

University of Birmingham Research at Birmingham

Routine sterile glove and instrument change at the time of abdominal wound closure to prevent surgical site infection (ChEETAh)

NIHR Global Health Research Unit on Global Surgery

DOI:

10.1016/S2214-109X(23)00538-7

License:

Creative Commons: Attribution (CC BY)

Document Version

Publisher's PDF, also known as Version of record

Citation for published version (Harvard):

NIHR Global Health Research Unit on Global Surgery 2024, 'Routine sterile glove and instrument change at the time of abdominal wound closure to prevent surgical site infection (ChEETAh): A model-based cost-effectiveness analysis of a pragmatic, cluster-randomised trial in seven low-income and middle-income countries', *Lancet Global Health*, vol. 12, no. 2, pp. e235-e242. https://doi.org/10.1016/S2214-109X(23)00538-7

Link to publication on Research at Birmingham portal

General rights

Unless a licence is specified above, all rights (including copyright and moral rights) in this document are retained by the authors and/or the copyright holders. The express permission of the copyright holder must be obtained for any use of this material other than for purposes permitted by law.

- •Users may freely distribute the URL that is used to identify this publication.
- •Users may download and/or print one copy of the publication from the University of Birmingham research portal for the purpose of private study or non-commercial research.
- •User may use extracts from the document in line with the concept of 'fair dealing' under the Copyright, Designs and Patents Act 1988 (?)
- •Users may not further distribute the material nor use it for the purposes of commercial gain.

Where a licence is displayed above, please note the terms and conditions of the licence govern your use of this document.

When citing, please reference the published version.

Take down policy

While the University of Birmingham exercises care and attention in making items available there are rare occasions when an item has been uploaded in error or has been deemed to be commercially or otherwise sensitive.

If you believe that this is the case for this document, please contact UBIRA@lists.bham.ac.uk providing details and we will remove access to the work immediately and investigate.

Download date: 30. Apr. 2024

Routine sterile glove and instrument change at the time of abdominal wound closure to prevent surgical site infection (ChEETAh): a model-based cost-effectiveness analysis of a pragmatic, cluster-randomised trial in seven low-income and middle-income countries



NIHR Global Health Research Unit on Global Surgery*

Summary

Background Surgical site infection (SSI) is a major burden on patients and health systems. This study assessed the cost-effectiveness of routine change of sterile gloves and instruments before abdominal wall closure to prevent SSI.

Methods A decision-analytic model was built to estimate average costs and outcomes of changing gloves and instruments before abdominal wall closure compared with current practice. Clinical data were obtained from the ChEETAh trial, a multicentre, cluster-randomised trial in seven low-income and middle-income countries (LMICs), and costs were obtained from a study (KIWI) that assessed costs associated with SSIs in LMICs. Outcomes were measured as the percentage of surgeries resulting in SSIs. Costs were measured from a health-care provider perspective and were reported in 2021 US\$. The economic analysis used a partially split single-country costing approach, with pooled outcomes data from all seven countries in the ChEETAh trial, and data for resource use and unit costs from India (KIWI); secondary analyses used resource use and costs from Mexico and Ghana (KIWI).

Findings In the base case, the average cost of the intervention was \$259.92 compared with \$261.10 for current practice (cost difference -\$1.18, 95% CI -4.08 to 1.33). In the intervention group, an estimated 17.6% of patients had an SSI compared with 19.7% of patients in the current practice group (absolute risk reduction 2.10%, 95% CI 2.07-2.84). At all cost-effectiveness thresholds assumed (\$0 to \$14000), the intervention had a higher likelihood of being cost-effective compared with current practice, indicating that the intervention was cost-effective. Similar results were obtained when the analysis using data from India was repeated using resource use and unit cost data from Mexico and Ghana.

Interpretation Routine sterile glove and instrument change before abdominal wall closure is effective and the costs are similar to those for current practice. Routine change of gloves and instruments before abdominal wall closure should be rolled out in LMICs.

Funding National Institute for Health and Care Research (NIHR) Clinician Scientist Award, NIHR Global Health Research Unit Grant, and Mölnlycke Healthcare.

Copyright © 2024 The Author(s). Published by Elsevier Ltd. This is an Open Access article under the CC BY 4.0 license.

Introduction

Surgical site infection (SSI) remains one of the most common postoperative complications in patients undergoing major abdominal surgery. SSI is more common in low-income and middle-income countries (LMICs), with an incidence of 23% in LMICs compared with 9% in high-income countries. Wound contamination is a key predictor of SSI: rates of SSI are higher in patients who have contaminated or dirty surgery than in patients who have clean-contaminated surgery (for definitions see appendix p 9). SSI affects patients, families, health systems, and communities, because it is associated with longer length of hospital

stay, poorer quality of life, and high health-care and productivity costs.⁵ Because SSI is associated with a high cost burden, SSI prevention is particularly important in LMICs where incidence rates are high.^{2,6}

Recommendations on SSI prevention include several measures, which are based on evidence of differing quality, and there is a lack of evidence on the cost-effectiveness of interventions, especially in LMICs.⁷⁻¹⁰ The ChEETAh trial assessed the effectiveness of routine sterile glove and instrument change at the time of abdominal wound closure to prevent SSIs.¹ These interventions were prioritised by front-line clinical staff who considered the evidence base and their clinical

Lancet Glob Health 2024:

*The writing committee is listed at the end of the Article and a complete list of collaborators is provided in the appendix (pp 2–8)

Correspondence to: Mr Mwayi Kachapila, Health Economics Unit, Institute of Applied Health Research, University of Birmingham, Edgbaston, Birmingham B15 2TT, UK

m.kachapila@bham.ac.uk See Online for appendix

Research in context

Evidence before this study

Surgical site infection (SSI) is a worldwide problem that is associated with excessive costs and is more common in lowincome and middle-income countries (LMICs), where the cost of SSI to the health-care system ranges from US\$174 to almost \$30 000. We searched PubMed, Embase, and the International Health Technology Assessment database for economic evaluations of glove and instrument change published in any language before Sept 1, 2022, with the terms "glove", "instrument", "cost-effectiveness", and "economic evaluation". The search identified only one study that assessed the cost of a preoperative bundle including glove and instrument change before abdominal wall closure in 173 patients in Australia. The investigators concluded that implementation of the intervention was cost-effective because it reduced the proportion of patients with SSIs from 12.9% to 3.4% and reduced costs by \$30 942 (converted to US\$ and inflated to 2021 in the current study) compared with pre-implementation.

Added value of this study

This study assessed the cost-effectiveness of glove and instrument change before wound closure to prevent SSIs in patients undergoing abdominal surgery at 80 hospitals in seven

LMICs using clinical data from a cluster-randomised trial (ChEETAh), which showed that the intervention was effective at reducing SSIs, and cost data from another study assessing cost of SSI in LMICs (KIWI). This economic evaluation found that the intervention was more effective at reducing SSIs and had similar costs to current practice, implying that the intervention was cost-effective. To our knowledge, this study is the first to assess the cost-effectiveness of routine glove and instrument change as a stand-alone intervention for SSI prevention. Furthermore, the study collected data from LMICs, which might have different resource use and costs compared with a high-income setting.

Implications of all the available evidence

We recommend that routine change of sterile gloves and instruments at the time of abdominal wound closure should be adopted in surgical practice in LMICs, because the intervention has been shown to be both effective and cost-effective. Routine change of gloves and instruments before wound closure improved outcomes but did not have a substantial effect on costs; therefore, this intervention will be important for reducing SSIs in LMICs. These findings will support policy makers in LMICs to introduce routine glove and instrument change at national and global level, without a pronounced effect on costs.

equipoise. One study has evaluated the cost-effectiveness of glove and instrument change as an SSI-prevention intervention, but the results of this study might not be applicable to LMICs because the study was done in Australia.¹¹

An economic evaluation can help inform decision makers in LMICs about whether it is worthwhile to allocate more resources to routine changing of gloves and instruments, to prevent SSIs. The aim of this study was to quantify the costs and outcomes of current practice versus routine sterile glove and instrument change at the time of wound closure to prevent SSIs in patients undergoing abdominal surgery in LMICs, to establish whether the ChEETAh trial intervention is cost-effective.

Methods

ChEETAh study design and outcomes

ChEETAh was a multinational, multicentre, pragmatic, cluster-randomised control trial done in seven LMICs (Benin, Ghana, India, Mexico, Nigeria, Rwanda, and South Africa) between June 24, 2020, and March 31, 2022. The trial assessed whether routine change of sterile gloves and instruments (needle holder, forceps, and scissors) before abdominal wall closure significantly reduced SSIs compared with current practice (appendix pp 9–13). Any hospitals (clusters) doing abdominal surgery in participating countries were eligible. Children and adults undergoing emergency or elective surgery for a

clean-contaminated, contaminated, or dirty operation with an abdominal incision of 5 cm or greater were Operations were classified as cleanincluded. contaminated if gastrointestinal or genitourinary tracts were entered, but no spillage occurred; contaminated if there was a minor spillage of gastrointestinal or genitourinary contents; and dirty if there was a gross spillage of gastrointestinal or genitourinary contents, or established peritonitis.1 Clusters were randomly assigned centrally (1:1) using a minimisation approach to the intervention or control groups. Ethical approval for the trial was granted by the University of Birmingham Research Ethics Committee (ERN 19-0719). In addition, national lead investigators sought ethical clearance from national or institutional ethics committees and patients provided written, verbal, or fingerprint consent for followup interviews.1 The primary outcome was SSI within 30 days of the operation. Results for patients with cleancontaminated and contaminated-dirty surgery were presented. The ChEETAh trial is registered with ClinicalTrials.gov, number NCT03980652.

The ChEETAh trial recruited 13 301 patients, of whom 7157 were in the current practice group and 6144 were in the intervention group (appendix p 11). Details of the results of the ChEETAh trial are presented in the appendix (pp 9–13), which shows that the intervention was effective at reducing SSIs (adjusted risk ratio 0.87, 95% CI 0.79–0.95; p=0.0032; intraclass correlation coefficient 0.06).1

Cost data

FALCON was a pragmatic, 2×2 factorial, stratified, multicentre randomised control trial done between Dec 10, 2018, and Sept 7, 2020, that assessed interventions for reducing SSIs in patients undergoing emergency or elective abdominal surgery (appendix pp 13-15).2 The trial randomly assigned (1:1:1:1) patients to either (1) 2% alcoholic chlorhexidine and non-coated suture, (2) 2% alcoholic chlorhexidine and triclosan-coated suture, (3) 10% aqueous povidone-iodine and non-coated suture, or (4) 10% aqueous povidone-iodine and triclosan-coated suture. The trial included 5788 patients and was done in the same countries that took part in the ChEETAh trial and in some hospitals that took part in the ChEETAh trial. Results of the FALCON trial were stratified by wound contamination: clean-contaminated and contaminated-dirty.2

Postoperative costs for this economic analysis were sourced from KIWI, a study within the FALCON trial.¹² KIWI collected data on postoperative resource use and unit costs at 30 days after surgery from 13 hospitals including three hospitals in India (appendix pp 15-18). KIWI compared costs of patients with and without SSI and presented postoperative inpatient costs, postdischarge health-care costs, and societal costs in 2020 international dollars.¹² For the current analysis, the KIWI costs were converted to 2020 Indian rupees and Mexican pesos using purchasing power parity (PPP) conversion factors, and Ghanaian cedis were converted to 2020 US\$ using implied PPP conversion factors.^{13,14} All costs were converted to US\$ using regular exchange rates published by the International Monetary Fund and inflated to 2021 costs using US Bureau of Labor Statistics rates (appendix pp 16-17).15,16 Unit costs from India were applied in the base case because the country had the highest patient representation in both the ChEETAh and KIWI studies.

Data on the cost of gloves were retrospectively collected from hospitals that participated in the KIWI study (appendix p 18). The FALCON trial was organised in terms of a hub hospital in each country (which was responsible for distributing the trial intervention) and various spoke hospitals. A project officer based at the University of Birmingham (Birmingham, UK) sent an email to hub directors and requested them to contact the KIWI hospitals. The hospitals provided the average cost of a box of gloves, number of gloves in a box, and the average number of surgical staff involved during abdominal surgery that would need to change gloves at the time of wound closure if it were adopted as current practice (see appendix p 18). Additional ethical approval for this cost data was not required as patient level data were not collected. The India and Ghana hub directors provided data for all hospitals that participated in the KIWI study. As such, there was no difference between hospitals that responded to the email and those that did not respond in the two countries. In Mexico, data were received from one of the three hospitals that were part of KIWI. Costs were collected in 2020 local currencies, converted to US\$ using regular exchange rates published by the International Monetary Fund and inflated to 2021 US\$ using US Bureau of Labor Statistics inflation rates (appendix p 18).^{15,16} All data included in the analysis have been presented in the manuscript and appendix.

Economic evaluation

A model-based cost-effectiveness analysis was done to estimate the costs and outcomes of abdominal surgery in patients in the intervention and control groups of the ChEETAh trial following the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement.¹⁷ A partially split one-country costing approach was used because it provides the highest statistical power of outcomes and does not distort the relation between resource use and unit costs. This approach pools outcomes data from all countries in a study, incorporates resource use data from one or a few countries in the study, and applies unit cost data from a single country.¹⁸ The current study pooled outcomes data from all seven countries that participated in the ChEETAh trial and applied resource use and unit cost data from India reported in the KIWI trial; secondary analyses used resource use and costs from Mexico and Ghana (KIWI).

A decision-tree depicting patient pathways of the ChEETAh trial was built in TreeAge Pro 2022. A decisiontree was considered an appropriate model for the analysis because of the short timeframe and non-repetitive nature of the events in the model.19 The decision was to change gloves and instruments before abdominal wall closure (see appendix p 9). In both groups, a surgical wound was classified as clean-contaminated or contaminated-dirty and a proportion of patients with both clean-contaminated and contaminated-dirty surgery developed an SSI (figure 1). The model focused on SSI incidence as the primary outcome of the ChEETAh trial and did not consider the effect of SSI on mortality or other harmful effects associated with SSI. Mortality in patients with SSI (7.8%) has previously been reported to be more than twice that in patients with no SSIs (3.5%);²⁰ however, in the ChEETAh trial, mortality was found to be the same in patients in the intervention and control groups (6.4%).1 As such, mortality was not expected to have any implications on the model results. The probabilities of patients passing through the pathways of the model were aggregated for patients recruited in the ChEETAh trial from all seven countries (table 1).

The perspective of an economic study defines the sectors from which costs and outcomes are measured.²¹ The base case analysis was done from a health-care provider perspective and considered only health-care costs for medicines, diagnostics, surgery, and hospital admission. Secondary analyses were done for (1) a patient perspective that included the health-care provider costs and out-of-pocket expenditures incurred by patients for

For **TreeAge software** see https://www.treeage.com

health-care visits, community health-care worker visits, wound dressing, and medication; and (2) a societal perspective that included all costs from health-care and patient perspectives, travel costs, and income loss to the patients and their families caused by inability to work because of the operation.²¹ Assumptions made to construct the model and to facilitate the analysis have been presented in the appendix (p 19).

Study procedures

The outcome measure was SSIs up to 30 days after surgery according to the US Centers for Disease Control and Prevention definition (appendix p 11). SSI rates for both groups were estimated using data obtained from the ChEETAh trial and are presented as percentages of patients with an SSI in each group (appendix p 12). Paper-based case report forms were completed, signed, and dated, and data were transferred from case report form booklets into the REDCap online database hosted by the University of Birmingham. All paper and electronic case report forms were checked for

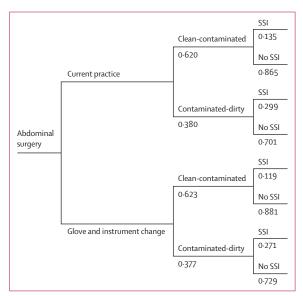


Figure 1: Decision-analytic model showing the pathways of patients recruited in the ChEETAh trial

Model shows the probabilities of each event in patients passing through the pathways of the model. SSI=surgical site infection.

completeness, consistency, and compliance with the study protocol. Discrepancies or missing data were reported to the research team at the hospital via the ChEETAh REDCap database. The ChEETAh trial had one hub hospital, and several spoke hospitals in each country. The central ChEETAh trial office at the University of Birmingham liaised directly with each hub to resolve any inconsistencies in data, which were identified centrally by manual searching. Additionally, a statistician reported any data inconsistencies identified during each data monitoring committee report and after the database had been locked.

Data analyses

The analysis used an adjusted multilevel logistic regression model to account for key confounding variables and bias that could have been introduced by the clustered nature of the trial. This model adjusted for type of hospital (rural vs district), operative approach (midline vs non-midline), country, wound contamination (clean-contaminated vs contaminated-dirty), and surgical urgency (elective vs emergency) as fixed effects. Country and hospital levels were included as random effects with hospitals nested within the country. Postestimation commands were used to estimate the SSI rate for each intervention, by wound contamination category. Intraclass correlation coefficient was estimated using a multilevel linear mixed effects regression model with similar structure as above.

A rollback technique was used to estimate the average costs and the percentage of patients with an SSI for both arms of the model.²³ The difference in costs and the difference in outcomes between the arms were calculated. The incremental cost-effectiveness ratio (ICER) was calculated by dividing the difference in costs by the difference in percentage of SSIs; the results were reported as cost per percentage point of SSI reduced. This was an incremental modelling approach that initially estimated an ICER for patients with contaminated-dirty surgery only and then added patients with clean-contaminated surgery to the model to estimate an ICER for all patients. Costs and outcomes were not discounted because of the short time horizon of the model.²¹

In Mexico, KIWI costs data were available only for patients with contaminated-dirty surgery, whereas in

	Intervention	Intervention		Current practice		Intervention and current practice	
	Number of patients	Probability of event (95% CI)	Number of patients	Probability of event (95% CI)	Distribution	Source	
Clean-contaminated	3606	0-623 (NA*)	4195	0-620 (NA*)	Fixed	ChEETAh1	
SSI if clean-contaminated	426	0.119 (0.930-0.141)	527	0.135 (0.107-0.163)	Beta	ChEETAh1	
SSI if contaminated-dirty	505	0-271 (0-224-0-320)	753	0.299 (0.252-0.341)	Beta	ChEETAh1	

NA=not applicable. SSI=surgical site infection. *This value represents the percentage of patients recruited in that pathway; as such, a confidence interval of patients recruited could not be calculated.

Table 1: Number of patients recruited in the ChEETAh trial and probabilities included in the model, by pathway

Ghana the costs data were available only for patients with clean-contaminated surgery. The secondary analyses pooled effectiveness data for all ChEETAh contaminated-dirty surgery and applied cost data from Mexico, and then pooled effectiveness data for all ChEETAh clean-contaminated-dirty surgery and applied cost data from Ghana (appendix p 17).

Sensitivity analysis

Deterministic sensitivity analysis was done to assess the sensitivity of the base case results to a change in a given input parameter when the rest of the parameters did not change. Because of unavailability of data on the cost of instrument per single use, the costs were sourced from a study that estimated cost of instruments per single use in the USA in 2012.24 The cost of needle holder, forceps, and scissors was included in the intervention arm (appendix p 19). Probabilistic sensitivity analysis was done by running the simulations of the values of costs and model probabilities based on the distributions assigned to the parameters. The costs were assigned gamma distributions while the probabilities were assigned beta distributions. This generated 10000 sets of costs and outcomes that were used to calculate incremental costs and outcomes that were presented using costeffectiveness planes and cost-effectiveness acceptability curves (appendix pp 19-20).23

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

In the model that included all patients, the average cost of the intervention was US\$259.92 compared with \$261.10 for current practice (cost difference -\$1.18, 95% CI -4.08 to 1.33; table 2). An estimated 17.6% of patients in the intervention group had an SSI compared with 19.7% of patients in the current practice group (absolute risk reduction 2.10%, 95% CI 2.07-2.84). Thus, the intervention had similar costs to current practice and was more effective. The intervention was cost-effective in patients who had contaminated-dirty surgery, with a similar cost and rate of SSI compared with current practice (appendix p 21).

The intervention was still cost-effective when cost data from Mexico and Ghana were used. For example, when costs from Mexico were applied to patients who had contaminated-dirty surgery, the difference between groups in SSIs was 1·60% (95% CI 1·59 to 1·62) and the cost difference between groups was \$0·15 (95% CI -\$1·78 to 2·18; table 2), which generated an ICER of \$0·09 per percentage point of SSI reduced. Thus, the intervention was cost-effective as it reduced SSIs and had similar costs to current practice. Cost-effectiveness was not changed when the perspective

	Cost (\$)	Cost difference, \$ (95% CI)	Outcome, %*	Difference in outcomes, % (95% CI)	ICER or comment			
India								
Intervention	\$259-92		17.6%					
Current practice	\$261.10	-\$1.18 (-4.08 to 1.33)	19.7%	2·10% (2·07 to 2·84)	Dominant			
Mexico								
Intervention	\$212.83		11.9%					
Current practice	\$212-68	\$0.15 (-1.78 to 2.18)	13.5%	1.60% (1.59 to 1.62)	\$0.09			
Ghana								
Intervention	\$261.65		27.1%					
Current practice	\$263-44	-\$1.79 (-8.82 to -0.48)	29.9%	2·8% (2·71 to 2·86)	Dominant			
All costs are average	All costs are average costs in 2021 US\$ ICEP-incremental cost-effectiveness ratio SSI-surgical site infection *Outcome							

All costs are average costs in 2021 US\$. ICER=incremental cost-effectiveness ratio. SSI=surgical site infection. *Outcome is the estimated percentage of patients with an SSI.

Table 2: Cost-effectiveness analysis results, by unit cost source

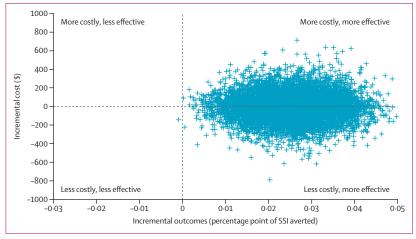


Figure 2: Cost-effectiveness plane

Incremental costs and outcomes of the intervention vs current practice are plotted across 10 000 iterations. The plane has four quadrants that show the incremental costs and outcomes between the two groups: (1) northeast, intervention is more costly and more effective (49% of the iterations); (2) southeast, intervention is less costly and more effective (51% of the iterations); (3) southwest, intervention is less costly and less effective (0·01% of the iterations); and (4) northwest, intervention is more costly and less effective (0·00% of the iterations). Costs are in 2021 USS. SSI=surgical site infection.

was broadened to include patient and societal costs (appendix p 21).

Results of the deterministic sensitivity analysis were favourable to the intervention for all changes made, even when the cost of changing instruments was incorporated in the model (appendix p 22).

Results of the probabilistic sensitivity analysis are shown in a cost-effectiveness plane (figure 2). Almost all the iterations, $99 \cdot 99\%$, were in the northeast and southeast quadrants, indicating that the intervention was more effective. However, there was uncertainty because the incremental costs were almost equally spread between the northeast (49%) and southeast (51%) quadrants, indicating that the costs between the two groups were similar.

Probabilistic sensitivity analysis results for the models that used costs data from Ghana and Mexico were similar

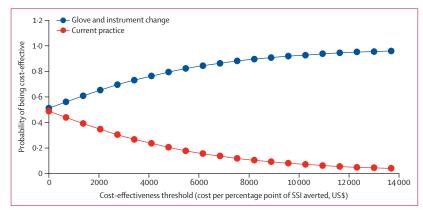


Figure 3: Cost-effectiveness acceptability curves SSI=surgical site infection.

to the probabilistic sensitivity analysis results that used base case data. The intervention reduced SSIs, had similar costs to current practice, and had a higher probability of being cost-effective compared with current practice (appendix pp 23–24).

The cost-effectiveness acceptability curves show the likelihood of the intervention or current practice being cost-effective across a range of cost-effectiveness thresholds (figure 3). At all the thresholds assumed (\$0 to \$14000), the intervention had higher probability of being cost-effective compared with current practice.

Discussion

Routine sterile glove and instrument change before abdominal wound closure reduced SSIs and was a costeffective intervention. This analysis showed that the intervention was more effective than current practice and costs were similar between the two groups. The analysis was done using pooled outcomes data from all seven countries in the ChEETAh trial and resource use and unit cost data from India. The results were confirmed by a wide range of deterministic sensitivity analyses that showed that even if the parameters in the model changed, the intervention would still be cost-effective. An exploratory analysis that included the cost of changing surgical instruments showed that the intervention would remain cost-effective even if there was a cost associated with changing instruments. This finding can be attributed to the fact that the costs of changing gloves and of cleaning and sterilising instruments are extremely low compared with the cost of treating an SSI, hence the intervention was found to be cost-effective even when the model parameters were changed in favour of the comparator. The probabilistic sensitivity analysis confirmed that the intervention was effective and had similar costs to current practice. The cost-effectiveness acceptability curves showed that at all thresholds assumed, the intervention had a higher likelihood of being costeffective compared with current practice. Overall, the results show that the intervention is highly likely to be costeffective in patients recovering from abdominal surgery.

There are little other health economic data relating specifically to the trial intervention, although data do exist for other SSI topics. A study in a single hospital in Australia assessed the effectiveness of a 12-item bundle, including change of gloves and instruments before wound closure, for prevention of organ space infection or SSI in patients that had elective left-sided colorectal surgery.11 The study found that the intervention was both effective and cost-effective at reducing SSIs; implementation of the SSI prevention bundle strategy reduced SSIs from 12.9% to 3.4% and reduced hospital costs by \$30942 overall (converted to US\$ and inflated to 2021 in the current study) compared with preimplementation.^{15,16} Although the investigators did not present the cost of some specific items in the bundle and the cost of the whole bundle, they concluded that the intervention was cost-effective. However, they acknowledged that it was difficult to identify the impact of individual items in the bundle at reducing organ space SSI. The point estimates for the current study established that the cost of glove and instrument change and the cost of current practice were similar, whereas the previous study found a substantial cost difference. This discrepancy might exist because the previous study retrospectively compared the median costs between patients with and without organ space infection or SSI before and after implementation of the intervention, whereas the current study did a full cost-effectiveness analysis that estimated mean costs and outcomes associated with the SSI prevention strategy and the

To the best of our knowledge, this is the first study to assess the cost of glove and instrument change before wound closure as a stand-alone intervention for reducing SSIs in patients of any surgical group. This evaluation used real trial data from a multicountry cluster-randomised control trial that established that the intervention is effective in seven LMICs.

This study had limitations, especially related to input cost data. First, the study pooled effectiveness data from seven countries but used resource use and unit cost data from just one country. This analytical approach has the potential to distort the relation between country-specific resource use and the pooled outcomes from the trial.¹⁸ The cost estimates might not be representative of India because they were sourced from only three hospitals. There were uncertainties in the cost estimates, which were shown by the scatterplots in the northeast and southeast quadrants of the cost-effectiveness plane (ie, more costly, more effective quadrant and less costly, more effective quadrant), implying that the costs were similar between the two groups. Second, the effectiveness and cost data were sourced from different studies done at slightly different periods, which might also distort the relation between resource use and unit costs and might have resulted in the uncertainties in the cost point estimates. Still, the cost-effectiveness acceptability curves

confirmed that the intervention was cost-effective at all thresholds assumed. Third, country-specific cost-effectiveness thresholds for determining the cost-effectiveness of natural units do not exist. The analysis did not compare the ICER against any specific cost-effectiveness thresholds, but used a dominance approach which considers an intervention that improves outcomes and reduces costs as cost-saving and certainly cost-effective. In both the base case and secondary analyses, the intervention improved outcomes and had similar costs to current practice, and as such the intervention is likely to be cost-effective at any threshold.

The results of this economic evaluation support the results obtained in the ChEETAh trial. Change of gloves and instruments before wound closure improved outcomes but did not have a substantial effect on costs; as such, this intervention will be important for reducing SSIs in LMICs. Therefore, it is recommended that routine change of sterile gloves and instruments at the time of abdominal wound closure should be adopted in surgical practice in LMICs because this intervention has been shown to be both effective and cost-effective.

Writing committee

Mwayi Kachapila (National Institute for Health and Care Research [NIHR] Global Health Research Unit on Global Surgery, University of Birmingham, Birmingham, UK; Health Economics Unit, University of Birmingham, Birmingham, UK), Raymond Oppong (NIHR Global Health Research Unit on Global Surgery, University of Birmingham, Birmingham, UK; Health Economics Unit, University of Birmingham, Birmingham, UK), Adesoji O Ademuyiwa (Paediatric Surgery Unit, Department of Surgery, University of Lagos, Lagos, Nigeria; Nigeria Hub, NIHR Global Health Research Unit on Global Surgery, Lagos, Nigeria), Aneel Bhangu (NIHR Global Health Research Unit on Global Surgery, University of Birmingham, Birmingham, UK; Institute of Applied Health Research, University of Birmingham, Birmingham, UK), Risikat Dauda (Department of Economics, University of Lagos, Lagos, Nigeria), Dhruva N Ghosh (India Hub, NIHR Global Health Research Unit on Global Surgery, Ludhiana, India; Department of Anaesthesia and Surgery, Christian Medical College, Ludhiana, India), Sivesh K Kamarajah (Institute of Applied Health Research, University of Birmingham, Birmingham, UK), Ismail Lawani (Faculty of Health Science, University of Abomey-Calavi, Abomey-Calavi, Benin; Benin Hub, NIHR Global Health Research Unit on Global Surgery, Abomey-Calavi, Benin), Antonio Ramos-De la Medina (Medical School, Universidad Autónoma de Veracruz, Veracruz, Mexico; Mexico Hub, NIHR Global Health Research Unit on Global Surgery, Veracruz, Mexico), Mark Monahan (Health Economics Unit, University of Birmingham, Birmingham, UK), Dion G Morton (NIHR Global Health Research Unit on Global Surgery, University of Birmingham, Birmingham, UK; Institute of Applied Health Research, University of Birmingham, Birmingham, UK), Omar Omar (NIHR Global Health Research Unit on Global Surgery), Maria Picciochi (NIHR Global Health Research Unit on Global Surgery), Stephen Tabiri (School of Medicine, University of Development Studies, Tamale, Ghana; Ghana Hub, NIHR Global Health Research Unit on Global Surgery, Tamale, Ghana), Tracy E Roberts (NIHR Global Health Research Unit on Global Surgery, Birmingham, UK; University of Birmingham, Birmingham, UK; Health Economics Unit, University of Birmingham, Birmingham, UK; Institute of Applied Health Research, University of Birmingham, Birmingham, UK).

Contributors

DGM, MK, TER, RO, and AB conceived and designed the study. MK chaired the writing committee, conducted the analysis, and drafted and edited the manuscript. RO, MM, and TER supervised data analysis, and edited and commented on the manuscript. MM and OO curated the

data and commented on the manuscript. All members of the writing committee commented on and edited the manuscript. All authors had access to all the data in the study and had final responsibility for the decision to submit for publication. MK and OO accessed and verified the data.

Declaration of interests

RO obtained a grant from the Institute of Global Innovation aimed at estimating the economic burden of antmicrobial resistance in Ghana. DGM received funding from the NIHR Global Health, participates in the University College London lung/gynae Trial Steering Committee, and is the Chair for Global Reach Committee European Society of Coloproctology. All other authors declare no competing interests.

Data sharing

Researchers conducting studies with clearly described objectives can request to access the data used in this study through the corresponding author. The request will be considered by the management group. Prespecified data will be made available subject to a written proposal and a signed data sharing agreement.

Acknowledgments

The ChEETAh trial was supported by an NIHR Clinician Scientist Award (CS-2018-18-ST2-013) and an NIHR Global Health Research Unit Grant (NIHR16.136.79) and the pilot study by the NIHR. The funder and sponsor had no role in study design or writing of this report. The funder has approved the submission of this report for publication. The views expressed are those of the authors and not necessarily those of the National Health Service, the NIHR, or the UK Department of Health and Social Care. Mölnlycke Healthcare provided sterile BioGel gloves to participating sites randomly assigned to the intervention group. This represented an unrestricted donation, and the company was not involved in any component of study protocol design, delivery, interpretation, or reporting.

References

- NIHR Global Research Health Unit on Global Surgery. Routine sterile glove and instrument change at the time of abdominal wound closure to prevent surgical site infection (ChEETAh): a pragmatic, cluster-randomised trial in seven low-income and middle-income countries. *Lancet* 2022; 400: 1767–76.
- NIHR Global Research Health Unit on Global Surgery. Reducing surgical site infections in low-income and middle-income countries (FALCON): a pragmatic, multicentre, stratified, randomised controlled trial. *Lancet* 2021; 398: 1687–99.
- 3 NIHR Global Research Health Unit on Global Surgery. Study protocol for a cluster randomised trial of sterile glove and instrument change at the time of wound closure to reduce surgical site infection in low- and middle-income countries (CHEETAH). Trials 2022; 23: 204.
- 4 Kamel C, McGahan L, Mierzwinski-Urban M, Embil J. Preoperative skin antiseptic preparations and application techniques for preventing surgical site infections: a systematic review of the clinical evidence and guidelines [internet]. Ottawa, ON: Canadian Agency for Drugs and Technologies in Health, 2011. https://www.ncbi.nlm.nih.gov/books/NBK174549/ (accessed Nov 9, 2023).
- 5 Badia JM, Casey AL, Petrosillo N, Hudson PM, Mitchell SA, Crosby C. Impact of surgical site infection on healthcare costs and patient outcomes: a systematic review in six European countries. J Hosp Infect 2017; 96: 1–15.
- 6 Monahan M, Jowett S, Pinkney T, et al. Surgical site infection and costs in low- and middle-income countries: a systematic review of the economic burden. PLoS One 2020; 15: e0232960.
- 7 Allegranzi B, Bischoff P, de Jonge S, et al. New WHO recommendations on preoperative measures for surgical site infection prevention: an evidence-based global perspective. *Lancet Infect Dis* 2016; 16: e276–87.
- 8 Allegranzi B, Zayed B, Bischoff P, et al. New WHO recommendations on intraoperative and postoperative measures for surgical site infection prevention: an evidence-based global perspective. *Lancet Infect Dis* 2016; 16: e288–303.
- 9 Berríos-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention guideline for the prevention of surgical site infection, 2017. JAMA Surg 2017; 152: 784–91.

- 10 WHO. Global guidelines for the prevention of surgical site infection, 2nd ed. 2018. https://qualityhealthservices.who.int/ quality-toolkit/qt-catalog-item/global-guidelines-for-the-preventionof-surgical-site-infection-2nd-ed (accessed Nov 9, 2023).
- 11 Faragher I, Tham N, Hong M, Guy S, Yeung J. Implementation of an organ space infection prevention bundle reduces the rate of organ space infection after elective colorectal surgery. BMJ Open Qual 2021; 10: e001278.
- Monahan M, Glasbey J, Roberts TE, et al. The costs of surgical site infection after abdominal surgery: Key resource use In Wound Infection (KIWI) study. J Hosp Infect 2023; 136: 38–44.
- 13 OECD Data. Purchasing power parities (PPP). https://data.oecd. org/conversion/purchasing-power-parities-ppp.htm (accessed Aug 18, 2022).
- 14 International Monetary Fund. Implied PPP conversion rate. 2023. https://www.imf.org/external/datamapper/PPPEX@WEO/ OEMDC/ADVEC/WEOWORLD (accessed Aug 8, 2023).
- 15 International Monetary Fund. Exchange rates selected indicators. https://data.imf.org/regular.aspx?key=61545850 (accessed Aug 18, 2022)
- 16 US Bureau of Labour Statistics. CPI inflation calculator. https://www.bls.gov/data/inflation_calculator.htm (accessed Aug 19, 2022).
- Husereau D, Drummond M, Augustovski F, et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) statement: updated reporting guidance for health economic evaluations. Value in Health 2022; 25: 3–9.

- 18 Reed SD, Anstrom KJ, Bakhai A, et al. Conducting economic evaluations alongside multinational clinical trials: toward a research consensus. Am Heart J 2005; 149: 434–43.
- 19 Barton P, Bryan S, Robinson S. Modelling in the economic evaluation of health care: selecting the appropriate approach. J Health Serv Res Policy 2004; 9: 110–18.
- 20 Kirkland KB, Briggs JP, Trivette SL, Wilkinson WE, Sexton DJ. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. *Infect Control Hosp Epidemiol* 1999; 20: 725–30.
- 21 Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. Methods for the economic evaluation of health care programmes. Oxford: Oxford University Press, 2015.
- 22 Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009; 42: 377–81.
- 23 Briggs AH, Claxton K, Sculpher MJ. Decision modelling for health economic evaluation. Oxford: Oxford University Press, 2011.
- 24 Stockert EW, Langerman A. Assessing the magnitude and costs of intraoperative inefficiencies attributable to surgical instrument trays. J Am Coll Surg 2014; 219: 646–55.