

ORIGINAL ARTICLE

Surgical site infection: poor compliance with guidelines and care bundles

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Key words

Care bundles; Compliance; Guidelines; Surgical site infection

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doi: 10.1111/iwj.12243

Leaper DJ, Tanner J, Kiernan M, Assadian O, Edmiston CE Jr. Surgical site infection: poor compliance with guidelines and care bundles. *Int Wound J* 2015; 12:357–362

Abstract

Surgical site infections (SSIs) are probably the most preventable of the health care-associated infections. Despite the widespread international introduction of level I evidence-based guidelines for the prevention of SSIs, such as that of the National Institute for Clinical Excellence (NICE) in the UK and the surgical care improvement project (SCIP) of the USA, SSI rates have not measurably fallen. The care bundle approach is an accepted method of packaging best, evidence-based measures into routine care for all patients and, common to many guidelines for the prevention of SSI, includes methods for preoperative removal of hair (where appropriate), rational antibiotic prophylaxis, avoidance of perioperative hypothermia, management of perioperative blood glucose and effective skin preparation. Reasons for poor compliance with care bundles are not clear and have not matched the wide uptake and perceived benefit of the WHO 'Safe Surgery Saves Lives' checklist. Recommendations include the need for further research and continuous updating of guidelines; comprehensive surveillance, using validated definitions that facilitate benchmarking of anonymised surgeon-specific SSI rates; assurance that incorporation of checklists and care bundles has taken place; the development of effective communication strategies for all health care providers and those who commission services and comprehensive information for patients.

Background: health care-associated infection and surgical site infection

The overall prevalence of health care-associated infection (HCAI) in England is 6.4% (confidence interval, 4.7–8.7%), with surgical site infections (SSIs) the third most commonly recorded infection (15.7%) (1). This is an underestimate, as these prevalence data do not include patients who develop an SSI outside secondary care. A national SSI surveillance service, administered by Public Health England (formerly Health Protection Agency), was established to enable hospitals to compare SSI rates against a national benchmark and improve the quality of patient care (2). Participating hospitals undertake surveillance in one or all of 17 categories of surgical procedures. In 2004, the Department of Health in England mandated that acute NHS hospital trusts, which undertake the

elective prosthetic orthopaedic surgery, should undertake a minimum of 3 months of surveillance each year in at least one specified category (3). Similar data have been collected internationally (4–6), but all these schemes underestimate the incidence of SSI that depends on surgical specialty, consistent use and interpretation of accepted and validated definitions,

Key Messages

- surgical site infection rates do not seem to be falling
- national and international guidelines and care bundles exist which are based on level I evidence-based medicine
- compliance to care bundles has to be audited and acted on

effectiveness of case finding and other intrinsic and extrinsic risk factors. Although most national SSI surveillance systems are similar, minor methodological differences that exist need to be considered when comparing variance in international SSI rates. These may relate to disparities in diagnostics, patient mix, intervention methods, the category of health care workers conducting the surveillance, length of stay (pre- and postoperatively) and selection (or self-selection) of participating hospitals. This also includes organisational aspects such as the effect of mandatory participation in surveillance schemes with public disclosure of infection rates.

Surveillance methodology has a considerable impact on SSI rates (7–12). Comprehensive post-discharge surveillance has reported that SSIs complicate 10–20% of procedures; failure to undertake it results in underestimation (13–15). Although interpretation of data derived from different surveillance schemes needs to be cautious, it is likely that SSI rates could be reduced though widespread and consistent implementation of evidence-based interventions that incorporate level I evidence.

In the USA, 'working towards zero' has been promoted by the Association for Professionals in Infection Control and Epidemiology (APIC) to improve outcomes (16). However, even if risk factors could be reduced and best evidence-based interventions reliably implemented, continuing development of surgical innovations exposes patients to additional risk, making 'zero' SSIs an unattainable goal. A zero tolerance to a lack of implementation of the best available evidence is more possible. Another relevant factor is the impact of future demographics. For example, the American Academy of Orthopedic Surgery has projected that 30 million joint procedures will be needed in the USA over the next 20 years (17). Even if existing morbidities could be eliminated, new diagnostic and surgical techniques may emerge, which result in new risk factors for the development of SSI.

Therefore, there is a continued requirement for the development of level I evidence-based interventions in guidelines and care bundles, which reduce SSIs. An example is the evidence that might justify screening and suppression of methicillin-sensitive *Staphylococcus aureus* (MSSA). A study published in the *New England Journal of Medicine* (18) made a salient case, but there were limitations in methodology, with only a small proportion of patients being randomised, and possibility of bias. The significance of the intervention was unclear, as universal MSSA screening and suppression were also part of a bundle of other unspecified measures (19); further studies are required before universal implementation could be considered. Nevertheless, further development of evidence-based, care bundles to reduce SSIs is appropriate.

National Institute for Health and Clinical Excellence (NICE) and Evidence Update Advisory Group (EUAG) guidelines for SSI prevention and treatment

Level I evidence and high impact intervention for SSI

Despite extensive experimental and level I clinical evidence from randomised clinical trials (20) and development of UK

guidance (21,22), the prevalence of SSI, and its accompanying morbidity, mortality and health care expenditure, is not falling. In the USA, the Surgical Infection Prevention (SIP) project and SCIP (23–25) have met with similar issues. After 10 years, little change in SSI rates has occurred, despite an alleged 95–100% compliance with four core process measures (26–28). Although the reason for this is not clear, significant and sustained potential reduction in SSIs can only be achieved with consistent compliance. Furthermore, institutional compliance has little predictable benefit in improving patient outcomes as opposed to a rigorous adherence to risk-adjusted outcome initiatives such as the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) (29,30).

The NICE guideline identified that hair removal, antibiotic prophylaxis, maintenance of normothermia and perioperative skin preparation were among the key areas for implementation of evidence-based interventions (21). Several other recommendations were made with key priorities for future inclusion. The Department of Health's high impact intervention (DH HII) (22) for SSI included 11 of these factors into a bundle which encompassed all three phases of surgery. Skin preparation with 2% alcoholic chlorhexidine has been widely adopted following the publication of one fairly compelling randomized controlled trial (RCT). However, this study has limitations relating to the pragmatic choice of comparing aqueous povidone-iodine and alcoholic-based chlorhexidine skin preoperative preparations (31). Prophylactic antibiotics (in most cases single dose), hair removal method and timing (where appropriate), avoidance of hypothermia (32), use of antiseptic-impregnated incise drapes and glucose control in patients with diabetes are accepted strategies with little controversy. Other recommended elements of this care bundle include nasal screening and suppression of methicillin-resistant *S. aureus* (MRSA), use of perioperative supplemental oxygen and interactive postoperative dressings. The lack of a level I, evidence base means that some care bundles are based on ritual and intuitive factors. Examples of these latter factors are to be found in orthopaedic (33,34), colorectal (35), gastrointestinal and hernia (36), mixed (37) and cardiothoracic surgery (38). However, not all care bundles are found to be effective even though elements are similar to those in NICE and the DH HII (39).

WHO Safe Surgery Saves Lives

The WHO surgical safety checklist, with or without minor modifications and revised in 2009, has been introduced into many countries and different surgical specialties (40–55). The checklist, primarily a patient safety intervention, has similar phases as the NICE and HII guidelines in the pre-, intra- and immediate postoperative periods. If the checklist and guidelines were combined, with wide adoption or mandated compliance, this could offer an even more powerful impact on SSI rates.

Several reports have highlighted the practical challenges of introducing the WHO surgical checklist into operating theatres with an associated poor compliance (45–53,56,57). Nevertheless, introduction of the checklist has been widely

accepted, endorsed by the National Patient Safety Agency, and introduced to all NHS hospital trusts in England (58). This has not always been smooth and attitudes are in need of change, particularly involving teamwork and collaboration between all operating theatre staff at the WHO style briefings, which require acceptance and leadership (59,60). All members of the team should be aware that increased compliance may also have a benefit in reducing surgical malpractice suits (58,61).

Compliance with NICE guidelines and HII for SSI: why are not rates falling?

Compliance appears to be an issue with the use of both checklists and bundle implementation and may be the cause of some of the disappointing US results, despite being in place for several years (23–28,62). Nevertheless, implementation of protocols can work in reducing SSI rates with the improvement of compliance using electronic prompts (63–65). The operating team are also responsible for ensuring that out of date, non-evidence-based practices are recognised and that using bundles with the best available evidence are implemented. Validated protocols can work and are effective in reducing the risk of SSIs, if reliably and measurably implemented (66–68). However, gaining acceptance and adoption requires considerable individual, cultural and institutional change with institutional support systems and governance (69–73). Surgeons are often identified as being key factors in non-compliance; some being unable to change personal and professional behaviour to comply with checklists. The inflational use of checklists in hospitals may result in ‘guideline blindness’, but evidence that they are being used effectively and beneficially may be shared with the operating team by highlighting the ‘near miss’ events prevented by their use. Although there are tools to evaluate this, compliance is still variable (20–60%) in UK and US studies (41–44).

Recommendations for future consideration

1. New commissioned research is needed to measure compliance levels with bundles, instead of focusing on individual component implementation, and relate compliance with improved outcomes (74). Qualitative research into reasons for non-adoption or acceptance of bundles is also required, so that effective implementation strategies for new interventions can be planned. Introduction of new checklists might incur some resistance. Observational studies of compliance, particularly of the operating surgeon, might become part of the revalidation process.
2. The incorporation of checklists and care bundles into the informed consent process could be considered, demonstrating the transparency of the process.
3. Robust, validated surveillance methods, with agreed SSI definitions that can be reliably interpreted into clinical practice, need development. Although the CDC definition is the most widely used, it does not recognise the severity of an SSI; some sort of risk stratification is needed (75). Surveillance also needs to be

precisely defined with trained, blinded, unbiased and independent observers. Without robust validation of a national scheme, it is impossible to benchmark SSI rates between institutions and compare standards of quality (76). Benchmarking of anonymised individual surgeon’s SSI rates may improve individual performance.

4. Continued updating of comprehensive, evidence-based, NICE guidelines is needed. The elements which have the strongest evidence base need emphasis and to be added to recommendations. Expert consensus on what level of evidence would be acceptable when studies are not of level I quality may be required.
5. Recognition and encouragement of operating theatre discipline/team work is needed and mandated through clinical governance. This will likely require a significant behavioural change, particularly by surgical team leaders.
6. Keeping a log of ‘near misses’, which could have been prevented or were intercepted through the use of a checklist or bundle, may be of benefit in demonstrating their worth at surgical governance meetings. Elements of care bundles with a level I evidence base must not be ticked off without the proof of implementation.
7. Planning implementation of new effective communication strategies and the provision of advice to health care provider organisations, clinicians and patients require a strategy which identifies the rationale of each element. Patients should be informed about the measures that will be taken to keep them safe before, during and after surgery and reduce their risk of SSI. Patient information needs to be clearly drafted, particularly if it is incorporated into consent forms, and may empower patients to ask questions and thereby increase compliance.

Conclusions

Reduction of the risk of SSIs and improvement of outcomes are not initially cost neutral, and resources are needed to implement and develop evidence-based guidelines. A further investment may be needed for the acquisition and maintenance of an infection prevention and control team who can facilitate surveillance, analysis and dissemination of data relating to SSI and compliance with effective clinical practice.

The US experience acts as a sentinel guide for health care professionals involved in improving surgical outcomes. When SCIP was implemented in 2006, a 25% reduction in surgical morbidity and mortality was projected by the year 2010 using a bundle similar to that advocated by NICE and the DH HII (21,22). SCIP was supported by the Federal Government’s Center for Medicare and Medicaid Services as a ‘process-initiative’, requiring high compliance (>95%) by health care institutions. The failure of SCIP to improve patient outcome, because of the increasing complexity of surgery and current level of patients’ comorbidity, has been documented in several publications (29,62,77). The failure is not a deficiency of the ‘care-bundle’ concept; simply measuring compliance does not override the need for direct measurement of surgical outcomes, especially in an environment where evidence-based medicine is continuously changing. Every patient should

receive the best, evidence-based interventions, on every occasion at the right time, and hospital trusts should demonstrate that this has been done.

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