Labour Management: Oxytocin in the context of the Millennium Development Goals

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Abstract:

The appropriate use of oxytocin, one of the drugs on which we are focusing in the 'Tracing Pharmaceuticals' project, is directly linked to Millennium Development Goals 4 and 5 (relating to child mortality and maternal health). Safe Motherhood initiatives have included Active Management of Third Stage of Labour (AMTSL) as a central part of the strategy to reduce maternal and perinatal morbidity and mortality. Recommendations for AMTSL include the administration of oxytocin by intramuscular injection to help prevent post-partum haemorrhage (PPH), one of the key causes of maternal mortality throughout the developing world. Yet these proposals seem to ignore the realities of access to and use of medicines in the Global South. Many drugs, including oxytocin, have lives independent of policy interventions. In this paper, we argue that focusing on pharmaceuticals use 'on the ground' can illuminate some of the problematic relationships between labouring women's experiences in the Global South and the policies put in place to ameliorate them.

We begin by outlining the clinical guidelines for oxytocin use, both intrapartum and postpartum. Then we present material from our project and from other studies in India and Nepal that indicate that oxytocin is readily available in the region and that report on the unmonitored use of oxytocin intrapartum (generally administered by IM injection) in rural home deliveries. Such use can result in adverse outcomes, including uterine rupture and foetal asphyxia. During our project, we also interviewed obstetricians and policy makers. Obstetricians working in small towns, or those with rural work experience, generally seemed familiar with this use of oxytocin; those working in large cities, however, were generally unaware of this practice. Some policy-makers in Delhi and Kathmandu also did not know about this use of oxytocin; others, though, knew about it, but argued that the risks were outweighed by the benefits of making oxytocin widely available for post-partum administration. Taking oxytocin as an example, we argue that there is an urgent need for those in the policy domain to engage with the everyday realities of drug availability and use in the Global South.

Introduction

In many parts of the Global South, and especially in Asia and Sub-Saharan Africa, maternal mortality ratios (MMR) have remained stubbornly high, although they are declining (if only) slowly in most parts of the world. For Asia, estimates suggest that MMRs had declined by nearly 20% in the 15 years between 1990 and 2005: but a fall of 5.5% per year was needed to meet the Millennium Development Goal 5 for MMR reduction (Hill, AbouZahr, Walker, Say, Inoue, & Suzuki, 2007). In northern India, for instance, MMRs were estimated to be about 900-950 in the early 1980s, were in the region of 700-750 around 1990 (Bhat, 2002) but had only declined to 517 (95 per cent confidence interval 461-573) by 2001-03 (Registrar-General India, 2006a). Similarly, some progress has been made in reducing rates of child and infant mortality in South Asia. But the bulk of the reduction in infant mortality has occurred in the *post-neonatal* period, not the perinatal and neonatal period. For instance, between 1992-93 and 2005-06, the post-neonatal infant mortality rate in Uttar Pradesh declined from 40 to 25 whilst the neonatal mortality rate declined from 60 to 48 (giving an overall decline in infant mortality rate from 100 to 73) (Griffiths, Hinde, & Matthews, 2001: 607; International Institute for Population Sciences (IIPS), 1995a, 1995b, 2007; International Institute for Population Sciences (IIPS) and Macro International, 2007).

Since the 1987 Safe Motherhood Conference in Nairobi, various policy proposals aimed at reducing maternal and perinatal morbidity and mortality have been developed. They include such suggestions as 'kangaroo care' for neonates (which entails body-to-body contact between the baby and an adult to help sustain the baby's body temperature) and Safe Motherhood initiatives that have involved the training of Skilled Birth Attendants, advocacy of institutional deliveries and the Active Management of Third Stage of Labour (AMTSL). AMTSL is seen as vital for reducing post-partum haemorrhage (PPH), which is one of the key causes of maternal mortality throughout the Global South. For instance, the Sample Registration Scheme (SRS) special study suggests that it accounts for some 38% of maternal mortality in India (Registrar-General India, 2006b: 15), whilst the Global Burden of Disease estimates for South Asia are that 31% of maternal deaths are due to haemorrhage (Registrar-General India, 2006b: 17).[1] Recommendations for AMTSL include the administration of either oxytocin (by intramuscular injection) of misoprostol (administered by pill) to help prevent PPH.[2]

In this paper, we begin by presenting the clinical guidelines relating to the use of oxytocin: first, intrapartum (highlighting the risks if guidelines are not followed) and, second, to prevent and arrest post-partum haemorrhage. Then we turn to the use and availability of oxytocin in South Asia. We present findings, from other projects as well as from the Tracing Pharmaceutical project, that indicate the widespread unmonitored *intrapartum* use of oxytocin outwith the formal health care system. During the Tracing Pharmaceuticals project, our interviews with personnel located at different levels of the drug supply chain (medical representatives, wholesale stockists and pharmacists, and rural practitioners) suggest that oxytocin is readily available in the market, even in apparently remote rural areas. We also interviewed obstetricians and policy makers. Obstetricians working in small towns, or those with rural work experience, generally seemed familiar with this use of oxytocin; those working in large cities, however, were generally unaware of this practice. Some policy-makers in Delhi and Kathmandu also did not know about this use of oxytocin; others, though, knew about it, but argued that the risks were outweighed by the benefits of making oxytocin widely available for post-partum administration. Taking oxytocin as an example, we argue that there is an urgent need for those in the policy domain to engage with the everyday realities of drug availability and use in the Global South.

[1] Post-partum infections and unsafe abortions account for about 11% and 10% respectively.

[2] Although we shall make passing reference to misoprostol in what follows, space does not permit a sustained account of misoprostol and the concerns that have been raised about its use in AMTSL.

Clinical guidelines for the use of oxytocin

Oxytocin is a natural hormone with uterine stimulant properties. It was described and first synthesised by Du Vigneaud in 1953 (Mousa & Alfirevic, 2007). In the late 1960s O'Driscoll advocated the use of oxytocin intrapartum as a component of 'the active management of labour' (AML) package aimed at limiting the length of labour in nulliparous women (O'Driscoll & Meagher, 1980). Later, oxytocin was found to be effective in preventing and controlling PPH in the third stage of labour (Prendiville, Elbourne, & McDonald, 2000). In addition to its intrapartum and postpartum use, oxytocin is also used to 'abort the fetus in cases of incomplete abortion or miscarriage' (www.drugs.com accessed 25/09/07). In this section we review the clinical evidence and guidelines related to oxytocin use to augment labour (in first and second stages) and to prevent and treat PPH in the third stage of labour.[3]

Oxytocin in the intrapartum period

Augmentation of labour is performed to increase the frequency, duration and strength of contractions. In the first stage, the intention is to cause the cervix to dilate and in the second stage, to cause the head to descend. The clinical guidelines formulated by O'Driscoll and Meagher for oxytocin use within the active management of labour (AML) were based on their 14-years of practising AML in the National Maternity Hospital in Dublin (O'Driscoll & Meagher, 1980). Apart from the use of oxytocin, the AML package includes a strict definition of labour, amniotomy and continuous support during labour. To avoid potential risks associated with the use of oxytocin, their recommendations considered several factors:

1. *Parity:* Augmentation of labour by oxytocin was recommended *only* for nulliparous women. In multiparas, inefficient uterine action is rare and slow progress of labour is more likely to be associated with other causes (e.g. foetal malpresentation or malformation). In addition, multiparas are prone to uterine rupture and oxytocin stimulation increases the risk of rupture. Therefore oxytocin should be used in multiparas only in exceptional cases which should be decided only by the obstetrician.
2. *Diagnosis and assessing the progress of labour:* The guidelines use a strict definition of labour to admit only women who are in labour. The progress of labour and interventions should be recorded on a partograph (on which contractions etc are recorded through time). Artificial rupture of membranes is the first intervention offered in the case of slow progress of labour (less than 1cm dilatation per hour). O'Driscoll and Meagher (1980) argue that artificial rupture of membranes is often sufficient to augment the labour. Moreover, oxytocin is often ineffective with intact membranes and can increase the risk of infusion of amniotic fluid into maternal circulation. The use of oxytocin is further conditional on there being a single foetus in the vertex presentation. After amniotomy, vaginal examinations should be performed on an hourly basis.
3. *Monitoring the woman and foetus during oxytocin administration:* Oxytocin may cause hyperstimulation of the uterine muscles and the effective dose varies across women. Therefore, to ensure optimal contractions, oxytocin should be administered cautiously by intravenous infusion and stopped immediately if hyperstimulation or foetal distress occurs. All labouring women were assigned a personal nurse who was present from their admission until the baby was born. The personal nurse monitored and recorded contractions and foetal heart rate (by

[3] It is worth noting that the 'medicalisation' of childbirth has not been uncritically accepted within professional circles, as well as beyond, but we cannot address this issue here.

direct auscultation for one minute every 15 minutes during the first stage and after each contraction during the second stage).

4. *Setting/availability of emergency facilities:* The practice of AML was recommended *only* for institutional deliveries in facilities with adequate equipment to deal with obstetric emergencies (such as might entail a Caesarean section).

Since the AML was first proposed in the 1960s, the practice with or without modifications 'has been widely adopted across the world' (WHO, 1996). Based on practice, various guidelines for oxytocin use in augmentation of labour have been proposed although *systematic* evidence for its use is lacking (Bugg, Siddiqui, & Thornton, 2008). The problem lies with the definition of 'delay' in the first and second stage of labour and, in practice, various criteria have been used (NICE [National Collaborating Centre for Women's and Children's Health], 2007), as well as various dosage regimens of oxytocin (Bugg et al., 2008; NICE [National Collaborating Centre for Women's and Children's Health], 2007). Oxytocin was found to be effective in shortening labour (Wei et al. 2007), but evidence from clinical trials did not support the belief that oxytocin reduces the rate of Caesarean sections (NICE [National Collaborating Centre for Women's and Children's Health], 2007).

A summary of the evidence relating to augmentation of the *first* stage of labour suggests no differences in outcomes, other than shortening its duration (NICE [National Collaborating Centre for Women's and Children's Health], 2007). There was no evidence of abnormal foetal heart rate or of changes in the Caesarean section rate due to oxytocin augmentation. Nevertheless, the NICE guidelines emphasise the need to monitor the foetal heart rate continuously when oxytocin is used for augmentation. The evidence comparing low-dose regimens (starting dose and an increment of up to 2mU/min) and high-dose regimens (starting dose and an increment of 4mU/min or more) shows that high-dose regimens result in shorter labours, lower Caesarean section rate and higher chance of vaginal delivery but more hyperstimulation of the uterine muscles. The data on neonatal outcomes were insufficient to draw any conclusions on neonatal morbidity and mortality. Current specific recommendations on oxytocin augmentation in the first stage include a consultation with the obstetrician about whether oxytocin should be considered. For multiparas, a full assessment, including an abdominal palpation and vaginal examination, is required. When oxytocin is used, the foetus needs to be continuously monitored; the time between dose increments should be at least 30 minutes and the dose should be increased until there are 4-5 contractions in 10 minutes. Women should be also advised to have a vaginal examination four hours after oxytocin is started. No evidence for oxytocin augmentation in the *second* stage of labour was identified. Moreover, since there is a risk of uterine rupture NICE guidelines do not recommend oxytocin use in this stage.

The WHO recommendations, however, do not distinguish between augmentation in the *first* and *second* stages of labour (WHO, 2003a). They suggest a starting dose of 2.5 units in 500ml of dextrose (or normal saline). The dose should be increased until 3 contractions lasting 40 seconds in 10 minutes are attained with maximum infusion rate of 60 drops per minute. If satisfactory contractions are not established, the concentration of oxytocin should be increased to 5 units in 500ml dextrose (or normal saline) with the same rate of infusion and increments as above. Women should be carefully observed throughout, and their pulse, blood pressure and contractions monitored; the foetal heart should be monitored every 30 minutes and the IV infusion should be stopped in the event of abnormal foetal heart rate or of uterine hyperstimulation. Apart from these differences, the guidelines provided by NICE and by WHO are alike in requiring oxytocin to be administered by IV infusion and the continuous monitoring of contractions and foetal heart rate.

Although the NICE guidelines summarise some high-quality evidence on the use of oxytocin in the first stage of labour, their conclusion emphasizes the importance of further research into the start dose and increments of oxytocin infusion. The data on neonatal outcomes were also insufficient. To provide clear recommendations for practice, the Cochrane Collaboration Group has proposed two systematic reviews in 2008. These aim to evaluate the available evidence on the effect of oxytocin administered

because of slow progress in the first stage of labour with respect to uterine hyperstimulation and its impact on changes in foetal heart rate, Caesarean section rate, and incidence of serious neonatal morbidity or perinatal death (e.g. birth asphyxia, neonatal encephalopathy, disability in childhood), and serious maternal morbidity or death (Bugg et al., 2008). A comparison will also be made between various dose regimes of oxytocin (i.e. starting doses and the increments in oxytocin infusion) (Mori, Ullman, Pledge, & Walkinshaw, 2008).

Nevertheless, although the clinical evidence is not always completely clear-cut, there is concern that oxytocin should be administered with care and that the labouring woman and her baby should be continuously monitored. Specifically, the WHO practical guide from 1996 warned against the intramuscular administration of oxytocin because it is harmful for the foetus and increases the risk of uterine rupture; moreover, in the absence of unequivocal evidence on the risks and benefits of oxytocin augmentation, they concluded that oxytocin augmentation should be restricted to labours supervised by obstetricians and to facilities that provide surgical services and (whenever possible) foetal surveillance by electronic monitoring (WHO, 1996). More recent WHO guidelines recommend either oxytocin IV infusion to be administered for augmentation of labour, with the precautions outlined above (WHO, 2003a), or that oxytocin only be used for the prevention of PPH in the third stage of labour (WHO, 2003b).

Oxytocin in the active management of the third stage of labour (AMTSL)

A Cochrane systematic review has found *active* management of the third stage superior to *expectant* management in terms of blood loss, PPH, and shortened labour (Prendiville et al., 2000). Active management of the third stage of labour (AMTSL) is a package of interventions including early cord clamping and cutting, controlled cord traction to deliver the placenta, and the routine administration of a *prophylactic* uterotonic drug just before, with, or immediately after, the birth of the baby (Begley, Devane, Murphy, Gyte, McDonald, & McGuire, 2008).[4]

Clinical evidence suggests that oxytocin and syntometrine are the drugs of choice for preventing PPH. Meta-analyses of clinical trials showed that prophylactic oxytocin is effective in reducing both blood loss greater than 500ml (RR 0.50; 95% CI 0.43 to 0.59; 7 trials, more than 3000 women) and the need for therapeutic oxytocics (RR 0.50; 95% CI 0.39 to 0.64) (Cotter, Ness, & Tolosa, 2001). When compared to oxytocin alone, syntometrine (a combination of oxytocin and ergometrine) is associated with a small but significant reduction in the risk of blood loss between 500 and 1000ml (RR 0.82; 95% CI 0.71 to 0.95); side-side effects such as nausea, vomiting and elevated blood pressure are, however, more common due to ergometrine (Su, Chong, & Samuel, 2007). Syntometrine should therefore not be administered to women with pre-eclampsia or cardiac conditions. More data on the side-effects, optimal dose and route of administration of oxytocin are needed, however (Cotter et al., 2001). In addition, the question of optimal timing remains open: timing might affect the blood perfusion to the baby and the loss of maternal blood during the delivery, whilst uterotonics administered before the delivery of the baby may cause acute perinatal asphyxia (Begley et al., 2008). The main recommendation is to administer the relevant drugs at the delivery of the anterior shoulder, but this might require additional staff to be present at the labour. Typically, the practical approach is to administer uterotonics intramuscularly or by IV infusion immediately after the birth of the baby. Oxytocics are, however,

[4] There are many possible variations of these three interventions. First, there are several uterotonic agents that can be used, with variations in timing, dose and route of administration (e.g. oxytocin can be administered as IV infusion or intramuscularly, syntometrine as an IM injection, and ergometrine IV or IM). Secondly, there are also possible variations in the timing of cord clamping and cutting and in the initiation of controlled cord traction. Variations in practice across health centres and countries mean that some women receive mixed management, a combination of expectant and active management that does not include all the components of either (Begley et al., 2008). For a discussion of the disparities in standards for AMTSL and in their implementation in practice of hospitals in developing countries, see (Stanton, Armbruster, Knight, Ariawan, Gbangbade, Getachew et al., 2009).

sometimes administered at the crowning of the head or even after the delivery of the placenta (Cotter et al., 2001).

On the other hand, oxytocin and ergot preparations are not stable in tropical climates: according to the product information for Syntocinon (a leading brand of synthetic oxytocin), it should be kept below 25°C and should not be frozen. In many parts of the Global South, rural health facilities in particular are unlikely to have reliable electricity supplies or refrigeration facilities. In addition, oxytocin and ergot preparations require syringe technologies and sterilisation equipment (although the possible introduction of "Uniject™" syringes might circumvent this). Thus, whilst oxytocin is very effective in preventing and controlling PPH, several recent clinical trials have studied the effectiveness of prostaglandins and particularly misoprostol, which is cheap, can be administered in pill form and is not heat labile.[5]

Other recent studies evaluated the impact of the various interventions entailed in AMTSL and showed some adverse *neonatal* outcomes, including an increased risk of acute perinatal asphyxia if uterotonics are administered before delivery of the baby, and lower haematocrit levels and haemoglobin concentration up to six months after birth due to early cord clamping (McDonald & Middleton, 2008). Based on this, a new systematic review on 'Active versus expectant management in the third stage of labour' has been proposed (Begley et al., 2008). Currently, only a protocol is available. Moreover, little is known about the effects of particular components of AMTSL or about how interventions involving uterotonic drugs (such as oxytocin) during the first and second stages of labour contribute to the risk of PPH (McDonald, Abbott, & Higgins, 2004). Active management, then, is associated with some adverse effects (e.g. nausea, vomiting and hypertension when ergometrine was used as a part of the routine care) as well as having effects on the baby. Nevertheless, organisations such as International Confederation of Midwives (ICM), International Federation of Gynaecology and Obstetrics (FIGO) and WHO have accepted the proposal in (Prendiville et al., 2000) that active management of the third stage of labour should be applied routinely in maternity hospitals.[6]
In sum, then, there are still some question-marks over the evidence about exactly how and when oxytocin should and should not be used. Some good quality clinical trials have been conducted but often they were small, based on different practices, and often reporting only selected maternal and neonatal outcomes. Therefore it is hard to compare them and to draw any conclusions and recommendations for the best practice. More seems to be known about the use of oxytocin in AMTSL but the evidence on adverse neonatal outcomes is again lacking. Moreover, interventions in the first

[5] When misoprostol was used there was a higher risk of severe PPH (RR 1.32, 95% CI 1.16 to 1.51; 16 trials, 29042 women) and greater use of additional uterotonics but fewer blood transfusions (RR 0.81, 95% CI 0.64 to 1.02; 15 trials, 27858 women) than when injectable uterotonics (oxytocin IM or IV, ergometrine, ergometrine plus oxytocin) were used. Oral misoprostol (600mcg) was associated with higher rates of side-effects, such as nausea, vomiting, diarrhoea, shivering and pyrexia (greater than 38 degrees C) when compared with injectable uterotonics as well as placebo. Results from a small number of trials suggest that side-effects associated with misoprostol use are dose related and that rectal misoprostol resulted in less pyrexia and shivering than oral misoprostol (Gulmezoglu, Forna, Villar, & Hofmeyr, 2007). Although less effective in preventing PPH than oxytocin, misoprostol showed promising results when compared to placebo and for its easier administration was tested in home-deliveries in developing countries (Derman, Kodkany, Goudar, Geller, Naik, Bellad et al., 2006; Miller, Lester, & Hensleigh, 2004). More research on the optimal dose and mode of administration is needed if misoprostol is to be recommended for resource-poor settings.

[6] The definitions of AMSTL differ slightly. FIGO-ICM prefer 10 IU oxytocin administered by IM injection, or IV injection, drip or push after induction or augmentation within one minute of foetal delivery, with 0.2 mg ergometrine administered in the same way as oxytocin or 600mcg misoprostol (oral tablet) or other prostaglandins as second line drugs. WHO prefer 10 IU by IM injection oxytocin within one minute of the baby's delivery, and if oxytocin is not available they recommend 0.2 mg IM ergometrine or prostaglandins; they also specify that a check is made before giving these medications that there are no additional baby(s): for more details, see http://www.who.int/reproductive-health/impac/Clinical_Principles/Normal_labour_C57_C76.html#C73%20Active%20management%20of%20the%20third%20stage

and second stage of labour were studied separately from interventions in the third stage and little is known about how intrapartum interventions impact on the need for further interventions postpartum. Nevertheless, clinical guidelines advocate that oxytocin should be used very cautiously, since oxytocin use is associated with several risks for the mother and her baby. We now shift our focus from the guidelines for oxytocin use to how it is actually being deployed on the ground in South Asia. Doing so enables us to see that the recommended precautions are often thrown to the wind, by untrained rural practitioners involved in home deliveries and by trained practitioners working in urban nursing homes and hospitals alike.

Oxytocin use in rural South Asia

As in other parts of the Global South, recent policy discussions in South Asia have included suggestions that oxytocin should be made more readily available in government rural health centres for use in the active management of the third stage of labour by the local-level government health workers, such as nurse-midwives whose responsibilities include dealing with labouring and parturient women. Studies from several parts of South Asia, however, indicate that oxytocin is *already* readily available outwith the formal health care system, even in apparently remote rural areas. Indeed, it is well-known to the various kinds of private practitioners who provide health care in the rural hinterland—as well as to the villagers they serve—and they use it in their practices, primarily *intrapartum*. As we noted above, clinical guidelines suggest that oxytocin should be administered intrapartum only under specific conditions, yet in South Asia is often used in circumstances in which few (if any) of those stipulations are met.

In rural home deliveries, when oxytocin is deployed it is used to *augment* rather than induce labour. Most reports specify that it is administered not by intravenous infusion but by intramuscular injection, which means that the effective dose cannot be ascertained or regulated. Usually it is administered by local rural practitioners, with or without training. A few studies provide details of the incidence of oxytocin use in this fashion, whilst others mention in without specifying the incidence but indicate that it is commonplace and well-known. A study conducted in twelve Uttar Pradesh districts found that oxytocin was being used in 48.2% of home deliveries (n=2,992) across the state (ranging from 74.7% in Muzaffarnagar to 16.7% in Chitrakoot). Almost two-thirds of the women who reported injections had had more than one. Traditional birth attendants and auxiliary nurse-midwives (ANMs) were the primary decision-makers for using the injection (29.8% and 29.6% respectively) and informal private practitioners and auxiliary nurse-midwives were the primary injection service providers (48.2% and 32.8% respectively) (Das, Agarwal, Tripathi, & Parveen, 2005). A study conducted in rural Kanpur reported similar patterns of use, although the absolute levels were lower at 23% (n=527), and there was a statistically significant relationship between injection use and the presence of a provider (trained or otherwise) (Sharan, Strobino, & Ahmed, 2005). Research by Patricia and Roger Jeffery in two villages in Bijnor district, western Uttar Pradesh, indicates that between 1983 and 1987, oxytocin was being administered in about 15% of deliveries (n=237) by the government pharmacist as part of his (illegal) private practice (Jeffery, Jeffery, & Lyon, 1989:111-112). By 1998–2002, oxytocin injections were being administered by untrained private rural medical practitioners (male) in almost half (48%) of deliveries (n=346) (Jeffery & Jeffery, 2008: 72). In the early 2000s, practitioners charged between Rs100 and Rs150 per injection: whilst this is a considerable mark-up on the retail price of around Rs20 for a phial of 10IU of oxytocin, such injections were not seen as prohibitively expensive even by poor families.[7] A Karnataka study reports that 'injections to increase pains (probably oxytocics) were injected in 21% of all home deliveries, including 51% of those attended by government auxiliary nurse-midwives (see also George, Iyer, & Sen, 2005 for a report on elsewhere in rural Karnataka; Matthews, Ramakrishna, Mahendra, Kilaru, & Ganapathy, 2005:397; Ramakrishna, Ganapathy, Matthews, Mahendra, & Kilaru, 2008: 96). Similarly, writing about rural Rajasthan, Iyengar notes that intramuscular oxytocin injections

[7] Our research on childbearing in Bijnor was funded by the Social Science Research Council (later Economic and Social Research Council in 1982-3 and 1985 and by the Wellcome Trust in 2002-4.

are 'widely used' intrapartum (Iyengar, Iyengar, Martines, Dashora, & Deora, 2008: S27), whilst Van Hollen describes its use as 'almost routine' for the local multi-purpose health worker during home deliveries in Tamilnadu (C. Van Hollen, 2003a & 2003b). Bang, Bang, Baitule, Raddy, & Dashmukh (2005) report that in rural Maharashtra oxytocin injections were administered in between 21.2% and 23.1% of the cases they studied (by unqualified private practitioners) and that they raised the risk of birth asphyxia and stillbirth threefold.[8]

During the Tracing Pharmaceuticals project, our interviews with rural practitioners (mostly untrained and working in a private capacity) also indicated that they are very familiar with oxytocin and that some routinely administered it by IM injection to augment labour. A few of them talked about the dangers of using oxytocin in home deliveries, but many administered oxytocin in circumstances comparable to those described above to women delivering in their homes, generally at the behest of the labouring woman and/or her female attendants, or because the traditional birth attendant recommended its use.
It is worth underscoring some further aspects of home deliveries (although few of the studies cited above explicitly mention them): parity, examination of the woman prior to administering oxytocin, monitoring after administering oxytocin, and ready access to emergency obstetric care. All these points derive from observations and interviews in the Bijnor study, but they are almost certainly very widely applicable in the region.

1. With respect to parity, Das et al. and Sharan et al. found that oxytocin use was more common in primagravidae (Das et al., 2005; Sharan et al., 2005). In the Bijnor study, Patricia and Roger Jeffery found that 62.3% of primagravidae (n=53) (whose labours can normally be expected to be longer than others) received injections, compared with 45% of women of higher parities (n=293) (unpublished data). Nevertheless, this means that substantial numbers of *multiparous* women were receiving oxytocin injections, often more than one.
2. Traditional birth attendants do not necessarily perform internal examinations to ascertain cervical dilatation before recommending an injection, although they may do so and they generally appear to do external examinations. Male practitioners seem generally to perform no examinations, whether external or internal. This means that neither the stage of labour (first or second) nor the presentation of the baby is necessarily ascertained before administering oxytocin. Several women reported footling breech or transverse presentations that were not diagnosed before the administration of oxytocin.
3. Neither traditional birth attendants nor rural practitioners possess or use equipment that would enable them to detect foetal distress, assess the frequency and strength of contractions or measure the mother's blood pressure etc. after the administration of oxytocin.
4. Finally, there is no facility for dealing with small or weak babies (resuscitation equipment, incubator etc.), and no operating facilities (anaesthesia, blood bank etc.) without taking the labouring women elsewhere (which raises questions about transport, time and distance that we cannot develop here).

One additional feature of oxytocin use is worth outlining: its cultural acceptability. In local understandings of pregnancy, a woman's body becomes increasingly 'hot' (in the humoral sense) until such a point that uterine contractions are sparked off. According to the Bijnor study, *desi* [folk] methods of heating labour—giving the labouring woman a heating drink such as tea containing unrefined sugar, loosening her plait, unlocking padlocks etc.—were still common in the early 1980s

[8] As we also note in (Jeffery, Das, Dasgupta, & Jeffery, 2007), similar usage was acknowledged in personal communications from colleagues in Bangladesh and Pakistan. Oxytocin may also be used in *urban* home deliveries, too: a study in a poor area of Delhi reported oxytocin use in 68.9% of home deliveries, administered by private doctors in 86.8% of cases (Caleb, 1995).

(Jeffery et al., 1989: 103ff.) but they had all but disappeared by the early 2000s. Rather, village women and their attendants saw intrapartum oxytocin injections as the most effective method of speeding up labour, especially in labours that were perceived as being lengthy and in which the contractions had 'cooled', that is, become less intense or infrequent. These injections were termed *dard barhāne kā tikkā* [pain/contraction enhancing injection]. They were popular with women who wanted their labour to be over quickly and many women reported having had several injections within the space of a few hours. Other sources talk of *garmī ri huī* (Iyengar et al., 2008: S27) or *garmī ki suī* [heating injection], or other variants on the theme that are widespread in the region. Further, as many sources have suggested, the hyperdermic needle is a powerful icon of 'modernity'. For instance, based on her study in Sitapur district [UP], Pinto argues that injections enable local practitioners to re-assert their quasi-institutional authority through association with modern biomedicine (Pinto, 2004, 2008). In line with this is the finding that intrapartum injections were more common among women of higher socio-economic status and among relatively more educated women, suggesting that oxytocin was used less because of need and more because of ability to pay, and an association with 'modernity' (Das et al., 2005).
We cannot be firm in our conclusions, and more work needs to be done establishing how commonplace such intrapartum use of oxytocin in rural home deliveries is. Nevertheless, this evidence suggests that it departs in several important ways from the guidelines that we outlined above.

Oxytocin availability in rural South Asia

Many discussions of how drugs are introduced into the market in inappropriate ways focus on incentives to those who prescribe the drugs, misleading literature, and trade advertisements. During our project, medical reps. often talked at length about the various strategies in which they engage to encourage practitioners to adopt particular drugs—free samples, opportunities for continuing medical education or to attend conferences, for instance. These strategies *may* have been relevant when synthetic oxytocin was marketed a few after its first synthesis in the 1950s. But the memories of our interviewees did not stretch back to that earlier era and we cannot be certain about how oxytocin was initially marketed in South Asia. These days, however, medical reps. in urban and rural setting alike say that oxytocin is *not* a drug that they actively promote—and that the main reason is that there are steady sales of oxytocin to urban clinics, small town pharmacies and so forth, that are sustained without any need for medical reps. to engage in explicit marketing strategies. In other words, at some stage since the introduction of oxytocin, its sales have become sufficiently buoyant for producing companies not to perceive any need for high profile and energetic marketing. Our interviews with stockists and retailers endorse this reading of the situation.[9]

According to our interviews and some spot checks on stocks in retail outlets, oxytocin is well known and is routinely kept in stock, by wholesalers and retailers alike. Whilst our research could not entail a comprehensive study of the availability of oxytocin, we do have evidence that it can readily be obtained in disparate places, ranging from retail outlets in the vicinity of urban nursing homes and hospitals offering delivery facilities—where women's attendants are often asked to purchase oxytocin from the local bazaar, even when attending government facilities—to small pharmacies in towns remote from large urban centres. Moreover, despite its designation as a prescription-only drug, oxytocin can easily be purchased over-the-counter (as indeed, our research assistants did on several occasions).[10]
Oxytocin, then, is a readily-available drug that is familiar to actors at various levels in the supply chain—medical representatives, stockists, retailers and rural practitioners as well as to parturient

[9] We have been unable trace data that provide overall information for South Asia on oxytocin sales over time, so we cannot comment on these assessments.

[10] In our research , we could not conduct a systematic study of the conditions under which drugs were transported and stored, for instance in relation to heat-labile drugs such as oxytocin. This is an issue that merits further work, since it has implications for how the efficacy of drugs might be affected by variations in such considerations as turnover and seasonality.

women and their attendants. In other words, oxytocin *already* has a significant life outwith the realm of government policy and provision—indeed, a life that is also beyond its purview. As with fluoxetine, one of the other drugs studied in the Tracing Pharmaceuticals project, the very existence and availability of oxytocin drives its use, often with unintended consequences.

The question that then arises is the extent to which this matters. As many studies in the region have shown, the bulk of health care is provided by private practitioners of various kinds—trained in various medical traditions or none—operating outwith the formal and government health care system. Indeed, given the lack of capacity of the government sector, it might be argued that the private sector plugs an important gap in provision. In this case, though, the circumstances under which oxytocin is being administered intrapartum give rise to considerable disquiet.

Urban obstetricians and oxytocin

What surprises us, however, is how little concern has emanated from the professional and policy circles that are closely involved with issues of reproductive and child health. How far do urban professionals, for instance, appreciate what is happening in the rural hinterland? During our project, we also interviewed urban obstetricians in Delhi, Lucknow, Bijnor, Kolkata and Kathmandu. In addition, we attended a number of meetings that focused on issues of reproductive and child health and interviewed people involved in the policy domain, mainly those based in Delhi and Kathmandu.

On the basis of our interviews with urban obstetricians, we would conclude that those in smaller towns and those who have had experience working in rural or small town settings are more aware than their colleagues in the metropolitan centres of the use of oxytocin in rural home deliveries. For example, an obstetrician at the government District women's hospital in Bijnor described oxytocin as the 'spinal cord of our speciality' and outlined its use in her current practice. She also talked about the problems she faced with labouring women from the rural hinterland who had been 'handled'; such women talk about having a '*garm* [hot] injection', which she described as a 'wrong use of medication' that is given even to women with a 'previously operated delivery' because the traditional birth attendants do not know the complications. Some labouring women had also begun coming in, she said, with misoprostol inserted in their vagina without their knowledge:

> So in that way, oxytocin was better known because it was injectible and people could tell us that "yes, they have given some injection" and we could know that she has been handled. With the tablet of misoprost, sometimes it becomes … difficult to know the patient has been handled or not [PJ: Yes] and in what way we should manage. So in a way I think this drug [misoprostol] is being used badly by some quacks, the persons who does not know the ABC. They are not the paramedical staff, neither paramedical staff, because paramedical staff got training—they know something or the other about this. So these days, especially since last one or two months, I am receiving the cases from the rural area though they are 99% handled. [Interview on 24 October 2007][11]

In a large government hospital in Kolkata, a male obstetrician nearing retirement talked about his 18 years of experience working in rural West Bengal, beginning in 1976: 'Absolutely interior parts. And there we used to get cases of ruptured uterus [PJ You did?] Ruptured uterus only because of giving these injections', a practice which he said has declined in the recent past since there are more qualified

[11] In similar vein, during the Bijnor project in 2002-4, doctors running private nursing homes and clinics in the town said they often admit 'handled cases', meaning women in labour whom they regarded as having been '*mis*handled' by local *dāīs* [traditional birth attendants] and rural practitioners: for instance, obstructed deliveries because of mal-presentation or cephalo-pelvic disproportion, cases in which the labouring women often tell the obstetrician that they had indeed been given one or more injections to 'heat up' the contractions.

practitioners now in rural Bengal.[12] When asked how the rural practitioners who had given the injections had heard about oxytocin, he initially said 'They took this lesson from these veterinary doctors. In cows' delivery they used to give oxytocin injection intramuscularly, just to hasten the delivery' but when Patricia asked him to elaborate, he commented:

> They learnt it mostly from MBBS doctors. You see, I have seen it, let me admit, even in medical colleges. I have seen people … in the last stage, in the end stage of the second stage of labour during delivery, just to hasten it, just to quicken, hasten the thing, they used to give a bolus injection of oxytocin. They [rural practitioners] learnt it basically from MBBS doctors, and to some extent also from the veterinary doctors, that giving the injection, this injection hastens the delivery. [Interview on 23 Nov 2007]

A number of obstetricians working in Butwal (Nepal) also talked about the use of oxytocin injections to augment labour in the local rural areas. One commented at length:

> Yes, there are a lot of cases and that is misuse of oxytocin. Because those who are not trained enough, especially those who are not trained enough, for instance, people who do not have the knowledge as to what complications can arise due to the use of oxytocin or on which cases oxytocin should only be administered … they use it for delivery and even some people give oxytocin IM … or even administer bolus dose IM which have led to intrauterine foetal death or even uterine rupture … we have come across such cases. [Interview on 15 January 2008]

When asked if he was certain that the guidelines for oxytocin use had not been adhered to, he retorted:

> In the hospitals, protocols regarding the use of oxytocin have been adhered to, but not outside the hospital in outlying areas. In the outlying areas what protocols are there? … Well what protocols have been maintained outside the hospital in Nepal, you tell me? [Interview on 15 January 2008]

When asked if the people administering oxytocin in the rural areas were trained health workers who had learnt about oxytocin from hospital doctors, he commented:

> More than the health personnel like CMAs and ANMs the ones who are doing it are "non-medical practitioners" for instance, quacks, those who are called "*jhole* [cloth bag] doctor" or those who have learnt to give injections, especially "*jhole* doctors" in the Terai region who carry drugs in their bags [*jhola*] and go from one house to another. These people have been administering oxytocin IM and cases of rupture have come. And these people are using it since it's the lack of knowledge of those villagers in those outlying areas of the Terai belt. […] From the hills it is usually cases of obstructed labour. But more cases of unregulated use of oxytocin use usually comes from the Terai belt. [Interview on 15 January 2008]

In the larger metropolitan cities, however, obstetricians generally seemed unaware of the practice of intrapartum intramuscular injection of oxytocin in rural home deliveries in the region and some even denied that oxytocin would be known about or available in the rural areas. In several interviews, Patricia had to repeat herself to emphasise that she was talking about IM injections, since several interviewees did not absorb Patricia's initial account and simply assumed that the oxytocin was being administered IV. In a couple of cases, the interviewee summoned junior colleagues who had had rural

[12] Likewise, another Kolkata obstetrician had seen cases of complications caused by intrapartum oxytocin injections during his rural employment, and he also said that the use of oxytocin injections had declined in rural West Bengal in recent years because villagers were more prepared to be referred to an institution for delivery if the labour became complicated [Interview on 16 Nov 2007].

experience and asked them to confirm our view that oxytocin is both available and used in the rural areas.

Systematic evidence about the extent of oxytocin usage in *institutional* deliveries in the region is hard to come by. During the Tracing Pharmaceuticals project, the urban obstetricians we interviewed strongly advocated the active management of labour, in which oxytocin use is taken for granted as routine, normal and appropriate in their repertoire of interventions. The obstetricians, including those nearing retirement, said that oxytocin use intrapartum had been widespread throughout their working lives and that they had learnt about it during their medical training. They regard oxytocin as the drug of choice for augmenting labour. Several obstetricians provided off-the-cuff estimates of intrapartum oxytocin usage in their institutions—sometimes upwards of 70%. Some of this apparently high usage might be attributable to the higher proportion of institutional deliveries that are difficult labours. Nevertheless, oxytocin was also being used in pre-booked deliveries, which suggests a more routinised usage in labours that are progressing normally. Moreover, a senior midwife and lecturer in nursing in Delhi told us of the arguments that she had with staff at the Safdarjang Hospital, the government hospital where her trainee midwives received their practical training. She wanted her students to experience 'normal deliveries'. The hospital staff said that they routinely used oxytocin for all women coming into the labour wards because of pressure of numbers: they had to ensure that women's labours were not protracted, because there were not enough beds in the labour rooms to meet the demand and they needed to maintain rapid through-put. [Interview on 10 March 2007].Our own observational data (for instance, from a couple of sessions of several hours each observing activities in the labour room of a large teaching hospital in Kolkata), also suggest that oxytocin is used in a large proportion of institutional deliveries. We cannot, however, adjudicate on the extent to which this level of usage is over and above what might be classed as 'medical need'.

In addition, the 'active management of labour' has a high profile in obstetrics circles in contemporary India. For instance, Daftary and colleagues have produced 'an indigenously developed protocol of labour management' (Daftary, Desai, & Nanavati, 2003), whilst Dr Shyam Desai, in his presidential address to the Federation of Obstetric and Gynaecological Societies of India (FOGSI), placed active management of labour—including its acceleration using oxytocics—at the heart of Safe Motherhood initiatives in India (Desai, 2005). The use of oxytocics for augmentation is part of 'programmed labour' discussed in several sources (e.g. Meena, Singhal, & Choudhary, 2006; Yuel, Kaur, & Kaur, 2008).
Whilst we cannot be definite, it seems that oxytocin use is very common and highly valued in institutional deliveries in the region. Why this might be remains uncertain. Several interviewees said that they had been taught that its use was appropriate during their training. Another reason may be to ensure that that labour room beds are vacated quickly and that oxytocin use is a form of 'crowd control' (as Van Hollen puts it in her discussion of busy hospitals in Chennai city: Van Hollen, 2003a & 2003b). The Bijnor obstetrician cited above suggested that its use enables (private) doctors to regulate the time when a woman will deliver: 'Because everything is money-oriented exactly. They want to work in day, take rest in night. And there are so many factors. [Interview on 24 October 2007]. And in the Bijnor research in 2002-4, lay people frequently (and cynically) suggested that the financial interests of non-government health care providers lead them to administer drugs (or conduct even more lucrative Caesarean sections) at the first opportunity when labouring women arrive at their nursing homes. Perhaps for several reasons, then, intrapartum oxytocin use seems to have become normalised in institutional deliveries in the region.

Moreover, our observations suggest that the clinical guidelines for intrapartum oxytocin use are not necessarily being followed in urban institutions. For instance, writing about Karnataka, Matthews et al. comment: '[m]ore than 90% of all women, and more than 75% of women with no complications, were given repeated *injections* or intravenous infusions of oxytocics to hasten labour. The situation at the private and mission hospitals was better in regard to the presence of the doctor at the delivery, but even here most women were given repeated *injections* of oxytocics to speed up labour' (Matthews et al.,

2005: 399, our emphasis).[13] During our observations in a Kolkata teaching hospital, women admitted to the labour ward were immediately given an examination (an internal to assess cervical dilatation, external assessment of the baby's presentation) and then most were straightaway attached to IV saline drips to which oxytocin had been added. We timed the procedures that took place thereafter: internal examinations of the mother, foetal heart monitoring, checking of the drip and so forth did not take place at frequent or even at regular intervals. There was no continuity of care by the staff on duty, with staff spending much of their time congregated at a desk at one end of the ward and labouring women left to their own devices, often two to a bed. This kind of evidence is troubling enough in its own right, since it suggests that the experiences of women undergoing institutional deliveries are far from satisfactory, either in terms of safety or in terms of quality of care.[14]

Beyond this, however, we need to consider the linkages between urban institutional deliveries and the widespread intrapartum use of oxytocin in rural deliveries. The obstetricians we interviewed were strikingly incurious about the routes through which oxytocin use might have become widespread in the rural areas. We have been unable to tap into any firm historical accounts, but the most likely explanation—alluded to by several interviewees—is the connection between rural medical practitioners and urban facilities.[15] Many rural medical practitioners have no formal medical qualifications. Some rural medical practitioners have training in Ayurveda, Unani or homeopathy, but their practice usually includes, or is even dominated by, cosmopolitan remedies. Rural medical practitioners have often had previous urban employment as compounders (pharmacists), ward boys etc. in urban facilities. In all probability, they learnt their trade by observing clinical practices there and have taken this knowledge with them to their rural practices. Interviews with rural practitioners also indicate that they maintain relationships with urban facilities, often accompanying labouring women whom they refer there (and in the 2002-4 Bijnor study, villagers alleged that they take a commission for doing so). There are, then, many opportunities for rural practitioners to observe the use of oxytocin in urban facilities. Even if that usage follows the clinical guidelines, there is no guarantee that rural practitioners will continue in the same vein in their own work if they are unaware of the reasons behind particular practices. And to the extent that it does not follow the guidelines, rural practitioners are unlikely to be aware of the risks involved in administering oxytocin IM in situations where they cannot adequately monitor the progress of the labour or provide emergency back-up care if matters go awry. In other words, the enthusiasm of MBBS doctors for using (and sometimes misusing) oxytocin in their management of labour in urban nursing homes and hospitals probably leads directly and indirectly to its use and misuse in the rural areas—a series of unintended consequences that most of the urban practitioners we interviewed were unwilling to acknowledge.

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[13] Judith Sim has worked on related issues in Jamshedpur. She reports that oxytocin use is routine in the two hospitals (one government, one run by Tata) where she observed deliveries. It was sometimes administered IV but sometimes IM, and by different grades of staff. In the government hospital, women received very little attention or monitoring, whereas monitoring was routine in the Tata hospital (personal communication 12 March 2009).

[14] Ellis enters a note of caution in his discussion of institutional deliveries in Kathmandu: writing about neonatal encephalopathy, he comments that 'the most striking potentially preventable risk factor for adverse outcome' was 'induction of delivery' using oxytocin infusion (M. E. Ellis, 1999: 167). See also (M. Ellis, Manandhar, Manandhar, & Costello, 2000).

[15] Several participants at the inception workshops for this project suggested that we explore the issue of bovine oxytocin use to enhance milk production, which is also widespread in South Asia. Certainly, bovine oxytocin is as readily available over the counter as oxytocin intended for human use, but we are not convinced that rural practitioners and traditional birth attendants would make the connection between using oxytocin to increase milk production in cattle and to augment labour in women.

Oxytocin in the policy domain

As noted at the beginning this paper, proposals to encourage active management of third stage of labour (AMTSL) include the suggestion that local-level staff should be supplied with oxytocin for intramuscular injection during the *third* stage of labour, in a bid to reduce levels of post-partum haemorrhage. The associated policy documents, however, are silent about oxytocin use at other stages in labour, and there is no mention of the widespread availability of oxytocin outwith the state sector. Indeed, the documents seem to imply that oxytocin needs to be included in the overall safe motherhood 'packages' to ensure that it is accessible to local-level staff dealing with deliveries. For instance, despite the evidence of small-scale studies such as those cited above, the National Family Health Survey (NFHS)—the main source of national-level information about pregnancy, delivery and post-partum care in India—has collected no information on intrapartum oxytocin use in its 1992-1993, 1998-1999, and 2005-2006 rounds. Similarly, the questionnaire used in a study of local delivery practices and neonatal care, conducted during 2006-7 in UP (among other states), contains no question about the use of oxytocin intrapartum.[16]

Indian government proposals for preventing PPH and encouraging AMTSL were launched in February 2007 at a meeting in Delhi. The White Ribbon Alliance-India had worked closely with the Ministry of Health and Family Welfare to develop guidelines and protocols for an essential package of maternal and child health services to be provided under RCH-II [Reproductive and Child Health-II]. The report, entitled *Promoting Skilled Attendance at Birth in India – A Brief Report,* referred to the MacArthur Foundation grant that had enable WRAI 'to work in collaboration with the Ministry of Health and Family Welfare, UNFPA, UNICEF, WHO India, FOGSI, TNAI [Trained Nurses Association of India] etc. to se you these guidelines and protocols that will increase the availability of skilled attendance at birth and also increase access to EmOC [emergency obstetric care]' (p.5). A crucial innovation would permit ANMs [Auxiliary Nurse-Midwives] to carry out a number of procedures hitherto (supposedly) forbidden to them, for instance administering injections, including oxytocin to manage PPH. Gaining acceptance of this proposal had entailed quite complex brokering between representatives of the medical profession (who opposed it) and nursing representatives (who favoured it). At the WRAI report launch, several speakers also acknowledged that ANMs attend only a small minority of rural births in many parts of the country and that training enough Skilled Birth Attendants to provide full coverage would take years.[17] Moreover, in one-to-one conversations later, several participants acknowledged that oxytocin is already being widely administered intrapartum in rural India and that this is a risky practice. One person involved in these discussions said that concerns had been raised about the misuse of oxytocin in rural areas. She knew that oxytocin is used intrapartum and that women want to have quick contractions and get the labour over soon, so there is demand for oxytocin from women. She said that traditional birth attendant often call in nurses or other people to give a shot to the labouring woman, and that they often give very high doses of oxytocin. She thought that many providers in the periphery had worked at one time in a nursing home or hospital and said she meant the '*jhola chhāp*' practitioners, who learnt by observation at the facility where they worked, and then moved out into the villages and began to practice. They would have seen oxytocin being administered, and for them 'ignorance is bliss'—they would not know anything about the side-effects. She went on to say that there had been some discussion about whether oxytocin should be given out to ANMs because of concern that it might be misused (as well as over issues of storage and the need for sterile needles) but oxytocin had nevertheless been included in the AMTSL package for India because it is more efficacious than misoprostol in *arresting* PPH. [Interview on 9 March 2007]

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[16] This study was entitled 'Concurrent Assessment of Health and Family Welfare Programs and Technical Support to Districts of Uttar Pradesh', and was sponsored under the Sector Investment Programme by GOI in partnership with the European Commission.

[17] Generalisation is probably rather misleading. In some parts of the India (especially in the north), very few delivering women have trained attendants at all, whereas in the south, institutional deliveries are more common.

We also interviewed several people in Delhi and Kathmandu working in organisations such as WHO, UNICEF, UNFPA with interests in reproductive and child health and specifically raised the issue of intrapartum oxytocin use with them. In some cases, they expressed surprise at our suggestion that oxytocin was being used intrapartum. One person insisted that oxytocin was being used in rural Nepal only during third stage and not to induce labour: staff had been told not to use oxytocin at all during pregnancy and MCHW had been trained to use it in only in the third stage. She said she 'would like to believe this is what happens' but she did not have the 'intelligence' to suggest otherwise, and nor had she had the opportunity to go to villages herself and find out. [Interview on 14 Sep 2007, Kathmandu] Other interviewees, though, said they were aware of intrapartum oxytocin use in the rural areas. One said this was well known and that the solution would be improved training:

> In fact all of us have been aware that people do … I mean it [oxytocin] has been misused. But then I think the kind of ideal condition would be to empower and to train our health workers because as obstetricians and as MBBS doctors also we are all so scared of giving oxytocin. Like if it is only 2 units we would not be able to go beyond 2 units. I think it's just ignorance, ignorance about the complications that could arise out of, you know, such inadvertent use of Oxytocin that is leading people to, kind of you know, to misuse it. So while we train our health workers, while we educate them on each and every aspect of skilled birth attendance, I think this thing needs to be kind of reiterated, you know, as to how some women have actually died because of uterine rupture and other complications which arose because the attendants were not sure of, but were actually misusing drugs like oxytocin .[PJ: Yes, yes …] But then there have been so many drugs, for that matter you know, which have been misused and one good strategy, and the only strategy is to actually equip people with knowledge about the use as well as about the side effects … [Interview on 20 March 2008 Delhi]

Another was aware of intrapartum oxytocin use in the rural areas, but considered that the issuing of oxytocin to prevent or arrest PPH to community-level workers in government service would not pose an additional problem since its use would be restricted to institutional deliveries:

> But the fact of the matter is that in the government of India programme there was a conscious decision that in outreach settings where an ANM is delivering at home in certain situations or in sub-centres where she is not under the medical doctor's supervision, the misoprostol remains the drug of choice [for PPH] because the stability and the whole issues of management. But wherever she is in institutions, if she is delivering a baby in a primary health centre under doctor's supervision, there are other nurses around then the oxytocin remains the drug of choice. And we have the experience from other countries from Indonesia, from Africa and other places where the community-based workers have been providing misoprostol successfully. So I think there should not be much of a problem there and gradually in India the focus is being given to institutions so we are safely covered over there. But for interim misoprostol is there … still prevents the PPH. [Interview on 31 March 2008 Delhi]

Another was also aware of intrapartum oxytocin use in the rural areas, but alluded more directly to how the issues of safety raised by such use have to be weighed up in relation to maternal mortality due to PPH:

> It's already there. We know that it's already there. [PJ: Within the institutions?] Within institution, outside institution. There is a large malpractice or illegal use of these substances. There is nothing that … you see this is a good concept but reality in a way is far ahead. We do have oxytocics use for abortion and illegal abortion or oxytocics in India, particularly in rural India, by so called Rural Medical Practitioners or quacks for a cost to let women abort. Now, how do we deal with this? This is an important issue for further evidence or research. But certainly it's inconsequential when we have to deal with the issue of maternal mortality and

> particularly again both the third stage management or the treatment of PPH. [PJ: By that you mean it's more dangerous *not* to have oxytocics available…] Obviously. [PJ … because the real problem is maternal mortality?] Exactly. [Interview on 24 March 2008]

Later in the interview, we mentioned the concerns voiced by a neonatologist we had interviewed in Kolkata about how intrapartum oxytocin use might affect the unborn baby, for instance, causing asphyxia or increasing the levels of bilirubins in the brain: he was aware of these possibilities but went on to say:

> We very much share this concern. Nevertheless, we need also to look case by case. This is a medical intervention. It is in a way demystified by a policy decision with the intention to tackle a very important point which is again complications of third trimester. … What comes first, difficult to say, right? Scientifically I had to share this concern he [neonatologist] has. Misuse of Oxytocin certainly increases stillbirth or intrauterine death, certainly increases risk of hyper-bilirubinia and very important brain damage in children, particularly low birth weight or very low birth weight, particularly that proportion of children below 1500 gms. It's a very difficult decision to make. Again I would specify, instead of largely advocating the use of injectible oxytocin, I would restrict, probably, to the advocacy of widely practising and using oxytocins within the facility and the medical supervision if possible. [Interview on 24 March 2008]

Conclusions

The active management of labour—including the use of oxytocin—was widely adopted in institutional deliveries in the developed world from the 1960s onwards. As we have indicated, clinical guidelines suggested that it should be used only under certain circumstances and with the exercise of considerable caution because of the potential risks to mother and baby. The guidelines specify that oxytocin should only be administered intrapartum by IV infusion, or that it should only be used in third stage to prevent PPH (WHO, 2003a, b) and there are explicit warnings against the use of IM injection of oxytocin intrapartum (WHO, 1996).

The evidence we have presented in this paper, however, suggests that these guidelines are often flouted in South Asia. We would emphasise that we are certainly not arguing that unmonitored intrapartum use of oxytocin is the only serious issue at stake. Nevertheless, most of the countries in the South Asian region will probably fail to attain MDGs 4 and 5—and oxytocin use is a revealing cipher that can help us to highlight aspects of 'unsafe motherhood' practices that need to be dealt with if MDGs 4 and 5 are to have any chance of being met. Maternal mortality (and morbidity) can have catastrophic effects on household wellbeing, when adult workers are lost or incapacitated and children are orphaned. Equally, the mortality of small children—here we are thinking particularly of stillbirths and perinatal deaths—almost certainly means that women have more pregnancies than they might otherwise, with all the well-known enhanced risks of maternal mortality or 'maternal depletion' and ill health and (again) their implications for household wellbeing. All these issues have a high profile in policy discourse and recent years have seen a plethora of proposals and programmes directed towards combating the enduringly high levels of maternal and infant mortality. But how fit for purpose are these proposals? Here we shall draw out some of the ways that our research points to issues that have not, in our view, been adequately addressed during the formulation of reproductive and child health programmes.

Firstly, despite new funding streams, there is a serious failure to address the systemic incapacities of government health care provision that will remain, at least in the short term, but almost certainly in the longer run. In particular, institutional deliveries supervised by Skilled Birth Attendants are seen as the prime means of attaining Safe Motherhood goals—yet it is implausible that the majority of births would meet the criteria of 'safe' within the foreseeable future. Training programmes for Skilled Birth Attendants in India would anyway have taken years to meet their target levels—but they have been slow to get moving. There are simply not enough institutional beds to take in all labouring women—whilst in remote areas, such as the hilly parts of Nepal or central India, it would be impossible to ensure

that all women can reach institutions and have 'safe' deliveries in a timely fashion. In any case, as we have noted above, it is not obvious that institutional deliveries as they are currently practised would always be deemed 'safe' according to the criteria set by WHO and others: the rampant and careless use of oxytocin intrapartum is just one example of the problems that are rife in institutions. For all these reasons, then, we doubt that institutional deliveries with Skilled Birth Attendants are going to prove the panacea that they are proclaimed to be. And, to be realistic, this means that women in South Asia (in many areas, the vast majority of women) will continue to deliver their babies at home.

This brings us to our second point. Public documents pertaining to those aspects of Safe Motherhood proposals that entail the use of oxytocin to avert or treat PPH contain no reference to the intrapartum oxytocin use beyond the purview of the state health care sector that we have been discussing in this paper. Yet our research makes clear that many drugs, including oxytocin, have existences that are independent of policy interventions, and, indeed, existences that are known to some of the actors involved in creating Safe Motherhood proposals. It would be possible to miss this understanding in policy documents, which tend to present government programmes as if they are hermetically sealed from the wider world in which they are embedded. We consider that this failure to address and comprehend the ground realities beyond the purview of government programmes threatens to jeopardise many policy interventions. In the realm of reproductive and child health, a huge range of activities takes place beyond the government sector or the programmes that are financed by overseas donors, NGOs and the like. Put another way, there is a lively market in health care and in the distribution of drugs.

Our third point leads on from this. The private sector in health care provision is huge and diverse and, of course, inflected with market incentives and the imperative to make money. For these very reasons, it should not be rendered invisible in policy interventions. Indeed, the implications of the health care market for Safe Motherhood initiatives *must* be addressed if policy interventions are to have their hoped-for impact. If most women in South Asia will continue to deliver outwith the government sector, attempts to reduce maternal and infant mortality rates must acknowledge the ground realities. On their own, Safe Motherhood initiatives cannot guarantee that motherhood will become safer, because they do nothing to address the wider context in which women undergo childbearing. But can mechanisms be put in place that will guarantee that home deliveries (as well as institutional deliveries, whether in private nursing homes or in the government sector) meet the safety criteria of Safe Motherhood initiatives? Tackling this question would require thinking through how to establish and sustain a plethora of regulatory systems encompassing the marketing and distribution of drugs (such as oxytocin) and the supervision and monitoring of medical practitioners of various kinds even in remote rural areas. Other papers drawing on our research in this project have addressed the question of regulation: suffice it to say here that this is a crucial element in any attempt to protect labouring women from exposure to unsafe birthing practices and to ensure that safe care is provided to all women wherever they live.

Tracing pharmaceuticals 'on the ground' and understanding how they are embedded in wider social and economic contexts provides an important entry into the analysis of the extremely problematic relationships between the conditions of reproductive and child health in the Global South and the policies put in place to ameliorate them. Starting from how drugs are actually being used raises many challenging questions about whether programmes developed at the national and even global level will meet with the success that their proponents desire.

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