Should we be Considering a Different Study Design? Stepped Wedge, Parallel Group or Individual Randomized Designs: Lessons Learned from the TSOS Pragmatic Trial

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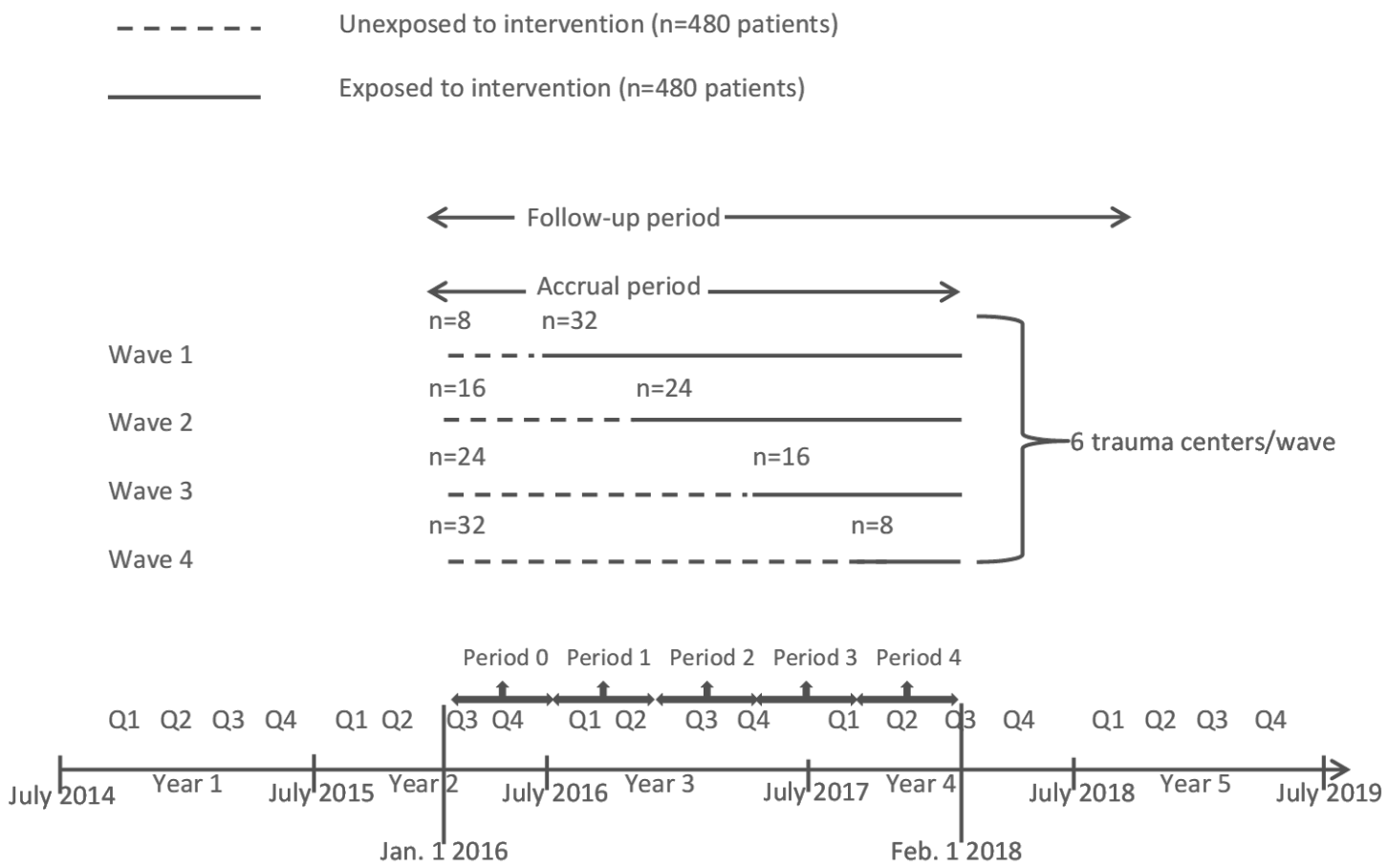
TSOS Research Question

- Will injured patients randomized to a collaborative care intervention demonstrate significant reductions in posttraumatic stress disorder (PTSD) symptoms when compared to injured patients randomized to a usual care control condition?

PICOTS applied to TSOS

- Population: 635 survivors of intentional and unintentional injury
- Intervention: Stepped collaborative care
- Comparator: Usual care control
- Outcomes: PTSD symptoms at baseline, 3-, 6-, & 12-mo. post-injury
- Timing: Intervention delivered first 6-months post-injury
- Setting: 25 US level I trauma centers

TSOS UH3 Stepped Wedge Cluster Randomized Trial Design: Regulatory Pause



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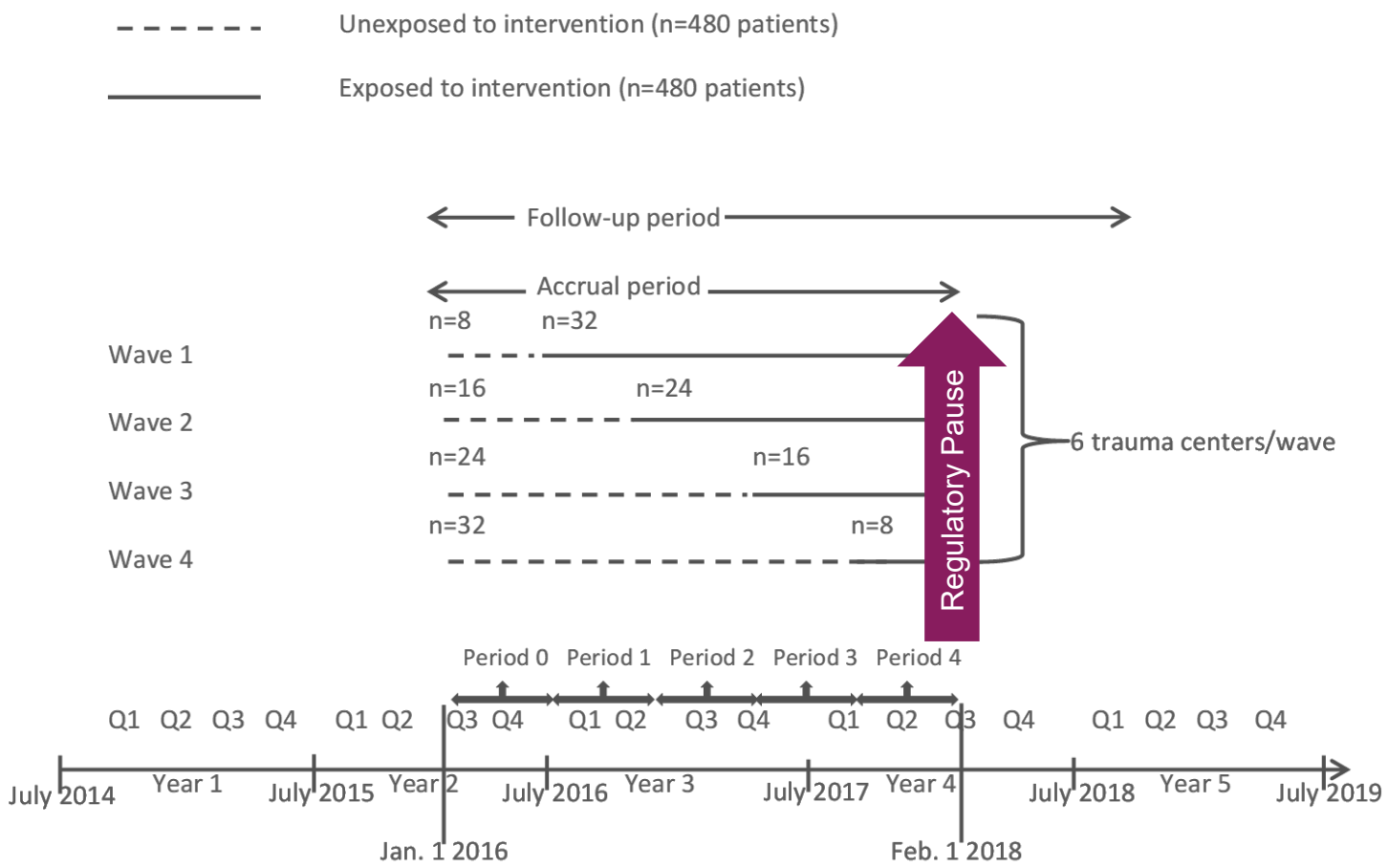

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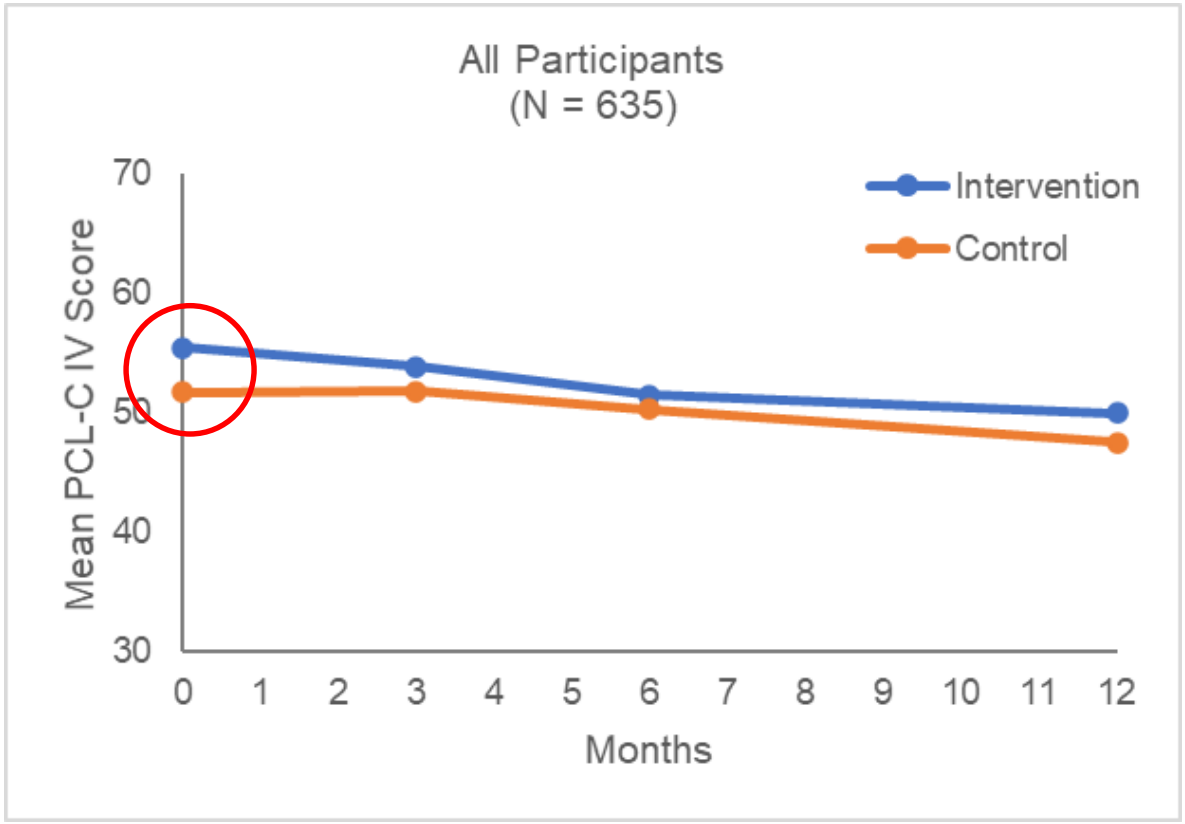
TSOS Enrollment Drift



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TSOS Site Heterogeneity: At Baseline & Differential Over Time

At Baseline

- Violent injury/PTSD
- Admission volume
- Information exchanges/care linkage

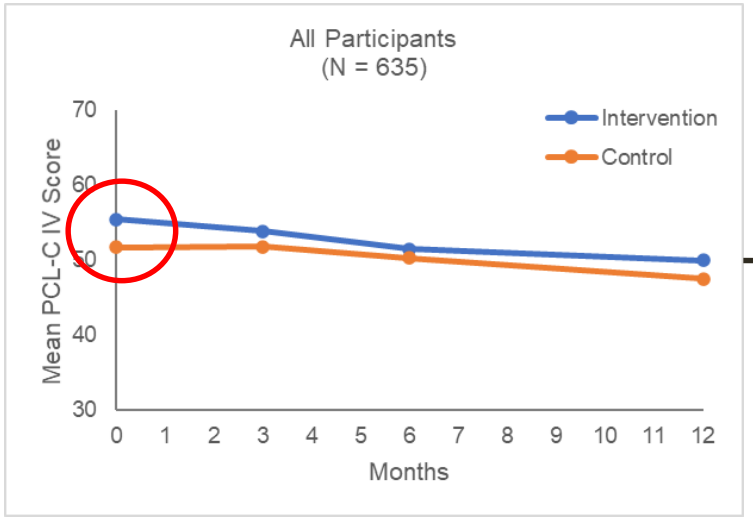
Differential Over Time

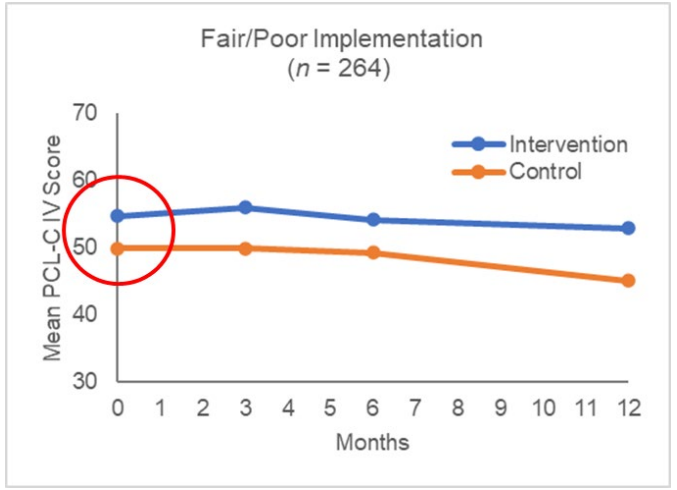
- Recruitment rates
- Regulatory lapses
- Leadership turnover
- Intervention quality

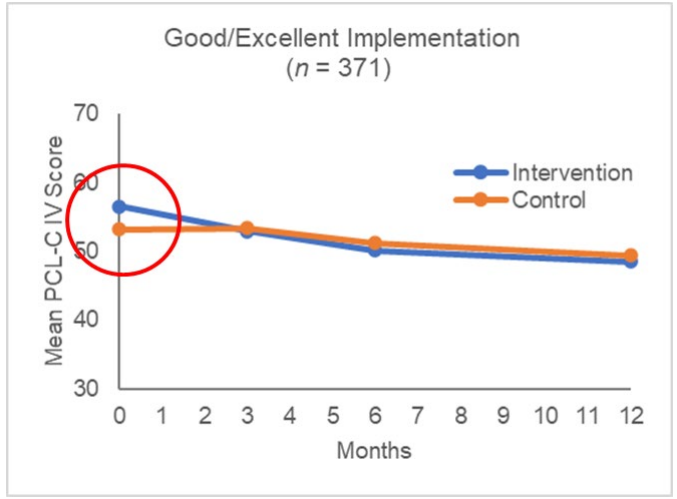
Differential Site Variability Influences Enrollment Drift

Differential Site Variability Over Time

– Recruitment rates
– Regulatory lapses
– Leadership turnover
– Intervention quality







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TSOS Lesson Learned

- Regardless of stepped wedge or parallel group cluster randomized design, site variability considerations favor individual level randomization when possible