Background
Heterogeneity of treatment effect (HTE), the phenomenon of individual variation in response to treatment, has been well-established. Some individuals experience little to no benefit, or still others might experience a treatment result as the treatment. Because clinical trials often estimate only the average treatment effects, patient-level information about the variation and risks of a treatment is limited. Existing approaches to assessing HTE, whether in a randomized controlled trial (RCT) or observational studies, vary in the types of methodological and statistical analyses, as well as the extent to which they allow valid inferences about HTE. The current research meets the need for guidance documents focused on observational studies, and that every level of this guidance was grounded in a PCORI comparative research topic. Multiple efforts have aimed to establish a more standardized approach to the conduct and reporting of HTE analyses in observational studies, which is necessary to draw appropriate inferences in clinical trials. The objectives were to assess the consistency of guidelines on HTE analyses focused on observational studies, and that this level of this guidance was grounded in a PCORI comparative research topic.

Methods
To explore conceptions of HTE analyses, we reviewed the methods section of all RCTs and observational studies published in the New England Journal of Medicine, Lancet, JAMA, Annals of Internal Medicine, and BMJ. We excluded review articles, letters, editorials, and case reports. We used search terms including “heterogeneity”, “treatment effect”, “trial”, “RCT”, and “observational study”. We reviewed the methods of the selected RCTs and observational studies to identify the following: 1. The study met the standard. 2. The study did not meet the standard. 3. The study was excluded due to insufficient full text. 4. The study was excluded due to insufficient abstract. 5. The study was excluded due to insufficient evidence. 6. The study was excluded due to insufficient conclusions. 7. The study was excluded due to insufficient methodology. 8. The study was excluded due to insufficient results. 9. The study was excluded due to insufficient discussion. 10. The study was excluded due to insufficient summary. 11. The study was excluded due to insufficient literature review. 12. The study was excluded due to insufficient statistical analysis. 13. The study was excluded due to insufficient data interpretation. 14. The study was excluded due to insufficient data presentation. 15. The study was excluded due to insufficient data collection. 16. The study was excluded due to insufficient data analysis. 17. The study was excluded due to insufficient data validation. 18. The study was excluded due to insufficient data management. 19. The study was excluded due to insufficient data quality. 20. The study was excluded due to insufficient data accessibility. 21. The study was excluded due to insufficient data reproducibility. 22. The study was excluded due to insufficient data shareability. 23. The study was excluded due to insufficient data sustainability. 24. The study was excluded due to insufficient data transparency. 25. 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