The Centre for International Public Health Policy

QUALITATIVE RESEARCH ON FLUOXETINE AND OXYTOCIN IN INDIA

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Introduction

The first paper for this workshop addresses some aspects of the formal distribution system of pharmaceuticals in South Asia and indicates some ways in which the ground situation departs from the requirements of the formal regulations. This paper addresses similar issues, but from a rather different angle. The consumption of pharmaceuticals in the global South has been increasing, but there are varying interpretations of the reasons behind this. One perspective, for instance, suggests that the social and economic changes being wrought by processes of globalisation have generated ailments for which people seek relief and that is reflected in increasing demands for pharmaceuticals: here, pharmaceutical companies are simply meeting those demands. A rather different reading suggests that drug companies have been actively and successfully creating demands for their products by extending the psychiatric disease classifications used by doctors and potential patients/consumers and actively marketing the antidotes that deal with these new found ailments.

In this paper we want to reflect on these perspectives by focusing on some issues that are emerging from the qualitative work (mainly semi-structured interviews) that has been conducted so far by the South Asia-based members of the "Tracing Pharmaceuticals" team.[1] Our project is tracing the social lives of three pharmaceuticals—rifampicin, fluoxetine and oxytocin [RIFLOX]—through their whole life-cycle from production to consumption. Here we shall look at just one small segment of this larger picture, but one that we hope provides fruitful insights into the *distribution of knowledge* about and the *creation of demand* for RIFLOX.

Despite their important differences, both perspectives on pharmaceuticals consumption in the global south locate the motor for the rising consumption in features of Euro-American globalization. We want to complicate this picture by suggesting that the two perspectives outlined above are both top-down in orientation and fail to incorporate local social and economic specificities or the agency of local-level actors into their models. In this paper, we are

[1] We are not aiming to deal comprehensively with the issues and questions that have arisen, nor have we gone into enough depth yet on any of them, and our analysis is still very preliminary.

going to focus on India and on only two of our chosen drugs—fluoxetine and oxytocin—in order to make a start with indicating how the situation on the ground is more complex than is usually allowed.

Firstly, we need to emphasise that the Indian context presents us with some special conditions that are not replicated in most countries in the global south, including our other study location, Nepal.[2] The Indian patenting regime dating from 1972 enabled Indian pharmaceutical companies to reverse-engineer and produce generic medications (Chaudhuri 2005). Before signing the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994, the Indian government negotiated a 10-year transition period, which enabled Indian pharmaceutical companies to continue producing generic versions of patented products until 2005. The World Trade Organization (WTO) agreements came into force in 2005, but for the most part TRIPS applies only to drugs patented in India *after* 2005, which prevents Euro-American companies from patenting products that are already generically available. In India, multinational companies still have a market share of around only 20% and most drug consumption is of Indian manufactured medications, nearly all of them off-patent generics. Some pharmaceuticals are manufactured in Nepal, but the industry there is much smaller than in India, and many medications available in Nepal are imported, especially from India. Moreover, there are numerous Indian pharmaceutical companies, most of them small-scale producers but also several large companies that have a significant presence on the world market. Hence the role of multinational pharmaceuticals corporations in India has been significantly different from their roles in other parts of the global south.

Secondly, we should be wary of over-generalising about pharmaceutical products. On the one hand, the RIFLOX drugs have things in common with one another and many pharmaceutical products that mark them off from yet others that are available in India. Most RIFLOX consumed in India is manufactured in India by Indian companies (although the active pharmaceutical ingredients or APIs may be imported). All three are off-patent generic drugs that have been available in the region for some years: oxytocin and rifampicin since the 1970s, whilst fluoxetine is a relative newcomer dating from the 1990s. Health insurance schemes cover only a small

[2] We shall develop the contrast between the Indian and Nepali situations in later work.

section of the population and most drugs are paid for out-of-pocket by patients: compared with many other medications, RIFLOX are not highly priced, and price is not an insurmountable barrier to access except for the very poorest sectors of the population. Further, all the RIFLOX drugs should be provided only on prescription by licensed practitioners, yet there is widespread use of RIFLOX in the rural areas, where MBBS doctors are extremely thin on the ground and (especially during the 1990s) processes of economic liberalisation were circumscribing the reach of government health care provision. Understanding how demand for RIFLOX is generated and maintained, then, entails looking at channels other than (or in addition to) pharmaceutical companies, medical reps, formally trained medical practitioners and the government sector and particularly at the cadre of "rural medical practitioners" (RMPs).

Yet, if we consider the RIFLOX drugs separately, we can also see how distinctive their emerging biographies are. Here we shall tease out some of the points of comparison and contrast with respect to fluoxetine and oxytocin. In passing, though, we would flag up that rifampicin presents a dimension that distinguishes it from both fluoxetine and oxytocin. Rifampicin is central in national and international efforts to control TB and is thus caught up in official channels of procurement, distribution and funding to an extent that does not apply to fluoxetine and oxytocin. This suggests questions and issues that we shall pursue in due course, such as how the marketing activities of companies that manufacture rifampicin might differ from companies manufacturing fluoxetine and oxytocin, how information about rifampicin is distributed, the roles played by medical representatives and non-government practitioners outwith the TB control programme, and so forth.[3] The central and simple point that we want to hold onto here, though, is that it will be impossible to provide a single account that could be applied to all drugs, in all locations, and at all points in their social lives.

Rural Medical Practitioners

[3] We are exploring all these questions in our current work and shall discuss them in future.

Over two days in February 2007, Stefan Ecks and our research associate Soumita Basu attended the annual convention of the Rural Medical Practitioners' Association (RMPA) in a modest meeting hall in central Kolkata. Unlike conferences of trained doctors that are heavily sponsored by pharmaceutical manufacturers, this meeting had no pharmaceutical funding. There were around 300 delegates from across West Bengal state. The meeting opened with hoisting the RMPA flag and garlanding the picture of the Association's idol, Dr. Norman Bethune (whose career had included spells working with Republicans during the Spanish Civil War and in China with the Mao's troops resisting the Japanese invasion), followed by speeches from a couple of honorary guests.

Thereafter several delegates made impassioned speeches about the state of the Association and the problems currently faced by its members. A major concern was that it is still illegal to practise as an RMP because they do not have formal medical qualifications. Demands were made for the government to stop treating them as mere "quacks" and unlicensed charlatans without any medical expertise. Calls were made for RMPs' grass-roots work for people's health to be acknowledged by the government, for their legalisation with immediate effect and for their incorporation into the government health care system. These demands have a familiar ring: in government as well as lay circles in north India, RMPs are widely slighted by terms such as "quacks", as *naqlī* [counterfeit], as *jholā chhāp* (referring to a cloth shoulder bag, a designation with fly-by-night connotations), and -- outside Bengal -- as "Bengali doctors".

During the meeting, Stefan and Soumita talked to several RMPs about their reasons for becoming medical practitioners. Most commonly, they said they had been unable to secure any other suitable employment and that there was a substantial unmet need for medical care in rural West Bengal since government facilities were few and far between, with staff often absent, equipment non-functional and basic drugs out of stock. Nevertheless, the RMPs all claimed to have cordial relations with doctors working in government and private sector health care facilities alike. Indeed, the RMPs' working knowledge of essential diagnosis and therapy was largely derived from watching licensed doctors in action and many had worked as assistants for college-trained practitioners (mainly MBBS) before starting their own rural practice.

This is in line with the situation in rural western UP where Patricia Jeffery and Roger Jeffery have been working since the early 1980s, where government health provision is scant and nowadays largely non-functional and there are few MBBS doctors or those formally trained in other medical systems (Ayurveda, Unani). Most rural practitioners maintain relationships with urban practitioners, which often entail receiving "commission" when they refer rural patients to their urban practitioner contacts.

Throughout rural north India, including western Uttar Pradesh and West Bengal, the bulk of the health care for rural patients is provided by untrained and unlicensed medical practitioners, at least in the first instance. Most rural practitioners learned on the job, through employment with urban practitioners and this seems to be an important means by which they have come to know about RIFLOX. But the trajectories for fluoxetine and oxytocin require us to look at them separately.

Fluoxetine

Prescriptions for antidepressants have been strongly increasing since the late 1980s, an increase that is also evident in developing countries. What is unclear, however, is exactly what or who is driving this process and *from where* this increase originates. Bhugra and Mastrogianni argued that urbanization, migration, deeper divisions between the rich and the poor and other changes associated with globalisation precipitate anguish and thus greater need for psychopharmaceuticals (Bhugra and Mastrogianni 2004). Alternatively, Kirmayer and Minas regard globalization as the very process that disseminates Euro-American psychiatric disease classifications and pharmaceutical antidotes around the world (Kirmayer and Minas 2000). The global demand for drugs is being created by transnational pharmaceutical corporations in tandem with professional medical interests. Healy puts it this way:

> "the marketplace, far from being shaped by the laws of supply and demand, is constructed by large corporations ... Companies act to control not only the supply of

> products to a market but also the flow of ideas to the ideas market and to regulate the demands that come from the market" (Healy 1998: 212).

On the whole, the second view on antidepressant proliferation in the global south is far more convincing than the first. Indeed, it is not even difficult to find people working in the pharmaceutical industry who say just as much. Nevertheless, this perspective does not fit altogether comfortably for India and even a few ethnographic insights can unsettle current conceptions of the globalization of antidepressants.

Whilst antidepressants were developed and first marketed in the west in the 1980s and 1990s, the current Indian market is dominated by the generic products of Indian companies. In 2007, at least 50 different generic versions of fluoxetine were available in India, with three to four producers capturing the lion's share of sales. Moreover, a recent WHO-sponsored study on the availability and affordability of drugs in West Bengal (Tripathi et al. 2005) reports that the most-sold generic brand of fluoxetine (Cadila's Fludac) is on sale in 74% of medicine shops and the lowest-price generic is sold in 77% of all shops. Its price makes it affordable, even for poorer rural populations. Fluoxetine is not used in any government health facility: all prescriptions come from private sector physicians. The study does not, however, report on *who* exactly these private sector prescribers are and how they first heard about antidepressants.

Thus far, our work on fluoxetine suggests that initially, from the mid-1990s onwards, fluoxetine was promoted to psychiatrists in private practice, often backed up by various enticements to those who agreed to prescribe it. Even in India's metropolitan cities, psychiatrists are thin on the ground, however: West Bengal's population of over 85 million is served by only 332 members (2005) of the local branch of the Indian Psychiatric Society, most based in Kolkata. Thus attaining a high sales volume required the promotion of fluoxetine to non-specialists, especially general practitioners and non-psychiatric consultants who often deal with chronic illness, such as cardiologists and gastroenterologists. Depending on therapeutic specialities, fluoxetine is pitched differently. Given the stigma of mental illness, patients are often reluctant to take medication that they believe to be an antidepressant. Thus diabetologists may be told

that fluoxetine reduces carbohydrate cravings, whereas liquid fluoxetine is promoted for use with resistant and non-compliant patients. By 2007, though, the zonal marketing director for one of the leading brands of fluoxetine said that his brand was firmly established among both psychiatrists and non-specialists alike. Indeed, fluoxetine had proved to be a "cash cow" that had provided the capital to launch new products. Between 2006 and 2007, he had doubled his fluoxetine sales through brief and focused marketing: "We had our focus to promote [our brand] to all the physicians and the result came instantly. These tremendous sales we got not from psychiatry, but from physicians, from diabeto, cardio and all." Generally, though, brief reminders seem to be enough to keep sales levels buoyant.

Apart from direct contact with doctors, marketing people mentioned the "floating prescription" as a hugely important source of demand. Psychiatrists are said to be the "trendsetters" in prescription patterns. Non-specialists, however, prefer drugs that are already tried and tested and they most commonly learn about new treatments through prescriptions that patients bring to them, not through medical representatives. A marketing director for a fluoxetine brand said:

> "Once the consultant prescription is done, it floats in the market and immediately it reaches the GP… when a consultant shows faith in a particular product, it is immediately picked up by the GP."

Sometimes a patient who is in regular treatment by a psychiatrist also seeks treatment from a GP, e.g. for illnesses that do not seem to require specialist attention. Alternatively, a patient consults the psychiatrist only a few times, perhaps because access is cumbersome or the fees are too high, but continues to take the drug: thereafter, any problems are taken to the GP who learns about the prescriptions and the problem they were intended treat. GPs and other non-specialists try to imitate the prescription style of psychiatrists because patients may return to the psychiatrist at any point, and expose any ignorance about diagnosis and treatment. Copying prescriptions and forming a consensus about a "good drug" from a "good company" is an easy way of avoiding loss of face. Interviews with psychiatrists in Lucknow, the capital of Uttar Pradesh, provided similar accounts.

Floating prescriptions can be strikingly long-lived: up to ten years in some instances. Marketing managers said they often can only guess where demand for a product is created, since floating prescriptions widen the gap between active product promotion and actual sales. The easy availability of antidepressants in medicine shops is crucial for the staying power of written prescriptions. As a "Schedule H" drug, fluoxetine should not be sold over the counter, yet it is easily available over the counter and it matters little if the prescription is old or was written for another person, or indeed if there is no prescription at all. Retailers generally excuse this illegal practice by arguing that people in a poor country such as India should not be compelled to waste money on doctors' fees. Indeed, retailers commonly act as unlicensed prescribers themselves, who learn about common treatments, and then readily sell prescription medicines to customers who seek their advice. Refusal to do so would damage business, whilst complying with requests maintains good customer relations. Other unlicensed prescribers, including RMPs, also learn about drugs such as fluoxetine from floating prescriptions, which seem to be crucial in establishing particular brands as the most commonly prescribed.

Drug companies are still far from *officially* endorsing unlicensed prescribers such as the RMPs, but in practice are now focusing on them almost as if they were licensed GPs. Medical representatives are less geared towards teaching unlicensed prescribers about fluoxetine and its uses than converting them to their own brand after they have already begun prescribing some kind of antidepressant. No companies have organised "depression awareness workshops" and similar brand building events for RMPs. Yet all the RMPs we interviewed said they were regularly visited by company medical reps simply because they promised good business for them. One RMP reported that the free samples provided by medical reps were often the only way that poorer patients could receive medication and he claimed to be visited by up to 35 medical reps each month:

> "In our Block, there are not more than four qualified doctors, whereas there are 170 RMPs. Naturally, *we* see most of the patients. So the companies try to capture this market. They did not visit the RMPs earlier because of their status, but now they know that their volumes will grow if they come to us."(RMP-5)

The consensus amongst RMPs was that "mental" problems were rising because of chronic economic insecurity and that their own patient profiles had changed over the years. One RMP noted that MBBS doctors had been changing their *prescription* habits over the years:

> "We get two kinds of patients. One, the psychiatric patients come to us who are already on psychiatric drugs that have been prescribed by some specialist. They start the medicine and then come to us to know what it is all about; or they may have stopped the medicine and then come to us for the problems that arise after stopping the medicine. Two, they may come for other health problems and in the process show us the prescriptions from where we can learn what they are taking"(RMP-2).

RMPs' perception that depression, anxiety, and other mental problems are increasing comes not from learning to diagnose symptoms, but from learning patients' medication history. Moreover, this process does not proceed in a linear fashion, but is often triggered by a patient's incomplete understanding of, or discontinuation or non-compliance with, treatments prescribed by licensed doctors. And patients come with prescriptions that the licensed doctors did not mean to be shown to other practitioners. In other words, RMPs learn about psychiatric treatments through doctor-shopping patients and they infer that mental illnesses are on the rise from a noticeable increase in psychotropic prescriptions by licensed doctors.

All the RMPs we talked to associated a range of physical symptoms with depression: including sleep disturbance, lack of concentration, lack of libido and sexual weakness, irritability, irregular thoughts, burning sensations in the head, digestive problems and "gas". Most of the RMPs were aware of anxiolytics and antidepressants. When we asked specifically about Fluoxetine, one of the RMPs asked us if we meant "the sleeping pill?" He went on to narrate how he had once suffered from stomach pains and went to see a city doctor about it:

> "I used to suffer from *gastritis* pains. I went to a doctor in the city and he gave me some medicines. I did not check with CIMS [*a drug reckoner*] to know what kind of medicine it is. After having it for a month, when I checked I found it was a sleeping pill. It was called

> Ativan [*generic name Lorazepam, a benzodiazepine*]. When I came to know it is a sleeping pill, I thought: 'Let me discontinue and see how I do.' … Then I started praying and used to fall asleep while praying. I used the same treatment for my patients. They get physical strength and mental peace, and their family relations improve." (RMP-3)

In this case, the RMP had learned through a combination of his own experiences as a patient with stomach aches and his readings in a drug manual that MBBS doctors prescribe psychotropics for such symptoms, and he started to apply this therapy in his own practice. It did not seem to perturb him that the licensed doctor had diagnosed him with a mental problem, nor that he had been told about neither the diagnosis nor about the type of drug prescribed. Some RMPs said they used anxiolytics and antidepressants frequently, with a certain preference for anxiolytics such as Alprazolam as the first-line treatment, followed by SSRIs (Selective Serotonin Reuptake Inhibitors) such as fluoxetine. Yet many RMPs still seemed hesitant about using antidepressants, for several reasons. The RMPs thought that most patients in rural areas had difficulties paying for them, especially as the treatment lasted for an extended period. Some felt that they did not know enough about these drugs, and also saw the root cause of the problem as economic and social and, as such, irreducible to drug treatment, even though psychotropics were perceived to alleviate mental problems in the short term: "I don't think this problem can be solved with medicines. The cause is socio-economical. But we use medicines to take care of the symptoms" (RMP-1).

Thus several processes are working to increase levels of fluoxetine consumption in India. Whilst active promotion of fluoxetine certainly plays a part here, the role of companies and their medical reps must be seen alongside "floating prescriptions", the personal experiences of RMPs and its ready accessibility over-the-counter.

Intrapartum use of Oxytocin

Oxytocin has been available in India since the 1970s. Although most oxytocin consumed in India these days is manufactured by Indian companies, Novartis is also an important supplier (though it markets oxytocin at a lower price than outside India). Several studies in rural UP have

indicated that oxytocin is widely used intrapartum to augment (rather than to induce) labour, usually administered by intramuscular injection (rather than intravenously). Patricia Jeffery and colleagues reported its use in labour in rural Bijnor district in the early 1980s (Jeffery et al. 1989: 211-212). By 2002, 48% of the village women received one or more injections of oxytocin during labour, administered by untrained private rural medical practitioners (male).[4] These injections were popular with women who wanted their labour to be over quickly and they were not prohibitively costly; many women reported having had several injections. Similarly, Abhijit Das et al. conducted a study in 12 UP districts that indicated similar use of oxytocin in home deliveries throughout the state (in nearly 75% of home deliveries in Muzaffarnagar, in western UP), with almost two-thirds the women who reported injections having had more than one (Das et al. 2005).[5] In another study in UP, Sharan et al. found no clear link between perceptions of complications and oxytocin use (Sharan et al. 2005). Das et al. found that oxytocin was more commonly used among women in more wealthy families and women who were relatively more educated, which suggests that oxytocin was being used less because of need and more because of ability to pay and because of an association of the hypodermic needle with 'modernity' (Das et al. 2005). This last point is endorsed by a study conducted in Sitapur district in UP (Pinto 2004). According to Das et al., the labouring woman's attendants generally suggested calling a practitioner to administer an injection (Das et al. 2005), whilst *dāīs* (traditional birth attendants, TBAs) are also reported to encourage oxytocin use (Sharan et al. 2005).

The conversations that Stefan and Soumita had with RMPs in West Bengal indicate that RMPs know about and may use oxytocin. RMPs report that oxytocin can be readily purchased over the counter in local pharmacies. Since they may be summoned at any time of day or night, RMPs who use oxytocin keep it in store and they sell it on when they administer it.[6] Oxytocin is not a highly priced drug: in India a phial of 5mg of oxytocin costs only a few rupees, although the RMP may charge Rs150 or more to administer the injection. RMPs are usually called in only after a woman's labour has begun. They do not examine the woman and rely on the *dāī's* advice that

[4] The research in Bijnor in 1982-3 and 1985 was funded in the 1980s by ESRC and that in 2002-4 by Wellcome Trust.

[5] Intrapartum oxytocin use has also been reported in Caleb, L. E. (1995), Van Hollen, C. (2003a & b), Pinto, S. (2004), George et al. (2005), Matthews et al. (2005), Sharan et al. (2005).

[6] This does raise some issues about efficacy (that we shall not pursue here), since oxytocin should not be stored for long periods without refrigeration.

the cervix is sufficiently dilated for the oxytocin to be safely administered. One RMP commented:

> "It is very important to see if the cervix has dilated before using oxytocin. But in the villages they don't allow us to see the cervix. We have to depend on the *dāī* for that but they don't understand it properly. They don't understand one-finger, two-finger, four-finger at all. Very often when it is only two-finger, they say it's four-finger. Trusting their judgement when I have given oxytocin, they suffered from 'failed uterus' [meaning ruptured uterus]" (RMP-5).

Subsequently, he stopped administering oxytocin to labouring women, although he does use it to combat post-partum haemorrhage (see below).[7] Another RMP denied using oxytocin in labour because of dangers that cannot be managed in a home delivery. Others, however, do use oxytocin in labour. Tellingly, for our purposes here, the RMP who no longer uses oxytocin intrapartum deals with requests for injections by giving a placebo (at least partly in order to retain his patients!):

> "We get a number of such requests. Now we just give a placebo to satisfy them. We cannot give oxytocin always. It may not be required and one needs to monitor it. It needs time. But if we don't give anything, they think we don't want to or that we don't want to attend to them at night" (RMP-5).

In rural north India, babies are usually born at home and birthing is a largely "un-medicalised" affair. Thus the current popularity of intrapartum use of oxytocin in rural home deliveries in north India presents something of a puzzle—although perhaps of a piece with the widely reported enthusiasm of villagers for biomedical remedies in general, especially when administered by a hypodermic needle. There appears to be a *demand-led* market for oxytocin, rather than one driven by pharmaceutical companies. Interviews with medical reps in Kolkata, for instance, suggest that pharmaceutical companies are not (currently) investing in oxytocin

[7] One RMP also claimed that oxytocin is widely used in rural West Bengal to induce abortions.

marketing and medical reps do not regard it as central to their portfolios. In any case, the potential for expanding its sales is limited by non-marketing factors (not least, the number of births in a locality), a feature of oxytocin that renders it rather different from some other drugs, including fluoxetine.

In all probability, the processes by which oxytocin reaches labouring rural women nowadays may be rather different from those that typified its early days in South Asia, and this has led us to try to "trace" oxytocin use in the *past*. How has such widespread use of oxytocin come about, apparently to the point where labouring women and/or their attendants demand its use? Over the past few months we have been learning a great deal about oxytocin use that we had not anticipated before we began the research, and which enables us to shed rather different light on the spread of knowledge about it and its uses. We shall touch on just three issues here: bovine oxytocin, institutional deliveries and the recent policy push to reduce post-partum haemorrhage.

Dairying and market gardening

In December 2006, we held two inception workshops for Tracing Pharmaceuticals, one in Delhi and one in Kathmandu. When Patricia raised the question of how and why oxytocin use had become so widespread in rural home births, participants in both workshops suggested that exploring the background of veterinary uses of oxytocin might enable us to trace out how RMPs and villagers alike became aware of oxytocin's uses. Could bovine oxytocin give us leverage over this history? Was it the route through which oxytocin first became known and available in the rural areas?

Over the following months, members of our team have interviewed vets and also asked other interviewees about bovine oxytocin. The picture that is emerging is that bovine oxytocin is

widely used in rural north India and Nepal, especially by people who engage in marketing milk, because it is believed that injecting oxytocin enhances the let-down response in cattle without needing to permit the calf to suckle (and reduce the amount of milk available for sale). For instance, we have been told about 'sharecropping' arrangements between rich farmers and landless or land-poor villagers, whereby cattle owned by the former are fed and milked by the latter, who rely upon milk sales for their incomes. Several people also claimed that peri-urban dairies use oxytocin (one health activist in Lucknow supported his argument by telling us about buying a load of cattle manure for his garden and extracting several dozen empty oxytocin phials from it). Bovine oxytocin is said to be widely available over the counter, indeed like other veterinary drugs to be sold from the same pharmacies in small towns that deal in medicines for human consumption. Some of the companies that manufacture human oxytocin also make bovine oxytocin, although bovine oxytocin is sold in larger phials and its unit price is lower. Some people have also claimed that its manufacturing process was less subject to quality controls, but we have not yet checked this out. One vet in Lucknow said that the UP government had banned the use of oxytocin to enhance milk production because it amounted to cruelty to animals: cattle injected daily with oxytocin suffer uterine contractions and in the longer term are liable to become infertile and even to develop ovarian cysts and cancer.[8]

Perhaps even more surprisingly, we have been told that vegetable growers inject items such as squashes and cucumbers with oxytocin a couple of days before harvesting because the oxytocin accelerates cell growth and division and plumps up the produce for market. We have not attempted to ascertain how market gardeners discovered this effect of oxytocin on vegetables and nor have we done a systematic search for studies of the effects of these uses of oxytocin on human consumers of milk and vegetables.

Clearly, however, knowledge about oxytocin is widespread and oxytocin is readily available—even though it is a scheduled drug supposedly obtained only with a prescription. Our interview material to date, however, does not enable us to arrive at an understanding of the relationship between bovine and vegetable uses of oxytocin and human uses of oxytocin—if there is one.

[8] In Nepal, too, over-the-counter sales of bovine oxytocin are illegal—but nevertheless apparently very widespread.

Would villagers and RMPs make a connection between the use of bovine oxytocin to enhance milk production and human oxytocin to augment labour? For the moment, we are inclined to think that knowledge about intrapartum use of oxytocin spread to the rural areas by other means, which takes us to the next point: institutional deliveries.

The normalisation of oxytocin use in urban facilities

Several interviewees have directed our attention to the intrapartum use of oxytocin in urban nursing homes and hospitals. A senior midwife and lecturer in nursing in Delhi, for instance, 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 maintain rapid through-put because there were not enough beds in the labour rooms to meet the demand. This kind of point was made by several other people to whom we have talked about this issue. In addition, in this project and also in the research Patricia Jeffery did in rural western UP in 2002-4, lay people frequently (and cynically) pointed to the financial interests of non-government health providers, that lead them to administer drugs (or conduct even more lucrative caesarean sections) at the first opportunity when labouring women arrive at their nursing homes. We have not conducted ethnographic work in labour wards and cannot judge the merits of these kinds of reports, but they do suggest that intrapartum oxytocin use has (perhaps for several reasons) become normalised in institutional deliveries in north India.[9] We are also unable to adjudicate on the extent to which this is over and above what might be classed as use determined by 'medical need'.[10]

As yet, we do not have any timeline for this development but we incline to the view that RMPs, who typically claim to have learnt their trade through their previous employment in urban

[9] This seems to be the case in urban Nepal too.

[10] Reported rates of oxytocin usage are significantly higher than those detailed in studies in those contexts from the global north where staff have no financial incentive to medicate and where pressure on labour room beds is low.

facilities, have observed the intrapartum use of oxytocin there and have taken this knowledge to their rural practices. Equally, RMPs report that they maintain relationships with urban facilities, for instance, through referrals. Indeed, some of the RMPs in Kolkata expressed uncertainty about how best to administer oxytocin and one said:

> "We are not well educated. We do whatever we have learnt from our gurus. We also try to follow how the doctors do treatments when our patients go to the cities. When we let a patient go and visit a doctor in the city, we closely follow what is being done. That is how we learn" (RMP-4).

We remain agnostic about how and when information about oxytocin reached the rural areas of north India and Nepal, and will continue to explore the topic. At the moment we feel that rural practitioners are more likely than veterinary sources to have been the means by which village-level demand for intrapartum oxytocin use has been generated and sustained. For the moment, though, we feel fairly confident in saying that oxytocin availability and intrapartum use in the region is much more pervasive than would be expected if information about it were merely spread by pharmaceutical companies via medical representatives and if it were administered only by formally trained medical practitioners. If this is so, however, a further puzzle arises, one that relates to some Indian government policy proposals which were announced in early 2007.

Post-partum haemorrhage and Active Management of Third Stage of Labour

One of the single most important causes of maternal mortality is post-partum haemorrhage (PPH): the Sample Registration Scheme (SRS) special study suggests that it accounts for some 38% of maternal mortality in India (Registrar-General India 2006: 15), whilst the Global Burden of Disease estimates for South Asia are that 31% of maternal deaths are due to haemorrhage (Registrar-General India 2006: 17).[11] Recently, PPH has been the focus of major policy initiatives around the world, partly because reducing maternal mortality is a Millennium Development

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

Goal.

In India, government policy proposals for preventing PPH and encouraging the "active management of third stage of labour" (AMTSL) were launched in February 2007 at a meeting in Delhi attended by Roger Jeffery and Patricia Jeffery. The White Ribbon Alliance-India had been working in close collaboration with Ministry of Health and Family Welfare, Government of India, to develop Guidelines and Protocols for delivery of essential package of maternal and child health services to be provided under RCH II [Reproductive and Child Health-II], with particular reference to the Skilled Attendance at Birth initiative that aimed to tackle maternal mortality through provision of skilled care in the community. The report, entitled *Promoting Skilled Attendance at Birth in India - A Brief Report*, referred to the MacArthur Foundation grant that had enabled 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 set out 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).[12] It continued:

> Under this grant, WRAI has successfully collaborated with MoHFW in bringing about policy changes to enable health providers at different levels to practice life saving skills. As a result of concerted advocacy and technical support by WRAI, the regulation on the use of drugs by the existing ANMs/LHVs [Auxiliary Nurse-Midwife/Lady Health Visitor] has been changed to facilitate their working as Skilled Birth Attendants. This was a landmark decision in India and required obtaining regulatory permission from Drug Controller of India. The ANMs and nurses will now be **permitted to administer life saving drugs** and perform certain procedures such as:

[12] The process entailed quite complex brokering of discussions amongst various parties, for instance persuading medical representatives to agree to proposals advocated by nursing representatives to permit ANMs to administer injections.

- Tablet Misopristol [sic] to prevent and Injection Oxytocin to manage post-partum haemorrhage[13]
- Injection Magnesium Sulphate to manage Eclampsia
- Parenteral Antibiotics to manage infection
- Intravenous infusion to manage shock
- Carry out life saving procedures in certain specified circumstances like removal of retained products of conception
- Active management of third stage of labour[14]
- Use of partograph to monitor labour for early detection and referral of obstructed labour to reduce maternal mortality[15]

At the launch meeting for the WRAI report, several speakers acknowledged that ANMs attend only a small minority of rural births and that training enough skilled attendants to provide full coverage would take years. Later, in one-to-one conversations, several participants at the launch also acknowledged that oxytocin is already being widely administered intrapartum in rural India and that this is a risky practice.

Yet the WRAI-brokered policy initiatives would see the even wider availability of oxytocin in rural areas since government-employed ANMs will be permitted to inject it in *third* stage labour.

[13] The use of oxytocin and misoprostol to manage PPH has raised issues about their relative appropriateness. Oxytocin is more effective in preventing and controlling PPH, but requires syringe technology and sterilisation equipment (although the possible introduction of "Uniject" syringes might reduce this problem). Further, according to the product information for Syntocinon, a leading brand, it should be kept below 25°C and should not be frozen; few rural health facilities have reliable electricity supplies or refrigeration facilities, however. And there is the possibility that oxytocin intended for administration in *third* stage of labour may be used intrapartum, either because health staff themselves use it in that way or because they sell it to local practitioners. Misoprostol is less effective in dealing with PPH but can be administered in pill form and is not heat labile; its possible use intrapartum—which could be extremely dangerous—does not seem to have been addressed in the policy discussions.

[14] AMTSL entails massage of the uterus and controlled traction on the cord, as well as 10 IU of oxytocin given by IM injection to encourage expulsion of the placenta and reduce the possibility of PPH.

[15] Partographs are charts on which birth attendants can plot a woman's labour (on various dimensions, such as frequency of contractions) so that progression can be monitored and judgements made about when emergency care should be sought.

More generally, public documents contain no reference to intrapartum oxytocin use beyond the purview of the state health care sector. For instance, despite the evidence of small-scale studies, 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 oxytocin.[16] And intrapartum oxytocin use seems not to be on the radar of organisations such as WHO, UNICEF and other INGOs concerned with reducing maternal and neonatal mortality.

Reflections

Fluoxetine and oxytocin, then, are widely available in India, including in the rural areas. Both are relatively low-price off-patent generics and the versions available are mostly those manufactured in India by Indian companies. In both instances, there is "irregular" usage at the fringes, prescribed and administered by unlicensed and uncredentialised practitioners.[17] The extensive reach of both fluoxetine and oxytocin reflects more general processes of commodification of health care. But the processes through which the markets for fluoxetine and oxytocin were established and have been sustained are probably not identical.

For many pharmaceuticals, medical representatives working amongst formally-trained MBBS doctors (including those working in the government sector) are key sources of information about pharmaceuticals for prescribers. For fluoxetine and oxytocin, they may have been crucial initially. Medical reps, however, are not *currently* the only part of that story—possibly because fluoxetine and oxytocin are not expensive drugs from which major windfalls could be anticipated, possibly because sales remain fairly buoyant without much active promotion by manufacturers.

[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. Data from this study have not been published at the time of writing this paper.

[17] Often, this usage is contrary to medical protocols, but this is an issue that we shall take up elsewhere.

Certainly, for fluoxetine, company-led increases in demand through the promotional activities of medical reps must comprise part of any account of increasing knowledge about and sales of the drug—although we need to stress that the main companies operating in India are *not* multinationals but Indian-owned companies. Yet there are limits on the extent to which the Indian market for fluoxetine could be grown if marketing activities remain focused on psychiatrists alone. It is thus that doctors trained in other medical specialities and untrained/unlicensed practitioners who receive their knowledge through indirect routes (such as "floating prescriptions" brought by patients who have previously consulted other doctors) must become central to our account of how knowledge about fluoxetine has spread so widely in little over a decade. Moreover, the market for fluoxetine (and for antidepressants more generally) could be grown more or less indefinitely. Indeed, through fluoxetine, it may be possible to disseminate and inculcate notions of mental distress as something to be dealt with by medication—with the upshot that mental illness diagnoses and the perceived need to medicate can be extended to cover conditions not previously considered to be ailments. More than that, fluoxetine (and other medications dealing with mental conditions) could encompass all sectors of the population—old, young, male, female etc.—as more conditions become defined as illnesses requiring medical intervention. The potential for market expansion and for the medicalisation of mental health is vast. In the somewhat longer term, under the post-TRIPS patent regime, non-Indian companies might be more able than Indian ones to develop and patent new molecules for such ailments, and to penetrate the Indian market more effectively than at present by riding on the back of the widened demand for mental health medications that is currently being generated. None of this immediately invalidates the model of a worldwide marketplace for antidepressants constructed and controlled by Euro-American drug corporations. But it does suggest that there are important processes taking place in the market for antidepressant drugs that are beyond the control of, even maybe beyond the commercial interests, of these corporations.

In several respects, oxytocin provides a rather different picture. There is little evidence that oxytocin is *currently* being actively marketed by its predominantly Indian manufacturers. Put rather differently, it seems that oxytocin sales can continue these days because a grassroots

demand for it has been firmly entrenched. But we still need to delve more deeply into the biography of oxytocin in India before we can develop a more rounded picture of how and why demand for oxytocin administered intrapartum has come to be so extensive, even in the rural areas where other aspects of birthing as so unmedicalised. Unlike fluoxetine, we have no indication of "floating prescriptions", but the RMP is certainly a key player who administers oxytocin directly to the labouring mother with any prescription intervening. On the face of it, a drug such as oxytocin does not offer virtually unlimited marketing opportunities, such as are potentially available for antidepressants, for (as yet anyway) human uses of oxytocin do not extend beyond the pregnant or newly-delivered woman. But we can still ask if the intrapartum use of oxytocin expands the spaces for the medicalisation of other aspects of childbearing in India—including the so-called "cascading of interventions" that have been so widely commented upon in respect of institutional birthing in the west. Further, it is too soon yet to comprehend the implications of recent policy commitments to tackle PPH by using oxytocin in third stage of labour for the sales and use of oxytocin and other medications associated with childbearing.

We still have a great deal to learn, but we hope to have indicated that frameworks privileging the roles of multinational pharmaceutical companies, and particularly the work of their medical reps, in increasing pharmaceutical consumption in the global south can provide only a partial view. There are "informal" routes that spread knowledge about and access to pharmaceuticals and these require us to examine the particularities of context as well as of the drugs themselves.

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