

Pragmatic Comparative Effectiveness Trials and Learning Health Systems in Pain Medicine: Opportunities and Challenges

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Section snippets

Key points

- Large pragmatic effectiveness trials generate evidence for real-world applications of treatment modalities by enrolling a large number of patients at a lower cost; the findings can be generalized to a wider population....
Alteration or waiver of a traditional informed consent discussion is crucial in successful application of large pragmatic effectiveness trials in pain medicine....
Learning health care systems can provide a dynamic and adaptable infrastructure that can facilitate data collection for...

Introduction to pragmatic comparative effectiveness trials

Despite increased available pain therapies, more than 50 to 100 million people in the United States still live with pain and 20 million live with high-impact chronic pain that frequently limits life or work activities.1, 2, 3 We know little about which treatments are best for which patient under their particular circumstances or the efficacy and safety of various treatments over time. There is a lack of empirical evidence regarding the effectiveness of the various approaches to anesthesia...

Application of pragmatic comparative effectiveness trials in pain medicine

Application of large pragmatic effectiveness trials provides multiple opportunities in pain medicine: (1) researchers can investigate more complex treatment modalities or treatment paths while giving the clinicians the flexibility to tailor the treatment to the needs of their patients; (2) this trial design also focuses on outcome measures that are more important to clinicians, for example, disability, social function, quality of life, or even cost-effectiveness instead of a simple pain score:...

Informed consent

The first step in successfully conducting pragmatic effectiveness trials in pain medicine is improving the ability to systematically recruit more patients while minimizing the research burden for study participants and clinicians. The traditional informed consent process can be burdensome for both participants and researchers and thus hamper the streamlined recruitment process. The traditional informed consent discussion involves explaining at least 3 important factors to the potential...

The learning health system and high-quality, real-world data collection

Effective systems to help practitioners integrate relevant measures and monitor patient outcomes have not existed until recently. The United States Institute of Medicine (IOM; now the National Academy of Medicine [NAM]) called for developing learning health care systems. As envisioned by the IOM, a Learning Health System (LHS) leverages an integrated digital infrastructure to provide data-based driven and coordinated care that is available just in time to the clinician and that is centered on...

The Stanford learning health system model and future directions

In recognizing the societal problem of pain, the IOM Relieving Pain In America report called for "greater development and use of patient outcome registries that can support point-of-care treatment decision making, as well as for aggregation of large numbers of patients to enable assessment of the safety and effectiveness of therapies."1 Similarly, in the Health and Human Services National Pain Strategy (Mackey; Co-Chair), the committee stated, "better data are needed to understand the problem..."

Summary

Application of large pragmatic effectiveness clinical trials in pain medicine poses certain unique challenges, considering the lack of more uniform, objective outcome measures. These challenges have limited the number of these trials in our literature. Pain researchers are thinking more creatively to build a better infrastructure of learning health care systems to streamline the informed consent process and embed data collection into routine clinical care. We can then successfully leverage...

Clinics care points

- When reading research papers, we should consider eligibility criteria more carefully to assess if the results can be applied to our patient population....
When reading research papers, we should pay attention to outcome measures and decide if they represent what is important for our clinical practice....

Conflict of interest statement

The authors do not have any conflict of interest about the material discussed in the article....

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