

# The Effect of a Quality Improvement Collaborative to Improve Antimicrobial Prophylaxis in Surgical Patients

## A Randomized Trial

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**Background:** Quality improvement collaboratives are used to improve health care quality, but their efficacy remains controversial.

**Objective:** To assess the effects of a quality improvement collaborative on preoperative antimicrobial prophylaxis.

**Design:** Longitudinal cluster randomized trial, with the quality improvement collaborative as the intervention.

**Setting:** United States.

**Participants:** 44 acute care hospitals, each of which randomly sampled approximately 100 selected surgical cases (cardiac, hip or knee replacement, and hysterectomy) at both the baseline and remeasurement phases.

**Intervention:** All hospitals received a comparative feedback report. Hospitals randomly assigned to the intervention group ( $n = 22$ ) participated in a quality improvement collaborative comprising 2 in-person meetings led by experts, monthly teleconferences, and receipt of supplemental materials over 9 months.

**Measurements:** Change in the proportion of patients receiving at least 1 antibiotic dose within 60 minutes of surgery (primary outcome) and change in the proportions of patients given any antibiotics, given antibiotics for 24 hours or less, given an appropriate drug, and given a single preoperative dose and receipt of any of the 5 measures (secondary outcome).

**Results:** The groups did not differ in the change in proportion of patients who received a properly timed antimicrobial prophylaxis dose ( $-3.8$  percentage points [95% CI,  $-13.9$  to  $6.2$  percentage points]) after adjustment for region, hospital size, and surgery type. Similarly, the groups did not differ in individual measures of antibiotic duration; use of appropriate drug; receipt of a single preoperative dose; or an all-or-none measure combining timing, duration, and selection.

**Limitations:** Hospitals volunteered for the effort, thereby resulting in selection for participants who were motivated to change. Implementation of the surgical infection prevention measure reporting requirements by the Centers for Medicare & Medicaid Services and The Joint Commission may have motivated improvement in prophylaxis performance.

**Conclusion:** At a time of heightened national attention toward measures of antimicrobial prophylaxis performance, the trial did not demonstrate a benefit of participation in a quality improvement collaborative over performance feedback for improvement of these measures.

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\*For members of the TRAPE Study Group, see the **Appendix**, available at www.annals.org.

Increased use of comparative clinical performance indicators has led to greater interest in the effectiveness of improvement strategies. “Audit and feedback,” the provision of comparative performance measure data, is a well-known strategy for hospital quality improvement, with demonstrated efficacy (1–3). Although comparative feedback is useful for establishing how well an individual or organization performs relative to peers, feedback reports typically do not provide detailed information on what aspects of the process need to be changed. Feedback can stimulate the

desire to change but rarely provides the means (such as skills, tools, and strategies) to implement the change. Quality improvement collaboratives are a more recent innovation; they bring together groups of practitioners from different health care organizations in a series of meetings to share and implement practical solutions for rapid improvement of processes for which the gap between knowledge and practice in health care is substantial (4, 5). Although the collaborative learning model has been applied widely across a variety of topics, some consider the effectiveness of this model to be unproven and based largely on shared beliefs and anecdotal affirmations. The efficacy of collaboratives has yet to be firmly established in controlled studies (6–9).

Errors in the timing, selection, and duration of antimicrobial prophylaxis can result in preventable surgical site infections (10). The salience of appropriate prophylaxis has increased dramatically since it became a priority topic in the Medicare quality improvement program in 2002. The Centers for Medicare & Medicaid Services (CMS)–sponsored National Surgical Infection Prevention (SIP) Project was designed to promote appropriate selection and timing

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Appendix

Appendix Tables

Appendix Figure

Conversion of graphics into slides

of prophylactic antimicrobials to decrease the morbidity and mortality associated with postoperative surgical site infections (11). Quality improvement collaboratives have been used to promote antimicrobial prophylaxis process improvement. For example, to “jump-start” hospitals toward preventing surgical infection, the National SIP Project began with the National SIP Collaborative (12).

Because relatively few studies have rigorously evaluated quality improvement strategies targeting institutions rather than individuals (13–18), we performed a cluster randomized trial to determine whether hospitals receiving comparative feedback reports plus instruction on and support for process change through a quality improvement collaborative achieve greater improvements in the antimicrobial prophylaxis process than hospitals receiving feedback reports alone. The TRAPE (Trial to Reduce Antimicrobial Prophylaxis Errors) was designed to address this gap in evidence-based quality improvement research.

## METHODS

### Design Overview

The TRAPE was part of the Project to Monitor Indicators, an ongoing collaboration among the Society for Healthcare Epidemiology of America, the Centers for Disease Control and Prevention, and The Joint Commission. The goal of the Project to Monitor Indicators is to create an intellectual infrastructure to support the effective use, development, understanding, and continuous improvement of clinical quality indicators through coordinated study by hospital epidemiologists (19).

The TRAPE was a cluster randomized trial with the hospital as the unit of randomization and intervention. The randomized groups received a comparative feedback report only or a feedback report plus enrollment in a quality improvement collaborative (Figure). The collaborative targeted infection control and surgical staff and focused on effective strategies for improving the timing of antimicrobial prophylaxis administration before surgery. All hospitals received a customized comparative feedback report of 5 performance measures derived from baseline data collected from May through November 2003. Sites were then randomly assigned to participate in the collaborative intervention or to receive feedback only. The 9-month intervention continued through January 2005. Remeasurement data were collected from February through July 2005. All sites received a second customized report after the remeasurement period that showed change within a hospital over time.

### Outcomes and Follow-up

The primary outcome measure was the change in the hospital's proportion of patients receiving appropriately timed prophylaxis, defined as the proportion of patients who received at least 1 prophylaxis dose administered within 60 minutes before incision (unless the drug was vancomycin, in which case the cutoff was 120 minutes).

### Context

Quality improvement collaboratives are widely used to promote safety and quality initiatives.

### Contribution

This cluster randomized trial demonstrated that a quality improvement collaborative provided no added benefit over feedback alone for improving the quality of preoperative antimicrobial prophylaxis.

### Caution

Hospitals volunteered and may have already been motivated to improve their practices. Mandatory reporting requirements may also have motivated improvements independent of the study interventions.

### Implication

Quality improvement collaboratives are not necessarily effective ways to promote quality improvement.

—The Editors

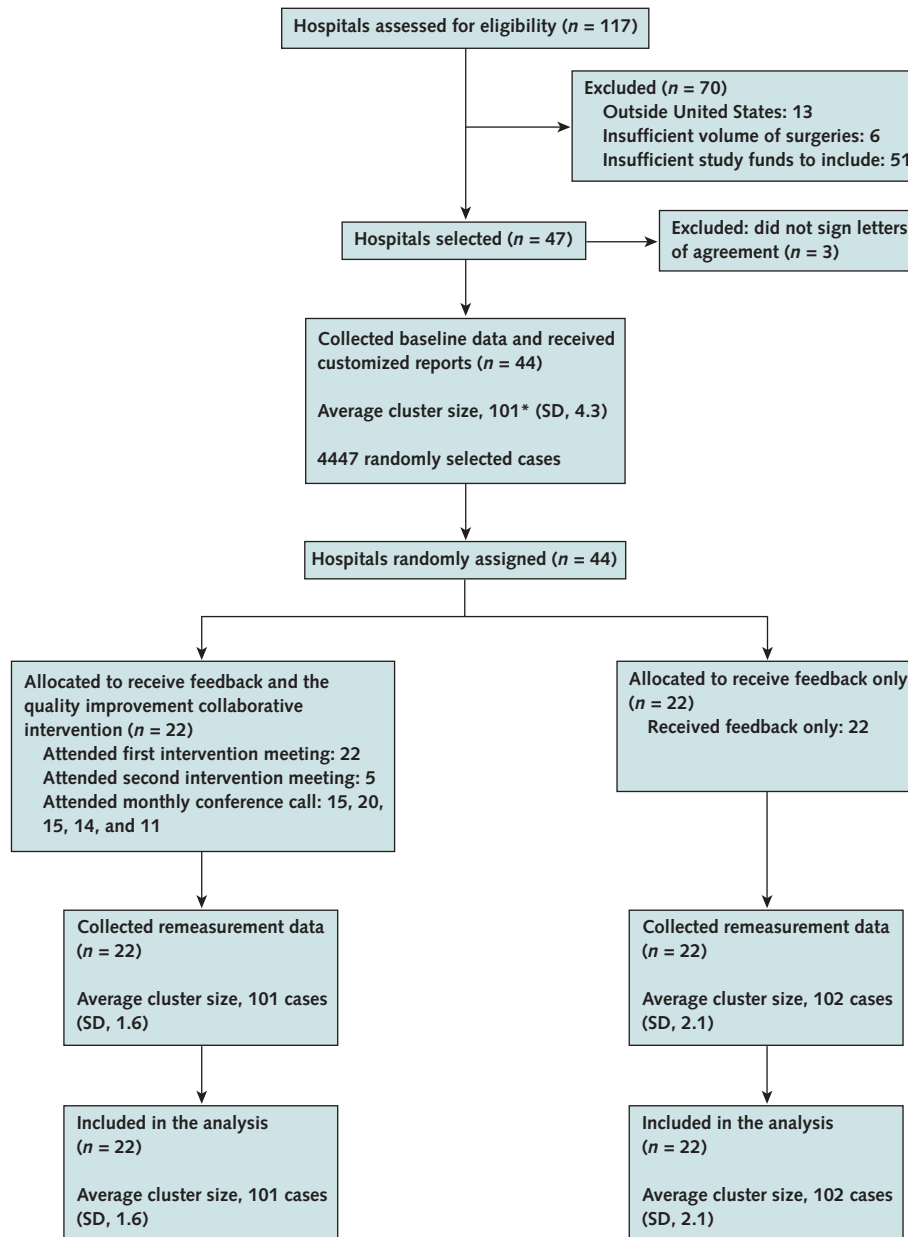
When more than 1 preoperative antibiotic was given, timing was based on the antibiotic given closest to the time of incision.

Secondary outcome measures were the hospital's proportion of patients who received any prophylaxis, the proportion for whom duration of antibiotic prophylaxis was no longer than 24 hours after surgical end time, the proportion who received a drug that was consistent with established recommendations, and the proportion who received a single dose before incision. The single dose measure was developed for this study to gauge the extent to which multiple antibiotic doses were given preoperatively either to ensure adequate coverage or to ensure that at least 1 dose was given within the recommended time frames. Multiple doses are generally not recommended because they can have the unintended consequence of contributing to the problem of antimicrobial resistance. Table 1 shows the numerator and denominator for each measure. Post hoc, we calculated an all-or-none measure that identified patients who received all recommended care measures according to the timing, selection, and duration indicators, which were the 3 indicators for which authoritative recommendations were available at the time of intervention.

### Setting and Participants

In fall 2002, hospitals were recruited through a mailing to members of the Society for Healthcare Epidemiology of America and electronic announcements. One hundred seventeen hospitals formally expressed interest. Forty-seven sites were randomly selected for participation in 2 size strata according to average daily census (<300 and ≥300 patients). Forty-four sites returned a letter of agreement to participate in the 4-year study, which described detailed expectations for sites and study personnel and was cosigned by hospital and study leadership.

Figure. Participation in TRAPE (Trial to Reduce Antimicrobial Prophylaxis Errors).



\*Number of randomly selected cases within hospitals (cluster size) was set by design to be approximately 100 at both the baseline and remeasurement data collection periods.

The intervention targeted staff who were responsible for antimicrobial prophylaxis among patients undergoing cardiac surgery (primarily coronary artery bypass graft and valve replacement), hip and knee replacement (excluding revision), and hysterectomy (both vaginal and abdominal), because widely used prophylaxis guidelines were available for these procedures at the beginning of the study. Individual surgical cases within hospitals were selected for inclusion through an automated random-selection process incorporated into the data collection software. On the basis of anticipated surgical volumes for each surgery type, the

data entry system directed the hospital to collect information on every  $n$ th surgical case after a random start at the beginning of every month. The proportion of cases selected was recalculated at the beginning of each month on the basis of the projected number of eligible cases and progress toward the study goals.

Surgical cases were considered eligible for inclusion in the analysis if 1) the case was the first surgery for this patient during this admission, 2) there was no evidence of infection between the time of admission and incision, and 3) incision time and time of antimicrobial prophylaxis ad-

ministration were documented when an antibiotic was given.

### Data Collection

Two staff members from each hospital received initial training on the data collection protocol, software, and data submission processes during an in-person meeting at the study coordinating center. Prespecified process-of-care items were collected for each surgical case, including method of ordering the drug; professional background of the person who ordered it; location of the patient when drug was administered; and professional background of the person who administered the drug. Before baseline data collection, sites abstracted and submitted test cases for quality assurance. Before remeasurement, all sites participated in a refresher training teleconference. Project staff provided additional in-person training when hospital staff turnover was extensive. Data quality and completeness were assured through ongoing review by project staff and follow-up with sites.

The validity of documented administration and incision times was verified in a substudy conducted at 25 hospitals where actual antibiotic administration and surgical incision times were observed by an independent observer and compared with documented times. The consistency in the timing indicator between the 2 methods was high ( $\kappa = 0.93$ ).

All sites recorded hospital-specific improvement activities on a separate activity log data collection form from January 2004 to June 2005. The log form was developed to document specific actions that each site undertook or events that occurred which were likely to influence the prophylaxis process. Sites were instructed to document all potentially relevant improvement activities or strategies and events and whether they were likely to have a positive influence, negative influence, or unpredictable effect on the prophylaxis process.

### Randomization and Intervention

To ensure comparability in size and baseline performance between the intervention and feedback-only groups, we stratified the 44 hospitals by average daily census, then paired them according to their performance on the timing

indicator. After completion of the baseline phase, the study statistician, who was blinded to hospital identification, used a computerized random-number generator to randomly allocate 1 hospital from each pair to the intervention group.

The group collaborative intervention consisted of promotion of specific process changes likely to reduce errors in timing (elimination of orders for “on-call” administration and development of prewritten order sets); 2 in-person meetings led by clinical and improvement experts; monthly telephone calls to share effective strategies, obstacles, and successes; and optional site visits by members of the steering committee. At the first meeting, led by a national expert in surgical antimicrobial prophylaxis and a certified quality improvement expert, hospitals discussed promising strategies and used their baseline report to determine which measures to improve. At the second meeting 8 months later, 2 organizational change experts presented strategies for overcoming obstacles and each site gave a 10-minute presentation describing the effectiveness of their attempted improvement strategies. Monthly 90-minute conference calls highlighted issues and successes experienced by sites. Project staff also shared guidelines, forms, and literature reviews among intervention hospitals.

During the intervention phase, sites that were randomly assigned to the feedback-only group did not receive any supporting materials or guidance from project staff. In late 2005, after completing remeasurement data collection, sites in the feedback-only group attended a meeting to receive materials from the intervention, share their experience, and review initial results.

### Statistical Analysis

Numerator and denominator specifications for calculating performance measure rates (available on request) were developed by a clinical indicators workgroup consisting of experts in hospital epidemiology, quality measurement, and statistics and were consistent with nationally authoritative recommendations at the time of implementation. These specifications were used to program the algorithms for measure calculations in SAS, version 9.1.3 (SAS Institute, Cary, North Carolina). A priori power calcula-

**Table 1. Performance Measures of the Antimicrobial Prophylaxis Process**

Prophylaxis Measure	Numerator	Denominator
Timing* (primary outcome measure)	Patients who received $\geq 1$ prophylaxis dose within the recommended time frame	All eligible surgical patients
Receipt	Patients who received $\geq 1$ antibiotic dose before surgery end time	All eligible surgical patients
Duration*	Patients who received prophylaxis for $\leq 24$ hours after surgery end time	All eligible patients who received prophylaxis
Selection*	Patients who received the recommended drug according to national guidelines	All eligible patients who received prophylaxis
Single preoperative dose	Patients who received prophylaxis before incision and received a single antibiotic dose for prophylaxis	All eligible patients who received prophylaxis before incision

\* Measure specifications were consistent with recommendations of the National Surgical Infection Prevention Project initiative (18).

**Table 2. Baseline Characteristics of Participating Hospitals and Types of Surgery**

Characteristic	Intervention Group, n (%)	Feedback-Only Group, n (%)
<b>Hospital</b>		
Average daily census*		
≤300 patients	11 (50)	11 (50)
>300 patients	11 (50)	11 (50)
Teaching status		
Teaching	16 (73)	17 (77)
Nonteaching	6 (27)	5 (23)
Region		
Northeast	4 (18)	7 (32)
South	10 (45)	5 (23)
Midwest	5 (23)	6 (27)
West	3 (14)	4 (18)
<b>Type of surgery†</b>		
Cardiac	859 (39)	790 (35)
Hip/knee	731 (33)	964 (43)
Hysterectomy	623 (28)	480 (22)

\* Sites were paired on the basis of performance on the timing indicator and stratified by average daily census (cutoff of 300 patients) before randomization.

† 2212 patients at intervention hospitals and 2234 patients at feedback-only hospitals were included.

tions determined that 40 hospitals sampling 100 cases per measurement period would give 80% power to detect a 15% difference in the pre–post change between groups in the timing of prophylaxis based on an intraclass correlation coefficient of 0.15, estimated from an earlier study of intensive care unit process improvement ( $\alpha = 0.05$ , 2-tailed test) (20). In SAS-callable SUDAAN, version 9.0.2 (RTI, Research Triangle Park, North Carolina), we used conditional margins to compare the change in the risk for an appropriate prophylaxis outcome by testing a treatment group–by–time interaction and adjusting for type of surgery, hospital size, and region by using PROC RLOGIST and specifying the jackknife design. In the analysis of process changes, several process categories were infrequently endorsed; as a result, we could not adjust for covariates. For consistency, covariates were omitted from all models of process change.

### Role of the Funding Source

The study was funded by a grant from the Agency for Healthcare Research and Quality, with additional support from the Centers for Disease Control and Prevention. The sponsors were not directly involved in any phases of the project. The protocol was approved by institutional review boards affiliated with the participating hospitals, the University of Tennessee Memphis, Wake Forest University, Centers for Disease Control and Prevention, and The Joint Commission. Data use agreements were established with each site to ensure compliance with the 1996 Health Insurance Portability and Accountability Act requirements.

## RESULTS

All 44 hospitals abstracted at least 100 eligible cases in both the baseline and remeasurement phases (Figure). The total number of eligible surgical cases included in the analysis was 4447 at baseline and 4463 at remeasurement; the mean number of cases per site was 101 (SD, 4.3) at baseline and 101 (SD, 1.9) at remeasurement. Hospitals in the intervention and feedback-only groups were similar at baseline in terms of organizational and patient characteristics (Table 2).

All hospitals randomly assigned to the intervention group participated in the intervention phase activities as planned. Twenty-two sites attended the first meeting, and 20 attended the second.

Project staff visited 2 sites to assess data collection accuracy and 1 site for training purposes. All sites participated in at least 1 of the 5 conference calls, with an average of 15 hospitals (range, 11 to 20 hospitals) per call. The professional backgrounds of participants in the monthly calls included hospital epidemiology, infection control, and pharmacy.

As shown in Table 3, the adjusted change in the proportion of patients in feedback-only hospitals who received a properly timed dose of antimicrobial prophylaxis was 10.5 percentage points (95% CI, 2.7 to 18.3 percentage points). The intervention group hospitals also improved by 6.7 percentage points (CI, 0.2 to 13.1 percentage points). The degree of improvement differed little between the 2 groups (–3.8 percentage points [CI, –13.9 to 6.2 percentage points]). The proportion of patients receiving prophylaxis for no more than 24 hours after the end of surgery increased in both groups, but the groups did not differ for this measure. The proportion of patients receiving prophylaxis or a recommended drug was already high at baseline, and modest improvements were seen in both groups. The all-or-none measure of correct antibiotic timing, selection, and duration also improved markedly in both groups, but the between-group difference in the extent of improvement was not substantial.

We examined the performance measures for each type of surgery (Appendix Table 1, available at [www.annals.org](http://www.annals.org)). The pattern of response was broadly similar to the overall results, and between-group differences were small. The all-or-none measure improved markedly among cardiac surgeries in the intervention group (21.2 percentage points [CI, 10.3 to 32.2 percentage points]) and among hip or knee surgeries in both groups (17.2 percentage points [CI, 6.7 to 27.7 percentage points] in the feedback-only group and 26.8 percentage points [CI, 12.1 to 41.5 percentage points] in the intervention group). This improvement was largely due to an increased proportion of patients not receiving an extended course of postoperative antibiotics.

### Antimicrobial Prophylaxis Process

Several changes were made over time to the process of ordering and administering prophylaxis (Table 4). The physical source of the order changed little in the intervention group, but a tendency toward greater use of partially preprinted orders was seen in the feedback-only group (17.8–percentage point increase [CI, 5.0 to 30.5 percentage points]).

Roughly one half of the antibiotic orders were written by the surgeon in both groups and at both time points. The proportion of orders in which the prescribing individual could not be identified decreased markedly in both groups, indicating improved documentation. There were few between-group differences; however, orders written by physician assistants, nurse practitioners, or pharmacists increased at the feedback-only sites (4.0–percentage point increase [CI, 0.1 to 8.0 percentage points]). Most doses were administered in 2 locations at both baseline and re-measurement: the inpatient operating suite or the inpatient preoperative suite. The proportion of cases receiving prophylaxis in the inpatient operating suite increased by 14.9 percentage points (CI, 2.9 to 26.9 percentage points) in the intervention group, the proportion receiving prophylaxis in the outpatient operating suite decreased in the feedback-only group, and both groups showed decreases in the administration of prophylaxis in the intensive care unit or on the floor.

Most antibiotics were administered by the anesthesiologist or another member of the surgical team. The proportion of cases receiving prophylaxis from the anesthesiologist increased by 19.6 percentage points (CI, 6.3 to 32.8 percentage points) in the intervention group but changed little in the feedback-only group, resulting in a 17.6–percentage point greater increase in the intervention group (CI, 1.1 to 34.2 percentage points).

### Improvement Strategies

Forty sites submitted activity logs for the full 18 months, 2 submitted them for 15 months, and 1 each submitted them for 12 months and 6 months. Project staff coded the infor-

mation on the logs into categories of improvement strategies. The categories were developed from the process changes suggested by sites and experts and from literature review. Activity log information was analyzed for differences in the types and number of improvement strategies undertaken between groups. One site included only activities that were categorized as preintervention rather than actual improvement interventions. Appendix Table 2 (available at [www.annals.org](http://www.annals.org)) shows the frequency of strategies explicitly mentioned by group. The median total number of strategies recorded was 8 (interquartile range, 5 to 12) for intervention group sites and 8 (interquartile range, 5 to 14) for feedback-only sites. The median number of different categories of strategies attempted was 5 (interquartile range, 4 to 5) in the intervention group and 4 (interquartile range, 3 to 5) in the feedback-only group.

### DISCUSSION

We compared participation in a quality improvement collaborative plus receipt of comparative feedback with receipt of feedback alone for improving the timeliness of surgical antimicrobial prophylaxis. Between the baseline and re-measurement phases, the timing and duration of prophylaxis measures improved. However, little evidence indicated that the extent of change differed between the groups for any of the study measures.

There are several possible reasons why the collaborative intervention did not provide incremental benefit over comparative feedback alone. Standardized data collection and comparative feedback reports are not routinely included in collaboratives. We intentionally chose comparative feedback as the control intervention because, on the basis of state, federal, and other agency practices, we believed that this feedback represented “usual care” and we wanted to evaluate the impact of collaborative participation beyond the potential benefits of this practice. In addition, the hospitals participating in the study were self-selected and perhaps motivated by a strong

Table 3. Performance on Antimicrobial Prophylaxis Measures over Time

Antimicrobial Prophylaxis Measure	Intervention Group			Feedback-Only Group			Difference in Adjusted Change (95% CI), percentage points*
	Baseline (n = 2213), %	Re-measurement (n = 2225), %	Adjusted Change (95% CI), percentage points*	Baseline (n = 2234), %	Re-measurement (n = 2238), %	Adjusted Change (95% CI), percentage points*	
Timing	76.3	83.2	6.7 (0.2 to 13.1)	74.8	85.3	10.5 (2.7 to 18.3)	–3.8 (–13.9 to 6.2)
Receipt of prophylaxis	97.4	98.9	1.1 (0.0 to 1.9)	96.5	98.7	1.8 (–0.0 to 3.6)	–0.8 (–2.8 to 1.2)
Duration	51.3	69.5	21.3 (12.5 to 30.1)	54.7	66.8	13.2 (2.1 to 24.3)	8.1 (–5.8 to 21.9)
Selection	93.8	94.7	0.5 (–0.9 to 1.9)	93.4	95.4	1.5 (–0.2 to 3.3)	–1.0 (–3.2 to 1.2)
Single preoperative dose	85.1	80.2	–4.6 (–10.3 to 1.2)	88.8	89.3	0.2 (–4.1 to 4.5)	–4.8 (–11.9 to 2.3)
All or none†	38.2	57.2	20.3 (12.0 to 28.6)	42.5	55.7	14.0 (3.1 to 25.0)	6.3 (–7.3 to 19.8)

\* Adjusted for hospital size, region, and surgery type. Values may not be exact because of rounding errors.

† Identified patients who received all recommended care in terms of timing, selection, and duration indicators.

**Table 4. Changes to Ordering and Administering Surgical Antimicrobial Prophylaxis over Time**

Process Factor	Intervention Group			Feedback-Only Group			Difference in Change (95% CI), percentage points*
	Baseline, %	Remeasurement, %	Change (95% CI), percentage points*	Baseline, %	Remeasurement, %	Change (95% CI), percentage points*	
<b>Source of prophylaxis order</b>							
Cases, <i>n</i>	2179	2151	–	2201	2230	–	–
Type of order							
Preprinted	39.1	35.6	–3.5 (–15.4 to 8.4)	37.7	37.8	0.2 (–12.7 to 13.1)	–3.7 (–21.2 to 13.9)
Handwritten	20.6	25.8	5.1 (–4.2 to 14.5)	19.7	16.5	–3.2 (–7.2 to 0.9)	8.3 (–1.9 to 18.5)
Partially preprinted	22.5	26.2	3.7 (–3.6 to 11.1)	13.2	31.0	17.8 (5.0 to 30.5)	–14.0 (–28.7 to 0.7)
Unable to determine	10.9	7.1	–3.9 (–13.4 to 5.7)	17.5	9.6	–7.9 (–16.3 to 0.6)	4.0 (–8.7 to 16.7)
Verbal	2.7	2.6	–0.2 (–0.9 to 0.6)	10.4	3.2	–7.2 (–14.5 to 0.2)	7.0 (–0.3 to 14.4)
Other	3.1	2.7	–0.3 (–0.6 to 0.0)	0.1	0.2	0.1 (–0.2 to 0.4)	–0.4 (–0.8 to 0.0)
Electronic	1.1	0.0	–1.1 (–2.6 to 0.5)	1.5	1.6	0.2 (0.1 to 0.3)	–1.2 (–2.7 to 0.3)
<b>Professional who wrote antibiotic order</b>							
Cases, <i>n</i>	2178	2148	–	2198	2227	–	–
Type of professional							
Surgeon	55.1	55.4	2.4 (–7.1 to 11.9)	48.4	48.0	–0.3 (–13.3 to 12.6)	2.7 (–13.3 to 18.8)
Unable to determine	15.8	7.9	–8.0 (–17.7 to 1.8)	21.2	11.8	–9.5 (–18.2 to –0.7)	1.5 (–11.6 to 14.6)
Physician assistant, nurse practitioner, or pharmacist	14.0	13.7	–0.2 (–4.2 to 3.8)	19.0	23.0	4.0 (0.1 to 8.0)	–4.2 (–9.9 to 1.4)
Intern or resident	8.1	7.0	–1.1 (–5.0 to 2.9)	6.6	6.4	–0.3 (–3.8 to 3.3)	–0.8 (–6.1 to 4.6)
Anesthesiologist	5.7	12.1	6.4 (–2.7 to 15.4)	2.0	2.6	0.6 (–1.3 to 2.6)	5.7 (–3.6 to 15.0)
Fellow	0.9	0.5	–0.4 (–1.7 to 0.9)	2.5	2.4	–0.1 (–2.1 to 1.9)	–0.3 (–2.7 to 2.1)
Other health professional or physician	0.5	1.3	0.8 (–0.6 to 2.3)	0.3	5.8	5.5 (–1.7 to 12.6)	–4.6 (–11.9 to 2.7)
<b>Location where prophylaxis dose was administered</b>							
Cases, <i>n</i>	2179	2151	–	2201	2230	–	–
Type of setting							
Inpatient operating suite	58.2	73.1	14.9 (2.9 to 26.9)	56.8	62.5	5.7 (–5.3 to 16.7)	9.2 (–7.1 to 25.5)
Inpatient preoperative suite	33.0	24.1	–8.9 (–20.1 to 2.4)	35.4	34.4	–1.0 (–9.8 to 7.8)	–7.9 (–22.1 to 6.4)
Outpatient preoperative suite	4.9	1.4	3.5 (–9.1 to 2.1)	1.2	1.3	0.2 (–1.4 to 1.7)	–3.6 (–9.5 to 2.2)
Intensive care unit, general, or other	3.1	0.9	–2.1 (–4.0 to –0.3)	2.0	0.8	–1.2 (–2.3 to –0.1)	–1.0 (–3.1 to 1.2)
Unable to determine	0.5	0.4	–0.1 (–0.6 to 0.4)	0.7	0.1	0.0 (–0.6 to 0.7)	–0.1 (–0.9 to 0.7)
Outpatient operating room or surgery center	0.4	0.0	–0.3 (–0.8 to 0.2)	3.9	0.2	–3.7 (–5.3 to –2.1)	3.4 (1.7 to 5.1)
<b>Professional who administered antibiotic dose</b>							
Cases, <i>n</i>	2179	2151	–	2201	2230	–	–
Type of professional							
Anesthesiologist	39.5	59.0	19.6 (6.3 to 32.8)	44.8	46.8	1.9 (–8.0 to 11.9)	17.6 (1.1 to 34.2)
Preoperative care nurse	23.6	19.7	–4.0 (–12.4 to 4.5)	16.1	14.6	–1.6 (–11.9 to 8.8)	–2.4 (–15.7 to 10.9)
Nurse anesthetist	21.8	13.6	–8.3 (–17.8 to 1.3)	23.1	23.4	0.3 (–7.8 to 8.4)	–8.6 (–21.1 to 4.0)
Operating room nurse, operating room team member, or unspecified	6.8	3.2	–3.6 (–10.9 to 3.6)	10.9	9.2	–1.7 (–7.6 to 4.2)	–1.9 (–11.2 to 7.4)
Unable to determine	3.2	0.7	–2.6 (–5.7 to 0.6)	2.8	2.3	–0.5 (–3.5 to 2.5)	–2.0 (–6.4 to 2.3)
Floor nurse	2.8	0.9	–1.9 (–3.7 to 0.0)	1.7	0.8	–0.9 (–1.9 to 0.1)	–1.0 (–3.0 to 1.1)
Other	1.8	1.9	0.1 (–0.6 to 0.8)	0.2	2.8	2.6 (–2.8 to 8.0)	–2.5 (–7.9 to 2.9)
Surgeon	0.4	1.0	0.6 (–0.3 to 1.5)	0.3	0.2	–0.1 (–0.4 to 0.2)	0.7 (–0.2 to 1.6)

\*Values may not be exact because of rounding errors.

interest in antimicrobial prophylaxis improvement. Thus, the hospitals receiving feedback only had both the information and motivation for process improvement, and the collaborative intervention may not have been needed to provide added impetus for improving the antimicrobial prophylaxis process.

Indeed, both the number and type of quality improvement activities undertaken by hospitals in the 2 groups were very similar.

Although the improvements in performance were substantial, only modest changes in the characteristics of anti-

microbial prophylaxis delivery were observed. The proportion of doses given in the operating suite increased in the intervention group, and the proportion of doses given outside the surgical suite declined to less than 1% in both groups. The change in administration location may be responsible for some of the improvement in the timing measure by reducing the number of steps in the prophylaxis process. Responsibility for administering the doses shifted toward anesthesiologists, significantly more so in the intervention group. Despite this differential change, both groups improved their antimicrobial prophylaxis process performance to an equivalent degree. This suggests that there is no single strategy for antimicrobial prophylaxis process improvement, but that hospitals seeking to improve antimicrobial prophylaxis performance can adopt several approaches. The diversity of the staff involved with making changes and the variety of approaches to performance improvement make it difficult to identify particular strategies associated with the greatest intrahospital improvement. Case studies of effective hospitals are needed to identify the organizational factors associated with the greatest change.

The collaborative process involves sharing information on which strategies were successful and which failed. Sharing these strategies may not be very helpful because local factors that are not generalizable to other hospitals may determine the applicability of a given solution. It is also possible that the hospital personnel participating in the collaborative may not have been the people ideally suited to effect change at their respective institutions. Most participants were physicians and nurses involved in infection control, and surgical staff or hospital leadership may have been insufficiently involved. Although all TRAPE sites obtained written agreement from leadership to participate, ongoing involvement of hospital administration was not required, as it is in some collaboratives.

Although the gains in process performance were substantial in both groups, without a “no feedback” group, we cannot conclude that feedback alone leads to quality improvement. During the study, there was great national interest in the antimicrobial prophylaxis process because of the SIP program implemented by CMS. National data from the SIP program shows a trend toward improved antimicrobial prophylaxis practice over the period of our study (11, 21); therefore, improvements observed may have resulted from any number of factors unrelated to study participation. Because the SIP measures related to timing, duration, and selection are publicly reported for accountability under the Hospital Quality Alliance initiative (22), the process of antimicrobial prophylaxis is likely to remain high on the national quality agenda for years to come. In 2007, CMS incorporated these measures into incentive payment structures (23). Improvements from these initiatives may also reduce wound infections and limit unnecessary use of antibiotics (24).

The National SIP Collaborative showed statistically

significant improvements in the timing and duration of prophylaxis and a statistically significant decrease in the surgical infection rate (12). However, the Collaborative did not have a control group and did not provide comparative feedback. This may imply that either strategy could be effective in stimulating quality improvement but that the effects may not be additive; additional research on this topic is required.

Our findings support previous research showing comparative feedback to be an effective strategy for driving change (1). It is important to remember that not all data feedback is the same. Some data feedback initiatives have been criticized for being nonspecific, too slow (“old” data), and less than credible. The effectiveness of feedback is also determined by how it is presented and to whom (16, 25). In TRAPE, the feedback was customized by graphically displaying the rank for that hospital (**Appendix Figure**, available at [www.annals.org](http://www.annals.org)) and was delivered to the hospital epidemiologist within 3 months of data collection.

Because the prophylaxis process involves the coordinated action of multiple individuals across multiple departments, the hospital is the natural unit of randomization and analysis for evaluative studies. No hospitals withdrew from the study over 4 years, and all submitted the required amount of data at baseline and remeasurement. Data quality was rigorously monitored, and findings from an ancillary observation study of the accuracy of documenting incision and administration time suggest that these data elements were reliable.

Hospitals that volunteered to participate were typically large teaching hospitals with Society for Healthcare Epidemiology of America—member epidemiologists, which may limit the generalizability of the study. The participating hospitals started and ended with better performance on the key indicators than hospitals nationally. For example, 47.6% of national SIP hospitals at baseline (2001) performed correctly on the timing measure, whereas baseline performance of TRAPE hospitals was 76%. By 2004, the national SIP rate on timing had increased to 69.7%, and that of TRAPE sites increased to 84.4% in 2005 (11). Finally, information on specific improvement strategies attempted was limited by variation in the level of detail reported in the individual hospitals’ open-ended descriptions.

Although our study focused on improving antimicrobial prophylaxis, the ultimate goal is to reduce the incidence of surgical site infections. Because of the expected low incidence rate based on national data, a much larger study would be required to have sufficient power to detect any but the largest differences in infection rates between groups. Furthermore, infection surveillance practices were not standardized across hospitals.

Our results should not be interpreted to mean that collaboratives are ineffective. However, our findings do not support broader use of this collaborative model as an adjunct to comparative feedback initiatives related to antimicrobial prophylaxis. Solberg (26) suggests that there are

many different models for collaboratives, and more research is needed to determine which models work best under which circumstances. Several ongoing community and regional collaboratives remain promising strategies in the infection control arena (27, 28).

In conclusion, the antibiotic prophylaxis process improved in both of our study groups. However, in a climate in which national attention was directed to a topic required by CMS for public reporting, we could not demonstrate incremental benefit of a quality improvement collaborative over performance feedback for improvement of antimicrobial prophylaxis measures.

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## APPENDIX: MEMBERS OF THE TRAPE STUDY GROUP

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**Appendix Table 1. Performance on Prophylaxis Measures, by Type of Surgery and Group over Time**

Type of Surgery and Prophylaxis Performance Indicator	Intervention Group			Feedback-Only Group			Difference in Adjusted Change (95% CI), percentage points*
	Baseline, %	Remeasurement, %	Adjusted Change (95% CI), percentage points*	Baseline, %	Remeasurement, %	Adjusted Change (95% CI), percentage points*	
<b>Cardiac</b>							
Cases, <i>n</i>	859	830	–	790	766	–	–
Indicator							
Timing	79.0	85.4	6.5 (0.3 to 12.7)	76.8	88.5	11.4 (1.9 to 20.8)	–4.9 (–16.1 to 6.4)
Receipt	99.1	99.8	0.6 (–0.1 to 1.2)	96.6	99.7	2.3 (0.1 to 4.5)	–1.7 (–4.0 to 0.6)
Duration	43.1	64.6	22.3 (10.1 to 34.5)	53.6	64.4	10.8 (–12.1 to 33.6)	11.5 (–14.4 to 37.5)
Selection	96.0	94.7	–1.1 (–3.3 to 1.1)	94.2	94.6	0.2 (–2.3 to 2.7)	–1.3 (–4.8 to 2.2)
Single preoperative dose	74.7	69.3	–5.5 (–15.8 to 4.7)	79.9	76.7	–3.7 (–14.8 to 7.3)	–1.8 (–16.6 to 13.0)
All or none†	34.0	54.2	21.2 (10.3 to 32.2)	44.8	56.8	12.0 (–9.8 to 33.8)	9.2 (–15.1 to 33.5)
<b>Hip or knee</b>							
Cases, <i>n</i>	731	845	–	964	1020	–	–
Indicator							
Timing	79.8	82.6	2.4 (–4.5 to 9.3)	75.4	84.5	9.2 (–0.7 to 19.2)	–6.9 (–19.0 to 5.3)
Receipt	98.2	99.1	0.8 (–0.4 to 1.9)	98.4	99.0	0.5 (–0.6 to 1.5)	0.3 (–1.3 to 1.9)
Duration	34.8	66.2	31.5 (15.2 to 47.8)	42.5	59.4	17.7 (5.4 to 30.0)	13.8 (–6.3 to 33.9)
Selection	96.4	98.3	1.5 (0.2 to 2.9)	97.8	98.5	0.7 (–0.9 to 2.4)	0.8 (–1.4 to 2.9)
Single preoperative dose	89.6	85.7	–3.3 (–12.9 to 6.3)	95.1	97.5	2.1 (–2.5 to 6.8)	–5.4 (–15.9 to 5.1)
All or none†	29.2	56.0	26.8 (12.1 to 41.5)	34.1	50.5	17.2 (6.7 to 27.7)	9.6 (–8.1 to 27.2)
<b>Hysterectomy</b>							
Cases, <i>n</i>	623	550	–	480	452	–	–
Indicator							
Timing	68.4	80.9	12.4 (–1.1 to 25.9)	70.4	81.6	11.7 (1.3 to 22.1)	0.7 (–15.8 to 17.3)
Receipt	94.2	97.3	2.7 (–1.2 to 6.7)	92.3	96.5	3.7 (–1.2 to 8.6)	–1.0 (–6.9 to 5.0)
Duration	83.1	82.4	–0.5 (–8.8 to 7.8)	82.8	88.3	5.6 (–1.3 to 12.6)	–6.1 (–16.4 to 4.2)
Selection	87.4	89.0	1.8 (–4.1 to 7.6)	82.4	89.4	7.1 (–1.4 to 15.6)	–5.3 (–15.7 to 5.0)
Single preoperative dose	95.0	88.9	–5.8 (–15.4 to 3.7)	90.5	92.3	1.5 (–0.9 to 4.0)	–7.4 (–16.7 to 2.0)
All or none†	55.2	63.7	9.4 (–5.5 to 24.4)	56.4	65.8	9.5 (–3.4 to 22.3)	0.0 (–19.7 to 19.7)

\* Adjusted for hospital size and region. Values may not be exact because of rounding errors.

† Identified patients who received all recommended care in terms of timing, selection, and duration indicators.

**Appendix Table 2. Improvement Strategies Attempted by Hospitals\***

Improvement Strategy Category†	Description	Examples from TRAPE	Sites Attempting the Strategy, n (%)	
			Intervention Hospitals	Feedback-Only Hospitals
Development or revision of policies, pathways, and forms	Formalize process in writing; documentation	<ul style="list-style-type: none"> <li>Revise clinical pathways or care designs</li> <li>Standardize forms</li> <li>Add antibiotic choice and dosing to surgeon preference cards</li> <li>Revise medical administration record to improve documentation of antimicrobial prophylaxis</li> <li>Add prophylaxis to time-out checklist</li> <li>Add check boxes on operative site verification list</li> <li>Revise pre- and/or postoperative orders</li> <li>Modify preoperative or anesthesia forms to specify where to document antimicrobial prophylaxis drug, dose, and time</li> <li>Document a protocol for potential <math>\beta</math>-lactam allergies</li> <li>Specify where to document allergy status and severity</li> <li>Designate accountability for documentation of antimicrobial prophylaxis orders and timing of administration</li> </ul>	18 (81.8)	13 (61.9)
Feedback and data sharing	Feedback of any summary of data or clinical performance for a specified period of time (behavioral approach); data can be compared internally over time or externally against others; disseminating aggregate data to relevant staff and stakeholders	<ul style="list-style-type: none"> <li>Convene committee meeting of quality control and infection control teams to discuss TRAPE report</li> <li>Present TRAPE data to intensive care, surgery, or administration to show what their rates look like and how they compare with those of other hospitals in the study</li> <li>Monthly feedback to surgeons by department</li> </ul>	17 (77.3)	14 (66.7)
Education: didactic	Dissemination of information (e.g., mailing guidelines); didactic educational interventions (e.g., lectures)—passive approach	<ul style="list-style-type: none"> <li>Continuing medical education lectures</li> <li>Mailing letters to surgeons, operating room team</li> <li>Dissemination of guidelines on selection and timing of antimicrobial prophylaxis administration and duration (e.g., share <i>Clinical Infectious Diseases</i> paper, <i>Medical Letter</i>)</li> <li>Implement an online antimicrobial prophylaxis resource</li> <li>Articles in newspaper</li> <li>Poster in physicians' lounge</li> </ul>	15 (68.2)	15 (71.4)
Microsystem changes and process changes	Modify or standardize process; changes are applied uniformly	<ul style="list-style-type: none"> <li>Reassign responsibilities; change who administers drug (e.g., to anesthesia or circulating nurse)</li> <li>Change where prophylaxis is given (e.g., in operating room or in preoperative holding room)</li> <li>Set up separate processes for vancomycin versus cefazolin</li> <li>Standardize antimicrobial choice</li> <li>Implement changes in clinical pathways or care designs to be consistent with the evidence</li> <li>Eliminate on-call orders</li> <li>Incorporate checking prophylaxis status into the time-out process</li> <li>Design a screening process to identify and manage patients with MRSA</li> <li>Implement a protocol for potential <math>\beta</math>-lactam allergies</li> <li>Implement auto-stop orders</li> </ul>	14 (63.6)	14 (66.7)
Reminders	Prompt health care professionals to perform a patient-specific clinical action (behavioral approach)	<ul style="list-style-type: none"> <li>Hang approved protocol on anesthesia cart</li> <li>Use stickers as reminders to give antimicrobial prophylaxis and to document it</li> <li>Use time-out checklist to remind to give antimicrobial prophylaxis and document time of administration</li> <li>Distribute pocket cards: pocket-sized reminders that have antimicrobial prophylaxis protocols</li> <li>Identify an activity to associate with when to give antimicrobial prophylaxis (e.g., surgeon scrubbing)</li> <li>Place tag on prophylaxis bag for start and stop times</li> <li>Use computer prompts to cue anesthesia</li> <li>Use screen saver with reminder to document antibiotic</li> </ul>	8 (36.4)	6 (28.6)

Appendix Table 2—Continued

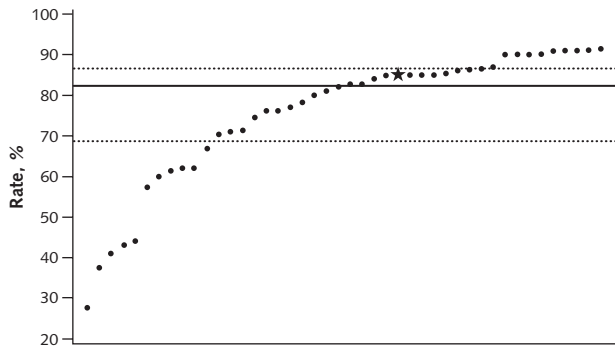
Improvement Strategy Category†	Description	Examples from TRAPE	Sites Attempting the Strategy, n (%)	
			Intervention Hospitals	Feedback-Only Hospitals
Equipment- or supplies-related changes	Structural changes to supplies or equipment	Purchase or try alternative or supplementary products and supplies with goal of reducing infection (e.g., new type of wound dressing; change of preoperative scrub product) to help respond to concerns about reduction of postoperative antibiotics to within 24 hours of surgery Standardize where antibiotics are located/dispensed (e.g., remove antimicrobial prophylaxis from holding area) Purchase additional equipment/supplies to enhance/facilitate process changes (e.g., order more infusion pumps) Initiate computerized physician order-entry; automate medical administration record	6 (27.3)	4 (19.0)
Academic detailing	Educational outreach—usually peer-to-peer (one-on-one educational approach)—to provide information on recommended practices; also referred to as <i>physician detailing</i> ; often used to “market” (i.e., the pharmaceutical model)	One-on-one educational meetings with individual surgeons and anesthesiologists, chief of surgery, and other team member to review the evidence-based literature	3 (13.6)	7 (33.3)
CQI teams	Multidisciplinary approach with ongoing meetings; data collection and analysis, formulation of hypotheses, and revision of interventions based on the data (administrative approach)	Organize multidisciplinary team with specific objectives and regular meetings Use multiple short plan, do, check, and act cycles to test small-scale changes	5 (22.7)	5 (23.8)
Clinician profiling	Reporting back practitioner-level data	Anesthesiologist-specific feedback (e.g., variances in prophylaxis discussed with each anesthesiologist by physician identification)	3 (13.6)	6 (28.6)
Quasi-coercive	Change or conformance mandated by internal leadership, management, or external group (e.g., purchaser, accreditor, Centers for Medicare & Medicaid Services)	Corporate office assigns high priority to initiative due to public reporting initiative Involvement in quality improvement organization/surgical infection prevention initiative; Institute for Healthcare Improvement collaboration Incorporate antimicrobial prophylaxis issues into credentialing process Enforce policies and procedures related to antimicrobial prophylaxis	4 (18.2)	4 (19.0)
Opinion leaders	Use leaders (clinical champions) to diffuse information across a social network (social influence approach)	Engage orthopedic and cardiac surgeon champions Invite visits from external experts	5 (22.7)	1 (4.8)
Education: interactive	Promoting learning from experience; problem-based learning; small group interactive learning and local consensus process-active approach	Operating room nursing staff undertake self-study Monthly TRAPE intervention site calls	1 (4.5)	0
Coercive	Required by law and regulations for practice; legal standards of care	NA	0	0
Patient-mediated interventions	Provide information to patients with the intention of changing provider behavior (social influence approach)	NA	0	0
Interactive: computer	Use the Internet to communicate between organizations and with the patient	NA	0	0
Interactive: telephone	Telephone follow-up and counseling to patients	NA	0	0

CQI = continuous quality improvement; MRSA = methicillin-resistant *Staphylococcus aureus*; NA = not applicable; TRAPE = Trial to Reduce Antimicrobial Prophylaxis Errors.

\* Our attempts at categorization of open-ended written comments without opportunity to clarify should be considered preliminary. We used an open-ended activity log to avoid suggesting categories of improvement strategies to participants; however, this resulted in substantial variation in the level of detail written. Some people were inclined to write more than others; some may have forgotten to mention activities or did not provide sufficient description to allow accurate categorization. The number of sites attempting an intervention is probably an underestimate in many categories. For example, teams may have been formed but not documented, and educational activities may have been interactive rather than didactic; this was particularly difficult to determine by the comments listed. Several preintervention activities were mentioned but were not considered as quality improvement strategies because they typically occurred before implementing change; examples include reviewing policies and procedures, clarifying current roles or processes, collecting baseline data, developing a flow chart of process and timeline, generating customized reports using pharmacy data, developing medical record audit tools, conducting ongoing monitoring, identifying which cases are most problematic, identifying which providers are least compliant with guidelines, getting leaders on board, strategizing a plan for improvement, identifying potential barriers and obstacles, and conducting failure mode and effects analysis.

† The intervention categories were identified from references 29 through 33 and were modified slightly for TRAPE. A microsystem is a small group of people who provide care to a discrete subpopulation of patients. It has clinical and business aims, linked processes, and a shared information environment, and it produces performance outcomes (per reference 32).

*Appendix Figure.* Sample graph from the comparative feedback report in TRAPE (Trial to Reduce Antimicrobial Prophylaxis Errors).



Each hospital received a customized report, with a star indicating that hospital's performance on the particular measure. The vertical axis shows the percentage of surgical patients in hospitals who received prophylaxis within the recommended time frame.