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Health Technology Assessment

Volume 29 • Issue 47 • September 2025

ISSN 2046-4924

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DOI 10.3310/DWKT1327

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Extended Research Article

Effectiveness of surgical interventions in patients with severe pressure ulcers: the SIPS mixed-methods exploratory study

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Published September 2025
DOI: 10.3310/DWKT1327

This report should be referenced as follows:

Reeves B, Pufulete M, Harris J, Dumville J, Adderley U, Burton A, *et al.* Effectiveness of surgical interventions in patients with severe pressure ulcers: the SIPS mixed-methods exploratory study. *Health Technol Assess* 2025;**29**(47). https://doi.org/10.3310/DWKT1327

Health Technology Assessment

ISSN 2046-4924 (Online)

Impact factor: 4

A list of Journals Library editors can be found on the NIHR Journals Library website

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This article

The research reported in this issue of the journal was funded by the HTA programme as award number NIHR127850. The contractual start date was in November 2019. The draft manuscript began editorial review in November 2023 and was accepted for publication in October 2024. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

This article presents independent research funded by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care.

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Abstract

Background: Surgical reconstruction to close a severe pressure ulcer has not been evaluated.

Aim and objectives: We aimed to investigate the feasibility of research to evaluate surgical reconstruction for severe pressure ulcers by:

1. systematically reviewing evidence about: the effectiveness of surgical reconstruction for severe pressure ulcers; the impact of pressure ulceration on health-related quality-of-life (review 2)
2. surveying primary and secondary care healthcare professionals about surgical referrals of patients with severe pressure ulcers and severe pressure ulcer management, including surgical reconstruction
3. describing patients with incident pressure ulcers and with severe pressure ulcers having surgical reconstruction
4. comparing outcomes in patients with severe pressure ulcers having/not having surgical reconstruction
5. seeking consensus about treatments and management strategies for severe pressure ulcers.

Design: Systematic reviews; surveys; binary choice experiment; retrospective cohort studies using routine data; consensus meeting.

Participants: General practitioners; nurses; and surgeons managing pressure ulcers; people with incident pressure ulcers and hospitalised with severe pressure ulcers.

Intervention: Surgical reconstruction.

Comparator: No surgical reconstruction.

Outcomes: Surgical reconstruction, time to next admission with a severe pressure ulcer time to next admission, hospital stay, all-cause mortality, surgical reconstruction after discharge.

Results: Review 1 included three studies comparing different surgical reconstruction techniques. None reported wound-free time. Recurrence occurred in ≈ 20%. Review 2 included three randomised controlled trials measuring health-related quality of life, but none observed benefits of interventions evaluated.

Among primary care survey respondents, 54% did not know surgical reconstruction can treat severe pressure ulcers; > 50% had never referred a patient to a surgeon. Among nurses, 72% had considered surgical reconstruction for a severe pressure ulcer; 54% believed surgical reconstruction should be more available. Among surgeons, 39% had never offered surgical reconstruction and 52% offered surgical reconstruction to < 50%; 68% believed surgical reconstruction should be more available.

Routine data recorded 367,884 admissions with severe pressure ulcer diagnoses in England over 7.5 years; surgical reconstructions were performed in at least 404 and at most 1018 admissions. Twenty English hospitals performed > 70% of the surgical reconstructions. Comparing surgical reconstruction (n = 325) versus no surgical reconstruction (n = 1474) patients, time to next admission with a severe pressure ulcer was longer in patients having surgical reconstruction (hazard ratio = 0.79, 95% confidence interval 0.61 to 1.03; p = 0.07).

Estimated pressure ulcer incidence in primary care was ≈ 5/10,000, but the true incidence was believed to be ≈ 7 times higher. Episodes of pressure ulcer care could not be identified.

There was consensus about a referral pathway for severe pressure ulcer patients wanting surgical reconstruction, including both community-led and surgically led multidisciplinary team meetings, and about the influence of several patient and severe pressure ulcer characteristics on suitability for surgical reconstruction.

Limitations: Surveys only considered factors one by one. Analyses of the Hospital Episode Statistics cohort depended on coding accuracy. For the comparison of surgical reconstruction and no surgical reconstruction, the no surgical reconstruction group had to be admitted. Routine data do not record wound healing outcomes. Primary care data

underestimated pressure ulcer incidence; pressure ulcer care episodes could not be identified. The consensus meeting did not include surgeons. The COVID-19 pandemic caused delays, made team members unavailable and restricted face-to-face meetings.

Conclusions: There is insufficient evidence to determine the effectiveness of surgical reconstruction on health-related quality of life or wound healing for severe pressure ulcers. Too few procedures are carried out to enable a randomised controlled trial to be feasible.

Future work: We identified three areas: qualitative research on the acceptability of surgical reconstruction and the impact of a SPU on a patient's quality-of-life; a core outcome set for interventions to treat pressure ulcers; and economic modelling of surgical reconstruction cost-effectiveness.

Study registration: This study is registered as PROSPERO 2019 CRD42019156436, 2019 CRD42019156450; ISRCTN13292620.

Funding: This award was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR award ref: NIHR127850) and is published in full in *Health Technology Assessment*; Vol. 29, No. 47. See the NIHR Funding and Awards website for further award information.

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Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/DWKT1327).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

A&E	accident and emergency
APC	Admitted Patient Care
BAPRAS	British Association of Plastic, Reconstructive and Aesthetic Surgeons
CB	commissioning brief
CENTRAL	Cochrane Central Register of Controlled Trials
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COS	core outcome set
CPRD	Clinical Practice Research Datalink
EQ-5D	EuroQol-5 Dimensions
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
GMR	geometric mean ratio
GP	general practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GIRFT	Getting It Right First Time
HES	Hospital Episode Statistics
HRQoL	health-related quality of life
HTA	Health Technology Assessment
ICD-10	International Statistical Classification of Diseases and Related Health Problems, Tenth Revision
IMD	Index of Multiple Deprivation
LSOA	lower super output area
MDT	multidisciplinary team
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NPIAP	National Pressure Injury Advisory Panel
NPWT	negative pressure wound therapy
NRSI	non-randomised studies of interventions
NSR	no surgical reconstruction (as defined by the study protocol) during index admission (work package 2)
ONS	Office for National Statistics
OPCS	Office of Population Censuses and Surveys
PAG	Patient Advisory Group
PICO	population, intervention, comparator, outcome
PPI	patient and public involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PU	pressure ulcer
PUPIS	Pressure Ulcer Prevention and Intervention Service
PU-QoL	pressure ulcer-quality of life
PU-QoL-P	pressure ulcer-quality of life – prevention
PU-QoL-UI	pressure ulcer-quality of life – utility index
RCT	randomised controlled trial
RoB2	Risk of Bias 2
ROBINS–I	Risk Of Bias In Non-randomized Studies – of Interventions
SF-6D	Short Form questionnaire-6 Dimensions
SF-12	Short Form questionnaire-12 items
SF-36	Short Form questionnaire-36 items
SMG	Study Management Group
SNOMED	Systemized Nomenclature of Medicine
SPN	specialist plastic surgery nurse
SPU	severe pressure ulcer

SR	surgical reconstruction (as defined by the study protocol) during index admission (work package 2)	TVN	tissue viability nurse
		UTS	up-to-standard
		VAS	visual analogue scale
TT	target trial	WD	wound day
TTH	time-to-healing	WS	workstream

Plain language summary

What was the question?

Is it feasible to research how well an operation to treat severe pressure ulcers works?

What did we do?

We reviewed previous studies about the effectiveness of surgery and the impact of a severe pressure ulcer on health-related quality of life. We surveyed surgeons, specialists and community nurses and general practitioners who manage patients with severe pressure ulcers to identify which people with severe pressure ulcers would benefit most from surgery. We analysed information about patients who have had severe pressure ulcers to find out how many operations are being carried out. We compared health outcomes for patients with severe pressure ulcers who had and did not have surgery.

What did we find?

Reviewing previous studies added very little to what was already known because high-quality research on the questions we asked has not been done. The surveys showed that healthcare professionals generally agree about who should be offered surgery. They also highlighted that decisions for individual patients were complicated and barriers exist to patients having surgery. It was difficult for us to identify exactly how many operations had been done but, between 2011 and 2018, the number of operations done in the National Health Service has been very low (estimated as between 54 and 136 per year).

What does it mean?

We found that the National Health Service carries out too few operations to treat severe pressure ulcers to enable future high-quality research on the cost-effectiveness of surgery. For people who might be suitable, the opportunity to have surgery varies in different parts of the United Kingdom. If patients in areas with limited opportunity had the same opportunity as those in areas with more opportunity, such research would probably be possible. The National Health Service should find out whether patients are suitable for surgery early on, and patients willing to consider an operation should be referred to a surgeon to discuss the appropriateness of surgery.

Scientific summary

Background

Surgical reconstruction (SR) to close a severe pressure ulcer (SPU) compared with management without reconstruction [no surgical reconstruction (NSR)] has not been evaluated. A planned randomised controlled trial (RCT) was unsuccessful because the surgical procedures requiring evaluation, the comparator, or the patient groups to be studied could not be defined.

Aim

This study investigated the feasibility of research to evaluate the effectiveness of SR compared to NSR.

Objectives

Three workstreams (WSs) addressed uncertainties in elements of the research question about the effectiveness and cost-effectiveness of SR. Objectives were to:

- perform systematic reviews and surveys (WS1) to:
  - Obj1 (a) estimate the effectiveness of SR to close SPUs (review 1) and (b) the impact of pressure ulceration on health-related quality of life (HRQoL; review 2)
  - Obj2 elicit responses from healthcare professionals to describe patients referred for a surgical opinion about SR, procedures performed and post-SR care, and usual care before initiating a referral
- use routinely collected primary care and hospital data (WS2) to:
  - Obj3 describe patients with incident SPUs and their care pathways
  - Obj4 describe patients diagnosed with SPU at hospital admission, their care pathways and health outcomes
  - Obj5 compare outcomes in groups of patients, similar on hospital admission, who did or did not have SR and explore subgroup interactions with SR
- seek consensus (WS3) about:
  - Obj6 appropriate treatments and management strategies.

Methods

Workstream 1

Reviews used established methods. Review 1 (Obj1) searched for RCTs and non-randomised studies of interventions (NRSI) of SR to close a SPU. Review 2 (Obj2) searched only for RCTs of pressure ulcer (PU) prevention or treatment.

Surveys were developed for general practitioners (GPs), and nurses and surgeons managing SPUs, using SurveyMonkey® (Palo Alto, CA, USA), with free-text boxes for additional responses. GPs were asked about their knowledge of SR, referrals to secondary care for SPUs, and factors influencing referrals. Nurses' and surgeons' surveys asked about SR and other treatments, how characteristics of SPUs and patients influenced referral decisions, SPU recurrence and barriers to SR.

A binary choice experiment (BCE; Obj2) explored how patient/SPU characteristics interact to influence decisions to consider SR. Nurse and surgeon participants made consider/do not consider decisions about suitability for SR for patients described in many hypothetical scenarios, created with different permutations of characteristics.

Workstream 2, hospital data (Hospital Episode Statistics cohort)

Participants
Hospital Episode Statistics (HES) data linked with Office for National Statistics (ONS) mortality data for 1 April 2010–31 March 2019 comprised data for adults (> 18 years) diagnosed in England with SPU (*International Classification of Diseases*-10 codes L89.2 or L89.3 or L89.9 or L89.X) during any finished consultant episode.

Intervention
Surgical reconstruction was defined by the Office of Population Censuses and Surveys (OPCS)-4 codes (S17–S20, S22, S24–S27).

Comparator
No surgical reconstruction was defined by the absence of a SR.

Outcomes
Surgical reconstruction during index admission (Obj4). After discharge, time-to-hospital-admission with SPU diagnosed on admission (primary); length of index admission; time to any admission; all-cause mortality; SR after discharge (Obj4 and Obj5).

Workstream 2, primary care data with linked hospital data (Clinical Practice Research Datalink cohort)

Participants
Clinical Practice Research Datalink (CPRD) data linked with HES and ONS mortality data for the period from 1 April 2008 to 31 March 2019 comprised data for adults (> 18 years) during up-to-standard registration with a Read or Systemized Nomenclature of Medicine code indicating a PU. Read codes for discharge from or referral to a service were identified. SR was defined as for the HES cohort.

Outcomes (Obj3)
Incident PU, events (referral, discharge, SR, death) after an incident ulcer.

Workstream 3 consensus
Summary findings of WS1 and WS2 were circulated to nurse and surgeon attendees before meeting online [Zoom (Zoom Video Communications, San Jose, CA, USA)]. Topic 1 was desirable features of a referral pathway for SR to close a SPU. Topic 2 was patient and ulcer characteristics influencing referral for SR. The first topic was important because it affects how many patients are referred for a surgical opinion. The second was important to inform eligibility for future research.

Statistical analysis

Workstream 1: Narrative syntheses were performed for the reviews.

Workstream 1: Descriptive statistics summarised quantitative data. Free-text responses were analysed by qualitative methods.

Workstream 2: Characteristics of patients in the HES cohort were summarised descriptively. Increasingly specific eligibility criteria were applied to identify SRs to close SPUs: SPU diagnosis on admission, SPU or osteomyelitis primary diagnosis, elective admission, absence of diagnoses/procedures incompatible with SR. Minimum and maximum SR numbers were based on applying these criteria or did not; SRs in the minimum subset were most likely performed to close SPUs.

We emulated a target trial to compare SR and NSR groups. Propensity scores for SR during the index admission were calculated, after applying eligibility criteria; SR defined the groups. Hazard ratios adjusted for propensity score and other variables were estimated using survival models.

Results

Workstream 1 review 1

No study compared participants who did and did not have SR. One RCT (20 participants; high risk of bias) and two retrospective cohort studies (165 participants and 181 ulcers; both at critical risk of bias) compared different flap techniques for SR. The average duration of follow-up was 19 months in the RCT, not described for one NRSI and 55 months in the other. Few relevant outcomes were reported numerically and fully. No study reported wound-free time. In the RCT, recurrence percentages were 10% and 60% in the alternative flap groups. Recurrence rates in the NRSIs were 19% (average follow-up duration not reported) and 16%.

Workstream 1 review 2

One prevention and two treatment RCTs were included. Two RCTs had low risk of bias and one had high risk of bias. HRQoL was measured with EuroQol-5 Dimensions in all RCTs and by Short Form questionnaire-12 items in one. Although HRQoL and ulcer outcomes were reported, no study observed a significant difference in ulcer outcomes, preventing estimation of the impact of ulceration on HRQoL.

Workstream 1 surveys

Surveys were initiated by 59 GPs, 146 nurses and 45 surgeons; all questions were answered by 44 GPs, 104 nurses and 26 surgeons. Most nurses worked in hospitals (60%) or the community (55%), with 25% working in multiple settings. Almost all (93%) were trained in wound care. Most surgeons were plastic surgeons (79%) in consultant roles (81%); 52% had ≥ 5 years' experience of SR to close SPUs.

Over half (54%) of primary care respondents did not know SR is a treatment option to close SPUs. Over half had never referred patients with SPUs to secondary care for a surgical opinion but 48% had referred them for other reasons. Most respondents (> 70%) stated that they would refer patients regardless of patient characteristics.

Most nurses (79%) had treated > 10 patients with a PU; 72% reported having considered SR for a SPU and most (81%) had referred a patient in the previous year, mainly to initiate a multidisciplinary team (MDT) meeting to discuss how to treat a patient's SPU. Over half (54%) believed that SR to close a SPU should be more widely available.

Surgeons reported that SR was not performed for most referred SPU patients; of referrals to them, 39% had never offered SR and 52% offered SR to < 50%. However, 68% believed that SR should be more widely available. Over half (59%) reported that referrals were often/always from/within hospitals; only 13% said that referrals were often/always from elsewhere. The most common procedure for SR was 'flap' surgery; very few surgeons performed primary wound closure, tissue expansion or skin graft surgery. Most (80%) reported an average length of postoperative stay after SR between 1 and 12 weeks with the reconstructed wound healing completely in > 50% and low recurrence of the same SPU.

Binary choice experiment

Fifty-two nurses and 10 surgeons made a decision about ≥ 1 scenario; 47 (75%) made decisions for all 16 scenarios. Nurses worked in one or multiple settings and all were trained in wound care, except for one. Six surgeons were plastic surgeons.

Decisions/scenarios ranged from 21 to 31; 843 were analysed and 60% were 'yes' (13–100%). Stage 4 SPU, no inflammation or scarring, no frailty and no comorbidity were moderately associated with 'yes' decisions (odds ratios between 1.5 and 2.0, borderline significance). Longer SPU duration, all non-surgical treatments attempted, no previous SR and adherence to PU prevention measures after surgery were strongly associated with 'yes' decisions (odds ratios > 2.0, $p < 0.001$).

Workstream 2 Hospital Episode Statistics cohort

The SPU admission cohort included 367,884 admissions over 7.5 years. Admitted patients had an average age of 78 years and many had comorbidities. Mortality after admission was high (> 50% by 12 months after admission), showing many admitted patients were elderly, probably with life-limiting conditions. Compared to the minimum subset comprising 404 admissions/SRs, the mean age in the whole ('maximum') SR group, comprising 1018 admissions/SRs,

was higher (58 vs. 52 years); comorbidities were more common and fewer had an inferred cause of impaired mobility (26% vs. 41% had an injury diagnosis and 16% vs. 26% had a neurodegenerative disease diagnosis). Time to first SR from first admission was shorter in the maximum than minimum SR subset but time to a second SR (when this occurred, in <20%) was shorter in the minimum SR subset. Survival was better in the minimum SR subset. SRs were identified by various OPCS codes. In the maximum SR subset, 86/124 English hospitals performed ≥ 1 SR in 7.5 years, the 10 performing the most accounting for 50% (505/1018) and the next 10 for 21% (216/1018). The remaining 66 hospitals accounted for only 29%.

In the target trial emulation comparing SR (n = 325) versus NSR (n = 1474), the time to next admission with a SPU diagnosis was longer in SR patients [adjusted hazard ratio = 0.79, 95% confidence interval (CI) 0.61 to 1.03; p = 0.07]; times to 15% cumulative probabilities of admission were ≈ 107 (72–137) and ≈ 189 (90–238) days in NSR and SR groups. For any next admission, the adjusted hazard ratio was 0.87 (95% CI 0.74 to 1.04; p = 0.12); median times to admission were ≈ 208 (182–238) and ≈ 258 (211–318) days in NSR and SR groups. Median length of stay was longer in the SR group. More patients in the SR than NSR group had a later eligible SR (16% vs. 4%). More patients died within 6 months in the NSR than the SR group (9% vs. 1%).

Workstream 2 Clinical Practice Research Datalink cohort

Median age of patients with an incident PU (n = 55,195) was 82 years; 58% were females. Incident PUs and an approximate CPRD denominator (≈ 20% of the 2011 mid-year England population of 53,107,000), yielded an observed PU annual incidence of ≈ 5/10,000. We aimed to describe patients' care pathways but just 0.4% of patients had a discharge code, preventing any exploration of episodes of PU care.

By comparing HES data linked to the CPRD cohort with the HES cohort, we estimated that incident PUs captured by coded activity in CPRD data accounted for only ≈ 1 of 7 that truly occurred. Observed incident PUs may represent a selected subgroup, for example patients with a spinal injury or a neurodegenerative disease.

Workstream 3 Consensus

Nine TVNs and one specialist plastic surgery nurse participated. Topic 1 covered issues captured by free-text survey responses about the referral pathway. Additional details included that: the pathway should include both community-led and surgically led MDT meetings; several services have relevant contributions to bring to each MDT. A referral pathway was also discussed with a team commissioned to provide care for SPUs in Wales. For topic 2, there was consensus, with qualifications, that:

1. A previous SR should not rule out another SR.
2. The time a SPU has been present should not influence referral for a surgical opinion about SR.
3. A stage 3 SPU could be referred for a surgical opinion about SR.
4. The cause of impaired mobility should not influence whether a patient is considered for referral.
5. Adherence to postoperative SPU prevention regimens is important.
6. Improving a patient's general health should be considered when deciding whether to refer a patient.

Strengths

Literature reviews used state-of-the-art methods. Surveys achieved high response rates and high quality, mainly complete, data; free text responses highlighted challenges in the referral pathway. The BCE supported the survey results. SRs performed in England over 7.5 years were quantified. We emulated a target trial of SR versus NSR. Challenges with further research on the effectiveness of SR are described, based on the consensus and feedback from the research team.

Limitations

The surveys considered factors only one by one; this limitation was mitigated by the BCE which gave consistent results. The BCE was able to investigate only a small number of factors.

Analyses of the HES cohort depended on coding accuracy. To address this uncertainty, we described maximum and minimum SR numbers based on different assumptions informed by the research team. The target trial emulation may have used an inappropriate comparator group due to limited understanding of the referral pathway to secondary care. We could not mitigate this limitation. Outcomes typically measured in wound research are not captured in HES data and could not be investigated. Analyses of the CPRD cohort underestimated PU incidence and episodes of PU care could not be described due to inadequate coding. The consensus meeting had to be online and did not include surgeons. We mitigated this limitation by discussing the findings with research team members, who had wide-ranging relevant expertise.

The COVID-19 pandemic caused delays, made team members less available and restricted face-to-face meetings. The last team meeting provided important insights about the referral pathway and factors that the patient and the surgeon need jointly to consider when deciding whether to have SR. The complexity of decision-making had not been evident or explored previously in virtual meetings.

Future work

We identified three areas of future work:

Qualitative research on the acceptability of SR to understand factors that predispose patients to want or decline SR, including sources of inequality in access and the impact of a SPU on a patient's HRQoL.

A core outcome set for interventions to treat PUs is needed; HRQoL should be carefully considered for inclusion, given the perceived importance of HRQoL in shared decision-making about whether to perform SR. HRQoL measured as quality-adjusted life-years is central to commissioning decisions.

Economic modelling may help to address the cost-effectiveness of SR. Prolonged non-surgical care and SR are both expensive and comparing their costs would inform whether SR might be cost-effective. HES data describe hospital resources, but data are lacking about resources to manage patients with SPUs in the community. The community services data set may provide these data in the future.

Conclusions

There is no high-quality evidence about the effectiveness of SR versus NSR nor how SPUs impact on HRQoL. SR is performed too infrequently in England to permit primary quantitative research. SR is commissioned in Wales, but the small population means few procedures are performed. There is indirect or anecdotal evidence that SR is effective and, were SR commissioned in England as in South Wales, a RCT might be feasible. SR procedures and the characteristics of suitable patients are known; relevant outcomes can be collected and should include HRQoL.

Study registration

This study is registered as PROSPERO Numbers: 2019 CRD42019156436 and 2019 CRD42019156450; ISRCTN Number: ISRCTN13292620.

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR award ref: NIHR127850) and is published in full in *Health Technology Assessment*; Vol. 29, No. 47. See the NIHR Funding and Awards website for further award information.

Chapter 1 Introduction

Description of pressure ulcers

Pressure ulcers (PUs), also known as bedsores, decubitus ulcers and pressure injuries, are localised areas of ischaemic injury to the skin and/or underlying tissue. Populations at greatest risk include non-ambulatory individuals and people with limited mobility or tactile sensation.[1–5] PUs usually affect people confined to bed or who sit in a chair or wheelchair for a long period of time. They are caused by prolonged external mechanical forces such as pressure or shear beyond the normal physiological constraints.[6] These forces are higher adjacent to an underlying bony prominence such as the sacrum, ischium, trochanter and heel,[7] which are the locations where pressure sores tend to occur.

Pressure ulcers vary in severity. One of the most widely recognised systems for categorising PUs is that of the National Pressure Injury Advisory Panel (NPIAP), which is summarised below:[8]

- Stage 1: intact skin with a localised area of non-blanchable erythema.
- Stage 2: partial-thickness skin loss with exposed dermis.
- Stage 3: full-thickness loss of skin in which adipose tissue is visible.
- Stage 4: full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer.
- Unstageable pressure injury: full-thickness skin and tissue loss that is obscured by slough or eschar so that the severity of injury cannot be confirmed.
- A deep tissue pressure injury: local injury of persistent non-blanchable deep red, maroon, purple discolouration or epidermal separation revealing a dark wound bed or blood-filled blister.

The NPIAP is an international organisation which uses the term 'stage' to describe PUs of varying severity. The World Health Organization's dictionary of *International Classification of Diseases* diagnosis codes version 10 (ICD-10) codes also uses the term 'stage' (https://icd.who.int/browse10/2019/en#). However, we are aware that organisations in the UK managing PUs prefer the term 'category'. We have used the term 'stage' throughout for consistency and for an international readership, even when original sources may have used a different term.

The SIPS study focuses on severe (full-skin thickness) pressure ulcers (SPUs). Some ulcers are full-skin thickness but are unstageable (above). Hence, for this research, we considered SPUs to comprise stage 3, stage 4 and unstageable ulcers. These three kinds of PUs are coded as L89.2, L89.3 and L89.9 in the World Health Organization's implementation of the ICD-10.[9] Exploration of a sample of anonymised Hospital Episode Statistics (HES) data showed that surgical reconstruction (SR) occurred as often in patients diagnosed as having an unstageable PU (L89.9) as in all patients diagnosed as having stage 3 and stage 4 PUs (L89.2 and L89.3).[10] Therefore, the study team defined any PU assigned one of these three codes as being relevant to the commissioning brief (see *Report Supplementary Material 1*).

Pressure ulcer prevalence estimates vary according to the population being assessed, the methods used to collect the data from which estimates are calculated and decisions about whether stage 1 PUs should be included (since there is no active wound at this stage, only a high risk of developing a wound). A large survey of hospital patients undertaken in several European countries reported a PU prevalence (stage 2 and above) of 10.5%.[7] In the UK, national PU data are collected across community and acute settings as part of the NHS Safety Thermometer initiative,[11] although data collection is not yet universal. Five per cent of patients across these settings were estimated to have a PU in January 2014.[12]

All the prevalence figures quoted above are for populations currently receiving medical care at a point in time. The point prevalence of pressure ulceration in the total population was recently estimated using a cross-sectional survey undertaken in Leeds, UK. Of the total adult population of 751,485, the point prevalence of pressure ulceration was 0.31

per 1000.[13] A community-specific PU prevalence estimate in the UK reported a prevalence of 0.77 per 1000 adults in a UK urban area.[14]

Health-related quality of life (HRQoL) is a multidimensional concept focused on how health/ill health and associated treatments impact on experiences of daily living and well-being. A PU, especially a SPU, can have a significant impact on a person's HRQoL because managing a PU can have a profound impact on a person's ability to perform activities of daily living. Achieving effective pressure relief when a SPU has occurred may involve long periods of bed rest or a similar requirement for immobilisation. A review of qualitative and quantitative literature on the impact of PUs on HRQoL identified 31 studies (21 quantitative studies and 10 qualitative).[15] Using a content analysis approach, the review characterised 11 HRQoL themes considered to be impacted by pressure ulceration, showing the link between pressure ulceration and negative HRQoL. These themes include social impact; physical impact and limitations; psychological impact; impact of symptoms and impact on general health and consequences. The research for the review together with interviews with 30 people with PUs led to the development of a conceptual framework for HRQoL in PUs containing four domains: symptoms, physical functioning; psychological well-being and social functioning. These domains have been used to develop a recently validated HRQoL tool specifically for pressure ulceration called the PU-QoL tool.[16]

Care delivery for severe pressure ulcers

Most pressure damage occurs in patients with limited mobility. In theory, if the pressure is removed and nutrition optimised,[13,14] most ulcers should heal although the time to heal may be affected by comorbidities. Treatment of PUs depends on how serious they are. Initial treatments may include wound dressings, moving position regularly or using specially designed mattresses and cushions to relieve the pressure. Additionally, surgical debridement can be undertaken with the aim of promoting healing. SR involves complete closure of the PU and is a more major operation than debridement alone.

In the UK, most people with or at risk of PUs are managed in the community (in their own homes, including care homes) by nurses (community nursing teams or care home staff, although some patients will receive care from a practice nurse). The general practitioner (GP) acts as a channel of communication between community and secondary care, if necessary. SPUs may be referred to specialist tissue viability nurses (TVNs; working as part of the community team or in an acute NHS trust) for advice and treatments such as negative pressure wound therapy, holistic patient assessment and care planning. Despite the existence of the National Institute for Health and Care Excellence (NICE) Pressure Ulcer Care clinical guidelines,[18] local pressure ulcer treatment pathways are heterogeneous and there is variation in practice.[7]

Tissue viability services are led by senior specialist nurses with advanced knowledge and skills, in both community and acute settings. TVNs are often responsible for the provision of advanced clinical care, the development of care pathways and provision of education both within their own organisation and to other external organisations such as nursing homes.

The SIPS study was commissioned specifically to research the feasibility of evaluating SR to close the wound as a treatment for SPUs; a previous review has concluded that: 'Currently there is no randomised evidence that supports or refutes the role of reconstructive surgery in pressure ulcer management'.[17] NICE guidance on PUs makes no recommendations about surgical management.[18] Other guidelines recommend obtaining 'a surgical consultation for possible operative repair in individuals with stage 3 or 4 pressure ulcers that are not closing with conservative treatment'.[6] This recommendation does not specify specific operations or indicate the patients likely to benefit and is based on indirect evidence or expert opinion. Surgical intervention other than for PU debridement, that is SR, is reported in the literature only to be considered after failure of conservative (non-surgical) care and usually only for stage 3 and 4 PUs.[19]

Surgical reconstruction methods may include the following:[20]

- Primary wound closure: This involves direct surgical advancement of the wound edges either directly or in layers to close the wound.[21]

- Skin grafting: This involves harvesting a thin piece of skin that is surgically removed from a donor area to replace skin in the defect or denuded area. Skin grafts are occasionally used to treat pressure ulceration when all precipitating factors for PU formation have been removed. They are used to facilitate quick wound cover and subsequently to accelerate wound healing.[22]
- Local random pattern flap: This reconstructive method involves surgically moving the local tissues around the wound, based on a random pattern of blood supply, into the wound defect.[23]
- Regional flap, including:
  - muscle or musculocutaneous flap: this surgical approach involves moving whole or part of a named muscle based on a defined blood supply with or without a skin island to provide cover to the wound[24]
  - fascial or fasciocutaneous flap: this surgical approach involves moving a surgically defined fascial-based island of tissue with its intact blood supply with or without skin to cover the wound[22,25]
  - perforator flap: this is a refinement of the previous musculocutaneous or fasciocutaneous flap approach whereby the specific perforating blood vessels are identified in the flap and dissected to allow either greater movement or less muscle sacrifice as well as separation of components to each flap.[26]
- Free flap: this surgical approach involves raising a defined island of tissue with an artery and vein that is surgically detached and moved to the site of the wound where other local arteries or veins of similar size are identified and then the vessels are surgically anastomosed to re-establish blood flow to the island of tissue.[27]
- Tissue expansion: this surgical approach involves a gradual increment and recruitment of tissue surrounding a PU. It is performed by expanding the skin with a tissue expander, which is inserted into a subcutaneous pocket near the ulcer and is slowly expanded at a defined rate with saline. Once the skin and soft tissues are expanded to a volume capable of covering the PU, the expander is removed, and the tissues are inset to cover the wound. Another method is to apply slow skin traction over the wound with an incremental traction dressing, which works on the same principle of gradual mechanical traction on skin, promoting tissue creep.[28] Eventually the extra skin recruited can be used to close the wound.

All the above approaches can be performed as a one-stage procedure, or as part of a multistage procedure to increase the likelihood of the tissue surviving manipulation, reduce the overall surgical impact on the patient or ensure that all infected or aggravating factors are minimised. This is particularly important as the skin quality around PUs is usually suboptimal. Other factors in addition to the choice of SR method may contribute to successful outcomes: treatment adherence, quality of local tissues, aetiological factors, patient comorbidities, education status and motivation.[29]

There is very limited information about how SR impacts on HRQoL in the short, medium and long term. In interviews with people who had previously had a pressure ulcer,[30] small numbers of patients variously reported surgery as successful or invasive, requiring long hospital stays with ulcers recurring. Recurrence is a key issue in those at risk of ulceration because, when healing occurs, the risk factors for ulceration often remain. People's access to and experience of SR for PUs are likely to be nested in wider issues around future prevention activity; all these aspects of care and behaviour are linked to self-reported HRQoL.

Evaluating interventions for severe pressure ulcers

In 2018, the National Institute for Health and Care Research (NIHR) advertised for research to address the following question: What further primary research is required to evaluate surgical interventions for stages 3 and 4 pressure ulcers? Information in the commissioning brief (CB) (supplementary file) clarified that the aim was not to evaluate any such intervention but 'to identify specific patient groups who may be appropriate to undergo surgical interventions for SPUs and to determine which interventions may be suitable for further evaluation of clinical effectiveness'. A previous CB for primary research to evaluate 'How effective are surgical operations to close pressure ulcers and assist healing?' proposed a randomised controlled trial (RCT) of surgical management compared to usual (non-surgical) care in people with a 'stage 3 and 4 pressure ulcer refractory to healing with conservative management' but did not commission a study.

Studying the ways in which SPUs are managed is challenging because the care pathway spans community- and hospital-based care. The study team set out to create a project which could define the unknown patient and surgical parameters, and so allow a RCT to be designed. In planning this study, we observed that SRs to close a SPU appeared to

be carried out infrequently in England, about 100 per year between 2014 and 2016.[10] This led us to conclude that, for this research, a prospective study would not be feasible and we proposed to analyse routinely collected NHS activity data. An important limitation of analysing routine data was the absence of longitudinal data about HRQoL. We originally proposed qualitative interviews as part of our application to address this limitation, but this element of the proposal was not commissioned.

Aims and objectives

The aim of the SIPS study was to clarify the population, intervention, comparator, outcome (PICO) elements that would need to be defined in a future RCT of SR for SPUs. We defined reconstructive surgery as any surgical procedure that leads to epithelial closure of the wound, typically distant or local flaps of skin and muscle/fascia.

We designed a study with three workstreams (WSs) to address uncertainties in the 'PIC' elements of a future potential PICO research question about the effectiveness and cost-effectiveness of reconstructive surgery:

Workstream 1 included systematic reviews and a survey of surgeons and nurses who manage patients with SPUs in either secondary care or community settings, with the following objectives:

1. systematically review evidence about: (a) the effectiveness of reconstructive surgery for treating PUs; (b) the impact of pressure ulceration on HRQoL
2. carry out comprehensive online surveys with relevant healthcare professions to describe: (a) the characteristics of patients in the UK currently being referred for a surgical opinion about SR; (b) variation in the operations and postoperative care currently being provided; and (c) variation in usual care provided before initiation of a surgical referral.

Workstream 2 comprised retrospective cohort studies assembled from routinely collected data sources [HES, Clinical Practice Research Datalink (CPRD) Gold and CPRD Aurum]. The CPRD cohort included data about the care pathway for patients with incident PUs, from diagnosis and management in primary care and, by linkage with HES, to secondary care and, potentially, SR. The HES cohort included information on 'index' inpatient admissions assigned an ICD-10 code for a SPU and subsequent HES activity. WS2 objectives were to:

3. describe, in the CPRD cohort, people with incident SPUs and their entire care pathways, for example usual management in the community, management by TVNs, admission to hospital and subsequent care
4. describe, in the HES cohort, people with a diagnosis of SPU at the time of hospital admission, their care pathways after admission and frequencies of health outcomes
5. compare, in the HES cohort, outcomes in groups of people who were similar on admission and who did (SR group) or did not have SR [no surgical reconstruction (NSR) group] during the index admission
6. explore, in the SR and NSR groups, subgroup interactions with SR that may influence outcomes, for example co-morbidities, and previous hospital admission without surgery.

Workstream 3 was a formal consensus process, with the objective to:

7. seek consensus about which management strategies are appropriate for whom and when, given findings from WS1 and WS2.

A Study Management Group (SMG) was formed, comprising the investigators. The SMG met every 3 months to review progress and to enable members to contribute their clinical insights.

A Patient Advisory Group (PAG) was assembled under the leadership of one of the investigators (RA). The study team advertised through several channels (e.g. North West People in Research; the charity Shine), inviting the input of people who have had SPUs, and those who had cared for people with SPUs. The role of this wider PAG was to provide regular

input on a range of issues pertinent to the study. The PAG provided input into the design of the surveys, reviewed preliminary findings and reports and advised on dissemination.

Ethical considerations with respect to WS2 were considered through applications for data extracts. We were uncertain whether other aspects of the study required a research ethics opinion and asked the Health Research Authority for an opinion. The Health Research Authority advisors considered that the study represented research but also agreed that it did not require review by an NHS Research Ethics Committee. Details of the justification are available from the authors on request.

Chapter 2 Changes to the study protocol

Following guidance from the NIHR, for the review of the effectiveness of reconstructive surgery for treating PUs (WS1), we changed the primary outcome of the review to 'wound-free time' to better capture the relevant outcomes of SR, when an open wound becomes a closed surgical wound.

For the on-line surveys with relevant healthcare professions (WS1), we added (a) GPs to the professions being surveyed and (b) a further survey ('binary choice experiment', BCE) to explore the inter-relationships between factors reported to influence decisions about the appropriateness of SR for patients with SPUs. We regret that the BCE was not added to the study protocol. The reason for failing to do so was because the BCE was added towards the end of the study when the research team were under pressure to complete the research activities before the funding for the study was used.

We were unable to carry out the formal consensus process (WS3) as planned due to the difficulty of face-to-face meetings during the COVID-19 pandemic and the limited availability of NHS colleagues due to a backlog of clinical work when restrictions on meetings were lifted. We used informal processes which are described in the corresponding chapter (see *Chapter 8*) and explored further in the discussion (see *Chapter 9*).

Chapter 3 Effectiveness of surgical reconstruction to treat pressure ulcers: a systematic review

Methods

The protocol for this review is registered as PROSPERO CRD42019156436 and is available on request. Before conducting the review, an amendment was made to the protocol that is not reflected in the registered protocol. In later discussions with stakeholders, it was recognised that the outcome of wound-free time was also an important primary outcome for this intervention. Wound-free time was defined as the number of wound-free days up to a defined end point; the outcome simultaneously considers healing and breakdown following surgery, recording time during the study when a participant is wound-free. No included studies reported this outcome. Secondary outcomes were added after subsequent protocol discussions but before conducting the review; these were HRQoL; wound infection; incidence of a secondary ulcer in different areas during follow-up and cost. None of these outcomes were reported in the included studies. Data used for analyses are presented in the report. No other materials listed are in the public domain but are available on request.

Study inclusion criteria

Types of study

Due to the known lack of RCTs in this area, we also included non-randomised studies of interventions (NRSI) with specific features that we considered to characterise the most relevant and rigorous approaches to address the question in the absence of randomisation. We mapped the design features of eligible studies in *Table 1* following the taxonomy of Reeves *et al.*[33] Study designs which explicitly involve allocation of clusters rather than individuals were considered ineligible given the nature of the intervention; any such study would have had to involve allocating surgeons to use one or other strategy/procedure or allocating individuals to surgeons who use only one strategy/procedure (i.e. expertise-based design). We deemed both of these scenarios to be unfeasible and extremely unlikely.

To summarise, these criteria mean that: (1) RCTs were included, as were (2) quasi-randomised controlled trials (studies using a system of quasi-randomisation for participant allocation); (3) NRSI with a clearly reported mechanism of group formation described methods of ascertainment of eligible participants and their recruitment and clear adjustment for confounding in the analysis. These studies could use any data source which, over time, followed the trajectory of relevant participants receiving different methods of treatment to assess how alternative strategies impacted on outcomes. Cross-sectional and case-control studies, and single cohorts where all participants were given the same type of surgery, were not eligible.

Types of participants

We included studies that recruited adults with a diagnosis of a PU (any stage) managed in any care setting. We accepted the study authors' definitions of stages. We expected studies to have recruited almost entirely people with stage 3 or 4 PUs because SR would rarely be carried out for less severe SPUs. We planned to exclude studies with mixed wound populations at baseline, that is studies that did not restrict inclusion to people with a PU, for example which may have included participants with other types of wounds such as venous leg or foot ulcers.

TABLE 1 Eligibility of non-randomised studies defined by specific design features

Was the intervention/comparator	Review eligibility criteria	Rationale
Allocated to (provided for/administered to/chosen by) individuals?	Eligible	We will include studies where individuals are allocated into groups
Allocated to (provided for/administered to/chosen by) clusters of individuals?	Not eligible	This feature describes studies which, by design, allocate clusters, for example clustered RCTs and most controlled before-and-after studies. Such studies are not eligible for this review
Clustered in the way it was provided (by practitioner or organisational unit)?	Eligible	This feature distinguishes studies with implicit clustering from studies which allocate clusters by design (described above, explicit clustering). Implicit clustering could arise at the surgeon, unit or hospital level. Studies with potential implicit clustering will be included with the clustering mechanism described where possible alongside any approaches undertaken to mitigate for the non-independent nature of observations within clusters
Were outcome data available		
After intervention/comparator only (same individuals)?	Eligible for specific outcomes	Eligible for all outcomes
Before (once) AND after intervention/comparator (same individuals)?	Eligible for specific outcomes	Eligible for all outcomes
Before (once) AND after intervention/comparator (not all same individuals)?	Not eligible	This is a defining feature of controlled before-and-after studies which are considered to be allocated by cluster and not eligible for this review
Multiple times before AND multiple times after intervention/comparator (same individuals)?	Eligible for specific outcomes	Eligible for outcome: HRQoL only
Multiple times before AND multiple times after intervention/comparator (not all same individuals)?	Not eligible	This is a defining feature of interrupted time series designs which are considered to be allocated by cluster and not eligible for this review
Was the intervention effect estimated by		
Change over time (same individuals at different time points)?	Eligible for specific outcomes	Eligible for outcome: HRQoL
Change over time (not all same individuals at different time points)?	Not eligible	This is a defining feature of controlled before-and-after studies and studies with an interrupted time series design which are considered to be allocated by cluster and not eligible for this review
Difference or ratio between groups (of individuals or clusters receiving either intervention or comparator)?	Eligible for specific outcomes	Eligible for outcomes: wound-free time, HRQoL and wound recurrence
Did the researchers aim to control for confounding (design or analysis)		
Using methods that control in principle for any confounding?	Eligible	
Using methods that control in principle for time-invariant unobserved confounding?	Eligible	
Using methods that control only for confounding by observed covariates?	Eligible	
No attempt to control for confounding	Ineligible	
Were groups of individuals or clusters formed by		
Randomisation?	Eligible	
Quasi-randomisation?	Eligible	

TABLE 1 Eligibility of non-randomised studies defined by specific design features (*continued*)

Was the intervention/comparator	Review eligibility criteria	Rationale
Explicit rule for allocation based on a threshold for a variable measured on a continuous or ordinal scale or boundary (in conjunction with identifying the variable dimension, below)?	Eligible	
Some other action of researchers?	Eligible in specific cases	We will include studies with allocation of individuals to groups based on researcher action where (a) there is a clear definition of the researcher/investigator and (b) the mechanism or decision rules which informed allocation are clearly described in the study report
Time differences?	Not eligible	This is a defining feature of controlled before-and-after studies, studies with an interrupted time series design which are considered to be allocated by cluster, or uncontrolled studies in which outcomes are measured before and after intervention/comparator. Studies of these kinds are not eligible for this review
Location differences?	Not eligible	This is a defining feature of controlled before-and-after studies which are considered to be allocated by cluster and not eligible for this review
Healthcare decision-makers/practitioners?	Eligible	
Participants' preferences?	Eligible	
Policy-maker	Not eligible	Allocation at policy level is usually a feature of clustered design, and not eligible for this review
On the basis of outcome?	Not eligible	Defining feature of a case-control study which are not eligible for this review
Some other process? (specify)	Not eligible	
Were the following features of the study carried out after the study was designed		
Characterisation of individuals/clusters before intervention?	Eligible	
Actions/choices leading to an individual/cluster becoming a member of a group?	Eligible	
Assessment of outcomes?	Eligible	
Were the following variables measured before intervention: (answer 'yes' to more than one item, if applicable)		
Potential confounders?	Eligible	
Outcome variable(s)?	Eligible	

Types of interventions

The primary intervention is reconstructive surgery for pressure ulceration that aims to achieve a closed wound with skin coverage. We anticipated likely comparisons would include surgery (i.e. primary wound closure, skin grafting and surgery involving flap closure or tissue expansion) compared with no surgery and different types of surgery compared with each other.

Reconstructive surgery will often include wound debridement, and we considered debridement as a cointervention. A study of SR compared with conservative care and debridement would be included, with some debridement presumed in the SR group. However, a study of PU debridement without SR compared to conservative care without reconstruction would be excluded. We planned to extract information on debridement and all other reported cointerventions described and consider whether they were applied differentially by the group in the risk-of-bias assessment.

Outcomes

Primary outcomes

We considered two primary outcomes.

1. Wound-free time, defined as the number of wound-free days up to a defined end point (applied to all groups), that is time with intact skin or similar. This outcome simultaneously considers healing and breakdown, recording time during the study when the participant is wound-free.
2. Complete wound healing, defined as the time to complete healing of study wound/(participants if cluster trial) or as the proportion of study wounds/participants that were completely healed by a defined end point (applied to all groups).

Secondary outcomes

- HRQoL measured using a validated scale, for example Short Form questionnaire-36 items (SF-36), EuroQol-5 Dimensions (EQ-5D) or the PU-QoL[16,34–36]
- wound infection, as defined by study authors
- cost
- incident second PU in a different area during follow-up
- dehiscence of a surgically closed wound (only applicable to surgically closed wounds)
- ulcer recurrence following complete healing.

As well as the outcomes listed above, we extracted relevant data for unspecified measures for consideration because we anticipated few studies would be included and might not report one or more of the outcomes specified. Definitions of all outcome measures were extracted. If a study was otherwise eligible (i.e. correct study design, population and intervention/comparator) but did not report a listed outcome, then we planned to contact the study authors to establish whether an outcome of interest was measured but not reported.

We reported outcomes at the latest time point available for a study (assumed to be the length of follow-up if not specified) and the time point specified in the methods of the included study as being the primary endpoint. For all outcomes we planned to categorise the timing of assessment of outcomes: short term (1–8 weeks); medium term [9–16 weeks; long term (> 16 weeks)].

Methods for identifying and selecting studies

We searched the Cochrane Wounds Specialised Register, the Cochrane Central Register of Controlled Trials (CENTRAL), Ovid MEDLINE, Ovid MEDLINE (In-Process and Other Non-Indexed Citations), EMBASE and EBSCO Cumulative Index to Nursing and Allied Health Literature (CINAHL) Plus. Search strategies are listed in *Appendix 1*, which were piloted before performing the final searches.

There were no restrictions with respect to language, date of publication or study setting. Citations were de-duplicated before screening. We aimed to identify other potentially eligible studies or ancillary publications by searching the reference lists of included studies as well as relevant systematic reviews, meta-analyses and HTA reports.

Study selection

Two review authors (Jo Dumville and Chunu Shi) independently assessed the titles and abstracts of the citations for relevance, and we obtained full-text copies of all study reports considered potentially relevant. Two review authors independently checked the full papers for eligibility. We planned to resolve disagreements by discussion and, when necessary, consulted a third review author. We recorded all reasons for excluding studies for which we obtained full copies. We completed a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart to summarise this process. Where studies were reported in multiple publications/reports, we planned to obtain all the available publications, extracting data from all reports to ensure that maximal relevant data for a study were obtained.

Data extraction and management

Two review authors extracted data independently for eligible studies, resolving disagreements by discussion and with the help of a third review author when required. When key data were missing from reports, we planned to contact the study authors to obtain this information. When a study with more than two intervention groups was included, we planned to extract data only for those intervention and control groups that met the eligibility criteria. We extracted the following details: study descriptors, participant eligibility criteria, baseline age, sex, ulcer area and duration, number of people with spinal cord injury, number of people with a recurrence ulcer, number of people with single or multiple ulcers at the time of surgery. Intervention and cointervention details, description of follow-up, outcome data and analytical approaches used, and missing data with reasons for missingness were noted.

Assessment of risk of bias

Two review authors independently assessed included studies for risk of bias,[37] using the Risk of Bias 2 (RoB2) instrument for RCTs[38] and the Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS–I) tool[39] for NRSI. Both instruments require the reviewer to specify the study result (outcome and treatment effect) being assessed for risk of bias. ROBINS–I also requires pre-specification of potential confounding domains and cointerventions to allow the risk of bias to be assessed, taking account of these aspects of a study and the ways in which they were handled for each result. We considered key potential confounding domains for studies in this review to be: participant's age; life expectancy; health status (e.g. fitness for surgery); and ulcer area and duration at baseline. Where possible, we assessed studies for differential use of the following discretionary cointerventions by group: support surfaces, repositioning regimens, negative pressure wound therapy and debridement (potentially used as a treatment in its own right).

Measures of treatment effect

Randomised controlled trials

For dichotomous outcomes, we planned to calculate the risk ratio (RR) with 95% confidence intervals (CI). For continuously distributed outcome data, we planned to calculate or extract the mean difference or standardised mean difference (if trials used different assessment scales) with 95% CI. We planned to report correctly analysed time-to-event data (e.g. time to healing) as hazard ratios (HR) where possible using the recommended method.[37] If a study did not report a HR for a time-to-event outcome, we planned to estimate this using other reported outcome data by applying available statistical methods.

Non-randomised studies of interventions

When available, we extracted unadjusted and adjusted treatment effects, recording the confounding domains which were controlled for. When multiple adjusted treatment effects were reported, we selected the one judged to control best for the pre-specified important confounding domains (recording the rationale for the decision).

Data synthesis

We synthesised included data narratively and planned to use meta-analysis where applicable (it was not possible and planned meta-analysis methods are not described). Comparisons were planned to be structured according to type of comparator and then by outcomes ordered by duration of follow-up period. Means for a limited number of data items are presented as a study-level summary.

Subgroup analyses

We planned to investigate heterogeneity using the methods described in Section 10.10 of the Cochrane Handbook for Systematic Reviews of Interventions.[37] These methods were not applied due to the small number of included studies.

Assessing the certainty of evidence and 'Summary of findings' tables

We planned to present an overall grading of the certainty of the evidence associated for the following outcomes assessed using the principle of the Grading of Recommendations Assessment, Development and Evaluation (GRADE):[40] wound-free time; complete wound healing; HRQoL.

Results of the review

Study selection

Details of the search results were run on 23 April 2019, and subsequent screening is summarised in *Figure 1*. Following de-duplication, we identified 1912 citations. A further six records were identified from authors' personal knowledge of the literature. The 1918 records were screened by the 2 reviewers who identified 69 records (corresponding to 67 full-text articles and 2 records from trial registries) to screen using full-text reports.

From full-text reports, we identified three studies as eligible for this review, one RCT[41] and two non-randomised studies.[42,43] One study which may have been eligible lacked enough detail about the surgical procedures conducted to make an assessment about inclusion.[44] We did not identify any relevant ongoing studies.

The study we were undecided about[44] was a retrospective cohort study conducted in the USA. It used data held in a database describing 1248 surgical cases of reconstructive surgery for pressure ulceration. It reported an overall complication incidence of 35.0% (where complications were defined as one or more of the following: 30-day mortality; surgical site infection; wound dehiscence; pneumonia; respiratory failure requiring reintubation; pulmonary embolism; need for postoperative ventilator support > 48 hours; renal insufficiency; renal failure; urinary tract infection; stroke; postoperative come for > 24 hours; peripheral nerve injury; cardiac arrest; myocardial infarction; postoperative blood transfusion; deep vein thrombosis; sepsis; septic shock; intraoperative cardiac arrest and intraoperative myocardial infarction). Specifically, 30-day mortality was 3.3% and wound dehiscence was reported at 4.6%. It was not clear whether any data reported were at a wound or a participant level. It was not possible to identify from the report which surgical procedures had been performed. Flap closures were noted in a multivariable analysis as being predictive of reduced odds of complications [odds ratio (OR) 0.71, 95% CI 0.55 to 0.91], but it was not clear what 'flap' procedures were used nor what procedures they were compared with. The authors did not respond to our request for more information. For these reasons, we did not consider the study further.

Excluded studies

Of the 69 studies which were obtained as full text, 30 studies were excluded because they did not clearly compare alternative approaches for SR to close a pressure ulcer or SR with another treatment intervention. A further 35 studies were not eligible because, despite exploring comparative surgical approaches, they did not adjust for confounding; hence, they were considered at critical risk of bias and not informative about comparative effectiveness. Several of these studies also failed to clearly specify the groups being compared. These studies provide a useful summary of comparative studies conducted and provide useful wider context (see *Appendix 2*, *Table 29*).

Included studies

One RCT[41] (*Table 2*) was conducted in a single hospital setting in the USA and included 20 participants with non-healing PUs (recorded as stage 4) aged 20–70 years. People with comorbidities considered by the study team to prevent optimal healing were excluded. The average duration of follow-up was 19 months.

Two additional studies (see *Table 2*) were NRSI. Sirimaharaj *et al.* was a retrospective observational study conducted in Thailand.[42,43] Over an 18 year-period (January 1998–December 2015), medical record data were abstracted for all patients recorded as receiving SR for a SPU (noted as stage 3 or 4) in a single plastic and reconstructive surgery department. The study reported data for 165 participants with a total of 272 PUs. The duration of follow-up data was not reported. Chiu *et al.* was also a retrospective cohort study but with some prospective follow-up.[43] Data were abstracted from medical records of people recorded as having had musculocutaneous, fasciocutaneous, or perforator-based flap reconstruction for reported stage 3 or 4 PUs over a 12-year period (January 2002–December 2013) in a single hospital in Taiwan. Follow-up data were abstracted up to December 2015 with a mean follow-up of 55.4 months [standard deviation (SD) 38.0]. The report suggested that outcome data were obtained for all participants. The report referred to 181 'cases', which seem to refer to PUs. However, we could not identify how many participants were recruited, that is whether any participants had multiple PUs; this seems likely given that a within-patient correlation was reported.

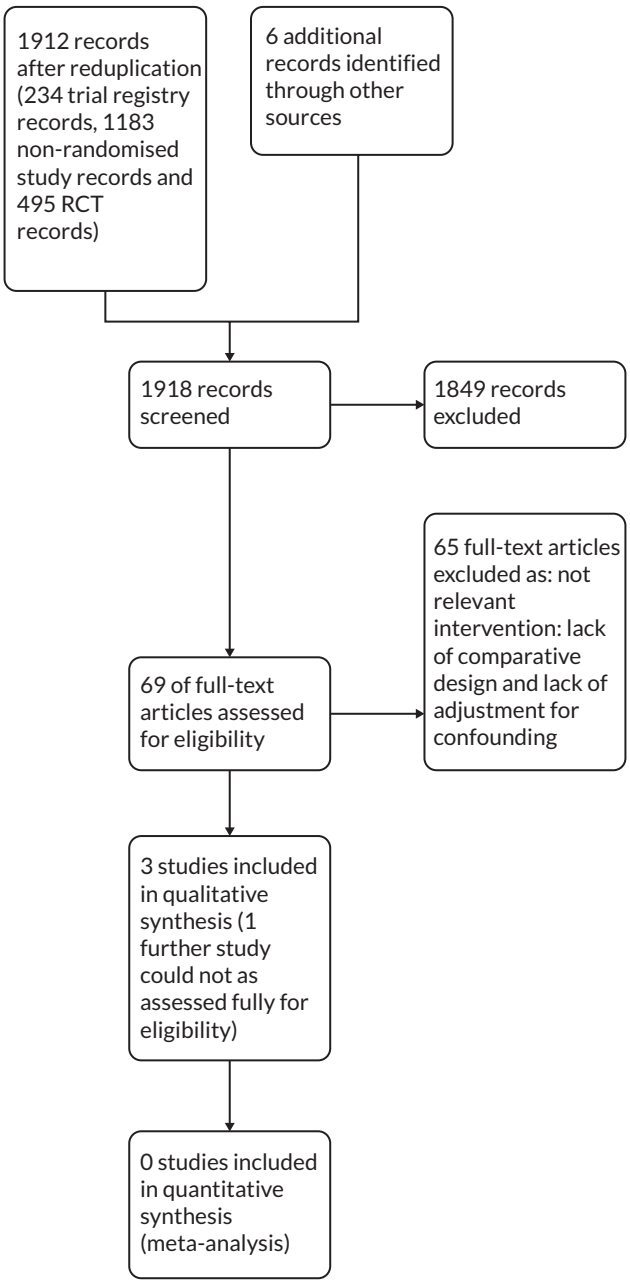


FIGURE 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram summarising citations identified and subsequent screening of citations for systematic review of the effectiveness of SR.

Interventions evaluated

Gargano *et al.*[41] compared a conventional method of flap surgery with a novel 'cone of pressure' method of flap surgery. In both groups, rotation fasciocutaneous flaps were used. For ischial ulcers, a posterior thigh flap was used, and for sacral ulcers a gluteus flap was used. Participants in the conventional care group had the flap sutured at the superficial layers, such as the subcutaneous layer, the dermis and the skin. Participants in the cone of pressure group had surgery in which a large portion of the flap tip was de-epithelialised and inset to obliterate the undermined ulcer. In terms of cointerventions, it was noted that all participants were treated with infection control; debridement with Versajet (Smith and Nephew, St. Petersburg, FL, USA); and negative-pressure wound vacuum therapy before surgery. Other cointerventions were used across participants: control of muscle spasms; pressure control devices such as air mattress beds (Clinitron, Hill-Rom, Chicago, IL, USA) and turning protocols; scheduled dressing changes to keep wounds clean; optimisation of nutrition with albumin > 3 g/dl.

TABLE 2 Summary of included studies, systematic review of the effectiveness of SR

Name	Study design	Location	Participants	Data source	Time period	Intervention	Control	Methods of 'adjustment' for potential confounding	Risk of bias
Gargano *et al.*[41]	RCT	USA	20 Participants with 'stage IV' PUs aged 20–70 14 participants were noted as having a spinal cord injury or being para or quadriplegic. Other participants had reported traumas such as gunshot wounds, falls or had reported medical events such as aneurysm or a fall Sex: 12/20 male with no sex reported for 3 participants Age: mean age of 45	Prospective data collection	Recruitment from 2011 to 2014	In both groups, rotation fasciocutaneous flaps were used for ischial (posterior thigh flap) and sacral (gluteus flap) PUs Cone of pressure flap. This technique is a modification of rotation fasciocutaneous flap in which a large portion of its tip is de-epithelialised and inset to obliterate the undermined ulcer	Conventional method. In this group, the flap was sutured only at the superficial layers, such as the subcutaneous layer, the dermis and the skin. This method does not obliterate completely the undermined areas and does not decrease the overlying shear forces between the flap and the underlying bone	While randomised small numbers. No details about statistical analyses reported in paper	High Some concerns about risk of bias due to randomisation process. High risk of bias for deviation from intervention delivery as intended and measurement of the outcome
Sirimaharaj *et al.*[42]	Retrospective cohort study	Thailand	Total of 165 participants with 272 pressure ulcers Those eligible were people with stage 3 and 4 PUs (*no further definition*) Age: median 43.5 years (IQR 29.5–54.3) Sex: 118/165 (71.5%) male Ulcer area: median 15 cm^2 (IQR 8–24) Ulcer duration: not reported Number of participants with spinal cord injury: 136/165 (82%) Stage 3 ulcer: 76/272 (28%) Stage 4 ulcer: 196/272 (72%) Recurrent ulceration: 67/272 (25%) Number of participants with multiple ulcers at time of surgery: not reported as participant-level outcome	Medical records	January 1998–December 2015 The length of follow-up is not noted; the median length of hospital stay is noted as 50 days (IQR of 28–82)	Range of reconstructive surgical approaches were conducted and subsequently compared in the analyses *The following techniques were utilised over the period* Direct skin closure 57/272 Fasciocutaneous flap 108/272 Myocutaneous flap 20/272 Gluteus and skin direct closure 52/272 Hamstring and skin direct closure 8/272 Gluteus and fasciocutaneous flap 13/272 Hamstring and fasciocutaneous flap 8/272 Split-thickness skin graft 6/272	See intervention	Factors associated with ulcer recurrence assessed using Cox proportional hazard model	Critical risk of bias (for wound recurrence outcome – only review relevant outcome reported)

TABLE 2 Summary of included studies, systematic review of the effectiveness of SR (*continued*)

Name	Study design	Location	Participants	Data source	Time period	Intervention	Control	Methods of 'adjustment' for potential confounding	Risk of bias
Chui[43]	Retrospective cohort study	Taiwan	181 cases (not clear if participants or ulcers) To be eligible participants had to have received musculocutaneous, fasciocutaneous, or perforator-based flap reconstruction for stage 3 or 4 pressure ulcers Ulcers had to be free of systemic infection or cellulitis at the time of reconstruction Age: mean (SD) 58.8 years (21.0) Sex: 115/181 male Ulcer area: mean (SD) 67.8 (74.4) Ulcer duration: not reported Participants with spinal cord injury (*noted as number with paraplegia*): 66/181 Stage 3 ulcer: not reported Stage 4 ulcer: not reported Recurrent ulceration (defined as previous same site failures): 43/181 Participants with multiple ulcers at time of surgery: 66/181 (36%)	Medical records	People having surgery between January 2002 and December 2013. With follow-up until December 2015 Length of follow-up varied by approach mean (SD) Fasciocutaneous flaps group: 58.6 months (37.6) Myocutaneous flap group: 47.4 months (31.2) Free-style perforator flap group: 58.9 (44.3)	Fasciocutaneous flaps group: *n* = 86/181 Myocutaneous flap group: *n* = 52/181 Free-style perforator flap group: = 43/181	See intervention	A multivariable logistic regression model using forward elimination was used with type of surgery included in the model. No data are present in relation to this model	Critical risk of bias (for wound recurrence outcome – only review relevant outcome reported)

IQR, interquartile range; SD, standard deviation.

Sirimaharaj *et al.*[42] included participants receiving any type of SR approach, listed as: direct skin closure; fasciocutaneous flap; myocutaneous flap; gluteus and skin direct closure; hamstring and skin direct closure; gluteus and fasciocutaneous flap; hamstring and fasciocutaneous flap; split-thickness skin graft. No further details on these surgical procedures are provided. No further information was provided about cointerventions delivered alongside surgeries and how if/how these varied either by participant type, surgery time or over time.

Chiu *et al.*[43] included data for patients undergoing three forms of flap reconstructive surgery: musculocutaneous, fasciocutaneous, or perforator-based flap reconstruction. It was noted that participants were routinely kept on bed rest after surgery for approximately 3 weeks, positioned to avoid bearing weight over the flap sites: after this time participants increased time lying on the surgical site with reduction if there was any break in the skin at the flap site.

Risk-of-bias assessment

The RCT was judged overall to be at high risk of bias (see *Appendix 3*, *Table 30*). Risk of bias in the two NRSI was only assessed for the outcome of ulcer recurrence, which was presented as part of an adjusted analysis by the included studies. Both studies were judged to be at critical risk of bias (see *Appendix 3*, *Table 31*). The study design and the lack of adjustment for key confounding domains in analyses were features giving rise to these judgements, as was the potential for selective reporting of results.

Key findings from included studies

Few outcomes relevant to the review were reported in the three included studies and are summarised below. No studies reported measuring wound-free time (*Table 3*).

Randomised controlled trial data

Complete wound healing and wound dehiscence

Gargano *et al.* did not fully report complete wound healing or the number of participants with complete healing.[41] The authors did report narratively that minor complications, which included delayed wound healing and wound dehiscence that did not require surgical intervention, were comparable between the groups. There were no numerical data available precluding any further analysis.

Pressure ulcer recurrence following complete healing

The authors reported wound recurrence rates (assumed to arise following healing, although this is not explicitly stated) as being variously 9% and 12% for the 11 participants in the cone of pressure flap group and as 60% for the 9 participants in the conventional flap coverage group at 16 months' follow up.[41] Due to the discrepancy in the reported percentages with recurrence in the cone of the pressure flap group, and because we were uncertain how the denominators were impacted by losses to follow-up, we could not analyse these data any further.

Wound infection

The authors stated that positive cultures (a surrogate outcome for wound infection) were seen in three participants in the cone of pressure group and two in the conventional group.[41] As we were uncertain what the denominator was due to unclear loss to follow-up, we could not calculate an effect estimate.

Non-randomised studies of surgical reconstruction interventions

Pressure ulcer recurrence following complete healing

Given the limitations of the available data, we present a narrative summary of ulcer recurrence outcome data for each study here (*Table 3*). No other outcome data relevant to the review were reported.

Sirimaharaj *et al.* compared the risk (or hazard) of ulcer recurrence in wounds having had direct skin closure and fasciocutaneous flap with wounds receiving muscle coverage, reporting a HR of 1.56 (95% CI 1.01 to 2.40).[42] The authors also compared the risk (or hazard) for ulcer recurrence of closure with a split-thickness skin graft compared with muscle coverage, reporting a HR of 3.82 (95% CI 2.54 to 5.76). The model was reported to adjust for the following baseline variables: age, sex, spasticity (not clear when measured), albumin levels; ulcer stage, location of pressure ulcer. Adjustment was also made for non-baseline measures of length of stay and incomplete healing before discharge.

TABLE 3 Summary of outcome data for included studies

	Gargano *et al.*[41]	Sirimaharaj *et al.*[42]	Chiu *et al.*[43]
Review primary outcomes			
Wound-free time	Not reported	Not reported	Not reported
Complete wound healing	Only reported indirectly and narratively – with no numerical data: *'minor complications, which included delayed wound healing and wound dehiscence which did not require surgical intervention, were comparable between the groups'*	Reported only that PUs had healed completely in 96% of cases before discharge. No comparative analysis was presented and no definition of healing provided	Not reported
Review secondary outcomes			
HRQoL	Not reported	Not reported	Not reported
Wound infection	Clinical infection was not reported. Positive cultures (a surrogate) were seen in three participants in the cone of pressure group and two participants in the conventional group	Not reported	This was noted as a secondary outcome in the methods, but no data are reported in the results
Cost	Not reported	Not reported	Not reported
Incident secondary ulcer	Not reported	Not reported	Not reported
Wound dehiscence	*As for complete wound healing above*	Not reported	Not reported: this is only reported as part of a composite outcome in the study of 'postoperative wound complication, including suture line dehiscence, infection, haematoma or flap necrosis'
Ulcer recurrence after complete healing	Recurrence rates were measured at 16 months follow-up. It was not clear they were after healing per se. Recurrence was reported variously as 9% and 12% of participants in the cone of pressure flap group and 60% in the conventional flap coverage group	There is no definition of recurrence given in the paper. The overall PU recurrence rate is noted as 16.5% (45/272 ulcers) with overall patient recurrence of 19.4% (32/165) An adjusted analysis for risk of recurrence is presented having used a Cox's regression; there is no clear indication of time to event data having been collected in the paper and results are not reported in this context. Data are presented for groupings of the different surgical techniques. From what is reported, it is not completely clear what the constituents of each group are and what the term 'muscle coverage' applies to in this context There does not seem to have been adjustment for clustering (of ulcers on person) Direct skin closure and fasciocutaneous flap vs. muscle coverage HR 1.56 (95% CI 1.01 to 2.40) Split-thickness skin graft vs. muscle coverage HR 3.82 (95% CI 2.54 to 5.76) The model is reported to adjust for the following baseline variables: age, sex, spasticity (*not clear when measured*), albumin levels; ulcer stage, location of PU. Adjustment is also made for non-baseline measures of length of stay and incomplete healing before discharge	Ulcer recurrence is presented this is defined as the appearance of skin break after total recovery of the previous surgical site There is an additional analysis which is presented as a subgroup analysis with predictors for the odds of recurrence within different surgical groups presented Only predictors with an associated estimate considered significant are reported and the reference group is not clear *Fasciocutaneous flap group* Increased odds of recurrence in those with paraplegia: OR 3.83 95% CIs 1.08 to 13.65 *Myocutaneous flap group* No variables retained in model *Free-style perforator flap group* Increased odds of recurrence in ischial wounds: OR 6.67, 95% CIs 1.28 to 34.84 Models were reported to adjust for: sex, age, wound location, wound, previous flap failure, pre-surgical albumin level, paraplegia status, the existence of other concurrent ulcers, and medical history of diabetes (*univariable data from Table 2 in the paper have not been extracted here*)

Chiu *et al.* only reported selected outcomes,[43] giving details of the odds of ulcer recurrence for specific groups who had certain surgical approaches (only statistically significant risks of recurrence were reported). Participants who had a fasciocutaneous flap and paraplegia were reported to have increased odds of recurrence (OR 3.83, 95% CI 1.08 to 13.65). Participants who underwent a free-style perforator flap reconstruction of ischial wounds were reported to have increased odds of recurrence (OR 6.67, 95% CI 1.28 to 34.8). The model was reported to adjust for the following baseline variables: sex, age, wound location, wound, pre-surgical albumin level, previous flap failure, paraplegia status, the existence of other concurrent ulcers and medical history of diabetes. These data are of limited relevance to the review question on the relative effectiveness of different surgical approaches for pressure ulcer reconstruction.

Application of Grading of Recommendations Assessment, Development and Evaluation to included evidence

We were only able to apply GRADE to the outcome of PU recurrence following PU healing. In all three studies, this outcome was considered to have very low certainty evidence due to very serious risk of bias (all three studies), and imprecision[43] or indirectness.[42]

Summary of main findings

We did not find any studies that compared SR with no SR in people with PUs.

Only three studies were included, one RCT and two NRSI, and these compared different types of SR in people with PUs.

All studies were at critical risk of bias.

The certainty of evidence for the odds of PU recurrence risk in two different SR approaches was very low (the only outcome for which certainty of evidence could be assessed).

Chapter 4 Assessing the impact of pressure ulceration on health-related quality of life: a systematic review

Methods

The protocol for this review is registered as PROSPERO CRD19156450 and is available on request. No amendment was made to the protocol after registration. Data used for analyses are presented in the report. No other materials listed are in the public domain but are available on request.

Study inclusion criteria

Types of study

People with PUs typically have other health conditions that also impact on their HRQoL, making it challenging to attribute HRQoL to the presence or changing status of the PU. We have focused this review on RCTs of interventions to prevent or treat PUs in order to try to control for these other factors. To be useful in estimating the impact of PUs on HRQoL, a RCT must also find a significant difference between intervention and comparator groups being studied in their PU experience. This approach confounded treatment and PU experience but controlled for the effects of other factors on HRQoL since the groups were balanced due to randomisation.

Eligible RCTs had to report at least one HRQoL score on a validated instrument in individuals with a PU or at risk of developing a PU. We excluded studies comparing methods of wound assessment, pilot studies and studies of split wounds or split body studies.

Types of participants

We included studies which had recruited adults (≥ 18 years of age) with a diagnosis of a PU (stage 2, 3, 4 or unstageable) managed in any care setting or at risk of developing a PU.

We excluded studies with populations of individuals with a range of wound types (not exclusively with PUs), who were in intensive care units or non-responsive (e.g. in a coma), and healthy volunteers.

Outcomes

The outcome of this review was HRQoL. Eligible generic measures considered were: SF-36; Short Form questionnaire-12 items (SF-12); Short Form questionnaire-6 Dimensions (SF-6D); EQ-5D (any version, utility or visual analogue measures); Nottingham Health Profile; Sickness Impact Profile and the World Health Organization Quality of Life Scale.[34,35,45–48] Validated disease-specific tools were also eligible; when the review was planned, the only eligible tool we were aware of was the PurPOSE PU-QoL tool.[16]

Methods for identifying and selecting studies

We searched the following electronic databases: The Cochrane Wounds Specialised Register; CENTRAL; Ovid MEDLINE; Ovid MEDLINE (In-Process and Other Non-Indexed Citations); Ovid EMBASE; EBSCO CINAHL Plus. *Appendix 4* describes the search strategies, which were piloted before performing the final searches.

There were no restrictions with respect to language, date of publication or study setting. Citations were de-duplicated as part of the search process. We aimed to identify other potentially eligible studies or ancillary publications by searching the reference lists of retrieved included studies as well as relevant systematic reviews, meta-analyses and HTA reports.

Study selection

Two review authors (Jo Dumville and Chunu Shi) independently assessed the titles and abstracts of the citations for relevance and full-text copies of all study reports considered potentially relevant were obtained. Two review authors

independently checked the full papers for eligibility. We resolved disagreements by discussion and, if required, involved a third review author. We recorded all reasons for excluding studies for which we obtained full copies. We completed a PRISMA flow chart to summarise this process. When studies were reported in multiple publications/reports, we obtained all the available publications and extracted relevant data from all reports.

Data extraction and management

Two review authors extracted data independently and resolved disagreements by discussion, drawing on a third review author if necessary. When required data were missing from reports, we planned to contact the study authors to obtain this information. We extracted the following data when reported: RCT type; participant age; comorbidities; included PUs stages (and methods used for assessment); time points assessed; HRQoL measure used; methods of analysis; outcome frequencies by group and treatment effects reported at specific time points (PU experience however measured and HRQoL).

Assessment of risk of bias in included studies

Risk of bias for included studies was relevant because it would potentially affect the treatment effect estimated for the primary outcome (PU experience by whatever outcome measured) and for HRQoL. Two review authors independently assessed included studies using the Cochrane RoB2 tool.[38]

Measures of treatment effect

Any measure of treatment effect was considered.

Data synthesis

Study-level data are presented narratively in terms of the study type; study population; HRQoL measure and outcome data. We anticipated that most data would be presented as mean values and SDs. We categorised follow-up times as short (≤ 8 weeks), medium (> 8–24 weeks) or long term (> 24 weeks). If repeated HRQoL measures in an individual over time were modelled, we planned to present summary data that were reported and treatment effects. Otherwise, we planned to present mean values from the latest time point possible. Wherever possible, we planned to present follow-up HRQoL means alongside proportions of wounds healed or PU incidence for reference. When reported, we present adjusted treatment effects.

We planned to explore clinical and methodological heterogeneity by pooling changes in HRQoL data by increases or decreases in PU outcomes. However, the small number of included studies meant meta-analyses were not conducted.

Results

Details of the search results, run on 14 April 2020, and subsequent screening are summarised in *Figure 2*. Following de-duplication, we identified 767 records. Two more records (for two studies) were identified from authors' personal knowledge of the literature. The 769 records were screened by 2 reviewers, and we identified 321 records to screen at the full-text stage.

Full-text reports comprised RCTs of PU prevention and treatment interventions. Almost all these studies were excluded from the review because they did not assess HRQoL using a validated generic or disease-specific measure. We were unable to obtain one Chinese language study after exhausting all options available to us.[49]

Included studies

We included three RCTs in this review[50–55] (see *Table 4*).

PRESSURE 2[50,51] is a UK PU prevention trial that compares the prophylactic effects of two different types of support surfaces in people at risk of pressure ulceration. The study recruited 2029 participants with an overall mean age of 78 years. Participants were recruited from secondary care and followed up for ulcer incidence with the primary follow-up time being 30 days. As participants could have PUs at baseline, these data are also reported, along with healing data. HRQoL was measured using the EuroQol-5 Dimensions, five-level version (EQ-5D-5L). Utility was also

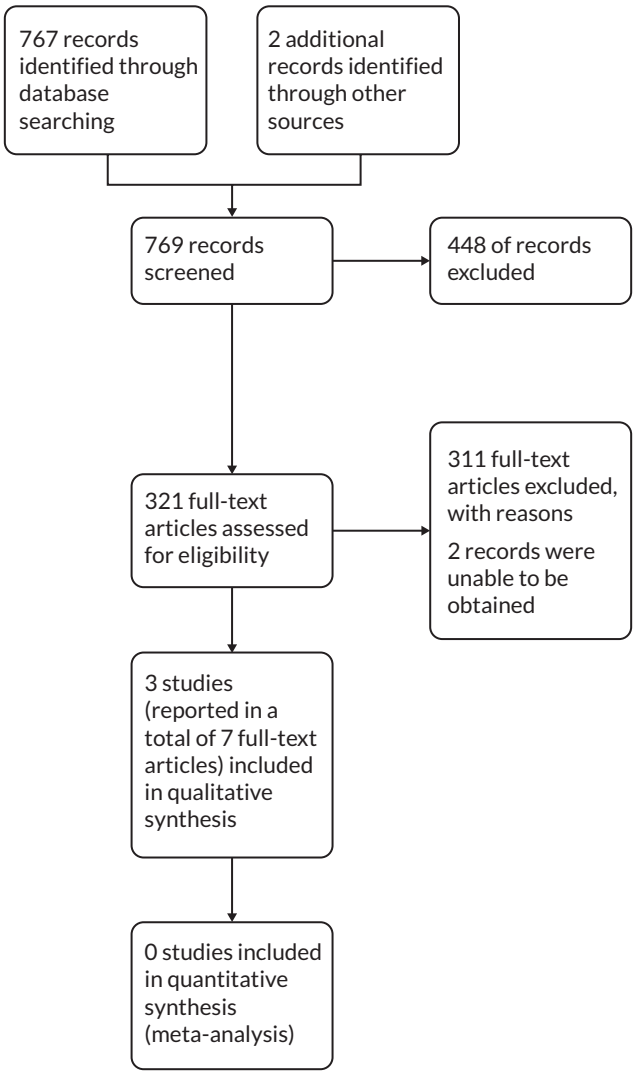


FIGURE 2 Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram summarising citations identified and subsequent screening of citations for systematic review 2.

assessed using a disease-specific measure related to the PU-QoL measure, the pressure ulcer-quality of life – utility index (PU-QoL-UI).[56] This is a seven-item measure that aims to measure PU-specific utility values for use in cost–utility analysis. The SF-12 and the pressure ulcer-quality of life – prevention (PU-QoL-P) measure were validated in a non-randomised substudy.

Stern *et al.*[52] is a Canadian treatment study that compared PU healing in people with PUs and offered multidisciplinary care via telemedicine or standard care. It recruited 161 participants in a stepped wedge study that ran over 17 months in 12 sites. The mean age of participants at baseline was 82 years. Ulcer stage at baseline was not reported. HRQoL was measured using the EQ-5D (version not specified). The main trial outcome was a change in ulcer size, which is considered a surrogate outcome as the ulcer remains in situ; limited other ulcer healing data were reported.

Arora *et al.*[53–55] is a PU treatment study conducted in India and Bangladesh. Participants in both trial groups managed their pressure ulcers alone at home. However, participants in the intervention group also received weekly advice over the telephone for 12 weeks about the management of their PUs from a trained healthcare professional. The 120 participants in this study had PUs secondary to spinal cord injury and the mean age of participants was 36 years. The majority of participants were reported as having stage 3 PUs at baseline. HRQoL was measured using the EQ-5D-5L and EQ-5D visual analogue scale (VAS). Time to ulcer healing (as well as the surrogate outcome change in wound size) was reported.

TABLE 4 Summary of included studies, systematic review 2

Study ID	Study details, including study design	Countries of conduct	Interventions being assessed	Eligibility criteria	Participant details at baseline, incl. comorbidities and PU details	Number of participants randomised	HRQoL (or utility) measure used	Time points assessed	Complete wound healing or wound incidence outcomes reported	ROB assessment
Arora[53–55]a/b (with Arora protocol)	Treatment trial investigating PU healing Follow-up of 12 weeks Parallel trial; individual randomisation	India and Bangladesh	Participants in both groups managed their PUs alone at home. However, participants in the intervention group also received weekly advice over the telephone from a trained healthcare professional for 12 weeks about the management of their PUs Group 1: standard care Group 2: standard care and telephone support	People living in the community with PUs secondary to SCI were randomised to a control or intervention group More specifically: were aged > 18 years; had sustained a SCI more than 3 months before recruitment; had at least one PU on the sacrum, ischial tuberosity or greater trochanter of the femur; were unlikely to be admitted to hospital for management within the next 12 weeks; were living in the community; were able to speak either sufficient Hindi (for the Indian sites) or Bengali (for the Bangladesh site) to allow them to participate in the trial without the assistance of a translator; had access to a phone; had the potential to benefit from advice provided over the telephone. Participants were excluded if they: had cognitive or verbal impairments; had any clinically significant medical condition that would compromise participation in the trial; were unable to be assessed at 12 weeks	Mean age (SD): Group 1: 36 (12) Group 2: 35 (11) Sex (% f/m): Group 1: 10/90 Group 2: 13/87 PU grade at baseline % Group 1: Stage 2 = 22 Stage 3 = 75 Stage 4 = 3 Group 2: Stage 2 = 37 Stage 3 = 63 Stage 4 = 0 Comorbidities: ASIA impairment scale (%) Group 1 A = 78 B = 3 C = 14 D = 2 Unknown = 3 Group 2: ASIA impairment scale Group 1 A = 87 B = 5 C = 3 D = 0 Unknown = 5	Group 1: standard care = 60 participants Group 2: standard care and telephone support = 60 participants	EQ-5D-5L EQ-5D-VAS	Baseline and 12 weeks with healing status for time to healing every 2 weeks	Primary outcome was wound size at 12 weeks Time to healing was a secondary outcome	Low

TABLE 4 Summary of included studies, systematic review 2 (*continued*)

Study ID	Study details, including study design	Countries of conduct	Interventions being assessed	Eligibility criteria	Participant details at baseline, incl. comorbidities and PU details	Number of participants randomised	HRQoL (or utility) measure used	Time points assessed	Complete wound healing or wound incidence outcomes reported	ROB assessment
Nixon[50,51]a/b; Brown[57]	Prevention trial, aiming to reduce the incidence of ulcers stage 2 and above Follow-up: key reporting point was 30-day follow-up	UK	Comparison of two types of support surface: alternating pressure mattress and high -specification foam Group 1: alternating pressure mattress Group 2: high specification foam mattress	a. Eligible if had evidence of acute illness through acute admission to secondary care hospital, community hospital or NHS-funded intermediate care/rehabilitation facility b. Inpatient secondary care, community hospital or NHS-funded intermediate care/rehabilitation facility with an onset of acute illness secondary to elective admission c. Recent secondary care hospital discharge to community hospital or NHS-funded intermediate care/rehabilitation facility AND d. Aged ≥ 18 years; expected total length of stay of ≥ 5 days; at a high risk of PU development due to one or more of the following: e. Bedfast/chairfast AND completely immobile/very limited mobility (Braden Scale31 activity score of 1 or 2 and mobility score of 1 or 2) f. Stage 1 PU on any pressure area skin site (c) localised skin pain on a healthy, altered or stage 1 pressure area skin site	Mean age (SD) Group 1: 77.8 (13.42) Group 2: 78.2 (12.87) Overall: 78.0 (13.1) Sex (%); F/M Group 1: 54.4/45.4 Group 2: 55.9/43.9 Overall: 55.2/44.7 PU grade at baseline (where relevant) % Group 1: No PU = 80.8 Stage 1 = 12.3 Stage 2 = 6.9 Group 2: No PU = 81.4 Stage 1 = 10.9 Stage 2 = 7.4 Comorbidities: Not reported per se, several reports of skin status and other risk factors for pressure ulceration such as mobility	Group 1: alternating pressure mattress = 1016 Group 2: high specification foam mattress = 1013	EQ-5D-5L SF-12 PU-QoL-P was developed and validated during this study PU-QoL-UI	EQ-5D-5L, PU-QoL-UI, SF-12 and PU-QoL-P (or proxy questionnaire pack) were completed weekly to day 30, then fortnightly to day 60 Between April 2014 and October 2015, a revised schedule was used with randomised allocation to a set of questionnaires (EQ-5D-5L/PU-QoL-UI or the SF-12/PU-QoL-P) at weeks 1 (visit 2) and 3 (visit 6) only. From November 2015 to November 2016, the PU-QoL-P questionnaire was omitted and the remaining questionnaires (EQ-5D-5L, PU-QoL-UI and SF-12 or proxy questionnaire pack) were reinstated for all participants at weeks 1 and 3	The primary end point was the time to development of a Stage ≥ 2 PU	Low

continued

TABLE 4 Summary of included studies, systematic review 2 (*continued*)

Study ID	Study details, including study design	Countries of conduct	Interventions being assessed	Eligibility criteria	Participant details at baseline, incl. comorbidities and PU details	Number of participants randomised	HRQoL (or utility) measure used	Time points assessed	Complete wound healing or wound incidence outcomes reported	ROB assessment
				Consented to take part [written, informed consent/witnessed verbal consent/consultee agreement or nearest relative/ guardian/welfare attorney (in Scotland)] Was expected to comply with the follow-up schedule Was on an electric profiling bed frame Patients were excluded if: they had previously participated in the PRESSURE 2 trial; they had a current or previous PU of stage ≥ 3; they had a planned admission to an intensive care unit where standard care was APM provision; they were unable to receive the intervention (e.g. slept at night in a chair or was unable to transfer to randomised mattress); they weighed less or more than mattress weight limits (< 45 kg or > 180 kg); it was ethically inappropriate to approach them					

TABLE 4 Summary of included studies, systematic review 2 (*continued*)

Study ID	Study details, including study design	Countries of conduct	Interventions being assessed	Eligibility criteria	Participant details at baseline, incl. comorbidities and PU details	Number of participants randomised	HRQoL (or utility) measure used	Time points assessed	Complete wound healing or wound incidence outcomes reported	ROB assessment
Stern[52]	Treatment trial investigating PU healing 17-month study period Stepped wedge (cluster) trial	Canada	Pressure ulcer multidisciplinary teams (MDT) via Telemedicine Group 1: standard care Group 2: MDT teams (not clear if in addition to standard care)	Facilities were eligible and approached for the study if they had a minimum of 100 beds, were within 100 km from the hospital the expert wound team, had a PU prevalence greater than the provincial average (5.5%, based on data collected from long-term care facilities in Ontario by the Canadian Institute of Health Research in 2009), and the facility administrator provided consent Residents in consenting long-term care facilities were eligible if they had a reported PU (stage 2 or greater) and provided informed consent. Their legal representative was approached for consent if the resident was deemed incapable by the most responsible clinician	Mean age (SD): Group 1: 81 (12) Group 2: 83 (12) Sex (% f/m): Group 1: 64/36 Group 2: 69/31 Pressure ulcer grade: Not reported Comorbidities % with following: Alzheimer's Dementia Group 1: 56.7 Group 2: 66.0 Diabetes Group 1: 32.8 Group 2: 38.3 Stroke/TIA Group 1: 29.9 Group 2: 30.9 Paraplegia/ hemiplegia Group 1: 16.4 Group 2: 16.0	Twelve centres in total Group 1: Standard care = 67 Participants* Group 2: MDT = 94 Participants * *42 participants crossed study phases, extending from control to intervention, that is double-counted Some participants had > 1 ulcer; multilevel modelling took into account different levels of clustering (at participant and organisational level) Not clear if clustering of data was considered in time to event models	EQ-5D (*version not reported*)	Baseline and noted that *'PUs were followed until healed or until the end of the study period, which came first'* Specific time points not mentioned.	The primary outcome was rate of reduction in PU surface area (cm^2/day) Relevant secondary outcomes were: time to complete healing (days), percentage of wounds healed; PU incidence, and PU prevalence, utility (EQ-5D), and cost-effectiveness	High

ASIA, American Spinal Injury Association; VAS, visual analogue scale.

Risk-of-bias assessment

The risk of bias for each included study was assessed, where appropriate based on ulcer outcome data. Summary risk-of-bias assessments are presented in *Appendix 5*. Two studies were considered to be at low risk of bias[50,51,53–55] and one study[52] was considered to be at high risk of bias.

Key findings on the impact of pressure ulceration on health-related quality of life over time when measured using validated tools

All three studies presented EQ-5D data using the index score/utilities (*Table 5*). Limited HRQoL/utilities data were available for Stern *et al.*[52] and, although extracted and presented in *Table 5*, these are not considered further.

All participants in Arora *et al.*[53–55] living in India or Bangladesh had PUs secondary to spinal cord injury and many had SPUs. The mean index EQ-5D scores at baseline in both groups were similar, as would be expected, and were negative values – implying a health state valued as being worse than dead. In contrast, the VAS score, which reflects the response to a question about your health today, was at the mid-point of around 50 where 0 = the worst health you can imagine and 100 the best health you can imagine.

Compared with the study by Arora *et al.*, baseline EQ-5D index scores were notably higher in the PRESSURE 2 study by Nixon *et al.*, in which people at risk of ulceration were recruited in the UK (although 6.2% of participants had a PU at baseline); a minority had spinal cord injury, perhaps explaining the difference in average baseline index scores. In this study, the mean EQ-5D score was 0.34 at baseline. For comparison, UK EQ-5D data from over 6000 people were reported in 1999, with the mean EQ-5D score in the 75+ years group being 0.78 (SD 0.26).[58] Baseline scores measured using the PU-QoL-UI were 0.69. To contextualise this mean score, since the PU-QoL-UI is a new measure, in previous validation work with 100 UK residents (of which 50% were wheelchair users) with one or more PUs the mean PU-QoL-UI index score was 0.70 (SD 0.18 n = 84), implying a similar baseline value in this group at risk of ulceration.

There were modest differences in the ulcer-related outcomes between intervention and comparator groups in the studies by Arora *et al.* and Nixon *et al.* Although health utility scores generally improved, it is not clear the extent to which this was related to changes in PU status.

Nixon *et al.* embedded a validation study for a newly developed variant of a disease-specific HRQoL measure (the PU-QoL-P) for those at risk of ulceration, rather than with current ulceration only. The measure was tested in 617 of the 1029 total trial participants and data were not presented by group. Rather, the validation work focused on comparing scores on the PU-QoL-P with scores on the SF-12 measure, also not presented in any detail. The only change data presented are for a small number of participants who had an ulcer at baseline that had healed by 30 days and who reported PU-QoL-P scores (approximately 30 people, slightly different for each reported domain) and an even smaller number (about 10 participants) who were ulcer free at baseline but who had ulcers at the 30-day follow-up point. The participants were selected and the findings, reported without reference to group allocation, do not control for changes in other factors over time (albeit 30 days is a short time).

Summary of main findings

We reviewed RCTs of interventions to treat or prevent PUs to minimise the risk of confounding of HRQoL measures by the multiple and serious comorbidities that people with PUs typically have. (Previous studies have tried to match both people with and without PUs to investigate the independent impact of pressure ulceration on HRQoL.[59])

Only 3 of more than 300 RCTs we identified (< 1%) measured HRQoL using a validated instrument. Unfortunately, these three RCTs found no differences in PU outcomes between intervention and comparator groups, precluding attribution of HRQoL changes to changes in PU status.

It has been reported that EQ-5D-3L, SF-12 (used to calculate the SF-6D)[60] and disease-specific measure PU-QoL-UI (see *Chapter 7 of Nixon et al.*)[56] can effectively capture the independent impact of PUs on HRQoL. One or more of these measures need to be included in RCTs of PU treatment and prevention to validate this claim.

TABLE 5 Summary of HRQoL data and ulcer outcomes in included studies

Outcome	Arora (2017)[51–53]		Nixon (2019)[48 49]		Stern (2014)[50]	
HRQoL Scores Mean (SD)	***n* = 58**	***n* = 57**	***n* = not reported**	***n* = not reported**	***n* = 67**	***n* = 94**
EQ-5D[a] baseline	−0.47 (0.29)	−0.52 (0.21)	0.34 (0.22)	0.34 (0.23)	Limited data Paper reports that 'Mean utilities were estimated to be 0.03 (−0.029, 0.088)' units lower during the intervention period than during the control period	
EQ-5D[a] follow up	*12 weeks* −0.39 (0.38)	*12 weeks* −0.37 (0.36)	*30 days* 0.52 (0.21)	*30 days* 0.52 (0.21)		
EQ-5D-VAS baseline	52.5 (18.4)	52.8 (15.4)	–	–		
EQ-5D-VAS follow-up	*12 weeks* 62.8 (19.2)	*12 weeks* 73.1 (16.4)	–	–		
PU-QoL-UL baseline	–	–	0.60 (0.16)	0.60 (0.16)	–	–
PU-QoL-UL follow-up	–	–	*30 days* 0.69 (0.13)	*30 days* 0.69 (0.13)	–	–
Ulcer healing	*n* = 58	*n* = 57	*N* = 1016	*N* = 1013		
Ulcer status at baseline	All participants had ulcer at baseline Group 1: Stage 2 = 22% Stage 3 = 75% Stage 4 = 3% Mean (SD) area cm^2 12.5 (13.2) cm^2	All participants had ulcer at baseline Group 2 Stage 2 = 37% Stage 3 = 63% Stage 4 = 0% Mean (SD) area cm^2 9.2 (11.6) cm^2	Participants with ulcer stage 2 or higher = 70 (6.9%)	Participants with ulcer stage 2 or higher = 75 (7.4%)	All participants had PUs at baseline; stage not reported	All participants had PUs at baseline; stage not reported
Ulcer status at follow-up	*12 weeks* The paper reports ulcer area as its primary outcome (described in the paper as ulcer size) The mean between-group difference in ulcer size was 2.3 cm^2 (95% CI − 0.3 to 4.9 favouring the intervention group); *p*-value 0.08 No reported data on number of healed ulcers		*30 days* The HR for time to ulcer healing in the intervention group relative to the control group was 1.12 (95% CI 0.74 to 1.68); *p*-value = 0.612		The HR for time to ulcer healing in the intervention group relative to the control group was 1.48 (95% CI 0.79 to 2.78); *p*-value = 0.22 (calculated from adjusted proportional hazards model)	
Ulcer incidence at follow-up	–	–	*30 days* The HR for time to ulcer development in the intervention group compared with the control group was 0.76, (95% CI 0.56 to 1.04); *p*-value 0.089		–	–

a EQ-5D-5L was used by Aurora *et al.* and Nixon *et al.* Stern *et al.* did not specify a version; the date of publication implies this would have been the EQ-5D-3L. Nixon *et al.* used the English value set. Arora *et al.* used the crosswalk method to map 5L responses to the 3L version. Stern *et al.* did not specify a method for deriving scores.

Chapter 5 Surveys of the views of health professionals about surgical reconstruction to close a severe pressure ulcer

Methods

Survey design

We surveyed three groups of health professionals: nurses, surgeons and GPs. Participants were asked to describe the characteristics of patients in the UK currently being referred for a surgical opinion about SR, variation in the operations and postoperative care currently being provided and variation in usual care provided before initiation of a surgical referral.

Three different surveys were designed for the different professional groups, including questions relevant to their roles in the care pathway of patients with SPUs. At the outset, respondents were asked 'Do you provide treatment for and/or inform treatment decisions for patients specifically for their pressure ulcers (PUs)?' If the answer was no, the survey was closed and no further responses were collected or analysed; respondents exiting the survey in this way were not considered to have initiated the survey. Nurses were specifically asked about the care they provide to patients with SPUs, their ability to refer these patients to secondary care, specifically, to a surgeon, and how they make referral decisions. Surgeons were asked about the operations they perform, barriers and facilitators that drive individual decisions to operate, institutional capacity for surgery in this patient population, and their personal views about SR for SPUs. GPs were asked about their knowledge of SR as a management option for patients with SPUs, referrals to secondary care for other treatments for SPUs (including SR), and factors which may influence their decisions to make a referral or not.

The nurses' and surgeons' surveys included 22 and 30 questions, respectively: demography (4 and 5 questions, respectively), SR and other treatments recommended to PU patients (5 and 10 questions, respectively), referrals, including the likelihood of referral for SR based on certain SPU and patient characteristics (6 and 5 questions, respectively), recurrence (3 questions, both surveys), barriers to SR (2 questions, both surveys), one question (both surveys) about any other information respondents feel is relevant to the survey, and one question (both surveys) about participating in future research related to SR of SPU. The primary care survey included 11 questions: demography (4 questions); PU referrals to other services (6 questions); and SR (1 question).

Open-ended questions (free-text comment boxes) were included to allow clinicians to highlight factors not addressed by the closed-ended questions and allow them to elaborate on the reasons for their responses to the closed-ended questions. Questions on the referral pathway were included because there is currently no standard referral pathway for SR of SPU in the UK. The surveys were created in SurveyMonkey® (Palo Alto, CA, USA), and then piloted online by three nurses and two surgeons. The GP survey was not piloted.

Recruitment of participants

Participants were recruited through professional organisations and contacts of SIPS team members by disseminating weblinks to the surveys. Surgeons were approached through professional bodies: the British Association of Plastic, Reconstructive and Anaesthetic Surgeons (BAPRAS); and the British Orthopaedic Association. Nurses were contacted through: Tissue Viability Nurses Together (TVN2gether); the Tissue Viability Society; the Royal College of Nursing District Nurses Forum; and the Queen's Nursing Institute. The SIPS team also used social media to distribute the weblinks to the survey to orthopaedic and plastic specialties that had been observed to perform SR in preliminary analyses of anonymised HES data set.[10] We could not target subgroups within organisations that were involved in the management of SPUs. However, when potential respondents opened the weblink, the first page of each survey (see *Report Supplementary Material 2-4*) explained what the survey was about and almost all respondents demonstrated their involvement in managing PUs/SPUs.

Primary care clinicians were invited through a range of primary care organisations. We asked the following to circulate the URL for the primary care survey to their members: Royal College of General Practitioners; NIHR School for Primary Care Research; Pulse Today (a website for UK GPs); Primary Care Dermatology Society; CRN West of England; Centre for Academic Primary Care, Bristol.

Data collection

The surveys went live in June 2020 and were kept open for 4 months, until September 2020. There was regular communication between SIPS team members and the above professional organisations to increase participation.

Data analysis

Quantitative data

The data analysis tools in SurveyMonkey and Microsoft Excel (Microsoft, Redmond, WA, USA) were used to calculate descriptive statistics. For each question, we calculated the percentage of respondents selecting each response option using the total number of responses for that question as the denominator.

Qualitative data

Free-text responses from nurses and surgeons were analysed using qualitative methods. Free-text responses were transferred from SurveyMonkey to Excel and then imported into QSR NVivo (QSR International, Warrington, UK) after removing any identifiable information. Separate files were created for nurses' and surgeons' responses. Auto-analysis was carried out using the software-created nodes for each open-ended question and grouped all responses under each node.

Analysis was both deductive (applying predetermined themes and identifying text that fitted into those themes) and inductive (developing the themes as the data set was analysed). Data from the nurses' and surgeons' surveys were analysed separately in the first instance. For the deductive analysis, we identified and discussed preliminary themes for potential coding through an iterative process, where we read the data and familiarised ourselves with it, shared our notes and produced relevant themes based on these interactions as a team.

For the inductive analysis, thematic categories were created to capture the topics raised by responders. Data were compared and contrasted within and across thematic categories and across the two data sets. Thematic categories which were shared across the nurse and surgeon data sets were then merged. As the analysis developed, thematic categories were either combined or split into further categories. Once these were established and coded, free-text responses were assigned to their relevant themes.

Two thematic maps (one for each overarching theme) were then constructed outlining the subthemes leading to their corresponding overarching theme. Multiple versions were tested, discussed and reviewed to guarantee the validity of the final thematic maps.

Results

Survey participants

The survey was initiated by 59 respondents from primary care, 146 nurses and 45 surgeons. Of these, 44 GPs (75%) 104 nurses (71%) and 26 surgeons (9%) completed all 11, 22 and 30 questions, respectively, in the survey; the rest completed only part of the survey. *Table 6* shows demographic data of GPs, nurses and surgeons who took the survey.

In the primary care survey, most respondents (76%) were GPs, but a proportion (23%) were nurses. Most respondents (74.5%) had practised for over 5 years.

Of the nurse respondents, most worked in hospitals (60%) or the community (55%). Thirty-six (25%) nurses worked in more than one setting, with 30 (21%) working in both hospital and the community. The majority (93%) were trained in wound care.

TABLE 6 Demographic details of survey participants

	Primary care participants		Nurse participants		Surgeon participants	
Participants' characteristics	***N* = 59**	**%**	***N* = 146**	**%**	***N* = 45**	**%**
Region where employed	***N* = 47**		***N* = 137**		***N* = 39**	
East of England	1	2	15	11	3	8
London	4	9	17	12	3	8
Midlands	3	6	12	9	5	13
North East England and Yorkshire	10	21	21	15	7	18
North West England	1	2	29	21	3	8
South East England	6	13	13	9	4	10
South West England	16	34	16	12	7	18
Scotland	3	6	3	2	4	10
Wales	2	4	2	1	0	0
Northern Ireland	1	2	7	5	0	0
Outside the UK	0	0	4	3	3	8
Role/health setting/specialty	***N* = 47**		***N* = 137**		***N* = 43**	
GP	34	72				
GP registrar	2	4				
Advanced nurse practitioner	2	4				
Other[a]	9	19				
Hospital nurse[b]			82	60		
Community nurse[b]			75	55		
Care home nurse[b]			17	12		
GP practice nurse[b]			13	9		
Other nurse role[b,c]			10	7		
Role/health setting/specialty	***N* = 47**		***N* = 137**		***N* = 43**	
Plastic surgeon					34	79
General surgeon					2	5
Spinal rehabilitation surgeon/physician					2	5
Orthopaedic surgeon/neurosurgeon					0	0
Other[d]					5	12
Years treating PUs/performing SR	***N* = 47**		***N* = 135**		***N* = 31**	
<5 years	12	26	17	13	15	48
≥5 years	35	74				
5–10 years			33	24	3	10
11–15 years			31	23	4	13
>15 years			54	40	9	29

TABLE 6 Demographic details of survey participants (*continued*)

Participants' characteristics	Primary care participants		Nurse participants		Surgeon participants	
	N = 59	%	*N* = 146	%	*N* = 45	%
Clinical contact/experience/surgical grade			***N* = 135**		***N* = 43**	
Trained in wound care			128	93		
Not trained in wound care			9	7		
Consultant					35	81
Associate specialist					2	5
Clinical academic					2	5
Other[e]					4	9

a Other primary care roles: hospital and community nurse; district nurse; clinical nurse advisor.
b Nurse health settings: multiple responses were allowed.
c Other nurse roles/health settings: TVN; hospital and community; district; mental health trust; clinical nurse advisor.
d Other surgeon specialties: gynaecological oncology surgeon; vascular surgeon; district nursing advanced assistant, intern.
e Other surgical grade: postcertificate of completion of training fellow; registrar; retired; district nursing advanced assistant.

Most surgeon respondents were plastic surgeons (79%) and in consultant roles (81%). None worked in Scotland or Northern Ireland, but some (10%) worked in Wales. About two-thirds (62%) had practised for 5 years or more and just under 50% had < 5 years' experience of SR to close SPUs.

Pressure ulcer referral and treatment

Primary care

Table 7 shows responses to the survey questions related to PU referral and treatment by the primary care respondents (*n* = 59). Over half the respondents stated that they were not aware of SR as a treatment option (54%). A similar proportion (57%) had never referred patients to secondary care for a surgical opinion. (Note that these questions were asked independently, so we presume that those who answered 'no' to the first question also answered 'no' to the second question.) Of those who had never made a referral (*n* = 31), about half stated that they had not had a patient who they felt needed SR (52%) and about a quarter stated that they had not had a patient who they felt was suitable for SR (23%). Just under half (48%) referred patients with a SPU to secondary care for reasons other than a surgical opinion.

Of those who reported making referrals to secondary care specifically for a surgical opinion, half referred less than once a year and half did so at least once a year. Most respondents who made a referral (> 80%) did so based on clinical indications or at the request of a community nurse or TVN. Under half (40%) did so at the request of the patient or a carer.

Most respondents (> 70%) stated that they would refer patients regardless of patient characteristics such as age, multimorbidity, and permanent wheelchair use, but just under half (47%) stated that they would not refer if a patient lacked a post-discharge support network. About a fifth of respondents across all characteristic categories were unsure about whether to refer or not based on patients' characteristics.

Nurses

Table 8 shows responses to the survey questions related to SPU referral and treatment by the nurse respondents (*n* = 146). Most nurses (79%) had treated more than 10 patients with a PU in the last 12 months and just under a quarter (24%) had treated more than 50. Almost three-quarters of nurses (72%) reported that they had considered surgery as a treatment option for a SPU and most (81%) had referred a patient for a surgical opinion in the previous year. Over half (54%) believed that SR to treat a SPU should be more widely available.

TABLE 7 Responses to the survey questions related to SPU referral and treatment by the primary care respondents[a]

Survey question	*N* (%) endorsing different response categories		
Are you aware that SR is a potential treatment for SPUs (n = 56)			
Yes	26 (46%)		
No	30 (54%)		
Have you ever made a referral to secondary care for patients specifically for a surgical opinion of their SPU? (n = 54)			
Yes	22 (39%)		
No	32 (57%)		
Please select the reasons why you have never referred a patient to secondary care for a surgical opinion on their PU[b] (n = 31)			
SR for SPU not available in my area	3 (10%)		
I do not think SR is a good treatment option for SPU	2 (6.5%)		
I have not had a patient who I think is suitable for SR	7 (23%)		
I have never had a patient who I thought required SR	16 (52%)		
I refer patients to secondary care for other reasons related to their PU, but not for surgical opinion	15 (48%)		
I'm not sure if I have referred a patient to secondary care for a surgical opinion on their SPU	3 (10%)		
None of the options are applicable	2 (6.5%)		
How often do you make a referral to secondary care for patients specifically for a surgical opinion of their SPU? (n = 22)			
Never	0 (0%)		
Less than once per year	11 (50%)		
Once per year	2 (9%)		
Twice or more per year	9 (41%)		
How likely are you to be influenced by the following factors when deciding to refer a patient to secondary care, specifically for treatment of their SPU? (n = 20)	**Unlikely**	**Neither likely nor unlikely**	**Likely**
Clinical indications	0	1 (5%)	19 (95%)
Request of community nursing team	1 (5%)	3 (15%)	16 (80%)
Request of TVN	1 (5%)	0 (0%)	19 (95%)
Request of patient	1 (5%)	11 (55%)	8 (40%)
Request of patient's relatives or carers	2 (10%)	10 (50%)	8 (40%)
Please select whether you would refer a patient with the following characteristics to secondary care, specifically for treatment of their SPU? (n = 17)	**Would refer**	**Would not refer**	**Not sure**
< 60 years of age	15 (88%)	1 (6%)	1 (6%)
60 years of age or older	13 (77%)	1 (6%)	3 (18%)
Multimorbidity (diabetes, cardiovascular disease, heart failure, etc.)	12 (71%)	2 (12%)	3 (18%)
Permanent wheelchair user	13 (77%)	1 (6%)	3 (18%)
Bedbound for reasons other than SPU	10 (59%)	2 (12%)	5 (29%)
Patient lacks post-discharge support network (e.g. family, care home)	8 (47%)	2 (12%)	7 (41%)

a Fifty-nine primary care respondents answered one or more of these questions.
b Respondents could endorse multiple response categories.

Most nurses sometimes, often or always requested a referral for a surgical opinion to initiate a multidisciplinary team (MDT) meeting to discuss how to treat a patient's SPU (88%) and have the SPU debrided (88%), rather than have the SPU surgically reconstructed (60%). Most nurse respondents recommended a variety of additional treatments regardless of whether a patient had surgery or not.

Surgeons

Table 9 shows responses to the survey questions related to SPU referral and treatment by the surgeon respondents (n = 45). Surgeons reported that referral for surgery did not result in SR for most patients. Just under two-fifths (39%) had not offered SR to any patient referred to them. Over half (52%) offered SR to less than half of all patients referred to them. Less than 1 in 10 reported performing SR in more than half of all patients referred to them. However, over two-thirds of respondents (68%) believed that SR for SPUs should be more widely available.

Over half of all referrals (59%) were hospital-based (internal ward, external tertiary referral, spinal unit, intensive care unit), with few (13%) being referred from primary care or the community.

Over a third of respondents (34.5%) had performed SR of multiple SPUs during the same operation and the most common type of surgery reported to be performed was 'flap' surgery, with very few performing primary wound closure, tissue expansion or skin graft surgery. Most respondents (80%) reported that the average length of postoperative stay after SR was between 1 week and 3 months, with over half (52%) reporting the stay to be between 1 week and 1 month. Most respondents (72%) reported complete healing of the reconstructed wound in half or more of their patients. Most also reported that recurrence of the same SPU was low; over three-quarters (76%) reported recurrence in less than half of all their patients.

Most respondents offered a variety of other treatments/care packages in addition to or instead of surgery, the most frequently reported being specialised low-pressure mattresses, education and repositioning, dressings, antibiotics, negative pressure wound therapy, detailed rehabilitation plan and a comprehensive social care package.

Other healthcare professionals reported to be involved in making recommendations for treatment included other clinicians (consultants from non-surgical specialties, surgeons/non-surgeons below consultant level), specialists (e.g. TVNs, consultant nurse practitioners) and non-specialists (e.g. staff nurses) and other healthcare professionals (e.g. occupational therapist, physiotherapist).

Patient and pressure ulcer indications for surgery

Nurses and surgeons were asked about factors (relating to the patient and to the PU) which prompt referral for SR (*Table 10*). Generally, there was good agreement between nurses and surgeons across most factors.

Over two-thirds of nurses and surgeons reported they would refer patients under 60 years of age, and fewer (50% of nurses and 33% of surgeons) would refer patients over 60 years old. Less than one-fifth (20% or less) would refer patients with multimorbidity, who are malnourished or frail, or have multiple SPUs.

About half of all respondents (49% of nurses and 52% of surgeons) reported they would refer patients with spinal cord injury for SR. Between a fifth and a half of respondents (22–53%) reported they would also refer people with mobility issues (permanent wheelchair users or those bedbound for other reasons). Only about a quarter of respondents (31% of nurses and 22% of surgeons) would refer patients with a long-term condition (e.g. stroke or multiple sclerosis) and very few (7% of nurses and 4% of surgeons) would refer patients with life-limiting illness (e.g. advanced cancer).

With regards to social factors, patient motivation and support networks, about three-quarters of respondents (between 70% and 81%) would refer patients who are motivated and considered able and willing to adhere to SPU care strategies, but most would not refer (21% of nurses and 4% of surgeons) if they felt that patients lacked post-discharge support.

TABLE 8 Responses to the survey questions related to SPU referral and treatment by the nurse respondents[a]

Survey question	*N* (%) endorsing different response categories			
Number of patients with SPU (grade 3, 4 or unstageable) treated specifically for their SPU in the last 12 months (respondents: n = 135)				
None	3 (2.2%)			
Fewer than 10 people	25 (18.5%)			
10–30 people	45 (33.3%)			
31–50 people	30 (22.2%)			
More than 50 people	32 (23.7%)			
Would you consider surgery as a potential treatment option for SPU? (respondents: n = 134)				
Yes	97 (72.4%)			
No	7 (5.2%)			
Not sure	30 (22.4%)			
Number of patients referred for a surgical opinion of their SPU in previous 12 months (respondents: n = 134)				
None	26 (19.4%)			
1–10	90 (67.2%)			
11–30	15 (11.2%)			
31–50	2 (1.5%)			
> 50	1 (0.7%)			
Should SR be more widely available? (respondents: n = 127)				
Yes	69 (54.3%)			
No	10 (7.9%)			
Not sure	48 (37.8%)			
Estimated percentage of people with a recurrence of the same SPU(s) that was operated on within 12 months of healing (respondents: n = 109)				
< 20%	32 (29%)			
25–50%	29 (27%)			
51–75%	11 (10%)			
> 75%	3 (3%)			
Not sure	34 (31%)			
Secondary care services that patients were referred to specifically for SPU treatment in previous 12 months[b] (respondents: n = 106)	**Never or rarely**	**Sometimes**	**Often or always**	**Not sure**
Accident and emergency	56 (53%)	31 (29%)	12 (11%)	7 (7%)
Spinal care unit	66 (62%)	27 (26%)	8 (8%)	5 (5%)
General surgery	49 (46%)	35 (33%)	20 (19%)	2 (2%)
Plastic surgery	15 (14%)	47 (44%)	44 (42%)	0 (0%)
Orthopaedic surgery	49 (46%)	39 (37%)	17 (16%)	1 (1%)
Vascular surgery	48 (45%)	30 (28%)	27 (26%)	1 (1%)

TABLE 8 Responses to the survey questions related to SPU referral and treatment by the nurse respondents (*continued*)

Survey question	*N* (%) endorsing different response categories			
If a patient requires a surgical opinion on their SPU, do you (respondents: n = 103)	**Never or rarely**	**Sometimes**	**Often or always**	**Not applicable**
Make a nurse referral directly from community to secondary care?	49 (48%)	10 (10%)	14 (11%)	30 (29%)
Make a nurse referral directly from primary to secondary care?	48 (47%)	9 (9%)	13 (8%)	33 (32%)
Request the patient's GP to refer patient to secondary care?	21 (20%)	15 (15%)	40 (39%)	27 (26%)
Within secondary care, directly request a surgical opinion?	33 (32%)	21 (21%)	28 (27%)	21 (20%)
Within secondary care, advise a clinician to request a surgical opinion?	18 (18%)	29 (28%)	38 (37%)	18 (18%)
Typically, when requesting or advising a request for a surgical opinion on a PU, is your intention to (respondents: n = 103)	**Never or rarely**	**Sometimes**	**Often or always**	**Not applicable**
Have a multidisciplinary discussion on how to treat the patient's SPU?	10 (10%)	32 (31%)	59 (57%)	2 (2%)
Have the SPU debrided?	13 (13%)	43 (42%)	47 (46%)	0
Have the SPU surgically reconstructed?	41 (40%)	43 (42%)	19 (18%)	0
Treatments recommended in addition to or instead of surgery (respondents: n = 110)	**For patients who have not had SR**	**For patients who have received SR**	**I never provide/recommend this treatment**	
Topical debridement (e.g. gels, chemical dressings, maggots)	108 (98%)	55 (50%)	2 (2%)	
Mechanical debridement on the ward	90 (82%)	43 (39%)	20 (18%)	
Mechanical debridement in hospital	80 (73%)	48 (44%)	27 (25%)	
NPWT	102 (93%)	82 (75%)	4 (4%)	
Education on repositioning	108 (98%)	97 (88%)	0	
Bed rest	97 (88%)	86 (78%)	10 (9%)	
Use of a specialised low-pressure mattress	107 (93%)	92 (84%)	3 (3%)	
Dressings	109 (99%)	93 (85%)	0	
Antibiotics	94 (85.5%)	82 (75%)	12 (11%)	
Topical treatments not for debridement	98 (89%)	81 (74%)	9 (8%)	
Counselling/psychology	71 (65%)	68 (62%)	33 (30%)	
Physiotherapy	94 (85.5%)	87 (79%)	13 (12%)	
Dietary advice	107 (97%)	95 (86%)	1 (1%)	
Comprehensive social care package	98 (89%)	86 (78%)	10 (9%)	

NPWT, negative pressure wound therapy.
a One hundred and forty-six nurse respondents answered one or more of these questions.
b Respondents could endorse multiple response categories.
c Other secondary care services used for referral (information obtained from free text comments): orthotics; diabetic foot clinic; podiatry; dermatology; infectious diseases; dietetics, physiotherapy.

TABLE 9 Responses to the survey questions related to SPU referral and treatment by the surgeon participants[a]

Survey question	*N* (%) endorsing different response categories		
In the last 12 months, in what proportion of patients referred to you for a consultation on their SPU did you perform reconstructive surgery? (respondents: n = 31)			
None	12 (38.7%)		
< 25%	8 (25.8%)		
25–50%	8 (25.8%)		
51–75%	1 (3.2%)		
> 75%	2 (6.5%)		
All	0 (0.0%)		
Do you ever perform reconstruction of multiple pressure ulcers at the same time during one operation? (respondents: n = 29)			
Yes	10 (34.5%)		
No	19 (65.5%)		
Should surgery for SPUs be more widely available? (respondents: n = 31)			
Yes	21 (67.7%)		
No	2 (6.5%)		
Not sure	8 (25.8%)		
Changes to the service that delivers SR for SPUs in the past decade in your unit (e.g. number of referrals, facilities improving or being taken away, local expertise, or the type of patients being referred) (respondents: n = 22)			
Yes	11 (50.0%)		
No	11 (50.0%)		
Which of the following types of referrals do you receive specifically for treatment of patients with a SPU?[b] (respondents: n = 31)	**Never or rarely**	**Sometimes**	**Often or always**
Hospital (internal ward referrals)	6 (19%)	17 (55%)	8 (26%)
Hospital (external 'tertiary' referral)	16 (52%)	12 (39%)	3 (10%)
Secondary care spinal unit	17 (55%)	9 (29%)	5 (16%)
Intensive care unit	20 (65%)	9 (29%)	2 (7%)
Primary care GP	16 (52%)	12 (20%)	3 (10%)
District nurse	21 (68%)	9 (29%)	1 (3%)
Other	24 (77%)	5 (16%)	2 (6%)
In the last 2 years, how often have you performed the following types of SR to close SPUs?[b] (respondents: n = 29)	**Never or rarely**	**Sometimes**	**Often or always**
Primary wound closure	27 (93%)	2 (7%)	0 (0%)
Skin grafts	29 (100%)	0 (0%)	0 (0%)
Local random flaps	24 (83%)	4 (14%)	1 (3%)
Regional flaps (muscle of musculocutaneous flaps)	17 (59%)	8 (28%)	4 (14%)
Regional flaps (perforator flaps)	19 (66%)	6 (21%)	4 (14%)
Free flaps	28 (97%)	1 (3%)	0 (0%)
Tissue expansion	29 (100%)	0 (0%)	0 (0%)

TABLE 9 Responses to the survey questions related to SPU referral and treatment by the surgeon participants (*continued*)

Survey question	*N* (%) endorsing different response categories				
Other[c]	28 (97%)	0 (0%)		1 (3%)	
Which of the following treatments do you recommend for your patients in addition to, or instead of, SR?[b] (respondents: n = 28)	**Never or rarely**	**Sometimes**		**Often or always**	
Topical debridement (e.g. gels, chemical containing dressings, maggots)	11 (39%)	19 (68%)		6 (21%)	
Mechanical debridement (e.g. cutting away parts of the wound)	18 (64%)	21 (75%)		0 (0%)	
Bed rest	16 (57%)	9 (32%)		9 (32%)	
Specialised low-pressure mattress	24 (86%)	16 (57%)		0 (0%)	
NPWT	21 (75%)	18 (64%)		1 (4%)	
Education and repositioning	24 (86%)	18 (64%)		1 (4%)	
Dressings	22 (79%)	20 (71%)		0 (0%)	
Antibiotics	20 (71%)	12 (43%)		4 (14%)	
Topical treatments not for debridement	12 (43%)	10 (36%)		13 (46%)	
Comprehensive social care package	20 (71%)	14 (50%)		3 (11%)	
Regular MDT input	22 (79%)	14 (50%)		3 (11%)	
Detailed rehabilitation plan	22 (79%)	16 (57%)		3 (11%)	
Counselling/psychology	14 (50%)	11 (39%)		11 (39%)	
Physiotherapy	19 (68%)	13 (46%)		6 (21%)	
Dietary advice	24 (86%)	17 (61%)		1 (4%)	
Who else at your hospital makes recommendations for treatments and/or management strategies for patients referred for SR to close a SPU?[b] (respondents: n = 28)	**Never or rarely**	**Sometimes**	**Often or always**	**Not sure**	**No such role**
Consultants from non-surgical specialty	11 (39%)	10 (36%)	4 (15%)	2 (7%)	1 (4%)
Surgeons below consultant level	10 (36%)	14 (50%)	2 (7%)	1 (4%)	1 (4%)
Clinicians below consultant level who are non-surgical	15 (54%)	8 (29%)	1 (4%)	3 (11%)	1 (4%)
TVN	3 (11%)	9 (32%)	16 (21%)	0 (0%)	0 (0%)
Specialist nurse (e.g. consultant nurse practitioner)	4 (14%)	9 (32%)	10 (36%)	1 (4%)	4 (14%)
Senior staff nurse	10 (36%)	12 (43%)	3 (11%)	3 (11%)	0 (0%)
Staff nurse	11 (39%)	11 (39%)	3 (11%)	3 (11%)	0 (0%)
Change nurse	11 (39%)	11 (39%)	3 (11%)	3 (11%)	0 (0%)
Matron	14 (50%)	8 (29%)	1 (4%)	5 (18%)	0 (0%)
Ward manager	18 (64%)	4 (14%)	1(4%)	4 (14%)	1 (4%)
Occupational therapist	8 (29%)	9 (32%)	5 (18%)	6 (21%)	0 (0%)
Physiotherapist	9 (32%)	8 (29%)	5 (18%)	6 (21%)	0 (0%)
Psychologist	17 (61%)	3 (11%)	0 (0%)	7 (25%)	1 (4%)

continued

TABLE 9 Responses to the survey questions related to SPU referral and treatment by the surgeon participants (*continued*)

Survey question	*N* (%) endorsing different response categories
Estimated average length of postoperative hospital stay in your unit specifically for recovery from SR to close a SPU (respondents: n = 25)	
< 1 week	0 (0%)
1 week–1 month	13 (52%)
> 1 month–3 months	7 (28%)
> 3 months–6 months	1 (4%)
> 6 months	1 (4%)
Not sure	3 (12%)
Estimated percentage of people who have had from SR to close a SPU who will have complete healing of their reconstructed wound within 6 months of surgery	
< 20%	1 (4%)
20–50%	3 (12%)
51–75%	9 (36%)
> 75%	9 (36%)
Not sure	3 (12%)
Estimated percentage of people who have had SR to close a SPU and have a recurrence of the same PU(s) that was operated on within 12 months of healing (n = 25)	
< 20%	10 (40%)
20–50%	9 (36%)
51–75%	1 (4%)
> 75%	0 (0%)
Not sure	5 (20%)

a Forty-nine surgeon respondents answered one or more of these questions.
b Respondents could endorse multiple response categories.
c Examples of other types of surgical procedures: distant flaps, for example vertical rectus abdominis myocutaneous (VRAM) and perforator flaps readvanced (in recurrent PUs).

TABLE 10 Patient and PU characteristics in relation to likelihood of SR: surgeons' and nurses' surveys

How likely you are to consider patients with the following characteristics as suitable for PU reconstructive surgery (assuming that the patient has been judged 'safe' for general anaesthesia)? Surgeons (n = 27), nurses (n = 122)				
	Unlikely	**Neither likely nor unlikely**	**Likely**	**Not applicable**
< 18 years of age				
Surgeons	4 (15%)	5 (18.5%)	18 (67%)	–
Nurses	20 (16%)	17 (14%)	80 (66%)	5 (4%)
18–60 years				
Surgeons	2 (7%)	7 (26%)	18 (67%)	–
Nurses	8 (7%)	20 (12%)	93 (76%)	1 (1%)
> 60 years				
Surgeons	8 (30%)	10 (37%)	9 (33%)	–
Nurses	20 (16%)	41 (34%)	60 (49%)	1 (1%)

TABLE 10 Patient and PU characteristics in relation to likelihood of SR: surgeons' and nurses' surveys (*continued*)

How likely you are to consider patients with the following characteristics as suitable for PU reconstructive surgery (assuming that the patient has been judged 'safe' for general anaesthesia)? Surgeons (n = 27), nurses (n = 122)				
	Unlikely	**Neither likely nor unlikely**	**Likely**	**Not applicable**
Multimorbidity (e.g. diabetes, cardiovascular disease, heart failure, etc.)				
Surgeons	16 (59%)	8 (30%)	3 (11%)	–
Nurses	64 (52.5%)	33 (27%)	25 (20%)	0
Patient has multiple PUs				
Surgeons	14 (52%)	8 (30%)	3 (11%)	–
Malnourished/frail				
Surgeons	22 (81%)	2 (7%)	3 (11%)	–
Nurses	90 (74%)	21 (17%)	11 (2%)	0
Permanent wheelchair user				
Surgeons	3 (11%)	15 (56%)	9 (33%)	–
Nurses	22 (18%)	35 (29%)	65 (53%)	1 (1%)
Bed bound for reasons other than PU				
Surgeons	11 (41%)	10 (37%)	6 (22%)	–
Nurses	46 (38%)	42 (34%)	33 (27%)	1 (1%)
Long-term condition (e.g. stroke, multiple sclerosis)				
Surgeons	9 (33%)	12 (44%)	2 (22%)	–
Nurses	44 (36%)	39 (32%)	38 (31%)	1 (1%)
Spinal cord injury				
Surgeons	4 (15%)	9 (33%)	14 (52%)	–
Nurses	15 (12%)	45 (37%)	60 (49%)	2 (2%)
Temporary cause of PU (e.g. recent surgery/fracture/trauma)				
Surgeons	14 (52%)	4 (15%)	9 (33%)	–
Nurses	25 (20%)	24 (20%)	73 (60%)	0
How likely you are to consider patients with the following characteristics as suitable for PU reconstructive surgery (assuming that the patient has been judged 'safe' for general anaesthesia)? Surgeons (n = 27), nurses (n = 122)				
	Unlikely	**Neither likely nor unlikely**	**Likely**	**Not applicable**
Life-limiting illness (e.g. motor neurone disease, terminal cancer)				
Surgeons	21 (78%)	5 (18.5%)	1 (4%)	–
Nurses	80 (66%)	33 (27%)	7 (6%)	1 (1%)
Patient considered able and willing to adhere to recommended SPU care strategies				
Surgeons	4 (15%)	4 (15%)	19 (70%)	–
Nurses	12 (10%)	19 (16%)	90 (74%)	1 (1%)
Patient motivated				
Surgeons	2 (7%)	3 (11%)	22 (81%)	–
Nurses	4 (5%)	19 (16%)	96 (79%)	1 (1%)

continued

TABLE 10 Patient and PU characteristics in relation to likelihood of SR: surgeons' and nurses' surveys (*continued*)

How likely you are to consider patients with the following characteristics as suitable for PU reconstructive surgery (assuming that the patient has been judged 'safe' for general anaesthesia)? Surgeons (n = 27), nurses (n = 122)				
	Unlikely	**Neither likely nor unlikely**	**Likely**	**Not applicable**
Patient lacks post-discharge support network (e.g. family or care home)				
Surgeons	13 (48%)	13 (48%)	1 (4%)	–
Nurses	39 (32%)	56 (46%)	26 (21%)	1 (1%)
To what extent do the following patient characteristics predict whether a patient with a healed SPU following SR will have recurrence of the same PU? n = 22 (surgeons) n = 105 (nurses)				
	A little or not at all		**A lot**	**Not sure**
Patient considered able and willing to adhere torecommended PU care strategies				
Surgeons	8 (36%)		14 (64%)	0
Nurses	31 (29.5%)		71 (68%)	3 (3%)
Age				
Surgeons	11 (50%)		10 (45.5%)	1 (5%)
Nurses	44 (42%)		57 (54%)	4 (4%)
Gender				
Surgeons	18 (82%)		1 (5%)	3 (14%)
Nurses	79 (75%)		9 (9%)	17 (16%)
Body mass index				
Surgeons	8 (36%)		14 (64%)	0
Nurses	25 (24%)		76 (72%)	4 (4%)
Primary reason for PU				
Surgeons	3 (14%)		19 (86%)	0
Nurses	19 (18%)		82 (78%)	4 (4%)
Degree of immobility				
Surgeons	5 (23%)		17 (77%)	0
Nurses	12 (11%)		90 (86%)	3 (3%)
To what extent do the following patient characteristics predict whether a patient with a healed SPU following SR will have recurrence of the same PU? n = 22 (surgeons) n = 105 (nurses)				
	A little or not at all		**A lot**	**Not sure**
Mental health				
Surgeons	6 (27%)		15 (68%)	1 (5%)
Nurses	19 (18%)		82 (78%)	9 (4%)
Smoking status				
Surgeons	6 (27%)		16 (73%)	0
Nurses	21 (20%)		79 (75%)	5 (5%)
Family/friends support network				
Surgeons	8 (36%)		14 (64%)	0
Nurses	27 (26%)		74 (70%)	4 (4%)

TABLE 10 Patient and PU characteristics in relation to likelihood of SR: surgeons' and nurses' surveys (*continued*)

How likely you are to consider patients with the following characteristics as suitable for PU reconstructive surgery (assuming that the patient has been judged 'safe' for general anaesthesia)? Surgeons (n = 27), nurses (n = 122)				
	Unlikely	**Neither likely nor unlikely**	**Likely**	**Not applicable**
Deterioration of general health				
Surgeons	3 (14%)		19 (86%)	0
Nurses	6 (6%)		96 (91%)	3 (3%)
Unresolved risk factors (e.g. poor nutritional status, poor diabetic control)				
Surgeons	1 (5%)		20 (91%)	1 (5%)
Nurses	7 (7%)		94 (89.5%)	4 (4%)
How likely you are to offer reconstructive surgery to a patient with the following pressure ulcer characteristics? n = 25 (surgeons) n = 120 (nurses)				
	Unlikely	**Neither likely nor unlikely**	**Likely**	**Not applicable**
Grade 2 PU				
Surgeons	23 (92%)	1 (4%)	1 (4%)	–
Nurses	110 (92%)	6 (5%)	3 (2.5%)	1 (1%)
Grade 3 PU				
Surgeons	10 (40%)	6 (24%)	9 (36%)	–
Nurses	53 (44%)	29 (24%)	37 (31%)	1 (1%)
Grade 4 PU				
Surgeons	3 (12%)	4 (16%)	18 (72%)	–
Nurses	9 (7.5%)	25 (20%)	85 (71%)	1 (1%)
Unstageable PU				
Surgeons	8 (32%)	6 (24%)	11 (44%)	–
Nurses	36 (30)	45 (37.5%)	38 (32%)	1 (1%)
PU on sacral area				
Surgeons	5 (12%)	8 (32%)	12 (48%)	–
Nurses	19 (16%)	39 (32.5%)	60 (50%)	2 (2%)
Osteomyelitis				
Surgeons	7 (28%)	4 (16%)	14 (56%)	–
Nurses	39 (32.5%)	31 (26%)	49 (41%)	1 (1%)
Delayed healing				
Surgeons	7 (28%)	10 (40%)	8 (32%)	–
Nurses	26 (22%)	28 (23%)	65 (54%)	1 (1%)
How likely you are to offer reconstructive surgery to a patient with the following pressure ulcer characteristics? n = 25 (surgeons) n = 120 (nurses)				
	Unlikely	**Neither likely nor unlikely**	**Likely**	**Not applicable**
Wound infection				
Surgeons	13 (52%)	7 (28%)	5 (20%)	–
Nurses	54 (32.5%)	37 (31%)	28 (23%)	1 (1%)

continued

TABLE 10 Patient and PU characteristics in relation to likelihood of SR: surgeons' and nurses' surveys (*continued*)

How likely you are to consider patients with the following characteristics as suitable for PU reconstructive surgery (assuming that the patient has been judged 'safe' for general anaesthesia)? Surgeons (n = 27), nurses (n = 122)				
	Unlikely	**Neither likely nor unlikely**	**Likely**	**Not applicable**
PU is causing sepsis				
Surgeons	11 (44%)	4 (16%)	10 (40%)	–
Nurses	38 (32%)	28 (23%)	53 (44%)	1 (1%)
PU had previous SR				
Surgeons	6 (24%)	12 (48%)	6 (28%)	–
Nurses	34 (28%)	38 (32%)	46 (38%)	2 (2%)
To what extent do the following PU factors predict whether a patient with a healed SPU following SR will have recurrence of the same PU? n = 22 (surgeons) n = 104 (nurses)				
	A little or not at all		**A lot**	**Not sure**
Poor skin quality				
Surgeons	3 (14%)		19 (86%)	0
Nurses	10 (9%)		92 (88.5%)	1 (2%)
Loss of muscle mass				
Surgeons	3 (14%)		19 (86%)	0
Nurses	14 (13.5%)		87 (84%)	3 (3%)
Bone deformity				
Surgeons	4 (18%)		17 (77%)	1 (5%)
Nurses	12 (11.5%)		93 (89%)	3 (3%)
Recurrent wound infection				
Surgeons	5 (23%)		17 (77%)	0
Nurses	5 (5%)		97 (93%)	2 (2%)
Sepsis				
Surgeons	5 (23%)		16 (73%)	1 (5%)
Nurses	13 (12.5%)		88 (85%)	3 (3%)
Fragile scar				
Surgeons	4 (18%)		18 (82%)	0
Nurses	13 (12.5%)		89 (86%)	2 (2%)
Osteomyelitis				
Surgeons	7 (32%)		13 (59%)	2 (9%)
Nurses	10 (10%)		91 (87.5%)	3 (3%)
Recurrent pressure				
Surgeons	1 (5%)		21 (95%)	0
Nurses	5 (5%)		97 (93%)	2 (2%)

For most of the factors listed above, about a quarter to one-half of nurses and surgeons were undecided regarding referral for surgery, reporting that they were neither likely nor unlikely to refer. There were few areas of disagreement between nurses and surgeons. However, nurses and surgeons disagreed about the referral/offering SR for a temporary cause of SPU (e.g. recent surgery, fracture or trauma); more nurses reported that they would refer than surgeons would offer SR (60% nurses vs. 33% surgeons) and more surgeons responded that they would not offer SR than nurses would not refer (52% surgeons vs. 20% nurses).

Respondents were also asked about the extent to which patient factors predict whether a patient with a healed SPU following SR will have a recurrence of the same SPU. Over two-thirds of surgeon and nurse respondents (between 64% and 91%) agreed that patient adherence to SPU care, family/friends support network, body mass index, primary reason for SPU, degree of immobility, smoking status, mental health, deterioration of general health and unresolved risk factors such as poor diabetic control influence the risk of recurrence 'a lot'. Age was considered an important factor for recurrence by only half of surgeons and nurse respondents, while gender was considered unimportant by most (> 75%) respondents.

The only PU factor that over two-thirds of respondents said would prompt referral for surgery was stage 4 SPU (72% of surgeons and 71% of nurses). For most of the other factors (stage 3 or unstageable SPU, SPU on sacral area, presence of osteomyelitis, delayed healing, sepsis due to SPU and SPU which had a previous SR), between one-third to one-half of all surgeon and nurse respondents stated that these would likely prompt referral for surgery. Wound infection was likely to prompt referral by less than one-quarter of respondents (20% of surgeons and 23% of nurses). The only factors that respondents stated were unlikely to prompt referral for surgery were grade 2 PUs (92% of surgeons and 92% of nurses stated they were unlikely to refer).

Respondents were asked about the extent to which SPU factors predict whether a patient with a healed SPU following surgery will have a recurrence of the same SPU. Three-quarters or more (73–95%) responded that poor skin quality, loss of muscle mass, bone deformity, recurrent wound infection, sepsis, fragile scar and recurrent pressure were likely to result in recurrence. For osteomyelitis, 88% of nurses but only 59% of surgeons stated that it was likely to predict recurrence.

Barriers to surgical reconstruction

Table 11 shows the main barriers to SR that surgeons and nurses experience in the workplace. For surgeons, the main barriers to performing SR were the need to prioritise other types of surgery (86% of respondents), suitability of patients for SR (77% of respondents), belief in the efficacy of SR (73% of respondents), concern regarding SPU recurrence (73% of respondents) and bed capacity (72% of respondents).

Factors that were less likely to be perceived as a barrier by surgeons were the availability of tissue viability expertise in the unit, the surgical experience of nursing staff, objections from other specialties in the MDT and the respondent's own surgical experience (66%, 55%, 55% and 50% of respondents, respectively, did not regard these factors as barriers to surgery).

For nurses, the main barriers to SR were the suitability of patients for surgery (92% of respondents), the willingness of primary care physicians to refer patients for SR (83% of respondents), the willingness of surgeons in their region to perform SR (82% of respondents), surgical experience available in the region (72%) and concern regarding recurrence (70% of respondents).

Fewer respondents thought the following factors were a barrier to surgery: bed capacity (50% of respondents), concerns about length of hospital stay (47% of respondents) and their own willingness to recommend patients for surgery (45% of respondents).

Free-text responses

The analysis of free-text responses was conducted for the nurses' and surgeons' surveys only. The primary care survey generated only 25 free-text comments and the majority of these related to GPs' lack of awareness of SR as a potential treatment for SPUs and their lack of involvement in treating SPUs.

TABLE 11 Perceived barriers to SR in the workplace

For each factor listed below, please indicate the extent to which it is a barrier to SR for SPUs in your main workplace	Not at all	Somewhat	A lot	Not sure
Surgeons n = 22				
Your own surgical experience	11 (50%)	9 (41%)	2 (9%)	0
The experience of performing SR for PUs among your colleagues	7 (32%)	14 (64%)	1 (5%)	0
Your own belief in the efficacy of SR	7 (32%)	9 (41%)	6 (27%)	0
The belief in the efficacy of SR among your colleagues	5 (23%)	13 (59%)	3 (14%)	1 (5%)
Bed capacity	5 (23%)	8 (36%)	8 (36%)	1 (5%)
Prioritisation of other types of surgery	3 (14%)	9 (41%)	10 (45%)	0
Availability of tissue viability expertise in your unit	15 (66%)	6 (27%)	0	1 (5%)
General nursing capacity in your unit	7 (32%)	9 (41%)	5 (23%)	1 (5%)
Surgical experience of nursing staff in your unit	12 (55%)	6 (27%)	3 (14%)	1 (5%)
Suitable patients for surgery	4 (18%)	13 (59%)	4 (18%)	1 (5%)
A lack of referrals for PU surgery	7 (32%)	13 (59%)	1 (5%)	1 (5%)
Your own concern regarding PU recurrence	6 (27%)	12 (55%)	4 (18%)	0
Your own concern regarding length of postoperative hospital stay	8 (36%)	13 (59%)	1 (5%)	0
Objection from other specialties on MDT	12 (55%)	7 (32%)	2 (9%)	1 (5%)
Other	9 (41%)	3 (14%)	2 (9%)	8 (36%)
Nurses n = 104				
Surgical experience available in your region (*n* = 100)	21 (21%)	22 (22%)	50 (50%)	7 (7%)
Your own willingness to recommend patients for surgery (*n* = 100)	45 (45%)	26 (26%)	19 (19%)	10 (10%)
The willingness of primary care physicians to refer patients for SR (*n* = 91)	10 (11%)	26 (29%)	48 (53%)	7 (8%)
The willingness of surgeons in your region to perform SR (*n* = 99)	9 (9%)	22 (22%)	59 (60%)	9 (9%)
Suitable patients for surgery (*n* = 101)	3 (3%)	25 (25%)	68 (67%)	5 (5%)
Your own concern regarding recurrence (*n* = 100)	25 (25%)	40 (40%)	30 (30%)	5 (5%)
Your own concern regarding length of hospital stay (*n* = 99)	47 (47.5%)	30 (30%)	17 (17%)	5 (5%)
Your own concern regarding post discharge care (*n* = 101)	27 (27%)	42 (42%)	27 (27%)	5 (5%)
Bed capacity (*n* = 100)	42 (40%)	25 (25%)	25 (25%)	8 (8%)
Prioritisation of other types of surgery (*n* = 101)	27 (27%)	33 (33%)	34 (34%)	7 (7%)
Objection from other specialties on MDT (*n* = 101)	29 (29%)	34 (34%)	29 (29%)	9 (9%)

Sixteen out of 22 questions in the nurses' survey and 22 of 30 questions in the surgeons' survey had open-ended, free-text comment boxes; *Appendix 6*, *Tables 33* and *34* show the total number of nurses and surgeons who submitted closed and open-ended responses for each question.

In the nurses' survey, the questions which elicited the maximum number of free-text responses asked about the characteristics of patients and SPUs that would cause them to recommend referral to a surgeon to consider SR to close the SPU (73 responses), factors which are barriers to referral for SR,[58] and whether SR should be more widely available.[42] In the surgeons' survey, the questions which elicited the maximum number of free-text comments asked

about factors which impact the decision not to consider SR (16 responses), changes to service delivery,[10] whether SR should be more widely available[8] and whether they perform SR to treat multiple SPUs at the same time.[7]

A total of 99 nurses (72%) and 24 surgeons (56%) submitted at least one free-text response, generating a total of 361 and 88 comments, respectively. Most responses related to factors influencing nurse respondents' decisions to refer or not refer patients to secondary care and factors shaping surgeons' decision-making about whether SR was appropriate.

Most free-text responses were about factors facilitating or impeding patient access to specialist assessment and treatment of SPU, including SR, (pathway factors) and reasons why SR would/would not be an appropriate option for individual patients (patient factors). Responses suggested that clinicians did not see SR as an appropriate choice for all SPU patients and, for those who might be deemed good candidates for SR, the availability of SR was affected by the lack of smooth and quick access from primary and community care teams to secondary care specialist teams. *Figures 3* and *4* show the two overarching themes and their corresponding subthemes.

Factors influencing patients' access to surgical reconstruction–care pathway issues

Respondents commented on many factors that influence a patient's access to secondary care specialists and appropriate treatment, including SR. These factors were felt to affect access to SR, through decision-making about whether SR is a viable choice, referral to specialist teams for assessment, or offering patients SR. A total of 49 nurse and 10 surgeon free-text responses reflected these issues.

Most comments highlighted the current lack of care pathways linking both community and primary care teams to secondary and tertiary specialists or their fractured nature, and the lack of awareness about PU services and treatments by referring clinicians. These factors all have the potential to hinder patients' access to specialist assessment and treatment, including SR. Of the free-text responses surrounding these issues, 13 were provided by nurses and 3 by surgeons (*Table 12*).

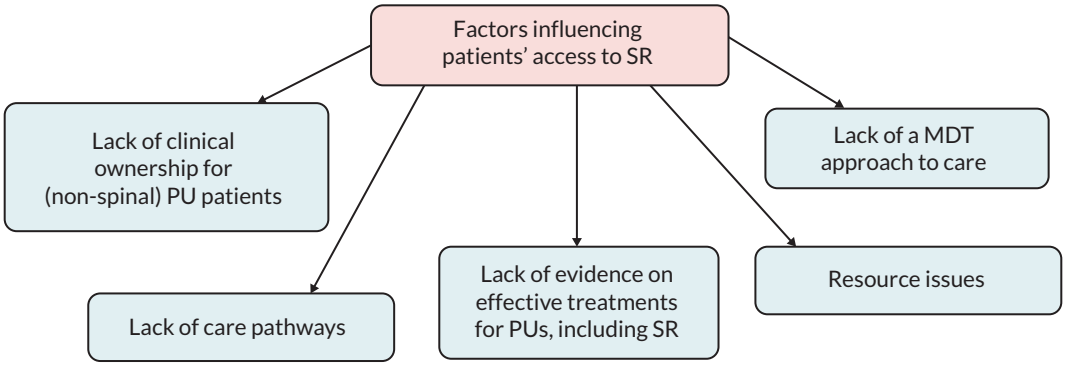


FIGURE 3 Thematic map of pathway factors elicited from open-ended responses.

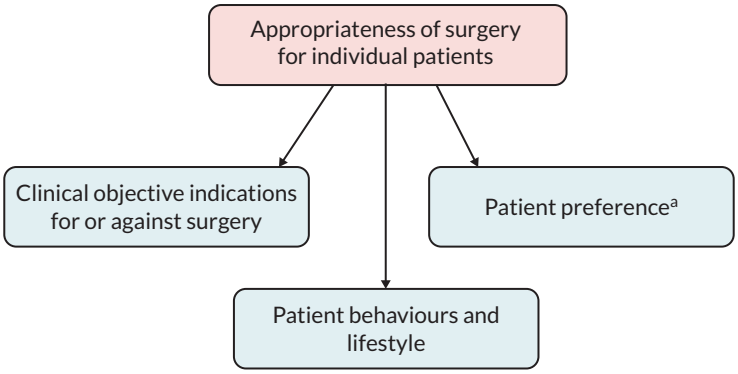


FIGURE 4 Thematic map of patient factors elicited from open-ended responses. a, Preferences include: unwilling to travel out of their area for SR, does not want to have surgery, fear of hospitals due to risk of infection.

TABLE 12 Free-text comments relating to care pathways

Barriers to referral for SR: Lack of care pathways
'Hospital consultants will not accept nurse referrals due to commissioning. We have sometimes linked in with known specialist nurses within secondary care if the patient is already known e.g. *spinal services'.* – #11765183799, community nurse
'I do not have the pathways in my local area to recommend this'. – #11709629803, community nurse
'Unable to refer directly to a surgical team'. – #11701581762, hospital nurse
'… whether the patient can actually be referred to a specialist unit – capacity, politics, funding, willingness of a specialist unit to accept the patient …' – #11698484840, TVN
'There is only 1 regional spinal unit who will consider accepting patients who have neurological conditions for SR. This is the go to unit for me. Plastics are rarely interested, other spinal units only accept their own spinal patients. It's very difficult for non spinal injury pressure ulcer patients'. – #11700949280, community nurse
'… there [needs to] *be designated pathways with services having the infrastructure to provide the care'.* – #11699991020, hospital nurse
'Often get asked by GP if I can make the referral – at present this is not possible. Often discuss referrals and work with the specialist teams such as plastics outreach teams'. – #11698933955, nurse working in the community, GP practice, care home and hospital
'Due to the administration procedure for referring a patient from community to surgeon – has to "go via" a GP. On the wards referrals also tend to be recommended by TVN but then Dr to Dr referral. TVNs cannot refer directly'. – #11698484840, TVN
'Patients have to be referred by GP to the local hospital system first rather than directly to spinal injury unit. If they don't have spinal injury process is even more complicated'. – #11698484840, TVN
'I have made many calls to other services across the UK. Practice varies so much depending on the willingness of reconstruction teams. I strongly feel that we should map out services and promote these as often many services are not aware what Plastics has to offer'. – #11699991020, hospital nurse
'Some patients are willing to travel out of the region for a surgical assessment. If would be good if we knew which surgeons from other areas we could refer to'. – #11698523484, community nurse
'… I think there needs to be greater awareness of what can be achieved as often the referring clinician has little understanding of the complexity of surgery'. – #11699991020, hospital nurse
'… They [burns patients] are admitted by other services with sepsis other develop them [PUs] *in hospital, at which point I am involved. It is poorly coordinated, and inefficient, but there is little hospital will do to change this'.* – #11702260536, plastic surgeon
Facilitators to referral for SR
'We get surgical referrals at quite a refined stage of the patient's management thanks to the input of the PUPIS team who basically take care of all the peripheral issues concerned with PU management which are crucial to successful surgery. When they get to see a plastic surgeon, they are almost always appropriately prepared for surgical intervention, which makes my job very easy'. – #11643405223, plastic surgeon from Wales
'The numbers that require surgery have dropped dramatically with the advent of a formal PUPIS pressure ulcer team with specialist nurse and rehabilitation engineer heading the team'. – #11600320252, plastic surgeon from Wales
'We have access to a Plastic Surgery out-reach Sister with whom we can discuss cases and refer via'. – #11701091357, community nurse

Most responses referred to different aspects of the care pathway as a major blocker of patients' journeys from community nurse-led care teams to specialist assessment and treatment of PUs. The issues included identifying where and how to access secondary care services from primary care or community nurse-led teams, the GP being a gatekeeper to secondary care, and navigating the system to access specialist teams for their clinical assessment.

Nurses based in community and GP practices pointed out the absence of a referral pathway connecting primary/community nurse-led care teams to secondary care services which made it problematic for them to refer these patients to these services. Multiple respondents highlighted that, even if a patient was referred, the referral was seldom accepted by secondary care consultants, with one reason being commissioning protocols, for example: '*hospital consultants will not accept nurse referrals due to commissioning*'. Respondents also referred to patients belonging to many different services, owing to the array of primary conditions and other comorbidities they have, arguably making it difficult for an unobstructed journey from one specialty to the next without an agreed clinical pathway put in place.

Two comments from the surgeons' survey, regarding the 'PUPIS team', related to facilitators in the referral pathway. The Pressure Ulcer Prevention and Intervention Service (PUPIS) in South Wales was the subject of the only mention of a standard referral pathway and was highly praised. Advantages of the PUPIS service include managing patients so that they are '*almost always appropriately prepared for surgical intervention …*' and how team members '*take care of all the peripheral issues concerned with SPU management which are crucial to successful surgery*'.

Respondents also highlighted issues surrounding clinicians' knowledge of existing services patients can be referred to, which points towards the current lack of care pathways in PU management. A lack of knowledge of where and how to refer these patients impacts patients' access to specialist assessment and appropriate treatment of their PU, including

SR. '*Mapping out*' of services was suggested by one respondent, which could be a solution to make clinicians more aware of what services are available to which these patients can be referred.

Lack of a multidisciplinary team approach to care

Respondents' comments highlighted the lack of a MDT approach to patient assessment, including the absence of a holistic post-treatment care plan and postsurgical resources. An important theme identified from the free-text responses was the need for a MDT-focused approach to assessment and treatment, including postsurgery care. A total of 13 nurse and 1 surgeon free-text responses reflected these issues (*Table 13*). A lack of postsurgical care was also mentioned as a barrier to SR, including '*rehab facilities*' and '*postdischarge support in the home and from hospital teams*'. Moreover, some respondents commented on inadequate cross-disciplinary and cross-sector communication as a factor impacting patients' journeys to specialist assessment and SR.

Another message identified from the nurses' responses was that there were substantial difficulties encountered in accessing psychological services. Moreover, one surgeon reported that a lack of knowledge among TVNs had resulted in giving the wrong advice.

Lack of clinical ownership of (non-spinal) pressure ulcer patients

An issue made apparent from the free-text responses was that there is no single specialty that has overall responsibility for PU patients, resulting in a lack of 'clinical ownership'. A total of 12 nurses' and 1 surgeon's comments reflect this subtheme (see *Appendix 7*, *Table 35*: Free-text comments from surveys). Respondents commented on surgeons often being '*reluctant to operate*' and that '*no one wants to accept overall responsibility for these patients*'. Responses also reported differences in the care pathway between patients for whom there was established service provision, such those with spinal injury, and other patients. A comment from a community nurse highlighted this specific point: '*There is only 1 regional spinal unit who will consider accepting patients who have neurological conditions for SR. This is the go-to unit for me. Plastics are rarely interested, other spinal units only accept their own spinal patients. It's very difficult for non-spinal injury pressure ulcer patients*'.

Lack of evidence on effective treatment for pressure ulcers, including surgical reconstruction

Some surgeons' unwillingness to offer SR is due to the current lack of evidence and clinical guidelines surrounding the treatment of PUs. Respondents commented on the benefits of SR for PUs being currently unknown and the need for

TABLE 13 Free-text comments relating to the lack of a MDT approach to care

'*… An MDT would have to be held with GP, patient, family/care providers and community nursing teams. As the procedure isn't without risks each patient needs to be fit for surgery and have suitable care input and pressure relief once at home*'. – #11765183799, community nurse
'*I work within an acute hospital trust. If we receive a referral for a PU, never managed within an MDT approach due to the referral system set up/lack of this specific MDT service approach*'. – #11722026134, hospital nurse
'*Needs an MDT approach with a lot of community support. Only places I see this is spinal centres*'. – #11722026134, hospital nurse
'*… I feel it is a post code lottery in the UK with the approach to a co-ordinated MDT. Often patients bounce between services before they get to us. If you are co-located within a spinal service the approach is much superior*'. – #11699991020, hospital nurse
'*The UK should have designated MDT teams with pathways of referrals similar to the Specialist commissioning service of burns where the clear direction of pt travel is clearly mapped. Centre level care for those units than can provide the full MDT and recon approach*'. – #11699991020, hospital nurse
'*If the service design has the full MDT approach the more likely that surgery will be offered. Surgery is 1 aspect of recon care, the aftercare is as important …*' – #11699991020, hospital nurse
'*… The use of SR to close a pressure ulcer may be helpful but does not undermine the need for continued pressure area care and a holistic approach to the care plan*'. – #11721774241, community and hospital nurse
'*… post discharge support in the home and from hospital teams*'. – #11701091357, community nurse
'*I think Rehab facilities play a part – surgeons do not seem to mind doing the surgery, but need the patient to move to other units for ongoing care*'. – #11702231208, nurse working in the community, GP practice, care home and hospital
'*Communication is not easy between care settings and practitioners*'. – #11701091357, community nurse
'*I feel a major issue is communication across all the different health environments. Time in communication*'. – #11698734120, nurse working in the community, GP practice and hospital
'*Limited access to psychologist/counselling*'. – #11698535032, community and hospital nurse
'*… psychological support* [not being] *available before and after surgery*'. – #11718260867, community and hospital nurse
'*Knowledge amongst TV nurses of risk of mobilising and sitting with PUs amongst the paralysed population. Many patients say that the District Nurses and often TVN would advise to continue mobilising and sit on their PUs which leads to further deterioration of the PUs and lead to osteomyelitis and much more complex PUs*'. – #12019512940, spinal rehabilitation surgeon/physician

guidelines and criteria to support clinicians in their decision-making. It was also reported in the surgeons' survey that the lack of clinical guidelines has allowed clinicians to '*shy away*' from SR. Comments of a total of eight nurses and one surgeon reflect this subtheme (see *Appendix 7*, *Table 36*: Free-text comments from surveys).

Resource issues

Other issues highlighted in both surveys related to a lack of tangible and intangible resources (see *Appendix 7*, *Table 37*: Free-text comments from surveys) affecting patients' access to SR, including the need to refer 'out of area'. A total of three nurse and four surgeon comments reflected this issue. The lack of resources incorporated inadequate bed capacity and postsurgical rehabilitation facilities and other services, which prevented referral locally (tangible), and local expertise including limited clinician knowledge and experience in managing and operating on these wounds (intangible). It was mentioned that these issues with resources can result in time delays, which also has an impact on patients' access to SR.

Appropriateness of surgical reconstruction for individual patients (patient factors)

One message made clear from the respondents was that SR is not appropriate for everyone. In their opinion, the overarching requirement is for a patient-centred approach to decision-making: treatment needs to reflect the needs and circumstances of patients, and patients need to agree that a specific treatment is what they need/prefer. A patient-centred approach to decision-making was highlighted in free-text comments by 29 nurses and 3 surgeons.

Overall, 13 nurse and 2 surgeon comments related to factors that indicated greater or lesser appropriateness of SR (objective clinical indications; see *Appendix 7*, *Table 38*: Free-text comments from surveys). These were broadly consistent with the findings from the closed-ended responses, for example if a patient has significant comorbidities, is frail, or has an infection risk (especially osteomyelitis), then treatment decisions would be more likely to be conservative. In terms of infection, specifically osteomyelitis, respondents commented that they would treat the infection first and then reassess the patient.

Nurse respondents commented on patients' treatment preferences being an important factor. This was not mentioned by surgeon respondents but was subsequently confirmed to be critical. Responses highlighted that some patients fear hospitals and the risks they believe are associated with them (such as infections), deterring them from specialist assessment and treatment. In this context, the potential need to travel a long distance to access care could determine whether a patient chooses to have SR. A total of seven nurse comments were about patients' preferences (see *Appendix 7*, *Table 39*: Free-text comments from surveys).

Patient behaviours and lifestyle

A further important issue highlighted by respondents is that people who develop PUs and those with recurring PUs already have behavioural risk factors which are likely to make them inappropriate candidates for SR in the first place. Respondents commented that a patient's likely adherence to pre- and postoperative protocols affects the decision of whether SR is an appropriate treatment. One surgeon highlighted the importance, stating that '[good] *compliance has sometimes resulted in over a decade of non-recurrence*'. It was also mentioned that asking patients to change their lifestyle to prevent recurrence is '*a massive ask*'. Comments by a total of nine nurses and one surgeon reflected this subtheme (see *Appendix 7*, *Table 40*: Free-text comments from surveys).

Comments about the survey questions

There were nine comments (six from nurses and three from surgeons) about specific survey questions (see *Appendix 7*, *Table 41*: Free-text comments from surveys). Three nurses' comments related to the question asking about what treatments they provide, answering that this question is '*confusing*' and '*ambiguous*'. Two comments were made about the likelihood of referral based on certain patient characteristics, stating '*it's difficult to comment on some of these generic situations …*' and '*this is not an easy question to answer …*'. One surgeon described the question asking about who makes recommendations for treatment strategies for patients that have been referred for SR as a '*poor question*'. The question regarding the likelihood of offering SR to a patient with certain PU characteristics was said to be '*too open*' due to having to consider combinations of too many characteristics.

Summary of findings

The main findings from the surveys can be summarised as follows:

- Referral from primary care for a surgical opinion is uncommon, either due to a lack of awareness of SR as a treatment option or because patients were considered to be unsuitable for SR.
- Most nurse respondents referred patients for a surgical opinion.
- The absence of an established referral pathway and MDTs for patients referred for a surgical opinion are key barriers to access to SR.
- There is good agreement among nurses and surgeons about the characteristics of patients and SPUs that affect suitability of SR to close a SPU.

Chapter 6 Binary choice experiment to explore interactions between characteristics of patients and pus in relation to appropriateness for surgical reconstruction

Methods

Design of binary choice experiment

Survey questions about the effect of the characteristics of patients and PUs on the likelihood of considering SR only asked about single variables. Free-text comments stressed that decisions are multifactorial, so we decided to carry out an additional survey, that is a BCE[61,62] The BCE explored whether respondents' views about how a patient or PU characteristic influences a decision to consider SR changes when information about other characteristics is varied (i.e. an interaction between characteristics).

A BCE is a special type of survey that asks respondents to make binary decisions from hypothetical but realistic scenarios describing a limited number of pieces of information (*Figure 5*). It is a subset of discrete choice experiments. In this case, participants had to decide whether SR should be considered for a particular patient. The decision was labelled as 'yes' or 'no' but can be considered to represent a choice between SR and conservative treatment without SR. The information provided in a scenario described several characteristics of the patient and the PU. The information about each characteristic was varied systematically to create many scenarios with different permutations of information about the characteristics being studied.

The design of the BCE required:

- a definition of SR
- specification of the characteristics to be investigated (factors) and variations in each factor (attributes) to be permuted in scenarios
- sampling the permutations of factors and their attributes in a systematic way to allow the univariable and multivariable effects of factors to be estimated.

Surgical reconstruction was defined as described previously. Factors and attributes are shown in *Table 14*.

With respect to making decisions, participants were advised as follows:

'*You need to interpret the phrase "should be considered" [for SR] in the context of the setting in which you work. Depending on your professional role this may mean:*

- *referring to or seeking advice from a colleague*
- *formally referring someone (or recommending a referral)*
- *offering surgical reconstruction.*

When responding, please consider what you believe to be the appropriate professional decision, rather than what is possible in existing care pathways in your care setting or what is feasible at present'.

The factors that were included in the design were chosen for one of two reasons:

* You are reviewing a *37-year-old man* with a pressure ulcer over *the sacrum*. The ulcer is classified as *category 3* and has been present for *over 18 months*. He has *had previous surgery to reconstruct a PU*. There are local skin/muscle options available for reconstruction; *the skin/muscle is scarred or inflamed*. The care team has *tried all available non-surgical treatment options*.[a] The patient has *full independent mobility*.[b] He is *frail*.[c] He has *one or more comorbidities*.[d] From your consultation, you believe he is *very likely* to be able to adhere[e] to ulcer prevention measures required after surgery.

Summary of patient and pressure ulcer characteristics

Age	37 years
Sex	Male
Location of PU	Sacrum
Pressure ulcer category	Category 3
Duration of ulcer at this severity	Over 18 months
Previous surgical reconstruction to treat a pressure ulcer	Yes
Quality of skin/muscle options for reconstruction	Scarred or inflamed
Available non-surgical treatment options[a]	All tried
Independent mobility[b]	Full
Frail[c]	Yes
Comorbidity[d]	Yes
Ability to adhere to ulcer prevention measures required after surgery[e]	Very likely

[a]Dressings, pressure relieving surfaces, repositioning, negative pressure wound therapy, debridement, etc.

[b]None: unable to move from one place to another without help from another person; limited: can move around using an assistive device/wheelchair; fully able to move unaided either by walking or independent use of a wheelchair (self-propelled or powered).

[c]Interpret this term as you would usually do in the context of the care you provide.

[d]One or more comorbidity, for example cardiovascular, respiratory, renal or diabetes. However, please assume that the patient's health can be improved before surgery so that they are'nt for surgery' from anaesthetic and surgical points of view.

[e]Please consider 'adhere' to include physical ability, motivation and available support from family, friends and carers.

FIGURE 5 Example of scenario presented in the BCE.

1. A similar factor had been included in the original surveys but the results were uncertain or discrepant between nurses and surgeons with respect to the influence of the factor on suitability for SR: PU stage; previous SR to close a PU; mobility (although asked less directly by several questions in the original surveys); frailty; comorbidity; ability to adhere to PU prevention measures after surgery.
2. The factor had been identified as potentially important during discussions in the SSG after the original surveys had closed: duration of the PU at the specified severity; quality of skin/muscle for reconstruction; and whether non-surgical treatment options had been attempted.

The STATA® dcreate command (STATA v16.1; STATA Corp, College Station, TX, USA) was used to create an efficient design for the BCE, thereby maximising 'the D-efficiency of the design based on the covariance matrix of the conditional logit model' (help documentation for the dcreate command). The design included 32 scenarios, which were randomised into two blocks of 16 scenarios each. Half the participants were assigned to one set of 16 scenarios and the other half to the other 16. We anticipated that participants would take up to an hour to make decisions for 16 scenarios. The order of presentation of the scenarios for a participant was random to avoid any order effect. Team members piloted the online survey to ensure that it functioned as intended.

TABLE 14 Factors and attributes included in the BCE

Factor	Attributes
Age[a]	46 years, or
	55 years, or
	64 years, or
	73 years
Sex[a]	Female, or
	Male
Location of pressure ulcer[a]	Sacrum, or
	Ischium
Pressure ulcer stage	Stage 3, or
	Stage 4
Duration of ulcer at this severity	< 6 months, or
	6–18 months, or
	> 18 months
Previous SR to treat a pressure ulcer	Yes, or
	No
Quality of skin/muscle options for reconstruction	Not scarred or inflamed, or
	scarred or inflamed
Attempted non-surgical treatment options[b]	Not all tried, or
	All tried
Independent mobility[c]	None, or
	Limited, or
	Full
Frail[d]	Yes, or
	No
Comorbidity[e]	Yes, or
	No
Ability to adhere to PU prevention measures required after surgery[f]	Very likely, or
	Likely, or
	Unsure

a These factors were included to make the scenarios more realistic; attributes were varied randomly rather than by the design.
b Respondents were advised that these should include use of appropriate pressure relieving surfaces and repositioning, dressings and use of negative pressure wound therapy.
c None – unable to move from one place to another without assistance from another person, for example wheelchair attendant; some – able to move from one place to another using an assistive device, for example walking stick/crutches/frame; full – able to move unaided from one place to another either by walking or independent use of a wheelchair (self-propelled or powered).
d Respondents were asked to interpret this term as 'you would usually do' in the context of the care/services you provide.
e One or more comorbidity, for example cardiovascular, respiratory, renal or diabetes. Respondents were asked to assume that the patient's health can be improved before surgery so that he or she is fit for surgery from anaesthetic and surgical points of view.
f Respondents were asked to consider 'adhere' to include physical ability, motivation and available support from family, friends and carers.

Recruitment of participants

Nurses and surgeons who had taken part in the nurses' or surgeons' survey and indicated they would be prepared to help further with the study, or whose details were provided by a Getting It Right First Time (GIRFT) collaboration reviewing plastic surgery (and other services) including for patients with full-skin-thickness PUs were invited to take part. Each participant was sent a covering e-mail and electronic link to the survey. Covering instructions describing the task were given (see *Appendix 8*).

Data collection

The survey was designed in SurveyMonkey, which collected data entered by respondents. SurveyMonkey had the facility to randomise participants to one or other set of 16 scenarios and present scenarios for each participant randomly. Invitations to do the BCE survey were sent to nurses and surgeons with an electronic link on 6 December 2021. The survey was kept open for responses until 10 January 2022. Periodic reminders to do the survey were sent during this period. The survey collected the characteristics of respondents and the attributes of factors in the scenarios presented, as well as respondents' decisions.

Data analysis

Data characterising participants, scenarios and participants' decisions were downloaded from SurveyMonkey and imported into STATA (v16.1). Summary statistics were described. The melogit STATA command was used to fit multilevel mixed-effects logistic regressions to estimate the effects of scenario factors on participants' decisions. All decisions made by participants were included in the analysis. The effects of scenario factors are reported as univariable and multivariable ORs and associated 95% CIs. Many statistical tests are reported and *p*-values ranging between 0.05 and 0.01 are considered to be of borderline statistical significance and *p*-values < 0.01 to be statistically significant. The extent to which the univariable and multivariable ORs differed for a factor was considered to reflect interactions between the factor for which the ORs were estimated and other factors in the BCE design.

A sensitivity analysis was performed after excluding decisions from participants who gave uniform decisions across scenarios.

Results

Survey participants

The survey opened on 6 December 2021 and remained open until 10 January 2022. The survey was initiated by 77 respondents, comprising 59 nurses, 13 surgeons, and 5 people with another profession. Fifteen respondents who initiated the survey (seven nurses, three surgeons and five people from other professions) did not make any decision about a scenario and were not considered further. *Table 15* shows the characteristics of 62 participants (52 nurses and 10 surgeons) who made at least one decision about a scenario.

Forty-seven of 62 participants (75%) made decisions for all 16 scenarios presented to them. The number of scenarios for which the other 15 participants made decisions ranged from 1 to 15. We have no information about why people who initiated the survey did not provide decisions for any/all scenario/s.

Most nurse respondents practised in North East England and Yorkshire (13/52, 25%) or South West England (11/52, 21%). One nurse had a national role across all England regions (not included in the 'region' characteristic in the table). Most nurse respondents worked in one setting only (hospital, 25; community, 16; GP, 1; care home 1). Nine worked in multiple settings (hospital, community, GP and care home, 2; hospital, community, and care home, 4; community, GP and care home, 1; community and hospital, 1; GP and hospital, 1). With one exception, all were trained in wound care.

Surgeon respondents worked across five regions (not more than two in any region), including two in Wales and one in Scotland. Six were plastic surgeons. About two-thirds (62%) had practised for more than 5 years. Four had < 5 years' experience of SR.

TABLE 15 Characteristics of respondents in the BCE

	Nurses		Surgeons	
Participants' characteristic	***N* = 52**	**%**	***N* = 10**	**%**
Region where employed[a]				
East of England	5	10	0	0
London	8	15	0	0
Midlands	2	4	0	0
North East England and Yorkshire	13	25	2	20
North West England	3	21	1	10
South East England	6	6	2	20
South West England	11	12	2	20
Scotland	1	21	1	10
Wales	0	19	2	20
Northern Ireland	2	4	0	0
Role/health setting/specialty[b]				
Hospital[b]	30	58		
Community nurse[b]	22	42		
Care home[b]	7	13		
GP practice[b]	4	8		
Other[b]	5	10		
Plastic surgeon			6	60
General surgeon			1	10
Spinal rehabilitation surgeon			2	20
Other			1	10
Years of practice1/performing SR	***N* = 52**	**%**	***N* = 10**	**%**
< 5 years	6	0	4	40
5–10 years	6	12	2	20
11–15 years	40	12	2	20
> 15 years		77	2	20
Trained in wound care	51	93		
Not trained in wound care	1	7		
Consultant			7	81
Clinical academic			3	5

a One nurse respondent worked across England, so region classifications sum to 51.
b Several nurses worked across multiple settings (see text). Percentages are with respect to the denominator of 52 so do not sum to 100%.

Effects of factors on decisions that surgical reconstruction should be considered

A total of 843 decisions were analysed in the multilevel mixed-effects logistic regressions. The number of decisions per scenario ranged from 21 to 31. A total of 509 (60%) decisions were 'yes' with the percentage per scenario ranging from 13% to 100% [median 58%, interquartile range (IQR) 45–80%]. Overall, the mean 'yes' percentage across participants was 62%, ranging from 0% to 100%; the median percentage was 63% (interquartile range 44–82%). The responses of 12 of 62 participants (19%) were uniformly 'consider' (11 participants, 112 decisions) or 'do not consider' (1 participant, 1 decision), but these decisions accounted for only 13% of all decisions in the analysis.

TABLE 16 Univariable and multivariable associations of factors/attributes with decisions that SR should be considered

Factor/attribute	Univariable OR (CI)	Univariable *p*-value	Multivariable 1[a] OR (CI)	Multivariable 1[a] *p*-value	Multivariable 2[b] OR (CI)	Multivariable 2[b] *p*-value
Age						
46 years	1.00	–	1.00	–	1.00	–
55 years	1.50 (0.96 to 2.35)	0.07	1.58 (0.95 2.33)	0.12	1.52 (0.79 2.91)	0.21
64 years	1.11 (0.70 to 1.75)	0.67	1.31 (0.71 to 2.45)	0.39	1.27 (0.68 to 2.39)	0.45
73 years	1.49 (0.95 to 2.33)	0.08	1.71 (0.87 to 3.35)	0.12	1.73 (0.87 to 3.44)	0.12
Sex						
Female	1.00	–	1.00	–	1.00	–
Male	1.12 (0.82 to 1.54)	0.46	1.30 (0.57 to 2.95)	0.54	1.32 (0.57 to 3.05)	0.52
Location of SPU						
Ischium	1.00	–	1.00	–	1.00	–
Sacrum	0.89 (0.65 to 1.21)	0.45	1.15 (0.76 to 1.76)	0.53	1.21 (0.79 to 1.86)	0.039
PU stage						
3	1.00	–	1.00	–	1.00	–
4	1.39 (1.01 to 1.90)	0.04	2.00 (1.05 to 3.81)	0.04	1.91 (1.00 to 3.69)	0.054
SPU duration						
> 6 months	1.00	–	1.00	–	1.00	–
12–18 months	2.16 (1.46 to 3.21)	< 0.001	2.77 (1.65 to 4.65)	< 0.001	2.82 (1.68 to 4.73)	< 0.001
< 18 months	1.75 (1.18 to 2.58)	0.005	4.11 (2.17 to 7.81)	< 0.001	4.03 (2.08 to 7.80)	< 0.001
Previous SR						
Yes	1.00	–	1.00	–	1.00	–
No	11.82 (1.32 to 2.50)	< 0.001	2.26 (1.46 to 3.50)	< 0.001	2.37 (1.52 to 3.69)	< 0.001
Tissue scarred/inflamed						
Yes	1.00	–	1.00	–	1.00	–
No	1.22 (0.90 to 1.67)	0.21	1.67 (1.07 to 2.59)	0.023	1.74 (1.12 to 2.71)	0.015
Non-surgical treatments						
Not all tried	1.00	–	1.00	–	1.00	–
All tried	12.4 (8.18 to 18.8)	< 0.001	17.2 (10.2 to 28.9)	< 0.001	16.8 (10.0 to 28.2)	< 0.001

continued

TABLE 16 Univariable and multivariable associations of factors/attributes with decisions that SR should be considered (*continued*)

Factor/attribute	Univariable OR (CI)	Univariable *p*-value	Multivariable 1[a] OR (CI)	Multivariable 1[a] *p*-value	Multivariable 2[b] OR (CI)	Multivariable 2[b] *p*-value
Independent mobility						
None	1.00	–	1.00	–	1.00	
Limited	0.97 (0.67 to 1.42)	0.88	0.80 (0.48 to 1.34)	0.40	0.84 (0.50 to 1.41)	0.51
Full	1.22 (0.83 to 1.79)	0.31	1.36 (0.80 to 2.30)	0.26	1.35 (0.79 to 2.30)	0.27
Frail						
Yes	1.00	–	1.00	–	1.00	–
No	1.77 (1.28 to 2.45)	0.001	2.14 (1.19 to 3.82)	0.011	2.12 (1.18 to 3.79)	0.012
Comorbidity						
Yes	1.00	–	1.00	–	1.00	–
No	1.44 (1.05 to 1.97)	0.025	1.53 (1.01 to 2.31)	0.046	1.49 (0.96 to 2.24)	0.074
Likelihood of adherence						
Unsure	1.00	–	1.00	–	1.00	–
Likely	2.43 (1.62 to 3.63)	< 0.001	5.15 (2.83 to 9.37)	< 0.001	5.39 (2.92 to 9.97)	< 0.001
Very likely	2.95 (1.96 to 4.43)	< 0.001	6.05 (3.26 to 11.2)	< 0.001	6.25 (3.35 to 11.7)	< 0.001

a Estimates from the primary analysis including data for all decisions (n = 843).
b Estimates from the sensitivity analysis excluding data for participants with uniform decisions (12 participants, n = 113 decisions); analysis uses data for 730 decisions.

The direction of all factors was transformed so that the reference categories reflected the attributes expected to lead to 'no' decisions (should not be considered). Univariable and multivariable OR estimates for all factors are shown in *Table 16* and show the increase in the likelihood of a 'yes' decision contingent on the tabulated attribute for a factor. None of the attributes for factors assigned randomly to promote the realism of scenarios reached statistical significance (ORs are shown for these factors for completeness).

Univariable and multivariable OR estimates for factors of interest were broadly consistent. The level of independent mobility did not affect decisions. A stage 4 SPU, absence of inflammation or scarring of tissue surrounding the SPU, absence of frailty and absence of comorbidity were of borderline statistical significance/moderately associated with higher odds of a 'yes' decision (ORs approximately between 1.5 and 2.0). Longer duration of the SPU, having tried all non-surgical treatments, not having had previous SR and being more likely to adhere to PU prevention measures after surgery were strongly and significantly associated with higher odds of a 'yes' decision. The latter two associations were consistent with the high percentages of nurses and surgeons who said that these factors were likely to be indications for SR.

Estimates from the sensitivity analysis are also shown in *Table 16*. The estimates are strikingly similar.

Summary of findings from the binary choice experiment

Factors included at random (not part of the BCE design) were not associated with decisions. This was also true for the extent of independent mobility.

Multivariable associations for all factors in the BCE design were stronger than univariable associations.

Factors observed to be strongly and significantly associated with decisions to consider SR were: duration of SPU; previous SR to close a SPU; all non-surgical treatments having been tried; and good adherence to PU prevention strategies. The associations for previous SR to close a SPU and good adherence to PU prevention strategies were consistent with the findings from the original survey.

Factors with associations of weaker and borderline significance with decisions to consider SR were: SPU stage; tissue scarred or inflamed; frailty; and comorbidity. The associations for the latter two factors were consistent with the findings from the original survey but appeared to be less strong.

Chapter 7 Retrospective cohort studies assembled from routinely collected data sources

Methods: Hospital Episode Statistics cohort

Structure of Hospital Episode Statistics data and terms of data-sharing agreement

National Health Service inpatient treatment is recorded by hospitals, collated by the Health and Social Care Information Centre, and released as part of HES. HES are recorded at the level of a finished consultant episode, which represents the time spent under the care of a single consultant. Finished consultant episodes are joined together to create spells, the time spent (by a patient) within a single hospital, and continuous inpatient spells, the entire period of a patient's inpatient care which may include spells at multiple hospitals. In this report, we refer to a continuous inpatient spell as an admission.

Reporting of HES data follows the HES reporting guidelines[63] which includes details on the suppression of small numbers and adheres to the data-sharing agreement with NHS Digital.

Data request and identification of people with a severe pressure ulcer

The original application to NHS Digital was for extracts from HES Admitted Patient Care (APC), HES outpatients and Office for National Statistics (ONS) mortality for the period from 1 April 2010 to 31 March 2019 for all records [including records in APC, outpatient (OP) and accident and emergency (A&E) data sets] for:

- Patients aged 18 years and over.
- With an ICD-10 diagnosis code for a SPU [L89.2 or L89.3 or L89.9; stage 3, stage 4 or full-skin thickness but uncategorisable, respectively, used after 1 April 2012 (ICD-10 definition of L89.9) is 'Decubitus ulcer and pressure area, unspecified' but all clinicians in the team and more widely advised that it is used only for full-skin thickness PUs] or L89.X (PU uncategorised, used from 1 April 2010 to 31 March 2012) assigned to any finished consultant episode. (We cannot be sure that patients admitted with ICD-10 diagnosis code L89.X had a SPU. However, we considered it unlikely that patients would have SR for a less serious PU, let alone satisfy additional eligibility criteria applied later, see *Analysis methods*.)

We subsequently created a cohort of admissions with a SPU diagnosis coded ('SPU admissions cohort') for analysis for the period 1 April 2011 to 30 September 2018. The first eligible admission was termed the index admission, that is the 'baseline' admission which led to cohort entry. Subsequently, additional eligibility criteria were applied in steps (see *Analysis methods*); at each step, the index admission was the first eligible admission based on the eligibility criteria applied at the step. All patients with an index admission had 1 year's HES data before cohort entry, which were used to characterise the patients with one or more index admissions. The cohort end date provided a minimum of 6 months of follow-up after the index admission.

Equality, diversity and inclusion

Equality, diversity and inclusion are guaranteed with respect to the English population by using HES data because these data record all hospital activity, either as an inpatient or outpatient, for a person who has contact with an English NHS hospital. Any exclusions applied to the data extract we obtained related to clinical characteristics or the circumstances of recorded hospital activity and not to any patient characteristics relating to equality, diversity or inclusion.

Definition of surgical reconstruction from Office of Population Censuses and Surveys-4 codes

The protocol specified that the HES cohort would assess SR operations coded with a variety of Office of Population Censuses and Surveys (OPCS)-4 codes. These codes were: distant flap of skin and muscle (S17), distant flap of skin and fascia (S18), distant pedicle flap of skin (S19), other distant flaps of skin (S20), hair-bearing flap of skin (S21), sensory flap of skin (S22), flap operations to relax contracture of skin (S23), local flap of skin and muscle (S24), local flap of skin and fascia (S25), local subcutaneous pedicle flap of skin (S26) and other local flaps of skin (S27). These codes were reviewed by a surgeon co-applicant (JKW) and two codes, S21 and S23, were removed from the list. Admissions assigned codes

for debridement or negative pressure wound therapy without a "S" code were excluded. Primary wound closure was also excluded because surgeons' responses to the survey had found this method is rarely used to close SPUs.

Definitions of other data used in the Hospital Episode Statistics and linked Office for National Statistics extracts

In the HES extract, we used additional ICD-10 diagnostic codes for three reasons. Firstly, we wanted to characterise the patients' comorbidities (*Table 17*). One aspect of comorbidity was the likely cause of impaired morbidity underlying the SPU. We derived the Charlson Comorbidity Index from ICD-10 diagnostic codes.[64] Secondly, some specific comorbidities were considered very likely to preclude SR (*Table 18*). Thirdly, we used a diagnosis of osteomyelitis (M86) when we compared patients who did and did not have SR during an index admission (below).

TABLE 17 Comorbidities defined by ICD-10 codes

Comorbidities	ICD-10 codes
Hypertension	I10 Essential (primary) hypertension
Diabetes	E10 Type 1 diabetes mellitus E11 Type 2 diabetes mellitus E12 Malnutrition-related diabetes mellitus E13 Other specified diabetes mellitus E14 Unspecified diabetes mellitus
Stroke	I64 Stroke, not specified as haemorrhage or infarction
Dementia	F00 Dementia in Alzheimer disease F01 Vascular dementia F02 Dementia in other diseases classified elsewhere F03 Unspecified dementia
Atrial fibrillation	I48 Atrial fibrillation and flutter
Cancer (excluding secondary cancers)	C01–C97 Malignant neoplasms, excluding C77 Secondary and unspecified malignant neoplasm of lymph nodes; C78 Secondary malignant neoplasm of respiratory and digestive organs; C79 Secondary malignant neoplasm of other and unspecified sites
Kidney disease	N18 Chronic kidney disease
Liver disease	K70 Alcoholic liver disease K71 Toxic liver disease K72 Hepatic failure, not elsewhere classified K73 Chronic hepatitis, not elsewhere classified K74 Fibrosis and cirrhosis of liver K75 Other inflammatory liver diseases K76 Other diseases of liver K77 Liver disorders in diseases classified elsewhere
Injury likely to be the cause of impaired mobility: any	T91 Sequelae of injuries of neck and trunk Y85 Sequelae of transport accidents Y86 Sequelae of other accidents S14 Injury of nerves and spinal cord at neck level *Additionally, among patients not already classified as having a neurogenerative disease cause:* *G82.2 Paraplegia, unspecified and* *T81.8 Other complications of procedures, not elsewhere classified or* *T90.5 Sequelae of intracranial injury or* *T94.1 Sequelae of injuries, not specified by body region or* *Y87.0 Sequelae of intentional self-harm or* *Y87.1 Sequelae of assault or* *Y88.3 Sequelae of surgical and medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure or* *Z89.5 Acquired absence of leg at or below knee*

continued

TABLE 17 Comorbidities defined by ICD-10 codes (*continued*)

Comorbidities	ICD-10 codes
Neurodegenerative disease likely to be the cause of impaired mobility	G35 Multiple sclerosis Q05 Spina bifida G80 Cerebral palsy G12 Spinal muscular atrophy and related syndromes *Additionally, among patients not already classified as having an injury cause:* *G82.1 Spastic paraplegia and* *G09.X Sequelae of inflammatory diseases of central nervous system or* *G95.0 Syringomyelia and syringobulbia or* *G95.8 Other specified diseases of spinal cord* *G82.2 Paraplegia, unspecified and* *G09.X Sequelae of inflammatory diseases of central nervous system or* *G95.8 Other specified diseases of spinal cord or* *Z86.6 Personal history of diseases of the nervous system and sense organs* *G82.4 Spastic tetraplegia and* *G90.4 Autonomic dysreflexia* *G82.5 Tetraplegia, unspecified and* *G09.X Sequelae of inflammatory diseases of central nervous system or* *G95.8 Other specified diseases of spinal cord*
Either injury or disease likely to be the cause of impaired mobility or likely cause unspecified	*Among patients not already classified as having an injury or neurogenerative disease cause:* *G82.0 Flaccid paraplegia* *G82.1 Spastic paraplegia* *Z99.3 Dependence on wheelchair* *G822 Paraplegia, unspecified and* *G90.4 Autonomic dysreflexia or* *K59.2 Neurogenic bowel, not elsewhere classified or* *N31.9 Neuromuscular dysfunction of bladder, unspecified or* *R26.3 Immobility* *G82.4 Spastic tetraplegia and* *G90.4 Autonomic dysreflexia* *G82.5 Tetraplegia, unspecified and* *G90.4 Autonomic dysreflexia or* *K59.2 Neurogenic bowel, not elsewhere classified or* *N31.9 Neuromuscular dysfunction of bladder, unspecified*
Likely cause of impaired mobility unassigned	All those not defined as injury, neurogenerative disease or unspecified cause

TABLE 18 Exclusions defined by ICD-10 codes

Exclusions	OPCS or ICD-10 codes
Dialysis (procedure)	X40 Compensation for renal failure
Secondary cancer (diagnosis)	C77 Secondary and unspecified malignant neoplasm of lymph nodes C78 Secondary malignant neoplasm of respiratory and digestive organs C79 Secondary malignant neoplasm of other and unspecified sites
Heart failure (diagnosis)	I50 Heart failure
Gangrene (diagnosis)	A48.0 Gas gangrene J85.0 Gangrene and necrosis of lung K40.1 Bilateral inguinal hernia, with gangrene K40.4 Unilateral or unspecified inguinal hernia, with gangrene K41.1 Bilateral femoral hernia, with gangrene K41.4 Unilateral or unspecified femoral hernia, with gangrene K42.1 Umbilical hernia with gangrene K43.1 Incisional hernia with gangrene K43.4 Parastomal hernia with gangrene K43.7 Other and unspecified ventral hernia with gangrene K44.1 Diaphragmatic hernia with gangrene K45.1 Other specified abdominal hernia with gangrene K46.1 Unspecified abdominal hernia with gangrene R02 Gangrene, not elsewhere classified

We also used the NHS acute trust ID to derive trust-specific rates of SR, the OPCS-4 code for dialysis to exclude patients who had had dialysis within 6 months of the index admission, and the route of admission to define elective admission (codes 11, 12 or 13; waiting list, booked or planned). In the linked ONS extract, we used the date of death if death was registered and the 2015 Index of Multiple Deprivation (IMD).

Analysis methods

Methods for defining and describing the Hospital Episode Statistics cohort of patients with a severe pressure ulcer diagnosis at the time of hospital admission and those who had surgical reconstruction

We summarised the characteristics of patients in the SPU admissions cohort using tabulations of averages and frequencies. We focused on (a) describing the frequency of SR during the index admission in patients with a diagnosis of SPU during an admission and (b) comparing this group with similar patients who did not have SR following admission (below).

It was challenging to identify patients in the SPU admissions cohort who had SR to close a SPU during the index admission due to uncertainty about the accuracy and completeness of coding. In consultation with surgeon members of the research team, we specified several further eligibility criteria which we applied successively. These criteria were that a patient should have: a diagnosis of SPU in the admitting episode, that is 'on admission'; SPU or osteomyelitis as the 'primary' diagnosis on admission; an 'elective' admission; and none of several further diagnoses or procedures which were judged to rule out SR. Patients who remained after all eligibility criteria had been applied were deemed most likely to have had SR to close a SPU. Patients identified when fewer exclusion criteria had been applied may nevertheless have had SR to close a SPU but with less certainty. The successive eligibility criteria are described in *Table 19*.

We also applied the exclusion criteria in two ways. The first method simply focused on patients who had a SR during the index admission, and then applied the exclusion criteria in sequence. Using this method, we describe the characteristics of the group who had SR, and the frequency of SR, both before applying any exclusion criteria (patients with a SR during the index admission, maximum SR subset) and after applying all exclusion criteria (minimum SR subset; these patients also formed part of the maximum SR subset).

TABLE 19 Eligibility criteria applied in successive steps to try to identify patients most likely to have had SR to close a SPU

Step	Maximum SR subset	Minimum SR subset	TT SR subset
None	SPU admissions cohort: adult admissions with SPU diagnosed	SPU admissions cohort: adult admissions with SPU diagnosed	SPU admissions cohort: admissions with SPU diagnosed
Step 1	Restrict to index admissions where SR was coded	Restrict to index admissions where SR was coded	(Applied as step 7)
Step 2	Restrict to first admissions with SR coded (one index admission per patient)	Restrict to first admissions with SR coded (one index admission per patient)	
Step 3		Restrict to patients with SPU diagnosis on admission[a]	Restrict to patients with SPU diagnosis on admission[a]
Step 4		Restrict to patients with SPU or osteomyelitis as the primary diagnosis on admission[b]	Restrict to patients with SPU or osteomyelitis as the primary diagnosis on admission[b]
Step 5		Restrict to elective index admissions[c]	Restrict to elective index admissions[c]
Step 6		Restrict to patients with no earlier diagnoses or procedures[d]	Restrict to adults[e] with no earlier diagnoses or procedures[d]
Step 7			Restrict to adults where SR was coded

a 'On admission' defined as SPU diagnosis coded in the admitting episode.
b 'Primary diagnosis' defined as the primary diagnosis in the admitting episode.
c 'Elective' defined as HES-coded waiting list, booked or planned routes of admission.
d Earlier diagnoses or procedure leading to exclusion comprised: renal dialysis within 6 months of the index admission; secondary cancer or heart failure within 12 months of the index admission; gangrene within 3 months of the index admission.
e 'Adult' defined by patient's age at index admission. The adult criterion was the first step for the maximum and minimum subsets but the last step for the comparison SR subset because it could not be applied until the admission with the SR code had been identified.

The second method focused on identifying patients who we considered potentially eligible for the comparison between patients who did and did not have SR during the index admission [target trial (TT) SR subset; below]. This divided patients according to whether they had SR during the admission only after applying all exclusion criteria and, therefore, generated a single estimate of SR frequency after all exclusion criteria had been applied.

Acknowledging that we did not have a definitive way to identify 'true positives' (patients who had SR to close a SPU), it may be helpful to think of the maximum SR subset as having high sensitivity but potentially low specificity for such patients. Conversely, the minimum SR subset can be thought of as having high specificity but potentially low sensitivity for such patients.

The characteristics of patients in the maximum and minimum SR subsets are summarised by descriptive statistics.

Methods for propensity-adjusted comparison of patients with a severe pressure ulcer who did (surgical reconstruction group) and did not have surgical reconstruction (no surgical reconstruction group)

We adopted the principle of defining a TT[65] to compare the effectiveness of SR with not having SR and then tried to emulate the TT using the HES data set. A TT is a hypothetical trial with study design elements chosen to test the research question; these elements do not have to be feasible. The key features of the TT were specified by the research team in consultation with members of the SMG and our criteria for emulating them are shown in *Table 20*. Applying the criteria to the SPU admissions cohort created the emulation cohort, comprising both patients who had SR (SR group) and those who did not have SR (NSR group). (The SR group in the emulation cohort is identical to the comparison SR subset, above.)

TABLE 20 Population, intervention, comparator, outcome components for evaluation of SR in the TT and emulation cohort

'PICO' component	TT	Emulation cohort
Population	The usual care pathway was conceived as follows: 1. Patient develops SPU in the community 2. Patient referred to surgical team for SR 3. Surgical team reviews patient and considers potentially suitable for SR 4. Patient's condition 'optimised' (e.g. nutrition, other comorbidities) 5. Surgical team reviews patient and, if fit for surgery, lists for SR 6. Patient has preoperative assessment 7. Patient who is fit and suitable for SR admitted to hospital within 1–2 weeks The TT population was defined as patients reaching step 6 above who give informed consent	Consecutive adults (age ≥ 18 years) with an elective HES admission with SPU or osteomyelitis as the primary diagnosis on admission To be eligible, patient must have: 1. ≥ 6 months of follow-up after the admission (i.e. no date of death), hence admission date between 1 April 2011 and 30 September 2018 2. 12-month data before the admission without an elective HES admission with SPU diagnosed on admission Exclusions: non-elective route of index admission; dialysis within 6 months of index admission; diagnosis of secondary cancer or heart failure within 12 months of index admission; gangrene within 3 months of index admission
Intervention	SR during elective admission, including appropriate postoperative care (hospital and community)	SR (as defined by in 1.1.3) during index admission
Comparator	NSR; community team continues care aiming to achieve closure with non-surgical interventions	NSR (as defined by in 1.1.3) during index admission
Time zero	Date of randomisation, at preoperative assessment	Date of discharge from index admission
Follow-up	Starts at randomisation and continues for 12 months	Starts at date of discharge and continues for up to 12 months (minimum 6 months)
Outcomes	Primary outcome: 'wound healing' (e.g. wound-free days). Secondary outcomes: wound complications, duration of hospital stay, recurrence, resource use, mortality	Primary outcome: time to HES admission with SPU diagnosed on admission. Secondary outcomes: length of index admission hospital stay, time to first HES admission (any), all-cause mortality at 6 months, SR after discharge from index admission
Analysis	Intention to treat, based on randomised assignment	Based on assignment (SR or not) during the index admission

The analyses aimed to estimate the relative effects of assigned SR intervention analogous to an intention-to-treat analysis of a RCT. In the TT cohort ['cohort' rather than subset because the cohort included patients who did (SR group) and did not (NSR group) have SR during the index admission], we calculated propensity scores for SR using a backward stepwise logistic regression with the significance level for removal from the model set at 0.25. All available confounders identified as possibly being related to SPU were included in the stepwise model: time; age; sex; IMD; hypertension; diabetes; stroke; dementia; atrial fibrillation; cancer; kidney disease; liver disease; cause (injury; neurodegenerative disease; injury or neurodegenerative disease; unspecified/unassigned); CCI; number of admissions in the previous year; number of SPU admissions in the previous year.

Criteria for excluding tails of propensity score distributions were decided by reviewing the distribution of primary outcome events (re-admission with SPU diagnosed on admission within 365 days of the index admission) for SR and NSR groups, in strata of propensity score: 0 to < 5th, 5th to < 25th, 25th to < 50th, 50th to < 75th, 75th to < 95th, and 95th to 100th percentiles. The intention was to exclude patients in extreme tails of the propensity score distribution when few primary outcome events were observed in either group. This approach would make it more likely that analyses were restricted to patients eligible to receive either SR or NSR.

Kaplan–Meier curves were generated after adjusting by the inverse probability of treatment weights using the propensity scores,[66] that is with weights defined as 1/propensity score for the treatment received. Time zero was the discharge date from the index admission. This time was chosen due to defining the primary outcome as a subsequent admission with SPU diagnosis on admission, that is the outcome could only be experienced after discharge from the index admission. If a patient had zero follow-up, for example due to dying in hospital during their index admission, follow-up was set at 0.5 days so that the patient could be included.

In the Cox's proportional hazard models, all continuous variables (calendar year, age, IMD, CCI, number of admissions in the previous year, number of SPU admissions in the previous year and propensity scores) were included as cubic splines with knots set at the 25th and 75th percentiles.

Pre-specified subgroup analyses (defined as tests of interactions of patient characteristics with reconstructive surgery that may influence outcomes, e.g. comorbidities, previous hospital admission without surgery) were investigated for the primary outcome by fitting interactions of the subgroup factors with SR. The subgroups were: age (≤ 60 vs. > 60 years); diabetes comorbidity (yes/no; see *Table 17*); injury comorbidity (yes/no; see *Table 17*); ≤ 1 versus > 1 previous HES admission; 0 versus ≥ 1 previous hospital admission with a coded SPU diagnosis.

Methods: Clinical Practice Research Datalink cohort

Structure of Hospital Episode Statistics data and terms of data sharing agreement

Clinical Practice Research Datalink is described as

> *'a real-world research service supporting retrospective and prospective public health and clinical studies. CPRD research data services are delivered by the Medicines and Healthcare Products Regulatory Agency with support from the National Institute for Health and Care Research (NIHR), as part of the Department of Health and Social Care'. (https://cprd.com) It '… collects anonymised patient data from a network of GP practices across the UK. Primary care data are linked to a range of other health related data to provide a longitudinal, representative UK population health dataset'.*

Data are held for about 60 million patients, with 18 million currently registered. The data are held in two databases, Gold and Aurum, depending on the practice software used by contributing GP practices [Vision® (Cegedim Healthcare Solutions, London, UK) and EMIS Web (EMIS Health, Leeds, UK), respectively].

Data request and identification of people with a pressure ulcer

A data set was supplied for this research under Independent Scientific Advisory Committee protocol 20_097. It contained the full CPRD Gold or CPRD Aurum coded records for all patients who were:

- registered at up-to-standard (UTS) GP practices, and
- who had a medical code indicating the presence of a PU during their UTS registration during the study period (1 April 2008 to 31 March 2019), and
- who were aged 18 years or older.

There were no exclusions based on linkage eligibility. The original code lists specified in the study protocol [see additional files www.fundingawards.nihr.ac.uk/award/NIHR127850 (accessed 21 May 2025)] described both the presence of a PU and also other care actions relating to a PU, for example referral to another service or discharge from service. Only the Read or Systemized Nomenclature of Medicine (SNOMED) codes describing the presence of a PU were used to identify the first PU diagnosis.

Eligibility criteria for the Clinical Practice Research Datalink cohort

We applied the following eligibility criteria to form the CPRD cohort:

- a patient had to have at least 365 days since first registration at the GP practice sending data to CPRD
- a patient had to have at least 365 days since permanent registration at the GP practice sending data to CPRD
- the date of the incident PU code had to be before the transfer out date (if recorded)
- the date of the incident PU code had to be before the last collection date for the patient's GP practice
- the date of the incident PU code could not be between 1 April 2008 and 31 March 2009 because data to characterise a patient were not available before 1 April 2008
- a patient had to be 18 years of age or older on the date when the incident PU code was recorded.

Equality, diversity and inclusion

Any limitation with respect to equality, diversity and inclusion arises from the voluntary nature of general practices' decisions to submit data to the Clinical Practice Research Database. It has previously been established that data submissions to CPRD are broadly representative of the English (and UK) population, so the limitation is minor, if it exists at all.[66,67] Any exclusions applied to the CPRD data extract we obtained related to clinical characteristics or the circumstances of recorded primary care activity and not to any patient characteristics relating to equality, diversity or inclusion.

Definitions of other data summarised for patients in the Clinical Practice Research Datalink cohort

Comorbidities were prepared from CPRD records using Read, ICD-10 and product code lists to identify all confounders, either from published sources or created by the study team [methodologists familiar with Read (CPRD) and ICD-10 (HES) coding systems and clinicians]. Further details are available at the SIPS study web page on the NIHR Funding and Awards website [see additional files www.fundingawards.nihr.ac.uk/award/NIHR127850 (accessed 21 May 2025)].

For the study population groups identified above, we were supplied with linked data from the following linked data sets when the data requested were available:

1. HES – England only: linked HES APC, OP, and A&E records (when one or more records existed) for all patients in the CPRD Gold and CPRD Aurum study population defined above, when the following additional criteria were also met:
   - the patient must have had at least 1 day of UTS follow-up which coincides with the data collection period for the linked data set
   - a set of identifiers had to be present in both the CPRD data set and linked data sets, to provide a minimum level of confidence in the linkage
   - the patient must have received NHS-funded inpatient treatment at a hospital in England during the data collection period (otherwise there would be no HES record)

2. ONS mortality data: linked ONS death registration record (where one exists) for all patients in the CPRD Gold and CPRD Aurum study populations defined above, and where the following additional criteria were also met:
   - the patient must have had at least 1 day of UTS follow-up which coincides with the data collection period for the linked data set. For the most recent linked ONS mortality date, the data collection period related to the date of death registration (not the date of occurrence) and covered the period from 2 January 1998 to 1 May 2019

- the patient must have died during the data collection period
- a set of identifiers had to be present in both the CPRD Gold and death registration record data set, to provide a minimum level of confidence in the linkage

3. Area-based IMD scores for 2015 (IMD2015): The patients' and GP practice postcodes were used to assign a lower super output area (LSOA). LSOA was linked to quintiles of IMD2015 score, calculated at the LSOA level. IMD2015 quintiles for all patients and GP practices in the CPRD study cohorts defined above were provided when the following additional criteria were also met:
   - patient has a valid postcode of residence recorded in CPRD Gold or CPRD Aurum
   - GP practice has a valid postcode of residence recorded in CPRD Gold or CPRD Aurum
   - the postcode can be assigned to a LSOA in England.

Analysis methods

We summarised the characteristics of patients in the CPRD cohort using tabulations of averages and frequencies. We focused on (a) describing the characteristics of patients with an incident PU frequency, (b) their care 'journeys' in primary care and (c) describing the characteristics of the subgroup who were admitted to hospital and whether they had SR during any hospital admission. We also compared frequencies of SR in the latter group and the HES SR subsets.

Reporting of CPRD and CPRD-HES data follows CPRD policy (https://cprd.com/how-access-cprd-data) and small numbers are suppressed. Data-sharing agreements with CPRD and HES are adhered to.

Results of analyses of the Hospital Episode Statistics cohort

Characteristics of patients in the severe pressure ulcer admissions cohort

A total of 367,884 SPU admissions from 1 April 2011 to 30 September 2018 were included in this cohort. *Table 44* (see *Appendix 9*: additional tables and figures for analyses of the HES cohort) describes the characteristics of the 291,268 patients who had one or more SPU admissions. Patients' first SPU admissions occurred at the same rate over time, with 12–13% of the total entering the cohort each year. (Percentages for 2011 and 2018 are lower because they represent incomplete years, with admissions for 9 or 6 months only being included.)

The mean age of 78 years and the high proportion of patients with various comorbidities show that the cohort mainly comprised elderly patients, many probably with life-limiting conditions. The ill health of many in the cohort is illustrated by the high mortality rate; more than 50% had died by 12 months after the first SPU admission (see *Appendix 9*, *Figure 22*: additional tables and figures for analyses of the HES cohort). Therefore, we did not describe more details of the care pathways after admission and frequencies of health outcomes in the overall SPU admissions cohort.

Number and characteristics of patients having surgical reconstruction

Figure 6 shows the numbers of first SRs in the SPU admission cohort before and after applying each of the exclusion steps described in *Table 19*. The maximum SR subset (n = 1018) is generated by identifying patients with one or more SRs and requiring patients to be 18 years or older. The minimum SR subset (n = 404) is generated by applying all the exclusion steps described in *Table 19*. The first three exclusion steps removed > 150 patients from the maximum subset: requiring admissions to have SPU diagnosed on admission resulted in 152 patients being excluded, requiring admissions to have L89/M86 as the primary diagnosis on admission resulted in a further 239 patients being excluded, etc. Applying the exclusion steps in a different order would have caused somewhat different numbers to be excluded at each step but would have resulted in a very similar minimum SR subset. The characteristics of patients in the maximum and minimum SR subsets are summarised in *Table 21*.

The TT SR subset (n = 325) was generated by applying the exclusion steps in a similar way but with three differences (*Figure 7*). Exclusion criteria were applied to admissions until the penultimate step because a patient might have had multiple SPU admissions with different admissions having varying information about eligibility. Since patients aged over time, the requirement to be an adult was also not applied until the penultimate step.

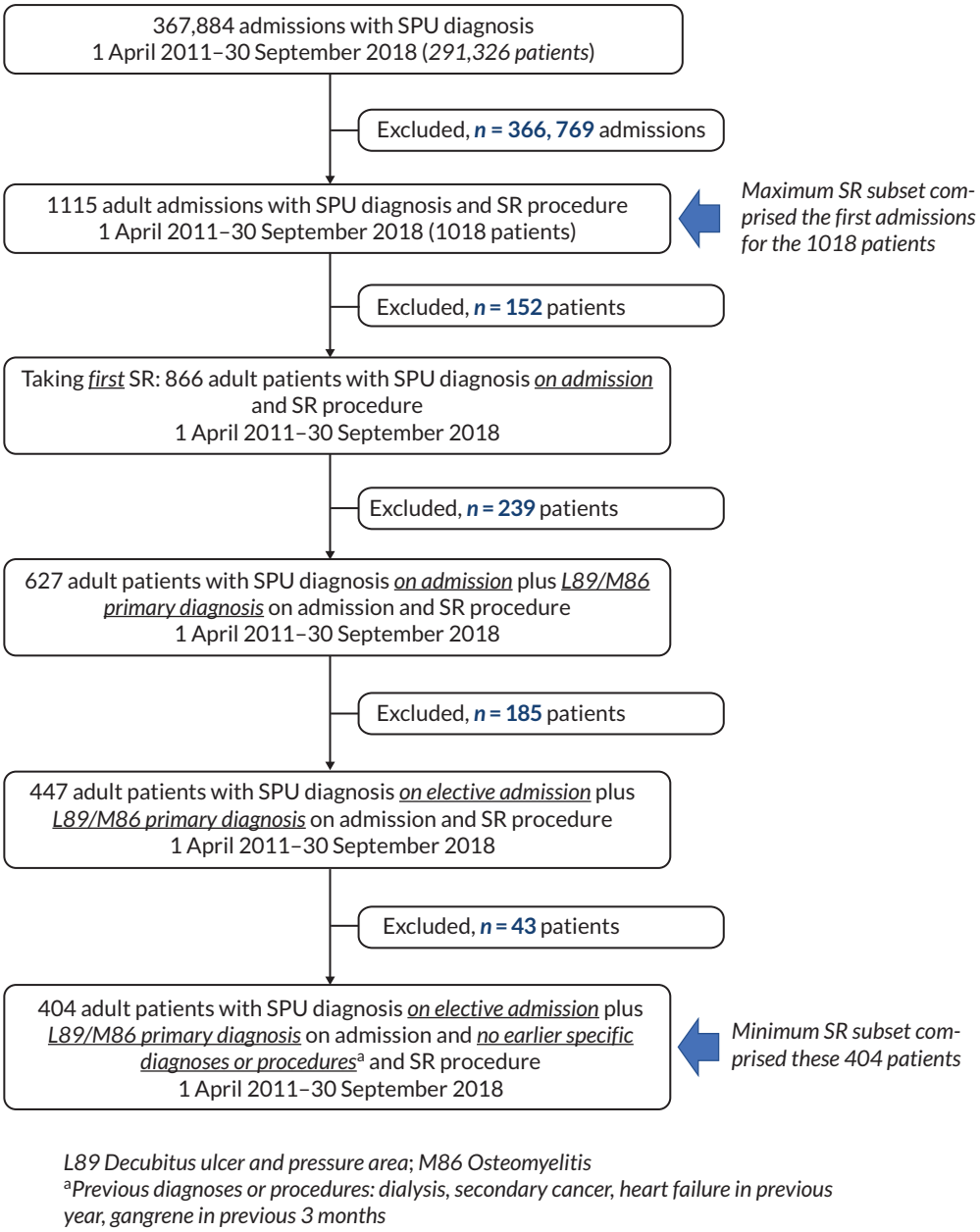


FIGURE 6 First SRs in adults in the SPU admissions cohort before and after applying eligibility criteria in *Table 19*.

Finally, in keeping with the concept of emulating a TT, patients who had SR were not identified until the final step – hence, this method of creating a SR subset only generates a 'minimum' subset, after all exclusion criteria had been applied.

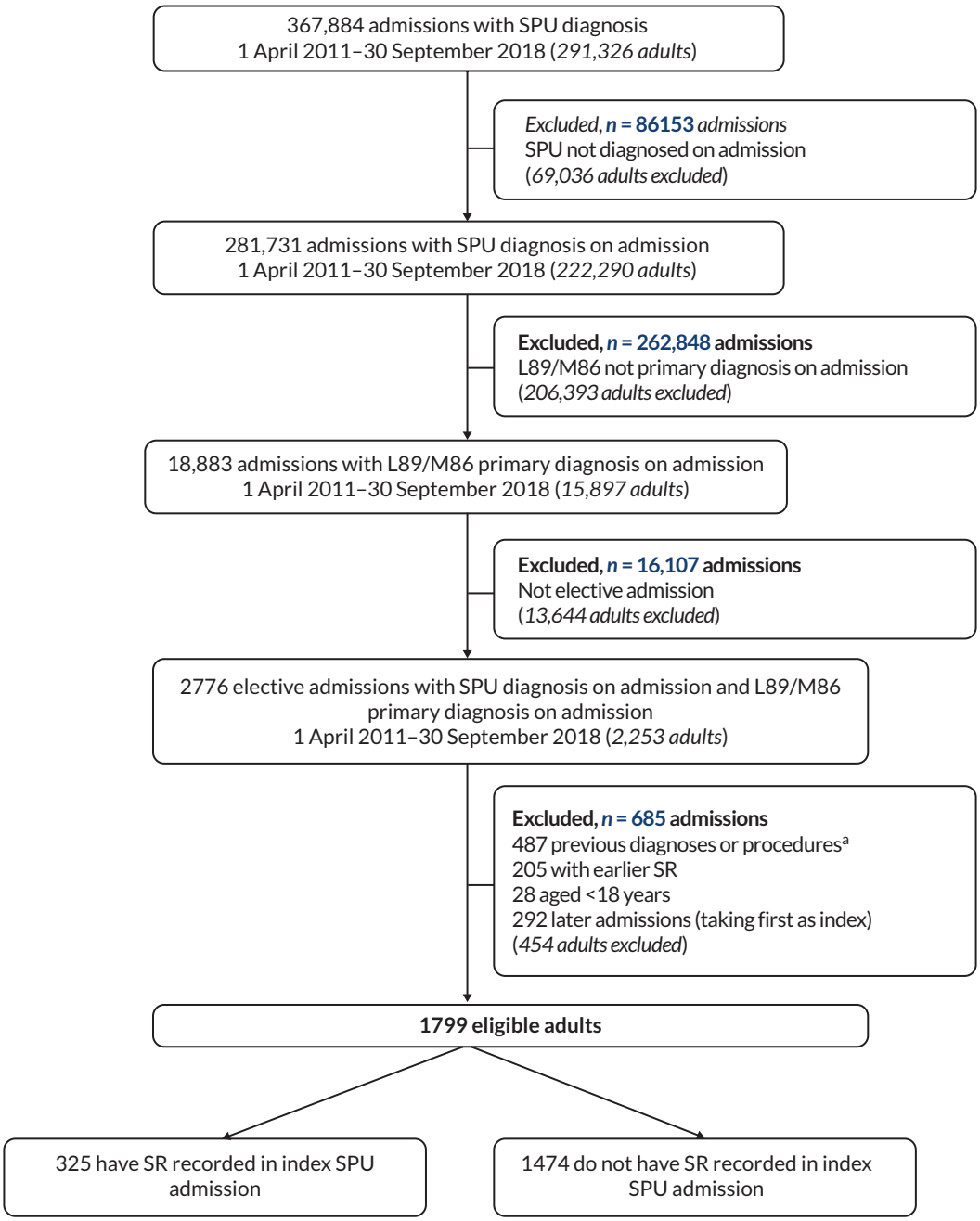
The characteristics of the patients in the minimum SR subset and the TT SR subset are similar (and include many of the same patients). Their mean age was 52 years (SD = 15), 70% were male and they had relatively few common morbidities (18–22% hypertension, 12% diabetes, ≤ 3% with stroke, dementia, atrial fibrillation, cancer, kidney or liver disease). With respect to the inferred causes of their impaired mobility, 41–45% had had an injury and 26–27% had a neurodegenerative disease. Even though it contained the minimum SR subset, the characteristics of patients in the maximum SR subset were different from the two smaller subsets: in the maximum SR subset, patients' mean age was 58 years (SD = 17), 67% were male and they had more common morbidities (26% hypertension, 17% diabetes, ≤ 2% with stroke dementia or liver disease but 11% with cancer, 8% with atrial fibrillation and 4% with kidney disease). With respect to the inferred causes of their impaired mobility, 26% had had an injury and 16% had a neurodegenerative disease. The much higher percentages of patients with an injury or neurodegenerative disease diagnosis in the smaller subsets are consistent with these patients being those having SR to close a SPU.

TABLE 21 Characteristics of patients in the maximum SR subset (*n* = 1018), the minimum SR subset (*n* = 404) and the TT SR subset at time of first SR

Patient characteristics		Maximum SR subset *n* = 1018	Minimum SR subset *n* = 404	TT SR subset (*n* = 325)
Calendar year; *n* (%)	2011	121 (12%)	51 (13%)	64 (20%)
	2012	142 (14%)	70 (17%)	47 (14%)
	2013	141 (14%)	53 (13%)	43 (13%)
	2014	150 (15%)	64 (16%)	52 (16%)
	2015	120 (12%)	54 (13%)	38 (12%)
	2016	117 (11%)	36 (9%)	26 (8%)
	2017	109 (11%)	30 (7%)	32 (10%)
	2018	118 (12%)	46 (11%)	23 (7%)
Age[a]; mean (SD)		58 (17)	52 (15)	52 (15)
Sex; *n* (%)	Male	684 (67%)	282 (70%)	226 (70%)
	Female	334 (33%)	122 (30%)	99 (30%)
IMD[b]; median (IQR)		18 (10–32)	17 (9–32)	16 (9–33)
Comorbidities in previous 12 months				
Hypertension; *n* (%)		262 (26%)	72 (18%)	70 (22%)
Diabetes; *n* (%)		172 (17%)	47 (12%)	38 (12%)
Stroke; *n* (%)		2 (0.2%)	0	0
Dementia; *n* (%)		24 (2%)	1 (0.2%)	0
Atrial fibrillation; *n* (%)		77 (8%)	11 (3%)	8 (2%)
Cancer (excluding secondary cancers); *n* (%)		109 (11%)	4 (1%)	7 (2%)
Kidney disease; *n* (%)		44 (4%)	10 (2%)	8 (2%)
Liver disease; *n* (%)		10 (1%)	3 (1%)	5 (2%)
Neurodegenerative disease; *n* (%)		161 (16%)	105 (26%)	87 (27%)
Injury; *n* (%)		265 (26%)	166 (41%)	147 (45%)
Cause could be either injury or disease (or unspecified); *n* (%)		47 (5%)	20 (5%)	18 (6%)
Cause unassigned; *n* (%)		545 (54%)	113 (28%)	73 (22%)
Any previous surgery in 6 months; *n* (%)		2 (0.2%)	-	6 (2%)
Charlson Comorbidity Index; median (IQR)		2 (0–2)	2 (0–2)	2 (1–2)
Number of admissions in previous 12 months; median (IQR)		2 (0–4)	2 (1–5)	1 (0–2)
Number of SPU admissions in previous 12 months; median (IQR)		2 (0–4)	2 (1–5)	0 (0–1)

a Age missing for 13, 0, 0 in each subset respectively.
b IMD missing for 27, 5, 5.

The numbers of SRs in patients in the subsets occurred over a period of 7.5 years. This means that from 2011 to 2018 the maximum number of 'first' SRs being carried out each year in England in people with a SPU was 136 (maximum SR subset, 1018/7.5), and the minimum number was 43 (TT SR subset, 325/7.5); the minimum SR subset gives an annual number of 54 (404/7.5).



L89 Decubitus ulcer and pressure area; M86 Osteomyelitis
[a]*Previous diagnoses or procedures: dialysis, secondary cancer or heart failure in previous year, gangrene in previous 3 months*

FIGURE 7 Severe pressure ulcer admissions (and patients) before and after applying the exclusion criteria described in *Table 19*, generating the TT SR subset (bottom left-hand box, *n* = 325).

Table 22 shows the frequencies with which different 'S' OPCS-4 procedure codes were assigned when an admission was classified as including an eligible SR (note that multiple codes can be assigned to one reconstruction). Some codes were assigned to similar percentages of reconstructions across the subsets and others with substantially different frequency percentages. However, when codes were assigned with similar percentages, the number of patients differed across subsets.

Figures 8–10 show Kaplan–Meier graphs for times from first admission in the SPU admissions cohort to three events for patients in the maximum and minimum SR subsets: (a) first SR, (b) second SR (when a patient had more than one); and (c) death.

TABLE 22 Frequencies OPCS codes for eligible SRs in the three SR subsets

OPCS code[a]	Maximum SR subset (*n* = 1018)		Minimum SR subset (*n* = 404)		TT SR subset (*n* = 325)	
	n	%	*n*	%	*n*	%
S24.9 Unspecified local flap of skin and muscle	134	13.2	64	15.8	46	14.2
S27.8 Other specified other local flap of skin	112	11.0	52	12.9	43	13.2
S27.9 Unspecified other local flap of skin	111	10.9	58	14.4	50	15.4
S24.2 Local myocutaneous subcutaneous pedicle flap NEC	99	9.7	43	10.6	32	9.8
S25.2 Local fasciocutaneous subcutaneous pedicle flap NEC	81	8.0	33	8.2	29	8.9
S25.9 Unspecified local flap of skin and fascia	78	7.7	38	9.4	33	10.2
S27.4 Random pattern local flap of skin NEC	74	7.3	38	9.4	31	9.5
S24.8 Other specified local flap of skin and muscle	57	5.6	25	6.2	19	5.8
S27.5 Local flap of skin to head or neck NEC	42	4.1	3	0.7	3	0.9
S25.8 Other specified local flap of skin and fascia	28	2.8	15	3.7	13	4.0
S18.3 Distant fasciocutaneous flap to head or neck NEC	22	2.2	0	0.0	0	0.0
S18.2 Distant fasciocutaneous subcutaneous pedicle flap NEC	20	2.0	4	1.0	3	0.9
S17.2 Distant myocutaneous subcutaneous pedicle flap NEC	16	1.6	4	1.0	1	0.3
S26.8 Other specified local subcutaneous pedicle flap of skin	16	1.6	5	1.2	5	1.5
S26.9 Unspecified local subcutaneous pedicle flap of skin	16	1.6	9	2.2	7	2.2
S17.8 Other specified distant flap of skin and muscle	15	1.5	0	0.0	2	0.6
S17.3 Distant myocutaneous flap to head or neck NEC	14	1.4	0	0.0	0	0.0
S26.4 Random pattern local subcutaneous pedicle flap of skin NEC	13	1.3	8	2.0	6	1.8
S18.8 Other specified distant flap of skin and fascia	12	1.2	1	0.2	1	0.3
S17.9 Unspecified distant flap of skin and muscle	11	1.1	2	0.5	2	0.6
S26.2 Axial pattern local subcutaneous pedicle flap of skin NEC	11	1.1	2	0.5	2	0.6
S18.1 Distant fasciocutaneous subcutaneous pedicle flap to head or neck	10	1.0	0	0.0	0	0.0
S27.2 Axial pattern local flap of skin NEC	10	1.0	5	1.2	5	1.5
S27.3 Random pattern local flap of skin to head or neck NEC	10	1.0	2	0.5	1	0.3
S18.9 Unspecified distant flap of skin and fascia	9	0.9	2	0.5	2	0.6
S17.1 Distant myocutaneous subcutaneous pedicle flap to head or neck	7	0.7	0	0.0	0	0.0
S20.9 Unspecified other distant flap of skin	5	0.5	0	0.0	0	0.0
S20.1 Axial pattern distant flap of skin to head or neck	4	0.4	0	0.0	0	0.0
S20.2 Axial pattern distant flap of skin NEC	4	0.4	0	0.0	0	0.0
S22.2 Neurovascular island sensory flap of skin NEC	4	0.4	3	0.7	3	0.9
S25.3 Local fasciocutaneous flap to head or neck NEC	4	0.4	1	0.2	1	0.3
S26.5 Local subcutaneous pedicle flap of skin to head or neck NEC	4	0.4	0	0.0	0	0.0
S27.1 Axial pattern local flap of skin to head or neck NEC	4	0.4	1	0.2	0	0.0
S20.5 Distant flap of skin to head or neck NEC	3	0.3	0	0.0	0	0.0

continued

TABLE 22 Frequencies OPCS codes for eligible SRs in the three SR subsets (*continued*)

OPCS code[a]	Maximum SR subset (*n* = 1018)		Minimum SR subset (*n* = 404)		TT SR subset (*n* = 325)	
	n	%	*n*	%	*n*	%
S24.1 Local myocutaneous subcutaneous pedicle flap to head or neck	3	0.3	0	0.0	0	0.0
S25.1 Local fasciocutaneous subcutaneous pedicle flap to head or neck	3	0.3	1	0.2	1	0.3
S19.1 Distant tube pedicle flap of skin to head or neck	2	0.2	0	0.0	0	0.0
S20.8 Other specified other distant flap of skin	2	0.2	0	0.0	0	0.0
S22.8 Other specified sensory flap of skin	2	0.2	0	0.0	0	0.0
S24.3 Local myocutaneous flap to head or neck NEC	2	0.2	0	0.0	0	0.0
S19.2 Distant tube pedicle flap of skin NEC	1	0.1	0	0.0	0	0.0
S19.8 Other specified distant pedicle flap of skin	1	0.1	0	0.0	0	0.0
S22.4 Local sensory flap of skin NEC	1	0.1	1	0.2	1	0.3
S22.9 Unspecified sensory flap of skin	1	0.1	1	0.2	0	0.0
S26.1 Axial pattern local subcutaneous pedicle flap of skin to head or neck	1	0.1	0	0.0	0	0.0
S26.3 Random pattern local subcutaneous pedicle flap of skin to head or neck	1	0.1	0	0.0	0	0.0

a Multiple codes can be assigned to one SR, so columns do not sum to the numbers of patients in the respective subsets.

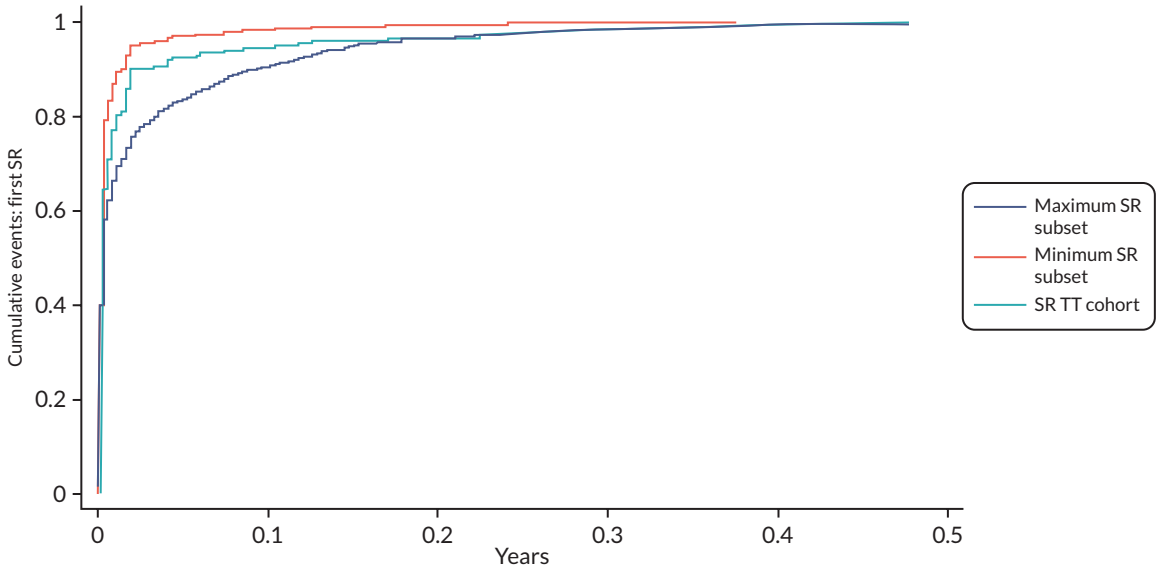


FIGURE 8 Time to first SR from first admission in the SPU admissions cohort for maximum, minimum and TT SR subsets.

Time to the first SR was shorter for patients in the maximum SR subset than the minimum SR subset but time to a second SR (when this occurred) was shorter for patients in the minimum SR subset than the maximum SR subset. Survival was similar in the minimum and TT SR subsets and better than in the maximum SR subset.

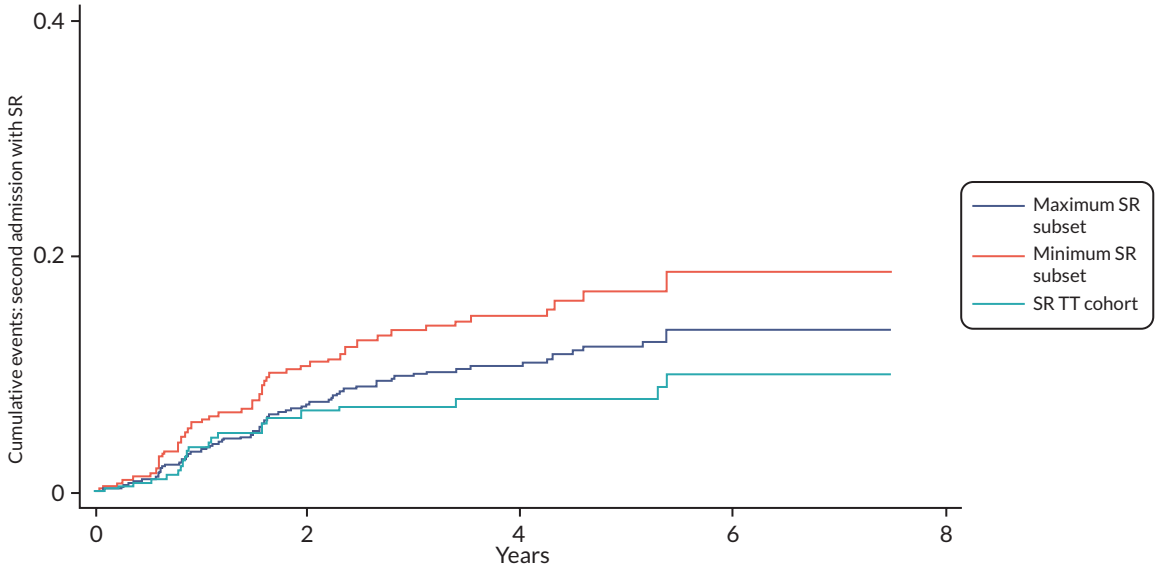


FIGURE 9 Time to second SR from first admission in the SPU admissions cohort for maximum, minimum and TT SR subsets.

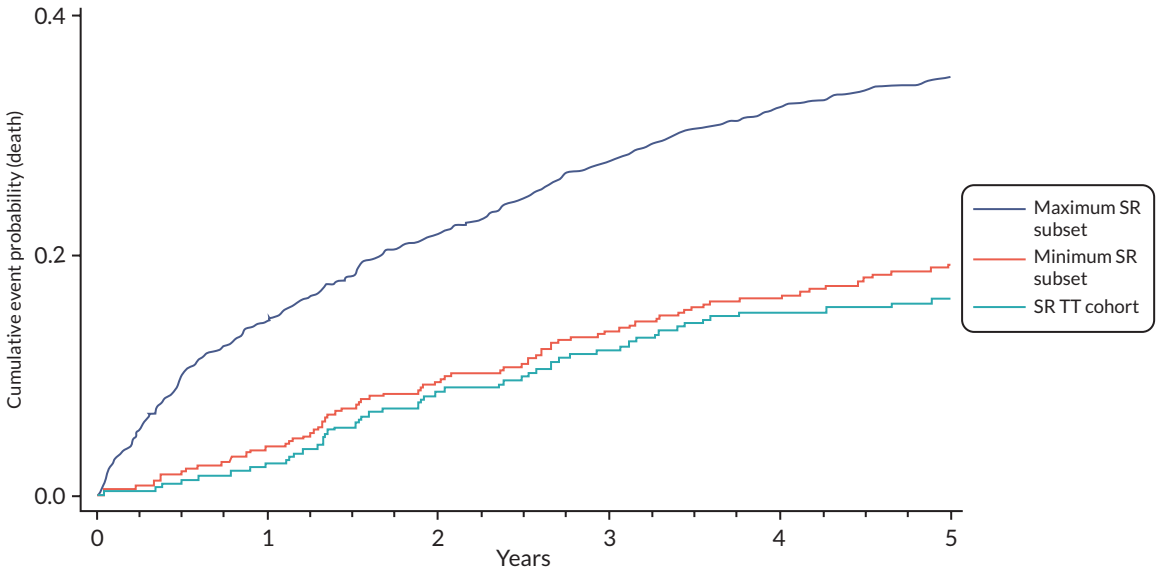


FIGURE 10 Time to death from first admission in the SPU admissions cohort for the maximum, minimum and TT SR subsets.

Hospitals performing surgical reconstruction

The numbers of SPU admissions and SRs performed by NHS providers in England from 1 April 2011 to 30 September 2018 are shown in *Table 43* (see *Appendix 9*: additional tables and figures for analyses of the HES cohort) for the maximum SR subset (*n* = 1018). Spinal injury centres and NHS providers with a plastic surgery unit are identified. The table also describes the annual rate of SPU admissions and SRs. (Providers performing NSRs are not identified.)

Eighty-six English acute hospital providers (of a total of 124) performed ≥ 1 SR in 7.5 years. The 10 providers performing the most SRs accounted for 49.6% of all SRs (505/1018) and the next 10 providers for 21.2% (216/1018). The remaining 66 providers performing any SR accounted for only 29.2%. The top 10 providers performed on average 4–13 SRs per year, and the next 10 providers 2–4 SRs per year. With an average of ≤ 2 SRs per year, a hospital is likely to have had some years in which no SRs were performed. Thirteen providers performed 2 SRs, and 19 just 1 SR, in the 7.5-year period. (Note that closing a SPU may not have been the indication for some SRs in the maximum SR subset.)

In the maximum SR subset, across all hospitals in England, 1018 SRs were recorded in 7.5 years, or an average of 136 per year. In the minimum SR subset and the TT SR subset, the annual average numbers were 54 and 43, respectively.

Comparison of surgical reconstruction and no surgical reconstruction groups in the emulation of the target trial

A flow diagram for the entire TT emulation cohort is shown in *Figure 7*. This figure shows how exclusion steps were applied to derive the cohort which comprised 1799 eligible patients. The penultimate step divided the cohort into SR (*n* = 325) and NSR (*n* = 1474) groups depending on whether SR was coded during an eligible index admission. The SR 'group' in the TT emulation cohort is identical to the TT SR subset (*n* = 325, described in *Table 21*).

The final model to estimate propensity scores included: age (splines), sex, kidney disease, cause of impaired mobility (injury/neurogenerative disease/unspecified cause/unassigned), number of admissions in the 12 months before the index admission (splines), number of previous SPU admissions in the 12 months before the index admission (splines). Comorbidities of stroke and dementia were excluded from the PS model; too few patients had had a stroke and there was none who had had SR, and none of the 55 patients with a diagnosis of dementia had SR.

The distributions of patients in SR and NSR groups by percentiles of PS are shown in *Table 44* in (see *Appendix 9*: additional tables and figures for analyses of the HES cohort). *Figure 11* shows the PS probability density functions for the two groups, which overlapped substantially in relation to the date of index admission. Patients with a propensity for SR less than the 5th percentile (lower fifth percentile of propensity scores, *n* = 89; *Table 44*) were excluded because few primary outcome events were observed in either group. The cohort for analysis therefore comprised 1710 patients. A small number of patients had zero follow-up (*n* = 37) due to either dying in hospital during their index admission (*n* = 29) or being discharged more than a year after the index admission and diagnosis date (*n* = 8). Follow-up was set at 0.5 days for these patients so that they could be included.

The five outcomes of interest are summarised in *Table 23*, by SR/NSR group and overall. The percentages of patients with a subsequent admission with a SPU diagnosis were similar in both groups. The median length of stay was considerably longer in the SR group, as expected due to the long hospital stay required after SR. A higher percentage of patients in the SR group (50/322, 16%) had a later eligible SR during the entire follow-up available and in the 12 months after the index admission (23/322, 7%) than in the NSR group (60/1388, 4% and 34/1388, 2%, respectively). Time to a later eligible SR (first SR for patients in the NSR group and second SR for patients in the SR group) is shown in *Figure 12*. About a third of SRs in patients in the SR group occurred in the first month or two (some potentially too quickly after

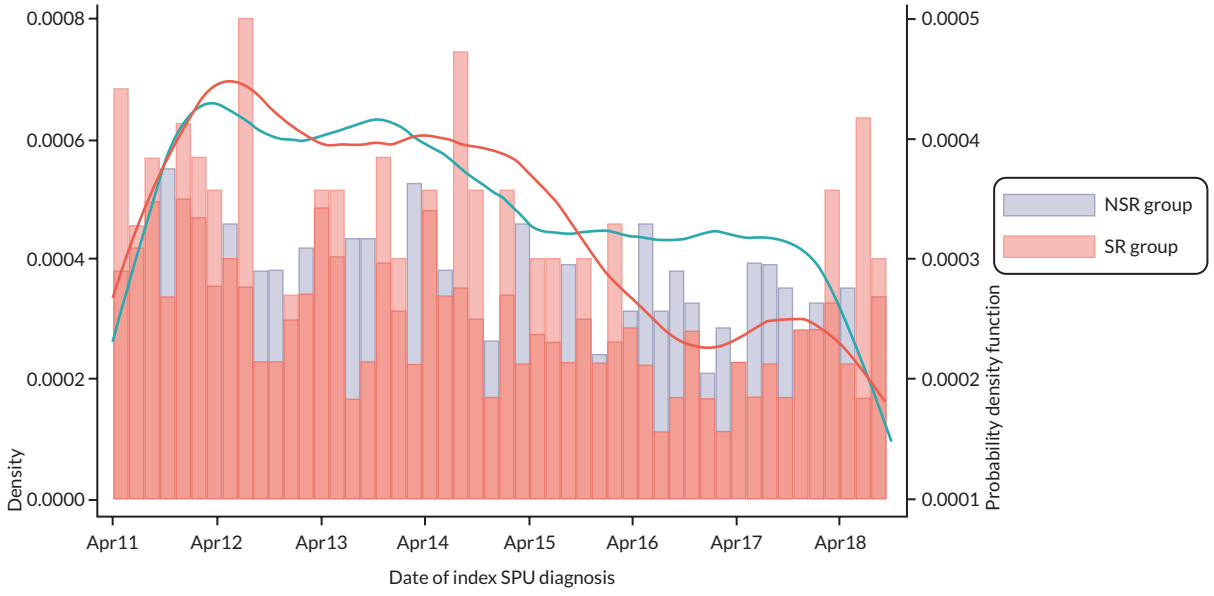


FIGURE 11 Probability density functions and histograms (bin-width = 2 months) of index admission dates in patients in the NSR and SR groups in the TT emulation.

TABLE 23 Percentages and medians (IQR) for all outcomes, by SR/NSR group and overall

Outcome	No SR in index admission *n* = 1388	SR in index admission *n* = 322	Overall *n* = 1710
Subsequent admission with SPU diagnosed after index admission; *n* (%)	319 (23%)	72 (22%)	391 (23%)
Length of stay; median (IQR)	10 (0–40)	28 (13–51)	14 (1–42)
Number of patients having a later eligible SR, that is first SR in the NSR group and second SR in the SR group; *n* (%)	60 (4%) had a later eligible SR 34 (2%) had later eligible SR within 1 year	50 (16%) had a later eligible SR 23 (7%) had later eligible SR within 1 year	110 (6%) had a later eligible SR 57 (3%) had later eligible SR within 1 year
Any HES admission after index; *n* (%)	786 (57%)	177 (55%)	963 (56%)
Died within 6 months; *n* (%)	124 (9%)	4 (1%)	128 (7%)

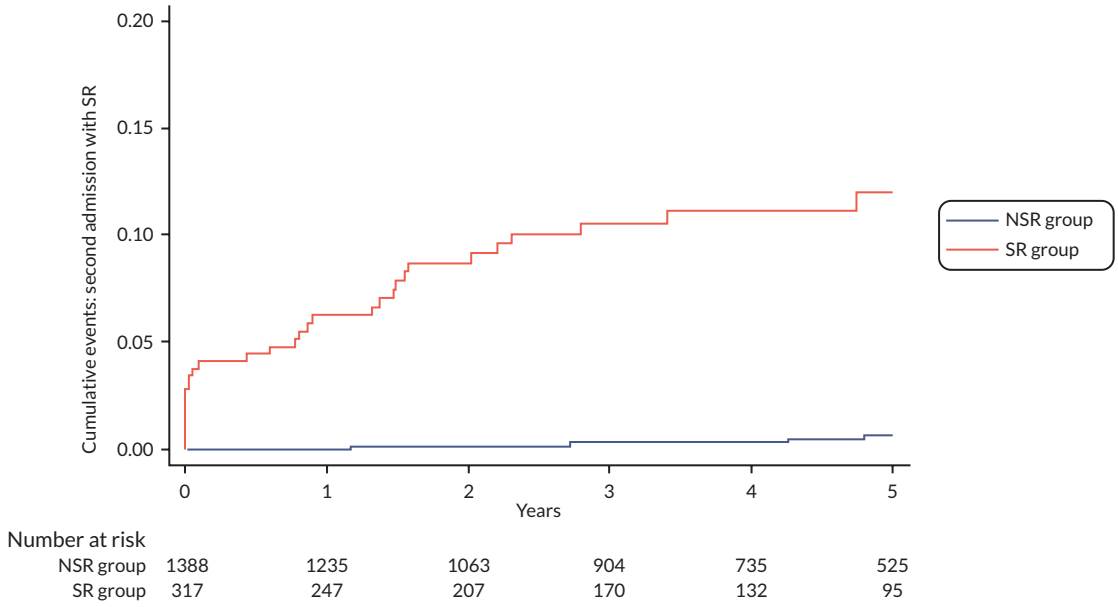
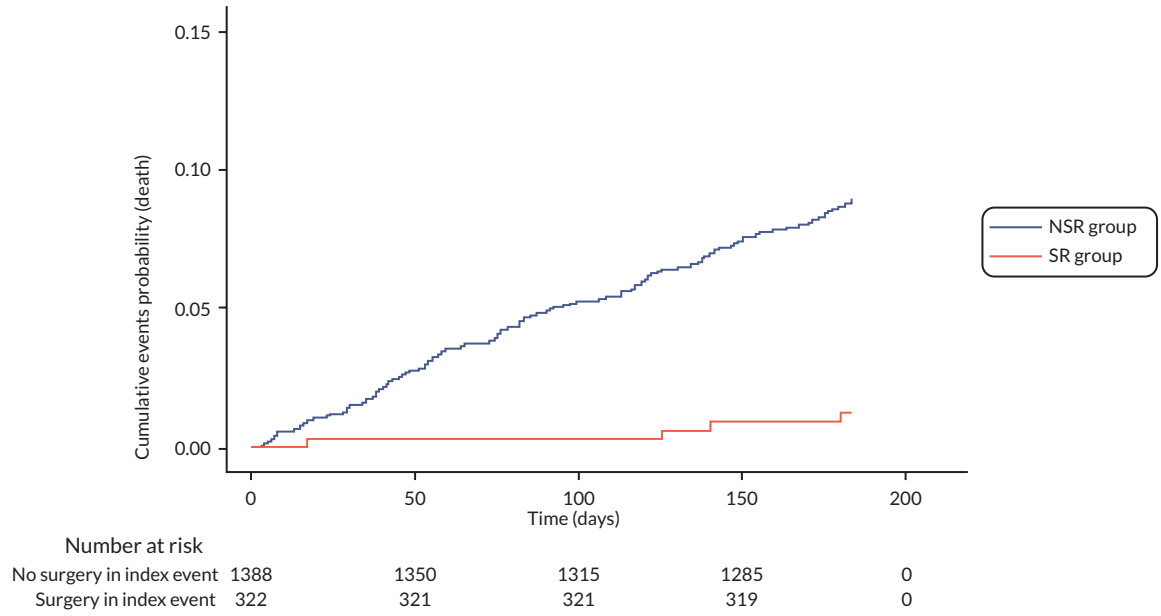


FIGURE 12 Time to a later eligible SR in patients in the SR (second SR) and NSR (first SR) groups in the TT emulation.

the first SR and may represent miscoding of complications of the first SR, rather than a repeat SR), then at a constant rate up to three or 4 years. SRs in patients in the NSR group occurred at a slow and constant rate up to 5 years. The percentage of patients dying within 6 months of the index admission was small in the SR group (1%) but high in the NSR group (9%); deaths in both groups occurred at a steady rate over the first 6 months (*Figure 13*).

The primary outcome of time to next admission with a SPU diagnosis and the secondary outcome of time to next admission (any diagnosis) were formally compared. Unadjusted and adjusted HRs are summarised in *Table 24*. The adjusted HR for the primary outcome was 0.79 (95% CI 0.61 to 1.03; $p = 0.07$), suggesting that SR during the index admission delayed a subsequent admission with a SPU diagnosis; times to a cumulative probability of admission of 0.15 were about 107 (72–137) and 189 (90–238) days in NSR and SR groups, respectively. For the secondary outcome of the next admission, the adjusted HR was 0.87 (95% CI 0.74 to 1.04; $p = 0.12$); median times to admission were about 208 (182–238) and 258 (211–318) in NSR and SR groups. Inverse probability-weighted survival graphs for these outcomes are shown in *Figures 14* and *15*.

Analyses of pre-specified subgroups for the primary outcome, time to next admission with a SPU diagnosis, are shown in *Figure 16*. None was statistically significant. The effects for age (≤ vs. > 60 years) and any previous admission with a coded SPU diagnosis were not in the expected direction, that is younger patients and those with a previous admission with SPU diagnosis had a lower hazard of re-admission (i.e. re-admission less likely) with a coded SPU diagnosis.



Number at risk					
No surgery in index event	1388	1350	1315	1285	0
Surgery in index event	322	321	321	319	0

FIGURE 13 Time to death in patients in the NSR and SR groups in the TT emulation.

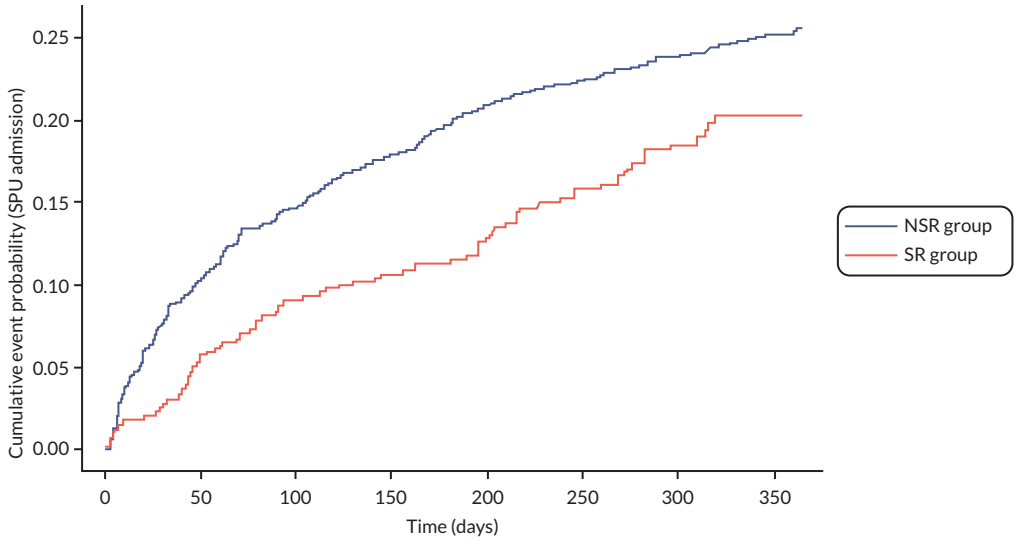


FIGURE 14 Time to next hospital admission with SPU diagnosis for SR and NSR groups in the TT emulation.

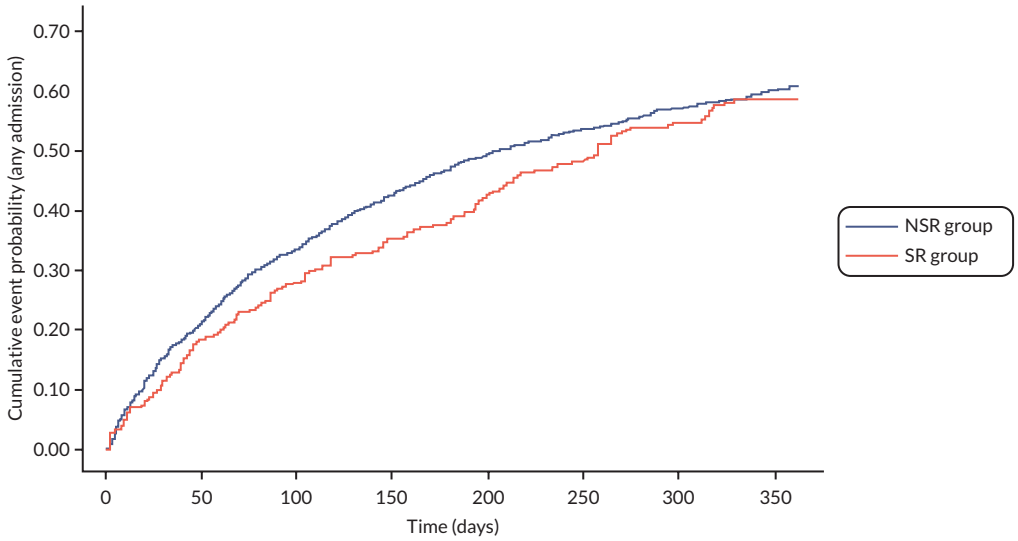


FIGURE 15 Time to next hospital admission for SR and NSR groups in the TT emulation.

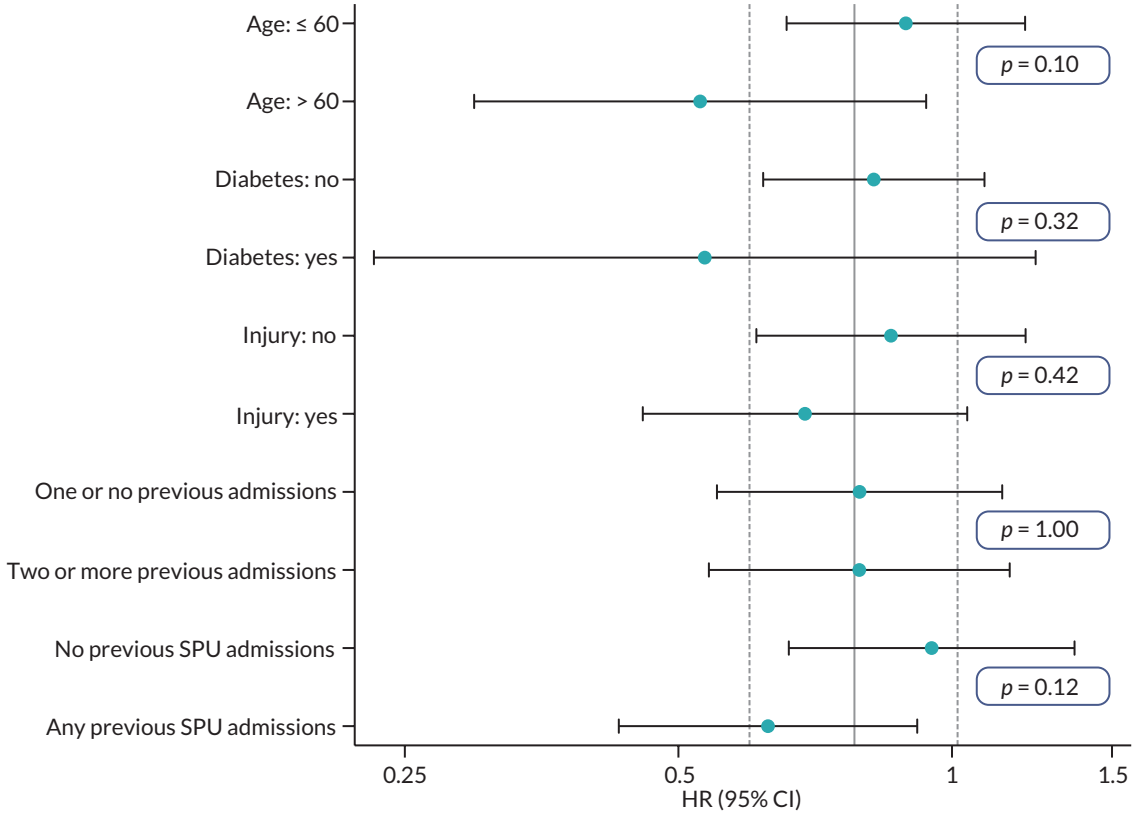


FIGURE 16 Hazard ratios for SR vs. NSR for time to next admission with SPU diagnosis for pre-specified subgroups in the TT emulation.

TABLE 24 Unadjusted and adjusted HRs for (a) re-admission to hospital with SPU diagnosed and (b) any re-admission in the TT emulation

Analysis	***n***	***Re-admission to hospital with SPU diagnosed***			
Primary outcome		*NSR group, n (%)*	*SR group, n (%)*	*HR (95% CI)*	*p-value*
Unadjusted model	1710	319/1388 (23.0%)	72/322 (22.4%)	0.92 (0.71 to 1.19)	0.53
Adjusted model[a]				0.79 (0.61 to 1.03)	0.07
Analysis	***n***	***Any re-admission to hospital***			
Secondary outcome		*NSR group, n (%)*	*SR group, n (%)*	*HR (95% CI)*	*p-value*
Unadjusted model	1553	786/1388 (56.6%)	177/322 (55.0%)	0.89 (0.75 to 1.04)	0.15
Adjusted model[b]				0.87 (0.74 to 1.04)	0.12

PS, propensity score.
a Adjusted for: age (splines), sex, IMD (splines), CCI (splines), kidney disease, cause (injury/neurogenerative disease/unspecified cause/unassigned), number of previous admissions (splines), number of previous SPU admissions (splines), PS (splines).
b Adjusted for: age (splines), CCI score (splines), dementia, cause (injury/neurodegenerative disease/unspecified cause/unassigned), number of previous admissions (splines), PS (splines).

Note
This table excludes those with lowest PS percentiles (< 5th percentile).

Results of analyses of the Clinical Practice Research Datalink cohort

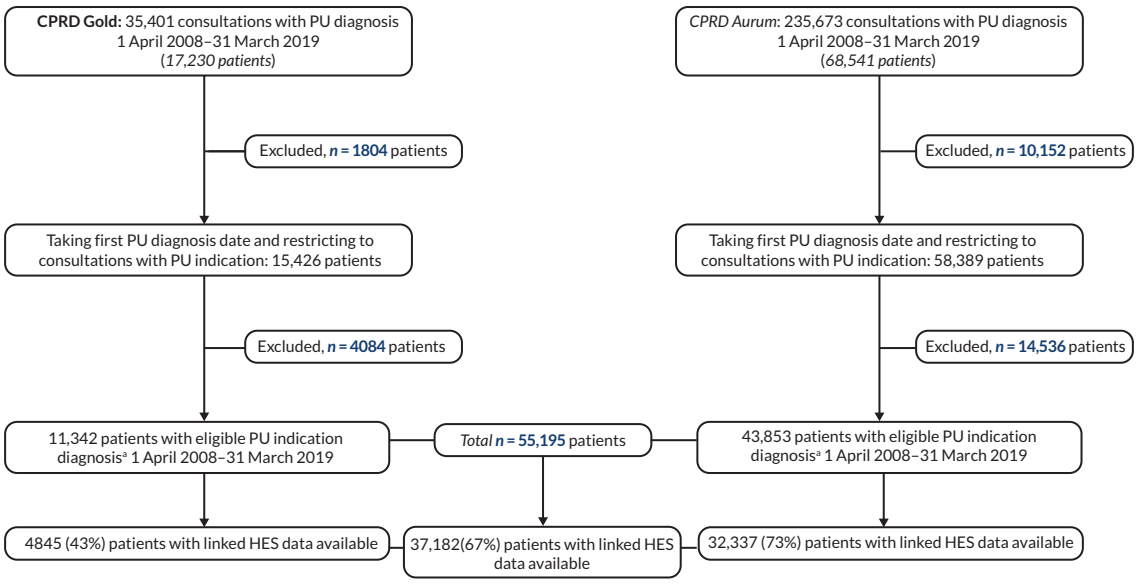
Characteristics of patients in the Clinical Practice Research Datalink cohort

Figure 17 shows how the Gold and Aurum data extracts of primary care consultations were filtered to generate cohorts of patients with an eligible incident PU indication between 1 April 2008 and 31 March 2019. The final cohort comprised 55,195 patients, 11,342 from the Gold extract and 43,853 from the Aurum extract. The characteristics of patients in the Gold and Aurum cohorts, and overall, at the time of their first consultations with a code indicating the presence of a pressure ulcer are shown in *Table 25*. Tables of frequencies of Read and SNOMED codes designating an incident ulcer are shown in *Tables 45* and *46* (see *Appendix 10*: additional tables and figures for analyses of CPRD cohort). Just 0.4% of incident ulcers in the Gold database and 2.6% of incident ulcers in the Aurum database had codes that specified the stage of the PU.

The data sets we analysed comprised all primary care consultations after the first recorded consultation (between 1 April 2008 and 31 March 2019) indicating that a PU was present. The data sets also included HES-linked data when available; some patients did not have any HES-linked records, for one or more of the reasons described previously. *Table 25* also shows the numbers and percentages of each cohort with HES-linked data.

The characteristics of patients in the Gold and Aurum cohorts, and those with and without HES linked data within each cohort, were broadly similar. Most patients were female (58%) and the median age was 82 years. The percentages with tabulated comorbidities were unexceptional and similar for patients for whom HES data were and were not available and for patients in the Gold and Aurum databases.

Estimating incidence depends on knowing the denominators for the Gold and Aurum databases. CPRD release notes in 2021 (Release Notes for CPRD Gold) suggest that about 3,100,000 patients were covered in the Gold database (4.7%) and about 11,800,000 patients were covered in the Aurum database (17.8%). Some patients will have been represented in both databases (because primary care practices have installed new software), but we received de-duplicated extracts.



[a]*Eligibility criteria:*
i. At least 365 days since patient first registered
ii. At least 365 days since patient first permanent registration
iii. Before the transfer out date (if recorded)
iv. Before the last collection date for GP practice
v. After the up to research standard date for that GP practice
vi. Is not between 1 April 2008 and 30 March 2009 (as does not provide one year to characterise the cohort)
vii. Minimum age 18 at time of consultation

FIGURE 17 Flow chart showing how Gold and Aurum data extracts from CPRD were filtered to generate the CPRD cohort.

TABLE 25 Baseline characteristics of patients with an incident ulcer in the CPRD cohort, for Gold and Aurum data sets separately and overall, with and without linked HES data

Characteristic	CPRD Gold: HES linked data available		CPRD Aurum: HES linked data available		CPRD Gold and Aurum: HES linked data available		
	No (*n* = 6497; 57%)	Yes (*n* = 4845; 43%)	No (*n* = 11,516; 26%)	Yes (*n* = 32,337; 74%)	No (*n* = 18,013; 33%)	Yes (*n* = 37,182; 67%)	Overall (*n* = 55,195)
Sex; n (%)							
Male	2783 (43%)	1992 (41%)	4943 (43%)	13,663 (42%)	7726 (43%)	15,655 (42%)	23,381 (42%)
Female	3714 (57%)	2853 (59%)	6573 (57%)	18,674 (58%)	10,287 (57%)	21,527 (58%)	31,814 (58%)
Age; median (IQR)	80 (70–87)	82 (73–88)	81 (71–88)	82 (72–88)	81 (71–88)	82 (72–88)	82 (72–88)
BMI[a] (most recent in 3 years); median (IQR)	25 (21–29)	25 (21–29)	25 (21–30)	25 (21–29)	25 (21–30)	25 (21–29)	25 (21–30)
Year of first PU diagnosis; n (%)							
2009	578 (9%)	617 (13%)	719 (6%)	2252 (7%)	1297 (7%)	2869 (8%)	4166 (8%)
2010	730 (11%)	823 (17%)	1058 (9%)	3133 (10%)	1788 (10%)	3956 (11%)	5744 (10%)
2011	764 (12%)	750 (15%)	1043 (9%)	2977 (9%)	1807 (10%)	3727 (10%)	5534 (10%)
2012	731 (11%)	702 (14%)	1061 (9%)	2971 (9%)	1792 (10%)	3673 (10%)	5465 (10%)
2013	729 (11%)	509 (11%)	1087 (9%)	3053 (9%)	1816 (10%)	3562 (10%)	5378 (10%)
2014	635 (10%)	432 (9%)	1109 (10%)	3027 (9%)	1744 (10%)	3459 (9%)	5203 (9%)
2015	615 (9%)	343 (7%)	1125 (10%)	3312 (10%)	1740 (10%)	3655 (10%)	5395 (10%)
2016	528 (8%)	222 (5%)	1228 (11%)	3336 (10%)	1756 (10%)	3558 (10%)	5314 (10%)
2017	539 (8%)	201 (4%)	1248 (11%)	3636 (11%)	1787 (10%)	3837 (10%)	5624 (10%)
2018	527 (8%)	200 (4%)	1447 (13%)	3764 (12%)	1974 (11%)	3964 (11%)	5938 (11%)
2019	121 (2%)	46 (1%)	391 (3%)	876 (3%)	512 (3%)	922 (2%)	1434 (3%)
Comorbidities in previous year							
IHD; *n* (%)	169 (3%)	128 (3%)	723 (6%)	2057 (6%)	892 (5%)	2185 (6%)	3077 (6%)
HF; *n* (%)	273 (4%)	242 (5%)	753 (7%)	2082 (6%)	1026 (6%)	2324 (6%)	3350 (6%)
Hypertension; *n* (%)	1004 (15%)	705 (15%)	2505 (22%)	7330 (23%)	3509 (19%)	8035 (22%)	11,544 (21%)
COPD; *n* (%)	293 (5%)	212 (4%)	839 (7%)	2498 (8%)	1132 (6%)	2710 (7%)	3842 (7%)
Asthma; *n* (%)	341 (5%)	290 (6%)	713 (6%)	2028 (6%)	1054 (6%)	2318 (6%)	3372 (6%)
Diabetes; *n* (%)	1445 (22%)	1064 (22%)	2777 (24%)	7704 (24%)	4222 (23%)	8768 (24%)	12,990 (24%)
Haemodialysis or renal disease; *n* (%)	256 (4%)	224 (5%)	710 (6%)	2090 (6%)	966 (5%)	2314 (6%)	3280 (6%)

BMI, body mass index; COPD, chronic obstructive pulmonary disease; HF, heart failure; IHD, ischaemic heart disease.
a Missing data: BMI missing for 4126, 15,374.

Our extracts predate these notes but this should mainly affect the ratio of Gold: Aurum, rather than the total coverage; in 2015, the Gold database was reported to cover 6.9% and in 2019 the Aurum database to cover about 13%.[67,68] Thus, we have assumed that about 20% of the English population were represented in our combined extracts.

The mid-year 2011 England population was 53,107,000.[40] Using PU incidence data derived from CPRD, this population estimate yields an annual PU incidence of about 5 per 10,000 (an average of 5017 per year in 20% of the English population (10,621,000) or 25,085 for the whole English population). There are no reliable existing estimates of pressure ulcer incidence or annual UK pressure ulcer prevalence data for comparison. However, given the number of inpatients with a recorded SPU from the HES cohort (291,326 adults over 7.5 years, or an average of 38,843 adults per year), we suspect that many PUs are not captured by CPRD activity codes. The issue of potential under-ascertainment of PUs is explored further below (*Clinical Practice Research Datalink patients with linked Hospital Episode Statistics data*). We were unable to relate the categories of incident PUs with other PU surveys because the PU stage was rarely described by the Read or SNOMED code assigned to a record.

Episodes of pressure ulcer management in primary care

When we applied to do the study, we had the ambition to describe patients' entire care pathways, from incident PU to, for a subset, first admission to hospital with a SPU. To this end, we identified Read codes (for the Gold data set) for discharge from a relevant primary care activity and referral in primary care for some other care activity (whether primary or secondary care). Given the emerging results (below) and the similarity between Gold and Aurum data sets in other respects, we did not attempt to map the Read codes on to SNOMED codes. Therefore, the results presented below are for the Gold data set only.

Figure 18 shows longitudinal primary records for two random samples of 25 patients identified with an incident PU, identifying additional dates when a PU was indicated (based on the same codes used to identify an incident PU), when discharge or referral was coded, when a patient died and the end of follow-up. Just 43 of 11,342 patients (0.4%) had a discharge code at any point in their longitudinal records; longitudinal records for all these patients are shown in *Figure 19*. We assumed that this was because discharge from community nursing care, for example, was rarely coded, rather than because such care continued over many years. The lack of discharge codes caused us to abandon any further exploration of the duration of episodes of PU care or repeat episodes of PU care.

Clinical Practice Research Datalink patients with linked Hospital Episode Statistics data

We used the HES data linked to the CPRD cohort for the same period as for the HES cohort (1 April 2011 to 30 September 2018 with the subsequent 6 months for the minimum duration of follow-up) to compare the proportions of patients in the HES and CPRD cohorts satisfying the various eligibility criteria applied to the HES cohort and the proportion of patients having SR (*Table 26*). This allowed us to (a) examine the extent of under-ascertainment of PUs in the CPRD cohort and (b) check that the proportions of patients admitted to hospital with SPUs and having SR were similar in the two cohorts. Incident PUs, but not admissions to hospital, could have been identified in the period 1 April 2008 to 31 March 2011. Both cohorts exclude patients who had a SR in the preceding year.

Two important observations arise from this table. Firstly, the CPRD inflated numbers and percentages suggest considerable under-ascertainment in the total number of patients admitted to hospital with a SPU that are accounted for by the CPRD cohort (< 15% of the number identified in the HES cohort). Secondly, the extent of the under-ascertainment decreases as further eligibility criteria are applied (lower rows in the table); for example, about 40% of elective admissions to hospital with L89/M86 as the primary diagnosis on admission, and over 70% of SRs, are accounted for by the CPRD cohort (< 10% of the number identified in the HES cohort).

These observations suggest that the CPRD data do not code PU for many patients and that patients who we identified with incident PU in the CPRD are a selected subgroup of people with an incident PU, more likely to be admitted to hospital with a SPU and more likely to have SR. We could not characterise the patients in the CPRD at the time of cohort entry in the same way as patients in the HES cohort with respect to an inferred cause of impaired mobility. However, we suspect that an indication of PU was more likely to be coded for patients perceived to be at risk of a PU, for example patients with a spinal injury or a neurodegenerative disease.

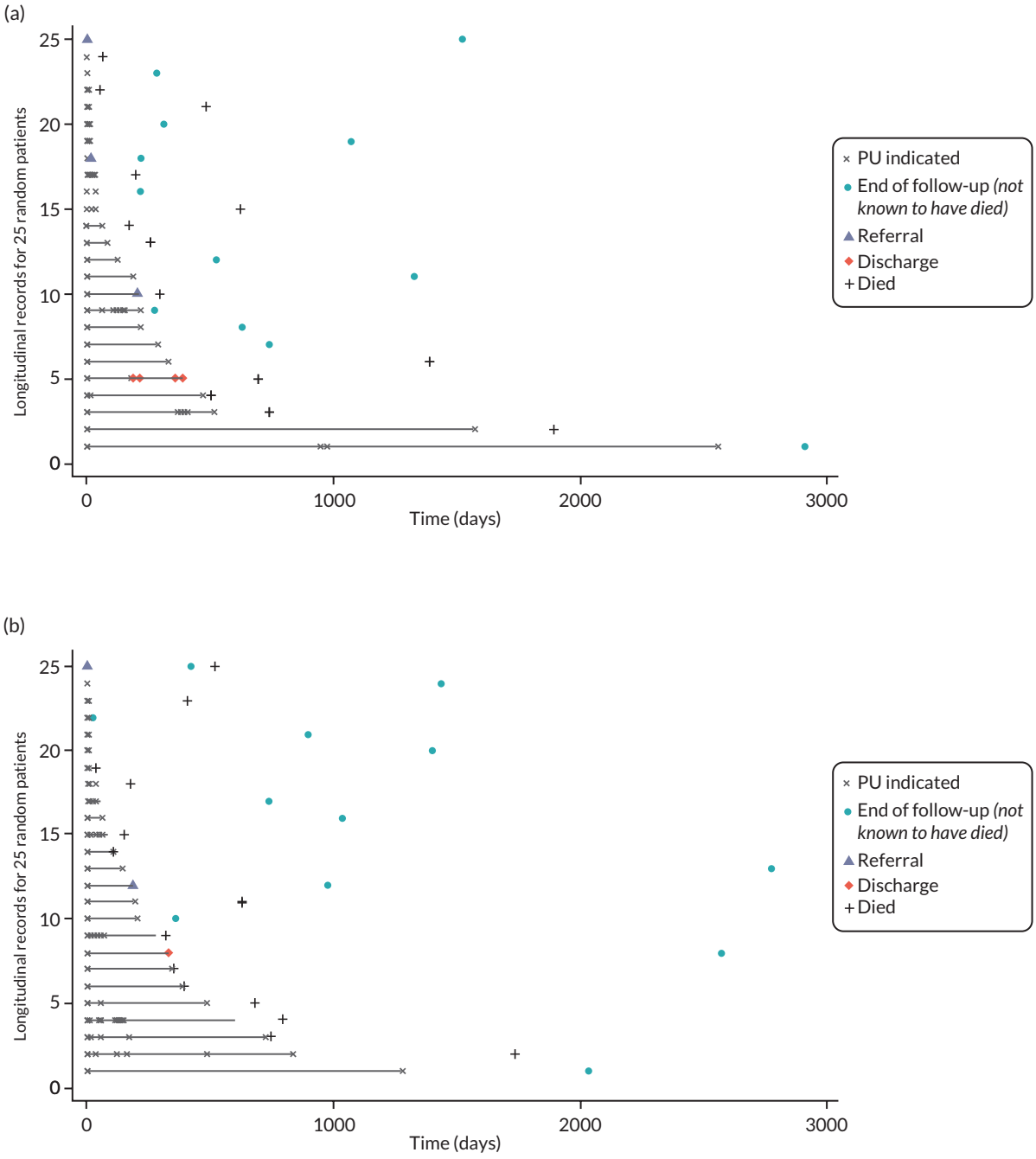


FIGURE 18 (a) and (b) – Two random samples of 25 patients (Gold CPRD extract only). Note: Time = 0 represents an incident PU. Symbols on the lines represent additional dates: when a PU was indicated, discharge or referral was coded, death or end of follow-up (31 March 2019).

Summary of main findings

The HES data showed that, between 2011 and 2018, SR to close a SPU was carried out rarely in England in the NHS. The data available did not permit unequivocal identification of SR to close a SPU in England; the maximum possible annual number was 136 and the minimum number was 43. We suspect the true number to be closer to the latter than the former number because patients represented in the maximum had a much higher risk of dying from any cause, were older and more likely to have important comorbidities, and less likely to have an assigned cause of impaired mobility at the time of admission.

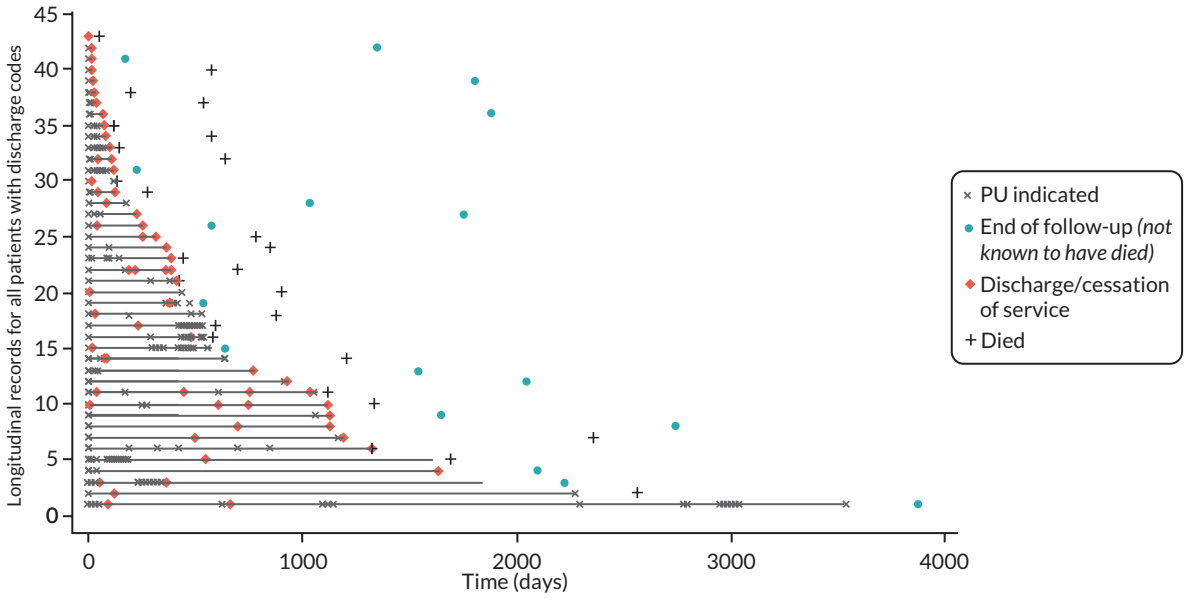


FIGURE 19 Longitudinal records for 43 patients with a discharge code. Note: Symbols along the horizontal lines distinguish additional times when: Time = 0 represents an incident PU. Symbols on the lines represent additional dates: when a PU was indicated, discharge was coded, death or end of follow-up (31 March 2019).

TABLE 26 Patients in the HES and CPRD cohorts satisfying various combinations of eligibility criteria and having SR

	HES cohort			CPRD cohort			CPRD inflated	
	N	%[a]	%[b]	*N*	%[a]	%[b]	*N*[c]	%[d]
Patients with SPU diagnosis during admission	291,326	100	–	5301	100	–	39,758	13.6
Patients with SPU diagnosis on admission	222,290	76.3	76.3	4788	90.3	90.3	35,910	16.2
Patients with L89/M86 as primary diagnosis on admission	15,897	5.5	7.2	805	15.2	16.8	6038	38.0
Patients with L89/M86 as primary diagnosis on elective admission	2253	0.8	14.2	116	2.2	14.4	870	38.6
Patients with L89/M86 as primary diagnosis on elective admission and no excluded comorbidity/procedure	1799	0.6	79.9	99	1.9	85.3	743	41.3
Patients with L89/M86 as primary diagnosis on elective admission and no excluded comorbidity/procedure and SR	325	0.1	18.1	31	0.6	34.3	233	71.5

L89, decubitus ulcer and pressure area; M86, osteomyelitis.
a Percentage calculated with respect to the number in the top row of the preceding column of the table.
b Percentage calculated with respect to the number in the preceding row of the preceding column of the table.
c Numbers are the numbers in the CPRD cohort column multiplied by 7.5 (since the CPRD cohort represented about 20% of the English population and only 67% of patients were eligible for HES linkage).
d Percentage calculated with respect to the number for the HES cohort in the same row of the table.

Between 2011 and 2018, 86 of 152 English acute NHS trusts performed one or more SRs (some of 17 specialist acute trusts would not be expected to carry out SR).[69] Ten English acute NHS trust providers accounted for half of all SRs carried out; a further 10 English acute NHS trusts providers accounted for another fifth of SRs carried out. All these 20 English acute NHS trusts hosted either a spinal injury centre or a plastic surgery unit.

We inferred that half to three-quarters of patients having SR had a cause of impaired mobility assigned at the time of admission, that is injury or neurodegenerative disease. Their mean age was between 50 and 60 years and about 70% were male.

We attempted to estimate the effectiveness of SR by emulating a RCT of SR versus NSR in the TT cohort, comparing 322 patients who had SR during their index admission with 1388 who did not. After adjusting for the propensity for SR and other available potential confounders, SR appeared to extend the time to a further admission with a diagnosis of SPU, and time to any further admission, but neither effect was statistically significant. We had concerns that the NSR group was not comparable, that is did not represent patients being managed to close a SPU without SR; the NSR group experienced much higher all-cause mortality than the SR group after their index admission.

The CPRD cohort was less informative than anticipated. Read and SNOMED codes for PU indications appeared not to be reliably assigned causing incident PUs to be under-ascertained. We could not follow patients longitudinally in primary care primarily because end dates for episodes of treatment for a PU could not be distinguished. By comparing information from the HES cohort with HES data linked to the CPRD cohort, we inferred that patients with a PU indication assigned in primary care were likely to represent a selected group.

Chapter 8 Consensus workshop

Methods

As explained in *Chapter 2*, we were unable to carry out the formal consensus process (WS3) as planned. Instead, we used informal processes to explore areas of uncertainty remaining after analysing the surveys. These processes and results are described in this chapter.

Invitations to attend a face-to-face meeting were sent to nurses and surgeons who had taken part in the WS1 surveys, the BCE or whose contact details had been supplied to us by the 'Getting It Right First Time' team. Several dates were offered and those responding were asked to indicate their availability for a half-day meeting at different venues or online. No date or venue was suitable for most participants, and we decided to hold the meeting online.

A summary of the findings from the study up to the time of the meeting was prepared and circulated to participants in advance. The meeting was held through Zoom (Zoom Video Communications, San Jose, CA, USA). With participants' consent, the entire meeting was video-recorded.

Two topics were chosen for discussion in the meeting: features of a care pathway for referral for SR to close a SPU; suitability of a patient for referral for SR to close a SPU. The first topic was chosen due to its importance for the number of patients being referred for consideration of SR; in view of the findings of WS2, we considered this to be a critical constraint on the feasibility of future research to estimate the effectiveness and cost-effectiveness of SR. The second topic was chosen to obtain consensus about the eligibility criteria for participation in a future study.

For the first topic, the qualitative findings from the surveys were presented. Then two questions were posed to participants for discussion:

1. How do you currently refer patients for SR?
2. What should the NHS care pathway look like for referral for SR?

The second topic drew on the findings of the surveys and the BCE, and an interview with a specialist plastic surgery nurse (SPN) who provided outreach in the community in November 2021; this nurse was also a participant in the consensus workshop. We chose six factors to ask further questions about their influence on suitability for SR:

1. influence of previous SR to close a SPU
2. influence of length of time the SPU has been present
3. SPU stage suitable for SR
4. influence of cause for immobility
5. influence of ability to adhere to postoperative SPU prevention regimens
6. influence of general health.

The factors were chosen for different reasons. For factors 1, 2 and 5, we wanted to confirm that these were very influential (as found by the surveys or BCE). For factors 3 and 6, which were of borderline significance in the BCE, we wanted to explore their influences in more detail. For factor 4, we wanted to try to find out whether participants agreed with the feedback received about referrals for SR in England being easier, or restricted to, patients with a spinal injury. We did not consider it necessary to consider the influence of all non-surgical treatments having been tried because the importance of this factor had been consistent throughout the study and it had the highest OR in the BCE.

At the outset, participants were instructed that 'Your answers should not consider NHS constraints (e.g. availability of beds)'. For each factor, a slide was shown summarising the findings from the previous elements of the study. Participants discussed the factor until the chair suggested moving to the questions, after about 5–10 minutes. The subsequent questions for a factor were also presented as slides. Participants entered their responses using the 'chat'

facility in Zoom, directing the response to the study manager only to prevent other participants from seeing the responses. There were two to four questions about each factor, with later questions usually being contingent on answers to an earlier question. Hence, some questions were not applicable to some participants, depending on their earlier answers. (The questions which were posed to participants are shown in *Table 27*).

With the permission of the participants, the meeting was video-recorded. For reasons described below, parts of the video-recording have been made available. The recording intentionally shows participants to credit them for their opinions and discloses their identities. Each participant consented to the recording being posted publicly and his or her identity being disclosed.

Results

Eleven nurses agreed to participate but one could not join the meeting. The remaining 10 participants comprised 9 TVNs and one SPN. Four participants reported that they worked mainly in the community, two across all settings including care homes (one working privately), two mainly in hospitals, one in both hospital and community, and one across all England. The SPN reported that she is based in a hospital but does outreach. No surgeon could attend the meeting, but a surgical perspective was obtained through the subsequent SMG meeting; this feedback was important in informing the discussion (see *Who should be considered for surgical reconstruction?*).

Results for topic 1: features of a care pathway for referral for surgical reconstruction

Participants initially introduced themselves, including the nature of their roles with respect to the management of SPUs. The vividness of these introductions in describing participants' roles and their frustrations with accessing a surgical opinion about SR cannot be captured by a summary text description. Inevitably, earlier free-text comments to the survey captured much of what participants said, but these introductions provided more detail (see *Report Supplementary Material 5* video-recording Part 1).

The discussion about a possible referral pathway (*Figure 20*) also covered the key issues captured by the free text responses to the survey. However, it provided important additional details. For example, participants concluded that the pathway should include two MDT meetings, the first one community-led and the second one surgically led. The meeting was also helpful in eliciting the range of service providers who have a contribution to make to each MDT. The meeting did not discuss the evidence to support these services, but participants considered them to be integral to optimising their roles. The full discussion of topic 1 is covered by *Report Supplementary Material 6* video-recording Part 2.

Further discussion about a possible referral pathway took place in a SMG meeting on 6 June 2022, when the consensus findings were presented. Aspects of referrals for a surgical opinion were also discussed with Sue Flavin, a TVN responsible for co-ordinating PUPIS, on 18 August 2022 and by e-mail with Mr Drew, a plastic surgeon performing SR in PUPIS, on 8 and 21 September 2022. Both have given their consent for their contributions to be described and their identities disclosed.

Results for topic 2: suitability of a patient for referral for surgical reconstruction to close a severe pressure ulcer

One TVN had to leave the meeting at the end of the discussion about a possible referral pathway to SR to close a SPU; hence, *Table 27* includes responses to questions about factors influencing eligibility for only nine participants.

Participants' responses to the questions posed in the consensus meeting are shown in *Table 27*. Where responses were qualified, qualifications are shown in the footnotes; these qualifications are important because they sometimes reverse the response given, for example the stated response relates to whether the situation 'ever' applies and the qualification describes whether it usually applies.

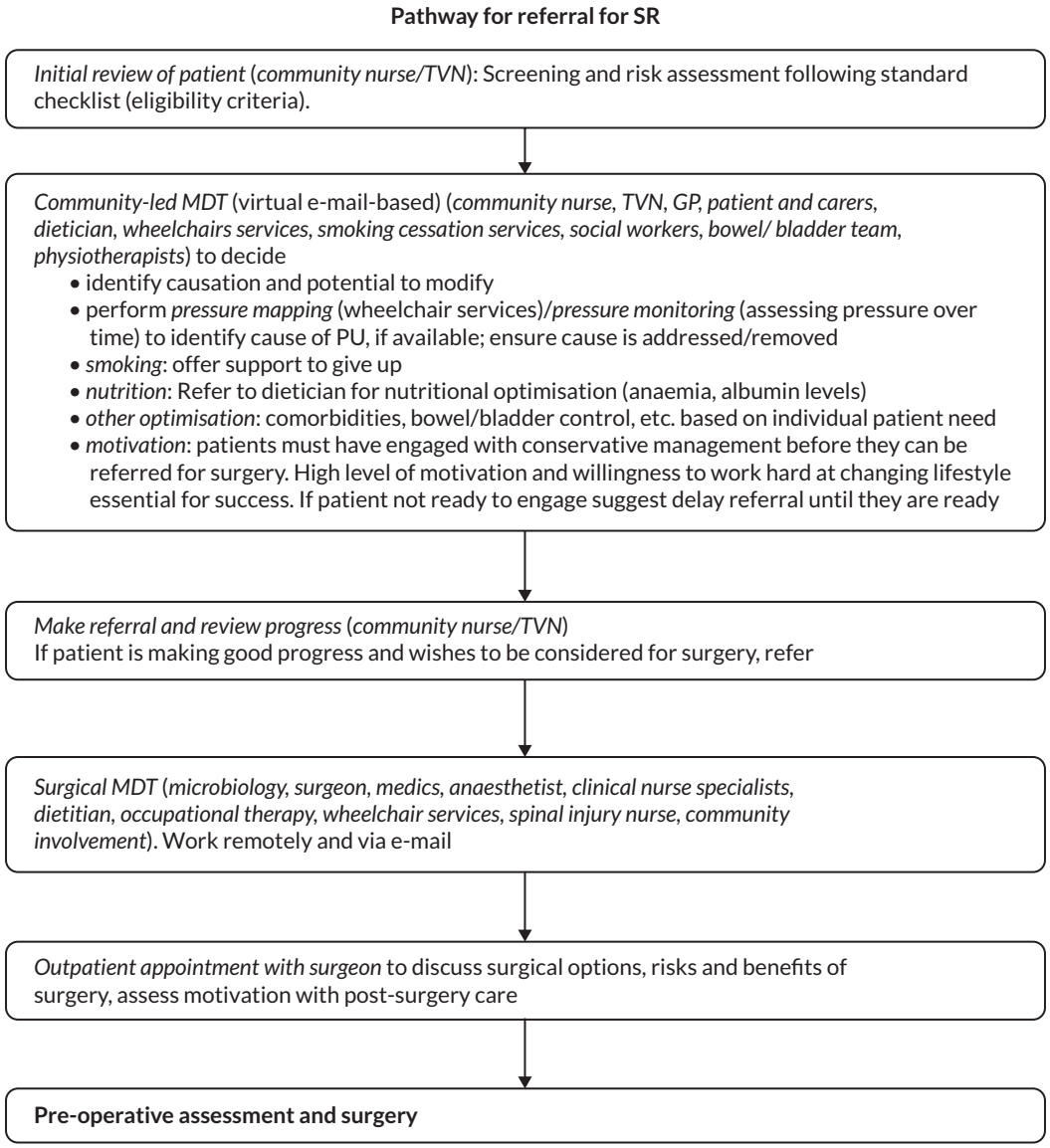


FIGURE 20 Consensus view of TVNs and a SPN about a possible referral pathway to SR for patients with a SPU.

Participants responses can be summarised as follows:

Factor 1: Previous SR should not rule out another SR. A further SR would not be possible if appropriate tissue (skin, muscle) is not available and unlikely to be appropriate if the reason for needing another SR is due to poor adherence to postoperative measures to prevent a PU.

Factor 2: The length of time a SPU has been present should not influence suitability for referral for a SR. This conclusion was qualified by requiring that all non-surgical interventions to promote healing of the SPU should have been tried. This conclusion was contradictory to the finding on this factor from the BCE; this inconsistency is discussed at greater length below (see *Who should be considered for surgical reconstruction?*).

Factor 3: Participants said that they would refer a stage 3 SPU for a surgical opinion about SR, if a patient was otherwise suitable. (The question about a stage 4 SPU was not discussed and participants did not provide responses.) This conclusion does not adequately reflect the discussion. Participants agreed that it would be unusual for a stage 3 SPU to undergo SR. However, given the likely time course for achieving the steps in the possible referral pathway (and current delays in accessing a surgical referral), it was considered very likely that a stage 3 ulcer would have become a stage 4 ulcer by the time a patient sees a surgeon.

TABLE 27 Consensus participants' responses to questions about the impact of various factors on suitability for SR

Consensus item	TVN1	TVN2	SPN	TVN3	TVN4	TVN5	TVN7	TVN9	TVN10
Factor 1: Effect of previous SR to close a SPU									
Question 1: Does any previous SR rule out someone for referral to be considered for further SR to treat a SPU?	No	Yes[a]	No	No	No	No	No[b]	No	Yes
Question 2: If no to question 1, does previous SR for a SPU at the current location rule out someone for referral to be considered for SR?	Yes	NA	No	No	No	No	No[c]	No	NA
Question 3: If no to question 1, does previous SR for a SPU at a different location rule out someone for referral to be considered for SR?	Don't know	NA	No[d]	No	No	No	No[e]	No	NA
Factor 2: Effect of length of time the SPU has been present									
Question 1: Does the length of time the SPU has been present influence whether you would refer a patient (otherwise suitable) for SR, providing that all non-surgical regimens to close the SPU have been tried?	No	No	Yes	No	DNR	No[f]	No	No	No
Question 2: If yes to question 1, does the length of time increase or decrease the likelihood that you would refer a patient (otherwise suitable) to be considered for SR?	NA	NA	Increase	NA	NA[g]	NA[h]	NA	NA	NA
Question 3: If yes to question 1, does the SPU have to have been present for at least/no longer than 6, 9, 12, 15, 18, 21, or 24 months?	NA	NA	6 months	DNR	NA	NA	NA	NA	NA
Factor 3: Category of SPU suitable for SR									
Question 1: Would you refer a patient (otherwise suitable) with a category 3 SPU to be considered for SR?	Yes	Yes	Yes	Yes	DNR	DNR	DNR	DNR	Yes
Question 2: Would you refer a patient (otherwise suitable) with a category 4 SPU to be considered for SR?	DNR	DNR	(Left meeting)	DNR	DNR	DNR	DNR	DNR	DNR
Factor 4: Effect of cause for immobility									
Question 1: Does the cause of a patient's immobility (spinal injury vs. neurodegenerative disease) influence whether you would refer a patient to be considered for SR?	No	No	(Left meeting)	No	No	No	No[i]	No	No
Question 2: If yes to question 1, would you refer a patient with a SPU due to immobility from a spinal injury (otherwise suitable) to be considered for SR?	NA	NA	(Left meeting)	NA	NA	NA	NA	NA	NA
Question 3: If yes to question 1, would you refer a patient with a SPU due to immobility from a **neurodegenerative disease** (otherwise suitable) to be considered for SR?	NA	NA	(Left meeting)	NA	NA	NA	NA	NA	NA
Factor 5: Effect of ability to adhere to postop SPU prevention regimens									
Question 1: Do you assess a patient's motivation to adhere to postop SPU prevention regimens when deciding whether to refer a patient to be considered for SR to treat a SPU?	Yes[j]	Yes	(Left meeting)	Yes	No	Yes[k]	Yes	Yes	Yes
Factor 5, question 2: Do you assess a patient's physical ability to adhere to postop SPU prevention regimens when deciding whether to refer a patient to be considered for SR to treat a SPU?	Yes	No[l]	(Left meeting)	Yes	No	Yes	Yes	Yes	Yes

TABLE 27 Consensus participants' responses to questions about the impact of various factors on suitability for SR (*continued*)

Consensus item	TVN1	TVN2	SPN	TVN3	TVN4	TVN5	TVN7	TVN9	TVN10
Factor 5, question 3: Do you assess a patient's access to help from a wider social network when deciding whether to refer a patient to be considered for SR to treat a SPU?	No	Yes	(Left meeting)	No	Yes	Yes	Yes	Yes	Yes
Factor 5, question 4: Please order the importance of: (a) motivation, (b) physical ability, (c) help from a wider social network when deciding whether to refer a patient to be considered for SR to treat a SPU?	(b) (a) (c)	(a) (c) (b)	(Left meeting)	(a) (b) (c)	(c) (a)= (b)=	(b) (c) (a)	(a) (b) (c)	(a) (c) (b)	(a)= (b)= (c)=
Factor 6, question 1: Do you consider whether a patient's general health can be improved when deciding whether to refer a patient to be considered for SR to treat a SPU?	Yes	Yes	(Left meeting)	DNR	Yes	Yes[m]	Yes[n]	Yes	Yes
Factor 6, question 1 – revised: Do you make a decision (yourself) that a patient's general health cannot be improved when deciding not to refer a patient to be considered for SR to treat a SPU?	No	Yes/ no[o]	(Left meeting)	No	No	Yes[p]	No	No	No
Factor 6, question 2: If yes to question 1, would you use a checklist (developed by surgeons and anaesthetists) to help assess whether a patient could be fit for SR?	(Left meeting)	DNR	(Left meeting)	No[q]	DNR	DNR	Yes	DNR	Yes

DNR, did not respond; NA, not applicable (due to contingent nature of questions).
Additional comments made by consensus participants as indicated by superscripts in the table:
a Yes, if needed due to not following guidance post surgery or frailty of tissue (several factors to consider).
b No, especially if on a different body area or has been some time (say 5 years) since previous surgery.
c No, but may limit choice and depends on time since previous reconstruction and SPU has recurred.
d No, however options may be limited.
e No, but as with first reconstruction would need to look at causation and modifiable behaviours/risks.
f No, if appropriate screening has been done and person suitable then SR should be an option.
g Ideally with this work and a pathway in place the length of time should reduce.
h I think all people should be referred at least once, irrespective of the age of the PU. Some PUs improve and deteriorate, so no one should be discriminated.
i No, should be about the benefit to the patient not why they got a PU.
j Not thoroughly enough.
k I assess motivation, but it would not stop me referring for SR.
l Physiotherapist and occupational therapist do this.
m Yes, the patient can be optimised – but this would not delay referral.
n Yes, mostly – although in some cases other risk factors will over-ride this.
o Yes and no – surgeons and anaesthetists will assess surgical risks, but TVN/nursing team will assess the wound and healing and patient's holistic circumstances.
p If a patient is at end of life, I would not refer.
q This question does not apply to me.

Factor 4: All participants said that the cause of impaired mobility should not influence whether a patient is considered for referral for a surgical opinion about SR. (These responses made subsequent questions about this factor unnecessary.)

Factor 5: The participants concluded that all three aspects of adherence to postoperative SPU prevention regimens are important. Where some participants responded 'no' this was because they did not perform these assessments themselves, not because the aspect of adherence was considered important. There was no apparent agreement about the relative importance of these three aspects of postoperative adherence.

Factor 6: All participants who responded said that they did consider whether a patient's general health can be improved when deciding whether to refer a patient for a surgical opinion about SR. None decided her/himself that a patient's general health cannot be improved (precluding a referral).

Further discussion about the characteristics of patients and SPUs that influence a decision to refer a patient for a surgical opinion about SR to close a SPU also took place at the SMG meeting on 6 June 2022. At this meeting, one of the surgeon applicants (JW) explained the complexities around surgical decision-making which are reflected in the *Chapter 9*, *Who should be considered for surgical reconstruction?*.

Summary

It was not possible to perform the consensus-seeking part of the study as intended. The consensus had to be held virtually, and no surgeon was able to participate.

The findings of topic 1 of the consensus meeting were consistent with the qualitative analysis of the free text comments from the surveys but added detail to a potential referral pathway for SR.

The findings of topic 2 of the consensus meeting were consistent with the quantitative analysis of surveys and, similarly, provided more details for participants' reasoning.

Interpretation of the consistency needs to take into account that most consensus participants had participated in the surveys of the BCE.

Chapter 9 Discussion

Main findings: challenges in carrying out the research

Despite an exhaustive search, we were unable to identify any randomised trial assessing the effects of SR compared with NSR. This lack of RCT evidence led us to include NRSI in the systematic review which we aimed to do as robustly as possible, setting eligibility criteria using the design features approach.[33] This novel approach was quite challenging to implement as the approach was theoretical and, to our knowledge, had not been used in practice before. The resulting review is now a useful precedent for how this approach can be operationalised. The systematic review assessing the impact of SPU on HRQoL was limited to RCTs to control for confounding. The RCTs were time-consuming to review; the yield of eligible RCTs was very low and ultimately the available evidence was not able to answer the question posed. We did not experience any challenges in conducting the initial surveys; however, addition of the BCE created a time pressure and the lack of face-to-face interaction with research partners (the value of such interactions is evidence by the success of the final SMG meeting). The included factors and their attributes may have differed in other circumstances.

We experienced a delay in obtaining the HES data extract and a mistake in the first extract generated added to this delay, although it was ultimately resolved by NHS Digital. We were confident about analysing the extract with respect to OPCS-4 procedure codes because, in our previous experience, these are carefully assigned by coders. We were less confident about the decisions we made based on ICD-10 diagnoses, coding of the primary diagnosis in an episode, and the timing of coding of diagnoses across episodes that comprise admissions. These challenges are common when analysing HES data extracts.

The initial CPRD extract was provided without delay after our application had been approved, under a licence agreement with the UoB. However, it took several months to obtain the linked HES data that had been requested. The fact that primary care records held by CPRD are split between two databases, Gold and Aurum, each with different codes to describe primary care activities made processing of the data extracts and their analyses time-consuming. In practice, JMH had to repeat the same steps while ensuring that the activities of interest were being captured accurately with two different sets of codes. Further investigation of the longitudinal nature of episodes of care was limited to the Gold data extract due to not having SNOMED codes for discharge from a service or referral to another service.

The greatest challenges to the conduct of the research arose in relation to WS3 and were mainly due to the COVID-19 pandemic, which caused delays, made team members less available and restricted face-to-face meetings. We were able to have only two face-to-face meetings with the members of the SMG, one in the first month of the study and one just 10 weeks before the final report was due. The latter meeting in particular provided insights about the referral pathway for SR and the factors that the patient and the surgeon need jointly to consider when deciding whether to have SR or not. We cannot unequivocally attribute this benefit to meeting face-to-face, but the complexity of the situation was better elucidated at this meeting than in previous virtual meetings.

The pandemic ruled out any face-to-face consensus meeting until early 2022. By this time, it proved impossible to convene such a meeting. All surgeons who we invited had very limited availability due to NHS clinic and theatre backlogs and nurses were only able to join a virtual meeting. Thus, there was no opportunity for nurses and surgeons to interact and we had to seek the views of surgeons about the findings from nurses' meetings by yet another online survey. The virtual nurses' meeting did not comprise a typical consensus process due to the evidence already obtained, the nature of uncertainties which we wanted to address, and the virtual meeting format. We circulated our provisional findings in advance and elicited nurses' responses about the key uncertainties.

Main findings

We describe the main findings from the WPs below in relation to likely questions that decision-makers will have and with reference to the original CB for this project. We provide our answers as far as we are able by drawing from

across the evidence we have assembled during the study, rather than as a catalogue of research findings from each research element.

How frequently is surgical reconstruction for pressure ulcers carried out in the United Kingdom?

We were able to answer this question for England using direct evidence from the WS2 HES data extract. Using these data, we estimated that the minimum and maximum numbers of SRs conducted per year in England, between 1 April 2011 and 30 September 2018 (7.5 years), were 43 and 134, respectively. This range does not reflect statistical uncertainty (the HES data cover all hospital admissions in England and do not comprise a sample) but, rather, uncertainty about whether the OPCS-4 code defining SR assigned to an individual truly represented a SR to close a SPU. The *minimum* number uses our assumptions, informed by clinical experts, about how we expected SR to close a SPU to be coded: SPU coded as the primary diagnosis on elective admission and without any of several defined diagnoses or procedures in the preceding months. The *maximum* number of SRs does not apply these assumptions and only restricts the number to one relevant SR code per patient with a SPU diagnosed at any time during any admission.

The people we identified as undergoing SR had a mean age in the mid-50s and were more likely to be men (about 70%). Our method of classifying the causes of people's impaired mobility suggested about 20% had permanent injury, about 35% had neurodegenerative disease, and the remainder could not be classified (diagnosis codes were non-specific, e.g. paraplegia, or none of the codes we considered was assigned). Otherwise, they had few serious comorbid diagnoses apart from hypertension (about 20%) and diabetes (about 15%). Mean age was lower in the minimum SR subset, injury and neurodegenerative disease were diagnosed more often, and comorbidities were less prevalent. Time to the first SR from the index admission with a SPU diagnosis was shorter for patients in the maximum SR subset than the minimum SR subset (when SPU was the primary diagnosis) but time to a second SR (when this occurred) was shorter for patients in the minimum SR subset than the maximum SR subset. Survival was better in the minimum SR subset than in the maximum SR subset (and similar to the TT SR subset). We think these differences between the minimum and maximum SR subsets are consistent with the former being more likely to comprise SRs to close a SPU.

We also described the hospitals in England which carried out the SRs and mapped the frequencies to the known locations of spinal injury centres and plastic surgery units. Based on the *maximum* number of SRs conducted per year (above), the 10 hospitals carrying out the most SRs all hosted plastic surgery units and half (5 of the top 6) were spinal injury centres. Hospitals ranked 1–5 carried out between 5 and 10 SRs per year; hospitals ranked 6–10 carried out fewer than five SRs per year.

The CPRD cohort suggested that incident PUs in the community are greatly underestimated using these primary care data. Nevertheless, the *proportions* of incident PUs identified in the community that were linked to hospital admissions with SPU on admission, with SPU as the primary diagnosis on admission, with elective admission, without specified comorbidity and having SR were more similar to these *proportions* in the HES cohort. We suggest that this apparent consistency supports our conclusion that the number of SRs to close a SPU being carried out in England each year is very small, and probably between 50 and 75.

Is there evidence to support the effectiveness of surgical reconstruction?

We answered this question by conducting a systematic review (WS1). Despite widening the study eligibility criteria from those used in a previous systematic review[17] (i.e. by including NRSI[33]), we did not find a single study of any design comparing the outcomes of SR with NSR. We suspect that this reflects a general difficulty in collecting information about patients managed without SR in the community, potentially over long periods of time. There have been many case series of SR, but we found none that described outcomes with non-surgical management.

Two low-quality NRSI[42,43] and a RCT[41] were identified. These studies compared different types of SR and were at moderate or high risk of bias. The two NRSI did not report any outcomes relevant to this current study. The RCT was carried out at a single centre in the USA, randomised just 20 participants and concluded that the incidence of minor wound complications did not differ between groups. However, PU recurrence was reported to be approximately 10% using the new approach to SR and 60% in the conventional SR group.

Some comparative evidence for a comparison of SR and NSR comes from our TT emulation (WS2) which used the HES cohort. The PS-adjusted estimates for the outcomes available in the data extract suggested that, compared with not having SR, SR reduced the hazard of another admission with SPU coded as the primary diagnosis by about 20% and the hazard of any further hospital admission by about 10%. However, we have serious concerns about the appropriateness of the NSR comparison group due to the substantial differences in the characteristics of the SR and NSR groups and the high mortality experienced by the NSR group (8% by 6 months after the index admission). The NSR group necessarily comprised patients admitted to hospital, whereas a more appropriate NSR group should probably comprise patients with SPUs managed only in the community. In the emulation, the median hospital stay after SR was 28 days (25th centile = 13 days); we do not how whether the median stay varies by hospital or according to the community care available, but the observed median was inconsistent with the experience of one surgeon applicant (JW). He said that the average minimum duration of hospital stay should be about 4 weeks. Moreover, SR is not performed primarily to reduce the risk of re-admission to hospital but improve a patient's wound experience and HRQoL. These important patient-focused outcomes are not recorded in HES data.

Our assertion that SR is performed primarily to improve a person's HRQoL and wound experience is based on data from the consensus meeting with nurses (WS3) and subsequent feedback from surgeons. The second systematic review (WS1) sought evidence to quantify the impact of PU on HRQoL. While not directly related to the effectiveness of SR, evidence that a PU (and particularly a SPU) substantially reduces HRQoL would raise the priority of finding more effective interventions. We reviewed over 300 RCTs of interventions to prevent or treat PUs, reasoning that only RCTs of effective interventions could reliably attribute a difference in HRQoL between groups to a PU. We found just three RCTs that assessed HRQoL. Unfortunately, none found the intervention evaluated to be effective.

Despite the lack of direct evidence about the effectiveness of SR to close a SPU, we consider that it is effective when performed by an experienced surgeon for four indirect reasons:

1. First, analyses of the HES cohort showed that re-admissions to hospital with a SPU were infrequent, about 12% by 6 months and about 20% by 12 months in the SR group in the emulation. These percentages are likely to include but may not be restricted to recurrences and we think it unlikely that a recurrence would be managed entirely in the community.
2. Secondly, published reports are broadly consistent with the findings from the HES cohort; of the studies included in the first review,[41–43] less than 20% of patients experienced a PU recurrence (follow-up 2 and 3 years, and not reported). Two relatively recently published case series (such studies were not reviewed systematically) reported similar recurrence rates of 17% (for operated SPUs; duration of follow-up not reported) and 27% (unclear whether operated SPU or a new SPU; mean follow-up of about 2 years, but including some with very long times to re-presentation).[42,70]
3. Thirdly, surgeon members of the research team, who perform SR, said that SR is effective in closing a SPU and that, with appropriate postoperative care in the hospital, complications are uncommon.
4. Fourthly, the small number of patients' histories (see *Report Supplementary Material 7*) we collected described the transformational nature of SR on patients' HRQoL.

Although this collection of evidence is of poor quality or anecdotal, collectively it suggests that the effectiveness of SR versus non-surgical interventions may not be the most important question to answer. That is, both treatment strategies may be effective to close a SPU, and the key question may be about the relative cost-effectiveness of the strategies (see *Might surgical reconstruction be cost-effective without being clinically effective?* below). The key gap in interpreting the above evidence is the lack of information about the percentage of SPUs closed successfully without SR, the length of time it takes to achieve closure and the percentage that recur. Our view that SR is effective is also informed by discussions from nurses and patient and public involvement (PPI) members about these outcomes.

Who should be considered for surgical reconstruction?

This question was addressed by the surveys of healthcare professionals (WS1), the BCE, the consensus meeting with nurses and subsequent feedback from surgeons (WS3). Responses to the surveys of nurses and surgeons were broadly consistent about the influence of individual patient and PU characteristics on decisions to refer for or offer SR. To

the extent that the same factors were explored in a multivariable manner in the BCE, considering combinations of factors together did not greatly alter the findings. The BCE also explored the influence of ulcer duration on decisions to consider SR and found that a longer duration of ulceration should increase consideration of SR.

From this work, we were able to derive core criteria that appear to confer eligibility for SR, namely people who:

a. have available skin/muscle for SR (this needs to be assessed by a surgeon)
b. would consider SR
c. have tried all conservative/non-surgical methods to close the SPU
d. are fit for surgery or able to become fit for surgery (e.g. through treatment for infection, by improved nutrition)
e. are able and motivated to adhere to postoperative regimens to prevent PU recurrence.

To fully characterise a potential future trial to evaluate SR, we attempted to define participant eligibility criteria. We found very few factors that definitively exclude patients to be considered for SR apart from: stage 2 PU; patients not wanting SR; not having tried all conservative methods to close the SPU. Similarly, we found no criteria that rule in SR. Moreover, some important eligibility criteria must be assessed subjectively, often by the surgical and anaesthetic team considering SR, with the potential for decisions about eligibility for SR to differ between clinical teams, as is often the case for most major surgery. The difference for SPUs is the small proportion of patients who are offered SR (about 25% in the commissioned PUPIS service in South Wales and lower in England). This makes it very difficult to specify which patients in the community should be referred to a surgeon (assuming appointments are limited), unless an initial community-based MDT assessment can be carried out, with 'triaging' done by a SPN who visits the patient in the community. The discussions with nurses for WS3, and subsequently with a surgeon (JW), demonstrated the complexity of decisions around managing patients with SPUs and referrals for a surgical opinion about SR.

All contributors (clinical experts in the research team, and nurses and surgeons discussing SR for WS3) fed back that, due to the risk of PU recurrence, SR must be considered as part of a wider package of care including future prophylaxis which may involve a change in lifestyle to prevent recurrence (item e in the list above). Hence, judging the likelihood of a patient adhering to prophylactic activities forms part of decision-making around eligibility for SR. Such complex assessments need to be made alongside standard assessments of clinical factors including general health, suitability of the wound area and tissue donor site for SR. Such decisions normally require multidisciplinary assessment from surgeons, anaesthetists but also nursing staff and potentially other specialties including occupational therapy. We also enquired about the nature of the current referral pathway in these discussions and, since the HES cohort had identified so few SRs, how the referral pathway might be optimised (which in turn would support future research).

The complexity of shared decisions about SR can be illustrated further by considering item a) in the above list. While having available tissue to perform the SR is a prerequisite, careful decision-making is still required for people eligible for SR on this criterion. Since available tissue for SR is limited, using local tissue 'now' (e.g. at first presentation with a SPU) may reduce the ongoing availability of tissue and limit or rule out another SR in the future. The decision to do a SR is therefore finely balanced, requiring the surgeon and the patient to weigh up carefully both the short-term potential benefits but also the longer-term implications. A patient may feel that the short-term potential HRQoL/mental health benefits of closing the SPU may outweigh any longer-term implications, but this view needs to be tempered by the short-term risk of the SR having a poor outcome, for example because the patient does not adhere to postop PU prevention regimens.

Decisions about the *eligibility* of patients for SR are closely linked to discussions about *when* people can or should be considered for SR. There was agreement that all conservative/non-surgical methods to close the SPU should have been tried. However, surgeons fed back that this does not necessarily equate to delaying consideration of SR until after long periods on conservative treatment that then fails. Failure of these methods implies no progress at all in wound healing. However, it may be that progress is being made, but the time to SPU healing using conservative treatment alone is so long and detrimental to patients' HRQoL that they and their surgeon jointly decide that SR is a better option, despite the potential risks. Put simply, people with SPUs want them healed and SR may offer an opportunity to achieve this. The decision to have SR (assuming service access and SR provision) depends on the health of the patient as with much major surgery, and crucially the perceived risk of recurrence. The duration for which the SPU has been present and

the corresponding duration of conservative treatment cannot provide straightforward criteria to judge eligibility for SR because healing progress and other factors also need to be considered.

The SPU patient population eligible for SR and access to SR via current and potential referral pathways are crucially important when thinking about the design and feasibility of future research. The discussions with nurses and surgeons for WS3 reinforced our quantitative findings that access to SR is limited and unequal across England, that is a suitable patient might be identified but experience significant barriers to accessing SR. SR as a potential intervention to close a SPU may be rarely mentioned to patients at present, perhaps because nurses in the community do not know about it (not supported by the nurses' survey) or know from experience that patients are not referred or are not offered SR when referred. Nurses also said that, in their experience, an established pathway only exists for patients with a spinal injury. This is not the case for Manchester University NHS Foundation Trust (where JW operates), which runs a complex wounds clinic. We do not know how many plastic surgery units provide a similar service. In fact, the characteristics of patients in the TT emulation suggested that more patients with neurogenerative disease than spinal cord injury undergo SR. This finding may arise if there are more people with neurodegenerative disease (and SPU) than spinal cord injury (and SPU) in the population; without the denominators, the *proportions* in each subgroup having SR cannot be estimated.

Is a comparative study of surgical reconstruction with no surgical reconstruction feasible?

We conclude that a study would be difficult to conduct at the current time. To explain this further, we have we have considered the conventional PICO research question elements for a comparative research question. Under each element, we describe what we believe we can specify and what we think the challenges are. We conceive the study as a RCT, comparing SR to close the SPU with non-surgical treatment (see below for further discussion of the study design).

Population:

- Recruitment to a trial must take place during a consultation between a patient and a surgeon about SR to close a SPU because the surgeon must determine that SR is feasible (e.g. the characteristic of the SPU and the availability of tissue for reconstruction), the patient must want SR and patient and surgeon together must decide that SR is the best course of management. An anaesthetist must also determine that the patient is fit for surgery.
- Relevant non-surgical treatment regimens should have been tried, with the rate of healing being judged as unsatisfactory.

Intervention:

- It is apparent from our review and wider findings that there is no clear sense from the literature which surgical intervention(s) are a priority for evaluation in terms of there being a 'signal' of possible clinical or cost effectiveness. The type of SR should represent a standard approach and otherwise be at the discretion of the surgeon SR. WS2 identified OPCS-4 codes that surgeons considered to be appropriate. We do not know the extent to which these codes represent discrete surgical options or are used to distinguish such options. In advance of a study, the key features of different SR methods should be identified to ensure that these are captured by case report forms.
- Cointerventions that are considered part of a particular SR method should be carefully defined in advance, including how cointerventions may vary by SR method. Elements of care to prevent *PU recurrence* should be the same for both groups and, if possible, be distinguished from non-surgical treatment options to achieve *closure* of the SPU. There is a risk of differential use of cointerventions by group because SR represents just one part of a package of care, many elements of which may be applicable whether SR is performed or not.

Comparator:

- Non-surgical treatment strategies to close the SPU should follow NICE guidance.[18] It would be important to define key aspects of the guidance in advance to ensure their application is captured by case report forms.
- We anticipate that it would be more difficult to standardise non-surgical treatment than SR but that this would not preclude a RCT being feasible.

Outcome(s):

- The immediate aim of SR is to close the SPU [shortening the time-to-healing (TTH) of the ulcer]. A longer-term aim, as part of a package of care, is to maximise the time a patient lives without a PU by preventing recurrence and, hopefully, improving a patient's HRQoL. This description identifies three important outcomes: TTH, wound days (WD; suggested by a NIHR reviewer during the study) over a specified period, and HRQoL. Note that wound refers to a reference wound (SPU that has not closed or site of SR) and should consider pressure injury (SPU yet to heal with non-surgical treatment), closed surgical wound not yet healed after SR or breakdown of a healed surgical wound after SR. We would expect TTH and WD to be strongly associated with the occurrence of wound complications but recommend that specific surgical site or wound complications (e.g. infection) are also captured.
- None of these outcomes can be blinded to allocation to intervention and comparator, so all are at risk of bias. Careful definitions and assessment methods are required to decide when a surgical wound or SPU has healed, ideally with blinded outcome assessment (although challenging when one wound is surgical), when a PU is present and when a complication has occurred.
- A core outcome set (COS) has recently been published for evaluation of the effectiveness of interventions to prevent a PU (Lechner *et al.*).[71] We are uncertain about the applicability of this COS for evaluating interventions to close a SPU.
- Wounds need to be assessed repeatedly for TTH and WD. TTH (if defined as epithelialisation of the surgical wound) should be achieved during the hospital admission for the SR group if healing is uneventful and could be assessed by the specialist nursing team. However, in the NSR group, TTH could take months or years and might need to be assessed by a non-specialist community nurse. The distributions of times to TTH and WDs might therefore be very different in the SR and NSR groups.
- HRQoL could be measured using a specific instrument designed to assess HRQoL in a person with a PU.[16] Given the wide-ranging consequences of a SPU on activities of daily living, a generic HRQoL (health status) instrument such as the SF-12[45] is also likely to be appropriate. The EuroQol should also be used to obtain utilities for an economic evaluation alongside the trial.

The period over which outcomes are measured should also be carefully considered. It is likely that a minimum follow-up of 12 months would be required for any evaluation of the effectiveness of SR versus NSR. [If a waiting-list design were to be used (see below), this would affect the duration of the follow-up.] TTH and WFDs would need further specification if multiple wounds may be present, for example due to the site of reconstruction and a donor site.

For illustration, potential sample sizes have been estimated considering different outcomes as 'primary'. TTH and WD have different advantages and disadvantages with respect to sample size. TTH should be analysed as time-to-event (i.e. 'survival' without healing). The analysis method is robust and loss to follow-up and deaths can be managed by censoring. However, a survival outcome would require a larger sample size. The distribution of WD is likely to be positively skewed, that is with a 'tail' of increasing WFDs in a decreasing number of patients; we propose WDs should be analysed after log transformation, estimating a geometric mean ratio (GMR; percentage change in WFDs) and requiring a smaller sample size. However, loss to follow-up and deaths would be challenging to manage. The distributions of WDs (potentially not continuous for patients having SR, with one distribution for patients whose surgical wounds heal successfully and another for patients whose wounds do not) might prevent estimation of a GMR by modelling and decrease the power of a sample size estimated in advance due to having to apply less powerful analysis methods. The distributions of SF-12 and EuroQoL scores in this population are unknown.

Example sample sizes are presented in *Table 28*. TTH is likely to be more persuasive to users of the study result. However, the difference in TTH between groups might be very large and the choice of this outcome as primary might be considered as a 'self-fulfilling prophecy' since a surgeon's main aim is to achieve prompt wound healing. Because healing is a binary outcome (although potentially analysed as time-to-event), it also requires a larger study than one with WDs as the primary outcome. WDs as a primary outcome would provide TTH (but not with adequate power) and likely report a GMR for WDs (% change in WDs). A study with HRQoL as the primary outcome would need the fewest patients due to the opportunity to adjust the outcome for a baseline measure of HRQoL and to measure HRQoL longitudinally; the estimates in *Table 28* do not allow for interaction between allocation and time since intervention, which would arise

TABLE 28 Illustrative sample sizes required for a RCT of SR vs. NSR with different primary outcomes and varying target differences

Outcome type	Assumptions	Target 'difference'	Total sample size
Wound healed by 12 weeks (yes vs. no)	• Effect estimate is risk difference (relative risk) • Proportion healed with non-surgical treatment by 12 weeks is 0.25[a]	Risk difference (risk ratio) • 0.050 (0.8) • 0.075 (0.7) • 0.100 (0.6)	 2928 1248 670
Time to healing (days)	• Proportion not healed with non-surgical treatment is 0.25. • Analysed as time-to event • Effect estimate is HR (relative increase in 'hazard' of healing, i.e. time to healing quicker in SR group if HR> 1)	HR (proportion not healed after SR) • 1.2 (0.190) • 1.3 (0.165) • 1.4 (0.144)	 1630 780 472
WDs	• Transform • Analysed as a continuously scaled variable, after log transformation • Effect estimate is GMR (% reduction in WFDs) • Distributions of WDs amenable to modelling	Target standardised differences in ln(WD) (% reduction in WD) • 0.2 (22%) • 0.3 (35%) • 0.4 (49%)	1054 470 266
HRQoL	• One baseline and three postintervention HRQoL measures • Correlation between baseline and postintervention measures = 0.5 • Correlation between repeated postintervention measures of 0.8 • Distributions of HRQoL scores amenable to modelling without transformation	Target standardised differences • 0.2 • 0.3 • 0.4	 648 288 162

a Surgeons said, in their experience, TTH after SR should occur within 4 weeks if there is no complication. Few high-quality data are available for SPUs treated by non-surgical methods but the estimate of 25% is based on extract of data for RCTs of various non-surgical interventions (Dumville, personal communication).

Note
Effect estimate estimated as SR vs. NSR. Two groups with allocation ratio 1 : 1. Power assumed 90%.

if HRQoL changed substantially over time in one group (e.g. recovery in the SR group) and less in the other (e.g. non-surgical treatment continuing as usual for the majority).

If the number of SRs to close a SPU currently being carried out is consistent with the estimates we have derived from the HES cohort, the estimated sample sizes imply that a RCT in England is not feasible at present. Assuming 100 SRs are carried out per year in the UK and 50% of people eligible for SR would be willing to be randomised, only with HRQoL as the primary outcome and the largest target difference might the required sample size be achieved in a reasonable time frame. SRs are also currently being carried out in very small numbers at many trusts (see *Number and characteristics of patients having surgical reconstruction*). Unless SR provision could be focused on a smaller number of trusts, a trial would be inefficient (high research cost per participant randomised) due to the cost of setting up a trial at many sites without any guarantee of a single participant being recruited at some. Findings from our effectiveness review also suggest that England is unlikely to be an outlier in having a low rate of people having SR to close a SPU. The numbers of included patients were low even in excluded studies which were case series, may not have required patient consent and often did not apply stringent eligibility criteria.

We have assumed that a RCT is the preferred design. Another challenge is that such a study would require eligible patients (i.e. after consultation with a surgeon) to accept a 50 : 50 chance of being randomised not to have SR. A waiting-list approach might be a feasible solution, comparing immediate SR with, for example, a 6-month delay before having SR. One surgeon member of the team (JFKW) thought this might be acceptable to patients, after careful discussion. This approach has been used in other wound care studies with success, where the surgery being evaluated was not widely being offered to the patients in the target population.[72] We considered but rejected the option to conduct a non-randomised intervention study due to the difficulty of controlling for important differences

between patients wanting SR and judged appropriate by the surgical team (see *Who should be considered for surgical reconstruction?*) with those not wanting SR or judged inappropriate.

Even a RCT would be at risk of various biases,[38] but arguably in a similar way to other surgical interventions evaluated in RCTs. The risk of bias due to deviations from the intended interventions from differential use of cointerventions has already been described. Participants and care teams could not be blinded to allocation and blinded evaluation of TTH or WDs would likely be impossible, given the presence of a surgical wound in the SR group. Allocation to delayed SR could impact on the behaviour of participants, for example they might not fully engage with lifestyle changes required to prevent recurrence and which might hasten healing until they have their SR. Participants allocated to the delayed group might also change their minds about the acceptability of the delay and request prompt SR; even if outcomes continue to be collected to allow an ITT analysis to be carried out, the results would be biased to the null. Withdrawals without subsequent data collection would cause potential bias from missing outcome data. Given the nature of the intervention and the unknown issues described above, further investigation of feasibility could be important. We also recommend that a RCT would require a process evaluation.

What might make such a study feasible?

Analyses of the HES cohort showed that the number of SRs currently being performed (a proxy for the number of patients potentially eligible for a study) is the factor that makes a study not feasible. It follows that this number needs to be increased to make a study feasible (although still at risk of bias). Three changes are needed to achieve this:

- Firstly, referrals to surgeons by community teams need to be promoted, potentially by publicising the availability of SR as a potential treatment option to community teams providing community-based PU management.
- Secondly, a referral pathway ideally including both community and surgical MDT meetings needs to be established in England.
- Thirdly, depending on the absolute increase in patients eligible for SR generated by the first two changes, provision for SR may need to be contracted separately so that acute NHS trusts can provide the required long stay after SR without curtailing other surgery procedures (particularly plastic surgery procedures which are typically performed as day cases or require short hospital stays).

It is desirable, from a research perspective, for any increase in provision of SR to be concentrated in a small number of hospitals, given the inefficiency of setting up many sites.

These changes would require substantial investment which might be difficult to justify in the absence of evidence of the effectiveness of SR. However, these elements may be necessary to obtain such evidence. Regardless of the effectiveness of SR, access for referrals for a surgical opinion about SR should be more equal geographically and for patients with different causes of impaired mobility. If this could be achieved, it alone should increase the number of referrals.

Could surgical reconstruction be cost-effective without being clinically effective?

Evidence from the current study cannot answer this question. However, surgeons participating in the research anecdotally reported that 'most SRs are successful' and that the number of SRs carried out by plastic surgeons is constrained by the availability of long-stay plastic surgery hospital beds. If it were true that SR is usually successful, SR might be cost-effective for patients who want it, due to their improved HRQoL, without necessarily being superior to non-surgical management with respect to wound healing.

Treating a SPU in the community incurs considerable costs: nurse time for travel to the patient and SPU management (e.g. three times per week), wound dressings, pressure-relieving surfaces and other interventions such as negative pressure ('vac') wound therapy (NPWT).[73,74] These costs accumulate if a SPU takes months and possibly years to close without surgery.

Estimating cost-effectiveness requires costs and consequences to be estimated for alternative care strategies. The CPRD data set we obtained was inadequate to describe community resource use. We were unable to find any evidence about the effects of a SPU, or closing/healing a SPU, on (health-related) quality of life which, as described above,

is a very important consideration when deciding whether or not a patient should have SR. Quality of life is also not an outcome in the COS for interventions to prevent pressure ulcers;[71] in the development of this COS, two of five stakeholder groups (77% of 111 respondents) considered 'quality of life in general', and three of five stakeholder groups (79% of 111 respondents) considered 'patient satisfaction', to be critically important. The final COS contained six outcomes, only one of which reflected the patient's perspective ('acceptability and comfort of intervention').

What other interventions used to manage (severe)pressure ulcers require evidence to support their use?

The CB for this study, focusing on SR to close a SPU, arose from a previous systematic review which found no RCTs, in turn prompted by the findings of a James Lind Appliance Pressure Ulcer Partnership.[17,75] It is important to consider whether there are competing interventions to close a SPU, also without high-quality existing evidence, which would be more suitable for further evaluation.

One such example is NPWT. A systematic review of RCTs comparing NPWT with other interventions to treat pressure ulcers identified four studies involving a total of 149 participants with PUs (not restricted to SPUs).[73,74] The authors were unable to draw any conclusions about the effectiveness of NPWT because the RCTs were small, and not well reported with short or unclear duration. Nevertheless, community care teams including TVNs often advocate the use of NPWT. Further important interventions in need of research are pressure redistributing devices (e.g. seating, mattresses) which are intended to reduce the amount and duration of pressure at vulnerable anatomical sites. An overview of reviews including a network meta-analysis[76] concluded from a total of only 12 studies (972 participants) that there is uncertainty about the relative effects of beds, overlays, and mattresses on pressure ulcer healing. Pressure mapping, often advocated by nurses managing PUs, is another intervention that has not been carefully evaluated.

Strengths and limitations

Strengths of the study

The surveys conducted for WS1 were directed to relevant professional groups of nurses, surgeons and GPs. The effectiveness of our invitations in reaching people managing patients with SPUs is evidenced by the high response rates and high quality, mainly complete, data. The commitment of the nurse and surgeon respondents to the care they provide was shown by the large number of free-text responses, which we analysed using qualitative methods to provide insights about, in particular, challenges in the referral pathway. In addition to our protocol, we performed a BCE to address the univariable nature of the surveys; the results of the BCE were consistent with the survey results, suggesting the latter are valid despite the limitation. The literature reviews which formed part of WS1, although largely uninformative, used state-of-the-art methods. In WS2, we also applied state-of-the-art methods to emulate a trial of SR versus NSR. We believe we have accurately described the challenges in further research on the effectiveness of SR at present, based on feedback received through WS3 and within the research team, and that our conclusions would not be altered had we been able to carry out a more formal consensus process.

Limitations of the study

There were no limitations of the literature reviews. The surveys conducted for WS1 were only able to consider factors relevant to eligibility for SR one at a time (due to the number considered). We addressed this limitation by performing the BCE, the results of which were consistent with the survey results. The BCE was limited by the small number of factors and attributes that could be studied.

Key limitations of analyses of the HES cohort (WS2) arose from potential limitations in the coding of diagnoses and route of admission, and a limited understanding of and wide variations in the referral pathway to secondary care (which were poorly captured in the literature before this work) and limited information about the outcome of admissions captured by HES data. Potential limitations in coding of diagnoses and route of admission meant that we could not quantify the number of SRs being carried out with certainty. We addressed this limitation by describing maximum and minimum numbers, based on clearly defined assumptions informed by the clinical members of the research team (e.g. admission for SR should be elective and SPU should be the primary diagnosis on admission). The lack of a shared understanding of the referral pathway meant that our emulation of a trial of SR versus NSR may have used

an inappropriate comparator group; we could not mitigate this limitation. The lack of important outcomes in the HES data (most relevant to the intervention) meant that our emulation could not estimate the effectiveness of SR for any outcomes typically measured in research on interventions to treat PUs; instead, we estimated the effects of SR on surrogates such as re-admission with a SPU diagnosis.

Analyses of the CPRD cohort were limited by considerable under-ascertainment of PUs in Gold and Aurum databases and insufficiently detailed coding of PU severity and activity relating to PU care, preventing us from describing episodes of PU care from incidence to healing. General practices' use of different coding systems (Read and SNOMED) in Gold and Aurum databases made analyses resource-intensive and complicated interpretation.

Workstream 3, in which we aimed to seek consensus about patients who should be considered for SR and the referral pathway for such patients, was limited by the COVID-19 pandemic (preventing face-to-face meetings and delaying earlier aspects of the study). Within the time remaining, clinical professionals who we invited and who were willing to meet could not attend a face-to-face meeting. Ultimately, we arranged a virtual meeting with nurses only and subsequently sought information from surgeons about the opinions of the nurses. The uncertainties that we sought to address in the meeting were also not well suited to standard consensus methods.

The greatest challenge to the conduct of the research arose from the COVID-19 pandemic, which caused delays, made team members less available and restricted face-to-face meetings. We were able to have only two face-to-face meetings with the members of the multidisciplinary SMG, one in the first month of the study and one just 10 weeks before the final report was due. The latter meeting provided important insights about the referral pathway for SR and the factors that the patient and surgeon need jointly to consider when deciding whether to have SR or not. We cannot unequivocally attribute these insights to meeting face-to-face, but the complexity of the situation had not been evident or explored during many previous virtual meetings.

Patient and public involvement

Our approach

We planned to ensure patients and members of the public had the opportunity to input over the whole course of the SIPS Study from its inception. Co-applicant Johnson joined the team for the stage 2 application to offer input from his perspective, namely that of a patient who had experienced several SPUs and who had undergone both conservative and surgical treatment at different times. Johnson was invited as a member of the SMG throughout the project. Unfortunately, although we managed to meet face-to-face on one occasion, restrictions of the COVID-19 pandemic prevented us from meeting in person again during the study period. Although illness prevented Johnson from attending virtual SMG meetings, we have maintained contact throughout the study and provided all study updates.

After initial meetings during the early stages of the study, we widened the PPI to ensure that the views of more patients and carers were represented. We did this by increasing the number of PPI contributors on the SMG, including three people who had experienced a SPU and two carers. We also encouraged involvement in a separate PAG which was intended as a way for people who did not want to be part of the SMG to contribute in an informal way. We recruited new members to our SMG and PAG by liaising with relevant organisations including the Spinal Injuries Association, Shine and People in Research.

Areas of input

Co-applicant Johnson was supportive of the original stage 2 study plan which aimed to undertake qualitative interviews with patients who have had surgery. Data about quality of life are absent from routine data sets and interviews with patients and carers would have helped to understand the negative impact of pressure ulceration on people's quality of life and provide granular information about their experiences of their treatment pathways.

In discussion with all members of the SMG, we decided to ask PPI contributors from both the SMG and PAG if they would be willing to provide a written account of their experience of having (or caring for someone with) a SPU. With support from co-applicant Atkinson, six people contributed to producing four anonymised 'patient stories' (see *Report*

Supplementary Material 7). These accounts allowed the contributors to describe their treatment pathway, including the care and treatments they received (conservative and surgical), timelines, their experience of surgery where relevant and the impact of their pressure ulcer on their quality of life. Contributors confirmed that the accounts were confirmed accurate representations of their experiences.

We discussed the way these accounts would be used. We proposed to make the stories available as a booklet to clinicians involved in making decisions about the treatment of patients with SPUs, for example during the consensus process, to highlight some of the issues patients may experience. We also made the booklet available to other stakeholders, including GIRFT, the Spinal Injuries Association and Shine. Each contributor gave consent for the account to be used for these purposes.

For WS1, our PPI contributors were given the opportunity to input into the content of our clinician surveys. We wanted to ensure patients and carers understood why we did these surveys and offer the opportunity for them to ask questions about the surveys. Contributors offered useful insights about the staff groups with whom they came into contact throughout their treatment pathway, which informed the distribution of surveys (i.e. to different nursing, medical and surgical groups). PPI contributors also described some of their experiences regarding the different treatments (other than SR) that they had been offered. Findings were fed back at SMG meetings to ensure other PPI contributors had the opportunity to seek clarification. We also asked contributors to give their opinion on the factors they believed should influence whether patients are offered surgery, as this was a useful way to check the sense of the findings.

Early in the study, some PPI contributors described how they would defer to the health professional for their opinion on their treatment of the patient, including surgery. This was exemplified by one of our PPI contributors' questions: 'What would you choose if this were you/your relative?' We described the SIPS Study, and the consensus process in particular, as a way of generating evidence in the absence of evidence from the literature to guide future research and practice.

Our PPI contributors' experiences regarding the treatment pathway for their pressure ulcer, in the context of their own circumstances (e.g. health status, age, living arrangements) were useful when developing the consensus process. The pros and cons of people's individual experiences were discussed at SMG meetings, and this helped us to develop some of the questions that would be posed at the consensus meeting with professionals.

We fed back findings of the consensus process to our SMG members, again to give them an opportunity to input and ask for clarification where needed.

Ways of working

We were flexible about the way PPI contributors were involved in the SIPS Study. Naturally, some contributed more than others, for a variety of reasons (see *Challenges*, below). We discussed the ways in which we would communicate and made efforts to accommodate people. It was agreed that all SMG members would attend meetings, review documents where possible and input verbally at meetings and in writing where applicable. Given that most meetings were held online, attendance at these was good but reduced in the latter stage of the study. Despite this, we received ongoing PPI input throughout and have agreed with two members of the SMG that they should contribute as coauthors to the final report.

We made efforts to ensure that the needs of those wishing to be involved were accommodated as far as possible. Meetings, except for the final SMG meeting in June 2022, were held remotely. We supported contributors by ensuring they received technical advice when required and provided relevant documentation in appropriate formats in advance of meetings. We also provided lay summaries of meeting minutes and convened separate PPI-focused meetings/debriefs at appropriate points in the study to ensure contributors had the opportunity to meet individually with the team or as a group to ask questions and provide further input. We also developed a glossary of terms from the outset to facilitate understanding, which was updated throughout the project.

We offered reimbursement at nationally recommended rates to all PPI contributors for their time and travel expenses. Administrative support was provided to ensure claim forms were completed on behalf of contributors, thereby reducing the burden on the contributors themselves.

Challenges

The SIPS Study continued throughout the COVID-19 pandemic. We succeeded in maintaining meaningful PPI throughout the study, but illness prevented some of our contributors from attending all meetings. One member of the SMG had previously been told that her long-standing (5 year) PU may never heal and that she could not have SR. She has now been considered for SR which was due to take place in the summer of 2022. Therefore, she was unable to attend the final SMG meeting in June 2022 but asked to remain involved and we will keep her updated about dissemination of the study findings. Unfortunately, we lost contact with two members of our SMG (one patient and her carer) in late 2021.

Lessons for the future: implications for decision-makers

Provision of surgical reconstruction

There does not appear to be any specialised commissioning of SR in England (WS3). Networks exist enabling patients with a spinal injury who have a SPU to be referred to a spinal injury centre but only five of eight English spinal injury centres have a plastic surgery unit. (The three spinal injury centres without a plastic surgery unit may subcontract this service from another NHS Trust.) No similar network exists for patients who have a SPU, but some other cause for impaired mobility. Some plastic surgery units may operate a clinic for people with complex wounds to which such patients can be referred but this does not represent a systematic referral pathway.

The lack of a standardised care pathway for SR in England inevitably leads to regional variation. In the absence of high-quality evidence about the effectiveness of SR compared with NSR to guide commissioners and surgeons, such variation may be unsurprising. However, surgeons and nurses with experience in SR reported to us their perception that SR is effective (SPU closed and patient discharged without a serious wound complication) for a high proportion (about 75%) of patients who have received it. Accepting that cohorts of patients who currently have SR may be highly selected (i.e. given the lack of provisions, surgeons choose the patients who have the best chance of success), published reports are consistent with these anecdotes; among the three studies included in the first review,[41–43] over 80% did not experience a PU recurrence (follow-up 2 and 3 years, and not reported).

The situation in England is in stark contrast with Wales, where NHS Wales commissions an integrated pressure ulcer service, for example PUPIS[77] in South Wales. The service integrates primary and secondary care teams, providing access to rehabilitation engineering (e.g. wheelchair services, pressure mapping), tissue viability and specialist plastic surgery nursing. Referrals for a surgical opinion are actively managed, with MDT meetings arranged as required. The service funds one dedicated hospital bed for 'long stay' patients having reconstruction; about six to eight SRs are carried out each year (pers. comm., Flavin). We identified one English trust, University Hospitals Leicester, in which a SPN co-ordinated community referrals and carried out home visits to determine a patient's circumstances before having a surgeon consultation (Claire Porter, personal communication; consent given for identity to be disclosed). Based on a South Wales population of 2.2 million and assuming this rate applies, this means that 150–200 SRs would be performed per year in England if a similar service were commissioned, higher than the number per year calculated from the HES maximum SR cohort (WS2). If the level of PUPIS provision (i.e. one long-stay bed) were to be appropriate for England, about 20–25 hospitals would have to be commissioned to provide the service.

Referral pathway

Nurses contributing to WS3, all of whom worked in England, said that a referral pathway only exists for patients with a spinal injury and that, even when such patients were referred, SR was rarely performed. They also stated that, in their view, the cause of a patient's immobility should not restrict access to SR (other factors relevant to eligibility for SR being equal). The components of a referral pathway were discussed by nurses during the consensus meeting (see *Results for topic 1: features of a care pathway for referral for surgical reconstruction*). MDT meetings in the community (first) and hospital teams (second), with information from relevant professions and investigations obtained in advance, were considered essential elements of a pathway.

Patients who should be considered for surgical reconstruction

Given the complex nature of shared decision-making about SR (see *Who should be considered for surgical reconstruction?*), we think that there is no need to specify eligibility for referral for a surgical opinion about SR other than that a patient has a SPU and wants SR. It is then for the surgeon and anaesthetist to judge whether a patient is fit for surgery and suitable for SR in other respects, and for the surgeon and patient jointly to decide whether SR is appropriate.

Future research

Effectiveness of surgical reconstruction

The small number of SRs currently being carried out is the main barrier to the feasibility of a RCT (or similar). While an international study involving some UK sites, comparing SR with NSR for people with SPU, *might* generate relevant evidence it would be challenging to harmonise eligibility criteria and their application. Careful and realistic assessment of the potential participant numbers in other countries would also be required. Furthermore, concern about variations in care systems (including community care) across countries and, in particular, non-surgical care and variations in cointerventions, might mean that evidence from a study with a minority of UK participants would not be applicable to the UK. Further discussion about the potential for and value of international collaboration for collaborative research would be required if this possibility were to be pursued. It might be possible to initiate such a discussion at large, relevant international conferences. The potential of a 'virtual' multinational working group with the expertise, networks, and drive to explore the feasibility of an international trial is appealing, but this would require co-ordination and leadership that currently seems to be lacking.

On a smaller scale and in the UK, further feasibility work would be required to test assumptions for sample size calculations and the acceptability of even hypothetical trial participation by potential participants (linked to *Qualitative research on the acceptability of surgical reconstruction*). Different study design options could also be explored. Finally, discussion with stakeholders such as NHS England and other clinically relevant and service-focused groups are required to explore whether the service-level changes highlighted, that is changes to referral practices, MDT involvement and increases in bed space here can be tested for feasibility, even as pilot projects. Rapid evaluation of such pilots is possible within the NIHR infrastructure.

Qualitative research on the acceptability of surgical reconstruction

Surgeons and nurses stressed that not all patients want to be considered for SR. We recommend that future qualitative research on the acceptability of SR is carried out to understand factors that predispose patients to want or decline SR, including sources of inequality in access. Some factors may arise from practical considerations, for example needing to spend a long time in the hospital, hospital performing SR some distance from home so visits might be limited, and others from a patient's circumstances. For example, a SPU may not be a major source of concern for a patient who has no sensation at the site of the SPU and for whom speed of healing may not be a priority; the need for regular visits by the community nursing team to dress a SPU may be seen as an imposition for an active patient or as a welcome opportunity for social contact by an inactive or socially isolated patient. The desire for SR is very likely to be linked with the impact of a SPU on a patient's HRQoL, which we think is a priority for research among both patients wanting and not wanting SR.

Core outcome set for interventions to treat pressure ulcers/severe pressure ulcers

We were surprised that only 1% of published RCTs of prevention *or* treatment interventions for PUs assessed HRQoL. The recent COS for PU prevention interventions is a good starting point, but we believe there is a need for a similar COS for interventions to treat PUs/SPUs. HRQoL should be carefully considered for inclusion in such a COS. Given the perceived importance of HRQoL in shared decision-making about whether to perform SR, any future research on the effectiveness of SR to close a SPU should include HRQoL. Moreover, treatments for SPUs, whether surgical or non-surgical, are expensive (see *Economic modelling*) and cost-effectiveness based on quality-adjusted life-years is central to decisions about commissioning interventions.

Routine data coding

Coding of OPCS-4 procedure codes is widely considered to be accurate because procedure codes are often used by health commissioners for reimbursement. The accuracy of diagnostic coding has been researched less often, although detailed code lists have been developed by researchers for specific diseases and comorbidities. We recommend that the accuracy of the coding of diagnoses should be researched, for example by comparing diagnoses coded in HES records with retrospective reviews of medical records; the research should also consider the appropriateness of the choice of primary diagnosis for an episode. Such research could generate initial guidance for coders to make HES data more consistent across NHS trusts and highlight the extent to which this information is fit for purpose for research.

Economic modelling

Economic modelling may be useful to address the impasse about the cost-effectiveness of SR, given that a future RCT of the effectiveness and cost-effectiveness of SR is not feasible. Both prolonged non-surgical care in the community (at a minimum including regular community nurse visits and wound dressings over many months) and SR are expensive (SR itself plus a minimum of 4 weeks in hospital). Collecting data to compare their costs would provide some information about whether SR could plausibly be a cost-effective intervention. Such data would ideally be complemented by longitudinal HRQoL data for patients who have and have not had SR.

Some information about the resources used for SR could be derived from HES data, for example SRs, days of hospital stay at different levels, and potentially some complications. Postoperative management in the community might also be obtained by interviewing key community personnel. As previously described, the key information gap concerns the resources used to manage patients with SPUs without SR in the community. NHS Digital's recently developed Community Services Dataset may be able to bridge this gap in the future (https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/community-services-data-set), but this was not available to us for the SIPS study. Alternatively, commissioning a service in England similar to PUPIS with high-quality data collection, even on a pilot basis, would provide a range of useful data: quantify the demand for surgical referrals, the proportion of patients wanting and suitable for SR and whether 'supply' (provision of SR) matched 'demand' (judgement by patients and their surgeons that SR is the preferred management) for SR, and outcomes (including HRQoL) and resources for patients having and not having SR.

Chapter 10 Conclusion

In 2012, a James Lind Pressure Ulcer partnership identified the question 'how effective are surgical operations to close pressure ulcers?' as a priority uncertainty. More than 10 years later there is still no RCT-derived evidence addressing this uncertainty. There is also no evidence about the impact of SPUs on patients' HRQoL, despite this being the key reason why a surgeon performs SR.

Surgical reconstruction is currently performed too infrequently in England to permit primary quantitative research to evaluate its comparative effectiveness. SR is commissioned in South Wales but very few procedures are carried out due in part to the relatively small national population. Small numbers of patients who have had SR are available in the UK and there is indirect or anecdotal evidence that SR is a treatment of potential value. However, its effectiveness compared with NSR cannot be estimated because there is no information about the resources expended and outcomes for patients who are managed entirely with non-surgical treatments. The Community Services Dataset may help to address this gap.

If SR were commissioned in England with the same level of provision as in South Wales, a RCT might be possible using a waiting-list design. The procedures comprising SR and the characteristics of patients who are suitable for SR are well enough understood for these elements of an evaluation of effectiveness not to be obstacles. There is no COS for treatment of SPUs, but relevant outcomes are also clear and feasible to collect; the most important ones include measures of wound healing, resource use and HRQoL.

Additional information

CRediT contribution statement

Barnaby Reeves (https://orcid.org/**0000-0002-5101-9487**): Conceptualisation (lead), Funding acquisition (equal), Methodology (lead), Visualisation (lead), Supervision (lead), Validation (equal), Writing – original draft (lead).

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Acknowledgements

We would like to thank:

James Johnson, Caroline Ramcharan, Dave Wyldes and Jayne Wyldes who (with Ashley and Michael Burton, authors of the report) provided PPI input to the research team and to the patients' histories.

Andy Brown, Nicci Aylward-Wotton, Jacqui Fletcher, Ayesha Marshall, Sue Murphy, Ines Pereira, Claire Porter, Suzy Pramod, Nicky Richardson and Chris Russell, who participated in the consensus meeting and preceding survey.

Professor Ken Dunn and Jacqui Fletcher, who have been working on the GIRFT Programme National Specialty Report on Plastic Surgery, Hand Surgery and Burn Care, who provided contact details for invitees for the surveys and BCE.

Claire Porter, Specialist Plastic Surgery nurse at Leicester University Hospitals, who we interviewed about her role in providing outreach to patients for whom SR to close a SPU is being considered.

Susan Flavin, Clinical Nurse Specialist with PUPIS and Swansea Bay University Health Board, who we interviewed about her role and the PUPIS service in general; also, Mr Peter Drew, plastic surgeon with PUPIS and Swansea Bay University Health Board, who replied to e-mails about the number of SRs to close SPUs performed under the PUPIS contract the success of SR in his experience.

This study was designed and delivered in collaboration with the Bristol Trials Centre, a UK Clinical Research Collaboration registered clinical trials unit in receipt of NIHR Clinical Trials Unit support funding during the period when some of the study was carried out.

Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation

Data-sharing statement

Citations from literature searches, data extracted for included studies, and responses to surveys and can be obtained by contacting the corresponding author. The HES and CPRD data sets cannot be shared under the terms and conditions of the agreements under which they were supplied.

Ethics statement

We were advised at the outset that there was no requirement to obtain a research ethics opinion for the professional surveys that we carried out for WS1. PPI participants volunteered the patients' histories. The ethics of the planned analyses of routinely collected data (WS2) was reviewed by the respective research governance committees of NHS Digital and CPRD through our applications for data extracts.

Information governance statement

University of Bristol and University of Manchester are committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, University of Bristol and University of Manchester are the joint Data Controllers, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officers here: https://tinyurl.com/ywaxycz3

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/DWKT1327.

Primary conflicts of interest: Barnaby Reeves reports former membership of the National Institute for Health and Care Research (NIHR) Health Technology Assessment Commissioning Board (from January 2012 to 31 March 2016) and the Health Technology Assessment Efficient Study Designs Board (October–December 2014). He also reports current membership of the Health Technology Assessment Interventional Procedures Committee B Methods Group and Systematic Reviews Programme Advisory Group (Systematic Reviews National Institute for Health Research Cochrane Incentive Awards and Systematic Review Advisory Group). He has no other competing interests.

Jo Dumville was a member of the NIHR Health Technology Assessment General Board from 2018 to 2023.

Una Adderley sat on the HTA Prioritisation Committee A (Out of Hospital) between 2018 and 2021.

Matthew Ridd is Co-lead for NIHR School for Primary Care Research (SPCR) Skin and Allergy Working Group and Co-chair for the Society for Academic Primary Care (SAPC) Dermatology Research Group. Matthew Ridd also sat on the HTA General Committee between 2016 and 2019, and the ESP Evidence Synthesis Programme Advisory Board between 2019 and 2022.

Jason Wong was on the Scientific Advisory Board and in receipt of consulting fees from Biotherapy Services Ltd. He also received travel fees and was invited to speak at the European Society of Trauma Reconstruction and Orthopaedic Regenerative Therapies. Mr Wong is also an unpaid member of the Manchester University NHS Foundation Trust Wound Care Committee.

Maria Pufulete, Jessica Harris, Ashley Burton, Michael Burton, Ross Atkinson, Madeleine Clout, Nicky Cullum, Abby O'Connell, Louise O'Connor, Stephen Palmer, Jeremy Rodrigues declared no conflicts of interest.

Publications

None has been published, but the following manuscripts are in press:

Pufulete M, Hackney M, Pithara C, O'Connell A, Adderley U, Cullum N, *et al*. Surgical reconstruction (SR) to treat severe pressure ulcers (SPU) in the UK: a mixed-methods analysis of surveys of healthcare professionals. *J Tissue Viability* 2025; in press.

Reeves BC, Harris JM, Pufulete M, Dumville JC, Adderley U, Atkinson R, *et al*. Surgical reconstruction of severe pressure ulcers in England from 01/04/2011 to 30/09/2018: retrospective cohort study using routinely collected data. *J Plast Reconstr Aesthet Surg* 2025; in press.

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Appendix 1 Search strategies for systematic review 1

For logistical reasons, search strategies were performed as separate searches rather than as a combined search. All searches were run on 23 April 2019.

RCT Searches

Cochrane Wounds Specialised Register

1 MESH DESCRIPTOR Surgical Procedures, Operative EXPLODE ALL AND INREGISTER
2 MESH DESCRIPTOR Surgical Flaps EXPLODE ALL AND INREGISTER
3 (surger* or surgical*) AND INREGISTER
4 (primary near3 closure*) AND INREGISTER
5 (skin near3 (graft* or transplant*)) AND INREGISTER
6 ((surg* or reconstruct* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) near2 flap*) AND INREGISTER
7 "tissue expansion" AND INREGISTER
8 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 AND INREGISTER
9 MESH DESCRIPTOR Pressure Ulcer EXPLODE ALL AND INREGISTER
10 (pressure NEXT (ulcer* or sore* or injur*)) AND INREGISTER
11 (decubitus NEXT (ulcer* or sore*)) AND INREGISTER
12 ((bedsore* or bed sore*)) AND INREGISTER
13 #9 OR #10 OR #11 OR #12 AND INREGISTER
14 #8 AND #13 AND INREGISTER

The Cochrane Central Register of Controlled Clinical Trials (CENTRAL)

#1 MeSH descriptor: [Surgical Procedures, Operative] explode all trees
#2 MeSH descriptor: [Surgical Flaps] explode all trees
#3 (surger* or surgical*).ti,ab,kw
#4 (primary near/3 closure*):ti,ab,kw
#5 (skin near/3 (graft* or transplant*)):ti,ab,kw
#6 ((surg* or reconstruct* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) near/2 flap*):ti,ab,kw
#7 "tissue expansion":ti,ab,kw
#8 {or #1-#7}
#9 MeSH descriptor: [Pressure Ulcer] explode all trees
#10 (pressure next (ulcer* or sore* or injur*)):ti,ab,kw
#11 (decubitus next (ulcer* or sore*)):ti,ab,kw
#12 ((bed next sore*) or bedsore*):ti,ab,kw
#13 {or #9-#12}
#14 (#8 and #13) in Trials

Ovid MEDLINE

1 exp surgical procedures, operative/
2 exp Surgical Flaps/
3 (surger* or surgical*).ti,ab.
4 (primary adj3 closure*).ti,ab.

5 (skin adj3 (graft* or transplant*)).ti,ab.
6 ((surg* or reconstruct* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) adj2 flap*).ti,ab.
7 tissue expansion.ti,ab.
8 or/1-7
9 exp Pressure Ulcer/
10 (pressure adj (ulcer* or sore* or injur*)).tw.
11 (decubitus adj (ulcer* or sore*)).tw.
12 (bedsore* or bed sore*).tw.
13 or/9-12
14 and/8,13
15 randomized controlled trial.pt.
16 controlled clinical trial.pt.
17 randomi?ed.ab.
18 placebo.ab.
19 clinical trials as topic.sh.
20 randomly.ab.
21 trial.ti.
22 or/15-21
23 exp animals/ not humans.sh.
24 22 not 23
25 14 and 24

Ovid EMBASE

1 exp surgical technique/
2 exp skin graft/
3 exp tissue flap/
4 exp tissue expansion/
5 (surger* or surgical*).ti,ab.
6 (primary adj3 closure*).ti,ab.
7 (skin adj3 (graft* or transplant*)).ti,ab.
8 ((surg* or reconstruct* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) adj2 flap*).ti,ab.
9 tissue expansion.ti,ab.
10 or/1-9
11 exp decubitus/
12 (pressure adj (ulcer* or sore* or injur*)).tw.
13 (decubitus adj (ulcer* or sore*)).tw.
14 (bedsore* or bed sore*).tw.
15 or/11-14
16 10 and 15
17 Randomized controlled trials/
18 Single-Blind Method/
19 Double-Blind Method/
20 Crossover Procedure/
21 (random* or factorial* or crossover* or cross over* or cross-over* or placebo* or assign* or allocat* or volunteer*).ti,ab.
22 (doubl* adj blind*).ti,ab.
23 (singl* adj blind*).ti,ab.
24 or/17-23

25 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or non-human/
26 human/ or human cell/
27 and/25-26
28 25 not 27
29 24 not 28
30 16 and 29

EBSCO CINAHL Plus

S27 S13 AND S26
S26 S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25
S25 TI allocat* random* or AB allocat* random*
S24 MH "Quantitative Studies"
S23 TI placebo* or AB placebo*
S22 MH "Placebos"
S21 TI random* allocat* or AB random* allocat*
S20 MH "Random Assignment"
S19 TI randomi?ed control* trial* or AB randomi?ed control* trial*
S18 AB (singl* or doubl* or trebl* or tripl*) and AB (blind* or mask*)
S17 TI (singl* or doubl* or trebl* or tripl*) and TI (blind* or mask*)
S16 TI clinic* N1 trial* or AB clinic* N1 trial*
S15 PT Clinical trial
S14 MH "Clinical Trials+"
S13 S7 AND S12
S12 S8 OR S9 OR S10 OR S11
S11 TI decubitus or AB decubitus
S10 TI (bed sore* or bedsore*) or AB (bed sore* or bedsore*)
S9 TI (pressure ulcer* or pressure sore*) or AB (pressure ulcer* or pressure sore*)
S8 (MH "Pressure Ulcer+")
S7 S1 OR S2 OR S3 OR S4 OR S5 OR S6
S6 TI tissue expansion OR AB tissue expansion
S5 TI ((surg* or reconstruct* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) N2 flap*) OR AB ((surg* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) N2 flap*)
S4 TI (skin N3 (graft* or transplant*)) or AB (skin N3 (graft* or transplant*))
S3 TI (primary N3 closure*) OR AB (primary N3 closure*)
S2 TI surger* or surgical* OR AB surger* or surgical*
S1 (MH "Surgery, Operative+")

US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov)

Surgery OR reconstruction OR flap OR graft OR transplant | Pressure Ulcer

Surgery OR reconstruction OR flap OR graft OR transplant | Pressure Injury

Surgery OR reconstruction OR flap OR graft OR transplant | Pressure Ulcers Stage II

Surgery OR reconstruction OR flap OR graft OR transplant | Pressure Ulcers Stage III

Surgery OR reconstruction OR flap OR graft OR transplant | Pressure Ulcer, Stage IV

World Health Organization International Clinical Trials Registry Platform

(surgery OR reconstruction OR flap OR graft OR transplant) [Intervention]

AND pressure ulcer [Title]

(surgery OR reconstruction OR flap OR graft OR transplant) [Intervention]

AND pressure ulcer [Condition]

(surgery OR reconstruction OR flap OR graft OR transplant)[Intervention]

AND Pressure sore [Title]

(surgery OR reconstruction OR flap OR graft OR transplant)[Intervention]

AND Pressure sore [Condition]

(surgery OR reconstruction OR flap OR graft OR transplant)[Intervention]

AND decubitus [Condition]

(surgery OR reconstruction OR flap OR graft OR transplant) [Intervention]

AND bed sore [Condition]

Non-randomised study searches

MEDLINE

1 exp surgical procedures, operative/
2 exp Surgical Flaps/
3 (surger* or surgical*).ti.
4 (primary adj3 closure*).ti,ab.
5 (skin adj3 (graft* or transplant*)).ti,ab.
6 ((surg* or reconstruct* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) adj2 flap*).ti,ab.
7 tissue expansion.ti,ab.
8 or/1-7
9 exp Pressure Ulcer/
10 (pressure adj (ulcer* or sore* or injur*)).ti,kw.
11 (decubitus adj (ulcer* or sore*)).ti,kw.
12 (bedsore* or bed sore*).ti,kw.
13 or/9-12
14 and/8,13
15 exp cohort studies/
16 cohort$.tw.
17 controlled clinical trial.pt.
18 epidemiologic studies/
19 or/15-18
20 14 and 19

EMBASE 1974

1 exp surgical technique/
2 exp skin graft/
3 exp tissue flap/
4 exp tissue expansion/
5 (surger* or surgical*).ti.
6 (primary adj3 closure*).ti,ab.
7 (skin adj3 (graft* or transplant*)).ti,ab.
8 ((surg* or reconstruct* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) adj2 flap*).ti,ab.
9 tissue expansion.ti,ab.
10 or/1-9
11 exp decubitus/
12 (pressure adj (ulcer* or sore* or injur*)).ti,kw.
13 (decubitus adj (ulcer* or sore*)).ti,kw.
14 (bedsore* or bed sore*).ti,kw.
15 or/11-14
16 10 and 15
17 exp cohort analysis/
18 exp longitudinal study/
19 exp prospective study/
20 exp follow up/
21 cohort$.tw.
22 or/17-21
23 16 and 22

CINAHL Plus

S18 S13 AND S17
S17 S14 OR S15 OR S16
S16 TI longitudinal or AB longitudinal
S15 TI cohort* or AB cohort*
S14 (MH "Prospective Studies+")
S13 S7 AND S12
S12 S8 OR S9 OR S10 OR S11
S11 TI decubitus or AB decubitus
S10 TI (bed sore* or bedsore*) or AB (bed sore* or bedsore*)
S9 TI (pressure ulcer* or pressure sore*) or AB (pressure ulcer* or pressure sore*)
S8 (MH "Pressure Ulcer+")
S7 S1 OR S2 OR S3 OR S4 OR S5 OR S6
S6 TI tissue expansion OR AB tissue expansion
S5 TI ((surg* or reconstruct* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) N2 flap*) OR AB ((surg* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) N2 flap*)
S4 TI (skin N3 (graft* or transplant*)) or AB (skin N3 (graft* or transplant*))
S3 TI (primary N3 closure*) OR AB (primary N3 closure*)
S2 TI (surger* or surgical*)
S1 (MH "Surgery, Operative+")

Database(s): Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) 1946–23 April 2019

1 exp surgical procedures, operative/
2 exp Surgical Flaps/
3 (surger* or surgical*).ti,ab.
4 (primary adj3 closure*).ti,ab.
5 (skin adj3 (graft* or transplant*)).ti,ab.
6 ((surg* or reconstruct* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) adj2 flap*).ti,ab.
7 tissue expansion.ti,ab.
8 or/1-7
9 exp Pressure Ulcer/
10 (pressure adj (ulcer* or sore* or injur*)).tw.
11 (decubitus adj (ulcer* or sore*)).tw.
12 (bedsore* or bed sore*).tw.
13 or/9-12
14 and/8,13
15 controlled clinical trial.pt.
16 14 and 15

Database(s): EMBASE 1974–23 April 2019

#SearchesResults

1 exp surgical technique/
2 exp skin graft/
3 exp tissue flap/
4 exp tissue expansion/
5 (surger* or surgical*).ti,ab.
6 (primary adj3 closure*).ti,ab.
7 (skin adj3 (graft* or transplant*)).ti,ab.
8 ((surg* or reconstruct* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) adj2 flap*).ti,ab.
9 tissue expansion.ti,ab.
10 or/1-9
11 exp decubitus/
12 (pressure adj (ulcer* or sore* or injur*)).tw.
13 (decubitus adj (ulcer* or sore*)).tw.
14 (bedsore* or bed sore*).tw.
15 or/11-14
16 10 and 15
17 Controlled clinical study/
18 16 and 17

CINAHL Plus 1937–23 April 2019

S15 S13 AND S14
S14 PT clinical trial
S13 S7 AND S12

S12 S8 OR S9 OR S10 OR S11
S11 TI decubitus or AB decubitus
S10 TI (bed sore* or bedsore*) or AB (bed sore* or bedsore*)
S9 TI (pressure ulcer* or pressure sore*) or AB (pressure ulcer* or pressure sore*)
S8 (MH "Pressure Ulcer+")
S7 S1 OR S2 OR S3 OR S4 OR S5 OR S6
S6 TI tissue expansion OR AB tissue expansion
S5 TI ((surg* or reconstruct* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) N2 flap*) OR AB ((surg* or random or region* or muscle or musculocutaneous or fascial* or fasciocutaneous* or perforat* or free) N2 flap*)
S4 TI (skin N3 (graft* or transplant*)) or AB (skin N3 (graft* or transplant*))
S3 TI (primary N3 closure*) OR AB (primary N3 closure*)
S2 TI surger* or surgical* OR AB surger* or surgical*
S1 (MH "Surgery, Operative+")

Appendix 2 Summary of excluded studies, systematic review 1

TABLE 29 Summary of excluded studies that evaluated reconstructive surgery for PUs and presented some extractable outcome data (*n* = 29)

Author(s)	Period over which data relates to	Country	Included participants (*n*)	Mean age (years)	Study population	Surgery Group 1	Participants *n*, surgeries *n*	Summary of outcomes reported for complete wound healing, recurrence or dehiscence (also considered flap necrosis here)
Ahluwalia 2009	1997–2007	Canada	78	43	Mixed population (94% had suffered spinal cord injuries)	Group 1: Fasciocutaneous flaps Group 2: Muscle/musculocutaneous flaps	Group 1: 63 flaps Group 2: 41 flaps	Recurrence was defined as the development of a pressure sore over a previously healed reconstructed site. It was recorded for 7% of reconstructed sites (not reported by group)
Berry 1980	1973–7	UK	46	45	Paraplegics	Group 1: Surgical repair including flaps and split-skin grafts Group 2: No surgery	Group 1: 65 ulcers Group 2: 8 ulcers	Four participants died during admission; one died shortly after discharge. Four patients were unhealed on discharge (residual sinuses); 17 participants were healed (not defined) at discharge but suffered recurrence of one or more ulcers within the first 3 months. 20 participants remained healed (with three developing ulcers at other sites).
Bertheuil 2014	1996–2010	France	33	Group 1: 40.3 Group 2: 54.8	People with spinal cord injury and ischial PU(s)	Group 1: Biceps femoris flap Group 2: Gluteus maximus myocutaneous flap	Group 1: 25 participants Group 2: 8 participants	Primary healing (not defined) Group 1: 32.0% and Group 2: 62.5%. Recurrence (recurrence not defined but average time to recurrence noted as 22.1 months) Group 1: 8 participants Group 2: 0 participants recurred but two wounds dehisced and wound were left to heal by secondary intention
Biglari 2014	2006–10	Germany	352	Not reported	People with spinal cord injury	Several different types of flap surgery	Group 1: 352 participants, 421 skin flaps Group 2: 66 participants, 100 ulcers	Twenty-seven cases of dehiscence along the suture line; 12 cases of partial necrosis and 9 cases of total flap necrosis
Bilkay 2006 (extracted from abstract only – paper in Turkish)	1984–2002	Turkey	66	Unable to extract	Mixed population	Flaps and grafts		Recurrence (not defined) 24% recurrence

TABLE 29 Summary of excluded studies that evaluated reconstructive surgery for PUs and presented some extractable outcome data (*n* = 29) (*continued*)

Author(s)	Period over which data relates to	Country	Included participants (*n*)	Mean age (years)	Study population	Surgery Group 1	Participants *n*, surgeries *n*	Summary of outcomes reported for complete wound healing, recurrence or dehiscence (also considered flap necrosis here)
Bocchi 2002	1994–2001	Italy	52	Not reported	People with spina bifida	Several different type of flap surgery	52 participants, 20 receiving reconstructive surgery	Recurrence (not defined) 4/20 had a recurrence and received re-operation.
Chen 2014	2007–12	Taiwan	63	Group 1: 73.6 years Group 2: 66.8 years	Sacral pressure sores	Group 1: Gluteal perforator flap Group 2: Gluteal fasciocutaneous rotation flap	Group 1: 31 participants Group 2: 32 participants	Flap necrosis: Group 1: 8 participants Group 2: 8 participants Wound dehiscence: Group 1: 2 participants Group 2: 6 participants Recurrence was defined as a pressure sore that occurred at the site of flap reconstruction more than 3 months after reconstruction Wound recurrence Group 1: 5 participants Group 2: 5 participants
Chiang 2018	2010–6	China	18	82.3 years	People with multiple PUs (at least three ulcers per person)	Range of surgical repair procedures	18 participants 56 ulcers	Two participants recorded as having late recurrence, no further definition.
Disa 1992	1981–9	USA	40	42 years	Mixed population of those with paraplegia and those without	Range of reconstructive flap surgeries	40 participants 66 ulcers	Wound dehiscence Some suture line dehiscences; exact figures not reported Complete wound healing (not defined) 78% ulcers completely healed and 80% of participants completely healed on discharged Noted that some participants had open ulcers that had not received surgery. Recurrence was defined as development of a new sore at the site of previous sore or new site. Participants with no recurrence were defined as those whose flaps remained healed during the entire follow-up period 35 participants had follow-up data post discharge (over median of 21 months) with 24 participants recorded as having recurred

continued

TABLE 29 Summary of excluded studies that evaluated reconstructive surgery for PUs and presented some extractable outcome data (*n* = 29) (*continued*)

Author(s)	Period over which data relates to	Country	Included participants (*n*)	Mean age (years)	Study population	Surgery Group 1	Participants *n*, surgeries *n*	Summary of outcomes reported for complete wound healing, recurrence or dehiscence (also considered flap necrosis here)
Djedovic 2017	2008–14	Austria	41	Group 1: 64.6 years Group 2: 65.3 years	All those with sacral PUs having relevant surgery over the period	Group 1: Gluteal rotation flap Group 2: Gluteal V-Y flap	Group 1: 20 participants Group 2: 23 participants	No relevant single outcome presented Group 1: Of 18 patients, 8 (44 · 4%) showed major complications (defined as haematoma, wound dehiscence, seroma formation with fistulation, wound infection) that required surgical revision. Group 2: Of 23 patients , 8 (34.8%) showed major complications (haematoma, wound dehiscence, seroma formation with fistulation, wound infection) and required surgical revision
Fujioka 2014	2011–2	Japan	20		Stage 4 sacral PUs	Group 1: Perforator flaps Group 2: Rotation flaps	Group 1: 9 participants Group 2: 11 participants	Complete wound healing (defined as wound healing was determined when all sutures were removed without wound complications, such as seroma, fistulae, infection, flap necrosis, or wound dehiscence, usually 10–14 days after surgery) All 20 sacral PUs healed within 80 days after surgery Group 1: The mean healing time was 34.0 ± 15.4 (range 10–58) days Group 2: 45.5 ± 24.0 (range 11–80) days Flap necrosis: Group 1: 4; Group 2: 1 Wound dehiscence: Group 1: 0; Group 2: 3
Garofalo 1996	1987–93	Italy	50 – allocation to groups not clear	Not reported	Mixed patient population	Group 1: Myocutaneous flap Group 2: Rotation or transposed flaps		Wound dehiscence: Five wounds were recorded as breaking down
Goodman 1999	1992–7	USA	48	54.2 years	Veterans with spinal cord injuries	Range of surgical repair procedures (majority were musculocutaneous flaps)	Forty-eight participants with 41 getting musculocutaneous flaps; 6 split-thickness skin grafts and 5 fasciocutaneous flaps. One participant was recorded as receiving direct closure and 4 debridement only	Complete wound healing (not defined): Notes that 95% of participants were discharged with healed wounds Describes 'wound separation' which was considered as wound dehiscence and reports 31.1% (not clear if ulcers or participants). Reports partial flap loss for 22.9%

TABLE 29 Summary of excluded studies that evaluated reconstructive surgery for PUs and presented some extractable outcome data (*n* = 29) (*continued*)

Author(s)	Period over which data relates to	Country	Included participants (*n*)	Mean age (years)	Study population	Surgery Group 1	Participants *n*, surgeries *n*	Summary of outcomes reported for complete wound healing, recurrence or dehiscence (also considered flap necrosis here)
Grassetti 2014	1999–2010	Italy	143	Median age 51 years	Mixed patient population	Different approaches to perforator flap surgery	One hundred and forty-three participants: Perforator flap used (*n*) I-GAP (63) S-GAP (34) PFAP-1 (12) PFAP-am (2) Reoperation (6)	Wound dehiscence: defined as 1. suture line dehiscence, any recorded break in skin, excluding the donor site that occurred at any point before or during the mobilisation protocol. 2. the occurrence of a significant dehiscence necessitating a return to the operating theatres Not specific data reported for this outcome Wound recurrence (not defined): The overall cumulative probability of recurrence at 2 years was noted as 22.4%
Gusenoff 2002.	1995–8	USA	22		Non-ambulatory, non-paraplegic, elderly Patients	Range of different surgical repair approaches	Twenty-two participants, 27 ulcers	Complete wound healing (not clearly defined, terms reported below). Initial success in healing flap = 9 Initial success in healing flap at mean follow-up of 6 months (different ulcers from above) = 7 Healing flap by secondary intention = 3 Healed at 6 months after revision = 1 Wound dehiscence: four ulcers (three requiring further surgery) Wound recurrence (not clearly define but at 6 months) one ulcer
Han 2016	2007–14	South Korea	88	55.6 years	Mixed patient population	Several different type of flap surgery (exploring one- and two-stage processes)	88 participants	*No outcome clearly reported 'A major complication is defined as a condition that requires a re-operation, whereas a minor complication is defined as a condition that can be treated conservatively. The three complications that developed in the multiple ulcer group included one case of flap necrosis, which required a re-operation within 2 weeks postoperatively, and two cases of wound disruption, in which complete healing was achieved conservatively'*

continued

TABLE 29 Summary of excluded studies that evaluated reconstructive surgery for PUs and presented some extractable outcome data (*n* = 29) (*continued*)

Author(s)	Period over which data relates to	Country	Included participants (*n*)	Mean age (years)	Study population	Surgery Group 1	Participants *n*, surgeries *n*	Summary of outcomes reported for complete wound healing, recurrence or dehiscence (also considered flap necrosis here)
Keys 2010	1993–2008	USA	135	Not reported	Mixed patient population	Flap coverage of PUs	257 operations on 135 participants	Complete wound healing (not clearly defined, recorded as noted below): 61 flaps (27%) healed without any complication in the postoperative period and never recurred Wound dehiscence (dehiscence was defined as any recorded break in the skin, excluding the donor site, occurring at any point before or during the mobilisation protocol. The occurrence of a significant dehiscence necessitating return to the operating room for revision of the flap was noted as distinct from suture line dehiscences that healed without intervention): 110 flaps (49%) had some suture line dehiscence, with 36 of these (16% of total, 33% of dehiscence) requiring a return trip to the operating room for revision after dehiscence Wound recurrence: recurrence of PU at the site of flap, defined as the appearance of skin break at the surgical site after patients had completed their post flap mobilisation protocol with intact skin In all, 88 flaps (39%) developed same-site recurrence
Kierney 1998	1977–89	USA	158	34.5 years	Mixed participant population	Range of surgical repair procedures	One hundred and fifty-eight participants, 268 ulcers	Wound recurrence (not defined): 51/268 of ulcers recurred in 39/158 participants
Kuo 2014	2003–12	Taiwan	99	59.7 years	Mixed patient population	Group 1: Perforator flaps Group 2: Perforator-based rotation fasciocutaneous flaps Group 3: musculocutaneous flaps	Group 1: 35 flaps Group 2: 37 flaps Group 3: 27 flaps	Wound dehiscence (not defined): Group 1: 3 Group 2: 4 Group 3: 1 Flap necrosis: Group 1: 4 Group 2: 5 Group 3: 0 Wound recurrence (not defined): Group 1: 1 Group 2: 2 Group 3: 2

TABLE 29 Summary of excluded studies that evaluated reconstructive surgery for PUs and presented some extractable outcome data (*n* = 29) (*continued*)

Author(s)	Period over which data relates to	Country	Included participants (*n*)	Mean age (years)	Study population	Surgery Group 1	Participants *n*, surgeries *n*	Summary of outcomes reported for complete wound healing, recurrence or dehiscence (also considered flap necrosis here)
Kuwahara 2005	1998–2003	Japan	16	76 years	Elderly patients	Group 1: Local fascial flaps Group 2: Simple closure	Group 1: 8 participants Group 2: 8 participants	Complete wound healing (defined as being when local treatment was no longer needed) Group 1: 8 Group 2: 8 Noted that on average, wound healing took 18.4 days Wound recurrence (not defined): 6 people had a recurrence but the group was not clear Note several people (*n* = 7) died in the study
Li 2013	2007–10	Taiwan	48	79.0 years	People with trochanteric sores (who had failed conservative treatment)	Group 1: Hatchet shaped tensor fascia lata flap Group 2: Pedicle anterior lateral thigh flap	Group 1: 26 flaps, 24 participants Group 2: 25 flaps, 24 participants	Wound recurrence (not defined) Group 1: 0 Group 2: 6
Mehta 2012	2002–8	USA	90	Median age Group 1: 60 Group 2: 58		Group 1: Fasciocutaneous flaps Group 2: Biplanar reconstruction	Group 1: 30 participants Group 2: 60 participants	Wound dehiscence (not defined): Group 1: 6 Group 2: 18 Wound recurrence (not defined) Group 1: 53% Median time to recurrence 20.5 months Group 2: 25% Median time to recurrence 14.0 months
Oksman 2018	2009–14	Brazil	32		Mixed patient population	Group 1: Local fasciocutaneous flap Group 2: Gluteus maximus myocutaneous flap	Group 1: 17 participants Group 2: 15 participants	Complete wound healing (not defined) Group1: 13 Group 2: 10 Wound dehiscence (not defined): 12 participants (group not defined) Flap necrosis (not defined): Group1: 6 Group 2: 0

continued

TABLE 29 Summary of excluded studies that evaluated reconstructive surgery for PUs and presented some extractable outcome data (*n* = 29) (*continued*)

Author(s)	Period over which data relates to	Country	Included participants (*n*)	Mean age (years)	Study population	Surgery Group 1	Participants *n*, surgeries *n*	Summary of outcomes reported for complete wound healing, recurrence or dehiscence (also considered flap necrosis here)
Reis 1999	1979–97	Portugal	301	40 years	Mixed patient population	Range of different surgical approaches	301 participants, 415 ulcers	Wound recurrence (not defined) Not presented by clearly articulated group in terms of whether all surgeries are represented or if this is a subgroup but notes: '*The ulcer recurrence rate was 22.6% at follow-up after 18 months* *In patients treated with direct closure or dermoepidermic grafts, the recurrence rate was 76 and 66%, respectively* *Patients treated with myocutaneous flaps (the most utilised procedure during the past 10 years) had a recurrence rate of only 13%. When the gluteal random rotation skin flaps or transposition local flaps were utilised, the recurrence rate was 28%. In patients treated with fasciocutaneous flaps, the recurrence rate was 9%*'
Rimareix 2000	Not noted	France	62	Mean 44 years	Para and tetraplegics with ischial PUs	Group 1: GM musculocutaneous flap Group 2: VY hamstring myocutaneous flap	Group 1: 62 participants Group 2: 28 participants	Wound recurrence (not defined) Group 1: 50% Group 2: 35%
Schryvers 2000	1976–96	Canada	Explored the treatment and outcome of all 168 admitted for SPU care. Data have been extracted for those recorded as being treated with specific types of surgery with outcome data	Not clear	People with spinal cord injury	Group 1: Primary closure Group 2: Cutaneous flap Group 3: Myocutaneous flap	Group 1: 75 ulcers Group 2: 253 ulcers Group 3: 93 ulcers	Complete wound healing (not defined) Average time from surgery to healed in days Group1: 67.3 days Group 2: 59.1 days Group 3: 82.2 days Wound dehiscence (not defined): Group1: 25 Group 2: 66 Group 3: 39 Wound recurrence (not defined) Group 1: 20, Group 2: 82, Group 3: 22 Mean time to recurrence in days Group 1: 1075, Group 2: 689, Group 3: 697
Wong 2006	1994–2004	China	38	Group 1: 62.2 years Group 2: 58.5 years	Mixed patient group	Group 1: Gluteal fasciocutaneous rotational flap Group 2: Myocutaneous flaps	Group 1: 18 participants Group 2: 20 participants	Complete wound healing (not defined) Number of ulcers Group1: 17, Group 2: 19 Mean time to healing (units not clear) Group 1: 2.89, Group 2: 3.25 Wound recurrence (not defined) Number of participants Group 1: 4, Group 2 : 0

TABLE 29 Summary of excluded studies that evaluated reconstructive surgery for PUs and presented some extractable outcome data (*n* = 29) (*continued*)

Author(s)	Period over which data relates to	Country	Included participants (*n*)	Mean age (years)	Study population	Surgery Group 1	Participants *n*, surgeries *n*	Summary of outcomes reported for complete wound healing, recurrence or dehiscence (also considered flap necrosis here)
Yoon 2018	2013–6	Korea	21	Group 1: 66.7 years Group 2: 61.0 years	Not reported	Group 1: Freestyle perforator-based peninsular flaps Group 2: Perforator-based peninsular flaps	Group 1: 9 participants Group 2: 12 participants	Wound dehiscence (not defined): Group 1: 1, Group 2: 1
Yoon 2016	2009–14	Korea	51	Group 1: 48.3 years Group 2: 48.5 years	Not reported	Group 1: Gluteal perforator group Group 2: Lumbar artery perforator group	Group 1: 39 participants Group 2: 12 participants	Wound dehiscence (not defined): Group 1: 5, Group 2: 2, Flap necrosis (partial) Group 1: 4, Group 2: 1 Wound recurrence (recurrence was defined as a pressure sore occurring at the flap reconstruction site > 3 months after reconstruction) Group 1: 3, Group 2: 1

Appendix 3 Risk-of-bias assessments for surgical reconstruction 1

TABLE 30 Risk of Bias 2 assessment for randomised study

Study	Domain 1: Risk of bias arising from the randomisation process	Domain 2: Risk of bias due to deviations from the intended interventions	Domain 3: Missing outcome data	Domain 4: Risk of bias in measurement of the outcome	Domain 5: Risk of bias in selection of the reported result	Overall risk of bias
Gargano *et al.*[41]	Some concerns Unclear if the allocation sequence was properly concealed and if the allocation sequence is random	High Participants and personnel likely knew the interventions assigned	Low Narrative results are available only, and there was no information on missing data	High Assessors likely know intervention groups	Low Unclear statistical analysis plan, but the data are presented narratively	High

TABLE 31 ROBINS–I risk of bias for included NRSI

Study ID	Sirimaharaj 2018[40]	Chiu 2017[41]
Outcome	Wound recurrence	Wound recurrence
Numeric result of outcome being assessed	From *Table 5* – results of adjusted analysis related to types of surgery (direct skin closure and fasciocutaneous flap HR 1.56, 95% CI 1.01 to 2.40 and split-thickness skin graft HR 3.82, 95% CI 2.54 to 5.76), both compared with muscle coverage (the myocutaneous flap, gluteus or hamstring muscle flap with skin direct closure, and gluteus or hamstring muscle flap with fasciocutaneous flap closure)	
Confounding domains		
Ulcer area at baseline	Measured/reported	Not reported
Ulcer duration at baseline	Not reported	Not reported
Health status	Not reported	Not reported
Life expectancy	Not reported	Not reported
Age	Measured/reported	Not reported
Cointerventions		
Use of support surface	Not noted	Not noted
Repositioning regime	Not noted	Noted below for all patients 'After surgery, our patients were routinely kept in a supine or lateral decubitus position to avoid bearing weight over the flap sites for a minimum of 3 weeks. Subsequently, the patients were permitted to begin lying on the flap for progressively longer times when possible. However, if skin broke at the flap site, this increasing frequency of contact was halted until the wound was healed'

TABLE 31 ROBINS I risk of bias for included NRSI (*continued*)

Study ID	Sirimaharaj 2018[40]	Chiu 2017[41]
Surgical debridement	Not noted	Not noted
Domain 1 Bias due to confounding		
1.1 Is there potential for confounding of the effect of the intervention in this study?	Yes This is a retrospective cohort study. There are several potential confounding variables which have not been considered in the adjusted analyses	Yes A logistic regression was used for adjustment. Limited confounding variables considered. And not measured to cover the domain – residual confounding a concern
1.2 Was the analysis based on splitting participants follow-up time according to intervention received?	No Time varying confounding not considered an issue here	No Time varying confounding not considered an issue here
1.3 Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome?	Not applicable	Not applicable
1.4 Did the authors use an appropriate analysis method that controlled for all the important confounding domains? *Question 1.5 not required*	No Not clear that Cox's regression was appropriate analytical approach. Some important domains were not controlled for and some which were, were not represented by adequate measures of the confounding factors	No Unclear analysis. Lack of suitable confounding factors. Data reported are not easy to interpret. Important domains were not controlled for
1.6. Did the authors control for any postintervention variables that could have been affected by the intervention?	Probably yes There was controlling for length of hospital stay.	No There is no report of controlling for postintervention variables that could have been affected.
Domain 1: Risk-of-bias judgement for confounding	CRITICAL At least one known important domain was not appropriately measured, or not controlled for. The use of the analytical approach is unclear and potentially not correct.	CRITICAL This is a study design at high risk of bias from confounding. The analytical approach taken in terms of design and the consideration of confounding domains was considered very poor and the risk of bias critical
Domain 2: Bias in selection of participants into the study		
2.1 Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of the study? *Questions 2.2 and 2.3 skipped as not required*	Probably no As this was a retrospective study, there is the potential for selective use if participants had specific responses to surgery. This is an issue inherent in the design rather than there being specific evidence that this occurred. However, there is no specific evidence that records have been excluded so we have selected probably no	Probably no As this was a retrospective study, there is the potential for selective use if participants had specific responses to surgery. This is an issue inherent in the design
2.4 Do start of follow-up and start of intervention coincide for most participants?	Probably yes Limited information but given taken from medical records which would have been collected pre-surgery to the postsurgical period we have selected yes	Probably yes Limited information but given taken from medical records which would have been collected pre-surgery to the postsurgical period we have selected yes
Domain 2: Risk-of-bias judgement	Moderate There is no specific evidence for bias selection of participants during the study; however, the nature of this design means this cannot be ruled out with	Moderate There is no specific evidence for bias selection of participants during the study; however, the nature of this design means this cannot be ruled out with

continued

TABLE 31 ROBINS I risk of bias for included NRSI (*continued*)

Study ID	Sirimaharaj 2018[40]	Chiu 2017[41]
Domain 3: Bias in classification of interventions		
3.1 Where the intervention groups clearly defined?	Probably yes The types of surgery are labelled. There is limited further detail given; however, the type of surgery is clear	Probably yes The types of surgery are labelled. There is limited further detail given; however, the type of surgery is clear
3.2 Was the information used to define intervention groups recorded at the start of the intervention?	Probably yes This was from medical record so should have been recorded. There is a risk in this design that details can be changed, but there is no evidence for this	Probably yes This was from medical record so should have been recorded. There is a risk in this design that details can be changed, but there is no evidence for this
Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome?	No information This is a risk here with retrospective data. It is not suggested that this occurred just that the design means it cannot be ruled out.	No information This is a risk here with retrospective data. It is not suggested that this occurred just that the design means it cannot be ruled out.
Domain 3: Risk-of-bias judgement	Moderate Intervention status is defined in a reasonable way. Given that intervention should have been recorded is not clear how knowledge of outcome could have affected classification/assignment to intervention status. This is a risk with retrospective data but does not seem high risk in this case	Moderate Intervention status is defined in a reasonable way. Given that intervention should have been recorded is not clear how knowledge of outcome could have affected classification/assignment to intervention status. This is a risk with retrospective data but does not seem high risk in this case
Domain 4: Bias due to deviation from intended interventions		
4.1 Were there deviations from the intended intervention beyond what would be expected in usual practice? *Question 4.2–4.6 skipped as not required*	No information Not clear from report, assumed no deviation from the surgery as this was reported in records. Of more concern here is that lack of detail on use of cointerventions as differential use of support surface and repositioning especially could introduce bias	No (limited) Not clear from report, assumed no deviation from the surgery as this was reported in records. Of more concern here is that lack of detail on use of cointerventions as differential use of support surface or application of the postoperative bed rest protocol especially could introduce bias. It was noted that all participants underwent the same turning protocol, but this detail was still considered very limited
Domain 4: Risk-of-bias judgement	No information	No information
Domain 5: Bias due to missing data		
5.1 Were outcome data available for all, or nearly all participants?	Probably yes 'To ensure accuracy and to limit missing results, data collected regarding all patients who matched the inclusion criteria were cross-checked using the surgical admission form at the outpatient department and the recording system in the operating room'	Probably no 'However, if a patient was lost to follow-up, we attempted contact by phone survey to collect the necessary additional data'. However, there were still 20 patients excluded because of incomplete data. The end of follow-up period
5.2 Were participants excluded due to missing data on intervention status?	No information No evidence for this – but a risk in this type of study due to the design. Selected no information	No information
5.3 Were participants excluded due to missing data on other variables needed for the analysis? *Questions 5.4 and 5.5 skipped as not required*	No information	No information

TABLE 31 ROBINS I risk of bias for included NRSI (*continued*)

Study ID	Sirimaharaj 2018[40]	Chiu 2017[41]
Domain 5: Risk-of-bias judgement	No information There is not enough information to understand if there were missing data and how it was treated	No information 20 participants were missing. It is not clear which surgeries these people received; there is limited information presented to make a judgement about bias here
Domain 6: Bias in measurement of outcomes		
6.1 Could the outcome measure have been influenced by knowledge of the intervention received?	Yes Assessment of recurrence can be subjective, although the outcome is not well defined in the study	Yes Assessment of recurrence can be subjective
6.2 Were outcome assessors aware of the intervention received by study participants?	Probably yes No indication that there was any attempt at blinding when looking at records	Probably yes There was no mention of blinding, and it can be difficult to blind to type of surgery due to the shape of the resulting closed wound/scar
6.3 Were the methods of outcome assessment comparable across intervention groups?	No information	No information
6.4 Were any systematic errors in measurement of the outcome related to intervention received?	No information	No information
Domain 6: Risk-of-bias judgement	SERIOUS The outcome measure was subjective (i.e. vulnerable to influence by knowledge of the intervention received by study participants); and The outcome was assessed by assessors aware of the intervention received by study participants	SERIOUS As with previous study, the nature of the study and outcome mean there is a serious risk of bias
Domain 7: Bias in selection of the reported results		
7.1. Is the reported effect estimate unlikely to be selected reporting, on the basis of the results, from multiple outcome measurements within the outcome domain?	Probably no The data appear to be at risk of selection. Significant results are presented and highlighted	Probably no There is evidence of the selection of significant results. Also, outcomes listed in the methods are not reported in the results
7.2. Is the reported effect estimate likely to be selected, on the basis of the results, from multiple analyses of the intervention-outcome relationship?	Probably yes	Probably yes
7.3. Is the reported effect estimate likely to be selected, on the basis of the results, from different subgroups?	Probably yes	Probably yes

continued

TABLE 31 ROBINS I risk of bias for included NRSI (*continued*)

Study ID	Sirimaharaj 2018[40]	Chiu 2017[41]
Domain 7: Risk-of-bias judgement	SERIOUS There is a high risk of selective reporting from among multiple analyses	CRITICAL This study seems at critical risk of selective reporting
OVERALL RISK-OF-BIAS ASSESSMENT FOR THIS OUTCOME/STUDY DYAD	CRITICAL The adjusted analysis does not appear adequately controlled nor does it adjust for clustering. The use of time to event data is not interpretable. The finding for this outcome cannot be used as useful evidence	CRITICAL Considered at critical risk of bias due to concerns about treatment of confounding domains and the possible selective reporting of results

Appendix 4 Search strategies for systematic review 2

CENTRAL:

We undertook a broad search using the MeSH term 'pressure ulcer' to identify all potentially relevant trials for manual screening. This was supplemented with more detailed searches of MEDLINE, EMBASE and CINAHL as detailed below.

Database(s): Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) 1946–14 April 2020

#SearchesResults
1 exp Pressure Ulcer/12192
2 (pressure adj (ulcer* or sore* or injur*)).tw. 10845
3 (decubitus adj (ulcer* or sore*)).tw. 1778
4 (bedsore* or (bed adj sore*)).tw.694
5 or/1-416640
6 exp "Quality of Life"/ 190705
7 "quality of life".mp. 337263
8 (HRQoL or HRQL).mp. 19512
9 exp "Activities of Daily Living"/ 100477
10 (activities of daily life or daily living activities or ADL).mp. 12142
11 exp Health Status/331741
12 exp Self Concept/108394
13 exp Patient Reported Outcome Measures/5373
14 exp Social Adjustment/23195
15 exp pain measurement/84924
16 health status.mp.151221
17 (self-concept or self concept or social-concept or social concept).mp. 57772
18 (wellness or wellbeing or well-being).mp. 97538
19 (functional adj ability).mp. 4841
20 good health.mp.8489
21 healthiness.mp.649
22 (social adj (adjustment* or function* or impact)).mp. 39133
23 (physical adj (limit* or funct* or impact)).mp. 27048
24 (psychological adj (well being or well-being or funct*)).mp. 12882
25 symptom*.mp.1137626
26 (pain adj3 measur*).mp. 94703
27 ((measuring or measurement) adj5 "quality of life").mp. 5371
28 or/6-271869287
29 (sf-36 or "short form-36").mp. 20209
30 (SF-12 or "short-form-12").mp. 5485
31 (SF-6 or "short form-6").mp. 572
32 (EQ-5D or EQ-5D-3L or EQ-5D-5L or EQ-5D-Y).mp. 7877
33 (PU-QOL or PurPOSE PUQOL).mp.8
34 nottingham health profile.mp.1150
35 sickness impact profile.mp.7878
36 world health organi?ation quality of life scale.mp.168
37 or/29-3640670
38 5 and 28 and 3736
39 randomized controlled trial.pt.503989
40 controlled clinical trial.pt.93621

41 randomi?ed.ab.569923
42 placebo.ab.206885
43 clinical trials as topic.sh.190776
44 randomly.ab.331233
45 trial.ti.216625
46 or/39-451317613
47 exp animals/ not humans.sh.4690854
48 46 not 471213961
49 38 and 487

Database(s): EMBASE 1974–14 April 2020

Search Strategy:

#SearchesResults

1 exp decubitus/20462
2 (pressure adj (ulcer* or sore* or injur*)).tw. 13245
3 (decubitus adj (ulcer* or sore*)).tw. 1993
4 (bedsore* or (bed adj sore*)).tw. 1008
5 or/1-424069
6 exp "quality of life"/ 481647
7 quality of life.mp.582847
8 (HRQoL or HRQL).mp. 32039
9 exp daily life activity/87772
10 (activities of daily life or daily living activities or ADL).mp. 22207
11 exp health status/234271
12 exp self concept/190951
13 exp patient-reported outcome/21244
14 exp social adaptation/118970
15 exp pain measurement/15271
16 health status.mp.158982
17 (self-concept or self concept or social-concept or social concept).mp. 89518
18 (wellness or wellbeing or well-being).mp. 150776
19 (functional adj ability).mp. 7125
20 good health.mp.11267
21 healthiness.mp.857
22 (social adj (adjustment* or function* or impact)).mp. 28112
23 (physical adj (limit* or funct* or impact)).mp. 41147
24 (psychological adj (well being or well-being or funct*)).mp. 28800
25 symptom*.mp.1795443
26 (pain adj3 measur*).mp. 31985
27 ((measuring or measurement) adj5 "quality of life").mp. 5380
28 or/6-272863740
29 (sf-36 or "short form-36").mp. 33672
30 (SF-12 or "short-form-12").mp. 10463
31 (SF-6 or "short form-6").mp. 352
32 (EQ-5D or EQ-5D-3L or EQ-5D-5L or EQ-5D-Y).mp. 15209
33 (PU-QOL or PurPOSE PUQOL).mp.6
34 nottingham health profile.mp.1624
35 sickness impact profile.mp.3294
36 world health organi?ation quality of life scale.mp.266

37 or/29-3661792
38 5 and 28 and 3769
39 Randomized controlled trials/177179
40 Single-Blind Method/36555
41 Double-Blind Method/147019
42 Crossover Procedure/62794
43 (random* or factorial* or crossover* or cross over* or cross-over* or placebo* or assign* or allocat* or volunteer*).ti,ab. 2188926
44 (doubl* adj blind*).ti,ab. 208109
45 (singl* adj blind*).ti,ab. 24692
46 or/39-452321485
47 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or non-human/27217453
48 human/ or human cell/20738870
49 and/47-4820676205
50 47 not 496541248
51 46 not 502031907
52 38 and 5114

HRQoL CINAHLPlus new RCt_20200415

S62	S38 AND S61
S61	S60 NOT S59
S60	S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53
S59	S57 NOT S58
S58	MH (human)
S57	S54 OR S55 OR S56
S56	TI (animal model*)
S55	MH (animal studies)
S54	MH animals+
S53	AB (cluster W3 RCT)
S52	MH (crossover design) OR MH (comparative studies)
S51	AB (control W5 group)
S50	PT (randomized controlled trial)
S49	MH (placebos)
S48	MH (sample size) AND AB (assigned OR allocated OR control)
S47	TI (trial)
S46	AB (random*)
S45	TI (randomised OR randomized)
S44	MH cluster sample
S43	MH pretest–posttest design
S42	MH random assignment
S41	MH single-blind studies
S40	MH double-blind studies

S39	MH randomized controlled trials
S38	S5 AND S28 AND S37
S37	S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36
S36	world health organi?ation quality of life scale
S35	sickness impact profile
S34	nottingham health profile
S33	(PU-QOL or PurPOSE PUQOL)
S32	(EQ-5D or EQ-5D-3L or EQ-5D-5L or EQ-5D-Y)
S31	(SF-6 or "short form-6")
S30	(SF-12 or "short-form-12")
S29	(sf-36 or "short form-36")
S28	(S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27)
S27	((measuring or measurement) N5 "quality of life")
S26	(pain N3 measur*)
S25	symptom*
S24	(psychological N1 (well being or well-being or funct*))
S23	(physical N1 (limit* or funct* or impact))
S22	(social N1 (adjustment* or function* or impact))
S21	healthiness
S20	good health
S19	(functional N1 ability)
S18	(wellness or wellbeing or well-being)
S17	(self-concept or self concept or social-concept or social concept)
S16	health status
S15	(MH "Pain Measurement")
S14	(MH "Social Adjustment")
S13	(MH "Patient-Reported Outcomes")
S12	(MH "Self Concept+")
S11	(MH "Health Status+")
S10	(activities of daily life or daily living activities or ADL)
S9	(MH "Activities of Daily Living+")
S8	(HRQoL or HRQL)
S7	quality of life
S6	(MH "Quality of Life+")
S5	S1 OR S2 OR S3 OR S4
S4	(bedsore* or (bed N1 sore*))
S3	(decubitus N1 (ulcer* or sore*))
S2	(pressure N1 (ulcer* or sore* or injur*))
S1	(MH "Pressure Ulcer+")

Appendix 5 Risk-of-bias assessments for systematic review 2

TABLE 32 Risk-of-bias assessment for included studies

Study	Domain 1: Risk of bias arising from the randomisation process	Domain 2: Risk of bias due to deviations from the intended interventions	Domain 3: Missing outcome data	Domain 4: Risk of bias in measurement of the outcome	Domain 5: Risk of bias in selection of the reported result	Overall risk of bias
Nixon 2019[50,51]	Low	Low	Low	Some concerns	Low	Low
Arora 2019[53–55]	Low	Low	Low	Low	Low	Low
Stern 2019[52]	High	Some concerns	Some concerns	Low	Low	High

Appendix 6 Additional tables for nurses' and surgeons' surveys

TABLE 33 Nurses' survey questions and the corresponding numbers of open and closed-ended responses

Question	Open-ended responses	Closed-ended responses
In the last 12 months, approximately how many people with SPUs have you treated, specifically for their PU?	5	135
Would you ever consider SR as a potential treatment option for severe (full-skin thickness) PUs?	73	134
In the last 12 months, how many of your patients do you think have been referred for a surgical opinion of their PU?	21	134
In the last 12 months, which secondary care services do you think your patients been referred to specifically for PU treatment?	28	106
If a patient requires a surgical opinion on their PU do you:	12	103
Typically, when requesting, or advising about a request, for a surgical opinion on a PU is your intention to <several questions>:	8	103
Do you think SR for PUs should be more widely available?	40	127
Select how likely you are to recommend a referral for PU SR for patients with the following CHARACTERISTICS.	18	122
Select how likely you are to recommend a referral for PU SR for patients with the following PRESSURE ULCER characteristics.	18	120
Which of the following treatments/management strategies do you recommend or provide for SPUs?	24	110
In your opinion, what percentage of people will have recurrence of the same PU(s) that was operated on within 12 months of healing?	13	109
To what extent do the following PATIENT factors predict whether a patient with a healed SPU following SR will have recurrence of the same PU?	7	105
In your opinion, to what extent do the following PRESSURE ULCER factors predict whether a patient with a healed SPU following SR will have recurrence of the same PU?	4	104
For each factor listed below please indicate the extent to which it is a BARRIER to SR for PUs in your main workplace.	7	104
Please tell us more about the factors which you think are a BARRIER for patients to be referred for SR of their PU.	56	-
Please describe any other information that you think may be relevant to this survey of SR for PUs.	27	-

TABLE 34 Surgeons' survey questions and the corresponding number of open and closed-ended responses

Question	Open ended responses	Closed-ended responses
In the past 12 months, approximately how many patients have been referred to you specifically for PU treatment	1	31
Which of the following types of referrals do you receive specifically for treatment of patients with a PU?	4	31
In the last 12 months, in what proportion of patients referred to you for a consultation on their PU did you perform PU SR?	5	31
Do you think that SR for PUs should be more widely available?	8	31
In the last 2 years, how often have you performed the following types of SR for the treatment of PUs?	3	29
Do you ever perform reconstruction of multiple PUs at the same time during one operation?	7	29
Which of the following treatments do you recommend for your patients in addition to, or instead of SR	4	28
Who at your hospital makes recommendations for treatments and/or management strategies for pts that have been referred for PU SR?	2	28
Please select how likely you are to consider patients with the following CHARACTERISTICS as suitable for PU SR	0	27
Please indicate how likely you are to offer SR to a patient with the following PRESSURE ULCER characteristics	3	25
Please estimate the average length of postoperative hospital stay specifically for recovery from reconstructive PU surgery in your unit	5	25
Please estimate the percentage of people who have had PU SR that will have complete healing of their reconstructed wound within 6 months of surgery?	1	25
Please estimate what percentage of people who have had PU SR have a recurrence of the same PU(s) that was operated on within 12 months of healing?	2	25
In your experience, to what extent do the following PATIENT factors predict whether a patient with a healed SPU following SR will have recurrence of the same PU?	2	22
In your experience, to what extent do the following PRESSURE ULCER factors predict whether a patient with a healed SPU following SR will have recurrence of the same PU?	1	22
For each factor listed below please indicate the extent to which it is a BARRIER to SR for PUs in your main workplace	5	22
Please tell us more about the factors which impact on the decision NOT to consider reconstructive PU surgery	16	-
In your unit, has there been any changes to the service that delivers SR for PUs in the past decade?	10	22
Please describe any other information that you think may be relevant to this survey of SR for PUs.	4	-
Please rate the following reasons for why you have never performed PU SR, where 1 = not true and 5 = very true	2	4
Which of the following PU treatments and/or management strategies do you recommend?	2	4
Who else at your hospital makes recommendations for treatments and/or management strategies for patients that have been referred for PU SR	0	4
Do you think that SR for PUs should be more widely available?	2	4

Appendix 7 Free-text comments from surveys

TABLE 35 Free-text comments relating to the lack of clinical ownership of (non-spinal) PU patients

'This is definitely lacking in our area. As TVNs we often feel like no one wants to accept overall responsibility for these patients … We are a wholly nurse-led service, so our influence is limited with certain other specialities. Both us and our patients are very much forgotten about, or the medical profession appear to "pass the reins" to us without any recognition of our limitations'. – #11721763599, nurse working in the community, care home and hospital
'In my opinion lots of medics feel that pressure ulcers are a nursing problem and has nothing to do with them. We are often dismissed by general and plastic surgeons when asking for help as we are seen as "the experts" so should be able to deal with all eventualities'. – #11721763599, nurse working in the community, care home and hospital
'It does not appear that plastic surgeons are trained in pressure ulcer reconstruction nowadays and pressure ulcer reconstruction is not considered in most cases. They appear even reluctant to get involved with surgical debridement'. – #11770638581, hospital nurse
'Ownership of the patient for example a medical patient who needs surgery, orthopaedics refusing as they think its general surgery and vice versa, plastics acceptance or refusal as they are from another Trust'. – #11705577788, hospital nurse
'Difficult to get surgical opinions for patients with pressure damage as no one really wants to take responsibility for this type of surgery …' – #11702231917, community and hospital nurse
'It would be really helpful if this was seen as a specific speciality, it falls between Plastics, vascular, ortho, general surgeons so becomes no one's problem', – #11698896355, hospital nurse
'We have sometimes linked in with known specialist nurses within secondary care if the patient is already known e.g. *spinal services'.* – #11765183799, community nurse
'There is only 1 regional spinal unit who will consider accepting patients who have neurological conditions for SR. This is the go-to unit for me. Plastics are rarely interested, other spinal units only accept their own spinal patients. It's very difficult for non-spinal injury pressure ulcer patients'. – #11700949280, community nurse
'… If they don't have spinal injury [the referral] *process is even more complicated'.* – #11698484840, TVN
'The Plastic team seem very reluctant to operate'. – #11770638581, hospital nurse
'Also the fact that there is a reluctance for this type of surgery to be performed but this is in part due to the risks involved and the numbers that fail'. – #11702231917, community and hospital nurse
'However I have found that plastic surgeons are often reluctant to perform the surgery'. – #11701030421, community nurse
'There is apparently a local reluctance to offer PU surgery, although I believe the spinal injury surgeons here do operate on their patients with PU'. – #12016499944, plastic surgeon

TABLE 36 Free-text comments relating to the lack of evidence on effective treatments for PUs, including SR

'Currently national guidance does not focus on this area of PU management. Need more research!' – #11881474116, nurse working in the community, GP practice, care home and hospital
'Surgeons experience in pressure injuries seems to have a big impact. Lack of research re positive outcomes of surgery'. – #11701030421, community nurse
'… lack of local expertise, lack of knowledge of evidence for SR, lack of confidence that surgery will improve quality of life …' – #11881474116, nurse working in the community, GP practice, care home and hospital
'Lack of information regarding outcomes of SR'. – #11754135145, TVN
'Difficult to ascertain data on success rate – own clinical opinion is varied outcomes'. – #11718315919, hospital nurse
'Previous studies, guidelines for criteria to assess patient/wound suitability prior to referral …' – #11701315443, community nurse
'… If we are going down this route [SR], need to have a criteria to support surgeons in their decision making …' – #11722026134, hospital nurse
'I work in Plastics so we have many referrals. I think there needs to be greater awareness of what can be achieved as often the referring clinician has little understanding of the complexity of surgery'. – #11699991020, hospital nurse
'… There should be some clearer guidelines for people shying away from SR and treating everything conservatively especially in Spinal injury patients with PU'. – #12025653706, plastic surgeon

TABLE 37 Free-text comments relating to local resources and the need to refer out of area

'… availability of suitable beds, availability of long term inpatient service'. – #12013836227, plastic surgeon
'Resources – theatre, Ward. Other workload'. – #12016499944, plastic surgeon
'Had Trust management involved to create bed elsewhere within the hospital as also within own unit to address long waiting times'. – #12019512940, spinal rehabilitation surgeon/physician
'Long waiting times due to lack of bed and theatre capacity'. – #12019512940, spinal rehabilitation surgeon/physician
'We have no availability to refer locally and have to refer out of area …' – #11765183799, community nurse
'… local plastics teams have limited experience in managing these wounds …' - #11701064783, hospital nurse
'Plastic surgery not being available in the Trust requires out of Trust referral'. – #11698535032, community and hospital nurse

TABLE 38 Free-text comments relating to clinical objective indications for or against surgery

'… the patient often has other underlying medical complications which may make surgery too high a risk for the patient's healthcare'. – #11723335900, nurse working in the community, GP practice and care home
'… if they have co-morbidities that may delay their healing potential, it may not be worth the risk'. – #11722235708, hospital nurse
'… pending patient's overall health/co-morbidities, by having the surgery, we potentially affect their mortality rate'. – #11722026134, hospital nurse
'… We would not consider [SR] *for the very frail, terminal/end of life or those with very complex ongoing co-morbidities'.* – #11721763599, nurse working in the community, care home and hospital
'Dependent on … patient co-morbidities I would consider referring to plastics for surgical debridement and SR …' – #11701114092, hospital nurse
'I would ensure the wound had been treated effectively for wound infection/sepsis prior to referral'. – #11793367740, community nurse
'Osteomyelitis would have had to be treated before any reconstruction normally'. – #11722026134, hospital nurse
'I would first treat the osteomyelitis and infection then reassess and consider if treatment [SR] *is an option'.* – #11721859829, hospital nurse
'If wounds are really chronic, patients have osteomyelitis or there is significant tissue loss we have considered surgical intervention if the patient agrees and they are medically fit'. – #11765183799, community nurse
'If a patient has a wound infection, including those with osteomyelitis and delayed healing secondary to infection, I would ensure that treatment is optimised to treat these issues prior to considering referral for SR'. – #11721763599, community, care home and hospital nurse
'… if there is a deep-rooted infection this would need to be treated and then the patient reassessed'. – #11702231917, community and hospital nurse
'Would not refer if the pressure ulcer is infected but would refer when the infection is fully resolved'. – #11701114092, hospital nurse
'In my experience most patients are very frail and are usually bed bound. Complex surgery frequently is not the most appropriate intervention'. – #11619709715, vascular surgeon
'If pressure damage has been severe resulting in a large amount of tissue loss then SR may help the wound to heal faster and give a better outcome for the patient'. – #11725402926, hospital nurse

TABLE 39 Free-text comments relating to patient preference

'The decision would be based on a holistic assessment of the patient being mindful of their own wishes and preferences …' – #11721763599, nurse working in the community, care home and hospital
'… we would carefully consider the outcome for them and also their own wishes and preferences for treatment …' – #11721763599, nurse working in the community, care home and hospital
'The views of the patient however should be taken into consideration so long as they have the capacity to take on board all the information and make an informed choice'. – #11702231917, community and hospital nurse
'Patients are often scared of being admitted to hospital as they feel they are a higher risk of contracting various infections in hospital and are scared to be admitted …' – #11723335900, nurse working in the community, GP practice and care home
'Patients' fear of surgery, patients view of their pressure ulcer impact on their life, patients fear of lack of control over own life while in hospital and after discharge …' – #11701091357, community nurse
'Usually this is the distance they have to travel to access the treatment. It is usually too far for next of kin to visit regularly. Costs of travel also have an impact'. – #11765183799, community nurse
'[Cannot refer locally so must refer out of area] … *This impacts greatly on the patient's decisions to accept treatment when offered'.* – #11765183799, community nurse

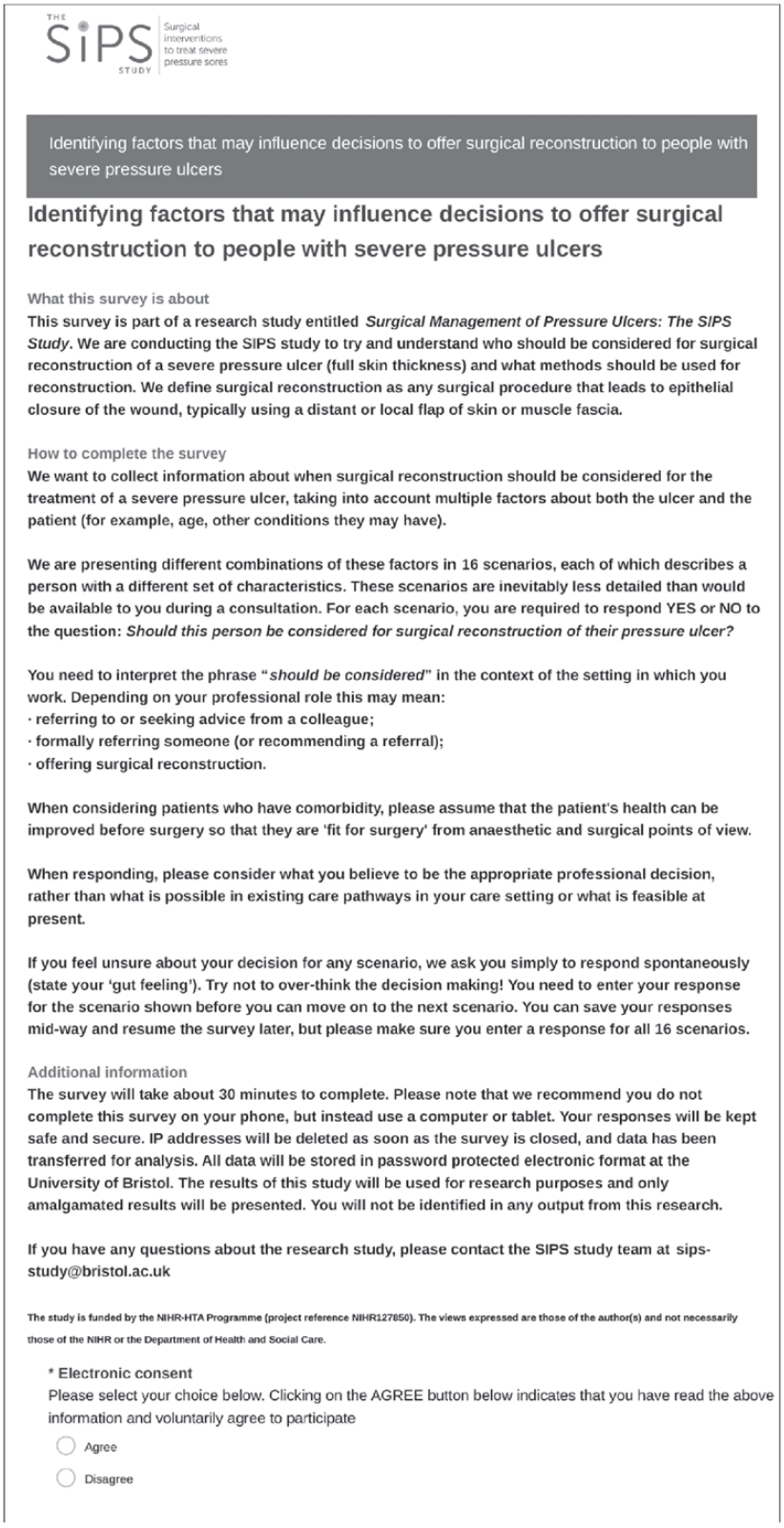
TABLE 40 Free-text comments relating to patient behaviours and lifestyle

'Based on individual patients and how committed they are to rehab post-surgery'. – #11718260867, community and hospital nurse
'Would however very much depend on the patient as the fact that someone has got a pressure ulcer requiring this usually means they may not have the ability to successfully heal and can lead to further breakdown which is more dramatic and even lead to the patient's demise'. – #11702231917, community and hospital nurse
'Buy in from the patient who may be reluctant to go into hospital in the first place and be willing to comply with the post-operative advice required'. – #11702231917, community and hospital nurse
'Patient willingness not just for surgery but for post-surgery care regime'. – #11701064783, hospital nurse
'Patients need to be committed to the recon journey and often need to stay in hospital for some time …' – #11699991020, hospital nurse
'Very dependent on patients needing to change their lifestyles, which is a massive ask'. – #11722026134, hospital nurse
'… SR may be inappropriate if the patients' behaviours don't change'. – #11721774241, community and hospital nurse
'… Reconstruction can be quite radical and the patient has to be very committed to staying off the area for a long period of time post op. This can be difficult for the patient …' – #11702231917, community and hospital nurse
'… If concordance is a major factor in PU development, then SR may be inappropriate if the patients' behaviours don't change …' – #11721774241, community and hospital nurse
'In our patients, compliance has sometimes resulted in over a decade of non-recurrence'. – #12025653706, plastic surgeon

TABLE 41 Free-text comments made about the survey questions

'Confusing question. … Also what does patients who have received SR mean? are they healed? Have they broken down again??' – #11770638581, hospital nurse
'It's difficult to comment on some of these generic situations as each patient would be considered individually …' – #11765183799, community nurse
'This is not an easy question to answer as each patient is evaluated individually and if surgery is best practice for patient then of course I would refer on to surgical consultant services'. – #11723335900, nurse working in the community, GP practice and care home
'Not sure I like the parameters given for this question as seem a bit vague …' – #11702231917, community and hospital nurse
'I don't understand Topical treatments not for debridement question …' – #11701091357, community nurse
'This is an ambiguous question as all the above would be considered following a holistic assessment …' – #11701114092, hospital nurse
'This is confusing question as you have specifically stated that this survey was about SR and not debridement. Debridement is important and surgery for this can speed the early stage. Mechanical debridement is surgery! I was going to consider the headings at the top to be "instead of reconstruction" and "in addition to reconstruction". I do not believe your results from this question can be assessed with any confidence. All of these elements required to be used for some patients and are part of the package but on a case by case basis – e.g. *some require bed rest but if I can I avoid this. I didn't want to answer this page but to move on it has to be – so the answers are meaningless'.* – #12015797797, plastic surgeon
'This is a poor question …' – #12015797797, plastic surgeon
'This question is too open as too many variables to answer appropriately'. – #11600320252, plastic surgeon

Appendix 8 Instructions to participants in the binary choice experiment



THE SiPS STUDY Surgical interventions to treat severe pressure sores

Identifying factors that may influence decisions to offer surgical reconstruction to people with severe pressure ulcers

Identifying factors that may influence decisions to offer surgical reconstruction to people with severe pressure ulcers

What this survey is about

This survey is part of a research study entitled *Surgical Management of Pressure Ulcers: The SIPS Study*. We are conducting the SIPS study to try and understand who should be considered for surgical reconstruction of a severe pressure ulcer (full skin thickness) and what methods should be used for reconstruction. We define surgical reconstruction as any surgical procedure that leads to epithelial closure of the wound, typically using a distant or local flap of skin or muscle fascia.

How to complete the survey

We want to collect information about when surgical reconstruction should be considered for the treatment of a severe pressure ulcer, taking into account multiple factors about both the ulcer and the patient (for example, age, other conditions they may have).

We are presenting different combinations of these factors in 16 scenarios, each of which describes a person with a different set of characteristics. These scenarios are inevitably less detailed than would be available to you during a consultation. For each scenario, you are required to respond YES or NO to the question: *Should this person be considered for surgical reconstruction of their pressure ulcer?*

You need to interpret the phrase "*should be considered*" in the context of the setting in which you work. Depending on your professional role this may mean:
· referring to or seeking advice from a colleague;
· formally referring someone (or recommending a referral);
· offering surgical reconstruction.

When considering patients who have comorbidity, please assume that the patient's health can be improved before surgery so that they are 'fit for surgery' from anaesthetic and surgical points of view.

When responding, please consider what you believe to be the appropriate professional decision, rather than what is possible in existing care pathways in your care setting or what is feasible at present.

If you feel unsure about your decision for any scenario, we ask you simply to respond spontaneously (state your 'gut feeling'). Try not to over-think the decision making! You need to enter your response for the scenario shown before you can move on to the next scenario. You can save your responses mid-way and resume the survey later, but please make sure you enter a response for all 16 scenarios.

Additional information

The survey will take about 30 minutes to complete. Please note that we recommend you do not complete this survey on your phone, but instead use a computer or tablet. Your responses will be kept safe and secure. IP addresses will be deleted as soon as the survey is closed, and data has been transferred for analysis. All data will be stored in password protected electronic format at the University of Bristol. The results of this study will be used for research purposes and only amalgamated results will be presented. You will not be identified in any output from this research.

If you have any questions about the research study, please contact the SIPS study team at sips-study@bristol.ac.uk

The study is funded by the NIHR-HTA Programme (project reference NIHR127850). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

* Electronic consent

Please select your choice below. Clicking on the AGREE button below indicates that you have read the above information and voluntarily agree to participate

○ Agree

○ Disagree

FIGURE 21 Instructions to participants in the BCE.

Appendix 9 Additional tables and figures for analyses of Hospital Episode Statistics cohort

TABLE 42 Characteristics of patients in the SPU admissions cohort

Patient characteristics		*n* = 291,268[a]
Year; *n* (%)	2011	37,100 (13%)
	2012	37,419 (13%)
	2013	34,758 (12%)
	2014	34,739 (12%)
	2015	36,750 (13%)
	2016	37,917 (13%)
	2017	40,535 (14%)
	2018	32,050 (11%)
Age[b]; mean (SD)		78 (14%)
Sex[c]; *n* (%)	Male	135,034 (46%)
	Female	156,217 (54%)
IMD[c]; median (IQR)		19 (11–32)
Comorbidities in previous 12 months		
Hypertension; *n* (%)		158,328 (54%)
Diabetes; *n* (%)		82,556 (28%)
Stroke; *n* (%)		1925 (1%)
Dementia; *n* (%)		60,040 (21%)
Atrial fibrillation; *n* (%)		88,581 (30%)
Cancer (excluding secondary cancers); *n* (%)		39,312 (13%)
Kidney disease; *n* (%)		61,018 (21%)
Liver disease; *n* (%)		14,050 (5%)
Neurodegenerative disease; *n* (%)		11,316 (4%)
Injury; *n* (%)		3907 (1%)
Cause could be injury or disease or unspecified; *n* (%)		9663 (3%)
Cause unassigned; *n* (%)		266,382 (91%)
Previous surgery in 6 months; *n* (%)		25,615 (9%)
Charlson comorbidity index; median (IQR)		2 (1–4)
Admissions in previous 12 months; median (IQR)		1 (0–2)
Admissions with SPU diagnosis in previous 12 months; median (IQR)		0 (0–0)

a Note this total excludes 58 patients where the first SPU diagnosis coded was after the recorded date of death.
b Age was missing for 4315; 7 patients were 17 years old.
c IMD was missing for 6449.

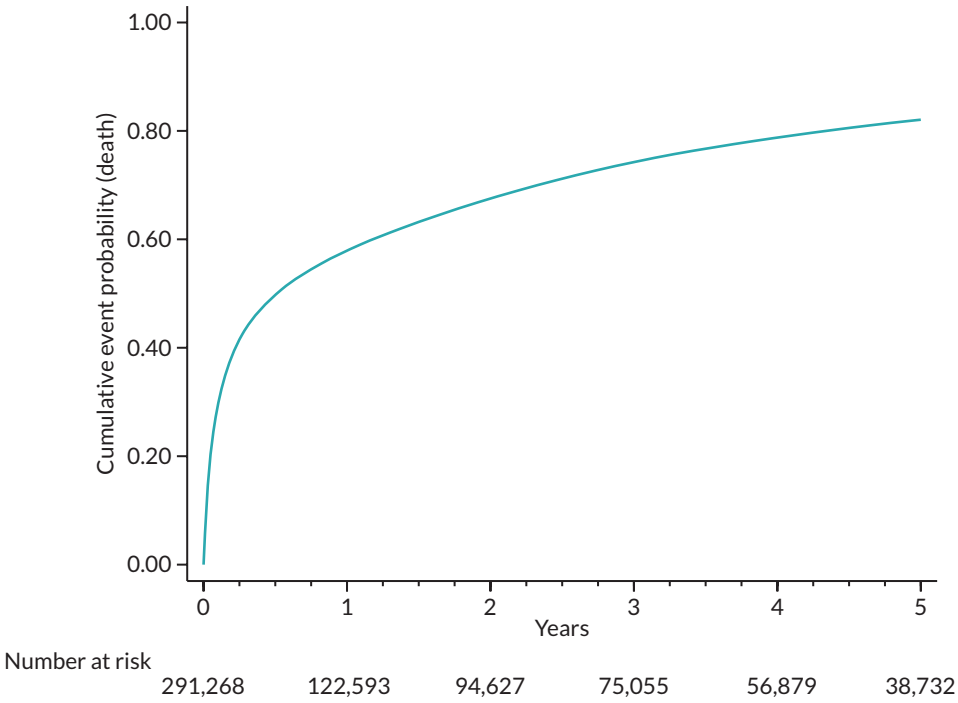


FIGURE 22 Kaplan–Meier survival graph for patients from the time of their first SPU admission in the SPU admissions cohort.

TABLE 43 English NHS provider trusts performing SR in the HES cohort, ranked by annual rate of SR (highest to lowest)

English NHS provider	Spinal injury centre[a]	BAPRAS unit[b]	SPU admissions with diagnosis[c]		Number of SR procedures[d]	
			1 April 2011–30 September 2018	Per year	1 April 2011–30 September 2018	Per year
Buckinghamshire Healthcare NHS Trust	Yes	Yes	2225	297	95	13
Oxford University Hospitals NHS Trust		Yes	3050	407	85	11
Salisbury NHS Foundation Trust	Yes	Yes	1340	179	70	9
Mid Yorkshire Hospitals NHS Trust	Yes	Yes	2135	285	55	7
South TEES Hospitals NHS Foundation Trust	Yes	Yes	2315	309	50	7
Sheffield Teaching Hospitals NHS Foundation Trust	Yes	Yes	3625	483	35	5
Mid Essex Hospital Services NHS Trust		Yes	1735	231	30	4
University Hospitals Birmingham NHS Foundation Trust		Yes	3260	435	30	4
North Bristol NHS Trust		Yes	2490	332	30	4
The Newcastle Upon Tyne Hospitals NHS Foundation Trust		Yes	1960	261	30	4
Cambridge University Hospitals NHS Foundation Trust		Yes	1800	240	25	3

continued

TABLE 43 English NHS provider trusts performing SR in the HES cohort, ranked by annual rate of SR (highest to lowest) (*continued*)

English NHS provider	Spinal injury centre[a]	BAPRAS unit[b]	SPU admissions with diagnosis[c]		Number of SR procedures[d]	
			1 April 2011–30 September 2018	Per year	1 April 2011–30 September 2018	Per year
Royal National Orthopaedic Hospital NHS Trust	Yes		435	58	25	3
Nottingham University Hospitals NHS Trust		Yes	4850	647	25	3
Queen Victoria Hospital NHS Foundation Trust		Yes	80	11	25	3
Barts Health NHS Trust		Yes	3875	517	25	3
St Helens and Knowsley Hospitals NHS Trust		Yes	2385	318	20	3
Lancashire Teaching Hospitals NHS Foundation Trust		Yes	2255	301	15	2
St George's Healthcare NHS Trust		Yes	2075	277	15	2
University Hospitals Coventry and Warwickshire NHS Trust		Yes	1765	235	15	2
University Hospital Of South Manchester NHS Foundation Trust		Yes	1185	158	15	2
Unknown			4885	651	15	2
Imperial College Healthcare NHS Trust		Yes	2755	367	15	2
Hull And East Yorkshire Hospitals NHS Trust		Yes	2435	325	15	2
Plymouth Hospitals NHS Trust		Yes	2205	294	15	2
Royal Free London NHS Foundation Trust		Yes	2065	275	15	2
Leeds Teaching Hospitals NHS Trust		Yes	3225	430	10	1
York Teaching Hospital NHS Foundation Trust		Yes	3015	402	10	1
Norfolk And Norwich University Hospitals NHS Foundation Trust		Yes	2960	395	10	1
Bradford Teaching Hospitals NHS Foundation Trust		Yes	2285	305	10	1
Gloucestershire Hospitals NHS Foundation Trust			2165	289	10	1
University Hospitals of Leicester NHS Trust		Yes	3525	470	10	1
County Durham and Darlington NHS Foundation Trust		Yes	2540	339	10	1
Guy's and St Thomas' NHS Foundation Trust		Yes	1180	157	10	1
University Hospital Southampton NHS Foundation Trust			2230	297	*	*

TABLE 43 English NHS provider trusts performing SR in the HES cohort, ranked by annual rate of SR (highest to lowest) (*continued*)

English NHS provider	Spinal injury centre[a]	BAPRAS unit[b]	SPU admissions with diagnosis[c]		Number of SR procedures[d]	
			1 April 2011–30 September 2018	Per year	1 April 2011–30 September 2018	Per year
Chelsea and Westminster Hospital NHS Foundation Trust		Yes	1820	243	*	*
Brighton and Sussex University Hospitals NHS Trust			1755	234	*	*
West Suffolk NHS Foundation Trust		Yes	1655	221	*	*
The Dudley Group NHS Foundation Trust		Yes	4065	542	*	*
Royal Liverpool and Broadgreen University Hospitals NHS Trust			2325	310	*	*
Frimley Park Hospital NHS Foundation Trust			1995	266	*	*
University College London Hospitals NHS Foundation Trust			980	131	*	*
Heart Of England NHS Foundation Trust			4115	549	*	*
University Hospital Of North Staffordshire NHS Trust			3085	411	*	*
Royal Devon and Exeter NHS Foundation Trust		Yes	975	130	*	*
Countess Of Chester Hospital NHS Foundation Trust		Yes	965	129	*	*
East Kent Hospitals University NHS Foundation Trust			3300	440	*	*
Northumbria Healthcare NHS Foundation Trust		Yes	3175	423	*	*
Peterborough and Stamford Hospitals NHS Foundation Trust			2405	321	*	*
Sandwell and West Birmingham Hospitals NHS Trust		Yes	1765	235	*	*
The Royal Marsden NHS Foundation Trust		Yes	195	26	*	*
Barking, Havering and Redbridge University Hospitals NHS Trust			3400	453	*	*
Portsmouth Hospitals NHS Trust		Yes	3015	402	*	*
East and North Hertfordshire NHS Trust		Yes	1685	225	*	*
Southport and Ormskirk Hospital NHS Trust	Yes		1045	139	*	*
Pennine Acute Hospitals NHS Trust			4430	591	*	*
King's College Hospital NHS Foundation Trust			3150	420	*	*

continued

TABLE 43 English NHS provider trusts performing SR in the HES cohort, ranked by annual rate of SR (highest to lowest) (*continued*)

English NHS provider	Spinal injury centre[a]	BAPRAS unit[b]	SPU admissions with diagnosis[c]		Number of SR procedures[d]	
			1 April 2011–30 September 2018	Per year	1 April 2011–30 September 2018	Per year
Worcestershire Acute Hospitals NHS Trust			2740	365	*	*
Luton and Dunstable University Hospital NHS Foundation Trust			2160	288	*	*
Salford Royal NHS Foundation Trust			1770	236	*	*
University Hospitals Bristol NHS Foundation Trust			1435	191	*	*
Great Western Hospitals NHS Foundation Trust			1430	191	*	*
Bedford Hospital NHS Trust			1410	188	*	*
The Rotherham NHS Foundation Trust			1130	151	*	*
Royal Surrey County Hospital NHS Foundation Trust			1035	138	*	*
Heatherwood and Wexham Park Hospitals NHS Foundation Trust		Yes	1035	138	*	*
South London Healthcare NHS Trust			830	111	*	*
The Royal Orthopaedic Hospital NHS Foundation Trust			50	7	*	*
The Royal Wolverhampton NHS Trust			3145	419	*	*
Western Sussex Hospitals NHS Foundation Trust			2515	335	*	*
Shrewsbury and Telford Hospital NHS Trust			2385	318	*	*
Bolton NHS Foundation Trust			2190	292	*	*
City Hospitals Sunderland NHS Foundation Trust			1780	237	*	*
Medway NHS Foundation Trust			1730	231	*	*
Royal Berkshire NHS Foundation Trust			1700	227	*	*
Hampshire Hospitals NHS Foundation Trust			1555	207	*	*
Northampton General Hospital NHS Trust		Yes	1535	205	*	*
Mid Cheshire Hospitals NHS Foundation Trust			1280	171	*	*
Barnet and Chase Farm Hospitals NHS Trust			1270	169	*	*
Ipswich Hospital NHS Trust			1235	165	*	*

TABLE 43 English NHS provider trusts performing SR in the HES cohort, ranked by annual rate of SR (highest to lowest) (*continued*)

English NHS provider	Spinal injury centre[a]	BAPRAS unit[b]	SPU admissions with diagnosis[c]		Number of SR procedures[d]	
			1 April 2011–30 September 2018	Per year	1 April 2011–30 September 2018	Per year
Central Manchester University Hospitals NHS Foundation Trust		Yes	1150	153	*	*
The Hillingdon Hospitals NHS Foundation Trust			1090	145	*	*
North West London Hospitals NHS Trust			1030	137	*	*
Dorset County Hospital NHS Foundation Trust			560	75	*	*
Royal Brompton and Harefield NHS Foundation Trust			385	51	*	*
Liverpool Women's NHS Foundation Trust			30	4	*	*
Circle			15	2	*	*
All other providers[e]			116,050	15,473	0	0
Total			291,268	38,835.7	1018	135.7

a Trust designated as a spinal injury centre.
b Trust designated as a plastics surgery unit by BAPRAS.
c Number and annual rate of SPU admissions in the SPU admissions cohort.
d Number and annual rate of SRs in patients admitted with a SPU.
e Number and annual rate of SPU admissions for providers carrying out no SRs are combined.

Note
Numbers and rates of SR are reported in accordance with Disclosure control methodology for HES and Emergency Care Data Set (ECDS), preventing reporting of small numbers. Where the number of SRs performed by a Trust was < 10, an asterisk is entered in the relevant cells, as required by the disclosure control methodology.

TABLE 44 Strata of percentiles of PS in TT emulation cohort: numbers in NSR and SR groups experiencing subsequent admission with the SPU diagnosed and crude HRs for each stratum

Percen-tile	NSR group (*n* = 1474)			SR group (*n* = 325)			Overall TT cohort (*n* = 1799)
	Max PS	Number	SPU on admission after index event; *n* (%)	Max PS	Number	SPU on admission after index event; *n* (%)	Crude HR (95% CI)
0–< 5	0.040	86	17 (20%)	0.03	3	0 (0%)	(Stratum excluded)
5–< 25	0.081	343	53 (15%)	0.079	17	1 (6%)	0.33 (0.05 to 2.39)
25–< 50	0.175	391	77 (20%)	0.174	60	12 (20%)	0.96 (0.52 to 1.77)
50–< 75	0.276	347	106 (31%)	0.275	99	21 (21%)	0.64 (0.40 to 1.02)
75–< 95	0.346	254	58 (23%)	0.346	110	23 (21%)	0.89 (0.55 to 1.44)
95–100	0.531	53	25 (47%)	0.4517	36	15 (42%)	0.89 (0.47 to 1.70)
Overall		1474	336 (23%)		325	72 (22%)	0.92 (0.71 to 1.18)

max, maximum; PS, propensity score.

Appendix 10 Additional tables and figures for analyses of Clinical Practice Research Datalink cohort

TABLE 45 Numbers and percentages of patients identified as having an incident PU by different Read codes; codes in bold font describe the stage of the PU

Read code	*n* = 11,342 (%)
M270.13 Pressure sore	8236 (72.62%)
Z1B3.00 Dressing of pressure sore	1225 (10.80%)
M270.11 Bed sore	895 (7.89%)
M270.00 Decubitus (pressure) ulcer	605 (5.33%)
Z174P00 Pressure sore care	304 (2.68%)
39C0.00 Pressure sore	13 (0.11%)
39C8.00 EPUAP (European Pressure Ulcer Advisory Panel) grade 2 ulcer	11 (0.10%)
39C7.00 EPUAP (European Pressure Ulcer Advisory Panel) grade 1 ulcer	9 (0.08%)
39C1.00 Superficial pressure sore	7 (0.06%)
39CA.00 EPUAP (European Pressure Ulcer Advisory Panel) grade 4 ulcer	7 (0.06%)
M270000 Hospital acquired PU	6 (0.05%)
39C9.00 EPUAP (European Pressure Ulcer Advisory Panel) grade 3 ulcer	6 (0.05%)
M270z00 Decubitus ulcer and pressure area NOS	5 (0.04%)
M270100 Nursing home-acquired PU	< 5
M270200 Community hospital-acquired PU	< 5
M270300 Hospice-acquired PU	< 5
M270400 Stage 1 decubitus ulcer and pressure area	< 5
M270500 Stage 2 decubitus ulcer	< 5
M270700 Stage 4 decubitus ulcer	< 5
39C2.00 Deep pressure sore	< 5
39C3.00 Pressure sore -deep + superfic	< 5
M270.14 Decubitus ulcer and pressure area	0
M270600 Stage 3 decubitus ulcer	0

TABLE 46 Numbers and percentages of patients identified as having an incident PU by different SNOMED codes; codes in bold font describe the stage of the PU

SNOMED code	*n* = 43,853 (%)
208311000006115 Pressure sore	14,994 (34.19%)
1779199011 Pressure sore	10,188 (23.23%)
908861000006110 [RFC] Pressure sore	8287 (18.90%)
608941000006119 Decubitus (pressure) ulcer	2551 (5.82%)
1787140012 Bed sore	2459 (5.61%)
256982011 Superficial pressure sore	1973 (4.50%)
904401000006116 Dressing of pressure sore	1040 (2.37%)
994521000006110 Pressure ulcer	521 (1.19%)
741801000000113 EPUAP (European Pressure Ulcer Advisory Panel) grade 2 ulcer	362 (0.83%)
907211000006112 [RFC] Pressure sores	293 (0.67%)
741821000000116 EPUAP (European Pressure Ulcer Advisory Panel) grade 3 ulcer	190 (0.43%)
256983018 Deep pressure sore	168 (0.38%)
741781000000112 EPUAP (European Pressure Ulcer Advisory Panel) grade 1 ulcer	165 (0.38%)
1647721000000110 Hospital-acquired PU	127 (0.29%)
741841000000111 EPUAP (European Pressure Ulcer Advisory Panel) grade 4 ulcer	88 (0.20%)
1816831000006112 Decubitus ulcer and pressure area	72 (0.16%)
1647741000000115 Nursing home-acquired PU	67 (0.15%)
1647761000000119 Community hospital-acquired PU	61 (0.14%)
1816841000006119 Stage 1 decubitus ulcer and pressure area	46 (0.10%)
1816881000006113 Decubitus ulcer and pressure area NOS	41 (0.09%)
1816851000006117 Stage 2 decubitus ulcer	38 (0.09%)
2617509017 Nonstageable PU	32 (0.07%)
1816871000006110 Stage 4 decubitus ulcer	23 (0.05%)
1816861000006115 Stage 3 decubitus ulcer	15 (0.03%)
1647781000000111 Hospice-acquired PU	14 (0.03%)
889551000006113 Decubitus/PU	10 (0.02%)
208331000006114 Pressure sore -deep + superfic	9 (0.02%)
926371000006117 Pressure sore	7 (0.02%)
1992981000006111 Pressure ulcer acquired in own home	6 (0.01%)
2016551000006119 Pressure ulcer self-management plan	5 (0.01%)
926381000006119 Superficial pressure sore	< 5
926401000006119 Pressure sore – deep + superficial	0
4936821000006118 Dressing of PU	0
1776931000006113 Reason for referral: PU	0

continued

TABLE 46 Numbers and percentages of patients identified as having an incident PU by different SNOMED codes; codes in bold font describe the stage of the PU (*continued*)

SNOMED code	*n* = 43,853 (%)
2003761000006117 Pressure ulcer clinical pathway protocol not followed	0
4590631000006116 Deep and superficial pressure sore	0
4590601000006112 Deep PU	0
8123071000006116 European Pressure Ulcer Advisory Panel grade 3 ulcer	0
4590561000006112 Pressure ulcer index value	0
6446491000006112 Assess PU care	0
8123031000006119 European Pressure Ulcer Advisory Panel grade 1 ulcer	0
4590621000006119 Deep and superficial PU	0
4590581000006119 Superficial PU	0
6446501000006116 Assess pressure sore care	0
2003861000006110 Pressure ulcer clinical pathway protocol followed	0
8123051000006114 European Pressure Ulcer Advisory Panel grade 2 ulcer	0
8123091000006115 European Pressure Ulcer Advisory Panel grade 4 ulcer	0
926391000006116 Deep pressure sore	0
1938931000006117 Pressure sore associated with indwelling urinary catheter	0
6974601000006113 Unstageable PU	0

EME
HSDR
HTA
PGfAR
PHR

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