

ANTISEPTIQUES PRÉOPÉRATOIRES POUR LA PEAU AFIN DE PRÉVENIR LES INFECTIONS DU SITE OPÉRATOIRE : QUE FAIRE?

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Conflit d'intérêts : Les auteurs ont déclaré n'avoir aucune affiliation qui pourrait être perçue comme un conflit d'intérêts.

RÉSUMÉ :

Contexte : Une désinfection de la peau des patients effectuée de manière sécuritaire et efficace en phase préopératoire est recommandée afin de prévenir les infections du site opératoire, réduire la morbidité chez les patients et réduire les coûts généraux. Il existe cependant un manque de consensus autour des recommandations de pratiques exemplaires concernant la meilleure solution antiseptique pour la peau et la meilleure méthode d'application.

Méthodes : En 2010 et en 2011, le comité consultatif des technologies de la santé du Surgery Operational Clinical Network (SOCN) des services de santé de l'Alberta a mené une analyse environnementale afin de déterminer les méthodes actuelles de désinfection préopératoire de la peau en Alberta, a révisé les principales publications et les lignes directrices existantes et a demandé une révision systématique de l'Agence canadienne

des médicaments et des technologies de la santé (ACMTS). À l'aide de cette information et d'un protocole établi pour les recommandations fondées sur des données probantes, le comité consultatif des technologies de la santé a fait des recommandations qui ont été révisées et approuvées en 2013 par la direction du SOCN et le groupe de prévention et de contrôle de l'infection des services de santé de l'Alberta.

Résultats : L'analyse environnementale a démontré qu'il existait des variantes dans la pratique en ce qui a trait aux types de solutions antiseptiques et aux méthodes d'application utilisées dans les 18 hôpitaux de l'Alberta ayant été sondés. L'examen systématique a suggéré que les douches antiseptiques préopératoires réduisaient la flore cutanée, mais que leurs effets sur les taux d'infections du site opératoire étaient peu concluants. Même si l'examen n'a pas permis de déterminer des preuves concluantes pour recommander une solution

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SKIN ANTISEPTICS (cont.)

antiseptique optimale ou une méthode d'application, les résultats de deux essais cliniques randomisés d'envergure portent à croire que la chlorhexidine dans de l'alcool à 70 % est plus efficace que la povidone-iode pour la prévention des infections du site opératoire. Ces résultats et les recommandations du programme Des soins de santé plus sécuritaires maintenant! de l'Institut canadien pour la sécurité des patients (ICSP), ont été utilisés pour contribuer aux recommandations des services de santé de l'Alberta. Ces recommandations préconisaient entre autres d'abandonner les douches préopératoires avec des antiseptiques, sauf pour les cas spéciaux (chirurgies à risques élevés, comme les sternotomies et les implants, tel que recommandé par le groupe IPC) et de normaliser les solutions et les méthodes d'application des antiseptiques cutanés pour utiliser la chlorhexidine (CHG) dans de

l'alcool à 70 %. Les interventions impliquant les oreilles, les yeux, la bouche, les membranes muqueuses, les tissus nerveux, les bébés et les nouveaux cas de traumatismes faisaient cependant exceptions où la povidone-iode devrait être utilisée.

Conclusion : En utilisant les meilleures preuves actuellement disponibles, il a été recommandé que les services de santé de l'Alberta normalisent l'antisepsie chirurgicale de la peau pour adopter la CHG à 2 % dans de l'alcool à 70 % comme méthode antiseptique de choix et la povidone-iode, comme solution de rechange lorsque la CHG est contre-indiquée, afin de réduire les infections du site opératoire, les variantes dans la pratique et les coûts de soins de santé. Davantage de recherche est nécessaire pour déterminer la solution antiseptique pour la peau optimale afin de réduire les infections du site opératoire.

KEYWORDS: SURGICAL SITE INFECTION, EVIDENCE-BASED MEDICINE, CHLORHEXIDINE, POVIDONE IODINE, SKIN ANTISEPSIS, PREOPERATIVE SKIN PREPARATION.

PREOPERATIVE SKIN ANTISEPTICS FOR PREVENTING SURGICAL SITE INFECTIONS: WHAT TO DO?

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ABSTRACT:

Background: Safe and effective patient preoperative skin antisepsis is recommended to prevent surgical site infections (SSIs), reduce patient morbidity, and reduce systemic costs. However, there is lack of consensus among best practice recommendations regarding the optimal skin antiseptic solution and method of application.

Methods: In 2010 and 2011 the health technology appraisal committee of the Surgery Operational Clinical Network (SOCN), of Alberta Health Services (AHS), conducted an environmental scan to determine the current preoperative skin antisepsis in Alberta, reviewed key publications and existing guidelines, and requested a systematic review from the Canadian Agency for Drugs and Technologies in Health (CADTH). Using this information, and an established protocol for evidence-informed recommendations, the health

technology appraisal committee made recommendations that were, in 2012, reviewed and endorsed by the SOCN executive and the AHS-Infection Prevention and Control (IPC) group.

Results: The environmental scan revealed practice variation in the types of antiseptic solutions and application methods being used in the 18 Alberta hospitals surveyed. The systematic review suggested that preoperative antiseptic showering reduces skin flora but the effect on SSI rates was inconclusive. While the review found no conclusive evidence to recommend an optimal antiseptic solution or application method, the results of two large randomized controlled trials suggest that chlorhexidine in 70% alcohol is more effective than povidone iodine in the prevention of SSIs. These results and the recommendations from Safer Healthcare Now!, a program of the Canadian Patient Safety Institute (CPSI), were used to inform the

recommendations for AHS. These recommendations included abandoning preoperative showering with antiseptics except for special cases (high-risk surgeries such as sternotomies and implants as recommended by IPC) and standardizing skin antiseptic application methods and solution to chlorhexidine (CHG) in 70% alcohol. The exception would be procedures involving the ear, eye, mouth, mucous membranes, neural tissue, infants and emergent trauma cases where povidone iodine should be used.

Conclusion: Using the best available evidence it was recommended that AHS standardize surgical skin antisepsis to 2% CHG in 70% alcohol as the preferred antiseptic and povidone iodine, as an alternative when CHG is contraindicated, to reduce SSIs, practice variation, and health care costs. Further research is required to determine the optimal skin antiseptic solution to reduce SSIs.

INTRODUCTION:

Patient skin antisepsis plays a significant role in preventing surgical site infections (SSIs) that may increase patient morbidity, mortality, length of hospital stay, need for secondary procedures, and systemic costs.¹ To reduce the risk of SSIs topical antiseptics are applied to the patient's skin before surgery to reduce skin flora at the surgical incision site. A multicenter, randomized controlled trial² reported, in 2010, that 2% chlorhexidine gluconate (CHG) in 70% isopropyl alcohol is superior to povidone iodine (PI) for preventing SSIs. One member of Alberta Health Services (AHS), prompted by this article, posed two questions:

- 1) What methods of surgical site skin preparation are used in Alberta?; and
- 2) Could SSIs be reduced by adopting CHG-alcohol antisepsis?

The objectives of this study were to survey antiseptic skin preparation practices in Alberta, systematically review the literature regarding the clinical effectiveness of preoperative skin antiseptic solutions and application techniques, and develop and report recommendations to Alberta Health Services (AHS).

METHODS:

The study involved gathering information on current practices via an environmental scan, reviewing evidence (literature review, systematic review), reviewing existing consensus guidelines (*Safer Healthcare Now!*), and developing recommendations for AHS.


Environmental Scan

In order to determine the skin antisepsis processes currently in use in Alberta an 18-member working group, with representatives from both urban and rural zones within AHS, was formed. The working group conducted an Alberta-wide environmental scan, in June 2010, using an electronic survey method. The survey included questions on policy and procedures, pre-surgical scrub protocols, and operating room techniques including trauma scrub protocols, surgical skin preparation protocols, and procedural skin preparation. The survey was sent to 18 operating room sites, representing both urban and rural sites, across five zones within the AHS. All of the 18 sites responded to the survey.

Literature Review, Systematic Review, and Consensus Guidelines Review

Members of the Department of Surgery and Surgical Services conducted a literature review focusing on two key articles.^{2,3} A request was made, to the Canadian Agency for Drugs and Technology in Health (CADTH), for a rapid safety review⁴

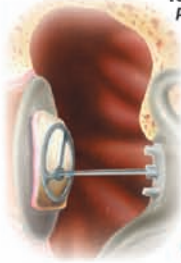
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and a systematic review⁵ of antiseptic effectiveness. The “Critical Appraisal Skills Programme” tool⁶ was used to evaluate the CADTH systematic review. The consensus guidelines for skin antisepsis, from “*Safer Healthcare Now!*”,⁷ were also reviewed and summarized.

Development of Recommendations

The Alberta Health Services health technology appraisal committee of the Surgery Operational Clinical Network⁸ met, after gathering the evidence, to review and make recommendations. The recommendation process was created by adapting the *Local HTA Decision-Support Program*.⁹ This program provides a method by which recommendations can be made in a systematic, consistent, and transparent manner using a defined set of criteria and a deliberative process. The major steps were as follows:

- **Criteria Review.** The criteria used for recommendations were from the *Local HTA Decision Support Program*.⁹ These criteria are grouped into five domains: health gain, service delivery, strategic fit, innovation, and financial;
- **Technology Evaluation.** Technologies were evaluated on a matrix using the “Technology Evaluation Worksheet” of the *Local HTA Decision Support Program*.⁹ Information provided for each of the criteria was discussed using a deliberative process;
- **Recommendations.** Recommendations were made using the “Recommendation and Decision Guide” of the *Local HTA Decision Support Program*;⁹ and
- **Feedback.** The surgical community at large provided comments and feedback on the first draft of the recommendations. The recommendations were then reviewed and endorsed by the Surgery Operational Clinical Network’s Executive Committee. The recommendations, once approved, were sent to the AHS Infection Prevention and Control group for additional review. Comments were incorporated into the final

recommendations to be used in the development of a standardized protocol.

RESULTS:

Environmental Scan:

A summary of the environmental scan is given below. The total percentage values of responses can exceed 100% as respondents were asked to select all answers that applied.

Policy and procedures

Of the 18 participating facilities 55% said that they had a general skin preparation policy versus a procedure-specific policy. Respondents all said that they adhered to *ORNAC Standards for Perioperative Nursing Practice* with some facilities referencing additional guidelines of the Association of periOperative Registered Nurses (AORN) and *Berry & Kohn's*.

Pre-surgical scrub

Approximately 78% of respondents said that patients are instructed to perform a pre-surgical scrub or shower prior to the surgical day. There was, however, variation in the products used and the instructions given to the patient. Screening for antibiotic-resistant organisms was done by 75% of respondents.

Operating Room Technique

a) *Trauma scrub.* Trauma scrub was performed by 83% of respondents and primarily by the surgeon (88%). All respondents reported using some type of personal protective equipment (100%). Antiseptic solutions used include a proprietary 7.5% povidone iodine (PI) scrub (80%), 0.9% saline (53%), CHG scrub (40%), 10% PI (13%), and 7.5% PI (7%). Two percent CHG-alcohol was not used by any of the respondents (0%). Saline with antibiotics was also mentioned in the “comments” field of the survey.

b) *Surgical skin preparation.* Skin antisepsis preparation was primarily

performed by the circulating nurse (100%) as well as by the surgeon when sterile (12.5%) or unsterile (31.3%). Hand hygiene prior to the skin prep was variable with soap (56%), antiseptic (44%) and surgical hand scrub (12%) being used in addition to sterile gloves. The surgical preparation technique varied from touch (56%) to no-touch (12%) using an aseptic technique (sterile gloves/sterile field, 100%) to a clean technique (clean gloves, 19%). The responses indicated practice variation in the method of application, number of applications, and drying time of the antiseptic product. Respondents avoided pooling of skin prep solutions by wringing out sponges, using blue pads, removing soiled linens, and visual inspection. Alcohol-based skin prep products were avoided, or adequate drying time was allowed, when using electro-cautery. Various sterile drapes were being used across Alberta from clear adherent to PI-impregnated drapes.

Products used for surgical skin preparation varied from multi-use bottles to single-use products. Skin preparations were performed using commercial skin preparation trays, on-site prepared trays, and single-use products that did not require a preparation tray. Various products were used including 10% PI paint (69%), 2% CHG-alcohol (56%), 7.5% PI scrub (31%), CHG scrub (25%), 2% CHG-aqueous (19%), 7.5% PI scrub (19%), 7.0% PI-alcohol (19%), and 4% CHG aqueous (12%). Other products identified in the comments include 0.05% CHG and 3% chloroxynol. Respondents indicated 50% had a policy addressing multi-use preparation solution storage and usage with variations in the length of time the product would be allowed to remain open.

c) *Procedural skin preparation.* Procedures that required skin preparation included central lines, arterial lines, epidural, spinal or pin insertions. Procedural skin preparations were performed by anaesthetists (94%), surgeons (38%),



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SKIN ANTISEPTICS (cont.)

and nurses (19%). Technicians were also mentioned in the "comments" field of the survey. Personal protective equipment was used (100%). Hand hygiene was performed by various methods including hand washing with soap (50%), hand washing with antiseptic soap (56%) and use of a surgical hand scrub (31%). Procedural skin antiseptic solutions included 10% PI (56%), 2% CHG-alcohol (44%), 7.5% PI (12%), a proprietary 7.5% PI scrub (12%), 2% CHG-aqueous (6%), and CHG scrub (6%); alcohol swabs were also mentioned in the "comments" field of the survey. Across the province there was a variation in preparation trays purchased with the majority being disposable trays for epidural trays (87%), spinal trays (87%), and central line trays (73%). A small percentage reported the use of non-disposable trays prepared on-site for epidural and spinal anesthetics, and central line insertion.

Literature Review:

The Darouiche RCT report,² that had initially prompted this investigation, showed that preoperative cleansing of a patient's skin with 2% CHG - 70% alcohol is superior, for preventing SSIs during clean-contaminated surgery, to cleansing with PI². As reported in a critical appraisal¹⁰ the study had several strengths including adequate sample size, appropriate randomization, blinding of subjects and evaluators, and use of multiple medical centres and procedures. Another, lesser quality, randomized controlled trial (RCT) study, by Paochaoroen et al.,¹¹ also suggested that 4% CHG is more effective than PI at preventing SSIs. The strength of the antiseptic solution (2% CHG² and 4% CHG)¹¹ and the combination with alcohol (2% CHG with 70% alcohol² versus 4% CHG with 0% alcohol)¹¹ differed in the RCTs making it difficult

to determine the most effective skin antiseptic solution for preventing SSIs, i.e., CHG, alcohol, or a combination of the two.¹⁰

A study by Swenson et al.³ compared three different skin preparation solutions as shown in Table 1.¹² While the sequential implementation method used is inferior to the RCT method employed by Darouiche, the Swenson study raises the possibility that iodophor-based compounds may be superior to CHG in preventing SSIs when combined with alcohol. Therefore, it is possible that many of the other commercially available antiseptic solutions may result reduced SSI rates if they were mixed with a 70% alcohol.

Systematic Review:

The systematic review,⁵ that had been requested from Canadian Agency for

Table 1: Clean-Contaminated SSI Rates^{1,2}

A comparison of data from Swenson et al.³ and Darouiche et al.²

Study	7.5% PI, 70% isopropyl alcohol, 10% PI ^a	Iodine povacrylex in 70% isopropyl alcohol ^b	2% CHG in 70% isopropyl alcohol ^c	10% PI ^d
Swenson 3	44/541 (8.1%)	27/414 (6.5%)	46/454 (10.1%)	---
Darouiche 2	---	---	39/409 (9.5%)	71/440 (16.1%)

Data are number of SSI/number of surgical procedures classified as clean-contaminated (%).

^a Sequential application of 7.5% PI (Betadine soap), 70% isopropyl alcohol, 10% PI (Betadine paint);

^b DuraPrep, 3M;

^c ChlorPrep, Cardinal Health;

^d Scrub Care Skin Prep Tray, Cardinal Health

Drugs and Technologies in Health (CADTH), included 12 RCTs and 8 observational studies. The critical appraisal¹⁰ of the systematic review determined that the reviewers asked clearly-focused questions, included the right type of studies, tried to identify all relevant studies, and assessed the quality of the studies. The results were tabulated and summarized narratively. No meta-analysis was undertaken given heterogeneity of the studies. The review lacked any Canadian or local data reflecting current SSI rates or any economic data. This, however, is not a criticism as it was beyond the scope of the review and was not requested.

Preoperative showering using antiseptics:

The results of the systematic review indicated that, while preoperative antiseptic showering reduces skin flora, the effect of antiseptic showering on SSIs rates is inconclusive. Showering regimens and compliance varied in the studies that were reviewed. Further evidence is needed to determine the optimal solution, strength, number, and timing of showers as well as the cost-effectiveness of antiseptic showers compared to normal hygiene.

Antiseptic application technique:

The review found that the method of antiseptic solution application, scrub versus paint, is inconsequential. Two RCTs suggested that applying PI, just prior to making an incision, is as effective as soap or saline for preventing SSIs. In three RCTs, no significant difference in SSI rates were found based on application techniques, i.e. scrub versus paint, but a large retrospective cohort study suggested that scrub and paint combined prevents more composite wound infections than paint alone.

Antiseptic solution:

The review found that, given the heterogeneity of the studies, conclusions about which antiseptic solution is most effective at reducing SSIs could not be drawn. Disinfectant products are often mixed with an alcohol or aqueous base which makes it difficult to form conclusions about the relative contribution of component ingredients to skin antiseptics.⁵

Given the results of the review, further evidence is needed to determine which antiseptic solution and application

method are most effective for reducing SSIs.

Safer Healthcare Now! Guidelines

Safer Healthcare Now! is a program of the Canadian Patient Safety Institute (CPSI) designed to help healthcare organizations improve safety through the use of quality improvement methods and the integration of evidence in practice. Safer Healthcare Now! conducted a broad narrative review,⁷ of the evidence for preventing SSIs, based primarily on prevention guidelines. It was published by numerous health organizations including National Institute for Health and Care Excellence, U.K. (NICE), Society for Healthcare Epidemiology of America, U.S.A. (SHEA), Centers for Disease Control and Prevention, U.S.A. (CDC), and World Health Organization, United Nations (WHO).

Safer Healthcare Now! developed a bundle of recommendations.⁷ Alcohol-based CHG antiseptic solutions were recommended over PI as antiseptic prophylaxis except for procedures involving the ear, eye, mouth, or neural

tissue.⁷ This recommendation of CHG was, however, not based on a systematic review of the literature.

Surgery Operational Clinical Network Recommendations:

Following the process outlined in the Methods, the Alberta Health Services (AHS) Surgery Operational Clinical Network health technology appraisal committee made the following recommendations:

Preoperative showering using antiseptics: There is no conclusive evidence to suggest that antiseptic showering reduces SSIs any more than showering with regular soap. The committee recommended that, with some exceptions, antiseptic showering should, where used in Alberta, be discontinued, thus realizing a cost savings. The AHS-Infection Prevention and Control group recommended preoperative showering with CHG for high risk surgeries, including sternotomies and implants, as it reduces bacteria and may lower SSI rates.^{5,13} Preoperative CHG showering may also be considered for specific procedures where local SSI rates are high.

Antiseptic application technique: There is no conclusive evidence to suggest that any particular method, by which antiseptics are applied, prevents more SSIs than any other. The committee recommended that the application technique be standardized to promote consistency in practice and to prevent errors. Standardization will be developed in collaboration with the nursing leads and the AHS-Infection Prevention and Control group in order to identify application techniques suitable for standardization and comparative costing. Single use skin markers are recommended to prevent the disappearance of skin marks during the application of antiseptic.

Antiseptic solution: The studies reviewed reported on a variety of disinfectants at various concentrations and often they were mixed with an alcohol or aqueous base that may

influence their effectiveness. There is no conclusive evidence, currently, to recommend any single skin antiseptic solution as the most effective in preventing SSIs. Further studies are needed to provide unequivocal evidence regarding the optimal antiseptic solution for preventing SSIs. CHG-alcohol was, however, more effective than PI for reducing SSIs according to the two large RCTs^{2,11} and of these two the study conducted in North America² was of very high quality. The committee, therefore, recommended that CHG in 70% alcohol be used as the reference standard solution to reduce SSIs. This would bring uniformity to practice within the province. A pink-coloured solution was preferred with an option for clear when ongoing surveillance of limb perfusion is required.

Special cases: The committee recommended that PI be used to prepare the skin of emergent trauma patients when there is insufficient time for CHG-alcohol solution to dry completely prior to making an incision. PI was also recommended for treating mucous membranes, which should not be exposed to alcohol, and for procedures involving the ear, eye, mouth, or neural tissue. The AHS-Infection Prevention and Control group also recommended that CHG-alcohol be contraindicated, and PI used, for patients with sensitivities or allergies to CHG and for infants less than two months old.

Safety and training: Safety issues when using alcohol-based solutions are rare, but can include operating room fires. To better address safety issues, regarding the use of CHG-alcohol solution, the committee recommended the adoption of the Safer Healthcare Now training recommendations.⁷

Care pathways: The committee recommended that their Skin Preparation Report, along with the Safer Healthcare Now recommendations (on appropriate use of prophylactic antibiotics, appropriate hair removal, maintenance of perioperative glucose control, and

perioperative normothermia) be used to create a Care Pathway for the prevention of SSIs in Alberta. This would apply to surgical services as well as central line insertion in diagnostic imaging, critical care and the catheter lab, and to minor surgery. Based on the above recommendations, the nursing leads have created standardized protocols that are currently under review by AHS. Once approved, these protocols will be distributed province-wide.

Implementation: The final report was distributed to all Surgery Chiefs and AHS leaders across the province (March 2013) for operational implementation. A feedback survey was sent to physicians and nursing staff asking if there were any disadvantages to using specific skin preparations in their practice. A provincial working group, comprising members of the Surgery Operational Clinical Network, AHS-Infection Prevention and Control staff and physicians, and AHS-Quality and Healthcare Improvement, has been formed to facilitate implementation. A standard provincial protocol and implementation strategy are being developed to minimize practice variation and reduce SSIs. Implementation of these recommendations will be monitored by surveying SSI rates in the province in conjunction with AHS-Infection Prevention and Control. The environmental scan could, alternatively, be repeated as a surrogate endpoint to detect a change in clinical practice and to ascertain costs/quantities of solutions used post-implementation.

DISCUSSION

This project was initially prompted by a question brought forward by one member of AHS: given the published article by Darouiche et al.,² demonstrating that CHG-alcohol is more effective than PI for preventing SSIs, should AHS adopt CHG-alcohol? Existing practices, within Alberta, were surveyed and a critical appraisal of current literature was carried out. There was a request for a systematic review⁵

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and a review of consensus practice guidelines⁷ was conducted. The Surgery Operational Clinical Network health technology appraisal committee then used this evidence to make recommendations based on established criteria and processes.⁹

Although there is currently no conclusive evidence regarding the optimal skin antiseptic solution for the prevention of SSIs the committee recommended that, where possible, AHS implement a standardized practice of using CHG-alcohol with a standardized application procedure. This recommendation is based on the benefit of using CHG-alcohol, compared with PI, in reducing SSIs and of abandoning less effective solutions that are currently in use in Alberta. It is also in alignment with the *Safer Healthcare Now!* Recommendations.⁷

When a skin antiseptic solution is standardized there are potential financial benefits that can result from bulk purchasing. A decision to use a multi- or single-use product has yet to be made by the AHS. Multi-use products increase the risk of contamination and waste due to individuals decanting more product than needed or the need to discard product due to contamination or expiry. Single-use products may have a higher unit cost and environmental impact. This area needs further evaluation.

The objective of developing a standardized application technique is to simplify training protocols, reduce errors, and reduce SSIs.^{14, 15} A provincial working group has been formed, in order to help meet this objective, comprising members of the Surgery Operational Clinical Network, AHS-Infection Prevention and Control, and AHS-Quality and Healthcare Improvement. The recommendation and standardization protocols may also be extended to percutaneous invasive procedures including insertion of central line catheters and vascular access devices used in diagnostic imaging procedures.

Although this report recommends using CHG 70% alcohol antiseptic, further

studies are needed to evaluate whether PI, or iodine povacrylex, in combination with isopropyl alcohol may be superior. A Clinical Trial working group has been initiated to investigate whether such a study could be designed and recognizing that the role of manufacturer sponsorship will need to be closely monitored to ensure non-biased outcomes. Similar trials are ongoing elsewhere but only for restricted applications such as colorectal surgery (e.g. Clinical Trial number NCT01233050).

This report demonstrates how a question from a single individual prompted a province-wide investigation resulting in an evidence-based decision to standardize practice variation and reduce SSIs in Alberta.

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