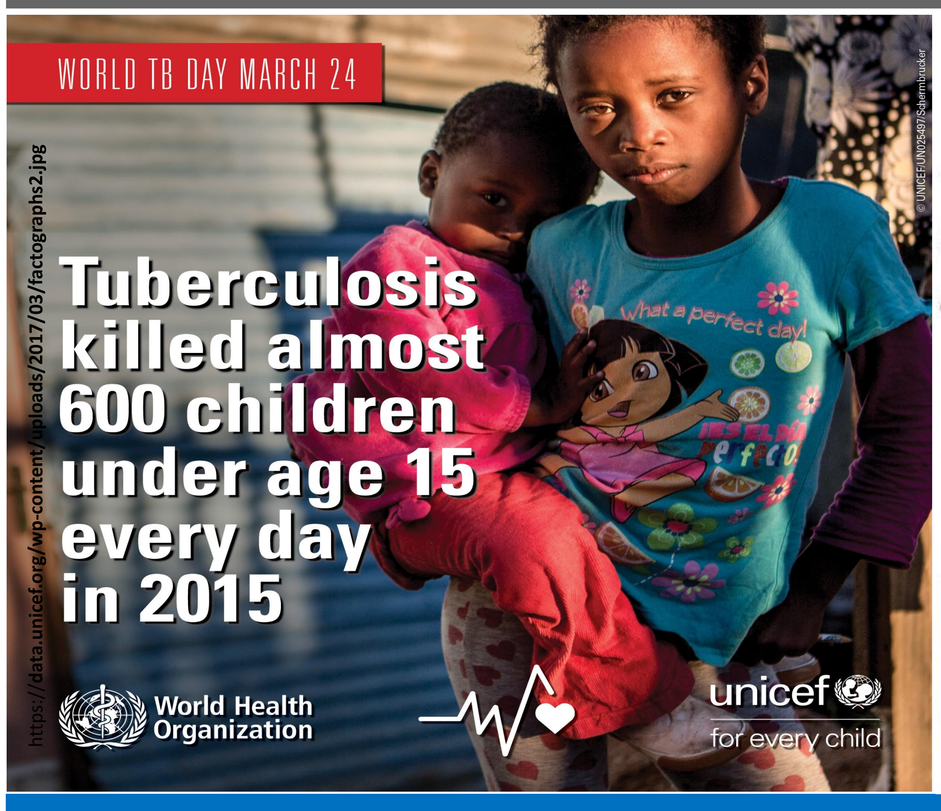
Childhood TB in Ghana: using immunodiagnostics to improve detection and monitoring of response to anti-TB therapy



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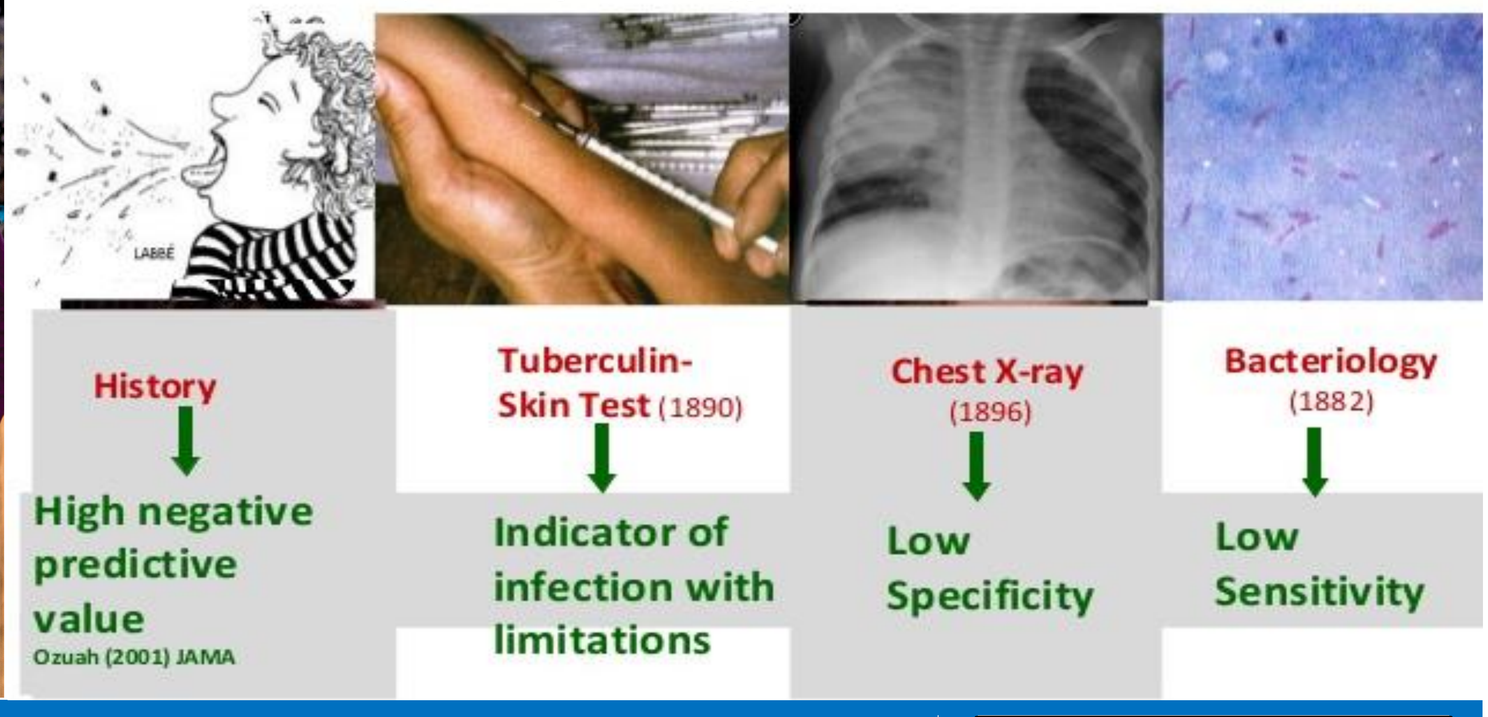
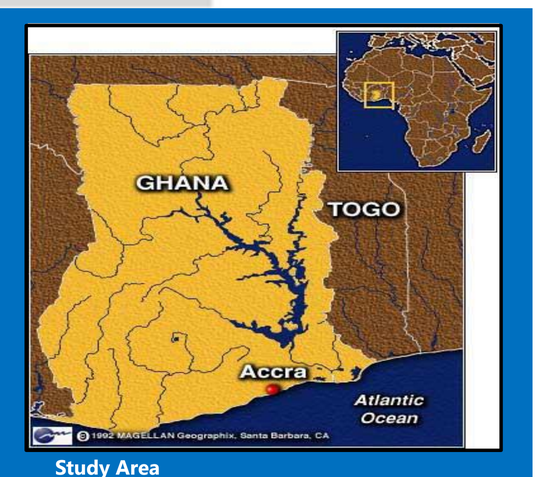


Introduction

TB disease is often paucibacillary in children and sputum is difficult to obtain particularly from younger children. Hence diagnosis is often based on clinical signs, symptoms and history of TB contact. This often results in over or under-diagnosis as this has poor specificity. This prospective longitudinal study seeks to provide a more accurate/improved diagnostic algorithm for TB in children utilizing a combination of existing and novel tools including blood-based immunodiagnostic assays.

Key Message: This study seeks to provide a more accurate/improved tool for confirming a clinical diagnosis of childhood TB and reduce cases of over or under-diagnosis



Study Area
Selected Health Facilities In Accra

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Acknowledgement

This work is supported through the DELTAS Africa Initiative [Afrique One-ASPIRE /DEL-15-008]. The DELTAS Africa Initiative is an independent funding scheme of the African Academy of Sciences (AAS)'s Alliance for Accelerating Excellence in Science in Africa (AESA) and supported by the New Partnership for Africa's Development Planning and Coordinating Agency (NEPAD Agency) with funding from the Wellcome Trust [107753/A/15/Z] and the UK government. The views expressed in this publication are those of the author(s) and not necessarily those of AAS, NEPAD Agency, Wellcome Trust or the UK government .

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Research Questions

- Would the addition of novel and existing blood-based diagnostic tools to existing sputum-dependent microbiological tests lead to a more accurate/improved diagnostic algorithm for TB in children?
- What are the risk factors and etiological agents of Childhood TB in Ghana?

Specific Objectives

1. To determine the utility of the QFT and TAM TB assay in addition to the traditional sputum-based methods for accurate diagnosis of TB in Children.
2. To determine the etiological agents of childhood TB in Ghana and drug resistance profile.
3. To monitor response to TB treatment in children using the TAM TB assay, QFT test and serum cytokine levels.
4. To determine the cytokine response profile of children with or without TB to MTB specific- antigens.
5. To determine the major risk factors for childhood TB in Ghana

Methodology

Study design
❑ Prospective/longitudinal (3 time points)

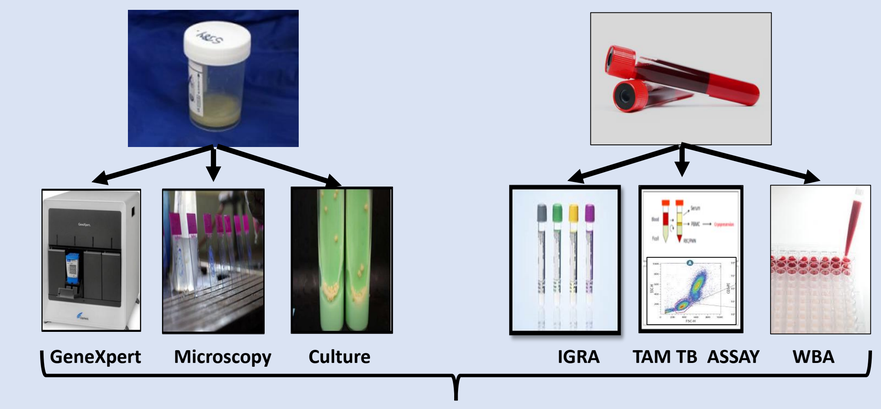
Eligibility
❑ Children below 15 years of age newly diagnosed with TB or presumptive TB

Study sites
❑ Selected Hospitals in Accra/Ghana

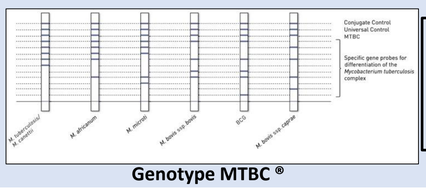
Sample size
100 cases and matched controls

Recruitment strategy
❑ Parental consent and child ascent
❑ Demographic details
❑ Sample collection (Blood and sputum)
  ❑ Before or within a week of treatment initiation [T1]
  ❑ After two months of treatment [T2]
  ❑ Treatment completion [T3]

Laboratory workflow



CLASSIFICATION	DIAGNOSTIC ALGORITHM					
	GENEXPERT	CULTURE	MICROSCOPY	IGRA	TAM TB	WBA
CONFIRMED TB	+	+	+	+/-	?	?
PROBABLE TB	-	-	-	+	?	?
EXPOSURE TO TB	-	-	-	+	?	?
NO TB	-	-	-	-	?	?



Genotype MTBC ®

All culture-positive isolates will undergo speciation using the Genotype MTBC ® from Hain Life Sciences to determine the etiological agents for childhood TB.

Expected outcome

The provision of a more robust diagnostic algorithm, which will allow clinicians to accurately classify children as being exposed, infected or having active TB. Knowledge of the risk factors for progression to active disease would help early initiation of appropriate prophylaxis or anti-TB treatment when needed.

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