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An integrated newborn care kit to save newborn lives and improve health outcomes in Gilgit-Baltistan, Pakistan: an open-label cluster-randomised controlled trial

Daniel Farrar¹, Lisa Pell¹, Yasin Muhammad², Falak Madhani^{3,4}, Shariq Paracha³, Adria Rose¹, Diego Bassani^{1,5}, Imran Ahmed Chauhadry⁴, Muhammad Karim⁴, Nazia Jabeen², Faisal Ali², Masood Ali Khan², Sajid Soofi⁴, Monica Taljaard^{6,7}, Rachel Spitzer^{1,5}, Sifat Wali², Sher Hafiz Khan², Zulfiqar Bhutta^{1,4,5}, Shaun Morris^{*1,5}

¹The Hospital for Sick Children, Toronto, ON, Canada; ²Aga Khan Health Service – Pakistan, Gilgit, Pakistan; ³Aga Khan Health Service – Pakistan, Karachi, Pakistan; ⁴Aga Khan University, Karachi, Pakistan; ⁵University of Toronto, Toronto, ON, Canada; ⁶Ottawa Hospital Research Institute, Ottawa, ON, Canada; ⁷University of Ottawa, Ottawa, ON, Canada

*shaun.morris@sickkids.ca

Introduction

Given the high neonatal mortality in Pakistan, community-based, low-cost, and scalable interventions are needed to prevent newborn deaths and improve newborn and maternal outcomes, particularly among rural populations. We aimed to estimate the effect of an integrated newborn care kit (iNCK) on neonatal mortality, omphalitis, low birthweight identification, and maternal postpartum haemorrhage.

Methods

We conducted an open-label, cluster-randomised controlled trial in Gilgit-Baltistan, Pakistan, from 14 March 2022 to 23 August 2024. Study clusters (n=77) were defined as Union Councils and were randomised (1:1) to either the iNCK group or control group (local standard of care). Lady health workers (LHWs) delivered the iNCK and/or standard of care to pregnant women during routine third trimester home visits. The iNCK included a clean birth kit, 4% chlorhexidine gel, sunflower oil emollient, ThermoSpot™ thermoindicator sticker, fleece blanket, click-to-heat warmer, three 200 µg misoprostol tablets, and educational pictorial guide and diary. Participants were prospectively assessed and administered questionnaires upon enrolment, and at 8 and 29 days after delivery. The primary outcome was the all-cause neonatal mortality rate (NMR). Secondary health outcomes assessed in comparative effectiveness analyses were newborn omphalitis (umbilical cord infection), maternal postpartum haemorrhage, and low birthweight identification. Effect of the iNCK was assessed using generalised estimating equations and multivariable robust Poisson regression, adjusting for reproductive, child, and cluster characteristics. This study is registered with ClinicalTrials.gov (NCT04798833).

Ethics

This study was approved by the Research Ethics Board at The Hospital for Sick Children (REB 1000063672), Ethics Review Committee at Aga Khan University (ERC 5250), and the National Bioethics Committee of Pakistan (NBC 580).

Results

We enrolled 19,344 pregnant women (8,719 in the control group, 10,625 in the iNCK group) and their 19,245 live-born newborns (8,684 in the control group, 10,561 in the iNCK group). Among 9,887 participants in the iNCK group who completed questionnaires on adherence and acceptance, 9,884 (>99.9%) used the iNCK and 9,822 (99.3%) of 9,827 felt it was safe and easy to use. 172 newborns died, 89 in the control group (NMR 10.2 deaths per 1000 livebirths) and 83 in the iNCK group (NMR 7.9 deaths per 1000 livebirths). Risk of neonatal mortality did not significantly differ between iNCK and control groups (risk ratio=0.77, 95% CI 0.52–1.12), and this finding remained non-significant in multivariable analyses (adjusted risk ratio [aRR]=0.92, 0.67–1.27). The iNCK reduced the cumulative incidence of newborn omphalitis (aRR=0.20, 0.12–0.36) and maternal postpartum haemorrhage (aRR=0.43, 0.20–0.92), and it improved the identification of low birthweight newborns (aRR=2.86, 2.20–3.71).

Conclusion

The iNCK might reduce neonatal mortality, and it prevented morbidity among newborns and women in Pakistan. The community-based LHW programme was effective at achieving high uptake and acceptance of the iNCK. The iNCK could be integrated into primary care programmes in high mortality settings.

Conflicts of interest

All authors declare no competing interests.