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# Prevalence of tuberculosis (TB) infection and disease among adolescents western Kenya: preparation for future TB vaccine trials

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**KEMRI/CDC**



Research And Public Health Collaboration



**E D C T P**

Partnership for TB Vaccine Development

# Background

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- Tuberculosis (TB) is a major global public health problem with 9.3 million new cases and 1.8 million deaths in 2007 affecting mainly Africa, South-East Asia and the Western Pacific (WHO).
- One third of the world's population is estimated to be infected with the tuberculosis mycobacterium.

**Source:** WHO report 2009: Global Tuberculosis Control

# TB Burden in Kenya

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- Nyanza Province has greatest TB burden in Kenya
  - TB notification (all types of TB): 440/100.000
- Prevalence of TB disease (all types) 319/100.000 in Kenya (2007)
- HIV prevalence in HIV-tested TB cases registered with TB program in Nyanza is ~75% (52% nationally)
- TB is the most common cause of death in people living with HIV.
- Those living with HIV have a 10% annual risk of contracting TB
- Kenya ranked 13th out of 22 TB high burden countries by the WHO

# TB Vaccination

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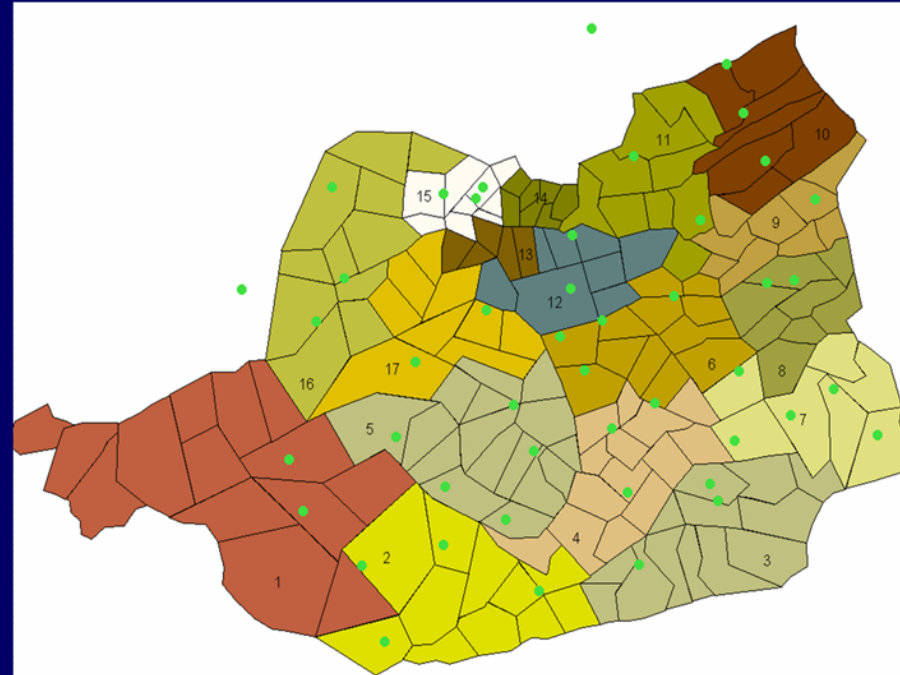
- Bacille Calmette Guérin (BCG) first administered in 1921.
- It is the mostly widely used vaccination today (about 100 million doses in 2002).
- However, its effectiveness is controversial.
- Nevertheless, there is broad consensus that it provides protection against severe forms of childhood TB.

# KEMRI / CDC Field Station, Western Kenya



# Karemo Division (Study Area)

- Under continuous demographic surveillance (DSS)
- Total Population 85,000
- Estimated 13,000 adolescents Aged 12-18 (both in and out of school) as estimated from DSS registers
- Divided into 17 equal sized clusters of approximately 800 adolescents each
- Clusters randomized to give each adolescent in the study area an equal probability of getting enrolled into the study



# Adolescents as a target group for research

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- Adolescents considered a high risk group for TB disease and difficult to recruit
- Captive population (in schools), access easier than mobile young adult population
- Attrition in progressing years of education a matter of concern for retention in clinical trials
- The planned epidemiological study involves invasive procedures
- We would expect this to potentially impact negatively on recruitment
- Little information in literature for TB in adolescents; Important to determine prevalence and incidence of TB disease in adolescents

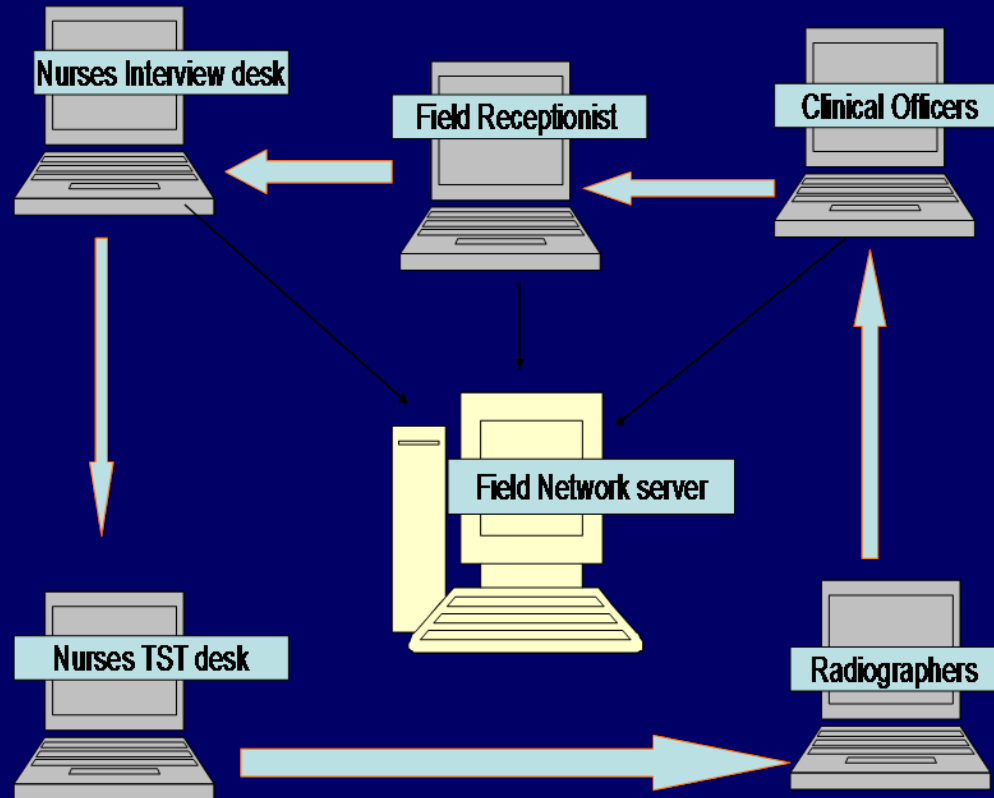
# Methods

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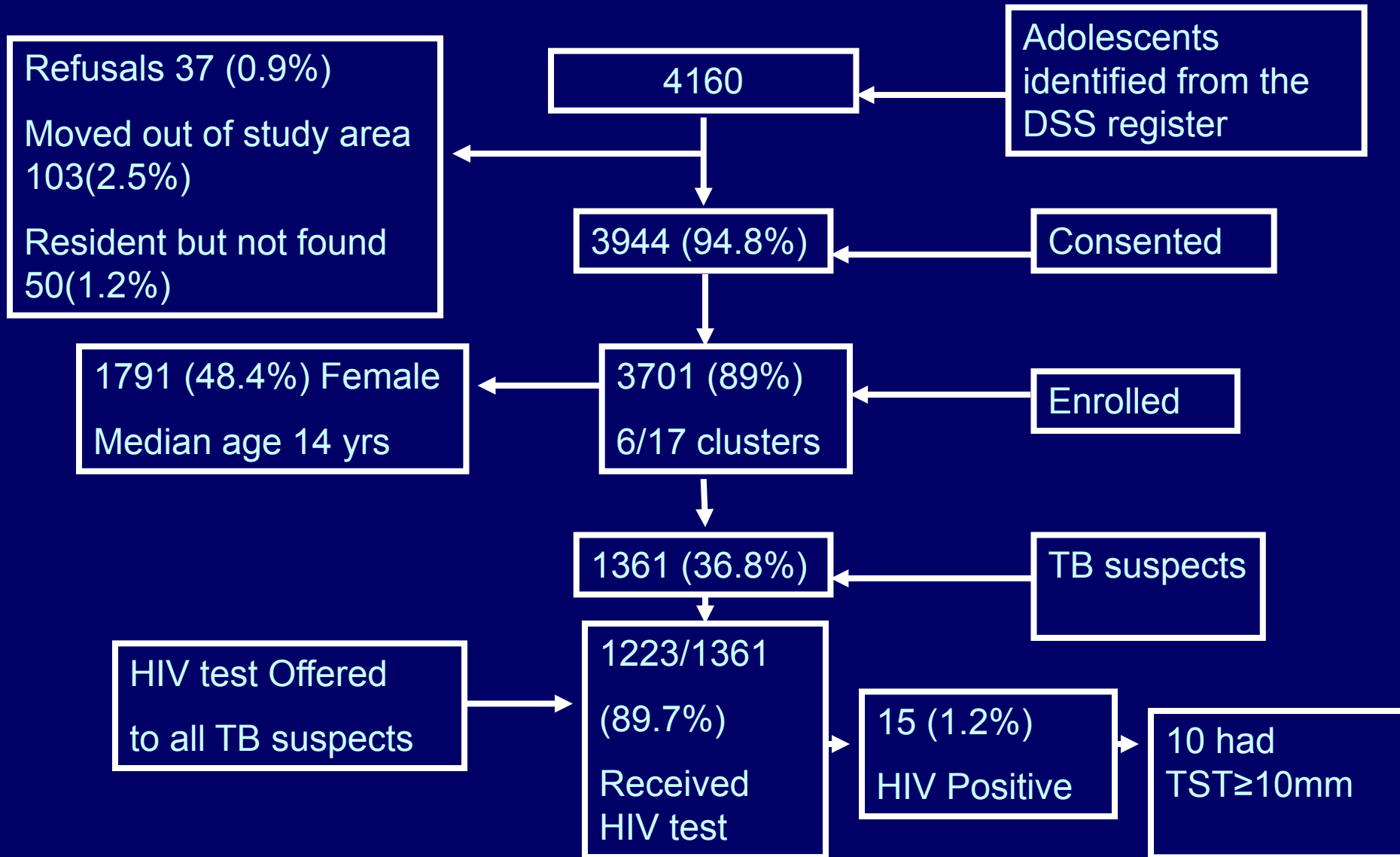
- Prospective Cohort Study of 5000 Adolescents Aged 12-18 years
- Clusters randomly approached for enrollment.
- Potential study subjects identified through DSS registers
- Parental consent and adolescent assent sort
- All consenting adolescents in a cluster enrolled until the full sample size achieved
- A questionnaire about symptoms, history of contact with a TB case and history of hospitalization administered
- Follow up every 4 months for 1-2 years
- TB suspects identified through:
  - History of Contact with a TB case
  - Clinical History
  - Tuberculin skin tests (TST) (considered positive when)
    - $\geq 10\text{mm}$  if HIV negative
    - $\geq 5\text{mm}$  if HIV positive
- TB suspects evaluated through:
  - HIV testing
  - sputum microscopy and culture
  - Chest x-rays
- Analysis
  - Cluster adjusted estimates of prevalence and infection

# Mobile Field Site

- Informed consent and adolescent assent are conducted at home and schools respectively
- Adolescents and their parents are invited to a central site usually in a school where enrollment activities take place
- Not all consenting parent/adolescent pairs showed up for enrollment
- Enrollment conducted on Thursday and Friday while tuberculin skin tests are read on Monday and Tuesday

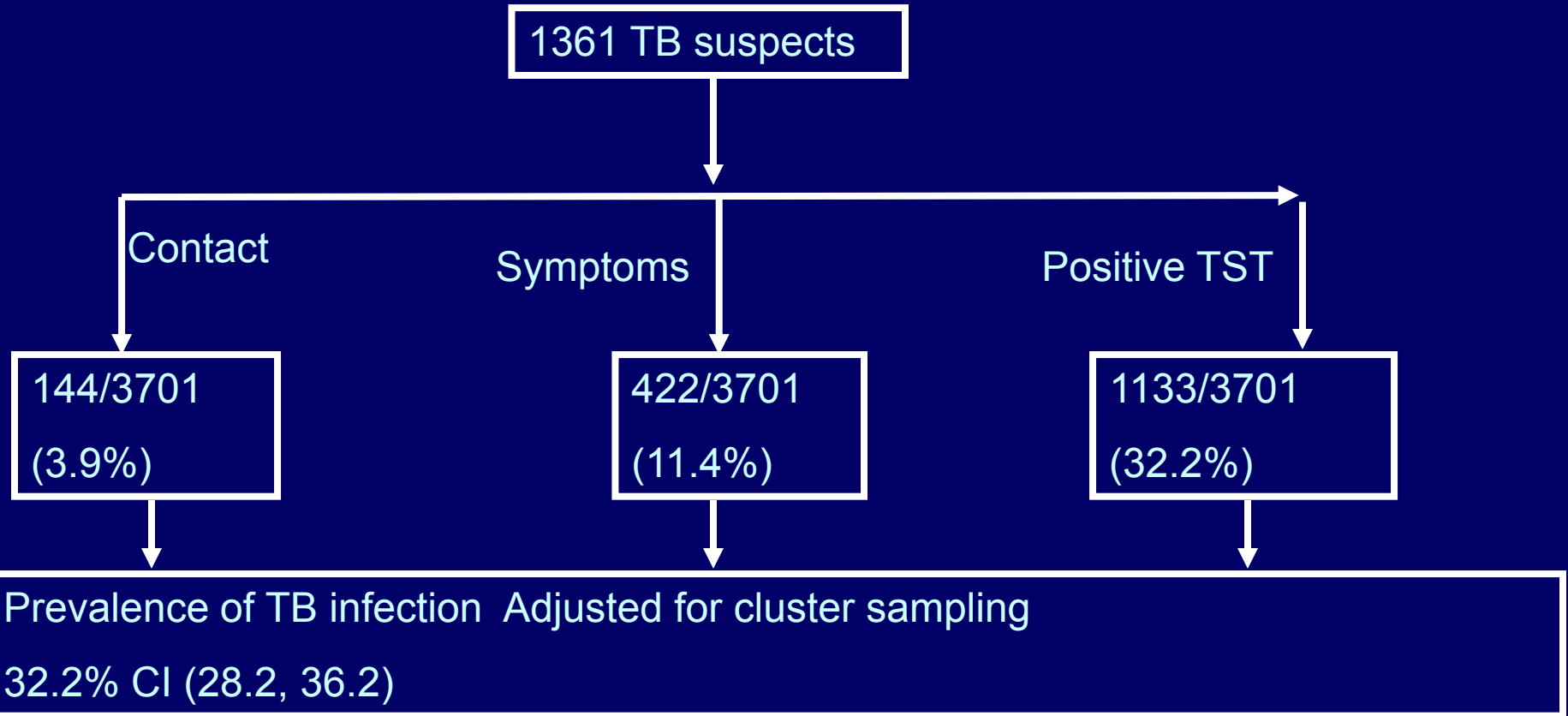


# Results (1)



# Results (2)

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# TB cases

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- 12 definite pulmonary TB (PTB) cases (2 fluorescent microscopy smear positive or culture positive (MTB on speciation))
- 4 probable PTB cases (clinically diagnosed but not culture or smear positive)
- 14/16 (87.5%) of TB cases had a positive tuberculin skin test.
- None of the TB cases was HIV positive
- prevalence estimates adjusted for cluster sampling:
  - 324/100,000 (definite) CI (157, 491) per 100,000 population
  - 432/100,000 (definite and probable) CI(176 -689) per 100,000 population

# Discussion

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- The prevalence of pulmonary disease among adolescents is similar to what was found in a recent prevalence survey, western Kenya by Anja Van't Hoog et al in 15-24 year olds for bacteriologically confirmed PTB (290/100.000 95% CI(99-480))
- The prevalence of TB infection (32.2%) is higher than reported previously in TST surveys in Kenya for school going children average age 8.4years (5.5%) whose estimated annual risk of infection was 0.6%.
- None of the identified prevalent TB cases presented had been diagnosed by the TB program

# Conclusion

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- The interim prevalence of TB is consistent with our expectations and indicates this will be a suitable target population for TB vaccine trials
- The ability to rapidly enroll adolescents shows this will be a suitable site to conduct clinical trials in adolescents especially TB vaccine trials

# Acknowledgement

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  - South African Tuberculosis Vaccine Initiative
  - Vienna School of Clinical Research
  - SRL Milan, Italy
  - Community in Karemo, Siaya District
  - Study team