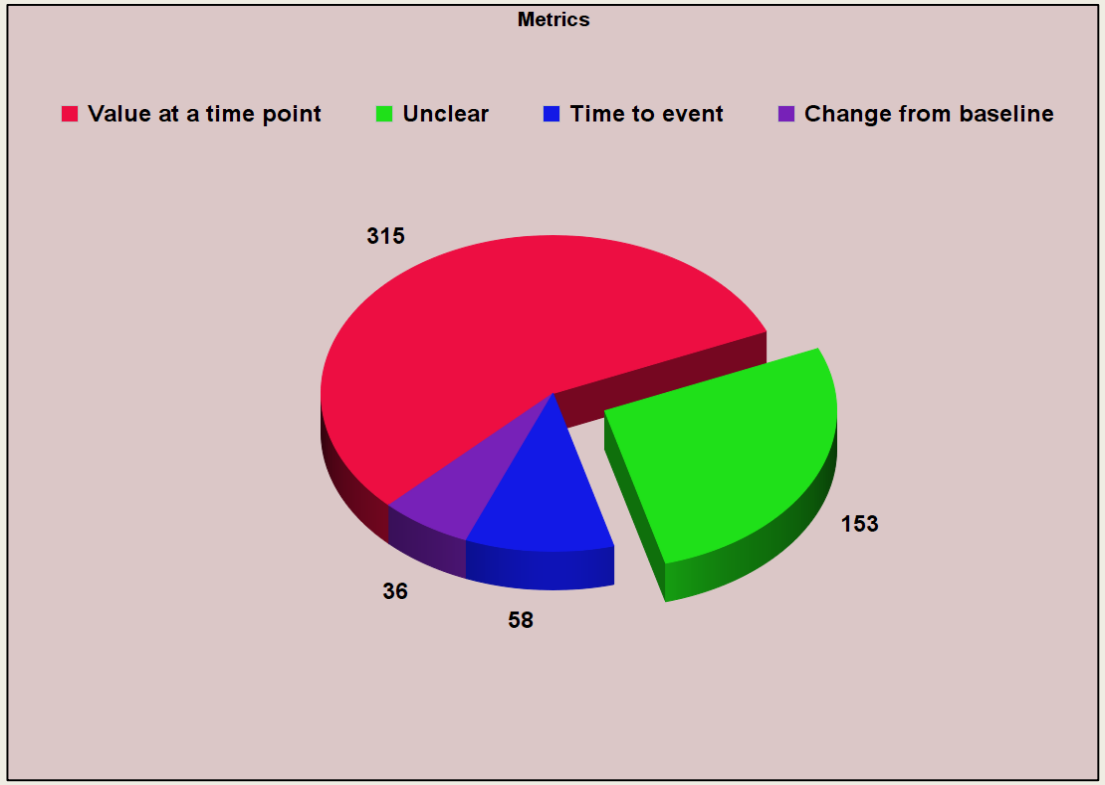
- After data collection and outcome categorization we summarized results using frequencies and percentages for outcomes and Stata 13.1 was used to produce descriptive statistics for study results

Results

- A total of 300 titles and abstracts were identified and screened through clinicaltrials.gov with 135 not meeting research criteria, 14 were excluded for ineligible intervention
- 151 studies were included for qualitative synthesis
- Almost one-half of the trials(*n* = 74, 49%) included for this review were completed. The remaining trials were at various stages, with 35 of those remaining trials in the recruiting stage. The overwhelming majority(n = 138 trials, 91%) were interventions, with the remaining trials either observational epidemiological, or diagnostic accuracy

Results

- As expected, the most commonly reported outcome was some form of pain measurement(n=116, 21%) , followed by total post-operative analgesic dosage(n=67, 12%), and the amount of time to rescue medication(n=20, 4%)
- There was an average of 4 outcomes reported per study, with a range between 1 and 15 outcomes reported per study
- The majority of devices used to describe domains (n=9, 75%) were unclear or unknown
- “Unclear” Metrics comprised more than a ¼ of all outcomes studies



Discussion

- Heterogeneity of reported outcomes creates problems in comparison among separate trials, hindering synthesis of a core outcome set in pediatric post-operative pain
- The obvious lack of complete reporting in clinicaltrials.gov impedes systematic reviewers utilizing the content of the registry while also taking away the usefulness of the registry as a public information database.
- Adequate reporting of outcome measurements could prevent certain biases (i.e. publication bias) in ongoing clinical trials and reviews utilizing clinicaltrials.gov.

Limitations

- Although there is a risk for outcome reporting bias in published literature, the literature needs to be searched in order to get a more complete view of outcomes reported in pediatric post-operative pain
- Subjective nature of pain and differences in developmental status of pediatric patients makes it a difficult topic to study
- The timeframe of when measurements were taken could have an effect on the outcomes produced in the study
- Procedural protocols regarding pain management evolve over time, making pain assessment still more difficult

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