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ORIGINAL SCIENTIFIC REPORT

Patient Self-Assessment of Surgical Site Infection is Inaccurate

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Abstract

Background Availability of surgical site infection (SSI) surveillance rates challenges clinicians, healthcare administrators and leaders and the public. The purpose of this report is to demonstrate the consequences patient self-assessment strategies have on SSI reporting rates.

Methods We performed SSI surveillance among patients undergoing general surgery procedures, including telephone follow-up 30 days after surgery. Additionally we undertook a separate validation study in which we compared patient self-assessments of SSI with surgeon assessment. Finally, we performed a meta-analysis of similar validation studies of patient self-assessment strategies.

Results There were 22/266 in-hospital SSIs diagnosed (8.3%), and additional 16 cases were detected through the 30-day follow-up. In total, the SSI rate was 16.8% (95% CI 10.1–18.5). In the validation survey, we found patient telephone surveillance to have a sensitivity of 66% (95% CI 40–93%) and a specificity of 90% (95% CI 86–94%). The meta-analysis included five additional studies. The overall sensitivity was 83.3% (95% CI 79–88%), and the overall specificity was 97.4% (95% CI 97–98%). Simulation of the meta-analysis results divulged that when the true infection rate is 1%, reported rates would be 4%; a true rate of 50%, the reported rates would be 43%.

Conclusion Patient self-assessment strategies in order to fulfill 30-day SSI surveillance misestimate SSI rates and lead to an erroneous overall appreciation of inter-institutional variation. Self-assessment strategies overestimate SSIs rate of institutions with high-quality performance and underestimate rates of poor performance. We propose such strategies be abandoned. Alternative strategies of patient follow-up strategies should be evaluated in order to provide valid and reliable information regarding institutional performance in preventing patient harm.

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Introduction

Surgical site infections (SSIs) are the most common nosocomial infection in surgical wards and the second most common within hospitals [1]. The consequences of SSIs include longer hospitalizations, readmissions post-discharge, further testing, extended antibiotic treatment, prolonged suffering for the patient, additional work loss days and increased mortality [2]. SSIs are estimated to be the cause of death in 38–75% of post-operative mortality cases and are associated with very high economic costs [1–4].

There are many factors that pre-determine the potential for developing an SSI; some are patient-related while others are related to the surgical procedure and its environs. However, it is well accepted that many infections can be prevented by implementation of well-known, evidence-based bundles [5, 6]. SSIs incidence serves as a quality measure in evaluating hospital performance [7].

When creating such measures for the purpose of comparison between medical institutions, a uniform definition of SSIs is needed and confounding factors such as the preoperative risk of infection must be controlled. The CDC's criteria define a SSI as an infection that appears in the incision within one month after the operation or within one year if an implant was left in place [8]. Additionally, a significant proportion of SSI becomes evident after patient discharge. Therefore, in order to assess 30-day incidence of SSIs, patient follow-up is necessary after discharge [9, 10]. Variation in the methods employed to ascertain the existence of infection after discharge could account for variation in SSI incidence rates and provide disservice to quality initiatives that aim to decrease outcome variation and drive improvement through competition between healthcare service providers.

Patient follow-up strategies include clinic follow-up and surgeon/physician diagnoses of SSIs. Another option would be to follow-up hospital readmission and referrals to emergency rooms, assuming the at least deep-wound infections would necessitate medical attention to those ends. These two strategies for follow-up are prone to selection bias and are dependent on varying diagnostic practices of doctors. Independent committees of healthcare professionals have also been proposed, though they associated with greater institutional resource consumption and can lead to tensions with the surgical staff under scrutiny [11, 12].

Patient self-assessment strategies and either patient sampling or complete follow-up have also been proposed. Using standard questions, patient responses could be consistent in their level of accuracy and relative to other strategies; these might consume less institutional resources to meet the ends of surveillance. Previous studies have tested the patient's ability to detect the presence or absence of SSI. They are limited in number and used various methods of self-evaluation. In these studies, the specificity was 92–99% while the sensitivity was 52–90% [9, 13–16].

This report resulted from a survey to measure and implement continuous surveillance of SSI rates. To that end, we instituted post-discharge surveillance via telephone calls to discharged patients. We tested the reliability of the patients' self-assessment survey by performing a validation survey and additionally performed a meta-analysis including our results and previous surveys of patient self-assessment.

Methods

We conducted two complementing studies: a prospective observational surgical site infection surveillance survey and a validation study to assess the reliability of telephone follow-up for the diagnosis of post-discharge surgical site infections.

We used the SSI diagnosis criteria as defined by the US Centers for Disease Control. SSIs were divided into three categories: superficial infection, deep infection or infection of an organ or cavity that were related to the surgery [8]. Surgery was classified as clean, clean-contaminated, contaminated or dirty [6, 17].

Surgical site infection surveillance survey

The study population was comprised of all patients who underwent an elective surgery in the general surgery wards of the Hadassah Ein-Kerem University Hospital between the months of August and November 2007. Patients who underwent anal surgery or collaborative surgery (for example, involving urologist or gynecologist) were excluded. In the event that a single patient underwent more than one surgery during the above period of time, only the first operation was included in the study. The survey included in-hospital and post-discharge surveillance.

During hospitalization, a registered nurse filled out daily a standardized form pertaining to each patient, using data from the patient's written and computerized records. During daily morning rounds, the house surgeons filled out a surveillance table and documented the wound characteristics. In the event that an infection was detected, it was recorded as superficial, deep or surgical organ/cavity infection.

A surveyor conducted a telephone survey 30 days post-discharge, using a standardized surveillance form. The patient was asked if there were any problems pertaining to the surgical incision. In the event that he responded in the affirmative, he was questioned regarding redness, serous exudate, purulent exudate, spontaneous or physician assisted separation of the wound edges, culture obtainment, antibiotic treatment and hospital referral/readmission. An SSI was defined by the CDC criteria, based on the information gathered. Patients, who were diagnosed with SSI prior to discharge, were not questioned by phone.

Additional data recorded included age, sex, pre-surgery blood glucose (below/above 150mb/dL), American Society of Anesthesiologists (ASA) score, surgery type (elective/urgent), length of surgery, pre-surgery antibiotics. We also determined the National Healthcare Surveillance Network (NHSN) risk index for each patient [1].

Table 1 Demographics of study group ($n = 266$)

	N (%)
Patients age in years	
18–30	49 (18.4%)
31–50	78 (29.3%)
51–70	104 (39.1%)
Over 71	35 (13.2%)
Female gender	125 (47%)
Cr > 150 μmol/L	8 (3%)
Glucose >150 mg/dl	24 (9%)
Physical status classification ASA score	
1	99 (37.2%)
2	115 (43.2%)
3	37 (13.9%)
4	3 (1.1%)
Missing data	12 (4.5%)

ASA American Society of Anesthesiologists score

Reliability of telephone follow-up study

We conducted a separate study to determine the reliability of the telephone survey. In this study, we compared the telephone survey results with the report from examination by a surgeon the following day.

The study included patients who underwent surgery in the general surgery department at Hadassah Ein-Kerem between the months of November 2007 and March 2008, excluding anal and collaborative surgery, and who were scheduled for follow-up in the surgical clinic. Data on patients, who visited the clinic more than once during the study period, were collected only from their first visit, and all other visits were excluded. Patients whose clinic visit was more than a day after the telephone survey were excluded from the study. Patients who were informed by a medical authority that they had a SSI prior to their clinic visit were excluded from the study.

The telephone survey, which utilized an identical form to the one in the *Surgical site infection surveillance survey*, was conducted on the evening prior to the scheduled clinic follow-up by a single surveyor.

On the next day, the patient was examined in the outpatient clinic by a surgeon who determined whether or not they had an SSI. The surgeon filled out the surgical wound assessment form and indicated whether there was an infection and if so, its type. The form used was identical to the one used during in-hospital surveillance. The surgeon was unaware of the results of the telephone survey conducted the day before. In event that patients visited the clinic and did not have a form filled out by the surgeon, the written documentation on the visit was inspected to abstract relevant data. The telephone survey results were compared with the surgeon reports, using the results of the surgeon's examination as the gold standard.

Statistical analyses

Surgical site infection surveillance survey

The proportion of patients who contracted at least one SSI was calculated with a 95% confidence interval.

Reliability of telephone follow-up study

McNemar's test was used to test whether there was a significant difference in the distribution between the telephone survey and the surgeon's diagnosis. Estimates of sensitivity and specificity were generated with the surgical diagnosis serving as the gold standard repetition. We also collected additional studies in the literature that assessed patients' self-diagnosis of surgical site infections. A meta-analysis was conducted to summarize these measures. The pooled sensitivity and specificity measures were weighted by study size, and we tested for heterogeneity (I^2) of the measures within the relevant studies.

Finally, we evaluated the effects of self-assessment of the reported SSI rates by inferring the diagnostic characteristics of patients' self-assessment from our study and from the meta-analysis.

The study was performed with approval from the institutional ethical board for performance of quality surveys.

Results

Surgical site infection surveillance survey

The survey included 266 patients who underwent surgical procedures. Seventeen patients have been excluded from the survey: 13 because of an excluded surgery type (anal and collaborative) and four due to readmissions. During the study period, one patient died a month after small bowel resection, due to disseminated metastatic disease.

Patient characteristics are presented in Table 1. The most prevalent type of surgery was bowel/stomach/esophagus (26.7%) followed by inguinal hernia repair (23.7%). Most operations were elective (72.9%) and non-laparoscopic (80.1%). The average surgery duration was 1.6 h (SD = 1.2). Prophylactic antibiotics were provided to 134 (50%) of the patients within an hour prior to the surgery.

During hospital stay, 22 of the 266 patients (8.3%) developed an SSI while the remaining 244 (91.7%) underwent the telephone survey a month post-surgery. Of the 244 telephone surveys conducted, 204 surveys

Table 2 SSI rate and classification of SSI

Classification of SSI	SSI detected during hospital stay $n = 22$ *N* (%)	Additional SSI detected after discharge $n = 16$ *N* (%)	Total $n = 38$ *N* (%)
Superficial SSI	16 (72.7%)	11 (68.7%)	27 (71%)
Deep SSI	2 (9%)	3 (18.7%)	5 (13.1%)
Organ/space SSI	3 (13.6%)	2 (12.5%)	5 (13.1%)
Unknown	1 (4.5%)	0	1 (2.6%)

Table 3 Telephone surveillance versus surgeon assessment of infection

	Diagnosis of SSI by surgeon		Total	
	Not infected *N* (%)	Infected *N* (%)		
Patient report of SSI (telephone survey)				
Not infected *N* (%)	226 (85.9%)	4 (1.5%)	230 (87.5%)	NPV:98.3%
Infected *N* (%)	25 (9.5%)	8 (3.0%)	33 (12.5%)	PPV:24.2%
Total	251 (95.4%)	12 (4.6%)	263 (100.0%)	
	Specificity: 90%	Sensitivity: 66.7%		

Table 4 Post-discharge surveillance: review

References	Survey	Gold standard	TP	TN	FP	FN	$\sum$	Sensitivity[a]	Specificity[a]
Reilly et al. [13]	Telephone interview to all patients by research nurse 10, 20, 30 days post-surgery	Research nurse; all patients identifying problems and 10% of those who did not were visited by a trained research nurse	6	72	2	1	81	85%	97%
Whitby et al. [14]—non-educated patients	Mailed Patient Questionnaire	Assessed weekly by experienced infection control nurses (ICNs)	25	261	5	5	296	83.3%	98.1%
Whitby et al. [14]—educated patients			30	240	16	6	292	83.3%	93.7%
Sands et al. [9]	Mailed Patient Questionnaire (+Mailed surgeon Questionnaire)	Computerized search of electronic records with codes indicative of SSIs, which were then confirmed by record review by ICPs	30	1699	53	14	1796	68.2%	96.9%
Seaman and Lammers [15]	Patient Interview by Medical Practitioners	Medical examiner (physician, nurse practitioner or physician's assistant)	11	381	31	10	433	52.3%	92.4%
Mitchell et al. [16]	Patient Questionnaire	Surgeon questionnaire	74	565	2	8	649	90.2%	99.6%
Current report	Patient Phone Interview by Medical Practitioner	Medical *examination* by surgeon	8	226	25	4	263	66.7%	90%
Overall								83.3%*	97.4%**
95% CI								78.7–87.9	96.9–97.9

* $p = 0.012$; ** $p < 0.001$ for heterogeneity

[a] Sensitivities and specificities are presented as reported. In events of arithmetic discrepancies, please refer to the original publications

(84%) yielded data and 40 surveys (16%) were unfruitful; 21 (8.6%) due to lack of coordination between the members of the research project and 19 (7.8%) due to technical difficulties in completing the survey (the patient was unavailable or had no common language with the surveyor). In the telephone survey, 16/204

Table 5 Expected positive responses with simulation of post-discharge follow-up using patient reports

True SSIs	No SSIs	Current report		Meta-analysis	
		Sensitivity = 0.67 True positive responses	1-specificity = 0.1 False positive responses	Sensitivity = 0.83 True positive responses	1-specificity = 0.03 False positive responses
10	990	6.7	99	8.3	29.7
50	950	33.5	95	41.5	28.5
100	900	67	90	83	27
150	850	100.5	85	124.5	25.5
200	800	134	80	166	24
500	500	335	50	415	15
True SSIs	No SSIs	Reported SSI rate[a]	Ratio of true/reported rate	Reported SSI rate[a]	Ratio of true/reported rate
10	990	0.11	0.09	0.04	0.26
50	950	0.13	0.39	0.07	0.71
100	900	0.16	0.64	0.11	0.91
150	850	0.19	0.81	0.15	1.00
200	800	0.21	0.93	0.19	1.05
500	500	0.39	1.30	0.43	1.16

[a] Rates per 1000 patients; R reported SSI rate = (expected true positive responses + expected false positive responses)/1000

patients (7.8%) reported positively to questions confirming they had SSIs.

There were no differences in patient characteristics of age, sex, creatinine level, glucose level and ASA index between those who participated in the telephone survey and those who did not. A higher percentage of patients who underwent telephone survey, 116 (56.8%), received prophylactic antibiotics on time (within an hour prior to surgery) compared to those who did not participate in the survey, 11 (27.5%); $p = 0.005$.

In total, 16.8% (38/226) of the patients experienced a SSI (95% CI 10.1 to 18.5). SSI depth distribution is presented in Table 2. The 40 patients with missing data on the telephone survey provide a range of error for the overall rate of SSI in our population: between 29% (if all 40 had SSIs) and 10% (if none of the 40 had SSIs).

Of the 16 patients with SSI detected through the telephone survey, five (31%) were re-hospitalized within less than a month; three (19%) due to an SSI (two superficial infections and one in an organ). One patient (6%) was hospitalized due to fever of unknown origin and another patient (6%) due to erythema, swelling and induration at the incision site, not thought to be an infection.

During the telephone survey, there were no reports of admissions to other hospitals in Israel. Two patients (12%) came to the emergency room and were treated with antibiotics, due to suspected SSI. One patient (6%) went to an emergency department of a hospital in France and was treated there with antibiotics, due to a deep wound infection.

Reliability of telephone follow-up study

The survey included 329 telephone contacts among post-surgery patients, up-to one month after surgery at the general surgery department. Of these, 263 fulfilled all criteria and were included in the study; 33 patients who participated in the telephone survey failed to appear for clinic follow-up the next day, 24 patients appeared in the survey more than once and only their first visit to the clinic was included, seven patients visited the clinic but had no surgical incision assessment form on file and no report on the surgical incision was found in the medical record or was available and two patients were hospitalized due to SSI and were not included in the survey analysis.

The mean (SD) age was 53 (18.9), and half of the respondents were women.

Among the completed telephone reports, 198 (75.3%) were compared to the surgical incision assessment form and 65 (24.7%) were compared to the surgeon's report in the patient's medical record.

A comparison of the telephone survey and the surgeon's exam is presented in Table 3. Of the 251 patients who were not diagnosed with an SSI, 226 patients answered that there was no SSI. This translates to a specificity of 90% (95% CI 86–94%) for patient self-assessment on a telephone survey. Of the 12 patients classified by the surgeon as having a SSI, eight answered on the survey that they had an SSI, with a sensitivity of 66.7% (95% CI 40–93%). We also calculated the positive likelihood ratio (95% CI) to be 6.7 (3.9–11.5) and the negative likelihood ratio (95% CI) to be 0.37

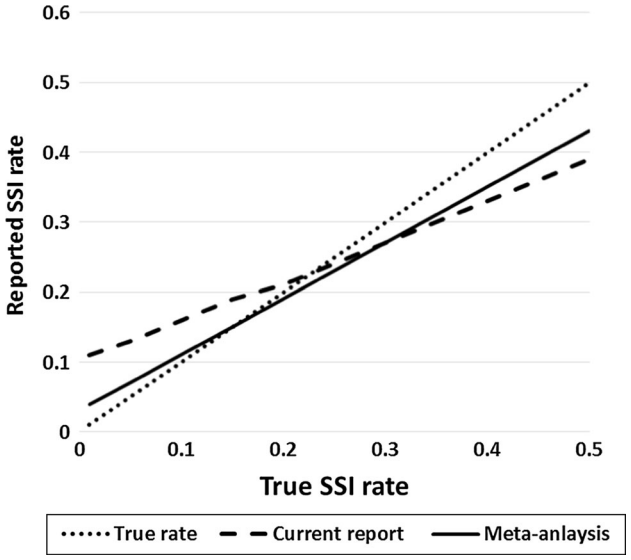

Fig. 1 SSI rate estimation error. The *dotted line* presents an ideal surveillance tool reporting the exact SSI rate. The *solid line* presents the rate reported of a surveillance tool with a sensitivity of 83% and a specificity of 97%, corresponding to the results of the meta-analysis. The *dashed line* presents the rate reported of a surveillance tool with a sensitivity of 67% and a 90% of specificity, corresponding to the results of our institutional study

(0.17–0.82). The probability of agreement was statistically significant (p value <0.001), and the kappa (95% CI) was calculated to be 0.31 (0.13–0.49). We repeated the analyses with stratification for the source of information (surgical incision assessment form vs. surgeon's report in medical record), and this yielded similar results.

Meta-analysis

We found five studies that examined the reliability of post-discharge surveillance and published their data so that specificity and sensitivity could be calculated and compared to the findings in our study. Table 4 summarizes the findings. Of the five studies reviewed, three were conducted by a mailed questionnaire and two by a phone interview with the patient. Reilly's phone study was conducted by one nurse [13], while Seaman and Lammers [15] conducted their survey using a number of surveyors. In all of the studies, except Mitchell's, the gold standard included a physical exam by a medical professional but not a physician [16]. None of the studies state the number of days that elapsed from the home survey to the gold standard exam. Sands, Whitby and Mitchell used a wide patient population from a number of surgical departments [9, 14, 16]. Seaman and Lammers [15] only included patients with lacerations treated at A&E. Reilly et al.'s [13] study population comprised of patients who underwent orthopedic surgeries.

Reilly, Whitby, Sands and Seaman all found sensitivity measures similar to the one found in the present study [9, 13–15]. The sensitivity found in Mitchell's study is higher than the one found by us [16]. In this study, a number of SSIs identified by patients but not by the surgeon were reevaluated and classified as SSIs. Seaman found specificity similar to ours, but all the other studies found higher specificities [15].

We performed a meta-analysis of these studies and ours. The results are presented in Table 4. The overall sensitivity is 83.3% (95% CI 79–88%), and the overall specificity is 97.4% (95% CI 97–98%). There is much variability between the studies with statistically significant heterogeneity for sensitivity and specificity ($p = 0.012$, $p < 0.001$, respectively).

In Table 5, we provide the results of simulating the effects of self-assessment inaccuracies on reported post-discharge SSI rates. The higher the true rate, the greater the ratio of true positive events versus false positive events. For examples, when the true infection rate is 1%, reported rates would be anywhere between 4 and 11% (range between our local results and meta-analysis); when the true rate is 50%, reported rates would range between 39 and 43%. Both the results of our validation survey of patient self-assessment and the results of the meta-analysis demonstrate that when the true post-discharge SSI rate is lower than 15%, the self-assessment inaccuracies lead to overestimation of the true SSI rate (the ratio of true rate vs. reported rate is below 1.0). Figure 1 demonstrates the error of SSI rate estimation using patient self-assessment using our institutional findings of the pooled results from the meta-analysis. In either case, rate estimation error reduced the variation between reported rates.

Discussion

In this report, we present a survey measuring our institutions 30-day post-surgical SSI rate, using telephone follow-up. The in-hospital SSI rate was 8.3%, and the telephone survey measured a 7.8% SSI rate among patients who were followed through the telephone survey. In order to evaluate the reliability of the telephone follow-up, we conducted a study comparing patient telephone responses to surgeon clinic assessment. In this study, we found that patient response had a sensitivity of 67% and a specificity of 90% (LR+ 6.7, LR− 0.37). Additionally we performed a systematic review of studies assessing patient self-report of SSIs. The overall sensitivity was 83% and the overall specificity 97%. However, significant heterogeneity was found between the studies.

There is an inherent paradox regarding the use of self-reported schemes for diagnosis of SSIs, assuming that surgeon clinical assessment is the gold standard. Given any

set of self-assessment test characteristics, the lower the true SSI rate, the greater the false positive rate of self-assessment, compared to true positives. Extrapolating our findings, assuming that among patients discharged from our institution there would indeed have occurred another 22 SSI cases, 37 patients in the telephone follow-up would have reported SSI, of which 15 would have been true positives and 22 would have been false positives. Using the meta-analysis data, the respective numbers would have been 25 SSI reports in total, 18 true positives and 7 false positives. Table 5 demonstrates the expected true positive and false positive count given increasing true SSI rates for cohorts of 1000 hypothetical post-surgical patients.

The rate of infection differs across hospitals, surgeons, patients and types of surgery. The American National Nosocomial Infection Survey (NNIS) held during the years 1992–2004 found SSI rates to range from 0.67% to 4.97% in general surgery operations, depending on the type of surgery and on the NNIS Risk Index [1]. In a review conducted by Holtz covering the years 1967–1990, SSI rates differed dramatically between studies, ranging from 22.3% in a report on appendectomies to 2.5% in a study that included all types of surgery. Research that included only general surgery cases identified an SSI rate of 13.5% [18]. Weiss' study conducted in Minnesota in the years 1993–1998 showed a 3.2% infection rate in general surgery operations [19]. In contrast, the SSI rate for general surgery operations, reported by London hospitals in 2004, ranged from 12.6–19.3%. Weinwurm's study, conducted in 2002–2004 in Canada, exclusively on bowel surgeries, showed a SSI rate of 23% [20]. The rate of SSIs reported in Thailand for general surgery, vascular, orthopedics and obstetrics-gynecology operations in the years 2003–2004 was 1.4% [21]. In Bolivia, in 1999 the SSI rate in general surgery, orthopedics and obstetrics-gynecology operations was 12% [22]. Follow-up surveillance only adds to this array of results. Interestingly, it will generally lead to an underestimation of the true variability. The inaccuracies will necessarily overestimate the rate of institutions with low rate and underestimate the results of institutions with high rates.

In contrast, assuming post-discharge diagnosis was accurate, not counting these events would lead to an underestimation of the true SSI rates [3]. Not all hospitals routinely monitor the incidence in SSIs for a full month; this includes our institution, where a month of surveillance is not standard practice.

Reilly studied the effect of post-discharge surveillance on SSI rates and found that the group that had post-discharge follow-up had a significantly higher SSI rate when compared to the group with no post-discharge surveillance [23]. In a review by Holtz, 68% of SSIs following general surgery operations were detected after discharge from the ward. In other types of surgery, the rate of SSIs detected post-discharge ranges between 13 and 71% in different studies [18]. In Weinwurm's study, the SSI rate during hospitalization was 15% and the post-discharge SSI rate was 8% [20]. Another study, conducted in Thailand, found that 27.6% of SSIs were detected post-discharge [21].

Therein lies the paradox, no follow-up means that there is underestimation of institutions' SSI rates. Inaccurate follow-up leads to flawed estimations which decreased the observed variability between institutions.

Reporting quality measures, among them SSI rates, is becoming standard. Like other quality improvement initiatives, it is intended to aid healthcare providers to direct attention to preventable harm to patients and thus improve outcomes and service. However, like other quality improvement initiatives, controversy and practical difficulties exist. In this report, we focus on two elements of SSI surveillance—post-discharge follow-up for complete 30-day SSI ascertainment and the use of patient self-report to diagnose post-discharge SSIs. Though 30-day post-discharge follow-up is necessary to estimate the TRUE SSI rates, this is not the aim of SSI surveillance. We demonstrate in this report how patient follow-up using self-report provides a disservice to the quality improvement cause. Even if standardization of patient self-report is achieved, institutions with better performance will have overestimation of their rates. As we commented with regard to CLABSI surveillance [24], methodology can lead to improvement disincentives, especially when inter-institution comparisons and public reporting are competitive considerations. A systematic review of various post-discharge telephone follow-up interventions, not limited to infection surveillance, concluded with similar findings [25].

Promotion of post-discharge surveillance of deep wound infections alone is a reasonable approach and likely less prone to diagnostic uncertainty and interpretation, and their occurrence is expected to be a notable event. We believe that our results support this course of action. However, appropriate investigations should examine potential pitfalls is such surveillance and assess their validity and reliability for quality surveillance, follow-up and comparisons. As mentioned above, professional independent committees could be charged with surveillance, though appropriate organizational action should facilitate their acceptance among surgical staff and plan to prevent disruptive behavior within the institutions [12].

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