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REVIEW ARTICLE

Obstetrics

Effective and simple interventions to improve outcomes for preterm infants worldwide: The FIGO PremPrep-5 initiative

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Abstract

Preterm birth remains the leading cause of mortality among under-5's and is a major contributor to the reduction in quality-of-life adjusted years and reduction in human capital. Globally, there are many interventions and care bundles that aim to reduce the impact of preterm birth once preterm labor has ensued and into the neonatal period; not all of these are applicable in all settings. Here, we introduce the FIGO PremPrep-5 initiative, which aims to disseminate key information on the most simple and effective interventions with the aim of increasing implementation globally. Before delivery, we recommend a course of antenatal corticosteroids, and intrapartum magnesium sulfate. At delivery, we recommend delayed cord clamping. Postnatally, we recommend early feeding with breast milk and immediate kangaroo care. While there are many other interventions that may improve outcomes at the time of labor and after preterm birth, these are clinically effective and relatively inexpensive options that can be practiced in most settings and supplemented with more advanced care. We include examples of a training video and infographics that will be used for dissemination.

KEYWORDS
antenatal steroids, breast milk, delayed cord clamping, kangaroo care, low- and middle-income countries, magnesium sulfate, prematurity, preterm birth

1 | INTRODUCTION

The 2023 WHO *Born Too Soon Report* highlights that preterm birth (delivery at viability but before 37 weeks of gestation) remains the greatest contributor to neonatal and infant mortality worldwide, and is one of the greatest contributors to lost human capital.[1] Survivors of preterm birth carry an increased risk of short-term morbidity, including intraventricular hemorrhage and necrotizing enterocolitis, and longer-term complications, such as developmental delay, cerebral palsy, and chronic lung disease.[2,3] In 2020, 10% of infants were born preterm, representing 13.4 million children. Complications of preterm birth remain the leading cause of mortality in under-5's, accounting for approximately 1 million deaths in 2021. Neonatal complications remain the leading cause of reduced daily adjusted life-years of all diseases.[1] There are significant demographic discrepancies in rates of preterm birth, with low- and middle-income countries (LMICs) bearing the burden of over 80% of all preterm deliveries.[4] As well as the large volume of preterm infants, LMICs face the additional challenges of less availability of the high level of neonatal and follow-up care often required by preterm infants, and infrastructural and economic barriers to which high-income countries (HICs) are less exposed.[1] While HICs benefit from care bundles for infants born preterm,[5] the equivalent for LMICs often still presume upon the option of a high level of neonatal care.[6]

While not all aspects of preterm care that are available in HICs easily translate to LMICs, there are several simple, effective, and low-cost interventions that could be implemented in most settings with the potential for significant improvements in neonatal outcomes. Antenatally, these include the administration of maternal corticosteroids and magnesium sulfate, and delayed cord clamping. Postnatally, early breast milk and kangaroo care can be supported. While simple, these are all considered gold-standard care for women at risk of preterm birth and their newborns.

A practical consideration throughout, particularly in antenatal and intrapartum care planning, is the estimation of gestational age. We believe that this should be done by the most sophisticated method available to the unit delivering care, with women informed that care can be stepped up or down if there is evidence of an error after delivery. The lack of availability of ultrasound should not preclude implementation of this care bundle, where symphyseal fundal height or palpation are highly suggestive of a viable but preterm fetus.

Here, we summarize the evidence for these interventions with respect to LMICs and give examples of integration into practice. We propose the introduction of a simple Prematurity Preparation Bundle (referred to as the PremPrep-5) of established effective interventions that are generalizable and offer an educational infographic and video for the dissemination of advice.

2 | ANTENATAL CORTICOSTEROIDS

Antenatal corticosteroid (ACS) therapy is recommended in women with a high risk of preterm birth within 7 days from viability up until the estimated gestational age of 34 completed weeks. Where there is concern that the course will not be completed, the first dose should still be given.

2.1 | The evidence

High-quality global literature confirms the value of ACS for the reduction in perinatal mortality and morbidity, particularly respiratory and neurological morbidity in the preterm infant.[7] The most recent WHO guidance on the administration of ACS advocates for their use across LMICs[8]: an international study of over 2800 women revealed a reduction in neonatal mortality among women in LMICs given antenatal steroids compared to gestation-matched controls without, with a concurrent economic analysis demonstrating a cost-saving effect with intervention in all participating countries.[9,10]

2.2 | Considerations in LMICs

Regarding the choice of ACS (dexamethasone vs betamethasone), more evidence exists for the use of dexamethasone (largely due to its preponderance in HICs) although there is no evidence for superiority of either agent. A meta-analysis has demonstrated no significant difference between the two in terms of perinatal morbidity or mortality.[11] Both are relatively heat-stable, and the choice should be made based on local availability.

Although there are theoretical concerns regarding administering ACS in women with suspected chorioamnionitis, this is not borne out in evidence and individualized decision making should be undertaken. The ACT trial did not demonstrate a significantly higher rate of chorioamnionitis among women in the ACS arm (odds ratio 1.46, 95% confidence interval [CI] 0.81–2.66).[12] From a practical point of view, there is no effective diagnostic tool for the antenatal diagnosis of chorioamnionitis.[13] There is no definitive evidence of worsened maternal outcomes after ACS in women with chorioamnionitis, and their care should be focused on delivery and supportive management of sepsis.

There is a practical recommendation in the current WHO guidance that suggests that ACS should only be given where there is access to neonatal non-invasive ventilation.[8] As most preterm infants worldwide do not have access to such facilities, this policy would preclude most infants who would benefit from ACS from receiving them. There is no evidence that the delivery of ACS in an area that cannot support high-level neonatal respiratory care worsens outcomes.

Where there is certainty about gestational age, there is no reason to give ACS between 34 and 36 weeks, where its benefits are currently not well evidenced. However, if there is uncertainty, the benefits are likely to outweigh harm if steroids are given. Nonetheless, ACS should never be given as a "just-in-case" therapy, given both the lack of benefit from this strategy and the potential risk of harm. A comparison study of 4000 term-born sibling pairs where there was steroid discordance demonstrated a hazard ratio of

1.33 (95% CI 1.26–1.41) for mental and behavioral disorders in those who had received steroids.[14,15]

Where preterm birth is indicated, such as pre-eclampsia, the numbers needed to treat are low and ACS may be justified when gestational age is uncertain. Trials have demonstrated lower rates of respiratory distress syndrome in pre-eclampsia LMIC settings when a majority of women receives ACS late preterm.

The integration of ACS into LMIC care is relatively well established, with multiple studies, such as the ACT and WHO-ACTION trials, demonstrating that intensive education does improve utilization. Utilization of face-to-face training as well as infographics have been demonstrated to increase uptake.

3 | MAGNESIUM SULFATE

Magnesium sulfate should be given to all women in active preterm labor before 30 weeks of gestation. It should be administered over 20–30 min via a peripheral cannula. If cannulation is not available, then 4 g can be given over at least 5 min intramuscularly into the buttock. Where possible, this can be followed by a 1 g/h continuous infusion for up to 24 hours or delivery, whichever is first.

Consideration should be given to the administration of magnesium sulfate beyond 30 weeks where feasible, as there is evidence of benefit between 30 and 34 weeks of gestation, with dosing as above.

3.1 | The evidence

Individual patient meta-analyzed data have demonstrated that the administration of antenatal magnesium sulfate reduces the risk of cerebral palsy or death (relative risk [RR] 0.86, 95% CI 0.75–0.99), with a number needed to treat of 41, falling to 37 when only deliveries before 30 weeks of gestation are included.[16] This is similar to data in a Cochrane review that give a RR 0.68 (95% CI 0.54–0.87) when used before 34 weeks of gestation, with a greater effect seen among infants delivering before 30 weeks of gestation (as would be expected given the higher background rates of cerebral palsy in this group; RR 0.69, 95% CI 0.54–0.88).[17] A recent placebo-controlled randomized trial from Australia and New Zealand demonstrated no difference in survival at 2 years without cerebral palsy after delivery between 30 and 34 weeks of gestation, suggesting that use may be more limited in this cohort.[18]

3.2 | Considerations in LMICs

Magnesium sulfate is cheap, heat-stable, and appears on the WHO's List of Essential Medicines.[19] While cannulation may be a barrier in some settings, intramuscular injection does provide an alternative route of administration. The benefit of continuous infusion after the initial loading dose is uncertain,[17] and while it can be offered where equipment and nursing skill allow, where access is not feasible the loading dose should still be offered. Where financial considerations are required, limiting use to deliveries before 30 weeks of gestation, given its greater efficacy in this group, may be justifiable.

A systematic review investigating reasons for non-compliance by healthcare staff to magnesium sulfate guidelines globally identified particular concerns regarding the toxicity of magnesium sulfate[20]: magnesium toxicity at the regimen suggested is very unlikely,[21] and (perhaps unlike in pre-eclampsia) women are most likely to have preserved renal function, further reducing the risk. Concerns were also raised regarding potential tocolytic effects, and staff can be reassured that these are not founded in evidence.[20,21]

Specific evidence relating to training and education in LMIC settings is lacking. However, a successful national program based in the UK (PReCePT) that aimed to increase the uptake of magnesium sulfate before preterm delivery relied heavily on the training of small numbers of staff across multiple sites who, in turn, could train other staff in interdisciplinary training, as well as infographics and patient information.[22,23] It is conceivable that something similar could be run in LMIC settings and that, given the similarities in methodology with the WHO ACT trial, this may be successful.

4 | DELAYED CORD CLAMPING

Delayed cord clamping (at least 1 min) should be offered to all preterm infants. The only medical exceptions are where there is no fetal heart rate and a member of staff can provide resuscitation, or where the mother requires immediate medical attention.

4.1 | The evidence

A Cochrane review of high-, middle-, and low-income countries reports a likely reduction in neonatal death after delayed cord clamping (adjusted RR 0.73, 95% CI 0.54–0.98). A recent systematic review has demonstrated that in LMICs, delaying cord clamping for 45 seconds or more may decrease the requirement for vasoactive drugs (RR 0.21, 95% CI 0.07–0.59). The same study also demonstrated an increase in hematocrit after delivery, with a reduced requirement for transfusion in the neonatal period (RR 0.44, 95% CI 0.21–0.91).[24] There is no clear evidence of harm when delayed cord clamping is implemented, and there is some evidence of reduced incidence of anemia at 12 months. Infants should be kept warm during delayed cord clamping. There is evolving evidence of various improved outcomes in both infancy and childhood, including a reduced incidence of anemia before the age of 12 months, and some improvements in developmental outcomes in children aged up to 4 years.[25–27] Reasons to clamp the cord at under 1 min include no detectable fetal heart rate after stimulation, or acute maternal concerns that cannot be managed while the cord remains unclamped either for medical or practical reasons, for example

(but not limited to), cardiac arrest, massive ongoing hemorrhage, or ongoing eclampsia.

4.2 | Considerations in LMICs

Increasing adherence to delayed cord clamping will rely mainly on education. One small study from Iran demonstrated that the training of ward nurses and midwives increased the average time of umbilical cord clamping from 13 to 62 seconds in infants weighing over 1500 g,[28] with similar findings in a study set in a rural Honduran community hospital.[29]

5 | BREAST MILK

Infant feeding should commence within 1 hour of delivery wherever possible, and the first feed should be breast milk.

5.1 | The evidence

The benefits of breast milk to the preterm infant are extensive and include reductions in feeding intolerance, late onset sepsis, retinopathy of prematurity, and, most significantly, necrotizing enterocolitis. These benefits persist where donor breast milk is given, although there are concerns that the dietary and immune value may not match exactly if it has been expressed at a gestation different to that of the infant and been through any form of storage process. Breast milk is also associated with improved neurological outcomes. Furthermore, early breastfeeding improves mother–infant bonding and encourages maternal involvement in the care of her infant even while in hospital.[30]

5.2 | Considerations in LMICs

The WHO and UNICEF have an established program to promote breastfeeding among preterm infants (*The Baby-Friendly Hospital Initiative for Small, Sick and Preterm Infants*), which relies on antenatal information, immediate postnatal care and support with breastfeeding (including mothers staying on neonatal care units with infants), and appropriate supplementation.[30] While this is for global use, evidence specific to LMICs has demonstrated that as well as hospital-level interventions, the use of peer support and mentoring in the community improves the initiation and longevity of breastfeeding of preterm infants.[31]

While breastfeeding rates are higher in LMICs than HICs, even in low-income countries, only approximately 37% of children are exclusively breastfed for 6 months.[32] Work to prevent the aggressive promotion of breast milk substitutes is promoted by The International Code of Marketing of Breastmilk Substitutes. However, national efforts to abide by this code can be limited, and effective implementation must be promoted by healthcare professionals.[33] Finally, healthcare professionals have a responsibility to ensure that medical treatment considers breastfeeding to be a gold standard within the infant's care and does not involve policies, such as mother–infant separation, that would contradict this position – ongoing adherence to the *WHO UNICEF Baby Friendly Initiative* as an integrated part of health care is likely to bring significant benefit here.

Specific to women with HIV, WHO recommends exclusive breastfeeding for at least 12 months concurrent with full adherence to an antiretroviral therapy regimen, which can be extended to 24 months if the mother wishes. They also recommend that communities and national health services work to implement strategies to ensure this can be achieved. Working on the acceptable, feasible, affordable, sustainable, safe (AFASS) principles, they recommend that when antiretrovirals are not easily available, health services both work to make these accessible and continue to promote breastfeeding. Conditions in which formula feeding is recommended include safe sanitation at the national and household levels, continuous access to formula, and access to comprehensive child health care.[34]

Access to donor milk is also potentially more complex in LMICs, where facilities for quality assurance and storage of donor milk may be less common. Vietnam's first milk bank has provided strong evidence that establishing both regular donors and a safety infrastructure is achievable after the publication of the outcomes of their first 4 years of operation, where 82% of donated milk passed pre- and post-pasteurization tests, and 16 235 infants received donor milk.[35] Elsewhere, a study from Nigeria has demonstrated that while knowledge of donating breast milk was low, it was acceptable among women who did understand the concept,[36] highlighting the potential benefits of widening education among women both in terms of increasing donors and increasing consent for infants to be given donated milk.

6 | KANGAROO CARE

Kangaroo care should be offered as part of the care for all preterm infants. It should be offered continuously and commence within the first 24 hours of life. The only reasons for a delay in commencing kangaroo care are if the infant is not breathing independently after initial resuscitation, is hemodynamically unstable, or is receiving mechanical ventilation.

6.1 | The evidence

Kangaroo care describes continuous skin-to-skin contact between the infant and their parent or carer. It should be offered continuously, but for a minimum of 8 hours per day.[37] There is a likely dose-dependent effect with more kangaroo care conferring greater benefit.[38] The provision of kangaroo care for preterm or low birth

weight infants is associated with a reduction in neonatal mortality for both infants being cared for at home and those being cared for in healthcare facilities. For infants weighing at least 1.5 kg at birth, kangaroo care reduces mortality by approximately 30%, regardless of whether the infant is being cared for at home or in a healthcare facility.[39] A second study looking at infants in hospital only and weighing 1–1.8 kg suggests a mortality reduction of 25% when kangaroo care is utilized, even when initial stabilization cannot be carried out.[40] These findings have been borne out in a meta-analysis, which also points to a probable greater impact in LMICs.[38] Furthermore, where kangaroo care is commenced within 24 hours of birth (rather than delaying beyond this point), there is a reduction in nosocomial sepsis and hypothermia.[38]

Kangaroo care improves parent–infant bonding and increases parental confidence in looking after their infant[41,42]; it has also been shown to reduce severe postnatal depression.[42] A longer-term follow-up of infants who participated in randomized controlled trials of kangaroo care demonstrated better neurological, behavioral, and education outcomes in children who had kangaroo care than those who did not.[43]

6.2 | Considerations in LMICs

While kangaroo care instinctively seems straightforward to implement in terms of its cost-effectiveness and minimal requirement for equipment, practical issues do need to be considered. For continuous kangaroo care to be offered, there must be constant access to neonatal care facilities for parents, and consideration of the best place of care for the mother and infant if the mother is unwell. The early involvement of fathers should also be encouraged and their access to the infant must not be restricted.[37] This is likely to require a reorganization of services, including in intensive and high-dependency care environments that must be combined with the training of staff to facilitate kangaroo care. The WHO's iKMC study carried out in multiple sub-Saharan countries and India required a redesign of neonatal care units to include beds, bathroom facilities, and meals for mothers to facilitate 24-hour maternal care. Postnatal maternal healthcare was also integrated into the same area.[40] Nonetheless, we should strive for a minimum of 8 hours per day of kangaroo care while services are being restructured to allow for continuous kangaroo care.

7 | THE PremPrep-5

The five interventions discussed here are associated with improved neonatal outcomes after preterm delivery. Two rely on access to cheap, heat-stable drugs that are listed on the WHO's Essential Medicines formulary and that can be given intramuscularly. The other three require no drugs or additional medical equipment and can be implemented with minimal resources. They represent basic perinatal interventions that, when used together, have the potential to reduce perinatal mortality and morbidity secondary to preterm birth and can be easily adopted in most settings. The largest challenges in implementation are likely to relate to promoting the benefits of these interventions over current practices that may be resistant to their application.

To better communicate these interventions and their benefits to a global audience, we propose the PremPrep-5 Care Bundle. In order to promote these interventions, this bundle will initially include an educational video (Video S1) that can be translated as required, infographics that can be used as posters in units, and that can be scaled down for use as checklists for individual patients.

There are many more interventions that could potentially improve outcomes once preterm labor has ensued, for example the transfer of patients to units with higher-level care and intrapartum antibiotics, or neonatally, for example caffeine, probiotics, volume-guided mechanical ventilation, and low-dose hydrocortisone. While the appropriate use of these interventions is to be commended, we have focused here on cheap, universally applicable interventions with an excellent evidence base across most settings to lay the foundations for good perinatal care for preterm infants born in all settings. For more advanced care bundles, examples such as the *WHO Recommendations for the Care of the Preterm or Low Birthweight Infant* can be followed.[8] There is now a need for dissemination via appropriate channels, such as FIGO member societies, and, where possible, to evaluate the impact in order to define the health and economic benefits for policymakers and inform international guidelines.

8 | CONCLUSION

Preterm birth remains the major cause of mortality among under-5's worldwide. Increasingly complex perinatal interventions have improved survival overall. We describe five basic interventions, all of which are associated with reduced mortality or morbidity, and that can be carried out in all settings. While more complex interventions should also be offered wherever available, these should form the basis of care of women in preterm labor or newborn preterm infants.

AUTHOR CONTRIBUTIONS

MH and AS conceived the idea. All authors developed the components of the bundle. MH prepared the original draft. All authors reviewed and edited the draft and approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

BJ reports research grants from Swedish Research Council and the US National Institute of Health; clinical diagnostic trials on NIPT with Natera (completed) with expenditures reimbursed per patient; clinical probiotic studies with product provided by FukoPharma (ongoing) and BioGaia (ongoing; also provided a research grant for the specific study); BJ is also FIG Division Director of Maternal and Newborn Health and the European Association of Perinatal Medicine's special interest group of preterm delivery; steering group member of Genomic Medicine Sweden; chairs the Genomic Medicine Sweden complex diseases group; and is the Swedish representative in the Nordic Society of Precision Medicine. MH, CMV, PS-P, KL, and AS have no conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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