What Is the Quality of Reporting of Studies of Interventions to Increase Compliance with Antibiotic Prophylaxis?

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BACKGROUND: Despite studies reporting successful interventions to increase antibiotic prophylaxis compliance, surgical site infections remain a significant problem. The reasons for this lack of improvement are unknown. This review evaluates the internal and external validity of quality improvement studies of interventions to increase surgical antibiotic prophylaxis compliance.

STUDY DESIGN: Three investigators independently performed systematic literature searches and selected eligible studies that evaluated interventions to improve perioperative antibiotic prophylaxis timing, type, and/or discontinuation. Studies published before the Surgical Infection Prevention project inception in 2002 were excluded. Each study was assessed based on modified criteria for evaluating quality improvement studies (Standards for Quality Improvement Reporting Excellence) and for facilitating implementation of evidence into practice (Reach-Efficacy-Adoption-Implementation-Maintenance).

RESULTS: Forty-six articles met inclusion criteria; 93% reported improvement in antibiotic prophylaxis compliance. Surgical site infections were evaluated in 50% of studies and 65% reported an improvement. Less than 5% of studies used randomization, allocation concealment, or blinding. Nine percent of studies described efforts to minimize bias in the design results and analysis and 13% described a sample size calculation. Approximately one-third of studies described participant adoption of the intervention (26%), factors affecting generalizability (33%), or implementation barriers (37%). Most studies (80%) used multiple interventions; no single intervention was associated with change in compliance. Studies with the lowest baseline compliance showed the greatest improvement, regardless of the intervention(s).

CONCLUSIONS: The methodology and reporting of quality improvement studies on perioperative antibiotic prophylaxis is suboptimal, and factors that would improve generalizability of successful intervention implementation are infrequently reported. Clinicians should use caution in applying the results of these studies to their general practice. (J Am Coll Surg 2013;217:770–779. © 2013 by the American College of Surgeons)

Surgical site infections (SSIs) are the second most common health care acquired infections and result in significant increases in length of stay, hospital readmissions, costs, and resource use.[1,2] The Surgical Care Improvement Project (SCIP) recommends multiple evidence-based measures to reduce SSIs, including appropriate timing, spectrum, and discontinuation of antibiotics.[3,4] Despite high quality evidence that antibiotic prophylaxis is effective across types of surgery and baseline risks,[5] the impact of SCIP on SSIs has been disappointing.[6-10]

Since the institution of the Surgical Infection Project in 2002, and subsequently of SCIP in 2006, studies have been contradictory with regard to the effect of interventions to increase antibiotic prophylaxis compliance on SSIs. One possible explanation is that these studies have poor internal validity due to methodologic flaws such as selection bias, confounding by temporal trends, and regression to the mean (whereby outlying values naturally trend toward the average over time).[11,12] Alternatively,

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Abbreviations and Acronyms
QI = quality improvement
RE-AIM = Reach-Efficacy-Adoption-Implementation-Maintenance
SCIP = Surgical Care Improvement Project
SQUIRE = Standards for Quality Improvement Reporting Excellence
SSI = surgical site infection

quality improvement (QI) interventions that are effective in a highly controlled trial may not work in the "real world." The effectiveness of QI strategies is considered to be context-sensitive, that is, dependent on local factors. So, the results of QI studies may have poor external validity, meaning they are not generalizable. In addition, the implementation of SCIP measures may have been inadequate. Implementation fidelity, or the performance of an intervention such that all aspects are carried out as intended, may be suboptimal.[13]

In 2008, the SQUIRE (Standards for Quality Improvement Reporting Excellence) guidelines were published,[14] similar to the CONSORT (Consolidated Standards of Reporting Trials) guidelines for randomized trials.[15] These guidelines address issues that contribute to internal and external validity. In addition to SQUIRE, there are different models and frameworks for evaluating implementation; one such model is RE-AIM, which stands for Reach, Effectiveness, Adoption, Implementation, and Maintenance. This is a tool that provides information about external validity and assists in the translation of evidence into practice.[16]

The purpose of this study was to evaluate the reporting of internal and external validity of studies evaluating interventions for implementing 1 or more of the SCIP antibiotic prophylaxis guidelines using criteria derived from SQUIRE and RE-AIM. We hypothesized that few studies of QI interventions to improve surgical antibiotic prophylaxis adhere to SQUIRE reporting guidelines or describe the adequacy of implementation of these interventions.

METHODS

Three investigators (SML, URP, LSK) independently performed a search using PubMed from January 1, 2002 to July 4, 2012. They selected studies written in English that evaluated interventions to improve compliance with antibiotic prophylaxis guidelines correlating to SCIP-1 (antibiotic administration 1 hour before incision), SCIP-2 (correct antibiotic type based on case type), and SCIP-3 (discontinuation of prophylactic antibiotics with 24 hours after surgery stop time or 48 hours in cardiac cases). Studies were included regardless of the type of surgical or gynecologic procedure. Exclusion criteria included studies published before 2002, the start of the Surgical Infection Prevention project; surveys, systematic reviews, meta-analyses, editorials, and large database studies; and studies that evaluated compliance with antibiotic prophylaxis guidelines but did not describe a specific intervention. Each study was reviewed for inclusion by 2 authors, and a third author resolved disagreements.

Articles that met inclusion criteria were reviewed by 2 authors each. Components of SQUIRE and RE-AIM that evaluated internal and external validity were selected based on author consensus. These components were included on a standardized data collection sheet and used to evaluate each article (Tables 1 and 2).[14,16,17] Data on the rates of compliance with each antibiotic prophylaxis measure and SSIs before and after the intervention were recorded for each study when available.

RESULTS

Results of search strategy

A total of 971 articles were identified, of which 46 (4.7%) met inclusion criteria (Table 3). Figure 1 shows the flowchart of included and excluded studies. The majority of studies were from North America (n = 31, 67%). The remainder were from Europe (n = 8, 18%), Asia (n = 5,

Table 1. Adherence to SQUIRE Guidelines[14] Relating to Internal Validity among the 46 Included Studies

Guideline	n	%
Methods		
Described study design	42	91
Described use of blinding or why blinding could not be used	2	4
Described efforts to minimize bias in design results and analysis	4	9
Described statistical analysis plan	36	78
Described sample size calculation	6	13
Data collected by specially trained staff	24	52
Described participant flow	4	9
Used randomization	1	2
Used allocation concealment	1	2
Accounted for outliers, missing data, and excluded data	13	28
Discussion		
Described efforts made to minimize study limitations	9	20
Described sources of bias	16	35
Described study limitations	35	76
Described study strengths	39	85

RE-AIM, Reach-Efficacy-Adoption-Implementation-Maintenance; SQUIRE, Standards for Quality Improvement Reporting Excellence.