**Title page**

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**c) Abstract**

This must contain fewer than 250 words in a structured format.

* Background: state why the study was done, the main aim and the nature of the study (randomized clinical trial, retrospective review, experimental study, etc.).
* Method: describe patients, laboratory material and other methods used.
* Results: state the main findings, including important numerical values.
* Conclusion: state the main conclusions, highlighting controversial or unexpected observations.

For systematic reviews/meta-analysis and randomized controlled trials please see guidelines for abstracts as reported by [PRISMA](https://dx.doi.org/10.1371/journal.pmed.1001419) and [CONSORT](https://doi.org/10.1371/journal.pmed.0050020).

**Abstract**

**Background:** Surgical site infection (SSI) is common after colorectal surgery but most hospitals do not know their SSI rates. Approximately half of SSI occurs after discharge and so post-discharge surveillance is needed for accurate measurement. There is evidence that peri-operative care bundles reduce SSI and one hospital in the West of England (WoE) had halved SSI using an evidence-based 4-point care bundle.

PreciSSion is a collaboration between 7 hospitals in the WoE. The aims were to establish reliable SSI measurement after elective colorectal surgery using 30-day patient-reported outcome measures and to implement the evidence-based 4-point care bundle. The overall aim was to halve SSI after elective colorectal surgery by March 2021.

**Method:** 30-day patient-reported SSI was measured using the Health Protection Agency Questionnaire and response rates were reported. Baseline data was collected and then the care bundle was implemented:

* 2% chlorhexidine skin preparation
* Second dose of antibiotic after 4 hours
* Use of a dual-ring wound protector
* Antibacterial sutures for abdominal wall closure

Compliance with all elements of the bundle was measured

All hospitals measured SSI and implemented the bundle between x2020 and May 2021. Average compliance with each element was 95%, 73%, 70% and 73% respectively. The regional average SSI rate halved from 18% (903 patients) to 9% (1147 patients).

**Conclusion**: We have demonstrated that a care bundle developed in a single hospital can be adopted and spread and the original outcome of a 50% reduction in SSI after elective colorectal surgery can be replicated in other hospitals and deliver results within 18 months

**d) Main text**

The main text of the paper should have separate Introduction, Methods, Results and Discussion sections (these sections may not be applicable to all article types, e.g. Reviews). A short Acknowledgements paragraph may also be included. When quoting specific materials, equipment and proprietary drugs, the name and address of the manufacturer must be given in parentheses. Generic names should normally be used. Any data mentioned in the abstract or discussion must be presented in the results section of the main text.

Introduction

Surgical site infection (SSI) accounts for 14.5% of hospital acquired infections in the UK. (1) It is a significant cause of patient morbidity including increased length of stay (2), readmission (3), wound dehiscence (4), hernia (5) critical care admission (6), and death (7,8). SSI rates of up to 27% have been reported after colorectal surgery where wounds are frequently contaminated by bowel content (9,10).ref changecurrently ref 13 However, prevalence is likely to be underestimated as SSI often presents after hospital discharge, so accurate measurement of SSI requires post discharge surveillance (11).

Public Health England requires mandatory SSI reporting following orthopaedic surgery but not for gastrointestinal surgery and incidence is only captured during inpatient stay or readmission (12). Data submitted to the national SSI surveillance service shows only 39% of UK trusts continuously monitor SSI after general surgery. Only 19 hospitals presented a complete dataset for lower gastrointestinal surgery and the reported rate of 8.7% (range 0.3 -24.5%) only includes inpatient and readmission data. The Getting It Right First Time (GIRFT) specialty report for general surgery showed that only 4% of hospitals (5 out of 138) knew their SSI rates (4 out of 50 in the first GIRFT report)(13).

The more robustly SSI is measured, the higher the rate. Research studies focusing on 30-day follow-up have shown SSI rates of 18 - 25% after abdominal surgery (14–16) This should be three references, ROSSINI, Bluebelle and VINCAT). This means that there is no benchmark for SSI after elective colorectal surgery and most hospitals do not know their SSI rates

Care bundles have been shown to reduce SSI(17). The existing World Health Organisation SSI bundle, which is part of the Surgical Safety Checklist, consists of four interventions which have been shown to independently reduce infection(18): Antibiotics within 1 hour of surgery, normothermia , blood glucose control in diabetics and appropriate hair removal. This is routinely used throughout the NHS. Despite high compliance with this, one hospital in the West of England (WoE) halved SSI using an additional 4 point care ‘surgical ‘care bundle (19). All elements of the bundle recommended by the National Institute of Clinical Excellence (NICE)(20) and the World Health Organisation (WHO) as interventions to prevent SSI (21).

The evidence-based care bundle consisted of:

* 2% chlorhexidine skin preparation
* A second dose of antibiotic after 4 hours
* Use of a dual ring wound protector
* Antibacterial (Triclosan coated) sutures for abdominal wall closure

Seven hospitals in the WoE had already worked together to improve care after emergency surgery as part of the Emergency Laparotomy Collaborative (22). The aim was to build on this collaborative approach to establish reliable SSI measurement after elective colorectal surgery using 30-day patient-reported outcome measures in all trusts and to implement this new evidence-based 4-point care bundle with the aim of reducing regional SSI by 50% by March 2021

**Materials and Methods**

This project started in 2019 using the IHI breakthrough collaborative model to spread best practice(23) and was supported by the West of England Academic Health Science Network (24). Teams were taught quality improvement methodology and measurement focused on process (bundle compliance and response rates) and outcome (SSI rates). Meetings were held with each team at the beginning of the project and there was one face-to-face event prior to the COVID-19 pandemic. All hospitals implemented the bundle just before the pandemic, so subsequent meetings were online and supplemented by online coaching. As the WHO checklist includes elements to reduce SSI, a spot audit was performed by all hospitals prior to implementing the new bundle.

Definitions and bundle components were agreed by the collaborative. Colorectal surgery was defined as colorectal resection, small bowel resection and reversal of Hartmann’s procedure. Those undergoing transanal surgery with no intra-abdominal procedure were excluded.

Measures were:

* 30-day patient-reported SSI rate
* Response rates
* Compliance with each bundle element

To establish reliable measurement of 30-day patient-reported SSI, the Health Protection Agency questionnaire, a validated questionnaire used to monitor SSI after surgery, was used (25). This is an evidence based tool designed to detect superficial wound infection based on patient assessed appearance and management of wound according to the following criteria:

Criterion 1 - Discharge pus AND antibiotics prescribed

Criterion 2 - Clinical signs\* AND dehiscence

Criterion 3 - Clinical signs\* AND antibiotics prescribed

\*clinical signs – at least 2 of the following must be present: pain, heat, redness or swelling

 Prior to the project, of the 7 hospitals other than the one where the bundle had been implemented, only one trust was continuously measuring SSI. They had already established a method of measuring in-hospital SSI, so this was included as well as 30 day patient-reported outcomes and so they had more robust data. One trust was unable to collect patient-reported measures but collected consistent measures pre and post bundle implementation electronically and from note review

An online toolkit was developed to aid implementation. This included QI resources, published evidence and documents to support data collection. Feedback on compliance was essential to continue engagement and coffee room posters were designed for teams to share within their hospitals. A video was designed to publicise the project including one especially for theatre nurses. The key to implementing the bundle was involvement of theatre teams to prompt surgeonss to do the right thing and also to measure compliance. Theatre teams were empowered to time operations to ensure a second dose of antibiotics was given after 4 hours and also to remind surgeons to use wound protectors and antibacterial sutures.

Project findings are reported in accordance with Standards for Quality Improvement Reporting Excellence (SQUIRE). Process (compliance with bundle elements) and outcome (SSI rates) data were plotted on run charts to monitor progress of individual hospitals and a statistical process control (SPC) chart was created to show aggregate data from all participating sites using locally collected data. The analysis was undertaken using ‘plot the dots’ software available for NHS Making Data Count (26). Percentage SSI is plotted over time and upper and lower control limits were calculated at three standard deviations from the mean. Following standard practice for SPC chart interpretation, mean and control limits were recalculated when a shift (7 or more successive data points above or below the mean) was identified. A shift is a data signal in an SPC chart that indicates a special cause variation, analogous to a significant, non-random, change in the data (*P <*0⋅05) (27)

Results

All hospitals successfully measured SSI achieving an average response rate of 81%. Unfortunately the COVID pandemic meant one hospital (Hospital 5) had a period where patient-reported data was not collected due to staff redeployment, so their post implementation data was limited to 5 months.

Baseline measures were collected before implementation and ongoing audits of compliance with each bundle element were measured by theatre teams, who also prompted the surgeons to use each bundle component. Average compliance of 95%, 73%, 70% and 73% was achieved for each element respectively. Overall compliance with whole bundle was 66%. The approach to measuring compliance varied. The aim was to record compliance for all patients but some hospitals struggled with data collection. On occasion, compliance data was collected for individual patients but was not complete. This meant that some bundle elements were recorded as not compliant when in fact the element had been delivered but not recorded on the data collection sheet. This was the case for hospitals 1 and 2 from a single trust who had lower compliance rates

The trust that had originally implemented the bundle in 2013 reduced SSI from 20% (208 patients) to 10% and sustained their reduction in SSI from 2013- 2021 (1870 patients).
All trusts, except one with a low baseline rate, demonstrated at least 27% improvement in SSI rate, the greatest being 75% improvement.

Combined regional average baseline SSI was 18% (range 8- 30%) pre November 2019 (903 patients). Implementation of bundle in all trusts between November 2019 and May 2020 resulted in 50% improvement in SSI rate to a regional average of 9% (range 6-15%) by January 2021 (1147 patients). This relates to saving 103 patients from an SSI, a significant improvement in patient experience.

The MDT approach and collaborative element enabled staff and trusts to support each other during the difficulties of the COVID-19 pandemic and engagement was high, with theatre teams in particular being empowered to make a difference.

The bundle is easily adaptable to other surgical procedures and three hospitals implemented the same bundle after emergency abdominal surgery during 2020, although this was not part of the original project. Measurement of SSI can be more challenging after emergency surgery as mortality rates are higher and a proportion of patients might have their abdomen left open initially after surgery (laparostomy). Patient-reported outcomes alone cannot measure the totality of SSI as a higher proportion of patients remain in hospital at 30 days, so a combination of in-hospital measurement and post-discharge surveillance is required. Compliance with the bundle is also more difficult as it is not always possible to use a wound protector. However, all 3 trusts reduced SSI. The average combined baseline SSI rate was 23.5% (range 13- 32 %) and decreased to 10% (range 7-12%) following bundle implementation. Average response rate was 75%.

**Discussion**

This project has demonstrated that with the collaborative approach, an evidence based care bundle already implemented in a single hospital can be adopted and spread and the original outcome of a 50% reduction in SSI after elective colorectal surgery can be replicated in other hospitals within 18 months. The aim of this paper is to learn from this approach rather than to assess the efficacy of the bundle or the risk factors for SSI which are reported elsewhere. There are very few QI projects focused on surgical topics. The Emergency Laparotomy Collaborative (18) and EPOCH (28) focused on improving care of patients undergoing emergency laparotomy and CholeQuic (29–31)this should be three references not aimed to increase the numbers of patients undergoing emergency cholecsytectomy The principles of the PreciSSIon collaborative align with the advice for QI in surgery from the RCS (32). For example, the collaborative events gave teams the space and time to improve and to learn from their own and others’ experience. The team support and coaching allowed time to check in with teams and understand their progress and challenges

There was a wide range of baseline SSI rates. This is in keeping with Public Health England data which demonstrates that large bowel surgery shows the greatest variability of SSI measured during inpatient and readmissions ranging from 0.3% to 24.9% and the highest inpatient SSI rate, at 8.7% (12) and fits with published rates of up to 30% in academic studies with 30 day follow up (14–16) REF rossini, bluebelle and vincat from above. This might also relate to difference in case mix, especially in one trust which reconfigured services between 2 hospitals during the project as a response to the pandemic. It might also reflect whether hospitals had made previous attempts to reduce SSI. For example, one hospital had already introduced negative pressure dressings for high risk closed wounds to reduce SSI but none had introduced antibacterial sutures. The purpose of the data was measurement for improvement and not for comparison. Ideally all hospitals would have used an identical measurement strategy but one hospital did not use 30 day PROMS and one used in-hospital surveillance in addition. This illustrates the problems with standardising measurement when there is local variation in resources

The agreed bundle consisted of 4 elements. There is some evidence that the more elements in a bundle, the more difficult it is to implement. This is true of the EPOCH study (28) which had 37 pathway elements to improve care of patients undergoing emergency laparotomy and demonstrated wide variations in which elements local QI teams chose to tackle, the rate of change they achieved, and their eventual success. This was also partially true of the Emergency Laparotomy Collaborative (22) which had 6 only elements in the care bundle as teams only tended to address the ‘easy wins’ and ignore more difficult or less well evidenced bundle elements.

All bundle elements were evidence-based and recommended by NICE and WHO ref. The ROSSINI study (14)needs to be referenced is often quoted as evidence against wound protectors. This is a UK study and well known among surgeons. However, meta analysis has shown that this is the only study which demonstrated no benefit (ref) (33–35). It is the most difficult bundle element to implement as it is not always possible to use a wound protector, due to obesity or adhesions adjacent to the wound. We therefore accept that unlike other elements where we would aim for 95% compliance, rates of >80% for wound protectors are unlikely. Although we agreed a basic bundle, one hospital added in humidified laparoscopic gas as they had demonstrated a problem with peri-operative hypothermia and several hospitals added in betadine to the wound (weak evidence for effectiveness in WHO guidance) and a reminder to change gloves on closure (no evidence but common sense if bowel contamination). As all hospitals reduced SSI, it is hard determine whether these extra elements reduced SSI above and beyond the basic bundle.

Standard QI methodology plots process and outcome measures on run charts. An example is shown in figure x. This demonstrates some of the issues with measuring SSI. Small numbers of patients can mean that only one additional patient with an SSI in a month can dramatically increase percentage SSI rates. This illustrates the benefit of continuous measurement as traditional snapshot audits over short period will not give accurate measurement of SSI. The other encouraging feature of the run charts is that the reduction in SSI seems to be sustained after introduction of the bundle.

Each hospital formed a multidisciplinary team to implement the project. The regional clinical lead for the project wrote to all medical directors and chief executive officers prior to starting the project to gain executive support and senior leaders were updated with the success of the project. The support available for the project varied between hospitals. One hospital had a SSI surveillance team in place. One hospital had a nurse to collect data during the GIRFT audit which had been withdrawn and other hospitals were starting from scratch. One hospital (the one that did not report PROMS) had a central team collecting PROMS and reporting to PHE but would not disclose the data to the team doing the QI project. This is an excellent example of where data is being collected to satisfy a reporting requirement but not to support improvement in care. This issue is currently being resolved.

This was a multidisciplinary project including staff along the whole patient journey. Success would not have been possible without the involvement of nursing or junior doctor teams to collect data to measure SSI and theatre teams who measured compliance. Theatre teams also encouraged teams to ‘do the right thing’ and prompted use of antibacterial sutures for example. They also helped time operations to prompt a second dose of antibiotics at 4 hours

Published literature estimates that development of an SSI after surgery leads to a 34-226% increase in cost (36) and GIRFT estimates that English NHS trusts have spent £35.2 million over 5 years on SSI-related medical negligence claims (13)(REF GIRFT). A UK study demonstrated that the cost of a SSI (measured using the same methodology as this study) after elective colorectal surgery is £4928 (range £4020-7503)(2) (JENKS et AL). Overall we estimate that we have saved 103 patients from developing a SSI since the start of the project. Using the estimate of £4928 per SSI, this would extrapolate to a cost saving of £509 574. This does not include additional savings from SSI reduction after emergency laparotomy. Triclosan-coated sutures are recommended by NICE but are approximately 85p more expensive per suture, equating to approximately £2.55 per patient. Economic analysis has demonstrated that this expenditure is cost-effective with a number needed to treat of 28 but despite this, teams found it difficult to persuade hospitals to fund the sutures. This is where executive sponsorship of the project was important. Dual-ring wound protectors were already in use for laparoscopic surgery but there was a small increase in cost related to increased use.

Strengths and limitations

This is the first example of the use of a care bundle to reduce SSI at scale in the UK. Previous reports are based on single centres. The project started in x 2019 and hospitals implemented the bundle between x 2019 and May 2020.

Patient-reported 30-day SSI using the health protection agency questionnaire was the outcome measure for this project . The introduction of enhanced recovery protocols after colorectal surgery has reduced length of stay to less than a week. As the median time to presentation of SSI is 13 days (9)(REF) post-operatively it is likely that previously reported SSI rates based on in-patient and readmission data have underestimated the true incidence. By using patient reported outcomes this was the first time that many hospitals knew their SSI rates after elective colorectal surgery.

The project was supported by the West of England Academic Health Science Network but costs were reduced by running events online. All teams delivered this quality improvement as part of their job and there was no backfill or funding to deliver the change. Apart from cost, the decreased incidence of SSI has undoubtedly had a significant impact on patient experience reducing the pain and discomfort associated with an infection as well as costs of patient time and travel.

One face to face meeting was held prior to the COVID-19 pandemic but the project achieved its ambition depite subsequent events being online. As most elective colorectal resections are for cancer, surgery continued during the pandemic, albeit in reduced numbers. Most hospitals implemented paper questionnaires and/or telephone calls to measure SSI and some used in-hospital surveillance in addition. This meant that standardising data collection was difficult. Data collection was undertaken by infection control nurses, enhanced recovery nurses, specialist cancer nurses or junior doctors which meant that the COVID pandemic led to challenges in sustaining measurement when staff were redeployed to other roles.

### Next steps

### Each hospital used different personnel to collect patient-reported outcome data using paper questionnaires, telephone follow-up or both. This incurs a manpower cost for data collection and upload. We are currently exploring other ways of measuring SSI. One hospital is trialling collection of SSI using e-PROMS which will involve a text questionnaire being sent to patients. We are also testing whether population health management data can be used to link primary and secondary care data to measure hospital-acquired and community-detected SSI after surgical procedures. By automating data collection, it should be easier for hospitals to accurately measure SSI reducing cost and facilitating adoption and spread.

### When we established the contents of the care bundle, use of negative pressure dressings for high risk closed wounds and bowel preparation plus oral antibiotics were considered as bundle elements. These were not included initially as we wanted bundle components that would be available to all patients, had a sound evidence base and were affordable. As we have now measured baseline and post implementation data, we are now in a position where hospitals can add in additional interventions to assess benefit. 3 hospitals have reduced SSI after emergency surgery and this care bundle can be adopted by any surgical specialty. We are currently exploring regional implementation in vascular surgery and post caesarean section as we have demonstrated that this care bundle can be adopted and spread at scale across a region leading to a significant reduction in SSI

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**e) Tables and Illustrations**

Submit each illustration as a separate file except compound figures e.g. 1a, 1b, 1c, etc., which should be supplied as a single file. Please avoid presenting tables in landscape format, portrait is preferred. If tables are too large to be displayed in portrait format please supply them as supplementary material and they will be available for download with the published article. Type each table on a separate page with a brief title. Supply artwork at the intended size for printing. Line drawings are acceptable as clear black on white graphics and must be high quality. Use hatchings, not tints. Illustrations should be provided in a 'true' figure format (tiff, jpeg, eps, etc.); pdfs, docs, ppts (or any Microsoft Office software format) will not be accepted. All illustrations must be supplied at the correct resolution:

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