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Research Article
Intrapartum care

Modification of oxytocin use through a coaching-based intervention based on the WHO Safe Childbirth Checklist in Uttar Pradesh, India: a secondary analysis of a cluster randomised controlled trial

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Objective To understand the prevalence of intrapartum oxytocin use, assess associated perinatal and maternal outcomes, and evaluate the impact of a WHO Safe Childbirth Checklist intervention on oxytocin use at primary-level facilities in Uttar Pradesh, India.

Design Secondary analysis of a cluster-randomised controlled trial.

Setting Thirty Primary and Community public health facilities in Uttar Pradesh, India from 2014 to 2017.

Population Women admitted to a study facility for childbirth at baseline, 2, 6 or 12 months after intervention initiation.

Methods The BetterBirth intervention aimed to increase adherence to the WHO Safe Childbirth Checklist. We used Rao-Scott Chi-square tests to compare (1) timing of oxytocin use between study arms and (2) perinatal mortality and resuscitation of infants whose mothers received intrapartum oxytocin versus who did not.

Main outcome measures Intrapartum and postpartum oxytocin administration, perinatal mortality, use of neonatal bag and mask.

Results We observed 5484 deliveries. At baseline, intrapartum oxytocin was administered to 78.2% of women. Two months after intervention initiation, intrapartum oxytocin (I) was administered to 32.1% of women compared with 70.6% in the control (C) ($P < 0.01$); this difference diminished after the end of the intervention (I = 48.2%, C = 74.7%, $P = 0.03$). Partograph use remained at <1% at all facilities. Resuscitation was performed on 7.5% of infants whose mother received intrapartum oxytocin versus 2.0% who did not ($P < 0.0001$).

Conclusions In this setting, intrapartum oxytocin use was high despite limited maternal/fetal monitoring or caesarean capability, and was associated with increased neonatal resuscitation. The BetterBirth intervention was successful at decreasing intrapartum oxytocin use. Ongoing support is needed to sustain these practices.

Keywords India, oxytocin, quality of care, WHO Safe Childbirth Checklist.

Tweetable abstract Coaching + WHO Safe Childbirth Checklist reduces intrapartum oxytocin use and need for newborn resuscitation.

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Introduction

Childbirth remains a time of high risk for women and their newborns, particularly in resource-limited settings.[1] Despite the increase in facility-based childbirth, the provision of high quality, safe childbirth care remains a challenge.[2–4] Effective labour management and early identification of complications are critical to reduce mortality, particularly

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at primary-level facilities without the resources or capability for Comprehensive Emergency Obstetric Care.[3] In low-resource settings, quality of care deficits are often characterised as care that is 'too little, too late',[5] and solutions are often focused on increasing staffing, infrastructure, supplies and training.[4] However, the more-is-better approach has limitations, as we have seen in higher-resource settings where over-medicalisation of childbirth can also lead to poor outcomes.[5]

It is widely accepted that oxytocin should be administered intramuscularly to women during the third stage of labour (immediately after delivery of the baby) to prevent postpartum haemorrhage. The increased availability and use of oxytocin postpartum has helped to decrease haemorrhage.[6] Oxytocin is also used in the intrapartum period to augment labour, specifically to shorten labour and increase contraction strength.[7] To avoid harm associated with this practice, the WHO recommends that fetal heart rate and contraction patterns be closely monitored during oxytocin augmentation and that augmentation should only occur in facilities that are able to manage potential sequelae, including the need for a caesarean delivery.[8]

The WHO Safe Childbirth Checklist is a bedside quality improvement tool to standardise evidence-based steps for healthcare workers to follow.[9] The Checklist addresses issues related to 'too little, too late' by listing actions required at four critical timepoints during childbirth: on admission, just before pushing, within 1 hour of delivery, and before discharge. Studies have evaluated the effectiveness of the Checklist in promoting desired practices but it is less understood whether a checklist-based coaching intervention can discourage unnecessary or potentially harmful practices.[10,11] This secondary analysis is based on the BetterBirth study, which found that the Checklist resulted in higher adherence to practices but had no impact on mortality.

The objective of this secondary analysis is to understand the prevalence of in-facility oxytocin use, to assess the impact of the BetterBirth intervention on intrapartum and postpartum oxytocin use, and to assess the perinatal and maternal outcomes associated with intrapartum oxytocin use at primary-level facilities in Uttar Pradesh, India.

Methods

Study design

The BetterBirth Trial was a matched-pair, cluster-randomised control trial that took place in 120 primary and community public health facilities in Uttar Pradesh, India, from 2014 to 2017. Sixty facilities were randomised to an intensive 8-month coaching-based programme aimed at increasing adherence to the Safe Childbirth Checklist, while the remaining 60 facilities maintained the current standard of care. The intervention began with a motivational training to introduce the Checklist at each intervention facility.[12] A coach, an independent nurse, was assigned to work with birth attendants to motivate changes in practice to adopt the Checklist and support birth attendants in problem-solving to overcome barriers. The Checklist is composed of 28 essential birth practices that are divided into four pause-points during childbirth (on admission, just before pushing or caesarean delivery, shortly after delivery, and before discharge). The coaching intervention aimed both to reduce routine intrapartum use of oxytocin and to increase oxytocin use during the active management of the third stage of labour for the prevention of postpartum haemorrhage.

Direct observation of labour and delivery was carried out in a convenience sample of 30 facilities (15 intervention, 15 control) in and around Lucknow, the capital of Uttar Pradesh. Observations occurred at baseline, 2, 6 and 12 months after the start of the intervention. At baseline and 6 months, only a subset of these facilities (10 facilities; five intervention and five control) were observed, as these time points were added after the initial trial design to better understand behaviour change over time (Figure 1). Further details and sample size calculations are described in detail elsewhere.[13] In the direct observations, trained nurses who were independent of both the facilities and the intervention coaching staff, were assigned to observe adherence to the Checklist and care provided to all or almost all birthing women and their newborn(s) from admission to 1 hour after delivery, including whether oxytocin was administered prior to delivery (presumably for labour augmentation) as well as within 1 minute after birth for the prevention of postpartum haemorrhage. Observers did not intervene in care but a notification system was in place in the case of an emergency or if there were critical concerns about the care provided.

In addition to direct observations, an overlapping cohort of women at these same facilities received a phone call between 8 and 42 days after delivery to obtain information on 7-day maternal and perinatal outcomes. When women could not be reached by phone, a field worker made a home visit to determine health outcomes. Due to the differing timing of recruitment, not all women whose labour was observed were enrolled in the health outcomes portion of the study.

Participants

Women admitted to a study facility for childbirth were eligible for the study. Women who were referred from another facility, delivered outside of the facility or admitted for an abortion were excluded. In these directly observed births, women or their surrogates provided written informed consent to be observed. Additionally, verbal

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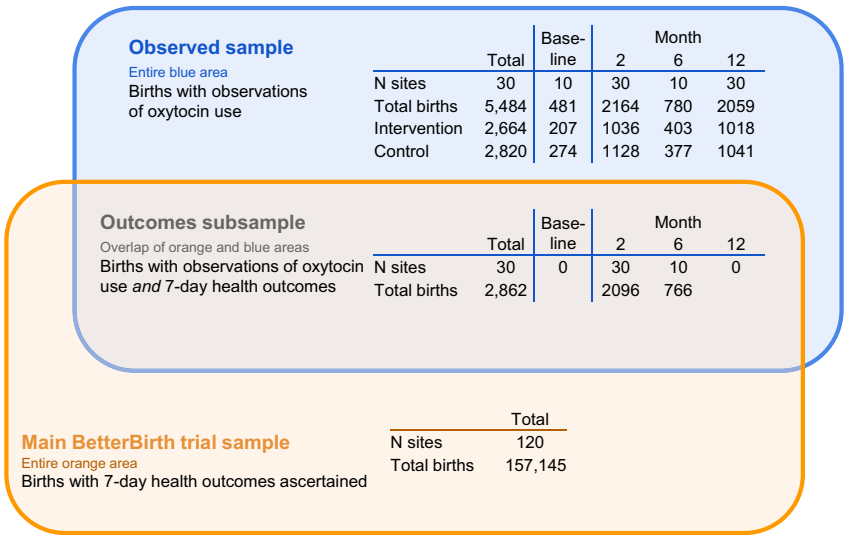

Figure 1. Description of the analytic sample. Blue area = observed sample (Births with observation of oxytocin use); Orange area = main BetterBirth Trial Sample (births with 7-day health outcomes ascertained); overlap of blue and orange areas = outcomes subsample (births with observations of oxytocin use and 7-day health outcomes).

consent was confirmed in follow-up calls to assess 7-day newborn outcomes and maternal morbidity. Birth attendants gave consent prior to the start of the trial and verbally confirmed consent before each observation.

Variables

Direct observers documented a standardised list of Safe Childbirth Checklist-related behaviours. Among the behaviours, binary information was obtained on oxytocin use before and after delivery, as well as partograph use and the use of a neonatal bag and mask. Oxytocin dosage, frequency of administration, exact timing (hour and minute), and drug potency were not documented as part of this protocol. The administration of misoprostol and methergine were documented only at the 12-month time point, after the intervention and data collection on health outcomes had been completed and therefore we excluded the administration of these drugs from this analysis due to a lack of comparable data. Measured health outcomes of interest included stillbirth, perinatal mortality, maternal postpartum haemorrhage, caesarean delivery and maternal mortality within 7 days of birth. The number of total births were extracted from facility registers, including documentation of stillbirth and in-facility deaths. All other health outcomes were self-reported by the patient or family.

We additionally assessed differences in oxytocin use by facility type and distance to district hospital, and ascertained whether birth attendants were administering oxytocin more during the last hour of their shift to encourage that a delivery (and associated payment) would occur. The trial was designed in 2011, before the launch of the core variable set initiative,[14] and thus core variable sets were not used. Subsequent core variable sets related to the use of oxytocin to augment labour have since been established, which could be used to strengthen the design of future related studies.[15]

Bias

To ensure data quality, a subset of births were observed by two data collectors and documented in a rigorous data quality assurance protocol.[16] Observer data had to match this secondary observation data exactly to be considered accurate. One or two observers were present at each facility; study staff observed one woman's case at a time (from admission to 1 hour after delivery). Observations took place during daylight hours due to safety concerns of study staff, which meant that not every stage of labour was observed for every case. Independent observers did not share their observation data with facility staff. Although birth attendants were aware of assignment to intervention or control, data collectors at call centres were unaware of the facility assignment when collecting patients' self-reported health outcomes.

Data analysis

We used Rao-Scott chi-square tests to compare (1) the timing of oxytocin use between the intervention and control arms, accounting for the matched-pair, cluster design and (2) health-related outcomes within 7 days of delivery, including perinatal mortality, caesarean delivery, neonatal bag-and-mask use, stillbirths and maternal morbidity for women who received intrapartum oxytocin versus those who did not. We did not stratify health outcomes analyses by intervention and control due to the reduced sample size

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available for health outcomes and the infrequency of morbidity and mortality, although we do provide the raw data for consideration. Analyses were adjusted for clustering at the facility level. We used a cut-off for significance of $P < 0.05$.

Ethics and patient participation

The BetterBirth trial protocol was approved by ethics committees at Community Empowerment Lab, Jawaharlal Nehru Medical College, the Harvard T.H. Chan School of Public Health, Population Services International, WHO, and the Indian Council of Medical Research. An independent Scientific Advisory Committee and a separate Data Safety and Monitoring Board met regularly throughout the trial. The BetterBirth trial and secondary analyses were funded by the Bill & Melinda Gates Foundation (INV-005587), who reviewed the trial design but were not involved in the data collection, analysis, interpretation or decision to submit this manuscript for publication. Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) (T76MC00001) also provided funding for this secondary analysis but were not involved in any aspect.

Patient representatives provided input on the design of the Safe Childbirth Checklist. A scientific advisory committee, comprised of global and local clinicians, researchers and government officials from Uttar Pradesh and Ministry of Health & Family Welfare, consulted on the overall BetterBirth trial research questions and design. There was no patient or public involvement in this committee, or for this secondary analysis on oxytocin use. Preliminary results of this secondary analysis were shared for feedback in India at the launch of the BetterBirth report and at a global conference (FIGO).

Results

Trained independent nurses observed 5484 deliveries from 30 health facilities; perinatal and maternal health outcomes were recorded on 2862 of the observed deliveries (Figure 1). Characteristics of the observed facilities, as well as characteristics of the women and newborns, were similar between intervention and control facilities (Table 1). The 30 facilities consisted of eight primary health centres, 18 community health centres, and four first referral units; no district hospitals or higher-level facilities were included in the study. During the year-long study, six of the 30 facilities performed any caesarean deliveries.

Labour augmentation

At baseline, oxytocin was observed to be administered prior to delivery in 78.2% of births ($n = 376/481$; 77.8% intervention, 78.5% control). After 2 months of the coaching intervention, observers at intervention sites recorded 32.1% ($n = 333/1036$) intrapartum oxytocin use compared with 70.6% ($n = 796/1128$) in control sites ($P < 0.01$). The sustainability of behaviour change was assessed 12 months after the initiation of the coaching intervention (4 months after the last coaching visit): intervention sites continued to have lower pre-delivery oxytocin use than control sites, with 48.2% use in intervention sites ($n = 491/1018$) and 74.7% in control sites ($n = 778/1041$; $P = 0.03$) (Figure 2). Among all women who received oxytocin before delivery, 76.1% received it intravenously—27.4% as an intramuscular injection and 3.5% intravenously and intramuscularly. Despite the frequent use of intrapartum oxytocin, partographs were infrequently used to monitor labour progress and fetal condition; at baseline, partographs were not used at any facility and showed minimal uptake (<1%) with the coaching intervention. The frequency of fetal heart monitoring and contraction monitoring were not documented separately from partograph use, although supply audits found that fetal monitoring supplies (fetoscope or doppler) were available at 23% of facilities at baseline. The availability of fetal monitoring supplies increased to 63% of facilities by the end of the study (Table 1). We found no difference in pre-delivery oxytocin administration based on birth attendant shift times, facility type or proximity to a district hospital.

Postpartum oxytocin administration (haemorrhage prevention)

At baseline, oxytocin was correctly administered following delivery to prevent postpartum haemorrhage in only 25.2% of women ($n = 121/481$). After 2 months of the coaching intervention, observers at intervention sites recorded 79.5% ($n = 824/1036$) postpartum oxytocin use compared with only 20.5% ($n = 231/1128$) in control sites ($P < 0.0001$). At 12 months after the initiation of the coaching intervention (4 months after the last coaching visit), intervention sites continued to have higher postpartum oxytocin provision (53.9%) compared with control sites (14.8%, $P < 0.0001$) (Figure 2).

Health outcomes

Among all observed births ($n = 5484$), neonatal resuscitation was performed on 7.5% (247/3291) of neonates whose mother had received oxytocin for labour augmentation compared with only 2.0% (44/2193) of neonates from births without oxytocin administration (relative risk [RR] 3.74, 95% CI 2.37, 5.90, $P \leq 0.0001$; Table 2). Among deliveries with known health outcomes ($n = 2862$), perinatal mortality was higher in births where intrapartum oxytocin was provided (54.5 deaths per 1000 births) than in those without intrapartum oxytocin (37.2/1000; RR 1.47,

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Table 1. Facility and patient characteristics*

	Overall	Intervention	Control
Facility characteristics			
No. of facilities (*n*)	30	15	15
Type of facilities (%)			
PHC	26.7	26.7	26.7
CHC	60.0	53.3	66.7
CHC-FRU	13.3	20.0	6.7
Annual delivery load, mean (95% CI)	1939 (1555–2323)	1957 (1441–2472)	1921 (1616–2227)
C-section ever performed at facility during trial (~1 year)	20%	20%	20%
Baseline supply availability for fetal monitoring (%)			
Fetoscope	20	26.7	13.3
Doppler	3.3	6.7	6.7
Either fetoscope or Doppler	23.3	26.7	20
Maternal characteristics			
No. of women with data (*n*)	2862	1390	1472
Maternal age, mean (95% CI)	25.8 (25.5–26.0)	25.8 (25.4–26.1)	25.8 (25.4–26.2)
Parity (%)			
0	35.2	33.9	36.4
1–3	58.4	60.5	56.5
4+	6.4	5.6	7.1
	Missing = 880	Missing = 443	Missing = 437
Preterm (%)	21.8	24.8	18.9
	Missing = 271	Missing = 145	Missing = 126
Twins (%)	0.7	0.6	0.9
Newborn characteristics			
No. of newborns with data	2883	1398	1485
Birthweight, mean (95% CI)	2822 (2796–2849)	2823 (2765–2882)	2821 (2767–2876)
Low birthweight (≤2500 g) (%)	34.4	33.5	35.3
Sex of baby (% male)	51.2	50.6	51.8

*Adjusted for facility; variables with missingness greater than 5% are noted in Table 1.

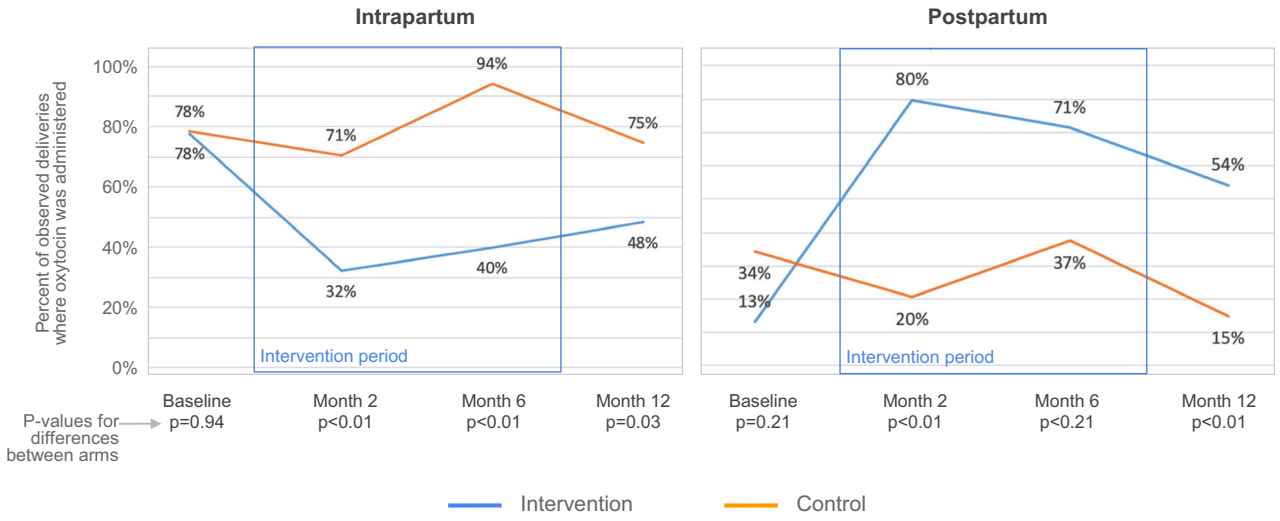

Figure 2. Observed oxytocin administration at primary and community health centres in Uttar Pradesh, India. Blue line: average oxytocin use in intervention facilities; orange line: average oxytocin use in control facilities.

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Table 2. Perinatal health outcomes associated with intrapartum oxytocin administration

	Overall				Intervention		Control	
	Received oxytocin	No oxytocin	Risk ratio	*P*-value	Received oxytocin	No oxytocin	Received oxytocin	No oxytocin
Perinatal mortality per 1000 births (*n*/*N*)	54.5 (87/1597)	37.2 (47/1265)	1.47 (95% CI 0.99–2.16)	0.055	71.6 (34/475)	30.6 (28/915)	47.2 (53/1122)	54.3 (19/350)
Use of neonatal bag and mask, % (*n*/*N*)	7.5% (247/3291)	2.0% (44/2193)	3.74 (95% CI 2.37–5.90)	<0.0001	6.7% (77/1146)	2.3% (35/1518)	7.9% (170/2145)	1.3% (9/675)

95% CI 0.99–2.16), although the *P*-value of 0.055 was slightly higher than our cut-off for significance.

We found no difference in stillbirth or maternal morbidity rates, including postpartum haemorrhage, associated with intrapartum oxytocin use. There was no significant reduction of postpartum haemorrhage for women who received oxytocin after delivery. There were no maternal deaths and a limited number of caesarean deliveries in our observed dataset; thus, we are unable draw make any conclusions related to oxytocin use and maternal mortality or caesarean delivery.

Discussion

Main findings

In public primary health facilities with limited maternal/fetal monitoring offering basic emergency obstetric care in Uttar Pradesh, India, the augmentation of labour with oxytocin is pervasive and is associated with an increased incidence of neonatal resuscitation and perinatal death. However, facilities that received the Safe Childbirth Checklist-based coaching intervention had substantially lower intrapartum use of oxytocin than the control after 2 months of the intervention, and sustained that decrease 4 months after the end of the intervention. Additionally, the intervention was associated with increased administration of oxytocin immediately after delivery, which can help to prevent postpartum haemorrhage,[6] although it was not associated with any health benefits in our sample.

Interpretation

As global efforts to increase facility-based childbirth continue, ensuring high quality care remains a challenge. In India, nationwide efforts have increased institutional deliveries to 79%,[17] yet the provision of high-quality care has struggled to keep up with demand, particularly at the primary level.[18] Oxytocin can be an important medication in the intrapartum period: the safety profile of oxytocin is well-documented[19] and intrapartum use has been found to shorten the duration of labour.[20] In high-resource settings, with routine labour monitoring and easy access to emergency care, the use of oxytocin is not associated with increased adverse outcomes.[7,20] However, without these resources, we found that the intrapartum use of oxytocin was associated with increased neonatal resuscitation and perinatal mortality. Additionally, more than a quarter of women in the study received oxytocin intramuscularly, which is not recommended due to the inability to titrate the medication in the case of uterine hyperstimulation or fetal distress.

Other studies have similarly found that intrapartum use of oxytocin in low-resource settings is associated with stillbirth, neonatal death, intrapartum-related respiratory

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depression, neonatal encephalopathy and maternal severe postpartum haemorrhage.[21–23] Qualitative studies from Uttar Pradesh and elsewhere have found that intrapartum oxytocin use is often described by practitioners and patients as being part of 'modern medicine' and the standard of care for childbirth,[24–26] as well as an aid to strengthening 'labour pains', expediting delivery and thus alleviating crowding at facilities.[24,27] The more-is-better approach prevails, and the risks associated with oxytocin are not widely acknowledged, particularly among women and community-based birth attendants.[26]

There is no agreed-upon optimal rate of uterotonic use for labour augmentation; rates of use range from 1% of home births up to 92% of facility births, depending on geography and proportion of primiparas.[28,29] However, WHO guidelines recommend that intrapartum oxytocin administration be avoided altogether in facilities without monitoring and caesarean capabilities, including most of the facilities in the study. Thus, changing healthcare worker behaviour is critical to reducing harm; reducing patient demand for oxytocin may be a key driver for sustaining that harm reduction.

The BetterBirth intervention was successful in dramatically lowering rates of intrapartum oxytocin use and increasing postpartum use. Other studies have found that checklists alone rarely change behaviour.[30] The peer-to-peer coaching strategy was key to identifying barriers, providing hands-on troubleshooting, and for ultimately shifting birth attendants' behaviour. For example, the version of the Checklist used with the intervention did not explicitly say not to give oxytocin before delivery, but its absence on the Checklist was a reminder that intrapartum oxytocin was not considered best practice or the standard of care. The Checklist did instruct that oxytocin should be given to every woman within 1 minute of delivery, a practice that showed a six-fold increase between baseline and 2 months. Intervention facilities continued to show reduced intrapartum use and increased postpartum use of oxytocin compared with the control after the completion of the 8-month intervention, although some decay is noted. Ongoing support and supervision of birth attendants is needed to sustain these practices.

Strengths

This secondary analysis offers actionable insights on how a coaching intervention can encourage birth attendants to change their behaviour related to oxytocin administration after 2 months. Decreasing intrapartum oxytocin use in the absence of appropriate maternal/fetal monitoring and access to caesarean deliveries could help to reduce the persistently high rates of neonatal asphyxia and perinatal deaths in Uttar Pradesh and in similar settings around the globe. This secondary analysis relies on data collected through direct observation of care, which is considered a gold standard in assessing outcomes. The matched-pair cluster-randomised controlled design of the overall study increases confidence in the findings.

Limitations

Although direct observation is considered gold standard, it also introduces the potential for a Hawthorne effect, whereby staff behaviour is different when being observed. However, researchers have found that the Hawthorne effect decays after more than 10–15 visits,[31] and the persistent daily presence of observers over a series of months is unlikely to have been overly affected by this. We were limited to only observing daytime deliveries due to safety concerns of research staff; it is possible that childbirth practices differ at night. Additionally, we do not have data on oxytocin administration that may have occurred before a woman's arrival at the health facility, which other studies have reported to be common,[24] or on the dosage or frequency of oxytocin administered to a woman at a facility, all factors that could potentially impact the associated health outcomes that we studied. Patient or public participation in the selection of research questions and design of the larger trial may have strengthened the study and resulted in fewer limitations. We did not measure the potency of the oxytocin, which has been found to be poor quality in many low resources settings,[32] including India,[33] a limitation that is likely evenly distributed across intervention and control sites, but which may have affected our results on health outcomes. We considered the risk of confounding by indication, whereby only women who had complications received oxytocin and thus had a higher risk of perinatal mortality and need for neonatal resuscitation independent of oxytocin use, but the baseline rate of oxytocin administration of 78% suggests that oxytocin was given as a standard of care rather than for a perceived complication. Although it would have been helpful to assign causation, we were limited by the study design. All facilities in our sample were clustered around Lucknow, the capital of Uttar Pradesh, for convenience of observation; this may limit the generalisability of the findings despite the matched-pair randomised study design. Finally, we would have liked to have complete health outcome data for all observed cases, but were constrained by the design of the larger BetterBirth trial.

Conclusion

The overuse of medical interventions, including the routine use of oxytocin to inappropriately augment labour, is a growing concern globally. While many health ministries and programmes in low-resource settings strive to address 'too little, too late' concerns, it is important to reflect that

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more does not always mean better. The BetterBirth intervention, which utilised a peer-coaching approach with the Safe Childbirth Checklist, was able to change healthcare worker practices related to oxytocin in a relatively short time period. Ongoing training and guidance for facility staff, community health workers and birthing women is needed to reinforce potential harm of oxytocin when it is used to augment labour inappropriately, and to emphasise that, if administered, fetal and contraction monitoring and an action-ready plan are needed to identify and address fetal distress early. Increasing patients' and birth attendants' knowledge around the postpartum benefits of oxytocin could help to drive and sustain its use.

Further research is needed to determine whether there is an optimal rate of intrapartum oxytocin use and to explore safer strategies to augment labour at primary level facilities. Additional research with greater patient and public participation and guidance is needed to understand how to reduce community demand for labour augmentation and address women's underlying concerns that help to drive intrapartum oxytocin use. The timing of oxytocin administration is critical: unmonitored intrapartum administration may cause harm, whereas postpartum administration may save lives. Encouraging this practice change, particularly at primary-level facilities, can reduce intrapartum-related complications and ultimately improve the quality of care.

Disclosures of interests

None declared. Completed disclosure of interest forms are available to view online as supporting information.

Contribution to authorship

MMD, KEAS, KM and VK conceived of this secondary analysis and design. TK supported the planning and execution of the intervention. BH, BJN and KM contributed to the analysis. MMD and RK drafted the manuscript. All authors contributed to the interpretation of findings and revision of the manuscript. All authors have agreed with the final version and agree to be accountable for the work.

Details of ethics approval

The BetterBirth study protocol was approved by the ethics committees of: Community Empowerment Lab (Ref no: 2014006, approved 30 April 2012), Jawaharlal Nehru Medical College (Ref no: MDC/IECHSR/2015–16/A-53, approved 5 May 2012), Harvard T.H. Chan School of Public Health (Protocol 21 975–102, approved 30 March 2012), Population Services International (Protocol ID: 47·2012, approved 28 November 2012), WHO (Protocol ID: RPC 501, approved 7 May 2012) and Indian Council of Medical Research (approved 25 September 2012). The protocol was reviewed and re-approved on an annual basis.

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Data availability

The data repository will be available upon publication on Harvard University Dataverse and will include de-identified data and a data dictionary. ■

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