

ECONOMIC AND SOCIAL RESEARCH COUNCIL END OF AWARD REPORT



For awards ending on or after 1 November 2009

This End of Award Report should be completed and submitted using the **grant reference** as the email subject, to **reportsofficer@esrc.ac.uk** on or before the due date.

The final instalment of the grant will not be paid until an End of Award Report is completed in full and accepted by ESRC.

Grant holders whose End of Award Report is overdue or incomplete will not be eligible for further ESRC funding until the Report is accepted. ESRC reserves the right to recover a sum of the expenditure incurred on the grant if the End of Award Report is overdue. (Please see Section 5 of the ESRC Research Funding Guide for details.)

Please refer to the Guidance notes when completing this End of Award Report.

Grant Reference	RES-167-25-0110		
Grant Title	Tracing Pharmaceuticals in South Asia: Regulation, Distribution and Consumption		
Grant Start Date	01 September 2006	Total Amount Expended:	£696,916.06
Grant End Date	31 December 2009		
Grant holding Institution	University of Edinburgh		
Grant Holder	Professor Roger Jeffery		
Grant Holder's Contact Details	Address	Email	
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		Telephone 0131 650 3976	
Co-Investigators (as per project application):		Institution	
Professor Allyson Pollock		University of Edinburgh	
Professor Patricia Jeffery		University of Edinburgh	
Dr Ian Harper		University of Edinburgh	
Dr Stefan Ecks		University of Edinburgh	

1. NON-TECHNICAL SUMMARY

Please provide below a project summary written in non-technical language. The summary may be used by ESRC to publicise your work and should explain the aims and findings of the project. *[Max 250 words]*

This research integrated sociological, public health and political economic approaches to analyse the diverse cultural, medical, economic and institutional factors that determine how three pharmaceuticals—oxytocin, rifampicin, fluoxetine—reach their end users in South Asia. The research also aimed to assist the development of effective interventions to improve MDG and other health outcomes and thereby contribute to poverty-reduction strategies, especially in relation to maternal and child health, infectious diseases and mental health. We innovatively combined detailed ethnographic interviews, semi-structured qualitative interviews with key opinion leaders and shapers, organisational analysis and secondary data sources using government statistics and pharmaceutical industry data.

Our main findings show how complex pharmaceuticals' supply chains in South Asia create continuing difficulties for the Governments of Nepal and India in regulating how pharmaceuticals reach consumers in ways that minimise both high prices and excessive and inappropriate consumption. Our case studies – including disputes over 'ethical practice' in Nepal, 'floating prescriptions' of psychiatric drugs, and controversies over the accessibility of uterotonic drugs – have illuminated some key areas of concern in governmental failures to regulate producers, suppliers, retailers and prescribers. Further, through analysing the available evidence of 'best practice' with respect to our three selected drugs, we have shown how little is reliably known about the 'global burden of disease' in respect of depression, about the most appropriate methods of delivering anti-TB drugs, and about the use of uterotonics to augment labour and prevent/arrest post-partum haemorrhage – not only in South Asia but elsewhere as well.

2. PROJECT OVERVIEW

a) Objectives

Please state the aims and objectives of your project as outlined in your proposal to the ESRC. *[Max 200 words]*

This research aimed to investigate pharmaceutical supply chains and health care delivery systems through three South Asian case studies, and compare actual practices with national regulatory standards and international best practice. We aimed to assess whether (and if so, how far) pharmaceutical misuse hinders efforts to reach key Millennium Development Goals; and what policy changes might improve the situation.

We planned to

- (a) develop a new framework for research on the socio-economic dynamics of pharmaceuticals, integrating the insights from the anthropology of global assemblages and the political economy of global commodity chains;
- (b) contribute to theories of global interdependency, integrating 'bottom-up' and 'top-down' approaches to local and global contexts through specific case-studies;
- (c) develop new approaches to global policy-making.

Our objectives were to:

1. map patterns of production, distribution, marketing and retail of three key generic drugs (oxytocin, rifampicin and fluoxetine) in South Asia
2. assess use of these three drugs in light of current international standards of best practice.
3. relate these processes to public health goals (maternal and child health, infectious diseases, mental health) and the poverty reduction agenda.
4. contribute to theoretical and methodological debates in public health, medical anthropology and political economy.

b) Project Changes

Please describe any changes made to the original aims and objectives, and confirm that these were agreed with the ESRC. Please also detail any changes to the grant holder's institutional affiliation, project staffing or funding. *[Max 200 words]*

No changes were made to the original aims and objectives, nor to the grant holder's institutional affiliation, to project staffing or to overall funding.

We changed the Indian partner to the Centre for Health and Social Justice, under the leadership of Dr Abhijit Das; since CHSJ wanted to develop a Kolkata office we managed the West Bengal research through them, because of problems linking to Indian Universities. By the time the grant was awarded, Anil Bhattarai was no longer with Martin Chautari in Kathmandu, but Dr Madhusudan Subedi, of Tribhuvan University became an Associate of Martin Chautari for the duration of the award.

Delays in the confirmation of the award of the grant resulted in a delayed start of the research; those working in India then faced further delays (amounting to a year) in acquiring research visas, severely limiting what could be done until they were granted. In addition, because of health problems faced by the Principal Investigator, the award was granted a no-cost extension to the end of December 2009, to allow Prof. Roger Jeffery to complete a schedule of interviews in Delhi and Mumbai.

c) Methodology

Please describe the methodology that you employed in the project. Please also note any ethical issues that arose during the course of the work, the effects of this and any action taken. *[Max. 500 words]*

In this inter-disciplinary project we innovatively combined detailed ethnographic interviews, semi-structured qualitative interviews with key opinion leaders and shapers ('studying up' or 'para-ethnography'), organisational analysis and secondary data sources using government statistics, and pharmaceutical industry data, as well as careful literature searches of the clinical data for evidence of best practice with respect to the selected drugs. This approach required sustained management, provided on a day-to-day basis by Roger Jeffery and Allyson Pollock.

Our inception workshops and Skype conferences ensured coherence across sites, selected drugs, and researchers with different disciplinary backgrounds. We also conducted training workshops with research staff to ensure common approaches in data collection and analysis.

In South Asia, research was conducted in three clusters (in Nepal, based in Kathmandu; in

West Bengal, based in Kolkata; and in Delhi and Uttar Pradesh, based in Delhi and briefly in Lucknow), in co-ordination with partners with experience in health related research. The research team had carried out extensive fieldwork in these areas and could draw on their networks in the three locations for which they were mainly responsible: Patricia Jeffery (Delhi and Uttar Pradesh); Ian Harper (Nepal); and Stefan Ecks (West Bengal). We carried out a total of 472 interviews across the sites and with a full range of producers, distributors, retailers, prescribers, medical representative and officers in representative associations.

The Edinburgh office co-ordinated all research activities and one research fellow (Petra Brhlikova) was recruited, to ensure a collective review of the relevant theoretical and methodological literature; to organize structured seminars across disciplinary boundaries; and to maintain the web-site and manage the data collected. She also collected material on clinical guidelines for the use of each drug, on the global burden of the relevant diseases, and on Good Manufacturing Practice. The projects of some MSc students from the Centre for International Public Health Policy were supervised by members of the research team, focusing on related topics, and their dissertations were very useful for our work, some material being incorporated into working papers.

With respect to ethical issues: In order to obtain research clearance in Nepal we completed an ethical review according to their own procedures, which we were happy to do. We became increasingly aware of the misuse of government funds in pharmaceuticals' procurement in both India and Nepal, and were regularly faced with evidence of behaviour and structures that were either illegal or not in accordance with regulatory standards (the absence of trained pharmacists from retail stores, or the dispensing of so-called dangerous or Schedule H drugs to patients without prescriptions from qualified practitioners, for example). We took an early decision to collect as much information as we could with respect to such behaviour but to keep it confidential. We were informed, sometimes elliptically, of corrupt practices by members of the regulatory agencies, but again, although we collected accusations of such behaviours, we did not see this as something that we should report further.

d) Project Findings

Please summarise the findings of the project, referring where appropriate to outputs recorded on *ESRC Society Today*. Any future research plans should also be identified. *[Max 500 words]*

Our research in India and Nepal suggests that international rules of Good Manufacturing Practice (GMP) are very threatening to small local producers focusing on domestic markets. GMP standards are strictly enforced in developed countries. Developing countries have adopted a strategic approach to GMP rules for domestic producers, but international procurement practices and requirements of donors often enforce higher quality standards than stipulated by national regulatory authorities. Although GMP rules originate from public health concerns about pharmaceuticals' quality and safety, their international harmonisation and implementation should be analysed in the context of the economic imperatives of viability of local industry and export potential. As the level of quality assurance is associated with the quality-price trade-off, the question is what quality standards do ensure appropriate quality at reasonable compliance costs and whether developing countries have sufficient technological know-how, trained staff and financial resources to maintain such standards.

Policy-makers urgently need to engage with the everyday realities of drug availability and use in South Asia. Despite the rising strength of Indian manufacturing capacity, India's system of pharmaceutical regulation remains partial, ineffective and has negative side-effects for each of the drugs we investigated. One reason for this is that the expertise mobilised in attempts to reform the current system is curiously detached from local contexts. For example, oxytocin – a natural hormone with uterine stimulant properties – plays a prominent role in everyday obstetric practice. Clinical guidelines for oxytocin use *intrapartum* emphasise that injudicious use has serious potential for adverse outcomes for mother and baby. Oxytocin, however, is readily available in South Asia and widely used in ways that flout these guidelines. Yet recommendations for active management of the third stage of labour include administering oxytocin to prevent post-partum haemorrhage – proposals that ignore oxytocin's already extensive life independent of policy interventions. Similarly, current estimates of 'treatment gaps' – e.g. in depression – take insufficient notice of the actual availability and affordability of drugs in India. Specifically, antidepressants are widely given without prescription, and 'off-label' uses are mostly beyond the control of licensed service providers. Over-prescription and misuse of antidepressants can be just as problematic as a lack of drugs and treatments. Finally, the market for TB drugs has generated many different combinations providing a widespread – and, for TB control programmes, worrying – availability of drugs within the private sector. From the private sector, however, perceptions are very different. Clues to the problems of integrating the private sector – given the market forces driving the market availability of drugs – can be found by focusing on how inconsistencies and slippages in official programmes are perceived by 'outsiders'.

A further research proposal was submitted to the EU FP-7 scheme, to follow some of these issues with respect to different drugs and in Uganda and South Africa, as well as elsewhere in India: this research will start in May 2010. Ian Harper, with the assistance of Roger Jeffery, has submitted a 'Follow On' grant proposal to the ESRC, for research training in qualitative methods to build capacity in the Nepal TB Control Programme.

e) Contributions to wider ESRC initiatives (e.g. Research Programmes or Networks)

If your project was part of a wider ESRC initiative, please describe your contributions to the initiative's objectives and activities and note any effect on your project resulting from participation.

[Max. 200 words]

This project was funded in the first round of the ESRC/DFID joint funding scheme, whose aim was to enhance the quality and impact of social science research addressing the key international development goal of reducing poverty amongst the poorest countries and peoples of the world, with particular reference to the Millennium Development Goals [MDGs]. It funded research with the potential for impact on policy and practice for poverty reduction. We attended a session on enhancing impact, run for grant-holders in this scheme, which we found very useful.

Our project addressed aspects of the three most health-related MDGs – numbers 4, 5 and 6, concerned with maternal and child health and the control of major communicable diseases, including TB. Our research helps to fill some gaps in understanding the actual and potential roles of pharmaceuticals in contributing to meeting these goals. Our contributions to meeting the goals comes as much from the results of personal

involvement in policy-advisory roles (especially Ian Harper and Patricia Jeffery) and through our engagement with advocacy groups (especially our partners in Delhi – the Centre for Health and Social Justice and CENTAD – and in Kathmandu – Martin Chautari).

3. EARLY AND ANTICIPATED IMPACTS

a) Summary of Impacts to date

Please summarise any impacts of the project to date, referring where appropriate to associated outputs recorded on *ESRC Society Today*. This should include both scientific impacts (relevant to the academic community) and economic and societal impacts (relevant to broader society). The impact can be relevant to any organisation, community or individual. [Max. 400 words]

Two-day dissemination workshops were held in Kathmandu and Delhi, in the week beginning 6 April 2009, and in Edinburgh on 17-19 June 2009. In Kathmandu, one day was devoted to academic papers from the project, and one day to activities designed to engage activist and advocacy groups to pursue some implications of the research findings with a view to influencing policy; as a result of contacts made there with the assistance of Martin Chautari, we published a brief article on the research in *Himal South Asia* (a widely distributed monthly magazine). The Delhi workshop was co-hosted with Centre for Health and Social Justice (our partner, a research and advocacy group) and CENTAD (an Oxfam-funded Indian NGO with special interests in international trade and public health). Many workshop papers were published in a special issue of an open-access e-journal, the *Journal of Health Studies: Pharmaceuticals in India: Issues of Production, Pricing, Distribution and Promotion*, with a wide readership in South Asia. Non-academic participants in Kathmandu and Delhi included members of advocacy and activist groups; at the Edinburgh workshop, one of the participants was Dr Andrew Chetley from MeTA (the DFID-funded Medicines Transparency Alliance).

We have also presented academic papers on 10 occasions in 2009, in various settings; additionally Roger Jeffery convened a panel at the Annual Meeting of the Society for Medical Anthropology, in Yale, September 2009, with Lawrence Cohen, University of California, Berkeley, as discussant. Prof. Cohen also mentioned our research as exemplary in his plenary lecture. An account by another participant, Prof. Kalman Applbaum, appeared at <http://www.somatosphere.net/2009/11/sma-panel-production-distribution-and.html>

We have also engaged with potential users and beneficiaries as follows:

Prof. Patricia Jeffery has joined a Technical Advisory Group for the Oxytocin Initiative coordinated led by PATH (Program for Appropriate Technology in Health, Washington DC) helping to construct interview-based research aimed at establishing the extent of misuse of Oxytocin in India, Ghana and elsewhere. Our work has also been used in preparing discussion reports for the TAG itself.

Dr Ecks provided a summary of our research on Fluoxetine to the Indian Medical Parliamentarians' Forum in 2009.

From July-December 2008, Dr Ian Harper was a member of the Nepal Tuberculosis Control Programme, with particular responsibility for negotiating with the Global Fund. He has thus been able both to gather insights into the working of the programme but also

to contribute insights from our research to members of the Nepal TB CP team.

b) Anticipated/Potential Future Impacts

Please outline any anticipated or potential impacts (scientific or economic and societal) that you believe your project might have in future. [Max. 200 words]

The main likely economic or societal impacts of our research will come from personal engagement of key members of the research team with policy-makers (especially in Nepal's TB Control Programme) and through influencing international donor advisors (especially in reproductive health and the global push to reduce maternal mortality in line with MDG 5 by using oxytocin to combat post-partum haemorrhage). We shall also contribute to debate about the problematic data bases used in creating global burden of disease estimates (especially for depression, but we need to wait for new estimates to be adopted). We shall also address how such estimates and the MDGs alike skew policy interventions in the global South.

The main scientific impacts of our research will probably come from a wider understanding among academics and advocacy groups of the research methods we have used. Our methods – involving 'following the drug' – have attracted appreciative comments at all the settings where we have reported our findings. We also expect to make a substantial impact through our publications in e-journals and other prominent circulated academic journals, a planned monograph, working papers as well as seminar and conference presentations.

You will be asked to complete an ESRC Impact Report 12 months after the end date of your award. The Impact Report will ask for details of any impacts that have arisen since the completion of the End of Award Report.

4. DECLARATIONS

Please ensure that sections A, B and C below are completed and signed by the appropriate individuals. The End of Award Report will not be accepted unless all sections are signed.

Please note hard copies are NOT required; electronic signatures are accepted and should be used.

A: To be completed by Grant Holder

Please read the following statements. Tick ONE statement under ii) and iii), then sign with an electronic signature at the end of the section.

i) The Project

This Report is an accurate overview of the project, its findings and impacts. All co-investigators named in the proposal to ESRC or appointed subsequently have seen and approved the Report. ✓

ii) Submissions to *ESRC Society Today*

Output and impact information has been submitted to *ESRC Society Today*. Details of any ✓

future outputs and impacts will be submitted as soon as they become available.

OR

This grant has not yet produced any outputs or impacts. Details of any future outputs and impacts will be submitted to *ESRC Society Today* as soon as they become available.

OR

This grant is not listed on *ESRC Society Today*.

iii) Submission of Datasets

Datasets arising from this grant have been offered for deposit with the Economic and Social Data Service.

OR

Datasets that were anticipated in the grant proposal have not been produced and the Economic and Social Data Service has been notified.

OR

No datasets were proposed or produced from this grant.