THE UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

Comparing the diagnostic performance of two smears versus three smears for the diagnosis of pulmonary tuberculosis in selected health centers of Lusaka district, Zambia

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DECLARATIONS

This dissertation is the original work of Eddie Solo. It has been prepared in accordance with the guidelines for MPH dissertations of the University Of Zambia. It has not been submitted elsewhere for a degree at this or another university.

Signature…………………………….. Date…………………………………

FOR SUPERVISORS ONLY

I have read this dissertation and approved it for examination.

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CERTIFICATE OF APPROVAL

This dissertation of Mr. Eddie Solo is approved as part of the fulfillment of the requirements of the award of the degree of Masters of Public Health by the University of Zambia.

Examiners' signatures

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DEDICATION

I dedicate this dissertation to my Son Kuken'ga Solo. I know you will equally perform well academically because you seem to like school.

ACKNOWLEDGEMENTS

ACRONYMS

AFB   Acid Fast Bacilli

AIDS   Acquired Immunodeficiency Syndrome

CDC   Centers for Disease Control and prevention

CDL   Chest Diseases Laboratory

CIDRZ   Center for Infectious Diseases Research in Zambia

CSO   Central Statistics Office

EQA   External Quality Assessment

FIND   Foundation for Innovate New Diagnostics

HIV   Human Immunodeficiency Virus

IUATLD   International Union Against Tuberculosis and Lung Diseases

JICA   Japan International Cooperation Agency

LDHMT   Lusaka District Health Management Team

LJ   Lowenstein Jensen

MGIT   Mycobacteria Growth Indicator Tube

MoH   Ministry of Health

MRC   Medical Research Council

NPV   Negative Predictive Value

LR-   Negative likelihood ratio

NTP   National Tuberculosis Control Program

LR+   Positive likelihood ratio

PPV   Positive Predictive Value

PTB   Pulmonary Tuberculosis

SS+   Sputum Smear positive

SS-   Sputum Smear Negative

TB   Tuberculosis

TDR   Tropical Diseases Research

UNZA   University of Zambia

UTH   University Teaching Hospital

WHO   World Health Organization

ZAMBART   Zambia Aids Related Tuberculosis.

TCTA   Tuberculosis Coalition for Technical Assistance

ZN   Zielh Neelsen

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DEFINITIONS OF TERMS

Sensitivity: the ability of the test to detect a disease when it is present.

Specificity: the ability of a test to indicate non disease when no disease is available.

Positive predictive Value (PPV): the probability of a disease being present when the test results are positive.

Negative Predictive Value (NPV): the probability of a disease being absent when the test results are negative.

ABSTRACT

Current World Health Organization (WHO) and International Union Against Tuberculosis and Lung Diseases (IUATLD) guidelines recommend that patients suspected of pulmonary tuberculosis (PTB) should submit three sputum samples as 'spot', 'morning' and another 'spot'. In recent years some TB experts have challenged the policy of examining three sputum samples per patient suspected of PTB. Arguments advanced are that these guidelines are based on old studies; increases cost and are not rewarding or cost effective. These experts have therefore suggested reducing the number of sputum samples required to be examined for diagnosis of PTB from the conventional three smears to two, particularly in resource limited settings. WHO has responded to this debate by recommending country specific studies to evaluate the operational effectiveness of the proposed two smears policy. The objective of this study was to compare the performance of the suggested two smears and the conventional three smears for the diagnosis of PTB in selected health centers of Lusaka district.

Between January 2011 and May 2012, we conducted a cross sectional study by reviewing routine Zielh Neelsen (ZN) smear results in four urban health centers laboratory registers and at the same time stored their actual sputum samples after routine use. We stratified the three routine smear results to form two strategies, namely; 'three smear strategy' (by considering results for all the three samples) and 'two smear strategy' (by restricting our analysis to the results for the first two samples). The stored specimens were transported to University Teaching Hospital TB laboratory for culture on Lowenstein Jensen (LJ) slopes. LJ culture results acted as gold standard and were used to compute the sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV), test efficiency and likelihood ratios for three smears strategy and two smears strategy respectively. We then compared the performances of the two strategies by testing the differences in the above variables using Yates's corrected Chi-square test. A result yielding a p value of $p<0.05$ was statistically significant.

Out of 1030 TB suspects analyzed, 350 were positive on LJ cultures providing a positivity rate of 34.0% (95% CI: 31.1%, 36.9%).

The sensitivity for three smears strategy was 61.4% (95% CI: 56.1%, 66.5%), whereas that for two smears strategy was 57.7% (95% CI: 52.5%, 62.9%), p = 0.355. The specificity for both three smear and two smear strategies was 98.1% (95% CI: 97.1%, 98.9%). The test efficiency for three smears strategy was 85.6% (95% CI: 83.4%, 87.7%). while that of two smears was 84.4% (95% CI: 82.2%, 86.6%), p = 0.459. The positive likelihood ratio for three smears strategy was 32.3 (95% CI: 18.6, 55.4) and for two smears strategy was 30.3 (95% CI: 17.5, 52.1),   P = 0.96. The negative likelihood ratio for three smears strategy was 0.39 (95%CI: 0.34, 0.44) whereas for two smears strategy was 0.43 (95% CI: 0.38, 0.48), p = 0.882. The p-values for all the variables tested showed no significant differences between the two strategies.

The performances of the two strategies were similar therefore this study concludes that the two smears strategy for diagnosis of pulmonary tuberculosis is adopted for Zambia.