

TITLE PAGE

Title: A prospective comparative study of methods in surgical site infection tracking in abdominal surgery patients: tracking by surgeons is a poor indicator of gold standard measured incidence of surgical site infections

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Running head: Registration of SSI in surgical patients

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Key words: abdominal infection, healthcare-associated infection, infection control, surgical site infection, wound infection

ABSTRACT

Background: The incidence of surgical site infections (SSI) is increasingly considered to be an indicator of quality. Daily inspection was performed by an independent, trained team to monitor the incidence of SSI (gold standard) and outcomes were compared with two department registration systems (performed by the surgeon involved) to evaluate the reliability of these latter systems as possible alternative methods.

Methods: 1000 adult patients scheduled to undergo open abdominal surgery in an academic teaching hospital were included in an incidence study between May 2007 and January 2009. Wounds were inspected daily to check for SSI according to definitions of the Centers for Disease Control and Prevention for healthcare-associated infections. Follow-up after discharge was performed at the outpatient clinic by telephone or letter combined with wound diaries and review of patient charts, discharge letters, electronic files and reported wound complications. Univariate and multivariate analyses were performed to identify putative risk factors for missing registrations.

Results: 33 patients were not evaluated. SSI were diagnosed in 26.9% of 967 remaining patients: 18.0% superficial, 5.5% deep and 3.4% organ/space. Over 60% of SSI were not reported in either of the department's tracking systems. For these systems, independent major risk factors for missing registrations were no occurrence of SSI, transplantation surgery, and admission to non-surgical departments.

Conclusions: The majority of SSI were not tracked with the department's systems. These systems proved poor alternatives to gold standard method of measuring SSI incidence and, therefore, quality of care. Protocolled wound assessment and on-site documentation are mandatory for measuring realistic SSI incidence.

INTRODUCTION

Surgical site infections (SSI) are the most frequent health care associated infections among surgical patients, constituting 38% of all nosocomial infections in this group.[1] SSI are associated with high morbidity and high costs due to increased length of stay, extra ambulatory care visits and higher readmission rates.[2-8] Tracking of surgical complications enables improvement of health care by identification of risk factors, risk groups and specific interventions.[9] SSI are increasingly considered to be indicators of quality of care. The extent of non-reported infections, however, remains unknown and depends on the methodology used. A prospective incidence study on SSI was performed to evaluate the reliability of the department's routine tracking systems as alternatives for measuring SSI incidence.

METHODS

The study was designed as a prospective observational cohort study and was performed at a 1200-bed academic teaching hospital. Approval for the study was obtained from the local ethics committee. Inclusion criteria included minimum age of 18 years and open abdominal surgery or converted laparoscopic procedure. Exclusion criteria were laparoscopic surgery, inguinal/umbilical hernia and day surgery in order to obtain a patient group that could be subjected to repetitious, daily in-hospital surveillance, with an estimated high risk of developing SSI in all three degrees (superficial, deep and organ/space). Informed consent was obtained from all study participants. In addition to demographic data (age, gender, department of admission), the following data were documented: body mass index, comorbidity (chronic obstructive pulmonary disease, diabetes mellitus), systemic corticosteroid use (oral, but not inhalation or dermal corticosteroid use), smoking, American Society of Anaesthesiologists (ASA) score, operation time, type of surgery, emergency surgery, transplantation surgery, National Research Council wound contamination class and National Nosocomial Infection

Risk Index. Furthermore, data on length of hospital stay, reoperation within 30 days after primary surgery, and in hospital mortality were collected. Included patients were subjected to the 'daily surveillance' tracking method, the primary outcome of which was incidence of SSI using the Centers for Disease Control and Prevention (CDC) definitions.[10] Other endpoints included abdominal wound dehiscence and wound pain. However, these results will not be discussed in this paper. For each patient, data reported in the department's two routine tracking systems were reviewed for occurrence of SSI in that particular system. In the Netherlands, national nosocomial infection tracking systems include the Dutch National Nosocomial Infection Surveillance System (Preventie Ziekenhuisinfecties door Surveillance [PREZIES]), which is mainly used for prevalence studies. In PREZIES, the SSI definition used is based on the definition used by the CDC, with the additional obligatory presence of clinical symptoms; diagnosis of SSI by the surgeon alone was not sufficient for SSI determination. Our study was different from PREZIES since these additions to the CDC definitions were not applied.

Daily surveillance tracking method ('gold standard')

Abdominal wounds were inspected and photographed daily by two research fellows from post-operative day 2 onwards (including weekends and holidays) to observe for presence of SSI. Research fellows were medical students in the 4th-6th year of training who participated in the study for a minimum period of five months, supervised daily by the first author (GHvR). All participants of this team tracked infections independently from the surgeon involved in the operation. At least once a week inspection rounds were performed with the supervisor. After 21 days of clinical observation or at discharge if earlier, patients were given diaries for wound problems until post-operative day 30. This period was chosen because the majority of SSI have been reported to present within 21 days post-operatively.[1] Follow-up was performed at

the outpatient clinic on post-operative day 30, or alternatively by telephone or letter. Patient charts, discharge letters, wound photographs, and culture results were reviewed by the first author (GHvR) after a minimum period of three months after discharge by the first author (GHvR) to verify SSI incidence. The surveillance team was impartial and compliance with the electronic and plenary tracking systems was not promoted by the team itself, in order to measure the 'true' sensitivities of the systems described below. Data collected by the surveillance team were not submitted to any national surveillance system.

Electronic tracking system

The electronic ward system was introduced in January 2007 and required residents to track in-hospital complications daily. Electronic sheets allowed documentation of presence (or absence, as possible marking) of complications and their severity. No application was included to alert physicians if this sheet was missing at discharge. These data were not submitted to any national surveillance system.

Plenary tracking system

For several years, the plenary tracking system consisted of the daily review of all patients discharged from surgical wards at the plenary morning report lead by the head of department. The occurrence of complications, including a short description and the severity of the most serious complication were scored on paper and filed for patients discharged approximately 3-5 days before. These data were not submitted to any national surveillance system.

In addition, physicians were required to issue discharge letters for all patients, including for patients who died in hospital.

Statistical analysis

A total number of 1000 patients were to be recruited, based on the hypothesis that 10% of included patients would develop SSI; thereby allowing for sufficient group sizes to compare patients with and without SSI. Putative risk factors for missing registrations from the tracking systems were evaluated with univariate analysis, using chi-square test and Mann-Whitney test for categorical and continuous data, respectively. Subsequently, variables that were significant in univariate analysis were entered in multivariate stepwise logistic regression with backwards elimination to identify major independent predictors of missing registrations. Cox regression analysis, with the occurrence of SSI as time-dependent factor, was performed to investigate the association between SSI and 30-day survival. SPSS (Chicago, version 15.0) was used for all analyses. P-values (two-sided) <0.05 were considered significant in all analyses.

RESULTS

Between May 2007 and January 2009, 1000/1459 eligible patients were included, 459 patients did not give informed consent. Thirty-three patients were not evaluated due to cancelled surgery or exclusion criteria fulfillment, leaving 967 patients for analysis.

Surgical procedures included: kidney transplantation (19.5%), liver (13.8%), colorectal (13.0%), oesophagus (11.5%), stomach-small intestines (9.4%), pancreas (8.3%), vascular (6.2%) and other (18.3%). Length of stay (10th-90th percentile) was 5-31 days for the group as a whole, with a median hospital stay of 11 days (5-25 days) for patients without SSI and 16 days (8-51 days) for patients with SSI (p<0.001). Forty-five patients with SSI were reoperated (17.4%; SSI diagnosis in 27 patients before or during reoperation and in 18 patients after reoperation) vs. 26 patients without SSI (p<0.001). In total, 41 patients (4.2%) died within 30 days after surgery (36 in hospital, 11 after SSI, 25 no SSI). Thirteen patients with SSI died

within 30 days after surgery vs. 28 patients without SSI (5.0 vs. 2.9%). In survival analysis, the hazard ratio for risk of death associated with SSI in the period 30 days after surgery was 2.7 (95% CI 1.3-5.5, $p=0.006$). Additional population characteristics are displayed in Table 1.

Daily surveillance tracking method ('gold standard')

Thirty-day follow-up was completed in 85.4% of 967 patients: 643 (77.9%) at the out patient clinic, 170 (20.6%) by telephone and 14 (1.7%) by letter or e-mail. Data from the plenary and electronic tracking systems were reviewed for all 967 patients. Patient charts of 946 patients (97.8%) were examined, 21 charts (2.2%) were lost. Using the daily surveillance tracking method, SSI were diagnosed in 259 of all patients (26.8%): 174 superficial (18.0%), 53 deep (5.5%) and 33 organ/space (3.4%), see Figure 1.

Median diagnosis of SSI was at post-operative day 9 (interquartile range 6-13 days). The majority of infections (81%) were diagnosed in hospital. Median hospital stay increased with SSI severity and was 14, 25 and 27 days for superficial, deep and organ/space infections, respectively ($p<0.001$). Patients with SSI were readmitted more than twice as often as patients without SSI (15.1% versus 7.4%, $p=0.009$). Mean number of ambulatory care visits within three months after surgery was 1.9 for patients with SSI versus 1.1 for patients without SSI ($p<0.001$).

Electronic tracking system

Registrations were made for 458/967 analyzed patients (47.4%), for the other patients no registrations of any complications were performed. For 509 patients, registrations were missing (52.6%). SSI were tracked for 64 of 259 patients with SSI (24.7%) (according to the daily surveillance tracking method). In compliance with the method, infections diagnosed

after discharge were tracked significantly less often than infections diagnosed in hospital (6/49 vs. 58/210 patients; $p<0.001$). Deep and organ/space infections were not reported more often than superficial SSI ($p=0.488$).

Plenary tracking system

Registrations were available for 709/967 analyzed patients (73.3%). Registrations were missing in 258 patients (26.7%). SSI were tracked in 79/259 patients (30.5%) with SSI (according to the daily surveillance tracking method). In compliance with the method, infections diagnosed after discharge were tracked significantly less often than infections diagnosed in hospital (4/49 vs. 75/210 patients; $p=0.042$). Deep and organ/space infections were not reported more often than superficial SSI ($p=0.097$).

Discharge letters were available for 946 patients (97.8%), 21 letters were missing (2.2%). Infections were reported in 40% of patients with superficial SSI (68/171), 70% of patients with deep infections (37/53) and in 61% of patients with organ/space infections (20/33). Deep and organ/space infections were reported significantly more often than superficial infections ($p<0.001$).

Missing registrations

In total, 40.2% of patients with SSI were reported in the plenary and/or electronic tracking systems. For the total population ($n=967$), SSI registrations were missing for 52.6% of patients in the electronic system and for 26.7% of patients in the plenary morning report. SSI missing from the plenary and/or electronic tracking systems ($n=218$) required readmission within 30 days in 14% ($n=30$), reoperation following SSI diagnosis in 15% ($n=32$), use of antibiotics in 32% ($n=46$), and 8% ($n=18$) resulted in death. Table 2 shows the frequency of

various putative risk factors and the results of univariate analyses. Risk factors for missing SSI registrations in the plenary and electronic system in univariate analysis were no occurrence of SSI, transplantation surgery, emergency surgery and admission to a non-surgical department. In hospital mortality and length of hospital stay were not risk factors for missing SSI registrations. In multivariate analysis, no occurrence of SSI, transplantation surgery and admission to a non-surgical department proved significant independent risk factors for missing SSI registrations (Table 3).

Table 4 shows infection rates calculated for different (combinations of) tracking systems. The infection rate for data from the plenary and electronic system combined was 10.3% (100/967). After addition of discharge letter data, the infection rate was 16.9%, and sensitivity with the daily surveillance tracking method as reference rose from 38.6% (100/259) to 61.8% (160/259). This rate remained significantly lower than the daily surveillance tracking method rate of 26.8% ($p < 0.001$). According to CDC criteria, a number of patients with opened wounds were wrongfully diagnosed as infected in the electronic ($n=2$) and plenary system ($n=7$), in presence of negative wound cultures and in absence of other symptoms to fulfill CDC criteria for SSI. Specificities of the electronic and plenary system were 99.4% and 98.6%, respectively.

DISCUSSION

The incidence of SSI in this study was 26.8%; SSI were associated with significant morbidity and increased 30-day mortality. The majority of SSI (61%) were not reported in any of the tracking systems used by surgeons. Based on the substantial morbidity associated with missed SSI, it would appear that a large proportion of these missed infections were clinically relevant. Methods of complication tracking procedures and classification systems vary

significantly in literature.[12-20] Tracking systems used by surgeons proved unreliable for monitoring the incidence of SSI, and consequently, this method of self-reporting constitutes a poor indicator of quality of care. A self-reporting bias for surgeons and residents may partly explain the low sensitivity of the tracking systems, whereas such a bias was unlikely to exist for members of the daily surveillance tracking method team in the tracking of SSI. The sensitivity of the daily surveillance tracking method and the high rate of follow-up may also explain the high infection rate, which was comparable to infection rates reported by other authors.[21, 22] Finally, tracking by a specialised team cannot be exchanged with surgeons' tracking systems without losing a great part of sensitivity. Comparison of these data with national data was partly possible due to a validation study of the PREZIES data which was performed between 1999-2004. It consisted of systematic retrospective chart review by the validation team and interviews with local infection control professionals. In that study, a positive predictive value of 0.97 and negative predictive value of 0.99 were found, both comparable with our study findings.[23]

Independent risk factors for missing registrations in the department's systems included no occurrence of SSI, transplantation surgery and admission to a non-surgical department. These risk factors most likely indicate non-compliance of surgeons and surgical residents in charge of patients admitted to the transplantation department and non-surgical departments, which may not be generalized to other institutions.

Our routine electronic tracking system relied on the individual responsibility of the residents and supervising surgeons involved. Heavy work load may have hindered reliability of medical records or electronic tracking, causing doctors to forget or ignore documentation of complications because of other priorities. Continuity of care can be endangered by frequent

shift changes and compensatory leave, allowing a superficial SSI to remain untracked. It might be useful to involve (trained) nurses or physician assistants in the tracking of SSI, since nurses generally inspect wounds more often than doctors. One study reported good results of routine electronic (computer) tracking by nurses of deviations from normal post-operative course on a daily basis and specifically before discharge from the post-operative ward, after which supervising physicians decided whether or not complications had occurred.[24] An additional weakness of our electronic system was the lack of alarm signals and supervision, which allowed missing registrations to remain unnoticed without consequences. However, we doubt whether patient safety would have been guaranteed with alarming signals and would, thereby, have covered 100% of all patients, as the sensitivity of the self reported system was far lower compared to the tracking method used by the specialised team.

The plenary tracking system during the morning report depended on by the continuity of care in the department. It was problematic that operated patients admitted to non-surgical wards in our local hospital, who were not primarily registered as surgical patients (urology, internal medicine), were not featured on discharge lists. Operation-associated complications, thus, remained untracked. Furthermore, data from the tracking systems were not routinely combined or evaluated. Evaluation of any single self-reporting system resulted in a lower number of infections than actually reported in all tracking systems combined. Routine evaluation of the tracking systems or other types of exogenous pressure to complete missing (SSI) data might have helped to achieve higher compliance.

The results of this study have raised awareness of the underestimated SSI rates in the departments of general surgery and infection control. Embedding the gold standard surveillance approach (including patients' diaries and post-discharge follow-up) into routine

practice has thus far proven to be challenging on financial and practical grounds, because this method is associated with an increase in work load and post-discharge surveillance has remained voluntary in the national nosocomial infections surveillance system. Another way of cost-effective surveillance can be performed by using an electronic or automatic selection of patients for nosocomial infections. This system of automated selection will be validated against this time-consuming but very reliable surveillance. Automated selection of high-risk patients, which deserves more and more attention, and will be our future, will be able to inform about rates of infections and at the same time leaving hands free for the intervention needed.

The discharge letters were expected to be fairly complete in the description of complications such as SSI, and it was hoped that the efficacy of the electronic and plenary complication tracking system would be easily deductable from these data. However, our data illustrated that the review of discharge letters for SSI follow-up was of limited value due to its mediocre sensitivity, especially for superficial SSI. In view of the fact that 19% of SSI in our patients were detected after discharge and up to 84% in previous studies, depending on the patient population, post-discharge data ought to be included in audit meetings.¹ Infection rates reported in literature, possibly apart from those rates reported in well-performed randomized controlled trials, will generally represent a fraction of the true number of affected patients. It is notoriously difficult to achieve complete follow-up and documentation of post-operative wound infections, even when charts are reviewed.[13, 19] In many studies, follow-up after discharge is omitted or performed by surgeon questionnaires only. The relative percentage of SSI detected after discharge is highly dependent of the intensity of post-discharge surveillance and can differ significantly between various countries even if comparable surveillance protocols and definitions are used. [25] According to a report by the European Centre for

Disease Prevention and Control, the Netherlands were amongst the countries with the highest percentage of infections diagnosed after discharge at 58% in 2007. [26] Furthermore, the type of surgery proved relevant for the percentage of SSI detected after discharge; with a relative low percentage of SSI reported for colon surgery (13%) compared to 48% overall in 2009. [27] Although follow-up of patients with implanted materials of non-human origin at one year after surgery is recommended by the CDC, it is often not performed in studies with general surgery patients. Implanted materials of non-human origin, such as mesh, are not frequently used in this patient group. The period of follow-up was limited to 30 days in this study.

Use of self-reported infection incidence as indicator of quality of care is not advisable due to low documentation rate (depending on the method used), favoring hospitals with the smallest 'tip of the iceberg'. Punishment of hospitals with high infection rates will promote low documentation of infections and alternative interpretation or use of definitions, which do not contribute to patient safety or the development of a self-critical climate. Structural shortcomings in care may then be less easily identified. A better system for measuring patient safety is not comparing outcome data (SSI, depending on case mix), but comparing process indicators for prevention of infections, such as timely administered antibiotic prophylaxis. To truly improve quality of care, a constructive approach towards the issue of SSI is needed from politicians and health insurance companies. In order to be able to compare hospital infection rates, uniform definitions must be used and surveillance and prevention of SSI should be integrated in resident training programs. Finally, comparing rates needs accurate correction for case mix and large numbers for adequate power. Reliability of SSI incidence rates depends on the quality of SSI documentation at the in and out patient departments, which should involve training of nurses and doctors in protocolled, regularly supervised assessment of acute surgical wounds as part of a continuous validation process.

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None of the authors have competing interests

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Table 1: Population characteristics and clinical data for the total population (n=967) and subpopulations without surgical site infections (No SSI, n=708) and with surgical site infections (SSI, n=259) according to gold standard

Variable	Age (years)*	Gender f/m	BMI*	COPD	Diabetes mellitus	Systemic corticosteroids	Smoking	Emergency surgery	Operation time (min) *	NRC class				NNIS risk index†			
										Clean	Clean-contaminated	Contaminated	Dirty-infected	0	1	2	3
Total n=967	56.4 ± 14.4 (35.0-74.0)	363/604	25.7 ± 4.8 (20.1-31.6)	88 (9)	133 (14)	126 (13)	401 (42)	217 (22)	262 ± 131 (128-461)	171 (18)	710 (73)	30 (3)	56 (6)	165 (17)	593 (61)	196 (20)	13 (1)
SSI n=259	57.0 ± 13.6 (37.0-73.0)	95/164	26.6 ± 5.0 (20.6-33.7)	32 (12)	44 (17)	42 (16)	95 (37)	67 (26)	295 ± 147 (126-505)	31 (12)	188 (73)	11 (4)	29 (11)	22 (9)	160 (62)	70 (27)	7 (3)
No SSI N=708	56.1 ± 14.6 (34.9-74.0)	268/440	25.4 ± 4.7 (20.0-31.2)	56 (8)	89 (13)	84 (12)	306 (43)	150 (21)	250 ± 123 (129-431)	140 (20)	522 (74)	19 (3)	27 (4)	143 (20)	433 (61)	126 (18)	6 (1)
Overall SSI %	-	-	-	36	33	33	24	31	-	18	26	37	52	13	27	36	54
P-value	0.425	0.796	<0.001	0.046	0.098	0.094	0.077	0.148	<0.001	<0.001				<0.001			

BMI: body mass index

COPD: chronic obstructive pulmonary disease

NRC class: National Research Council (NRC) wound contamination class

* Values present mean ± standard deviation and range (10th-90th percentile) or numbers of patients (percentage)

† NNIS risk index: National Nosocomial Infection (NNIS) risk index was calculated by awarding 1 point for each of the following: (1) a patient with ASA class 3, 4, or 5, (2) an operation classified as contaminated or dirty-infected, and (3) an operations lasting over T hours, where T depends upon the operative procedure being performed.¹¹

Table 2: Results of univariate analyses of putative risk factors for missing registrations per tracking system

Variable	Plenary system				P value	Electronic system				P value
	<i>Missing registration</i>		<i>Missing registration</i>			<i>Missing registration</i>		<i>Missing registration</i>		
	<i>Yes</i>	<i>No</i>	<i>Yes</i>	<i>No</i>		<i>Yes</i>	<i>No</i>	<i>Yes</i>	<i>No</i>	
	<i>n=258</i>	<i>n=709</i>	<i>n=509</i>	<i>n=458</i>		<i>n=509</i>	<i>n=458</i>	<i>n=509</i>	<i>n=458</i>	
	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>		<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	
No occurrence of SSI	212	82.2	496	70.0	<0.001	396	77.8	312	68.1	0.001
Transplantation surgery	155	60.1	98	13.8	<0.001	195	38.3	58	12.7	<0.001
Emergency surgery	74	28.7	143	20.2	0.006	131	25.7	86	18.8	0.011
Admission to non-surgical department	46	17.8	58	8.2	<0.001	67	13.2	37	8.1	0.015
In hospital mortality	16	6.2	35	4.9	0.538	33	6.5	18	4.0	0.103
Length of stay (days) *	13	(6-30)	12	(5-32)	0.064	12	(5-29)	12	(5-34)	0.653

Values represent median and range (10th-90th percentile)

Table 3: Results of multivariate stepwise logistic regression analyses for missing registrations of surgical site infections (SSI) per tracking system

Risk factor	<i>Plenary system</i>				<i>Electronic system</i>			
	<i>Odds ratio</i> (OR)	<i>95% C.I. for OR</i> Lower limit Upper limit		<i>P-value</i>	<i>Odds ratio</i> (OR)	<i>95% C.I. for OR</i> Lower limit Upper limit		<i>P-value</i>
No occurrence of SSI	1.92	1.27	2.89	0.002	1.53	1.13	2.08	0.002
Transplantation surgery	14.35	9.91	20.8	<0.001	4.74	3.39	6.62	<0.001
Admission to non-surgical department	7.57	4.69	12.2	<0.001	1.72	1.72	4.11	<0.001

Table 4: Calculated infection rates per tracking method or combination of tracking methods for the population

Registration	No. of patients with reported SSI	Infection rate*
Plenary tracking system only	79	8.2%
Electronic tracking system only	64	6.6%
Discharge letters only	128	13.5%
Plenary and electronic tracking systems combined	100	10.3%
Plenary and electronic tracking systems and discharge letters combined	160	16.9%
Study total according to gold standard	259	26.8%

* Infection rate calculated as number of patients with **tracked** surgical site infections (SSI) divided by the number of analyzed patients (n=946 for ‘discharge letters only’ and ‘plenary and electronic systems and discharge letters combined’ and n=967 for all others)

Table 5: Calculated infection rates per registration method or combination of methods for the population

Registration	No. of patients with reported SSI	Infection rate*
Plenary system only	79	8.2%
Electronic system only	64	6.6%
Discharge letters only	128	13.5%
Plenary and electronic systems combined	100	10.3%
Plenary and electronic systems and discharge letters combined	160	16.9%
Study total according to gold standard	259	26.8%

* Infection rate calculated as number of patients with reported surgical site infections (SSI) divided by the number of analyzed patients (n=946 for ‘discharge letters only’ and ‘plenary and electronic systems and discharge letters combined’ and n=967 for all others)

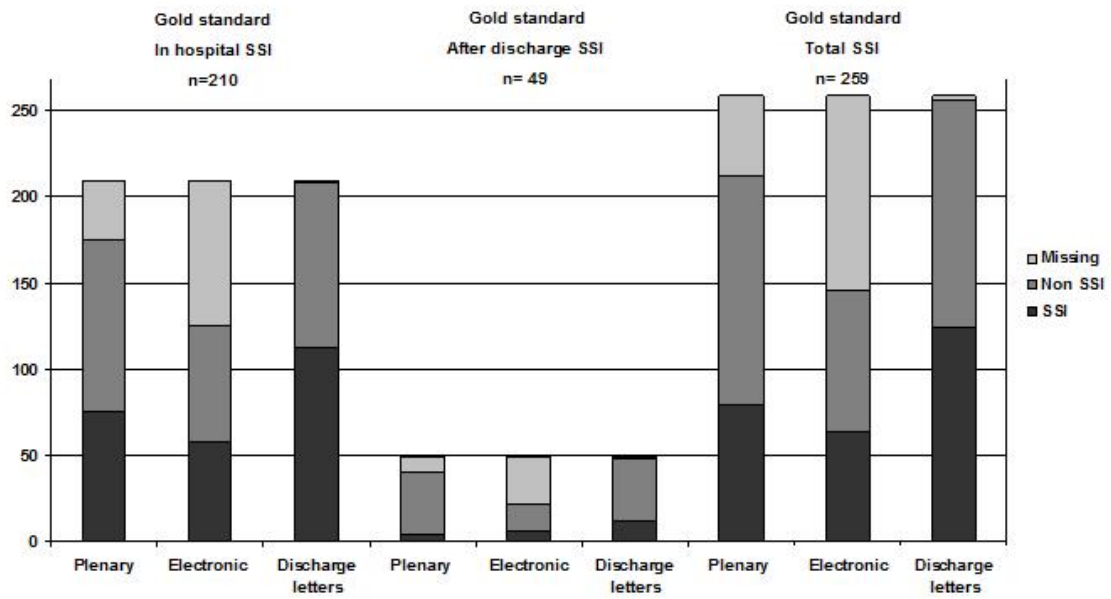


Figure 1: Surgical site infections (SSI) according to gold standard were tracked as SSI, not tracked as SSI (Non SSI) or registrations were missing (missing). Bars demonstrate proportionate distribution by tracking method (plenary, electronic and discharge letters) and timing of diagnosis.