

Scaling uptake of ChEETAh trial evidence into practice: Mixed-methods development of an implementation research logic model

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Abstract

Introduction: Implementation of best clinical evidence to practice is often slow. Surgical site infection (SSI) is the most common complication after surgery. The ChEETAh trial demonstrated changing gloves and instruments before closing the abdominal wound reduces SSI rates and is cost-effective. Scaling this intervention is important to bring wider benefits to patients globally. The aim of this study was to co-design an implementation research logic model (IRLM) with stakeholders across low- and middle-income countries (LMICs).

Methods: This mixed-methods study was delivered in three phases. In phase 1, we completed a multicentre cohort study across seven LMICs to determine post-trial implementation rates. In phase 2, to explore reasons for incomplete implementation, we undertook a survey of key stakeholders (surgeons, principal investigators, research staff) to identify barriers and facilitators. In phase 3, we conducted a workshop with the Study Management Group (SMG) to develop and refine the IRLM with key stakeholders in two subsequent workshops.

Results: In phase 1, the cohort study included 492 patients across 88 centres in seven LMICs. Overall implementation was 27.0% and was higher in hospitals that had participated in the ChEETAh trial compared to those who did not (38.9% vs 14.4%). In phase 2, the commonest barriers limited available resources such as procurement costs and equipment (46.7%, n=14/30), executing the intervention complex emergency settings (26.7%, n=8/30), and low individual-level motivation (20.0%, n=6/30) and capability (16.7%, n=5/30). In phase 3, findings from both phases were discussed and potential strategies to scale implementation were discussed in these workshops. Local strategies included (i) embedding the intervention into local guidelines; (ii) integrating the intervention within the WHO checklist; (iii) identifying local champions to monitor and feedback on performance; (iv) developing training protocols for simulation; and (v) developing a toolkit which includes business cases. National strategies included (i) embedding intervention into national guidelines; and (ii) regional and national-level systems to monitor performance on a regular basis. The importance of adopting context-specific implementation strategies was highlighted by workshop participants and incorporated in to the final IRLM.

Conclusion: While implementation of the ChEETAh intervention has improved from baseline, it remains inconsistent, especially in hospitals that did not participate in the trial. The gaps in implementation suggest a need for targeted efforts, particularly in non-trial settings. Future initiatives should prioritise stakeholder engagement to co-develop tailored strategies that address local barriers and promote sustainable, system-wide adoption. While lockdowns affected surgical access, overall surgical volumes and patient outcomes were preserved. These findings highlight the importance of strategic planning in maintaining essential surgical care during health crises.

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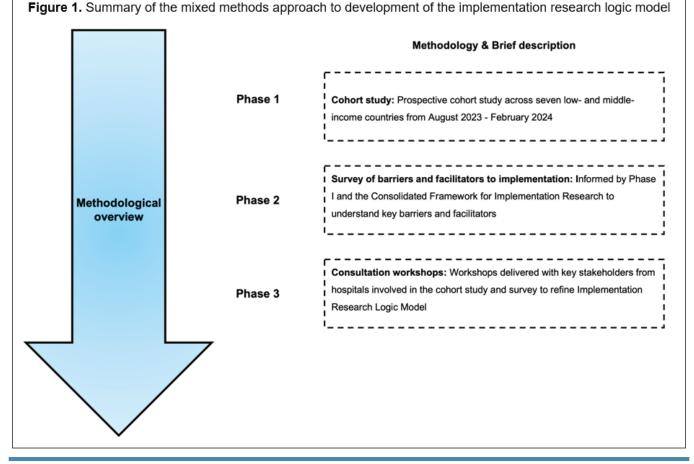


Introduction

Translating evidence-based interventions from highquality randomised clinical trials into routine practice is critical for maximising benefit to patient globally¹. Improved patient outcomes will lead to high quality of clinical care within health systems. Despite this, incorporation of evidence has been slow with research showing that it takes on average 17 years for 50% adoption of known effective interventions into clinical practice². Several barriers at multiple levels of healthcare delivery, from policy to patient, hinder implementation of research findings into patient benefit³. Inability to translate effective health services research into practice means patients do not benefit from these and healthcare systems experience opportunity costs that are avoidable. Despite this, comparatively little research goes into the uptake of surgical interventional trials and their impact on patient and healthcare systems⁴.

Although the quality of surgical research and outcomes have improved over the past decade,¹ surgical site infections are still common postoperative complications disproportionately worse in low- and middle-income settings where the rates are as high as 22.0%^{5,6}. They are devastating to patients, families and to communities, associated with prolonged hospital stay, increased hospital costs, increased mortality⁶. Reducing wound infection after surgery has been identified as a core priority to frontline clinicians and patients in low- and middle-income countries⁷. However, the evidence base on effective interventions to reduce surgical site infection in LMICs are limited. To address this, the ChEEtAh trial, a large multicentre cluster randomised trial including >13,000 patients across 81 centres from seven LMICs compared change of gloves and instruments prior to wound closure in patients undergoing abdominal surgery with routine practice⁸. All electives and emergency procedures with clean-contaminated, contaminated and dirty wounds in all ages were included in the study. The intervention led to a clinically significant reduction in surgical site infection by 2.1%, from 19.7% to 17.6% and was found to be cost-effective⁸.

With evidence showing clinical and cost-effectiveness of changing gloves and instruments, scaling up implementation of this intervention is important to ensure benefits for the global surgical population is maximised. Despite the success of the ChEETAh trial intervention, its uptake into routine practice since the study was published remained unclear. This study aimed to co-design an implementation research logic model (IRLM),⁹ mapped to the Consolidated Framework for Implementation Research to guide implementation activities on a wider scale. This study has three main objectives: (i) understand the scale of implementation since the ChEETAh trial in seven LMCs; (ii) identify barriers and facilitators to routinely adoption of the intervention; and





(iii) engagement of local and national stakeholders to develop an IRLM.

Methods

Methodological process of assessing implementation

To co-design the IRLM with stakeholders across seven LMICs, we undertook a multiphase mixed-methods approach. A summary of the key methodological process is described in Figure 1. In phase 1, we conducted a multicentre cohort study across seven LMICs to understand the current implementation rates of the ChEETAh intervention. In phase 2, we undertook a survey across key stakeholders (surgeons, principal investigators, research staff) within hospitals involved in the ChEETAh trial to identify barriers and facilitators to implementation. In phase 3, an initial draft IRLM was developed by the SMG. This draft was subsequently refined during two workshops into a definite IRLM with key stakeholders, triangulating findings from phases 1 and 2.

Theoretical and conceptual frameworks

The Consolidated Framework for Implementation Research (CFIR) is a determinant framework used to guide data collection and analysis to identify barriers and facilitators of implementation¹⁰. The framework consists of individual- and organisational-level constructs consolidated from several theories and models, organised into five overarching domains. These include intervention characteristics, outer setting, inner setting, characteristics of individuals, and process¹¹. A summary of these different domains and constructs are presented in Table S1. To understand relevant strategies, the we defined them according to the Expert Recommendations for Implementing Change framework¹². The ERIC framework is a compilation of implementation strategies developed through a consensus process of implementation scientist and clinicians to improve conceptual clarity, relevance, and comprehensiveness of discrete implementation strategies. Both these frameworks are complimentary to each other and can be used to take a system-level approach to understanding these complex interventions better^{13,14}. The Proctor and colleagues' taxonomy of implementation outcomes¹⁵ and the IRLM⁹ informed our data analysis and synthesis9,15. The IRLM is a visualization tool to depict causal pathways between intervention components, determinants (i.e., barriers and facilitators) of implementation, implementation strategies, mechanisms of action, and implementation9. Mechanisms of action define how implementation strategies operate to influence outcomes. We used the IRLM to elucidate the relationships between determinants, mechanisms, and implementation outcomes.

Phase 1: Prospective cohort study

In phase 1, we delivered a prospective multicentre cohort study across seven LMICs to understand the scale of implementation of the ChEETAh intervention. This cohort study included all consecutive patients (i.e., children and adults) undergoing elective or emergency abdominal surgery for any indication and any degree of contamination (i.e., clean, clean-contaminated, contaminated or dirty). Exclusion criteria was patients undergoing caesarean section. Any theatres where these operations are performed are eligible to be included. To capture the broad range of implementation practices, eligible patients were identified by local surgical teams over two one- month periods between August 2023 to February 2024. This also allowed for assessment of variability at different times of the year.

The primary outcome of this cohort study is the ChEETAh intervention. implementation of the Implementation was defined as complete when instruments were changed, and all scrubbed personnel changed their gloves before closing the abdominal wound. Implementation was considered incomplete if: (i) only gloves or instruments were changed or (ii) change of both gloves and instruments were done by either surgeons or scrub nurse. For this cohort study, a prespecified data collection form was used to collect data on patient and operative-level characteristics for each patient (Table S2). Patient- and operative level variables within the cohort study were: (i) age (defined in years); (ii) sex (male or female); (iii) body mass index (kg/m²); (iv) ASA physical status (grade 1 to 5); (v) indication for surgery (i.e., benign or malignant); (vi) urgency (i.e., elective or emergency); and surgical approach (i.e., open or minimally invasive). Data collected by the surgical teams and research nurses were uploaded unto the secure Research Electronic Data Capture server.¹⁶

Phase 2: Survey of clinical network

Following the cohort study, we prospectively designed and delivered a survey in our network to identify main barriers and facilitators for routine implementation of the ChEETAh intervention. The survey included specific free-text responses on the barriers and facilitators to the uptake of the ChEETAh intervention and rating of valuable strategies for implementation. This survey was distributed across all the hospitals involved in either the ChEETAh RCT or the prospective cohort study (phase I). Barriers identified by survey respondents were mapped onto the CFIR framework.^{10,13} Following this, the barriers were mapped to the CFIR-ERIC Matching Tool¹⁷ to generate "recommended" implementation strategies, according the ERIC framework.¹² Each CFIR construct deemed a barrier was used in the Excel guery. The resulting output includes the percent endorsement by individual barriers and the cumulative percentage endorsement denoting



the most to least recommended strategies. The top 20 highest cumulative percentage strategies became the "recommended" strategies, alongside key strategies described by the survey respondents.

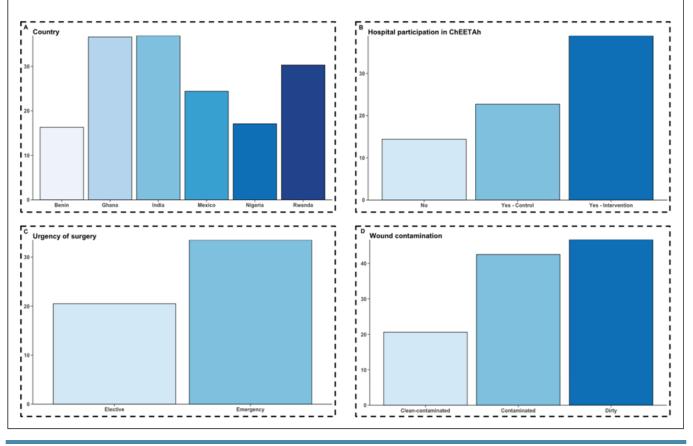
Phase 3: Consultation workshops with local and national stakeholders

In phase 3, the SMG developed a draft IRLM using data from phases 1 and 2 during a workshop. The SMG consisted of surgical care providers from both high, middle- and low-income countries and methodologists involved with the delivery of the ChEETAh trial. Other members of the SMG were the seven LMICs surgeons who were national principal investigators for the ChEETAh trial. The structure of the workshop was adapted from the Theory of Change formats¹⁸ and was structured to include a brief introduction of the project and the approach, the importance of implementation of evidencebased interventions into routine practice and a mapping exercise using structured group discussions and small group exercises. The workshop was characterised by the output, an IRLM (and gaining agreement on this among the involved stakeholders) rather than just giving views and opinions. In addition, the facilitators generally had a more active role than those moderating focus groups,

given that the aim was not only to obtain participants' views but to create an IRLM together. A summary of the topic guide containing themes and guestions asked in the workshop are summarised in Table S3. The results of the scale of implementation (Phase I) was used to generate discussion and prompt questions concerning the implementation barriers and strategies to achieve the long-term outcome and to check whether all levels of change (patient level; clinician level; and the facility) were considered.¹⁹ During this workshop, all components of the IRLM were considered such as key determinants, strategies, mechanism of action and outcomes (i.e., implementation-, clinical- and patient-level). After this workshop, SKK & TK drafted an IRLM map which incorporated findings of the barriers and strategies and subsequently discussed with the study management group.

Finally, we held two structured workshops with stakeholders (surgical care providers, principal investigators, research staff) involved in both phases I and II of this study. These workshops focused on refining the draft IRLM, ensuring that the strategies and mechanisms identified were relevant to the local contexts of the seven LMICs involved. The structure of both workshops was similar to those delivered with the SMG. The feedback

Figure 2. Scale of ChEETAh implementation in the prospective cohort study (A) By country (B) By hospital involved in the ChEETAh cluster randomised trial (C) By urgency of surgery (i.e., elective or emergency (D) By wound contamination





from participants was critical in shaping the final model to ensure it addressed pragmatic and context-specific challenges in diverse healthcare settings. After the second workshop, the core research team met a few times to finalise the different components of the IRLM, including potential mechanisms of action that can lead to widespread implementation. The map was subsequently checked against relevant literature proposed by the core research group and the four attributes (plausible, doable, meaningful and testable) for a good IRLM⁹.

Results

Phase 1: Prospective cohort study

This prospective cohort study included 492 patients from 88 sites across seven LMICs with an overall implementation rate of 27.0%. The sites involved included those from the ChEETAh trial (60 sites) and new sites (28 sites). Of the 60 ChEETAh sites, 33 were intervention sites and 27 were control sites. Majority of patients were either ASA grade I (n=161, 32.7%) or grade II (n=225, 45.7%). Of the 492 patients, 248 patients (50.4%) were emergency, and 244 patients (49.6%) were elective. The most common indication for surgery was benign (n=321, 65.2%). Majority of procedures were clean-contaminated (n=359, 73.0%), open-midline (n=276, 56.1%) and opennon-midline (n=166, 33.8%) surgery. The completion of the WHO checklist was high (n=426, 86.6%). A summary of the baseline characteristics of the included patients are presented in Table S4.

Implementation was variable across the different countries, from Country A (n=8/49, 16.3%) to Country C (n=24/65, 36.9%). Implementation rates were highest in hospitals from the ChEETAh trial's intervention arm (n=72/185, 38.9%) (Figure 2). Dirty cases (n=28/60, 46.7%) and emergency surgeries (n=83/248, 33.5%) had the highest uptake of the intervention. A summary of the rates of implementation by country, hospital, and patient- and operative level characteristics are presented in Table S5.

Phase 2: Survey of clinical network

This survey included 30 responses from national hub directors and hospital leads. The commonest barriers reported were limited available resources such as procurement costs and equipment (46.7%, n=14/30), executing the intervention complex emergency settings (26.7%, n=8/30), and low individual-level motivation (20.0%, n=6/30) and capability (16.7%, n=5/30). (Table S6). The top 10 barriers identified from the survey were mapped unto the CFIR-ERIC matching tool to generate a list of potential strategy recommendations. The list of top 20 strategies identified included educational initiatives and identification of local champions to drive the implementation. The rest of the strategies are listed in Table S7.

Phase 3: Consultation workshops with local and national stakeholders

To refine and iterate the ILRM, top barriers identified and its recommended strategies from phase 2 and 3 were presented over two consultation workshops, including 39 stakeholders of hospital leads, hub directors, and hub managers. A summary of key demographics of stakeholders are presented in Table S8. A finalised IRLM is presented in Figure 3.

Determinants for implementation

Key barriers identified were the lack of available resources for each procedure (Inner setting), given the high caseload in some hospitals and the perceived benefit from delivering the intervention, relative to other priority areas. In addition, financial barriers to procuring gloves and instrument hindered implementation of the intervention. At an individual level, low motivation amongst surgeons, especially in busy emergency service hindered implementation. In the implementation process domain, a major barrier was the lack of iterative feedback on performance of operating theatres within hospitals.

Strategies to implement

To address these major barriers, context-specific implementation strategies were identified as important, both at a local- and national-level. Local level strategies prioritised as important were: (i) embedding the intervention into local guidelines; (ii) integrating the intervention within the WHO checklist (Figure S1), both before- and towards the end of the operation; (iii) identifying local champions to monitor and feedback on performance of surgical teams; (iv) developing training protocols for simulation; and (v) developing a toolkit which includes business cases (i.e., impact budget modelling) that can be used for investment into the intervention by hospital administration team. National-level strategies include: (i) embedding intervention into national surgical guidelines; and (ii) regional and national-level systems to monitor performance on a regular basis. Workshop participants highlighted the importance of adopting context-specific implementation strategies.

Mechanism of actions

Implementation of the intervention would be driven by three broad mechanisms. First, the strategies will create new working systems to address clinical barriers. These include improved motivation and confidence to change gloves and instrument. Second, through perceived improved strength and quality of evidence, especially for hospital administration. This will enable increased financing for wider scaling with hospitals (i.e., different operating theatres) and countries (i.e., other hospitals). Third, through improved stakeholder engagement. These include engagement of local champions, senior leadership within hospitals and increased awareness



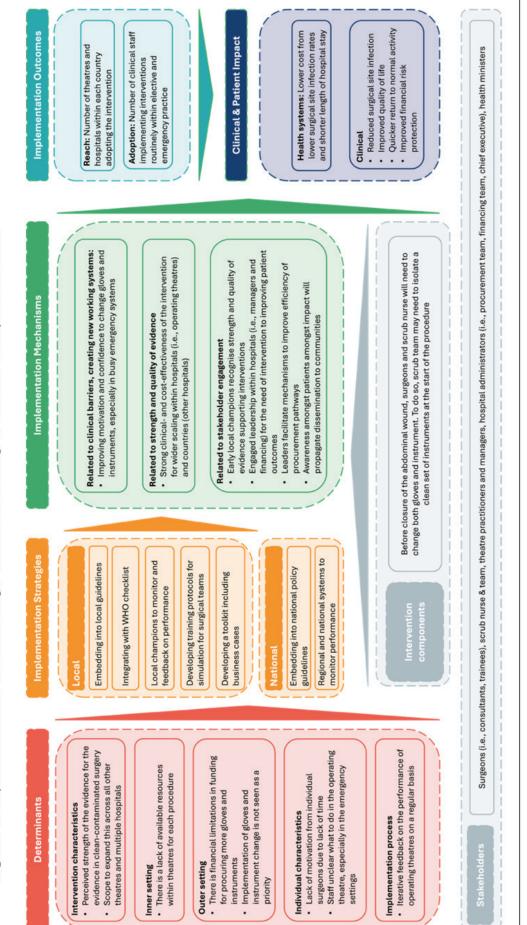


Figure 3. Implementation Research Logic Model for scaling of ChEETAh implementation



amongst patients to propagate wider dissemination to communities on the value of driving adoption of this intervention.

Implementation-, Clinical, and Health-system Impact

The consultation process identified three broad areas for maximising impact of the intervention by measuring relevant outcome measures. First, two implementation outcome measures such as reach and adoption should be assessed when scaling the intervention. Reach will be measured through number of theatres and hospitals within each country implementing the intervention and adoption as the number of clinical staff routinely changing gloves and instrument in both elective and emergency settings. Second, clinical outcome measures such as surgical site infection, quality of life and return to normal activity will improve because of widespread implementation of the intervention. Third, these will improve healthcare costs to the wider health system allowing allocation of costsavings to other areas within the health system.

Discussions

In this study, we co-designed an IRLM, together with stakeholders and real-world data to rapidly support implementation of the ChEETAh intervention. A key finding of this study was identification of important strategies that have led to an increase in implementation from 0.8% pre-trial to 27% found in this study across 88 hospitals. Strategies prioritised locally included embedding intervention into local guidelines or existing activity such as the WHO checklist and identifying local champions. Important national strategies highlighted were incorporation into national guidelines and regular monitoring. The main barriers to implementation were lack of resources and lack of leadership engagement. This study has demonstrated upscaling a major surgical trial intervention with context-specific local- and nationallevel strategies across seven LMICs and several hospitals.

The global burden of surgical disease such as cancer, hernia, and chronic degenerative joint disease is high, with as many as 313 million people requiring surgery annually^{20,21}. Importantly, deaths within 30-days after surgery is the third most common cause of death worldwide²². Over the past decade, there has been improvement in quality of global surgical research towards interventional trials¹. Despite this, research to improve widespread implementation of evidence to practice is limited²¹. Several surgical interventions²³ have demonstrated clinical effectiveness in high-quality randomised clinical trials such as the WHO surgical safety checklist. Although high-quality evidence demonstrates reduction in mortality, its real-world implementation has been poor, especially in low- and middle-income countries. A qualitative study24 across 15 hospitals in Africa highlighted key enablers to implementing the checklists were strong hospital leadership support, local consensus group discussions and regular meetings to feedback any issues impeding implementation.

One of the major strengths of this paper is the use of theory to understand the different strategies that enabled rapid scale-up within these countries, including the use of IRLM to understand interaction of different components within a complex health system^{9,25}. In this regard, we had deep rooted engagement with frontline healthcare professionals in understanding barriers to change and co-developed an implementation research logic model with these key stakeholders. The adoption of theory within our implementation process will allow us to rapidly scale the intervention into policy and practice. However, there are important limitations to address. First, the barriers to scaling implementation of ChEETAh are unclear beyond these seven LMICs since we have not assessed barriers to implementation in other contexts. However, we seek to explore this in our next phase of formative research to understand barriers and strategies in other contexts. Second, it is challenging to understand the implementation strategies which are most highvalue in different contexts, since there is "no one size fits all" in these contexts. However, adaptive trial designs may allow testing of different strategies to understand implementation of evidence in the real world, which may identify a blueprint for these centres.

Rapidly closing the implementation gap is crucial for the ChEETAh intervention, since it has strong evidence of clinical- and cost-effectiveness. First, embedding findings into national guidelines through surgical organisations and Ministries of Health will enforce change in practice amongst frontline clinicians. Secondly, creating national plans for routine assessment of high-quality interventions such as ChEETAh will drive a cycle of improvement in performance at a hospital-, regional- and national level, thus improving patient-level outcomes. Thirdly, integration of the ChEETAh intervention into existing interventions such as the WHO surgical safety checklist may allow improved preparedness of frontline teams, especially in dynamic emergency care systems.

Moving forwards, research is needed to understand highvalue strategies that may rapidly facilitate implementation of interventions into practice and identify ways to ensure long-term sustainability, independent of research programmes. A recent step-wedge cluster randomised trial²⁶ examined improvement in surgical site infection of the Clean Cut program through a bundle of enhanced implementation strategies. These strategies were structured education and training materials, and wider hospital engagement. This trial delivered across seven Ethiopian hospitals (n=3,364) reduced surgical site by 34.0%. Importantly, there was improved implementation of evidence based interventions such as surgical Safety Checklist (16.3% to 43.0%), surgeon hand and patient skin antisepsis (46.0% to 66.0%), and timely antibiotic



administration (17.8% to 39.0%). This amplifies the need for growing research through clinical trials in testing enhanced implementation strategies to improve uptake of evidence-based intervention. Learning through realworld solutions will allow rapid scaling globally to frontline clinicians.

While implementation of the ChEETAh intervention has improved from baseline, it remains inconsistent, especially in hospitals that did not participate in the trial. The gaps in implementation suggest a need for targeted efforts, particularly in non-trial settings. Future initiatives should prioritise stakeholder engagement to co-develop tailored strategies that address local barriers and promote sustainable, system-wide adoption. Further, embedding implementation of successful interventions into national and global policies could transform patient care.

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Authors' contributions: TTKA, SKK, AAB, DGM, DN, DG, and IL conceptualized the study, developed the research questions, and defined the scope of the review. TTKA, SKK, and DN conducted data analysis and preparing tables and figures. TTKA, SKK, AAB, DN, DG, and IL developed the draft manuscript and all other authors provided critical input into the organisation, analysis and interpretation of the results. All authors read and approved the final manuscript.

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