Improvement of tuberculosis case detection and reduction of discrepancies between men and women by simple sputum-submission instructions: a pragmatic randomised controlled trial

Mishal Khan¹, Osman Dar², Charalambos Sismanidis¹, S. Karam Shah³, Peter Godfrey-Faussett¹

¹London School of Hygiene and Tropical Medicine; ²Addenbrooke’s Hospital, Cambridge; ³National TB Control Programme, Pakistan

Contact: mishal.khan@lshtm.ac.uk

**Background** Detecting patients whose sputum is smear-positive (smear+) on microscopic examination is an essential public health strategy to control tuberculosis (TB). It is estimated that only 53% of smear+ cases were notified under DOTS in 2004, indicating that a significant proportion of smear+ cases are going undetected within DOTS areas worldwide. Recent studies have suggested that women in particular are at risk of under-detection as they test smear+ less often than males. At the Federal TB Centre in Rawalpindi, Pakistan, specimens from female patients tested smear+ only half as frequently as specimens from men. A review of laboratory registers indicated that women submitted more salivary specimens than men. We hypothesised that submission of poor quality sputum specimens by women may be one reason for the gender difference in smear results.

**Methods** We conducted a pragmatic randomised controlled trial to evaluate the impact of sputum submission instructions on patients at the Federal TB Centre, Pakistan. Between May–July 2005, 3,252 TB suspects were referred for a sputum test. 3,055 TB suspects (1,494 females, 1,561 males) were eligible for the trial. Participants were randomised to receive sputum submission guidance prior to submission or to submit specimens without guidance, according to prevailing practice at the TB centre. The primary outcome measure was the proportion of females testing smear+. Secondary outcome measures were the proportion of males testing smear+, the proportion of saliva specimens submitted by males and females, and the proportion of males and females returning the next day with an early morning specimen to complete the diagnostic procedure.

**Results** Instructed females were far more likely to test smear+ than the control group. Using a case definition of 2 specimens positive, instructions resulted in a 63% increase in smear+ case detection (8% in the control arm vs. 13% in the intervention arm (p=0.002)). Under the newer WHO TB case definition of 1 specimen positive, instructions resulted in a 46% rise in smear+ case detection (10% in the control arm vs. 14% in the intervention arm (p=0.007)). Instruction was associated with a decrease in spot-saliva submission (p=0.003), and an increase in the number of women returning with an early morning specimen (p=0.02). Instructed men showed increased smear-positivity and improvement in specimen quality, but the magnitude of the improvement was not statistically significant. The cost per extra case detected was very low (129 PKR, ~US$2).

**Conclusion** The biggest factor leading to increased smear-positivity in instructed females was most likely a reduction in poor quality specimen submission. The effect of instruction was most likely greater in women because they know less about the difference between sputum and saliva. Also, men are physically more able and comfortable with expectorating sputum. The intervention was cheap and easily replicable in low-income countries. Sputum-submission guidance is a cost-effective intervention to improve smear+ case detection and reduce gender disparity in TB control in low-income countries.