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The design and application of surveillance systems in improving health outcomes and identifying risk factors for healthcare associated infections

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Appendices

The Published Works

Appendix 1.1.

Secondary publication 1: Cooke EM, Coello R, Sedgwick J, Ward V, Wilson J, *et al* (2000)

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LEADER

A national surveillance scheme for hospital-associated infections in England

From the team of the Nosocomial Infection National Surveillance Scheme:
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A. Pearson

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The Nosocomial Infection National Surveillance Scheme (NINSS) was established in 1996 by the Public Health Laboratory Service (PHLS) and the Department of Health (DH). The scheme is based upon the advice of the Hospital Infection Working Group of the DH and PHLS¹ which recommended that 'a voluntary national reporting system should be established, which will enable hospitals to compare their data against aggregated anonymized data from other hospitals. Investigation by the hospital of areas where it appeared to differ significantly from the norm would then be possible'. In addition, a previous project by the PHLS and the DH² demonstrated the feasibility of a centrally organized surveillance scheme in the UK which, together with the increasing interest in quality assurance and audit in the Health Service, suggested that hospitals would like to participate in such a scheme. The NINSS also took into account the experience of the National Nosocomial Infections Surveillance System in the USA.³ The scheme is now available to acute hospitals in both the National Health Service and private sector in England. Participation is voluntary and confidential.

Surveillance is targeted on specific infections, units or groups of patients and data collection is for one or more three-month surveillance periods. Where possible, selective methods are used to identify infections. This approach is particularly suitable for Infection Control Teams (ICTs) with limited resources. The scheme comprises a set of modules, for each of which a standard protocol has been developed. To date, three protocols have been

developed that focus on specific infections – hospital-acquired bacteraemia, surgical site infection and catheter-associated urinary tract infection (UTI). Those for hospital-acquired bacteraemia and surgical site infections are fully implemented, and the pilot for catheter-associated UTI has just been completed.

The modules were chosen with the help of ICTs and the protocols developed with the advice of a multidisciplinary group of colleagues with expertise in surveillance or practical day-to-day experience of hospital infection. For each module, a pilot study was carried out to test the methodology, evaluate the feasibility of the protocol, and to determine the time required for data collection, handling and analysis. Hospitals choose which modules they wish to follow. Regular workshops and annual meetings are held for participants. So far, 139 hospitals have participated in one or more of the three modules. Further modules may include units, such as intensive care, or particular groups of patients, such as burns patients.

At the outset, it was realized that computer data entry might not be possible for all hospitals, so a paper-based system for data collection was chosen as the initial method. Forms for data collection were based upon an Optical Mark Recognition (OMR) system. Completed forms are returned to NINSS, where they are scanned through the OMR system and the data downloaded to an appropriate software package for analysis and report production. It is recognized that advances in information technology must be exploited to increase the efficiency and effectiveness of data collection, processing and reporting.

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Data collection varies between modules. For some modules, data from infected and uninfected patients are collected by the ICTs and this has proved to be very efficient. For other modules, however, the ICTs only collect data from infected patients (numerator data); denominator data, i.e., demographic and discharge data from infected and uninfected patients, are provided by the hospitals' Information Departments using the Patient Administration System (PAS), or similar systems. This last approach has created some difficulties because of the variation in the systems used.

Within eight weeks of sending their data to NINSS, hospitals receive a quarterly report with their own results and aggregated data from hospitals participating in the same surveillance module. For the surgical site infection module, data are cumulative over time. For the bacteraemia module an additional annual report is provided. This allows hospitals to compare their infection rates for different surveillance periods, and with other participants, and to assess these rates against their infection control practices. Comparisons must be made with care, however, until more data become available and risk factor analysis is better developed.^{4,5} For the bacteraemia module, specialty-specific bacteraemia rates are reported. As more data are accumulated and more hospitals participate, these rates will be stratified by hospital type and possibly for major risk factors. Collection of central intravascular catheter data from one or more specialties is optional. Catheter-associated bacteraemia rates and catheter utilization, both by specialty, are only reported if more than three hospitals provide this information. For the surgical site infection module, infection rates are reported by categories of surgical procedures and stratified by the American National Nosocomial Infections Surveillance System risk index.⁶

The surveillance results are sent to one individual nominated by the hospital, usually the Infection Control Doctor or Nurse, and it is expected that this person will disseminate the results as appropriate within the hospital. As the success of surveillance depends on support and assistance from many areas in the hospital, information about the scheme, but not the results, is also sent to the Chief Executive, the Medical Director and the Director of Nursing.

Data security, and hospital and patient confidentiality are important for participating hospitals. Data security conforms to the PHLs Information Technology Security Policy.⁷ Results for individual

hospitals are known only to those hospitals and to the staff within the Nosocomial Infection Surveillance Unit who are involved in their production. The results are not disseminated within the PHLs or elsewhere. If it is desirable to link NINSS data with that of other surveillance schemes or with laboratory results, for example antibiotic resistance data, permission will be sought from the participating hospitals. In the unusual event that a hospital has an outstanding infection problem, however, it may be necessary to seek the advice of the Regional Director of Public Health. Such an event is likely to be extremely rare.

The PHLs Ethics Committee considers that a surveillance scheme of this type does not require formal Ethics Committee approval, as the surveillance modules do not involve collection of new data. This aspect has been queried by some hospitals, and so the ethical considerations have been detailed in a paper which is available to participating hospitals.

The enthusiastic response to the scheme, together with the recent report from the National Audit Office,⁸ indicate that there is considerable interest in a national surveillance scheme. Its value will increase as more data are accumulated and as more modules are added. The plan is to develop further unit-specific surveillance modules, such as intensive care, and to introduce hospital-based data entry, analysis and reporting. When, or indeed whether, the scheme should be extended to non-acute hospitals and other healthcare settings is for discussion, as is the relationship of the data collected in the scheme to that in other surveillance schemes, notably antibiotic resistance and bacteraemia data.

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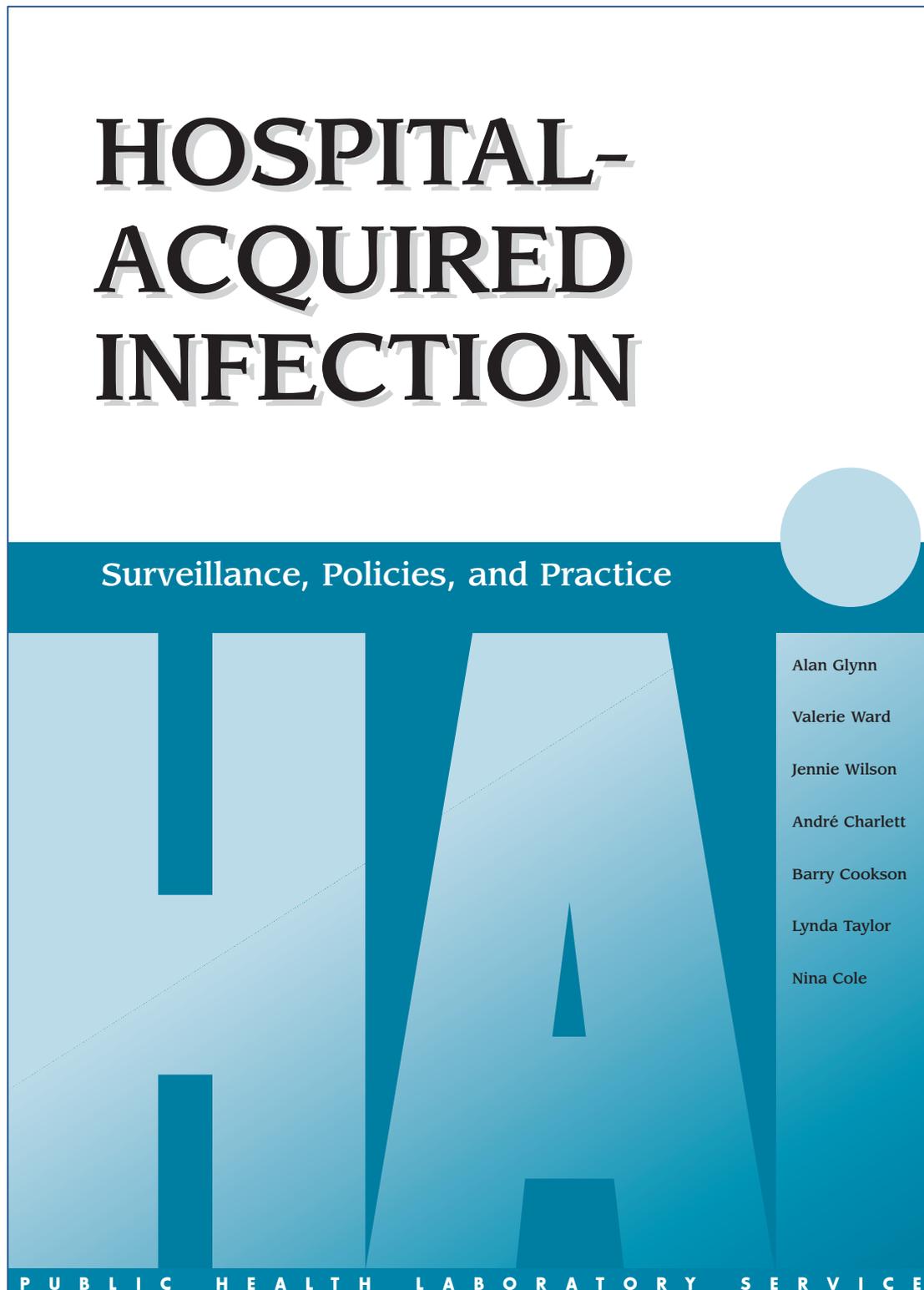
Dr M. O'Mahony, Communicable Diseases Surveillance Centre, for their advice; and Dr R. Gaynes and his colleagues, Centers for Diseases Control, USA, for their initial advice on establishing the project. We thank the administrative staff in the Nosocomial Infection Surveillance Unit for their help and hard work.

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Appendix 2.1.

Secondary publication 2: Glynn A, Ward V, Wilson J, *et al* (1997)



HOSPITAL- ACQUIRED INFECTION

Surveillance Policies and Practice

A report of a study of the control of hospital-acquired infection in
nineteen hospitals in England and Wales

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Hospital-Acquired Infection

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SUMMARY

The main components of the project were:

- The surveillance of certain hospital-acquired infections in order to assess the method of surveillance used, the value of control of infection activities, and the role of some risk factors
- The analysis of those aspects of hospital policies relating to the control of infection
- The comparison of policies with observed practice.

SURVEILLANCE

The control of hospital-acquired infections (HAIs) was audited in 19 hospitals over a period of one year. Specially appointed audit project nurses (APNs) in each hospital collected data on the incidence of HAIs of the urinary tract, respiratory tract, and the bloodstream in adult patients receiving treatment in the specialties of medicine, surgery, gynaecology, and orthopaedics. Almost all infection control teams monitor micro-organisms ('alert organisms') likely to cause outbreaks, but are less concerned with these, mostly endemic infections, apart from special surveys. Where possible, demographic data and diagnoses were also obtained from patient administration systems; if not, the APNs extracted the information from the notes. So that diagnoses could be checked, information was collected on the relevant clinical and laboratory findings in supposedly infected patients. Data were collected on casemix and some of the known risk factors for HAI, such as device use, length of stay, and severity of underlying disease. All data were collated and analysed by the audit project team at the Public Health Laboratory Service (PHLS) Central Public Health Laboratory and interim reports sent back to the hospitals.

In all, 2148 HAIs were recorded in 80 752 patient-episodes (72 434 patients), i.e. a rate of 2.7 per 100 patient-episodes. Where an invasive device was used, the rate was 7.2 HAIs per 100 patient-episodes. Where no device was used the rate was 1 HAI per 100 patient-episodes. These figures hide an intricate picture of how the incidence of each of the infections studied is affected by risk factors and casemix, the complexity of their interactions, and how all three vary from specialty to specialty, and from hospital to hospital. Although the variations may be large, they can be reduced by correcting crude infection rates for the main risk factors, most of which can be readily quantified, although quantification of device use remains difficult. Such corrected rates give a better idea of how effectively infection is being controlled in a unit, provided, of course, that the data are based on reliable surveillance.

The method of surveillance was labour intensive. Its use would only be feasible if surveillance were limited to well defined targets for limited periods, and if it were easier to retrieve data from medical and nursing records and computerised patient administration systems.

Although intensive care units (ICU) had a higher infection rate (20 per 100 patient-episodes) than general wards, data collection in ICU was easier because of their higher standard of record-keeping. As the audit of ICU was short, the results give an indication only of their infection problems, and a fuller study would be useful.

POLICIES AND PRACTICE IN THE CONTROL OF INFECTION

An analysis of those components of hospital policies dealing with the control of infection showed there were a number of gaps. For example, there were too few references to hand washing. Few of the components considered in individual policies were present in all. Some of the procedures described in the policies were observed in practice. Recommended methods were more likely to be followed if they were in a hospital's policy (54%) than if they were not (35%). Some variations from policy could be justified by advances in clinical practice, but about half the staff carrying out a procedure did not know that a relevant policy existed.

Antibiotics

Policies dealt with antibiotic prescribing, though they varied in the stress laid on individual aspects of it. Cost control was discussed as well as clinical effectiveness. Many policies gave useful information on prophylaxis. As with general policies, discrepancies between antibiotic policy and prescribing practice were frequent, though some, but not all, could be justified by advances in therapy.

The audit led to an increased interest among the hospitals in infection control policy and to expressions of intent to review policy more often.

THE PROBLEMS ENCOUNTERED

The most difficult problems were related to data collection.

- Collection of data was based on the laboratory based ward liaison surveillance method. Although laboratory data on possibly infected patients was usually easy to obtain, in a small number of laboratories results were only available after significant delay.
- Definitions of hospital-acquired infection are not entirely satisfactory and it was difficult to ensure that they were interpreted consistently.
- Laboratory results should have been used, with the help of ward nurses, to identify infected patients. However, recent changes in nursing organisation had made it

difficult to find one nurse with knowledge of all patients in a ward. The need to find several nurses meant repeated and time-consuming visits by the project nurse. These difficulties increased the need to rely on medical and nursing notes, which were too frequently inadequate in the recording of both the presence of an infection and the duration of exposure to an invasive device.

- Basic demographic, admission, and discharge data were usually obtained from the patient administration system. However, clinically important data, such as principal and other diagnoses present on admission and discharge, were more difficult to get quickly. All these items form part of the minimum data set which all hospitals are required to collect, but unfortunately do so using a

variety of software programs. Few of the 19 hospitals could provide the data asked for without excessive help from the project's data manager. In 8% of the records used, the primary diagnosis was missing and in 11% it was invalidly coded. The 19 hospitals varied widely in the quality of their coding, but 13 successfully coded over 80% of cases.

- The delay in obtaining data made it difficult to provide adequate and timely feedback, and left too little time for the hospitals to examine their records and review their infection control activities.

Recommendations on how to improve surveillance by overcoming these and other problems are made.

Appendix 2.2.

Secondary publication 3: Wilson J. (2013a)



Surgical site infection: the principles and practice of surveillance. Part 1: Key concepts in the methodology of SSI surveillance

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Key words: Surgical site infection, surveillance, post-discharge, case-finding, validation

Abstract

Surgical site infections (SSI) account for a major proportion of healthcare associated infections (HCAI) yet many hospitals capture little data on the risk of SSI in patients undergoing surgery and therefore have little assurance about the quality of infection prevention in their operating departments. This paper is the first part of a two part series that will examine the principles and practice of surveillance of SSI. Part 2 will examine the analysis of SSI data and the use of the results to change practice. This paper reviews the principles that underpin SSI surveillance methodology, key concepts that affect the accuracy of data capture systems and strategies for addressing them, including risk factors and active case finding systems to ensure detection of SSI, including those that develop after discharge from hospital.

Introduction

The risk of a patient developing an infection of the tissues involved in an operative procedure (a surgical site infection (SSI)) depends on a combination of factors including: the number of micro-organisms introduced into the operative site, the number that remain when the wound is closed, the ability of micro-organisms to multiply and invade tissues, and the efficacy of the host's immune defences against them (National Collaborating Centre for Women's and Children's Health, 2008). Prevalence surveys indicate that SSI is the third most common healthcare associated infection (HCAI), accounting for approximately 15% of all HCAI (Smyth et al, 2006; Health Protection Agency, 2012). However such surveys underestimate the true risk of SSI because many infections do not become apparent while the patient is still in hospital, and only patients undergoing surgery can acquire an SSI; in this group the prevalence is estimated to be 5% (Smyth et al, 2006). Surgical site infections are associated with considerable morbidity and mortality, estimated to double the length of postoperative stay, and in the most severe infections significantly

increase the risk of death (Astagneau et al, 2001; Coello et al, 2005). In addition, as demonstrated in a case control study of patients undergoing proximal femoral fracture repair, when repeat admissions to hospital, re-operations and other treatments are taken into account, severe SSI can quadruple the costs of care and decrease the quality of life of affected patients (Whitehouse et al, 2002). Similar effects on costs and mortality have been identified in cardiac surgery (Hollenbeak et al, 2000).

Pathogens that cause SSI may derive from the patient's own microbial flora on the skin and in the body, or from the skin or mucous membranes of operating personnel, or from the operating room environment (including air), and the instruments and tools used during the procedure. Occasionally, micro-organisms from a distant infection in the body can establish an SSI by attaching to a prosthesis or other implant left in the operative site (David and Vrahas, 2000).

Practices to prevent SSI are therefore aimed at minimising the number of micro-organisms introduced into the operative site, for example removing micro-organisms that normally colonise the skin; preventing the multiplication of micro-organisms at the operative site using prophylactic antibiotics; enhancing the patients' defences against infection, for example by minimising tissue damage and maintaining normal body temperature during the procedure; and preventing access of micro-organisms into the incision postoperatively by use of a wound dressing (Mangram et al, 1999; National Collaborating Centre for Women's and Children's Health, 2008). Although guidance exists to endorse these principles, adherence to best practice is more difficult to assure and in the absence of data on patient outcomes, the connection between theatre practice and subsequent surgical site infections can be overlooked.

Evidence for the potential impact of surveillance of SSI was first published by Cruse and Foord (1973, 1980), who analysed the impact of 10 years of surveillance on the epidemiology of SSI, demonstrated key factors that influenced the rate of SSI and significant reductions associated with systematic monitoring and feedback of rates to

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surgeons. In 1980, the Centers for Disease Control and Prevention (CDC) initiated a large, controlled, multicentre study to determine the magnitude of the problem of HCAI in hospitals and the extent to which the surveillance and control programme approach was effective in reducing the risk of infection. The study drew on a sampling frame of more than 6,000 hospitals with programmes of varying levels of intensity. A stratified random sample of 338 of these hospitals was used to estimate the impact of surveillance and control activities on rates of HCAI by reviewing case records of a random sample of 500 patients in 1970 and 1976 (Haley et al, 1980). This study demonstrated that hospitals with the most effective programmes reduced their rate of hospital-acquired infection of 32% during this period, and parallel analyses of surgical site infection, indicated that rates of SSI were reduced by up to 38% where surveillance with feedback to surgeons was in place and a healthcare epidemiologist was involved in reporting (Haley et al, 1985). The SENIC study had a major impact on HCAI surveillance systems. It not only endorsed the value of the investment required to establish robust data capture and reporting, but also provided the basis for developing standardised case definitions and approaches to risk adjustment (Culver et al, 1991).

Rates of SSI derived from a robust surveillance system can be used to assess the quality of infection control practice related to surgical procedures, increase awareness of the risk of SSI and encourage surgical teams to take appropriate action if rates increase. Indeed, as the SENIC study concluded, "Infection control problems and the need for prevention efforts were not apparent to physicians, nurses or administrators until they were given quantitative measures of the problem derived from surveillance data" (Haley et al, 1985). In addition, although there is a clear expectation that patients will be provided with reliable information about risks of SSI, in reality this is rarely possible in the absence of robust surveillance systems (National Collaborating Centre for Women's and Children's Health, 2008). Enabling comparison with other similar organisations can enhance the impact of surveillance through identifying outliers and driving reduction strategies. The potent effect of benchmarking has been demonstrated by significant reductions in rates of SSI in hospitals that participate in national surveillance schemes (Geubbels et al, 2004; Gastmeier et al, 2005; Rioux et al, 2007). However, while external benchmarks can be a powerful driver for change they require considerable effort and co-ordination to develop and must use principles that assure, as far as possible, the validity of comparisons, including standardised case definitions and case finding methods, analysis that accounts for variation in case mix, precision of estimated rates and period of postoperative follow-up and some assurance about the quality of data through validation systems (Cooke et al, 2000; Gaynes et al, 2001; Wilson et al, 2002).

Definition of SSI

The ability to consistently identify SSI in operative wounds is essential for reliable surveillance systems, because changes in rates of SSI observed must reflect true changes in occurrence of infection rather than the accuracy of case finding. Because skin is normally colonised by a range of micro-organisms that could cause infection, defining an SSI cannot rely only on the micro-organisms present in a wound culture sent to the laboratory but should be determined by evidence of clinical signs and symptoms of infection. A number of approaches to defining SSI have been proposed, ranging from simply the presence of pus in the wound (Cruise and Foord, 1970) to more complex scoring criteria such as ASEPSIS (Wilson et al, 1986) most of which include subjective elements that could be prone to error. Although scoring systems such as ASEPSIS provide a more objective method, they may not be easy to apply in a routine surveillance system and if comparability with other published data or institutions is a key aim of the surveillance, rates based on different definitions will not be compar-

able (Wilson and Elgohari, 2008). Most SSI surveillance systems use definitions based on those described by the Centers for Disease Control and Prevention, which recognise that SSI can affect the following parts of the operative site (Horan et al, 1992, 2008):

- *Superficial incisional*: involves only the skin or subcutaneous tissue of the incision
- *Deep incisional*: involves the deep tissues (i.e. fascia and muscle layers)
- *Organ/space infection*: involves any part of the anatomy (i.e. organ and/or space), other than the incision, opened or manipulated during the surgical procedure.

To meet the definition SSI must align to a specific set of criteria and superficial incisional SSI must occur within 30 days of the operation. Deep incisional and organ/space SSI must occur within 30 days of the operation provided non-human material (implant) is not left permanently in the operative site, in which case an SSI can occur up to one year from the operation (Horan et al, 1992; Horan and Emori, 1997). Objective criteria are more difficult to apply to superficial SSI. Microbiological cultures from the wound may reflect colonisation rather than infection and whilst the CDC criteria refer to 'aseptically obtained tissue or fluid' the detailed provenance of specimens is often not documented. The presence of clinical signs (such as inflammation) may be variously interpreted as SSI by the attending physician and some surveillance systems have chosen to address this subjectivity by requiring specific evidence of clinical signs rather than only a clinician's diagnosis (Health Protection Agency, 2011a). The presence of pus is less prone to subjectivity, although reliance on this as a sole indicator of infection would reduce the sensitivity of case findings. Evidence from the analysis of criteria used to define 436 superficial SSI reported to a national SSI surveillance service in England between January 2003 and December 2007 suggests that pus is used to define over 40% of superficial SSI, with a combination of clinical signs and clinician's diagnosis or opening of wound a further 38% (Figure 1). (Wilson and Elgohari, 2008).

SSI surveillance methods

Most national SSI surveillance systems use methods based on those developed in the 1990s for the National Nosocomial Infection Surveillance System (NNIS) in the USA and which were built on the findings of SENIC (Emori et al, 1991). Surveillance is structured to monitor a set of operations and determine the risk of SSI, usually calculated as the cumulative incidence or percentage of operations that result in SSI. To calculate this metric, each patient who has a relevant operation needs to be followed-up prospectively to determine if they develop an SSI. However, the methods of case finding have a major effect on the probability of detecting SSI and therefore the accuracy of the metric. Prospective, active surveillance will find more cases of infection than retrospective or passive methods, i.e. those where infections are reported by staff who do not have designated responsibility for the surveillance programme (Perl, 1997). In addition, Glenister et al (1992) showed that even active methods of surveillance have different sensitivities of case finding depending on the reliability of the data sources queried. Surveillance based on the telephone follow-up of laboratory reports identified only 36% of HCAI compared to the 76% detected by a combination of follow-up of laboratory results, liaison with ward staff and review of case notes to identify.

National surveillance systems must prescribe methods designed to minimise the risk of selection and measurement bias in order to support their primary aim of permitting inter and intra-hospital comparisons. In the case of SSI Surveillance Service in England, these principles were guided by a defined method of identifying patients

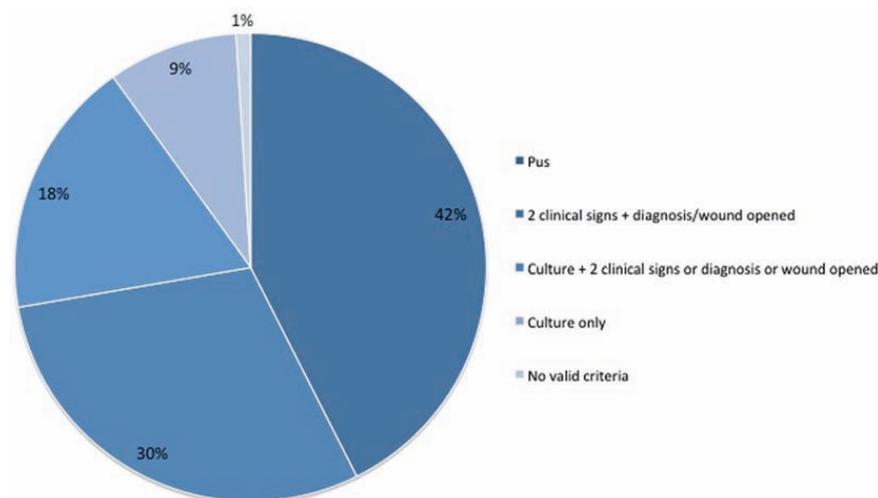


Figure 1. Criteria used to define superficial SSI in data submitted to Surgical Site Infection Surveillance Service in England between January 2003 and December 2007. Source: Wilson & Elgohari 2008

Table 1. Cumulative incidence and time to surgical site infection, NHS hospitals in England, April 2006 – March 2011

	No. operations	Median length of hospital stay	Rate of surgical site infection (%) Inpatient and readmission	Time to infection (days)	
				Median	Interquartile range
Abdominal hysterectomy	5,388	4	1.5	8	5–12
Coronary artery bypass graft	26,468	7	4.4	11	7–16
Hip prosthesis	150,149	5	0.8	13	7–20
Repair neck of femur	39,830	13	1.6	14	10–24.5
Large bowel	13,534	8	10.1	8	5–12

Source: Surgical Site Infection Surveillance Service, Health Protection Agency, 2011

eligible for surveillance (the denominator), the application of standard, and as far as possible objective, criteria to determine cases of infection (the numerator) with prescribed methods of case finding based on previous research evidence (Glenister et al, 1992; HPA, 2011).

In the USA, responsibility for surveillance generally lies with the infection control team, often under the auspices of the quality assurance structures within the hospital. Indeed, the finding of SENIC that one infection control nurse (ICN) for every 250 beds was required to achieve reductions in HCAI was on the basis that ICNs spent a considerable proportion of their time on surveillance activities (Haley et al, 1985). While the day-to-day data capture may not need to be the responsibility of a qualified ICN, accurate rates can only be measured if active methods are employed and this requires the use of trained personnel, designated to employ a variety of methods to follow-up all patients included in the denominator. Such commitment is unlikely to be possible for clinical staff with other responsibilities, and designating responsibility for surveillance to them is likely to result in a passive surveillance system with accompanying inaccurate representation of rate of SSI. SSI surveillance undoubtedly requires considerable organisation and commitment of resources to ensure

that it can be conducted systematically and consistently over sufficient periods to provide accurate estimates of SSI rate. However, evidence from Wilson et al (2007) suggests that a comprehensive surveillance programme, which collected post discharge surveillance (PDS) data from 80% of patients, cost less than £100,000 per annum, was associated with significant reductions in rates of SSI, and costs were outweighed by the savings made from reductions in rates of SSI after 2 years (Wilson et al, 2007). Similarly, Stockley et al (2001), who followed up 667 patients in five categories of surgery estimated the time for surveillance as 30 minutes per patients with an additional 10 minutes for telephoning patients post-discharge.

Post-discharge surveillance: For many categories of surgery, SSI do not become apparent until after discharge. Many studies have found that up to 70% of SSI were detected post-discharge, depending on the type of surgery and median length of postoperative stay (Stockley et al, 2001; Reilly et al, 2006). Table 1 shows the median time to detection of SSI for a range of categories. Apart from large bowel surgery, the median time to SSI as detected during the admission or on readmission to hospital is several days after the median length of stay. This presents particular problems as SSI are much more difficult to

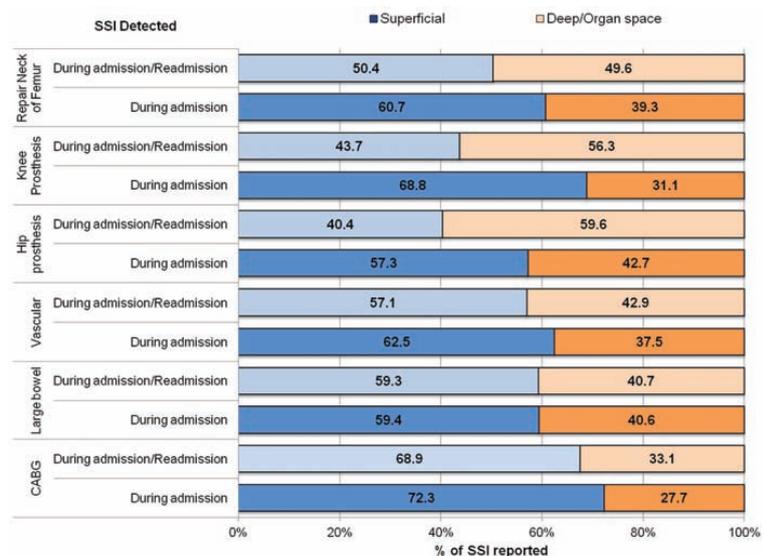


Figure 2. Variation in distribution of type of surgical site infection (superficial and deep/organ space) by detection during admission only and detection during admission and on readmission. Source: HPA, 2011b

detect when the patient has left hospital. Active surveillance after discharge is difficult to implement consistently, and variation in the intensity of case finding is likely to introduce significant variation in reported rates (Reilly et al., 2006). A number of different approaches to PDS have been developed although the efficacy of detection methods varies (Petherick et al., 2006). Common approaches include review of patients at outpatient visits, surgeon questionnaire, electronic search of patient records, patient questionnaires, report cards or telephone interviews. The more passive approaches tend to suffer from poor response rates. Low sensitivity and specificity of case finding by healthcare professionals not trained in application of the case definitions is also a key problem (Manian et al., 1997; Whitby et al., 2002; Sands et al., 2003; Taylor et al., 2003; Mannien et al., 2006; McNeish et al., 2007). Several studies have based PDS on patient reporting. These studies suggest response rates of approximately 80% are achievable, together with a high negative predictive value, with over 90% of patients able to reliably indicate that they did not have an SSI. The positive predictive value of patient reporting of SSI appears to be lower (approximately 30–50%) and therefore possible signs of SSI reported by a patient should be confirmed either by trained surveillance staff or by contact with the GP or other healthcare personnel who have seen the wound (Whitby et al., 2002; Wilson et al., 2006).

Another approach to PDS is to systematically capture SSI in patients readmitted with SSI. This has the advantage of detecting most severe, deep and organ/space infections but will underestimate the occurrence of superficial SSI where the patient is likely to be treated in the community (HPA, 2011b). Figure 2 illustrates the increase in proportion of deep and organ/space SSI reported in the English surveillance system once readmission surveillance was made mandatory. In the orthopaedic categories, which have a short length of stay and prolonged risk of developing, readmission surveillance markedly increases the proportion of deep and organ/space SSI detected. Whatever method used for PDS, caution should be used when comparing rates either over time or between institutions, as both the length of postoperative stay and the proportion of patients followed up post-discharge is likely to have a significant impact on the estimated rate of SSI.

Risk factors for SSI

The case-mix of patients undergoing surgery may have a significant effect on the risk of SSI, and methods of adjusting rates of infection for intrinsic variation in the population at risk have been developed to support valid comparisons between centres or within centres over time. Most SSI surveillance systems use a risk stratification system first developed from analysis of the SENIC data. Culver et al (1991) developed a risk index based on the presence of three factors at the time of the operation and demonstrated a significant association between increasing score and risk of SSI. This risk index became the standard method of risk stratification for comparing rates of SSI and was adopted by the majority of national surveillance systems. This risk index comprises three factors: wound classification of contaminated or dirty, a preoperative American Society of Anesthesiologists' (ASA) classification of physical status score of 3 or more and a duration longer than the T time for the category of procedure. A wound classification developed by the National Research Council in the USA is used to distinguish the likelihood and degree of wound contamination at the time of operation, taking account of both microbial contamination associated with normal flora present at the operative site, evidence of infection or inflammation at the site at the time of surgery or an intra-operative event that results in contamination of the operative site. The preoperative ASA score provides an assessment of the patient's preoperative physical condition, and whilst it is vulnerable to inter-rater variation, it provides a crude but easily captured measure to distinguish patients with systemic underlying illness, and despite its limitations it does seem to be reliably associated with risk of SSI, especially if comparing groups with scores below 3 with those of 3 and above between which adjusted odds ratios for risk of SSI of between 1.5 and 3 have been reported (Ridgeway et al., 2005; Kaye et al., 2005; Neumayer et al., 2007).

The T time represents the duration of surgery at the 75th percentile of the distribution of operation times within a given category of surgical procedures. This time is then rounded up to the nearest hour to indicate procedures of prolonged duration which may be considered to represent increased risk of SSI due to the complexity of the procedure, although this may also reflect the experience of the surgeon. While the standard T times were derived from data captured for the

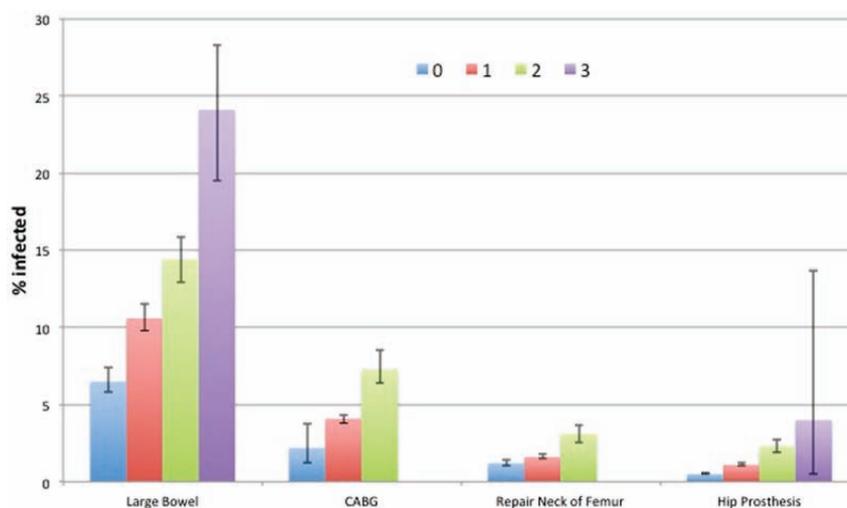


Figure 3. Trends in rates of surgical site infection by National Nosocomial Infection Surveillance System risk index group with 95% confidence limits by category of procedures. Source: HPA, 2011b

SENIC study (Culver et al, 1991), they have been shown to be sufficiently robust to apply to most categories of surgical procedures undertaken in the UK now. Procedures with durations longer than the T times are significantly associated with increased risk of SSI (Russo and Spelman, 2002; Ridgeway et al, 2005; Leong et al, 2006). Each of these three risk factors contributes one point to the risk index, and each operation is allocated a score of between 0 (none of the risk factors present) to 3 (all of the risk factors present). If captured on all patients at risk of SSI it can be used to determine rates of SSI for specific risk groups and the effect that variation in distribution of risk groups has on the rate of SSI and observed differences between centres. Although the risk index represents a relatively simple approach to adjustment, it does appear to discriminate differences in risk of SSI (Figure 3), and although it does not explain all variation in risk, it is a better indicator of risk than wound classification (Culver et al, 1991; Freidman et al, 2007). More complex systems of risk adjustment have been recommended for some types of surgery (Rosso and Spelman, 2002; Neumayer et al, 2007), however, any form of risk index stratification is dependent on data being available for all three variables and practical problems emerge when incomplete data is captured as part of a surveillance programme. These issues will be covered in more detail in Part 2.

There is evidence that other factors increase the risk of SSI. In particular the risk significantly increases with age, obesity, diabetes, peripheral vascular disease and malnutrition (Kaye et al, 2005; National Collaborating Centre for Women's and Children's Health, 2008; Neumayer et al, 2007; HPA, 2011a). However, as most of these factors are captured in an ASA score of 3 or more there may be little additional benefit in capturing detailed data on each one. Since the standard approach to SSI surveillance requires detailed risk factor data to be collected on each patient included in the denominator in addition to prospective methods of case finding, it is particularly resource intensive. One way to reduce the time taken to undertake SSI surveillance has been proposed by the European Centre for Disease Control (ECDC) in its new protocol for SSI surveillance. This provides a 'light' option where risk factor data are not captured and rates are calculated using an aggregate denominator for the hospital or surgical unit (ECDC, 2012). An aggregate denominator determining eligible procedures undertaken during a defined period can be obtained from the hospital patient administration system, and surveillance effort can therefore focus on

identifying patients who develop an SSI that meets the case definitions. This approach may be very valuable in providing ongoing feedback on changes in rates of SSI that could be used to trigger more detailed investigations where results indicate this may be necessary. However, risk adjusted rates may be more appropriate when surveillance is initiated to address concerns of surgical teams of the impact of risk factors on their rates of SSI.

Validation of surveillance data

Reliability of surveillance methods to accurately determine the denominator and numerator is desirable if surveillance data is to be trusted by surgical teams and effectively support decision making in relation to infection control practice. Some national surveillance systems have established mechanisms of validating data capture systems in participating hospitals (Huotari et al, 2007). For example, in the Netherlands hospitals are required to undergo a one-day onsite validation visit every three years when the data collection methods are assessed by a structured interview and case finding validated by a review of medical records (Mannien et al, 2007).

In conclusion, SSI accounts for a major proportion of HCAI and yet many hospitals have little data on the risk of SSI in patients undergoing surgery and therefore offer little assurance about the quality of infection control in their operating departments. The direct costs of SSI are significant and it is associated with considerable morbidity and mortality. There is considerable evidence that surveillance and feedback of rates of SSI contribute to reduction in rates particularly when combined with benchmarking. However, surveillance systems must incorporate robust systems for capturing accurate denominator data on patients undergoing surgery within specified categories and active case finding systems to ensure detection of SSI, including those that develop after discharge from hospital.

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Conflict of interests

None declared.

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Appendix 2.3.

Secondary publication 4: Wilson J. (2013b)



Surgical site infection: the principles and practice of surveillance: Part 2: analysing and interpreting data

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Key words: infection risks, rate, risk adjustment, risk index, statistics, surgical site infection, surveillance

Abstract

In Part 1 of this two-part series on surveillance of surgical site infection (SSI) the principles of surveillance methodology and the role of surveillance in reducing the risk of infection were discussed. This second part focuses on the analysis and interpretation SSI surveillance data, the challenges this presents and of some of the solutions. The risk of SSI is conventionally expressed as the percentage of operations that develop SSI. However, this metric is strongly dependant on the length of post-operative stay, since infections take several days to become apparent and are difficult to identify after discharge. Comparisons based on more severe infections detected in inpatients or those readmitted with SSI are more likely to provide reliable data for inter-hospital comparisons. The precision of the estimated rates and adjustment for intrinsic risk factors are important considerations, although ultimately mechanisms for discriminating significantly higher rates merely indicate a problem requiring further investigation rather than definitive evidence of poor practice.

Introduction

Surgical site infection (SSI) accounts for 15% of all healthcare-associated infections and is a major cause of morbidity, additional healthcare costs and extended lengths of hospital stay. Surveillance, in particular the feedback of rates to surgeons, is recognised as an effective strategy to reduce the risk of SSI (Haley et al, 1985; Cruse and Foord, 1980). However, whilst on the face of it the risk of SSI can be simply represented by the proportion of operations that result in infection, in order to make valid comparisons key issues to be considered are the effect of the methodology on the length of follow-up and completeness of case-finding, the precision of estimated rates and the effect of variation in intrinsic risk factors for infection.

Metrics for calculating rates of surgical site infection

The conventional method of measuring SSI is the cumulative incidence, which is usually expressed as the number of SSIs per 100

Box 1. Cumulative incidence

$$\frac{\text{No. SSI in a defined group of procedures}}{\text{No. operations performed}} \times 100 = \% \text{ SSI}$$

operations (see Box 1). This is more accurately described as the risk of SSI but is commonly referred to as a rate of SSI (Gaynes et al, 2001).

As with all measures of risk, cases in the numerator must be drawn from the population included in the denominator. Most national SSI surveillance systems use methods based on those developed in the 1990s for the National Nosocomial Infection Surveillance (NNIS) System in the USA which were built on the findings of the Study on the Efficacy of Nosocomial Infection Control (SENIC) (Emori et al, 1991). Surveillance is structured to calculate this metric by following up each patient who has a relevant operation prospectively to determine if they develop an SSI. Standard definitions for SSI include infections detected up to 30 days after the procedure if no non-human material is implanted into the surgical site, but up to 1 year for deep or incisional organ/space SSI if there is an implant (Horan et al, 2008). A major problem with this standard measure of SSI risk is that it assumes that all patients are surveyed for the whole period in which they could develop an SSI.

This presents a problem because the signs and symptoms of SSI can take many days to become apparent. Figure 1 illustrates the time to SSI derived from 3365 SSI detected in inpatients and post discharge, in a combined set of more than 100,000 procedures in six categories of surgical procedure from the European Hospitals in Europe Linked in Infection Control through Surveillance (HELICS) surveillance network. Whilst this suggests that most SSI are detected between day 6 and 10, the decline in rate after day 10 is also influenced by the decline in sensitivity of case-finding once the patient has been discharged (HELICS, 2006). As discussed in

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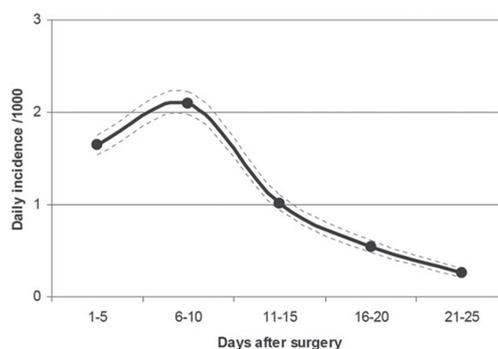


Figure 1. Incidence rate of surgical site infection by number of days since operation and 95% confidence curves (dotted lines) in 5-day analysis periods (smoothed)
Source: HELICS 2004

Table 1. Change in median length of post-operative hospital stay in England (2000 and 2006) and rates of SSI measured as cumulative incidence and incidence density

	Median length of stay		Cumulative incidence (%)		Incidence density ^a	
	2000	2006	2000	2006	2000	2006
Abdo. hysterectomy	5	4	2.11	1.59	3.61	3.47
CABG	7	7	3.87	3.94	4.4	4.03
Hip prosthesis	9	6	2.47	0.7	2.09	0.91
Knee prosthesis	9	6	1.75	0.39	1.54	0.54
Hip hemi		14	4.23	3.29	2.14	1.86
Large bowel	12	9	9.9	9.19	7.03	8.01
Vascular	9	8	7.95	3.36	6.84	3.01

^aNo. SSI per 1000 days of inpatient post-operative follow-up
Source: Health Protection Agency

Part 1, case-finding after discharge is difficult to conduct, and even if active surveillance is possible, for example through use of routine visits by a healthcare professional, the proportion of patients followed-up post discharge can vary widely between centres (Wilson et al, 2013). Rates of SSI based on cumulative incidence are therefore biased by the intensity of case-finding post discharge, especially where the average length of hospital stay is short, and robust comparisons between hospitals is problematic (Wilson et al, 2013). Whilst some authors assert that rates of SSI are not valid without intensive surveillance (Tanner et al, 2013), in practice the resource required to assure complete follow-up after discharge probably outweighs the benefit, particularly as the majority of additional cases will be superficial SSI (Lamagni et al, 2013). The important principle is that the methods of post-discharge surveillance applied are able to reliably detect a consistent proportion of SSI, and that the interpretation of rates takes into account the intensity of case-finding.

If rates are based only on SSI detected in hospital, the length of post-operative stay is a potential source of bias, since the proportion of SSI detected by active in-hospital surveillance will depend on how many days after the operation the patient stays in hospital. If the length of post-operative stay varies between hospitals or over time then changes in the cumulative incidence will not be comparable. This problem is

Box 2. Incidence density

$$\frac{\text{No. SSI}}{\text{No. inpatient days of follow-up}} \times 1000 = \text{No SSI/1000 patient days}$$

illustrated in Table 1 which shows changes in median length of stay in English hospitals participating in the Surgical Site Infection Surveillance Service (SSISS) between 2000 and 2006. Whilst in some categories there was no change in median length of stay, in hip and knee replacement surgery the median length of stay declined by a third during this time. Incidence density is an alternative metric, which can be used to account for variation in the proportion of SSI detected as a result of differences in the duration of inpatient surveillance (Box 2). The incidence density uses the number of days of post-operative follow-up as the denominator instead of number of procedures.

Although it accounts for some of the observation bias associated with different periods of follow-up, adjustment is only partial as the risk of SSI cannot be assumed to occur at a constant rate, and for

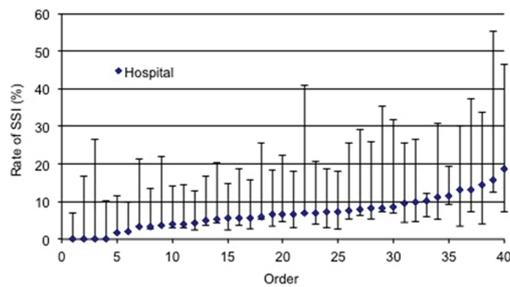


Figure 2. Crude rates of surgical site infection in vascular surgery from 40 hospitals participating in the Surgical Site Infection Surveillance Service, with corresponding 95% confidence limits
Source: Wilson, 2002

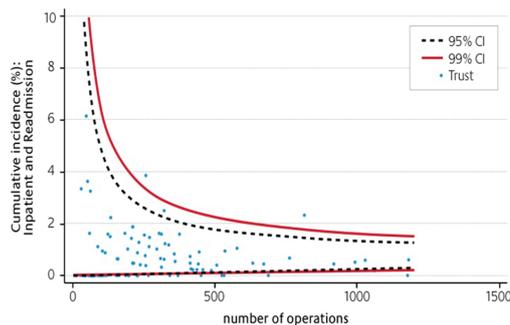


Figure 3. A funnel plot illustrating the cumulative incidence of SSI (detected in inpatients and readmissions) for hip prosthesis plotted against the number of operations by NHS Trust in England, 2009–10
Source: Health Protection Agency, 2010

post-operative stays of less than 4 days the proportion of SSIs detected will be very low (see Figure 1). Since the numerator and denominator must be linked, the incidence density must be based only on those SSI detected during the hospital stay. Whilst this has the disadvantage of underestimating the risk of SSI (as infections detected post discharge will be excluded) and is not as readily understood as the cumulative incidence, it better meets the requirement of a valid comparator where there is wide variation in length of post-operative stay (Wilson et al, 2007).

Another approach is to include surveillance for patients readmitted to hospital with SSI (Wilson, 2013). This tends to increase the detection of more severe SSI, as they are more likely to be consistently identified and to require readmission for treatment (Anderson et al, 2008). Comparisons of rates will therefore be based on follow-up beyond the inpatient stay, and whilst not capturing data on all post-discharge infections is relatively cost-efficient (Mu et al, 2011; National Quality Forum, 2008; Public Health England, 2013; Health Protection Scotland, 2013). To further minimise the effect of differences in length of post-operative stay on case ascertainment, the inclusion of only deep or organ/space SSI, which are more reliably detected by inpatient and readmission surveillance, has been recommended as a means of improving the reliability of comparisons (National Quality Forum, 2008; Mu et al, 2011). However, this approach has to be balanced against the loss in precision of estimates, as these more severe SSI only account for around 50% of all SSI (Coello et al, 2005)

Effect of precision of estimated rates of SSI

Rates of SSI are best calculated on a relatively large set of similar procedures because the rate of SSI calculated from a small set of

procedures is likely to be imprecise. Similarly, if the risk of SSI is very low, it may be necessary to capture data on many procedures in order to identify any infections. This means that data may need to be collected over several months and trends based on 3 or 6-month periods of surveillance (Wilson et al, 2008). If the rate is based on less than 50 operations it is likely to be very imprecise with wide confidence intervals (CI), and the true rate could lie anywhere between the two intervals. Similarly, when comparing rates of SSI between two centres the observed differences may not be real where the CI around the rates overlap. Figure 2 illustrates the rate of SSI in vascular surgery from 40 hospitals that participated in SSISS and submitted data on between 12 and 317 operations. Whilst the crude rates varied from 0–18%, in the majority the CI overlapped.

One method of addressing this problem is to present data in a funnel plot; these graphs allow for the imprecision of the observed rate by plotting the rate of SSI (either cumulative incidence or incidence density) against the number of operations or days of inpatient post-operative stay on which the rate is based (Wilson et al, 2008). Two-sided confidence limits equivalent to exact 95% CIs and 99% CIs around the pooled incidence rate can be used to distinguish unusually high and low rates that might merit further investigation whilst taking account of the imprecision of rates based on small numbers of operation (Figure 3) (Morton et al, 2011). These funnel plots, in common with statistical process control (SPC) charts, are based on the principle of distinguishing normal (or common cause) variation from special cause (due to events or untypical circumstances). Statistical process control methods can also be applied to rates of SSI within an organisation in order to monitor quality or demonstrate the

Box 3. Standardised infection ratio (SIR)

Total observed SSI (all risk groups)

Total expected SSI (all risk groups)

effect of a change in practice (Benneyan et al. 2003). Rather than making judgements about rates from data cumulated over time, SPC charts enable real-time detection of rates that reflect a statistically important change compared with what would normally be expected by chance for the particular centre. Since the rate of SSI in a week or month is small, the recommended type of SPC chart is a G chart (based on the geometric distribution) where the number of operations between SSI is plotted over time. The advantage of this approach is that the relevance of each SSI can be evaluated immediately rather than waiting until the end of each cumulation period (Benneyan et al. 2003). Other more complex forms of SPC such as cumulative expected – observed variable life – adjusted display (VLAD) charts have also been proposed that both address the problem of monitoring rare events and provide a mechanism of adjusting the rate for major risk factors (Morton et al. 2010).

Adjusting for case mix

The final consideration in analysing and comparing rates of SSI is the extent to which the rate is explained by the particular risk of infection associated with the procedure or the patient. The aim of risk adjustment is to account for the differences in distribution of intrinsic factors that increase the risk of SSI. These are factors that are inherent in the procedure itself (the presence of micro-organisms at the operative site), the patient (e.g. underlying severity of illness that increases susceptibility to infection), or the complexity of the procedure that may result in prolonged handling and exposure of the tissues. If the risk attributable to these factors can be accounted for, then remaining variation is more likely to be due to extrinsic factors related to peri-operative practice (Wilson, 2013). Since the risk of SSI varies according to the presence of normal body flora at the operation site, categories of procedure are commonly created to group operations that have a broadly similar intrinsic risk of SSI. This approach minimises variation explained by the intrinsic risk associated with the combination of procedures included in the rate (Gaynes et al. 2001). It is an important principle if meaningful rates are to be reported to specific surgeons and clinical teams. Indeed, surgeon-specific reporting has been found to be a key factor in achieving reductions in rates of SSI as discussed previously (Wilson, 2013).

There are different approaches to risk adjustment. The NNIS Risk Index stratifies procedures according to the presence of one or more of three, largely intrinsic, risk factors (American Society of Anesthesiologists (ASA) score, operation duration and wound classification). The ability of this risk index to reflect increased risk of SSI is demonstrated by the statistically significant trend across risk groups in most major categories of surgical procedure (Coello et al. 2005; Anderson et al. 2008). It has also been demonstrated to predict the risk of SSI when superficial infections are excluded (Anderson et al. 2008). A standardisation method can then be used to provide a risk-adjusted summary measure to compare rates of SSI between individual centres and a reference dataset (for example, combined data from all participating centres) (Rioux et al. 2006). The standardised infection ratio (SIR) is calculated by multiplying the number of procedures in each risk

group by the mean SSI rate for the analogous risk group in the reference dataset, and then dividing by 100 to obtain the *expected* number of SSIs (if the rate were comparable with the reference dataset). The total number of *observed* SSI is then divided by the number of *expected* SSI to obtain the SIR, as illustrated in Box 3 (Brümmer et al. 2008).

Thus an SIR of less than 1 suggests that the rate of SSI adjusted for risk factors is less than the rate for the reference dataset, and if greater than 1 the rate is higher (Gaynes et al. 2001). Records can only be included in the SIR calculation if complete data are available for each risk factor, and if many records have to be excluded because of missing risk factor data the resulting SIR will be based on a smaller proportion of the records and may be imprecise or biased.

The power of a set of risk factors to predict accurately the risk of SSI can be measured by constructing a receiver operating characteristic curve by plotting the sensitivity versus 1-minus the specificity over the range of points for a given index and calculating the area under the curve (c-index). A c-index of 0.5 indicates no predictive power, 1 perfect predictive power (Mu et al. 2011). Whilst the risk index may predict increasing risk of SSI, it tends to have a low c-index indicating that it does not explain a high proportion of the factors contributing to SSI. Various authors have proposed more sophisticated risk adjustment based on logistic regression analysis of a wider range of potential risk factors to identify procedure-specific risk models (Geubbels et al. 2006; Mu et al. 2011). Whilst these models have been found to significantly improve the c-index, they still do not increase it much beyond 0.7 (Geubbels et al. 2006; Mu et al. 2011). This is perhaps to be expected, since they are designed to adjust only for intrinsic risk and the remaining extrinsic risk is more likely to reflect the variation in practice that is the target of such comparisons. There is also evidence that in European datasets, risk adjustment does not substantially alter the rank positions of individual centres because the risk factors are relatively uncommon and their distribution is similar across most acute care hospitals (Wilson, 2002; Brümmer et al. 2006). A balance therefore needs to be struck between the purpose and value of risk adjustment and the effort required to collect risk factor data, although they are considered essential where rates are used for public reporting (Geubbels et al. 2006; Mu et al. 2011).

Whilst risk adjustment is an important consideration, other key methodological issues are also important, in particular comparability of methods used to capture denominator and numerator data, the robustness of the analytical methods used to take account of the precision of point estimates and the effects of sampling and case-finding variation. The purpose of surveillance is to provide an effective monitoring and alert system. In the absence of unlimited resources, methods of data capture, risk adjustment and systems to detect outliers are inevitably imperfect and can only indicate a potential problem worthy of further investigation rather than definitive poor performance. Mechanisms of representing data to non-expert audiences that make the results accessible whilst minimising the possibility of misinterpretation are therefore also an essential requirement to ensure data are used wisely.

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Declaration of conflicting interests

The author declares that there is no conflict of interest.

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Appendix 2.4.

Secondary publication 5: McDougall C, Wilson J & Elgohari S. (2007)

3:00-3:15 PM

Publication Number 244

A Review of Compliance with the National Protocols for Surveillance of Surgical Site Infection. Does Deviance Impact on the Quality of Data and Detection of SSI?

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BACKGROUND/OBJECTIVES: The Surgical Site Infection Surveillance Service (SSISS) co-ordinates the mandatory surveillance of Surgical Site Infection (SSI) in orthopaedic surgery in England. It also supports voluntary

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surveillance of 9 other categories of surgery. Hospitals are required to submit data for quarterly surveillance periods. They receive a report on the data they have submitted which also enables them to compare their rates of SSI against a benchmark rate estimated from the pooled mean rate of other participating hospitals. For this comparison to be valid participating hospitals are required to employ standard methods to identify both the study population (patients undergoing a procedure in a specific category of procedures) and cases (SSI). Defined methods are set out in a comprehensive surveillance protocol and training is provided. Hospitals reporting persistently low rates of SSI may reflect poor case-finding and non-compliance with surveillance methodology. Our objective was to evaluate compliance with the defined methodology at hospital level and to determine whether any deviation from defined methods affect the quality of the data and detection of SSI.

METHODS: The surveillance co-ordinator at each participating hospital was sent a questionnaire about the methods they used to collect data SSI surveillance data. Hospitals with rates persistently below the 10th percentile were identified from the SSI database and their results evaluated against the surveillance methodology reported in the questionnaire.

RESULTS: Completed questionnaires were received from 172 hospitals (response rate of 61%). In 78% of hospitals the infection control team were responsible for overseeing the surveillance. 94% of respondents were using more than one source of information to find demographic and operation data and 86% were very or fairly confident that they were including all eligible operations in the surveillance. In terms of case finding, although 68% (n = 109) of respondents reported using the active method described in the protocol, 16% (n = 25) indicated they used a passive method and 2% (n = 4) reported using a retrospective method. However, 82% were using a combination of data sources to establish if SSI meet the definitions and only 5% (n = 8) relied on ward staff to decide. Of those hospitals reporting a passive method to find SSI, nearly one third (n = 7) were reporting rates below the 10th percentile in hip prosthesis.

CONCLUSIONS: Mandatory surveillance of SSI is intended to provide comparative data on rates of infection for the Government and public. However, to obtain reliable results systems must be in place to ensure that all eligible patients are included and that active case finding is used to find infections. The results of this questionnaire illustrate that despite being mandated to undertake surveillance, the majority of hospitals use robust surveillance methods. However, it is of concern that a small proportion do not and as a result may be under-reporting. Methods of validating case-finding need to be developed to enable standardised comparisons.

Appendix 2.5.

Secondary publication 6: Wilson JA, Ward VP, Coello R, *et al* (2002)

Journal of Hospital Infection (2002) 52: 114–121

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A user evaluation of the Nosocomial Infection National Surveillance System: surgical site infection module

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Summary: The Nosocomial Infection National Surveillance Scheme (NINSS) enables hospitals in England to undertake surveillance of healthcare associated infection, compare their results with national aggregated data, and use the information to improve patient care. A surgical site infection (SSI) module was introduced in 1997, and participation has increased steadily since its inception. This survey was undertaken to assess the views of users on the current service, and how the module should be developed to best meet their needs and resources. Survey forms were sent to infection control teams (ICTs) at the 113 hospitals that had participated at any time during the first three years of the programme. The response rate was 90% (102). The views of users were generally very positive and indicated considerable support for the approach to this type of surveillance. The ability to compare hospital infection rates with national data, the availability of standardized surveillance methods, and centralized data analysis and report production were key reasons for participation for over 80% of users. Most did not wish to see any major changes made to the protocol, although more than a third of users suggested additional data items. Overall, users were satisfied with both the content and timescale for receipt of feedback reports, and 77% disseminated them to at least three groups of clinicians and managers. The majority of ICTs (89%) gave the results directly to the surgeons. For some users (29%) it was too early to assess the value of the surveillance. Of the remainder, although results provided evidence of good performance for some, 46% identified high rates of SSI in one or more groups of surgical patients. In about two-thirds of these hospitals, a review or change in clinical practice was initiated as a result. Three main areas for development were identified: an extended range of surgical procedures, post-discharge surveillance and improved local data collection and analysis systems. Users said they would also like training in handling and interpreting surveillance data. These needs should be addressed in order to ensure the continuing success of national surveillance.

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Keywords: Surveillance; surgical site infection; evaluation.

Introduction

Healthcare-associated infections (HAI) are an important cause of morbidity and mortality and impose a considerable burden on the healthcare

sector, patients, and their families.¹ The surveillance of HAI has been acknowledged as an important component of infection control programmes for many years, and is increasingly recognized as key to improving clinical outcomes.^{2–4}

In 1996 the Department of Health and the Public Health Laboratory Service established the Nosocomial Infection National Surveillance Scheme (NINSS) in England. The aim of this service was to enable hospitals to undertake surveillance of HAI

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and compare their results with national aggregated data. The comparison could be used to identify where rates were high, focus infection control activity on these areas and improve patient care.⁵ Key to this objective was the development of standard surveillance methods and case definitions.^{6,7}

Since the surgical site infection (SSI) surveillance module has been available, there has been a steady increase in hospitals joining NINSS and in the level of participation by existing users. To evaluate the user perspective of this service, a review of the current system was undertaken to assess how it matched their needs and resources.

NINSS methodology

The protocol for the surveillance of SSI was based on that used by the National Nosocomial Infection Surveillance (NNIS) system operated by the Centers for Disease Control and Prevention (CDC) in the USA.⁸ It was developed with advice from a multidisciplinary National Health Service (NHS) group and other experts. After extensive development and piloting, the surveillance module became available in October 1997, establishing voluntary national surveillance for the first time in England.^{5,9}

NINSS uses an active surveillance system to achieve maximum reliability and validity of data, with trained personnel collecting surveillance data prospectively from the time of surgery until discharge.⁶ Hospitals are required to collect data for a minimum of three months. Data collection is co-ordinated by the infection control team (ICT) in the majority of hospitals. Surveillance is targeted at specific categories of clinically similar surgical procedures that are commonly performed and/or are associated with a high risk of infection, and that usually require more than three days of postoperative stay. Hospitals are able to choose one or more of 12 categories currently available.⁹

A basic set of 16 demographic and surgical data items is collected for each patient who undergoes a procedure in a chosen category. These patients are monitored at regular intervals during their postoperative stay in hospital. A further six data items are collected when a SSI that meets the case definitions is identified. The NINSS definitions of infection are based on those developed for the American NNIS system¹⁰ and are detailed in the NINSS protocol.⁹ The data collection system is paper-based, using forms designed to be scanned

by an optical mark recognition system at the co-ordinating centre. Data submitted are extensively checked using a computer program for inaccuracies and logical inconsistencies that may invalidate the results. Queries are referred back to participating hospitals, and the database amended accordingly. Data are analysed by surgical category to provide each hospital with their incidence of SSI at the end of each surveillance period. This can then be compared with their cumulated incidence over previous surveillance periods, and the incidence from data aggregated from all hospitals. The rates are stratified by the risk index developed by the American NNIS system to take account of important factors related to patient susceptibility and peri-operative events that are known to influence the risk of SSI.¹¹

A surveillance report is sent to each hospital quarterly. An automatic report generation program developed by NINSS is used to produce the reports, and most are sent out about six weeks after the end of the 30 day follow-up period for patients still in hospital. Reports for hospitals whose incidence of SSI is above the 90th percentile take slightly longer, to allow for additional analysis and interpretation of data. Data from individual hospitals can also be extracted from this database and returned electronically to users for local analysis.

Methods

A structured questionnaire was designed with dichotomized or multiple response formats and space for verbatim comments where appropriate. Twelve infection control nurses (ICNs) and six infection control doctors (ICDs) reviewed both the format and content of the drafts, which were modified accordingly. The questionnaire asked users to evaluate the current service provision provided by NINSS in relation to a number of key elements, namely data requirements, definitions of infection, surveillance reports, and the value of the surveillance process to the hospital. Users were also asked for their views on potential future developments such as requirements for local data analysis, the value of regional comparisons, additional categories of surgical procedures, and post-discharge surveillance.

In August 2000, survey forms were sent to ICTs at the 113 hospitals that had taken part in the surveillance since October 1997. The ICN and ICD at each hospital could complete the questionnaire independently or collaboratively. Data were processed using an optical mark recognition system

(TeleformTM), and downloaded into a statistical package (Stata¹²) for analysis.

Of the hospitals surveyed, two were from independent Trusts and eight were private hospitals; the remaining 103 hospitals were from 99 NHS Trusts. This represented approximately half of all general acute NHS Trusts in England. More than one quarterly surveillance period had been completed by 102 hospitals: the majority had carried out surveillance intermittently, but 23 had been participating continuously since joining NINSS. Eleven (10%) had stopped after completing a single three month period, but some of these had continued surveillance at a different hospital within the same Trust.

Results

Survey forms were completed and returned by 74 (65%) of the ICTs within three weeks. After receiving a reminder, a further 28 returned forms giving a final response rate of 90%. The majority of survey forms were completed collaboratively by the infection control team. The ICN and ICD at eight hospitals completed them independently, giving a total of 110 responses from 102 hospitals.

The reasons given by users for participating in NINSS are given in Table I. The majority of responders valued the ability to compare their own infection rates with national data ($N=96$, 87%). A similar percentage appreciated the availability of standardized surveillance methods ($N=94$, 86%), and centralized data analysis and report production ($N=90$, 82%). Over three-quarters ($N=85$, 77%) used NINSS as a quality indicator.

Evaluation of current service

Surveillance protocol

Most users ($N=97$, 90%) found the amount of information they were required to collect acceptable. However, over a third (37%) considered that more data should be collected, with an additional 56 data

items suggested by 36 users; these are detailed in Table II. Additional risk factors were cited by 23, with diabetes being the most commonly mentioned (six responses). Four other users also cited additional factors they considered increased the risk of infection, e.g., length of hospital stay. These factors are not included in Table II as they could be analysed using the current dataset without the need to collect additional data items.

The majority of the 95 who responded to this question ($N=80$, 84%) did not wish to see any changes made to the protocol. A range of minor changes were proposed by 15, five of which related to some aspect of the definition of SSI. Others suggested minor changes to the classification of data, and matching data requirements to those required for other initiatives, e.g., fractured femur audit, British Orthopaedic Association (Scotland).

In each category of staff, over 90% found the definitions of SSI to be acceptable or mostly acceptable (see Table III). Seven responders from six hospitals stated that surgeons found the definitions unacceptable. However, the reasons given were generally not related to the actual definition of

Table I Reasons given for participating in NINSS

Reason	No.	%
Able to compare with national data	96	87
Provides standardized methods for surveillance	94	86
NINSS analyses data and provides surveillance reports	90	82
Provides measure of quality	85	77
Other reasons	15	14

Table II Additional data items of interest to users

Data item	No.
Additional risk factor data (e.g., diabetes, immunosuppression, steroids)	23
Surgery-related factors (e.g., use of drains, type of suture or dressing)	6
Antibiotic prophylaxis (type and/or dose, whether given as per protocol)	5
Theatre factors (which theatre used, conventional or laminar airflow)	5
Preoperative skin preparation	5
Alternative risk index (Douglas, Parsonnet, Waterlow)	3
Additional re-admission data	2
Other	7

Table III Acceptability of NINSS definitions to hospital staff

Category	Acceptable		Mostly acceptable		Not acceptable	
	No.	%	No.	%	No.	%
Surgeon	45	46	47	48	7	7
Infection control doctor	73	73	25	25	2	2
Infection control nurse	83	78	23	22	0	—
Other	24	71	7	21	3	9

SSI, but more to other aspects of the protocol, for example the definition of what constituted an emergency procedure.

One of the criteria used to define SSI is the culture of micro-organisms from a wound swab or aspirate. However, to distinguish wounds that are infected from those that are colonized, pus cells must be present in the specimen. As laboratory practice may vary in this respect, users were asked whether their laboratory looked for pus cells. Of the 106 who responded, only 55 (52%) routinely carried out microscopy on wound swabs.

Surveillance reports

Overall, 51% of the 102 who responded considered the quarterly reports to be good and 47% satisfactory. Two users thought the reports were poor. The majority ($N=88$, 85%) found them easy or reasonably easy to understand. Most users ($N=85$, 87%) considered the amount of information contained in the reports was about right. Of the remainder, seven thought there was too much information, and six too little. Some additional analyses were suggested, most of which could be achieved using the current dataset, e.g., inter-hospital comparative data on the average length of stay. Other suggested analyses would require the collection of additional data items, for example effectiveness of antibiotic prophylaxis regimens and preoperative skin preparation. Stratification of the results by the CDC NNIS Risk Index was considered useful by 57 (56%), although 36 (36%) were unsure whether it was useful. Of the eight who did not find it useful, most commented that their number of procedures was probably too small to make stratification meaningful at present.

Approximately three-quarters ($N=81$, 76%) of users had been involved with the feedback of surveillance reports to a range of staff within the hospital (Table IV). The reports were disseminated to at least three groups of clinicians/managers within the hospital (range one to 11). The majority ($N=72$, 89%) gave the results to the surgeons, either directly (61%) to the surgical teams (67%), via the director of surgery (42%) or by a combination of these routes. The nine who only fed back the results to one group sent them directly to either the surgeons or the Infection Control Committee. Users commented that the reports were generally well received.

Users were asked about the acceptability of the reporting timescale. Of the 102 who responded to

Table IV Dissemination of surveillance results

Category	No.	%
Infection Control Committee	63	78
Surgical teams	54	67
Individual surgeons	49	61
Ward staff	39	48
Director of surgery	34	42
Chief Executive	32	40
Theatre staff	21	25
Trust Board	20	25
Consultant in Communicable Disease Control	20	25
Audit Committee	16	20
Clinical Governance Board	3	4
Other	5	6

this question, 47 (46%) were satisfied and 43 (42%) fairly satisfied with the reporting time. Twelve were not satisfied, but three of these acknowledged that reporting times had improved since the inception of NINSS, and two that a shorter timescale was probably not feasible with the amount of data being processed.

Value of NINSS surveillance

For 31 (29%) users it was too early to assess the value of the surveillance. Of the remaining users, 66 had found it to be of value. For those hospitals, the most frequently cited benefit was the improved awareness of infection control issues within the hospital, with some responders commenting on improved communication and working relationships between the ICT, ward and clinical directorate staff. Evidence of good performance was provided for 41 hospitals. Thirty hospitals had identified high rates of SSI in one or more of the surgical categories included in the surveillance. Some had initiated a review and/or change of practice, and were able to report a subsequent reduction in the incidence of infection. Eleven users (10%) had not found the surveillance useful, but only three of these considered this was due to the surveillance system: one felt that the receipt of results was too slow, and two that it was of no value without post-discharge surveillance. The remainder commented on the low throughput of relevant procedures at their hospital, lack of resources for surveillance, and the difficulties of using data to effect change.

When asked whether specific actions had been taken in response to surveillance results, 33 (57%) reported that action had been taken. This mostly involved a review of one or more of the clinical

Table V Action taken in response to surveillance results

Clinical practice	Reviewed	Changed
Antibiotic practice	17	5
Ward practice	16	7
Wound care	12	5
Preoperative care	11	3
Theatre practice	11	4
Surgical techniques	10	0
Surgeon workload	3	1
Other	7	1

areas listed in Table V, with a subsequent change of practice where problems were identified. Prophylactic antibiotics was the area most commonly reviewed, necessitating a change in practice on about 30% of occasions. Where care of the surgical wound and ward practice were reviewed, changes were made as a result on over 40% of occasions. Other actions cited included decontamination of physiotherapy equipment, increasing the number of sinks for handwashing, and increasing the space between beds. No action was deemed necessary by 31 (35%) of the 89 who answered this question.

Future developments

There were three main areas where users expressed an interest in seeing the surveillance system developed: new categories of surgical procedures, post-discharge surveillance, and data analysis systems. The suggested improvements to the scheme are summarized in Table VI.

Categories of surgical procedure

Previously, a number of users had requested the inclusion of additional categories of surgical procedures. In order to establish demand, users were asked to indicate which they would like to be available. The most frequently cited were caesarian sections ($N=70$, 64%), breast surgery ($N=68$, 62%) and hernia repair ($N=51$, 46%). An interest in surveillance specifically for paediatric areas was also of interest to 39 (37%) users.

Post-discharge surveillance

Eighteen (16%) users indicated that they currently carried out some form of systematic post-discharge surveillance for selected patient groups. Forty-seven (44%) users indicated that they would definitely consider doing post-discharge surveillance if it was

Table VI Summary of the characteristics of the current NINSS and developments suggested by users

Characteristics of NINSS surveillance system	Developments suggested by user comments
Standardized methodology	
Case definitions	Little demand for change
Process	Little demand for change
Inpatient surveillance only	Interest in post-discharge surveillance if more resources available
Categories of surgical procedure	Extend number of categories
Minimum dataset	Some demand for additional data items and category specific risk factors
Centralized data handling	Service highly valued
Centralized report production	Service highly valued Some demand for additional analyses
Centralized advice service	Service highly valued Training in interpreting and using data

an option, and a further 46 (43%) would probably consider it. However, the majority of responders (94%) indicated that additional resources would be required. The more serious HAIs are likely to require re-admission to hospital. However, only 53 (52%) indicated that it would be possible to routinely identify these patients.

Data analysis

The majority of users ($N=87$, 83%) preferred the analysis of their data to be handled centrally, with only 18 (17%) users interested in the option to receive and analyse their own data locally.

Most users ($N=74$, 70%) thought it would be an advantage to compare their data with other hospitals in their NHS region. Seven of the 31 who thought this would not be useful were concerned that hospitals within a region may not be comparable, and they may have more in common with hospitals in other regions.

The majority of users (71%), indicated that they would like to receive more help and advice from NINSS if their incidence of infection appeared high. Some commented that they had already sought and received extra help, and that they valued advice on epidemiology, risk factors, and statistical analyses. There was a demand from the majority of users ($N=91$, 87%) for training workshops on interpreting and using surveillance data. Six users also mentioned

that they would like the opportunity to share information and compare practice with other users who had a low incidence of infection, particularly if they had successfully implemented interventions to reduce infection rates.

Discussion

The NINSS surveillance was found to increase awareness of infection control issues within hospitals. Over 60% of users reported they had already found the surveillance to be of value, even though many may not have been participating for very long; and it had demonstrated evidence of good performance for over a half. For many with high rates of infection, the surveillance provided an important stimulus for initiating a review or change of clinical practice. Some were already able to report reductions in their incidence of infection as a result. A few hospitals encountered difficulties in encouraging surgeons and others to act on the results. At present there are limited opportunities to share information about local practice. This process may be facilitated if the current voluntary and confidential nature of this service was changed.

Using the NINSS system to compare local infection rates with national data was clearly valued. Standardized methods of surveillance, the availability of credible national data, centralized data analysis and report production were seen by over 80% of users to be key reasons for participating in NINSS.

Like other national surveillance systems in the United States and Europe, NINSS currently uses a standard dataset for all types of surgery.¹³ Some of the changes suggested in this survey, for example, matching the data with the British Orthopaedic Association fractured femur data, would require the development of a more flexible dataset that varies for the surveillance of different types of surgery. Over a third of users indicated that they would like additional data to be collected, particularly in relation to risk factors, antibiotic prophylaxis, and theatre and surgical practices. Although it may not be feasible to collect all these data items as part of a minimum dataset for a routine surveillance system, it does suggest that there is a demand for increasing rather than reducing the complexity of the surveillance. Investment in advanced computer technology may enable hospitals to collect and analyse additional local data.

An important aspect of the definitions of SSI is that they are accepted by those responsible for using

the surveillance results to improve patient care. It is therefore noteworthy that over 90% of surgeons, ICNs, and ICDs considered the NINSS definitions of SSI either acceptable or mostly acceptable. In the original CDC definitions for SSI, an infection could be defined by the criterion of 'organisms isolated from aseptically cultured fluid or tissue'. The NINSS Module Development Group recommended that this be amended so that the presence of pus cells was also required to reduce the possibility of colonized wounds being reported as SSIs. The disadvantage, as shown by this survey, is that not all laboratories currently routinely perform microscopy on wound swabs to detect pus cells. Other methods of assuring that a pathogen recovered from a surgical wound is causing a SSI may need to be considered such as combining this criterion with the presence of clinical symptoms.

Presenting surveillance data in an accessible format can be difficult. Overall, satisfaction with the content of NINSS surveillance reports was high, with most users finding that they were easy or reasonably easy to understand, and contained about the right amount of information. There was reasonable satisfaction with the current production timescale, but these times could be shortened if systems for local data entry and electronic data transfer could be developed.

Although it has been suggested that surveillance data should be analysed locally by the hospital,⁴ the overwhelming majority of users (83%) indicated they would prefer their data to be handled centrally. The facility for hospitals to receive their own NINSS data in electronic format has been available for two years, but currently few hospitals take up this option. This perhaps reflects the level of data manipulation and analysis skills among infection control practitioners. This is borne out by the number indicating a need for more help and advice from NINSS, and the demand for training in interpreting and using surveillance data. The importance of the development of such a training programme is evident. If appropriate resources were available, this could be integrated with the development of software for local collection and analysis of data, possibly using web-based technology to provide an interface between local and national data.

A number of hospitals participating in NINSS have asked for more categories of surgical procedure to be available. This survey shows that there is considerable demand for extending the surveillance, with almost two-thirds of users indicating their

interest in surveillance of breast surgery and caesarean sections. As the average postoperative stay in these two categories is short, some form of post-discharge surveillance would be necessary, but is probably feasible using breast care nurses and community midwives to facilitate data collection.

Surveillance of appendectomies and hernia repairs were requested by more than a third of users, but these categories are also likely to have a short hospital stay and would also require some form of post-discharge surveillance. However, there is no systematic follow-up of these patient groups by community/specialist nurses. The current NINSS methodology allows data on post-discharge SSI to be collected, but these are not included in the comparative data as systematic post-discharge surveillance was not considered to be feasible for most hospitals. This was borne out by the results of this survey where most users indicated that they were interested in post-discharge surveillance, but would require extra resources to undertake it. A possible approach for a limited form of post-discharge surveillance is the systematic detection of patients readmitted to hospital with SSI. However, this would require further evaluation, as only half of the users indicated that they would be able to identify these patients routinely and ascertainment would be incomplete. The Department of Health has convened an expert group to consider options for extending the current national surveillance system to include some form of post-discharge surveillance. Just over a third of users indicated an interest in surveillance of paediatric SSI. As the surgical procedures involved are likely to differ significantly from those commonly performed in adults, it might be more appropriate to consider a separate module to cover these infections.

In recent years there has been an increasing focus on quality and performance monitoring within the NHS.^{14,15} SSI are an important cause of morbidity among hospital patients, and NINSS data have shown that the infection rate for clinically similar groups of procedures varies considerably between hospitals in England.^{16,17} This national SSI surveillance service has now been established for four years. Although participation is voluntary, it currently provides a service for over 165 hospitals in England and comprises a database of more than 75 000 records. These hospitals are distributed throughout the English NHS Regions and are representative of the national mix of hospitals, including district general, teaching and specialist

hospitals. Whilst voluntary participation may lead to some selection bias it does ensure data quality and enhance the ability to make meaningful comparisons. This survey has demonstrated the value to users of a national system that provides standardized surveillance methods and comparative data. Results have been used to initiate changes in clinical practice, increase awareness of infection control, and demonstrate good quality care. The responses given by the users were generally very positive and suggest considerable support for the general approach to this type of surveillance. Most did not wish to see any major changes made to the surveillance protocol, and found the amount of data they were required to collect acceptable. However, for continued success there is a need to develop methods for the surveillance of other categories of surgical procedures and to provide training in handling and understanding surveillance data. In the future, investment in information technology such as handheld computers and web-based data entry would serve to enhance local data entry and analysis, facilitate the surveillance process and increase its flexibility for users.

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healthcare systems, practices, patient-mix, type of hospital, and reasons for participating in a national surveillance network.²⁸ In addition, the total number of operations in the English system for some surgical categories, such as limb amputation, vascular surgery, small bowel surgery and open reduction of long bone fracture, is still small, giving an imprecise estimate of the incidence of SSI which is reflected by wide confidence intervals. Lastly, it is likely that the postoperative LOS differs between countries; if patients, in general, remain longer in hospital in England, it is likely that more infections will be detected. For example, the postoperative LOS for uninfected patients was longer in our study for large bowel surgery, open reduction of long bone fracture and joint replacement than that found by Kirkland *et al.*¹⁶ in the USA for similar categories of surgery. Interestingly, the LOS for uninfected patients undergoing similar categories of surgery was shorter in our study than that found by the Dutch surveillance network.⁵

The LOS for patients with SSI was at least twice that of those without SSI for most of the categories of surgery. However, the estimated extra LOS was imprecise for some procedures (e.g. limb amputation, small bowel surgery and open reduction of fracture) because of the relatively small sample size. In addition, for these categories of surgery, the date of discharge was unknown for a large proportion of patients, contributing to the imprecision of these estimates of extra LOS.

There is a wide variation in the extra postoperative LOS attributable to SSI in published studies, particularly when considering specific categories of surgery. For example, the extra LOS attributable to SSI for CABG varies from 3 to 18.5 days,^{16,29} and was 13.4 days in our study. For colon surgery, the published extra LOS varies from 6 to 13.8 days,^{9,16} and was 9.4 days in our study. For abdominal hysterectomy, the extra LOS attributable to SSI in English hospitals was 3.3 days; about half of that found by Green and Wenzel (6.5 days)⁹ in the USA. These differences may relate to differences in the healthcare systems between countries, to the methodology used to determine the extra LOS, and to the year of the study. Not surprisingly, and in line with others,^{5,30} we found that patients with deep incisional and organ/space SSI stay in hospital for longer than those with superficial SSI, and this stay was at least 1.6 times longer for all categories of surgery, with the exception of small bowel surgery and limb amputation where the extra LOS was similar for all types of SSI.

Several studies in the UK^{11,15,18} found that the extra LOS accounted for about 90% of the additional

cost attributable to SSI. Thus, the most costly SSIs are to be found in those categories of surgery with the largest extra LOS attributable to SSI. Overall, we found a wide variation in the extra cost attributable to SSI for the different categories of surgery, ranging from £959 for abdominal hysterectomy to £6103 for limb amputation. Deep incisional and organ/space SSIs have a higher extra LOS than superficial incisional SSI and therefore a higher attributable cost. This was particularly so for CABG and hip and knee prostheses, where the estimated cost was more than doubled. The estimate of the cost of SSI per extra bed-day in this study was derived from the figures for the mean additional cost and LOS found in the study by Plowman *et al.*,¹⁸ who also used logistic regression techniques to control for those factors which may impact on resource use. However, as Plowman *et al.*'s estimate was derived from all surgical procedures and all types of SSI in a single district general hospital, these costs may have been an underestimate for the teaching and specialist hospitals that were included in our study.

When assessing costs, it is important to take into account the volume of operations. Categories of surgery with many operations and a low incidence of infection may be more costly overall than categories with very few operations, even though they have a high incidence of SSI and large extra LOS.

We found that for all categories of surgery, the crude mortality rates were higher for patients with SSI (all types combined) than those without SSI. However, the adjusted ORs show that only patients with hip prosthesis and SSI have a mortality rate that was significantly higher, nearly twice that of those without SSI. In addition, for hip prosthesis, patients with superficial incisional SSI and those with deep incisional and organ/space SSI also have a significantly higher mortality rate than those without SSI. Although we controlled for several major risk factors, it is possible that there were other factors not included in this study that also influence mortality. This may explain our finding that, for patients with hip prosthesis, those with superficial SSI apparently had a significantly higher mortality rate than those without SSI. Large bowel and vascular surgery also had an adjusted mortality rate associated with deep incisional and organ/space SSI that was significantly higher than for patients without SSI.

The overall crude mortality rates for all patients who underwent abdominal hysterectomy, large and small bowel surgery, and hip and knee prostheses in our study were similar to those found by Astagneau *et al.*⁶ for similar categories. However, the crude

mortality rates for patients with SSI in our study compared with those published by Astagneau *et al.* varied depending on the category of surgery. For example, the mortality rate for patients who developed SSI following small bowel surgery was higher in our study than that of Astagneau *et al.* (12.9% vs. 3.9%, respectively), but was lower for patients with SSI after hip and knee prostheses (5.7% vs. 16.8%, respectively), and large bowel surgery (7.0% vs. 8.4%, respectively). Unfortunately, Astagneau *et al.* did not provide adjusted ORs for patients with SSI compared with those without SSI by surgical categories. Unlike Hollenbeak *et al.*,³¹ we could not find any increased mortality associated with deep and organ/space SSI following CABG.

The NINSS surveillance of SSI in English hospitals was not primarily designed to measure the adverse impact associated with the development of SSI. Therefore, several limitations are inherent in this study. Firstly, because of the voluntary participation of hospitals and their choice of surgical category, the possibility of selection bias cannot be excluded. For example, hospitals may have chosen a particular category of surgery because they suspected that they had specific problems in that type of surgery. If so, this might result in higher rates of SSI. Conversely, this study did not attempt to include infections detected after discharge from hospitals or on re-admission, and this implies an underestimation of the overall incidence of SSI as it is well known that a large proportion of SSIs are only detected after discharge.³²⁻³⁵ Secondly, the extra LOS would be increased if re-admissions were taken into account, as was shown by Kirkland *et al.*¹⁶ Thirdly, this study is based on surveillance data and the actual date of discharge was not known for all patients; thus the estimated extra LOS was imprecise for some categories of surgery, such as limb amputation, small bowel surgery and open reduction of fracture, partially due to the fact that date of discharge was unknown for a relatively large proportion of patients.

In conclusion, despite the limitations, this study provides useful information on the incidence of SSI and the adverse consequences of these infections based on a large number of English hospitals. It shows for the first time that the extra LOS, cost and mortality associated with SSI vary widely depending on the surgical category. By determining which surgical procedures are associated with a more severe adverse impact of SSI, such information should be useful in establishing priorities for the surveillance and prevention of these infections.

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Appendix 3.2.

Primary publication 2: Ridgeway S, Wilson J, Charlett A, *et al* (2005)



Infection of the surgical site after arthroplasty of the hip

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We wished to estimate the incidence of surgical-site infection (SSI) after total hip replacement (THR) and hemiarthroplasty and its strength of association with major risk factors. The SSI surveillance service prospectively gathered clinical, operative and infection data on inpatients from 102 hospitals in England during a four-year period.

The overall incidence of SSI was 2.23% for 16 291 THRs, 4.97% for 5769 hemiarthroplasty procedures, 3.68% for 2550 revision THRs and 7.6% for 198 revision hemiarthroplasties. *Staphylococcus aureus* was identified in 50% of SSIs; 59% of these isolates were methicillin-resistant (MRSA). In the single variable analysis of THRs, age, female gender, American Society of Anesthesiologists (ASA) score, body mass index, trauma, duration of operation and pre-operative stay were significantly associated with the risk of SSI ($p < 0.05$). For hemiarthroplasty, the ASA score and age were significant factors. In revision THRs male gender, ASA score, trauma, wound class, duration of operation and pre-operative stay were significant risk factors. The median time to detection of SSI was eight days for superficial incisional, 11 days for deep incisional and 11 days for joint/bone infections. For each procedure the mean length of stay doubled for patients with SSI. The multivariate analysis identified age group, trauma, duration of operation and ASA score as significant, independent risk factors for SSI. There was significant interhospital variation in the rates of SSI. MRSA was the most common pathogen to cause SSI in hip arthroplasty, especially in patients undergoing hemiarthroplasty, but coagulase-negative *Staph. aureus* may be more important in deep infections involving the joint.

More than 40 000 total hip replacements (THRs) are performed in England each year and are generally effective in reducing pain and increasing mobility.¹ In addition, more than 50 000 patients are admitted to hospital annually with fractures of the proximal femur, a large proportion of whom require a hemiarthroplasty.² Surgical-site infection (SSI) after hip arthroplasty can have serious consequences for the patient, may lead to revision surgery and have long-term effects on health and mobility.¹ These infections impose a considerable economic cost both to health care and to patients and their families, while treatment contributes towards antimicrobial resistance.^{3,4}

A low incidence of infection may depend upon the design of the operating theatre, meticulous surgical technique and rigid aseptic discipline.⁵ Surveillance has an important role in the reduction of the risk of hospital-acquired infection and has allowed the incidence of SSI to be reduced by up to 38%.^{6,7} Understanding the risk factors associated with SSI is impor-

tant for meaningful comparisons of rates and to allow proper prevention.⁸

In 1996, the Department of Health and the Public Health Laboratory Service (Health Protection Agency) established a surveillance service in England. This was originally called the Nosocomial Infection National Surveillance (NINS) Service and has now been renamed the Surgical Site Infection Surveillance Service (SSISS). This is based upon the protocols used by the Center for Disease Control (CDC) in the United States. The key aims were to facilitate hospitals to undertake surveillance of hospital-acquired infection and to enable them to compare their results with those of other participating institutions.⁹ A fundamental requirement was the development of standard surveillance methods and definitions for all the participating hospitals as well as establishing the usefulness of methods for adjusting the rates associated with the major risk factors.

We have therefore analysed the data collected from 24 808 primary and revision THRs and hip hemiarthroplasties from 102 hospitals

Table I. Definitions of SSI* (note: 1, stitch abscesses, defined as minimal inflammation and discharge confined to the points of suture penetration, and localised infection around a stab wound are not classified as SSI and are excluded; and 2, an infection which involves more than one site will be classified according to the deepest level of SSI)

Superficial incisional	Occurs within 30 days of surgery Involves only skin and subcutaneous tissue and meets at least one of the following criteria: <ol style="list-style-type: none"> 1. Purulent drainage from superficial incision 2. Organisms are grown and pus cells seen from aseptically obtained swab/tissue from the superficial incision 3. At least two of the following symptoms and signs: Pain or tenderness, localised swelling, redness or heat, and a) the clinician diagnoses an infection or b) the superficial incision is deliberately opened by a surgeon to manage the infection, unless the incision is culture-negative
Deep incisional	Occurs within 30 days (no implant) or one year (implant) of surgery Involves deep fascia and muscle layers Appears to be related to the procedure and meets at least one of the following criteria: <ol style="list-style-type: none"> 1. Purulent drainage from the deep tissue but not the joint or bone 2. Organisms are grown and pus cells seen from aseptically obtained swab/tissue from the deep incision 3. A deep incision which spontaneously dehisces or is opened by the surgeon when the patient has fever (> 38°C), localised pain or tenderness, unless the incision is culture-negative 4. An abscess or other evidence of deep infection found during re-operation, or by histopathological or radiological examination
Joint/bone infection	Occurs within 30 days (no implant) or one year (implant) of surgery Involves joint and/or bone related to the site of the operation with any other tissues Appears to be related to the procedure and meets at least one of the following criteria: <ol style="list-style-type: none"> 1. Purulent drainage from a drain which is placed through a stab incision into the joint 2. Organisms are grown and pus cells seen from aseptically obtained swab/tissue from the joint/bone 3. An abscess or other evidence of joint/bone infection found during re-operation, or by histopathological or radiological examination 4. The patient has at least two of the following signs or symptoms with no other recognised cause: joint pain, swelling, tenderness, heat, evidence of effusion or limitation of movement and at least one of the following: <ol style="list-style-type: none"> a) Organisms and white blood cells seen on Gram stain of the joint b) Positive antigen test on blood, urine, or joint fluid c) Cellular profile and chemistry of joint fluid compatible with infection and not explained by an underlying rheumatological disorder d) Radiological evidence of infection, e.g. abnormal findings on radiographs, CT scans, MRI, radiolabelled scan (gallium, technetium, etc)

* SSI, surgical site infection

in England in order to estimate the incidence of SSI and its strength of association with major risk factors.

Patients and Methods

Hospitals participating in this surveillance were required to collect data for a minimum period of three months. A basic set of 17 items of clinical and surgical data was collected for all patients undergoing an eligible surgical procedure during this time. These patients were then monitored three times a week during their post-operative stay in hospital for signs and symptoms of SSI which met standard definitions (Table I). The latter were based on internationally recognised definitions of SSI. The surveillance methodology was described in a detailed protocol while surveillance personnel attended a training programme. These active, prospective methods improved the reliability of identifying cases.¹⁰ In the absence of standard methods for post-discharge surveillance, only those infections which developed during the inpatient stay were identified and therefore mostly reflected SSIs which occurred in the immediate post-operative period (Coventry type 1).¹¹

The categories of arthroplasty included THR, hemiarthroplasty, and revision procedures. These were specified by the Office of Population Censuses and Surveys surgical operation codes.¹² The classification of physical status of

the American Society of Anesthesiologists (ASA) was used as a measure of the severity of any underlying illness.¹³ Operations were allocated a risk group score based on the NINS risk index which comprised an ASA score of ≥ 3 , an operating time of more than two hours and a wound class of either contaminated or dirty.¹³ A classification of 'operations due to trauma' was added to the dataset after the first year of collection of data. This was defined as 'an operation performed because of blunt or penetrating traumatic injury to the patient'. Patients meeting these criteria did not include those with pathological fractures, or those which had occurred without a history of injury. Operations were allocated a wound class ranging from clean to dirty depending upon the likelihood of micro-organisms being present in the wound at the time of surgery.¹⁴ The duration of the operation was defined as the time between incision and closure. Peri-operative antibiotics were defined as the administration of one or more antibiotics during the peri-operative period, intended for prophylaxis. Data on specific antibiotics, the use of antibiotic-impregnated cement, the type of implant and the indication for revision were not collected.

The data were submitted to a validation process at the co-ordinating centre, checked for inaccuracies using an automated system and missing, incompatible or improbable data queries were reviewed, referred back to participat-

Table II. Incidence of SSI* in hip arthroplasty procedures by procedure and type of SSI, by number and *percentage* (95% confidence intervals (CI))

Procedure	Number of operations	SSI†		Type of SSI†		
		Number	95% CI	Superficial incisional	Deep incisional	Joint
THR	16 291	363 (2.23)	2.0 to 2.5	294 (1.80)	38 (0.23)	30 (0.18)
Hemiarthroplasty	5 769	288 (4.97)	4.47 to 5.47	190 (3.29)	62 (1.07)	35 (0.61)
Revision of THR	2 550	95 (3.73)	2.99 to 4.37	70 (2.75)	19 (0.75)	5 (0.2)
Revision of hemiarthroplasty	198	15 (7.58)	4.7 to 10.46	12 (6.06)	1 (0.51)	2 (1.01)
Total	24 808	761		566	120	72

* SSI, surgical site infection

† type of SSI was not reported for three infections (1 THR, 1 hemiarthroplasty, 1 revision THR)

ing hospitals and the database amended accordingly. Using this system, 0.94% of records were deleted when errors could not be corrected.

Statistical analysis. Stata statistical software (Stata v 8.0, Stata Corporation, College Station, Texas) was used for all analyses.¹⁵ A generalised linear model was used to determine significant, independent predictors of the risk of SSI, while taking into account the confounding effect of other predictors. Backward stepwise logistic regression was applied to data on all arthroplasty procedures, with the type of procedure included as a predictor. Length of stay could not be included in the linear model since it appeared after the outcome of SSI and was therefore not a predictor. Body mass index (BMI) was also not included in the logistic regression model, since it would have restricted the application of the model to the 33% of patients for whom data were available. Poisson regression analysis, using length of post-operative stay as the exposure variable, was also performed to estimate whether differences in length of stay explained variations in rates of SSI between hospitals. A *p* value ≤ 0.05 was regarded as significant.

Results

Between October 1997 and October 2001, 102 hospitals contributed data on 24 808 hip arthroplasty operations thereby allowing calculations of the incidence of surgical site infection to be made. The superficial incision was affected in 74% (566) of SSIs, the deep incision in 16% (120) and the joint in 10% (72) (Table II). The incidence of SSI varied significantly between hospitals for both primary THR (interquartile range (IQR) 1.6% to 3.4%) and primary hemiarthroplasty (IQR 2.1% to 7.1%).

Characteristics of patients undergoing THR. Patients undergoing a hemiarthroplasty were older with a median age of 83 years (IQR 11) compared with 70 years (IQR 15) for those undergoing THR. A greater proportion of those aged 75 years or older received a THR (82%) than a hemiarthroplasty (32%). Of the hemiarthroplasty patients, 85% had their procedures performed because of trauma compared with only 4% of patients with THR. Patients who underwent a hemiarthroplasty also had a higher median ASA score (3 *vs* 2); were more likely to be women (80% *vs* 62%) ZP and to be in a higher risk group. In addition, patients undergoing a hemiarthroplasty stayed in hospital for longer (median, 14

Table III. Single variable analysis of risk factors for SSI* in primary THR

Variable	SSI			Odds ratio	95% CI†	<i>p</i> value
	No SSI	Number	(%)			
Risk index						
0 or 1	12565	276	(2.2)	1.00	Baseline	
2 or 3	499	27	(5.4)	2.46	1.64 to 3.69	
N/A	2864	60	(2.1)	0.95	0.72 to 1.26	<0.01
Gender						
Male	6073	117	(1.9)	1.00	Baseline	
Female	9797	245	(2.5)	1.30	1.04 to 1.62	0.02
Peri-operative prophylaxis						
No	192	6	(3.1)	1.00	Baseline	
Yes	15352	347	(2.3)	0.72	0.32 to 1.64	0.44
Trauma						
No	13038	287	(2.2)	1.00	Baseline	
Yes	562	27	(4.8)	2.18	1.46 to 3.27	<0.01
Age (yrs)						
< 65	5198	91	(1.8)	1.00	Baseline	
65 to 74	5488	101	(1.8)	1.05	0.79 to 1.40	
75 to 79	2605	82	(3.1)	1.80	1.33 to 2.43	
≥ 80	2499	85	(3.4)	1.94	1.44 to 2.62	<0.01
Body mass index						
< 20	298	5	(1.7)	1.11	0.44 to 2.78	
20 to 30	4440	67	(1.5)	1.00	Baseline	
> 30	1491	44	(3.0)	1.96	1.33 to 2.87	<0.01
Pre-operative delay (days)						
0	1301	26	(2.0)	0.92	0.61 to 1.38	
1	13248	288	(2.2)	1.00	Baseline	
2	574	19	(3.3)	1.52	0.95 to 2.44	
3	271	9	(3.3)	1.53	0.78 to 3.00	
> 3	534	21	(3.9)	1.81	1.15 to 2.84	0.03
ASA score (grouped)						
Class < 3	10683	214	(2.0)	1.00	Baseline	
Class ≥ 3	2628	94	(3.6)	1.79	1.40 to 2.28	<0.01
Duration of surgery (min)						
< 60	1923	47	(2.4)	1.33	0.93 to 1.89	
60 to 89	5108	94	(1.8)	1.00	Baseline	
90 to 119	5030	106	(2.1)	1.15	0.87 to 1.52	
≥ 120	3476	106	(3.0)	1.66	1.25 to 2.20	<0.01
Wound class (grouped)						
Clean	15839	361	(2.3)	1.00	Baseline	
Other	89	2	(2.2)	0.99	0.24 to 4.02	0.98
Cement						
No	2371	40	(1.7)	1.00	Baseline	
Yes	13191	309	(2.3)	1.39	1.00 to 1.94	0.07

* SSI, surgical site infection

† CI, confidence interval

Table IV. Single variable analysis of risk factors for SSI* in primary hemiarthroplasty

Variable	No SSI	SSI		Odds ratio	95% CI†	p value
		Number (%)				
Risk index						
0 or 1	4324	223 (5.2)		1.00	Baseline	
2 or 3	79	2 (2.5)		0.49	0.12 to 2.01	
N/A	1078	63 (5.8)		1.13	0.85 to 1.51	0.40
Gender						
Male	1096	69 (6.3)		1.00	Baseline	
Female	4370	219 (5.0)		0.80	0.60 to 1.05	0.11
Peri-operative prophylaxis						
No	112	3 (2.7)		1.00	Baseline	
Yes	5227	275 (5.3)		1.96	0.62 to 6.22	0.25
Trauma						
No	716	28 (3.9)		1.00	Baseline	
Yes	4042	234 (5.8)		1.48	0.99 to 2.21	0.06
Age (yrs)						
< 65	228	5 (2.2)		1.00	Baseline	
65 to 74	771	30 (3.9)		1.77	0.68 to 4.63	
75 to 79	1005	55 (5.5)		2.50	0.99 to 6.30	
≥ 80	3423	196 (5.7)		2.61	1.06 to 6.41	0.05
Body mass index						
< 20	147	4 (2.7)		0.40	0.14 to 1.13	
20 to 30	633	43 (6.8)		1.00	Baseline	
> 30	63	4 (6.3)		0.93	0.32 to 2.69	0.20
Pre-operative delay (days)						
0	731	37 (5.1)		0.98	0.68 to 1.42	
1	2773	143 (5.2)		1.00	Baseline	
2	910	40 (4.4)		0.85	0.60 to 1.22	
3	417	24 (5.8)		1.12	0.72 to 1.74	
> 3	650	44 (6.8)		1.31	0.93 to 1.86	0.38
ASA score (grouped)						
Class < 3	2015	87 (4.3)		1.00	Baseline	
Class ≥ 3	2451	144 (5.9)		1.36	1.04 to 1.79	0.03
Duration of surgery (min)						
< 60	2260	111 (4.9)		0.93	0.71 to 1.22	
60 to 89	2077	110 (5.3)		1.00	Baseline	
90 to 119	699	40 (5.7)		1.08	0.75 to 1.57	
≥ 120	238	11 (4.6)		0.87	0.46 to 1.65	0.84
Wound class (grouped)						
Clean	5431	282 (5.2)		1.00	Baseline	
Other	50	6 (12.0)		2.31	0.98 to 5.44	0.06
Cement						
No	2492	145 (5.8)		1.00	Baseline	
Yes	2783	131 (4.7)		0.81	0.63 to 1.03	0.09

* SSI, surgical site infection

† CI, confidence interval

Table V. Single variable analysis of risk factors for SSI* in revision of THR

Variable	No SSI	SSI		Odds ratio	95% CI†	p value
		Number (%)				
Risk index						
0 or 1	1733	52 (3.0)		1.00	Baseline	
2 or 3	290	21 (7.2)		2.41	1.43 to 4.07	
N/A	432	22 (5.1)		1.7	1.02 to 2.82	< 0.01
Gender						
Male	924	48 (5.2)		1.00	Baseline	
Female	1529	47 (3.1)		0.59	0.39 to 0.89	0.01
Peri-operative prophylaxis						
No	41	1 (2.4)		1.00	Baseline	
Yes	2351	91 (3.9)		1.59	0.22 to 11.66	0.65
Trauma						
No	1911	65 (3.4)		1.00	Baseline	
Yes	101	14 (3.9)		4.08	2.21 to 7.51	< 0.01
Age (yrs)						
< 65	699	22 (3.1)		1.00	Baseline	
65 to 74	768	26 (3.4)		1.08	0.60 to 1.92	
75 to 79	469	21 (4.5)		1.42	0.77 to 2.62	
≥ 80	501	23 (4.6)		1.46	0.80 to 2.65	0.94
Body mass index						
< 20	64	2 (3.1)		0.85	0.20 to 3.69	
20 to 30	651	24 (3.7)		1.00	Baseline	
> 30	168	7 (4.2)		1.13	0.48 to 2.67	0.93
Pre-operative delay (days)						
0	190	7 (3.7)		1.10	0.50 to 2.44	
1	1823	61 (3.3)		1.00	Baseline	
2	119	0 (0.0)				
3	40	3 (7.5)		2.24	0.67 to 7.44	
> 3	283	24 (8.5)		2.53	1.55 to 4.13	< 0.01
ASA score (grouped)						
Class < 3	1580	48 (3.0)		1.00	Baseline	
Class ≥ 3	495	32 (6.5)		2.13	1.35 to 3.37	< 0.01
Duration of surgery (min)						
< 60	157	7 (4.5)		1.37	0.53 to 3.48	
60 to 89	398	13 (3.3)		1.00	Baseline	
90 to 119	450	14 (3.1)		0.95	0.44 to 2.05	
≥ 120	1252	46 (3.7)		1.12	0.60 to 2.10	< 0.01
Wound class (grouped)						
Clean	2369	87 (3.7)		1.00	Baseline	
Other	86	8 (9.3)		2.53	1.19 to 5.39	0.02
Cement						
No	592	17 (2.9)		1.00	Baseline	
Yes	1782	65 (3.6)		1.27	0.74 to 2.18	0.39

* SSI, surgical site infection

† CI, confidence interval

days) than those undergoing a THR (median, 9 days) regardless of whether they developed SSI. Patients receiving a revision THR were generally younger with 61% aged under 75 years and 19% aged over 80 years. In the revision hemiarthroplasty patients, 34% were younger than 75 years of age and 43% more than 80 years of age.

Risk factors associated with SSI in primary THR (Table III). Most patients undergoing a THR were women and had a significantly higher rate of SSI compared with men. The risk of infection also increased significantly with age and ASA score. Data for calculation of the BMI were only available for 38% of patients included in the surveillance. The risk of

SSI was significantly higher in patients with a BMI > 30 compared with values between 20 and 30. Only 4.1% of THRs were performed after trauma but their incidence of SSI was significantly higher (4.8%) when compared with elective procedures (2.2%). The risk of SSI varied according to the length of surgery, with the greatest risk for procedures which lasted 120 minutes or more. Although only 4% of patients were in the highest NINS risk index groups (2 and 3), they were significantly more likely to develop SSI. Most patients were admitted to hospital on the day before their operation (83%), but the longer patients were in hospital before surgery the higher was the incidence of SSI.

Table VI. Length of post-operative stay by type of operation and SSI*

	Median length of stay (days)		Interquartile range (days)	
	No SSI	SSI	No SSI	SSI
Primary THR	9	17	5	15
Primary hemiarthroplasty	14	31.5	14	26
Revision THR	11	22	6	20
Revision hemiarthroplasty	14	18	17	35
Total	10	23	6	20

* SSI, surgical site infection

Table VII. Micro-organisms identified as causing SSI* by type of procedure (%)

	Total hip replacement	Hip hemi-arthroplasty	Revision THR	Revision hemi-arthroplasty
MRSA†	24.3	20.3	41.3	39
MSSA‡	21.9	20.3	22.6	11
<i>Coag. negative staph.</i>	15.3	13.5	6.5	5.5
<i>Enterococcus Spp.</i>	8.6	6	8.7	5.5
Coliforms	7.7	7.5	5.9	5.5
<i>Pseudomonas Spp.</i>	7.5	4.5	3.9	11
<i>Proteus Spp.</i>	1.5	2.2	1.9	5.5
<i>Bacillus Spp.</i>	2	3	1	0
Other	11.1	21.8	9	17

* SSI, surgical site infection

† MRSA, methicillin-resistant *Staphylococcus aureus*‡ MSSA, methicillin-sensitive *Staphylococcus aureus***Table VIII.** Multivariate analysis of risk factors for SSI* in all types of hip replacement

Variable	Odds ratio	95% CI†	p value
Trauma			
No	1.00	Baseline	
Yes	1.87	1.50 to 2.34	< 0.001
Age (yrs)			
< 65	1.00	Baseline	
65 to 74	1.13	0.85 to 1.50	
75 to 79	1.56	1.16 to 2.10	
≥ 80	1.66	1.24 to 2.21	0.001
ASA score (grouped)			
Class < 3	1.00	Baseline	
Class ≥ 3	1.55	1.29 to 1.88	< 0.001
Duration of surgery (min)			
< 60	1.04	0.82 to 1.34	
60 to 90	1.00	Baseline	
90 to 120	1.23	0.96 to 1.57	
> 120	1.58	1.23 to 2.03	0.004

* SSI, surgical site infection

† CI, confidence interval

Primary hemiarthroplasty (Table IV). Of the 5769 patients who had hemiarthroplasty, 80% were women. The risk of SSI increased significantly with age. The odds ratio of developing SSI after hemiarthroplasty in patients aged 80 years or more was 2.61 compared with those aged 65 years or less. Data on BMI were only available for 16% of patients, and while there appeared to be a trend in the risk of SSI with increasing BMI, the numbers were too small to conclude statistical significance. The risk of SSI was significantly greater in those patients with an ASA score of three or more. There was no significant association between the

risk of SSI in hemiarthroplasty procedures and the duration of surgery. Most hemiarthroplasties (86%) were performed after trauma and, although the risk of SSI was higher in this group, the difference was not significant.

Revision procedures (Table V). For the 2550 revision THRs, significant risk factors for SSI were an ASA score of three or more, a pre-operative stay of three or more days compared with admission on the day before surgery, a wound class other than clean, surgery as a result of trauma and male gender.

Procedures in the NINS risk groups 2 or 3 were at a significantly increased risk of infection compared with those in groups 0 or 1. There was no linear relationship between the risk of SSI and the duration of surgery, although procedures which lasted less than one hour had a significantly higher risk.

There were only 198 revision hemiarthroplasty procedures and an ASA score of three or more was the only significant risk factor for SSI identified in this group. Because of the small numbers involved, no results have been presented, although the data have been included in the multivariate regression.

Length of stay in hospital, time to infection and causative micro-organisms. The median length of stay for patients undergoing primary THR, hemiarthroplasty and revision THR was approximately doubled in those who developed a SSI (Table VI). For the small group of patients who underwent a revision hemiarthroplasty, the median length of stay increased by only four days for those who developed a SSI. This smaller increase could have been due to differences in underlying illness in this group, which affected their length of stay in hospital. For all procedures the median time to diagnosis of superficial infections was eight days (IQR 5 to 12), for deep incisional infections 11 days (IQR 8 to 16), and for infections of the joint/bone 11 days (IQR 7 to 14).

One or more causative micro-organisms were identified in 88% of SSIs. *Staphylococcus aureus* was the main pathogen (Table VII) and was identified in 50% of SSIs. Of these isolates 59% (29.5% of all SSIs) were methicillin-resistant *Staph. aureus* (MRSA). This was a more common cause of SSI in hemiarthroplasty procedures than THR, and was responsible for 40% of SSIs in primary hemiarthroplasty, for 39% in revision hemiarthroplasty, but only for 23% in primary THR and for 21% in revision THR.

Multivariable analysis. Analysis using logistic regression found four significant, independent risk factors associated with the risk of SSI, namely, ASA score, age group of the patient, duration of the procedure and procedures performed after trauma (Table VIII). The type of procedure did not have a significant effect on the risk of SSI once these other risk factors had been taken into account. In a Poisson regression analysis, normalising for the length of post-operative stay, both trauma and ASA score remained significant predictors of SSI. Age group and duration of procedure were no longer significant predictors. If the hospital where the procedure was performed was included in the models there was a significant difference in the risk of SSI between hospitals. This suggests that there is a considerable hetero-

generality between hospitals in their rates of SSI which cannot be explained by the other predictors in these models.

Discussion

Clinical governance has increased awareness of the importance of quality and the need for monitoring outcomes. The recent National Audit Office study of the management of the control of infection in acute NHS Trusts in England suggested that there was scope for hospitals to reduce rates of infection and that systems for monitoring healthcare-associated infections were a key requirement.¹⁶ Many hospitals have developed local audit systems to focus on particular issues, but data collected by hospitals participating in the surveillance service allowed comparisons to be made with other institutions and also information to be added to a national dataset for England. This provided a unique opportunity for evaluating the risk factors for SSI in different types of procedure for hip replacement. In the surgical literature, risk factors for SSI are often used to describe those which are associated with the development of SSI, but these are not necessarily shown to be independent predictors of infection. The multivariate methods used in our analysis have allowed factors to be identified which have both a significant and an independent association with SSI after prosthetic surgery on the hip. Although the ability of the standard case-definition used for SSI surveillance, to discriminate between SSIs affecting the incision and those affecting the joint may be contentious, our analysis has focused on the risk factors associated with the development of any SSI.

The rates of infection from this dataset are similar to those reported by surveillance schemes in the USA and other European countries, although differences between types of arthroplasty are rarely reported or investigated.^{17,18} Conventionally, hemiarthroplasty procedures are considered to differ greatly from THRs. Indeed, the crude incidence of SSI for a primary hemiarthroplasty in this dataset is more than twice that for a primary THR. However, our multivariate analysis suggested that differences in the incidence of SSI, are explained by the underlying characteristics of the patients rather than being related to the type of procedure. Thus, the high risk of SSI in patients undergoing a hemiarthroplasty is likely to be due to three factors, namely, age, underlying illnesses (as reflected by an increased ASA score) and traumatic injury. The last, as well as being an independent predictor of SSI, more than doubles the odds of developing SSI in patients undergoing a THR. This suggests that local and systemic reactions to trauma may predispose to an increased risk of infection. The fourth independent predictor of the risk of SSI is the duration of the operation, with the risk significantly increased in procedures which lasted for 120 minutes or more. This perhaps reflects more complex surgery, in which a combination of prolonged surgical exposure and tissue damage during the procedure, increases the risk of SSI.

Our results suggest that, although the prevention of SSI in patients undergoing elective THR is important, the

underlying characteristics of patients undergoing a hemiarthroplasty make them more vulnerable to SSI. This reinforces the need for the highest standards of the prevention of infection in the management of such patients.

Other factors which emerge from our analyses include a significant association between the risk of SSI and periods of pre-operative stay longer than 48 hours for hemiarthroplasty patients, prolonged operations in both primary and revision THRs, and the increased risk associated with operating on wounds which were not classified as clean.

Significant variation between hospitals remained, even after adjustment for the risk factors included in the multivariate analysis. This may be explained by other components of case-mix which varied between hospitals but which were not taken into account by the factors included in our analysis. Mangram et al⁵ reviewed the evidence for risk factors for SSI.⁷ For some of these, such as age, pre-operative stay and duration of operation, data have been included in our analyses. Diabetes, although often not shown to be an independent predictor, was frequently cited as a risk factor for SSI. However, in our analysis diabetes would probably influence the ASA score. Data on the use of steroids, or the presence of malnutrition were found to be inconsistent. In orthopaedic surgery, rheumatoid arthritis may be an important risk factor for SSI. Again, because it is a systemic disease its influence should be reflected within the ASA staging. Evaluation of rheumatoid arthritis as an independent factor is difficult because of the number of confounding covariables such as the use of steroids, methotrexate and other immunocompromising drugs. In our study, a single variable analysis indicated that the body mass index was significantly associated with the risk of SSI, for both hemiarthroplasty and THR. However, because of insufficient data this variable could not be included in the multivariate analysis, even although it is possible that BMI will one day be shown to be an important, independent predictor of SSI.

It would therefore seem to be likely that our analysis has included the main patient-related risk factors for SSI. Even if the key factors were missing, the proportion of patients with these characteristics would need to vary significantly between different facilities if they were to explain the variation in incidence of SSI between hospitals. Mangram et al⁵ also cited evidence for the effect of a range of factors related to surgery, and how it is performed, on the risk of SSI. These included the operating theatre environment (e.g. ultra clean air), pre-operative factors such as prophylactic antimicrobial therapy and skin preparation, intra-operative factors such as surgical technique (effective haemostasis, gentle handling of tissues) and post-operative management of the wound. Since trauma is a significant risk factor, it may be that hospitals with separate facilities for trauma and elective patients may one day be shown to be a significant factor in the analysis of risk. The extent to which some of these practices are adopted in different hospitals may explain some of the variation in rates of infection. This variation can therefore provide a useful opportunity for evaluating

local clinical practice in relation to current recommendations to ensure that the risk of SSI is minimised.

Our study also highlights the impact of SSI on morbidity and the subsequent use of resources. The length of hospital stay for patients with SSI was more than twice that of those without SSI for all types of hip arthroplasty. However, it was not possible to establish the exact relationship between the length of stay in hospital, the severity of underlying illness and the development of SSI.³ The factors included in our model predict the risk of SSIs which develop during a stay in hospital. The data for time to diagnosis and mean length of hospital stay show that there is often a small interval between the detection of a SSI and the discharge of the patient from hospital, particularly with deep and joint infections. Patients who stay in hospital longer are more likely to have their SSI detected. In the simplistic adjustment for length of post-operative stay using a Poisson regression, age group was no longer a significant predictor of SSI. This suggests that part of the increased risk of SSI in older patients was related to their increased length of post-operative stay and the resulting, increased opportunity for SSI to be detected.

Our study has also demonstrated the extent to which the emerging problem of infection due to methicillin-resistant strains of *Staph. aureus* has affected orthopaedic surgery. Nearly two-thirds of isolates of *Staph. aureus* were methicillin-resistant, which has important implications for both antimicrobial prophylaxis and the treatment of SSI in orthopaedic surgery. The risk of acquiring SSI caused by MRSA was particularly high in patients undergoing a hemiarthroplasty. The characteristics of these patients probably increases the likelihood that they will be colonised with MRSA before surgery. There may, for example, be a history of exposure to an earlier hospitalisation, chronic wounds and other underlying illness.¹⁹ However, the relationship between colonisation with MRSA and risk of subsequent SSI in patients undergoing surgery requires further study.

With continuing emphasis on clinical governance and quality control, there is increasing demand from both patients and government for methods of assessing surgical results. Rates of morbidity and mortality may play important roles in these assessments. However, our study has indicated that, when crude comparisons between hospitals in the incidence of SSI are made, these should at least be stratified by the type of procedure. A better comparison can be made by combining data for all types of hip arthroplasty, and standardising the rates of SSI, in order to allow for the significant factors (i.e. age, trauma, duration of operation and ASA score) which may vary between hospitals. These factors can be taken into account when making comparisons and should perhaps be considered when allocating special care to high-risk patients.

There are some limitations to our study. Currently, there is no satisfactory and cost-effective system for the routine surveillance of post-operative patients who have been discharged from hospital. For this reason post-discharge SSIs were not included in our study. While the rates of post-

discharge SSI do not represent all SSIs which develop after hip arthroplasty, it is likely that a considerable proportion will have become apparent before the patient is discharged from hospital. However, it is also possible that the risk factors for SSI which we identified in this analysis may not apply to SSIs detected after discharge. Risk factors included in our analysis were only those for which data were available, although most major factors appear to have been incorporated. Hospitals contributing data were a self-selected group, which may introduce a small element of bias (e.g. participating because they consider their rates to be low or high). However, a large proportion of the NHS Trusts in England have contributed data and, for many, the reason for participation was an interest in auditing rates of SSI rather than particular concerns about its magnitude.

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Appendix 3.3.

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Duration of operation as a risk factor for surgical site infection: comparison of English and US data

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Summary T times are used to categorize surgical procedures into long and short durations. They constitute a part of the US National Nosocomial Infection Surveillance (NNIS) risk index that is widely used internationally in surveillance for surgical site infections (SSIs). The objective of this study was to compare the US NNIS T times with data collected in England. The Surgical Site Infection Surveillance Service in England holds data collected by 168 hospitals in 13 categories of surgical procedures between 1997 and 2002. The 75th percentile and corresponding T time were calculated from English data and compared with US times. Differences in rates of SSI above and below the T times were compared. Graphical methods were used to assess the cut points that exhibited an association with risk of SSI. The results show that English and US T times were the same for all surgical categories except coronary artery bypass graft and vascular surgery, where the English T time was 4 h. The 75th percentile time for hip hemiarthroplasties was 40 min less than for total hip replacements (THR). Although the incidence of SSI in THR was significantly higher in operations lasting for longer than the T time ($P < 0.05$), no association between risk of SSI and T times set at 1, 1.5 or 2 h was observed for hip hemiarthroplasties. In conclusion, operations lasting for longer than the T time were associated with a higher risk of SSI in most categories. In the hip prosthesis category, this association only applied to THR.

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Introduction

The Study on the Efficacy of Nosocomial Infection Control (SENIC) project (US Centers for Disease Control and Prevention) developed a simple four-variable risk index to predict the likelihood of a patient developing a surgical wound infection.¹ This risk index comprised an additive score of four risk factors: an operation that involved the abdomen, an operation lasting for longer than 2 h, an operation classified as either contaminated or dirty, and a patient with three or more underlying diagnoses at discharge.¹ The risk index was later modified and is now used to stratify rates of surgical site infection (SSI) by the National Nosocomial Infection Surveillance (NNIS) system in the USA.^{2,3} It has also been widely adopted by other surveillance systems. The NNIS risk index combines three factors: an American Society of Anesthesiologists' (ASA) score of 3 or more (measuring the patient's state of health at the time of surgery), a wound class of contaminated or dirty, and an operation lasting for longer than T h, where T varies with the category of surgical procedure. The risk index is similar to that used in the SENIC study as it scores each operation by counting how many of these risk factors are present.

The duration of an operation is a measure of the length of exposure to potential contamination, but may also reflect the complexity of the procedure and surgical technique. It is defined as the time between skin incision and completion of skin closure. The 75th percentile of the duration of the operation is used to determine the cut point between operations of short and long duration.² The T time is the 75th percentile of the distribution of procedure duration, rounded to the nearest hour, and is calculated for each category of surgical procedure. This cut point for specific groups of procedures is more appropriate than the 2-h time period used in the SENIC risk index^{1,2} as it accounts more accurately for differences in the usual time taken to perform different operative procedures.⁴

The Surgical Site Infection Surveillance Service (SSISS), previously called the Nosocomial Infection National Surveillance Scheme, was established in England in 1997 to enable hospitals to undertake surveillance of hospital-acquired infections and to compare their results with national aggregated data. The SSISS currently uses the risk index devised by the US NNIS system to stratify rates of SSI. However, more than a decade has elapsed since the T times developed by Culver *et al.* (1991) were published.² Changes in operative technique that have occurred during this time may mean

that these T times are no longer applicable. In addition, the US T times may not be relevant to surgery performed in England.

This paper describes an analysis of data collected on surgical procedures in England. The 75th percentile of the duration of operation data contributed to SSISS was used to develop an English T time for 13 categories of surgical procedure. This was compared with the T time from the US NNIS system.^{2,3} The English T times were then assessed for their impact on risk stratification and association with increased risk of SSI.

Methods

Data from October 1997 to September 2002 from 168 English hospitals participating in SSISS were collected and captured in an in-house database using scanning software (Formic™, Formic Ltd, Kingston-upon-Thames, UK). Participation in the scheme was voluntary and data were collected according to a standard protocol for a minimum of three months. Data collected included the category of surgical procedure (Table I) and the specific Office of Population Censuses and Surveys (OPCS)⁵ operative procedure code, together with the three risk factors that comprise the US NNIS index: wound classification, ASA score and duration of operation in minutes. Active systematic surveillance was undertaken by participating hospitals to identify patients that developed an SSI during the inpatient stay that met the case definitions.

Since, in the English surveillance system, all coronary artery bypass graft (CABG) procedures are included in a single category, OPCS codes were used to subdivide CABGs into the 'chest only' and 'chest and donor site' categories used by the US NNIS. OPCS codes were also used to subdivide the hip prosthesis procedures into total hip and hemiarthroplasties (partial hip replacement), and vascular surgery into procedures performed on the aorta, the carotid artery, the femoral artery and other procedures.

Data on 105 863 operations were available for inclusion in the analysis. Operations where the duration of operation or relevant OPCS codes were missing were excluded (3016 operations). Data from 102 847 operations from 168 hospitals were included in the analysis.

English T times were obtained by calculating the 75th percentile of the duration of operation in minutes for each surgical category and rounding it to the nearest whole number of hours. Where the 75th percentile was on the half hour, it was

Table I Distribution of the duration of operation and number of surgical site infections (SSIs) in English data by category of surgical procedures

Category of surgical procedure	Number of operations	SSI	(% SSI)	Range of times (min)	Times at percentiles (min)		
					p25	p50	p75
Abdominal hysterectomy	8581	193	(2.2%)	17–500	52	66	90
Bile duct, liver, pancreas surgery	188	21	(11.2%)	35–600	141	200	240
Cholecystectomy	115	4	(3.5%)	20–375	60	90	140
CABG – chest and donor site	13 777	539	(3.9%)	35–980	160	195	235
CABG – chest only	985	34	(3.5%)	45–555	140	180	215
Gastric surgery	342	34	(9.9%)	15–515	60	107	200
Total hip replacement	28 431	652	(2.3%)	12–490	73	95	120
Hemiarthroplasty	9647	494	(5.1%)	12–459	45	60	80
Knee prosthesis	19 923	316	(1.6%)	11–300	70	90	110
Large bowel surgery	8965	814	(9.1%)	20–940	90	130	175
Limb amputation	1449	223	(15.4%)	10–230	32	55	79
Open reduction of long bone fracture	4330	184	(4.2%)	10–470	52	75	110
Small bowel surgery	1056	94	(8.9%)	10–525	65	105	160
Vascular – aorta	1557	85	(5.5%)	10–770	135	180	230
Vascular – carotid	855	2	(0.2%)	14–380	90	120	150
Vascular – femoral	2114	238	(11.3%)	10–995	115	160	219
Vascular – other	532	38	(7.1%)	25–800	105	155	210

CABG, coronary artery bypass graft.

rounded up to the nearest whole number of hours. This was the same method used to determine the US NNIS T times for data captured since 1987.²

Chi-square test was used to compare the rates of SSI between operations of long (greater than the T time) and short (less than or equal to the T time) duration using both the English and the US T times by surgical category.

The validity of the T time in denoting procedures at higher risk of SSI was tested for each category of surgical procedure by plotting the *P* value for the difference between rates of SSI for procedures above and below a cut point, with cut points set at 15-min intervals in the duration of the operation. Where the *P* value at a particular cut point is below 0.05, this indicates a significant difference in the rate of SSI between operations above and below the time. This difference may indicate that the rate of SSI above the cut point is either significantly higher than the rate of SSI below the cut point time or significantly lower. If there is no significant difference between rates of SSI above and below the T time for a particular category of procedures, this suggests that either this T time is not associated with SSI or there is insufficient power to detect an association. The latter is most likely to occur at very long or short durations where the number of operations is small.

Data analysis was performed using Stata Version 8.x. (StataCorp, College Station, TX, USA).

Results

Table I shows the number of procedures, rate of SSI and distributions in duration of operation. These were positively skewed for all categories.

Comparison between English and US T times

The duration of operation at the 75th percentile in the English data was different to the US 75th percentile time in all categories of surgical procedure. The 95% confidence intervals suggest that these differences were significant for all categories except for large bowel surgery. However, when the English 75th percentile time was converted into a T time by rounding the time to the nearest whole hour, the English and US T times (in hours) were the same for all surgical categories except CABG (chest and donor sites) and vascular surgery (Table II).

The segregation of vascular surgery into four groups of procedures showed considerable variation in 75th percentile time between different types of procedure (Table I). Procedures involving the aorta had a 75th percentile time that was 80 min longer than procedures on the carotid artery. Apart from carotid surgery (3 h), all groups had a T time of 4 h. These times compared with a US T time for vascular surgery of 3 h.

Table II Comparisons of English and US T times

Category of surgical procedure	English T times			US T times	
	p75	95% CI	T (h)	p75	T (h)
Abdominal hysterectomy	90	90–90	2	120	2
Bile duct, liver, pancreas surgery	240	230–260	4	224	4
Cholecystectomy	140	120–165	2	110	2
CABG – chest and donor site	235	235–240	4	276.6*	5
CABG – chest only	215	210–220	4	255*	4
Gastric surgery	200	180–215	3	152	3
Hip prosthesis	113	112–115	2	130.8*	2
Knee prosthesis	110	110–111	2	121.8*	2
Large bowel surgery	175	175–180	3	180	3
Limb amputation	79	75–81	1	85	1
Open reduction of long bone fracture	110	105–110	2	130	2
Small bowel surgery	160	150–170	3	199	3
Vascular surgery	210	205–210	4	202	3

*p75 times, personal communication (J. Edwards and T.C. Horan).
CI, confidence intervals; CABG, coronary artery bypass graft.

The segregation of hip prostheses into total hip replacement and hemiarthroplasty procedures showed a difference of 40 min in the 75th percentile time for these two types of procedure, converting to T times of 2 and 1 h, respectively. Distributions of the duration of operation of the two procedures were also markedly different, with a shorter range of times for hemiarthroplasties (Table I).

Proportion of operations above the T time

In 14 categories of surgical procedures (Table I), the proportion of procedures with the duration of surgery above the English T time was between 8% and 25%. In three categories, a higher proportion of procedures were above the T time: gastric surgery (29%), cholecystectomy (31%) and limb amputation (39%). Moving the cut point can markedly affect the proportion, e.g. changing the T time for CABG (chest and donor sites) from 5 h to 4 h increases the percentage of operations above the cut point from 5% to 21%. However, if the T time of 2 h for hip prosthesis surgery was applied to hip hemiarthroplasty operations, only a very small proportion of operations (4%) would be above the T time. Rounding the 75th percentile of 80 min to 1 h resulted in almost half the hemiarthroplasty operations being above the cut point, whereas a T time

of 1.5 h had a more acceptable proportion of operations (15%) above the cut point.

Relationship between T time and incidence of SSI

In total, 3965 SSIs (overall infection rate of 3.9 infections/100 operations) were reported to the SSISS during the five years. The percentage of operations that developed an SSI varied by category of procedure (Table I).

To evaluate whether T time was associated with risk of SSI, the incidence of SSI in operations with a duration greater than the T time was compared with the incidence of SSI in operations with a duration at or below the T time. The incidence of SSI was higher in procedures with durations above the T time in all categories except for hip prosthesis, and was significantly higher in abdominal hysterectomy, CABG, gastric surgery, knee prosthesis, large bowel surgery and vascular surgery. This difference was observed for both the English and the US T times. When hip prostheses were segregated into total hip replacement and hemiarthroplasty, the incidence of SSI in total hip replacements was also significantly higher for procedures with duration of operation greater than the T time (Figure 1). In hip hemiarthroplasty, the incidence of SSI was higher in procedures with a duration of 1.5 h, but the difference was not statistically significant. In vascular surgery, only procedures involving the femoral artery had a significantly higher incidence of SSI above the T time.

The association between risk of SSI and duration of operation is illustrated in Figure 2. In abdominal hysterectomy, there is an association between incidence of SSI and T time when the cut points for duration of operation are between 45 and 240 min. This is illustrated by a *P* value of less than 0.05 for the difference in incidence of SSI above and below these times (Figure 2a). In the hip prosthesis category, where both total and hip hemiarthroplasty were grouped together, there was an association between risk of SSI and operations of between 195 and 215 min. However, there was no association at the T time of 120 min for this category (Figure 2b). If separated into total hip and hip hemiarthroplasty procedures, there was only a significant association between risk of SSI and duration of operation at the T time for total hip replacements (Figure 2c). In hip hemiarthroplasties, no clear cut point was associated with a significant difference in risk of SSI. This suggests that the T time at either 1, 1.5 or 2 h is not a good indicator of risk of SSI in this category of procedures (Figure 2d).

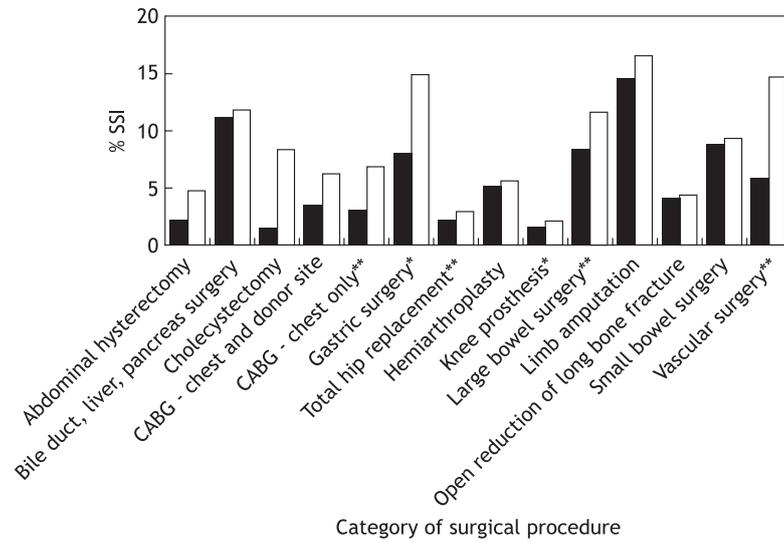


Figure 1 Risk of surgical site infection (SSI) in operations with durations above (open bars) and equal to or below (solid bars) the English T time by category of surgical procedure. * $P < 0.01$, ** $P < 0.05$. CABG, coronary artery bypass graft.

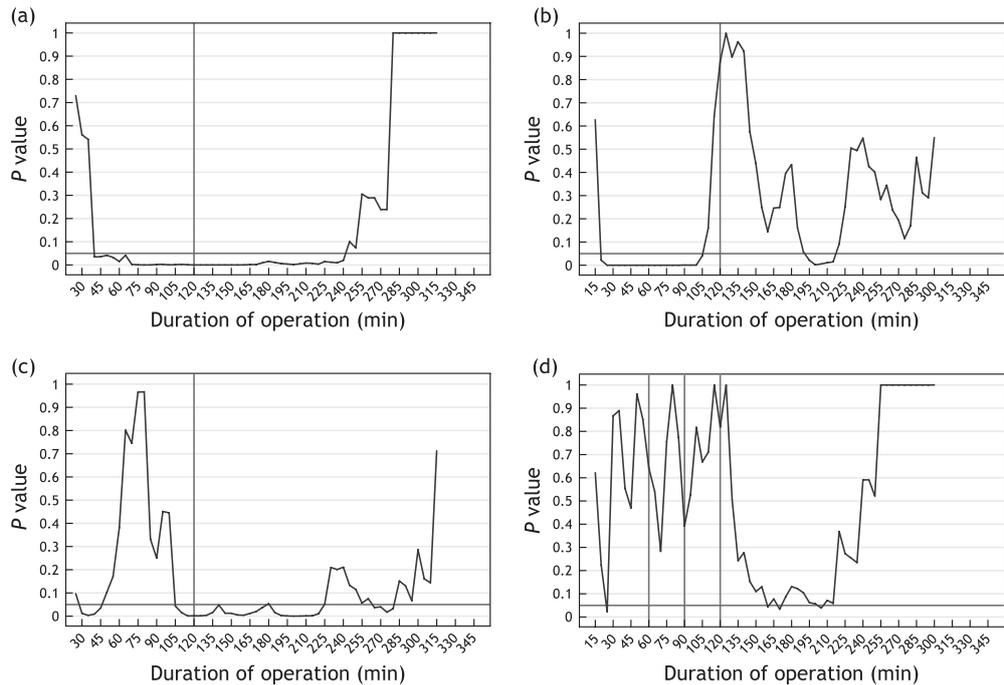


Figure 2 Association between P value and cut point for duration of operation for (a) abdominal hysterectomy procedures, (b) hip prosthesis procedures (both total hip and hemiarthroplasty), (c) total hip prosthesis procedures, and (d) hip hemiarthroplasty procedures. *X-line indicates both the US and English T times at 120 min (2 h) and the English T time at 60 min (1 h) and 90 min (1.5 h) for hip hemiarthroplasty procedures.

A significant difference in the incidence of SSI could indicate that the risk above the cut point is either higher or lower than the risk of SSI below the cut point. In the categories included in this analysis, the incidence of SSI was significantly higher above the cut point, except in the hip prosthesis category, where the rate of SSI was significantly lower above the cut point times between 15 and 105 min (Figure 2b).

Digit preference in recording the duration of operation was observed in all surgical categories. This occurs because the actual duration of the operation was rounded (up or down) to the nearest 5 or 10 min by the person recording the data. This effect is reflected by the small peaks or dips in association between risk of SSI and duration of operation that can be seen in Figure 2. The effect of digit preference is illustrated in Table III where the number of operations with a duration of operation at 120 min (T time for total hip prosthesis) is disproportionately greater than the neighbouring times.

Discussion

Extended duration of surgery has been identified as an independent risk factor for SSI by some studies, and may serve as a marker for the complexity of the individual case, some aspect of surgical technique, prolonged exposure to microorganisms in the operating environment, and diminished efficacy of antimicrobial prophylaxis.^{2,6}

The duration of operation is a component of the US NNIS risk index, which is widely used internationally as a means of stratifying SSI surveillance

data by risk. It has also been used to stratify data for the SSI surveillance scheme in England since the scheme commenced. Changes in the US 75th percentile times have been observed over the years, possibly due to changing operative techniques and case mix.^{7–12} As a result, some alterations have been made to the NNIS T times. These include the separation of joint prosthesis into hip, knee and other prosthesis, and the separation of CABG into operations involving a chest incision only and those with incisions at both the chest and donor sites.⁷ In 1997, the T time of the CABG (chest incision only) procedure decreased from 5 h to 4 h,⁸ and in 2003, the T time for the limb amputation procedure increased from 1 h to 2 h.¹¹

Campos *et al.* argued that since the length of operation may reflect not only factors intrinsic to the patient but also the influence of extrinsic factors surrounding the operation, a locally defined cut point may be a better predictor of the risk of SSI inherent in the local setting.¹³ The disadvantage of this approach is that rates cannot be compared with those published by the Centers for Disease Control and Prevention and other institutions and countries using the standard NNIS T times.⁴

Since surgical techniques may vary between countries, some national surveillance systems have developed their own approach to determining a cut point for duration of operation. Some countries use a 75th percentile time in minutes derived from their own data as the cut point for stratification in the risk index instead of the NNIS T times.^{14–16} However, it is important to consider the advantages of using a T time rather than a specific 75th percentile time. In particular, since the T time is rounded to the nearest hour, it provides a more stable indicator of procedures that are of unusually long duration.

It is also important to take account of the proportion of procedures denoted as being of unusually long duration by a particular cut point. In Brazil, surveillance data from a hospital collected over six years showed that the risk of SSI associated with operations of long duration was overestimated when the NNIS T time was applied.¹³ Most of their surgical procedures had a longer duration of surgery, shown by their higher cut points when compared with the NNIS T times, which would imply that the proportion of infection above the NNIS T time would not be indicative of a long duration of surgery in Brazil.¹³

This large English dataset of operation times has provided an opportunity to evaluate the 75th percentile and T times compared with US data. The

Table III An example of digit preference in the allocation of duration of operation for total hip prosthesis

Time (min)	Number of operations
114	58
115	715
116	64
117	81
118	92
119	46
120*	1337
121	51
122	70
123	72
124	55
125	450
126	54

*Total hip prosthesis T time of 2 h (120 min).
Shaded rows indicate effect of digit preference.

analysis has shown that although there is a significant difference in 75th percentile time for most of the 13 categories of surgical procedures, this only affected the T time in two categories: CABG (chest and donor sites) and vascular surgery.

The 75th percentile time for CABG (chest and donor sites) procedures in England was 42 min less than the US time. While this may reflect differences in surgical technique between the two countries, it is also conceivable that the NNIS 75th percentile time derived in 1991 does not match current surgical practice in the USA. The difference in 75th percentile time between English and US data (235 min vs 277 min) reduced the English T time for CABG (chest and donor sites) procedures to 4 h from the US T time of 5 h. However, both of these T times were significantly associated with an increased risk of SSI. Using the English T time for CABG (chest and donor sites) resulted in 21% of operations being classified as of long duration as opposed to 4% with a T time of 5 h. Although this proportion may be considered more representative of operations of long duration, it is of note that the majority of CABG procedures performed in England involved a donor site (93%), and this may reflect underlying differences in case-mix or clinical management.

In vascular surgery, the English T time was 1 h longer than the US T time. However, subcategorization of these procedures suggests that the T time varies in different types of procedure, and the variation between the English and US T times may be explained by the frequency with which different types of procedure are performed. However, this analysis suggests that the current US T time of 3 h adequately discriminates operations at increased risk of SSI.

Hip hemiarthroplasty procedures account for about one-quarter of hip prosthesis procedures in England and have a cumulative rate of SSI detected in inpatients that is more than twice that of total hip procedures. The approach of the English SSISS has therefore been to separate the two procedures. The method of defining T time by rounding to the nearest whole hour presents difficulties when the duration of the operation is short. Rounding to the nearest whole hour would indicate a T time of 1 hour for hip hemiarthroplasties. However, for operations of such a short duration, rounding to a whole hour obscures the 75th percentile time and results in a T time that does not discriminate procedures of long duration. The English SSISS has chosen a T time of 1.5 h for hip hemiarthroplasty as this time designates a more reasonable proportion of the operations as being of long duration. However, the duration of operation does not seem to be a significant risk factor for SSI in hip hemiarthroplasties.

Digit preference is acknowledged as a problem associated with the measurement of continuous variables.¹⁷ This analysis has shown the strong effect that digit preference has on recorded operation times, leading to a non-uniform distribution.¹⁷ Since a T time will always represent a specific number of whole hours, digit preference will result in a proportion of operations with durations close to the T time being recorded with durations the same as the T time. However, since only those operations with duration above the T time are classified as being at greater risk of SSI, digit preference is likely to result in more operations being classified as less than the T time than is truly the case. The effect of digit preference on this analysis would therefore be to underestimate the true association between risk of SSI and operations lasting for longer than the T time. This is unlikely to introduce a large bias into the association and, as can be seen in [Figure 2](#), the association between risk of SSI and duration of operation (or lack of it) is not crucial to the T time.

In conclusion, this analysis has demonstrated that despite differences in the 75th percentile times, the current US T times are the same as those calculated from English data in 11 out of 13 categories.

Whilst some countries have chosen to use local 75th percentile times as the cut-off point between procedures of high and low risk of SSI, this analysis supports the use of the T time as it reliably discriminates between procedures of low and high risk of SSI. In addition, it provides a more stable indicator of the cut point between operations of long and short duration, is less likely to be affected by small imprecisions in estimating the length of the operation or improvements in surgical techniques, and is less vulnerable to changes that would affect the comparability of historic data.

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Appendix 4.1.

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Hospitals in Europe Link for Infection Control through Surveillance (HELICS). Inter-country comparison of rates of surgical site infection – opportunities and limitations

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KEYWORDS

Surgical site infection;
Surveillance;
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Summary Many countries in Europe have created national systems for the surveillance of healthcare associated infections (HCAI). The Hospitals in Europe Link for Infection Control through Surveillance (HELICS) has provided a standardised approach to surveillance of HCAI and formed a 'network of networks' to enable data from hospitals contributing to national networks also to be submitted to the HELICS database. This paper describes the set of surgical site infection surveillance data collected in 2004. It includes 111,361 operations in six categories of surgical procedure from 14 countries. The analysis demonstrates that incidence density provides a better measure for comparison than cumulative incidence as it takes some account of difference in length of post-operative stay and post-discharge surveillance. Comparisons should also take account of differences in mix of procedures, variation in risk factors and sensitivity of case finding. This rich dataset provides a unique opportunity to explore variation in rates of SSI and improve understanding of factors that impact on inter-country comparisons.

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Introduction

Surgical site infections (SSI) account for between 11% and 26% of healthcare associated infection.¹⁻⁹ They cause considerable morbidity, increase the

costs of healthcare, and in some cases, increase the risk of death.^{4,10} The risk of developing a SSI depends on a number of factors related to both the patient and the operation. Whilst it may not be possible to prevent all SSI, studies have shown that peri-operative procedures, the skill of the surgeon and post-operative care are critical in minimising the risk.¹¹ In addition, surveillance and feedback

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Table 1
Data contributed to HELICS in 2004^a

Procedures	No. of countries	No. of operations	Percentage of surgical infections (95% CI)
Coronary artery bypass graft	8	12,234	3.7 (3.3–4)
Cholecystectomy	8	16,380	1.3 (1.2–1.5)
Colon surgery	9	10,778	8.9 (8.3–9.4)
Caesarean section	8	19,580	2.7 (2.5–3)
Hip prosthesis	14	49,496	2.2 (2.1–2.4)
Laminectomy	6	2,913	1.2 (0.9–1.7)
Total	14	111,361	

^a The 4 countries in the United Kingdom have been counted separately.

of data on SSI to clinical staff has been shown to be a key factor in achieving reductions in rates of SSI.^{12–14}

The Hospitals in Europe Link for Infection Control through Surveillance (HELICS) was established to facilitate both a standardised approach to surveillance of healthcare associated infections (HCAI) and to encourage the development of new surveillance systems for HCAI. Many countries in Europe have created national surveillance systems focused on monitoring HCAI and based on local networks of hospitals contributing standard datasets to a central organisation. The surveillance of surgical site infections (SSI) are an important focus of activity for many of these European systems. Therefore, rather than creating a new layer of surveillance HELICS has formed a 'network of networks', with partner countries adopting the standard HELICS protocol within their own surveillance systems and enabling data from hospitals contributing to National networks to also be submitted to the HELICS database. The standard protocol for the surveillance of SSI has been largely based on other internationally-recognised approaches to surveillance of HCAI¹⁵ and is currently focused on six categories of surgical procedure (Table 1). A major issue for HCAI surveillance is the resources required to collect, analyse and feed back the data to local clinicians. To address this problem HELICS has developed software that enables hospitals to collect and analyse data for both SSI and ICU surveillance.

The aims of the HELICS protocol are to contribute to nosocomial infection surveillance in Europe by describing the epidemiology of SSI, improving our understanding of inter-country variation in rates of SSI and facilitating improvements in quality of care in a multi-centre setting. Partner countries began contributing data from their national networks to HELICS from 2000. This paper reports data contributed to HELICS in 2004 and explores some of the strengths and limitations of the dataset. More

detailed analyses can be found in statistical reports available on the HELICS website.

Methods

The approach taken by HELICS to SSI surveillance is to enhance comparability of data by targeting clearly defined groups of procedures and collecting data that enable adjustment for variation in case-mix. Procedures eligible for inclusion in the surveillance are defined in the surveillance protocol using National Nosocomial Infection Surveillance (NNIS) procedure code, and the International Classification of Diseases 9 – CM code collected where available. A set of demographic and surgical operation data are collected on all patients undergoing an eligible procedure and additional data provided on those patients that subsequently develop an SSI. Infections reported should meet the specific criteria described in the standard case-definitions that were adopted from the NNIS system.¹⁵ Adjustment for case-mix is based on the NNIS risk index.¹⁶ This is comprised of wound class of contaminated or dirty (reflecting the likelihood of microbial contamination in the wound); American Society of Anesthesiologists' (ASA) physical status classification score of 3 or more (indicating severe underlying systemic disease in the patient); and a duration of operation of greater than the time at the NNIS 75th centile time (T time) for that group of procedures. Each factor is equivalent to one point and each operation is therefore allocated a risk index score of between 0 and 3 depending on how many of the factors are present.

Two indicators have been used to express the risk of SSI: the cumulative incidence, which is the crude percentage of operations resulting in a SSI, and the incidence density, which is the number of SSI per 1000 post-operative days at risk (i.e. without prior SSI) in the hospital. The incidence density is the preferred measure for the comparison of incidence between countries as it

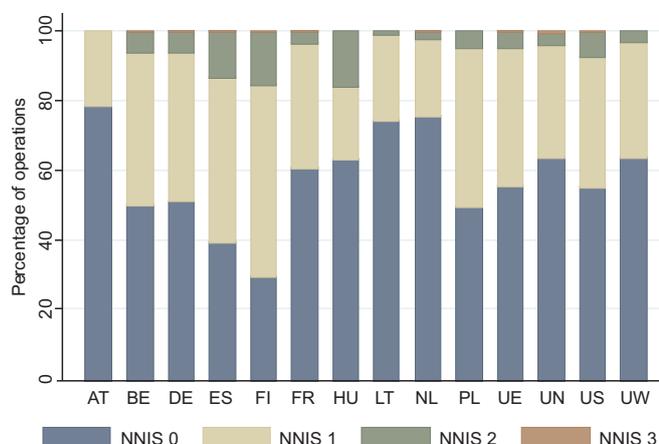


Fig. 1. Distribution of hip prosthesis (HPRO) procedures by NNIS risk index group and country. Key: AT Austria, BE Belgium, DE Germany, ES Spain, FI Finland, FR France, HU Hungary, LT Lithuania, NL Netherlands, UE England, UN Northern Ireland, US Scotland, UW Wales.

uses only observations during the hospital stay in both numerator and denominator and comparison are therefore less affected by variation in length or post-operative stay or intensity of case-finding post-discharge. However, the incidence density can only be calculated when the discharge date is known.

Results

Participation in HELICS-SSI surveillance in 2004

SSI surveillance data were received from 14 networks in 11 countries and included over 600 hospitals (Table 1). The types and numbers of operations reported by each partner country depended on the scope and capacity of their national surveillance systems.

Characteristics of patients and surgical procedures

The distribution of patient age and gender were broadly similar across countries and across most categories of surgical procedure. However, variation in the mix of procedures within a specific category can result in considerable within category variation. This effect is particularly marked in hip surgery where the median age of patients varied from 83 years for partial hip prosthesis to 69 years for total hip replacements. Such variation can be important when comparing rates of SSI between countries with a different mix of procedures.

Stratification by NNIS risk index also demonstrated evidence of between-country variation in the prevalence of risk factors. This is illustrated by the distribution of risk index for hip surgery shown in Figure 1.

Characteristics and rates of SSI

The cumulative incidence of SSI for each category of surgical procedures is shown in Table 1. For most categories of procedure the incidence increased with risk index group. In hip prosthesis differences in the mix of total and partial hip procedures included in the hip prosthesis category may impact on the rate of SSI as the risk of SSI varies by procedure (see Table 2). In some countries only total hip procedures have been included in the category (e.g. Scotland, Germany, Hungary) while in other countries (e.g. England, Northern Ireland and Spain) more than 20% of operations in the category are partial hip procedures. Major

Prosthesis	ICD-CM9	Cumulative incidence (% SSI) at 30 days post-op	Incidence density In-hospital SSI per 1000 post-op days
All hip		2.2	1.8
Total hip	81.51	1.6	1.7
Partial hip	81.52	4.0	2.2

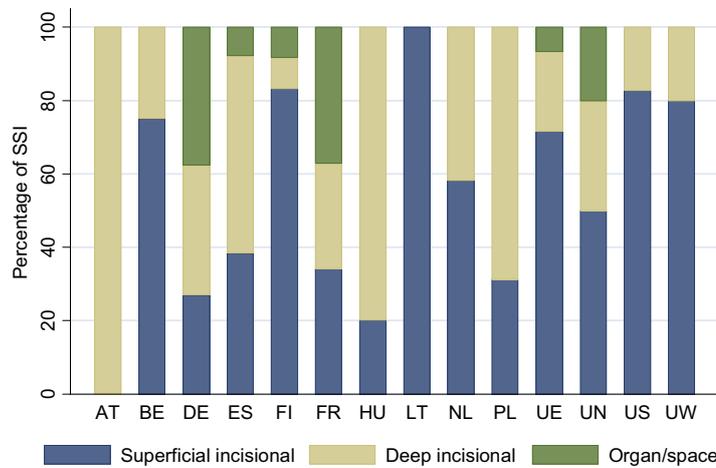


Fig. 2. Type of surgical site infection reported for the hip prosthesis (HPRO) category of surgical procedures by country. Key: see Fig. 1.

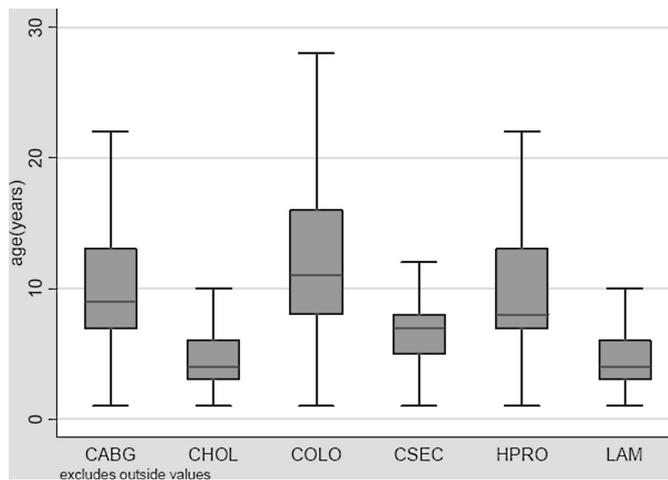
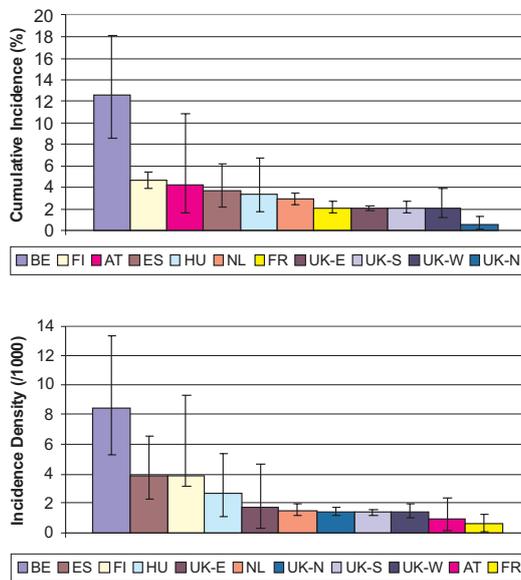


Fig. 3. Median and range of post-operative patient-days in hospital by category of surgical procedures, aggregated by hospital. Key: CABG, coronary artery bypass graft; CHOL, cholecystectomy; COLO, colon surgery; CSEC, caesarean section; HPRO, hip prosthesis; LAM, laminectomy.

differences between countries were also observed in the type of SSI reported within the same operation category. For example, in hip prosthesis superficial SSI accounted for about 80% of the infections in the data from Belgium, Finland, England, Scotland and Wales, but in Germany, Spain, France and Poland they accounted for only 30% of infections (Figure 2).

The median length of post-operative stay in hospital varied considerably, both between categories and within countries (see Figure 3). In addition, the intensity of post-discharge surveillance (PDS) also varied markedly between countries with some countries, e.g. England, undertaking no

PDS. These factors have a major impact on the validity of inter-country comparisons based on cumulative incidence of SSI. Therefore in-patient incidence densities are preferred for such comparisons as they take some account of variation in follow-up period. Figure 4 demonstrates that when countries are ordered by rate of SSI their relative position varies according to whether the cumulative incidence or incidence density is used. This figure also illustrates the importance of taking account of the precision of the estimated rate. For example, although the rates in Belgium are high they are based on only 191 operations from four hospitals.



Country	No. of hospitals	No. of procedures
Belgium (BE)	4	191
Spain (ES)	6	379
Finland (FI)	10	2,854 ^a
Hungary (HU)	11	235
England (UK-E)	136	18,443
Netherlands (NL)	25	4,079
Northern Ireland (UK-N)	NA ^b	2,001
Scotland (UK-S)	NA	3,010
Wales (UK-W)	NA	472
Austria (AT)	2	93
France (FR)	278	2,759

^a 2003 data. ^b NA, not available.

Figure 4. Comparison between (top) cumulative incidence and (bottom) incidence density of SSI for hip prosthesis by country. Bars represent 95% confidence limits.

Discussion

This analysis of HELICS data provides an important opportunity to explore inter-country variation in rates of SSI and some of the underlying causes. The data suggest that whilst most of the basic characteristics of patients undergoing surgical procedures are similar there are important differences between countries in terms of case mix (as reflected in the risk index score), reporting of SSI (as reflected by the proportion of superficial infections) and length and intensity of post-operative follow-up. The effect of the latter

is particularly important when comparing inter-country differences in rates of SSI.

Observation periods and methods of follow-up differ between countries: some countries only observe SSI during hospital stay, while others undertake post-discharge surveillance on some or all patients included in the surveillance. Moreover, length of stay and therefore the in-hospital observation period differs between operation types, between countries, between hospitals and between individuals within those hospitals. These differences probably reflect both differences in healthcare services (e.g. early discharge/rehabilitation facilities, bed occupancy pressures) and types of procedure included in the surveillance (e.g. less complex procedures). The duration of post-operative stay in hospital is an important factor in determining whether SSI will be detected. Once the patient has been discharged detection of SSI will depend on whether post-discharge surveillance is undertaken and, if so, its efficacy. Measuring rates of SSI as incidence density has the advantage of removing some of the observation bias caused by the both the different lengths of observation in hospital and intensity of surveillance post-discharge by dividing only those SSI detected in hospital by the period of in-hospital observation. However, it is important to recognise that by 3 weeks after the operation the reported incidence of SSI is very low (probably a combination of fewer infections occurring and low intensity of surveillance after discharge from hospital). Therefore rates of SSI are progressively underestimated as time from operation increases.

Some of the variation in incidence of SSI may also be explained by the considerable difference in number and type of procedures supplied by participating countries. Furthermore, there was also evidence of heterogeneity in the types of procedures performed within a category. This effect was most notable in the hip prosthesis category. As a result, some of the overall analyses were strongly influenced by data from one or two of the participating networks, while some country data were based on very few procedures from a small number of hospitals and may therefore not be generalisable to the country as a whole. The impact of these effects should diminish as newer networks become more established and are able to submit more data, from more hospitals, to HELICS.

The observed differences between countries in the type of SSI reported may be due to true differences in the severity of infections, in the interpretation of the case definition, in the sensitivity of case finding/reporting, or to a combination of all these reasons. These differences may

also lead to bias when comparing rates between countries and points to the need to encourage more validation of the surveillance systems since accurate case-finding is also important for within country comparisons.

Comparisons between countries in rates of HCAI are increasingly being used to draw conclusions about the quality of healthcare and infection control practice. Whilst in some circumstances this may be valid, this analysis has demonstrated some of the difficulties associated with making inter-country comparisons of rates of HCAI. The data contributed to HELICS have the advantage of providing relatively detailed, patient-level data on HCAI and consequently enable variation in both risk factors and methodology to be explored. Understanding the impact of these factors is essential to prevent inappropriate conclusions being drawn. In addition, this large and rich dataset provides an opportunity to investigate the occurrence of SSI before and after discharge from hospital and some of the causes for heterogeneity, both within surgical categories and between countries, in rates of SSI.

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Appendix 4.2.

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ORIGINAL ARTICLE

Rates of Surgical Site Infection After Hip Replacement as a Hospital Performance Indicator: Analysis of Data From the English Mandatory Surveillance System

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OBJECTIVE. To describe rates of surgical site infection (SSI) after hip replacement and to use these data to provide a simple mechanism for identifying poorly performing hospitals that takes into account variations in sample size.

DESIGN. Prospective surveillance study.

SETTING. A total of 125 acute care hospitals in England that participated in mandatory SSI surveillance from April 1, 2004 through March 31, 2005.

PATIENTS. Patients who underwent total hip replacement (THR) or hip hemiarthroplasty (HH).

METHODS. A standard data set was collected for all eligible operations at participating hospitals for a minimum of 3 months annually. Defined methods were used to identify SSIs that occurred during the inpatient stay. Data were checked for quality and accuracy, and funnel plots were constructed by plotting the incidence of SSI against the number of operations.

RESULTS. Data were collected on 16,765 THRs and 5,395 HHs. The cumulative SSI incidence rates were 1.26% for THR and 4.06% for HH; the incidence densities were 1.38 SSIs per 1,000 postoperative inpatient days for THR and 2.3 SSIs per 1,000 postoperative inpatient days for HH. The risk of infection associated with revision surgery was significantly higher than that associated with primary surgery (2.7% [95% confidence interval, 2.0%-3.5%] vs. 1.1% [95% confidence interval, 1.0%-1.2%]; $P = .003$). Rates varied considerably among hospitals. Nineteen hospitals had rates above the 90th percentile. However, the use of funnel plots to adjust for the precision of estimated SSI rates identified 7 hospitals that warranted further investigation, including 2 with crude rates below the 90th percentile.

CONCLUSIONS. Funnel plots of rates of SSI after hip replacement provide a valuable method of presenting hospital performance data, clearly identifying hospitals with unusually high or low rates while adjusting for the precision of the estimated rate. This information can be used to target and support local interventions to reduce the risk of infection.

Infect Control Hosp Epidemiol 2008; 29:219-226

Surgical site infection (SSI) accounts for up to 15% of health-care-associated infections (HAIs) and is associated with considerable morbidity, mortality, and an increase in the cost of care.¹⁻⁵ Surveillance of SSI was first recognized as an important tool for reducing rates of infection in the 1980s.^{6,7} Since then, many national systems aimed at facilitating surveillance and benchmarking rates of HAI have been established.⁸⁻¹³ In recent years, consumer demand for information about the performance of healthcare providers has led to the compulsory public reporting of data on HAIs.¹⁴ This reporting has highlighted the need to define effective indicators that can be used to target and measure the efficacy of infection prevention strategies, as well as the need to communicate more clearly the risks of HAI to patients.¹⁵

Surveillance of SSI in orthopedic surgery patients became

mandatory in England in April 2004 and was supported by the Surgical Site Infection Surveillance Service (SSISS). Mandatory surveillance required that all National Health Service hospitals undertake, for a minimum of 3 months annually, surveillance of SSI associated with at least 1 category of orthopedic procedure. Results are reported back to individual hospitals at the end of each surveillance quarter, and the rates of SSI by procedure and hospital are published annually.

Although the public reporting of SSI rates has the benefit of providing consumers and stakeholders with information for making healthcare choices,¹⁴ for these choices to be properly informed, mechanisms must be in place that ensure the quality of the data and that take into account the precision of estimated rates. Simple league tables, although easy to read, can be highly misleading, because the precision of an esti-

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ated rate will vary according to the total number of operations and the period of surveillance. The aim of such benchmarking should be to identify those units for which resources can be effectively directed at improving their performance. A mechanism for identifying poorly performing hospitals that is simple but not misleading and that takes into account chance variations is therefore required.¹⁶

This article describes the data collected during the first year of mandatory surveillance of SSI in orthopedic surgery for patients who underwent total hip replacement (THR) or hip hemiarthroplasty (HH) in England. It uses these data to explore the strengths and weaknesses of the methods used to identify hospitals with outlying rates, and to provide a method of presenting hospital performance data that aims to meet the key goals of simplicity and avoiding misinterpretation.

METHODS

Surveillance Method

Hospitals that participate in the surveillance are required to collect data on a standard set of demographic and surgical factors for all eligible procedures performed according to a defined protocol. This includes data on 3 major risk factors for infection: an American Society of Anesthesiologists physical status classification of 3 or more, a wound class of "contaminated" or "dirty," and an operation lasting longer than 2 hours for THR¹⁷ or 1.5 hours for HH.¹⁸ Each operation is allocated a risk index score of 0 (no risk factors) through 3 (all risk factors).¹⁷ Hospitals are required to submit records for each operation undertaken in the relevant surveillance period, even if the risk factor data are not complete. Patients are then systematically monitored during their postoperative inpatient stay, and those who develop an SSI that meets the case definition are identified. The case definition is based on that used in the National Nosocomial Infection Surveillance (NNIS) system, but with some modifications (Appendix). Regular training programs in the surveillance method are held by the Health Protection Agency for personnel with designated responsibility for the surveillance.

Data Management

Once a patient has been discharged, data are submitted to the SSISS via a Web-based system that enables errors and inconsistencies to be flagged and corrected on entry. At the end of each surveillance quarter, a report that contains the results, together with comparisons with benchmark data from all participating hospitals, is generated by the SSISS and sent to each participating hospital.

Statistical Analysis

The cumulative incidence rate is assumed to have a binomial distribution, and the number of infections is assumed to come from the closely related Poisson distribution. Only the first SSI detected is included in the analysis. The cumulative in-

idence rate was calculated by dividing the number of SSIs by the number of operations performed in that category of surgical procedure. Incidence densities were calculated by dividing the number of SSIs by the number of postoperative inpatient days of surveillance (ie, days between date of operation and date that surveillance was discontinued or date that SSI was first identified).

Funnel plots were constructed by plotting the incidence rate from the data collected by each hospital against the number of operations or the number of postoperative inpatient days on which the rate was based. Conventional warning and action limits equivalent to exact 95% and 99% confidence intervals (CIs) around the pooled incidence rate were applied, together with an additional 90% CI. Two-sided CIs were used to enable one to distinguish unusually high rates that merit investigation from unusually low rates that may reflect either an exceptionally good performance worthy of emulation by others or the poor sensitivity of case finding.

Exact CIs have been used because normal approximation methods are unreliable when the number of SSIs is less than 10, and, in this situation, they will generate lower limits below zero.¹⁹ It was assumed that occurrences of SSI are independent of each other because, generally, these infections are not transmitted among patients. There was no strong evidence of overdispersion.

RESULTS

A total of 125 acute care hospitals submitted data on 22,160 hip replacement operations from April 1, 2004 through March 31, 2005 (Table 1). The average number of operations included per hospital per calendar quarter was 59 (interquartile range [IQR], 13-78) for THR and 30 (IQR, 19-36) for HH. A total of 28 (22%) hospitals undertook surveillance for 4 quarters (10 [8%] for 3 quarters, 36 [29%] for 2 quarters, and 51 [41%] for 1 quarter).

Rates of SSI

The cumulative incidence rates shown in Table 1 suggest that the risk of SSI after HH is 3 times greater than the risk after THR. However, because the surveillance currently only detects SSIs that occur while the patient is still in the hospital, this incidence rate will be affected by the length of the postoperative stay. The median length of the postoperative stay for THR patients was 7 days (IQR, 5-10), compared with 14 (IQR, 9-25) for HH patients. Calculating the rate of SSI as incidence density showed that, although the risk of SSI after HH was still higher, the difference was reduced to 1.7 times the risk of SSI after THR (Table 1).

The most common indication for THR was osteoarthritis (11,400 [68%] of 16,765 operations); 2,012 (12%) of THR operations were revision surgery of a previous arthroplasty. The risk of infection associated with revision surgery (2.7% [95% CI, 2.0%-3.5%]) was significantly higher than that associated with primary surgery (1.1% [95% CI, 1.0%-1.2%];

TABLE 1. Incidence Density and Cumulative Incidence Rate of Surgical Site Infection (SSI), by Procedure

Procedure	No. of hospitals	No. of procedures	No. of postoperative inpatient days	No. of SSIs	Cumulative incidence rate, %	Incidence density, SSIs per 1,000 postoperative inpatient days
Total hip replacement	108	16,765	152,830	211	1.26	1.38
Hip hemiarthroplasty	71	5,395	95,268	219	4.06	2.30
Overall	125	22,160	248,098	430	1.94	1.73

$P = .003$), and risk was even higher for revision surgery to treat infection (10.9% [95% CI, 6.5%-16.9%]; $P < .001$) (Table 2). Trauma was the primary indication for surgery for 4,656 (86%) of 5,395 HH operations.

The SSI cumulative incidence rate increased when the number of risk factors present for both THR (χ^2 test for trend $P < .001$) and HH (χ^2 test for trend $P = .001$) (Table 3) increased. In 18% of the records, a risk index score could not be calculated because data were missing on at least 1 of the risk index factors.

Most of the SSIs reported were superficial. However, 56 (27%) of the 211 SSIs in THR patients and 73 (33%) of the 219 SSIs in HH patients were deep incisional or organ-space infections. Data on the probable causative organism were available for 363 (84%) of all 430 SSIs. *Staphylococcus aureus* was responsible for 233 infections, and 155 (67%) of the *S. aureus* isolates were methicillin-resistant, and a similar proportion of SSIs were caused by methicillin-resistant *S. aureus* (MRSA) isolates in THR and HH patients (66% vs 67%).

Variation in SSI Rates Among Hospitals

The SSI rates varied considerably among hospitals. Figure 1 shows the SSI rates at each hospital for THR and HH. The rates at the 90th percentile for these operations were 4.5% and 8.7%, respectively. The crude SSI rates suggest that hospital A is the worst performing hospital for THR and that

hospital L is the worst performing hospital for HH (Table 4). However, in both categories, the rates at 5 hospitals are based on fewer than 50 operations, and the exact CIs are correspondingly wide. If normal approximation CIs appropriate for small numbers were used, the lower limits would extend below zero (Table 4).

In Figure 2, the same data are presented as funnel plots. These graphs make allowance for the imprecision of the observed rate by plotting the rate of SSI (cumulative incidence) against the number of operations on which the rate is based (Figure 2a and 2b), and make allowance for the length of postoperative follow-up by plotting the incidence density of SSI against the number of days of postoperative inpatient stay (Figure 2c and 2d). Three potential action limits that denote hospitals with outlying rates of SSI have been added to these graphs, representing the 90%, 95%, and 99% CIs. Using this method with the THR results, we show in Figure 2a that only 2 hospitals (E and I in Table 4) have rates above the 95% CI and that an additional 2 hospitals (A and D in Table 4) have rates above the 90% CI. In Figure 2c, in which the length of postoperative follow-up has been taken into account, the rate of 1 hospital moves to above the 99% control limit, and an additional hospital is identified with a rate above the 90% CI. This hospital has a rate of 2.9% (based on 7 SSIs in 238 operations) that was not above the 90th percentile for cumulative incidence. In Figure 2b, for HH, no hospitals are

TABLE 2. Rates of Surgical Site Infection (SSI) for Total Hip Replacement and Hip Hemiarthroplasty, by Primary Indication for the Procedure

Primary indication	Total hip replacement			Hip hemiarthroplasty		
	No. of operations	No. of SSIs	SSI rate, %	No. of operations	No. of SSIs	SSI rate, %
Osteoarthritis	11,431	108	0.94	46	2	4.3
Inflammatory joint disease	359	5	1.39	2	0	0.0
Avascular necrosis	159	1	0.63	6	1	16.6
Trauma and/or fracture	246	9	3.66	4,735	196	4.1
Revision						
All reasons	1,965	53	2.70	172	5	2.8
Previous infection	156	17	10.90	6	2	3.0
Fracture	112	6	5.36	68	1	1.5
Other reason	1,416	25	1.77	57	2	3.5
Reason unknown	281	5	1.78	19	0	0.0
Other	351	5	1.42	22	2	9.0
Unknown	2,254	30	1.33	434	13	3.0
Overall	16,765	211	1.26	5,395	219	4.06

TABLE 3. Cumulative Incidence Rate of Surgical Site Infection (SSI), by Procedure and Risk Index Score

Risk index score	Total hip replacement ^a			Hip hemiarthroplasty ^b		
	No. of operations	No. of SSIs	SSI rate, %	No. of operations	No. of SSIs	SSI rate, %
0	8,644	73	0.8	1,441	47	3.3
1	4,343	70	1.6	2,618	108	4.1
2 and 3	794	36	4.5	394	28	7.1
Unknown	2,984	32	1.1	942	36	3.8
Overall	16,765	211	1.3	5,395	219	4.1

^a $P < .001$.^b $P = .0012$ (χ^2 test for trend [risk index score, 0–3]).

identified with rates above the 95% CI, but 2 have rates above the 90% CI. Of these, 1 hospital has a rate that is also above the 90th percentile, but the other, with a rate of 7.1% (based on 15 SSIs in 211 operations), would not have been detected as having an outlier rate by the box plot method. In Figure 2*d*, only this last hospital is identified as having an outlier rate by the 90% CI; all other hospitals with a crude rate in the top 10% have rates that lie within the 95% control limits.

DISCUSSION

In the present climate of increased concern about the risk of HAI, the prevention of HAIs continues to be the focus of considerable public and academic debate, and the demand for measures of performance and publicly reported rates of HAI has increased inexorably during the last decade.¹⁴ Surveillance undertaken locally, where participants are aware of factors in their environment that may influence the results, can be based on simple data sets. However, if a surveillance program aims to make interhospital comparisons and if the results are used to form the basis of monitoring performance, then the collection of comparable and accurate data is of paramount importance to inform reliable judgments. A key underpinning principle of surveillance and performance indicators is “information for action”; that is, that data should be used to target activities for which there is evidence that infection control procedures could be improved. Therefore, there is also a need to have an effective means of identifying exceptions that merit, at least, further investigation. One of the main problems with using SSI rates as a performance indicator is that the number of surgical procedures available for analysis is relatively small and may vary considerably among hospitals. Estimates of SSI rates made from these small volumes of data are correspondingly imprecise and therefore difficult to compare. One solution is to accumulate data over time until the number of operations is sufficient to provide a reasonably precise estimate of the SSI rate. The disadvantages of this approach are that the precision of the estimates will still vary according to the number of operations performed at different facilities, that the estimate from data collected during a prolonged period may not reflect the more

relevant current risk, and that the time taken to detect poor performance will be extended.

In this analysis, by simply ranking hospitals by crude rates of SSI for orthopedic surgery, we identified 19 hospitals in 2 categories of procedure with rates of SSI in the top 10%. However, 10 of these rates were based on fewer than 50 operations, and the estimated rates were therefore imprecise. Although exact CIs are commonly used as a mechanism for determining whether 2 rates are significantly different, for the small sample sizes associated with SSI data, the value of exact CIs is limited because they tend to be conservative. This method can imply a difference among rates that may not be real. However, normal approximation CIs, which are more appropriate for small samples, are problematic because they could generate lower limits that are below zero.

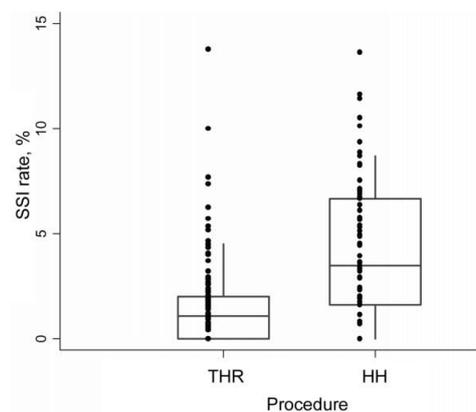


FIGURE 1. Box-whisker plot comparing rates of surgical site infection (SSI) by hospital and procedure. Each dot represents the cumulative incidence of SSI at a single hospital. The end of the upper whisker indicates the 90th percentile; the upper line of the box, the 75th percentile; the middle line of the box, the 50th percentile; the lower line of the box, the 25th percentile; and the end of the lower whisker, the 10th percentile. HH, hip hemiarthroplasty; THR, total hip replacement.

TABLE 4. Crude Rates of Surgical Site Infection (SSI) at Hospitals With Rates Greater Than the 90th Percentile, by Category of Procedure

Procedure and hospital	Period of surveillance, months	No. of operations	No. of SSIs	SSI rate, % (95% confidence interval)
Total hip replacement				
A	12	29	4	13.79 (3.89-31.66) ^a
B	3	20	2	10 (1.23-31.7)
C	6	10	1	10 (0.25-44.5) ^b
D	3	65	5	7.69 (2.54-17.05)
E	12	122	9	7.38 (3.43-13.54)
F	3	16	1	6.25 (0.16-30.23)
G	3	70	4	5.71 (1.58-13.99)
H	3	56	3	5.36 (1.12-14.87)
I	9	174	9	5.17 (2.39-9.59)
J	3	43	2	4.65 (0.57-15.81)
K	3	89	4	4.49 (1.24-11.11)
All hospitals	...	16,765	211	1.26 (1.1-1.44)
Hip hemiarthroplasty				
L	3	22	3	13.64 (2.91-34.91)
E	12	43	5	11.63 (3.89-25.08)
M	3	35	4	11.43 (3.2-26.74)
N	3	19	2	10.53 (1.3-33.14)
O	12	79	8	10.13 (4.47-18.98)
P	6	64	6	9.38 (3.52-19.3)
K	3	45	4	8.89 (2.48-21.22)
Q	12	69	6	8.7 (3.26-17.97)
All hospitals	...	53,95	219	4.06 (3.55-4.62)

^a Normal approximation confidence limits, 1.2-26.3.^b Normal approximation confidence limits, -0.09 to 29.

The funnel plots described in this article aim to address these problems by providing a relatively simple, visual means of identifying hospitals with SSI rates that are unusually high while allowing for the precision of the estimate. This method provides essential information with which to both inform and reassure patients who are about to undergo such operations and with which to convince clinicians about the need to investigate high rates of SSI. Although the probability of a rate lying above the 95% control limit by chance is low, such a finding may still be explained by chance or may reflect an unusual case mix. However, the value of using this method is that it provides an impetus to further investigate the underlying causes of this finding and minimizes the use of resources to investigate high rates of SSI that represent normal chance variation.^{20,21}

An important consideration in the construction of funnel plots is the threshold for the detection of outlier rates. In this article, we used the limits conventionally used in statistical process control charts (95% and 99% CIs). However, it is possible that different limits are required for biological systems, in which variation is probably much greater than it is in industrial systems. Although, ideally, the threshold chosen should perfectly distinguish between rates that reflect a problem and those that do not, in practice there is a balance to

be struck between detecting false-negative and false-positive results. Because there are costs attached to the investigation of hospitals identified as outliers, the selection of a threshold should be determined by local priorities that reflect the demand for action to be taken in response to high rates and the resources available to investigate rates, even when based on imprecise estimates. This flexibility is reflected in this analysis by the fact that we use a lower limit of the 90% CI that will identify more hospitals with outlying rates but with a lower certainty that all will reflect true problems. The funnel plots clearly identified hospitals with high rates based on relatively large numbers of operations that merited investigation. In addition, the lower threshold of a 90% CI also highlighted hospitals with particularly high rates based on relatively low numbers of operations and some hospitals with crude rates that would not place them above the 90th percentile. In these plots, we have only used data from 1 year, to reflect the current risk of SSI; however, the analysis of performance could be extended to include data accumulated over more than 1 year or to focus on different groups of hospitals (eg, those with high or low numbers of operations).

Using this approach to identify hospitals with unusually high rates of SSI would enable resources to be focused on the investigation of those hospitals most likely to have prob-

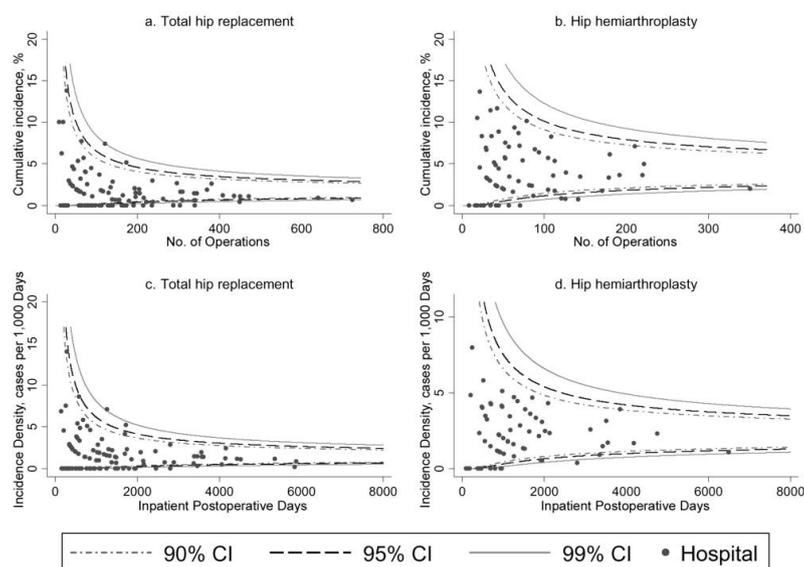


FIGURE 2. Funnel plots comparing rates of surgical site infection by hospital, for total hip replacement (*a* and *c*) and hip hemiarthroplasty (*b* and *d*); the lines indicate the 90%, 95%, and 99% confidence intervals (CIs) around the pooled cumulative incidence and incidence density.

lems. Use of the funnel plot has additional advantages: it makes distinctions between hospitals in a way that can be readily interpreted, is more likely to be accepted by clinicians, and is less likely to mislead the public, who are concerned about their real risk of acquiring infection. However, because the demands and objectives of measuring hospital performance vary, our work could be usefully extended by using simulation studies to further explore optimal limits.

Funnel plots are probably best viewed as a useful tool to be used in combination with other methods for evaluating and comparing hospital performance. In situations where the general rate across all hospitals investigated is considered unacceptably high, this type of funnel plot may not be an appropriate method for comparing performance because, in this situation, focusing on only those hospitals with the highest rates may not affect the overall rate. However, funnel plots could then be constructed using the target rate to define the limits, rather than the pooled incidence rate. Indeed, it could be considered that the results for HH in our analysis may merit such an approach, because the pooled incidence rate for HH was approximately twice that for THR.

The data collected for the SSISS have the advantage of being relatively detailed and of high quality. This means that the risk of findings being distorted by inaccurate or poor quality data is minimized. However, some problems remain that affect the analysis and that need to be taken into account when interpreting the results.

First, although data on major risk factors for SSI intrinsic

to the patient or type of operation are collected (NNIS risk index), to accurately reflect the rate of SSI in a given surveillance period, the surveillance system requires that records be submitted, even if risk factor data are missing, and, in 18% of the records, these data are incomplete. Thus, although a method that adjusts the rate of SSI for case mix would be desirable, the lack of complete case-mix data makes such adjustment problematic, because records with incomplete risk factor data would have to be excluded or these data would have to be imputed. However, the effect of these risk factors is relatively weak, and they are associated with, rather than predictive of, SSI.²² In addition, although risk adjustment may be desirable, its main value is to account for the variation in the distribution of risk factors among hospitals. The evidence from data submitted to the SSISS is that the distribution of risk factors for SSI is broadly similar among hospitals. This finding is not unexpected, because the categories reflect a set of similar operations likely to be undertaken for a relatively homologous group of patients. Case mix is therefore an unlikely explanation for all the observed variation in rates. Even if case mix contributed to a rate being high, identification of such a rate as an outlier should be viewed as an impetus to explore possible causes (which may be found to be related to case mix), rather than as a definitive indicator of poor quality care.

Second, although attention tends to be directed toward those hospitals that appear to have high rates of SSI, hospitals that report low rates of SSI may also be of interest, because

these low rates may signify either an excellent performance worthy of emulation (ie, by sharing best practices) or inadequate surveillance methods and a low sensitivity of case finding. The latter is a particular problem in surveillance of HAI, because definitions of infection are complex and because the data required to identify them are often not readily available from patients' clinical records. Although the SSISS has the advantage of a comprehensive protocol that details the active surveillance methods required, if benchmarking is to be used to penalize hospitals with high rates of infection, then resources also need to be directed toward validation systems that ensure that hospitals apply similar rigor to their surveillance.

Finally, the current surveillance system is based on detection of SSIs during the inpatient stay and therefore underestimates the true rate of SSI. Several studies have shown that a considerable proportion of SSIs do not become apparent until after the patient has been discharged.^{23,24} Although a system that monitors SSIs that develop after hospital discharge is desirable, it has considerable implications for the allocation of resources. In addition, variation in the intensity and quality of case finding after hospital discharge, which will mostly rely on passive surveillance methods, will be much more marked than that during inpatient surveillance, in which active methods can be applied more easily. This variation would have a major effect on the validity of interhospital comparisons of rates based on postdischarge surveillance, with the danger that those hospitals with more effective postdischarge surveillance systems would be more likely to be identified as having high outlier rates. In the absence of postdischarge surveillance, many SSIs will be missed; however, provided that the length of postoperative stay is similar, the proportion of SSIs detected by surveillance is also likely to be similar, and valid comparison is possible. The value of using incidence density to compare rates of SSI is that it takes some account of variation in length of postoperative stay.^{9,22} Our analysis showed that, when variation in length of postoperative stay was taken into account, the funnel plots still identified the same hospitals with outlying rates of SSI. However, further work is needed to explore the impact of variation in length of hospital stay and to explore the methods of incorporating data on SSIs detected after hospital discharge into systems that enable reliable comparisons of rates among hospitals.

Infection after joint replacement is associated with considerable morbidity and an increased risk of mortality. Coello et al.⁴ found that patients who developed an SSI after hip replacement had an increased length of hospital stay of 11.5 days and a significantly increased risk of death, with an adjusted odds ratio of mortality of 1.8. In addition, this analysis has shown that, in England, 36% of SSIs associated with hip replacement are caused by MRSA. Serious MRSA infections can be difficult to treat, more so in the presence of prostheses. Although further work is required to characterize these infections, this finding emphasizes the need to identify and treat

colonized patients and to review antimicrobial prophylaxis for patients at high risk of developing postoperative wound infection.

It is widely recognized that surveillance of SSI provides data that can inform and influence practice and that feedback of data to hospitals has a major impact on minimizing the risk of SSI. A key aim of this SSI surveillance program is the provision of data that supports local clinical interventions to reduce the risk of infection. However, the adoption and public reporting by government agencies of rates of HAI as indicators of hospital performance increase the imperative to develop systems to ensure validation of the data and mechanisms that enable such benchmarks to be easily and reasonably interpreted by a range of audiences, including the media, the public, and service users. Funnel plots provide a useful means of presenting performance data on rates of SSI because they clearly identify unusually high or low rates of infection while adjusting for the precision with which the rate has been estimated.

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Potential conflicts of interest. All authors report no conflicts of interest relevant to this article.

APPENDIX

Definitions of Surgical Site Infection (SSI) Used by the English Surgical Site Infection Surveillance Service

Superficial incisional SSI

- A. Occurs within 30 days after surgery
- B. Involves only skin and subcutaneous tissue
- C. Meets at least 1 of the following criteria
 1. Purulent drainage from superficial incision
 2. Organisms are grown, and pus cells seen, from aseptically obtained swab and/or tissue from the superficial incision
 3. At least 2 of the following symptoms and signs: pain or tenderness, localized swelling, redness, or heat
 - a. The clinician diagnoses an infection, or
 - b. The superficial incision is deliberately opened by a surgeon to manage the infection, unless culture-negative

Deep incisional SSI

- A. Occurs within 30 days (no implant) or 1 year (implant) after surgery
- B. Involves deep fascia and muscle layers
- C. Appears to be related to the procedure and meets at least 1 of the following criteria
 1. Purulent drainage from the deep tissue but not the joint or bone

2. Organisms are grown, and pus cells seen, from aseptically obtained swab and/or tissue from the deep incision
3. A deep incision that spontaneously dehisces or is opened by the surgeon when the patient has the following: fever (>38°C), localized pain or tenderness, unless the incision is culture-negative
4. An abscess or other evidence of deep infection found during reoperation, or by histopathological or radiological examination
5. Clinician's diagnosis of deep SSI

Joint and/or bone infection

- A. Occurs within 30 days (no implant) or 1 year (implant) after surgery
- B. Involves joint and/or bone related to operation site with any other tissues
- C. Appears to be related to the procedure and meets at least 1 of the following criteria
 1. Purulent drainage from a drain that is placed by a stab incision into the joint
 2. Organisms are grown, and pus cells seen, from aseptically obtained swab and/or tissue from the joint and/or bone
 3. An abscess or other evidence of joint and/or bone infection found during reoperation, or by histopathological or radiological examination
 4. The patient has at least 2 of the following signs or symptoms, with no other recognized cause: joint pain, swelling, tenderness, heat, evidence of effusion or limitation of motion, and at least 1 of the following
 - a. Organisms and white blood cells seen on Gram stain of joint fluid
 - b. Positive antigen test for blood, urine, or joint fluid
 - c. Cellular profile and chemistry of joint fluid compatible with infection and not explained by an underlying rheumatological disorder
 - d. Radiographic evidence of infection (eg, abnormal findings on X-rays, computed tomography scan, magnetic resonance imaging, radio-labeled scan [including gallium and technetium])
5. Clinician's diagnosis of organ-space infection

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Appendix 4.3.

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Inter-hospital comparison of rates of surgical site infection following caesarean section delivery: evaluation of a multicentre surveillance study

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SUMMARY

Background: Short postoperative stays following caesarean section delivery make it difficult to assess accurately the risk of surgical site infection (SSI). Methods of case-finding that minimize variation are required to support effective surveillance systems, especially where used for benchmarking.

Aim: To evaluate the efficacy of case-finding methods for SSI following caesarean delivery and their utility in establishing benchmark rates of SSI.

Methods: Hospitals conducted surveillance over one or two 13-week periods. Patients were reviewed during their inpatient stay, post partum by community midwives and via patient questionnaire at 30 days post delivery. To estimate the reliability of case-finding methods, case-note reviews were undertaken in a random sample of four hospitals.

Findings: A total of 404 SSIs were detected in 4107 caesarean deliveries from 14 hospitals. The median time to SSI was 10 days, 66% were detected in-hospital or by community midwives, and an additional 34% were patient-reported. The rate of SSI was 9.8% but the proportion of patients followed up varied significantly between centres. The estimated sensitivity and specificity of case-finding was 91.4% [95% confidence interval (CI): 53.4–98.4] and 98.6% (95% CI: 98.4–98.8), the positive predictive value 91.0% (95% CI: 82.4–96.1) and negative predictive value 98.6% (95% CI: 93.9–99.5).

Conclusions: Combined case ascertainment methods are a feasible way to achieve active post-discharge surveillance and had high negative and positive predictive values. Additional SSIs can be detected by patient questionnaires but rates of SSI were strongly influenced by variation in intensity of both healthcare worker- and patient-based case-finding. This factor must be taken into account when comparing or benchmarking rates of SSI.

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Introduction

Caesarean section is an increasingly performed surgical intervention. In the 1980s about 10% of births in England were by caesarean section delivery; however, by 2008 almost

150,000 caesarean deliveries were performed annually, accounting for a quarter of births.¹ Although frequently life-saving, this mode of delivery can result in infection and associated complications and healthcare costs.^{2–4}

Surveillance and feedback of data on rates of infection have been proposed as important instruments in driving improvements in quality of practice. In particular, a number of surveillance systems enabling rates of SSI to be benchmarked have demonstrated significant reductions in a range of surgical procedures including caesarean delivery.^{5,6} However, if such benchmark systems are to be effective in facilitating valid comparison of rates of SSI, they need to be based on standard surveillance methods that can reliably detect SSI and minimize variation in sensitivity and specificity of case-finding between participating centres.⁷ In addition, many surveillance systems have relied on identification of infections during the inpatient stay, as such infections are both easier to detect and standard case definitions can be applied consistently. Since SSI may take several days to become apparent and the average length of postoperative stay in hospital following caesarean delivery has declined to 3 days or less, methods that assure active post-discharge surveillance are a prerequisite for effective surveillance of SSI following caesarean delivery. This is particularly important when making comparisons between centres, although there is a paucity of evidence on the efficacy of different methods in detecting SSI or the impact of post-discharge surveillance on the validity of benchmarking rates of infection.⁸ The Health Protection Agency's Surgical Site Infection Surveillance System (SSISS) in England has captured data on a range of surgical procedures since 1997. Case-finding had mostly focused on the inpatient stay until standard methods of post-discharge surveillance were introduced in 2008 which included detection of SSI in patients readmitted to hospital and an optional post-discharge patient questionnaire (PDQ).⁹ The aim of this study was to evaluate: the ability of these standard surveillance methods to reliably identify SSI following caesarean delivery; the efficacy of using the community midwife to identify SSIs post discharge in the context of their statutory requirement to visit post-partum women up to the 10th day after delivery; and the utility of these methods in establishing benchmark rates of SSI.

Methods

Fifteen hospitals that had participated in SSISS were recruited in response to a request for volunteers to capture data on SSI following caesarean delivery for at least one of two 13-week surveillance periods between April and September 2009. All patients who underwent a caesarean delivery during the defined period were eligible for inclusion in the surveillance, and demographic and surgical data were captured on each patient. Systematic review of these patients to detect SSI was then conducted by local trained surveillance personnel during the hospital stay and through a wound surveillance record completed by the community midwife during their standard post-partum follow-up care. Hospitals were encouraged to assign surveillance co-ordinators from both infection control and maternity departments. The surveillance co-ordinators at each hospital attended training on the surveillance methods and definitions of SSI. Community midwives were then trained locally by the surveillance co-ordinator. Inter-rater reliability

was not assessed. The community midwife visited each patient the day after discharge and at day 5 and day 10 after delivery, although more frequent visits occurred if warranted by the condition of the mother or baby. In addition, patients were asked to complete a wound surveillance post-discharge questionnaire (PDQ) at 30 days after caesarean delivery. This was given to the patient on discharge, posted, or administered by telephone at 30 days, with postal or telephone reminders made if the PDQ was not returned. Patients who reported signs and symptoms indicative of SSI on this questionnaire were contacted by the surveillance co-ordinator to determine whether these met the case definitions. SSIs detected by midwives and hospital doctors were defined according to modified Centers for Disease Control and Prevention definitions used by the SSISS surveillance system in the UK since 1997 (Table 1). These criteria were adapted for identifying patient-reported infections.¹⁰ SSIs were categorized as healthcare professional-detected (during the admission, on readmission, at outpatient clinic or by community midwife) or, where only detected in the PDQ, patient-reported SSIs. Where SSIs were reported by both healthcare professional and patients these SSI were classified as healthcare professional-detected SSI. A proportion of patients who reported no problems with their wound on the PDQ were followed up to confirm that they had no SSI.

A multinomial linear mixed model was used to study the relationship between the observed rate of SSI and proportion of patients reviewed by community midwife or with PDQ returned. The model included detection categories (PDQ, healthcare professional and no-SSI), survey period as addition factor and hospital as random effect to take into account extra variation that was not explained by the detection method. These random effects were allowed to vary by detection method and termed category-specific hospital effect. The model benefited from borrowing strength over both hospitals and detection category in determining the significance of the effect.

Since it was not possible to review the records of all patients included in the surveillance, the sensitivity and specificity of the surveillance methods in identifying cases of SSI was estimated by selecting four hospitals at random and subjecting a sample of their data to a 'gold standard' method. This comprised review of the clinical records (hospital case notes, patient-held postnatal notes, community midwife records and patient PDQs) by two expert assessors to find evidence for the presence of SSI that met the case definitions. Records were selected for inclusion in the review by taking a random sample (without replacement) of 10% of patients where no SSI had been reported ('test-negative' cases), together with all patients reported to have an SSI ('test-positive' cases). Where clinical records were missing the patient was excluded from the review. The values from test-negative cases and test-positive cases were treated as two samples from two independent binomial distributions. A simple logistic linear mixed effect model was fitted to the data from two populations (distributions). The linear predictor also included hospital random effect to account for the extra variation not explained by fixed effects. The estimated values along with predicted random effects were used in predicting non-sampled cases and these were added to sample cases to determine the best linear unbiased-type estimates for prevalence, sensitivity, specificity, positive

Table I
Definition of surgical site infection (SSI) following caesarean section delivery

Type of SSI	Criteria meets at least one of:
Superficial incisional (involves skin or subcutaneous tissue)	<ol style="list-style-type: none"> 1. Purulent drainage from superficial incision 2. Organisms from culture of aseptically aspirated fluid or tissue or from a swab and pus cells are present. 3. At least two signs of infection (pain or tenderness, localized swelling, redness, heat) <i>and</i> superficial incision is deliberately opened by surgeon to manage infection <i>or</i> clinician diagnoses a superficial infection
Deep incisional (involves fascial and muscle layers)	<ol style="list-style-type: none"> 1. Purulent drainage from deep incision 2. Organisms from culture of aseptically aspirated fluid or tissue or from a swab and pus cells are present 3. Deep incision spontaneously dehisces or deliberately opened by surgeon <i>and</i> either fever (>38 °C) or localized pain and tenderness 4. Abscess or other evidence of infection involving the deep incision identified at reoperation, by histopathological or radiological examination 5. Diagnosis of deep incisional SSI by attending clinician
Organ/space (involves any part of the anatomy opened or manipulated during surgery)	<ol style="list-style-type: none"> 1. Purulent drainage from organ/space 2. Organisms from culture of aseptically aspirated fluid or tissue or from a swab and pus cells are present 3. Abscess or other evidence of infection involving the deep incision identified at reoperation, by histopathological or radiological examination 4. Diagnosis of organ/space SSI by attending clinician
(a) Endometritis	Organisms cultured from fluid/tissue from endometrium <i>or</i> At least two of the following without other recognized cause: fever (>38 °C), abdominal pain, uterine tenderness, or purulent drainage from uterus
(b) Other reproductive tract	Organisms cultured from fluid or tissue from affected site <i>or</i> Abscess or other evidence of infection of affected site seen at operation, by histopathological or radiological examination <i>or</i> At least two of the following without other recognized cause: fever (>38 °C), nausea, vomiting pain, tenderness or dysuria <i>and</i> organisms cultured from blood or diagnosis by physician of other reproductive tract infection
Patient-reported incisional	<ol style="list-style-type: none"> 1. Discharge pus from wound <i>and</i> antibiotics prescribed 2. At least two clinical signs (pain, heat, redness or swelling) <i>and</i> dehiscence 3. At least two clinical signs (pain, heat, redness or swelling) <i>and</i> antibiotics prescribed
Patient-reported organ/space	<ol style="list-style-type: none"> 1. Uterine tenderness and antibiotics 2. Abdominal pain and antibiotics 3. Purulent drainage from uterus and antibiotics

and negative predictive values and their associated 95% confidence intervals (CIs).

To determine the accuracy with which the surveillance identified all caesarean deliveries, the number of operations captured by the surveillance was compared with the number of caesarean delivery operations recorded in the hospital patient administration system during the same period. Data on the staff resources used for the surveillance were captured by the surveillance co-ordinator during each surveillance period. A structured questionnaire was sent to each surveillance co-ordinator at the end of the study to evaluate their experience of establishing local surveillance systems.

Results

Fifteen National Health Service hospitals in England were recruited to participate in the surveillance. All were general

acute hospitals performing between 2000 and 11,000 deliveries per year; all had a special care baby unit and eight had neonatal intensive care units. One hospital discontinued the surveillance after 6 weeks and was excluded from the study. Data were captured in a total of 21 surveillance periods with seven hospitals participating in both periods. A total of 4107 operations were included in the study, a median of 183 operations per hospital per surveillance period (range: 120–408). In eight hospitals data were validated against electronic records; in seven, 94% of the caesarean deliveries performed were included in the surveillance; in one hospital, only 64% were included.

The median length of stay in hospital post-caesarean delivery was 3 days (interquartile range: 2–4).

Based on all methods of detection, 404 SSIs were detected in 401 patients, with three women developing two separate infections, superficial incisional SSI and endometritis. Of these SSIs, 266 (66%) were detected by a healthcare

professional: 21 (5.2%) during the admission, 24 (5.9%) on readmission, 221 following discharge by community midwife or at outpatient clinic. An additional 138 (34%) were reported by the patient only.

The cumulative incidence of SSI, based on detection by healthcare professional, was 6.5% (interhospital range: 0.8–18.3%). Of these, 84.6% affected the superficial incision, 19 (7.1%) the deep incision and 22 (8.3%) were endometritis or reproductive tract (organ/space) infections. The cumulative incidence based on both healthcare professional- and patient-reported SSI was 9.8% (interhospital range: 2.5–26.7%) (Table II). For 394 SSI with complete data on date of onset, the median time to infection was 10 days post operation (interquartile range: 7–14 days); 55% of infections were detected within 10 days of operation, 75% within 14 days and 90% within 20 days (Figure 1). In the nine hospitals that collected data on readmission to hospital, 65 (3.0%) patients were readmitted and 33 (51%) of these readmissions were due to an SSI.

Completeness of follow-up by community midwife

The proportion of patients for whom the community midwife returned a surveillance record ranged from 8.8% to 97.8% (median: 70.6%). The median period of postoperative follow-up by community midwife was 14 days (interquartile range: 10–19 days). In the 11 surveillance periods where at least 70%

of patients were followed-up by the community midwife, the cumulative incidence of SSI detected by healthcare professional was 8.3%; however, only half of hospitals in the study achieved this proportion of community midwife follow-up (Figure 2a). Whereas the rate of SSI detected was more likely to be higher when the community midwife review rate was higher, the relationship was not clearly linear (R^2 : 22%). In the multinomial mixed effect model the odds ratio of detecting SSI increased significantly with each unit (percentage) increase above the mean (62.4%) in proportion of patients reviewed (odds ratio: 1.02; 95% CI: 1.005–1.026; $P = 0.003$).

Patient post-discharge questionnaires

A completed patient PDQ was available for 1789 (43.6%) operations (range for surveillance periods: 5.6–73.4%). Seven hospitals achieved at least 50% return rate for the PDQs. The three hospitals where more than 70% of PDQs were returned used a method that involved telephoning the patient. Data provided on 3912 (95.3%) patients indicated that 24% returned their PDQ without prompt, and a further 28% with one or more prompts in the form of either a second postal PDQ or telephone call. Figure 2b shows the relationship between reported rate of SSI and PDQ response rate. In the multinomial mixed effect model the \log_{10} odds ratio of detecting SSI increased significantly with each unit (percentage) increase above the mean

Table II
Number of procedures, infections and rates of SSI by method of detection and participating hospital

Hospital	Surveillance period ^a	No. of operations	Healthcare professional-detected			Patient-reported	All SSIs (%) ^d
			Inpatient and readmission	CMW and PD ^b	Total ^c (%)		
1	B	191	0	6	6 (3.1)	7	13 (6.8)
2	A	227	0	14	14 (6.2)	5	19 (8.4)
2	B	232	4	13	17 (7.3)	8	25 (10.8)
3	B	143	0	12	12 (8.4)	6	18 (12.6)
4	A	120	5	17	22 (18.3)	10	32 (26.7)
4	B	130	1	13	14 (10.8)	6	20 (15.4)
5	A	130	3	17	20 (15.4)	1	21 (16.2)
5	B	139	0	4	4 (2.9)	2	6 (4.3)
6	B	328	2	12	14 (4.3)	19	33 (10.1)
7	A	135	0	9	9 (6.7)	3	12 (8.9)
7	B	122	0	1	1 (0.8)	3	4 (3.3)
8	A	192	0	17	17 (8.9)	5	22 (11.5)
8	B	184	0	11	11 (6.0)	0	11 (6.0)
9	A	153	3	6	9 (5.9)	4	13 (8.5)
9	B	163	1	8	9 (5.5)	4	13 (8.0)
10	B	408	6	3	9 (2.2)	40	49 (12.0)
11	B	247	9	22	31 (12.6)	13	44 (17.8)
12	B	160	0	4	4 (2.5)	0	4 (2.5)
13	B	183	2	13	15 (8.2)	1	16 (8.7)
14	A	255	5	8	13 (5.1)	1	14 (5.5)
14	B	265	4	11	15 (5.7)	0	15 (5.7)
All		4107	45	221	266 (6.5)	138	404 (9.8)

SSI, surgical site infection; CMW, community midwife; PD, post discharge.

^a A: April to June 2010; B: July to September 2010.

^b SSI detected by community midwives and healthcare professionals at post-discharge outpatient visits.

^c SSI detected during inpatient and readmission as well as by community midwives and healthcare professionals post discharge.

^d Patient-reported and healthcare professional-detected.

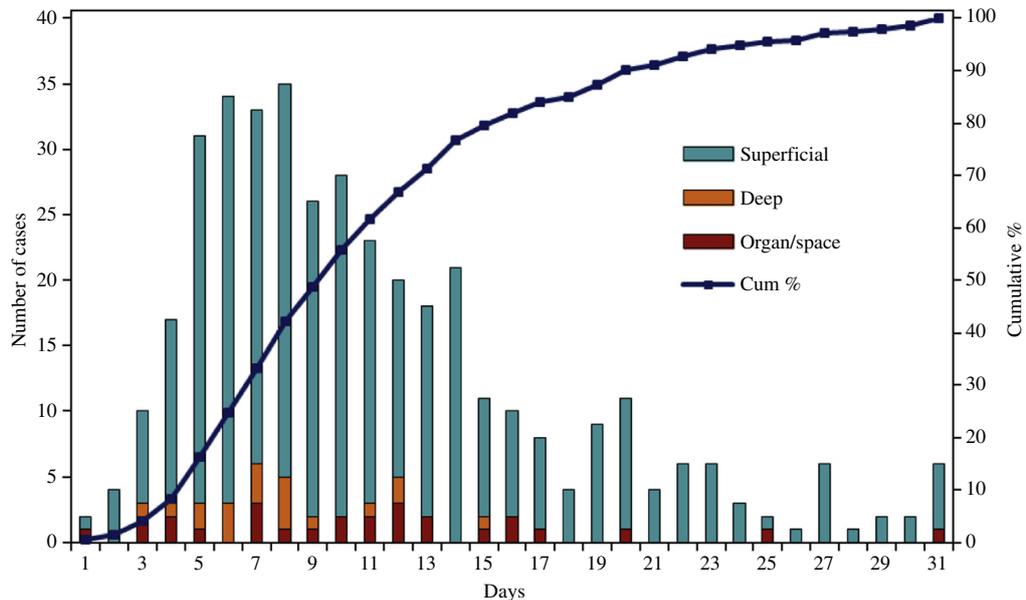


Figure 1. Number of days to detection of surgical site infection (SSI) following caesarean section delivery by type of SSI.

(43.5%) in proportion of patients with PDQ returned (odds ratio: 1.034; 95% CI: 1.016–1.052; $P = 0.025$).

Details of the patient responses were available for 96.6% (1728/1789) of PDQ, in which 426 (24%) indicated potential symptoms of SSI. In 54% (229/426) the surveillance co-ordinator was able to confirm an SSI, and for 52% of these (118/229) the SSI had also been detected by the healthcare professional surveillance methods. In 39% (166/426) they decided that the symptoms were not indicative of SSI judged against set criteria; in 7% (31/426) it was not possible to contact the patient. A sample of 19% (258/1363) PDQs where the patient reported 'no SSI' was followed-up by the surveillance co-ordinator and no evidence of SSI was found in 250 (97%).

Case-note review to measure reliability of surveillance in detecting SSI

In the four hospitals selected for clinical record review, the records of 90 patients where no SSI had been reported to the SSISS surveillance system were reviewed and one was found to have an SSI meeting the surveillance case definition. A total of 165 SSIs were eligible for review; 29 cases could not be reviewed as the patient records were not available. Of the remaining 136 SSIs (in 133 patients), there was evidence in the clinical records to confirm the presence of an SSI in 120 (88.2%); in 13 (10 at hospital A and one at each of the others) insufficient evidence was available. The majority (10) of false-positive

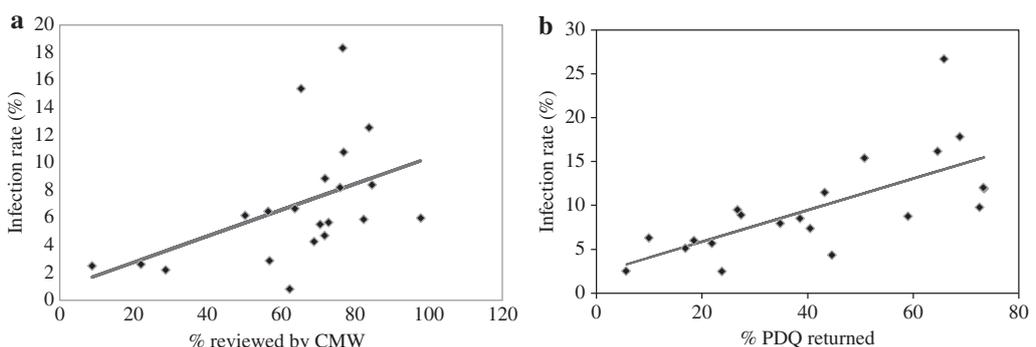


Figure 2. Relationship between proportion of operations with post-discharge follow-up and rate of surgical site infection (SSI). In both graphs, each plot represents percentage SSI for a surveillance period at a study hospital. (a) Percentage of community midwife (CMW) forms returned versus the rate of SSI (detected by healthcare professional). $y = 0.1x + 0.86$; $R^2 = 0.22$. (b) Percentage of patient post-discharge patient questionnaire (PDQ) completed versus the rate of SSI (detected by all methods). $y = 0.17x + 2.65$; $R^2 = 0.48$.

reports were related to the interpretation of data captured in the PDQ. The mixed effect regression model estimated the overall sensitivity of case finding as 91%, specificity 99%, the prevalence of SSI as 13%, and positive predictive value of 91% and negative predictive value of 99% for these four hospitals (Table III).

Effectiveness of the surveillance systems

Ten hospitals reported that the surveillance was completed successfully and resulted in improvements in operative care as a result of the focus provided by the surveillance process, e.g. stopping preoperative shaving and making changes to surgical wound dressings. Five of seven hospitals that completed two surveillance periods showed a mean decrease of 50% in SSI rate. Key factors reported as contributing to the effective implementation of surveillance were: high quality information technology systems; a designated surveillance co-ordinator; specific training of community midwives to apply definitions; and involvement of a senior member of the maternity department. In the six surveillance periods where the surveillance was co-ordinated by maternity rather than infection control personnel, the return rate of community midwife surveillance records was significantly higher (79.2% vs 56.3%; $P < 0.001$) but the response rate for PDQs was significantly lower (35.1% vs 46.6%; $P < 0.001$) than for those periods co-ordinated by infection control.

Table III

Sensitivity, specificity, positive (PPV) and negative (NPV) predictive values of case-finding as determined by expert case-note review and based on mixed effects model

Hospital	Parameter	Estimate	LCL	UCL
A	Sensitivity	0.84	0.44	0.96
	Specificity	0.97	0.96	0.98
	PPV	0.80	0.57	0.94
	NPV	0.98	0.94	0.99
	Prevalence	0.11	0.10	0.22
B	Sensitivity	0.91	0.49	0.99
	Specificity	1.00	0.99	1.00
	PPV	0.97	0.84	1.00
	NPV	0.99	0.95	1.00
	Prevalence	0.11	0.10	0.20
C	Sensitivity	0.96	0.71	1.00
	Specificity	0.99	0.98	1.00
	PPV	0.96	0.91	1.00
	NPV	0.99	0.94	1.00
	Prevalence	0.21	0.19	0.28
D	Sensitivity	0.92	0.50	0.99
	Specificity	0.99	0.97	1.00
	PPV	0.95	0.71	1.00
	NPV	0.99	0.94	1.00
	Prevalence	0.12	0.11	0.22
All	Sensitivity	0.91	0.53	0.98
	Specificity	0.99	0.98	0.99
	PPV	0.91	0.82	0.96
	NPV	0.99	0.94	1.00
	Prevalence	0.13	0.12	0.23

LCL, lower confidence limit; UCL, upper confidence limit.

Resources required for caesarean section delivery surveillance

These data were reported by 10 hospitals. The median time spent on surveillance was 140 h (range: 28–219) per 100 caesarean delivery operations including time spent following up community midwife surveillance forms and PDQs. This is equivalent to 23 person-hours per week in a hospital performing 200 caesarean deliveries in a quarter. Although a hospital that spent more time on the surveillance might be expected to achieve better response rates, this was not necessarily the case; whereas the median for PDQ surveillance for all hospitals was 19 h per 100 operations, one of these hospitals achieved a 70% response rate by telephoning all patients and spent 17 h per 100 operations.

Discussion

This study has demonstrated the feasibility of undertaking surveillance in women undergoing caesarean delivery using combined case ascertainment methods to achieve active surveillance during the post-discharge period. However, it highlights some of the important problems associated with benchmarking rates of SSI following surgery where post-operative hospital stays are too short for in-hospital surveillance systems to reliably detect infections, with only 11% of SSIs detected while the patient was in hospital. Post-discharge surveillance may include review of case records, surgeon-reporting, and patient-reporting.^{11–14} Unlike other types of surgery, patients undergoing caesarean delivery in the UK are reviewed by a healthcare professional for at least 10 days after surgery, providing a potential opportunity for systematic, active surveillance during this period.² Although this facilitated the identification of an additional 55% of SSIs by a healthcare professional post discharge, community midwife visits cease for most women 10 days post delivery and case ascertainment will be correspondingly reduced between 11 and 30 days. The use of a PDQ to identify SSIs missed by the community midwife captured a further 34% of SSI.

The combination of community midwife review and patient-reporting as a method of post-discharge surveillance for this study was found by the case note review to be a highly reliable method for determining patients without an SSI, with a NPV of 99%, although the PPV was lower at 91%. It may have been possible to have further improved the sensitivity of case-finding by employing a validation system, e.g. requiring hospitals to demonstrate competence using test records of SSIs. Other studies found patient-reporting to have a high specificity but lower sensitivity for case-finding SSIs.^{14–16} However, whereas relying on patient-reported symptoms alone would not provide accurate data on SSI, the surveillance co-ordinator was able to review patient-reported symptoms by telephone in more than 90% of PDQs where symptoms were indicated, and this review excluded half of the potential patient-reported SSIs. In addition, more than half of the SSIs reported by patients were also detected by the community midwife or as a result of readmission. Telephone interview would seem to be the most effective method of patient follow-up after discharge for this group of patients, although different approaches were not formally evaluated.

The greatest challenge for effective surveillance was the response rate achieved for both community midwife wound surveillance reports and PDQ. In the context of requiring an accurate and comparable rate of SSI, not only were these generally low (62% and 43% respectively) but they also varied widely between hospitals. Thus, whereas Petherick *et al.* highlighted the need to develop valid and reliable methods of case ascertainment post discharge, the present study has demonstrated an additional challenge of reproducibility of follow-up across institutions even when using a standard protocol.⁸ The variation in the proportion of patients lost to follow-up has an effect on the number of SSIs reported, underestimating the number of infections, and therefore the accuracy of the rate reported. This was borne out by the multinomial linear mixed model that demonstrated the significant association between proportion of patients followed up and rate of SSI. Provided that the proportion remains reasonably stable this may not be important when a hospital is comparing its own rates over time, but it will have a significant impact on the ability to reliably benchmark rates. Benchmarking systems must therefore incorporate methods that ensure active follow-up of a minimum proportion of operations included in the surveillance.

The local organization of the surveillance is a key factor in achieving high rates of post-discharge follow-up. The positive effect of clinical involvement in the surveillance is perhaps demonstrated in the higher response rates from community midwife in surveillance periods co-ordinated by the maternity department. However, this study outlined the challenge of securing clinical engagement in the majority of centres.

These variations in case-finding reflect the practical difficulties of establishing robust surveillance but limit the value of the study in accurately estimating the rate of SSI following caesarean delivery or in identifying hospitals with outlying rates of SSI. Although both community midwife and PDQ methods were instrumental in improving detection of SSI, the study was not designed to determine which specific elements of approach to PDS are most effective. This would need to be the subject of further research.

The burden of SSI associated with caesarean delivery is considerable, with 10% of patients developing an SSI reported by either a healthcare professional or patient.^{2,3,16} There was a wide disparity in rates of SSI reported by the 14 hospitals not explained by variation in case-mix, which is the subject of a separate paper.¹⁰ Whereas some of these differences were due to case ascertainment, the variation in rate of SSI from 5% to 18% in those hospitals that obtained community midwife follow-up data on at least 70% of patients suggests that differences in practice may be a factor. Changes to perioperative care, made by the participating hospitals as a result of the surveillance, point to factors that may contribute to this variation and demonstrate the potential to minimize the risk of SSI by optimizing practice. Gregson *et al.* reported reductions in rates of caesarean delivery SSI associated with replacing pre-operative shaving with hair clipping, covering the wound for 48 h and using an interactive wound dressing.¹⁷ Other studies have achieved significant reductions in rates of infection through the implementation of quality improvement initiatives and strategies to enhance compliance with SSI prevention guidelines.^{18,19} This is particularly relevant to caesarean deliveries which are generally performed outside the main operating department, frequently without the input of full-

time, trained operating theatre personnel. In the context of an increasing frequency of caesarean deliveries combined with rising levels of obesity in pregnant mothers, effective surveillance systems that can help drive quality improvement and reduce the risk of SSI are of paramount importance.¹⁰

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Conflict of interest statement

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Appendix 4.4.

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Information in practice

Surgical wound infection as a performance indicator: agreement of common definitions of wound infection in 4773 patients

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Abstract

Objective To assess the level of agreement between common definitions of wound infection that might be used as performance indicators.

Design Prospective observational study.

Setting London teaching hospital group receiving emergency cases as well as tertiary referrals.

Participants 4773 surgical patients staying in hospital at least two nights.

Main outcome measures Numbers of wound infections based on purulent discharge alone, on the Centers for Disease Control (CDC) definition of wound infection, on the nosocomial infection national surveillance scheme (NINSS) version of the CDC definition, and on the ASEPIS scoring method.

Results 5804 surgical wounds were assessed during 5028 separate hospital admissions. The mean percentage of wounds classified as infected differed substantially with different definitions: 19.2% with the CDC definition (95% confidence interval 18.1% to 20.4%), 14.6% (13.6% to 15.6%) with the NINSS version, 12.3% (11.4% to 13.2%) with pus alone, and 6.8% (6.1% to 7.5%) with an ASEPIS score > 20. The agreement between definitions with respect to individual wounds was poor. Wounds with pus were automatically defined as infected with the CDC, NINSS, and pus alone definitions, but only 39% (283/714) of these had ASEPIS scores > 20.

Conclusions Small changes made to the CDC definition or even in its interpretation, as with the NINSS version, caused major variation in estimated percentage of wound infection. Substantial numbers of wounds were differently classified across the grades of infection. A single definition used consistently can show changes in percentage wound infection over time at a single centre, but differences in interpretation prevent comparison between different centres.

Introduction

Surgical site infections represent a substantial burden of disease for patients and health services. Patients with such infections experience substantial morbidity, pain and discomfort, inconvenience, and cost and, occasionally, may die. From the perspective of health services, patients with surgical site infections stay in hospital on average about twice as long as uninfected patients, and the cost of total care is more than doubled—inpatient costs of surgical site infections alone were estimated to be about £65m in England in 1995.¹

The UK government is changing the way postoperative infections are monitored in the NHS. Surveillance of surgical site

infection, still commonly referred to as wound infection, became mandatory for orthopaedics in April 2004, and this will soon spread to other specialties.² The feedback of infection data to surgeons clearly reduces infection rates.^{3,4} Given that the percentage of wounds classified as infected will probably be used as a performance indicator,⁵ it is vital that the new surveillance system allows reliable comparisons across NHS institutions, and with overseas health institutions.

Although the UK Department of Health has consulted with experts, it has given little guidance on the definition of surgical site infection that is to be used for surveillance in England, namely the nosocomial infection national surveillance scheme (NINSS) version of the definition set out by the Centers for Disease Control (CDC) in 1992.⁶ There has been little or no critical evaluation of either the original or modified definition. Moreover, the version or interpretation of the definition used varies between hospitals and regions.^{7,8} Choosing an appropriate definition and ensuring that the definition is applied consistently are necessary conditions for observed rates of wound infection across hospitals to be valid.

Designers of a national surveillance system must judge the available definitions by their ability to identify infections that matter most to patients and to health services. The practicability of collecting the required information must also be considered, since laborious or complex definitions are less likely to be implemented consistently across hospitals.

We therefore compared agreement between four common definitions of surgical site infection—namely (a) the CDC 1992 definition, (b) the NINSS modification of the CDC definition, (c) the presence of pus, and (d) the ASEPIS scoring method⁹—applied to the same series of surgical wounds. We also compared the percentage of infection based on the CDC definition and on the NINSS modification to investigate the potential effect of subjective CDC criteria and of variation between hospitals in data collection methods.

Participants and methods

Since May 2000, surgical wound surveillance has been conducted at University College London Hospitals. Cardiac, thoracic, orthopaedic, general, obstetric, gynaecological, urological, maxillofacial, plastic, and vascular surgical specialties have participated, each for at least six months each year. Only patients staying in hospital for at least two nights are included. Information is collected on patients and their surgical wounds, allowing us to apply the different definitions of wound infection.^{5,7,9,10}

Definitions of surgical site infection

The 1992 CDC definition requires the observation of 16 wound or patient characteristics in order to classify infection and has two subjective criteria, namely a surgeon's diagnosis of infection and the culture of micro-organisms from the wound.⁶ The US national nosocomial infections surveillance system (NNISS) recommends that the latter criterion should be based only on positive cultures of fluid and tissue rather than wound swabs,^{6, 8} but this interpretation does not seem to be applied generally.⁸ The English NINSS method modified the CDC definition to exclude the need for a surgeon's diagnosis and required that pus cells be present to satisfy the criterion of micro-organisms cultured from the wound.⁷ Another definition of infection simply requires the presence of pus, even though some infections are missed.¹⁰ ASEPSIS is a quantitative scoring method that provides a numerical score related to the severity of wound infection using objective criteria based on wound appearance and the clinical consequences of the infection.^{8, 9}

For purposes of comparison, we classified ASEPSIS scores > 20 as infected. ASEPSIS scores of 10-20 ("disturbance of healing") are known to describe some infections, but most reflect wound breakdown due to other causes.¹¹ Moderate to severe infections score >30. The CDC definition also describes the severity of infection, classifying infections as "none," "superficial," or "deep or organ space" (termed "deep" in this article). Both definitions purport to describe the importance of an infection with respect to the patient's morbidity and the likely clinical consequences.

Data collection

Surveillance staff assessed patients every two or three days by direct observation, case note review, and questioning of the nurses caring for the patients. We contacted patients by post or telephone one to two months after their operations to complete a questionnaire designed to ascertain late infections. Thus, we followed up patients either until their wounds had healed without infection or until an infection was detected, but the precise duration of follow up varied depending on patients' length of stay in hospital and when they were contacted to ascertain late infections. We therefore classified wounds as infected or not and recorded the proportion of wounds classified as infected at any time during follow up.

Statistical analysis

Information collected was entered into an Access database, but microbiological results and demographic and some operative information came directly from interface with other computer databases. We gave quarterly reports of wound infection to surgeons.

We exported the relational Access database to Stata version 8.2, with each observation representing one wound. Counts and percentages presented are of wounds unless otherwise indicated. Confidence intervals for proportions of infection were adjusted for clustering on patient by means of the robust variance estimators from Stata's "svy" commands. We summarised agreement between the different definitions of infection by means of the κ statistic and the proportional agreement of ASEPSIS and CDC respectively for positive (Ppos) and negative (Pneg) diagnoses of infection.¹² Confidence intervals for the agreement statistics were adjusted for clustering on patient and calculated by bootstrap methods. The values shown are "bias-corrected."

Table 1 Characteristics of 4773 hospital inpatients who underwent surgery. Values are numbers (percentages) of patients unless stated otherwise

Characteristic	Value
Mean (95% CI) age (years)	53.5 (53.0 to 54.1)
Female	2281 (47.8)
Median (interquartile range) hospital stay (days)	8 (6-14)
Median (interquartile range) duration of operation (minutes)	111 (62-180)
Surgical specialty:	
Cardiothoracic surgery	1703 (29.3)
Orthopaedic surgery	1103 (19.0)
Urology	957 (16.5)
Obstetrics or gynaecology	632 (10.9)
General surgery	564 (9.7)
Other	845 (14.6)

Results

A total of 5804 surgical wounds in 4773 patients were assessed during 5028 separate hospital admissions to all surgical specialties in the hospital group between May 2000 and July 2003 (table 1). The patients' median age was 53.5 years (interquartile range 37.5-69.6), and 2281 (48%) of the patients were female. The median hospital stay was 8 days (6-14), and duration of operation 111 minutes (62-180).

The mean percentage of wound infection differed substantially with the different definitions; 19.2% (95% confidence interval 18.1% to 20.4%) with the CDC definition, 14.6% (13.6% to 15.6%) with the NINSS version, 12.3% (11.4% to 13.2%) with pus alone, and 6.8% (6.1% to 7.5%) with an ASEPSIS score > 20. Table 2 shows the level of agreement between the ASEPSIS and CDC systems. When superficial infections (according to CDC category) were included, 13% (778) of all observed wounds received conflicting diagnoses, and 6% were classified as infected by both definitions. When superficial infections were excluded, the two definitions estimated about the same overall percentage infection (6.8% and 7.0% respectively), but there were almost twice as many conflicting infection diagnoses (n=371) as concordant ones (n=215).

Table 2 Comparison of crude rates of surgical site infection reported with Centers for Disease Control (CDC) 1992 definition and with ASEPSIS scoring method. Wounds were considered to be infected if they met the CDC criteria for either superficial or deep infection (top half of table) or if they met the criteria for deep infection only (bottom half of table). Values are numbers (percentages) of wounds, with 95% confidence intervals for percentages, adjusted for multiple wounds in the same patients

ASEPSIS results	CDC results		Total
	Uninfected	Infected	
Wounds with superficial or deep infections according to CDC considered infected			
Uninfected (score ≤ 20)	4660 (80.3)	750 (12.9)	5410 (93.2, 95% CI 92.5 to 93.9)
Infected (score >20)	28 (0.5)	366 (6.3)	394 (6.8, 95% CI 6.1 to 7.5)
Total	4688 (80.8, 95% CI 79.6 to 81.9)	1116 (19.2, 95% CI 18.1 to 20.4)	5804 (100)
Wounds with deep infections only according to CDC considered infected			
Uninfected (score ≤ 20)	5218 (89.9)	192 (3.3)	5410 (93.2, 95% CI 92.5 to 93.9)
Infected (score >20)	179 (3.1)	215 (3.7)	394 (6.8, 95% CI 6.1 to 7.5)
Total	5397 (93.0, 95% CI 92.3 to 93.7)	407 (7.0, 95% CI 6.3 to 7.7)	5804 (100)

Agreement statistics: for top half of table, $\kappa=0.43$ (95% CI 0.40 to 0.46), Ppos=0.48 (0.45 to 0.52), Pneg=0.92 (0.92 to 0.93); for bottom half, $\kappa=0.50$ (0.46 to 0.55), Ppos=0.54 (0.49 to 0.58), Pneg=0.97 (0.96 to 0.97).

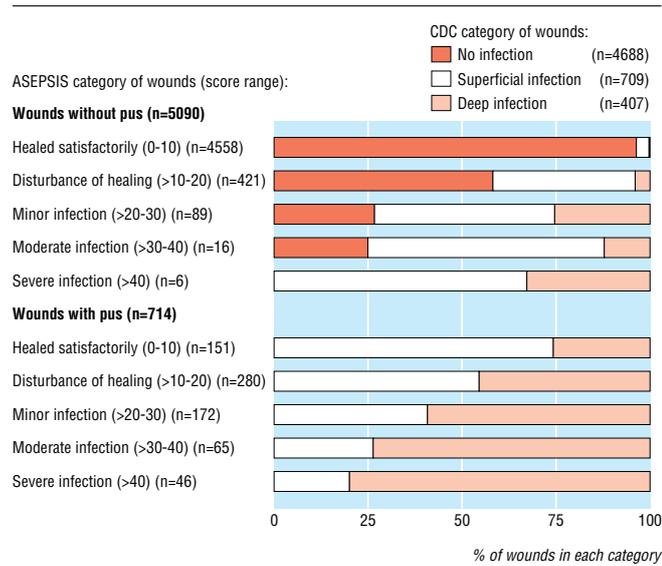


Fig 1 Comparison of diagnoses of surgical site infection in 5804 wounds reported with Centers for Disease Control (CDC) 1992 definition and with ASEPSIS scoring method, for wounds with and without pus

Wounds with pus were automatically diagnosed as infected by the CDC, NINSS, and pus alone definitions, but only 39% of these (283/714) had ASEPSIS scores >20 (fig 1). For these wounds, the CDC scale also consistently diagnosed greater infection severity than did ASEPSIS. Most wounds with pus were classified by ASEPSIS as having a “disturbance of healing” (39%, 280/714) or as healing satisfactorily (21%, 151/714). Of these latter 151 wounds, 26% were classified as deep infections by the CDC definition.

In wounds without pus the relation of ASEPSIS and CDC scales was less consistent (fig 1). For example, 42% (177/421) of wounds classified only as “disturbance of healing” by ASEPSIS were classified as infected by the CDC definition, with 3.8% (16) classified as deep infections. Conversely, four of the six wounds classified as “severe wound infections” by ASEPSIS were classified as superficial by the CDC definition.

Figure 2 compares the wound classification with the CDC definition and with the NINSS version. Each category of infection showed unique discrepancies between the two definitions. For example, more than 30% of wounds defined as superficially infected with CDC were classified as not infected with NINSS (229/709). In the CDC “superficial infection” category 94% (222/237) of the observed discrepancy was attrib-

utable to the NINSS modification of the CDC criterion related to positive bacterial cultures. In the CDC “deep infection” category the discrepancy observed was due to the exclusion of infections based solely on a surgeon’s diagnosis.

Discussion

We compared four different definitions of surgical site infection and found that they varied widely in the estimated percentage of wounds infected. Comparing the 1992 CDC definition and the ASEPSIS scoring method, we found more than twice as many wounds were classified as infected by only one definition (n = 778) as were classified as infected by both (n = 366).

Potential limitations of this study

We made some assumptions in applying the definitions, but these are unlikely to explain the extent of the discrepancies observed. For the CDC definition, we often assumed the requirement for a surgeon’s diagnosis of infection to be satisfied when a decision was made to start specific antibiotic treatment or to provide surgical treatment. For example, opening of a wound under general anaesthetic for drainage of pus was taken to indicate deep infection. In other studies, differences in results

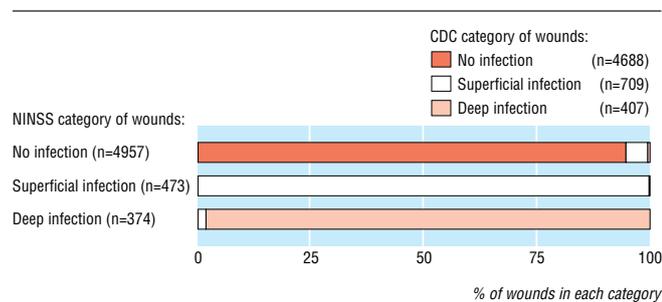


Fig 2 Comparison of diagnoses of surgical site infection in 5804 wounds reported with the Centers for Disease Control (CDC) 1992 definition and with the nosocomial infection national surveillance scheme (NINSS) version of the CDC definition

between CDC and other surveillance methods have been associated with lack of follow up, use of positive culture results, or clinical criteria.¹³ Although our study was conducted in a single group of hospitals, data came from multiple sites, many surgical specialties, and a large number of surgeons, so that most of the relevant sources of variation were represented.

Comparison of the different definitions

Both the CDC and ASEPSIS definitions describe the severity of wound infections—CDC describing three categories (none, superficial, or deep), whereas ASEPSIS has scores up to 50 or more. The CDC definition consistently tended to rate wounds with pus as more severely infected than did ASEPSIS. CDC also tended to rate wounds without pus as being more severely infected than did ASEPSIS, but some wounds classified as moderately or severely infected by ASEPSIS (31–40 points and >40 points respectively) were classified as not infected or only superficially infected by CDC.

The criteria needed to satisfy the CDC definition are complicated, and some are subjective. They were modified in the English NINSS version of the CDC definition to make it practicable in a hospital setting.⁷ However, the equivalent Scottish surveillance system adopted the original CDC definition.⁸ Unfortunately, none of the methods of determining wound infection has been validated against outcomes that it would be expected to influence, such as length of stay of hospital inpatients or prescription of antibiotics after discharge.

Therefore, choosing an optimal definition is extremely difficult. A definition that is too sensitive will give rise to high estimates of infection rates and may cause public alarm. Moreover, if overall rates are influenced primarily by minor infections of relatively little consequence to patients and health services, the use of such a definition could mask important differences between institutions. In contrast, a definition that lacks sensitivity would not identify infections that are avoidable.

An agreed definition needs to capture all infections of clinical importance and be accepted by patients, doctors, and managers. Other health outcome measures have been psychometrically evaluated,¹⁴ but similar information is lacking for most definitions of wound infection.¹⁵ ASEPSIS in its original form was reported to be repeatable and related to outcome,^{11 16} but it has since been modified and reproducibility is currently being reassessed.

The absence of a clear pattern to the type of wounds classified as infected by CDC but as not infected by NINSS supports the view that the CDC criteria responsible for the discrepancy are difficult to apply consistently. Small changes made to the CDC definition or even to its interpretation, as with the NINSS version, causes substantial variation in the apparent percentage of infected wounds. This lack of robustness is disquieting, because the elaborate and labour intensive CDC definition would probably need to withstand similarly varied adaptations in any nationwide surveillance programme.⁸ Although the CDC definition has been adopted in many countries to allow international comparison, this faith seems unwarranted.

Conclusions

Surveillance systems that monitor rates of wound infection and provide feedback to clinicians have been shown to contribute to quality improvement and are acknowledged as an important component of local programmes to prevent and control infection.^{3 4 10 17} Indeed, we recorded reductions in infection rate in our own programme after giving feedback to surgeons. Provided the same definition is used over time, any changes

What is already known on this topic

Surgical site infections are a major cause of morbidity and increased costs in health care

The percentage of surgical wounds classified as infected is an obvious potential performance indicator, but common definitions have not been validated or compared

What this study adds

To assess the robustness of four common definitions of wound infection, their agreement in wound classification was determined

Classifications with different definitions disagreed for more than twice as many wounds as those for which they agreed, and small changes in the interpretation of a definition caused substantial variation in the percentage of wounds classified as infected

Although feedback of rates of wound infection within an institution using a consistent definition is effective in reducing infection rates, infection rates cannot be used as a performance indicator to compare hospitals without a more robust definition

recorded should be accurate.¹⁸ However, using wound infection rates as a performance indicator to compare centres or countries is premature. Without a means to interpret absolute rates, such comparisons will be compromised by discrepancies in the way that infections are defined. External agencies should not judge the quality of medical care on these measures.¹⁹ Comparative performance tables should be reported only once a scientifically based and agreed definition has been produced.

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Contributors: APRW planned and supervised the study and drafted the paper. BH was in charge of the data collection. BCR and CG were responsible for statistical analysis and helped to write the paper. DP and ML constructed and maintained the database. ZHK and JB helped to write the paper and to apply the definitions of infection. JW and AP helped to write the paper and to apply the NINSS definition. APRW is guarantor for the study.

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Competing interests: None declared.

Ethical approval: This was not deemed necessary as the surveillance was part of the hospital audit programme.

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Appendix 5.1.

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ORIGINAL ARTICLE

EPIDEMIOLOGY

Trends among pathogens reported as causing bacteraemia in England, 2004–2008

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Abstract

The Health Protection Agency in England operates a voluntary surveillance system that collects data on bacteraemias reported by over 90% of laboratories in England. Trends in causative microorganisms reported between 2004 and 2008 were analyzed using a generalized linear model with a log link function for Poisson distribution. In 2008, 101 276 episodes of bacteraemia were reported; a rate of 189 per 100 000 population. More than one-half occurred in those aged over 65 years and males. The most common organisms reported were *Escherichia coli* (23%), coagulase-negative staphylococci (CNS) (16.9%) and *Staphylococcus aureus* (11.4%). Between 2004 and 2008, *E. coli* bacteraemia increased by 33% ($p < 0.001$); the species now accounts for more than 30% of bacteraemia in those aged over 75 years. There also were significant increases in bacteraemia caused by other Gram-negative pathogens and marked seasonal variation. Bacteraemia caused by *S. aureus* increased until 2005, with a decline after 2006 ($p < 0.001$) entirely due to methicillin-resistant strains. CNS bacteraemia have declined significantly since 2007. The renewed dominance of Gram-negative pathogens as major causes of bacteraemia in England is of particular concern because they are associated with a high morbidity and increasing resistance to antibiotics. Further investigation of the underlying causes and prevention strategies is a public health priority. Recent declines in methicillin-resistant *S. aureus* bacteraemia have not been reflected in other pathogens, including methicillin-susceptible *S. aureus*.

Keywords: Coagulase-negative staphylococci, *Escherichia coli*, *Staphylococcus aureus*, surveillance

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Introduction

Bacteraemias are a significant cause of morbidity and mortality [1,2]. They may result from microorganisms introduced to the bloodstream via an invasive device, or be secondary consequences of infections at another body site; both types are commonly associated with healthcare. The epidemiology of bacteraemia is likely to be influenced by a range of factors, including advances in medical care and the use of more invasive operative and diagnostic technologies and therapeutics, increases in longevity, and changes in prevalence of chronic diseases, such as renal or hepatic failure. All these factors increase vulnerability to bacteraemia.

In England the Health Protection Agency (HPA) has operated a voluntary system for the capture of data on microorganisms of clinical significance, including those isolated from blood cultures, since the 1970s, with the aim of gathering information on temporal trends and epidemiology. Electronic data capture systems were introduced in the early 1990s, and data are now collected from pathology systems and transmitted from microbiology laboratories to the national database (LabBase2) using software that transforms them into the required format. Laboratory mergers and reconfigurations have resulted in an overall reduction in the number of laboratories during the last decade and, by 2008, virtually all laboratories in England were reporting to the database, with the vast majority using automated data transfer systems [3]. The reporting laboratories provide services for all types of facilities, including university and general hospitals and specialist or regional centres. Participating laboratories submit data on all positive blood cultures, although, where possible, they exclude those considered not to be clinically significant. Despite some caveats on data completeness and laboratory changes over this time, these data provide a very

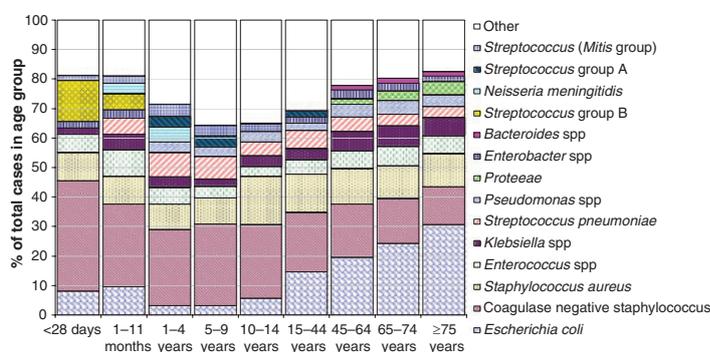


FIG. 1. Common isolates causing bacteraemia in England by age group in 2008 (all laboratories; $n = 167$)

Age group	No of episodes of	% of total	Rate per 100,000
<1 year	4598	4.8	688.7
1–4 years	2099	2.2	85.3
5–9 years	859	0.9	30.1
10–14 years	720	0.7	23.6
15–44 years	14098	14.6	66.3
45–64 years	22176	23.0	172.6
65–74 years	17491	18.1	409.3
75+ years	34382	35.7	857.1
Total	96423*		187.4*

*The total number of isolates and the overall rate for the combined age groups is slightly lower in this analysis due to records without age data being excluded.

spp., *Enterobacter* spp. and Proteaeae (Table 2). Eight thousand three hundred and sixty-nine episodes (9%) were polymicrobial.

TABLE 1. Ranking of common pathogens causing bacteraemia in England in 2008 by sex (all laboratories)

Gender	Organism	Order	Number of episodes	% of total organisms
Male	<i>Escherichia coli</i>	1	10 070	19.4
	CNS	2	8519	16.4
	<i>Staphylococcus aureus</i>	3	6932	13.3
	<i>Enterococcus</i> spp.	4	3422	6.6
	<i>Klebsiella</i> spp.	5	3282	6.3
	<i>Streptococcus pneumoniae</i>	6	2279	4.4
	<i>Pseudomonas</i> spp.	7	2210	4.3
	Proteaeae	8	1732	3.3
	<i>Enterobacter</i> spp.	9	1303	2.5
	<i>Bacteroides</i> spp.	10	692	1.3
	<i>Streptococcus</i> group B	11	690	1.3
	<i>Streptococcus (mitis)</i> group	12	609	1.2
Total of 12 most common			41 740	80.3
Other pathogens total			10 240	19.7
Total organisms			51 980	100.0
Female	<i>E. coli</i>	1	11 572	26.5
	CNS	2	7541	17.3
	<i>S. aureus</i>	3	4193	9.6
	<i>Klebsiella</i> spp.	4	2328	5.3
	<i>Enterococcus</i> spp.	5	2266	5.2
	<i>S. pneumoniae</i>	6	2062	4.7
	<i>Pseudomonas</i> spp.	7	1462	3.3
	Proteaeae	8	1021	2.3
	<i>Enterococcus</i> spp.	9	902	2.1
	<i>Streptococcus</i> group B	10	735	1.7
	<i>Bacteroides</i> spp.	11	588	1.3
	<i>Streptococcus</i> group A	12	549	1.3
Total of 12 most common			35 219	80.6
Other pathogens total			8484	19.4
Total organisms			43 704	100.0

CNS, coagulase-negative staphylococci

Numbers reported include only those episodes where data on gender were available

Trends in episodes of bacteraemia between 2004 and 2008

Between January 2004 and December 2008, a total 458 660 episodes of bacteraemia were reported by 210 laboratories. In the subset of 137 consistently-reporting laboratories, 361 263 episodes of bacteraemia were reported, representing 79% of all episodes. In this subset, the number of reported episodes of bacteraemia increased by 15% between 2004 and 2006, but subsequently declined, leaving an overall increase of 7% between 2004 and 2008 ($p < 0.001$). Over 90% of the recent decline between 2006 and 2008 was associated with *S. aureus* (58% of the decline) and CNS (34%) (Fig. 2 and Table 2).

Trends in the most common pathogens between 2004 and 2008

In the consistently-reporting laboratories, the 12 most-commonly-reported pathogens accounted for 80% of all episodes of bacteraemia (Fig. 2 and Table 2). *E. coli* was the most common pathogen in each of the 5 years, with the number of reports increasing 32% from 12 579 in 2004 to 16 663 in 2008 ($p < 0.001$) (Table 2). By 2008, the overall proportion of bacteraemias caused by *E. coli* was 23%, increasing to 30.5% in the those aged over 75 years, and with a particularly marked increasing trend in this age group (data not shown). There was a marked seasonal trend both for *E. coli* and other Gram-negatives such as *Klebsiella* spp. and *Pseudomonas* spp., with a peak in the summer (Fig. 2).

Aside from *E. coli*, there also were significant increases in the numbers of bacteraemias caused by other Gram-negative pathogens from 2004 to 2008. Those due to *Klebsiella* spp.

comprehensive national picture of the relative importance and trends among pathogens responsible for bacteraemia [4].

In this analysis, we have addressed the potential effect on trends of changes in case ascertainment over time by identifying a core set of laboratories that had established automated data transfer systems and submitted consistent volumes of data between 2004 and 2008. These data therefore represent the best available estimate of national trends in pathogens causing bacteraemia.

Materials and Methods

Microbiological data for bacteraemia reported by all 210 hospital laboratories in England that had submitted data between 2004 and 2008 were extracted from LabBase2. Repeat culture reports of the same organism taken from the same patient within 14 days were identified using probabilistic matching rules based on the organism identified, NHS number and other identifiers, and were removed from the analysis. If more than one pathogen was isolated from the same blood culture, the pathogens were reported individually but counted as a single episode of bacteraemia. Whilst laboratories are asked to report only cultures related to infections, in the absence of clinical details about the patient, some episodes may reflect contamination of the specimen by skin organisms, particularly coagulase-negative staphylococci (CNS), rather than true infection. We have therefore considered trends in terms of the proportion of episodes caused by specific pathogens adjusted for changes in number of episodes over time. In 2008, 167 laboratories reported data on bacteraemia (representing approximately 95% of all microbiology laboratories in England at this time). These data were used to evaluate the current prevalence and distribution of pathogens. Incidence rates by age and sex were calculated using Office for National Statistics mid-year population estimates for 2008 as the denominator.

A subset of 137 laboratories (65% of the total 210 laboratories that had submitted data) that had reported consistently in each year between 2004 and 2008 was obtained by excluding sites that had changed from manual to automated reporting; had not submitted data in each year; or had submitted incomplete data in one or more years (as demonstrated by large fluctuations in number of reports not explicable by reconfiguration of services or reporting arrangements). Data from these 137 laboratories were used to analyze trends in reported pathogens.

The predominant pathogens were defined at genus or species level as: *Escherichia coli*, *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Enterococcus* spp. (including Group D

streptococcus), *Klebsiella* spp., Proteaeae (including *Proteus* spp., *Morganella morganii*, *Providencia* spp.), *Pseudomonas* spp., *Enterobacter* spp. and coagulase-negative staphylococci (*Staphylococcus epidermidis*, *S. saprophyticus*). Other streptococci were grouped according to the taxonomy described elsewhere [5].

Trends were analyzed in STATA, version 9.2 (StataCorp, College Station, TX, USA) using a generalized linear model with a log link function for the Poisson distribution, comparing proportions between years with an offset to account for the variability in the total number of organisms per year. The model was based on a Poisson distribution (because the data comprised counts of episodes of infections) and was re-parameterized four times using different base years to allow rolling 2-year comparisons of the proportions. Incidence rate ratios, with 95% CIs and p-values, were estimated to determine significant changes in the relative proportion of bacteraemia caused by specific organisms.

Results

Rates of bacteraemia and main causative pathogens in 2008

During 2008, 97 195 episodes of bacteraemia were reported by 167 laboratories, comprising an overall rate of 189 per 100 000 population, ranging from 24 per 100 000 population in those aged 10–14 years to 857 per 100 000 population in those aged 75 years or more. More than one-half of the bacteraemias occurred in people aged over 65 years, more than one-third in those aged 75 years or more, and fewer than 10% in children (Fig. 1). The distribution of pathogens by age group in 2008 (Fig. 1) demonstrated marked differences. In the younger age groups, Gram-positive pathogens predominate, with CNS being the most common isolates up to the age of 44 years.

Bacteraemias occurred more commonly in males, who accounted for 54% of episodes. The population-based rates were 23% higher in males than females: 205 per 100 000 population vs. 167.3 per 100 000 population ($p < 0.001$). Males were less likely than females to have bacteraemia caused by *E. coli* (19% compared to 27% of episodes; $p < 0.001$) but more likely to have bacteraemia caused by *S. aureus* (13% vs. 10%; $p < 0.001$) (Table 1).

In 2008, the 12 most common pathogens accounted for 80% of all episodes of bacteraemia reported. *E. coli* was the most frequent agent, accounting for 22.5% of all episodes, followed by CNS (16.9%) and *S. aureus* (11.6%); a further 14% of episodes were caused by the other main Gram-negative pathogens: *Klebsiella* spp., *Pseudomonas*

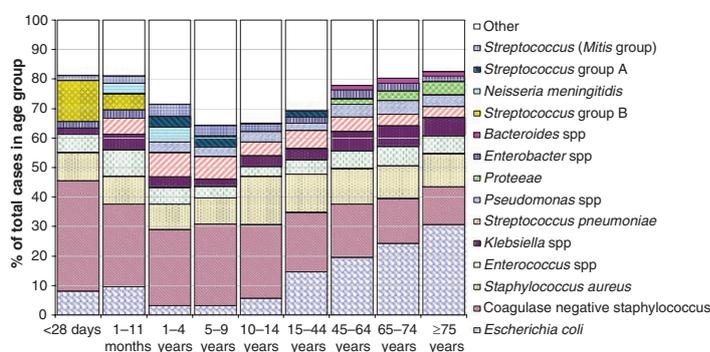


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	<i>Enterococcus</i> spp.	4	3422	6.6
	<i>Klebsiella</i> spp.	5	3282	6.3
	<i>Streptococcus pneumoniae</i>	6	2279	4.4
	<i>Pseudomonas</i> spp.	7	2210	4.3
	Proteaeae	8	1732	3.3
	<i>Enterobacter</i> spp.	9	1303	2.5
	<i>Bacteroides</i> spp.	10	692	1.3
	<i>Streptococcus</i> group B	11	690	1.3
	<i>Streptococcus (mitis)</i> group	12	609	1.2
Total of 12 most common			41 740	80.3
Other pathogens total			10 240	19.7
Total organisms			51 980	100.0
Female	<i>E. coli</i>	1	11 572	26.5
	CNS	2	7541	17.3
	<i>S. aureus</i>	3	4193	9.6
	<i>Klebsiella</i> spp.	4	2328	5.3
	<i>Enterococcus</i> spp.	5	2266	5.2
	<i>S. pneumoniae</i>	6	2062	4.7
	<i>Pseudomonas</i> spp.	7	1462	3.3
	Proteaeae	8	1021	2.3
	<i>Enterococcus</i> spp.	9	902	2.1
	<i>Streptococcus</i> group B	10	735	1.7
	<i>Bacteroides</i> spp.	11	588	1.3
	<i>Streptococcus</i> group A	12	549	1.3
Total of 12 most common			35 219	80.6
Other pathogens total			8484	19.4
Total organisms			43 704	100.0

CNS, coagulase-negative staphylococci

Numbers reported include only those episodes where data on gender were available

Trends in episodes of bacteraemia between 2004 and 2008

Between January 2004 and December 2008, a total 458 660 episodes of bacteraemia were reported by 210 laboratories. In the subset of 137 consistently-reporting laboratories, 361 263 episodes of bacteraemia were reported, representing 79% of all episodes. In this subset, the number of reported episodes of bacteraemia increased by 15% between 2004 and 2006, but subsequently declined, leaving an overall increase of 7% between 2004 and 2008 ($p < 0.001$). Over 90% of the recent decline between 2006 and 2008 was associated with *S. aureus* (58% of the decline) and CNS (34%) (Fig. 2 and Table 2).

Trends in the most common pathogens between 2004 and 2008

In the consistently-reporting laboratories, the 12 most-commonly-reported pathogens accounted for 80% of all episodes of bacteraemia (Fig. 2 and Table 2). *E. coli* was the most common pathogen in each of the 5 years, with the number of reports increasing 32% from 12 579 in 2004 to 16 663 in 2008 ($p < 0.001$) (Table 2). By 2008, the overall proportion of bacteraemias caused by *E. coli* was 23%, increasing to 30.5% in the those aged over 75 years, and with a particularly marked increasing trend in this age group (data not shown). There was a marked seasonal trend both for *E. coli* and other Gram-negatives such as *Klebsiella* spp. and *Pseudomonas* spp., with a peak in the summer (Fig. 2).

Aside from *E. coli*, there also were significant increases in the numbers of bacteraemias caused by other Gram-negative pathogens from 2004 to 2008. Those due to *Klebsiella* spp.

TABLE 2. Number and proportion of episodes of bacteraemia caused by the most common pathogens (England)

Pathogen	All laboratories (n = 167)			Consistently reporting laboratories (n = 137)				p-value ^a	
	2008			2004		2008			
	Number of episodes	%	Rate per 100 000 population	Number of episodes	%	Number of episodes	%		
<i>Escherichia coli</i>	21 878	22.5	42.5	12579	18.8	16 663	23.3	+32.5	<0.001
CNS	16 443	16.9	32.0	9086	13.5	10 165	14.2	+11.9	0.003
<i>Staphylococcus aureus</i>	11 234	11.6	21.8	11370	17.0	8660	12.1	-23.8	<0.001
<i>Enterococcus</i> spp.	5814	6.0	11.3	4980	8.1	4531	6.3	-9.0	<0.001
<i>Klebsiella</i> spp.	5678	5.8	11.0	3739	5.6	4274	6.0	+14.3	0.004
<i>Streptococcus pneumoniae</i>	4402	4.5	8.6	3616	5.4	3415	4.8	-5.6	<0.001
<i>Pseudomonas</i> spp.	3753	3.9	7.3	2290	3.4	2829	4.0	+23.5	<0.001
Proteaeae	2779	2.9	5.4	1859	2.7	2101	2.4	+13.0	0.095
<i>Enterobacter</i> spp.	2225	2.3	4.3	1812	2.4	1653	2.3	-8.8	<0.001
<i>Streptococcus</i> group B	1446	1.5	2.8	879	1.3	1135	1.6	+29.1	<0.001
<i>Bacteroides</i> spp.	1300	1.3	2.5	909	1.4	978	1.4	+7.6	0.932
<i>Streptococcus (mitis group)</i>	1164	1.2	2.3	864	1.3	818	1.1	+4.2	0.011
Total	78 116	80.4	151.8	53 983	80.9	57 222	80.1	+6.0	0.067
Other pathogens	19 079	19.6	37.1	12 704	19.1	14 246	19.9	+12.1	<0.001
Total (all episodes)	97 195		188.9	66 687		71 468		+7.2	<0.001

CNS, coagulase-negative staphylococci
^aFrom the generalized linear model with log link function comparing the change in probability of episodes by pathogen for 2008 to the base year 2004 with offset for total organisms.

increased by 14%, *Pseudomonas* spp. by 24% and Proteaeae by 13% (Table 3). Although the proportion of bacteraemia associated with these organisms has increased significantly over the whole period, the generalized linear model showed the trends were not linear for all pathogens. For example, the Proteaeae only increased significantly between the years 2006/07 and 2007/08, and *Klebsiella* spp, although increasing significantly over the 5 years, only showed a significant inter-year increase between 2007 and 2008 (Table 3).

There was a significant increase in episodes of CNS bacteraemia reported between 2004 and 2007 followed by a significant decline between 2007 and 2008, with an overall rise of 12% between 2004 and 2008 (Fig. 2 and Table 3). The decline was only apparent for adult patients, not children (data not shown).

Reports of bacteraemia caused by *S. aureus* increased until 2005, but declined by 24% between 2006 and 2008. This decline was only associated with methicillin-resistant strains: whereas

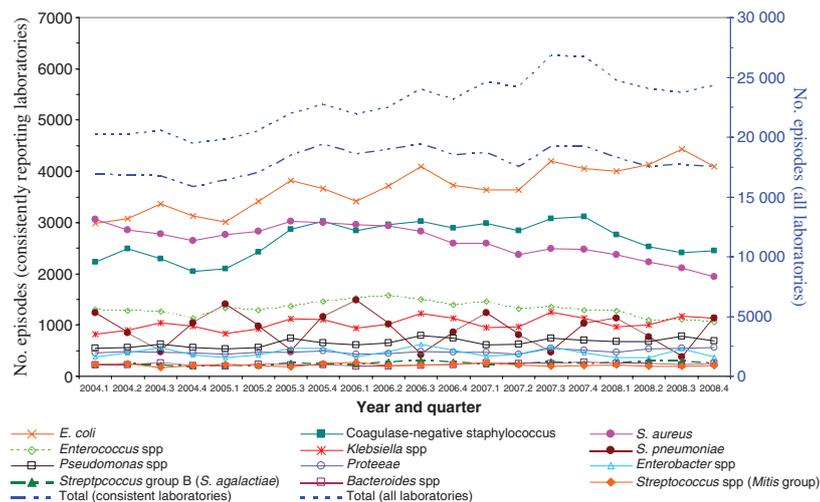
**FIG. 2.** Trends in total number of reported episodes of bacteraemia in England for all laboratories (n = 210) and for the 12 most common pathogens in consistently-reporting laboratories (n = 137) between 2004 and 2008.

TABLE 3. Relative in change in proportion of bacteraemia episodes attributable to a causative pathogen using rolling 2-year comparisons

	2005 vs. 2004 (base)			2006 vs. 2005 (base)			2007 vs. 2006 (base)			2008 vs. 2007 (base)			2008 vs. 2004 (base)		
	IRR	95% CI	p-value												
Coagulase-negative staphylococci	1.07	1.036–1.096	<0.001	1.06	1.033–1.089	<0.001	1.04	1.013–1.066	0.003	0.89	0.866–0.913	<0.001	1.04	1.015–1.074	0.003
<i>Escherichia coli</i>	1.03	1.003–1.053	0.028	1.02	0.993–1.040	0.174	1.05	1.026–1.073	<0.001	1.13	1.104–1.153	<0.001	1.24	1.208–1.265	<0.001
<i>Klebsiella</i> spp.	0.99	0.951–1.039	0.792	1.02	0.975–1.063	0.411	1.01	0.967–1.052	0.705	1.05	1.002–1.090	0.040	1.07	1.021–1.114	0.004
<i>Staphylococcus aureus</i>	0.95	0.925–0.974	<0.001	0.92	0.897–0.944	<0.001	0.89	0.865–0.913	<0.001	0.92	0.890–0.943	<0.001	0.71	0.691–0.731	<0.001
Methicillin-resistant <i>S. aureus</i> *	1.00	0.954–1.038	0.824	0.95	0.911–0.993	0.022	0.80	0.761–0.837	<0.001	0.76	0.720–0.809	<0.001	0.58	0.546–0.609	<0.001
Methicillin-sensitive <i>S. aureus</i> *	1.00	0.969–1.038	0.857	1.03	0.998–1.067	0.069	1.12	1.085–1.160	<0.001	1.10	1.065–1.140	<0.001	1.28	1.236–1.324	<0.001
<i>Streptococcus pneumoniae</i>	1.04	0.997–1.090	0.071	0.88	0.844–0.922	<0.001	0.95	0.907–0.994	0.026	1.01	0.963–1.058	0.691	0.88	0.841–0.923	<0.001
<i>Enterococcus</i> spp.	1.02	0.978–1.056	0.423	1.04	1.001–1.078	0.042	0.92	0.884–0.951	<0.001	0.88	0.843–0.913	<0.001	0.85	0.815–0.884	<0.001
Proteaceae (<i>Proteus</i> spp., <i>Morganella</i> spp. and <i>Providencia</i> spp.)	0.93	0.874–0.994	0.032	0.93	0.869–0.988	0.20	1.08	1.013–1.151	0.018	1.13	1.063–1.202	<0.001	1.05	0.991–1.122	0.095
<i>Pseudomonas</i> spp.	1.01	0.954–1.069	0.729	1.06	1.003–1.117	0.040	0.98	0.926–1.029	0.376	1.10	1.048–1.164	<0.001	1.15	1.091–1.218	<0.001
<i>Enterobacter</i> spp.	0.96	0.903–1.028	0.260	1.00	0.938–1.064	0.964	0.94	0.886–1.006	0.074	0.94	0.877–1.002	0.055	0.85	0.796–0.910	<0.001
<i>Streptococcus</i> Group B	1.00	0.911–1.095	0.982	1.11	1.019–1.212	0.017	0.93	0.852–1.009	0.081	1.17	1.075–1.274	<0.001	1.20	1.103–1.316	<0.001
<i>Bacteroides</i> spp.	0.90	0.818–0.985	0.022	0.90	0.818–0.989	0.029	1.26	1.149–1.378	<0.001	0.99	0.905–1.078	0.787	1.00	0.917–1.099	0.932
<i>Streptococcus</i> spp. (<i>mitis</i> group)	0.93	0.843–1.018	0.111	1.03	0.937–1.128	0.557	0.96	0.877–1.053	0.393	0.97	0.878–1.062	0.471	0.88	0.803–0.972	0.011
All 12 pathogens	1.00	0.993–1.016	0.446	1.00	0.985–1.008	0.511	0.99	0.978–1.001	0.064	1.00	0.988–1.010	0.847	0.99	0.978–1.000	0.067
All other pathogens	0.98	0.957–1.005	0.114	1.02	0.993–1.041	0.173	1.05	1.021–1.069	<0.001	1.00	0.982–1.028	0.698	1.05	1.022–1.072	<0.001
All pathogens (without offset)	1.08	1.066–1.089	<0.001	1.06	1.048–1.069	<0.001	0.99	0.978–0.998	0.014	0.95	0.942–0.962	<0.001	1.07	1.060–1.083	<0.001

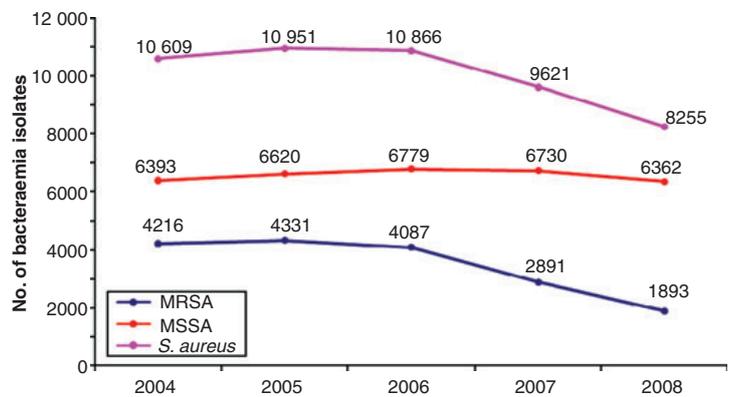
IRR, incidence rate ratio (ratio of proportions between years adjusted for total number of organisms from a generalized linear model).
*Based on all *S. aureus* isolates with susceptibility tests, adjusted for the total number of *S. aureus* organisms.

the number of episodes and proportion of all bacteraemia caused by methicillin-susceptible *S. aureus* (MSSA) increased significantly between 2004 and 2008 (Fig. 3 and Table 3). In 2004, methicillin-resistant *S. aureus* (MRSA) accounted for 41% of *S. aureus* bacteraemia but only 23% by 2008.

Reports of bacteraemia due to *Enterococcus* spp. declined by nearly 6% between 2004 and 2008, with significant decreases each year from 2005. Episodes of *S. pneumoniae* bacteraemia declined by 6% between 2004 and 2008, temporally associated with the introduction of conjugate vaccine to the childhood immunization schedule in England in

2006 [6]. The seasonal variation of episodes of bacteraemia caused by this pathogen showing the expected winter peaks is clearly illustrated in Fig. 2. Episodes of bacteraemia due to group B streptococci increased by 30% between 2004 and 2008, and, by 2008, accounted for 1.6% of all bacteraemia, with the majority of cases occurring in children under 1 year (Fig. 1). Reports of bacteraemias due to *Bacteroides* spp. increased significantly between 2004 and 2006, but there was no significant overall change between 2004 and 2008. Streptococci from the 'mitis' group declined between 2004 and 2008.

FIG. 3. Trends in episodes of bacteraemia caused by *Staphylococcus aureus* by resistance to methicillin in consistently reporting laboratories in England. MRSA, methicillin-resistant *S. aureus*; MSSA, methicillin-susceptible *S. aureus*.



Location of patient when blood culture were taken based on consistently reporting laboratories 2004–2008

For the 247 676 (69%) episodes where the location of the patient when the blood cultures were taken was reported, the great majority (81%) were in hospital, but 11% were out-patients (likely reflecting patients receiving invasive therapy such as renal dialysis or chemotherapy) and 5% were found in accident and emergency cases.

Discussion

During the 1990s, *E. coli* was the most commonly reported agent of bacteraemia in England, but reports of *S. aureus* bacteraemia then increased markedly so that, by 2000, it accounted for over 20% of cases and replaced *E. coli* as the leading pathogen [4,7]. This analysis shows that *E. coli* not only has re-emerged as the most prevalent agent of bacteraemia, accounting for almost one-quarter of all episodes by 2008, but also that it has shown sustained significant annual increases since 2004. This trend is particularly evident among those aged over 75 years, in whom *E. coli* accounted for almost one-third of all bacteraemia by 2008, suggesting an important change in the epidemiology of bacteraemia in England.

There appear to be important differences between Europe and the USA. In many other European countries, *E. coli* is also reported as the most common pathogen of bacteraemia and *S. aureus* second, whereas, in the USA, *S. aureus* is far more common (accounting for more than one-quarter of episodes) and *E. coli* second [8]. *E. coli* bacteraemia is most likely to be secondary to a focal infection such as urinary tract, abdominal, hepato- or biliary sepsis, or surgical infections, although association with central vascular devices has also been reported [9]. Although some of these cases may be truly community-acquired, Marschall *et al.* [10] reported that in over 80% of patients admitted with Gram-negative bacteraemia the infection was associated with prior health-care; in particular, more than two-thirds had been recently hospitalized or were receiving outpatient treatment such as haemodialysis or intravenous chemotherapy [10].

The marked increasing trend in bacteraemia caused by *E. coli* is of particular concern because the species has shown sharp recent increases in resistance to important antimicrobial agents. A recent detailed analysis of *E. coli* isolates from a set of sentinel laboratories in the UK and Ireland demonstrated striking increases in the prevalence of resistance to oxyimino-cephalosporins such as ceftoxime and ceftazidime; from approximately 2% in 2001 to 12% in 2006, ciprofloxacin from 4% in 2000 to 26% in 2006, and gentamicin from 5% in

2001 to 11% in 2006 [11]. Over 80% of the isolates resistant to oxyimino-cephalosporins were co-resistant to quinolones and gentamicin. These increases were linked to the emergence and spread of strains producing CTX-M type extended spectrum β -lactamase and strains with these enzymes are reportedly carried in the gut of a high proportion of elderly patients in nursing homes, comprising a major source of repeat admissions to hospital [12]. Reliance on urinary catheters for the management of elderly incontinent patients in hospital, and the continued use of these catheters when patients are transferred to residential or nursing homes, may be a contributory factor in *E. coli* bloodstream infection [13].

Reported episodes of bacteraemia caused by Gram-negative pathogens besides *E. coli* also increased between 2004 and 2008 and these organisms now account for almost one-half of the twelve commonest pathogens. Bacteraemia due to *Pseudomonas* spp., is mostly hospital-acquired, with the genitourinary and respiratory tracts, and intravenous devices, cited as the most common sources. Except for ciprofloxacin, where almost one-quarter of isolates are resistant, antimicrobial resistance rates remain low among bloodstream *Pseudomonas* isolates in England [14]. Nevertheless, they are associated with a case-fatality rate of over 30% [15]. Approximately two-thirds of bacteraemia caused by *Klebsiella* spp. are reported as hospital-acquired, with intravenous devices and the genitourinary tract being common sources [16]. These organisms have also shown dramatic increases in antimicrobial resistance since 2001, with mechanisms similar to *E. coli* [14]. The urinary tract is the major source of protease bacteraemias, with many of them linked to the use of long-term urinary catheters [14]. The marked increase in bacteraemia associated with *E. coli* in particular, but also other Gram-negative pathogens, in the summer has been recently observed by Al-Hassan *et al.* [17]. Because these bacteraemia are commonly associated with urinary tract infections and at least one-third occurred in the very elderly, dehydration linked to deficits in thirst recognition may be a possible contributory factor [18].

The data show a significant decrease in *S. aureus* as a cause of bacteraemia, and, by 2008, this organism had become only the third most common agent, accounting for 12% of episodes. This decline was entirely due to reductions in MRSA because the numbers of episodes of bacteraemia due to MSSA were not significantly changed over this period. The proportion of *S. aureus* resistant to meticillin declined markedly between 2004 and 2008 and MRSA accounted for only approximately 3% of all bacteraemia in 2008, compared to 6% in 2004. Indeed, both the increase in *S. aureus* as a cause of bacteraemia in the early 2000s, and subsequent

decline in the last 5 years, were associated with MRSA [19]. Major national initiatives targeted at MRSA bacteraemia in England since 2004 [3] appear to have been successful, but do not appear to have had any appreciable impact on MSSA. A key component of this MRSA reduction strategy has been the prevention of intravenous-device associated infections and it might be expected that these initiatives would have also prevented MSSA infections. It is therefore possible that targeted detection and decolonization of patients carrying MRSA have accounted for a greater part of the effect. A further complicating factor is that recent data suggest a decline starting before 2001, and therefore prior to the major control programme, in one of the two major hospital MRSA strains (EMRSA-16), perhaps indicating an effect predicated on natural biological trends [20]. At least part of the explanation for the differential effect of these preventative strategies may therefore lie in factors that underpin the ecological success of different strains of *S. aureus*. Certainly, the emergence and disappearance of MRSA strains for reasons that remain largely obscure is not a new phenomenon, as exemplified by the virtual disappearance of the once-prevalent EMRSA-1 and 3 strains [21].

By contrast to *S. aureus*, reports of CNS increased from 2004 to 2007 before declining in 2008. Although universal skin commensals, CNS are important pathogens in healthcare-associated infection, especially device-associated bacteraemia in neonates, haematology and oncology patients, and cause deep surgical infection in surgical implants [22,23]. The more recent decline is interesting because it was counter to the previous trend. It may have been influenced by changes in practice in relation to taking of blood cultures associated with the publication of national guidance in 2006 [24]. This guidance aimed to improve the technique of taking blood cultures in order to minimize contamination with skin organisms. Alternatively, because CNS are commonly associated with central vascular devices, this decline may also be linked to the other national initiatives aimed at preventing MRSA infections [3]. Curiously, the decline was most marked in patients aged over 75 years and was not apparent in children [6].

The trends among pathogens causing bacteraemia may be influenced by aspects of healthcare treatment and delivery but, currently, there are few data on the factors contributing to bacteraemia, the primary sources of infection and the extent to which these infections can be prevented. In more than 80% of episodes, the specimens were reported as being taken in hospital patients, although it is not possible to determine the source of the primary infection, or whether they were associated with hospital care. Moreover, with changes in the delivery of healthcare and shorter lengths of hospital stay, the distinction between hospital- and community-acquired bacteraemias

is being eroded because many of those admitted with bacteraemia have recently received healthcare [10,25]. Although total episodes of bacteraemia reported to the HPA have increased each year since the early 1990s, it has been difficult to distinguish the extent to which this reflected an increased participation in this voluntary surveillance system rather than a real increase [4]. In this analysis, the effect of variation in case ascertainment was minimized by focusing on laboratories reporting consistently over the 5-year period. Although the overall number of blood culture reports from these laboratories has decreased since 2006, much of this decrease was attributable to CNS and MRSA, whereas the number and proportion of episodes of bacteraemia due to Gram-negative pathogens has increased. Moreover, although there may have been changes in blood culture taking practice during this time, it is difficult to see how these might have influenced the data presented because the common pathogens found, apart from CNS, would be expected to represent clinical infections if recovered from blood. In addition, the analysis of trends has focused on independent changes in proportions of specific pathogens and accounted for the numbers of episodes reported in each year. The data presented are also unlikely to be affected by misclassification bias because all laboratories in England must be accredited; a process that involves checking the quality of diagnostic methods.

The recent declines in MRSA bacteraemia may demonstrate the potential impact of surveillance and control initiatives. However, these have not had an apparent positive collateral effect on other pathogens causing bacteraemia, nor even on MSSA. In the last 2 years, there have been national shifts in England away from hospital-prescribing of cephalosporins and quinolones, predicated on concerns about *Clostridium difficile*, and these are likely to bring different selection pressures and challenges in the future. The growth of Gram-negative pathogens as agents of bacteraemia has also been reported by other countries and in specific patients groups. It is of particular concern because these organisms are associated with both a high mortality and increasing resistance to antimicrobial agents, particularly cephalosporins and quinolones, but increasingly also carbapenems [11,14,26–29]. Further investigation of the factors precipitating these infections and effective strategies for their prevention should be a major public health priority.

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Appendix 5.2.

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Trends in sources of meticillin-resistant *Staphylococcus aureus* (MRSA) bacteraemia: data from the national mandatory surveillance of MRSA bacteraemia in England, 2006–2009

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SUMMARY

The national mandatory surveillance system for reporting meticillin-resistant *Staphylococcus aureus* (MRSA) bacteraemia in England has captured data on the source of reported bacteraemias since 2006. This study analysed episodes of MRSA bacteraemia ($N = 4404$) where a probable source of infection was reported between 2006 and 2009. In 2009, this information was available for one-third of reported episodes of MRSA bacteraemia. Of these, 20% were attributed to intravascular devices and 28% were attributed to skin and soft tissue infection. Sixty-four percent of the patients were male, and urinary tract infection was a significantly more common source of MRSA bacteraemia in males compared with females (12% vs 3%). Detection of bacteraemia within two days of hospital admission does not reliably discriminate between community- and hospital-associated MRSA bacteraemia as community cases are frequently associated with an invasive procedure/device. Between 2006 and 2009, there was a significant decline in the proportion of episodes of MRSA bacteraemia associated with central vascular catheters [incidence rate ratio (IRR) 0.42, 95% confidence interval (CI) 0.29–0.61; $P < 0.001$], peripheral vascular catheters (IRR 0.69, 95% CI 0.48–0.99; $P = 0.042$) and surgical site infection (IRR 0.42, 95% CI 0.25–0.72; $P = 0.001$), and a significant increase in the proportion of episodes of MRSA bacteraemia associated with skin and soft tissue infection (IRR 1.33, 95% CI 1.05–1.69; $P = 0.017$) and attributed to contamination of the specimen (IRR 1.96, 95% CI 1.25–3.06; $P = 0.003$). Since data were not available for all cases, the generalizability of these trends depends on the assumption that records with source data reflect a reasonably random sample of cases in each year. These changes have occurred in the context of a general decline in the rate of MRSA bacteraemia in England since 2006.

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Introduction

Staphylococcus aureus is an important cause of invasive infection, associated with significant morbidity and mortality, especially in strains resistant to key antimicrobial agents such as meticillin.^{1–3} Bloodstream infections caused by *S. aureus* may result directly from a primary infection (e.g. introduced via an invasive device) or from a secondary source of infection at another body site (e.g. an abscess). In 2001, the Department of Health in England made it

mandatory for National Health Service (NHS) acute hospitals to report all cases of meticillin-resistant *S. aureus* (MRSA) bacteraemia. This policy decision was made in the context of a rising number of reports of MRSA bacteraemia identified by the existing voluntary surveillance system, and evidence that the proportion of *S. aureus* bacteraemia that were MRSA had increased from less than 5% in the early 1990s to over 40% by 2000.⁴

A national strategy for reducing MRSA bacteraemia was co-ordinated by the Department of Health comprising a range of policies and other initiatives for use by acute NHS hospitals.⁵ A key component of this strategy was a root cause analysis to identify factors that gave rise to patients acquiring MRSA bacteraemia. Understanding the sources of MRSA bacteraemia is critical to driving improvements in clinical practice. In particular, the ability

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to distinguish between primary infections (associated with invasive devices) and secondary infections (where the focal infection could have been avoided or managed) can support appropriate targeting of preventative measures.

Initially, the mandatory surveillance was based on the aggregate number of positive MRSA blood cultures. However, in October 2005, a web-enabled surveillance system was established that captured patient-level data on each episode of MRSA bacteraemia. In 2006, this system was enhanced to support the capture of data on the probable source of MRSA bacteraemia on a voluntary basis. This paper describes the sources of MRSA bacteraemia reported via the voluntary fields of this data capture system, and evaluates the trends in reported sources between 2006 and 2009, a period when the incidence of MRSA bacteraemia declined sharply.⁶

Methods

The national mandatory surveillance system requires that hospitals report all blood cultures positive for MRSA, excluding repeat cultures taken within 14 days from the same patient, regardless of whether or not the organism is considered to be clinically significant. Data on sources of MRSA bacteraemia were extracted from all episodes of MRSA bacteraemia reported to the mandatory surveillance system between 1 January 2006 and 31 December 2009. Episodes where there was uncertainty about the reported source were excluded, and those where the source was recorded as 'other' with a free-text description were reviewed and, where possible, allocated to a defined category. Records where the source was specifically reported as 'unknown' were included. Dialysis-related bacteraemias included those where the source was considered to be a fistula, graft, peritoneal dialysis or other device used for dialysis.

The representativeness of the sample of episodes where the source of bacteraemia was reported was determined by reviewing proportions and using Chi-squared test to compare their characteristics with those cases without a certain source. Cases were considered to be hospital associated if the location of the patient when the specimen was taken was reported as an acute hospital 'inpatient', 'day patient' or 'emergency assessment patient'; and the specimen date was on, or after, day 3 of hospital admission (day 1 = day of admission).

Differences in distribution of sources between sexes were analysed using Pearson's Chi-squared test for independence. Trends in reported sources of MRSA bacteraemia were analysed using Stata Version 9.2 (Stata Corp., College Station, TX, USA). Since the total number of episodes of MRSA bacteraemia decreased significantly between 2006 and 2009, the analysis of trends in sources over this time needed to take into account the decline in the absolute number of episodes (i.e. the proportion of episodes attributable to each source rather than just the actual number of cases). For this reason, a generalized linear model with a log link function for the Poisson distribution was used to compare counts between years, with an offset to account for the variability in the total number of counts of MRSA bacteraemia per year for each source. The model was reparameterized using different base years to allow rolling two-year comparisons of the incidence rate ratio (IRR) of proportions attributable to each source, adjusted for the total counts, with 95% confidence intervals (CI) and *P*-values for each comparison. The effects of age and sex on trends in sources over time were also modelled.

Results

Data on the source were available for 6892 (40%) of 17,022 episodes of MRSA bacteraemia reported between 1 January 2006 and 31 December 2009. Of these, 4404 records (26% of all MRSA bacteraemia) where the source was reported as 'certain', 'highly

Table 1

Characteristics of cases of methicillin-resistant *Staphylococcus aureus* bacteraemia with source information supplied compared with all other cases reported in England between 2006 and 2009

	All years (2006–2009)		
	All records <i>N</i> = 17,022	Source uncertain or not completed <i>N</i> = 12,618	Source completed and certain <i>N</i> = 4404
Patient demographics			
Male (%)	10,677 (62.7%)	7843 (62.2%)	2834 (64.4%)
Median age (years)	74 (97.1%)	74 (96.7%)	73 (98.3%)
Main specialty (any completed)			
General medicine	6482 (38.1%)	4808 (38.1%)	1674 (38.0%)
General surgery ^a	2231 (13.1%)	1603 (12.7%)	628 (14.3%)
Geriatric medicine ^a	2232 (13.1%)	1707 (13.5%)	525 (11.9%)
Nephrology ^a	913 (5.4%)	648 (5.1%)	265 (6.0%)
Trauma and orthopaedics ^a	787 (4.6%)	544 (4.3%)	243 (5.5%)
Urology	474 (2.8%)	336 (2.7%)	138 (3.1%)
Gastroenterology	532 (3.1%)	393 (3.1%)	139 (3.1%)
Hospital associated	11,088 65.1%	8248 65.4%	2840 64.5%

^a *P* < 0.05.

likely' or 'probable' were included in the analysis. In 866 episodes, the source was described as free-text; these were reviewed and allocated to one of 15 defined categories. At least one source of MRSA bacteraemia was reported by 152 of 167 NHS hospital trusts, with 37 reporting the source for more than 50 episodes of MRSA bacteraemia and 44 reporting the source for less than 10 episodes.

The number of episodes where the source of bacteraemia was reported increased from 14% (925/6776) in 2006 to 33% (1630/4928) in 2007, 36% (1149/3210) in 2008 and 33% (700/2180) in 2009. Comparison between the cases with a reported source of MRSA bacteraemia and all other cases entered over the same time period is shown in Table 1. There were no significant differences in age and sex, or whether the bacteraemia was classified as hospital associated. Significant but minor differences between specialties were found, with cases with a reported source of bacteraemia being slightly more likely to be under the care of general surgery (12.7% vs 14.3%; *P* = 0.01) or trauma and orthopaedics (4.3% vs 5.53%; *P* = 0.00), and slightly less likely to be under the care of geriatric medicine (13.5% vs 11.9%; *P* = 0.01).

Table 2 indicates the overall proportion of episodes ascribed to each source. The most common reported source of MRSA bacteraemia was skin and soft tissue infection (*N* = 1032, 23%); of these cases, specific sites were identified in 61 episodes, 40 of which were described as abscesses at various sites and 12 were associated with parotitis. The next most frequently reported sources of MRSA bacteraemia were central vascular catheters (CVCs) (*N* = 735, 17%) and peripheral vascular catheters (PVCs) (*N* = 509, 12%). Other major sources were the respiratory tract (9%) and the urinary tract (9%).

In 7% (*N* = 282) of episodes, the source was ascribed to an invasive device or procedure other than a CVC or a PVC; of these, dialysis access was the most frequently cited device, accounting for 183 (4%) episodes, followed by ventilator-associated pneumonia (*N* = 27). However, pacemaker wires (*N* = 16), nephrostomy tubes (*N* = 12) and percutaneous gastrostomy tubes (*N* = 9) were also frequently identified devices. In addition, it is likely that a high proportion of episodes of MRSA bacteraemia where urinary tract infection (UTI) was the source may have been associated with a urinary catheter.⁷ Six percent (*N* = 255) of infections were associated with bones and joints [osteomyelitis, surgical site infection (SSI) in orthopaedic patients, septic arthritis and bone abscess], including nine reports of discitis and 21 bone-related abscesses. Three hundred and forty (8%) episodes were attributed to contaminated specimens, and the source was specifically reported as 'unknown' in 4%.

Table III
Distribution of sources of methicillin-resistant *Staphylococcus aureus* (MRSA) bacteraemia by speciality, England 2006–2009

Speciality ^a	Source of MRSA bacteraemia											
	CVC	PVC	Devices	Skin and soft tissue	UTI	SSI	Respiratory	Other	Contaminant	Unknown	Total	
General medicine	N 170 (%) (10)	204 (12)	49 (3)	471 (28)	178 (11)	43 (3)	215 (13)	104 (6)	161 (10)	79 (5)	1674 (28)	
General surgery	N 214 (%) (34)	60 (9)	13 (2)	156 (25)	18 (3)	58 (9)	18 (3)	43 (7)	30 (5)	18 (3)	628 (14)	
Geriatric medicine	N 22 (%) (4)	90 (17)	8 (2)	137 (26)	73 (14)	21 (4)	79 (15)	26 (5)	50 (10)	19 (4)	525 (12)	
Nephrology	N 67 (%) (25)	9 (3)	124 (47)	26 (10)	5 (2)	2 (1)	5 (2)	13 (5)	5 (2)	9 (3)	265 (6)	
Trauma and orthopaedics	N 14 (%) (6)	14 (6)	2 (1)	65 (27)	8 (3)	85 (35)	12 (5)	29 (12)	7 (3)	7 (3)	243 (6)	
Gastroenterology	N 44 (%) (32)	21 (15)	7 (5)	22 (16)	5 (4)	2 (1)	8 (5)	9 (6)	9 (6)	12 (8)	139 (3)	
Urology	N 8 (%) (6)	7 (5)	17 (12)	11 (8)	67 (49)	7 (5)	2 (1)	5 (4)	9 (6)	5 (4)	138 (3)	
Subtotal	N 539 (%) (15)	405 (11)	220 (6)	888 (25)	354 (10)	218 (6)	339 (9)	229 (6)	271 (7)	149 (4)	3612 (82)	
Total	N 735 (%) (17)	509 (12)	255 (6)	1032 (23)	397 (9)	269 (6)	435 (10)	252 (6)	340 (8)	181 (4)	4404 (82)	

CVC, central vascular catheter; PVC, peripheral vascular catheter; UTI, urinary tract infection; SSI, surgical site infection.

^a Represents the speciality in which the patient was located at the time of MRSA bacteraemia. Includes specialties with at least 100 sources reported.

bacteraemias associated with CVCs, PVCs or other invasive devices were more likely to occur in hospital-associated cases, 20% of CVC infections were classified as community associated because the patient had not been admitted to hospital, or had been in an acute hospital for less than two days when the specimen was taken. UTIs were evenly distributed between hospital- and community-

associated cases, and SSIs were more commonly reported as community associated, probably because of patients re-admitted with SSIs that became apparent after the initial discharge; these are, by definition, hospital associated. Dialysis access was a more common source in community-associated cases, reflecting the delivery of renal replacement therapy in outpatient or community

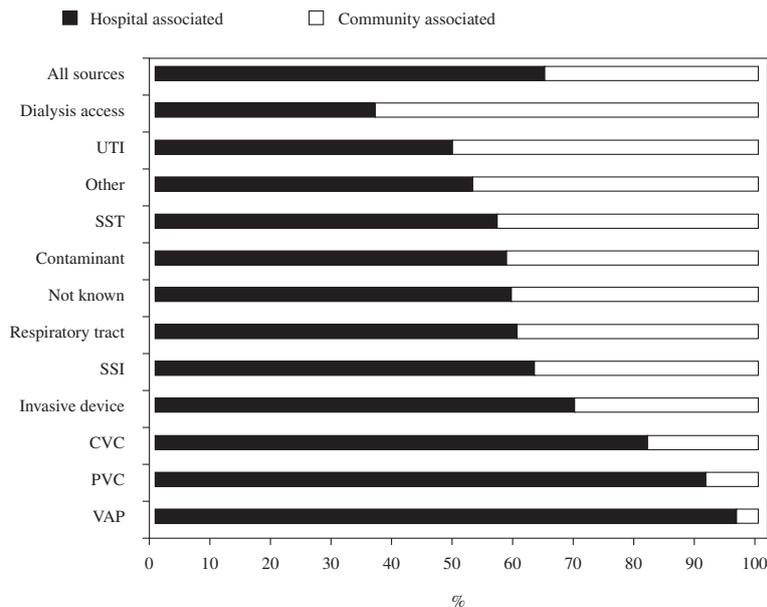


Figure 2. Sources of methicillin-resistant *Staphylococcus aureus* (MRSA) bacteraemia by classification of 'hospital associated' or 'community associated' (N=4404). CVC, central vascular catheter; PVC, peripheral vascular catheter; UTI, urinary tract infection; SSI, surgical site infection; SST, skin and soft tissue; VAP, ventilator-associated pneumonia.

Table IISources of methicillin-resistant *Staphylococcus aureus* (MRSA) bacteraemia in England: *N* (%) of cases by reported source for 2006–2009, and total for all years (*N* = 4404)

Source of MRSA bacteraemia	Year									
	2006		2007		2008		2009		All years	
	<i>N</i> cases	% of all sources								
PVC	110	12	237	15	112	10	50	7	509	12
CVC	201	22	276	17	167	15	91	13	735	17
Dialysis access	43	5	63	4	53	5	24	3	183	4
Invasive device	16	2	25	2	18	2	13	2	72	2
VAP	9	1	7	0	6	1	5	1	27	1
Respiratory tract	88	10	153	9	96	8	71	10	408	9
Skin and soft tissue	192	21	362	22	282	25	196	28	1032	23
SSI	73	8	92	6	77	7	27	4	269	6
UTI	79	9	134	8	107	9	77	11	397	9
Contaminant	39	4	132	8	102	9	67	10	340	8
Other	44	5	84	5	77	7	46	7	251	6
Not known	31	3	65	4	52	5	33	5	181	4
Total	925		1630		1149		700		4404	

CVC, central vascular catheter; PVC, peripheral vascular catheter; VAP, ventilator-associated pneumonia; SSI, surgical site infection; UTI, urinary tract infection.

Reported source of MRSA bacteraemia by age and sex of patient

Of the 4404 episodes of MRSA bacteraemia with a reported source, 4148 contained valid data on sex of the patient. Sixty-five percent (*N* = 2704) of episodes of MRSA bacteraemia occurred in males. Skin and soft tissue infection was the most common source in both sexes, accounting for approximately one-quarter of episodes. However, there were differences between sexes with respect to the other sources of MRSA bacteraemia (Figure 1). UTIs accounted for most of the difference between males and females, and were significantly more likely to be the source of MRSA bacteraemia in males (13% vs 3%). Both CVCs and SSIs, however, accounted for a greater proportion of episodes in females (20% vs 16% and 8% vs 5%, respectively). These differences between sexes were significant (χ^2 , $P < 0.001$). If UTIs, CVCs and SSIs were excluded, the overall difference between the sexes in terms of sources was no longer significant ($P = 0.983$).

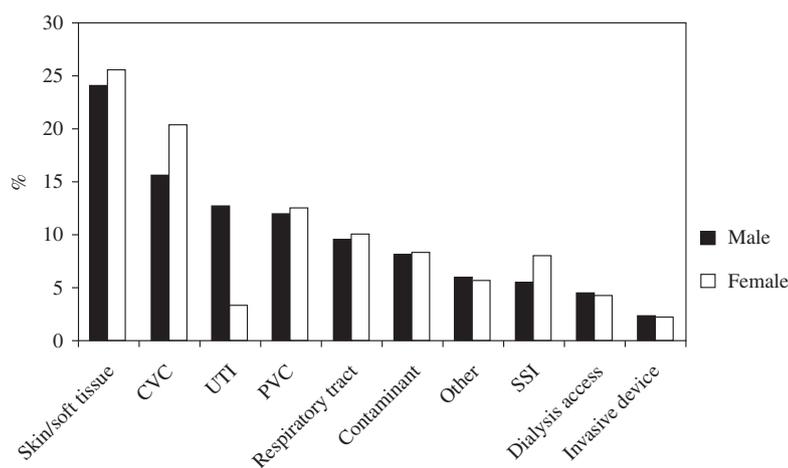
Variation in source of MRSA bacteraemia in main specialty groups

The main specialties in which patients with MRSA bacteraemia were located are shown in Table III. The episodes were allocated to

a specialty by the reporting hospital, although it is recognized that some (e.g. geriatric medicine) are not precisely defined. These specialties accounted for 82% of the bacteraemias included in this analysis. Almost 40% occurred in patients in general medicine. Skin and soft tissue infection was the most frequently reported source of MRSA bacteraemia in both general (28%) and geriatric medicine (25%), with a further 20% of episodes also associated with intra-vascular devices in these specialties. In general surgery, CVCs were the most common source (34%), followed by skin and soft tissue infection (25%). In trauma and orthopaedic surgery, the most frequent source was SSI (35%), and this specialty accounted for one-third of all cases where the source was reported as SSI. Almost half of the sources of MRSA bacteraemia in nephrology were associated with dialysis access; similarly, just under half of the episodes in urology were associated with UTI.

Hospital- vs community-associated MRSA bacteraemia

The sources of bacteraemia for patients who were classified as hospital associated were compared with those classified as community associated (Figure 2). Overall, 64% of episodes of MRSA bacteraemia were classified as hospital associated. Whilst

**Figure 1.** Distribution of main reported sources of methicillin-resistant *Staphylococcus aureus* (MRSA) bacteraemia by sex of patient (*N* = 4138), England, 2006–2009. CVC, central vascular catheter; PVC, peripheral vascular catheter; UTI, urinary tract infection; SSI, surgical site infection.

settings. Overall, an invasive device or surgery was identified as the source for 27% of episodes of MRSA bacteraemia in community-associated cases.

Trends in reported source of MRSA bacteraemia over time

Table II shows the distribution of reported sources between 2006 and 2009. This indicates a decline in CVCs and PVCs as a source of MRSA bacteraemia (34% of infections in 2006 and 20% in 2009). Skin and soft tissue infection has shown a relative increase as a source of MRSA bacteraemia, accounting for 21% of episodes in 2006 and 28% in 2009. In addition, the proportion of episodes attributable to respiratory tract infections and UTIs increased between 2006 and 2009. The proportion of reports of MRSA bacteraemia attributed to a contaminated specimen also increased from 4% to 10% over this period.

However, the change in the actual number of cases attributable to a particular source will be influenced by the total number of reports of MRSA bacteraemia, which declined overall by 34% during this time (IRR 0.76, 95% CI 0.69–0.83; $P < 0.001$). The generalized linear model was used to determine the changes in proportion of bacteraemias attributed to different sources whilst adjusting for variation in the number of cases over time. The results are shown in Table IV, and indicate that there were significant reductions in some of the reported sources of MRSA bacteraemia between 2006 and 2009: CVCs (IRR 0.6, 95% CI 0.47–0.77; $P < 0.001$), PVCs (IRR 0.6, 95% CI 0.43–0.84; $P < 0.003$) and SSIs (IRR 0.49, 95% CI 0.31–0.76; $P = 0.001$). Over the same period, a significant increase in the proportion of episodes of MRSA bacteraemia due to skin and soft tissue infection (IRR 1.35, 95% CI 1.11–1.65; $P = 0.003$) and contaminants (IRR 2.27, 95% CI 1.53–3.37; $P < 0.001$) was observed.

Overall, 2% of the 4404 records used for examining trends in the sources of bacteraemia had missing data on patient sex, and this varied between years from 4% (2008) to 0.1% (2007). The data on age were available for all records. When age and sex were included in the model, the effects based on the comparison between 2009 and 2006 remained unchanged, except for the 'other' category where the trend changed from non-significant to significant. The adjusted analysis resulted in some changes in the effects in the intervening period: between 2006 and 2007, the reduction in SSIs as the source of MRSA bacteraemia was converted from significant to non-significant; and between 2007 and 2008, a non-significant increase for skin and soft tissue infection as the source was converted to a significant increase.

Discussion

The data presented in this analysis provide a unique insight into the likely sources of MRSA bacteraemia from a large number of hospitalized patients, across a wide range of hospitals and over a prolonged period. Few other studies have examined the sources of MRSA bacteraemia, and these have been based on relatively small case series or focused on specific patient groups.^{8,9} The present study indicates the importance of skin and soft tissue infection as a major source of MRSA bacteraemia, accounting for half of all these infections, and is an area worthy of more detailed investigation. In common with other studies, invasive devices considered together accounted for a further one-third of cases. Although SSI is a less frequent source overall, it was responsible for over one-third of episodes of MRSA bacteraemia in trauma and orthopaedic surgical specialties. Indeed, bone and joint infections have an important association with MRSA bacteraemia, and some of these infections, notably osteomyelitis, discitis and septic arthritis, are of particular concern because of the considerable associated morbidity.¹⁰ Although bone and joint infections may arise in community settings, they have a complex aetiology and frequently reflect secondary infection originating from a primary device-related bacteraemia or other source.¹⁰ Those caused by MRSA may also reflect colonization acquired during a previous hospitalization, although it is not possible to distinguish such cases within the current dataset.¹¹ As far as less frequent sources of bacteraemia are concerned, the 12 cases of parotitis reported in this series, although not a numerically significant source of MRSA, do emphasize the importance of considering the oral mucosa as a potential source of staphylococcal bacteraemia.¹² Staphylococcal mucositis is recognized as a problem in the debilitated elderly, in whom it can be associated with significant morbidity.¹³ Gastrostomy sites were also a reported source of MRSA bacteraemia, indicating the importance of preventing infection in these devices.¹⁴ Coello *et al.* found that wounds and intravascular catheters were independent risk factors for the development of MRSA infection in patients colonized with MRSA, and this emphasizes the need to identify these patients and eliminate colonization where possible.¹⁵ In some patients, it is not possible to determine the source of bacteraemia. In this study, only 4% of cases were reported as not having an identifiable source of bacteraemia; however, this may be an underestimate if hospitals did not enter data on the source for such cases. Male patients appear to be at higher risk of MRSA bacteraemia than females, and this analysis suggests a strong association with UTIs, probably reflecting the use of catheters for management of disease of the prostate.

Table IV

Relative change in the number of episodes of methicillin-resistant *Staphylococcus aureus* (MRSA) bacteraemia in England between two years using rolling two-year comparisons^a by reported source adjusted for age and sex

	2007 vs 2006 (baseline)			2008 vs 2007 (baseline)			2009 vs 2008 (baseline)			2009 vs 2006 (baseline)		
	IRR	95% CI	P-value	IRR	95% CI	P-value	IRR	95% CI	P-value	IRR	95% CI	P-value
CVC	0.75	0.59–0.95	0.018	0.79	0.61–1.03	0.078	0.71	0.48–1.05	0.083	0.42	0.29–0.61	<0.001
PVC	1.21	0.94–1.56	0.148	0.69	0.54–0.88	0.003	0.83	0.58–1.18	0.302	0.69	0.48–0.99	0.042
UTI	0.97	0.72–1.29	0.817	1.08	0.83–1.41	0.558	1.28	0.94–1.74	0.111	1.34	0.97–1.86	0.079
Dialysis	0.72	0.43–1.21	0.211	1.48	0.92–2.39	0.104	0.68	0.36–1.26	0.218	0.72	0.37–1.39	0.327
Skin/soft tissue	1.08	0.88–1.32	0.482	1.20	1.01–1.43	0.043	1.03	0.84–1.27	0.772	1.33	1.05–1.69	0.017
SSI	0.77	0.55–1.08	0.135	1.03	0.73–1.44	0.867	0.53	0.31–0.90	0.019	0.42	0.25–0.72	0.001
Respiratory tract	1.00	0.75–1.34	0.989	0.94	0.71–1.23	0.637	1.20	0.87–1.66	0.275	1.13	0.80–1.59	0.495
Invasive device	0.57	0.31–1.08	0.084	1.19	0.62–2.27	0.598	1.20	0.57–2.52	0.624	0.82	0.40–1.70	0.596
Contaminant	1.74	1.17–2.59	0.006	0.96	0.71–1.30	0.798	1.17	0.81–1.69	0.400	1.96	1.25–3.06	0.003
Other	1.23	0.79–1.91	0.369	1.22	0.85–1.76	0.274	1.15	0.76–1.74	0.517	1.72	1.05–2.81	0.030
Unknown	1.00	0.63–1.59	0.997	1.09	0.72–1.65	0.672	1.11	0.68–1.82	0.683	1.21	0.71–2.07	0.478
All sources	1.83	1.66–2.01	<0.001	0.71	0.66–0.78	<0.001	0.59	0.53–0.65	<0.001	0.77	0.68–0.86	<0.001

CVC, central vascular catheter; PVC, peripheral vascular catheter; SSI, surgical site infection; UTI, urinary tract infection; IRR, incident rate ratio; CI, confidence interval.

^a IRRs from a generalized linear model with a log link function for Poisson distribution to estimate the relative risk; significant values denoted by bold text.

The time trends in reported sources of MRSA bacteraemia demonstrate significant declines in CVCs and PVCs as the source between 2006 and 2009 that were not explained by changes in the age or sex distribution of cases. These sources also showed constant declines in the intervening period (from 2006 onwards for CVCs and from 2007 onwards for PVCs). Meanwhile, a significant increase in skin and soft tissue infection as a reported source was seen between 2006 and 2009, with constant increases in the intervening period. The study data show that, by 2009, intravenous devices accounted for only 20% of episodes, compared with between one-third and two-thirds of episodes in earlier accounts of factors contributing to MRSA bacteraemia.^{9,16} These trends have occurred in the context of major national initiatives to reduce MRSA bacteraemia since 2004, that were particularly targeted at preventing intravenous-device-associated bacteraemia. A concomitant decline in the prevalence of EMRSA-16 strains prior to these initiatives may also play a part in the change.¹⁷ SSIs have also declined significantly as a reported source of MRSA bacteraemia over this period; a trend also apparent in data from the national SSI Surveillance Service.⁵ This may reflect an increase in the use of screening and decolonization in response to national government targets.⁵ In contrast, the proportion of episodes of MRSA bacteraemia with skin and soft tissue infection as the reported source has increased significantly, and this has now emerged as the predominant source of MRSA bacteraemia overall, although there are important differences across specialties reflecting differences in the case mix.

Since the national mandatory surveillance scheme requires that hospitals report all cultures positive for MRSA, regardless of whether or not the organism is considered to be clinically significant, it is to be expected that some of the cases reported will be due to contaminated specimens rather than true clinical infections. This analysis suggests that these cases inflate the rate of MRSA bacteraemia reported by the surveillance system by approximately 10%. The proportion of cases of bacteraemia attributed to contamination increased significantly between 2006 and 2009, although the reasons for this are not clear.

For the purpose of simplicity, the surveillance scheme attributed infection as community or hospital associated according to the widely accepted principle of whether the bacteraemia was identified in patients in an acute hospital during or after the first two days of admission. However, the analysis indicated that use of time from admission to distinguish the MRSA bacteraemia as community or hospital associated is limited. More than one-third of cases with SSI as the reported source occurred in cases classified as community associated and other patients allocated to this group; for example, dialysis access, intravascular devices or other invasive devices clearly had an ongoing healthcare intervention that was the source of MRSA bacteraemia. This concurs with the findings of Tacconelli *et al.* that patients whose MRSA bacteraemia was diagnosed within 24 h of admission frequently had a history of exposure to hospital.¹¹ It illustrates the general difficulty of separating hospital-associated infections from community-acquired infections, which is compounded by the fact that much healthcare is now delivered in non-hospital settings.^{16,18} On the basis of these data, the use of the two-day cut-off in admission to an acute hospital to distinguish between community- and hospital-associated bacteraemia, although pragmatically useful, is not definitive and further work is needed to develop a better means of discrimination. One possible alternative approach is for the reporting hospital to assign the bacteraemia as hospital acquired, healthcare associated or community acquired using more specific definitions that allow for patients having infection associated with an invasive device or procedure.

One limitation of the present study is that the sources described were not based on standard case definitions but on the judgement of the data collector. There may also have been variation in the extent to which hospitals specified less common sources of MRSA bacteraemia that were not included in the predefined list, and the data did not necessarily capture all the contributory factors; for example, whether an abscess described as the source was, in fact, related to an SSI. In addition, since the source of infection was only reported in one-third of cases, the generalizability of these trends depends on the assumption that records with source data reflect a reasonably random sample of cases in each year. Although the sample was based on available data and did not involve random selection, there was no evidence of major bias. In the future, such surveillance systems can be designed to focus on the mandatory collection of a much smaller, but well-defined, dataset in order to capture more complete information.

In summary, the trends observed in this analysis indicate a significant decline in intravenous devices as a source of MRSA bacteraemia, with skin and soft tissue infection emerging as the predominant source, and UTI, possibly in association with catheterization, being a major source of MRSA bacteraemia in men. Use of bacteraemia detection within two days of hospital admission as a criterion to define community-acquired cases of MRSA bacteraemia is not a reliable method of discriminating these from hospital-associated cases.

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