

Institution: The University of Edinburgh

Unit of Assessment: 23 Sociology

7: Impact of Research on Maternal Health and Unregulated Pharmaceutical Use in South Asia

1. Summary of the impact

Globally, there are around 290,000 maternal deaths per year, 83,000 of them in South Asia. Post-partum haemorrhage [PPH] is a major contributor to maternal mortality. Currently, oxytocin is advocated as a key life-saving drug for arresting/preventing PPH when administered immediately **after birth**. Edinburgh University research on home deliveries in India exposed one important but largely unacknowledged and unquantified risk-factor for maternal mortality: widespread misuse of oxytocin **during labour** to speed up the process. These and other findings in relation to the supply and unregulated use of pharmaceuticals in South Asia have been brought to the attention of advocacy groups and international donors, thus helping frame pharmaceuticals policy debate, e.g. by highlighting the need to reduce the diversion of oxytocin for dangerous use during labour. The research has also increased recognition of the importance of ethnographic research in facilitating evidence-based public-health policy-making and enhanced the capacity of advocacy groups to provide evidence-led input on crucial policy questions.

2. Underpinning research

The research was conducted by Patricia Jeffery (PJ: Lecturer, then Reader, and since 1996 Professor of Sociology at University of Edinburgh) and Roger Jeffery (RJ: Lecturer, then Senior Lecturer, and since 1997 Professor of Sociology of South Asia at University of Edinburgh). During 'Demographic change in north India' (Wellcome Trust: 2002-5), PJ's detailed ethnographic work found that in rural north India most people associate institutional deliveries with ruinous costs and poor quality of care (P Jeffery and R Jeffery 2008, 2010) and women agree to give birth in an institution only when they feel there is no option. This fieldwork also entailed attending home deliveries, where untrained male practitioners were observed administering synthetic oxytocin during labour (intra-partum) with *intra-muscular injections* (P. Jeffery et al. 2007).

Worldwide, oxytocin is used to induce/augment labour. According to international protocols, oxytocin should be used intra-partum only under specified circumstances: including monitored *intra-venous* administration and continual monitoring of the mother and unborn infant by trained staff within institutions capable of providing emergency obstetric care. None of these requirements obtains in rural home deliveries. Intra-partum oxytocin misuse can cause uterine rupture, internal haemorrhage and maternal death (and/or foetal distress, foetal brain damage and fresh stillbirth). Further, although oxytocin is a scheduled drug in India, supposedly obtained only on prescription, it is readily and cheaply available over-the-counter from private pharmacies (see Brhlikova, P. Jeffery et al. 2009).

The research findings link directly into global health-policy. They highlight the dangers of health policy-making devoid of in-depth understandings of quotidian medical practice and of the crucial role of unregulated markets in widening access to drugs. The violation of international protocols for oxytocin use, its unregulated availability and other aspects of birthing practices in rural India are all largely invisible to health policy-makers.

Among other targets, Millennium Development Goal 5 aims to reduce the maternal mortality ratio (MMR, number of maternal deaths per 100,000 live births) by 75% between 1990 and 2015. Although India seems to be moving in the right direction, civil registration systems are weak and estimates of MMR are almost certainly undercounts. A major cause of maternal mortality is post-partum (after birth) haemorrhage [PPH] and a central recommendation for MDG-5 implementation was to make oxytocin available through government channels for injection *post-partum* to prevent/arrest PPH—in apparent ignorance of its already widespread availability over-the-counter and of its inappropriate use *intra-partum*.

Dissemination activities associated with this research (workshop in Delhi, publications) attracted the attention of some public-health advocacy groups in India and resulted in 'Tracing Pharmaceuticals in South Asia' [TPSA] (ESRC: 2006-9), research on unregulated pharmaceutical use in relation to Safe Motherhood, TB and mental health. During this research PJ interviewed government and private-sector obstetricians (and medical specialists in related fields) about their practices and she also observed institutional deliveries: oxytocin is widely used intra-partum in institutional deliveries in South Asia and this use also often violates international protocols for

oxytocin use intra-partum. In this research, the Edinburgh scholars collaborated with advocacy groups, especially SAHAYOG and CHSJ [Centre for Health and Social Justice] in Lucknow and Delhi respectively, both of which have excellent track-records in relation to health-related gender issues, including inputs into maternal and child health policy-making.

The TPSA research was methodologically innovative in 'following the drug' (oxytocin, rifampicin, and fluoxetine) rather than looking at particular disease conditions, and it was subsequently extended to additional medicines and more countries in 'Access to Medicines in Africa and South Asia' [AMASA] (EU FP7: 2010-13) and 'Biomedical and Health Experimentation in South Asia' [BHESA] (ESRC/DfID: 2010-12). The TPSA and AMASA projects have e.g. identified the dangers that arise from unregulated markets for pharmaceuticals and the sources of the mistrust that characterises many (if not all) relationships amongst stakeholders engaged in South Asia's pharmaceuticals supply chains, mistrust which generates high transaction costs and impacts upon the capacity of South Asian producers to enter the global medicines arena. The BHESA project addresses ethical and other issues connected with drugs trials.

3. References to the research

Brhlikova, Petra, **Patricia Jeffery**, Gitanjali Priti Bhatia and Sakshi Khurana (2009): 'Intrapartum Oxytocin (Mis)use in South Asia' *Journal of Health Studies* 2 (1, 2, and 3): 33-50, <http://jhs.co.in/articles/showArticle.aspx?aid=46>

Brhlikova, Petra, Ian Harper, **Roger Jeffery**, Nabin Rawal, Madhusudhan Subedi and M. R. Santhosh (2011): 'Trust and the Regulation of Pharmaceuticals: South Asia in a Globalised World' *Globalisation and Health*, 7 (10), DOI: [10.1186/1744-8603-7-10](https://doi.org/10.1186/1744-8603-7-10). In REF2.

Jeffery, Patricia, Abhijit Das, Jashodhara Dasgupta and **Roger Jeffery** (2007): 'Unmonitored Intrapartum Oxytocin Use in Home Deliveries: Evidence from Uttar Pradesh, India', *Reproductive Health Matters* 15 (30): 172-178, DOI: [10.1016/S0968-8080\(07\)30320-0](https://doi.org/10.1016/S0968-8080(07)30320-0)

Jeffery, Patricia and **Roger Jeffery** (2008): "'Money itself discriminates": Obstetric Emergencies in the Time of Liberalisation' *Contributions to Indian Sociology* 42 (1): 59-91, DOI: [10.1177/006996670704200104](https://doi.org/10.1177/006996670704200104). In REF2.

Jeffery, Patricia and **Roger Jeffery** (2010): "'Only when the boat has started sinking": A Maternal Death in Rural North India' (in Special Issue on Loss in Childbearing), *Social Science and Medicine* 71 (10): 1711-1718, [10.1016/j.socscimed.2010.05.002](https://doi.org/10.1016/j.socscimed.2010.05.002). In REF2.

Main underpinning research grants:

2002-5: *Demographic Change in North India: A Longitudinal Micro-Study* (Wellcome Trust) (Patricia Jeffery PI, with Roger Jeffery) (£87,000) (067231/Z/02/Z)

2005-10: *Improving the Outcomes of Education for Pro-Poor Development: Breaking the Cycle of Deprivation* [RECOUP] (DfID). PI Professor Christopher Colclough, Centre for Commonwealth Education, University of Cambridge with consortium partners in Edinburgh (including RJ and PJ), Oxford, India, Pakistan, Kenya and Ghana (£2,500,000, of which £363,160 came to Edinburgh).

2006-9: *Tracing Pharmaceuticals in South Asia: Regulation, Distribution and Consumption* [TPSA] (ESRC/DfID Joint Programme) (Roger Jeffery PI; with Stefan Ecks, Ian Harper, Patricia Jeffery and Allyson Pollock) (£717,000).

2010-12: *Biomedical and Health Experimentation in South Asia* [BHESA] (ESRC/DfID) (Roger Jeffery PI; with colleagues in Edinburgh, Durham, Mumbai, Kathmandu and Colombo) (£399,514).

2010-13: *Access to Medicines in Africa and South Asia* [AMASA] (EU FP7) (Roger Jeffery PI with Allyson Pollock and partners in Ghent, Basel, Mbarara, Kampala, Pune, Cape Town) (€2,995,790).

4. Details of the impact

These research undertakings have shaped and informed policy debate in two main ways: first, through personal engagement of key members of the research team with advocacy groups and policy-makers in India and via dissemination workshops in South Asia (e.g. Delhi, Kathmandu, Hyderabad, Colombo) attended by government officers, NGO workers etc.; second, through engagement with international donor advisors.

Impact on policy-framing in India (corroboration sources: sections 5.1, 5.3 and 5.4)

In a post-colonial context, research impact on government policy in India is often best achieved through local advocacy groups, in this instance especially SAHAYOG and CHSJ (see above) who work to ensure that government policy and programmes on reproductive and child health etc. are

informed by rural ground realities beyond the normal purview of the state. The research has had two distinct but inter-related impacts on their work: it has alerted them to the prevalence of oxytocin misuse intra-partum and the importance of ensuring that policy targeting PPH through the use of oxytocin post-partum is not undermined by such misuse; and it has provided them with qualitative research training to enable them to generate an evidence-base from around India on this and other aspects of birthing experiences, for use in their advocacy work on Safe Motherhood.

The research conducted by PJ and RJ has shown how small-scale research can reveal and crystallise key issues to be addressed by larger-scale research projects that can then influence policy-makers. Thus health activist [text removed] writes that this research "has made important contribution in the framing of policy debate around health in India ... in respect to the production and use of drugs" (email, 26 June 2013). [Text removed] writes that it provides "a detached, scholarly voice to the political aspects of access to medicine in India and is a great help for rational drug policy advocates in India" (email, 26 June 2013).

During the RECOUP project (2005-10), RJ and Dr Nidhi Singal (University of Cambridge) developed a training-package on qualitative research methods

(http://manual.recoup.educ.cam.ac.uk/wiki/index.php/Main_Page). The training-package has been used in a variety of contexts: it has e.g. been translated into Russian and Kazakh for use by Kazakhstani teachers in school-based research informing education reform. It was used by [text removed] (SAHAYOG) and [text removed] (CHSJ) for a four-day workshop in 2008 to train activists/advocacy workers from various Indian states, so that they could conduct community-based investigations into the experiences of women and their family members with respect to 'near-misses' (obstetric emergencies that almost resulted in maternal death). With on-going guidance from PJ, [text removed] and her colleagues analysed the state-level interview data and compiled an overarching evaluation report on the quality of maternity service provision at the grassroots. [Text removed] was appointed to manage civil society monitoring of the Indian Government's National Rural Health Mission (NRHM), and used this report in his evaluation of NRHM as well as in his work on the Steering Committee on Health working on 12th Five Year Plan under the auspices of the Planning Commission. In a joint statement [text removed] confirm that the TPSA project contributed to their work in the following ways:

1. (...) helped CHSJ to develop its research skills, particularly in the appropriate use of qualitative research and mixed method research and small scale research which is policy focussed. CHSJ subsequently used this competency to conduct/steer more than 25 small scale studies on different policy aspects. These studies by CHSJ have been acknowledged by the Planning Commission of India and the Ministry of Health and Family Welfare as sources of independent feedback for improving the health system performance. It has also acknowledged CHSJ's expertise by appointing [text removed] as a member of the Steering Committee on Health for the 12th Five Year Plan.
2. SAHAYOG developed its skills in using rigorous research for policy advocacy through its association with the TPSA project. SAHAYOG took the issue of quality of maternal health services forward, from the oxytocin component of study into a process of collaborative research and advocacy. SAHAYOG received support from Prof Patricia Jeffery in designing a collaborative study of quality of care of institutional delivery. This study has been widely presented and reported in global circles. The collaboration has led to the formation of national network - National Alliance on Maternal Health and Human Rights - which continues to advocate for better quality services with the Ministry of Health and Family Welfare, Government of India. The issue of poor quality maternal health as a serious concern has now been mainstreamed in the global policy arena and SAHAYOG is intimately connected with the global advocacy around the region through its involvement in the International Initiative on Maternal Mortality and Human Rights, and with the Office of the High Commissioner of Human Rights at the UN. (email, 5 June 2013)

Impact via international donors (corroboration sources: section 5.2).

PJ has been invited to contribute in various ways to programme development among international donors. Her main involvement has been through Seattle-based **PATH (Program for Appropriate Technology in Health)**. PATH is a hugely-influential global health NGO (it funded, for instance, the world's first successful malaria vaccine), and it has a Gates Foundation-funded project to

develop Uniject™, “an easy-to-use, injection-ready tool that ensures an accurate dose in a non-reusable, sterile device with minimal preparation and minimum waste”, containing heat-stable oxytocin. In 2009, PJ was asked to join PATH’s Oxytocin Initiative Technical Advisory Group [TAG] to contribute to landscaping analyses of oxytocin availability and use in India, Ghana, Nepal and elsewhere. PATH is now carefully planning the roll-out of Uniject™ to minimise the risks of unregulated access and misuse identified by PJ and to establish in-country systems to ensure that oxytocin designated for post-partum use to prevent PPH is not siphoned off for dangerous intra-partum use. [Text removed] comments:

Patricia Jeffery's ethnographic finding - that unmonitored intrapartum oxytocin injections are widespread in home deliveries in India - has had a crucial impact in alerting the international donor community to the need to keep the risks of unmonitored use in mind when formulating policy in respect to access to oxytocin. (email, 5 June 2013)

In 2012, PJ was invited to advise another Gates Foundation funded project (developing inhaled, low-cost, heat-stable oxytocin dry powder for combatting PPH) on the safeguards needed to prevent unregulated availability of the new product. [Text removed] comments:

The intrapartum use and misuse of oxytocin is now recognised widely as an issue for all forms of oxytocin and particularly so in South Asia, and responsible product developers need to keep this firmly in mind. The results of Patricia Jeffery's fieldwork have been vitally important in achieving the widespread recognition of this crucial practical issue. (email, 24 June 2013)

Note re testimony: [text removed] were participants in the process of impact delivery, as described above. [Text removed] worked with us in the BHESA project. [Text removed] are reporters on the process.

5. Sources to corroborate the impact:

PDFs of individual emails and letter available from the University of Edinburgh; larger email corpuses available on request.

5.1 Impact on policy-framing in India

Email messages on file in Edinburgh from senior members of: SAHAYOG/CHSJ (5 June 2013); [text removed] (26 June 2013); [text removed] (26 June 2013).

Corpus of email messages documenting our team’s interactions with SAHAYOG and CHSJ.

5.2 Impact via international donors

Letter from Director, Oxytocin Initiative, PATH (27 Feb 2009) inviting Prof. Patricia Jeffery to contribute her ‘extensive experience and well-known expertise in this area’ to the Technical Advisory Group.

Corpus of email messages documenting Prof Patricia Jeffery’s interactions with PATH.

Email messages on file from: [text removed] (5 June 2013) and [text removed] (24 June 2013).

5.3 Individual users/beneficiaries who could be contacted to corroborate claims:

The contribution of this research to advocacy work in relation to maternal health in India and beyond can be corroborated by Director of Centre for Health and Social Justice, Delhi, and by the Coordinator of SAHAYOG, Lucknow.

Trustee, Anusandhan Trust: can corroborate the contribution of the research on pharmaceuticals in India in framing policy debates.

Joint Convenor, All-India Drug Action Network: can corroborate contribution to advocacy work concerned with rational drug policy in India.

Former Lead Economist for Health, Nutrition, and Population in India, World Bank: can corroborate long-term contribution of research to policy interventions in relation to healthcare in India.