

Study Protocol and Statistical Analysis Plan

Easy Hands Trial

Official Title: Easy Hands: A Cluster Randomized Cross-Over Trial Evaluating a Simplified 3-Step Hand Hygiene Technique Versus the WHO 6-Step Technique on Healthcare-Associated Infections

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1. Title

Easy Hands: A Cluster Randomized Cross-Over Trial Evaluating a Simplified 3-Step Hand Hygiene Technique Versus the WHO 6-Step Technique on Healthcare-Associated Infections

2. Background

Healthcare-associated infections (HAIs) remain one of the leading causes of preventable morbidity, prolonged hospitalization, antimicrobial exposure, healthcare costs, and mortality worldwide. Effective hand hygiene is recognized as the cornerstone of infection prevention in healthcare settings.

The World Health Organization (WHO) recommends a 6-step hand hygiene technique intended to maximize coverage of all hand surfaces. However, adherence to the complete technique may be reduced in real-world clinical practice because of workload, time pressure, workflow interruptions, and human factors. Simplified hand hygiene approaches may improve feasibility and compliance while preserving clinical effectiveness.

The Easy Hands trial is designed to evaluate whether a simplified 3-step hand hygiene technique can be implemented without increasing the risk of HAIs when compared with the WHO standard 6-step technique under routine hospital conditions.

3. Objectives

Primary Objective

To evaluate the effect of a simplified 3-step hand hygiene technique compared with the WHO standard 6-step technique on the risk of healthcare-associated infections (HAIs) in hospitalized patients.

Specific Objectives

- To describe the demographic and clinical characteristics of individuals belonging to the study clusters.
- To compare hand hygiene adherence levels in clusters assigned to the 3-step technique versus those assigned to the 6-step technique.
- To determine differences in cumulative incidence of healthcare-associated infections between clusters assigned to the intervention and those assigned to the control strategy.
- To compare microbiological indicators during periods assigned to the 3-step technique versus periods assigned to the 6-step technique.
- To estimate the effect of the intervention relative to control through a relative risk measure for development of healthcare-associated infections.

4. Design

This study uses a pragmatic, interventional, cluster randomized cross-over design conducted in hospital clinical services. Participating units are randomized to one of two intervention sequences:

- Sequence AB: 3-step technique followed by 6-step technique
- Sequence BA: 6-step technique followed by 3-step technique

After completion of the first study period, clusters cross over to the alternate technique according to the predefined implementation schedule.

This design is selected to reduce contamination within services, preserve operational feasibility, and allow each cluster to contribute data under both interventions.

5. Population and Sample

Source Population

The source population consists of hospitalized patients admitted to participating critical care and inpatient units during active study periods.

Adult patients are included from:

- General Intensive Care Unit
- Cardiovascular Intensive Care Unit

- Extracorporeal Cardiovascular Support Unit (USVEC)
- General hospitalization wards

Pediatric patients are included from:

- General pediatric hospitalization
- Pediatric Intensive Care Unit

A total of 14 clusters are considered.

General Hospitalization Clusters

- 1A
- 1B
- 1 SUR
- 2A
- 2B
- 2 SUR
- 2 NORTE
- 3 NORTE
- 4 NORTE
- Pediatrics

Critical Care Clusters

- General Intensive Care Unit
- Extracorporeal Life Support Unit
- Cardiovascular Intensive Care Unit
- Pediatric Intensive Care Unit

Emergency Department and Operating Rooms are excluded.

Sampling Strategy

Consecutive eligible admissions during the implementation period are included.

Eligibility Criteria

Inclusion Criteria

- Admission to a participating cluster during an active intervention period.
- Adult or pediatric hospitalized patient.
- Availability of admission and discharge dates.
- Eligibility for institutional infection surveillance.

Exclusion Criteria

- Admission to Emergency Department or Operating Rooms.
- HAI present at baseline (t_0).
- HAI occurring during the first two hospital days.

6. Collected Variables

Cluster-Level Variables

- Cluster identifier
- Randomization sequence
- Study period
- Assigned hand hygiene technique

Individual-Level Variables

- Age
- Sex
- Admission source
- Charlson comorbidity index
- Length of stay
- Outcome status

Time-Varying Variables

- Central venous catheter
- PICC
- Dialysis catheter
- Peripheral catheter
- Mechanical ventilation
- Urinary catheter

7. Interventions

Experimental Intervention

Simplified 3-step hand hygiene technique implemented at the cluster level.

Comparator Intervention

WHO standard 6-step hand hygiene technique implemented at the cluster level.

Training and implementation procedures follow institutional infection prevention standards.

8. Outcomes

Primary Outcome

Time from hospital admission to first healthcare-associated infection during hospitalization.

Secondary Outcomes

- Cumulative incidence of HAI
- Incidence density
- Adjusted hazard ratios
- Device-associated infection risk estimates
- Hand hygiene compliance
- Microbiological indicators

9. Statistical Methods

9.1. General Principles

All analyses will be conducted using Stata version 17 (StataCorp, College Station, TX, USA). Two-sided p-values < 0.05 will be considered statistically significant. Estimates will be reported with 95% confidence intervals.

9.2. Descriptive Analysis

Categorical variables will be summarized as frequencies and percentages.

Continuous variables will first be assessed for normality using graphical methods and formal tests, including the Shapiro–Wilk test when appropriate. Normally distributed variables will be summarized using mean and standard deviation. Non-normally distributed variables will be summarized using median and interquartile range.

Between-group comparisons will use:

- Chi-square test or Fisher’s exact test for categorical variables
- Student’s t test for normally distributed variables
- Mann–Whitney U test for non-normally distributed variables

9.3. Incidence Measures

$$CI = \frac{D}{N}$$

$$IR = \frac{D}{PT}$$

Poisson regression with logarithmic offset of patient-time will be used for rate comparisons.

9.4. Primary Survival Analysis

The primary inferential analysis will use a Cox proportional hazards model estimated on a counting-process (start–stop) structure:

$$h_{ij}(t) = h_0(t) \exp \left[\beta_1 Treatment_{ij}(t) + \beta_2 Period_{ij}(t) + \beta_3 Sequence_j + \gamma^\top \mathbf{X}_{ij} + \delta^\top \mathbf{Z}_{ij}(t) \right] \quad (1)$$

Where:

- $h_{ij}(t)$ = hazard of first HAI for participant i in cluster j
- $h_0(t)$ = baseline hazard
- $Treatment_{ij}(t)$ = assigned hand hygiene strategy
- $Period_{ij}(t)$ = study period
- $Sequence_j$ = cluster randomization sequence
- \mathbf{X}_{ij} = vector of baseline covariates
- $\mathbf{Z}_{ij}(t)$ = vector of time-varying covariates

Cluster-robust standard errors will be used to account for intracluster correlation.

9.5. Supplementary Analyses

- Kaplan–Meier curves
- Landmark Kaplan–Meier curves by period
- Adjusted survival curves derived from Cox models
- Sensitivity analyses using frailty models

9.6. Model Diagnostics

- Schoenfeld residuals
- Cox–Snell residuals
- Martingale residuals
- Deviance residuals

10. Sample Size Considerations

Sample size is determined pragmatically by the number of eligible consecutive admissions during the implementation period. Statistical precision is expected to depend primarily on the number of observed HAI events.

11. Ethics

The study is conducted in accordance with the Declaration of Helsinki, Good Clinical Practice principles, and applicable Colombian regulations. The protocol is approved for conduct by the Research Ethics Committee of Fundación Abood Shaio according to Meeting Minutes No. 405 dated May 7, 2025.

Given the pragmatic cluster-level implementation of the intervention and the use of routinely collected institutional surveillance data for assessment of the primary outcome, the Research Ethics Committee waived the requirement for individual informed consent for each hospitalized patient included in the primary endpoint analysis.

However, written informed consent is approved and required for specific secondary objectives involving direct participant or staff assessment, including:

- Hand Hygiene Compliance measurements
- Comparison of microbiological indicators

All analyses use de-identified data. Confidentiality and data protection procedures comply with institutional and national privacy requirements.

12. Data Sharing

There is currently no plan to make individual participant data publicly available.

13. Version Control

Protocol Version: 1.0

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