PAPER

Enhancing Compliance With Medicare Guidelines for Surgical Infection Prevention

Experience With a Cross-disciplinary Quality Improvement Team

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Hypothesis: The Center for Medicare and Medicaid Services instituted standardized reporting of measures aimed at surgical infection prevention (SIP). The complexity and number of medical personnel involved in antibiotic administration requires multiple disciplines to successfully improve compliance.

Design: Survey study.

Setting: Tertiary care university hospital.

Patients: All patients undergoing the following operations from July 2004 through December 2005 were monitored for compliance with SIP: (1) coronary artery bypass graft, (2) other cardiac, (3) vascular, (4) hysterectomy, (5) colon resection, (6) hip arthroplasty, and (7) knee arthroplasty.

Intervention: A team including a surgeon, an anesthesiologist, nurses (preoperative, operating room, and floor), a pharmacist, a hospital infection control committee member, and quality improvement and operations specialists was created in July 2004. Hospital guidelines for SIP were defined, personnel roles defined and processes standardized, and communication/education for health care professionals was enhanced.

Main Outcome Measures: Compliance with 3 SIP measures over 3 consecutive periods of 6 months each: (1) percentage of patients receiving antibiotics within 1 hour of incision, (2) percentage of patients with appropriately selected antibiotics, and (3) percentage of patients with antibiotics discontinued within 24 hours of operation end time.

Results: One thousand seventy-two patients were monitored. Measure 1 compliance improved from 72.25% to 83.78% ($P<.001$, Cochran-Armitage trend test); improvement or high performance (>90% compliance) was demonstrated in 5 of 7 services. Measure 2 compliance remained uniformly high (approximately 98%). Measure 3 compliance improved from 54.5% to 87.16% ($P<.001$); improvement was seen in 5 of 7 services.

Conclusions: The clearly defined roles of a cross-disciplinary team and the process improvements discussed in this article can easily be implemented in other institutions. These elements were integral to our success in improving the timely delivery and discontinuation of prophylactic surgical antibiotics.

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SURGICAL SITE INFECTION (SSI) remains a major morbidity of surgical procedures and is associated with prolonged hospital stay, higher use of intensive care units, and a 2- to 3-fold increased risk of perioperative death.[1,2] Additionally, there is a significant increase in use of health care resources and associated costs of health care. Surgical site infections increase hospital length of stay by 7 days and charges by $3000 on average.[1,3] For cardiac surgery and complex orthopedic procedures, such as hip or knee arthroplasty, SSI may result in additional costs as high as $30 000.[4] In an effort to more broadly establish effective measures to minimize SSI, the Centers for Medicare and Medicaid Services (CMS) in collaboration with the Centers for Disease Control and Prevention convened an expert advisory panel in 2002 to consider proposals for standardized recommendations, which might be more widely adopted nationwide. Recommendations of this advisory panel were formalized in an advisory panel report.[5,6] These recommendations were subsequently endorsed by CMS in developing guidelines and reporting standards for surgical infection pre-

vention (SIP) measures, as part of the CMS National Voluntary Hospital Reporting Initiative and the National Quality Data Project. While "voluntary" in nature, the Medicare Modernization Act of 2003 provided a financial incentive for hospitals to report quality data by linking it to payments received for Medicare beneficiaries. Acute care hospitals not reporting will have a 0.4% reduction in their Medicare fee schedule update.

The 3 original SIP measures proposed were (1) percentage of surgical cases with prophylactic antibiotics started within 60 minutes of surgical incision, (2) percentage of surgical cases receiving prophylactic antibiotics consistent with current guidelines, and (3) percentage of surgical cases receiving prophylactic antibiotics whose antibiotics were discontinued within 24 hours of operation end time. The first and third measures have subsequently been formally adopted as part of the CMS Hospital Quality Alliance and were released on September 1, 2005, for public access. Patients and payers may now compare hospitals in the same region for compliance with these measures on the CMS Web site, www.cms.hhs.gov/hospitalqualityinits. Our hospital, Fletcher Allen Health Care (FAHC), participated in the initial CMS voluntary initiative. Fletcher Allen Health Care is a tertiary health care center serving the state of Vermont and northern New York State and is the academic teaching hospital of the University of Vermont School of Medicine. Fletcher Allen Health Care is an open-staff hospital with an average inpatient census of 350 patients. This report describes our hospital's initial efforts from 2003 to 2005 to improve compliance with the 3 original SIP measures.

METHODS

PATIENTS

All surgical patients undergoing either elective or emergency surgery with a principal or secondary procedure *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) code consistent with the procedures identified by CMS were included (colon surgery, coronary artery bypass graft [CABG], other cardiac or thoracic procedures, vascular surgery, hysterectomy, hip arthroplasty, knee arthroplasty).

EXCLUSION CRITERIA

Patients who had a principal diagnosis suggestive of a preoperative infectious disease and patients who were receiving antibiotics at the time of hospital admission were excluded (with the exception of colon surgery patients taking oral prophylactic antibiotics).

Through the CMS National Quality Data Project, our hospital contracted with a vendor, University Health Care Consortium, to assist in patient selection and data reporting. A list of all inpatient discharges with *ICD-9-CM* codes from our hospital was submitted to University Health Care Consortium quarterly, and from those, a large sample of surgical cases performed with the appropriate *ICD-9-CM* codes was selected. Medical records were then abstracted and reviewed by a trained auditor from the FAHC Quality Improvement Office. Preoperative orders, nursing flow sheets, and anesthesia records were reviewed for appropriate documentation of prophylactic antibiotic delivery, including time of initiation of antibiotic infusion, antibiotic selection, and the operative start time. Other records reviewed included operative reports, postoperative orders, and medication administration records for evidence of the need for postoperative antibiotics and timing of last antibiotic delivery.

SIP MEASURES

The 3 SIP measures we used were as follows: (1) Percentage of surgical cases with prophylactic antibiotics started within 60 minutes of surgical incision. Patients receiving antibiotics requiring prolonged infusion (ie, vancomycin hydrochloride) are allowed 120 minutes per CMS guidelines. (2) Percentage of surgical cases receiving prophylactic antibiotics consistent with current guidelines. Antibiotic choices were available on the CMS Web site and were consistent with the advisory council statement.[5] (3) Percentage of surgical cases receiving prophylactic antibiotics whose antibiotics were discontinued within 24 hours after surgery end time.

STATISTICAL ANALYSIS

Compliance with the 3 SIP measures was analyzed over 3 consecutive periods of 6 months each. The statistical significance of a time trend for the compliance rate for each measure was assessed with the Cochran-Armitage test.[7] The following 3 ordinal time groups were used: 1) the last 2 quarters of 2004, 2) the first 2 quarters of 2005, and 3) the last 2 quarters of 2005. The null hypothesis for the test is that there is no difference in compliance rates and the alternative hypothesis is that the rates are unequal and ordered (increasing or decreasing) with the period. Statistical significance was defined as a P value $<.05$.

RESULTS

MULTIDISCIPLINARY TASK FORCE

In July 2003, we convened a multidisciplinary committee at FAHC to clearly identify current hospital practice patterns for surgical antibiotic prophylaxis to enhance compliance with the 3 SIP measures. The committee was composed of a surgeon (committee chair), an anesthesiologist, a pharmacist, a hospital infection control committee member, a team of nurses (representing preoperative nursing, operating room [OR] nursing, and floor nursing), a member of our hospital quality improvement office, and a clinical operations specialist who had contact with all surgeons' offices. The committee met monthly over the course of the 2-year period. During the first 3 months, testimony was obtained from both committee members and the broader hospital community regarding current practice patterns in regard to the ordering, selection, and delivery of prophylactic antibiotics. The major results of our fact-finding period are listed in **Table 1**. During the subsequent 3-month period, institution-specific (FAHC) guidelines were developed and communication of new guidelines was distributed.

Consecutive surgical service audits were then performed monthly. Each surgical service was internally monitored for 30 consecutive surgical procedures, and a detailed report was generated identifying compliance with both our new FAHC SIP guidelines and each of the 3 SIP measures. Detailed failure analysis allowed identification of errors as process specific or provider specific (surgeon or anesthetist). After specific categories of

Table 1. Fact-Finding Period

Major Findings	Consequences	Intervention
Surgeon variability in writing orders for prophylactic antibiotics	Preoperative nursing could not keep track of multiple surgeons' individual preferences; day-of-surgery orders minimized the ability of the pharmacy to identify allergies and drug interactions	Surgeons to complete written order for all antibiotics for scheduled surgery at preoperative office visit; surgeons responsible for appropriate antibiotic selection (consistent with operative procedure and patients' allergy profile)
Anesthetist variability in the administration of prophylactic antibiotics and recording time administered	Administered after incision for cases where order never written; often administered in preoperative hold, too early for patients requiring central venous catheters and epidurals	Anesthetists were assigned role of appropriate timing, administration, and recording administration time of prophylactic antibiotics
Nursing variability in practice of hanging, administering, and confirming antibiotics	Preoperative hold administration often too early secondary to inability to judge operation start times; inpatient nursing administration "on call" resulting in administration too early	Nurses were assigned role of confirming antibiotics ordered; nurses were assigned role of attaching (not administering) preoperative antibiotics; operating room nurses were assigned role of confirming antibiotics administered as part of "golden moment" prior to surgical incision

Table 2. Process Improvements

Policy Initiation Roll out	Findings	Intervention	Results
SIP measure 1	Greater failure rate for inpatients	Inpatient preoperative antibiotic delivery process developed; nursing education given on surgical floors; antiinfective form changes; avoidance of "on call to OR" order terminology	Subsequent quarter with improvement for inpatients
	30%-50% of failures identified were related to anesthesia documentation	Anesthesia in-service on surgical infection prevention; OR nursing in-service on "golden moment" adaptation	Improvement in awareness of anesthesia and OR nursing on the importance of antibiotic timing before incision
SIP measure 2	Lack of documentation on oral antibiotic regimen for colon surgery	Standardized preoperative order sheets documenting oral antibiotic regimen	Improvement in documentation of oral antibiotics given
SIP measure 3	Orthopedic surgery and cardiac surgery had common use of 5-7 d of antibiotics postoperatively	Physician education; standardized postoperative order sheets modified; follow-up physician leaders on infection rates	Rapid improvement

Abbreviations: OR, operating room; SIP, surgical infection prevention.

common failures were identified, small task force teams were convened for 1 to 3 months to correct these areas and new hospital processes were implemented as necessary (**Table 2**). Educational efforts to enhance compliance with new processes were initiated. The ability to identify individual surgeons' compliance with the 3 SIP measures was ultimately added to the monitoring process to allow surgeons and physician leaders to become aware of individual surgeon compliance rates.

COMMUNICATION STRATEGY

The SIP committee chair communicated quarterly to the surgery division quality officers, surgery division chiefs, and the chairs of respective surgery departments. Information initially included committee findings and recommendations and, subsequently, reports highlighting their respective division/department compliance with SIP measures. Graphs of hospital divisional compliance and comparisons to national benchmarks were posted in widely accessible staff areas around the OR (locker rooms and OR staff lounge). Presentations on the efforts of the SIP committee were initially communicated bimonthly to the Department of Surgery Quality Committee. Updated presentations with divisional performance results were presented to the Department of Surgery Quality Committee, the hospital quality committee, and ultimately to the quality committee of the hospital board of trustees.

SIP OUTCOMES

During the 18-month period, a total of 1072 operations were audited by our hospital. The procedures monitored included 191 CABGs (18%), 120 non-CABG cardiac surgeries (11.1%), 149 hip arthroplasties (13.8%), 168 knee arthroplasties (15.7%), 133 colon surgeries (12.4%), 120 vascular surgeries (11.1%), and 191 hysterectomies (17.8%). Overall, the number of operating surgeons performing the monitored procedures was 63, with the largest pools of surgeons performing hysterectomies (27), followed by colon surgeries (14) and orthopedic joint replacement (12).

SIP Measure 1

Overall compliance across all services improved from 72.25% in the first 6-month period to 83.78% (**Table 3**). Two procedures (hip and knee arthroplasties) had demonstrated good compliance in the first 6 months, and though a trend toward improvement was seen, this was not statistically significant. For cardiac surgery (CABG and non-CABG cardiac procedures) and vascular surgery, improve-

Table 3. Compliance With SIP Measures

Group	SIP Measure	Sample Size*	% 2004 Quarters 3 and 4	% 2005 Quarters 1 and 2	% 2005 Quarters 3 and 4	Trend	*P* Value
CABG	Within 1 h	191	64.21	82.35	75.56	+	.04
	Selection	191	100.00	100.00	100.00	NA	NA
	DC<24 h	178	39.29	84.31	95.35	+	<.001
Cardiac surgery	Within 1 h	120	55.56	73.91	85.11	+	.003
	Selection	122	100.00	100.00	100.00	NA	NA
	DC<24 h	111	40.00	86.67	93.48	+	<.001
Colon surgery	Within 1 h	133	63.46	62.50	75.61	+	.12
	Selection	135	90.00	92.68	90.91	+	.43
	DC<24 h	126	79.17	73.68	92.50	+	.06
Hip arthroplasty	Within 1 h	149	86.96	94.23	92.16	+	.19
	Selection	147	100.00	100.00	100.00	NA	NA
	DC<24 h	144	26.19	80.39	80.39	+	<.001
Knee arthroplasty	Within 1 h	168	83.33	92.59	88.89	+	.17
	Selection	168	98.33	98.15	100.00	+	.21
	DC<24 h	164	19.64	61.11	81.48	+	<.001
Hysterectomy	Within 1 h	191	78.16	81.13	82.35	+	.27
	Selection	182	98.67	92.45	96.30	–	.20
	DC<24 h	193	93.18	90.57	90.38	–	.27
Vascular surgery	Within 1 h	120	66.67	88.37	84.09	+	.04
	Selection	122	96.97	100.00	97.78	+	.43
	DC<24 h	109	58.62	87.18	78.05	+	.049
Overall	Within 1 h	1072	72.25	82.89	83.78	+	<.001
	Selection	1067	97.92	97.65	97.95	+	.50
	DC<24 h	1025	54.50	80.36	87.16	+	<.001

Abbreviations: CABG, coronary artery bypass graft; DC, discontinued; FAHC, Fletcher Allen Health Care; NA, no trend; SIP, surgical infection prevention; +, increasing trend; –, decreasing trend.
*Represents the number of FAHC patients in the category.

ments were demonstrated over the periods evaluated. For both colon surgery and hysterectomy, there was no demonstrated improvement in compliance with delivery of antibiotics within 60 minutes of incision.

SIP Measure 2

Antibiotic selection at our institution was uniformly very high (>95% agreement with CMS recommendations) in each of the 3 periods evaluated. No trend toward improvement was identified.

SIP Measure 3

Significant improvement in avoiding prolonged postoperative antibiotic use was demonstrated at our institution (55%-87%). This improvement was noted in 5 of the 7 surgical procedures monitored, with a trend toward improvement for colon surgery (79%-93%; $P=.06$).

COMMENT

Surgical site infections remain a major source of postoperative morbidity, with an estimated 500 000 SSIs occurring annually in the United States.[8] Patients taken to the OR for clean surgery are estimated to develop an SSI in 2% to 5% of nonabdominal surgeries and in 20% of abdominal procedures.[9] In an effort to minimize SSI, prophylactic antibiotic use was identified some 3 to 4 decades ago as an effective measure.[10-12] The timing of surgical prophylactic antibiotic delivery was determined to be most effective when administered within a short duration (1-2 hours) prior to surgical incision.[13,14] A recent sample of 34 000 Medicare patients undergoing the same operations monitored under the CMS SIP Project revealed that only 55.7% of patients received antibiotics within 1 hour prior to incision, and only 40.7% had antibiotics appropriately discontinued within 24 hours after surgery end time, suggesting implementation of best practices may be challenging.[4] Methods or descriptions on how to successfully implement these recommended practices at larger hospitals are limited in the literature.

Our institution's approach toward quality improvement was to convene a cross-disciplinary team representing multiple medical disciplines combined with individuals with expertise in quality improvement and measurement. We felt multiple disciplines were necessary to identify all potential processes requiring improvement, facilitate communication and education of process change, and assist in monitoring changes as new polices were implemented. Previous assessments of systems approaches toward improving surgical quality and safety have identified the unanticipated complexity of hospital systems and health care delivery as a barrier to improve-

ment.[15] Limiting evaluation only to patient profiles and individual surgeon outcomes greatly underestimated the complexity of surgical outcomes. A wider assessment of factors affecting outcomes and broader expertise were identified as important components to effectively institute quality improvement.[15] The findings of our initial fact-finding period did suggest that the practice of ordering and delivering prophylactic surgical antibiotics in a narrow time frame involved multiple hospital personnel. These personnel had wide variability in both their perceived role and understanding of the importance of timing in successfully completing this task.

Prior to the implementation of our committee, there was no consistency among surgeons in the writing of antibiotic orders prior to the day of surgery and additional inconsistency in the handling of antibiotic orders by preoperative nursing. Both pharmacists and nurses believed last-minute orders minimized additional safety checks for patients. Some surgeons indicated immediately available antibiotic selection was limited. As a result, commonly used prophylactic antibiotics were made available in the OR automated medication-dispensing stations (Pyxis; Cardinal Health, San Diego, Calif).

We also identified considerable variability in both anesthetists' perceived role and practices regarding the administration of prophylactic antibiotics. Misjudging the time required for placement of central venous catheters, epidural catheters, and room turnover often resulted in antibiotic administration that was too early. Anesthesiologists felt responding to a late antibiotic order, verbally given at the initiation of surgery, was not a priority at the time of anesthesia induction. The early development of our own FAHC institutional guidelines for medical professional roles in the delivery of surgical antibiotic prophylaxis was viewed as an essential component of our strategy for improvement. The responsibilities of the surgeons, anesthetists, and nursing were clearly defined.

Inpatients were initially noted to be significantly more problematic for SIP measure 1. Some inpatients went to preoperative hold, while others went directly into their specific OR. Delivery of antibiotics "on call" to the OR was resulting in administration outside of the desired 60-minute window prior to incision. Significant process changes were instituted after receiving input from numerous groups (floor nursing, perioperative nursing, OR nursing, anesthesia) to improve outcomes for our inpatients (**Figure**).

The rapid and significant improvement in compliance with SIP measure 3 can largely be attributed to changes made in standardized postoperative order forms for both the orthopedic service as well as cardiac surgery and willingness of surgeons to change practice. Widespread use of prolonged postoperative antibiotic "prophylaxis" was commonplace prior to initiating this project. Close monitoring with our surgical infection committee was important to verify and communicate to surgeons that there was no increase in surgical infection rates after discontinuing the practice of prolonged postoperative antibiotic use.

The improvement of SIP measure 1, while satisfying, did fall short of our committee goal of 90% compliance and highlights the complexity of bringing about changes

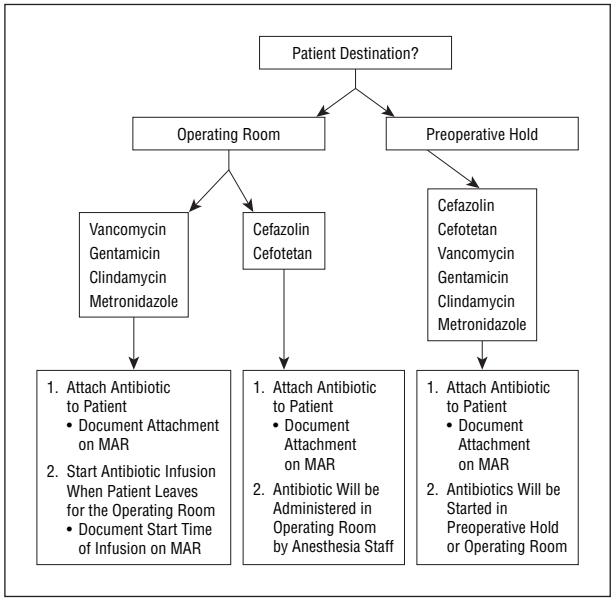

Figure. Surgery inpatient and emergency department preoperative antibiotic algorithm. Vancomycin was given as vancomycin hydrochloride. MAR indicates medication administration record.

at hospitals with a large number of surgeons and anesthetists. While our institution did develop specific guidelines for instituting change, these did remain guidelines and not hospital policy. Procedures (hysterectomy) performed by a large number of surgeons were ultimately more problematic in instituting change than procedures where fewer surgeons were involved. Formal communication strategy relied heavily on communication to surgeons, which may have been a shortcoming in our process of change, as surgeons ultimately were involved in only limited aspects of prophylactic antibiotic delivery.

In summary, nationwide attempts to improve patient safety in the surgical setting involve a wide range of efforts, including reducing surgical infection through the appropriate delivery of prophylactic antibiotics. We have demonstrated that these changes can be successfully implemented at a tertiary care, open-staff hospital. An interdisciplinary team approach, which was used at our institution, was effective in implementing change in a practice involving multiple medical disciplines. Further efforts at improving patient safety, while critical to enhancing the health care of our patients, should not underestimate the complexity, cost, and expertise required to bring about these changes.

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DISCUSSION

Rocco Orlando, MD, Hartford, Conn: Dr McCahill, I commend you on your efforts at your institution. We have gone through a similar process and have been able to get to 97% on-time delivery of antibiotics, but the 2 most vexing problems that I would be interested in how you solved them have been vancomycin, because of the time required to infuse the drug, and the 2-antibiotic patient population, typically colorectal surgery, for example. Those have been the most difficult to hit the target on. How are you dealing with those 2 groups?

Dr McCahill: I will address colorectal first. One of the things that in terms of Medicare guidelines they do accept for oral antibiotics is the Nichols prep of oral erythromycin and neomycin as acceptable prophylaxis. Initially, our colorectal surgeons were upset when this data was getting posted and indicated their patients were all receiving a Nichols prep plus cefotetan. Unfortunately, they had no documentation of oral prep being given so we improved our documentation. Preoperative nursing now inquires, and has added to the preoperative form, that oral antibiotics were given. Preoperative nursing now documents that the oral antibiotics were actually received. As far as Medicare is concerned, that is acceptable antibiotic prophylaxis for colon resection. Vancomycin is a bigger problem, especially in the era of resistant organisms. The main thing that we have done is try to do inpatient nursing in-services and anesthesia in-services because they were not all previously aware that the timing of antibiotic delivery is so critical. The Medicare guidelines do allow a 2-hour time window for an infusional drug, such as vancomycin, so you do have more leeway in terms of time frame in which it can be delivered.

Randolph Reinhold, MD, New Haven, Conn: My question is in a similar vein, because we looked at that problem because we are all facing it. My question is how much of your improvement was really a documentation improvement as opposed to a practice pattern change? We know for example in the delivery within 1 hour antibiotics at the beginning it is really a question of when the anesthesiologist or nurse anesthetist writes it down on the anesthetic record. What we found is that the vast majority of times the surgeons ordered it and the drug was given but in the hecticness of inducing anesthesia somebody did not write it down until 5 minutes after the incision was begun and that in fact puts you outside the guideline. Did you actually change practice or just improve your documentation?

Dr McCahill: Both. I think in the first 6- to 8-month time period we definitely had surgeons who had variable ordering practices, such as ordering after the patient was already anesthetized, and we were able to demonstrate that antibiotics were actually being infused after incision. So there was clear documentation that patients were receiving the prophylactic antibiotics 20 minutes, 30 minutes after incision, which is clearly less effective. That was really how this problem was brought to my attention when I came to this hospital 4 years ago. I'd be operating for 15, 20 minutes and anesthesia would ask would I like some antibiotics and I was sort of taken aback, so I do think we really fixed that problem. We now include, in the "golden moment" before incision, both patient name and operative site verification, as well as whether antibiotics have been given.

I think that our actual delivery of antibiotics is probably over 90% in the last 6 months. We do internal monitoring of our processes to see where it falls down, and as you have suggested, appropriate documentation on the anesthesia record remains a big issue. The last time we monitored internally, we were able to document that the surgeons had written an order around 97% of the time. We actually had documentation that antibiotics were given, but if anesthetists did not write down the time, that was a hit. So improved documentation is probably our last threshold to get over 90%.

Richard Wait, MD, Springfield, Mass: We had a similar experience and rapidly increased our rate of compliance up to about 98% of giving it within an hour. That was top decile for a long time. Now it is almost second decile because everybody else has improved so fast, and we are just now going to an opt-out policy where they get something unless they write to get something else. That specifically is because people are choosing other antibiotics. The colorectal surgeons, some of them are choosing Levaquin [Ortho-McNeil Pharmaceuticals, Titusville, NJ]

rather than cefotetan or cefoxitin. We have now gone to an opt-out policy. I was just curious as to whether you had tried anything like that.

The second issue that we have had is repeating the dose of antibiotics during the operations. We got anesthesia to give them preop by linking their pay to giving it.

Dr McCahill: One of my observations is that it seems smaller hospitals have been more successful in quickly crossing the 90% success rate. The reason I showed how many surgeons are involved, and that we are an open-staff hospital, is that I think it can be more challenging to get a larger place to shift their practice. You are actually fining people now?

Dr Wait: They get a bonus if they get close to 100% but we do 28 000 cases so it is not small, but it is a big problem now in getting them to give them after 4 hours into the case because no one is remembering. It is not part of a checklist. I was wondering if you have approached that problem.

Dr McCahill: Your first question was about an opt-out policy. I am not sure I fully understand that. I know one of the reasons that Medicare is not monitoring SIP measure 3, appropriate antibiotic selection, right now is because cefotetan is no longer being manufactured. There was too much movement in the area of what was appropriate so they decided not to monitor that.

David W. Butsch, MD, Montpelier, Vt: I enjoyed the paper. I know that you have done a good job of pleasing the government. Do you have any idea of the patient outcomes with this change?

Dr McCahill: No. I think that is probably the best question of all in terms of are we really impacting surgical infection rates. I think if you actually look at the numbers that would be required to demonstrate that, Dr Butsch, it is going to require a much larger number of patients. If you are talking about trying to shift an infection rate of 4% down to 2%, the power required to do that and the need to control for diabetes and other risk factors would require several thousand patients. I think in the end the government is following evidenced-based medicine based on level 1 evidence of randomized trials. I think that is the best we can do. For hospitals to really show changes in surgical infection rates they are going to have to look at time frames of 1 full year, not just these shorter blocks of time.

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