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# Management of unhealed surgical wounds in the community in clinical practice in the UK: costs and outcomes



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**ORIGINAL ARTICLE**

# MANAGEMENT OF UNHEALED SURGICAL WOUNDS IN THE COMMUNITY IN CLINICAL PRACTICE IN THE UK: COSTS AND OUTCOMES

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**Running title:** Health economic impact of unhealed surgical wounds in the UK

**Keywords:** Burden; cost; surgery; surgical wounds; wounds; UK.

## ABSTRACT

**Objective:** To examine patients' pathways attributable to managing unhealed surgical wounds in clinical practice, from initial presentation in the community in the UK.

**Methods**: This was a retrospective cohort analysis of the records of 707 patients in the THIN Database whose wound failed to heal within four weeks of their surgery. Patients' characteristics, wound-related health outcomes and health care resource use were quantified, and the total National Health Service (NHS) cost of patient management was estimated at 2015/2016 prices.

**Results**: Inconsistent terminology was used in describing the wounds. 83% of all wounds healed within 12 months from onset of community management, ranging from 86% to 74% of wounds arising from planned and emergency procedures, respectively. Mean time to healing was 4 months per patient. Patients were predominantly managed in the community by nurses and only half the patients were recorded as having had a follow-up visit with their surgeon. Up to 68% of all wounds may have been clinically infected at the time of presentation, and 23% of patients subsequently developed a putative wound infection a mean 4 months after initial presentation. Mean NHS cost of wound care over 12 months was £7,300 per wound, ranging from £6,000 to £13,700 per healed and unhealed wound, respectively. Additionally, the men NHS cost of managing a wound without any evidence of infection was ~£2,000 and the conflated cost of managing a wound with a putative infection ranged between £5,000 and £11,200.

**Conclusion:** Surgeons are unlikely to be fully aware of the problems surrounding unhealed surgical wounds once patients are discharged into the community, due to inconsistent recording in patients' records coupled with the low rate of follow-up appointments. These findings offer the best evidence available with which to inform policy and budgetary decisions pertaining to managing unhealed surgical wounds in the community.



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## STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is the first study to evaluate the patient pathways and associated resource use, health outcomes, and corresponding costs attributable to managing unhealed surgical wounds over 12 months from the onset of community management. This was undertaken using real world evidence derived from the anonymised records of a sample of patients in The Health Improvement Network (THIN) database (a nationally representative database of clinical practice among >11 million patients registered with general practitioners in the UK).

- The estimates were derived following a systematic analysis of patients' characteristics, wound-related health outcomes and all community-based and secondary care resource use contained in the patients' electronic records.

- Computerised information in the THIN database is collected by general practitioners (GPs) for clinical care purposes and not for research. Additionally, prescriptions issued by GPs and practice nurses are recorded in the database, but it does not specify whether the prescriptions were dispensed or detail patient compliance with the product.

- The analysis does not consider the potential impact of patients' surgical wounds that heal within four weeks of the surgical procedure or those patients who remain in hospital until their surgical wound heals. The THIN database may have under-recorded use of some healthcare resources outside the GP's surgery, however the impact of this was addressed in sensitivity analyses.

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The study's sponsors had no involvement in the study design, the collection, analysis and interpretation of the data, the writing of this manuscript and the decision to submit this article for publication. The views expressed in this article are those of the authors and not necessarily those of the NHS, the NIHR, the Department of Health or Smith & Nephew.

## COMPETING INTERESTS

None declared.

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## CONTRIBUTORS

J.F.G. designed the study, managed the analyses, performed some analyses, checked all the other analyses, and wrote the manuscript.

G.W.F. conducted much of the analyses.

P.V. scrutinised the analyses, suggested further analyses, helped interpret some of the findings, and edited the manuscript.

J.F.G. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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## DATA SHARING STATEMENT

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## INTRODUCTION

More than 10 million operations were performed by the National Health Service (NHS) in England [1] in 2015/16, with the majority involving an incision [2]. Most incised surgical wounds generally heal by primary intention. However, some heal by secondary intention, either because the wound has intentionally been left open or has dehisced following primary closure [3, 4]. Surgical wounds healing by secondary intention are thought to be common in the UK, and to account for 26-28% of all surgical wounds requiring continued nursing intervention [5]. Such wounds may remain open for an extended period and are susceptible to infection, requiring on-going treatment [6]. Surgical wound dehiscence (SWD), defined as the rupture or splitting open of a previously closed surgical incision site, may be either superficial or deep [7]. Dehisced wounds may be left to heal fully through secondary intention, or closed surgically after partial healing.

The management of patients with an unhealed surgical wound remains challenging because of the potentially high chance of developing further wound complications [8]. Such complications can result in hospital re-admission, further surgery, prolonged hospitalisation and may require intensive management in the community. The National Institute for Health and Care Excellence (NICE) estimated that 5% of all surgical procedures result in a surgical site infection (SSI) in the UK and account for up to 20% of cases of health care associated infections [9]. The SSI data collected by hospitals could be an underestimate as most patients develop signs and symptoms after discharge [10].

The Burden of Wounds study reported that unhealed surgical wounds accounted for 11% (n=250,000 patients) of all wounds managed in the UK by the NHS in 2012/2013 [11]. The annual NHS cost attributable to managing these wounds and associated comorbidities was estimated to be £982.9 million [12]. After adjustment for comorbidities, the annual NHS cost was estimated to be between £957.4 and £985.8 million [12].

Wound management is now of sufficient concern among the wound care community in the UK, that the UK Parliament (House of Lords) debated developing a national strategy for improving the standards of wound care in the NHS [13]. All health care systems recognise the importance of healing surgical wounds without complications. Nevertheless, there is a lack of information surrounding the characteristics of patients with surgical wounds healing



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by primary or secondary intention, the time taken for these wounds to heal, wound treatment and patient management within the community. Additionally, the health care costs associated with SWD are poorly reported and are frequently conflated with the cost of SSI. This paucity of data limits our understanding of the health care needs of patients with an unhealed surgical wound and also hinders the planning and allocation of the relevant resources. The aim of the present analysis was to follow a cohort of patients in clinical practice from initial presentation of their surgical wound in the community, to evaluate in greater depth how managing patients with an unhealed surgical wound impacts on healing and NHS costs.

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## METHODS

### Study Design

This was a retrospective cohort analysis of the case records of patients with an unhealed surgical wound (defined as one that had not healed within four weeks of the surgical procedure), randomly extracted from The Health Improvement Network (THIN) database.

### The Health Improvement Network Database

The THIN database (IMS, London, UK) contains electronic records on >11 million anonymised patients entered by GPs from 562 practices across the UK. The patient composition within the THIN database has been shown to be representative of the UK population in terms of demographics and disease distribution [14], and the database theoretically contains patients' entire medical history, as previously described [11]. Hence, the information contained in the THIN database reflects actual clinical practice.

### Study Population

The authors have previously obtained the electronic records of a random sample of 6,000 patients with a wound from the THIN database. The study population of 707 patients were selected from this cohort of 6,000 patients according to the following criteria:

- Were 18 years of age or over.
- Had undergone a surgical procedure either during or after 2012.
- Had a surgical wound which had remained unhealed for 4 weeks after the surgical procedure
- Had at least 12 months continuous medical history in their case record from the first mention of their surgical wound unless it healed.

Patients whose wound healed within 4 weeks of their surgical procedure or those with a dermatological tumour were excluded from the data set, as was any patient with an unhealed surgical wound that died within a year of initial presentation in the community.



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## Patient and Public Involvement

Patients and members of the public were not directly involved in this study. The study population was limited to the anonymised records of patients in the THIN database.

## Ethics Approval

Ethics approval to use patients' records from the THIN database for this study was obtained from the Research Ethics Committee that appraises studies using the THIN database.

## Study Variables and Statistical Analyses

Information was systematically extracted from the patients' electronic records over a period of 12 months from initial presentation of their unhealed surgical wound in the community. This included patients' characteristics, comorbidities (defined as a non-acute condition that patients were suffering from in the year before the start of their wound), wound-related health care resource use, prescribed medication and clinical outcomes. If a patient received a bandage or dressing on a specific date, but a clinician visit was not documented in their record, it was assumed the patient had been seen outside of the general practice by a district nurse.

Differences between two subgroups were tested for statistical significance using a Mann–Whitney U-test or $\chi 2$ test. Differences between three subgroups were tested for statistical significance using a Kruskal–Wallis test or $\chi 2$ test. Logistic regression was used to investigate relationships between baseline variables and clinical outcomes. Kaplan–Meier analyses were undertaken to compare the healing distribution of different subgroups. All statistical analyses were performed using IBM SPSS Statistics (IBM UK Ltd, Portsmouth, Hampshire UK).

## Cost of Patient Management

Unit costs at 2015/2016 prices [15-17] were assigned to the resource use values to estimate the mean NHS cost of managing an unhealed surgical wound over 12 months from initial presentation in the community.



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**Sensitivity Analyses**

Deterministic sensitivity analyses were undertaken to assess how the cost of managing an unhealed surgical wound changes by varying the values of clinical outcomes and resource use.

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## RESULTS

### Patients' Characteristics

This analysis has essentially studied a cohort of patients with SWD and an open wound left to heal by secondary intention. However, the term open wound or dehiscence was only recorded in 4% of the patients' case records. The most frequently used terms were "dressing of wound" or "dressing of surgical wound". The age of the study population was a mean of 62.6 years per patient. 58% of the cohort were >60 years of age, and 26% were ≤50 years of age. 71% of patients had undergone a planned surgical procedure and 29% an emergency procedure. Two-thirds (67%) of all the patients were discharged from hospital into the community within 2 weeks of their surgical procedure; the median length of stay was 10 days. Patients' baseline characteristics and anatomical site of surgery are summarised in Table 1. 22% of all the wounds arose from abdominal surgery, and 14% arose from limb (vascular) surgery of which 62% the procedures involved either a minor or major amputation.

The cohort had a mean of 5.3 comorbidities per patient, ranging from 5.2 comorbidities per patient who had a planned surgical procedure to 5.5 comorbidities per patient who underwent an emergency procedure. These differences were not significantly different. Additionally, 29% of all patients had diabetes (27% and 34% of patients who underwent a planned and emergency procedure, respectively). Patients' comorbidities are summarised in Table 2. There were no significant differences in the incidence of comorbidities between patients whose wound did or did not heal within 12 months from initial presentation in the community (not shown), with the exception that 42% of patients whose wound remained unhealed had diabetes compared to 27% of healed patients; $p<0.01$.

### Clinical outcomes

83% of all the wounds in this study's cohort healed within 12 months from initial presentation in the community (Figure 1), with healing ranging from 86% of wounds arising from a planned procedure to 74% of wounds arising from an emergency procedure. The time to healing was a mean of 4.2 months per patient. However, this ranged from a mean of 3.9 months for patients who had undergone planned surgery to 4.3 months for those who had undergone an emergency procedure.



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The distribution of healing between the wounds arising from planned and emergency procedures was not significantly different ($p$ = 0.26 from a Kaplan Meier analysis). The healing rates stratified by anatomical site of surgery is shown in Figure 2. All the groin procedures healed, 93% of the minor lower limb procedures healed and 88% of the other minor procedures healed within 12 months from initial presentation in the community. Conversely, only 62% of back procedures and 69% of vascular lower limb procedures healed during this period. Irrespective of the other anatomical sites of surgery, between 76% and 82% of all the other procedures healed within 12 months from initial presentation in the community.

Healing was not affected by a patient's BMI. 94% of patients with a BMI <20kg/m$^2$ healed during the study period compared to 89% of patients with a BMI of 20-29kg/m$^2$, 84% of those with a BMI of 30-35kg/m$^2$ and 84% of those with a BMI of >35kg/m$^2$. None of these rates were significantly different from one another. Moreover, there was no significant difference in the BMI of those patients who underwent planned and emergency procedures. Additionally, significantly more wounds of patients without diabetes healed over the 12 months follow-up period compared to patients who had diabetes (88% versus 80%; $p$ = 0.002).

Logistic regression showed that anatomical site of surgery, having diabetes, having a suspected infection (see the Infection section below) and undergoing an emergency procedure are potential independent risk factors for non-healing:

- Suspect infection: Odds ratio 0.497; $p$ = 0.03
- Lower limb (vascular) surgery: Odds ratio 0.538; $p$ < 0.03
- Diabetes: Odds ratio 0.546; $p$ = 0.007
- Emergency surgery: Odds ratio 0.660; $p$ < 0.05

Smoking was not identified as being an independent risk factor for non-healing; 50% of patients in both the healed and unhealed groups were smokers or ex-smokers at the time of surgery.

**Patient Management**

At the onset of their wound management in the community, 46% of patients were prescribed an absorbent dressing, 39% an antimicrobial dressing, 39% a soft polymer, 36% a foam, 32%



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an alginate, 32% a permeable dressing 29% a hydrocolloiod and 24% a hydrogel (Table 3). Dressing use for the initial treatment was unaffected by whether a patient had undergone a planned or emergency procedure.

Patients continued to be prescribed their initial mix of dressings until such time as their wound healed (Table 4). Over half the patients received multiple dressings at each dressing change in the first month of treatment, decreasing to 10% of patients by the twelfth month of treatment (Figure 3). Patients who were treated with multiple dressings received between a mean of 2 and 4 dressings. Overall, patients' dressings were changed three times a week. Additionally, <1% of patients who had undergone a planned procedure and 2% of those who had undergone an emergency procedure received negative pressure wound therapy.

In addition to dressings and bandages, 42% of patients were prescribed an analgesic or non-steroidal anti-inflammatory drug (NSAID), and 36% were prescribed a systemic anti-infective at the time of initial presentation in the community. Over the study period, 66% of all patients were prescribed an anti-infective and 59% of all patients received an antimicrobial dressing.

Health care resource use associated with managing an unhealed surgical wound in the community, is shown in Table 5. Patients were predominantly managed in the community by nurses. Only 3 patients were documented as having had a single visit by a tissue viability nurse. Two of these patients had undergone a planned procedure and one an emergency procedure.

59% of all patients were recorded as having had a follow-up visit with their surgeon within three months from discharge into the community, ranging from 54% of patients who had undergone a planned procedure to 66% of those who had undergone an emergency procedure. 58% of all patients (58% and 57% of those who had undergone a planned or emergency procedure, respectively) still had a wound at 3 months and only 53% of them had a follow-up visit with their surgeon. Additionally, 39% of all patients (38% and 40% of those who had undergone a planned or emergency procedure, respectively) still had a wound at 6 months and only 40% of them had a follow-up visit with their surgeon. Furthermore, 19% of patients were re-admitted into hospital a mean of 3.6 months after original discharge, including 9% within 30 days of discharge.



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**Cost of Patient Management**

The mean NHS cost of wound care over 12 months, following initial presentation in the community, was an estimated £7,345 per surgical wound, ranging from a mean of £7,163 to £7,800 per wound that arose following a planned or emergency procedure, respectively (Table 6). Figure 4 illustrates the monthly cost of managing these wounds, and shows how the monthly wound management cost starts to increase around month 5/6 if the wound fails to heal. The mean NHS cost of wound care of managing a wound that remained unhealed was at least double that of managing a wound that healed (mean of £5,997 versus £13,682 per unhealed surgical wound) (Table 7). The mean NHS cost of wound care stratified by anatomical site of surgery is shown in Figure 5.

District nurse visits were the primary cost driver and accounted for ≥52% of the cost of patient management. Hospital re-admissions accounted for up to a further 22% of the cost and hospital outpatient visits a further 4-6%. Dressings and bandages accounted for up to 17% of the cost of patient management. 18% of the total NHS cost of managing a wound arising from a planned procedure and up to 23% for a wound arising from an emergency procedure was incurred in secondary care, the majority of which related to hospital re-admission. The remainder was incurred in the community.

The mean NHS cost of wound care over 12 months decreased inversely as a patient's BMI increased (Table 8). Additionally, the mean NHS cost of wound care over 12 months was 43% more among patients with diabetes than among those without the disease (Table 8).

**Infection**

The terms "surgical site infection" or "SSI" were not found in any of the patients' case records. The most frequently used term in the records were "postoperative wound infection", "skin and subcutaneous tissue infection", "local infection of skin/subcutaneous tissue" and "cellulitis of wound".

13% of the patients' records documented their wound as being clinically infected at the onset of their management in the community. Another 55% of patients were prescribed a systemic anti-infective and/or antimicrobial dressing at this time, suggesting that as many as 68% of all



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the wounds in our study population may have been considered to be at risk of infection or infected at the time of the initial presentation in the community (Table 9). Additionally, 31% of patients with a putative infection had diabetes compared to 18% of patients who did not have an infection; $p<0.005$.

18% of patients received only an antimicrobial dressing, indicative of concern about the local bioburden or a possible localised wound infection, and 66% were prescribed a systemic anti-infective. The duration of continuous prescribing of an antimicrobial dressing in the patients' records was a mean of 4.2 months per patient. However, 28% of patients received continuous prescribing of topical antimicrobials for >6 months, according to documentation in their case record.

Of the 16% of patients who were never recorded as having an infection, 92% of the wounds healed within a mean of 1.9 months. The healing rate was lower among patients with a putative infection, and the mean time to healing was longer (Table 9). Furthermore, the cost of wound management of an uninfected wound was at least 60% less than that of a putatively infected wound (Table 9). The percentage of putative infections and associated costs was relatively unaffected by whether the wound had arisen from a planned or emergency procedure (Table 10). Hence, the mean NHS cost of managing an unhealed surgical wound without any evidence of infection was estimated to be ~£2,000 per wound, and the mean conflated cost of managing an unhealed surgical wound with a putative infection ranged between £5,000 and £11,200 per wound.

23% of patients subsequently developed a putative wound infection a mean 4.3 months after initial presentation, for which an anti-infective was prescribed. The cost of wound management among these patients was a mean of £12,890 per patient.

Logistic regression showed that in this cohort of patients, the anatomical site of surgery, prior presence of immunological symptoms and diabetes were all potential independent risk factors for infection:

- Chest and breast surgery: Odds ratio 3.231; $p < 0.03$
- Immunological symptoms: Odds ratio 2.678; $p < 0.02$
- Lower limb (vascular) surgery: Odds ratio 2.485; $p < 0.03$
- Abdomen surgery: Odds ratio 1.814; $p < 0.03$
- Diabetes: Odds ratio 1.734; $p = 0.04$



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**Sensitivity Analyses**

Sensitivity analysis showed that if the:

- probability of healing was reduced by 25%, from 83% to 62%, the mean NHS cost of wound care over 12 months would increase by 22% to an estimated £8,929 per wound. Conversely, if the probability of healing was increased by 20%, from 83% to 99%, the mean NHS cost of wound care over 12 months would decrease by 17% to an estimated £6,077 per wound.
- number of district nurse visits changed by 25% below or above the base case value, the mean NHS cost of wound care over 12 months would diverge by 14% from the mean value (range £6,298–£8,392 per wound).
- number of practice nurse visits changed by 25% below or above the base case value, the mean NHS cost of wound care over 12 months would diverge by 1% from the mean value (range £7,282–£7,408 per wound).
- number of hospital admissions changed by 25% below or above the base case value, the mean NHS cost of wound care over 12 months would diverge by 4% from the mean value (range £7,073–£7,617 per wound).
- number of hospital outpatient visits changed by 25% below or above the base case value, the mean NHS cost of wound care over 12 months would diverge by 1% from the mean value (range £7,258–£7,432 per wound).
- unit cost of wound care products was decreased or increased by 25%, the mean NHS cost of wound care over 12 months would diverge by 4% from the mean value (range £7,074–£7,616 per wound).

Changes to the use of other health care resources had minimal impact on the mean NHS cost of wound care over 12 months, following initial presentation in the community.

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## DISCUSSION

This study's population comprised those patients who were discharged from hospital into the community with a wound that remained unhealed for longer than four weeks after their surgery, and may well be different to the cohort of patients whose wound heals within four weeks of their surgical procedure or those who remain in hospital until their surgical wound heals. Nevertheless, this analysis provides the first evidence of how unhealed surgical wounds are managed in clinical practice in the UK, following initial presentation in the community.

This cohort consisted of patients with SWD and an open wound left to heal by secondary intention. SSI is one of the risk factors for SWD, but the occurrence of SWD can increase the risk of developing an SSI [18]. Although the secondary care and economic implications of SSI are well recognised [19, 20], those of SWD remain largely unquantified [21], as is the community cost of treating both [22]. One study comments that a rigorous and consistent classification system is needed if patients with SWD are to be effectively diagnosed and managed [21]. Our study found considerable variation in documentation standards and terminology pertaining to both the nature of the wound and infection. Consequently any reporting system on SWD and SSI in the community would be under-reported and inaccurate. In an attempt to address this variance, a post-discharge SSI assessment has been developed and is currently undergoing further testing [23].

The lack of secondary care involvement in many of the cases identified in this study would suggest that surgical teams may be unaware of the extent of the problem, and that both SWD and SSI may therefore be under-reported. A point prevalence study of wounds in north-east England identified that the largest proportion of wounds were surgical wounds, and that community nurses were involved in the care of over 70% of patients with wounds [24]. Another study found that one-third of surgical complications occurred after discharge, that two-thirds were managed in the community and that one-third resulted in readmission to hospital [25]. The authors emphasised that research and audit based solely on inpatient data significantly underestimates surgical wound morbidity rates [25]. In comparison, 19% of this study's patients were re-admitted into hospital as a direct result of their unhealed surgical wound.



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Our analysis suggests that unhealed surgical wounds occur in patients with significant co-morbidities, the management of which is associated with significant resource use. Moreover, two-thirds of all the unhealed surgical wounds in this data set were considered to be at risk of infection or infected at the time of presentation. This estimate was based on documentation of infection in the patients' records and the use of antimicrobial dressings and anti-infective prescriptions. The authors recognise the potential weakness of this estimate as systemic anti-infectives can be prescribed in general practice on the basis of wound swabs alone. Furthermore, antimicrobial dressings are prescribed prophylactically in clinical practice for wounds that are both infected and uninfected. The relative effectiveness of any antiseptic, antibiotic or anti-bacterial agent delivered either systemically or topically on surgical wounds healing by secondary intention is unclear [26]. NICE recommends that patients with a SSI are offered treatment with an antibiotic that covers the likely causative organisms, and is selected based on local resistance patterns and the results of microbiological tests [9]. Moreover, prophylactic use of antibiotics carries a risk of adverse effects and increased prevalence of antibiotic-resistant bacteria. Therefore, NICE recommends that prophylactic use of antibiotics should be limited to cover the organisms most likely to cause infection and be influenced by the strength of the association between the antibiotic used and these adverse effects [9].

Resource use associated with managing a putatively infected wound was found to be greater than that of an uninfected wound as the healing rate was lower and time to healing was longer. So too was resource use associated with managing the wounds that remained unhealed compared to those that went on to heal. Consequently, the cost of managing an unhealed wound was at least double that of managing a wound that healed (mean of £5,997 versus £13,682 per wound), and the cost of managing a putatively infected wound was at least 60% less than that of an uninfected wound. The mean cost of managing a putatively infected wound with an anti-infective and an antimicrobial dressing (£11,200) was not too dissimilar to Tanner's cost estimate of managing a post-surgical wound infection in the community (£10,523) [27]. Moreover, the analysis found the mean NHS cost of wound care over 12 months from initial presentation in the community to be an estimated £7,300 per wound, ranging from a mean of £7,200 to £7,800 for a wound that arose from a planned or emergency procedure, respectively. It is important to note that these estimates are the amounts by which the costs of the original episodes of surgery are increased as a result of the surgical wound not having healed. Others have also reported that SWD increases health care



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expenditure, due in part to the need for community nursing and associated support and increased use of wound care products [19, 28-32].

These findings from this cohort of patients with unhealed surgical wounds are consistent with our Burden of Wounds study [11, 12, 33]. The time to healing a wound is clearly an important factor in driving costs. Accordingly, the cost of surgical wound management can be affected by a combination of resources required for dressing changes, complexity of some treatment regimens and infection [12]. Furthermore, the Burden of Wounds study [11, 12, 33] provided insight into areas where care improvements could potentially result in improved clinical outcomes whilst generating significant cost savings. Nevertheless, cost-effective management and healing of unhealed surgical wounds in the community is likely to remain a challenging problem. One of the reasons may be due to the inadequate involvement of specialist clinicians in the management of the wounds in this study's cohort. Only three patients were recorded as having seen a tissue viability nurse and only around half the patients were recorded as having had an outpatient visit with their surgeon in the 12 months from initial presentation. However, it is possible that more patients were receiving multidisciplinary care than those for whom that was recorded in the THIN database. However, there was minimal evidence of this within the records, and there was no evidence of a coordinated shared treatment plan.

This study highlights the apparent lack of treatment planning, re-assessment and re-evaluation of care for most patients with an unhealed surgical wound in the community. The patients' combination of dressings and bandages remained unchanged for the length of time the wound remained unhealed, and there was minimal correlation between wound duration and senior involvement in direct patient care. Given the nature of these wounds, there was a surprising under-utilisation of topical negative pressure therapy in this cohort of patients. This may have resulted from either a lack of product availability, item cost considerations, skill mix and/or a failure to follow escalation pathways involving senior staff. Another community-based study in Australia study reported similar findings [21], and interestingly, the distribution of dressing use in our study was concordant to that used to treat SWD in the Australian study [21]. Clearly, improving management practices should lead to a better outcome for patients and would be cost-effective for the NHS.



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The authors suggest that an improvement in five key areas of clinical and service management would enhance healing and other patient outcomes while reducing overall management costs. These are:

- Working to common definitions and reporting standards across primary and secondary care.
- Integrating care across providers.
- Escalating care appropriately with greater senior involvement.
- Rational use of products with access to advanced wound treatments when necessary.
- Recognising high-risk patients and responding with nutritional support and co-morbidity management as appropriate

In turn, with improved healing, these actions should reduce workload and associated health care resource use and lead to reductions in the overall cost of wound care. All health care systems recognise the importance of managing unhealed surgical wounds and the relative risk of developing a SSI. Clearly, training non-specialist nurses in the appropriate management of unhealed surgical wounds is a pre-requisite to overcoming some of the problems encountered in clinical practice and to achieving better health outcomes than those currently being observed.

**Study limitations**

The advantages and disadvantages of using patients' records in the THIN database for health economic studies in wound care have been previously discussed [11]. In summary, the advantage of using the database is that the patient pathways and associated resource use are based on real-world evidence derived from clinical practice. However, the analyses were based on clinicians' entries into their patients' records and inevitably subject to a certain amount of imprecision and lack of detail. Moreover, the computerised information in the database is collected by GPs and nursing teams for clinical care purposes and not for health economics research. Prescriptions issued by GPs and practice nurses are recorded in the database, but it does not specify whether the prescriptions were dispensed or detail patient compliance with the product. Despite these limitations, it is the authors' opinion that the real-world evidence contained in the THIN database has provided a useful perspective on the management of unhealed surgical wounds in the community in the UK and the associated costs.



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The analysis was truncated at 12 months and does not consider the potential impact of those wounds that remained unhealed beyond the study period. Also excluded is the potential impact of managing hospital inpatients with a surgical wound and those being cared for in nursing/residential homes. The analysis only considered NHS resource use and associated costs for the 'average patient' and was not stratified according to gender, comorbidities, disease-related factors and level of clinicians' skills. Costs incurred by non-NHS organisations (such as the provision of social care), patients' costs and indirect societal costs as a result of patients being absent from work were also excluded from the analysis.

Further research is required to quantify both the incidence and prevalence of unhealed surgical wounds, SWD and SSI in the community and to elucidate more fully the risk factors for their development.

**Conclusion**

The real-world evidence in this study provides important insights into a number of aspects of surgical wound management in clinical practice in the community in the UK that have been difficult to ascertain from other published studies. Surgeons are unlikely to be fully aware of the problems surrounding unhealed surgical wounds once patients are discharged into the community, due to the inconsistent recording in patients' records coupled with the finding that no more than half of all patients who still have a wound at 3 months see their surgeon for a follow-up appointment. Additionally, it provides the best estimate available of NHS resource use and costs with which to inform policy and budgetary decisions pertaining to managing these wounds. Clinical and economic benefits to both patients and the NHS could accrue from strategies that focus on improving documentation in patients' records, wound-healing rates and reducing infection. Clinicians managing unhealed surgical wounds may wish to consider the findings from this study when making treatment decisions.



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**Table 1: Patients' baseline characteristics.**

| | |
|---|---|
| Mean age at time of surgery per patient (years) | 62.6 |
| Percentage female | 54% |
| Mean systolic blood pressure (mm Hg) per patient | 131.0 |
| Mean diastolic blood pressure (mm Hg) per patient | 75.4 |
| Mean body mass index (kg/m$^2$) per patient | 29.6 |
| Percentage with BMI <18.5 kg/m$^2$ | 3% |
| Percentage with BMI ≥30.0 kg/m$^2$ | 46% |
| Percentage who were smokers | 21% |
| Percentage who were ex-smokers | 29% |
| Percentage who were non-smokers | 50% |
| Percentage with abdominal surgery | 22% |
| Percentage with lower limb (vascular) surgery | 14% |
| Percentage with minor surgery | 12% |
| Percentage with lower limb (orthopaedic) surgery | 10% |
| Percentage with upper limb surgery | 9% |
| Percentage with skin surgery | 8% |
| Percentage with chest surgery | 8% |
| Percentage with unspecified surgery | 4% |
| Percentage with head and/or neck surgery | 4% |
| Percentage with perineal surgery | 3% |
| Percentage with lower limb (minor) surgery | 2% |
| Percentage with back surgery | 2% |
| Percentage with groin surgery | 1% |

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**Table 2: Patients' comorbidities.**

| Comorbidity | Percentage of patients with a comorbidity | | |
|---|---|---|---|
| | All | Planned procedures | Emergency procedures |
| Cardiovascular | 70% | 69% | 71% |
| Cerebrovascular | 7% | 6% | 9% |
| Dermatological | 54% | 54% | 54% |
| Endocrinological | 48% | 47% | 50% |
| Gastroenterological | 41% | 39% | 45% |
| Genito-urinary | 32% | 32% | 30% |
| Haematological | 7% | 7% | 8% |
| Hepatological | 3% | 2% | 3% |
| Immunological | 13% | 12% | 15% |
| Musculoskeletal | 68% | 67% | 70% |
| Neurological | 27% | 27% | 28% |
| Oncological | 25% | 24% | 27% |
| Ophthalmological | 12% | 12% | 10% |
| Otolaryngological | 22% | 20% | 28% |
| Psychiatric | 38% | 38% | 38% |
| Renal | 24% | 24% | 24% |
| Respiratory | 39% | 37% | 42% |

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**Table 3: Dressings prescribed at the time of initial presentation in the community.**

| | Percentage of patients who were treated with the following dressings for their initial treatment | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Absorbent** | **Alginate** | **Antimicrobial** | **Foam** | **Hydrocolloid** | **Hydrogel** | **Low-adherence** | **Odour absorbent** | **Other** | **Permeable** | **Soft polymer** |
| **All** | 46% | 32% | 39% | 36% | 29% | 24% | 24% | 0% | 37% | 32% | 39% |
| **Emergencies** | 46% | 34% | 39% | 38% | 32% | 26% | 27% | 0% | 37% | 32% | 41% |
| **Planned** | 46% | 30% | 39% | 36% | 29% | 23% | 23% | 0% | 37% | 32% | 39% |

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**Table 4: Dressings prescribed over the 12 months following initial presentation in the community.**

| | Percentage of patients who were treated with the following dressing | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Month of treatment** | **Absorbent** | **Soft polymer** | **Antimicrobial** | **Other** | **Foam** | **Permeable** | **Alginate** | **Hydrocolloid** | **Low-adherence** | **Hydrogel** | **Odour absorbent** |
| 1 | 46% | 39% | 39% | 37% | 36% | 32% | 32% | 29% | 24% | 24% | 0% |
| 2 | 38% | 35% | 35% | 32% | 13% | 29% | 28% | 29% | 24% | 25% | 0% |
| 3 | 32% | 31% | 31% | 28% | 32% | 26% | 25% | 25% | 23% | 24% | 21% |
| 4 | 28% | 28% | 28% | 26% | 29% | 24% | 24% | 25% | 21% | 22% | 0% |
| 5 | 25% | 25% | 25% | 23% | 26% | 21% | 21% | 22% | 19% | 20% | 0% |
| 6 | 21% | 21% | 22% | 20% | 22% | 18% | 18% | 18% | 17% | 17% | 0% |
| 7 | 16% | 17% | 17% | 16% | 18% | 15% | 13% | 15% | 13% | 13% | 0% |
| 8 | 14% | 15% | 15% | 14% | 15% | 13% | 12% | 13% | 12% | 12% | 11% |
| 9 | 12% | 12% | 14% | 12% | 12% | 12% | 11% | 11% | 11% | 11% | 0% |
| 10 | 11% | 12% | 12% | 10% | 11% | 10% | 10% | 10% | 9% | 9% | 0% |
| 11 | 8% | 9% | 9% | 18% | 9% | 17% | 7% | 10% | 7% | 7% | 0% |
| 12 | 12% | 10% | 11% | 10% | 10% | 9% | 9% | 10% | 10% | 9% | 0% |

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**Table 5: Health care resource use associated with managing unhealed surgical wounds in clinical practice.**

| | Mean amount of resource use per patient over 12 months from initial presentation | | |
|---|---|---|---|
| **Resource use** | **All** | **Planned procedures** | **Emergency procedures** |
| Bandages | 18.88 | 19.10 | 18.30 |
| District nurse visits | 72.00 | 73.10 | 69.20 |
| Dressings | 177.50 | 182.50 | 164.50 |
| GP visits | 2.80 | 2.90 | 2.50 |
| Hospital admissions | 0.31 | 0.28 | 0.39 |
| Hospital outpatient visits | 2.20 | 2.10 | 2.50 |
| Laboratory tests | 0.78 | 0.79 | 0.75 |
| Negative pressure wound therapy | 0.16 | 0.15 | 0.20 |
| Practice nurse visits | 10.30 | 10.80 | 9.20 |
| Prescriptions for analgesic and non-steroidal inflammatories | 5.60 | 5.80 | 5.20 |
| Prescriptions for anti-infectives | 2.40 | 2.40 | 2.20 |
| Topical treatments | 3.30 | 2.10 | 6.20 |

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**Table 6: Cost of health care resource use associated with managing unhealed surgical wounds in clinical practice (percentage of total cost is in parenthesis).**

| | Mean cost of resource use per patient over 12 months from initial presentation in the community | | |
|---|---|---|---|
| **Resource** | **All procedures** | **Planned procedures** | **Emergency procedures** |
| District nurse visits | £4,186.81 (57%) | £4,142.62 (58%) | £4,297.30 (55%) |
| Hospital admissions | £1,086.76 (16%) | £972.30 (14%) | £1,372.91 (18%) |
| Dressings | £763.73 (10%) | £772.50 (11%) | £741.82 (10%) |
| Hospital outpatient visits | £348.55 (5%) | £326.04 (5%) | £404.84 (5%) |
| Practice nurse visits | £253.29 (3%) | £262.33 (4%) | £230.69 (3%) |
| GP visits | £219.33 (3%) | £227.02 (3%) | £200.11 (3%) |
| Bandages | £214.65 (3%) | £202.20 (3%) | £245.77 (3%) |
| Analgesics and non-steroidal anti-inflammatories | £118.42 (2%) | £118.31 (2%) | £118.68 (2%) |
| Wound care appliances | £83.61 (1%) | £75.35 (1%) | £104.24 (1%) |
| Anti-infectives | £43.44 (1%) | £43.51 (1%) | £43.26 (1%) |
| Topical treatments | £17.17 (<1%) | £12.35 (<1%) | £29.22 (<1%) |
| Negative pressure wound therapy | £6.00 (<1%) | £5.18 (<1%) | £8.03 (<1%) |
| Laboratory tests | £2.85 (<1%) | £2.85 (<1%) | £2.85 (<1%) |
| Tissue viability nurse visits | £0.25 (<1%) | £0.24 (<1%) | £0.27 (<1%) |
| **TOTAL** | **£7,344.86 (100%)** | **£7,162.81 (100%)** | **£7,800.00 (100%)** |



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**Table 7: Cost of health care resource use associated with managing unhealed surgical wounds stratified by planned/emergency procedures and healing in clinical practice (percentage of total cost is in parenthesis).**

| | Mean cost of resource use per patient over 12 months from initial presentation in the community | | | |
|---|---|---|---|---|
| **Resource** | **Planned/healed procedures** | **Planned/unhealed procedures** | **Emergency/healed procedures** | **Emergency/unhealed procedures** |
| District nurse visits | £3,457.82 (58%) | £8,328.58 (59%) | £3,104.09 (52%) | £7,651.79 (59%) |
| Hospital admissions | £921.22 (15%) | £1,284.56 (9%) | £1,314.78 (22%) | £1,536.34 (12%) |
| Dressings | £627.04 (10%) | £1,661.62 (12%) | £558.83 (9%) | £1,256.28 (10%) |
| Hospital outpatient visits | £293.21 (5%) | £526.69 (4%) | £331.36 (6%) | £611.42 (5%) |
| Practice nurse visits | £191.80 (3%) | £693.48 (5%) | £164.96 (3%) | £415.48 (3%) |
| GP visits | £182.28 (3%) | £500.49 (4%) | £161.89 (3%) | £307.56 (2%) |
| Bandages | £117.25 (2%) | £721.50 (5%) | £86.36 (1%) | £693.92 (5%) |
| Analgesics and non-steroidal anti-inflammatories | £106.13 (2%) | £192.77 (1%) | £91.42 (2%) | £195.32 (2%) |
| Wound care appliances | £57.95 (1%) | £181.74 (1%) | £77.48 (1%) | £179.46 (1%) |
| Anti-infectives | £37.73 (1%) | £78.83 (1%) | £33.78 (1%) | £69.90 (1%) |
| Topical treatments | £6.21 (<1%) | £49.89 (<1%) | £39.62 (1%) | £0.00 (<1%) |
| Negative pressure wound therapy | £5.92 (<1%) | £0.69 (<1%) | £1.89 (<1%) | £25.30 (<1%) |
| Laboratory tests | £1.89 (<1%) | £8.70 (<1%) | £1.78 (<1%) | £5.86 (<1%) |
| Tissue viability nurse visits | £0.28 (<1%) | £0.00 (<1%) | £0.37 (<1%) | £0.00 (<1%) |
| **TOTAL** | **£6,006.73 (100%)** | **£14,229.54 (100%)** | **£5,968.61 (100%)** | **£12,948.63 (100%)** |



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**Table 8: Cost of health care resource use associated with managing unhealed surgical wounds stratified by BMI and diabetes.**

| | % of patients | % healed | % emergencies | NHS cost per patient |
|---|---|---|---|---|
| BMI <20 | 5% | 94% | 31% | £9,269 |
| BMI 20-29 | 45% | 89% | 27% | £6,938 |
| BMI 30-35 | 20% | 84% | 35% | £7,096 |
| BMI >35 | 20% | 84% | 28% | £7,812 |
| | | | | |
| Diabetes | 29% | 80% | 33% | £9,349 |
| No diabetes | 71% | 88% | 27% | £6,526 |

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**Table 9: Incidence of putative infection with associated healing and costs.**

| | Percentage of patients | Percentage of patients who healed | Mean time to healing per patient (months) | Mean cost of wound care per patient |
|---|---|---|---|---|
| No infection | 16% | 92% | 1.86 | £2,001 |
| Received only an antimicrobial dressing | 18% | 83% | 5.79 | £6,966 |
| Prescribed an anti-infective with or without an antimicrobial dressing | 66% | 85% | 6.46 | £8,742 |
| Prescribed an anti-infective with an antimicrobial dressing | 41% | 82% | 8.11 | £11,169 |
| Prescribed an anti-infective without an antimicrobial dressing | 25% | 90% | 3.62 | £4,961 |

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**Table 10: Incidence of putative infection with associated healing and costs stratified by planned/emergency procedures.**

| | Percentage of cohort | Percentage of cohort that healed | Mean time to healing per patient (months) | Mean cost of wound care per patient |
|---|---|---|---|---|
| **Planned procedures** | | | | |
| No infection | 17% | 90% | 1.81 | £2,143 |
| Received only an antimicrobial dressing | 17% | 86% | 5.99 | £6,966 |
| Prescribed an anti-infective | 66% | 87% | 6.66 | £8,507 |
| Prescribed an anti-infective with an antimicrobial dressing | 43% | 84% | 8.19 | £10,606 |
| Prescribed only an anti-infective | 23% | 93% | 3.79 | £4,581 |
| **Emergency procedures** | | | | |
| No infection | 16% | 97% | 1.97 | £1,649 |
| Received only an antimicrobial dressing | 21% | 79% | 5.29 | £7,165 |
| Prescribed an anti-infective | 63% | 79% | 5.98 | £9,574 |
| Prescribed an anti-infective with an antimicrobial dressing | 38% | 76% | 7.93 | £12,018 |
| Prescribed only an anti-infective | 25% | 83% | 3.20 | £5,633 |

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Figure 1: Wound healing stratified by planned/emergency procedures.

Figure 2: Wound healing stratified by anatomical site of surgery.

Figure 3: Patients who received a combination of multiple dressings at each dressing change.

Figure 4: Monthly cost of health care resource use associated with managing surgical wounds stratified by planned/emergency procedures and healing in clinical practice.

Figure 5: Cost of health care resource use associated with managing surgical wounds in clinical practice stratified by anatomical site of surgery.

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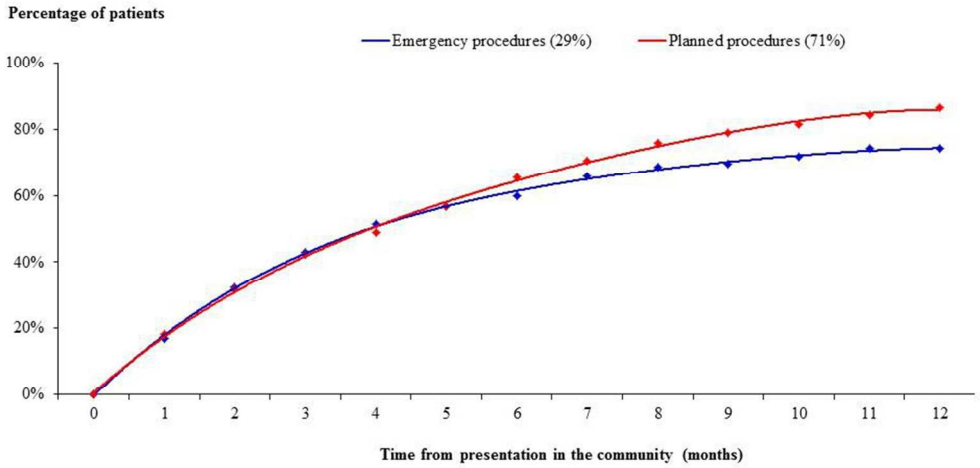


Figure 1

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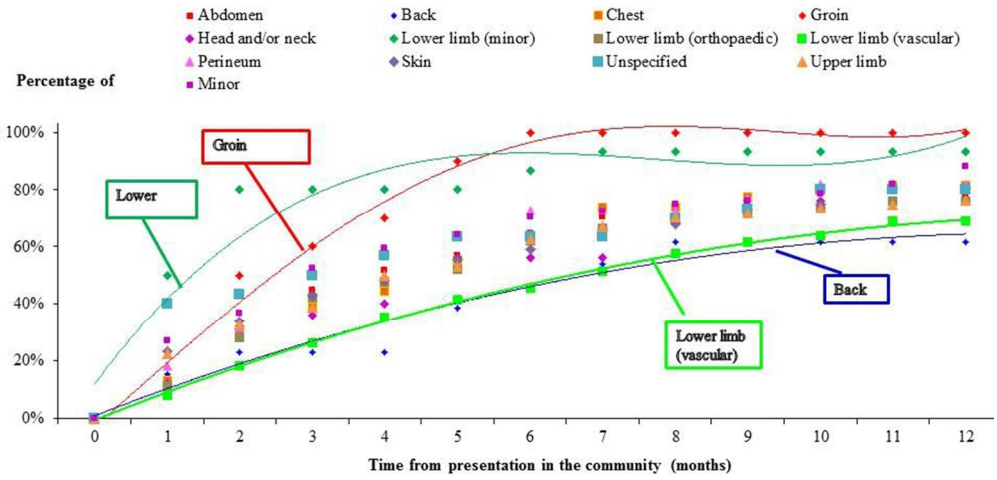


Figure 2

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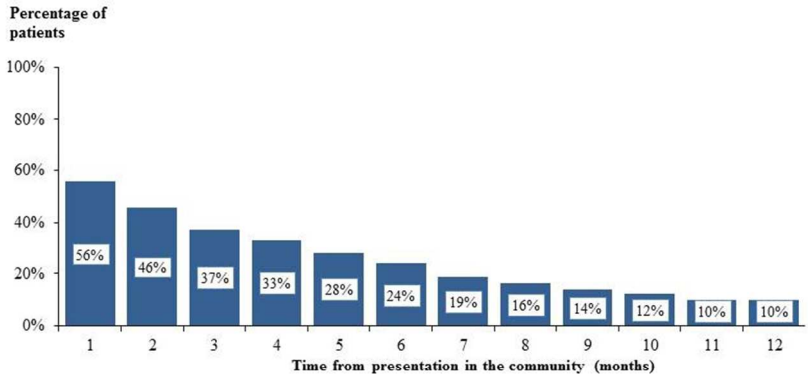


Figure 3

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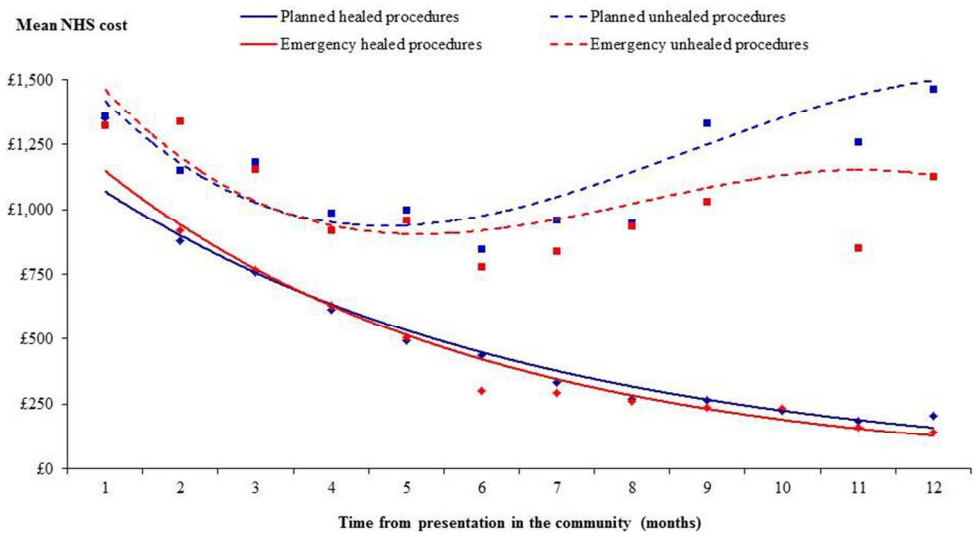


Figure 4

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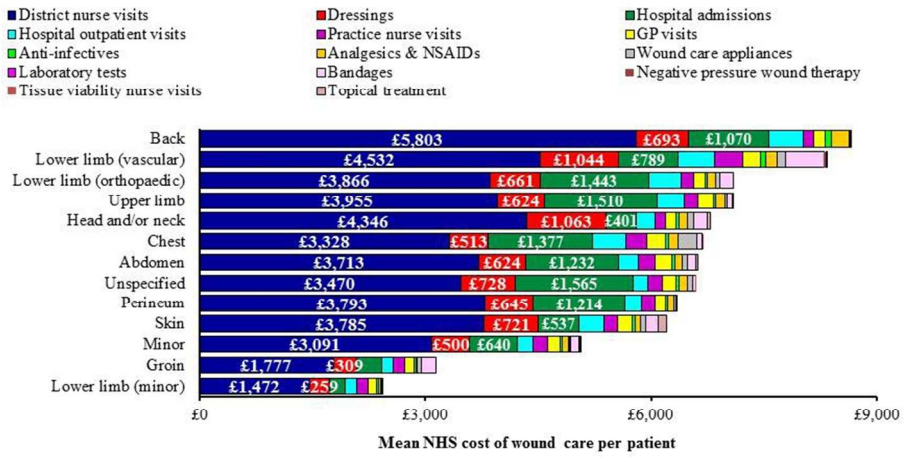


Figure 5

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# A cohort study evaluating management of unhealed surgical wounds in the community in clinical practice in the UK: costs and outcomes

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**ORIGINAL ARTICLE**

# A COHORT STUDY EVALUATING MANAGEMENT OF UNHEALED SURGICAL WOUNDS IN THE COMMUNITY IN CLINICAL PRACTICE IN THE UK: COSTS AND OUTCOMES

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**Running title:** Health economic impact of unhealed surgical wounds in the UK

**Keywords:** Burden; cost; surgery; surgical wounds; wounds; UK.

## ABSTRACT

**Objective:** To evaluate the patient pathways and associated health outcomes, resource use and corresponding costs attributable to managing unhealed surgical wounds in clinical practice, from initial presentation in the community in the UK.

**Methods**: This was a retrospective cohort analysis of the records of 707 patients in The Health Improvement Network (THIN) Database whose wound failed to heal within four weeks of their surgery. Patients' characteristics, wound-related health outcomes and health care resource use were quantified, and the total National Health Service (NHS) cost of patient management was estimated at 2015/2016 prices.

**Results**: Inconsistent terminology was used in describing the wounds. 83% of all wounds healed within 12 months from onset of community management, ranging from 86% to 74% of wounds arising from planned and emergency procedures, respectively. Mean time to healing was 4 months per patient. Patients were predominantly managed in the community by nurses and only around a half of all patients who still had a wound at 3 months were recorded as having had a follow-up visit with their surgeon. Up to 68% of all wounds may have been clinically infected at the time of presentation, and 23% of patients subsequently developed a putative wound infection a mean 4 months after initial presentation. Mean NHS cost of wound care over 12 months was £7,300 per wound, ranging from £6,000 to £13,700 per healed and unhealed wound, respectively. Additionally, the mean NHS cost of managing a wound without any evidence of infection was ~£2,000 and the conflated cost of managing a wound with a putative infection ranged between £5,000 and £11,200.

**Conclusion:** Surgeons are unlikely to be fully aware of the problems surrounding unhealed surgical wounds once patients are discharged into the community, due to inconsistent recording in patients' records coupled with the low rate of follow-up appointments. These findings offer the best evidence available with which to inform policy and budgetary decisions pertaining to managing unhealed surgical wounds in the community.




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## STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is the first study to evaluate the patient pathways and associated health outcomes, resource use and corresponding costs attributable to managing unhealed surgical wounds over 12 months from the onset of community management.

- This study undertaken using real world evidence derived from the anonymised records of a sample of patients in The Health Improvement Network (THIN) database (a nationally representative database of clinical practice among >11 million patients registered with general practitioners in the UK).

- The estimates were derived following a systematic analysis of patients' characteristics, wound-related health outcomes and all community-based and secondary care resource use contained in the patients' electronic records.

- Computerised information in the THIN database is collected by general practitioners (GPs) for clinical care purposes and not for research, consequently the accuracy of wound descriptors and other terminology have not been validated, but does reflect real world documentation in clinical practice.

- The analysis does not consider the potential impact of patients' surgical wounds that heal within four weeks of the surgical procedure or those patients who remain in hospital until their surgical wound heals.

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The study's sponsors had no involvement in the study design, the collection, analysis and interpretation of the data, the writing of this manuscript and the decision to submit this article for publication. The views expressed in this article are those of the authors and not necessarily those of the NHS, the NIHR, the Department of Health or Smith & Nephew.

**COMPETING INTERESTS**

None declared.

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## CONTRIBUTORS

J.F.G. designed the study, managed the analyses, performed some analyses, checked all the other analyses, and wrote the manuscript.

G.W.F. conducted much of the analyses.

P.V. scrutinised the analyses, suggested further analyses and helped interpret some of the findings.

All the authors were involved in revising the manuscript and gave final approval. J.F.G. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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## DATA SHARING STATEMENT

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## INTRODUCTION

More than 10 million operations were performed by the National Health Service (NHS) in England [1] in 2015/16, with the majority involving an incision [2]. Most incised surgical wounds generally heal by primary intention. However, some heal by secondary intention, either because the wound has intentionally been left open or has dehisced following primary closure [3, 4]. Surgical wounds healing by secondary intention are thought to be common in the UK, and to account for 26-28% of all surgical wounds requiring continued nursing intervention [5]. Such wounds may remain open for an extended period and are susceptible to infection, requiring on-going treatment [6]. Surgical wound dehiscence (SWD), defined as the rupture or splitting open of a previously closed surgical incision site, may be either superficial or deep [7]. Dehisced wounds may be left to heal fully through secondary intention, or closed surgically after partial healing.

The management of patients with an unhealed surgical wound remains challenging because of the potentially high chance of developing further wound complications [8]. Such complications can result in hospital re-admission, further surgery, prolonged hospitalisation and may require intensive management in the community. The National Institute for Health and Care Excellence (NICE) estimated that 5% of all surgical procedures result in a surgical site infection (SSI) in the UK and account for up to 20% of cases of health care associated infections [9]. The SSI data collected by hospitals could be an underestimate as most patients develop signs and symptoms after discharge [10].

The Burden of Wounds study reported that unhealed surgical wounds accounted for 11% (n=250,000 patients) of all wounds managed in the UK by the NHS in 2012/2013 [11]. The annual NHS cost attributable to managing these wounds and associated comorbidities was estimated to be £982.9 million [12]. After adjustment for comorbidities, the annual NHS cost was estimated to be between £957.4 and £985.8 million [12].

Wound management is now of sufficient concern among the wound care community in the UK, that the UK Parliament (House of Lords) debated developing a national strategy for improving the standards of wound care in the NHS [13]. All health care systems recognise the importance of healing surgical wounds without complications. Nevertheless, there is a lack of information surrounding the characteristics of patients with surgical wounds healing



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by primary or secondary intention, the time taken for these wounds to heal, wound treatment and patient management within the community. Additionally, the health care costs associated with SWD are poorly reported and are frequently conflated with the cost of SSI. This paucity of data limits our understanding of the health care needs of patients with an unhealed surgical wound and also hinders the planning and allocation of the relevant resources. The aim of the present analysis was to follow a cohort of patients in clinical practice from initial presentation of their surgical wound in the community, to evaluate in greater depth how managing patients with an unhealed surgical wound impacts on healing and NHS costs.

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## METHODS

### Study Design

This was a retrospective cohort analysis of the case records of patients with an unhealed surgical wound (defined as one that had not healed within four weeks of the surgical procedure), randomly extracted from The Health Improvement Network (THIN) database. The perspective of the analysis was that of the UK's NHS and the time horizon was 12 months from initial presentation in the community.

### The Health Improvement Network Database

The THIN database (IMS, London, UK) contains electronic records on >11 million anonymised patients entered by GPs from 562 practices across the UK. The patient composition within the THIN database has been shown to be representative of the UK population in terms of demographics and disease distribution [14], and the database theoretically contains patients' entire medical history, as previously described [11]. Hence, the information contained in the THIN database reflects actual clinical practice.

### Study Population

The authors have previously obtained the electronic records of a random sample of 6,000 patients with a wound from the THIN database. The study population of 707 patients was identified within this cohort of 6,000 patients according to the following criteria:

- Were 18 years of age or over.
- Had undergone a surgical procedure either during or after 2012.
- Had a surgical wound which had remained unhealed for 4 weeks after the surgical procedure
- Had at least 12 months continuous medical history in their case record from the first mention of their surgical wound unless it healed.

Patients whose wound healed within 4 weeks of their surgical procedure or those with a dermatological tumour were excluded from the data set. Any patients with an unhealed surgical wound who died within a year of initial presentation in the community was also



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excluded, since the study design was to examine the trajectory of these wounds over a full 12 months from initial presentation unless it healed.

**Patient and Public Involvement**

Patients and members of the public were not directly involved in this study. The study population was limited to the anonymised records of patients in the THIN database.

**Ethics Approval**

Ethics approval to use anonymised patients' records from the THIN database for this study was obtained from the Research Ethics Committee that appraises studies using the THIN database (Reference number 13-061).

**Study Variables and Statistical Analyses**

Information was systematically extracted from the patients' electronic records over a period of 12 months from initial presentation of their unhealed surgical wound in the community. This included patients' characteristics, comorbidities (defined as a non-acute condition that patients were suffering from in the year before the start of their wound), wound-related health care resource use (i.e. dressings, bandages, topical treatments, negative pressure wound therapy, district nurse visits [who provide care within a patient's home], practice nurse visits [who provide care within a GP's surgery], GP visits, hospital outpatient visits, laboratory tests), prescribed medication (i.e. analgesics, NSAIDs and systemic anti-infectives [principally antibiotics]) and clinical outcomes (i.e. healing and putative infection). If a patient received a bandage or dressing on a specific date, but a clinician visit was not documented in their record, it was assumed the patient had been seen outside of the general practice by a district nurse. No other assumptions were made regarding missing data and there were no other interpolations.

Differences between two subgroups were tested for statistical significance using a Mann–Whitney U-test or $\chi 2$ test. Differences between three subgroups were tested for statistical significance using a Kruskal–Wallis test or $\chi 2$ test. Multivariate logistic regression (using the



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enter method in which all the independent variables were entered into the analysis simultaneously) investigated relationships between baseline variables and clinical outcomes. Kaplan–Meier analyses were undertaken to compare the healing distribution of different subgroups. The $p$ values <0.05 were considered statistically significant and have been reported. All $p$ values ≥0.05 were not considered to be statistically significant and these numerical values have not been reported, All statistical analyses were performed using IBM SPSS Statistics (IBM UK Ltd, Portsmouth, Hampshire UK).

**Cost of Patient Management**

Unit costs at 2015/2016 prices [15-17] were assigned to the resource use values to estimate the mean NHS cost of managing an unhealed surgical wound over 12 months from initial presentation in the community.

**Sensitivity Analyses**

Deterministic sensitivity analyses were undertaken to assess how the cost of managing an unhealed surgical wound changes by varying the values of clinical outcomes and resource use.

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## RESULTS

### Patients' Characteristics

This analysis has essentially studied a cohort of patients with SWD or an open wound left to heal by secondary intention. However, the term dehiscence or open wound was only recorded in 4% of the patients' case records. The most frequently used terms were "dressing of wound" or "dressing of surgical wound". The age of the study population was a mean of 62.6±17.8 years per patient. 58% (n=411) of the cohort were >60 years of age, and 26% (n=184) were ≤50 years of age. 71% (n=505) of patients had undergone a planned surgical procedure and 29% (n=202) an emergency procedure. Two-thirds (67%) of all the patients were discharged from hospital into the community within 2 weeks of their surgical procedure; the median length of stay was 10 days. Patients' baseline characteristics and anatomical site of surgery are summarised in Table 1. 22% of all the wounds arose from abdominal surgery, and 14% arose from limb (vascular) surgery of which 79% the procedures involved either a minor or major amputation.

The cohort had a mean of 5.3±2.7 comorbidities per patient, ranging from 5.2±2.7 comorbidities per patient who had a planned surgical procedure to 5.5±2.6 comorbidities per patient who underwent an emergency procedure. These differences were not significantly different. Additionally, 29% (n=205) of all patients had diabetes (27% (n=137) and 34% (n=68) of patients who underwent a planned and emergency procedure, respectively). Patients' comorbidities are summarised in Table 2. There were no significant differences in the incidence of comorbidities between patients whose wound did or did not heal within 12 months from initial presentation in the community (not shown), with the exception that 42% of patients whose wound remained unhealed had diabetes compared to 27% of healed patients; $p<0.01$.

### Clinical outcomes

This study was an analysis of unhealed surgical wounds following a documented surgical procedure in the patients' medical records. The THIN database does not define what a wound is and nor does it define wound healing. Wound healing was a clinical observation not necessarily confirmed by a specialist and it is unknown if the nurses/GPs who managed these



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patients used any consistent definition. On that basis, 83% (n=607) of all the wounds in this study's cohort were estimated to have healed within 12 months from initial presentation in the community (Figure 1), with healing ranging from 86% of wounds arising from a planned procedure to 74% of wounds arising from an emergency procedure. The time to healing was a mean of 4.2±3.0 months per patient. However, this ranged from a mean of 3.9±3.0 months for patients who had undergone planned surgery to 4.3±2.8 months for those who had undergone an emergency procedure.

The distribution of healing between the wounds arising from planned and emergency procedures was not significantly different ($p$ = 0.26 from a Kaplan Meier analysis). The healing rates stratified by anatomical site of surgery is shown in Figure 2. All the groin procedures healed, 93% of the minor lower limb procedures healed and 88% of the other minor procedures healed within 12 months from initial presentation in the community. Conversely, only 62% of back procedures and 69% of vascular lower limb procedures healed during this period. Irrespective of the other anatomical sites of surgery, between 76% and 82% of all the other procedures healed within 12 months from initial presentation in the community.

Healing was not affected by a patient's BMI. 94% of patients with a BMI <20kg/m$^2$ healed during the study period compared to 89% of patients with a BMI of 20-29kg/m$^2$, 84% of those with a BMI of 30-35kg/m$^2$ and 84% of those with a BMI of >35kg/m$^2$. None of these rates were significantly different from one another. Moreover, there was no significant difference in the BMI of those patients who underwent planned and emergency procedures. Additionally, significantly more wounds of patients without diabetes healed over the 12 months follow-up period compared to patients who had diabetes (88% versus 80%; $p$ = 0.002).

Binary logistic regression showed that within the limitations of the data documented in the records, anatomical site of surgery, having diabetes, having a suspected infection (see the Infection section below) and undergoing an emergency procedure are potential independent risk factors for a wound not healing:

- Suspect infection: Odds ratio 0.497 (95% CI: 0.223; 0.935); $p$ = 0.032
- Lower limb (vascular) surgery: Odds ratio 0.538 (95% CI: 0.310; 0.934); $p$ = 0.028



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- Diabetes: Odds ratio 0.546 (95% CI: 0.301; 0.903); $p = 0.007$
- Emergency surgery: Odds ratio 0.660 (95% CI: 0.408; 0.990); $p = 0.045$

Smoking was not identified as being an independent risk factor for non-healing; 50% of patients in both the healed and unhealed groups were smokers or ex-smokers at the time of surgery.

**Patient Management**

At the onset of their wound management in the community, 46% of patients were prescribed an absorbent dressing, 39% an antimicrobial dressing, 39% a soft polymer, 36% a foam, 32% an alginate, 32% a permeable dressing 29% a hydrocolloiod and 24% a hydrogel (Table 3). Dressing use for the initial treatment was unaffected by whether a patient had undergone a planned or emergency procedure.

Patients continued to be prescribed their initial mix of dressings until such time as their wound healed (Table 4). Over half the patients received multiple dressings at each dressing change in the first month of treatment, decreasing to 10% of patients by the twelfth month of treatment (Figure 3). Patients who were treated with multiple dressings received between a mean of 2 and 4 dressings. Overall, patients' dressings were changed three times a week. Additionally, <1% of patients who had undergone a planned procedure and 2% of those who had undergone an emergency procedure received negative pressure wound therapy.

In addition to dressings and bandages, 42% of patients were prescribed an analgesic or non-steroidal anti-inflammatory drug (NSAID), and 36% were prescribed a systemic anti-infective at the time of initial presentation in the community. Over the study period, 66% of all patients were prescribed an anti-infective and 59% of all patients received an antimicrobial dressing.

Health care resource use associated with managing an unhealed surgical wound in the community, is shown in Table 5. Patients were predominantly managed in the community by nurses. Only 3 patients were documented as having had a single visit by a tissue viability nurse. Two of these patients had undergone a planned procedure and one an emergency procedure.



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59% of all patients were recorded as having had a follow-up visit with their surgeon within three months from discharge into the community, ranging from 54% of patients who had undergone a planned procedure to 66% of those who had undergone an emergency procedure. 58% of all patients (58% and 57% of those who had undergone a planned or emergency procedure, respectively) still had a wound at 3 months and only 53% of them had a follow-up visit with their surgeon. Additionally, 39% of all patients (38% and 40% of those who had undergone a planned or emergency procedure, respectively) still had a wound at 6 months and only 40% of them had a follow-up visit with their surgeon. Furthermore, 19% of patients were re-admitted into hospital a mean of 3.6 months after original discharge, including 9% within 30 days of discharge.

**Cost of Patient Management**

The mean NHS cost of wound care over 12 months, following initial presentation in the community, was an estimated £7,345±6,673 per surgical wound, ranging from a mean of £7,163±6,366 to £7,800±6,405 per wound that arose following a planned or emergency procedure, respectively (Table 6). Figure 4 illustrates the monthly cost of managing these wounds, and shows how the monthly wound management cost starts to increase around month 5/6 if the wound fails to heal. The mean NHS cost of wound care of managing a wound that remained unhealed was at least double that of managing a wound that healed (mean of £5,997 versus £13,682 per unhealed surgical wound) (Table 7). The mean NHS cost of wound care stratified by anatomical site of surgery is shown in Figure 5.

District nurse visits were the primary cost driver and accounted for ≥52% of the cost of patient management. Hospital re-admissions accounted for up to a further 22% of the cost and hospital outpatient visits a further 4-6%. Dressings and bandages accounted for up to 17% of the cost of patient management. 18% of the total NHS cost of managing a wound arising from a planned procedure and up to 23% for a wound arising from an emergency procedure was incurred in secondary care, the majority of which related to hospital re-admission. The remainder was incurred in the community.

The mean NHS cost of wound care over 12 months decreased inversely as a patient's BMI increased (Table 8). Additionally, the mean NHS cost of wound care over 12 months was 43% more among patients with diabetes than among those without the disease (Table 8).



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**Infection**

The terms "surgical site infection" or "SSI" were not found in any of the patients' case records. The most frequently used term in the records were "postoperative wound infection", "skin and subcutaneous tissue infection", "local infection of skin/subcutaneous tissue" and "cellulitis of wound".

13% of the patients' records documented their wound as being clinically infected at the onset of their management in the community. Another 55% of patients were prescribed a systemic anti-infective and/or antimicrobial dressing at this time, suggesting that as many as 68% of all the wounds in our study population may have been considered to be at risk of infection or infected at the time of initial presentation in the community (Table 9). Additionally, 31% of patients with a putative infection had diabetes compared to 18% of patients who did not have an infection; $p<0.005$.

18% of patients received only an antimicrobial dressing, indicative of concern about the local bioburden or a possible localised wound infection, and 66% were prescribed a systemic anti-infective. The duration of continuous prescribing of an antimicrobial dressing in the patients' records was a mean of 4.2 months per patient. However, 28% of patients received continuous prescribing of topical antimicrobials for >6 months, according to documentation in their case record.

Of the 16% of patients who were never recorded as having an infection, 92% of the wounds healed within a mean of 1.9 months. The healing rate was lower among patients with a putative infection, and the mean time to healing was longer (Table 9). Furthermore, the cost of wound management of an uninfected wound was at least 60% less than that of a putatively infected wound (Table 9). The percentage of putative infections and associated costs was relatively unaffected by whether the wound had arisen from a planned or emergency procedure (Table 10). Hence, the mean NHS cost of managing an unhealed surgical wound without any evidence of infection was estimated to be ~£2,000 per wound, and the mean conflated cost of managing an unhealed surgical wound with a putative infection ranged between £5,000 and £11,200 per wound.



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Additionally, 23% of patients subsequently developed a putative wound infection a mean 4.3 months after initial presentation, for which an anti-infective was prescribed. The cost of wound management among these patients was a mean of £12,890 per patient.

Binary logistic regression showed that within the limitations of the data documented in the records of this cohort of patients, the anatomical site of surgery, prior presence of immunological symptoms and diabetes were all potential independent risk factors for patients developing an infection:

- Chest and breast surgery: Odds ratio 3.231 (95% CI: 1.127; 9.263); $p = 0.029$
- Immunological symptoms: Odds ratio 2.678 (95% CI: 1.197; 5.992); $p = 0.016$
- Lower limb (vascular) surgery: Odds ratio 2.485 (95% CI: 1.130; 5.466); $p = 0.024$
- Abdomen surgery: Odds ratio 1.814 (95% CI: 1.076; 3.058); $p = 0.025$
- Diabetes: Odds ratio 1.734 (95% CI: 1.025; 2.933); $p = 0.04$

**Sensitivity Analyses**

Sensitivity analysis showed that if the:

- probability of healing was reduced by 25%, from 83% to 62%, the mean NHS cost of wound care over 12 months would increase by 22% to an estimated £8,929 per wound. Conversely, if the probability of healing was increased by 20%, from 83% to 99%, the mean NHS cost of wound care over 12 months would decrease by 17% to an estimated £6,077 per wound.
- number of district nurse visits changed by 25% below or above the base case value, the mean NHS cost of wound care over 12 months would vary by 14% from the mean value (range £6,298–£8,392 per wound).
- number of practice nurse visits changed by 25% below or above the base case value, the mean NHS cost of wound care over 12 months would vary by 1% from the mean value (range £7,282–£7,408 per wound).
- number of hospital admissions changed by 25% below or above the base case value, the mean NHS cost of wound care over 12 months would vary by 4% from the mean value (range £7,073–£7,617 per wound).
- number of hospital outpatient visits changed by 25% below or above the base case value, the mean NHS cost of wound care over 12 months would vary by 1% from the mean value (range £7,258–£7,432 per wound).



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- unit cost of wound care products was decreased or increased by 25%, the mean NHS cost of wound care over 12 months would vary by 4% from the mean value (range £7,074–£7,616 per wound).

Changes to the use of other health care resources had minimal impact on the mean NHS cost of wound care over 12 months, following initial presentation in the community.

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## DISCUSSION

This study's population comprised those patients who were discharged from hospital into the community with a wound that remained unhealed for longer than four weeks after their surgery, and may well be different to the cohort of patients whose wound heals within four weeks of their surgical procedure or those who remain in hospital until their surgical wound heals. Nevertheless, this analysis provides the first evidence of how unhealed surgical wounds are managed in clinical practice in the UK, following initial presentation in the community.

This cohort consisted of patients with SWD or an open wound left to heal by secondary intention. SSI is one of the risk factors for SWD, but the occurrence of SWD can increase the risk of developing an SSI [18]. Although the secondary care and economic implications of SSI are well recognised [19, 20], those of SWD remain largely unquantified [21], as is the community cost of treating both [22]. One study comments that a rigorous and consistent classification system is needed if patients with SWD are to be effectively diagnosed and managed [21]. Our study found considerable variation in documentation standards and terminology pertaining to both the nature of the wound and infection. Consequently any reporting system on SWD and SSI in the community would be under-reported and inaccurate. In an attempt to address this variance, a post-discharge SSI assessment has been developed and is currently undergoing further testing [23].

The lack of secondary care involvement in many of the cases identified in this study would suggest that surgical teams may be unaware of the extent of the problem, and that both SWD and SSI may therefore be under-reported. A point prevalence study of wounds in north-east England identified that the largest proportion of wounds were surgical wounds, and that community nurses were involved in the care of over 70% of patients with wounds [24]. Another study found that one-third of surgical complications occurred after discharge, that two-thirds were managed in the community and that one-third resulted in readmission to hospital [25]. The authors emphasised that research and audit based solely on inpatient data significantly underestimates surgical wound morbidity rates [25]. In comparison, 19% of this study's patients were re-admitted into hospital as a direct result of their unhealed surgical wound.



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Our analysis suggests that unhealed surgical wounds occur in patients with significant co-morbidities, the management of which is associated with significant resource use. Moreover, two-thirds of all the unhealed surgical wounds in this data set were considered to be at risk of infection or infected at the time of presentation. This estimate was based on documentation of infection in the patients' records and the use of antimicrobial dressings and anti-infective prescriptions. The authors recognise the potential weakness of this estimate as systemic anti-infectives can be prescribed in general practice on the basis of wound swabs alone. Furthermore, antimicrobial dressings are prescribed prophylactically in clinical practice for wounds that are both infected and uninfected. The relative effectiveness of any antiseptic, antibiotic or anti-bacterial agent delivered either systemically or topically on surgical wounds healing by secondary intention is unclear [26]. NICE recommends that patients with a SSI are offered treatment with an antibiotic that covers the likely causative organisms, and is selected based on local resistance patterns and the results of microbiological tests [9]. Moreover, prophylactic use of antibiotics carries a risk of adverse effects and increased prevalence of antibiotic-resistant bacteria. Therefore, NICE recommends that prophylactic use of antibiotics should be limited to cover the organisms most likely to cause infection and be influenced by the strength of the association between the antibiotic used and these adverse effects [9].

Resource use associated with managing a putatively infected wound was found to be greater than that of an uninfected wound as the healing rate was lower and time to healing was longer. So too was resource use associated with managing the wounds that remained unhealed compared to those that went on to heal. Consequently, the cost of managing an unhealed wound was at least double that of managing a wound that healed (mean of £5,997 versus £13,682 per wound), and the cost of managing a putatively infected wound was at least 60% less than that of an uninfected wound. The mean cost of managing a putatively infected wound with an anti-infective and an antimicrobial dressing (£11,200) was not too dissimilar to Tanner's cost estimate of managing a post-surgical wound infection in the community (£10,523) [27]. Moreover, the analysis found the mean NHS cost of wound care over 12 months from initial presentation in the community to be an estimated £7,300 per wound, ranging from a mean of £7,200 to £7,800 for a wound that arose from a planned or emergency procedure, respectively. It is important to note that these estimates are the amounts by which the costs of the original episodes of surgery are increased as a result of the surgical wound not having healed. Others have also reported that SWD increases health care



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expenditure, due in part to the need for community nursing and associated support and increased use of wound care products [19, 28-32].

These findings from this cohort of patients with unhealed surgical wounds are consistent with our Burden of Wounds study [11, 12, 33]. The time to healing a wound is clearly an important factor in driving costs. Accordingly, the cost of surgical wound management can be affected by a combination of resources required for dressing changes, complexity of some treatment regimens and infection [12]. Furthermore, the Burden of Wounds study [11, 12, 33] provided insight into areas where care improvements could potentially result in improved clinical outcomes whilst generating significant cost savings. Nevertheless, cost-effective management and healing of unhealed surgical wounds in the community is likely to remain a challenging problem. One of the reasons may be due to the inadequate involvement of specialist clinicians in the management of the wounds in this study's cohort. Only three patients were recorded as having seen a tissue viability nurse and around a half of all patients who still had a wound at 3 months were recorded as having had a follow-up outpatient visit with their surgeon. However, it is possible that more patients were receiving multidisciplinary care than those for whom that was recorded in the THIN database. However, there was minimal evidence of this within the records, and there was no evidence of a coordinated shared treatment plan.

This study highlights the apparent lack of treatment planning, re-assessment and re-evaluation of care for most patients with an unhealed surgical wound in the community. The patients' combination of dressings and bandages remained unchanged for the length of time the wound remained unhealed, and there was minimal correlation between wound duration and senior involvement in direct patient care. Given the nature of these wounds, there was a surprising under-utilisation of topical negative pressure therapy in this cohort of patients. This may have resulted from either a lack of product availability, item cost considerations, skill mix and/or a failure to follow escalation pathways involving senior staff. Another community-based study in Australia reported similar findings [21], and interestingly, the distribution of dressing use in our study was concordant to that used to treat SWD in the Australian study [21]. Clearly, improving management practices should lead to a better outcome for patients and would be cost-effective for the NHS.



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The authors suggest that an improvement in five key areas of clinical and service management would enhance healing and other patient outcomes while reducing overall management costs. These are:

- Working to common definitions and reporting standards across primary and secondary care.
- Integrating care across providers.
- Escalating care appropriately with greater senior involvement.
- Rational use of products with access to advanced wound treatments when necessary.
- Recognising high-risk patients and responding with nutritional support and co-morbidity management as appropriate

In turn, with improved healing, these actions should reduce workload and associated health care resource use and lead to reductions in the overall cost of wound care. All health care systems recognise the importance of managing unhealed surgical wounds and the relative risk of developing a SSI. Clearly, training non-specialist nurses in the appropriate management of unhealed surgical wounds is a pre-requisite to overcoming some of the problems encountered in clinical practice and to achieving better health outcomes than those currently being observed.

**Study limitations**

The advantages and disadvantages of using patients' records in the THIN database for health economic studies in wound care have been previously discussed [11]. In summary, the advantage of using the database is that the patient pathways and associated resource use are based on real-world evidence derived from clinical practice. However, the analyses were based on clinicians' entries into their patients' records and inevitably subject to a certain amount of imprecision and lack of detail. Moreover, the computerised information in the database is collected by GPs and nursing teams for clinical care purposes and not for health economics research. Prescriptions issued by GPs and practice nurses are recorded in the database, but it does not specify whether the prescriptions were dispensed or detail patient compliance with the product. Additionally, the patients' records do not consistently document plasma glucose levels and amounts of alcohol intake, both of which could potentially impact on wound healing. Despite these limitations, it is the authors' opinion that the real-world evidence contained in the THIN database has provided a useful perspective on the



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management of unhealed surgical wounds in the community in the UK and the associated costs.

The analysis was truncated at 12 months and does not consider the potential impact of those wounds that remained unhealed beyond the study period. Also excluded is the potential impact of managing hospital inpatients with a surgical wound and those being cared for in nursing/residential homes. The analysis only considered NHS resource use and associated costs for the 'average patient' and was not stratified according to gender, comorbidities, disease-related factors and level of clinicians' skills. Costs incurred by non-NHS organisations (such as the provision of social care), patients' costs and indirect societal costs as a result of patients being absent from work were also excluded from the analysis.

Further research is required to quantify both the incidence and prevalence of unhealed surgical wounds, SWD and SSI in the community and to elucidate more fully the risk factors for their development.

**Conclusion**

The real-world evidence in this study provides important insights into a number of aspects of surgical wound management in clinical practice in the community in the UK that have been difficult to ascertain from other published studies. Surgeons are unlikely to be fully aware of the problems surrounding unhealed surgical wounds once patients are discharged into the community, due to inconsistent recording in patients' records coupled with the finding that only around a half of all patients who still had a wound at 3 months saw their surgeon for a follow-up appointment. Additionally, it provides the best estimate available of NHS resource use and costs with which to inform policy and budgetary decisions pertaining to managing these wounds. Clinical and economic benefits to both patients and the NHS could accrue from strategies that focus on improving documentation in patients' records, wound-healing rates and reducing infection. Clinicians managing unhealed surgical wounds may wish to consider the findings from this study when making treatment decisions.



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**Table 1: Patients' baseline characteristics.**

| | |
|---|---|
| Mean age at time of surgery per patient (years) | 62.6 |
| Percentage female | 54% |
| Mean systolic blood pressure (mm Hg) per patient | 131.0 |
| Mean diastolic blood pressure (mm Hg) per patient | 75.4 |
| Mean body mass index (kg/m$^2$) per patient | 29.6 |
| Percentage with BMI <18.5 kg/m$^2$ | 3% |
| Percentage with BMI ≥30.0 kg/m$^2$ | 46% |
| Percentage who were smokers | 21% |
| Percentage who were ex-smokers | 29% |
| Percentage who were non-smokers | 50% |
| Percentage with abdominal surgery | 22% |
| Percentage with lower limb (vascular) surgery | 14% |
| Percentage with minor surgery | 12% |
| Percentage with lower limb (orthopaedic) surgery | 10% |
| Percentage with upper limb surgery | 9% |
| Percentage with skin surgery | 8% |
| Percentage with chest surgery | 8% |
| Percentage with unspecified surgery | 4% |
| Percentage with head and/or neck surgery | 4% |
| Percentage with perineal surgery | 3% |
| Percentage with lower limb (minor) surgery | 2% |
| Percentage with back surgery | 2% |
| Percentage with groin surgery | 1% |

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**Table 2: Patients' comorbidities.**

| Comorbidity | Percentage of patients with a comorbidity | | |
|---|---|---|---|
| | All | Planned procedures | Emergency procedures |
| Cardiovascular | 70% | 69% | 71% |
| Cerebrovascular | 7% | 6% | 9% |
| Dermatological | 54% | 54% | 54% |
| Endocrinological | 48% | 47% | 50% |
| Gastroenterological | 41% | 39% | 45% |
| Genito-urinary | 32% | 32% | 30% |
| Haematological | 7% | 7% | 8% |
| Hepatological | 3% | 2% | 3% |
| Immunological | 13% | 12% | 15% |
| Musculoskeletal | 68% | 67% | 70% |
| Neurological | 27% | 27% | 28% |
| Oncological | 25% | 24% | 27% |
| Ophthalmological | 12% | 12% | 10% |
| Otolaryngological | 22% | 20% | 28% |
| Psychiatric | 38% | 38% | 38% |
| Renal | 24% | 24% | 24% |
| Respiratory | 39% | 37% | 42% |

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**Table 3: Dressings prescribed at the time of initial presentation in the community.**

| | Percentage of patients who were treated with the following dressings for their initial treatment | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Absorbent** | **Alginate** | **Antimicrobial** | **Foam** | **Hydrocolloid** | **Hydrogel** | **Low-adherence** | **Odour absorbent** | **Other** | **Permeable** | **Soft polymer** |
| **All** | 46% | 32% | 39% | 36% | 29% | 24% | 24% | 0% | 37% | 32% | 39% |
| **Emergencies** | 46% | 34% | 39% | 38% | 32% | 26% | 27% | 0% | 37% | 32% | 41% |
| **Planned** | 46% | 30% | 39% | 36% | 29% | 23% | 23% | 0% | 37% | 32% | 39% |

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**Table 4: Dressings prescribed over the 12 months following initial presentation in the community.**

| | Percentage of patients who were treated with the following dressing | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Month of treatment** | **Absorbent** | **Soft polymer** | **Antimicrobial** | **Other** | **Foam** | **Permeable** | **Alginate** | **Hydrocolloid** | **Low-adherence** | **Hydrogel** | **Odour absorbent** |
| 1 | 46% | 39% | 39% | 37% | 36% | 32% | 32% | 29% | 24% | 24% | 0% |
| 2 | 38% | 35% | 35% | 32% | 13% | 29% | 28% | 29% | 24% | 25% | 0% |
| 3 | 32% | 31% | 31% | 28% | 32% | 26% | 25% | 25% | 23% | 24% | 21% |
| 4 | 28% | 28% | 28% | 26% | 29% | 24% | 24% | 25% | 21% | 22% | 0% |
| 5 | 25% | 25% | 25% | 23% | 26% | 21% | 21% | 22% | 19% | 20% | 0% |
| 6 | 21% | 21% | 22% | 20% | 22% | 18% | 18% | 18% | 17% | 17% | 0% |
| 7 | 16% | 17% | 17% | 16% | 18% | 15% | 13% | 15% | 13% | 13% | 0% |
| 8 | 14% | 15% | 15% | 14% | 15% | 13% | 12% | 13% | 12% | 12% | 11% |
| 9 | 12% | 12% | 14% | 12% | 12% | 12% | 11% | 11% | 11% | 11% | 0% |
| 10 | 11% | 12% | 12% | 10% | 11% | 10% | 10% | 10% | 9% | 9% | 0% |
| 11 | 8% | 9% | 9% | 18% | 9% | 17% | 7% | 10% | 7% | 7% | 0% |
| 12 | 12% | 10% | 11% | 10% | 10% | 9% | 9% | 10% | 10% | 9% | 0% |

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**Table 5: Health care resource use associated with managing unhealed surgical wounds in clinical practice.**

| | Mean amount of resource use per patient over 12 months from initial presentation | | |
|---|---|---|---|
| **Resource use** | **All** | **Planned procedures** | **Emergency procedures** |
| Bandages | 18.88 | 19.10 | 18.30 |
| District nurse visits | 72.00 | 73.10 | 69.20 |
| Dressings | 177.50 | 182.50 | 164.50 |
| GP visits | 2.80 | 2.90 | 2.50 |
| Hospital admissions | 0.31 | 0.28 | 0.39 |
| Hospital outpatient visits | 2.20 | 2.10 | 2.50 |
| Laboratory tests | 0.78 | 0.79 | 0.75 |
| Negative pressure wound therapy | 0.16 | 0.15 | 0.20 |
| Practice nurse visits | 10.30 | 10.80 | 9.20 |
| Prescriptions for analgesic and non-steroidal inflammatories | 5.60 | 5.80 | 5.20 |
| Prescriptions for anti-infectives | 2.40 | 2.40 | 2.20 |
| Topical treatments | 3.30 | 2.10 | 6.20 |

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**Table 6: Cost of health care resource use associated with managing unhealed surgical wounds in clinical practice (percentage of total cost is in parenthesis).**

| | Mean cost of resource use per patient over 12 months from initial presentation in the community | | |
|---|---|---|---|
| **Resource** | **All procedures** | **Planned procedures** | **Emergency procedures** |
| District nurse visits | £4,186.81 (57%) | £4,142.62 (58%) | £4,297.30 (55%) |
| Hospital admissions | £1,086.76 (16%) | £972.30 (14%) | £1,372.91 (18%) |
| Dressings | £763.73 (10%) | £772.50 (11%) | £741.82 (10%) |
| Hospital outpatient visits | £348.55 (5%) | £326.04 (5%) | £404.84 (5%) |
| Practice nurse visits | £253.29 (3%) | £262.33 (4%) | £230.69 (3%) |
| GP visits | £219.33 (3%) | £227.02 (3%) | £200.11 (3%) |
| Bandages | £214.65 (3%) | £202.20 (3%) | £245.77 (3%) |
| Analgesics and non-steroidal anti-inflammatories | £118.42 (2%) | £118.31 (2%) | £118.68 (2%) |
| Wound care appliances | £83.61 (1%) | £75.35 (1%) | £104.24 (1%) |
| Anti-infectives | £43.44 (1%) | £43.51 (1%) | £43.26 (1%) |
| Topical treatments | £17.17 (<1%) | £12.35 (<1%) | £29.22 (<1%) |
| Negative pressure wound therapy | £6.00 (<1%) | £5.18 (<1%) | £8.03 (<1%) |
| Laboratory tests | £2.85 (<1%) | £2.85 (<1%) | £2.85 (<1%) |
| Tissue viability nurse visits | £0.25 (<1%) | £0.24 (<1%) | £0.27 (<1%) |
| **TOTAL** | **£7,344.86 (100%)** | **£7,162.81 (100%)** | **£7,800.00 (100%)** |



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**Table 7: Cost of health care resource use associated with managing unhealed surgical wounds stratified by planned/emergency procedures and healing in clinical practice (percentage of total cost is in parenthesis).**

| | Mean cost of resource use per patient over 12 months from initial presentation in the community | | | |
|---|---|---|---|---|
| **Resource** | **Planned/healed procedures** | **Planned/unhealed procedures** | **Emergency/healed procedures** | **Emergency/unhealed procedures** |
| District nurse visits | £3,457.82 (58%) | £8,328.58 (59%) | £3,104.09 (52%) | £7,651.79 (59%) |
| Hospital admissions | £921.22 (15%) | £1,284.56 (9%) | £1,314.78 (22%) | £1,536.34 (12%) |
| Dressings | £627.04 (10%) | £1,661.62 (12%) | £558.83 (9%) | £1,256.28 (10%) |
| Hospital outpatient visits | £293.21 (5%) | £526.69 (4%) | £331.36 (6%) | £611.42 (5%) |
| Practice nurse visits | £191.80 (3%) | £693.48 (5%) | £164.96 (3%) | £415.48 (3%) |
| GP visits | £182.28 (3%) | £500.49 (4%) | £161.89 (3%) | £307.56 (2%) |
| Bandages | £117.25 (2%) | £721.50 (5%) | £86.36 (1%) | £693.92 (5%) |
| Analgesics and non-steroidal anti-inflammatories | £106.13 (2%) | £192.77 (1%) | £91.42 (2%) | £195.32 (2%) |
| Wound care appliances | £57.95 (1%) | £181.74 (1%) | £77.48 (1%) | £179.46 (1%) |
| Anti-infectives | £37.73 (1%) | £78.83 (1%) | £33.78 (1%) | £69.90 (1%) |
| Topical treatments | £6.21 (<1%) | £49.89 (<1%) | £39.62 (1%) | £0.00 (<1%) |
| Negative pressure wound therapy | £5.92 (<1%) | £0.69 (<1%) | £1.89 (<1%) | £25.30 (<1%) |
| Laboratory tests | £1.89 (<1%) | £8.70 (<1%) | £1.78 (<1%) | £5.86 (<1%) |
| Tissue viability nurse visits | £0.28 (<1%) | £0.00 (<1%) | £0.37 (<1%) | £0.00 (<1%) |
| **TOTAL** | **£6,006.73 (100%)** | **£14,229.54 (100%)** | **£5,968.61 (100%)** | **£12,948.63 (100%)** |



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**Table 8: Cost of health care resource use associated with managing unhealed surgical wounds stratified by BMI and diabetes.**

| | % of patients | % healed | % emergencies | NHS cost per patient |
|---|---|---|---|---|
| BMI <20 | 5% | 94% | 31% | £9,269 |
| BMI 20-29 | 45% | 89% | 27% | £6,938 |
| BMI 30-35 | 20% | 84% | 35% | £7,096 |
| BMI >35 | 20% | 84% | 28% | £7,812 |
| | | | | |
| Diabetes | 29% | 80% | 33% | £9,349 |
| No diabetes | 71% | 88% | 27% | £6,526 |

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**Table 9: Incidence of putative infection with associated healing and costs at the onset of wound management in the community.**

| | Percentage of patients | Percentage of patients who healed | Mean time to healing per patient (months) | Mean cost of wound care per patient |
|---|---|---|---|---|
| No infection | 16% | 92% | 1.86 | £2,001 |
| Received only an antimicrobial dressing | 18% | 83% | 5.79 | £6,966 |
| Prescribed an anti-infective with or without an antimicrobial dressing | 66% | 85% | 6.46 | £8,742 |
| Prescribed an anti-infective with an antimicrobial dressing | 41% | 82% | 8.11 | £11,169 |
| Prescribed an anti-infective without an antimicrobial dressing | 25% | 90% | 3.62 | £4,961 |

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**Table 10: Incidence of putative infection with associated healing and costs stratified by planned/emergency procedures at the onset of wound management in the community.**

| | Percentage of cohort | Percentage of cohort that healed | Mean time to healing per patient (months) | Mean cost of wound care per patient |
|---|---|---|---|---|
| **Planned procedures** | | | | |
| No infection | 17% | 90% | 1.81 | £2,143 |
| Received only an antimicrobial dressing | 17% | 86% | 5.99 | £6,966 |
| Prescribed an anti-infective | 66% | 87% | 6.66 | £8,507 |
| Prescribed an anti-infective with an antimicrobial dressing | 43% | 84% | 8.19 | £10,606 |
| Prescribed only an anti-infective | 23% | 93% | 3.79 | £4,581 |
| **Emergency procedures** | | | | |
| No infection | 16% | 97% | 1.97 | £1,649 |
| Received only an antimicrobial dressing | 21% | 79% | 5.29 | £7,165 |
| Prescribed an anti-infective | 63% | 79% | 5.98 | £9,574 |
| Prescribed an anti-infective with an antimicrobial dressing | 38% | 76% | 7.93 | £12,018 |
| Prescribed only an anti-infective | 25% | 83% | 3.20 | £5,633 |

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Figure 1: Wound healing stratified by planned/emergency procedures.

Figure 2: Wound healing stratified by anatomical site of surgery.

Figure 3: Patients who received a combination of multiple dressings at each dressing change.

Figure 4: Monthly cost of health care resource use associated with managing surgical wounds stratified by planned/emergency procedures and healing in clinical practice.

Figure 5: Cost of health care resource use associated with managing surgical wounds in clinical practice stratified by anatomical site of surgery.

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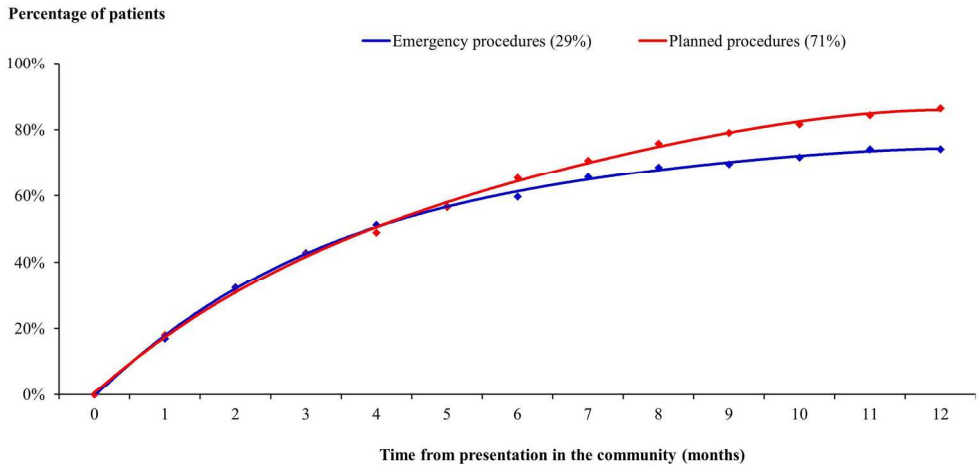


Figure 1

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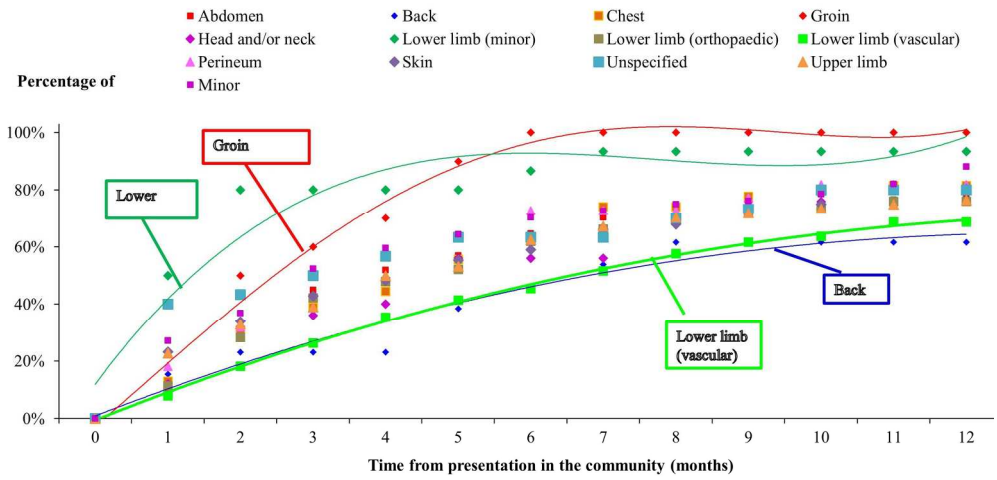


Figure 2

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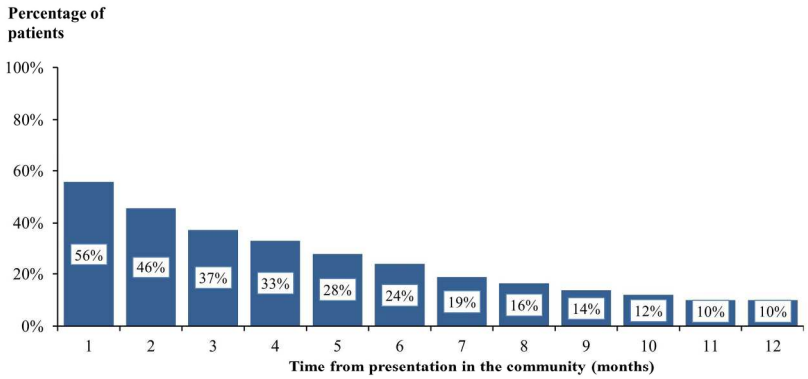


Figure 3

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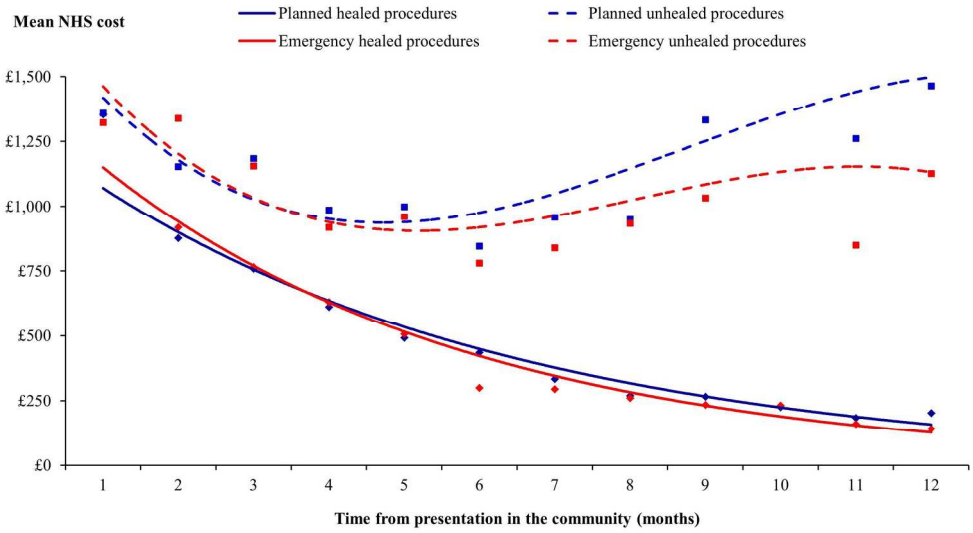


Figure 4

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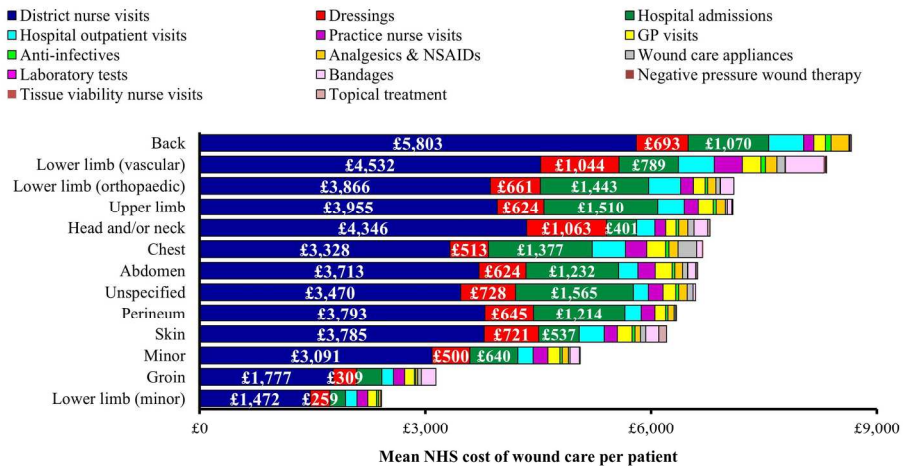


Figure 5

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**The RECORD statement – checklist of items, extended from the STROBE statement, that should be reported in observational studies using routinely collected health data.**

| | Item No. | STROBE items | Location in manuscript where items are reported | RECORD items | Location in manuscript where items are reported |
|---|---|---|---|---|---|
| **Title and abstract** | | | | | |
| | 1 | (a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found | Page 1 | RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included.<br><br>RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract.<br><br>RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract. | Page 1<br><br>Page 1<br><br>N/A |
| **Introduction** | | | | | |
| Background rationale | 2 | Explain the scientific background and rationale for the investigation being reported | Pages 6, 7 | | |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | Page 7 | | |
| **Methods** | | | | | |
| Study Design | 4 | Present key elements of study design early in the paper | Page 8 | | |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | Pages 8, 9 | | |

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| | | | | | |
|---|---|---|---|---|---|
| Participants | 6 | *(a) Cohort study* - Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br>*Case-control study* - Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls<br>*Cross-sectional study* - Give the eligibility criteria, and the sources and methods of selection of participants<br><br>*(b) Cohort study* - For matched studies, give matching criteria and number of exposed and unexposed<br>*Case-control study* - For matched studies, give matching criteria and the number of controls per case | Page 8<br><br>N/A<br><br>N/A<br><br>N/A | RECORD 6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided.<br><br>RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided.<br><br>RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage. | Page 8<br><br>N/A<br><br>N/A |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable. | Page 9 | RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided. | N/A |
| Data sources/ measurement | 8 | For each variable of interest, give sources of data and details of methods of assessment (measurement).<br>Describe comparability of assessment methods if there is more than one group | Page 9 | | |

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| | | | | | |
|---|---|---|---|---|---|
| Bias | 9 | Describe any efforts to address potential sources of bias | N/A | | |
| Study size | 10 | Explain how the study size was arrived at | Page 8 | | |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why | Page 8, 9 | | |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding<br>(b) Describe any methods used to examine subgroups and interactions<br>(c) Explain how missing data were addressed<br>(d) *Cohort study* - If applicable, explain how loss to follow-up was addressed<br>*Case-control study* - If applicable, explain how matching of cases and controls was addressed<br>*Cross-sectional study* - If applicable, describe analytical methods taking account of sampling strategy<br>(e) Describe any sensitivity analyses | Page 9<br>Pages 9, 10<br>Page 9<br>N/A<br>N/A<br>N/A<br>Page 10 | | |
| Data access and cleaning methods | | .. | | RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population. | Page 8 |

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| | | | | | |
|---|---|---|---|---|---|
| | | | | RECORD 12.2: Authors should provide information on the data cleaning methods used in the study. | N/A |
| Linkage | | .. | | RECORD 12.3: State whether the study included person-level, institutional-level, or other data linkage across two or more databases. The methods of linkage and methods of linkage quality evaluation should be provided. | Page 8 |
| **Results** | | | | | |
| Participants | 13 | (a) Report the numbers of individuals at each stage of the study (*e.g.*, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed)<br>(b) Give reasons for non-participation at each stage.<br>(c) Consider use of a flow diagram | Pages 11-17<br><br>N/A<br><br>N/A | RECORD 13.1: Describe in detail the selection of the persons included in the study (*i.e.,* study population selection) including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram. | Pages 8 and 11 |
| Descriptive data | 14 | (a) Give characteristics of study participants (*e.g.*, demographic, clinical, social) and information on exposures and potential confounders<br>(b) Indicate the number of participants with missing data for each variable of interest<br>(c) *Cohort study* - summarise follow-up time (*e.g.*, average and total amount) | Pages 11, 28, 29 | | |
| Outcome data | 15 | *Cohort study* - Report numbers of outcome events or summary measures over time | Pages 11-17 | | |

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| | | | | | |
|---|---|---|---|---|---|
| | | *Case-control study* - Report numbers in each exposure category, or summary measures of exposure<br>*Cross-sectional study* - Report numbers of outcome events or summary measures | N/A<br><br>N/A | | |
| Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included<br>(b) Report category boundaries when continuous variables were categorized<br>(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | Pages 11-17<br>Pages 28-38<br><br>N/A<br><br>N/A | | |
| Other analyses | 17 | Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses | Pages 16, 17 | | |
| **Discussion** | | | | | |
| Key results | 18 | Summarise key results with reference to study objectives | Pages 18-21 | | |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | Pages 21, 22 | RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported. | Pages 18-21 |

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| | | | | | |
|---|---|---|---|---|---|
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | Pages 18-21 | | |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | Pages 18-21 | | |
| **Other Information** | | | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | Page 3 | | |
| Accessibility of protocol, raw data, and programming code | | .. | | RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code. | N/A |

*Reference: Benchimol EI, Smeeth L, Guttmann A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM, the RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. *PLoS Medicine* 2015; in press.

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BMJ Open

# A cohort study evaluating management of unhealed surgical wounds in the community in clinical practice in the UK: costs and outcomes

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| Primary Subject Heading: | Health economics |
| Secondary Subject Heading: | Surgery, Health services research, Health economics, Evidence based practice |
| Keywords: | Burden, Cost, Surgical wounds, WOUND MANAGEMENT, SURGERY |
| | |

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**ORIGINAL ARTICLE**

# A COHORT STUDY EVALUATING MANAGEMENT OF UNHEALED SURGICAL WOUNDS IN THE COMMUNITY IN CLINICAL PRACTICE IN THE UK: COSTS AND OUTCOMES

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**Running title:** Health economic impact of unhealed surgical wounds in the UK

**Keywords:** Burden; cost; surgery; surgical wounds; wounds; UK.

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## ABSTRACT

**Objective:** To evaluate the patient pathways and associated health outcomes, resource use and corresponding costs attributable to managing unhealed surgical wounds in clinical practice, from initial presentation in the community in the UK.

**Methods**: This was a retrospective cohort analysis of the records of 707 patients in The Health Improvement Network (THIN) Database whose wound failed to heal within four weeks of their surgery. Patients' characteristics, wound-related health outcomes and health care resource use were quantified, and the total National Health Service (NHS) cost of patient management was estimated at 2015/2016 prices.

**Results**: Inconsistent terminology was used in describing the wounds. 83% of all wounds healed within 12 months from onset of community management, ranging from 86% to 74% of wounds arising from planned and emergency procedures, respectively. Mean time to healing was 4 months per patient. Patients were predominantly managed in the community by nurses and only around a half of all patients who still had a wound at 3 months were recorded as having had a follow-up visit with their surgeon. Up to 68% of all wounds may have been clinically infected at the time of presentation, and 23% of patients subsequently developed a putative wound infection a mean 4 months after initial presentation. Mean NHS cost of wound care over 12 months was £7,300 per wound, ranging from £6,000 to £13,700 per healed and unhealed wound, respectively. Additionally, the mean NHS cost of managing a wound without any evidence of infection was ~£2,000 and the conflated cost of managing a wound with a putative infection ranged between £5,000 and £11,200.

**Conclusion:** Surgeons are unlikely to be fully aware of the problems surrounding unhealed surgical wounds once patients are discharged into the community, due to inconsistent recording in patients' records coupled with the low rate of follow-up appointments. These findings offer the best evidence available with which to inform policy and budgetary decisions pertaining to managing unhealed surgical wounds in the community.




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## STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is the first study to evaluate the patient pathways and associated health outcomes, resource use and corresponding costs attributable to managing unhealed surgical wounds over 12 months from the onset of community management.

- This study undertaken using real world evidence derived from the anonymised records of a sample of patients in The Health Improvement Network (THIN) database (a nationally representative database of clinical practice among >11 million patients registered with general practitioners in the UK).

- The estimates were derived following a systematic analysis of patients' characteristics, wound-related health outcomes and all community-based and secondary care resource use contained in the patients' electronic records.

- Computerised information in the THIN database is collected by general practitioners (GPs) for clinical care purposes and not for research, consequently the accuracy of wound descriptors and other terminology have not been validated, but does reflect real world documentation in clinical practice.

- The analysis does not consider the potential impact of patients' surgical wounds that heal within four weeks of the surgical procedure or those patients who remain in hospital until their surgical wound heals.

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## FUNDING

This analysis was originally commissioned and part funded by the National Institute for Health Research (NIHR) Wound Prevention and Treatment Healthcare Technology Co-operative (NIHR WoundTec HTC), Bradford Institute For Health Research, Bradford, West Yorkshire, UK and part funded by Smith & Nephew Medical Limited, Hull, East Riding Of Yorkshire, UK.

The study's sponsors had no involvement in the study design, the collection, analysis and interpretation of the data, the writing of this manuscript and the decision to submit this article for publication. The views expressed in this article are those of the authors and not necessarily those of the NHS, the NIHR, the Department of Health or Smith & Nephew.

## COMPETING INTERESTS

None declared.

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## CONTRIBUTORS

J.F.G. designed the study, managed the analyses, performed some analyses, checked all the other analyses, and wrote the manuscript.

G.W.F. conducted much of the analyses.

P.V. scrutinised the analyses, suggested further analyses and helped interpret some of the findings.

All the authors were involved in revising the manuscript and gave final approval. J.F.G. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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## DATA SHARING STATEMENT

The Corresponding Author has the right to grant on behalf of all authors and does grant on behalf of all authors, a worldwide licence to the Publishers and its licensees in perpetuity, in all forms, formats and media (whether known now or created in the future), to i) publish, reproduce, distribute, display and store the Contribution, ii) translate the Contribution into other languages, create adaptations, reprints, include within collections and create summaries, extracts and/or, abstracts of the Contribution and convert or allow conversion into any format including without limitation audio, iii) create any other derivative work(s) based in whole or part on the on the Contribution, iv) to exploit all subsidiary rights to exploit all subsidiary rights that currently exist or as may exist in the future in the Contribution, v) the inclusion of electronic links from the Contribution to third party material where-ever it may be located; and, vi) licence any third party to do any or all of the above. Questions concerning the data underlying the results can be obtained from the Corresponding Author. However, the THIN data set cannot be shared as this restriction was a condition of the Ethics approval obtained from the Research Ethics Committee (Reference number 13-061).

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## INTRODUCTION

More than 10 million operations were performed by the National Health Service (NHS) in England [1] in 2015/16, with the majority involving an incision [2]. Most incised surgical wounds generally heal by primary intention. However, some heal by secondary intention, either because the wound has intentionally been left open or has dehisced following primary closure [3, 4]. Surgical wounds healing by secondary intention are thought to be common in the UK, and to account for 26-28% of all surgical wounds requiring continued nursing intervention [5]. Such wounds may remain open for an extended period and are susceptible to infection, requiring on-going treatment [6]. Surgical wound dehiscence (SWD), defined as the rupture or splitting open of a previously closed surgical incision site, may be either superficial or deep [7]. Dehisced wounds may be left to heal fully through secondary intention, or closed surgically after partial healing.

The management of patients with an unhealed surgical wound remains challenging because of the potentially high chance of developing further wound complications [8]. Such complications can result in hospital re-admission, further surgery, prolonged hospitalisation and may require intensive management in the community. The National Institute for Health and Care Excellence (NICE) estimated that 5% of all surgical procedures result in a surgical site infection (SSI) in the UK and account for up to 20% of cases of health care associated infections [9]. The SSI data collected by hospitals could be an underestimate as most patients develop signs and symptoms after discharge [10].

The Burden of Wounds study reported that unhealed surgical wounds accounted for 11% (n=250,000 patients) of all wounds managed in the UK by the NHS in 2012/2013 [11]. The annual NHS cost attributable to managing these wounds and associated comorbidities was estimated to be £982.9 million [12]. After adjustment for comorbidities, the annual NHS cost was estimated to be between £957.4 and £985.8 million [12].

Wound management is now of sufficient concern among the wound care community in the UK, that the UK Parliament (House of Lords) debated developing a national strategy for improving the standards of wound care in the NHS [13]. All health care systems recognise the importance of healing surgical wounds without complications. Nevertheless, there is a lack of information surrounding the characteristics of patients with surgical wounds healing



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by primary or secondary intention, the time taken for these wounds to heal, wound treatment and patient management within the community. Additionally, the health care costs associated with SWD are poorly reported and are frequently conflated with the cost of SSI. This paucity of data limits our understanding of the health care needs of patients with an unhealed surgical wound and also hinders the planning and allocation of the relevant resources. The aim of the present analysis was to follow a cohort of patients in clinical practice from initial presentation of their surgical wound in the community, to evaluate in greater depth how managing patients with an unhealed surgical wound impacts on healing and NHS costs.

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## METHODS

### Study Design

This was a retrospective cohort analysis of the case records of patients with an unhealed surgical wound (defined as one that had not healed within four weeks of the surgical procedure), randomly extracted from The Health Improvement Network (THIN) database. The perspective of the analysis was that of the UK's NHS and the time horizon was 12 months from initial presentation in the community.

### The Health Improvement Network Database

The THIN database (IMS, London, UK) contains electronic records on >11 million anonymised patients entered by GPs from 562 practices across the UK. The patient composition within the THIN database has been shown to be representative of the UK population in terms of demographics and disease distribution [14], and the database theoretically contains patients' entire medical history, as previously described [11]. Hence, the information contained in the THIN database reflects actual clinical practice.

### Study Population

The authors had previously obtained a random sample of records of 6,000 adult patients with a documented history of a wound for whatever reason from the THIN database, for previous wound studies. The study population of 707 patients was identified within this cohort of 6,000 patients according to the following criteria:

- Were 18 years of age or over.
- Had undergone a surgical procedure either during or after 2012.
- Had a surgical wound which had remained unhealed for 4 weeks after the surgical procedure
- Had at least 12 months continuous medical history in their case record from the first mention of their surgical wound unless it healed.

Patients whose wound healed within 4 weeks of their surgical procedure or those with a dermatological tumour were excluded from the data set. Any patients with an unhealed



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surgical wound who died within a year of initial presentation in the community was also excluded, since the study design was to examine the trajectory of these wounds over a full 12 months from initial presentation unless it healed.

**Patient and Public Involvement**

Patients and members of the public were not directly involved in this study. The study population was limited to the anonymised records of patients in the THIN database.

**Ethics Approval**

Ethics approval to use anonymised patients' records from the THIN database for this study was obtained from the Research Ethics Committee that appraises studies using the THIN database (Reference number 13-061).

**Study Variables and Statistical Analyses**

Information was systematically extracted from the patients' electronic records over a period of 12 months from initial presentation of their unhealed surgical wound in the community. This included patients' characteristics, comorbidities (defined as a non-acute condition that patients were suffering from in the year before the start of their wound), wound-related health care resource use (i.e. dressings, bandages, topical treatments, negative pressure wound therapy, district nurse visits [who provide care within a patient's home], practice nurse visits [who provide care within a GP's surgery], GP visits, hospital outpatient visits, laboratory tests), prescribed medication (i.e. analgesics, NSAIDs and systemic anti-infectives [principally antibiotics]) and clinical outcomes (i.e. healing and putative infection). If a patient received a bandage or dressing on a specific date, but a clinician visit was not documented in their record, it was assumed the patient had been seen outside of the general practice by a district nurse. No other assumptions were made regarding missing data and there were no other interpolations.

Differences between two subgroups were tested for statistical significance using a Mann–Whitney U-test or $\chi 2$ test. Differences between three subgroups were tested for statistical significance using a Kruskal–Wallis test or $\chi 2$ test. Multivariate logistic regression (using the



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enter method in which all the independent variables were entered into the analysis simultaneously) investigated relationships between baseline variables and clinical outcomes. Kaplan–Meier analyses were undertaken to compare the healing distribution of different subgroups. The $p$ values <0.05 were considered statistically significant and have been reported. All $p$ values ≥0.05 were not considered to be statistically significant and these numerical values have not been reported, All statistical analyses were performed using IBM SPSS Statistics (IBM UK Ltd, Portsmouth, Hampshire UK).

**Cost of Patient Management**

Unit costs at 2015/2016 prices [15-17] were assigned to the resource use values to estimate the mean NHS cost of managing an unhealed surgical wound over 12 months from initial presentation in the community.

**Sensitivity Analyses**

Deterministic sensitivity analyses were undertaken to assess how the cost of managing an unhealed surgical wound changes by varying the values of clinical outcomes and resource use.

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## RESULTS

### Patients' Characteristics

This analysis has essentially studied a cohort of patients with SWD or an open wound left to heal by secondary intention. However, the term dehiscence or open wound was only recorded in 4% of the patients' case records. The most frequently used terms were "dressing of wound" or "dressing of surgical wound". The age of the study population was a mean of 62.6±17.8 years per patient. 58% (n=411) of the cohort were >60 years of age, and 26% (n=184) were ≤50 years of age. 71% (n=505) of patients had undergone a planned surgical procedure and 29% (n=202) an emergency procedure. Two-thirds (67%) of all the patients were discharged from hospital into the community within 2 weeks of their surgical procedure; the median length of stay was 10 days. Patients' baseline characteristics and anatomical site of surgery are summarised in Table 1. 22% of all the wounds arose from abdominal surgery, and 14% arose from limb (vascular) surgery of which 79% the procedures involved either a minor or major amputation.

The cohort had a mean of 5.3±2.7 comorbidities per patient, ranging from 5.2±2.7 comorbidities per patient who had a planned surgical procedure to 5.5±2.6 comorbidities per patient who underwent an emergency procedure. These differences were not significantly different. Additionally, 29% (n=205) of all patients had diabetes (27% (n=137) and 34% (n=68) of patients who underwent a planned and emergency procedure, respectively). Patients' comorbidities are summarised in Table 2. There were no significant differences in the incidence of comorbidities between patients whose wound did or did not heal within 12 months from initial presentation in the community (not shown), with the exception that 42% of patients whose wound remained unhealed had diabetes compared to 27% of healed patients; $p<0.01$.

### Clinical outcomes

This study was an analysis of unhealed surgical wounds following a documented surgical procedure in the patients' medical records. The THIN database does not define what a wound is and nor does it define wound healing. Wound healing was a clinical observation not necessarily confirmed by a specialist and it is unknown if the nurses/GPs who managed these



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patients used any consistent definition. On that basis, 83% (n=607) of all the wounds in this study's cohort were estimated to have healed within 12 months from initial presentation in the community (Figure 1), with healing ranging from 86% of wounds arising from a planned procedure to 74% of wounds arising from an emergency procedure. The time to healing was a mean of 4.2±3.0 months per patient. However, this ranged from a mean of 3.9±3.0 months for patients who had undergone planned surgery to 4.3±2.8 months for those who had undergone an emergency procedure.

The distribution of healing between the wounds arising from planned and emergency procedures was not significantly different ($p$ = 0.26 from a Kaplan Meier analysis). The healing rates stratified by anatomical site of surgery is shown in Figure 2. All the groin procedures healed, 93% of the minor lower limb procedures healed and 88% of the other minor procedures healed within 12 months from initial presentation in the community. Conversely, only 62% of back procedures and 69% of vascular lower limb procedures healed during this period. Irrespective of the other anatomical sites of surgery, between 76% and 82% of all the other procedures healed within 12 months from initial presentation in the community.

Healing was not affected by a patient's BMI. 94% of patients with a BMI <20kg/m$^2$ healed during the study period compared to 89% of patients with a BMI of 20-29kg/m$^2$, 84% of those with a BMI of 30-35kg/m$^2$ and 84% of those with a BMI of >35kg/m$^2$. None of these rates were significantly different from one another. Moreover, there was no significant difference in the BMI of those patients who underwent planned and emergency procedures. Additionally, significantly more wounds of patients without diabetes healed over the 12 months follow-up period compared to patients who had diabetes (88% versus 80%; $p$ = 0.002).

Binary logistic regression showed that within the limitations of the data documented in the records, anatomical site of surgery, having diabetes, having a suspected infection (see the Infection section below) and undergoing an emergency procedure are potential independent risk factors for a wound not healing:

- Suspect infection: Odds ratio 0.497 (95% CI: 0.223; 0.935); $p$ = 0.032
- Lower limb (vascular) surgery: Odds ratio 0.538 (95% CI: 0.310; 0.934); $p$ = 0.028
- Diabetes: Odds ratio 0.546 (95% CI: 0.301; 0.903); $p$ = 0.007



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- Emergency surgery: Odds ratio 0.660 (95% CI: 0.408; 0.990); $p = 0.045$

Smoking was not identified as being an independent risk factor for non-healing; 50% of patients in both the healed and unhealed groups were smokers or ex-smokers at the time of surgery.

**Patient Management**

At the onset of their wound management in the community, 46% of patients were prescribed an absorbent dressing, 39% an antimicrobial dressing, 39% a soft polymer, 36% a foam, 32% an alginate, 32% a permeable dressing 29% a hydrocolloiod and 24% a hydrogel (Table 3). Dressing use for the initial treatment was unaffected by whether a patient had undergone a planned or emergency procedure.

Patients continued to be prescribed their initial mix of dressings until such time as their wound healed (Table 4). Over half the patients received multiple dressings at each dressing change in the first month of treatment, decreasing to 10% of patients by the twelfth month of treatment (Figure 3). Patients who were treated with multiple dressings received between a mean of 2 and 4 dressings. Overall, patients' dressings were changed three times a week. Additionally, <1% of patients who had undergone a planned procedure and 2% of those who had undergone an emergency procedure received negative pressure wound therapy.

In addition to dressings and bandages, 42% of patients were prescribed an analgesic or non-steroidal anti-inflammatory drug (NSAID), and 36% were prescribed a systemic anti-infective at the time of initial presentation in the community. Over the study period, 66% of all patients were prescribed an anti-infective and 59% of all patients received an antimicrobial dressing.

Health care resource use associated with managing an unhealed surgical wound in the community, is shown in Table 5. Patients were predominantly managed in the community by nurses. Only 3 patients were documented as having had a single visit by a tissue viability nurse. Two of these patients had undergone a planned procedure and one an emergency procedure.



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59% of all patients were recorded as having had a follow-up visit with their surgeon within three months from discharge into the community, ranging from 54% of patients who had undergone a planned procedure to 66% of those who had undergone an emergency procedure. 58% of all patients (58% and 57% of those who had undergone a planned or emergency procedure, respectively) still had a wound at 3 months and only 53% of them had a follow-up visit with their surgeon. Additionally, 39% of all patients (38% and 40% of those who had undergone a planned or emergency procedure, respectively) still had a wound at 6 months and only 40% of them had a follow-up visit with their surgeon. Furthermore, 19% of patients were re-admitted into hospital a mean of 3.6 months after original discharge, including 9% within 30 days of discharge.

**Cost of Patient Management**

The mean NHS cost of wound care over 12 months, following initial presentation in the community, was an estimated £7,345±6,673 per surgical wound, ranging from a mean of £7,163±6,366 to £7,800±6,405 per wound that arose following a planned or emergency procedure, respectively (Table 6). Figure 4 illustrates the monthly cost of managing these wounds, and shows how the monthly wound management cost starts to increase around month 5/6 if the wound fails to heal. The mean NHS cost of wound care of managing a wound that remained unhealed was at least double that of managing a wound that healed (mean of £5,997 versus £13,682 per unhealed surgical wound) (Table 7). The mean NHS cost of wound care stratified by anatomical site of surgery is shown in Figure 5.

District nurse visits were the primary cost driver and accounted for ≥52% of the cost of patient management. Hospital re-admissions accounted for up to a further 22% of the cost and hospital outpatient visits a further 4-6%. Dressings and bandages accounted for up to 17% of the cost of patient management. 18% of the total NHS cost of managing a wound arising from a planned procedure and up to 23% for a wound arising from an emergency procedure was incurred in secondary care, the majority of which related to hospital re-admission. The remainder was incurred in the community.

The mean NHS cost of wound care over 12 months decreased inversely as a patient's BMI increased (Table 8). Additionally, the mean NHS cost of wound care over 12 months was 43% more among patients with diabetes than among those without the disease (Table 8).



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**Infection**

The terms "surgical site infection" or "SSI" were not found in any of the patients' case records. The most frequently used term in the records were "postoperative wound infection", "skin and subcutaneous tissue infection", "local infection of skin/subcutaneous tissue" and "cellulitis of wound".

13% of the patients' records documented their wound as being clinically infected at the onset of their management in the community. Another 55% of patients were prescribed a systemic anti-infective and/or antimicrobial dressing at this time, suggesting that as many as 68% of all the wounds in our study population may have been considered to be at risk of infection or infected at the time of initial presentation in the community (Table 9). Additionally, 31% of patients with a putative infection had diabetes compared to 18% of patients who did not have an infection; $p<0.005$.

Over the 12 months follow-up period, 18% of patients received only an antimicrobial dressing, indicative of concern about the local bioburden or a possible localised wound infection, and 66% were prescribed a systemic anti-infective. The duration of continuous prescribing of an antimicrobial dressing in the patients' records was a mean of 4.2 months per patient. However, 28% of patients received continuous prescribing of topical antimicrobials for >6 months, according to documentation in their case record.

Of the 16% of patients who were never recorded as having an infection, 92% of the wounds healed within a mean of 1.9 months. The healing rate was lower among patients with a putative infection, and the mean time to healing was longer (Table 9). Furthermore, the cost of wound management of an uninfected wound was at least 60% less than that of a putatively infected wound (Table 9). The percentage of putative infections and associated costs was relatively unaffected by whether the wound had arisen from a planned or emergency procedure (Table 10). Hence, the mean NHS cost of managing an unhealed surgical wound without any evidence of infection was estimated to be ~£2,000 per wound, and the mean conflated cost of managing an unhealed surgical wound with a putative infection ranged between £5,000 and £11,200 per wound.



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Additionally, 23% of patients subsequently developed a putative wound infection a mean 4.3 months after initial presentation, for which an anti-infective was prescribed. The cost of wound management among these patients was a mean of £12,890 per patient.

Binary logistic regression showed that within the limitations of the data documented in the records of this cohort of patients, the anatomical site of surgery, prior presence of immunological symptoms and diabetes were all potential independent risk factors for patients developing an infection:

- Chest and breast surgery: Odds ratio 3.231 (95% CI: 1.127; 9.263); $p = 0.029$
- Immunological symptoms: Odds ratio 2.678 (95% CI: 1.197; 5.992); $p = 0.016$
- Lower limb (vascular) surgery: Odds ratio 2.485 (95% CI: 1.130; 5.466); $p = 0.024$
- Abdomen surgery: Odds ratio 1.814 (95% CI: 1.076; 3.058); $p = 0.025$
- Diabetes: Odds ratio 1.734 (95% CI: 1.025; 2.933); $p = 0.04$

**Sensitivity Analyses**

Sensitivity analysis showed that if the:

- probability of healing was reduced by 25%, from 83% to 62%, the mean NHS cost of wound care over 12 months would increase by 22% to an estimated £8,929 per wound. Conversely, if the probability of healing was increased by 20%, from 83% to 99%, the mean NHS cost of wound care over 12 months would decrease by 17% to an estimated £6,077 per wound.
- number of district nurse visits changed by 25% below or above the base case value, the mean NHS cost of wound care over 12 months would vary by 14% from the mean value (range £6,298–£8,392 per wound).
- number of practice nurse visits changed by 25% below or above the base case value, the mean NHS cost of wound care over 12 months would vary by 1% from the mean value (range £7,282–£7,408 per wound).
- number of hospital admissions changed by 25% below or above the base case value, the mean NHS cost of wound care over 12 months would vary by 4% from the mean value (range £7,073–£7,617 per wound).
- number of hospital outpatient visits changed by 25% below or above the base case value, the mean NHS cost of wound care over 12 months would vary by 1% from the mean value (range £7,258–£7,432 per wound).



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- unit cost of wound care products was decreased or increased by 25%, the mean NHS cost of wound care over 12 months would vary by 4% from the mean value (range £7,074–£7,616 per wound).

Changes to the use of other health care resources had minimal impact on the mean NHS cost of wound care over 12 months, following initial presentation in the community.

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## DISCUSSION

This study's population comprised those patients who were discharged from hospital into the community with a wound that remained unhealed for longer than four weeks after their surgery, and may well be different to the cohort of patients whose wound heals within four weeks of their surgical procedure or those who remain in hospital until their surgical wound heals. Nevertheless, this analysis provides the first evidence of how unhealed surgical wounds are managed in clinical practice in the UK, following initial presentation in the community.

This cohort consisted of patients with SWD or an open wound left to heal by secondary intention. SSI is one of the risk factors for SWD, but the occurrence of SWD can increase the risk of developing an SSI [18]. Although the secondary care and economic implications of SSI are well recognised [19, 20], those of SWD remain largely unquantified [21], as is the community cost of treating both [22]. One study comments that a rigorous and consistent classification system is needed if patients with SWD are to be effectively diagnosed and managed [21]. Our study found considerable variation in documentation standards and terminology pertaining to both the nature of the wound and infection. Consequently any reporting system on SWD and SSI in the community would be under-reported and inaccurate. In an attempt to address this variance, a post-discharge SSI assessment has been developed and is currently undergoing further testing [23].

The lack of secondary care involvement in many of the cases identified in this study would suggest that surgical teams may be unaware of the extent of the problem, and that both SWD and SSI may therefore be under-reported. A point prevalence study of wounds in north-east England identified that the largest proportion of wounds were surgical wounds, and that community nurses were involved in the care of over 70% of patients with wounds [24]. Another study found that one-third of surgical complications occurred after discharge, that two-thirds were managed in the community and that one-third resulted in readmission to hospital [25]. The authors emphasised that research and audit based solely on inpatient data significantly underestimates surgical wound morbidity rates [25]. In comparison, 19% of this study's patients were re-admitted into hospital as a direct result of their unhealed surgical wound.



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Our analysis suggests that unhealed surgical wounds occur in patients with significant co-morbidities, the management of which is associated with significant resource use. Moreover, two-thirds of all the unhealed surgical wounds in this data set were considered to be at risk of infection or infected at the time of presentation. This estimate was based on documentation of infection in the patients' records and the use of antimicrobial dressings and anti-infective prescriptions. The authors recognise the potential weakness of this estimate as systemic anti-infectives can be prescribed in general practice on the basis of wound swabs alone. Furthermore, antimicrobial dressings are prescribed prophylactically in clinical practice for wounds that are both infected and uninfected. The relative effectiveness of any antiseptic, antibiotic or anti-bacterial agent delivered either systemically or topically on surgical wounds healing by secondary intention is unclear [26]. NICE recommends that patients with a SSI are offered treatment with an antibiotic that covers the likely causative organisms, and is selected based on local resistance patterns and the results of microbiological tests [9]. Moreover, prophylactic use of antibiotics carries a risk of adverse effects and increased prevalence of antibiotic-resistant bacteria. Therefore, NICE recommends that prophylactic use of antibiotics should be limited to cover the organisms most likely to cause infection and be influenced by the strength of the association between the antibiotic used and these adverse effects [9].

Resource use associated with managing a putatively infected wound was found to be greater than that of an uninfected wound as the healing rate was lower and time to healing was longer. So too was resource use associated with managing the wounds that remained unhealed compared to those that went on to heal. Consequently, the cost of managing an unhealed wound was at least double that of managing a wound that healed (mean of £5,997 versus £13,682 per wound), and the cost of managing a putatively infected wound was at least 60% less than that of an uninfected wound. The mean cost of managing a putatively infected wound with an anti-infective and an antimicrobial dressing (£11,200) was not too dissimilar to Tanner's cost estimate of managing a post-surgical wound infection in the community (£10,523) [27]. Moreover, the analysis found the mean NHS cost of wound care over 12 months from initial presentation in the community to be an estimated £7,300 per wound, ranging from a mean of £7,200 to £7,800 for a wound that arose from a planned or emergency procedure, respectively. It is important to note that these estimates are the amounts by which the costs of the original episodes of surgery are increased as a result of the surgical wound not having healed. Others have also reported that SWD increases health care



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expenditure, due in part to the need for community nursing and associated support and increased use of wound care products [19, 28-32].

These findings from this cohort of patients with unhealed surgical wounds are consistent with our Burden of Wounds study [11, 12, 33]. The time to healing a wound is clearly an important factor in driving costs. Accordingly, the cost of surgical wound management can be affected by a combination of resources required for dressing changes, complexity of some treatment regimens and infection [12]. Furthermore, the Burden of Wounds study [11, 12, 33] provided insight into areas where care improvements could potentially result in improved clinical outcomes whilst generating significant cost savings. Nevertheless, cost-effective management and healing of unhealed surgical wounds in the community is likely to remain a challenging problem. One of the reasons may be due to the inadequate involvement of specialist clinicians in the management of the wounds in this study's cohort. Only three patients were recorded as having seen a tissue viability nurse and around a half of all patients who still had a wound at 3 months were recorded as having had a follow-up outpatient visit with their surgeon. However, it is possible that more patients were receiving multidisciplinary care than those for whom that was recorded in the THIN database. However, there was minimal evidence of this within the records, and there was no evidence of a coordinated shared treatment plan.

This study highlights the apparent lack of treatment planning, re-assessment and re-evaluation of care for most patients with an unhealed surgical wound in the community. The patients' combination of dressings and bandages remained unchanged for the length of time the wound remained unhealed, and there was minimal correlation between wound duration and senior involvement in direct patient care. Given the nature of these wounds, there was a surprising under-utilisation of topical negative pressure therapy in this cohort of patients. This may have resulted from either a lack of product availability, item cost considerations, skill mix and/or a failure to follow escalation pathways involving senior staff. Another community-based study in Australia reported similar findings [21], and interestingly, the distribution of dressing use in our study was concordant to that used to treat SWD in the Australian study [21]. Clearly, improving management practices should lead to a better outcome for patients and would be cost-effective for the NHS.



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The authors suggest that an improvement in five key areas of clinical and service management would enhance healing and other patient outcomes while reducing overall management costs. These are:

- Working to common definitions and reporting standards across primary and secondary care.
- Integrating care across providers.
- Escalating care appropriately with greater senior involvement.
- Rational use of products with access to advanced wound treatments when necessary.
- Recognising high-risk patients and responding with nutritional support and co-morbidity management as appropriate

In turn, with improved healing, these actions should reduce workload and associated health care resource use and lead to reductions in the overall cost of wound care. All health care systems recognise the importance of managing unhealed surgical wounds and the relative risk of developing a SSI. Clearly, training non-specialist nurses in the appropriate management of unhealed surgical wounds is a pre-requisite to overcoming some of the problems encountered in clinical practice and to achieving better health outcomes than those currently being observed.

**Study limitations**

The advantages and disadvantages of using patients' records in the THIN database for health economic studies in wound care have been previously discussed [11]. In summary, the advantage of using the database is that the patient pathways and associated resource use are based on real-world evidence derived from clinical practice. However, the analyses were based on clinicians' entries into their patients' records and inevitably subject to a certain amount of imprecision and lack of detail. Moreover, the computerised information in the database is collected by GPs and nursing teams for clinical care purposes and not for health economics research. Prescriptions issued by GPs and practice nurses are recorded in the database, but it does not specify whether the prescriptions were dispensed or detail patient compliance with the product. Additionally, the patients' records do not consistently document plasma glucose levels and amounts of alcohol intake, both of which could potentially impact on wound healing. Despite these limitations, it is the authors' opinion that the real-world evidence contained in the THIN database has provided a useful perspective on the



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management of unhealed surgical wounds in the community in the UK and the associated costs.

The analysis was truncated at 12 months and does not consider the potential impact of those wounds that remained unhealed beyond the study period. Also excluded is the potential impact of managing hospital inpatients with a surgical wound and those being cared for in nursing/residential homes. The analysis only considered NHS resource use and associated costs for the 'average patient' and was not stratified according to gender, comorbidities, disease-related factors and level of clinicians' skills. Costs incurred by non-NHS organisations (such as the provision of social care), patients' costs and indirect societal costs as a result of patients being absent from work were also excluded from the analysis.

Further research is required to quantify both the incidence and prevalence of unhealed surgical wounds, SWD and SSI in the community and to elucidate more fully the risk factors for their development.

**Conclusion**

The real-world evidence in this study provides important insights into a number of aspects of surgical wound management in clinical practice in the community in the UK that have been difficult to ascertain from other published studies. Surgeons are unlikely to be fully aware of the problems surrounding unhealed surgical wounds once patients are discharged into the community, due to inconsistent recording in patients' records coupled with the finding that only around a half of all patients who still had a wound at 3 months saw their surgeon for a follow-up appointment. Additionally, it provides the best estimate available of NHS resource use and costs with which to inform policy and budgetary decisions pertaining to managing these wounds. Clinical and economic benefits to both patients and the NHS could accrue from strategies that focus on improving documentation in patients' records, wound-healing rates and reducing infection. Clinicians managing unhealed surgical wounds may wish to consider the findings from this study when making treatment decisions.



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**Table 1: Patients' baseline characteristics.**

| | |
|---|---|
| Mean age at time of surgery per patient (years) | 62.6 |
| Percentage female | 54% |
| Mean systolic blood pressure (mm Hg) per patient | 131.0 |
| Mean diastolic blood pressure (mm Hg) per patient | 75.4 |
| Mean body mass index (kg/m$^2$) per patient | 29.6 |
| Percentage with BMI <18.5 kg/m$^2$ | 3% |
| Percentage with BMI ≥30.0 kg/m$^2$ | 46% |
| Percentage who were smokers | 21% |
| Percentage who were ex-smokers | 29% |
| Percentage who were non-smokers | 50% |
| Percentage with abdominal surgery | 22% |
| Percentage with lower limb (vascular) surgery | 14% |
| Percentage with minor surgery | 12% |
| Percentage with lower limb (orthopaedic) surgery | 10% |
| Percentage with upper limb surgery | 9% |
| Percentage with skin surgery | 8% |
| Percentage with chest surgery | 8% |
| Percentage with unspecified surgery | 4% |
| Percentage with head and/or neck surgery | 4% |
| Percentage with perineal surgery | 3% |
| Percentage with lower limb (minor) surgery | 2% |
| Percentage with back surgery | 2% |
| Percentage with groin surgery | 1% |

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**Table 2: Patients' comorbidities.**

| Comorbidity | Percentage of patients with a comorbidity | | |
|---|---|---|---|
| | All | Planned procedures | Emergency procedures |
| Cardiovascular | 70% | 69% | 71% |
| Cerebrovascular | 7% | 6% | 9% |
| Dermatological | 54% | 54% | 54% |
| Endocrinological | 48% | 47% | 50% |
| Gastroenterological | 41% | 39% | 45% |
| Genito-urinary | 32% | 32% | 30% |
| Haematological | 7% | 7% | 8% |
| Hepatological | 3% | 2% | 3% |
| Immunological | 13% | 12% | 15% |
| Musculoskeletal | 68% | 67% | 70% |
| Neurological | 27% | 27% | 28% |
| Oncological | 25% | 24% | 27% |
| Ophthalmological | 12% | 12% | 10% |
| Otolaryngological | 22% | 20% | 28% |
| Psychiatric | 38% | 38% | 38% |
| Renal | 24% | 24% | 24% |
| Respiratory | 39% | 37% | 42% |

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**Table 3: Dressings prescribed at the time of initial presentation in the community.**

| | Percentage of patients who were treated with the following dressings for their initial treatment | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Absorbent** | **Alginate** | **Antimicrobial** | **Foam** | **Hydrocolloid** | **Hydrogel** | **Low-adherence** | **Odour absorbent** | **Other** | **Permeable** | **Soft polymer** |
| **All** | 46% | 32% | 39% | 36% | 29% | 24% | 24% | 0% | 37% | 32% | 39% |
| **Emergencies** | 46% | 34% | 39% | 38% | 32% | 26% | 27% | 0% | 37% | 32% | 41% |
| **Planned** | 46% | 30% | 39% | 36% | 29% | 23% | 23% | 0% | 37% | 32% | 39% |

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**Table 4: Dressings prescribed over the 12 months following initial presentation in the community.**

| | Percentage of patients who were treated with the following dressing | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Month of treatment** | **Absorbent** | **Soft polymer** | **Antimicrobial** | **Other** | **Foam** | **Permeable** | **Alginate** | **Hydrocolloid** | **Low-adherence** | **Hydrogel** | **Odour absorbent** |
| 1 | 46% | 39% | 39% | 37% | 36% | 32% | 32% | 29% | 24% | 24% | 0% |
| 2 | 38% | 35% | 35% | 32% | 13% | 29% | 28% | 29% | 24% | 25% | 0% |
| 3 | 32% | 31% | 31% | 28% | 32% | 26% | 25% | 25% | 23% | 24% | 21% |
| 4 | 28% | 28% | 28% | 26% | 29% | 24% | 24% | 25% | 21% | 22% | 0% |
| 5 | 25% | 25% | 25% | 23% | 26% | 21% | 21% | 22% | 19% | 20% | 0% |
| 6 | 21% | 21% | 22% | 20% | 22% | 18% | 18% | 18% | 17% | 17% | 0% |
| 7 | 16% | 17% | 17% | 16% | 18% | 15% | 13% | 15% | 13% | 13% | 0% |
| 8 | 14% | 15% | 15% | 14% | 15% | 13% | 12% | 13% | 12% | 12% | 11% |
| 9 | 12% | 12% | 14% | 12% | 12% | 12% | 11% | 11% | 11% | 11% | 0% |
| 10 | 11% | 12% | 12% | 10% | 11% | 10% | 10% | 10% | 9% | 9% | 0% |
| 11 | 8% | 9% | 9% | 18% | 9% | 17% | 7% | 10% | 7% | 7% | 0% |
| 12 | 12% | 10% | 11% | 10% | 10% | 9% | 9% | 10% | 10% | 9% | 0% |

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**Table 5: Health care resource use associated with managing unhealed surgical wounds in clinical practice.**

| | Mean amount of resource use per patient over 12 months from initial presentation | | |
|---|---|---|---|
| **Resource use** | **All** | **Planned procedures** | **Emergency procedures** |
| Bandages | 18.88 | 19.10 | 18.30 |
| District nurse visits | 72.00 | 73.10 | 69.20 |
| Dressings | 177.50 | 182.50 | 164.50 |
| GP visits | 2.80 | 2.90 | 2.50 |
| Hospital admissions | 0.31 | 0.28 | 0.39 |
| Hospital outpatient visits | 2.20 | 2.10 | 2.50 |
| Laboratory tests | 0.78 | 0.79 | 0.75 |
| Negative pressure wound therapy | 0.16 | 0.15 | 0.20 |
| Practice nurse visits | 10.30 | 10.80 | 9.20 |
| Prescriptions for analgesic and non-steroidal inflammatories | 5.60 | 5.80 | 5.20 |
| Prescriptions for anti-infectives | 2.40 | 2.40 | 2.20 |
| Topical treatments | 3.30 | 2.10 | 6.20 |

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**Table 6: Cost of health care resource use associated with managing unhealed surgical wounds in clinical practice (percentage of total cost is in parenthesis).**

| | Mean cost of resource use per patient over 12 months from initial presentation in the community | | |
|---|---|---|---|
| **Resource** | **All procedures** | **Planned procedures** | **Emergency procedures** |
| District nurse visits | £4,186.81 (57%) | £4,142.62 (58%) | £4,297.30 (55%) |
| Hospital admissions | £1,086.76 (16%) | £972.30 (14%) | £1,372.91 (18%) |
| Dressings | £763.73 (10%) | £772.50 (11%) | £741.82 (10%) |
| Hospital outpatient visits | £348.55 (5%) | £326.04 (5%) | £404.84 (5%) |
| Practice nurse visits | £253.29 (3%) | £262.33 (4%) | £230.69 (3%) |
| GP visits | £219.33 (3%) | £227.02 (3%) | £200.11 (3%) |
| Bandages | £214.65 (3%) | £202.20 (3%) | £245.77 (3%) |
| Analgesics and non-steroidal anti-inflammatories | £118.42 (2%) | £118.31 (2%) | £118.68 (2%) |
| Wound care appliances | £83.61 (1%) | £75.35 (1%) | £104.24 (1%) |
| Anti-infectives | £43.44 (1%) | £43.51 (1%) | £43.26 (1%) |
| Topical treatments | £17.17 (<1%) | £12.35 (<1%) | £29.22 (<1%) |
| Negative pressure wound therapy | £6.00 (<1%) | £5.18 (<1%) | £8.03 (<1%) |
| Laboratory tests | £2.85 (<1%) | £2.85 (<1%) | £2.85 (<1%) |
| Tissue viability nurse visits | £0.25 (<1%) | £0.24 (<1%) | £0.27 (<1%) |
| **TOTAL** | **£7,344.86 (100%)** | **£7,162.81 (100%)** | **£7,800.00 (100%)** |

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**Table 7: Cost of health care resource use associated with managing unhealed surgical wounds stratified by planned/emergency procedures and healing in clinical practice (percentage of total cost is in parenthesis).**

| | Mean cost of resource use per patient over 12 months from initial presentation in the community | | | |
|---|---|---|---|---|
| **Resource** | **Planned/healed procedures** | **Planned/unhealed procedures** | **Emergency/healed procedures** | **Emergency/unhealed procedures** |
| District nurse visits | £3,457.82 (58%) | £8,328.58 (59%) | £3,104.09 (52%) | £7,651.79 (59%) |
| Hospital admissions | £921.22 (15%) | £1,284.56 (9%) | £1,314.78 (22%) | £1,536.34 (12%) |
| Dressings | £627.04 (10%) | £1,661.62 (12%) | £558.83 (9%) | £1,256.28 (10%) |
| Hospital outpatient visits | £293.21 (5%) | £526.69 (4%) | £331.36 (6%) | £611.42 (5%) |
| Practice nurse visits | £191.80 (3%) | £693.48 (5%) | £164.96 (3%) | £415.48 (3%) |
| GP visits | £182.28 (3%) | £500.49 (4%) | £161.89 (3%) | £307.56 (2%) |
| Bandages | £117.25 (2%) | £721.50 (5%) | £86.36 (1%) | £693.92 (5%) |
| Analgesics and non-steroidal anti-inflammatories | £106.13 (2%) | £192.77 (1%) | £91.42 (2%) | £195.32 (2%) |
| Wound care appliances | £57.95 (1%) | £181.74 (1%) | £77.48 (1%) | £179.46 (1%) |
| Anti-infectives | £37.73 (1%) | £78.83 (1%) | £33.78 (1%) | £69.90 (1%) |
| Topical treatments | £6.21 (<1%) | £49.89 (<1%) | £39.62 (1%) | £0.00 (<1%) |
| Negative pressure wound therapy | £5.92 (<1%) | £0.69 (<1%) | £1.89 (<1%) | £25.30 (<1%) |
| Laboratory tests | £1.89 (<1%) | £8.70 (<1%) | £1.78 (<1%) | £5.86 (<1%) |
| Tissue viability nurse visits | £0.28 (<1%) | £0.00 (<1%) | £0.37 (<1%) | £0.00 (<1%) |
| **TOTAL** | **£6,006.73 (100%)** | **£14,229.54 (100%)** | **£5,968.61 (100%)** | **£12,948.63 (100%)** |



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**Table 8: Cost of health care resource use associated with managing unhealed surgical wounds stratified by BMI and diabetes.**

| | % of patients | % healed | % emergencies | NHS cost per patient |
|---|---|---|---|---|
| BMI <20 | 5% | 94% | 31% | £9,269 |
| BMI 20-29 | 45% | 89% | 27% | £6,938 |
| BMI 30-35 | 20% | 84% | 35% | £7,096 |
| BMI >35 | 20% | 84% | 28% | £7,812 |
| | | | | |
| Diabetes | 29% | 80% | 33% | £9,349 |
| No diabetes | 71% | 88% | 27% | £6,526 |

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**Table 9: Incidence of putative infection with associated healing and costs over the 12-months follow-up period.**

| | Percentage of patients | Percentage of patients who healed | Mean time to healing per patient (months) | Mean cost of wound care per patient |
|---|---|---|---|---|
| No infection | 16% | 92% | 1.86 | £2,001 |
| Received only an antimicrobial dressing | 18% | 83% | 5.79 | £6,966 |
| Prescribed an anti-infective with or without an antimicrobial dressing | 66% | 85% | 6.46 | £8,742 |
| Prescribed an anti-infective with an antimicrobial dressing | 41% | 82% | 8.11 | £11,169 |
| Prescribed an anti-infective without an antimicrobial dressing | 25% | 90% | 3.62 | £4,961 |

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**Table 10: Incidence of putative infection with associated healing and costs stratified by planned/emergency procedures over the 12-months follow-up period.**

| | Percentage of cohort | Percentage of cohort that healed | Mean time to healing per patient (months) | Mean cost of wound care per patient |
|---|---|---|---|---|
| **Planned procedures** | | | | |
| No infection | 17% | 90% | 1.81 | £2,143 |
| Received only an antimicrobial dressing | 17% | 86% | 5.99 | £6,966 |
| Prescribed an anti-infective | 66% | 87% | 6.66 | £8,507 |
| Prescribed an anti-infective with an antimicrobial dressing | 43% | 84% | 8.19 | £10,606 |
| Prescribed only an anti-infective | 23% | 93% | 3.79 | £4,581 |
| **Emergency procedures** | | | | |
| No infection | 16% | 97% | 1.97 | £1,649 |
| Received only an antimicrobial dressing | 21% | 79% | 5.29 | £7,165 |
| Prescribed an anti-infective | 63% | 79% | 5.98 | £9,574 |
| Prescribed an anti-infective with an antimicrobial dressing | 38% | 76% | 7.93 | £12,018 |
| Prescribed only an anti-infective | 25% | 83% | 3.20 | £5,633 |

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Figure 1: Wound healing stratified by planned/emergency procedures.

Figure 2: Wound healing stratified by anatomical site of surgery.

Figure 3: Patients who received a combination of multiple dressings at each dressing change.

Figure 4: Monthly cost of health care resource use associated with managing surgical wounds stratified by planned/emergency procedures and healing in clinical practice.

Figure 5: Cost of health care resource use associated with managing surgical wounds in clinical practice stratified by anatomical site of surgery.

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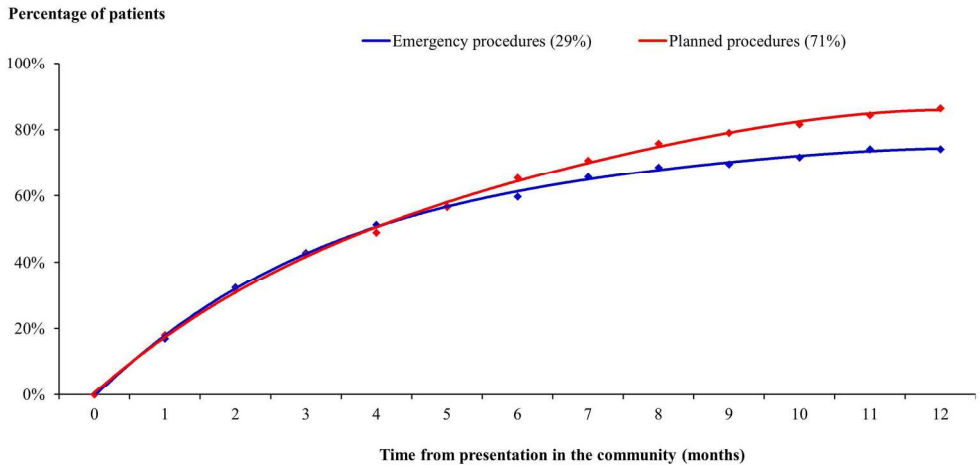


Figure 1

190x142mm (300 x 300 DPI)

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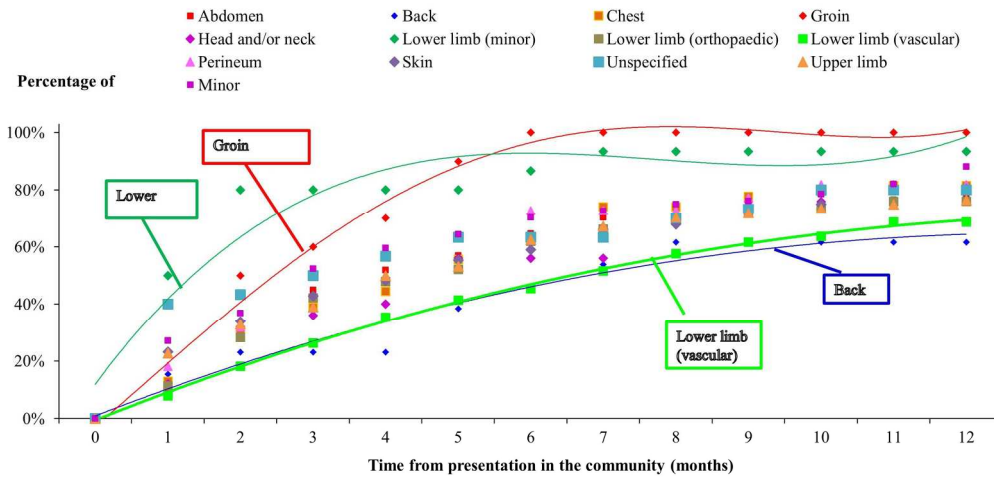


Figure 2

190x142mm (300 x 300 DPI)

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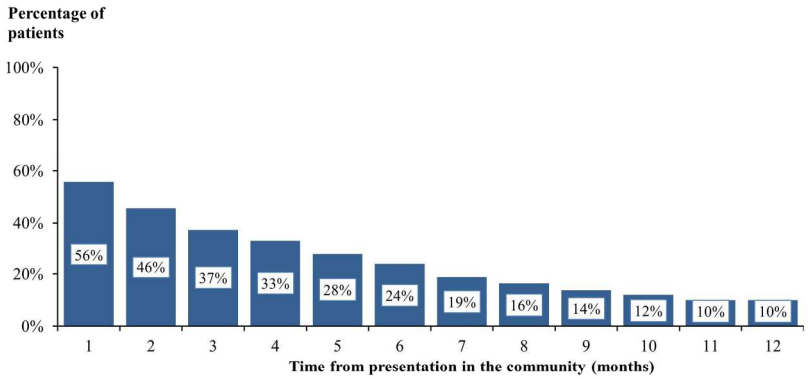


Figure 3

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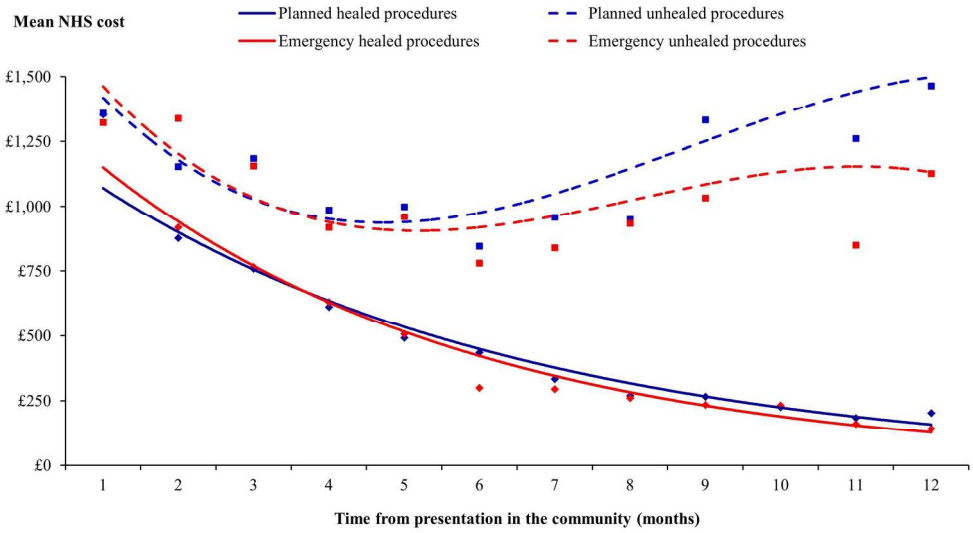


Figure 4

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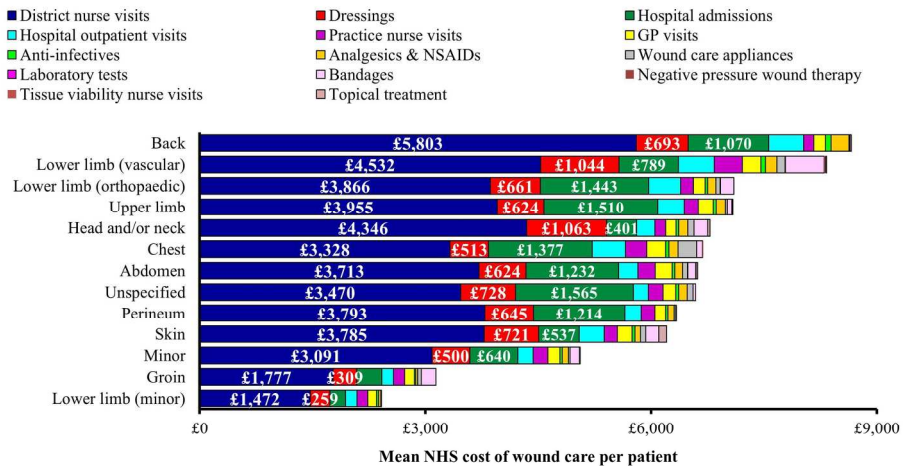


Figure 5

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**The RECORD statement – checklist of items, extended from the STROBE statement, that should be reported in observational studies using routinely collected health data.**

| | Item No. | STROBE items | Location in manuscript where items are reported | RECORD items | Location in manuscript where items are reported |
|---|---|---|---|---|---|
| **Title and abstract** | | | | | |
| | 1 | (a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found | Page 1 | RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included.<br><br>RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract.<br><br>RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract. | Page 1<br><br>Page 1<br><br>N/A |
| **Introduction** | | | | | |
| Background rationale | 2 | Explain the scientific background and rationale for the investigation being reported | Pages 6, 7 | | |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | Page 7 | | |
| **Methods** | | | | | |
| Study Design | 4 | Present key elements of study design early in the paper | Page 8 | | |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | Pages 8, 9 | | |

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| | | | | | |
|---|---|---|---|---|---|
| Participants | 6 | *(a) Cohort study* - Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br>*Case-control study* - Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls<br>*Cross-sectional study* - Give the eligibility criteria, and the sources and methods of selection of participants<br><br>*(b) Cohort study* - For matched studies, give matching criteria and number of exposed and unexposed<br>*Case-control study* - For matched studies, give matching criteria and the number of controls per case | Page 8<br><br>N/A<br><br>N/A<br><br>N/A | RECORD 6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided.<br><br>RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided.<br><br>RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage. | Page 8<br><br>N/A<br><br>N/A |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable. | Page 9 | RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided. | N/A |
| Data sources/ measurement | 8 | For each variable of interest, give sources of data and details of methods of assessment (measurement).<br>Describe comparability of assessment methods if there is more than one group | Page 9 | | |

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| | | | | | |
|---|---|---|---|---|---|
| Bias | 9 | Describe any efforts to address potential sources of bias | N/A | | |
| Study size | 10 | Explain how the study size was arrived at | Page 8 | | |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why | Page 8, 9 | | |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding<br>(b) Describe any methods used to examine subgroups and interactions<br>(c) Explain how missing data were addressed<br>(d) *Cohort study* - If applicable, explain how loss to follow-up was addressed<br>*Case-control study* - If applicable, explain how matching of cases and controls was addressed<br>*Cross-sectional study* - If applicable, describe analytical methods taking account of sampling strategy<br>(e) Describe any sensitivity analyses | Page 9<br>Pages 9, 10<br>Page 9<br>N/A<br>N/A<br>N/A<br>Page 10 | | |
| Data access and cleaning methods | | .. | | RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population. | Page 8 |

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| | | | | | |
|---|---|---|---|---|---|
| | | | | RECORD 12.2: Authors should provide information on the data cleaning methods used in the study. | N/A |
| Linkage | | .. | | RECORD 12.3: State whether the study included person-level, institutional-level, or other data linkage across two or more databases. The methods of linkage and methods of linkage quality evaluation should be provided. | Page 8 |
| **Results** | | | | | |
| Participants | 13 | (a) Report the numbers of individuals at each stage of the study (*e.g.*, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed)<br>(b) Give reasons for non-participation at each stage.<br>(c) Consider use of a flow diagram | Pages 11-17<br><br>N/A<br><br>N/A | RECORD 13.1: Describe in detail the selection of the persons included in the study (*i.e.,* study population selection) including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram. | Pages 8 and 11 |
| Descriptive data | 14 | (a) Give characteristics of study participants (*e.g.*, demographic, clinical, social) and information on exposures and potential confounders<br>(b) Indicate the number of participants with missing data for each variable of interest<br>(c) *Cohort study* - summarise follow-up time (*e.g.*, average and total amount) | Pages 11, 28, 29 | | |
| Outcome data | 15 | *Cohort study* - Report numbers of outcome events or summary measures over time | Pages 11-17 | | |

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| | | | | | |
|---|---|---|---|---|---|
| | | *Case-control study* - Report numbers in each exposure category, or summary measures of exposure<br>*Cross-sectional study* - Report numbers of outcome events or summary measures | N/A<br><br>N/A | | |
| Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included<br>(b) Report category boundaries when continuous variables were categorized<br>(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | Pages 11-17<br>Pages 28-38<br><br>N/A<br><br>N/A | | |
| Other analyses | 17 | Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses | Pages 16, 17 | | |
| **Discussion** | | | | | |
| Key results | 18 | Summarise key results with reference to study objectives | Pages 18-21 | | |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | Pages 21, 22 | RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported. | Pages 18-21 |

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| | | | | | |
|---|---|---|---|---|---|
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | Pages 18-21 | | |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | Pages 18-21 | | |
| **Other Information** | | | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | Page 3 | | |
| Accessibility of protocol, raw data, and programming code | | .. | | RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code. | N/A |

*Reference: Benchimol EI, Smeeth L, Guttmann A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM, the RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. *PLoS Medicine* 2015; in press.

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