CIPHUR
Service
Evaluation

Title

Chlorhexidine Gluconate versus Povidone-Iodine Skin Antisepsis Prior to Upper Limb Surgery (CIPHUR): A Prospective National Service Evaluation

Introduction

In 2016, the NHS commissioned 196,016 operations for hand conditions, of which 58% were elective[1]. Surgical site infection (SSI) is the most common and costly postoperative complication[2,3]. Given that 1-35% of hand surgery patients develop SSI[4–10] and the impending crisis surrounding antimicrobial resistance[11], there is a need to reduce SSI following hand surgery.

The World Health Organisation (WHO)[12], United States of America Centre for Disease Control (CDC)[13] and United Kingdom National Institute for Health and Care Excellence (NICE)[14] recommend alcoholic chlorhexidine gluconate (CHG) for preoperative skin preparation to reduce the risk of SSI. Our recent network meta-analysis addressed a void in the literature concerning antiseptics in clean surgery (i.e. the majority of hand surgery) and showed that alcoholic CHG 4-5% halves the risk of infection compared to any formulation of povidone-iodine (PVI). However, there were no studies on upper limb procedures and there is still substantial variation in the type (alcoholic or aqueous, povidone-iodine or chlorhexidine gluconate) and the concentration preoperative antiseptic preparatory solutions used by hand surgeons[15–17].

To evaluate current upper limb surgery services and SSI rates in the UK, a prospective audit is required.

Methods

Prospective service evaluation conducted under audit framework, comparing local practice (antiseptic use) to the standards outlined by the NICE[14].

Setting

Any secondary care hospital within the United Kingdom which offers upper limb surgery in an operating theatre.

Participants

Any adult or child undergoing surgery (elective or emergency) distal to the shoulder joint.

Inclusion criteria

Consecutive adults or children identified prior to any form of surgery distal to the shoulder joint.

Exclusion criteria

Any active infection at the time of upper limb surgery, anywhere in the body. Active infection is defined pragmatically by a suspicion of the treating medical team or the provision of any medical or surgical treatment for suspected or confirmed infection.

Recruitment Caveats

Other than the inclusion/exclusion criteria defined above, no other selection criteria should be applied. This ensures that all eligible patients are audited without bias. Importantly, please do not 'match' patients or 'balance' the patients you audit in any way (e.g. by including a child for every adult), do not include alternate cases, do not deliberately include a single surgeon's workload, etc. This service evaluation is designed to capture the full breadth of activity within the NHS in an unbiased fashion. Therefore, all eligible individuals should be included where possible.

Outcomes

The primary outcome was surgical site infection (SSI), defined pragmatically as either suspected or confirmed infection which required any form of medical and/or surgical treatment, within 3 months of surgery.

Variables

See the data dictionary (available in the downloads section at http://reconstructivesurgerytrials.net/clinical-trials/ciphur/) for details of the variables which must be recorded prospectively.

Analysis plan

We plan to use mixed effects logistics regression (multilevel and multivariable) to estimate the risk of surgical site infection for each antiseptic. The random-effects will vary by hospital (cluster) if there are substantial differences between a single level and multilevel model. The fixed effects will include: age as a continuous covariable; diabetes, smoking, peripheral vascular disease, immunosuppression, the WHO wound status (clean, contaminated or dirty), preoperative antibiotic provision and the antiseptic used as categorical covariables. A sensitivity analysis will be performed for trauma surgery which will include the time from injury to surgery as a continuous as an additional covariables in the mixed-effects model.

Ethics and Governance

This is a prospective service evaluation which will be conducted to audit practice against the NICE guidance[14]. Local investigators should contact their Research departments to determine whether local (audit) registration is required. National Research and Ethical Approval is not required. Patients do not need to provide written consent for their data to be gathered and used in this study, provided that the usual care pathway is unchanged and collected data is anonymised.

Collaborator Authorship Status

Investigators who submit 20 complete records will be eligible for co-authorship on all publications derived from this study, provided they also participate in the writing or approve the final manuscript(s). These criteria are prescribed by the ICMJE. Investigators providing fewer than 20 complete records or those who chose not to engage in writing/reviewing/approving draft manuscripts will be named in the acknowledgement section.

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