

## Clean Cut for Cesarean Section (CLEAN-CS) trial demonstrates improved compliance and decreased maternal and perinatal mortality following cesarean section in Ethiopia.

Addis Ababa, Ethiopia — August 20, 2024 — A <u>study</u> published in <u>JAMA Network Open</u> shows the significant impact of The Checklist Expansion for Antisepsis and Infection Control in Cesarean Section (CLEAN-CS) trial in reducing complications and improving compliance with surgical standards during cesarean deliveries across nine hospitals in Ethiopia.

The CLEAN-CS trial involved 9755 women undergoing cesarean section. It tested a quality improvement intervention developed by <u>Lifebox</u> aimed at enhancing compliance with perioperative care standards and reducing maternal and neonatal complications associated with c-sections in low-resource settings. The trial was funded by a Bill and Melinda Gates Foundation Grand Challenge Grant supported by the UBS Optimus Foundation.

The intervention under evaluation, called Clean Cut, focuses on six critical perioperative infection prevention standards: appropriate skin preparation, maintenance of the sterile field, confirmation of instrument sterility, appropriate antibiotic administration, complete swab counts, and appropriate use of the WHO Surgical Safety Checklist. Compliance with these standards improved significantly following implementation of Clean Cut, from an average of 4.2 to 5.2 out of 6. Each of these standards are critical components of perioperative care, and require attention during every operation.

Although the study did not find a statistically significant reduction in surgical site infections (SSIs), there was a notable decrease in the composite outcome of SSIs, maternal mortality, and perinatal mortality. Maternal mortality decreased from 0.65% to 0.27%, and perinatal mortality reduced from 5.68% to 3.03%.

"This study demonstrates the power of Clean Cut in improving surgical compliance and reducing complications in diverse healthcare settings and specialities," said Dr Tihitena Negussie, Global Clinical Director of Lifebox and co-senior author. "The significant reductions in maternal and perinatal mortality are encouraging and suggest that improved perioperative processes can substantially impact patient outcomes."

Each year, over 22 million cesarean sections are performed globally, with a substantial number taking place in low-resource settings. These surgeries, while lifesaving, carry a high risk of infections and complications, contributing to the alarmingly high rates of maternal and neonatal mortality. The Clean Cut program, designed specifically for such settings, addresses these challenges through a comprehensive quality improvement approach that considers these regions' resource constraints and unique healthcare landscape.

"Data-driven, locally tailored interventions are essential for successful quality improvement. Doing this in the setting of a rigorous trial has enabled us to claim with confidence the power of Clean Cut to improve compliance with critical perioperative care standards," said Prof Thomas Weiser, co-senior author. "By empowering local teams to identify and address process gaps, we can achieve meaningful improvements in surgical safety and make a profound difference in maternal and neonatal health outcomes."

The success of the CLEAN-CS trial highlights the importance of scaling the Clean Cut program to more hospitals in other low-resource settings.

The trial was a collaborative effort between Lifebox, Addis Ababa University, Stanford University, Boston Medical Center, the Ethiopian Society of Obstetricians and Gynecologists, and several Ethiopian healthcare institutions. Additional support was provided by the Fogarty International Center of the National Institutes of Health.

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## **About Lifebox:**

Lifebox is a global nonprofit that saves lives through safer surgery and anesthesia. Through tools, training, and partnerships, Lifebox addresses the critical gaps in surgical systems to make surgery and anesthesia safer worldwide. Lifebox focuses on three core areas: anesthesia safety, surgical teamwork, and reducing surgical infection. Co-founded by Dr. Atul Gawande in 2011, Lifebox has worked in 116 countries and trained more than 13,000 healthcare providers to make 248 million surgeries safer. To learn more about Lifebox, visit <a href="https://www.lifebox.org">www.lifebox.org</a>.

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