

Appendix 2b: Studies related to changing of gloves vs. retaining gloves: SSI outcome

Author, year, reference	Country/ study period	Type of study/ setting	Intervention	Comparator	Primary outcome	Results	Limitations
Ventolini 2004 (12)	USA 1996-1999	RCT: randomized by opening sealed, consecutive envelopes. Caesarean section (n=92)	Change of gloves following the delivery of the placenta by the entire team (n=46)	Retaining gloves, that is, no change of surgical gloves during the procedure (n=46)	Wound infection was defined as the presence of cellulitis (hyperemia, induration and tenderness), purulent drainage from the incision and/or fluctuant, tender, erythematous incision margins). Unknown follow-up.	5.5% in the change group. 25% in the no change group. Relative risk: 4.5 (95% CI: 0.982-29.8)	Blinding unknown. Follow-up period unknown. No validated SSI definition.
Cernadas 1998 (9)	USA 1995-1996	RCT: randomized by opening a consecutively numbered and sealed envelope. Caesarean section (n=108) Group A (n=26): no glove change with manual placental delivery. Group B (n=27): no glove change with expressed placental delivery. Group C (n=27): glove change with manual placental delivery. Group D (n = 28): glove change with expressed placental delivery.	Change of gloves If a patient was assigned to a glove change group, the delivery hands of the primary surgeon were double-gloved prior to surgery. The external second glove was removed by a circulating nurse after delivery of the fetus. (Group C+D: n=55)	No change of surgical gloves during the procedure. (Group A+B: n=53)	Postpartum febrile morbidity The diagnosis of endometritis was assigned based on the attending physician's clinical impression in conjunction with the presence of a maternal temperature $\geq 100.4^{\circ}$ F (38° C) occurring 24 hours after caesarean section in combination with a greater than expected uterine tenderness in the absence of another source of infection. Unknown follow-up.	For febrile morbidity: 27.3% with glove change; 18.9% with no glove change. Relative risk: 0.7 (95% CI: 0.3-1.4) For endometritis: 14.5% in the glove change group; 17% in the no glove change group Relative risk: 1.2 (95% CI: 0.5-2.8)	Follow-up period unknown. No validated SSI definition.

Atkinson 1996 (8)	USA 1993-1994	<p>RCT: randomized by opening the next numbered, opaque sealed envelope.</p> <p>Caesarean section (n=643)</p> <p>Four study groups</p> <p>A: No glove change plus manual placental extraction.</p> <p>B: No glove change plus spontaneous placental delivery.</p> <p>C: Glove change plus manual extraction.</p> <p>D: Glove change plus spontaneous delivery.</p>	<p>Change of gloves.</p> <p>If a patient was assigned to either of the glove change groups, the contaminated gloves were removed by the circulating nurse after delivery of the fetus and a sterile pair of gloves was donned.</p> <p>(n= 317)</p>	<p>No change of surgical gloves during the procedure.</p> <p>(n=326)</p>	<p>Endometritis was diagnosed by the finding of a maternal temperature of at least 38°C and either uterine tenderness or foul-smelling lochia in the absence of another clinically obvious source.</p> <p>Unknown follow-up.</p>	<p>27% in the glove change group.</p> <p>26% in the no change group.</p> <p>Relative risk: 1.0 (95% CI: 0.79-1.3; P=0.9)</p>	<p>Blinding unknown. No clear inclusion and exclusion criteria. Follow-up period unknown. No validated SSI definition. Number of patients lost to follow-up unknown. Crude results unknown.</p>
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SSI: surgical site infection; RCT: randomized controlled trial; CI: confidence interval.