

## Could clinical audit improve the diagnosis of pulmonary tuberculosis in Cuba, Peru and Bolivia?

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### Summary

**OBJECTIVES** To assess the effectiveness of clinical audit in improving the quality of diagnostic care provided to patients suspected of tuberculosis; and to understand the contextual factors which impede or facilitate its success.

**METHODS** Twenty-six health centres in Cuba, Peru and Bolivia were recruited. Clinical audit was introduced to improve the diagnostic care for patients attending with suspected TB. Standards were based on the WHO and TB programme guidelines relating to the appropriate use of microscopy, culture and radiological investigations. At least two audit cycles were completed over 2 years. Improvement was determined by comparing the performance between two six-month periods pre- and post-intervention. Qualitative methods were used to ascertain facilitating and limiting contextual factors influencing change among healthcare professionals' clinical behaviour after the introduction of clinical audit.

**RESULTS** We found a significant improvement in 11 of 13 criteria in Cuba, in 2 of 6 criteria in Bolivia and in 2 of 5 criteria in Peru. Twelve out of 24 of the audit criteria in all three countries reached the agreed standards. Barriers to quality improvement included conflicting objectives for clinicians and TB programmes, poor coordination within the health system and patients' attitudes towards illness.

**CONCLUSIONS** Clinical audit may drive improvements in the quality of clinical care in resource-poor settings. It is likely to be more effective if integrated within and supported by the local TB programmes. We recommend developing and evaluating an integrated model of quality improvement including clinical audit.

**keywords** clinical audit, tuberculosis, professional behaviour, quality, diagnosis, smear-negative TB

### Introduction

There have been increasing efforts to influence change in health professionals' behaviour and practice (Bauchner *et al.* 2001). This is mainly driven by a realisation of unacceptable variations in service provision in healthcare (Steinberg 2003). Moreover, despite huge advances in healthcare knowledge achieved through research, and a significant body of evidence available on 'what works', very little has been put into practice by health professionals (Eddy 1982). Failure to provide clinical care in accordance with standards known to be associated with improved health outcomes has been one of the major causes of poor quality in healthcare provision in developing countries

(Marquez 2001). WHO urges health systems to focus on bringing existing evidence into practice: this often means influencing health professionals' behaviour (WHO 2003).

Several reviewers in recent years have examined the evidence for the effectiveness of interventions aimed at influencing professional behaviour (Freemantle *et al.* 2000; O'Brien *et al.* 2000a; b, 2001; Jamtvedt *et al.* 2003). But, most of this evidence is based on studies conducted in developed countries. One such well-researched intervention is the clinical audit, defined as an ongoing process to improve the quality of healthcare through critical examination of current performance against agreed standards, leading to the identification and use of opportunities for bringing practice closer to that standard (Mancey-Jones &

K. Siddiqi *et al.* **Clinical audit and TB diagnosis**

Brugha 1997). Clinical audit is a complex intervention, influenced by the context in which it is implemented (Kerrison *et al.* 1993; Lord & Littlejohns 1997). It is likely that a model developed for well-resourced health systems would not be effective in middle- and low-income countries. We recently conducted a systematic review of the evidence of the effectiveness of clinical audit in developing countries and found that it has the potential to improve quality of care in these settings, where adherence to evidence-based guidance is generally poor and resource constraints are high (Siddiqi *et al.* 2005). But, the evidence of its effectiveness remains weak because of the scarcity and methodological limitations of published research in this area. This realisation provided the rationale for conducting this study.

We investigated the effectiveness of clinical audit in improving the quality of diagnostic care of patients suspected of tuberculosis and attempted to establish the contextual factors which impede or facilitate the audit's success in improving quality in a range of settings. We selected tuberculosis as it continues to be a major cause of mortality and morbidity; inadequate case detection has been identified as one of the reasons for a mounting global TB burden (Maher *et al.* 1997; Lauzardo & Ashkin 2000). Diagnosing pulmonary tuberculosis especially in the absence of positive smears remains a major challenge and relies heavily on the clinical judgement of physicians (Siddiqi *et al.* 2003). We hypothesised that, because of the plausible influence on clinical practice, clinical audit can improve the quality of clinical care provided to patients with suspected tuberculosis, which itself relies heavily on the clinical behaviour of physicians. There is currently no model of implementing clinical audit as an intervention in TB programmes and our study is a small but initial step in developing and evaluating one.

### Current TB situation in Peru, Bolivia and Cuba

Peru has been hailed as a success story with a declining TB incidence (–5.7% per year) and with both the case detection rate (83% in 2004) and the treatment success rate (89% in 2004) achieving WHO targets in recent years (WHO 2006d); but initial progress after the introduction of DOTS in the early 1990s has slowed in recent years. Another major change that took place recently in Peru was a shift in the national TB programme from being a vertical to a horizontal programme in 2001. Similarly, Bolivia has also shown signs of some decline in TB incidence (–2.2% per year), but remains a high TB burden country (WHO 2006b). Bolivia's case detection rate (71% in 2004) and treatment success rate (81% in 2004) have also improved. In Cuba, TB incidence has dropped to less than 10 new

cases per 100,000 per year (WHO 2006c). With both case detection rates (90%) and treatment success rates (93%) above WHO targets, Cuba is on the verge of eliminating TB. The differing success of the TB programmes in controlling TB in these three countries provided an opportunity to examine the influence of this on the effective implementation of clinical audit.

## Methods

### Overall design

The Medical Research Council (MRC) proposes a phased framework to design and evaluate complex interventions (Campbell *et al.* 2000; MRC 2000) such as clinical audit. In this study, we attempted to conduct phases I and II of the MRC framework. This proposes a framework for recognising the contexts in which the intervention will be implemented and, therefore, maximise the probability of success. In this study, we designed our intervention using existing evidence in similar settings and conducted an exploratory trial using an uncontrolled before-and-after design (Cook & Campbell 1979) and a qualitative case study (Yin 1994) in each study site.

### Study sites

The study was conducted in primary care settings in Peru, Bolivia and Cuba from January 2002 to December 2005. In Peru, eight health centres were selected from Canto Grande, a deprived urban area in the District of San Juan de Lurigancho in northern Lima. Clinical audit was implemented in the eight health centres as one study site. In Bolivia, eight health centres were selected, four in each of Metropolitano Sur district (urban) and Valle Bajo district (rural) in Cochabamba. In Cuba, the study was conducted in 10 health zones, five in each of the Havana (urban) and Las Tunas (semi-urban) municipalities. These study sites were selected on the basis of high reported TB incidence and willingness to participate.

### Research procedures and quantitative analysis

Health professionals were invited to form an audit committee consisting of key stakeholders representing all professions and participating health centres. Committee meetings were chaired by a senior professional in the committee but facilitated by the project coordinators in each country. Members of the committee were asked to make a list of problems faced in delivering high-quality diagnostic-related care to patients with suspected PTB. They were asked to consider clinical guidelines, patient

K. Siddiqi *et al.* **Clinical audit and TB diagnosis**

care pathways and analyses of critical points in healthcare delivery. The audit committees then identified common problems, and converted these into measurable criteria and standards (Box 1). The committees prioritised these using the nominal group technique of consensus development (Murphy *et al.* 1998) and four selection criteria: strength of evidence; clinical significance and likely health impact; measurability; and feasibility for change (Fraser *et al.* 1997; Hearnshaw *et al.* 2002). For each audit criterion, numerator and denominator were clearly defined. Where these could not be measured using routine clinical records, a new inquiry tool was introduced after piloting. To assist health professionals in achieving the agreed standards, user-friendly clinical tools (i.e. patient pathways and algorithm) were designed and implemented alongside the new inquiry tool. Before each feedback, data were collected to measure these criteria covering the previous 6 months. The results were fed back to the health professionals in the next committee meeting. Each committee assessing the performance of the participating health centres using the agreed standards conducted a problem analysis using fishbone diagrams and developed recommendations and action plans (Baker *et al.* 1999). The whole process was repeated in the next 6 months. The clinical audit criteria were measured continuously, providing aggregated monthly data points throughout the project.

**Box 1** Terminology

*Audit criteria* (indicator) are explicit statements that define what is being measured and represent elements of care that can be measured objectively. Each criterion consists of a numerator and a denominator  
 A *standard* is the threshold of the expected compliance for each criterion (these are usually expressed as a percentage)

The 'effectiveness' (result or outcome) of the audit cycle was measured in terms of improvement in the audit criteria based on the processes related to diagnostic care of patients suspected of TB. For each health centre and each study site, the absolute difference ( $P_d$ ) and relative difference ( $P_e$ ) (Shep's modification) between the mean proportions of patients meeting each criterion for the first and last 6 months were estimated using the formulas (Fleiss *et al.* 2003):

$$P_d = P_a - P_b$$

$$P_e = \frac{P_a - P_b}{1 - P_b}$$

Standard errors were estimated as follows:

$$SE[\text{Inverse log}(1 - P_e)] \\ = \text{Square root}[P_a/d_a(1 - P_{ai}) + P_b/d_b(1 - P_{bi})]$$

An approximately 95% confidence interval for  $\ln(1 - P_e)$  is

$$\text{Inverse log}(1 - P_e) - 1.96 \times SE \leq \text{Inverse log}(1 - P_e) \\ \leq \ln(1 - P_e) + 1.96 \times SE$$

$$CI^{\text{lower}} \leq P_e \leq CI^{\text{upper}}$$

where  $P_d$  is the absolute difference,  $P_e$  is the relative difference,  $P_a$  is the mean percentage of patients meeting each criterion for the last 6 months,  $P_b$  is the mean percentage meeting each criterion for the first 6 months, and  $d_a$  and  $d_b$  are the number of patients that could have met the criterion in the last and first 6 months, respectively.

Results were presented to the respective audit committee comparing improvements between health centres, but in this paper we present only the combined results for each study site.

**Qualitative case studies**

To establish the contextual factors, which impede or facilitate the audit's success in improving quality, we also conducted a case study in each country. Three methods of evidence gathering were employed: document analysis; participant-observation; and interviews with key informants. In document analysis, we used written communications between audit facilitators and committee members, minutes of the committee meetings and progress reports to corroborate and augment evidence collected through interviews and inform further investigations. Project coordinators facilitated and collected an account of the dynamics of the audit committee by keeping personal diaries as participant-observers. Purposive sampling was used to conduct semi-structured interviews with key informants in each case study during the project. These included audit committee members as well as other professionals working in the participating health centres. In order to provide a loose structure to the interview, a framework was used in the form of three to four opening statements. These statements helped to define the contextual factors that the study aimed to explore.

We used an inductive design and relied on developing grounded theory during the course of data collection and analysis. Different settings of each case study helped in exploring whether the theory generated from these case studies could be sustained in different settings. Data collected in each case study was analysed using an open coding method (Strauss & Corbin 1990). Raw data were

broken down and compared to similarities and differences between recorded incidents, phenomena and thoughts. All similar incidents were labelled and grouped in categories according to their properties and dimensions. Each category was given a conceptual name, using phrases either from the interviewees themselves (*in vivo* coding) or from the literature. Axial coding, a process of relating codes to each other, was also used to make connections between categories. Categories were developed in terms of their causal conditions and context. The theoretical explanations generated from the analysis were compared with the chronology of events.

## Results

In Peru, five audit criteria were selected and measured over 24 months. During this period, we completed three audit cycles including four six-month data collection periods and feedback sessions. In Bolivia, six audit criteria were selected in the study period, during which two audit cycles were completed. There was delay in the start of the project in Cuba, restricting it to a period of 18 months, as a number of committee members went abroad to take part in an international cooperation project. A total of 13 audit criteria were selected in Cuba. Four criteria were selected in Havana at the start of the project. Four more were added after the first audit cycle. Similarly, two more criteria were added in Las Tunas after completing the first cycle on the initial three criteria. Therefore, two audit cycles were completed for all criteria in Cuba. TB incidence and health facilities differed strikingly between Cuba and the other two countries (Table 1). Table 2 compares the four audit committees and the timing of different audit cycles.

We measured 24 criteria in three Latin American countries (Tables 3 and 4). There was a statistically significant absolute improvement in 15 of 24 criteria, while two showed deterioration (Figure 1); however, observed deterioration had little clinical meaning as the criteria were very close to agreed standards at the outset. Seven criteria did not change significantly. There was significant relative improvement in 17 of 24 criteria. Three criteria deteriorated and four showed no significant change. In Peru, there was an absolute and relative improvement of statistical significance in two (1 and 4a) of five criteria. None of the criteria, at the end of the project, reached the standards agreed by the committee. In Bolivia, there was an absolute improvement of statistical significance in two (4 and 5) of six criteria, but relative improvement was observed in three (2, 4 and 5). By the end of the project, only one criterion reached the standards agreed by the committee. In Cuba, there was a relative improvement in 12 of 13 criteria and

**Table 1** Background information on the study sites

Study area	Lima (Peru)	Cochabamba (Bolivia)	Cochabamba (Bolivia)	Havana (Cuba)	Las Tunas (Cuba)
Urban/rural	Canto Grande	District Metropolitan Sur	District Quillacollo, Valle Bajo	Municipality: Havana Vieja, Marianao, 10 de Octubre	Municipality: Puerto Padre, Majibacoa, Las Tunas
Population covered	Urban 469,072	Urban 336,286	Rural 260,312	Urban 699,927	Semi-urban 318,124
Sm + TB incidence per 100,000	179	70.7	60.3	5.5	5.7
Health facilities reporting to NTP	Fifteen primary care health centres. One also provides secondary level care	Nine primary care health centres. One also provides secondary level care	Eight primary care health centres. One also provides secondary level care	Seventeen 'Policlinicos': primary care health centres with some specialist support	Ten 'Policlinicos': primary care health centres with some specialist support
Centres with TB lab	12	4	6	17	10
Centres with X-ray facility	2	2	1	17	8
General practitioners	75	14	24	1591	862
Chest specialists	1	1	1	1 (dedicated to TB control)	2
Radiologists	0	0	0	17	2
Culture lab in (or <10 km from) study area	1	1 (reference lab outside study area)	0	3 (reference lab in Havana)	1

**Table 2** Audit committees in the study sites

	Peru	Bolivia	Havana (Cuba)	Las Tunas (Cuba)
Number of health centres involved	8	8	5	5
Number of members in the committee	8 + 1 (facilitator)	14 + 1 (facilitator)	8 + 1 (facilitator)	8 + 1 (facilitator)
Timing of meeting	3 h (working hours)	Evenings initially (2003), working hours (2004–2005)	3 h (working hours)	3 h (working hours)
1 <sup>st</sup> cycle	October 2003–March 2004	November 2003–April 2004	October 2004–March 2005	October 2004–March 2005
2 <sup>nd</sup> cycle	April 2004–September 2004	August 2004–January 2005	April 2005–September 2005	April 2005–September 2005
3 <sup>rd</sup> cycle	April 2004–September 2004	August 2004–January 2005	April 2005–September 2005	April 2005–September 2005
Attendance of those in a position to implement change (Mean in %)	October 2004–March 2005	May 2005–October 2005	October 2005–March 2006	October 2005–March 2006
Facilitators	Project coordinator	Project coordinator	Not conducted	Not conducted
	67%	63%	100%	100%
	Project coordinator	Project coordinator	From TB programme	From TB programme

an absolute improvement in 11, for which Cuba also reached the standards agreed by the committees by the end of the project.

We conducted 16 interviews in Peru with key health professionals [eight doctors (general practitioners), seven nurses and one laboratory technician). In Cuba, 14 healthcare professionals were interviewed (eight in Havana and six in Las Tunas): eight doctors, four nurses and two laboratory technicians. Thirteen healthcare professionals were interviewed in Bolivia, including three interviewees outside the audit committee. Table 5 presents a list of facilitating and inhibiting factors in improving clinical care.

### Joint ownership between TB programme and clinicians

Audit in Peru had little involvement and ownership by the TB programme. The criteria selected were sometimes seen by the interviewees as being in conflict with programme targets e.g. Criterion 1 in Peru urged clinicians to use microscopy services only where clinically indicated as unnecessary testing was seen to compromise the quality of the service. On the contrary, the TB programme asked all health centres to meet a target number of smear examinations every month, pressuring staff to do these tests where not clinically indicated. The TB programme guidance for diagnosing and managing TB was not accepted fully by clinicians and, therefore only partially implemented. There were clear disagreements among clinicians on some aspects of the guidance and such tensions were apparent in the interviews: “*The MINSA [National TB Programme at the Ministry level] goal for recruiting ‘sintomáticas respiratorios’ has a negative influence, since it forces us to recruit non-‘sintomáticas respiratorios’ patients to reach the goal*” (TB Programme laboratory technician).

Similarly, in Bolivia, audit activity was not entirely integrated within the TB programme and clinicians often referred to the lack of programme support in either providing appropriate guidance or meeting their educational needs. On the contrary, clinical audit activity was fully integrated within the TB programme in Cuba. Health professionals felt that the audit process received help and support from the TB programme and senior health service management. TB programme coordinators not only took part in all audit committee meetings but also facilitated the discussions. Respondents considered this ownership to be a major cause of improvement.

### Patients’ beliefs and clinicians’ perceptions

Clinicians’ perceptions of patients’ beliefs and attitudes play a major role in determining their professional behaviour. In the interviews, clinicians acknowledged that they

**Table 3** Audit criteria and the absolute and relative differences for all study sites

Criteria (Standard in %)	Mean proportion in the last 6 months	Mean proportion in the first 6 months	Absolute difference (95% CI; <i>P</i> -values)	Relative difference (95% CI; <i>P</i> -values)
<b>LIMA (PERU)</b>				
1. Percentage of patients having smear examination for AFB (registered as SR) who comply with the definition of SR† (85%)	53%	46%	7% (2 to 11%; <i>P</i> < 0.001)	13% (9 to 17%; <i>P</i> < 0.001)
2. Percentage of patients with SN PTB, whose cultures are reported back in the treatment register (70%)	60%	53%	7% (-25 to 38%; <i>P</i> = ns)	14% (-18 to 38%; <i>P</i> = ns)
3. Percentage of SR† who were not asked to have X-rays at the first appointment (70%)	43%	42%	1% (-5 to 7%; <i>P</i> = ns)	1% (-5 to 7%; <i>P</i> = ns)
4a. Percentage of SR† patients followed up at their second appointment who had a smear request at their first visit (70%)	55%	37%	18% (12 to 23%; <i>P</i> < 0.001)	28% (24 to 32%; <i>P</i> < 0.001)
4b. Percentage of SR† patients returning for their follow-up appointment with a smear result (90%)	69%	83%	-14% (-21 to -7%; <i>P</i> < 0.001)	-85% (-99 to -72%; <i>P</i> < 0.001)
<b>COCHABAMABA (BOLIVIA)</b>				
1. Percentage of SR†(TB?)‡ patients whose case notes could be retrieved (90%)	78%	85%	-7% (-12 to -2%; <i>P</i> < 0.002)	-47% (-55 to -40%; <i>P</i> < 0.001)
2. Percentage of SR† (TB?)‡ patients who complied with the agreed definition of SR*(95%)	84%	82%	2% (-4 to 8%; <i>P</i> = ns)	11% (6 to 16%; <i>P</i> < 0.05)
3. Percentage of SR† (TB?)‡ patients who were requested to have smear for AFB (90%)	91%	91%	0% (-4 to 4%; <i>P</i> = ns)	-3% (-7 to 1%; <i>P</i> = ns)
4. Percentage of SR† (TB?)‡ patients requested to have a smear test who provided a sample to the laboratory (90%)	72%	60%	12% (5 to 19%; <i>P</i> < 0.001)	30% (25 to 35%; <i>P</i> < 0.001)
5. Percentage of SR† (TB?)‡ patients that reported to the laboratory for AFB smear test, who provided at least two samples that were not salivary (90%)	73%	50%	23% (14 to 32%; <i>P</i> < 0.001)	46% (41 to 51%; <i>P</i> < 0.001)
6. Percentage of SR† (TB?)‡ patients who were not asked to have X-ray at their first appointment (90%)	83%	84%	-1% (-6 to 5%; <i>P</i> = ns)	-3% (-9 to 3%; <i>P</i> = ns)
<b>HAVANA (CUBA)</b>				
1. Percentage of patients with cough for >21 days who had a chest X-ray (90%)	100%	78%	22% (15 to 29%; <i>P</i> < 0.001)	100% ('-'; <i>P</i> < 0.001)
2. Percentage of patients with cough for >21 days, 2 negative smears and a chest X-ray compatible with PTB who were referred to the Commission for Smear-negative TB (80%)	100%	83%	17% (-13 to 47%; <i>P</i> = ns)	99.5% (99 to 100%; <i>P</i> < 0.001)
3. Percentage of patients with cough >14 days who had a valid (not salivary) second sputum sample examined in the laboratory within 72 h of sputum collection (80%)	98%	48%	50% (46 to 54%; <i>P</i> < 0.001)	95% (94 to 96%; <i>P</i> < 0.001)

**Table 3** (Continued)

Criteria (Standard in %)	Mean proportion in the last 6 months	Mean proportion in the first 6 months	Absolute difference (95% CI; <i>P</i> -values)	Relative difference (95% CI; <i>P</i> -values)
4. Percentage of patients with cough for >14 days who had sputum results recorded in the general practice register (80%)	91%	85%	6% (2 to 10%; <i>P</i> < 0.001)	43% (40 to 46%; <i>P</i> < 0.001)
5. Percentage of patients with cough for >14 days who had second sputum sample delivered to the laboratory within 72 h of consultation (90%)	96%	85%	11% (8 to 14%; <i>P</i> < 0.001)	74% (73 to 75%; <i>P</i> < 0.001)
6. Percentage of patients with cough for >14 days who had a second sputum sample of suitable quality for being processed in the laboratory (90%)	92%	75%	17% (13 to 21%; <i>P</i> < 0.001)	68% (67 to 69%; <i>P</i> < 0.001)
7. Percentage of patients with cough for >14 days for whom cultures were requested to the central laboratory and the samples were found adequate (95%)	83%	59%	24% (18 to 29%; <i>P</i> < 0.001)	57% (54 to 60%; <i>P</i> < 0.001)
8. Percentage of medical request for sputum smear microscopy with complete clinical information (95%)	86%	74%	12% (8 to 17%; <i>P</i> < 0.001)	47% (44 to 50%; <i>P</i> < 0.001)
LAS TUNAS (CUBA)				
1. Percentage of SR† patients for whom AFB is requested, who have their first sample submitted and processed within 48 h of medical consultation (90%)	93%	85%	8% (5 to 11%; <i>P</i> < 0.001)	54% (52 to 56%; <i>P</i> < 0.001)
2. Percentage of SR† patients for whom AFB is requested, who have their second sample submitted and processed within 72 h of medical consultation (85%)	92%	88%	4% (2 to 7%; <i>P</i> < 0.001)	37% (35 to 39%; <i>P</i> < 0.001)
3. Percentage of samples for AFB cultures that are not contaminated (90%)	97%	97%	0% (–1 to 1%; <i>P</i> = ns)	–14% (–12 to –16%; <i>P</i> < 0.05)
4. Percentage of patients with cough >14 that have the ‘Consultation of Classification’ who have a chest X-ray and two sputum smear examination (95%)	98%	92%	6% (3 to 8%; <i>P</i> < 0.001)	71% (70 to 72%; <i>P</i> < 0.001)
5. Percentage of patients with cough >21 days that access the ‘Commission of Diagnosis’ with proof of tuberculin and prior antibiotic trial (95%)	100%	87%	13% (3 to 23%; <i>P</i> < 0.05)	100% (‘–’; <i>P</i> < 0.001)

†SR refers to ‘Sintomáticos Respiratorios’; defined as all patients with cough and expectoration for more than 2 weeks.

‡In Bolivia all patients with a diagnosis of TB? were also included in the denominator.

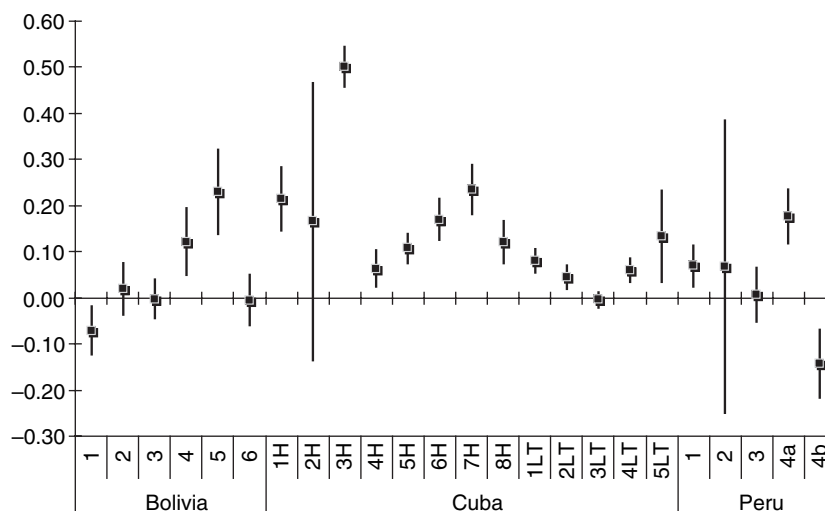
deviated from evidence-based practice because of their perceptions about patients’ reactions to a specific clinical decision. While these issues were acknowledged after feedback, few actions were planned to deal with them. For example, clinicians in Peru often felt obliged to conduct X-rays against the clinical policy of the programme in

order to meet the perceived expectations of patients. This resulted in lack of improvement in criterion 3: “... *the patient feels mistreated if they’re not asked for X-rays*” (TB Programme head of a health centre in Peru [doctor]).

In Bolivia, committee members stated that patients’ beliefs and attitudes play a key role in influencing clinical

**Table 4** A summary of results in the three Latin American Countries

Results and other inferences	Peru	Bolivia	Cuba
Audit cycles completed	3	2	2
Major changes and modifications made in the clinical record keeping system	Partial (in some health centres)	Yes (in almost all health centres)	Minimal (few alterations)
Statistically significant improvement in audit criteria (absolute)	2 out of 5 (40%)	2 out of 6 (33%)	11 out of 13 (85%)
Statistically significant improvement in audit criteria (relative)	2 out of 5 (40%)	3 out of 6 (50%)	12 out of 13 (92%)
Performance reached agreed standards by the end of the project	Nil out of 5 (0%)	1 out of 6 (17%)	11 out of 13 (85%)
Selection of criteria where performance was close to the desired level at the start	None	3 out of 6 criteria	8 out of 13 criteria
TB programme involvement in the audit activity	None	Partial	Full
Agreement on targets and guidelines between clinicians and TB programme managers	Little	Partial	To a large extent
Many strategies for improvement beyond clinicians' control	Yes	some	some
Clinicians related improvements to the audit activity	Not stated by clinicians	Stated by the clinicians	Stated by the clinicians
Clinicians exploited training opportunities through audit	Not mentioned	Mentioned frequently	Mentioned by the interviewees
Poor coordination between clinicians and laboratories	Yes	Yes	Some (mainly due to resource constraints)
Perception of patients beliefs influencing professional practice	Identified but no strategy suggested	Identified and strategies suggested	Not identified as an issue
Lack of resources (premises, equipment, etc.)	Yes	Yes	Yes (but addressed later through another initiative)
Political interferences, staff changes and favouritism	Yes	Yes	No (only staff changes)

**Figure 1** A comparison of the absolute improvement observed in all audit criteria in Peru, Bolivia and Cuba [Havana (H) and Las Tunas (LT)].



**Table 5** Themes generated from the three case studies

	Peru	Bolivia	Cuba
Factors facilitating success of clinical audit	Participatory leadership No blame culture Safe environment	Opportunity for training and professional development Appreciation of the relationship between quality improvement initiatives and improved performance Investing time in educating patients Participatory leadership Supportive tools (guidelines, care pathways, algorithms) Good communication and inter-personal skills Rewarding competence	TB programme support Opportunity for training and professional development Participatory leadership Appreciation of the link between quality improvement initiatives and direct benefit to the patients Better working environment Shared goals Good communication and inter-personal skills Recentralisation of diagnostic services
Factors inhibiting the success of clinical audit	Lack of support from the TB programme Patient perception Lack of resources Poor communication Patients' inability to bear the cost of repeated visits  Frequent changes in policies and personnel Differential treatment towards healthcare professionals (favouritism) TB related stigma	Poor system for clinical record keeping  Partial support from the TB programme  Frequent changes in policies and personnel Differential treatment towards healthcare professionals Poor coordination between laboratory and clinics Lack of resources Patients' poor access to services	Lack of resources Poor coordination Rapid staff turnover

practice. To address this issue, committee members educated and monitored patients.

#### Lack of coordination

In Peru, health professionals acknowledged a clear lack of coordination at the interface between laboratories and clinicians. The processes to ensure timely and accurate sample reception, processing and reporting were not established or not followed. Although some of these issues were identified through the audit cycle and addressed through regular coordination meetings between the laboratory and clinical staff, they remained unresolved by the end of the project. Respondents also saw lack of coordination between health centres and laboratories as a key factor in the relatively modest improvements in criteria 4 and 5 in Bolivia and criterion 4 in Peru.

#### Frequent staff changes, political interference and favouritism

In Peru and Bolivia, political interference resulting in constant staff changes was seen as a major limiting factor in bringing improvement in Peru and Bolivia. Often such changes resulted in new clinical policies, directives and guidelines creating confusion among staff. Interviewees believed that constant political interference and preferential treatment towards some members of staff led to incompetent people being promoted and appointed, often causing frustration among others.

#### Training opportunities

In Bolivia and Cuba, interviewees and audit committee members acknowledged that clinical audit created

K. Siddiqi *et al.* **Clinical audit and TB diagnosis**

opportunities for staff to develop themselves professionally and to keep up to date with current guidance on TB management. Audit facilitation also involved translating TB programme clinical guidance into user-friendly clinical tools such as desktop guides, care pathways plotted in the clinical notes, charts with patient pathways and algorithms. These were found to be particularly useful in Bolivia in implementing good practice and acted as aide-memoire for clinicians.

### Link with improvements

In Cuba and Bolivia, clinicians saw improvements as a direct result of the audit. Clinicians therefore considered audit a worthwhile activity and found it to be a key motivational factor and facilitator in improving clinical practice.

### Discussion

We found that the clinical audit was most effective in improving the selected standards of care in Cuba. In Bolivia, audit produced mixed results with some clear improvement in certain areas but less in others. In Peru, clinical audit had limited success in improving performance. Integration of clinical audit within the district TB programme was seen as one of the most important factors facilitating change. TB programme support was most obvious in Cuba, less in Bolivia and least in Peru. In addition, lack of coordination between the laboratories and health centres, lack of resources, political interference and perceived patients' beliefs were also identified as key deterrents to improvement. We also found that the appreciation of a visible relationship between audit activity and real improvements was a key motivational factor for clinicians to change their practice as seen in both Cuba and Bolivia. Similarly, provision of opportunities for training, education and user-friendly tools (pathways, algorithms, charts, etc.) was seen as a vehicle for promoting and motivating clinicians to change their practice in Cuba and Bolivia.

### Methodological limitations and strengths

Our study had a number of methodological limitations. Audit is a complex intervention and is highly context dependent. Its effectiveness depends upon personalities, relationships, professional and organisational structures, and processes making it difficult for its evaluation to have strong external validity (Kerrison *et al.* 1993; Lord & Littlejohns 1997). Evaluation requires some standardisation of the intervention which in the case of audit is likely

to reduce clinicians' ownership (Lord & Littlejohns 1997). Standardisation of the components of a complex intervention such as clinical audit would limit the intervention and oversimplify its assessment (Hawe *et al.* 2004). In such interventions, it should be the principles of the intervention which should be standardised. This would allow the intervention to be tailored to the local context and retain its integrity if based on the principles of the hypothesised change process.

We conducted an un-controlled study, which has the inherent weakness of ignoring potential confounding factors influencing outcomes. But at this preliminary stage, a controlled trial would have been inappropriate and difficult to resource. The MRC recommends evaluation of a complex intervention in stages and suggests conducting an exploratory study in order to inform the intervention and research methods before attempting a larger controlled trial (Campbell *et al.* 2000; MRC 2000). Our study provides the initial two phases of the MRC framework for evaluating complex interventions and will inform future controlled trials.

The outcomes we used to evaluate the effectiveness of audit were the same as the audit criteria decided by the audit committees. There is an inherent potential bias in this approach. This approach also makes it impossible to assess the impact of audit on other aspects of the care process (e.g. staff morale, team building, etc.). We were unable to find any example from the literature that evaluated clinical audit using criteria other than the audit criteria themselves. We were also unable to assess the effectiveness over a longer period: other studies have also indicated this difficulty and the empirical evidence of the effectiveness of audit over a long period is non-existent even in developed countries (Robinson *et al.* 1998).

Selection of the audit criteria is partly based on clinical significance and their relevance to the quality of clinical care. Committees did not consider if sufficient sample size would accumulate at each participating health centre between audit cycles to demonstrate statistically significant difference for each criteria. Therefore, significance testing at individual health centres may well be inappropriate and irrelevant. What is relevant is empirical evidence of sustained improvement. An alternative method called rapid-cycle sampling has recently been introduced to address this issue (Alemi *et al.* 2000).

In both Bolivia and Las Tunas (Cuba), criteria were often selected in clinical areas where performance was already optimal or close to the desired level. This led to a missed opportunity of measuring some other aspects of care where feedback could have made bigger improvements.

K. Siddiqi *et al.* **Clinical audit and TB diagnosis**

Our study contributes to the limited evidence on the effectiveness of clinical audit in poorly resourced health systems. A review on this topic identified only 15 such studies in low- and middle-income countries (Siddiqi *et al.* 2005). Our study was unique in some respects. We used a standard process of clinical audit in three settings using different audit criteria to evaluate the effectiveness of clinical audit in improving TB diagnostic care. This standardised application in three settings attempting to address the issue of TB diagnosis adds to the external validity of our study. We also used a systematic process (qualitative case study) to elucidate the facilitators and barriers to the success of clinical audit where it did and did not work, respectively.

In implementing clinical audit, one of the underlying assumptions is the existence of a routinely collected data set to measure the numerator and the denominator agreed for each audit criterion. Our study found that on numerous occasions, the existing data collection system was insufficient. It was decided that a data collection system would be improved where deficient and introduced where absent before the intervention began.

**Clinical audit and TB programme**

One of the key inferences of our study is that clinical audit appears to be more effective in settings where it is implemented as an integrated component of the TB programme. There is already a strong case for TB programmes to incorporate an integrated model of quality improvement interventions to meet targets and international standards set by WHO and other professional bodies (WHO 2006a). The existing supervision and monitoring arrangements in TB programmes can improve some aspects of care but do not engage clinicians in improving other aspects of care, especially clinical care related to diagnosing and managing TB. TB programmes have rightly placed emphasis on translating evidence into guidelines, protocols and educational materials: this is necessary but not sufficient to establish standardised clinical practice (Dick *et al.* 2004). Our research combined with the operational knowledge of TB programmes can help in developing a quality improvement package that can be added to the current StopTB strategy. This can then be further evaluated under TB control programme settings at various sites. An evaluation of such pilots can inform decisions whether to include processes for improving the quality of clinical care in future revisions of the StopTB strategy.

In our study, TB programme guidelines for diagnosing and managing TB existed in Bolivia and Peru. But these were WHO guidelines neither adapted to the local context

nor available in user-friendly formats; they also lacked sufficient detail to be used by the clinicians. Therefore, clinical audit was introduced in a setting where guidelines were not developed systematically or implemented in the health centres. Future researchers and policy makers need to prepare the ground for introducing quality improvement by first investing in developing and disseminating clinical guidelines in a systematic way or preferably developing and implementing integrated care pathways (Campbell *et al.* 1998).

We found that despite using a systematic approach the selection of audit criteria was difficult. This was mainly because of the inability of committee members to review literature in assessing the impact of each criterion, the absence of measures of baseline performance to determine potential opportunities for improvement, clinical bias and lack of familiarity with routine data. Others have also noted that audit criteria are often not based on agreed desirable characteristics, and inappropriate selection of the audit criteria is an important factor in the failure of demonstrating the beneficial effect of clinical audit (Hearnshaw *et al.* 2002, 2003). We propose the approach used by The National Institute of Health and Clinical Excellence (NICE) in England and suggest TB programmes propose a list of audit criteria with their clinical guidance (National Institute of Health and Clinical Excellence). Local committees can shortlist these and modify them according to the local context.

There are parallels between clinical audit and the three principles of quality assurance (i.e. defining quality by the principal actors, measuring quality and improving quality (Silimperi *et al.* 2002). But it needs to be acknowledged that clinical audit, designed to improve quality by influencing professional practice, is only one component of a whole-systems approach to quality assurance.

Clinical audit is likely to be of limited influence unless introduced alongside a quality assurance system that works at different levels within the health system (Grol 2001). It has been argued that quality improvement interventions are unlikely to achieve their objectives unless explicit consideration is given to the multilevel approach to quality assurance (Ferlie & Shortell 2001). Such an approach consists of four interdependent levels: individual approaches (e.g. education and training); team approaches (e.g. clinical audit); organisational initiatives [e.g. total quality management (TQM)]; and, larger system/national level schemes (e.g. NICE.) It is also generally acknowledged that if clinicians are aware of the evidence, are willing to change, and if there is a conducive environment, then change is more likely to happen (Grol & Grimshaw 2003).

### Research implications

One of the key questions for future research is to determine if clinical audit can generate sufficient health and efficiency gains to offset the cost of implementing audit in the TB programme over and above existing supervision and monitoring arrangements. The cost-effectiveness of clinical audit in improving quality of TB care also needs to be compared against other models based on existing supervision and monitoring arrangements for regular internal review. Our study can assist in developing the research methods necessary for future evaluation of clinical audit in resource-poor settings by highlighting problems of determining sample size, selecting audit criteria and outcomes to assess the effectiveness of the intervention. A useful alternative to the standard cluster RCT—which may not be feasible for evaluating audit in programme settings (Cook & Campbell 1979; Habicht *et al.* 1999)—is offered by the stepped wedge trial design. In such a design, an intervention is rolled out sequentially in the participating clusters over a number of equally spaced time-periods (Brown & Lilford 2006). The number of clusters included each time is usually dependent on the financial and logistical constraints of the programme; however, randomisation can be used for allocation at each time interval. At the end of the trial, all clusters will have received the intervention. If a country's TB control programme decides to roll out clinical audit sequentially over a certain period, this gives the opportunity to implement a stepped wedge trial.

This study provides the first guidance informing the development of an evidence-based audit intervention, which addresses issues of implementation, for a TB control programme setting. It also highlights that since it is a complex intervention, audit needs to be evaluated using evaluation designs that take account of and assess the influence of the context in which the audit is implemented.

### Conclusion

Our study demonstrates that clinical audit can be implemented without additional costs in resource-poor settings and has the potential to be effective in influencing clinical practice under a favourable organisational environment. But, further research is required to establish the effectiveness of clinical audit in developing countries, in not only improving quality of care but also generating sufficient health and efficiency gains to justify its implementation.

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K. Siddiqi *et al.* **Clinical audit and TB diagnosis**

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