Original Article

Performance of the Newly Introduced NHSN Logistic Risk Model for Classification Postcholecystectomy Surgical Site Infection

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Objective: To compare the predictive performance of the new CDC NHSN logistic risk model and the former National Nosocomial Infections Surveillance (NNIS) risk index for post-cholecystectomy surgical site infection (SSI) classification.

Materials and Methods: Surveillance of data for post-cholecystectomy SSIs were retrieved from the Infection Control Unit of Songklanagarind Hospital. The surveillance system uses the former NNIS risk index for SSI risk adjustment. The study included 2,422 patients that underwent gall bladder surgery in the hospital between January 2005 and December 2016. Medical records were reviewed for additional information including emergency operation, and gastrointestinal cancer. The predictive performance of the former NNIS risk index was then compared to the new NHSN model by mean of area under receiver operating curve (AUC).

Results: The study identified 71 operations with post-cholecystectomy SSI while the former and the new model predicted 21.6 and 14.0 SSIs, respectively. AUC of the new model (65.7%; 95% CI 59.1 to 72.3) was not significantly (p=0.5) different from the former one (64.5%; 95% CI 58.0 to 71.0).

Conclusion: The predictive performance of the new CDC NHSN and the former NNIS risk index model was about the same for classification risk of post-operative cholecystectomy SSI.

Keywords: Cholecystectomy, Surgical site infection (SSI), Risk stratification, Surveillance

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Surgical site infections (SSI) after cholecystectomy is a common event (11%)[1]. This serious complication has a high mortality rate and is a financial and environmental burden to patients.

To predict the patients' risk of developing SSIs before the surgery, risk stratifications is a crucial method. The former National Nosocomial Infections Surveillance (NNIS) risk model has been used for decades and found poor efficacy in predicting SSI after several surgical procedures[2]. The novel National Healthcare Safety Network (NHSN) risk adjustment model was developed to cope with the problem. No reports evaluate the performance of the new model compared to the former one. The authors intended to assess the efficacy of the new model in prediction of post-cholecystectomy SSI rate.

Materials and Methods

Setting

The present study was conducted in Songklanagarind Hospital, a tertiary referral hospital, medical school and research center in Southern Thailand.

Inclusion criteria

The target population in the present study comprised of all patients that underwent cholecystectomy in Songklanagarind Hospital between January 2005 and December 2016. Cholecystectomy procedures were defined by the ICD-9-CM procedure codes.

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Table 1. Criteria for defining a surgical site infection (SSI)

Superficial incisional SSI	Infection occurs within 30 days after the operation and infection involves only skin or subcutaneous tissue of the incision and at least one of the following:
	1. Purulent drainage, with or without laboratory confirmation from the superficial incision.
	2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
	3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative.
	4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.
	Do not report the following conditions as SSI:
	1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).
	2. Infection of an episiotomy or newborn circumcision site.
	3. Infected burn wound.
	4. Incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).
Deep incisional SSI	Infection occurs within 30 days after the operation if no implant† is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision and at least one of the following:
	1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
	2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38℃), localized pain, or tenderness, unless site is culture-negative.
	3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
	4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.
	Notes:
	1. Report infection that involves both superficial and deep incision sites as deep incisional SSI.
	2. Report an organ/space SSI that drains through the incision as a deep incisional SSI.
Organ/space SSI	Infection occurs within 30 days after the operation if no implant† is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation and at least one of the following:
	1. Purulent drainage from a drain that is placed through a stab wound# into the organ/space.
	2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
	3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
	4. Diagnosis of an organ/space SSI by a surgeon or attending physician.

† National Nosocomial Infection Surveillance definition: a nonhuman-derived implantable foreign body (e.g., prosthetic heart valve, nonhuman vascular graft, mechanical heart or hip prosthesis) that is permanently placed in a patient during surgery

If the area around a stab wound becomes infected, it is not an SSI. It is considered a skin or soft tissue infection depending on its depth

Exclusion criteria

The study excluded the patient who 1) had an incomplete or concealing data or 2) had operative time longer than five interquartile range (IQR) (314 minutes, a 10-minute increase in operative duration that was analyzed for expected SSI is continuous data, making this factor had no upper limit value. For this reason, the Centers for Disease Control and Prevention (CDC) suggested to set the upper limit value at five times of IQR, thus the upper limit of this value is 314 minutes).

Duration of study

Between December 26, 2016 and January 31, 2017.

Table 2. ASA physical status classification

ASA score	Definition
I	A normal healthy patient
II	A patient with mild systemic disease
III	A patient with severe systemic disease
IV	A patient with severe systemic disease that is a constant threat to life
V	A moribund patient who is not expected to survive without the operation
VI	A declared brain-dead patient whose organs are being removed for donor purposes

ASA=American Society of Anesthesiologists

Table 3. Surgical wound classification

Classification	Definition
Class I or clean	An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria.
Class II or clean-contaminated	An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.
Class III or contaminated	Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered are included in this category.
Class IV or dirty-Infected	Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

Definition

Criteria for defining a surgical site infection: Surgical site infection or SSI was defined and classified by the CDC(3). The criteria used for the definition of SSI are shown in Table 1.

ASA score: The American Society of Anesthesiologists (ASA) score was used to classify the patients into six groups with different degrees of severity of illness during an admission (Table 2)[4].

Wound classification: Surgical patient wounds were classified by the CDC. This classification was used to classify the patients into five groups with different degrees of hygienic of wound (Table 3)[3,5].

Data collection

Data in the present study were recorded in the medical records of hospital information system (HIS) recorded by experienced doctors and nurses. The data including age, gender, body weight, body height, admission date, discharge date, presence of diabetes mellitus and its complications, presence of any cancers, the ASA score, wound classification, emergency operation, endoscopic operation, presence of SSI complication, causative pathogens, and duration of operation were recorded.

Statistical analysis

Descriptive statistics: In demographic data, continuous data were described as arithmetic mean with 95% confidence interval (CI). Categorized data were showed with percentage (%) and 95% CI.

Inferential statistics: To test the hypothesis of difference of continuous data between two independent groups, unpaired t-test or Wilcoxon rank-sum test was used whether the data were near Gaussian distribution or not. Test of independent between discrete data were done by Pearson's chi-square test.

The predictive performances of the various models were assessed by area under curve (AUC) of receiver operating characteristic (ROC) curves.

The strength of association between risk factors and SSI were demonstrated in terms of odds ratio (OR), adjusted OR with 95% CI and evaluated with univariate and multivariate analysis by logistic regression model. The statistical analyses were performed with Software Stata® v.13.

Ethical approval

The study protocol was approved by the Institutional Review Board of the Faculty of Medicine, Prince of Songkla University (REC: 60-005-09-1). Because of the observational nature of the study, written informed consent was not required.

Results

Data of the present study were retrospectively collected from 2,453 patients that underwent cholecystectomy in Songklanagarind Hospital between 2005 and 2016. Among these patients, nine patients were excluded because the operations had a duration of cholecystectomy longer than 314 minutes or had incomplete or concealing data.

The authors identified 71 operations with post-cholecystectomy SSI yielding the SSI rate of 2.93%. The characteristics of the studied patients are shown and compared between patients with and without SSI in Table 4.

Most of patients were female (54.9%), age 59.9 (56.4 to 63.3) years old, and had body mass index (BMI) 24.3 (23.4 to 25.1) kg/m². The underlying diseases included diabetes mellitus 31.0% (20.5 to 43.1), diabetes mellitus with complications 5.6% (1.6 to 13.8), and cancer 8.5% (3.2 to 17.5). Classified patients' physical status by anesthesiologist most was ASA class II 66.2% (54.0 to 77.0). In the part of surgical procedures, there were emergency 5.6% (1.61 to 3.8), endoscope 54.9% (42.7 to 66.8), and time of operation was spent for 4.5 (4.4 to 4.6) hours. In the operative fields, surgeons assessed wound class as contaminated in 16.9% (9.0 to 27.7), and dirty in 2.8% (0.3 to 9.8).

Model comparison

Predictive performances of the three models were analyzed by ROC curve method and shown in Figure 1. The area under ROC curve of the former NNIS risk index, the new NHSN risk model, and the author-developed model yielded 0.645, 0.657, and 0.680, respectively.

The difference between the area under ROC curve of the NNIS risk index and the new NHSN risk model had p-value of 0.551. Similarly, the difference between the area under ROC curve of the author-developed model compared to the NNIS risk index and the new NHSN risk model were not statistically significant with p-value of 0.412.

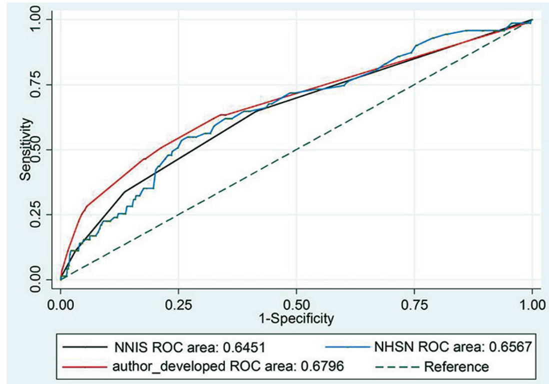

Figure 1. Comparison of ROC curves between the former NNIS risk index, the new NHSN risk model, and the author-developed model.

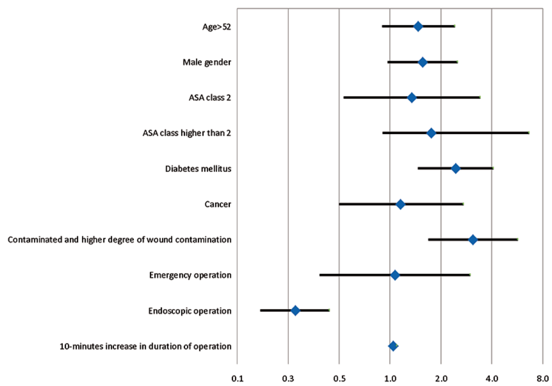

Figure 2. Forest plot of factors associated with post-operative cholecystectomy surgical site infections (SSI) by univariate analysis.

Risk factors associated with SSI after cholecystectomy

Patients with and without post-cholecystectomy SSI were compared to identify the risk factors associated with SSI after cholecystectomy. The result is shown in Table 4.

According to Table 4, the variables included both patient-related and procedure-related risk factors. The significant variables were age, diabetes mellitus, duration of operation, endoscopic operation, and wound classification. The other factors were considered non-significant.

Table 4. Comparison of patient characteristics between the patients with and without postoperative cholecystectomy SSIs

	SSI (n=71) Mean (95% CI)	No SSI (n=2,360) Mean (95% CI)	p-value
Age (arithmetic)	59.9 (56.4 to 63.3)	55.0 (54.4 to 55.7)	0.01*
Sex (%)			0.07¶
Male	45.1 (33.2 to 57.3)	34.5 (32.6 to 36.5)	
Female	54.9 (42.7 to 66.8)	65.5 (63.5 to 67.4)	
Body mass index (arithmetic)	24.3 (23.4 to 25.1)	24.9 (24.7 to 25.1)	0.3*
Diabetes mellitus (%)			<0.001¶
Yes	31.0 (20.5 to 43.1)	15.5 (14.1 to 17.1)	
No	69.0 (56.9 to 79.5)	84.5 (82.9 to 85.9)	
Diabetic with complication			0.1¶
Yes	5.6 (1.6 to 13.8)	2.6 (2.0 to 3.4)	
No	94.4 (86.2 to 98.4)	97.4 (96.6 to 98.0)	
Preoperative stay (geometric)	0.8 (0.6 to 1.2)	0.7 (0.7 to 0.7)	0.06*
Operation duration (geometric)	4.5 (4.4 to 4.6)	4.4 (4.4 to 4.4)	0.03*
ASA score (%)			0.2¶
I	7.0 (2.3 to 15.7)	10.5 (9.3 to 11.8)	
II	66.2 (54.0 to 77.0)	73.1 (71.2 to 74.8)	
III	26.8 (16.9 to 38.6)	15.9 (14.5 to 17.5)	
Cancer (%)			0.7¶
Yes	8.5 (3.2 to 17.5)	7.4 (6.4 to 8.5)	
No	91.5 (82.5 to 96.8)	92.6 (91.5 to 93.6)	
Emergency (%)			0.9¶
Yes	5.6 (1.6 to 13.8)	5.4 (4.5 to 6.4)	
No	94.4 (86.2 to 98.4)	94.6 (93.6 to 95.5)	
Endoscope (%)			<0.001¶
Yes	54.9 (42.7 to 66.8)	81.4 (79.8 to 83.0)	
No	45.1 (33.2 to 57.3)	18.6 (17.0 to 20.2)	
Wound classification (%)			0.002¶
Clean	1.4 (0.0 to 7.6)	0.8 (0.5 to 1.3)	
Clean-contaminated	78.9 (67.6 to 87.7)	91.8 (90.6 to 92.9)	
Contaminated	16.9 (9.0 to 27.7)	6.2 (5.2 to 7.2)	
Dirty/infected	2.8 (0.3 to 9.8)	1.2 (0.8 to 1.8)	

SSI=surgical site infection; CI=confidence interval

* Unpaired t-test, ¶ Pearson chi-square test

Univariate analysis

Ten variables were listed with its relation to post-cholecystectomy SSI in Figure 2. Significant variables included patient factors such as diabetes mellitus (OR 2.45, 95% CI 1.51 to 4.00; p=0.001) and contaminated and higher degree of wound contamination (OR 3.11, 95% CI 1.75 to 6.25; p<0.001), and operative factors such as endoscopic operation (OR 0.28, 95% CI 0.18 to 0.47; p<0.001) and 10-minutes increase in duration of operation (OR 1.05; p=0.036).

Multivariate analysis

All variables from the univariate analysis were taken for a multivariate logistic regression by using

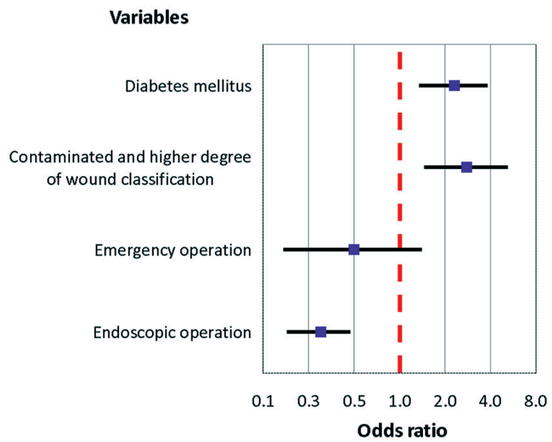

Figure 3. Forest plot of factors associated with post-operative cholecystectomy surgical site infections (SSI) by multivariate analysis.

backward stepwise multiple logistic regression model. The authors remove variables that had a p-value greater than 0.2 out of analysis. The result in Figure 3 showed that only three variables were significant, which were diabetes mellitus (adjusted OR 2.28, 95% CI 1.35 to 3.85; p=0.002), contaminated and higher degree of wound contamination (adjusted OR 2.76, 95% CI 1.45 to 5.33; p=0.002), and endoscopic operation (adjusted OR 0.29, 95% CI 0.19 to 0.48; p<0.001). Emergency operation factor was not a significant variable in both univariate and multivariate analysis, but p-value of emergency operation was 0.185 in multivariate analysis, so emergency operation was still an associated factor with SSI in the present study.

Discussion

Owing to severe complications from cholecystectomy, the mortality and morbidity rate are potentially increasing. For decades, NHIS and NHSN risk indexes are used for predicting patient's risk of acquiring SSI after procedure. Nevertheless, some studies showed that it had poor sensitivity and specificity. To the authors' knowledge, there has been no report about comparing the NNIS and the NHSN risk model for cholecystectomy. Therefore, procedures-specific risk index's model has been established to improve the accuracy in predicting SSIs for each procedure by adding procedures-specific element.

Comparing the performance of predicting SSIs risk between the former NNIS, NHSN, and the author-developed risk model, the authors applied the ROC curve to represent the association between the false-positive and true positive rates for every possible cut-off value. Accuracy of a diagnostic test is measured by the AUC. An area of 1 represents a perfect test, while an area of 0.5 represents a worthless test. The results demonstrated that (Figure 1) the authors' new model had significant difference in statistical compared to the former ones in prediction post-cholecystectomy SSI rate. Three models yielded AUC of 0.645, 0.657, and 0.680 for the NNIS, the NHSN, and the author-developed model, respectively. The difference of the area under the ROC curve of the author-developed model compared to the NNIS and the NHSN risk index were not statistically significant with p-value of 0.412 due to small study sample.

Based on the NHSN risk model, the authors combined an emergency operation and diabetes mellitus to the authors' model. First, the diabetes mellitus is a significant factor that increases the SSI risk with an adjusted OR 2.28; 95% CI 1.35 to 3.85 in multivariate analysis concordantly with the results of the study "Diabetes and Risk of Surgical Site Infection"[6] with adjusted OR 4.71. They also claimed that history of diabetes mellitus remained a significant risk factor for SSI despite the implementation of a patient care pathway targeting glucose control during the time of surgery. Second, the endoscopic procedure is a dominant variable lowering SSI risk with adjusted OR 0.29 (95% CI 0.19 to 0.48) consistently with Zhang et al[7]. They reported that laparoscopic cholecystectomy was associated with a lower risk for SSI than open cholecystectomy, even after adjusting for other risk factors. Third, the wound classification more than or equal contaminated, it's also significant to SSI with an adjusted OR of 2.76; 95% CI 1.45 to 5.33 in the present study. Aga et al[8] study reported that the SSI rate was highest in dirty wound classification (27.7% vs. 3.11%). Analyzed by the multivariate logistic regression analysis, the results presented that dirty wound classification was significantly associated with development of SSI (adjusted OR 4.08; 95% CI 2.85 to 5.82). Fourth, the important finding from the present study was that an emergency variable was no statistical significance in both univariate analysis (OR 1.07; 95% CI 0.38 to 2.99) and multivariate analysis (adjusted OR 0.49; 95% CI 0.17 to 1.41). However, the authors combined in the present model as well. According to the NHSN risk model, which divided wound classification to two groups (Table 5), a group of less contaminated and a group of contaminated combined with dirty wound classification, it means that whether it be

Table 5. Comparison between risk factors of NHSN model and the present study's model

NHSN model	Odds ratio	Same	This study's model	Odds ratio (95% CI)
Age >52 years old	1.26	X	Age >52 years old	Not statistical significant
ASA score =2	1.05	X	ASA Score =2	
ASA score >2	1.35	X	ASA Score >2	
10 minutes increasing in procedure duration	1.01	X	10 minutes increasing in procedure duration	
Operated under endoscope	0.32	✓	Operated under endoscope	0.29 (0.19 to 0.48)
Wound class > contaminated	2.37	✓	Wound class ≥ contaminated	2.76 (1.45 to 5.33)
			Emergency operation	0.49 (0.17 to 1.41)
			Diabetes mellitus	2.28 (1.35 to 3.85)

NHSN=National Healthcare Safety Network; ASA=American Society of Anesthesiologists; CI=confidence interval

contaminated or dirty, it will be included in the same group. Due to the ROC Figure 1, it illustrated that the area under the ROC curve of the authors' model was greater than both NNIS and the NHSN risk model, nevertheless, it is not statistically significant. This can be explained that there are few patients in the present study, thus, it does not have enough influence to show how significant. The multivariate analysis showed that each 10 minutes increase in duration of operation, age more than 52 years old, and ASA score (ASA=2 and ASA>2) variables have no statistically significant association with SSI after procedures.

Conclusion

In the present study, the author-developed model is not better than the former NISS risk index and the NHSN procedure specific model in prediction of post-operative cholecystectomy SSI in Songklanagarind Hospital. There is no significant difference between the three models due to post-cholecystectomy SSI yielding the SSI rate is only 2.93%.

The results shown that age above 52 years old, male gender, ASA score, cancer, emergency operation, and 10-minute increased in duration of operation were not statistically significant on multivariate analysis. Only diabetes mellitus, contaminated and higher degree of wound classification, and endoscopic operation significantly increased risk of SSI after cholecystectomy. These findings may assist clinicians in decisions regarding to patient risk stratification, informed consent, type of operative procedure, timing of surgery, or pre-operative antibiotic prophylaxis.

What is already known on this topic?

The former NNIS risk model has been used for decades and found poor efficacy in predicting SSI after several surgical procedures. A novel NHSN risk adjustment model was developed to cope with the problem. There has not been any reports to evaluate the performance of the new model compared to the former one.

What this study adds?

The predictive performance of new CDC NHSN and the former NNIS risk index model achieved similar classification risk of post-operative cholecystectomy SSI.

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Conflicts of interest

The authors declare no conflict of interest.

References

1. Akhter MS, Verma R, Madhukar KP, Vaishampayan AR, Unadkat PC. Incidence of surgical site infection in postoperative patients at a tertiary care centre in India. J Wound Care 2016;25:210-2, 4-7.
2. Clements AC, Tong EN, Morton AP, Whitby M. Risk stratification for surgical site infections in Australia: evaluation of the US National Nosocomial Infection Surveillance risk index. J Hosp Infect 2007;66:148-55.
3. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol 1999;20:250-78; quiz 79-80.
4. Daabiss M. American Society of Anaesthesiologists physical status classification. Indian J Anaesth 2011; 55:111-5.
5. Ju MH, Cohen ME, Bilimoria KY, Latus MS, Scholl

LM, Schwab BJ, et al. Effect of wound classification on risk adjustment in American College of Surgeons NSQIP. J Am Coll Surg 2014;219:371-81.e5.
6. Martin ET, Kaye KS, Knott C, Nguyen H, Santarossa M, Evans R, et al. Diabetes and risk of surgical site infection: a systematic review and meta-analysis. Infect Control Hosp Epidemiol 2016;37:88-99.
7. Zhang Y, Zheng QJ, Wang S, Zeng SX, Zhang YP, Bai XJ, et al. Diabetes mellitus is associated with increased risk of surgical site infections: A meta-analysis of prospective cohort studies. Am J Infect Control 2015;43:810-5.
8. Aga E, Keinan-Boker L, Eithan A, Mais T, Rabinovich A, Nassar F. Surgical site infections after abdominal surgery: incidence and risk factors. A prospective cohort study. Infect Dis (Lond) 2015;47:761-7.