Small-Volume Blood Collection Tubes to Reduce Transfusions in Intensive Care: The STRATUS Randomized Clinical Trial

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Research question

In adult ICU patients, does the routine use of tubes that collect less blood for lab testing reduce red blood cell transfusion?

Tubes that *automatically* collect less blood

a.k.a short-draw or soft-draw or low vacuum

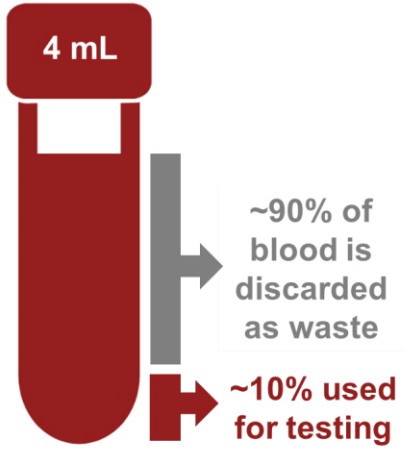
Less vacuum = fill to lower volume

Same cost

Same physical dimensions

Same analyzers

Not used routinely in adults!



Stepped wedge cluster randomized trial

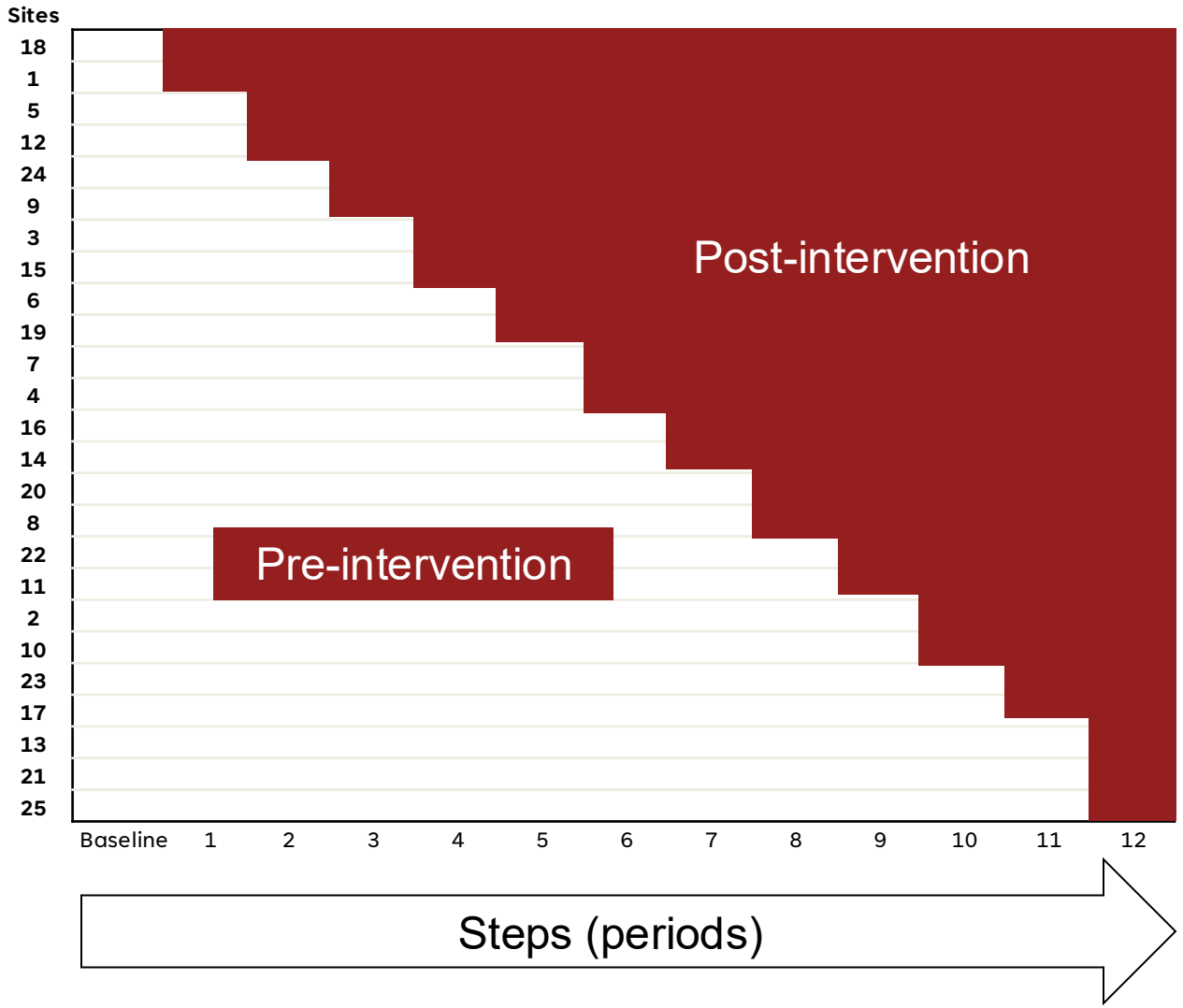
Introduction of new policy or treatment

Intervention introduced in timed “steps”

≥1 sites receive intervention at each step

Timing of switch is randomized

Eventually all sites have intervention

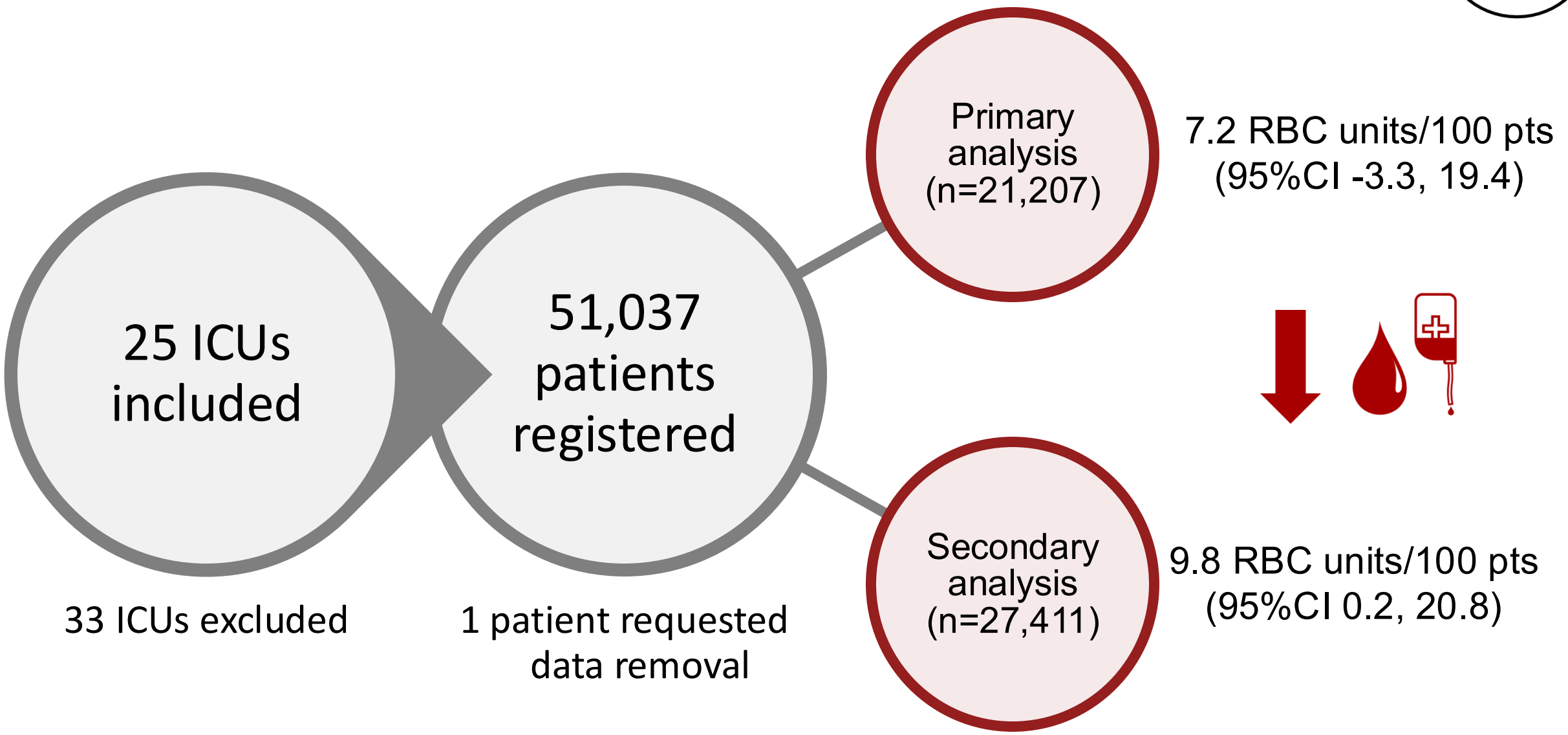


Study design and population

ICU eligibility
Adults
Medical-surgical ICU
≥14 beds
Invasive mechanical ventilation
Standard-volume tubes
Electronic data available

- All patients admitted to ICU
- Waiver of consent
- Electronic data exclusively

Results


25 ICUs included
33 ICUs excluded
51,037 patients registered
1 patient requested data removal
Primary analysis (n=21,207)
7.2 RBC units/100 pts (95%CI -3.3, 19.4)
Secondary analysis (n=27,411)
9.8 RBC units/100 pts (95%CI 0.2, 20.8)

Discussion

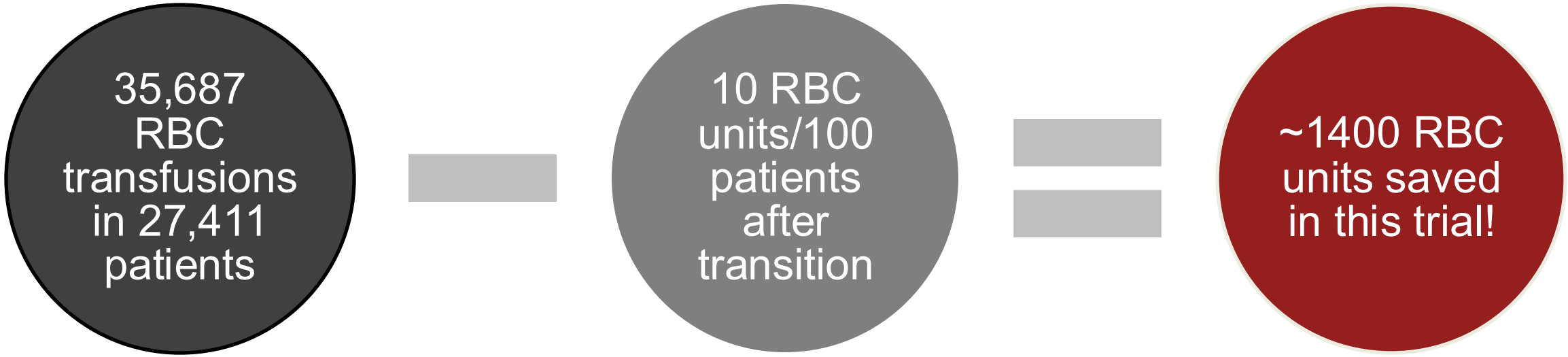
Comparison of two minimal risk standard of care interventions

Exclusively electronic data collection

Not possible without waiver of consent

Posters and letters notified patients/caregivers

Total cost of trial ~$750,000



McMaster University

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HEALTH THROUGH KNOWLEDGE

The effect of Routine Autologous Priming on transfusion requirements after cardiac surgery (TheRAPy)

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Research question

Does an **institutional policy** of routine autologous priming decrease the mean number of units of RCCs transfused **within a center** up to 72 hours after cardiac surgery when compared with an institutional policy of crystalloid priming?

Pragmatic trial about clinical effectiveness, NOT efficacy.

Study interventions

Routine RAP policy

RAP for all patients having cardiac surgery on CPB (minimum 300mL)

Accepted avoidance of RAP in patients with a contraindication, e.g., hemodynamic instability

Expected crystalloid in ≤10%

Crystalloid policy

Crystalloid priming for all patients undergoing cardiac surgery on CPB

Accepted use of RAP in patients with an absolute indication for RAP, e.g., Jehovah's witness

Expected use of RAP in ≤10%

Study design: cluster crossover randomized trial

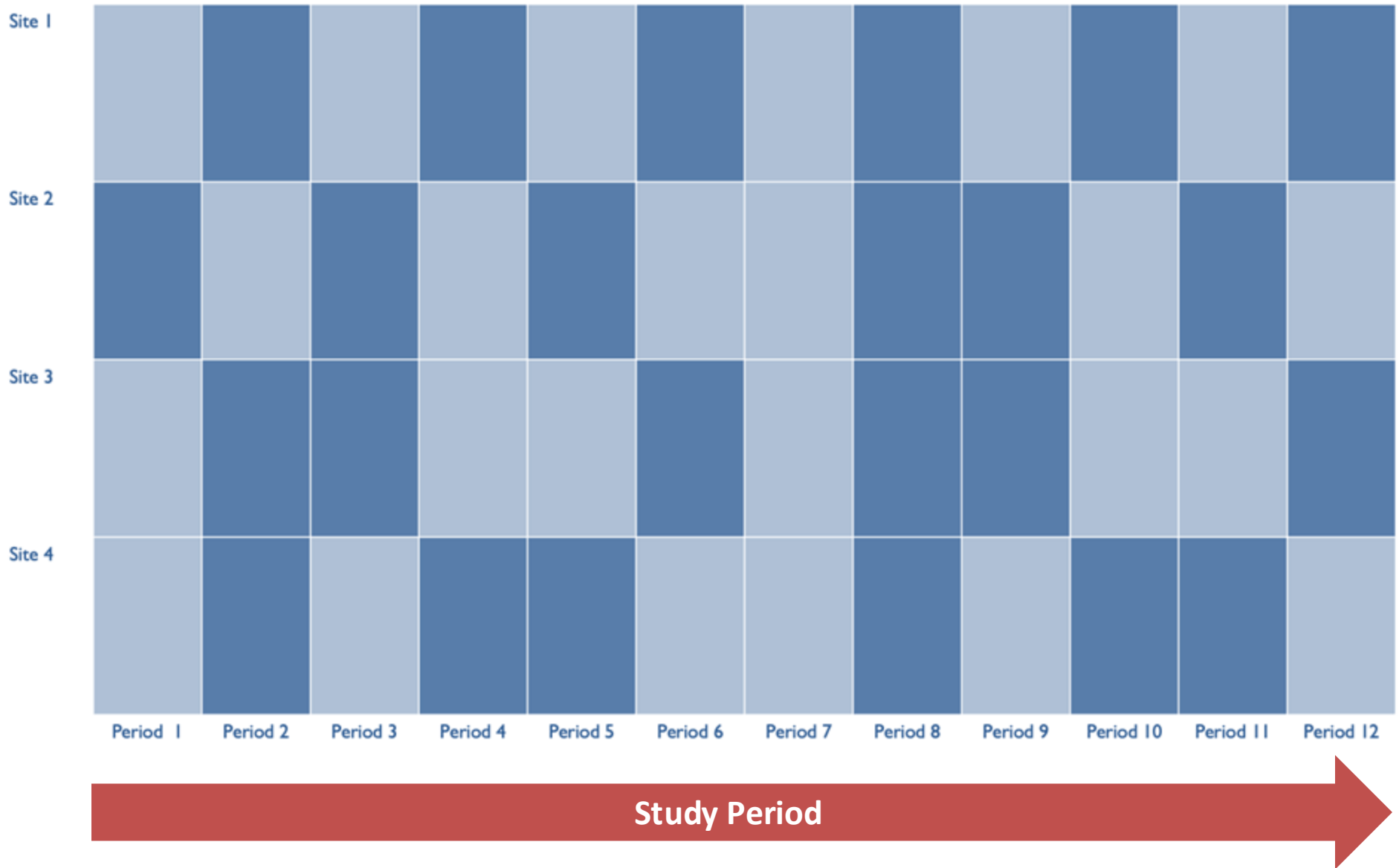
Hospital = cluster

Hospitals randomized instead of patients

Hospitals are randomized to use the two policies in random sequence during 12, 4-week crossover periods

All patients undergoing on-pump cardiac surgery during the study period are included

Example randomization schedule



Waiver of consent

Altered consent required to answer the question

Minimal risk, standard of care interventions

Lack of consent will not adversely affect participant welfare

Information provided to participants

Benefits outweigh risks of not obtaining informed consent