Data Quality in Norwegian Surgical Site Infection Surveillance

Implementation and validation of a national system for surveillance of surgical site infections in Norway

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Contents

Preface

Since the submission of this thesis, Paper II has been published in BMC Infectious Diseases:

Lower HL, Eriksen HM, Aavitsland P, Skjeldestad FE. The quality of denominator data in surgical site infection surveillance versus administrative data in Norway 2005-2010. BMC Infect Dis 2015;15:549.

Summary

Surgical site infections (SSIs) constitute about one quarter of all healthcare-associated infections in Norway and are associated with a substantial cost for hospitals, patients and the community. Surveillance with feedback has been proven to be a useful tool in prevention of adverse events. In Norway, SSI surveillance was initiated through the establishment of the Norwegian Surveillance System for Antibiotic Consumption and Healthcare-Associated Infections (NOIS) by regulation in 2005.

The overall aim of this thesis was to describe and validate NOIS-SSI in order to ensure good data quality through a uniform, robust and feasible system for monitoring and controlling SSIs. This was achieved through three sub-studies, each reported in a separate paper. The first study gives a description of the methodology of NOIS-SSI, and the value of a mandatory system with automated data collection and post-discharge surveillance. The second study is an investigation of the completeness, representativeness and accuracy of the denominator data by comparing NOIS-SSI to administrative data. The third study is an investigation of the necessity of post-discharge surveillance and the consequences of differing duration and intensity of follow-up of patients after hospital discharge.

Paper I reports a steadily increasing participation in NOIS-SSI during 2005-2009, with many hospitals implementing computerized systems and submitting extra data voluntarily. We found reasonable quality of the risk-adjustment variables and a very good post-discharge follow-up, with 81% of SSIs being detected after hospital discharge. Paper II shows that the completeness of NOIS-SSI's denominator data improved greatly between 2005-2010 and that hospital participation became more representative over time. However, NOIS-SSI did not achieve representativeness for all surgical procedures. The hospitals which participated, submitted accurate denominator data and all the computerized systems delivered data of high quality. In paper III, we found that 82% of the deep SSIs after hip arthroplasty in 2005-2011 were detected after discharge from hospital. All of the patients with deep SSIs that were detected between 30 days and one year after hospital discharge were

readmitted, which means that they could have been detected through the hospitals' computer systems instead of by patient questionnaire.

A mandatory surveillance system should give more complete and unbiased data than a voluntary system. NOIS-SSI was not complete and representative and this was mostly due to a flexible and incremental implementation strategy. The upside of this flexibility was the establishment of electronically based surveillance systems in almost all hospitals. Electronically based systems have led to good quality of risk-adjustment variables and excellent accuracy. Because most SSIs are detected after hospital discharge, active follow-up of the patient after discharge is important for correct case ascertainment. Active follow-up is resource demanding, but without it most SSIs would go undetected and the infection rates would be incorrect. Validation of correct classification of SSIs according to surveillance definitions has not been performed in Norway. Some studies have indicated good-to-excellent sensitivity and specificity in SSI validation by retrospective chart review, whereas others have found poor inter-rater agreement. Information technology in surveillance is in rapid development, and much has been published about computer algorithm-assisted case detection in existing clinical and administrative databases. Although there are many potential pitfalls in utilizing more automated surveillance, it is time and cost efficient and circumvents many of the issues associated with manual systems.

All-year, all-procedure mandatory surveillance was implemented in Norway from 2012/2013. The findings of this thesis have led to changes in the Norwegian surveillance system, and one-year follow-of hip arthroplasty patients by letter will be replaced by surveillance through readmissions in 2015. By continually improving and upgrading the system we hope to achieve a surveillance system that is robust, efficient and useful. Acting on the basis of surveillance data in a clinical setting is the ultimate goal of a surveillance system. High quality data are essential in this process, and more use of automated case-finding may be an important asset in achieving this.

List of publications

I. Lower HL, Eriksen HM, Aavitsland P, Skjeldestad FE. Methodology of the Norwegian Surveillance System for Healthcare-Associated Infections: the value of a mandatory system, automated data collection, and active post-discharge surveillance. Am J Infect Control. 2013 Jul;41(7):591-6. PubMed PMID: 23318091. DOI: 10.1016/j.ajic.2012.09.005

II. Lower HL, Eriksen H-M, Aavitsland P, Skjeldestad FE. The quality of denominator data in surgical site infection surveillance versus administrative data in Norway 2005-2010. Submitted to BMC Infectious Diseases. MS ID: 1115429480167925.

III. Lower HL, Dale H, Eriksen HM, Aavitsland P, Skjeldestad FE: Surgical site infections after hip arthroplasty in Norway, 2005-2011: Influence of duration and intensity of postdischarge surveillance. Am J Infect Control 2015, 43(4):323-328. PubMed PMID: 25672951. DOI: 10.1016/j.ajic.2014.12.013.

Abbreviations and definitions

CDC	Centers for Disease Control and Prevention
ECDC	European Centre for Disease Prevention and Control
EHR	Electronic health record
HAI	Healthcare-associated infection
HELICS	Hospitals in Europe Link for Infection Control through Surveillance
ICD-9	International Classification of Diseases, 9th revision
ICM	Infection control module (computer software used in surveillance)
ICP	Infection control practitioner
NHSN	National Healthcare Safety Network (previously NNIS)
NIPH	Norwegian Institute of Public Health
NNIS	National Nosocomial Infection Surveillance System (now NHSN)
NOIS	Norwegian Surveillance System for Antibiotic Consumption and Healthcare-Associated Infections
NPR	Norwegian Patient Register (national administrative database for specialist health services)
PDS	Post-discharge surveillance (follow-up of patients after they are discharged from hospital)
SIR	Standardized infection ratio
SSI	Surgical site infection
SENIC	Study on the Efficacy of Nosocomial Infection Control
WHO	World Health Organization

1 Introduction and background

1.1 General Introduction

Healthcare-associated infections (HAIs) are a major cause of morbidity and mortality in Norway and worldwide.[1-3] In developed countries about 8-11% of in-patients[4,5] have a HAI at any point in time. HAIs are responsible for increasing healthcare costs and prolonged hospital stays for patients. Studies indicate as much as a doubling of costs of hospital stays because of HAIs.[6-10] Longer life expectancy due in part to improved medical technology contributes to sicker, older and more fragile patients. Furthermore, the adverse developments in antibiotic resistance[11,12] have increased the interest in prevention of infections. There has also been an increased attention given to HAIs as an important aspect of patient safety by politicians, patients and healthcare providers[13-15] as well as public reporting of quality indicators.[16-18] All of these issues have led to a strengthened interest in HAIs in the recent years.

Surgical site infections (SSIs) account for about one quarter (23-28%) of the four most prevalent HAI types in Norway.[3,19] It has been indicated that SSIs account for an additional median length of stay of ten days and a substantial increase in various hospital, community and patient costs.[20-23] About 400,000 surgeries are performed in Norway each year.[24] Recent data show that between 2.2% and 13.5% of patients who undergo surgery in Norway develop an SSI.[25]

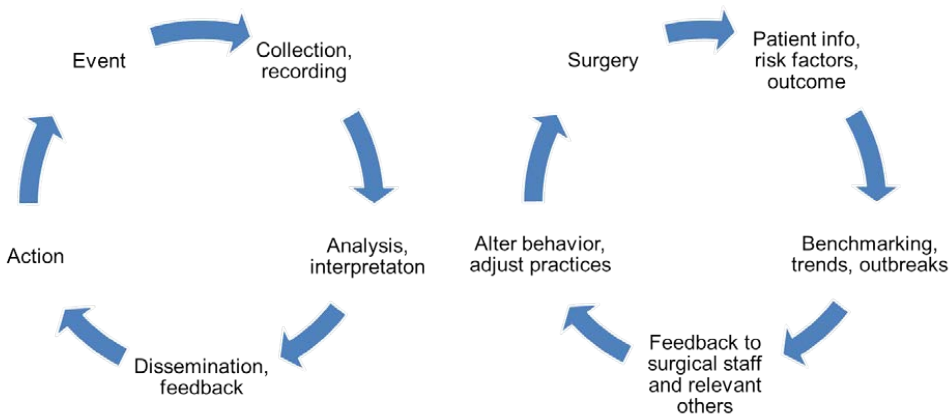
The purpose of this thesis is to investigate and document the data quality of the surgical site infection (SSI) module of the Norwegian Surveillance System for Antibiotic Consumption and Healthcare-Associated Infections (NOIS) in order to provide a basis for improvement of the system and proper interpretation and use of results from the system. In this background chapter I will describe the development of surveillance systems for SSIs, present the situation in Norway, define and explain central concepts of SSI surveillance, as well as describe the rationale and purpose of surveillance systems.

1.2 Surveillance of SSIs - why and how?

1.2.1 What is surveillance?

Surveillance is a tool used to detect and monitor epidemics and public health emergencies. Surveillance as a concept is attributed to William Farr's work with the London cholera epidemic in the 1840s. [26,27] [28,29] In the 1950s surveillance as a term began being used about watching diseases rather than individuals,[30] and the definition of "the routine process of collection, collation and dissemination of health data" came about .[28] In a more recent definition, public health surveillance is "the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health".[31] This definition encompasses an additional element, action (Figure 1). Surveillance is "information for action" and it is essential that the information (data) is of good quality in order to ensure that the end user trusts the output of the system in order for action to be taken.[32] Without action being taken to prevent the occurrence of new adverse events on the basis of quality data there is little point in collecting, interpreting, and disseminating. Surveillance systems monitor trends, document the impact of HAIs, and evaluate the effectiveness of prevention efforts. SSIs are one type of HAI where surveillance with feedback has been shown to have good effect.[33-38]

Figure 1. The surveillance loop



1.2.2 SSI surveillance, the international perspective

The findings of the landmark Study on the Efficacy of Nosocomial Infection Control (SENIC),[33] which was initiated in 1974 by the US Centers for Disease Control and Prevention (CDC), is the foundation and rationale for most of today's HAI surveillance systems. The SENIC project found a strong association between the establishment of surveillance systems with feedback and reduction in HAI rates, indicating that simply having such systems in place in the hospitals reduced HAI rates by as much as 32%. Following the SENIC project, the National Nosocomial Infection Surveillance System (NNIS) was introduced by the CDC in 1992.[39] From 2005 it was included in the National Healthcare Safety Network (NHSN) which was established to integrate three existing surveillance systems. One aim of NHSN is to provide hospitals with comparable data.

Many European countries established surveillance systems for HAIs during the 1990s. The Hospitals in Europe Link for Infection Control through Surveillance (HELICS) project in 1994/95 was an initiative to, among other goals, standardize surveillance methods in order to generate comparable data in Europe.[40,41] HELICS has collected SSI incidence data in a European database since 2004.[42] The project was included in the portfolio of the European Centre for Disease Prevention and Control (ECDC) in 2008. The HELICS/ECDC protocol[43] is based on the NHSN model. Many European countries have documented the positive effects of surveillance systems on HAI rates.[37,44-46] HAI surveillance based on the CDC model is performed in many other countries worldwide.[47]

1.2.3 SSI surveillance in Norway

Calculating costs and burden of HAIs in Norway has previously been difficult because of the lack of good surveillance data. Prevalence surveys have been conducted in Norway since 1991[2] and on a regular basis semi-annually since 2002. However they are uncertain, as they only give data from one day. Point prevalence studies do not document risk factors and cause-and-effect relationships. In order to obtain better and more reliable surveillance data, prospective surveillance through NOIS was introduced by regulation in Norway in 2005.[48] NOIS is one of 17 central health registers in Norway which have been established through the Personal Health

Data Filing System Act §8.[49] These registers are nationwide and are governed by separate acts and have been established to ensure national functions (and do not require patient consent).

The first module of NOIS was the surveillance of surgical site infections (NOIS-SSI).[50] NOIS-SSI was originally based on the HELICS project and NHSN definitions[51] and is described in the NOIS-SSI protocol.[52] The objectives of NOIS are to describe the occurrence of healthcare-associated infections by time and other characteristics, detect outbreaks, provide a basis for preventive measures, and to evaluate such measures. The regulation requires that the data sent to the national database are de-identified. This entails that personal identifiers such as name and personal identification number for each patient are removed before submission. NOIS is administrated by the Norwegian Institute of Public Health (NIPH). NOIS-SSI has three important key characteristics:

1. It is a mandatory, national surveillance system
2. It has a highly computerized data collection system in the hospitals
3. It has an active, mandatory post-discharge surveillance (PDS) for 30 days (one year for implants) after surgery

1.2.4 Hospital structure in Norway

The Regional Health Authorities Act of 2002 led to a major reform of the specialist health care services in Norway with a transfer of the responsibility for all public hospitals from the county councils to the national government. Five Regional Health Authorities were originally set up to govern the specialist services within each of the health care regions. In 2007 south and east merged, leaving four (Figure 2). The Regional Health Authorities are owned by the Norwegian Ministry of Health and Care Services which appoints their board. The Regional Health Authorities own 21 subsidiary healthcare trusts, each consisting of one or more hospitals, which provide the actual hospital services. In addition, some private specialist healthcare facilities are partners to the healthcare trusts on a contractual basis, and there are a few independent private hospitals. Six healthcare trusts have been approved as university hospitals, at least one within each Regional Health Authority.

There have been several closures and mergers of hospitals within the healthcare trust structure during the years, and what is considered a hospital is not consistent between trusts. For example, two separate hospitals may have merged into one hospital with two locations. This makes it difficult to report data on hospital level. The Directorate of Health's report on the specialist health services, 2012,[24] uses 27 “units” whereof 20 healthcare trusts and seven individual hospitals. The size of hospitals in Norway varies from about 30 to 1300 beds, and about 43% of the beds are in surgical wards. The average length of hospital stay for surgical inpatients was 5.2 days.[24] About 4.7% of the patients were readmitted within seven days, and 10.4% within 30 days.[24]

Figure 2. *Norway’s Regional Health Authorities*

Source: Norway and health: An Introduction, The Ministry of Health and Care Services https://helsedirektoratet.no/publikasjoner/norway-and-health-an-introduction

1.2.5 Organization of infection control in Norwegian hospitals

Infection control in Norwegian hospitals is governed by a regulation for infection control in healthcare.[53] It requires that healthcare institutions have measures in place for infection prevention and control, including surveillance. It also states that an adequate number infection control practitioners are to be employed, and that these are to have sufficient time and resources available to perform the required tasks. Each Regional Health Authority is to have a competence center for healthcare associated infection prevention and control, led by an infection control physician. The competence center coordinates, supports, and stimulates infection control activities in the healthcare institutions.

1.3 Objectives

The overall aim of this project was to describe and validate the surveillance system in order to ensure good data quality which is an important element in ensuring a uniform, robust and feasible system for monitoring and controlling the occurrence of SSIs in Norway. This project was register-based, mostly utilizing data from NOIS-SSI, but also using administrative data.

The project did not endeavor to evaluate and validate the whole surveillance system, but rather focused on certain important elements. This was achieved through three parts. Part one described the implementation of the system and the methods, and the completeness of reporting and the quality/accuracy of the collected data. Part two validated the denominator data, focusing especially on diverging systems and consequences for reporting. Part three explored the added value of active, mandatory post-discharge surveillance.

> "Good surveillance does not necessarily ensure the making of the right decisions, but it reduces the chances of wrong ones." Alexander Langmuir[30]

2 Materials and Methods

2.1 Evaluating and describing data quality in a surveillance system

Evaluation of the surveillance system is important in order to assess system performance and is an integral part of operating a surveillance system. It is important in promoting the best use of public health resources through the development of efficient and effective systems. In 2001 CDC published updated guidelines for evaluating public health surveillance systems;[31] these have been considered the cornerstone in surveillance system evaluation in recent years. In 2006 the World Health Organization (WHO) published a guide to monitoring and evaluating communicable disease surveillance systems.[54] In 2014 ECDC published a handbook for data quality monitoring and surveillance system evaluation,[55] which builds on the previous guidelines by CDC and WHO. All of these guidelines define similar attributes and methodology, such as engaging stakeholders, describing the system, gathering evidence of the system's performance, making recommendations, using the findings, and sharing the lessons learned. The terminology may differ, but the basic concepts are similar. This project has mainly focused on the aspect of gathering evidence of the system's performance, more specifically, evaluation of data quality. The 2013 NHSN Data Quality Guidance and Toolkit for Reporting Facilities[56] states that validation of SSI surveillance data should include; (i) the completeness and accuracy of the procedure denominator, (ii) the quality of risk-adjustment variables and (iii) the completeness of case ascertainment and correct case classification.

In this project we have evaluated data quality in NOIS-SSI by investigating:

(i) The completeness and accuracy of the procedure denominator by comparing NOIS-SSI with another data source, the Norwegian Patient Register (NPR) (paper II)

(ii) The quality of risk-adjustment variables by describing the completeness of the data (paper I) and the representativeness and accuracy by comparing NOIS-SSI with NPR (paper II)

(iii) The completeness of case-ascertainment by exploring the added value of active follow-up after hospital discharge (paper I and III)

The three studies in this project do not cover the comprehensive area, as described by NHSN, but focus on certain elements. Paper I also gives a general description of the functioning of the surveillance system.

2.2 About NOIS-SSI

NOIS-SSI covers several common surgical procedures (Table 1), as defined by the Nordic Medico-Statistical Committee's Classification of Surgical Procedures.[57] To minimize the workload on the hospitals, a three-month surveillance period was established. September through November was chosen because this is a time of year with normal operation in the hospitals, no major holidays or other events which may disrupt the schedule. To encourage hospital participation, only data from the highest prioritized procedures under surveillance were required during the first years. From September 2012, mandatory surveillance of all five procedures and all year surveillance was introduced. Table 1 shows how the requirement for data submission to the NIPH has changed over time. In order to encourage the establishment of suitable computer based systems, exemption from submitting surveillance data was granted to hospitals during the first few years.

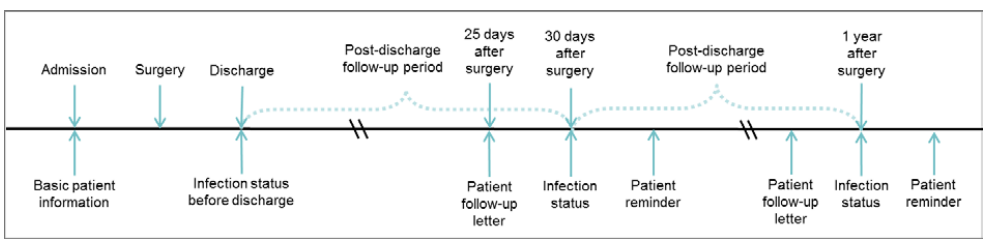
Table 1. Changes in requirements for data submission to the National Institute of Public Health 2005-2015. Cell value for each procedure indicates level of priority in the surveillance system.

	2005	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012-2015**
Minimum number of procedures required	1	1	1	1	1	2	2	All[3]
Procedure and priority								
Coronary artery bypass graft	1	1	1	1[1]	1	1	1	N/A
Cesarean section	2	2	2	2	2	2	2	N/A
Primary hip arthroplasty[2]	3	3	3	3	3	3	3	N/A
Appendectomy	4	4	4	4	-	-	-	N/A
Cholecystectomy	5	5	5[1]	5[1]	4	4	4	N/A
Colon surgery	-	-	-	-	5	5	5	N/A

[1] Mixed procedures excluded
[2] One year follow-up
[3] All procedures under surveillance

Post-discharge surveillance methods differ between countries in both intensity of case-finding and duration of follow-up after hospital discharge.[58,59] In NOIS-SSI, all patients are followed up by patient questionnaire sent from the hospital about 25 days after surgery (Figure 3), and an additional questionnaire after one year for hip arthroplasty. Data on SSI status is recorded at three postoperative intervals; discharge, 30 days and one year after implant surgery. We also register whether a patient has been readmitted (with or without a re-operation) due to an SSI within 30 days and one year (for implants) of surgery. SSIs for non-hospitalized patients are confirmed by a physician, either the patient's general practitioner or at a hospital outpatient clinic. Patient-reported infections are also collected, but these are coded separately. The patient-reported infections are not included in this project for several reasons: surgeons are generally skeptical to them, we are unsure of the quality of reporting from the hospitals, and these data are not comparable with most other countries.

Figure 3. Points in time for recording information during 30-day and one year follow-up in NOIS-SSI.



The key measure in NOIS-SSI is the incidence proportion of SSIs (herein also denoted as SSI rate). This is defined as the proportion of patients who develop an SSI within 30 days after surgery (one year for implant surgery). The quality of this measure depends of correct counting of number of patients who have undergone surgery (the denominator) and the correct identification of patients who develop an SSI (the numerator).

NOIS-SSI collects information on several variables which capture the risk of both patient related and other risk factors that may explain, confound or modify the risk of infection and is based on the CDC/ECDC protocols (Table 4). This information may

be used for identifying causes of infection or for risk adjustment in between-hospital comparisons. A combination of some of these variables make up the NHSN risk index, and have previously been proven to be a simple and fairly robust for risk adjustment[60,61]. It originally consisted of three factors (1) the condition of the patient (American Society of Anesthesiologists (ASA) score), (2) surgical wound contamination classification, and (3) duration of surgery is longer then the 75th percentile. It was later modified to include a factor for risk reduction in endo- or laparoscopic surgery. In 2010, the NHSN introduced a new method of risk adjustment, the standardized infection ratio (SIR). [62] The SIR uses several risk factors which have been identified through logistic regression modelling to provide better risk adjustment than the NHSN risk stratification. It allows for all available risk factors to be included, as well as allowing the risk factors to be procedure specific.

The NOIS group at the NIPH organizes an annual "surveillance day" for ICPs (and surgeons). At this meeting the latest data are presented, problems with data collection and quality are discussed and dissemination experiences are shared. Because Norway is a small country with only about 50-60 hospitals which perform surgical procedures, most hospitals participate with at least one representative. This is an excellent opportunity for networking and exchanging experiences. In conjunction with the surveillance day there is also a meeting of the NOIS reference group. This group consists of representatives from the infection control community and surgeons from the different surgical specialties under surveillance. The main purpose of the reference group is to give advice on system functioning, maintenance and future directions.

2.2.1 NOIS-SSI in the hospitals

One of the objectives when implementing NOIS-SSI was to utilize as much of the existing data in hospital information systems as possible, in order to limit the burden on hospital staff and ensure good data quality. The resources used to operate NOIS-SSI in the hospitals vary greatly, depending on the sophistication of the IT-systems and the organization of the data collection and feedback. In a Master's thesis from 2010, [63] ICPs report large variations in time spent on data collection and quality assurance, from 1-2 days per month to full time. Data collection was mostly done by infection control nurses and secretaries, and quality checks by infection control

nurses. Interpretation and dissemination of data was primarily done in approximately equal parts by infection control doctors, infection control nurses and surgeons.

Some of the Norwegian hospitals had already implemented surveillance systems with data harvesting from underlying systems when the national system was initiated. These systems were used as templates when establishing the national database and protocol. Because the hospitals and health care regions had different suppliers of information systems, several different infection control modules (ICMs), were developed. The systems utilize data extracted from different sources. The most common method is to use patient and risk adjustment data extracted from administrative sources, such as the patient record, combined with the surgery planning system and anesthesiology system.

There are three major suppliers of ICMs in Norway and several in-house systems. Some systems are developed by the electronic health record (EHR)-supplier and are integrated in the EHR-system work flow, and some are “stand-alone” systems that harvest data from other system suppliers. The trend is towards fewer and more professional ICM systems. None of the Norwegian systems include automated identification of infections. Some efforts have been made to assist case identification by tagging potential infections on the basis of microbiology or pharmacy data, but none have been successfully implemented.

How the ICM interacts with the users varies between systems and hospitals. Some are decentralized, and the individual surgical units ensure case identification, post-discharge surveillance (PDS) and proper collection of data, with the infection control practitioner (ICP) providing coordination and final quality assurance. Some are very centralized, with the ICPs performing the case-finding, PDS and quality assurance tasks. Some ICMs have advanced report modules which display statistics and graphics, and some do not.

The ICM ensures de-identification by giving each procedure a unique number. This key allows the ICP to identify the patients for quality assurance, while it ensures that the data that are transferred to the national level are de-identified. The ICM

generates export files in a specific format, which can be easily imported into other systems.

2.2.2 The national NOIS-SSI database

The national database is located at the NIPH and receives de-identified data in batches from the hospitals at set times during the year. Until 2012, when data were collected only during September-November, data were submitted annually. The deadline for submitting data was usually March, and the annual report would be published by the NIPH in June. The original database was not accessible from outside the NIPH, so data had to be sent on CDs, memory sticks or by encrypted e-mail. The data files were uploaded to the national database by NIPH personnel. The NIPH database contained many validation rules and checks to ensure the quality and consistency of the data. These validation rules were made available to the ICM-suppliers, so they could implement similar checks in the hospital ICMs. The NIPH has an extensive dialog with the hospitals' ICPs regarding quality assurance of the data and the hospitals receive reports on data quality, such as percent of missing values for each variable and post-discharge follow-up rate, after each data collection period.

2.3 Paper I

Title: Methodology of the Norwegian Surveillance System for Healthcare-Associated Infections: The value of a mandatory system, automated data collection, and active post-discharge surveillance

In this paper we aimed to describe and explain the functioning of NOIS-SSI in a national perspective. Firstly, we examined reporting compliance and how the nature of the system has affected reporting. Secondly, we aimed to evaluate the effectiveness of automated data collection. Thirdly, we aimed to evaluate the added value of active post-discharge surveillance by patient questionnaire.

We used national data on surgical procedures collected during the first five years of operation (2005-2009), and used the following measures: We documented reporting compliance by investigating what proportion of the hospitals submitted data on the different procedures for each year. The effectiveness of automated data harvesting

was documented by investigating the percentage of missing data for the risk-adjustment variables overall and for those which were included in the NHSN risk index.[60] The impact of post-discharge surveillance was evaluated by investigating the proportion of procedures with complete 30-day follow-up and the proportion of these which developed an SSI.

2.4 Paper II

Title: The quality of denominator data in surgical site infection surveillance versus administrative data in Norway 2005-2010

The objective this paper was to investigate denominator data quality by comparing SSI surveillance data from NOIS-SSI with administrative data from the Norwegian Patient Register (NPR)[64,65] in order to explain discrepancies and recommend improvements.

We used de-identified data from four surgical procedures from 2005-2010. In evaluating completeness and representativeness we used all procedures during the three-month NOIS-SSI surveillance window and all procedures in NPR for the same period. Completeness was evaluated by dividing NOIS-SSI by NPR. Representativeness was investigated by comparing the distribution of data in the two registers by hospital size and type, region, age, sex. In investigating accuracy we restricted the comparison to hospitals and reporting months which were present in both registers, and used the same variables as above. In addition accuracy was investigated with regard to which IT-system for surveillance was used by the hospitals. Differences in the distribution between the registers were evaluated using chi-squared analysis.

2.5 Paper III

Title: Surgical site infections after hip arthroplasty in Norway 2005-2011: Influence of duration and intensity of post-discharge surveillance

The norm for PDS duration after hip arthroplasty has been one year until CDC's NHSN from 2013 reduced this to 90 days.[66] The balance between the wish for high

quality data and the resource demands of diligent PDS at both 30 days and one year was the focus of paper III. We investigated how long it is necessary to follow up hip arthroplasty patients for SSIs after surgery and if passive PDS can be used in lieu of active PDS to detect SSIs.

We used 2005-2011 NOIS-SSI hip arthroplasty data with one year follow-up and readmission data. We investigated the effect of the duration of PDS on the incidence rates and the proportion of SSIs detected before and after discharge and at different postoperative time intervals. The influence of the intensity of PDS was assessed by investigating the proportion of deep SSIs detected by patient questionnaire (active PDS) compared with SSIs which could have been detected solely through readmissions (passive PDS). We used one year active PDS as a proxy "gold standard" and calculated sensitivity with 95% confidence intervals (Adjusted Wald) for different postoperative time intervals and case-finding strategies. We here defined sensitivity as the proportion of all infections in the one-year observation window that would have been detected already at the other time intervals and case finding strategies.

2.6 Ethical issues

NOIS-SSI is de-identified and is governed by a separate act,[48] and patient consent is not required. NPR was also de-identified at the time the data were extracted for this project, and is also governed by a separate act[64] and does not require patient consent. The study which compares NOIS-SSI and NPR (paper II) was approved by the Regional Committee for Medical and Health Research Ethics.

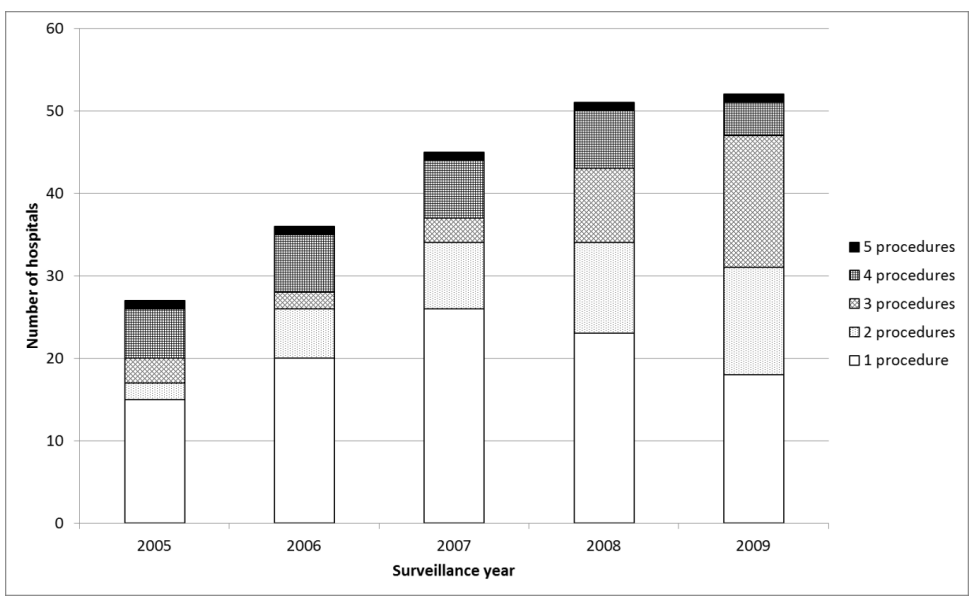
3 Summary of results

3.1 Describing the functioning of the system, the quality of risk adjustment variables and the value of post-discharge surveillance (paper I)

3.1.1 The functioning of the system - compliance

During the first five years of operation, participation in NOIS-SSI increased from about half of the hospitals to almost all. In 2005, data on 2,371 individual procedures were submitted, increasing to 6,089 in 2009. The majority of the procedures were primary hip arthroplasties and cesarean sections. The proportion of hospitals submitting data from more than one procedure voluntarily increased steadily from under half of the hospitals in 2005 to over two thirds in 2009 (Figure 4), and the procedures with the highest priority showed the greatest increase.

Figure 4. Number of surgical procedure types under surveillance by hospitals in NOIS-SSI 2005-2009



3.1.2 The quality of risk adjustment variables

23.3% of the records had at least one missing value for the risk-adjustment variables. Antibiotic prophylaxis and wound contamination class were the most important

contributors to the proportion of missing data. 6.8% of the risk-adjustment variables that were included in the NHSN risk index were missing in 2005-2009.

3.1.3 The value of post-discharge surveillance

Overall, 90.7% of the procedures had complete post-discharge follow-up (PDS) and 81% of the SSIs with complete PDS were detected after hospital discharge (Table 2). There was a large variation between procedures in which proportion of SSIs were detected post-discharge.

Table 2. Proportion of patients with complete follow-up and proportion thereof of infections detected after hospital discharge, totals NOIS-SSI 2005-2009 (modified from table 1 and 2 in paper I)

Procedure	Complete follow-up, %	Detected after discharge, %
Coronary artery bypass graft	92	94
Cesarean section	88	83
Primary hip arthroplasty	96	76
Appendectomy[1]	74	73
Cholecystectomy	89	75
Colon surgery[2]	84	50
Total	91	81

[1] Surveillance discontinued from 2009
[2] Surveillance started in 2009

3.2 Completeness, representativeness and accuracy of the procedure denominator (paper II)

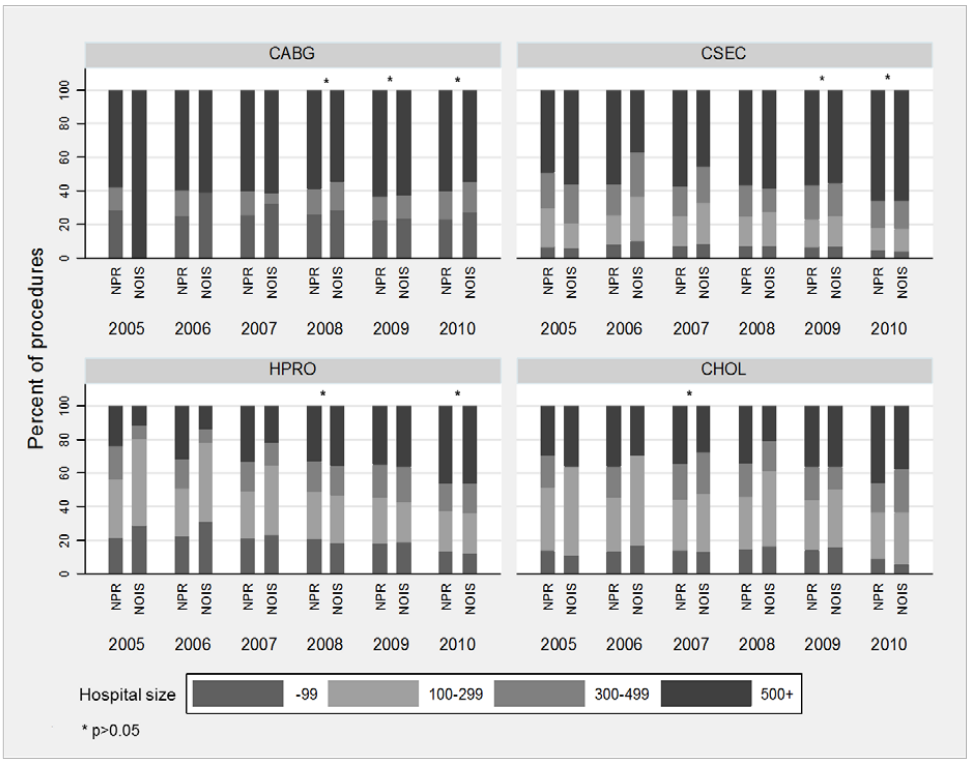
3.2.1 Completeness and representativeness

The completeness of NOIS-SSI improved from 29.2% in 2005 to 79.8% in 2010 as compared with NPR. In 2010, cesarean section had the best completeness (96.1%), followed by hip arthroplasty (81.7%), coronary artery bypass graft (76.9%) and cholecystectomy (44.2%).

NOIS-SSI's data quality in terms of representativeness improved during the study period. Figure 5 shows how the distribution by hospital size differed significantly from

NPR during the first years of operation, but became more similar in the latter years especially for the highest prioritized procedures. It also demonstrates changes in healthcare trust structure, with a tendency to report data from larger units rather than from individual hospitals in the latter years. Hospital type (data not shown) shows a similar pattern. By regional distribution NOIS-SSI did not achieve representativeness, with a few sporadic exceptions. It was representative with regard to age and sex for all years and procedures.

Figure 5. Representativeness: Proportion of procedures (in %) by hospital size in NOIS-SSI and NPR (2005-2010) by type of procedure (CABG: Coronary artery bypass graft, CSEC: Cesarean section, HPRO: Primary hip arthroplasty, CHOL: Cholecystectomy)



3.2.2 Accuracy

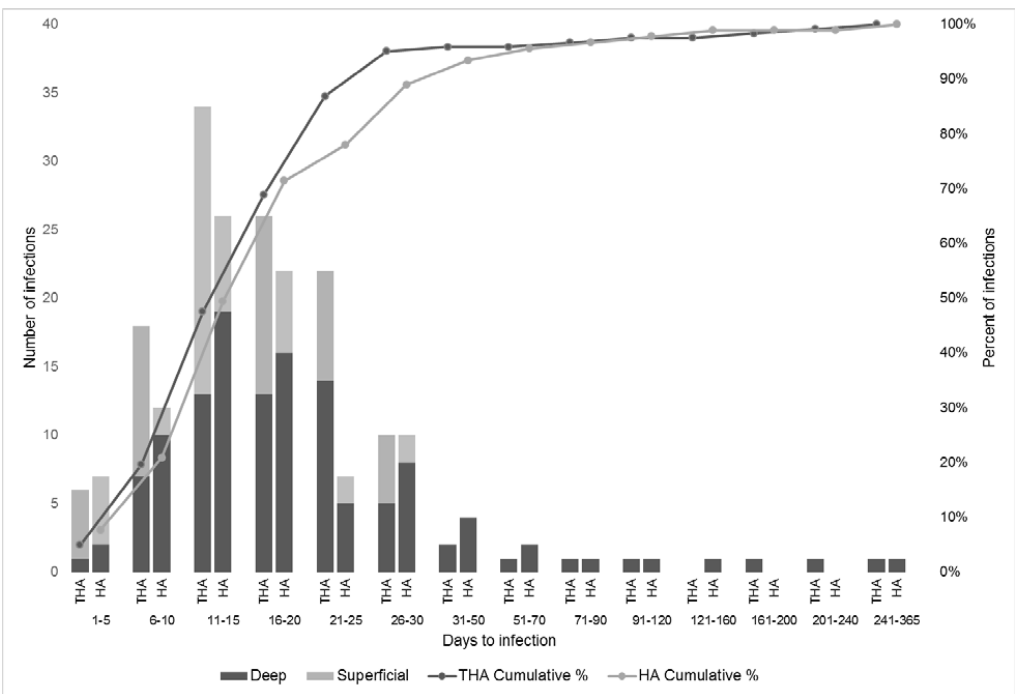
When we compared only hospitals and reporting periods that were present in both registers the overall accuracy for all years was 94.8%. In 2010, cesarean section and hip arthroplasty had an accuracy of 98.8%, followed by coronary artery bypass graft

with 93.9% and cholecystectomy with 90.0%. There were no significant differences between regions, hospital type and size, age or sex for each year and procedure. All electronic and other surveillance systems in the hospitals performed well.

3.3 Case-ascertainment through post-discharge surveillance (Paper III)

In this study of SSIs after primary hip arthroplasty in Norway, using data from NOIS-SSI with one year active PDS, we found that 79% of all SSIs were detected after hospital discharge and 82% of deep SSIs. 95% of all SSIs were detected within 90 days after surgery (Figure 6). The overall SSI rate was 3.6%, 2.8% for total hip arthroplasty and 5.9% for hemiarthroplasty. We observed a reduction in the median postoperative length of stay from seven (2005-2008) to five (2009-2011) days for total hip arthroplasty and from eight to six days for hemiarthroplasty. We also observed that the proportion of deep SSIs detected after discharge increased from 79% in 2008-2008 to 85% in 2009-2011.

Figure 6. Number of days to SSI and percent of infections detected at different points in time after total hip arthroplasty (THA) and hemiarthroplasty (HA) by SSI type, NOIS-SSI 2005-2011*



All 18 deep SSIs which were detected between 31 days and one year after surgery were readmitted because of their SSI and thus could have been detected by passive PDS. Active PDS for the first 30 days and passive PDS thereafter achieved the same sensitivity as active PDS for one year for deep SSIs (Table 3).

Table 3. Deep SSI rates and sensitivity of case-finding using different surveillance durations and intensities, NOIS-SSI 2005-2011*

	Total hip arthroplasty			Hemiarthroplasty			Total		
Surveillance method	Deep SSIs	SSI rate %	Sensitivity (95% CI)	Deep SSIs	SSI rate %	Sensitivity (95% CI)	Deep SSIs	SSI rate %	Sensitivity (95% CI)
Active PDS for one year	61	1.2	Ref	70	4.3	Ref	131	2.0	Ref
Active PDS for 90 days	57	1.2	0.93 (0.84-0.98)	67	4.1	0.96 (0.88-0.99)	124	1.9	0.95 (0.89-0.98)
Active PDS for 30 days	53	1.1	0.87 (0.76-0.93)	60	3.7	0.86 (0.75-0.92)	113	1.7	0.86 (0.79-0.91)
Active for 30 days and passive to one year	61	1.2	1.00 (0.93-1.00)	70	4.3	1.00 (0.94-1.00)	131	2.0	1.00 (0.97-1.00)
Active for 30 days and passive to 90 days	57	1.2	0.93 (0.84-0.98)	67	4.1	0.96 (0.88-0.99)	124	1.9	0.95 (0.89-0.98)
Passive PDS for one year	52	1.1	0.85 (0.74-0.92)	60	3.7	0.86 (0.75-0.92)	112	1.7	0.85 (0.78-0.91)
Passive PDS for 90 days	48	1.0	0.79 (0.67-0.87)	57	3.5	0.81 (0.71-0.89)	105	1.6	0.80 (0.72-0.86)
Passive PDS for 30 days	44	0.9	0.72 (0.60-0.82)	50	3.1	0.71 (0.60-0.81)	94	1.4	0.72 (0.63-0.79)
Inpatient only	6	0.1	0.10 (0.04-0.20)	18	1.1	0.26 (0.17-0.37)	24	0.4	0.18 (0.13-0.26)

* SSIs with missing infection date excluded

4 Discussion

Surveillance of surgical site infections, as with any surveillance, should be information for action. Action to prevent SSIs should be taken by the clinical teams in the hospitals. For them to act upon information from surveillance, they must trust the data and feel ownership of the surveillance system. The work described in this thesis endeavors to increase the understanding of the functioning and data quality of surgical site infection surveillance in Norway in order to encourage more active use of the data in prevention efforts.

Specifically we have:

- Described the implementation of the system and the methods, and the completeness of reporting and the quality/accuracy of the collected data (paper I).
- Validated the system denominator, focusing especially on diverging systems/infrastructure and consequences for reporting (paper II).
- Explored the added value of active, mandatory post-discharge surveillance (paper III).

4.1 The overall methodology of the surveillance system

The protocols used in SSI surveillance have been fairly uniform between countries, and in Europe especially in recent years with the establishment of a European protocol by ECDC.[43] Many SSI surveillance systems worldwide are based on the CDC's methodology.[47] Despite a common methodology, there are large differences in the degree of implementation, rules and regulations, financing, culture, interpretation, and local adaptations between countries. Direct comparison of SSI rates is therefore generally not reliable. Even within fairly similar European systems, the discrepancies make comparisons difficult.[67,68]

4.1.1 Mandatory versus voluntary surveillance

A national mandatory surveillance system will give a broader and better overview of the infection status in a country in comparison with a voluntary system, and will instigate surveillance activity in hospitals that would not otherwise participate.[69] In a

review of four national systems, Haustein et al[70] found that the proportion of hospitals voluntarily reporting never surpassed 50%. Additionally, in voluntary systems, the participant population will change over time as hospitals join, leave, and rejoin the system. Hospitals which participate voluntarily may not be representative of the country as a whole.[68,71] There is evidence that smaller hospitals may be more reluctant to participate.[5,72,73] It may be presumed that small hospitals have fewer ICPs and may not have the resources to implement surveillance. Also, very small hospitals will perform very few procedures, and the calculation of incidence proportions and other statistics may not be perceived as useful to the hospital.

4.1.2 Flexibility in reporting of procedures

Our data show an increase in the proportion of hospitals that submitted data for more than the mandated minimum of number procedure types (Figure 4). Most hospitals started with the required minimum of one type of procedure, but many exceeded the minimum requirements and included more procedures voluntarily as routines came into place. This can be interpreted as the hospitals finding the surveillance useful, and therefore submitting more procedures voluntarily. Only five Norwegian hospitals perform all five procedures and six small or specialized hospitals perform only one of the surveillance procedures.

A mandatory system may give poorer data quality because hospitals are required to participate even when they do not have the resources available to have a good data collection system in place. Voluntary systems may provide more enthusiastic participation, but may also be prone to selection bias.[69,70,74]

4.2 Completeness and accuracy of the procedure denominator

The main focus of validating outcome measures of SSI surveillance has been application of surveillance definitions to identify cases. Validating the quality of the denominator (number of procedures) has received much less attention. Denominator data are important in order to reliably describe occurrence on a national level, benchmarking, and inter-country comparisons. Regardless of how diligent case-finding is, incidence proportions and rates only make sense if the correct denominator is used.[75,76] Comparison of denominator data between registers can

give an indication of the quality of the data in both registers and reflect the quality of the data extraction at the individual hospital.

There are very few studies that validate the denominator data of SSI surveillance systems. In Scotland[77] researchers found that 91% of eligible procedures were included in the surveillance data. In the US (New York)[78] researchers found 98% matches between administrative data and surveillance data. A study from England found that the surveillance database contained 95% of the procedures that were recorded in the patient administration system.[79] In a recent review the accuracy of administrative coding[80] none of the included studies mention the quality of the denominator data.[81-89] Several Norwegian studies have evaluated the quality of different registers against NPR and found good completeness.[90-95] As in other countries, there has been a discussion in Norway about hospitals using "creative coding" practices in order to gain financial benefit from administrative/billing data, and thus undermining the quality of NPR data. An investigation by Norway's Office of the Auditor General in 2008[96] found that the hospitals claimed refunds for 2.7% more procedure codes than they were entitled to. 36.2% of main diagnosis codes were miscoded. Correcting for miscoding led to a reduction in refunds to the hospitals by 5.2%. Weak coding practices may undermine the usefulness of patient statistics for planning, evaluating and governing of the health services and limit the usefulness of the data for surveillance and medical research purposes.

Despite their potential weaknesses, hospital databases are increasingly being used to capture data, with the intention of replacing resource demanding manual tasks. Because SSI surveillance is patient based, denominator collection is not as complex as for other types of HAI, such as device-associated infections which use aggregated device data.[75] In SSI surveillance, the numerator and denominator are tied together. If, for example, all procedures with a specific procedure code are not harvested because of a computer flaw, both numerator and denominator will be lost. If this was a procedure code with a higher (or lower) risk of infection, the remaining data would be biased.

4.2.1 Completeness and representativeness

The completeness of NOIS-SSI denominator data was poor compared with NPR during the first years, but improved over time. The data were also not representative during the first years when we compared region and hospital type and size. This is partly due to many hospitals being granted exemption, which led to several regions and trusts submitting little or no data, and that the same hospitals did not participate each year. The system by which the hospitals were required to submit the highest prioritized procedure(s) may be another contributor to NOIS-SSI not being representative is (Table 1). This led to under-representation of some lower priority procedures. An example of this is large university hospitals being required to report on coronary artery bypass graft (only 6 hospitals perform this surgery) and thus some not reporting on cesarean sections, leaving fewer cesarean sections reported from large university hospitals. NOIS-SSI was representative by age and sex for all years.

NOIS-SSI only collected national data during September-November during the project period. The ECDC reports on Surveillance of Surgical Site Infections in Europe show no trend towards a reduction in incidence proportions for SSIs in the Norwegian data during 2006-2009[97] and 2008-2011,[98] as observed in some other countries. We believe that this is at least in part due to the three-month surveillance period. Only operating for three months at a time means hospitals have to “reset” the system each year which may have this unfortunate effect.[99] It may be argued that such cyclical surveillance, rather than all year focus, leads to less attention on SSI prevention during the remainder of the year. Some have shown that it takes time to achieve the "surveillance effect"[44,45,100-102] and that the greatest effect is in the first few years,[37,100] whereas others do not find an effect over time.[103,104] The UK and France,[74,105] like Norway, have systems where surveillance is only required for some months of the year.[106] Both these countries show a reduction in the incidence proportions only for some procedures in the ECDC reports, and may be experiencing the same issue as with the Norwegian data. In other French and UK studies, however, an overall reduction in SSIs over years is shown.[35,107-109] Some hospitals in Norway performed all-year surveillance voluntarily, but these data have not been reported to the national level. Many said that they found it more resource demanding and inefficient to stop and restart the surveillance system than to operate it all year.

Keeping abreast of training of new personnel and updates to computer systems were reported as easier with all-year surveillance.

Another issue with only collecting data during a three-month period is seasonal variation. Additional NPR-data show that 28% of our procedures under surveillance were performed during the September-November surveillance window, a relatively larger proportion than during the other three-month periods. This is especially true for elective procedures, as these are not performed during holiday periods, and must be taken into account in analyses and interpretation.

The importance of representative data depends on how the surveillance data are to be used. For evaluating risk factors and implementing preventive measures in the individual hospitals, representative data on a national level are not of great importance. For benchmarking and public reporting representative data are very important. As commented in the review of four surveillance systems by Haustein et al[70], mandatory reporting is recommended in order to assure that data are not biased. NOIS-SSI has mandatory reporting, but as long as hospitals are not required to submit all procedures, it will not be fully representative by hospital size and type. Although NOIS-SSI has been mandatory since inception, implementation was incremental, creating much of the selection bias one might expect to see in a voluntary system.

4.2.2 Data source agreement and accuracy

When we compared only hospitals and months which were present in both NOIS-SSI and NPR, we found good agreement between the two registers for all the risk-adjustment variables. This means that when the hospitals did submit data they appeared to contain the correct number of records and were accurate. This implies that the way the ICMs harvest the data from hospital subsystems is good. It is, however, difficult to assess true agreement without having access to linked data.

Investigations need to be done on a regular basis in order to assure that the number of procedures received from the hospitals is correct. There are some examples of problems with data collection in NOIS-SSI. One example is seen clearly in paper II where the accuracy for cesarean sections in 2008 is lower than the other years. This

was discovered retrospectively and located to two hospitals having incomplete data extraction. We have also discovered some instances of hospitals inadvertently only submitting total hip arthroplasties, and omitting hemiarthroplasties because of protocol misunderstandings. Similarly, some hospitals have only submitted non-mixed coronary artery bypass graft procedures because of misunderstandings. These types of omissions are difficult to discover without consistency analysis or comparisons with other data sources. The magnitude of such errors is probably not very large in Norway, but this is difficult to ascertain without linked data. The consequences of the errors will vary. In the case of the cesarean sections, it will probably have few consequences, as there is no reason to believe that there is a systematic difference in infection risks between months. In the case of the hip arthroplasties and bypass surgery the consequences may be greater because the procedures which were lost had higher risk of infection,[110,111] and therefore the reported incidence rates would consequently be lower for these hospitals.

4.3 The quality of the risk-adjustment variables

Risk adjustment indexes for SSI rates have existed for decades,[112] and the NHSN risk index was in use from 1991.[60] Much attention has been given to evaluating and optimizing the NHSN risk index over the years.[113-117] Some advantages of the NHSN risk index were its simplicity and transparency, and disadvantages included its inability to sufficiently differentiate for some types of surgery where patients and procedures are very homogenous. The variables that were included in the NHSN risk index were generally easily available in hospital computer systems, and although other variables may be better predictors, they are not necessarily easily available or of good quality.[118] With the introduction of the NHSN's standardized infection ratio (SIR) in 2010, more variables were included in the risk adjustment algorithm.[62] One of the advantages of this was that the included risk stratification variables could be tailored for each specific procedure. The original NHSN risk index variables are included in the SIR and some additional predictive factors have been added. New risk factors include patient related elements (e.g. age, sex and body mass index), and structural elements (e.g. hospital size and university affiliation).

Paper I shows that 23.3% of the records in NOIS-SSI had at least one missing value for the risk-adjustment variables in 2005-2009. Most were attributable to missing data on antibiotic prophylaxis (21.0%). As can be seen in Table 4, NOIS-SSI's data quality is generally good as compared to the European average.[97] In NOIS-SSI we have identified the key variables that generate the most missing values and have worked systematically to improve these. We have strived to achieve a high degree of completeness of risk-adjustment variables by encouraging implementation of computer systems in hospitals. It is, however, difficult to improve the quality of the risk-adjustment variables if they are not available or correct in the underlying computer systems. There is a considerable resistance among ICPs and other hospital personnel to manual coding when they expect the computer system to be able to harvest these variables correctly. The complexity of collecting data from diverging subsystems can be underestimated and creates extra demand for a good dialog with IT personnel. Misunderstandings, small programming errors and systematic errors in data input can mean poor data quality and can have major consequences. Accuracy can be improved through checks and subroutines that are programmed into the ICMs. Incorrect coding of variables in the source system is an issue, but the same would apply to a manual surveillance system.

Another potential problem area in utilizing automated data collection is the use of default values in computer systems. An example of this would be automatically coding all total hip arthroplasties as "clean" procedures (wound class 1) by default because this would be correct in most cases. One would then expect hospital staff to change the coding where this is applicable, but in many cases this will not be done. Although the intentions are good, this type of practice is difficult to detect and can lead to risk-adjustment being erroneous. We have also seen differences in manual coding practices because of non-uniform interpretation of risk-adjustment variables in different hospitals. It is very difficult to assess the magnitude of this type of problem and its impact on outcomes.

Table 4. Percent of missing values in ECDC's HAI-Net and NOIS-SSI by variable and time period

Variable	ECDC HAI-Net 13 countries, 655,000 records [97] 2008-2009	NOIS-SSI 26,000 records 2005-2009
Overall	N/A	23.3
Sex	0.2	<1.0
Age		<1.0
Antibiotic prophylaxis	63.6	21.0
Urgent or elective surgery	25.2	4.5
NHSN risk index procedures	N/A	6.8
Endoscopic procedure	1.9	0[1]
Wound contamination class	1.1	5.3
Duration of surgery	3.1	<1.0
ASA[2] physical status	4.8	1.7

[1] Included in the surgical procedure code (NCSP)
[2] American Society of Anesthesiologists[119]

In collaboration with the Norwegian Arthroplasty Register we examined the risk factors for infection after total hip arthroplasty and hemiarthroplasty.[110] Both systems collect many of the same background variables, but through different channels. Although the NOIS-SSI data were from a three-month period and not all hospitals were included (completeness issues), the adjusted risk of SSIs in NOIS-SSI supported the adjusted risk for revision due to infection in the Norwegian Arthroplasty Register for many of the risk-adjustment variables. This supports the general impression that the risk-adjustment variables in NOIS-SSI are of good quality.

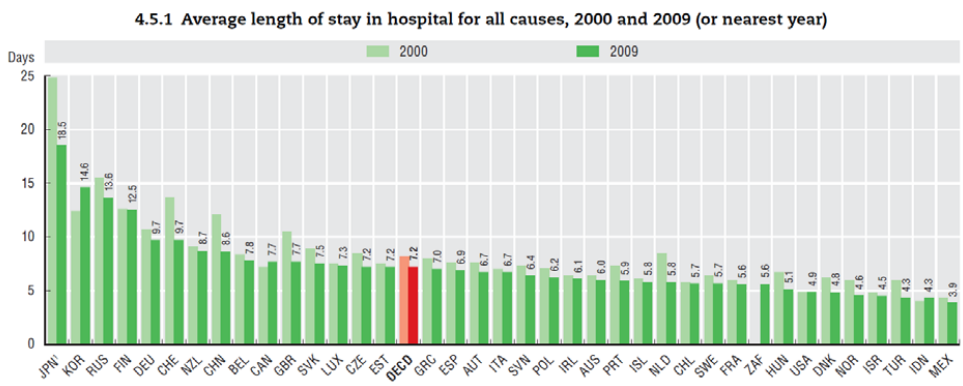
Taking the above into consideration, it is interesting to note the lack of focus in the literature on the data quality of risk-adjustment variables and how these data are collected. No matter how well an index is constructed, it is of little value if the quality of the included variables is insufficient. In our experience, collection of risk variables is a resource demanding and important component of surveillance. Benchmarking and public reporting cannot be properly stratified without this information being of good quality.[120-122] Norway has not yet introduced the SIR, and the Norwegian data have not been formally used for public reporting at hospital level, although we have published reports with between-hospital comparisons.[25] Many of the NHSN SIR patient related risk factors are available and of good quality in the NOIS-SSI and the

structural elements, such as hospital size and type, are easily available. Constructing an SIR adapted to Norwegian conditions would be possible and very useful.

4.4 Completeness of case-ascertainment and correct case-classification

Detecting cases according to stringent definitions[51,66] is a main component of surveillance systems. Surveillance of most types of HAIs is generally only done in the hospital setting, but for SSIs case ascertainment is complicated further by the fact that infections may become clinically manifest after the patients are discharged from hospital.[108,123-129] A paradigm shift towards shorter length of hospital stay and more day-surgery (no overnight stay) has made PDS even more important in detecting all infections.[130-132] The OECD found a reduction in overall average length of stay from 8.2 to 7.2 days from 2000 to 2009[133] (Figure 7). Figure 8 shows how overall mean length of stay has decreased in Norway during the last decades from about eight days in 1990 to about four in 2010 for all hospitalizations.[24] These trends are even more prominent in surgery because of advances in surgical techniques which lead to more day surgery, shorter recovery and shorter length of stay.[134] We found a reduction in postoperative length of stay from seven to five days for total hip arthroplasties and eight to six days in hemiarthroplasties in paper III.

Figure 7. Average length of hospital stay in hospitals for all causes, 2000 and 2009 OECD countries[133]

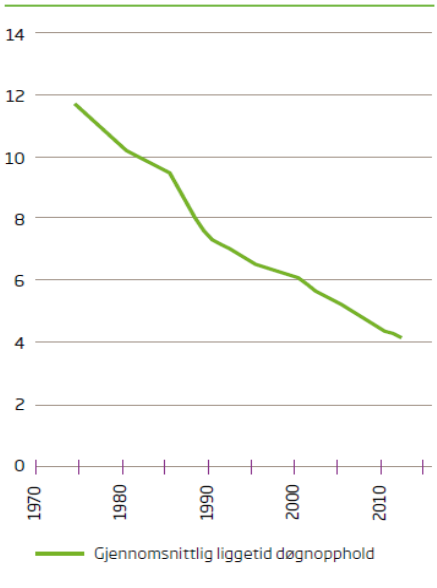


1. The data for Japan refer to average length of stay for acute care (excluding long-term care beds in hospitals).

Source: OECD Health Data 2011; WHO-Europe for the Russian Federation and national sources for other non-OECD countries.

StatLink http://dx.doi.org/10.1787/888932524659

Figure 8. Average length of hospital stay in acute care hospitals in 1974-2012, Norway[24]



Figur 2.2 Gjennomsnittlig liggetid for døgnopphold på somatiske sykehus 1974–2012.

4.4.1 Case ascertainment

Post-discharge follow-up is an important, resource demanding and complicated aspect of incidence surveillance of SSI,[124,135] and concern has been raised with regard to "surveillance fatigue" that may result in less diligent case-finding by traditional methods over time.[136] Active PDS by patient questionnaire is labor intensive and passive PDS has been associated with sacrificing sensitivity in case-finding.[137,138] The extensive use of electronic health records in hospitals makes it appealing to passively use data that already exists (passive PDS).[80,139-141] In paper III we specifically investigated whether one-year follow-up of primary hip prosthesis by patient letter (active PDS) was necessary in order to detect all SSIs, and found that it was not. Although SSIs may manifest several years after surgery,[142,143] several other studies have found that patients with deep SSIs that manifest late (more than 30 days after surgery) will return to hospital because of symptoms or complications, and thus active PDS is not necessary in order to detect these SSIs.[137,144,145]

However, this is not the case for 30-day follow-up, where active PDS is very important. In papers I and III we found that a substantial proportion of SSIs were

detected after hospital discharge (Table 2). We found that about half the SSIs after hip arthroplasty would not have been detected without active PDS. Because of increasingly shorter length of stay, the completeness of case ascertainment is closely related to the method, duration and intensity of PDS. Active PDS is necessary because many patients are treated for their SSIs by other healthcare providers and are thus not readmitted to the index hospital. This means that the SSIs would not have been detected with passive PDS, [144-149] unless health information can be collected from other data sources.

Some recent studies show that between 50% and 95% of SSIs are detected after discharge from hospital,[104,150-154] but this proportion varies with different PDS intensities and between surgical procedure types. In paper I we found that 81% of the SSIs following all procedures in NOIS-SSI were detected after discharge. The original HELICS protocol did not specify any specific form of PDS.[41] However, in the subsequent ECDC protocol,[43] a variable for collecting information on the method of post-discharge surveillance was introduced. The countries which do perform post-discharge surveillance do this in a multitude of ways ranging from passive to active and voluntary to mandatory.[59,97,98,120,155,156]

Although the NHSN reduced PDS duration following hip arthroplasty from one year to 90 days in 2013,[66,157] we concluded in paper III that 90-day PDS was not an option in Norway because this would not be in line with ECDC definitions. However, a very recent Dutch study has revealed that ECDC intends to adopt 90-day PDS.[158] They found that a shortened PDS duration from one year to 90 days would result in 5-6% of SSIs following total hip arthroplasties being missed. Similarly, a US study[157] shows that about 9% of SSIs would be lost by reducing PDS duration from one year to 90 days for hip arthroplasty. Our data indicate that 7% of SSIs would be missed by reducing active PDS from one year to 90 days. However, our data also show that the same would be the case by adopting 30 days active PDS followed by passive PDS up to 90 days.

The Dutch conclude that PDS intensity is of more importance than PDS duration in detecting SSIs, which we also find is true for the first 30 days, but thereafter this is not the case. Another argument for 90-day PDS is the timeliness of the feedback of

data as compared with one year. In Norway, we collect data at both 30 days and one year which enables us to give timely feedback after 30 days of follow-up. It is unclear whether other countries have similar practices, with two separate follow-up points. It is this practice that has prompted us to recommend 30 day active PDS followed by passive PDS up to one year, because the data collection burden on healthcare personnel is doubled by active PDS by patient questionnaire at two separate points in time.

4.4.2 Case classification

As of now, we have not validated actual case-finding in the hospitals in NOIS-SSI. In an evaluation of validity of HAI classification in our semi-annual prevalence surveys, we found 69% sensitivity and 96% specificity in two Norwegian hospitals.[159] However, this study included several types of HAIs, not exclusively SSIs. Several studies have validated SSI surveillance data by chart review, which has traditionally been considered to be the "gold standard".[71,77,160-164] Most found high sensitivity and all found very high specificity and high positive predictive values (PPVs) and negative predictive values (NPVs), which indicated that case classifications were robust and correctly applied (Table 5). Interestingly, inter-rater agreement studies have found poor consistency between health care professionals in evaluating case-vignettes for SSIs[18,165,166] or HAIs in general.[167] There may be several reasons for this discrepancy. One reason may be a form of confirmation bias in the validation studies, where the investigator is more partial to seek confirmation of existing classifications. Another reason may be that case vignettes may provide abbreviated case descriptions, thereby limiting the ability to interpret the case correctly. There are also indications that some aspects of case-classification are more difficult than others, especially the severity of the infection,[163,168,169] and that CDC's surveillance definition criteria for superficial SSI are difficult to apply.[170,171] There is a substantial ongoing effort in finding reliable automated and semi-automated methods for detecting SSIs as an alternative or supplement to the traditional case-finding by ICPs, which I will discuss in the next section of this thesis.

Table 5. Validation studies by chart review

	Sensitivity	Specificity	PPV	NPV
Cardo, 1993[162]	84	100	97*	99*
McCoubrey, 2005[77]	97	99	95	99
Huotari, 2007[160]	95*	98*	94	99
Mannien, 2007[161]	96*	99*	97	99
Friedman, 2007[163]	62	100	91*	98*
Wilson, 2013[71]	91	99	91	99
Reilly, 2015[164]	98	100	98	100

* Calculated based on data in the article

4.5 The role of information technology in surveillance

The use of computers in surveillance of HAI has been topic of discussion for over 30 years. Since the time of the Study on the Efficacy of Nosocomial Infection Control (SENIC) until the present, the ability of computers to generate alerts and enhanced screening for HAI and thereby reducing time spent on manual tasks such as case-finding has been a topic of discussion.[61] The time and effort saved by computer-aided HAI surveillance was documented by Evans et al in 1986,[172] showing a 65% reduction in time spent as compared with traditional case-finding methods. Automated data collection is becoming a very important tool in surveillance of HAI.[75,173] Much has happened in the area of EHRs and data linkage since the 1980s and much is presently being done with regard to automated HAI case-finding, ranging from searching for codes in administrative or laboratory data to advanced computer algorithms which utilize several sources.[80,139-141,174,175]

4.5.1 Types of electronic case-finding

Woeltje[176] makes a distinction between two basic types of electronic surveillance systems; electronically assisted surveillance and fully electronic surveillance. The first is a system that electronically tags possible cases, but still requires human interaction to confirm or reject the presence of an SSI according to surveillance definitions. This type of system will favor sensitivity over specificity because manual review will remove the false positives. The second, which is fully automatic, only requires computer algorithms to define whether the surveillance definition has been

met. Such systems may use only in-hospital data, or may utilize data from medical claims, health maintenance organizations, and other external data sources.

NOIS-SSI does not fit either of these definitions despite being highly automated, because there is no automated case-finding in NOIS-SSI. We still consider it an electronic system, because the hospitals' ICMs harvest relevant procedure codes and risk-adjustment variables (denominator data) and display these in a user interface. Some of the hospital systems require the discharging physician to enter infection status before the patient can be discharged (and for the hospital to be refunded for the procedure). The patient letters are also partially automated. They are generated automatically and most systems include a bar code which identifies the patient so that it can be easily appended to the patient record in the ICM when returned by mail.

4.5.2 Positive aspects of automated case-finding

In the 1980s, Evans et al[172] found that the computer-aided method detected 85% of the SSIs, while ICPs detected only 58%. Although traditional case-finding by ICPs has been considered the "gold standard" of HAI surveillance, several newer studies show that this is not necessarily the case: computer-aided surveillance may be more time-efficient and superior in case-finding. Many studies have compared traditional surveillance by ICPs with case-finding using surveillance definitions to available data sources such as ICD-9 diagnostic codes and other administrative coding;[78,81,87,89,177-181] microbiology, laboratory or pharmacy data;[182-185] or a combination of these[84,137,146,184,186-189]. Some have utilized advanced algorithms to detect SSIs and validate these against ICP case-finding.[83,88,185,190-199]

Computer systems should reduce the workload on ICPs, thereby making all-year surveillance of several procedures an achievable goal for surveillance systems. Gathering more standardized data is another opportunity which may arise from electronic surveillance, and may be useful in generating more objective benchmarking between hospitals.[177,197,200-202] Automated data collection may be less prone to inter-rater differences and may help alleviate "surveillance fatigue", and thereby ensure more consistent data over time.

4.5.3 Challenges in automated case-finding

There are some issues to overcome if more automated case-finding is to be used in regular SSI surveillance. Traditional SSI surveillance definitions do not necessarily match the clinical definitions which are coded in the electronic systems, and may need revision if we are to rely more heavily on available electronic health records. This can be partially overcome by advanced algorithms which mimic the surveillance definitions.

Automated systems which solely rely upon in-hospital data (inpatients and re-hospitalizations) will not detect the large and probably increasing portion of the SSIs which are detected by other healthcare providers such as general practitioners and other hospitals.[203] Advances in data mining, data linkage and electronic surveillance systems make post-discharge patient information more easily obtainable than previously.[204-206] This means that the distinction between active and passive PDS will be blurred, and that passive PDS may become more sensitive in the future.[88,89,141,191,203,207,208] Regardless of degree of automation and data sources, passive PDS requires high quality systems for data harvesting and good and uniform coding practices by health care personnel.[155] Additionally, using data for a purpose for which they were not intended can mean that they are not appropriate for the task.[209-211]

Despite numerous studies and reviews describing the benefits of electronic case-finding in HAI surveillance[80,139-141,174,202,212] only a handful of systems of this type are actually in use in regular clinical routine,[174,213,214] and only some of these are applied in an SSI-surveillance setting. To the best of my knowledge, no national or statewide surveillance system depends solely on electronic detection of SSIs. One can only speculate regarding the reason for this. One reason may be the sheer complexity of the systems and the data.[211,215] Other reasons may be human factors such as the ICPs understanding of automated surveillance processes, financial and leadership support, the perception of data as meaningful, and acceptance that some issues cannot be solved by automated systems.[216]

4.6 Limitations and methodological considerations

There are several important limitations to the findings in this thesis. We have not done a study in the hospitals to validate the application of the surveillance definitions by the hospital staff. Although other countries have found good results in such validation studies, we cannot be certain that the same would apply in Norway. Interpretation of the risk-adjustment variable definitions may not be consistent between hospitals. Different IT-system suppliers and system owners may interpret the surveillance protocol and specifications differently. They may also be influenced to make modifications to the system, such as implementing default values, which make surveillance less labor intensive, but corrupts the system.

There may be differences in case mix because not all hospitals submit data each year. Norway is a small country, and with only three months of the year under surveillance, the numbers are small and results may be uncertain. Patient questionnaires, as defined by NOIS-SSI, may not be the optimal way of detecting SSIs after hospital discharge. However, there is no alternative method available which would ensure better detection at present.

The data in paper II are not linked, but compared on an aggregated level. We cannot be certain that NOIS-SSI is a subset of NPR, as both registers may contain unique records.

Paper III only includes hip arthroplasty and results may therefore not apply to other types of surgery. The study is restricted to hospitals which have completed one year PDS (about half of the hospitals), and may not be representative of all hospitals in Norway. Some of the reasons why all the late SSIs were coded as readmitted in NOIS-SSI may be due to health care personnel manually checking for readmissions after the patient has returned the questionnaire with an SSI indication. They may not have been detected by passive PDS alone if the hospital electronic health records are not adequately coded and harvested or if the patient is readmitted to another hospital.

4.7 Concluding remarks and future perspectives

This thesis gives a comprehensive description of a functioning mandatory, national surveillance system, with active post-discharge surveillance, which is largely based on automated data extraction form hospital IT-systems. We describe pitfalls and potential problem areas to be avoided or adjusted for by others wishing to implement such systems. The development of computerized systems is complex and would not have been possible without a flexible implementation strategy. We find this is a double-edged sword – on one hand the flexibility has made it possible to implement advanced computerized systems which give good accuracy. On the other hand this flexibility has contributed to the data not being sufficiently representative. By highlighting problem areas and discussing others' findings we hope to pave the way for more sophisticated automation of SSI surveillance systems in Norwegian hospitals.

Documenting NOIS-SSI's representativeness issues has contributed to the implementation of all year and all procedure surveillance from 2013. In this way we hope to achieve more unbiased results. Investigating and documenting post-discharge surveillance for one year after hip arthroplasty has led to a recommendation to revise the surveillance protocol. Follow-up of hip arthroplasty patients beyond 30 days will be passive (through readmissions), rather than active (by patient questionnaire). This will hopefully lead to time and costs saved by hospital staff and more hospitals completing one year follow-up.

In an update after 25 years,[217] Evans concludes that the key elements to the success of surveillance systems are clinical ownership, clinically knowledgeable IT-personnel, knowledge of the underlying data, continual upgrades of the system, and good communication between ICPs and IT-personnel. In light of this, there is still much work to be done in order to ensure that NOIS-SSI is functioning optimally.

In order to complete the surveillance circle and alter behavior, clinical ownership and informing clinicians about the quality and usefulness of the data are key elements. This is closely linked to two issues; the ability of ICPs to communicate outcomes and trust in case ascertainment. Both these areas need improvement in NOIS-SSI.

Hospital data compared with national data has been sent to the hospitals annually from the NIPH. However, better training of ICPs in the use and communication of national and local surveillance results is needed.[218-220] Another road to clinical ownership is use of the data for research. Several publications by clinicians have used local surveillance data[221-223] and collaborations between clinicians and the NIPH have resulted in publications on different SSI-related topics.[110,224-227] Encouraging more use of data for research and a validation study focusing on correctness of case ascertainment will hopefully contribute to clinicians using and trusting the data. In order to generate more interest in using NOIS data for research, linked data on a person-identifiable level is important, and efforts are being made to make NOIS person-identifiable.

On a national and regional level, clinically knowledgeable IT-personnel are involved in the development and maintenance of NOIS-SSI. Because we basically only have three major systems, it is not critical to have clinically knowledgeable IT-personnel at each individual hospital. It is, however, necessary to have an on-going dialog with the IT-system suppliers to ensure correct specification of data extraction and quality control. In Norway this communication needs to be better coordinated between the hospitals and Regional Health Authorities. It has been the responsibility of the hospitals and regions to purchase and implement IT-systems, and thus it has not been the role of the national level (NIPH) to be directly involved in system specifications and design.

Knowledge of the underlying data has two aspects; technical and clinical. Technically, this knowledge is made difficult by diverging systems at different hospitals and continual changes and upgrades in underlying computer systems. Clinically, an understanding of the underlying data is necessary for interpretation, analysis and quality assurance. We believe that the ICPs in Norway have a good understanding of this, but there is always room for improvement. Training of new ICPs is an important part of ensuring a stable surveillance system. We have experienced that technically competent ICPs are a valuable resource.

Judging by the amount of studies on computer-based and automated systems, the future of surveillance will certainly rely more on this type of technology. A heavier

surveillance workload on ICPs due to, among other demands, public reporting, antimicrobial stewardship programs and patient safety initiatives will leave traditional surveillance methods insufficient in meeting demands.

Because we already have good quality computer-based systems in place, Norway is in a unique position to begin using computer-assisted case-finding in hospitalized and re-hospitalized patients. However, data from other sources such as general practitioners are not easily accessible at present, but may be in the future. An interesting project would be to develop an algorithm for case-finding for use in Norwegian hospitals.

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6 Appendices

Papers I-III
Ethical approval

II

The Quality of Denominator Data in Surgical Site Infection Surveillance versus Administrative Data in Norway 2005-2010

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Abstract

Background

High quality of surveillance systems for surgical site infections (SSIs) is the key to their usefulness. The Norwegian Surveillance System for Antibiotic Consumption and Healthcare-Associated Infections (NOIS) was introduced by regulation in 2005, and is based largely on automated extraction of data from underlying systems in the hospitals.

Methods

This study investigates the quality of NOIS-SSI's denominator data by evaluating completeness, representativeness and accuracy compared with de-identified administrative data for 2005-2010. Comparisons were made by region, hospital type and size, age and sex for 4 surgical procedures.

Results

The completeness of NOIS improved from 29.2% in 2005 to 79.8% in 2010. NOIS-SSI became representative over time for most procedures by hospital size and type, but not by region. It was representative by age and sex for all years and procedures. Accuracy was good for all years and procedures by all explanatory variables.

Conclusions

A flexible and incremental implementation strategy has encouraged the development of computer-based surveillance systems in the hospitals which gives good accuracy, but the same strategy has adversely affected the completeness and representativeness of the denominator data. For the purpose of evaluating risk factors and implementing prevention and precautionary measures in the individual hospitals, representativeness seems sufficient, but for benchmarking and/or public reporting it is not good enough.

Keywords

Electronic Surveillance

Register data

Incidence

Infection control

Background

Surveillance of surgical site infections (SSIs) is increasingly regarded as a cornerstone in infection prevention. Many hospitals and countries have successfully implemented surveillance systems [1]. High quality of the systems is a prerequisite for their usefulness. National surveillance of SSIs in Norway was established with the Norwegian Surveillance System for Antibiotic Consumption and Healthcare-Associated Infections (NOIS) Act [2] in 2005, and we have earlier reported in detail on the rationale and functioning of this system [3, 4]. NOIS is based on the Hospital in Europe Link for Infection Control through Surveillance (HELICS) [5] which was transferred to the European Centre for Disease Prevention and Control (ECDC) [6], and the definitions from the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN) [7].

Describing and evaluating the performance of a surveillance system is key to understanding its potential usefulness for public health authorities, hospitals, surgeons and hospital epidemiologists [8]. Validating the quality of the denominator data are important in order to ensure correct incidence rates and proportions. The objective of this study is to investigate denominator data quality by comparing surgical site infection surveillance data from NOIS-SSI with administrative data from the Norwegian Patient Register (NPR). We compare de-identified denominator data for the years 2005-2010 on an aggregated level in order to identify possible discrepancies in terms of completeness, representativeness and accuracy, and to recommend improvements.

Methods

NPR was established in 1997 and contains information on all patients who receive specialist health care in Norway. Upon treatment in a hospital, an outpatient clinic or by a contracted private specialist, a series of data are recorded at the treatment site and transmitted to NPR three times a year. The objective of NPR is to form a basis for administration, management and quality assurance in specialist health care services, including financing and funding hospitals [9]. It is considered to be the complete database for hospital care in Norway [10]. NPR-data are harvested electronically from the hospital electronic health records (EHR). It is operated by the Norwegian Directorate of Health. The NPR-data in the present study include variables for all admissions related to the procedure under observation: Patient identifier (de-identified), procedure code (Nordic Medico-Statistical Committee's Classification of Surgical

Procedures (NCSP))[11], diagnosis codes (International Classification of Diseases (ICD10)), dates and times of admission, discharge and procedure, length of stay, year of birth, sex, type of admission and hospital identifier.

NOIS was established in 2005 and is a national, mandatory surveillance system for health-care institutions [2]. The objective of the system is to describe the occurrence of healthcare-associated infections by time and other characteristics, detect outbreaks, provide a basis for preventive measures, and to evaluate such measures. It is coordinated by the Norwegian Institute of Public Health (NIPH) in collaboration with the hospitals. The first NOIS-module encompasses SSIs following several common surgical procedures, and is described in-depth in our previous publication [3]. Data are collected during an annual three-month surveillance period (September-November). The data are de-identified by replacing the personal identifier with a serial number before the annual submission to the NIPH. The surveillance system relies to a great extent on automatic extraction of patient data from EHRs. There are three major suppliers of electronic infection control modules (ICMs) in use in Norway. In addition some hospitals have self-developed systems, some have manual systems and some have a combined manual and electronic system.

The following surgical procedures are included in this study (in order of priority in NOIS-SSI): coronary artery bypass graft (CABG), cesarean section (CSEC), hip prosthesis (HPRO) and cholecystectomy (CHOL). During the first few years of NOIS-SSI, exemption from submitting surveillance data was given to hospitals so that they could establish suitable ICMs. Through 2009 hospitals were required to submit data from at least one of the surgical procedures under surveillance, and from 2010 and onwards at least two procedures [3]. Mixed CABG procedures (where aorta or ventricle surgery where performed in addition to bypass) were excluded in 2008 and mixed CHOL procedures (where other procedures are performed during the same surgery) were excluded in 2007 and 2008. NOIS-SSI includes data on the following variables of interest for this study; dates of admission, discharge and surgery, NCSP codes, age, sex, and hospital identifier.

We define a hospital as a single physical unit/location. A health care trust is a legal entity, often including several hospitals. There is a trend towards hospitals reporting data on a trust level. This causes the "hospital type" to be an ambiguous categorization over time, as one trust may include several different hospital types in the latter years. We have manually categorized hospitals according to ECDC classifications [6] as follows: primary (district hospital), secondary (provincial hospital), tertiary (university hospital), and specialized (non-profit/idealistic, private, contracted hospitals that mostly perform elective surgery within

certain procedure types single specialty). Hospital size was also manually categorized and is influenced by the same issues as hospital type with regard to reporting on a trust level the latter years. Regions are designated according to the official categories, South-East, West, Central and North. Type of ICM was manually coded into four categories according to whether the NOIS-SSI data for a specific year was generated from of one of the three ICM suppliers (A, B or C), or from a manual or in-house system (other).

NOIS-SSI contains the patient's actual age in years on the date of surgery, but the NPR-data only provides the year of birth. To correct for this, we calculated age by generating pseudo-random birth months (1-12) and days (1-28) for the NPR procedures in order to spread the patients evenly throughout the year. In surveillance of SSIs, the denominator is the number of surgical procedures performed. One patient may undergo several procedures, such bilateral or staged hip replacement which counts as 2 procedures.

The NPR-data received had one record per admission related to the surgical procedure. We converted this to one record per procedure based on the patient identifier, year of birth, sex, hospital identifier and date of surgery. Missing procedure dates in NPR (especially 2009) were substituted by date of admission. We excluded procedures which were duplicates, had invalid surgical procedure codes or were from private clinics with inconsistent data in both registers. In addition we excluded procedures from NOIS-SSI which were outside the 3-month surveillance window, and procedures from NPR from outside 2005-2010. NOIS-SSI data were appended to NPR-data for data analysis purposes.

We evaluated the data quality of NOIS-SSI with regard to the completeness, representativeness and accuracy of the denominator data compared with NPR. We defined completeness as the total number of procedures in NOIS-SSI divided by the total number of procedures in NPR during the 3-month surveillance period for each procedure and year. Representativeness was assessed by comparing the distribution of data in NOIS-SSI with the distribution of data in NPR by hospital type and size, region, age and sex for each procedure and year. We defined accuracy as the agreement of data from hospitals and months which were present in both registers. We thus excluded data from hospitals or months which were not present in both registers from the comparison and divided the number of procedures in NOIS-SSI by NPR. We further compared the distributions in the two registers by the same variables as for representativeness. In addition we evaluated the accuracy based on the type of ICM used for collecting NOIS-SSI data. Frequencies were calculated for each of the surgical categories for each year, the whole period, and for each included variable. NOIS-SSI was evaluated against NPR in terms of percentages and chi-

squared analysis. All data cleaning and analysis was done using Stata v.11 (Stata Statistical Software, College Station, TX). The study has been approved by the Regional Committee for Medical and Health Research Ethics. It does not require patient consent as both NPR and NOIS are national health registers governed by separate acts.

Results

After data cleaning 162,509 procedures remained from NPR for 2005-2010, whereof 45,347 (27.9%) from September - November. From NOIS-SSI, 26,250 procedures were included from September-November of 2005-2010.

Table 1 shows completeness as the number of procedures submitted to NOIS-SSI divided by the total number of procedures in NPR for the 3-month surveillance period in 2005-2010. For the whole period, NOIS-SSI encompassed 57.9% of the total number of surgical procedures in NPR. The overall completeness improved from 29.2% in 2005 to 79.8% in 2010.

Figure 1 shows the representativeness of NOIS-SSI by comparing the distribution of the procedures in NOIS-SSI with NPR by hospital size for each year. During the first years of operation NOIS-SSI differed significantly from NPR. As more hospitals submitted data during the subsequent years the distributions became more similar and thus more representative for most procedures. There was similar pattern by hospital type (data not shown), and the differences between registers cease to be significant for CABG from 2008 and for CSEC from 2009. For HPRO, only 2009 had no significant differences between the registers. For CHOL the differences are significant for all years by hospital type. By region (data not shown) the differences in distribution between NOIS-SSI and NPR were greater. Only CABG in 2008 and 2009 and CSEC in 2010 had no significant differences. There were no significant differences in distribution by age and sex between NOIS-SSI and NPR ($p>0.05$). The median age was about 66 for CABG, 31 for CSEC, 73 for HPRO and 49 for CHOL.

Table 2 shows the accuracy of NOIS-SSI compared with NPR by surgical procedure and year, for hospitals and reporting months which were present in both registers. Overall accuracy was 94.8%, the lowest was 2008 with 90.6% and the highest was 2010 with 97.5%. The procedures with the highest overall accuracy were HPRO and CSEC. There were no significant differences in distribution by region, hospital type and size, age or sex for each year and procedure ($p>0.05$) between NOIS-SSI and NPR.

Figure 2 shows the development of ICMs from one major supplier and several manual and in-house systems in 2005, to most data from major ICM suppliers in 2010. All ICMs and other systems in the hospitals perform well, and we only find significant differences between NOIS-SSI and NPR for CSEC in 2008 ($p=0.001$). System B had the highest overall accuracy (97.5%). The three commercial systems demonstrate less variability than manual/other systems but the differences were not significant ($p>0.05$).

Discussion

The Norwegian Surveillance System for Antibiotic Consumption and Healthcare-Associated Infections (NOIS-SSI) included 79.8% of the procedures in the administrative data during September-November 2010, up from 29.2% in 2005. NOIS-SSI was not representative with regard to hospital size and type during the earliest years, but became representative with time for some procedures. NOIS-SSI was representative with regard to age and sex for all years and procedures. The accuracy was 97.5% in 2010, an increase from 92.7% in 2005 and there were no differences in the distribution by any explanatory variables, except by type of infection control module (ICM) for CSEC in 2008.

Comparing denominator data between two registers gives an indication of the quality of the data in both registers. It also reflects the quality of the data extraction at the individual hospital. Denominator data are important in order to reliably describe infection occurrence on a national level, in hospital benchmarking, and inter-country comparisons. Regardless of how diligent numerator (infection) case finding is, incidence proportions only make sense if the correct denominator is used [12]. In a recent review, Goto [13] investigated the accuracy of administrative coding, but none of the included SSI-related studies reported on the quality of denominator data. McCoubrey [14] found that 91% of eligible procedures were included in the Scottish surveillance data. Haley [15] found 98% matches between administrative- and surveillance data. Most validation studies report only on the numerator in terms of infection as outcome. A number of studies have investigated the completeness of other Norwegian health registers compared with NPR. Among these, 0.4% more CSECs were found in the Medical Birth Register of Norway [16], the Norwegian Vascular Register found a completeness of 84% for abdominal aortic aneurism repair [17], and the Norwegian Arthroplasty Register found 97% completeness of primary HPRO compared with NPR [18]. These studies are important because in addition to ascertaining the quality of the individual registers, validate the quality of NPR. Although it has improved, NOIS-SSI still only received 78.8% of the procedures performed during September-November 2010.

Because NOIS-SSI only collected data during September-November during the study period, it was dependent on those 3 months being representative. The explanatory variables which reflect hospital participation (region, hospital type and size), show that NOIS-SSI was generally not representative for most procedures until the last years. There are several possible explanations for this.

During the first years, many hospitals were granted exemption from submitting data in order to facilitate the establishment of ICMs. The ICMs were generally purchased or developed for whole trusts or regions, which led to several regions submitting little or no data during the first years. Most hospitals and regions had installed ICMs by 2007, but some were not functioning optimally. This led to some hospitals and trusts being exempted also in the later years, and NOIS-SSI not being representative by region.

During 2005-2009 NOIS-SSI only required data from one procedure, the one with the highest priority. This means that hospitals were only required to submit data from the highest prioritized procedure which they performed. All hospitals which performed CABG procedures were required to submit data, but exemptions were granted to some regions and hospitals the first years. In addition, some hospitals did not submit data in later years despite it being required. If a hospital reported on CABG, it did not have to submit any other procedures. In principle this meant that none of the tertiary hospitals, which almost all performed CABG, were required to submit CSEC data causing poor representativeness by type of hospital for CSEC. This also affected representativeness by hospital size, because the tertiary hospitals are generally the largest. From 2010 a minimum of 2 procedures were required and this improved the representativeness for CSEC by hospital size and type. However, CSEC representativeness was already good in 2009, probably attributable to "enthusiastic volunteers". For HPRO, representativeness by hospital size started improving in 2008. Some of the hospitals which perform HPRO are specialized orthopedic hospitals, and these have submitted data consistently over the years. Many other hospitals have submitted HPRO data voluntarily, and this may explain why representativeness started improving before the implementation of minimum 2 procedures in 2010. For CHOL representativeness was generally poor, which is to be expected as this procedure had the lowest surveillance priority. For age and sex NOIS-SSI was representative, meaning that there were no differences between NOIS-SSI and NPR in the patient population for these variables.

In a review of four surveillance systems Haustein et al [19] recommended mandatory reporting in order to assure that data are not biased. They found that none of the voluntary systems they investigated ever surpassed 50% participation, and that representativeness

improved when reporting was made mandatory. NOIS-SSI was mandatory since inception, but a flexible implementation policy (granting exemptions) caused it not to be representative on a national level and caused participant population to change over time. The additional complication of hospitals changing from individual hospital to trust level reporting produces data which is less useful for stratification and risk purposes. This is demonstrated in Figure 1, where a greater proportion of large hospitals are evident during the latter years. For example, 2 small primary hospitals and 1 large tertiary hospital reported individually until 2008 and from 2009 they reported as one large trust on the tertiary level.

The importance of representative surveillance data depends on how data are to be used. For evaluating risk factors and implementing preventive measures in the individual hospitals, NOIS-SSI seems to provide useful data. For hospital benchmarking and/or public reporting, NOIS-SSI was not good enough.

We found the agreement between the two registers to be good, which means that when the hospitals did submit data to NOIS-SSI they appeared to be accurate. We only observed a significant difference (p=0.001) between the registers by ICM for CSEC in 2008, which was mainly due to technical issues in two hospitals with the same ICM-supplier resulting in incomplete data extraction. Another reason for somewhat lower accuracy in some procedures and years was that the NOIS-SSI protocol was modified with regard to mixed procedures. The exclusion of the mixed CABG procedures in 2008 gave a dip in the accuracy of NOIS-SSI (not significant). For CHOL, exclusion of mixed procedures did not appear to influence accuracy, which is reasonable because over 90% of CHOLs were laparoscopic procedures [20] and generally not mixed (Table 2).

Automated data collection is becoming a very important tool in surveillance of HAI. It reduces the workload on hospital staff and, hopefully, human errors [21-30]. In NPR all data are collected electronically from the hospitals' EHR and in NOIS-SSI most explanatory and background variables are collected electronically, so we expect denominator data to be identical. As demonstrated by the lower accuracy in CSEC for 2008, one cannot be certain that denominator data are correct even if they are extracted directly from hospital computer systems. Computer systems are not infallible, and it is necessary to routinely check if data are being harvested correctly. We observe some variability between the ICMs and other systems and it appears that the accuracy overall for the ICMs was more consistent than the manual/other systems, but none of the differences were significant.

The development of ICMs is complex and would have been more difficult without a flexible implementation strategy. As shown in Figure 2, the hospitals quite quickly purchased or developed ICMs. We found the flexible implementation to be a double-edged sword. On one side the flexibility made good cooperation with hospitals and ICM suppliers possible and has led to quality ICMs which give good accuracy. On the other side this flexibility contributed to less representative data. Although NOIS-SSI is mandatory, the flexible implementation introduced selection bias giving poor representativeness for variables that reflect hospital participation.

NOIS-SSI improved over the first six years, but data were still not fully complete and representative in 2010. The accuracy of NOIS-SSI was good, because the hospitals which submitted data have had consistently good denominator quality throughout the years, with a few exceptions. We also saw an indication that automated data harvesting gave slightly better denominator data quality. It is, however, difficult to assess true completeness, representativeness and accuracy without having access to linked data [31]. Being able to compare surveillance data with administrative data on a regular basis, in order to give hospitals feedback on data quality, could be a useful tool in improving quality and instilling trust in the surveillance system performance. Some have argued that administrative systems can provide more economical, standardized and unbiased outcome data than traditional surveillance systems if used correctly [32-34].

The data in this study are not linked and are compared on an aggregated level. We cannot be certain that NOIS-SSI is a subset of NPR, as both registers may contain unique records. Some variables were coded manually by the authors, and may contain unintentional errors. Birth month and date for the NPR data were generated by a pseudo-random function and does not reflect different annual birth rate patterns. For calculation of accuracy some hospitals and months were excluded from analysis, and this may give an incorrect impression of the quality of NOIS-SSI.

Conclusions

NOIS-SSI had a completeness of 79.8% of the procedures in the administrative data (NPR). The NOIS-SSI denominator data were not representative by hospital size and type during the first years of surveillance system operation, but became representative for some procedures with time. NOIS-SSI was generally not representative by region. This means that data from this period should not be used for hospital benchmarking and/or public reporting. NOIS-SSI was representative by age and sex for all procedures. For the purpose of evaluating risk

factors and implementing prevention and precautionary measures in the individual hospitals, representativeness seems sufficient. Denominator data agreement between NOIS-SSI and NPR of almost 95% indicates that the accuracy of submitted data of was good. A flexible and incremental implementation strategy has encouraged development of computer-based surveillance systems in hospitals which gives good accuracy, but has adversely affected the representativeness of the data during the first years of system operation.

Table 1. Completeness: The number of procedures by type of surgical procedure and year and proportion of the procedures in NOIS versus NPR, September-November 2005-2010.

	2005	2006	2007	2008	2009	2010	Total
CABG							
NOIS	167	599	680	718	746	612	3,522
NPR	1,067	1,006	1,046	928	817	796	5,660
Completeness	*15.7 %*	*59.5 %*	*65.0 %*	*77.4 %*	*91.3 %*	*76.9 %*	*62.2 %*
CSEC							
NOIS	883	1,322	1,634	1,948	2,171	2,484	10,442
NPR	2,210	2,304	2,443	2,513	2,509	2,586	14,565
Completeness	*40.0 %*	*57.4 %*	*66.9 %*	*77.5 %*	*86.5 %*	*96.1 %*	*71.7 %*
HPRO							
NOIS	903	1,052	1,338	1,853	2,522	2,565	10,233
NPR	2,621	2,628	2,870	2,776	3,106	3,141	17,142
Completeness	*34.5 %*	*40.0 %*	*46.6 %*	*66.8 %*	*81.2 %*	*81.7 %*	*59.7 %*
CHOL							
NOIS	166	234	339	342	409	563	2,053
NPR	1,356	1,308	1,394	1,362	1,285	1,275	7,980
Completeness	*12.2 %*	*17.9 %*	*24.3 %*	*25.1 %*	*31.8 %*	*44.2 %*	*25.7 %*
TOTAL completeness	*29.2 %*	*44.3 %*	*51.5 %*	*64.1 %*	*75.8 %*	*79.8 %*	*57.9 %*

NOIS: Norwegian Surveillance System for Antibiotic Consumption and Healthcare-Associated Infections
NPR: Norwegian Patient Register

Figure 1. Representativeness: Proportion of procedures (in %) by hospital size in NOIS and NPR (2005-2010)

Table 2. Accuracy: The number of procedures by type of surgical procedure and year and proportion of the procedures in NOIS versus NPR for selected hospitals and reporting months, 2005-2010.

	2005	2006	2007	2008	2009	2010	Total
CABG[1]							
NOIS	167	402	519	580	503	520	2,691
NPR	237	446	589	709	514	554	3,049
Accuracy	*70.5 %*	*90.1 %*	*88.1 %*	*81.8 %*	*97.9 %*	*93.9 %*	*88.3 %*
CSEC							
NOIS	883	1,304	1,607	1,826	2,051	2,402	10,073
NPR	904	1,346	1,660	2,014	2,065	2,431	10,420
Accuracy	*97.7 %*	*96.9 %*	*96.8 %*	*90.7 %*	*99.3 %*	*98.8 %*	*96.7 %*
HPRO							
NOIS	903	1,052	1,338	1,853	2,151	2,335	9,632
NPR	943	1,087	1,451	1,959	2,194	2,363	9,997
Accuracy	*95.8 %*	*96.8 %*	*92.2 %*	*94.6 %*	*98.0 %*	*98.8 %*	*96.3 %*
CHOL[1]							
NOIS	159	234	339	341	405	524	2,002
NPR	194	274	359	395	464	582	2,268
Accuracy	*82.0 %*	*85.4 %*	*94.4 %*	*86.3 %*	*87.3 %*	*90.0 %*	*88.3 %*
TOTAL accuracy	*92.7 %*	*94.9 %*	*93.7 %*	*90.6 %*	*97.6 %*	*97.5 %*	*94.8 %*

NOIS: Norwegian Surveillance System for Antibiotic Consumption and Healthcare-Associated Infections

NPR: Norwegian Patient Register

[1] Mixed procedures excluded from NOIS for CABG in 2008 and for CHOL in 2007 and 2008

Figure 2. Proportion of hospitals submitting data to NOIS from different electronic systems (A, B and C) and other data sources, 2005-2010

Competing Interests

The authors declare that they have no competing interests and nothing to disclose. The project is fully financed through the Norwegian Institute of Public Health's budget.

Authors' contributions

HLL has planned and designed the study, made substantial contributions to data collection, has analyzed and interpreted data and has drafted and revised the manuscript. HME has been involved in the planning and design of the study, has been involved in data collection and participated in the analysis and interpretation of data. PA has been involved in the planning and design of the research study. FES has made a substantial contribution to the

planning and design of the research study and has made a substantial contribution to data acquisition. All authors have substantially contributed to the draft and revising of the manuscript critically and have approved the final version.

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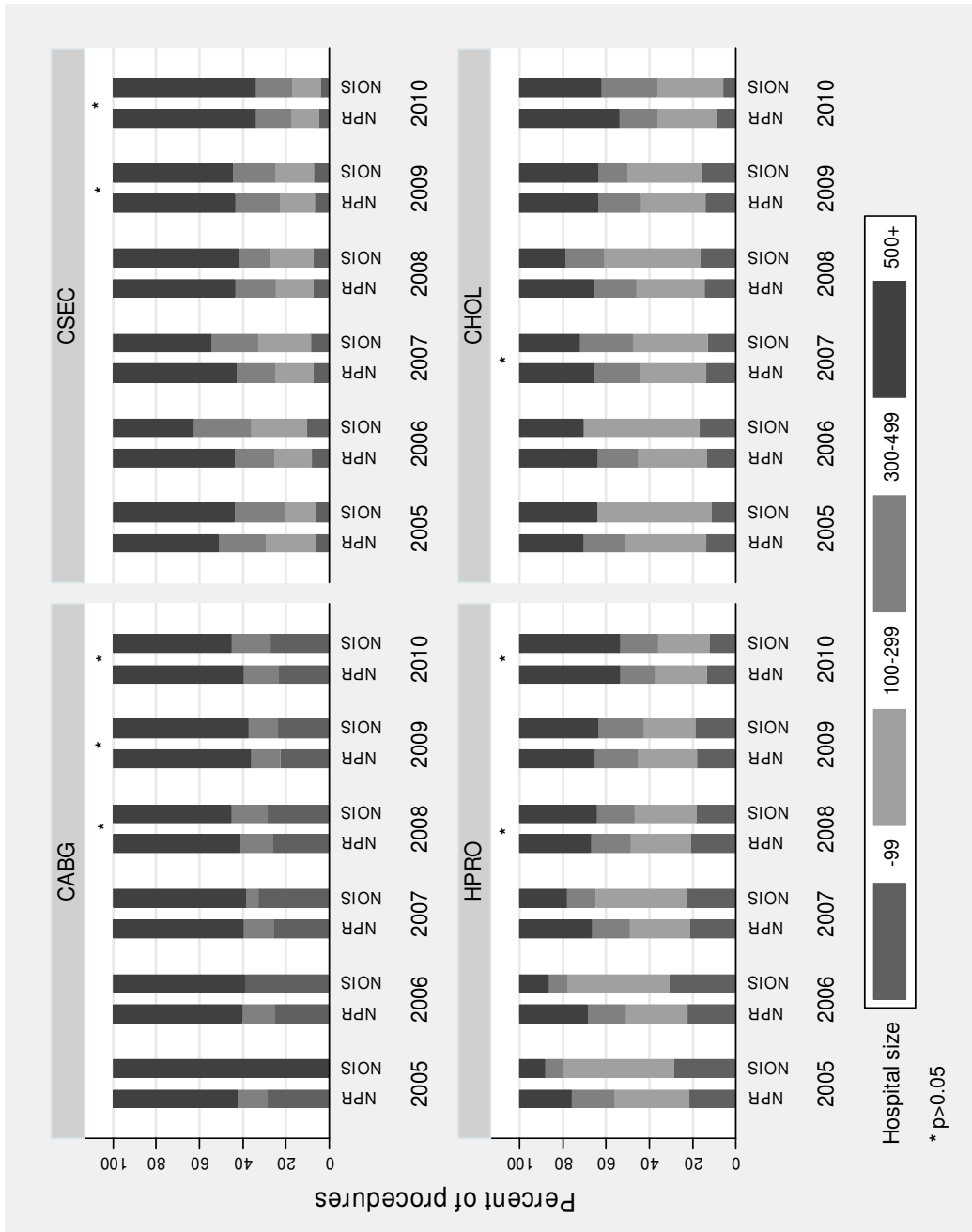
CABG
CSEC
CHOL
HPRO
Percent of procedures
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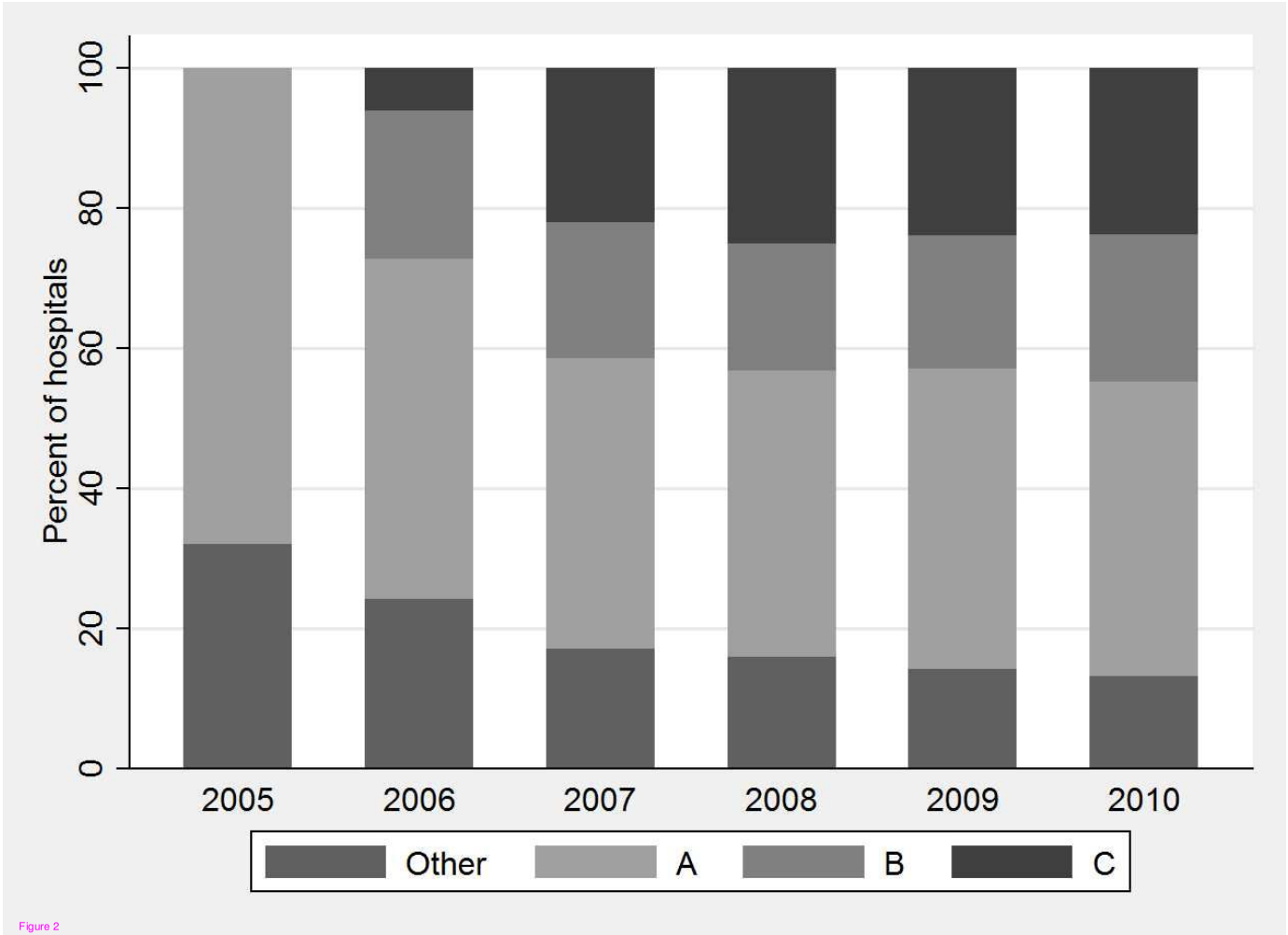
* p>0.05

Figure 1


Percent of hospitals
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Other
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B
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Figure 2

III

Appendices

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Dato: 12.10.2009
Deres ref.:
Vår ref.: 2009/1346b, 2009/1347b

2009/1346b Surveillance of surgical site infections in cesarean section
2009/1347b En validering av data registrert i Norsk overvåkningssystem for infeksjoner i sykehus mot data i Norsk pasientregister

Forskningsansvarlig: Nasjonalt Folkehelseinstituttet
Prosjektleder: Professor/forskningsveileder Finn Egil Skjeldestad

REK viser til søknad om godkjenning av forskningsprosjektene *Surveillance of surgical site infections in cesarean section* og *En validering av data registrert i Norsk overvåkningssystem for* som ble sendt inn til fristen 07.09.09. Komiteen har vurdert søknadene i sitt møte 29. september 2009 med hjemmel i helseforskningsloven § 10, jf. forskningsetikkloven § 4. Komiteen oppfatter at disse prosjektene hører sammen og har følgelig funnet det hensiktsmessig å behandle dem under ett.

Saksfremstilling
Surveillance of surgical site infections in cesarean section oppfattes som et delprosjekt i *En validering av data registrert i Norsk overvåkningssystem for infeksjoner i sykehus mot data i Norsk pasientregister.*

I hovedstudien skal det brukes data fra NPR og NOIS for å evaluere insidens og risikofaktorer for postoperative sykehusinfeksjoner. Utvalget av pasientgrupper er bestemt av Helsedirektoratet for utvalget i NOIS. Prosjektet omfatter en nasjonal populasjon. I alt vil studien omfatte 30-34000 forskningsdeltakere på årsbasis. Prosjektet vil foreta en kobling mellom registrene NOIS og NPR.

I studien *Surveillance of surgical site infections in cesarean section* skal data fra NOIS og MBR kobles for å lage en datakilde for studier om årsaker til og effekt av ulike forebyggende tiltak i tilslutning til keisersnitt infeksjoner. Alle kvinner som får utført keisersnitt i Norge i årene 2005-2020 er potensielle deltakere for oppfølgning med hensyn til postoperativ infeksjon de første 30 dager etter operasjon. Kvinner som ikke utvikler infeksjon utgjør kontrollgruppe.

Forskningsetisk vurdering
Prosjektene beskrives i søknadene som datakvalitetssikringstiltak og studier som bedre utnytter eksisterende data i kompletterende helseregistre. Prosjektene anses ikke som helsefaglige forskningsprosjekter som har til hensikt å skaffe ny kunnskap om helse og sykdom. Prosjektene anses derfor ikke å være fremleggelsespliktige for REK jf. helseforskningsloven § 10, jf. forskningsetikkloven § 4 annet ledd. Etter at den nye helseforskningsloven trådte i kraft, er imidlertid REK delegert fullmakt til å gi dispensasjon fra taushetsplikten også for andre forskningsprosjekter enn de rent helsefaglige. Søknaden om dispensasjon fra taushetsplikten blir derfor behandlet.

Dette er kobling mellom helseregistre som i forskrift ikke har forskriftsmessig rett til sammenstilling av data. Det søkes om godkjenning for ikke å innhente samtykke og dispensasjon fra taushetsplikt.

Vedtak
Det gis dispensasjon fra taushetsplikten med hjemmel i helsepersonelloven § 29 og forvaltningslovens § 13d. Dispensasjonen fra taushetsplikten er gitt på bakgrunn av at prosjektene oppfattes å være av vesentlig interesse for samfunnet og hensynet til deltakernes velferd og integritet er ivaretatt. Alle opplysningene som fremkommer både i registre og ved koblingen av registre skal oppbevares strengt konfidensielt. Dispensasjonen fra taushetsplikten gjelder kun for en gjennomføring av prosjektet i samsvar med prosjektbeskrivelse og informasjon i søknadsskjemaene.

Dispensasjonen fra taushetsplikten gjelder:
Hanne-Merete Eriksen, Hilde Magnussen Løwer, Thale Berg, Oliver Kacelnik og Finn Egil Skjeldestad. Dispensasjonen gjelder kun for de navngitte personene i dette brevet fra REK. Det er prosjektleders ansvar å påse at taushetsplikten overholdes i henhold til helseforskningsloven § 7 og forvaltningsloven §13.

Det gjøres oppmerksom på at det ikke er gitt dispensasjon fra taushetsplikt til andre enn angitt eller til overføring av opplysninger til land utenfor EØS-området.

Dispensasjonen fra taushetsplikten gjelder for tidsrommet 1. oktober 2009 til prosjektslutt 31.12.2024. Alle data skal slettes når prosjektet avsluttes i 31.12.2024. Dette innebærer at det etter denne dato må alle opplysningener generert fra de forskjellige registerkoblingene være anonymisert på en slik måte at identifisering av enkeltpersoner ikke er mulig ved at koblingsnøkkel ("liste") er destruert.

Forskningsprosjektets data skal oppbevares forsvarlig, se Personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren
(URL:
http://www.helsedirektoratet.no/samspill/informasjonssikkerhet/norm_for_informasjonssikkerhet_i_helsesektoren_232354)

Tillatelsen gjelder til 31.12.2020. Prosjektet skal sende sluttmelding på eget skjema (se helseforskningsloven § 12) senest et halvt år etter prosjektslutt.

Komiteens avgjørelse var enstemmig.

Vennligst oppgi vårt saksnummer/referansenummer i korrespondansen.

Med vennlig hilsen

Stein Opjordsmoen Ilner (sign.)
Leder

Julianne Krohn-Hansen
Komitésekretær (sign)

Dokumentet er godkjent elektronisk

Kopi: Forskningsansvarlig Nasjonalt folkehelseinstitutt v/Preben Aavitsland
praa@fhi.no

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Ida Persson	22845513	10.04.2013	2009/1347 REK sør-øst B
			Deres dato:	**Deres referanse:**
			20.03.2013	

Vår referanse må oppgis ved alle henvendelser

Til Finn Egil Skjeldestad

2009/1347b En validering av data registrert i Norsk overvåkningssystem for infeksjoner i sykehus mot data i Norsk pasientregister

Forskningsansvarlig: Nasjonalt folkehelseinstitutt
Prosjektleder: Finn Egil Skjeldestad

Vi viser til søknad om prosjektendring datert 20.03.2013 for ovennevnte forskningsprosjekt. Søknaden er behandlet av leder for REK sør-øst på fullmakt, med hjemmel i helseforskningsloven § 11.

De omsøkte endringene er beskrevet i skjema for prosjektendringer og dreier seg om:
- endring av prosjektleder fra Finn Egil Skjeldestad til Hanne-Merete Eriksen.
- endring av forskningsansvarlig institusjons kontaktperson fra Preben Aavitsland til Karin Rønning.
- oppdateringer i liste over prosjektmedarbeidere, aktuelle prosjektmedarbeidere er Agnes Hadju, Finn Egil Skjeldestad, Pål Høvding, Håvard Dale og Torunn Aalbu.

Komiteens vurdering
Komiteen har ingen forskningsetiske innvendinger til prosjektet slik det nå foreligger.

Vedtak
Komiteen har vurdert endringsmeldingen og godkjenner prosjektet slik det nå foreligger med hjemmel i helseforskningsloven § 11.

Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i endringsmeldingen.

Dersom det skal gjøres vesentlige endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren».

Prosjektet skal sende sluttmelding på eget skjema, senest et halvt år etter prosjektslutt, jf. helseforskningsloven § 12.

Komiteens vedtak kan påklages til Den nasjonale forskningsetiske komité for medisin og helsefag, jf. Forvaltningslovens § 28 flg. Eventuell klage sendes til REK Sør-øst. Klagefristen er tre uker fra mottak av dette brevet.

Besøksadresse:
Gullhaugveien 1-3, 0484 Oslo

Telefon: 22845511
E-post: post@helseforskning.etikkom.no
Web: http://helseforskning.etikkom.no/

All post og e-post som inngår i saksbehandlingen, bes adressert til REK sør-øst og ikke til enkelte personer

Kindly address all mail and e-mails to the Regional Ethics Committee, REK sør-øst, not to individual staff

Vi ber om at alle henvendelser sendes inn med korrekt skjema via vår saksportal: http://helseforskning.etikkom.no. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: post@helseforskning.etikkom.no.

Med vennlig hilsen

Stein Opjordsmoen Ilner
professor dr. med.
leder REK sør-øst B

Ida Persson
Førstekonsulent

Kopi til: *pacra@fhi.no; folkehelseinstituttet@fhi.no*