THE PREVALENCE OF ACTIVE PULMONARY TUBERCULOSIS AMONG PRISONERS AT KAMITI MAXIMUM SECURITY PRISON.

PRINCIPAL INVESTIGATOR

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H58/7955/05

A dissertation submitted in part fulfillment of the requirements for the degree of Master of Medicine in Internal Medicine of the University of Nairobi.
DECLARATION

I certify that this dissertation is my original work and that it has not been submitted for a degree in any other university.

Signature...........................................

Date ..................................................

6/10/09
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DEDICATION

I want to dedicate this work to the Lord Jesus for the strength to carry this study to completion, to my dear wife for her encouragement and sacrifice for the sake of making this study possible and also to my daughter who was born as this work was seeing the light of the day.
ACKNOWLEDGEMENTS

I want to thank my competent team of supervisors whose contribution have been invaluable at all stages of this dissertation.

I want to acknowledge the co-operation of the Kenya prison authorities particularly the Director of Prison Health Services Dr Kibosia, the Officer-In-Charge of Kamiti Maximum Prison Mr Njuguna, the prison warders, and all the prisoners who took part in the study in one way or another.

I also want to thank the laboratory and radiology technicians at Kamiti Prison health centre clinic and the entire staff at the National TB Reference Laboratory.
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<table>
<thead>
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<th>Acronym</th>
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<tbody>
<tr>
<td>AFB</td>
<td>Acid Fast Bacilli</td>
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<tr>
<td>BMI</td>
<td>Body Mass Index</td>
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<tr>
<td>CDC/MOH</td>
<td>Center for Disease Control /Ministry Of Health</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>CXR</td>
<td>Chest Radiograph</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>HIV/AIDS</td>
<td>Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome</td>
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<tr>
<td>ISTC</td>
<td>International Standard for Tuberculosis Care</td>
</tr>
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<td>IUATLD</td>
<td>International Union Against TB and Lung Diseases</td>
</tr>
<tr>
<td>KNH</td>
<td>Kenyatta National Hospital</td>
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<tr>
<td>L-J media</td>
<td>Lowenstein- Jensen media</td>
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<tr>
<td>MDG</td>
<td>Millennium Development Goals</td>
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<tr>
<td>M. tuberculosis</td>
<td>Mycobacterial tuberculosis</td>
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<tr>
<td>OR</td>
<td>Odds Ratio</td>
</tr>
<tr>
<td>PTB</td>
<td>Pulmonary Tuberculosis</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>SPSS</td>
<td>Statistical Package for Social Sciences</td>
</tr>
<tr>
<td>UON</td>
<td>University Of Nairobi</td>
</tr>
<tr>
<td>VCT</td>
<td>Voluntary Counselling and Testing</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<td>Z-N</td>
<td>Ziehl Neelsen</td>
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ABSTRACT

**Background:** Prisoners form a group of the society with a high risk of tuberculosis. Where studies have been done, the prevalence of active pulmonary tuberculosis has been found to be 6 to 100 times higher than that of the civilian population. One retrospective study based on data from death registers in 13 Kenyan prisons found TB to account for up to 30% of the mortality. Death register and TB notification data are not considered reliable in estimating the prevalence of TB. Hence there was need to do a study to estimate the prevalence of TB in prison. Kamiti Maximum Security Prison was chosen due to its proximity to the principal investigator.

**Objective:** To determine the prevalence of active pulmonary tuberculosis among prisoners at Kamiti Maximum Security Prison.

**Study design:** A cross-sectional survey.

**Setting:** Kamiti Maximum Security Prison.

**Study Period:** November 2007 to May 2008.

**Study population:** Inmates at the prison.

**Study methodology:** All the blocks were visited systematically and enquiry made for those prisoners with a cough of 2 or more weeks duration. Those who agreed to participate in the study signed an informed consent. After recruitment into the study the prisoners' baseline characteristics were taken. Those prisoners with a productive cough gave 3 sputum specimens and if smear microscopy was negative for AFB, a chest radiograph was done. For those with dry cough, a chest radiograph was done. Prisoners found to have active pulmonary TB were requested to undergo diagnostic counselling and testing for HIV.

**Data management and analysis:** The data collected was recorded in a proforma then later transferred to SPSS version 14.0 statistical package for analysis. The data for active pulmonary TB by passive case finding was abstracted from the TB notification summaries available at the prison clinic.

**Results:** By the passive case finding the prevalence of TB was 1425 per 100,000 of population. The active case finding strategy used in this study yielded an extra 931/100,000 of population. The prevalence of active pulmonary TB in this prison was 2356 per 100,000 of population. The yield of smear positive TB by passive case finding was 19% as compared to 47% by active case finding.
Only age was found to have a statistically significant association (p value <0.05) with a prisoners’ TB status with an OR of 1.03 (95% CI 1.00-1.06) on univariate analysis and 1.05 (95% CI 1.01-1.08) on multivariate analysis.

Conclusion: The prevalence of active pulmonary TB in Kamiti Maximum Security Prison is high at 7 times the national prevalence. The rate of smear positivity by the current passive case finding was quite low as compared to the yield from active case finding and the national figures which are based on passive case finding.
Tuberculosis (TB) is one of the oldest diseases to afflict man as evidenced by mummies from pre-Pharaonic dynasties and was unknown in Sub-Saharan Africa prior to the 20th century. Tuberculosis is caused by *Mycobacterium tuberculosis*. The mode of transmission of this mycobacterium is person to person spread via aerosolization of 1-5 micrometer droplet nuclei. The likelihood of transmission is influenced by the number of organisms expelled into the air, the concentration of organisms in the air, the length of time an individual is exposed and the integrity of the cellular immune status.

Currently, 32% of the global population is infected with *M. tuberculosis* and 80% of these are in 22 high burden countries. Nine out ten of the high incidence rates per capita are in Africa. The high incidence rates being witnessed in Africa are related to the Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome (HIV/AIDS) pandemic. In 1993, TB was declared a global emergency. The sixth Millennium Development Goal (MDG) target is to halt and begin to reverse the incidence of TB by 2015. In order to achieve this target, the Stop TB Partnership came up with various strategies geared towards TB control. The target is to detect 70% of new sputum positive cases and cure at least 85% of them. This will lead to reduction of the annual incidence by between 7-12%. This will subsequently lead to a reduction of TB prevalence by 50% relative to 1990 and finally eliminate TB as a public health problem by the year 2050. In addition to improving the case detection and cure rates, part of the World Health Organization: Stop TB strategy is to address special groups such as prisoners, refugees and other high risk groups.

Kenya is ranked 10th among the 22 high burden countries. Based on 2006 estimates, the prevalence of TB in Kenya is 334/100 000 population. The case detection rate of 49% still falls far below the 70% target. However it is encouraging to note that the current treatment success rate is approaching the 85% target for the achievement of MDG. The incidence of TB peaks at 25-44 years and the peak is higher for men than women. This is precisely the population that is most likely to be found in prison.

Overcrowding is common in prisons. According to information posted at the International Centre for Prison Studies website as of July 2006, the prison occupancy
level was 287% in Kenya. This overcrowding makes prisoners to be at a high risk of being infected with TB. Thirty per cent of the mortality in Kenyan prisons is attributable to TB according to a retrospective survey done by Odhiambo J et al 6. Tuberculosis has also been found to account for up to 24% of prison mortality in other developing countries 7. The control of tuberculosis in prison must not be neglected. As was succinctly put by a former prison commissioner8, "Men are sent to prison as punishment, not for punishment". Contacting TB in prison because of inadequacies in TB control will be an unintended punishment. The prison systems are an integral of the part of the society and they are not completely sealed from influencing the society as many would like to think. Prisoners interact with the guards, their families during prison visits and upon release to the society. Therefore it is impossible to confine tuberculosis infection by the prison walls.

Kamiti Maximum Security prison is Kenya's largest prison holding approximately 3650 prisoners. The prison has seven blocks labelled A to G, a ward for sick prisoners and an outpatient clinic within its confines. The prison health services are run by the Ministry of Health which also supplements the services offered by the confinement clinic with a dispensary outside the prison enclosure but within the larger less restricted compound of the prison. This dispensary is has a fully equipped laboratory manned by 2 laboratory technologists and is specifically equipped to handle tuberculosis diagnosis. A fully functional radiography department run by two technologist was also set up by Center for Disease Control /Ministry Of Health (CDC/MOH) collaboration 6 years ago.

Cases of tuberculosis are usually identified though passive case finding method whereby the prisoners refers himself after noticing the relevant respiratory symptoms. This study employed active case finding method in which prisoners are asked if they have the symptoms and then investigated appropriately.

**LITERATURE REVIEW**

Prisoners around the world have higher rates of tuberculosis infection and disease than the general population 9, 10, 11. In Georgia, a former state in the Union of Soviet Socialist Republics, TB among prisoners was reported to be 200 times more prevalent than in the general population.
A few studies have been done to document the prevalence of tuberculosis among prisoners in Africa. A study done in Botswana\textsuperscript{12} by CDC in collaboration with the Botswana Ministry of Health and the Division of Prisons and Rehabilitation to determine the prevalence of TB and drug-resistant TB in Botswana, screened prisoners and guards at four prisons during April-May 2002. Prisoners 16 years and older were requested to fill an active case finding questionnaire and those who consented were interviewed to establish their demographic characteristics, work history, duration of incarceration, previous medical history and presence of symptoms consistent with TB. Those prisoners who reported a cough underwent sputum smear examination and mycobacterial culture. Those who were unable to produce sputum underwent a radiological examination. The main outcomes were classified as smear positive TB, smear negative culture positive TB, and smear negative but with a chest radiograph consistent with TB. Most of the prisoners and guards (n=1290) consented and were included in the study. The majority of the prisoners (96\%) were men and the median age was 26 years with a median duration of incarceration being 15 months. A total of 509 reported cough and 371 of them were able to produce sputum. A total of 39 prisoners had TB. Forty-two per cent were smear positive, 58\% were smear negative culture positive and 30\% of the TB patients who consented to undergo voluntary counselling and testing were HIV positive. This translated to a high point prevalence of TB among prisoners in Botswana of 3,797 cases per 100,000 population in a population where the point prevalence among the civilian population was 620 per 100,000 population.

In 1995 Nyangulu D S et al\textsuperscript{13} performed a study in Zomba Central Prison in Malawi. This study involved an active case finding survey in which they screened 70\% of the prisoners for TB. They interviewed prisoners, and those with a cough of at least 1 week’s duration were screened by sputum-smear microscopy. Those found to be smear positive were started on treatment while those found to be smear negative were given a broad spectrum antibiotic (co-trimoxazole) and later reassessed. If there was no improvement in symptoms, the prisoners underwent chest radiography and if the radiograph was suggestive of TB, the patient was classified as smear negative TB. The prisoners who had a cough went through voluntary counselling and testing for HIV infection. Altogether 47 prisoners (5.1\% of those screened) had pulmonary TB.
14 were already on treatment for TB, 7 were diagnosed in the prison hospital ward while 26 were identified in the prison cells.

In the early 90’s, a study done in Ivory Coast found a high prevalence of smear positive TB in one of their main prison in Bouake at 5.8%. In this study, Koffi N et al examined all the 1681 prisoners regardless of the presence of symptoms. Sputum or gastric fluid microscopy was done on those who were suspected to have TB. If the pleura was affected the prisoner had a punch biopsy done. Chest radiography and HIV test were also done. Smear positive TB was diagnosed in 108 prisoners.

Factors associated TB in prisons
Various factors have been found to be associated with development of tuberculosis in prison. Most of these factors have to do with the dynamics of transmission within the prison system and before imprisonment.

The age of the prisoners is considered one of the factors that have been explored for a possible association with pulmonary tuberculosis. Most of the studies done in Africa have not looked at the association between age and tuberculosis. The study done in the Malawian prison system did not demonstrate the association between age and tuberculosis. Carbonara et al found that age more than 30 years was associated with increased odds of acquiring TB infection. Other studies have not been able to demonstrate an independent statistically significant association between age and risk of TB infection in prison.

Repeated imprisonment has been found to be associated with increased likelihood of developing tuberculosis among prisoners. A Spanish study found the odds ratio of being infected with TB in prisoners who have been imprisoned more than once to be 7.3 as compared to their counterparts who have been imprisoned once. A large urban jail in Tennessee, United State of America reported that prisoners who developed TB disease had a median of 15 incarcerations.

Length of stay in prison is significantly associated with an increased risk of TB infection and disease. One year of jail term in New York City prisons doubled the odds of developing TB disease in inmates who were not infected with TB on entry
Incarnation >6 months was found to be a risk factor for active TB in prisoners in Botswana. Russian prisoners who were incarcerated for two years or more had a higher rate of developing TB than those who were incarcerated for less than a year.

Inadequate ventilation and enclosed spaces also have been shown to be a risk factor for transmission of tuberculosis. Overcrowding is common in the prison systems throughout the world. Overcrowding in prison facilitates transmission of TB bacteria among inmates.

HIV exacerbates the already increased risk of TB in the incarcerated populations. In one study in Brazil, the incidence of active TB in incarcerated women was found to be 9.9 per 100 person-years for the HIV-infected as opposed to 0.7 per 100 person-years in those uninfected with HIV. Where rates of HIV in civilian and detained populations have been compared, up to 75-fold increase in TB prevalence has been reported. Other studies have also demonstrated an increased risk of TB in the inmates who are infected with HIV.

The association of TB infection with the body mass index (BMI) has also been studied. Aerts et al found a BMI of less than 20 to be associated with TB. The low BMI probably reflects the poor level of nutrition in the prisons but again it may be a symptom of tuberculosis infection. A study done in a Tanzanian hospital found that 68.4% of all the prisoners admitted to the hospital with active TB had malnutrition. This finding had also been demonstrated earlier in the Ivory Coast study with a slightly higher percentage of prisoners having malnutrition. Malnutrition lowers the immunity of the prisoners making them more susceptible to develop of active TB.

Prisoners with a history of TB previously are more likely to develop active TB. Souza et al in a study done in Brazil found that 39% of the prisoners with TB had previously been treated for TB and this was statistically significant. However, the study done in Botswana found a non-statistical significant tendency of those who previously had TB to be diagnosed with TB.
A history of drug use has been found to have an important association with TB among inmates. In a case control study\textsuperscript{29} done in St Petersburg Russia, a history of narcotic use was associated with increased risk of TB.

The effect of smoking on the risk of developing TB in prison has not been explored. Chronic exposure to tobacco not only impairs the normal clearance of secretions on the tracheobronchial tree but also impairs the function of pulmonary alveolar macrophages which are an important defence against \textit{M. tuberculosis} infection. A recent meta-analysis by Lin et al\textsuperscript{30} found consistent evidence that smoking is associated with an increased risk of TB. Some of the studies analyzed demonstrated a dose response relationship.

\textbf{Spread of TB from the prison to the community}

The spread of TB from the prisons to the community is well documented in literature. This occurs through releases, amnesties and through regular contact with staff and visitors\textsuperscript{31, 32}. Indeed one study done in Botswana\textsuperscript{12} documented very high prevalence of TB among the prison wardens. Prisons may act as a reservoir for TB, pumping the disease into the community at large.

\textbf{TB case finding strategies in prison}\textsuperscript{33}

There are three main strategies for TB case finding in prison:

\textbf{Passive case finding}

In this case, it is the prisoner who refers himself and comes to seek medical attention upon noticing respiratory symptoms. This can be a good strategy but it has some limitations. It can work well when the prisoners are aware of the symptoms suggestive of TB. The prisoner must be willing to seek treatment. This strategy cannot work well in prisons where there may be repercussions for having a diagnosis of TB.

\textbf{Enhanced case finding}

This is where the prisoners are sensitized about the symptoms of tuberculosis and then encouraged to present themselves for investigation for TB.
Active case finding
This involves systematic searching of prevalent TB cases in the prison at a particular time. This is a strategy of identifying cases in order to deal with the reservoir of TB in the prison. A lot of resources are required in order to carry out this kind of exercise.

Screening of prisoners at entry to prison
This is in line with the United Nations recommendations. This can help to prevent building up a reservoir of infectious TB in prisons. It can also be done during transfers between prisoners and upon release to decrease transmission of TB to the community.

The best strategy of dealing with TB is not any one particular strategy but a combination of all the above strategies. Passive case finding by self-referral should be coupled with screening for TB at entry to prison and active case finding of existing cases in the imprisoned population.

TB case finding methods in prison
Since TB is a public health problem, most of the focus is normally on identifying the infectious smear positive cases. The method of identifying which prisoner should submit sputum is less well established. Various methods have been reported.

Symptoms
Symptoms can be used for screening for active TB. Symptoms develop soon after the onset of disease and are present in 90% of cases with infectious TB. Using symptoms in identification of TB leads to a large proportion of the incarcerated population being classified as TB suspects. An example is in the former USSR state of Georgia where 38.4% had suggestive symptoms. In a Malawian study, 26% of the prisoners who enrolled in the study had a cough of longer than 1 week’s duration making them TB suspects.

A recent Thailand study on the prevalence of smear positive TB in prisons compared the Standard World Health Organization (WHO) score and the International Standards for Tuberculosis Care (ISTC) criteria. The WHO guidelines scores the presence of cough >2 weeks duration, sputum production, loss of weight, loss of appetite, previous anti TB treatment and BMI while in the ISTC, a single
question about cough ≥2 weeks is used. This study found the ISTC to have a higher positive predictive value as compared to the WHO guidelines (5.9% vs. 1.2%). The advantage of the ISTC single question is that it can be administered by non health care workers especially in resource constrained settings as is common in most prison systems in Sub Saharan Africa. However the findings of this study are limited by the fact that the comparison was only made for prisoners with smear positive TB.

**Radiography**

Chest radiography is an important tool in the diagnosis of pulmonary TB. According to the WHO guidelines the use of chest radiography should be restricted to diagnosing smear-negative TB among those suspects whose sputum examination is negative. In patients suspected to have TB, the sensitivity of chest radiography has been reported to be up to 95%. However, this sensitivity can be as low as 73% and specificity as low as 69%. The sensitivity and specificity of chest radiography depends on the intensity and the presentation of the disease.

Notwithstanding the above limitations, the method of identifying pulmonary TB suspects must be sensitive enough to correctly detect likely TB cases, without missing a significant proportion of genuinely infectious TB cases. However, it must also be specific enough to correctly exclude prisoners without TB, so that large numbers do not unnecessarily go through laboratory investigations for TB. This balancing act is necessary to detect as many infectious cases as possible and to conserve resources at the same time. In resource limited settings it has been suggested that good estimates of the prevalence of disease can be obtained by symptom screening and microscopy.
STUDY JUSTIFICATION

TB is one of the leading causes of mortality in Kenyan prisons accounting for 30% of the deaths. No accurate and systematic studies have been done to determine the prevalence of active pulmonary TB in this population. The estimates of TB prevalence in other African prisons range from 3.8-5.8%. With such high prevalence compared to the civilian populations, prisons can act as reservoirs for *M. tuberculosis* infection.

This study set out to determine the prevalence of active pulmonary tuberculosis in prison. Kamiti Maximum Security Prison was chosen because its proximity and the availability of radiography and laboratory services within its confines.

The result of the study will add to the knowledge base and also form a basis for strategies to reduce and control TB in prison and the country as a whole.

RESEARCH QUESTION

What is the prevalence of active pulmonary TB among prisoners in Kamiti Maximum Security Prison?

OBJECTIVES

Broad objective

To determine the prevalence of active pulmonary tuberculosis among prisoners in Kamiti Maximum Security Prison.

Specific objectives

1. To document the prevalence of active pulmonary tuberculosis by the current passive case finding method.
2. To determine proportion of smear positive TB among prisoners by active case finding.
3. To determine the association between age, duration of stay in prison, number of incarcerations, smoking history, history of previous treatment for TB, presence of co-morbidities, body mass index, prison density/m², history of alcohol or drug abuse and tuberculosis.
Secondary objective
To determine the prevalence of HIV infection among prisoners with active pulmonary tuberculosis in Kamiti Maximum Security Prison.

METHODOLOGY

STUDY DESIGN
A cross-sectional descriptive survey.

STUDY POPULATION
The study population comprised of all inmates at Kamiti Maximum Security Prison during the study. The total prison population was approximately 3650 inmates. This population comprised of remand, convicted and condemned prisoners.

STUDY AREA
This study was done at the Kamiti Maximum Security Prison. The prison has 7 blocks labelled A, B, C, D, E, F and G. Each block is further subdivided into several rooms. Each block holds certain categories of prisoners and has a lock but the prisoners are highly mobile within the block and are able to mix freely between the rooms.

SAMPLE SIZE
Studies done in other African prisons\textsuperscript{12, 13, 14} found an average prevalence of 4.9\%. Targeting a 95\% confidence level and a degree of precision of 2.5\% the formula below was used to calculate the sample size.

\[
\text{Sample size} = \frac{Z^2 \cdot p \cdot (1-p)}{c^2}
\]

Where:
\(Z= 1.96\) (standard normal deviate for 95\% confidence level)
\(P= \text{average prevalence of TB in African prisons (Ivory coast, Malawi, Botswana)} = 4.9\%\)
\(c= \text{the precision expressed as a decimal (0.25)}\)

Substituting these values in the above formula, the minimum sample size required was found to be 289 prisoners.
**SAMPLING METHOD**

With the assistance of the prison warders and the prisoners in charge of each block, we inquired for those prisoners who had a cough of two or more weeks duration. Those who had a 2 or more weeks cough and agreed to give an informed consent were selected for the study.

**CASE DEFINITION OF ACTIVE PULMONARY TUBERCULOSIS**

Any prisoners with either sputum smear positive or sputum smear negative pulmonary TB as per the following definition:

a) **Sputum smear-positive pulmonary TB**

One or more initial sputum smear examinations positive for AFB or one culture positive for *M. tuberculosis*.

b) **Sputum smear-negative pulmonary TB**

A case of pulmonary TB that does not meet the above definition for smear positive TB. This should include at least three sputum smears negative for AFB with radiographic abnormalities consistent with active TB.

**INCLUSION CRITERIA**

- All prisoners who had a cough of 2 or more weeks duration and agreed to give informed consent.

**EXCLUSION CRITERIA**

- Failure to give informed consent
CLINICAL METHODS

After explanation of the nature and purpose of the study, all the prisoners who met the inclusion criteria were requested to give a signed informed consent [appendix 1(a)] and enrolled into the study.

Their baseline characteristics with respect to age, duration of stay in prison, number of incarcerations, smoking history, history of previous treatment for TB, presence of other co-morbidities, body mass index, prison density and a history of alcohol or drug abuse were obtained for the prisoners that were enrolled in this study. The data obtained was recorded in a proforma (appendix 2).

Participants who had a productive cough submitted three sputum samples and all measures were taken to adhere to the WHO protocol for sputum collection from prisoners45. Two spot sputum and one early morning sample were taken. Standard ZN microscopy for the sputum specimens were done at the prison health facility. Part of the early morning sputum specimen was taken for mycobacterial culture at the National Reference Laboratory. Those study participants who had negative sputum smears and/or dry cough had a chest radiograph done. The chest radiographs were taken to a consultant radiologist for reporting. Where the results of Z-N smears were not available in time, chest radiography was done regardless of smear microscopy status. Depending on the outcome of the above procedures the prisoners were classified as either having active pulmonary TB or not having pulmonary TB. The prisoners with active pulmonary TB were requested to undergo voluntary counseling and testing for HIV. All the prisoners who had active pulmonary tuberculosis or had HIV infection were referred to the relevant clinic to be managed appropriately.
LABORATORY METHODS

a) Sputum smear procedure
As much as possible care was taken to ensure that the right prisoner produced the sputum, in the open air and as far away as possible from fellow prisoners. Instructions were provided on how to cough so that the expectorated came from as deep as possible. The sputum expectorated was checked to ensure they are of appropriate volume and quality. Sputum with solid or purulent material was considered good quality. However if only saliva was obtained, the specimens were still forwarded for processing according to
IUATLD recommendation\textsuperscript{46}. This is a more common occurrence where spot specimens are involved. The standard Ziehl Neelsen staining method was used for sputum examination as part of quality assurance. In the laboratory, the sputum bottle and the slides were labelled appropriately with laboratory numbers. A bamboo stick applicator was used to spread the sputum evenly over the corresponding slide to make a smear of about 20mm by 10mm. The smears were fixed and covered with 0.3% carbol fuchsin for 5 minutes. The slides were then heated and excess carbol fuchsin was removed by rinsing with tap water. Afterwards, decolourization was done using acid-alcohol for 3 minutes. The acid alcohol was washed away and the smears then counterstained with methylene blue for 1 minute. Rinsing was done and the slides air dried ready for examination.

The slides was then observed under the microscope (using the x100 oil immersion lens and x10 eyepiece lens) over about 100 fields and reported as per WHO recommendation for reporting slides as shown below:

Table 1: Reporting of slides as per WHO recommendation

<table>
<thead>
<tr>
<th>Number of bacilli</th>
<th>Result report</th>
</tr>
</thead>
<tbody>
<tr>
<td>No AFB per 100 oil immersion fields</td>
<td>0</td>
</tr>
<tr>
<td>1-9 AFB per 100 oil immersion fields</td>
<td>Scanty (or number of AFB seen)</td>
</tr>
<tr>
<td>10-99 AFB per 100 oil immersion fields</td>
<td>+ (1+)</td>
</tr>
<tr>
<td>1-10 AFB per oil immersion field</td>
<td>++ (2+)</td>
</tr>
<tr>
<td>&gt;10 AFB per oil immersion field</td>
<td>+++ (3+)</td>
</tr>
</tbody>
</table>

b) Mycobacterial culture procedure\textsuperscript{47}

The sputum samples were taken to the national TB reference laboratory for sputum culture. This was done using the Lowen-Jensen (L-J) media. The sputum specimens were first decontaminated using Petroff method. This was comprised mixing sputum with 4% sodium hypochlorite for 15-30 minutes and neutralising with potassium hydroxide orthophosphate. The sputum was then centrifuged and the deposit inoculated into 3 tubes of L-J media. Incubation was done at 35-37 degrees Celsius and weekly inspection done for mycobacterial growth for up to 8 weeks.
RADIOLOGICAL METHODS

The radiographs were taken for reporting at the Department of Diagnostic Radiology of the University of Nairobi by an independent consultant radiologist. Based on the clinical features and the radiograph findings, the radiographs were reported as being highly suggestive or not suggestive of active pulmonary TB. Features that were considered to be highly suggestive of pulmonary TB included: Upper lobe interstitial infiltrates, bilateral interstitial infiltrates, cavitations, pulmonary fibrosis and shrinkage. Any other lesions not fitting the above were considered not suggestive with pulmonary TB.

DATA ANALYSIS

The data that was collected was recorded into the study proforma (appendix 2) and thereafter transferred into Statistical Package for Social Sciences (SPSS) version 14.0. Data was cleaned and verified. The data for the prevalence of active pulmonary TB by passive case finding was abstracted from the TB notification summaries available at the prison clinic.

The prevalence of pulmonary TB (both smear positive and smear negative) by the passive case finding was calculated as equal to prisoners with documented pulmonary TB multiplied by 100,000 divided by the total prison population. The proportions of smear positive and smear negative pulmonary tuberculosis by active case finding were determined. The additional yield of active pulmonary tuberculosis by active case finding was also calculated. The Chi squared test was used to find the association between the case finding strategies and the smear status. The prevalence of active pulmonary tuberculosis in the prison was determined by combining the yield from active and passive case finding methods.

The mean, median, standard deviation and frequency distributions of each numerical variable (age, duration of stay in prison, number of times incarceration, body mass index and prison density) were determined. Categorical variables (smoking history, history of previous treatment for TB, presence of other co-morbidities and history of alcohol or drug abuse) were analysed by using percentages.
Statistical tests (Chi squared test for categorical variables and student t-test for continuous variables) were used for comparisons. Univariate and multivariate logistic regression analyses were used to evaluate the characteristics associated with tuberculosis. In each analysis, odds ratios (OR) and 95% confidence intervals (CI) around estimates of association were generated. Statistical significance for all analyses was set at alpha = 0.05.

The proportion prisoners with active pulmonary tuberculosis who had HIV infection was calculated by dividing the number of prisoners with TB/HIV co-infection by the total number of prisoners with TB who underwent testing. The results are presented in form of pie charts, graphs and tables.

**ETHICAL CONSIDERATION**

This study was undertaken after approval by the Department of Internal Medicine, University of Nairobi, the KNH/UON Ethics and Research Committee and the relevant prison authorities. Enrolment into the study was voluntary. Informed consent to participate in the study was provided by the prisoner after the purpose and study procedures had been explained to the prisoner in a language they could understand. Care was taken to ensure that the prison warden did not influence the signing of informed consent.

This study did not involve the performance of procedures that exposed the participant to unnecessary risks. The confidentiality of the study participants was protected. Prisoners who had a diagnosis of active pulmonary TB voluntarily underwent diagnostic counselling and testing for HIV in line with WHO recommendation and ISTC standard number 12. This was done by a trained VCT counsellor. Transportation of sputum specimens to the reference laboratory was done in an appropriate manner. The prisoners who were diagnosed to have TB and or HIV infection were referred to the personnel manning the relevant clinic for appropriate care. The prisoners who took part in the study were free to withdraw from the study without prejudicing their care or access to any services.
RESULTS

Recruitment
The study was conducted between November 2007 and May 2008 at the Kamiti Maximum Security Prison. On average there were three thousand, six hundred and fifty prisoners residing at the prison during the duration of the study. Out of the 3650 prisoners, three hundred and fifteen prisoners representing 8.6% of the total prison population had a cough of 2 or more weeks duration and were eligible for the study. Four prisoners declined to give an informed consent, 12 prisoners were lost to follow up due to failure/refusal to present themselves for investigation and one prisoner was transferred to another prison. A total of 298 prisoners completed the study. The following figure represents the study results.

FIGURE 1: ACTIVE CASE FINDING STUDY RESULTS FLOW CHART

Using sputum smear microscopy, 8 prisoners were found to have *M. tuberculosis*. Following TB culture, an additional 8 prisoners were found to have tuberculosis. A
total of 25 prisoners had chest radiograph findings highly suggestive of active pulmonary tuberculosis. Six of these prisoners with chest radiographs highly suggestive of TB were later found to have positive culture for TB while the rest (n=17) had no TB on culture. Based on chest radiographic findings, only one prisoner with a dry cough had TB. One of the prisoners with a chest radiograph suggestive of TB had complete resolution of symptoms while on antibiotics. This prisoner had a previous history of treatment for pulmonary TB.

The following table contains the radiographic findings that were suggestive of active pulmonary tuberculosis:

<table>
<thead>
<tr>
<th>Radiographic findings</th>
<th>Number of prisoners with findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper lobe infiltrates</td>
<td>8</td>
</tr>
<tr>
<td>Bilateral infiltrates</td>
<td>4</td>
</tr>
<tr>
<td>Upper lobe cavitations</td>
<td>5</td>
</tr>
<tr>
<td>Lung collapse</td>
<td>1</td>
</tr>
<tr>
<td>Combination of upper lobe infiltrates and cavitations</td>
<td>4</td>
</tr>
<tr>
<td>Combination of bilateral infiltrates and cavitations</td>
<td>3</td>
</tr>
</tbody>
</table>
DEMOGRAPHIC DATA

Age
The mean age was 33.49 years with a median of 31.0 years and a standard deviation of 11.498 years. The majority of the prisoners in this study were between 21 to 40 years old. This age group represented 69% of the prisoners who were recruited into this study.

Figure 2: Age distribution of prisoners

Duration of prison stay
In this study population, the prisoners had been in the prison for a mean duration of 3.4 years with a standard deviation of 4.0 years. The prisoners recruited in this study had been in prison for a period ranging from one week to twenty two years.

Number of incarcerations
Two hundred and fifty three prisoners representing 85.8% of the participants were in their index imprisonment. Fourteen per cent of them had been incarcerated more than once. None had been incarcerated more than 5 times in his lifetime.
**Body Mass Index (BMI)**

The study population was fairly homogenous with regard to BMI with the mean, median and mode BMI being 21.0 with a standard deviation of 2.59.

![Figure 3: The BMI distribution of the prisoners](image)

**Density of prisoners**

Each square metre of prison room held a mean of 1.19 prisoners. The median prisoner density was 1.03 prisoners per square metre with a standard deviation of 0.43 prisoners per square metre.

**History of previous anti-TB treatment, smoking, alcohol or drug use history**

The following table shows the characteristics of the prisoners with regards to various categorical variables:

**Table 3: The characteristics of the study population by categorical variable.**

<table>
<thead>
<tr>
<th>Variable</th>
<th>No(%) of prisoners with the variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous anti TB treatment(n=298)</td>
<td>55(18.5%)</td>
</tr>
<tr>
<td>Smoking history(n=298)</td>
<td>162(54.4%)</td>
</tr>
<tr>
<td>Alcohol or drug use(n=298)</td>
<td>95(31.9%)</td>
</tr>
</tbody>
</table>
Majority of the prisoners (81.5%) in the sample population had never been diagnosed nor treated for tuberculosis. Fifty five out of 298 prisoners (18.5%) of the prisoners had been on antituberculous medication at one time or another. Slightly more than half the prisoners (54.4%) had a history of smoking for 5 pack years or more. A third of the prisoners had a history of alcohol use or illicit drug use. Eight prisoners had COPD while 3 had diabetes. None of these illnesses were found to be a co-morbid condition in those who had tuberculosis.

**Prevalence of tuberculosis**

The number of active pulmonary tuberculosis both by active case finding and passive case finding strategies in the whole prison population of 3650 prisoners are presented in the following $2 \times 2$ contingency table.

**Table 4: The yield of active pulmonary TB from the two case finding strategies.**

<table>
<thead>
<tr>
<th>Smear microscopy status</th>
<th>Case finding strategy</th>
<th>Smear positive</th>
<th>Smear negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Passive (n=52)</td>
<td>10 (19%)</td>
<td>42 (81%)</td>
</tr>
<tr>
<td></td>
<td>Active (n=34)</td>
<td>16 (47%)</td>
<td>18 (53%)</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>26</td>
<td>60</td>
</tr>
</tbody>
</table>

There was a statistically significant difference between the two case finding strategies above with a two tailed p value of 0.0122 on Chi squared testing.

By passive case finding, 52 prisoners had TB out of the 3650 prison population. This is equal to a prevalence of 1425 per 100 000 of population. The rate of smear positivity was higher using the active case finding strategy (47%) as compared to passive case finding strategy (19%). A total of 86 prisoners out of the 3650 prisoners in the prison were diagnosed to have pulmonary TB by both the passive and active case finding strategies. Therefore the prevalence of active pulmonary TB in Kamiti Maximum Security Prison was 2356 per 100 000 of population during the period of the study.
Factors associated with tuberculosis

Only age was found to have a statistically significant association with having tuberculosis among the prisoners both on univariate and multivariate analysis. Prisoners who had tuberculosis were on average older than prisoners who did not have tuberculosis. The following table is a summary of the association of various variables with tuberculosis among prisoners. It contains both the univariate and multivariate analyses of each of the factors.

Table 5: Association of various variables with tuberculosis among prisoners

<table>
<thead>
<tr>
<th>Factor</th>
<th>No PTB Mean ±SD or n (%)</th>
<th>With PTB Mean ±SD or n (%)</th>
<th>Univariate OR (95% CI)</th>
<th>P value</th>
<th>Multivariate OR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>32.87±11.36</td>
<td>38.32±11.75</td>
<td>1.03(1.00-1.06)</td>
<td>.011</td>
<td>1.05(1.01-1.08)</td>
<td>.006</td>
</tr>
<tr>
<td>Duration of prison stay (yrs)</td>
<td>3.42±4.09</td>
<td>3.40±3.44</td>
<td>.10(.91-1.09)</td>
<td>.97</td>
<td>.98(.87-1.10)</td>
<td>.68</td>
</tr>
<tr>
<td>No. of incarceration</td>
<td>1.19±0.53</td>
<td>1.33±0.85</td>
<td>1.41(.85-2.32)</td>
<td>.183</td>
<td>1.52(.81-2.82)</td>
<td>.190</td>
</tr>
<tr>
<td>Prison density (prisoners/m²)</td>
<td>1.20±0.45</td>
<td>1.09±0.26</td>
<td>.50(.19-1.36)</td>
<td>.18</td>
<td>.33(.01-1.14)</td>
<td>.08</td>
</tr>
<tr>
<td>Prev. anti TB Treatment</td>
<td>48(18.75%)</td>
<td>7(20.59%)</td>
<td>1.13(.47-2.68)</td>
<td>.79</td>
<td>1.49(.57-3.93)</td>
<td>.419</td>
</tr>
<tr>
<td>Smoking</td>
<td>139(52.65%)</td>
<td>23(67.65%)</td>
<td>1.88(.88-4.01)</td>
<td>.103</td>
<td>2.02(.79-5.19)</td>
<td>.143</td>
</tr>
<tr>
<td>Alcohol/drug use</td>
<td>80(30.30%)</td>
<td>15(44.12%)</td>
<td>1.82(.88-3.75)</td>
<td>.11</td>
<td>1.3(.52-3.24)</td>
<td>.568</td>
</tr>
</tbody>
</table>

SD= Standard Deviation or n= number of prisoners with a particular characteristics, CI= Confidence Interval, OR= Odds Ratio, yrs= years, No. = number, Prev = previous

Prisoners who had tuberculosis had been incarcerated for a mean of 1.33 times compared to those who did not have tuberculosis who had been incarcerated for a mean of 1.19 times. There was no statistical difference between prisoners who had TB
and those who did not have TB in terms of the prison density of the room they were staying in.

Among the prisoners who were diagnosed to have TB, 20.8% had previously been treated for tuberculosis compared to 18.8% among those who did not have tuberculosis. There were a greater percentage of smokers and prisoners with a history of alcohol or drug use among prisoner with pulmonary TB as compared to those without TB. The association of these factors with pulmonary TB did not reach statistical significance.

**Prevalence of HIV infection among prisoners with active pulmonary tuberculosis**

HIV test results were available for 29 out of the 34 prisoners with active pulmonary tuberculosis. Nine (31%) prisoners were HIV positive by rapid tests.

**DISCUSSION**

In this study the prevalence of active pulmonary tuberculosis was found to be 2356 prisoners per 100,000 of population. The most recent estimate of the prevalence of tuberculosis as per WHO in the civilian population in Kenya was 334/100,000 of population (5). The prevalence of tuberculosis in this Kenyan prison is therefore 7 times that of the civilian population. A similar study conducted by the CDC in collaboration with the Botswana Ministry of Health and the Division of Prisons and Rehabilitation in Botswana found a tuberculosis prevalence of 3,797 cases per 100,000 prisoners which was 6 times the tuberculosis prevalence in the civilian population. A study done by Nyangulu et al more than 10 years ago in one of Malawi’s main prison found the prevalence of TB to be 5142 per 100,000 while a study done earlier in Ivory Coast found a prevalence 5803 per 100,000.

The prevalence we got was slightly lower than what they found in these other African studies probably because our study comes many years later after concerted effort to control tuberculosis and indeed the prevalence of tuberculosis in Kenya has been decreasing with time. According to WHO country profile, the prevalence of tuberculosis has been decreasing at a rate of 9.2% in Kenya.

Another possible explanation is that in the Malawian study, they included prisoners with cough of 1 week duration while in the Ivorian study they did not have any cut off
for cough duration. The presence of a fully functional TB laboratory and a chest radiography machine within the Kamiti Prison compound could have increased the TB case detection rate prior to the study thereby improving the control of tuberculosis in this prison as reflected by the lower prevalence of TB in this prison as compared with other prisons in Africa which lack the benefit of such diagnostic facilities.

Sixteen of the prisoners with cough for 2 or more weeks duration were not included in the study as previously mentioned. No particular characteristic was noted about these prisoners that could put them at a particular risk for TB.

This study was based on symptom inquiry and may have underestimated the prevalence of TB as demonstrated by Gopi et al. When compared with mass radiography, symptom screen has a lower sensitivity for detecting cases of active pulmonary TB.

The rate of smear positivity was lower in the passive case finding as compared to active case finding strategy. The lower rate of smear positivity in the passive case finding may be due to the fact that those prisoners who present themselves and get investigated for TB may have had other symptoms similar to those of TB which could easily lead to misdiagnosis as smear negative TB. This low rate of smear positivity under passive case finding in this prison may also be a reflection of the sputum handling process right from collection to examination. The most recent available statistics indicate that 45% of the cases of pulmonary tuberculosis in Kenya are smear positive. In the Botswana study, 42% of the prisoners had smear positive tuberculosis which was similar to our study.

Factors Associated With Tuberculosis

The age of the prisoner was associated with having tuberculosis in this study. The older a prisoner was, the higher the chances of him having tuberculosis. This finding was consistent with a study by Carbonara et al, in which they found that being more than 30 years was associated with increased odds of acquiring TB infection. This increase in the susceptibility to tuberculosis with age could be attributed to a greater likelihood of older prisoners being exposed to \textit{M. tuberculosis} and an increased likelihood of the infection thus acquired to be reactivated with age related decline in
immunity\textsuperscript{50, 51}. Other studies\textsuperscript{17, 37} have not demonstrated a statistically significant association between age and risk of pulmonary TB in prison.

There was a statistically non significant tendency for those who had stayed for shorter period to be more likely to have TB. This is in keeping with the findings in the Ivory Coast and Tanzanian studies\textsuperscript{14, 27} which demonstrated that most of the TB cases (61\% and 50.3\%) tended to occur in the first 2 or 3 years of imprisonment. This either implies that these inmates had tuberculosis before they were sentenced, or that the high transmission and poor living conditions led to rapid progression of the disease. A casual observation made during the study was that generally long stay prisoners tended to be given better nutrition than remandees. This may also explain this finding that prisoners who had stayed for shorter duration were more likely to have TB. However some other studies have also shown a direct relationship between the duration of stay and having active pulmonary TB. Incarceration for more than 6 months was found to be a risk factor for active TB in prisoners in Botswana\textsuperscript{12}. Russian prisoners who were incarcerated for two years or more had a higher rate of developing TB disease than those who were incarcerated for less than a year\textsuperscript{9}.

Prisoners who had active pulmonary tuberculosis had been incarcerated more often than those who did not have TB. However, this was not statistically significant. The association of active pulmonary TB with the frequency of incarceration may be due to repeated exposure to \textit{M. tuberculosis} that comes with repeated imprisonment. A few studies have been able to demonstrate statistically significant increase of tuberculosis risk among prisoners with higher numbers of incarcerations. Sanchez et al\textsuperscript{16} et al in a study in which they were investigating for the predictive factors of \textit{M. tuberculosis} infection demonstrated that the odds of having tuberculosis were higher in prisoners with more than 1 imprisonment. They found that prisoners who had been incarcerated for more than once had 7.3 odds of having TB compared to their counterparts who had been incarcerated only once. The failure for repeated imprisonment to reach statistical significance is most probably due to the small number of prisoners included in the analysis.

No statistically significant association was found between previous anti tuberculosis treatment and a diagnosis of tuberculosis. Other studies have shown a relationship
between a previous history of tuberculosis and having tuberculosis. Prisoners with a
to history of TB previously are more likely to develop active TB\textsuperscript{9,12,16}. The Botswana study\textsuperscript{12} found that prisoners with a previous history of tuberculosis were thrice as
likely to have TB compared to their counterparts who did not have such a history.
Souza et al\textsuperscript{28} in a study done in Brazil found that 39\% of the prisoners with TB had
previously been treated for TB. In our study, one fifth of the prisoners who had TB
had been treated for TB previously. This may be due to persistence of specific
predisposing conditions in these patients such as HIV/AIDS although this study was
designed to explore such a possibility.

This study did not find an association between the density of prisoners in a room and
having pulmonary tuberculosis. This may be explained by the observation that
overcrowding was quite uniform across the prison and that the prisoners were free to
intermingle within an individual block. However in some prisons where studies have
been done, overcrowding has been found to be associated with increased prevalence
of tuberculosis\textsuperscript{21,22}.

There is a paucity of data on the possible association between a history of smoking
and pulmonary tuberculosis among inmates. A meta-analysis of studies among
civilians found that smoking increases the risk of having tuberculosis \textsuperscript{30}. Despite
smoking being illegal in the prison, 54.4\% of the prisoners enrolled in our study
were active smokers. Chronic exposure to tobacco not only impairs the normal
clearance of secretions on the tracheobronchial tree but also impairs the function of
pulmonary alveolar macrophages which are an important defence against \textit{M. tuberculosis}
infection. In our study, smoking doubled the odds of having tuberculosis though not in a statistically significant way. The lack of statistical significance could be due to the inability of a study to eliminate the confounding effect of passive smoking in the prison.

Neither a history of alcohol or drug abuse prior to imprisonment was found to be
associated with tuberculosis. Few studies in the published literature have explored the
possible association. In a case control study\textsuperscript{29} done in St Petersburg Russia, a history
of narcotic use was associated with increased risk of TB.
HIV Infection among Prisoners with Tuberculosis.

Thirty one per cent of the prisoners with tuberculosis had HIV infection. The rate of HIV infection among Kenyan civilians with active pulmonary tuberculosis is currently at fifty two percent. Whether this lower rate of TB/HIV co-infection in the prison as compared with the national TB/HIV co-infection reflects a lower prevalence of HIV in the prison is unknown. There is no published study on the prevalence of HIV in Kenyan prisons. This study was done in an exclusively male population and the probable low prevalence of HIV in these prisoners with tuberculosis could also be attributed to a generally lower prevalence of HIV among males as compared to females in Kenya as demonstrated by the Kenya Aids Indicator Survey of 2007. 25.9% of Tanzanian inmates with tuberculosis also had HIV infection which was comparable with the 33% HIV infection among tuberculosis patients in the civilian population at that time.

CONCLUSION

1. The prevalence of active pulmonary tuberculosis in Kamiti Maximum Security prison is high at 7 times the national prevalence.
2. Prisons are still an important reservoir for tuberculosis.
3. The current passive case finding of tuberculosis in prison yields a far lower prevalence of smear positive TB (19%) compared to the national prevalence of smear positive TB (45%) by passive case finding.

LIMITATIONS OF THE STUDY

1. This study may have underestimated the prevalence of active pulmonary TB due to the use of a symptom screen.
2. Exclusion of prisoners with a cough of less than 2 weeks duration may have underestimated the prevalence of tuberculosis.
3. This study did not take into account the differences in ventilation of the various blocks in the prison and whether these differences in ventilation had any association with active pulmonary tuberculosis.
4. This study did not address the issue of quality control at the local laboratory at Kamiti by comparing it with the national reference laboratory at Kenyatta. However what was observed was that there was a high degree of inter-laboratory agreement with regards to Z-N stain smear microscopy since none of the smear
negative at the local laboratory turned out to be Z-N stain smear positive at the national reference laboratory.

RECOMMENDATIONS

1. Interventions targeting tuberculosis control in Kamiti Maximum Security Prison and other prisons in Kenya need to be strengthened in order to consolidate the gains that may have been made.

2. The National Leprosy and TB control programme needs to specifically target the prison with measures to increase the yield of sputum microscopy.

3. A large scale study involving several Kenyan prisons needs to be done to assess the magnitude of tuberculosis in the prisons and to determine the factors associated with it. Kamiti Maximum Security Prison may not be representative of the whole prison population in Kenya.

4. Periodic active case finding is needed to increase detection of smear positive pulmonary TB in the prisons.

5. A more precise study that incorporates mass radiography needs to be done to determine the prevalence of active pulmonary tuberculosis.
References:


20. Bellin E Y, Fletcher D D, Safyer S M. Association of tuberculosis infection with increased time in or admission to the New York City jail system. *JAMA* 1993; 269(17): 2228-31


52. Kenya Aids Indicator Survey 2007
Appendix 1(a): Research consent explanation

Title of the Study: Prevalence of active pulmonary tuberculosis among prisoners in Kamiti Maximum Security Prison.

Principal Investigator: Dr Okaru Cosmas Nyaturu (Phone: 0722958676)

Description of the research

You are invited to participate in a research whose aim is to find out how common TB is among prisoners in Kamiti Maximum Security Prison. This study is being done on all prisoners who have been coughing for 2 or more weeks and are willing to participate in the study.

What will my participation involve?

If you decide to participate in this research you will be requested to answer a few questions about yourself, provide 3 sputum samples and if thought to be necessary, you may undergo a radiological examination of your chest.

Are there any risks to me?

There are no risks associated with participation in this study. What will be done in this study is part of the normal work up for patients suspected to have TB.

Are there any costs to me?

There are no costs to you associated with this study.

Are there any benefits to me?

Yes. The benefits are that if you are found to have TB you will be referred to the clinic to start treatment but even if you don’t have TB the results of this study will help in coming up with recommendations that may reduce the occurrence of TB in prison. You will receive no money nor any form of compensation for participating in this study.

How will my confidentiality be protected?

Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. While there will probably be a publication as a result of this study, your name will not be used. Only group characteristics will be published.
Whom should I contact if I have questions?
You may ask any questions about the research at any time. If you have any questions to ask about the study, you can contact the Principal Investigator on the mobile phone number provided above.

**What are the terms of my participation?**
Your participation is completely voluntary. Your decision not to participate in this study will have no effect on any services or treatment you are currently receiving or need to receive. There are no penalties for withdrawing your participation at any stage of the study.

**RESEARCH CONSENT FORM**
Having got explanation about the nature and purpose of this study, the procedures, the potential benefits and risks associated in participating in this study, I hereby voluntarily agree to participate in the study by appending my signature.

Name of Participant: ..........................................................Signature...
Witness................................................Signature .............. Date..............................
I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions raised have been answered.
Signature of PI: .............................................................Date: ..............................................
Appendix 1(b): Consent explanation for diagnostic counselling and testing for HIV

Having been diagnosed to have TB, I request you to undergo diagnostic counselling and testing for HIV. Having HIV infection increases the risk of having TB. It is now standard practice to perform an HIV test for all patients with TB.

This is a 3 stage process conducted by a qualified voluntary counselling and testing (VCT) counsellor. The first stage will involve pre test counselling as per standard protocol. This will be followed by the test which will involve drawing a drop of blood by a finger prick. The results will be ready in around 15 minutes. You will then undergo post test counselling.

Drawing blood by pin prick method involves minimal pain. The potential benefit of undergoing the test is that regardless of the outcome of the test, you can be advised appropriately on the measures you can take to safeguard your health. If you are found to be infected with the HIV virus, you will be referred appropriately for further management and follow up. This testing is confidential. Your identity and outcome of the test shall not be divulged to any third party. There are no charges associated with this test. If you decide not to undergo the process, you will receive the usual care. There will not be any penalty associated with refusal or withdrawal from undergoing the diagnostic counselling and testing.

Diagnostic Counselling and Testing For HIV Consent Form

I have received sufficient explanation on the importance of HIV testing and counselling in patients with TB. Having been found to have TB, the VCT procedure, potential risks and benefits have been explained to me and I hereby consent to undergo the VCT process.

Name of participant: ........................................ Signature: ........................................
Witness: ........................................ Signature: .......................... Date: ..............................

I certify that I have explained to the participant the nature, purpose, risk and benefit of HIV testing and counselling in patients with TB.

Signature of PI: ........................................ Date: ........................................
Appendix 2
STUDY PROFORMA

a) Baseline characteristics

Date: /.../... Cell/ Block: Study No.
Age: years
Duration of stay in prison: months
Number of incarcerations

Previous anti-tuberculosis treatment: yes | no
(In the previous 5 years)

Weight: kg | Height: m | BMI: kg/m²

Prison density | no. of prisoners in the cell

Dimension of prison cell m²

Smoking or history of smoking > 5 pack years: yes | no

History of alcohol use or other drug abuse: yes | no

Presence of other co-morbidities

Diabetes

Chronic obstructive pulmonary disease
b) Laboratory results

Z-N stain

<table>
<thead>
<tr>
<th></th>
<th>Positive for AFB</th>
<th>Negative for AFB</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st specimen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd specimen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd specimen</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mycobacterial culture:  
- positive □  
- negative □

c) Chest radiograph report

- Highly suggestive of TB □  
- Not suggestive of TB □

d) Final diagnosis

- Smear positive TB □  
- Smear negative TB □  
- No TB □
17/07/07

TO: CHAIRMAN, KNH ETHICAL AND RESEARCH COMMITTEE

RE: PREVALENCE OF ACTIVE PULMONARY TUBERCULOSIS AMONG PRISONERS AT KAMITI MAXIMUM SECURITY PRISON

RESEARCHER: DR. OKARU COSMAS NYATURU

The above research proposal has been presented to the Department of Clinical Medicine and Therapeutics Academic Members of Staff meeting held on 7th June, 2007.

It has been fully discussed and passed. It can now be presented to your committee for approval on content and ethics.

Thank you.

Yours Faithfully,

DR. A.J.O. WERE.
CHAIRMAN, DEPARTMENT OF MEDICINE RESEARCH COMMITTEE
Dr. Okaru Cosmas  
Department of Internal Medicine  
School of Medicine  
University of Nairobi  
P.O. BOX 29761-00202  
NAIROBI

RE: PERMISSION TO CONDUCT STUDY IN PRISON

The Commissioner of prisons has given you permission to conduct study in prison.

You will need the usual approval of your protocol by the Kenyatta National Hospital ethics and Research committee and will work with the Director, Prison Health Services.

Wishing you the best.

[Signature]

DR. J.C. KIBOSIA  
DIRECTOR PRISONS HEALTH SERVICES