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Challenges – Damage Done

- IRB review caused significant delay and waste (but less so with each iteration)
- DSMB review caused significant delay and still causes significant waste
Challenges – Ongoing

- Adapting to variability in EHRs
  - Between sites
  - Within sites over time
- Improving follow-up care in supply-constrained systems
- “Slippage” in systematic use of outcome measures
Challenges – Upcoming

- Re-validating outcome specifications after switch to ICD-10
- Re-evaluating sample size in light of:
  - Switch to ICD-10 diagnoses
  - Differing event rates across sites
Lessons

- Need clearer charter and tools for safety monitoring of pragmatic trials
- Need more engagement with EHR vendor(s) at the beginning
- Need guidance for restimating (and re-estimating) sample size in PCTs