Safety In Mines Research Advisory Committee
Project Summary : Gen 524

Project Title:	A Randomized Controlled study of the effectiveness of annual and 6-monthly screening with mass miniature radiography (MMR) for the active case-finding of cardiopulmonary TB patients

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Report Date:	7th May 2003	**Related Projects:**	HEALTH 701, HEALTH 705
Category:	Health	**Applied Research**	Occupational medicine

Summary

Background
Despite an expanded tuberculosis (TB) control programme, TB case rates in the gold mining industry have risen progressively during the 1990s to levels of over 3,000 per 100,000 men per year. Deaths while on TB treatment now account for twice as many deaths among gold miners each year as deaths from mine accidents. The increase in TB case and fatality rates among South African gold miners corresponds with the evolving HIV epidemic.

The mining industry has used a radiological screening programme (RSP) to screen for pneumoconioses and mycobacterial diseases for decades. In a gold mining workforce, in the Free State Province, the proportion of TB cases detected by the RSP declined from 77% in 1990 to 49% in 1996. Although radiological screening has been used for decades, the efficacy of the RSP has never been formally evaluated. Both 6-monthly and annual radiological screening have been used in different companies and no data were available as to which approach was the more effective, particularly with an emerging HIV epidemic in the workforce.

Aim
To determine the effectiveness of 6-monthly compared to annual radiological screening.

Methods
Study design
This was a randomised controlled trial. Study participants were individually randomised into one of two arms comparing 6-monthly (intervention arm) with annual screening (control arm) over a period of two years.

Study site and population
The study was conducted among employees, who derive their health benefit from the company provided health service (group 3-8), at a single gold mining company in the Free State Province of South Africa.

Results
A total of 22634 miners were randomised to the intervention or control arms. Of those individuals randomised, 2.7% (622/22634) were excluded from analysis, leaving 10997 and 11015 miners in the intervention and control arms respectively.

Almost a third of miners were lost to follow up, largely due to retrenchments. The two groups were similar with respect to median age, occupational group, duration of follow up and proportion lost to follow up and reason for loss to follow up.

The proportion of TB cases detected by the RSP was similar in the control and intervention arms (28% and 29% respectively, p=0.67). The proportion of sputum culture positive pulmonary TB cases, detected by the RSP or self presentation, that were smear negative did not differ significantly between the control or intervention arms (16% and 14% respectively, p=0.56).

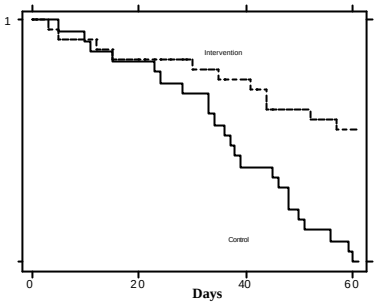
The prevalence of TB detected through the RSP was not significantly different between the intervention and control arms at the time of the final annual screening radiograph (0.65% [46/7075] and 0.91% [65/7111] respectively, p=0.07). TB incidence was similar in the control and intervention arms (2.72 and 2.90 per 100 person years respectively, p=0.3).

The mortality rate during the first two months of TB treatment was significantly lower in the intervention arm compared to the control arm (10.1 and 22.5 per 100 person years respectively, unadjusted hazard ratio 0.45

[0.22 – 0.92], p=0.024) (Figure). The mortality rate, from TB diagnosis to end of follow up, was significantly reduced in the intervention arm compared to the control arm (Control arm: 19.0 per 100 person years and Intervention arm: 14 per 100 person years, unadjusted hazard ratio 0.73 [95% CI 0.55 – 0.97], p=0.03).

TB cases in the intervention arm, compared to the control arm, had less extensive radiological disease (based on zone score) at diagnosis (p=0.05), but not at the end of TB treatment (p=0.7)

Figure. Survival estimates during the first 2 months of TB treatment



Discussion

This large individually randomised study, comparing radiological screening once a year to twice a year, has failed to demonstrate a significant difference in the proportion of TB cases detected by the intensified RSP, but did demonstrate a significant reduction in the mortality rate during the first two months of TB treatment. Although the proportion of TB cases detected by the radiological screening programme has decreased over the past decade in parallel with the increasing HIV epidemic, a sizeable proportion of TB continues to be detected by the RSP. Companies doing 6-monthly radiological screening should continue to do so and those using annual radiological screening should consider the cost benefit of deaths averted by doing 6-monthly radiological screening. Intensification of the active case-finding programme through the use of a screening tool with a high sensitivity, such as sputum cultures, warrants further investigation.