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**Article title:** Development of a risk of bias assessment tool specifically for meta-analysis of trials for surgical site infection

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**Abstract**

**Background:** Surgical site infections (SSIs) occur in up to 20% of post-surgical patients, contributing to higher morbidity, prolonged hospital stays, and increased costs. Current tools for assessing the risk of bias (RoB) in randomized controlled trials (RCTs), such as RoB-2, are not specifically designed for surgical studies. An SSI-specific RoB tool is needed to ensure accurate evaluation of RCTs and improve the reliability of meta-analyses focused on SSI prevention.

**Method:** A four-stage consensus process involving international experts in SSI trials, including surgeons, statisticians, and methodologists, was undertaken to develop an adapted SSI-specific RoB-2 tool. Experts from organizations such as the NIHR Global Health Research Unit and the Royal College of Surgeons contributed to refining the tool. The process identified key domains relevant to SSIs, with a focus on maintaining essential quality assessment criteria.

**Results:** The final SSI-specific RoB-2 tool includes eight essential domains, with additional adaptation from the original Cochrane RoB-2 tool. Two domains—blinding of patients and surgeons—were categorized as desirable but not essential, as they are often impractical in SSI trials. The new tool provides a more focused assessment framework tailored to SSIs.

**Conclusion:** The SSI-specific RoB-2 tool fills a critical gap in evaluating RCTs in surgical research. Its application can improve the quality of future trials and meta-analyses, guiding better clinical practice and policy decisions for SSI prevention and management.