

<p>Institution: University of Leeds</p>
<p>Unit of Assessment: UoA2</p>
<p>Title of case study: Making tuberculosis care more patient-centred in Nepal and Pakistan</p>
<p>1. Summary of the impact</p>
<p>Leeds research has led to adoption of effective, patient-friendly tuberculosis (TB) care delivery in Nepal and Pakistan, relaxing the global TB treatment strategy's requirement that (generally very poor) patients attend a health centre every day for 2 months for supervision and support that led to unemployment, poverty and debt. This impact has reach across the more than 300,000 people a year treated for TB in Nepal and Pakistan; and its significance is that patients can retain their usual employment yet still have a high likelihood of cure. Our research demonstrated that home-based care was feasible under routine low-income country TB programme conditions, was as effective as health centre-based care, and was much more acceptable than health centre-based care.</p>
<p>2. Underpinning research</p>
<p>TB is a major global cause of illness and death: the World Health Organisation (WHO) reports that in 2011, 8.7 million people fell ill with TB, and 1.4 million people died from TB; and over 95% of TB deaths occur in low- and middle-income countries. Until 2006, the TB control policy recommended by WHO included Direct Observation of Treatment (DOT) by a health worker at a health centre daily for at least the first 2 months of treatment. We observed that this strategy caused substantial hardship to poor patients, severely disrupting their ability to work, since health centres are generally only open during working hours. During treatment, many employed TB patients lost their jobs; daily labourers could not get work; farmers struggled to access clinics; household duties including childcare were disrupted; and school and college students had difficulties continuing their studies. Health centre DOT ignores the imperatives of daily survival for poor people, and forces many people to seek care in the private sector, which has poor treatment outcomes, leading to further illness and death, and continuing transmission of TB.</p> <p>Despite being part of global policy, there was no evidence to support the use of health centre DOT rather than more flexible ways of encouraging continuation and completion of treatment. We hypothesised that flexible strategies could produce cure rates as good as or better than daily health centre DOT and be more patient-friendly. We planned from the outset that if the context-appropriate strategies we developed proved effective, we would use our good relationships with National TB Programmes to encourage changes in policy and help implement such strategies.</p> <p>From 1996 to 2000, our research team at the University of Leeds carried out an individually randomised controlled trial in Pakistan to compare treatment outcomes and patient satisfaction using daily health centre DOT with those obtained using more patient-friendly strategies of treatment supervision and patient support by community health volunteers or family members at or near the patient's home. The team was led by John Walley (Professor of International Public Health, employed by UoL 1992-) with James Newell (Professor of International Public Health, 1995-) and Amir Khan (UoL PhD graduate, who set up a Pakistani NGO – the Association for Social Development – to operationalize the research and development).</p>
<p>The trial demonstrated that patient-friendly approaches led to higher cure rates than daily health worker DOT (1). Our development of these approaches was guided by a social science study identifying constraints to TB control from patients' and providers' perspectives (2); and we also carried out a study demonstrating the cost-effectiveness of the approaches (3).</p>
<p>We then carried out the first cluster-randomised controlled trial to investigate the impact of patient-friendly strategies for treatment supervision and patient support. The trial randomised districts in hill and mountain areas of Nepal, where standard daily health centre DOT was clearly not feasible because of the unavailability of accessible clinics. This trial demonstrated that under normal health</p>

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service conditions, patient supervision at home by a family member or by a community health volunteer achieved cure rates of 89% and 85% respectively (4), higher than the international target of 85%; and patient satisfaction was high. A subsequent costing analysis demonstrated that the costs of the two strategies were similar, and affordable to the Nepal NTP (5). The research team was led by **James Newell** and included **Sushil Baral** (UoL PhD graduate, who set up a Nepali NGO – the Health Research and Development Forum – to operationalize the research and development); **Tolib Mirzoev** (Senior Lecturer, 2004-) and **Andrew Green** (Professor of International Health Planning, 1983-2004).

Our contribution to the field of study was that, at the time, although there had been a small number of studies comparing DOT to non-DOT (unsupervised self-administered) TB care, our studies were the only ones comparing different DOT strategies and demonstrating their effectiveness.

3. References to the research

[University of Leeds staff at the time of the research in bold]

1. **Walley JD, Khan MA, Newell JN, Khan MH** (2001). Effectiveness of the direct observation component of DOTS for tuberculosis: a randomised controlled trial in Pakistan. *Lancet*, 357, 664-669. doi:10.1016/S0140-6736(00)04129-5. Cited 110 times.
Results from the first trial to show that more patient-friendly approaches to DOT are effective.
2. **Khan MA, Walley J, Newell J, Imdad N** (2000). Tuberculosis in Pakistan: socio-cultural constraints and opportunities in treatment. *Social Science and Medicine*, 50, 247-254. doi: 10.1016/S0277-9536(99)00279-8.
Identification of problems of daily health centre DOT from patient/health provider perspectives.
3. **Khan MA, Walley JD, Witter SN, Imran A, Safdar N** (2002). Costs and cost effectiveness of different DOT strategies for the treatment of tuberculosis in Pakistan. *Health Policy and Planning* 17(2), 178-186. doi: 10.1093/heapol/17.2.178.
Analysis of the trial (1) showing that the patient-friendly DOT strategies we developed are more cost effective than daily health centre DOT.
4. **Newell JN, Baral SC, Pande SB, Bam DS, Malla P** (2006). Family member DOTS and community DOTS for TB control in Nepal: district randomised trial. *Lancet*, 367 (9514), 903-909. doi:10.1016/S0140-6736(06)68380-3.
Results from a large cluster-randomised trial showing effectiveness of our strategies within usual health service care.
5. **Mirzoev T, Baral SC, Karki D, Green AT, Newell JN** (2008). Community-based DOTS and family member DOTS for TB control in Nepal: costs and cost-effectiveness. *Cost Effectiveness and Resource Allocation* 2008, 6:20. doi:10.1186/1478-7547-6-20
Analysis showing the two approaches tested in Nepal (4) were affordable and comparable.

Grant support (open competition peer-reviewed grants)

Walley – TB DOT project trial in Pakistan (DFID 1995-98 £313,824); Newell – TB service delivery in areas with poor access to health facilities in Nepal (DFID 2000-3 £247,094).

4. Details of the impact

Our work has directly led to changes to government policy and public service guidelines and practices for TB control across Nepal and Pakistan, improving care for more than 300,000 people with TB annually, and helping to protect nearly 200 million people from TB annually. The strategies we developed and demonstrated were effective, which have been rolled out since 2008, have led to improved quality of life for patients through reduced financial burden, better treatment outcomes, reducing risk of TB spread and development of drug resistant strains of TB. Without our research, and development support, it is unlikely that any change to care would have occurred. These strategies have also been adopted in other low-income countries, such as Swaziland.

Impacts on international development

From the outset, to ensure our research influenced policy and practice at large scale, we adopted a deliberate strategy of working closely with National TB Programmes. This strategy develops

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trust; ensures our research addresses national priorities; ensures findings are relevant for policy makers; promotes policy-makers' ownership of the research findings; and encourages joint development of subsequent policy, operational guidelines and training methods and materials. Much of our research uptake was made possible through our partnership with in-country research and development NGOs, set up by ex-students/employees of the University of Leeds. TB Programme Managers and members of their teams were involved from conception (responding to their prioritisation of the problems) to completion. This included joint development of the interventions to be tested, regular briefings and discussions of likely implications of findings.

Our research and research uptake strategy have together led directly to better, evidence-informed, public policy and improved public services in Nepal and Pakistan for people with TB. We were involved in the development of draft national policy and operational plans published since 2008. National guidelines adopted since 2008 have been revised to take account of our findings, and our patient-friendly approaches have been implemented in both in Nepal (**A-G**) and Pakistan (**H-J**).

We have also jointly developed training materials and courses that have been used by the TB Programmes from 2008 onwards to train health workers in the new strategies. Walley and Newell have provided on-going advice and support to the NTPs throughout the assessment period.

More widely, the research influenced key WHO/Stop TB Partnership (www.stopTB.org) documents (**K-M**) (including the Stop TB strategy 2006), in which the requirement for DOT has been replaced by a more patient-centred approach of 'supervision and patient support'. Although publication of these documents falls outside the assessment period, their influence in encouraging adoption of this strategy across low-income countries has continued throughout the assessment period.

Impacts on health and welfare

Our research and our research uptake strategy have together led to 100% reach across our intended target populations – the (overwhelmingly poor) people of Nepal and Pakistan receiving care for TB – starting in 2008 and continuing to date. This means improved care for 30,000 people with TB in the mountain/hill districts of Nepal annually, helping protect 30 million people from TB infection in Nepal (**A-G**); and improved care for 300,000 people with TB in Pakistan annually, helping protect 177 million people in Pakistan (**H-J**) (based on WHO statistics on numbers at risk).

Our research has also contributed to improved TB treatment outcomes in both countries (**N**).

- in Nepal, the TB treatment success rate was 48% (case detection 56%) in 1995 prior to our research, and 85% (case detection 71%) in 2011: mortality fell by 900 to 7,000.
- in Pakistan, the TB treatment success rate was 70% (case detection 4.5%) in 1995, and 91% (case detection 65%) in 2011: mortality fell by 31,000 to 59,000.

Our research has also led to significantly improved quality of life for people with TB in Nepal and Pakistan, who no longer need to attend a clinic daily, and can therefore continue their usual employment/duties and follow normal lives (**4**), reducing the burden and costs of TB.

- In Nepal, we estimated costs to patients using family/community health worker DOT were US\$32 lower than using standard health centre DOT (a reduction of nearly 50%) (**5**). To put this in context, the average annual income (2001) was US\$400 and 55% of the population earned less than the international poverty line (IPL) of US\$1.25 per day.
- in Pakistan, we estimated costs to patients using family/community health worker DOT were US\$27 lower than using standard health centre DOT (a reduction of 50%) (**3**). The average annual income (2001) was US\$750 and 23% of the population earned less than the IPL.

5. Sources to corroborate the impact

Key external outputs

A. Nepal Ministry of Health and Population (2010). National Strategic Plan – Implementation of Stop TB Strategy 2067/68-2071/71 (16 July 2010-15 July 2015). Kathmandu: National Tuberculosis Centre. (See section 2.9, p50, and acknowledgement on page 16.) Available at www.nepalccm.org/resources/tuberculosis/pdf/nationalstrategicplan2010-15.pdf

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- B.** Nepal Ministry of Health and Population (2012). Nepal NTP General Manual 3rd edition. (See pages 4, 9, 10, 31 for role of family members in TB patient support.) Available at http://nepalntp.gov.np/theme/images/uploads/1373865242general_Manual_en.pdf
- C.** Nepal Ministry of Health and Population (2009). Tuberculosis Case Management Guideline 1st edition. (Also in Nepali.) (See page 18 for role of family members in TB patient support.) <http://library.elibrary-mohp.gov.np/mohp/collect/mohpcoll/archives/mohp:204/9.dir/doc.pdf>
- D.** Annual Report 2008/09, Ministry of Health and Population, National Tuberculosis Programme, Nepal. Available at <http://www.docstoc.com/docs/140273075/Department-of-Health-Services---Ministry-of-Health-and-Population>
- E.** Annual Report 2008/09, Ministry of Health and Population, National Tuberculosis Programme, Nepal. (See pages 2, 9 for role of family members in TB patient support; and acknowledgement on page 32.) Available at http://nepalntp.gov.np/theme/images/uploads/1359021203I_Report_NTP_2011.pdf
- F.** The current Chief of the Policy Planning and International Cooperation Division of the Nepal Ministry of Health and Population can confirm the impact of our research on TB service delivery in Nepal.
- G.** The Deputy Director of the Nepal National Tuberculosis Programme during the period when our findings were incorporated into Nepal national policy can confirm the influence of our research on national health policy in Nepal.
- H.** National TB Control Programme Pakistan (2008). Desk guide for doctors. (See pp8-9 for role of family members and community health workers in TB patient support; p20 for acknowledgement of input from Nuffield Institute for Health, University of Leeds.)
- I.** National TB Control Programme, Ministry of Health, Government of Pakistan (2008). Refresher module for doctors. (See p18 for role of community health workers in TB patient support.) http://ntp.gov.pk/uploads/ntp_1369816170_Doctor_Module_Nov_2008.pdf
- J.** Letter from the Programme Manager of the Pakistan National TB Programme during the period when our findings were incorporated into Pakistan national policy confirming the impact of our research on national health policy in Pakistan.
- K.** The Stop TB Strategy. WHO and the Stop TB Partnership 2006 (WHO document number WHO/HTM/STB/2006.37). (See p2 for acknowledgement of input from John Walley.) <http://www.who.int/tb/strategy/en/>
- L.** The Global Plan to Stop TB 2011-2015. WHO and the Stop TB Partnership (WHO document number WHO/HTM/STB/2006.35). (See p7 for acknowledgement of input from James Newell.) <http://www.stoptb.org/global/plan/>
- M.** An Expanded DOTS Framework for Effective Tuberculosis Control. WHO (WHO document number WHO/CDS/TB/2002.297). (See p2 for acknowledgement of input from John Walley.) http://www.who.int/tb/publications/expanded_dots_framework/en/
- N.** Global Tuberculosis Control: WHO Report 2012. (WHO document WHO/HTM/TB/2012.6). http://www.who.int/tb/publications/global_report/en/

All manuals, guidelines and training materials listed above have been developed by the national bodies responsible in the relevant countries (National Tuberculosis Control Programmes, etc). (NB WHO rules prohibit staff from providing letters of support that could be perceived as favouring any individual or establishment.)