# STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

**Using a randomized control trial to evaluate the effectiveness of glove changing in reducing wound-related complications following cesarean section in Vietnam**


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**Abbreviations**

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| CS | Cesarean section |
| SSI | Surgical site infection |
| CPR | Cardiopulmonary resuscitation |
| ASA | American Society of Anesthesiologists |
| NYHA | New York Heart Association |

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## 1. Introduction

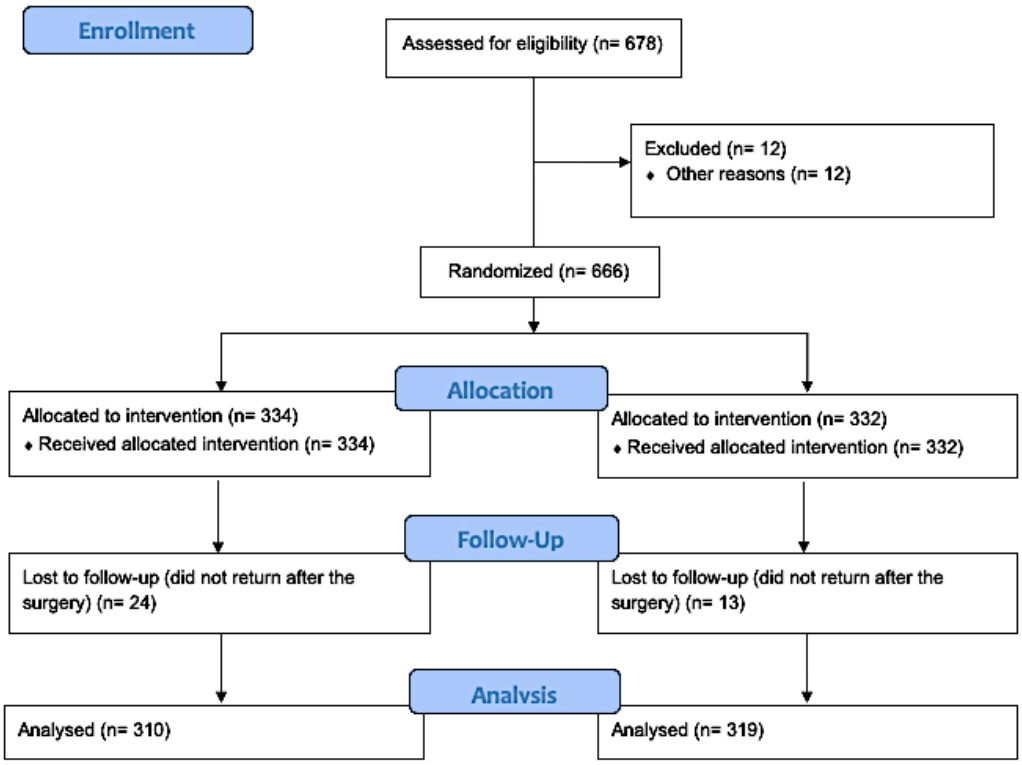
The aim of this study is to investigate the effect of glove changing on wound complications after cesarean surgery in Vietnam. We hypothesize that changing gloves prior to abdominal closure reduces the incidence of infectious complications following cesarean surgery.

## 2. Study design

Study subjects will be recruited from December 2020 to February 2021 at Hung Vuong hospital, Ho Chi Minh city, Vietnam. Inclusion criteria for participants in this study include pregnant women who are 18 years old or higher; who have CS performed at Hung Vuong hospital; and who live close to Ho Chi Minh city and agree to return for postpartum care one-month post-surgery. Exclusion criteria include pregnant women who have fever during labor; who have systemic infectious conditions; who have surgical site infection SSI or sexually infectious conditions; who have ongoing internal conditions such as pre-eclampsia, severe anemia, American Society of Anesthesiologists (ASA) ≥ 3, New York Heart Association (NYHA) class 3 or above, pulmonary edema, or severe asthma. Data collection will be stopped when pregnant women require cardiopulmonary resuscitation (CPR) or have damaged pelvic organs during CS; when they need extra surgery after CS; or when the surgical team has double gloving or the gloves get punctured during surgery.

The study is a parallel-group randomized control trial with 2 arms. Arm 1 includes patients who will have glove changed prior to abdominal closure during CS. Aim 2 includes patients who will not have glove changed prior to abdominal closure during CS. All patients are randomized using computer-generated sequences with allocation ratio 1:1. Clinic visits are performed at 2 time points, unless emergency check-up is recommended after hospital discharge. Visit 1 is at 2-3 days post-surgery and visit 2 is at 30 ± 2 days post-surgery where primary and secondary outcomes are measured. The study is concluded when we finish the second data collection or when patients are discharged from the hospital after a required immediate check-up. Patients who do not return for postpartum care will be considered lost to follow up. The study design is visualized in Figure 1 below.

Figure 1: The CONSORT flow diagram of the study




Sample size calculation

The sample size is calculated based on the following formula:

$$n = \frac{\left( Z_{1-\frac{\alpha}{2}}\sqrt{2P(1-P)} + Z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)} \right)^2}{(P_1 - P_2)^2}$$

Where:

n: required minimum sample size in each group

P1: rate of superficial SSI in group 1 (i.e., glove change group)

P2: rate of superficial SSI in group 2 (i.e., control, or usual care group)

$$P = \frac{P1 + P2}{2}$$

α: type I error, α = 0,05 → Z1- α/2 = 1,96

β: type II error, β = 0,15 (statistical power = 0,85) → Z1- β = 1,04

Based on the results from Scrafford's group where they reported the rates of superficial SSI in the glove change group and the usual care group were 6.4% and 13.6%, respectively [1], we will calculate the sample size for each group. In order to achieve the statistical power of 0.85, the required minimum sample size in each group is 310. To account for 5% of the sample lost

during the study, the sample size in each group is increased to 327 based on the calculation 310/0.95=327. Thus, the required minimum sample size for both groups in our study will be 327*2=654.

## 3. Aims and objectives

The aims are 1) to evaluate whether changing gloves during CS reduces complications and SSI, and 2) to identify other factors that are associated with complications and SSI.

## 4. Outcomes

The primary outcomes of interest are any wound complications occurring after the surgery, including seroma, hematoma, wound separation, and wound infection. Secondary outcomes are any signs of SSI, including fever, swelling, redness, and pain surrounding the incisional area. The outcomes will be evaluated during clinic visits by qualified medical practitioners who are blind to the intervention group assignment.

## 5. Populations and subgroups to be analyzed

Populations: intention-to-treat

Subgroups: the glove change and usual care group. These 2 subgroups will be analyzed using intention-to-treat populations.

## 6. Analyses

Data will be analyzed using Stata 16 (StataCorp LLC, College Station, TX). Normally distributed data will be expressed as mean ± standard deviation, while non-normally distributed data will be shown as medians with interquartile ranges. T-test for normally distributed continuous variables and Mann-Whitney-U test for non-normally distributed continuous variables will be used to compare between groups. Categorical variables will be reported as absolute numbers and percentages; the Chi-square test or Fisher's exact test will be utilized for comparison. A *p*-value of $<0.05$ will be considered statistically significant. Multiple logistics regression analysis will be performed to identify factors affecting the superficial incisional complications.

## 7. References

[1] J. D. Scrafford, B. Reddy, C. Rivard, and R. I. Vogel, “Effect of intra-operative glove changing during cesarean section on post-operative complications: a randomized controlled trial,” *Arch Gynecol Obstet*, vol. 297, no. 6, pp. 1449–1454, Jun. 2018, doi: 10.1007/s00404-018-4748-y.