Methods For Identifying Surgical Wound Infection After Discharge From Hospital: a systematic review.

Emily S Petherick, Jane E Dalton, Peter J Moore Nicky Cullum

1Department of Health Sciences, University of York, Seebohm Rowntree Building, York, UK.
2Centre for Reviews and Dissemination, University of York, York, UK.
3Department of Surgery, Scunthorpe General Hospital, Scunthorpe, UK.

Corresponding author

EP, JED and NAC undertook the systematic review and audit of infection control personnel. ESP, JED, NAC and PJM participated in the design of the study and the drafting of the manuscript. All authors read and approved the final version of the manuscript.

Email addresses:
ESP: ep9@york.ac.uk
JED: jd518@york.ac.uk
PJM: enid.bridge@nlg.nhs.uk
NAC: nac2@york.ac.uk
Abstract

Background
Wound infections are a common complication of surgery that adds significantly to the morbidity of patients and costs of treatment. The global trend towards reducing length of hospital stay post-surgery and the increase in day case surgery means that surgical site infections (SSI) will increasingly occur after hospital discharge. Identification of SSIs is important so that they may be treated appropriately and also because rates of SSI are viewed as a measure of hospital performance, however accurate detection post-hospital discharge is not straightforward.

Methods
We conducted a systematic review of post discharge surveillance for surgical wound infection and undertook a national audit of current post-discharge surveillance for surgical site infection practice within the United Kingdom NHS Trusts.

Results
Five post-discharge surveillance comparative studies were located, all of which had methodological flaws, making the relative judgement of validity problematic. The audit identified a wide range of relevant post-discharge surveillance programmes in England, Scotland and Wales; however, these programmes used varying approaches for which there is little supporting evidence of validity and/or reliability.

Conclusions
Future research should concentrate on the development of a method for monitoring post-surgical infection that is sufficiently accurate. We believe that at this time, the Centers for Disease Control definition of wound infection serves as the most reliable definition to be used as a gold standard of diagnosis for all further research. This definition should then be used for comparisons between alternative surveillance...
methods using appropriate diagnostic test methodologies with adequate follow-up post diagnosis to measure the impact of detection on costs and outcomes.
Background

Surgical site infections (SSIs) have been estimated to occur in up to 15% of elective surgical patients and approximately 30% of patients whose surgical procedure was classed as contaminated or “dirty” [1]. The proportion of SSIs that are preventable is unknown, however there are wide variations in infection rates and an international drive to minimise them [1]. Accurate, standardised methods of defining and monitoring SSIs are essential in order to detect and treat infections (treatment), compare the performance of different surgical services (performance monitoring) and of different interventions (research). Two main problems exist in this area. These being:

- The lack of an agreed “gold standard” method of PDS (post-discharge surveillance) for SSI
- Paucity of studies comparing different methods in a consistent way (large variations in definition of SSIs; staffing, setting and timings used in existing studies).

A previous systematic review addressed a broad range of questions relating to adverse events of surgery, and included SSIs [1]. We sought to build on this review in relation to PDS SSI.

This study will attempt to answer the following two questions:

1. What is the current evidence for the validity, reliability and practicality of different systems of PDS of SSIs?
2. What are the features of existing post discharge surveillance systems in terms of coverage; source of denominator data; diagnostic characteristics; other data collected; methods of data collection?

Definition of Surgical Site Infection
For this review we have taken the Centers for Disease Control and Prevention (CDC) definition [2] of surgical site infection as being the gold standard definition. Many other definitions of surgical site infection are available and we have not excluded studies from this review that have used alternative diagnostic criteria.

Methods
Existing surveillance systems were identified and described using a combination of literature review and a national audit.

Literature review – all studies
The literature search based on that undertaken for the Bruce et al [1] review (search dates from 1993 to 1999) and was updated using the databases shown (Table 1). This was undertaken to answer the question: What is the current evidence for the validity, reliability and practicality of different systems of PDS of SSI?

Table 1  Electronic databases searched for this review

In order to be eligible for inclusion, studies had to:

a) Describe a method of post discharge surveillance for surgical site infection OR
b) compare at least two of post discharge surveillance for surgical site infection

    OR

c) describe an economic evaluation of a post discharge surveillance system for surgical site infection.

Papers were excluded if they met any of the following criteria;

a) Paper gave no indication that post discharge follow up was performed OR

b) post-discharge follow up was carried out for reasons other than for surveillance of surgical wound infection, OR

c) appeared to be routine patient follow up post operation with no methodological detail provided of how post-discharge follow up was achieved.

Two abstractors assessed potentially eligible articles, independently applying the inclusion and exclusion criteria. Any disagreements were solved by discussion. For completeness it was decided to re-abstract and include the comparative surveillance studies from the previous review [1].

Validation studies

In addition to the inclusion criteria above, in order for validation studies to be eligible for inclusion in this review they had to compare alternative ascertainment techniques, and furthermore patients had to receive both methods of surveillance regardless of the results of either method.

The Quality Assessment of Diagnostic Accuracy Studies (QUADAS) checklist [3] was used to assess the validity of the studies that were comparing different methods of post discharge surveillance. The QUADAS checklist includes 14 questions about the
spectrum of patients studied, selection criteria, test verification, test description, blinding, uninterpretable results, and study withdrawals [4].

**National Audit**

PDS systems for SSIs currently in use in the UK were identified by audit. A brief audit form was sent to infection control personnel within all UK primary care trusts and hospital trusts to identify those Trusts that were undertaking any form of PDS for SSIs.

**Results**

**Literature Review**

Our literature search overlapped with the Bruce *et al* [1] search by one year (1998). The search yielded a total of 3,548 article titles and/or abstracts, from which 130 papers were ordered for full text assessment.

A total of 78 papers referred to post discharge surveillance for surgical site infections. Of these, 73 papers described a single surveillance programme. No studies were located that looked at the impact on patient outcomes of having a post discharge wound surveillance programme in place. Only three papers found by this search reported research that compared different surveillance methods. Two studies located in a previous review were re-abstracted for completeness bringing the total number of comparative studies included in this study to five.

The PDS methods used to detect post-discharge SSI in the literature were:

- direct observation of the wound by health professional (n=31)
- telephone interviews with patients (n=17)
- patient questionnaire (n=13)
- other methods (n=21). Other methods used included review of operating logs to examine surgical revisions; cards to be used by patients to notify health care personnel of a surgical site infection; examination of hospital readmission data; review of pharmacy data; and using mixed methods.
- method not stated (n=9)
- staff questionnaires (n=8).

It should be noted that a combination of methods of PDS was used in some studies (e.g. patient self diagnosis and nurse diagnosis of SSI) however in these studies no comparison was made between the methods.

The CDC definition was the most commonly used definition of SSI and was applied in 38% (n=28) of studies included. Other definitions used included authors’ own (n=8, 11% of studies) and other methods or methods unclear (n=10, 14% of studies). No formal definition of surgical wound infection was provided in 26 reports (36%) of studies.

The duration of follow up within the post discharge surveillance programmes varied between 3 days post-discharge to several years; 30 days was the most common duration (n=34, 50%). The use of a 30-day follow up point is consistent with that stipulated in the CDC definition of surgical wound infection (30 days is stipulated by the CDC as the required duration of follow up after operation if no implant is left in place or one year if implant is in place and the infection appears to be related to the operation) [2].
Studies comparing the validity of alternative methods of post-discharge surgical site infection surveillance.

Studies identified as validation studies were categorised by the methods used to assess validity and accuracy [1].

1) comparison of different processes of case ascertainment of SSI, including case ascertainment by different health care professionals (no studies)

2) assessment of patients’ own ability to self diagnose wound infection, compared with health professional diagnosis (4 studies)

3) validation reports of data capture methods, in particular, manual versus automated data entry (1 study)

4) studies of the validity of systems and examination of the feasibility of using existing data-collection systems (e.g. feasibility of antibiotic utilisation as a measure of surgical site infections) (1 study)

1. Validation of case ascertainment

We found none of these studies.

2. Validation of patient self-diagnosis

Four studies were identified that looked at the validation of patient self-diagnosis as a method of post discharge surveillance. Two of these studies [5, 6] were included in a previous review [1] and data were re-extracted for this review for completeness.

These studies compared patient self-diagnosis with health professional diagnosis.

Seaman & Lammers [5] found that patients were unable to recognise infections in their own wounds. Of the 21 wound infections that were identified by health care
professional assessment only 11 were detected by patients themselves, (a false negative diagnostic rate of 48%). However, the paper did not detail the questions asked of the patients.

In Mitchell et al [6], both patients and surgeons agreed that wound infection was absent in 565 cases. Surgeons classified infection as present in 59 wounds whilst patients classified infection as present in 74 wounds; the researchers on further investigation then re-classified 23 wounds regarded as not infected by surgeons as infected — rejecting the gold standard in favour of patient assessment. Reasons for misclassification were given as surgical wound assessment preceding the development of infection and patients having reported their infection to someone other than their surgeon. False negative rates for patient assessment were also very low. Overall the agreement between surgeon and patient assessment was fair, with a Kappa of 0.73. However, there was high proportion of missing data in the study.

The results of this study are difficult to interpret since surgeon and patient assessment did not coincide in time (and so were not assessing a wound in an identical ‘state’) and response rates were low. The results do provide some evidence that patients may be able to self diagnose wound infection with a reasonable level of agreement with the surgeon.

Whitby et al [7] analysed the validity of post-discharge self-diagnosis in Australia, by comparing self diagnosis by questionnaire with both Infection Control Nurse diagnosis and independent medical assessment of wound photographs for evidence of discharge and/or swelling. This study found that patients were unable to effectively self assess surgical site infections post discharge (positive predictive value of 29% - in other words only 29% of people who assessed themselves as having an infection
actually had one). However, the negative predictive value for patient assessment was high (98% of patients who assessed themselves as not having an infection did not have one). Data presented in the publication did not allow for the calculation of the sensitivity and specificity of any of the methods compared with the gold standard; however sensitivity and specificity are required to make an assessment of the validity of the methods. Furthermore, both the positive and negative predictive values reported in this study are highly dependant upon the prevalence of infection in the population and as such cannot be generalised to other populations.

The fourth study [8] compared patient assessment with health care (clinic and general practitioner) data. Of the 92% of patients who responded, 64 (4.2%) reported having had an infection or inflammation of the wound. Scrutiny of clinic and general practitioner data identified 9 (0.5%) cases. It is not clear whether this disagreement is due to time lag bias or use of different criteria for diagnosis. No a priori definition of wound infection was described. It is unclear if all practitioners were using the same criteria by which a judgement of wound infection could be objectively and consistently made and it is not clear that routine outpatient follow up is a robust enough method of detection to be regarded as a reference method.

It is difficult to draw conclusions about the ability of patients to self diagnose PDS SSI from these studies, given the varied methods of self assessment used, different comparisons and methodological flaws. Nevertheless it is quite likely that, asked the right questions, patients would be able to identify infections and more research is required to establish the best method.
3. Validity of systems and existing data collection systems.

Only one study compared the validity of using existing data systems to capture patients with SSIs to prospective hospital based surveillance using NNIS [9]. This resulted in 388 eligible patients from a total of 1352 Coronary Artery Bypass Graft patients in the United States.

Surveillance based on health insurance data identified approximately 50% more infections than did hospital-based surveillance and more than twice the number of infections occurring post discharge.

There were considerable methodological problems inherent in this study; not least the lack of gold standard comparison and therefore no sense of the extent of misclassification by either system, neither of which involved purposeful patient examination. Rather, the authors have taken the combined figure of positive results of infection irrespective of method of diagnosis to be the true positive rate. Whilst this may have increased the reported sensitivity of the tests, the ratio of difference between the two tests would remain the same. Sufficient detail was not available to calculate the specificity of either of the methods.

Therefore, whilst one study suggested that health insurance administrative data may detect more patients with SSIs than hospital based surveillance in the United States, its applicability in the UK is low due to the amount, type and quality of routine data capture in the UK health system. Furthermore, the study is uninformative regarding post-discharge SSI detection.

4. Validation of data capture methods
No studies were found that compared a “gold standard” reference method with an existing data collection system only although there was some component of this in one of the studies found and described above [9].

All studies were then assessed for validity using the QUADAS tool. The result of this assessment is shown below in Table II.

Overall, methodological weaknesses were observed in all 5 comparative studies and the quality of reporting was also poor, as evidenced by the frequency of “unclear” responses to the QUADAS questions. The most common methodological weaknesses encountered in the studies was the lack of description of the time points at which assessments of infection were made and the criteria used to define whether a wound infection was present.

National audit
In total, 361 Infection Control personnel from 317 trusts or health boards were sent an audit form in May 2004, and asked to return the form irrespective of whether they were performing post discharge surveillance. Overall, 46% (n=146) of trusts and health boards returned the audit form (only one response was counted in the numerator where multiple responses were received from single institutions within trusts or health boards). Of those trusts that responded, 29% (n=42/146) reported performing some form of post-discharge surveillance and 71% (n = 104) said they were not.

In a small minority of trusts that reported performing PDS, 14% (n=6/42) reported doing so in all surgical areas. Otherwise, orthopaedics was the speciality most commonly undertaking PDS for SSI with obstetrics (post-caesarean section) also being common (23%, n=10). Other surgical procedures that were followed in smaller
numbers were vasectomies, craniotomies, CABG, large bowel surgery, breast surgery, general surgery, hernia repair, vascular surgery and day surgery.

The most common methods of PDS reported in the audit were of routine clinical follow up (45% or n=19/42) and direct observation of the wound (41% or n=17/42) of positively responding trusts. An even greater number of respondents (50% or n=21/42) reported using another method or a combination of methods. These included: giving forms to patients or primary care providers to return in 30 days; looking at hospital readmission data at 30 days post discharge; writing letters to, or telephoning General Practitioners to enquire as to any signs of infection post discharge or a combination of these and other methods. Other methods such as surgeon surveys, patient telephone or postal questionnaires were less frequently undertaken.

**Discussion**

The optimum study design for evaluating diagnostic tests (post-discharge detection of SSI can be regarded as such a test) has been proposed to contain three key features: a series of patients which represents an appropriate clinical spectrum; patients receive both the new test and the reference or ‘gold standard’ test irrespective of the results of either test; the reference or ‘gold standard’ should be measured independently of the new test.[10] A study of this kind would allow for the calculation of test accuracy values of sensitivity and specificity. None of the studies identified in this review provided the information necessary to calculate sensitivity or specificity for the diagnostic method being evaluated, thus limiting the conclusions that can be drawn from these studies.
There is great variation in the methods of PDS SSI used in practice and particularly in the sources of data used. Multiple methods are commonly used including routine clinic follow up plus data from primary care providers. Orthopaedics and obstetrics were the most frequently observed surgical specialities undertaking PDS SSI. Importantly, whilst there are national policies to capture SSIs (for example the Health Protection Agency’s mandatory orthopaedic surgical site infection surveillance which began on April 1st 2004), these schemes do not require post-discharge surveillance and do not give guidance as to how this could be undertaken.

Only five studies comparing alternative methods of surveillance for SSI were located. These studies compared:

- **ascertainment of SSI by the capture of data from existing systems (claims and pharmacy dispensing data, medical records) with prospective hospital based surveillance using NNIS criteria [9].** This study found that data from existing administrative systems (in the USA) were better able to detect surgical site infections than routinely collected data.

- **Surgeon questionnaire-based assessment of patient wound status compared with patient self-assessment of wound status by postal questionnaire [6].** This study found that there was fair agreement between surgeons and patients regarding the status of their wounds – however, surgeon assessment data were missing for 50% of patients.

- **Patient self-diagnosis by interview compared with health professional diagnosis** found that patients were unable to diagnose infection or recognise signs of inflammation producing false negative rates of 48% [5].

- **Infection control nurse diagnosis compared with patient self-assessment, surgeon diagnosis, infection department physician/microbiologist and patient**
recall of general practitioner antibiotic prescription [7]. This study found that patients were not able to adequately identify infected wounds (i.e., a high false negative rate). Further results in this study are uninterpretable since analysed as correlation rather than agreement, although it is noteworthy that correlation between methods was poor.

- Patient reported symptoms of infection with outpatient clinic physician diagnosis [8]. This study found that similar rates of infection were detected via patient report and outpatient clinic follow up.

Two main issues arose from the comparative studies. Firstly, variations in data collection procedures and classification systems between countries limits comparability and prevents synthesis of the post discharge surveillance data. Many studies did not provide clear description of the criteria by which a diagnosis of infection was made. Secondly, the source of data affects the external validity of the study, as information collected in one country may not be readily available in another.

Together these two factors limit the applicability of the available evidence to the United Kingdom where vastly different data collection systems are in place. In addition, methodological limitations evident in these studies make the interpretation of conclusions difficult, especially in the light of apparent limited internal and external validity. Furthermore due to the lack of follow-up of patients with detected wound infections, it remains unclear whether there are significant benefits to patients’ health or if such surveillance programmes are cost-effective.

The type of post-discharge surveillance programme undertaken may depend upon the type of groups that the programme wishes to target. In groups of higher risk patients surveillance programmes are useful to ensure that appropriate treatments are made available. For those patients at a lower risk, surveillance programmes may have more
use as a performance monitoring tool, as infections will be more preventable in this group.

**Conclusions**

More research on methods to measure surgical site infection rates after hospital discharge is needed. Preliminary work should develop an appropriate reference (gold standard) system that is sufficiently accurate. As has been concluded previously, for consistency, the CDC definition of wound infection should be used in future studies unless evidence arises to suggest that this definition is unsatisfactory or that a more valid or reliable definition is developed [1]. This should then serve as the basis of methods of detection and comparisons between alternative methods such as self-diagnosis, which should use accepted methods of comparing diagnostic tests. As length of hospital stay continues to decline, there will be a greater proliferation of wound infections occurring outside of this setting. This will require the development of valid and reliable mechanisms for detecting and measuring surgical wound infections [10].

**Competing interests**

None declared.

**Authors' contributions**

NC and ESP designed the study. ESP and JED screened articles for inclusion, designed the data abstraction form, abstracted data and wrote the manuscript. NC and PJM revised the manuscript. PJM provided critical input in clinical issues of surgical wounds. ESP, JED and NC analysed the data.

**Acknowledgements**

The authors would like to thank Sandi Newby and Corinna Petre for their administrative assistance with the project. The authors would also like to thank CRD for their assistance in updating and undertaking of the search for this review. The authors would also like to acknowledge that this work was funded by a grant funded by the NHS R&D Methodology Programme.
References


Figures

None

Tables

Table I  Electronic databases searched for this review

<table>
<thead>
<tr>
<th>Database</th>
<th>Period/Issue covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medline (OVID)</td>
<td>1999–02/2004</td>
</tr>
<tr>
<td>EMBASE</td>
<td>1999–03/2004</td>
</tr>
<tr>
<td>CINAHL</td>
<td>1999–03/2004</td>
</tr>
<tr>
<td>The Cochrane Library Database of Systematic Reviews</td>
<td>1999–2004 Issue 1</td>
</tr>
</tbody>
</table>

Table II  Assessment of comparative studies using the QUADAS tool

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the spectrum of patients representative of the patient who will receive the test in practice?</td>
<td>No. CABG patients only.</td>
<td>No. Chose moderate to high-risk patients only.</td>
<td>No. Only included patients with lacerations treated at A &amp; E</td>
<td>Yes</td>
<td>Unclear. Not enough information presented</td>
</tr>
<tr>
<td>Were the selection criteria clearly described?</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Is the reference standard likely to correctly classify the target condition.</td>
<td>No. Relies on reporting, no observation.</td>
<td>Unclear*</td>
<td>Yes</td>
<td>Unclear</td>
<td>No</td>
</tr>
<tr>
<td>Is the time period between the reference standard and index test short enough to be reasonably sure that the target condition did not change between the two tests?</td>
<td>Unclear</td>
<td>Unclear</td>
<td>No</td>
<td>Unclear</td>
<td></td>
</tr>
<tr>
<td>Did the whole sample or a random selection of the sample, receive verification using a reference standard of diagnosis?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No. Only those whose surgeon completed the questionnaire</td>
<td>Yes</td>
</tr>
<tr>
<td>Did patients receive the same reference standard regardless of the test result?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Was the reference standard independent of the index test (i.e. the index test did not form part of the reference standard)?</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Was the execution of the index test described in sufficient detail to permit replication of the test?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Unclear</td>
<td>Yes</td>
</tr>
<tr>
<td>Was the execution of the reference test described in sufficient detail to permit replication of the test?</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Were the index test results interpreted without knowledge of the results of the</td>
<td>Unclear</td>
<td>Yes</td>
<td>Yes</td>
<td>Unclear</td>
<td>Yes</td>
</tr>
<tr>
<td>Question</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-----</td>
<td>-----</td>
<td>---------</td>
<td>-----</td>
<td></td>
</tr>
<tr>
<td>Were the results of the reference standard interpreted without knowledge of the results of the index test?</td>
<td>Unclear</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>Yes</td>
</tr>
<tr>
<td>Were the same clinical data available when test results were interpreted as would be available when the test is used in practice?</td>
<td>No. The information available in this standard would not be available in the UK.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Were uninterpretable/intermediate test results reported?</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Unclear</td>
</tr>
<tr>
<td>Were withdrawals from the study explained?</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Yes</td>
<td>Unclear</td>
<td>Unclear</td>
</tr>
</tbody>
</table>

**Additional files**

*None*