Xpert MTB/RIF ® implementation in MSF projects
First results

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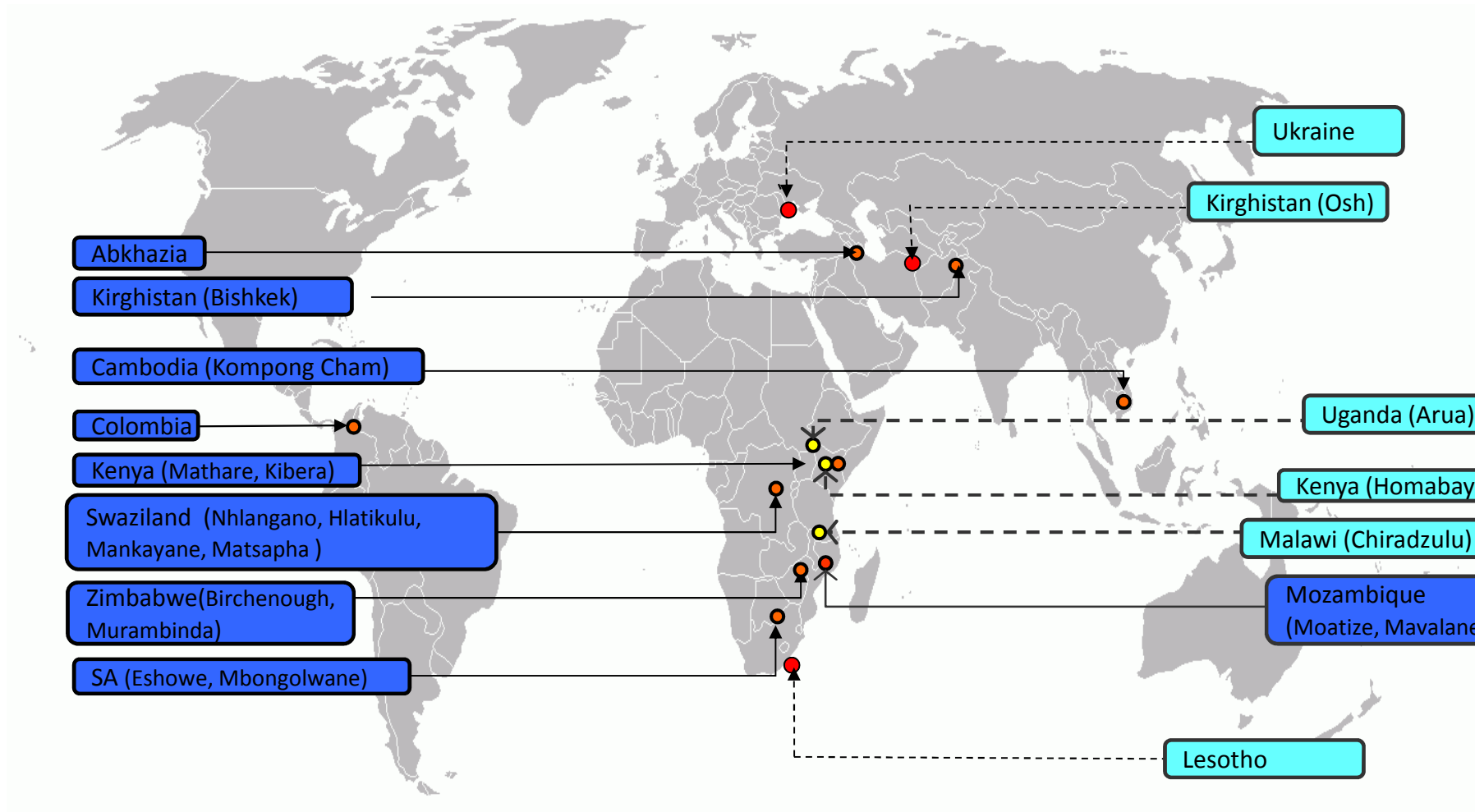**GLI meeting**

Annecy, 18/04/2012

Projects overview

- **First introduced in April 2011**

- **Routine clinical use in 16 projects, in 9 countries by end 2011**

- **Distribution by epidemiological situation**

	High HIV	Low HIV	Total
High MDR	7	2	9
Low MDR	6	1	7
Total	**13**	**3**	

- **Distribution by health facility level**
    - **Regional**   2
    - **District**   7
    - **Sub-district**   7

Xpert MTB/RIF® introduction

- Ukraine
- Kirghistan (Osh)
- Abkhazia
- Kirghistan (Bishkek)
- Cambodia (Kompong Cham)
- Colombia
- Kenya (Mathare, Kibera)
- Swaziland (Nhlangano, Hlatikulu, Mankayane, Matsapha)
- Zimbabwe(Birchenough, Murambinda)
- SA (Eshowe, Mbongolwane)
- Uganda (Arua)
- Kenya (Homabay)
- Malawi (Chiradzulu)
- Mozambique (Moatize, Mavalane)
- Lesotho

Objectives

- **Xpert MTB+/RIF results in routine MSF projects conditions**

  - Gain in specimens confirmation with Xpert compared to microscopy

  - Description of inconclusive results

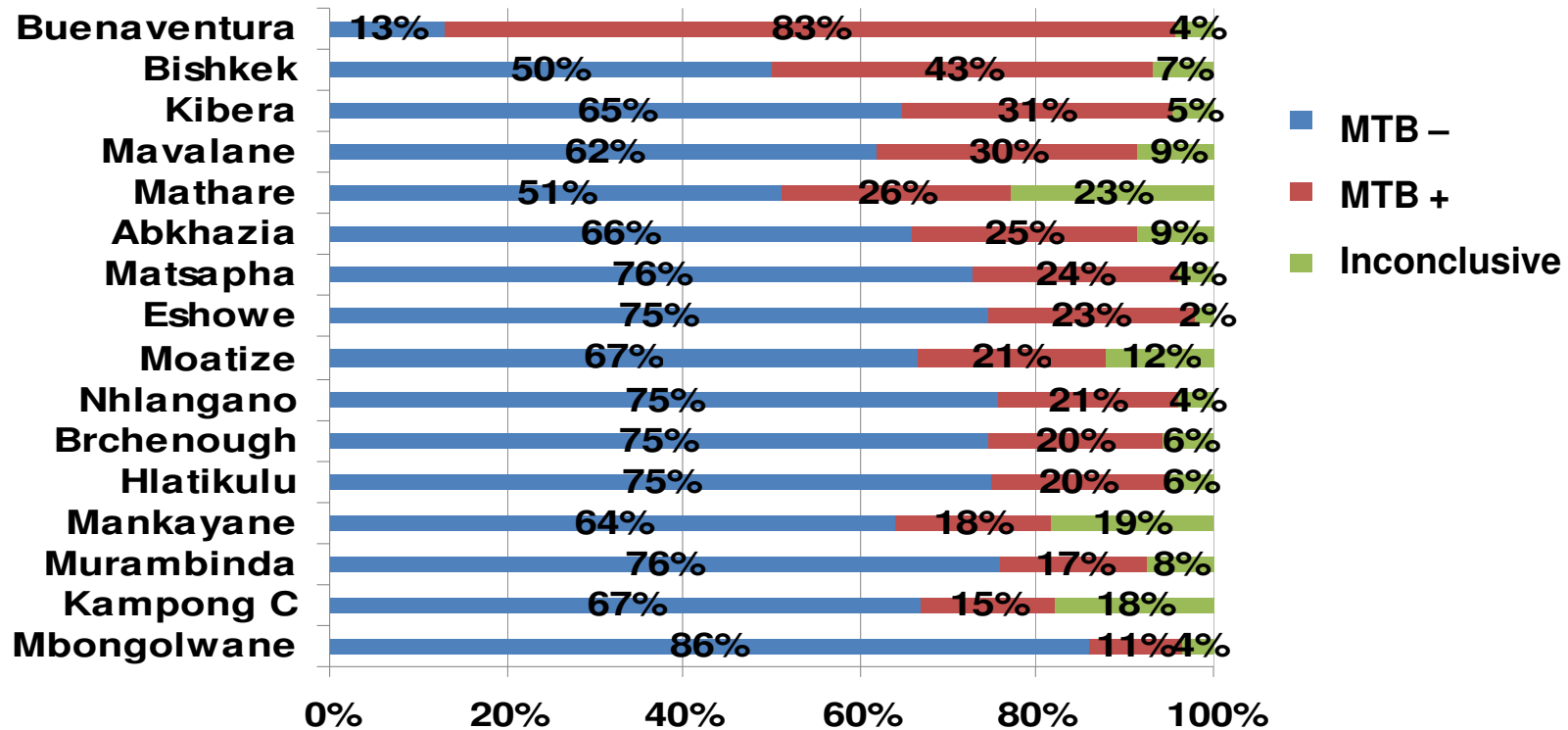- **Practical considerations and lessons learnt**

Methods

- **Data from laboratory registers and data system**

- **Sputum smear microscopy (SSM)**
  - Parallel testing in 14 projects
  - Fluorescence in 7 projects
  - Ziehl Neelsen in 7 projects

- Two periods
  - Initial period: April-August 2011
  - 2nd period: September-December 2011

- Definitions
  - **Positive SSM according to WHO recommendation** (≥1AFB)

  - **Relative gain (%)**: additional number of laboratory confirmed samples by Xpert/ number of samples confirmed by SSM

  - **Proportion of inconclusive Xpert results** : number of errors, invalid and no results/total number of samples tested by Xpert
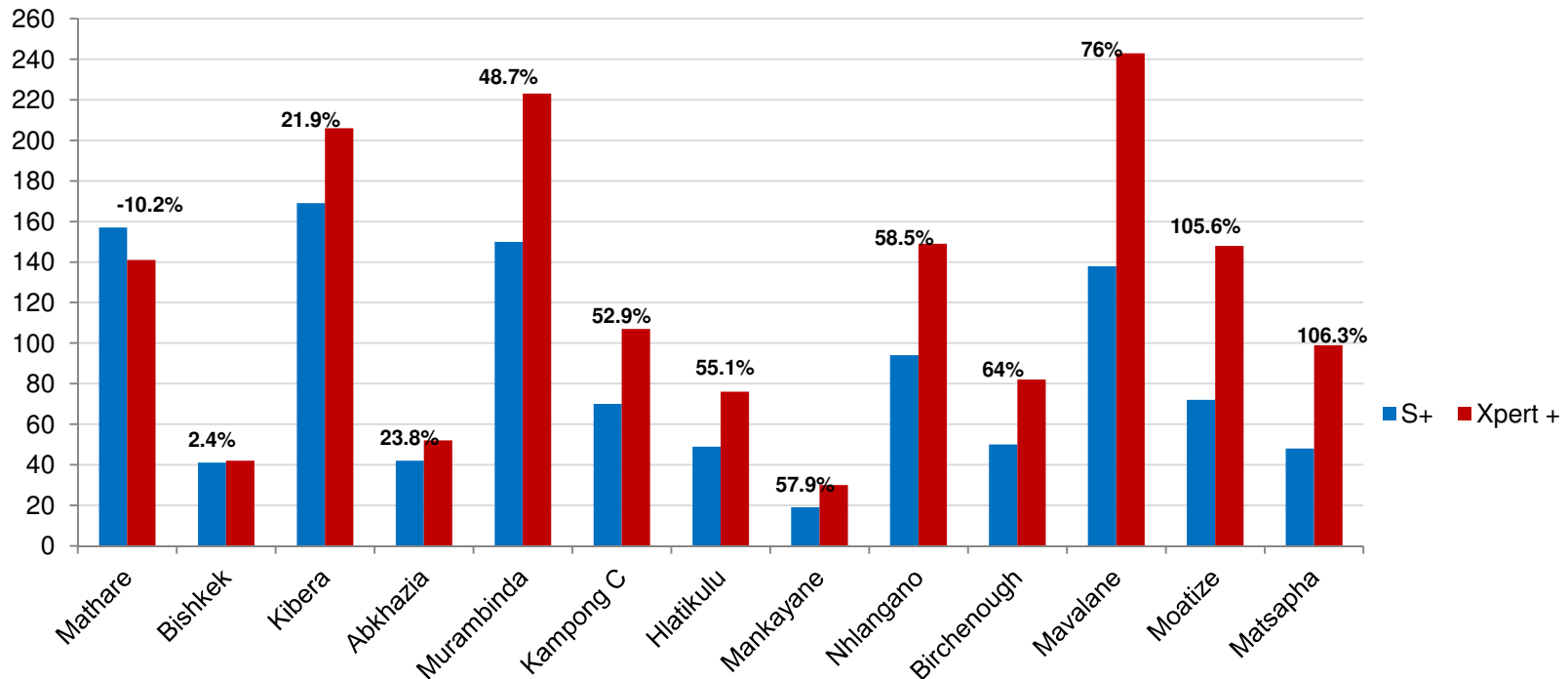
Results

Xpert MTB results

10,960 specimens in 16 projects (Apr-Dec. 2011)

- **Different detection strategies**
- **Average Xpert MTB positivity rate 21% (11 to 43%) MTB+ results (Buenaventura exc.)**
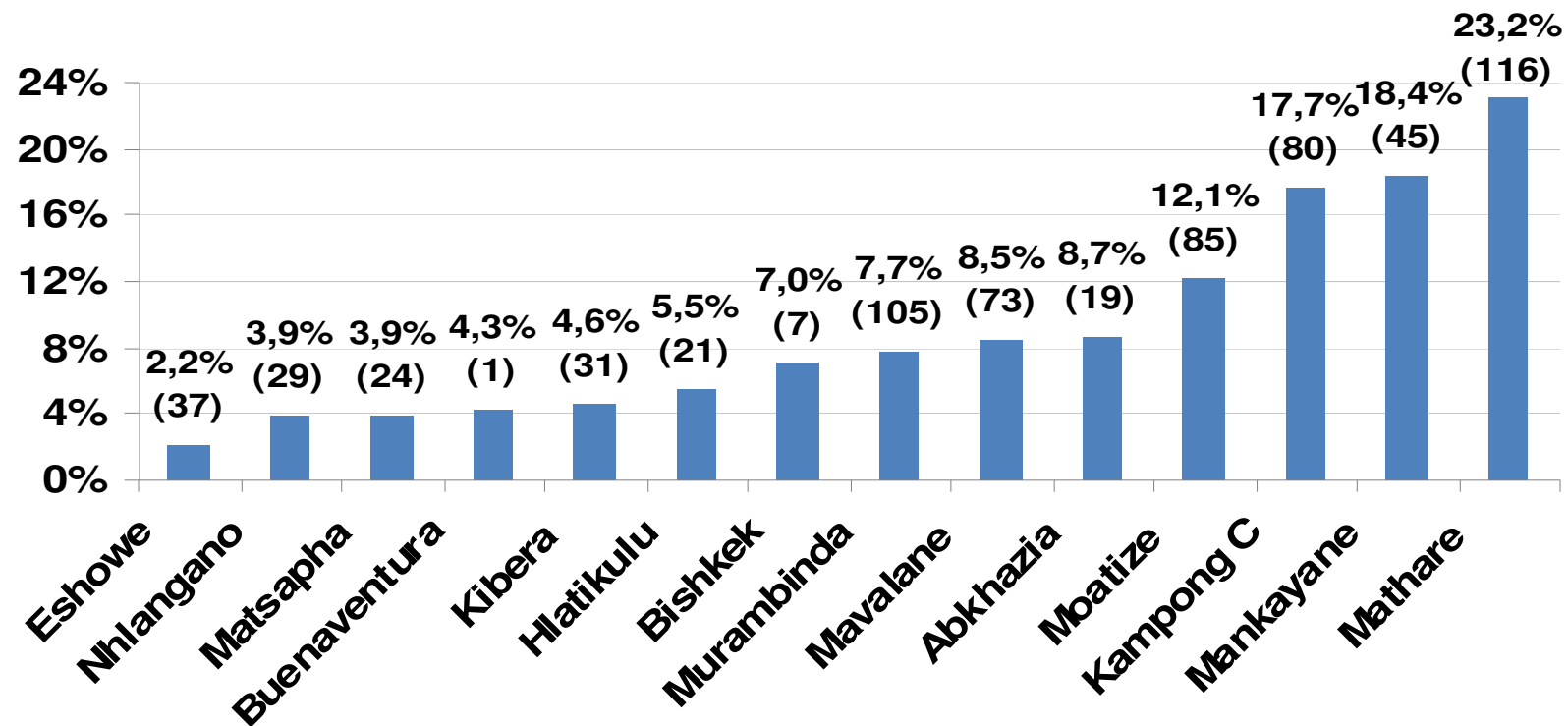
Relative gain vs SSM

6,981 specimens in 13 projects (Apr-Dec. 2011)

- **From 2 to 106% relative gain except for Mathare (-10%)**
- **48 % average relative gain (27% vs. FM, 54% vs. ZN)**
- **Time to result: 1-3 days**

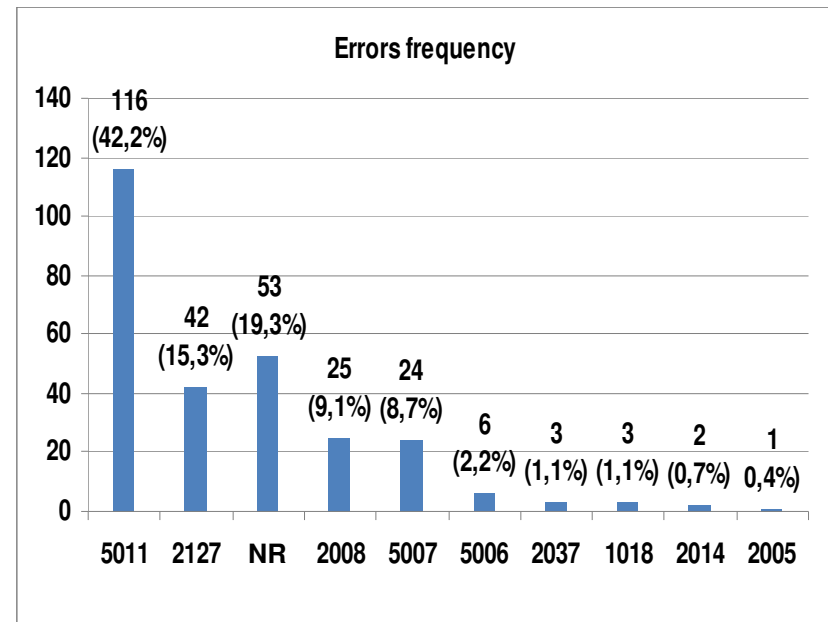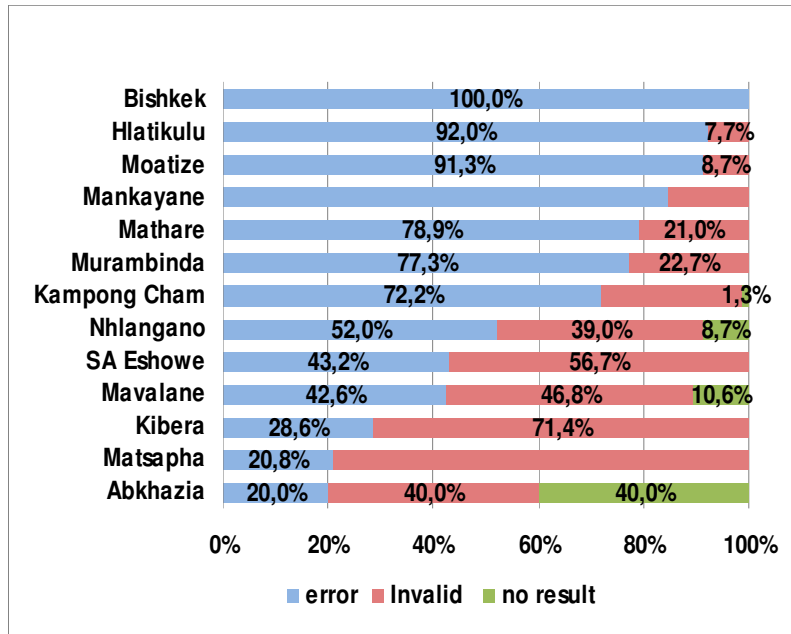# Proportion of inconclusive results by projects

14 projects (Apr-Dec. 2011)

- Average inconclusive results : 7% (2-23%)
- Big variations across projects
- 10 modules changed since April
- Improved over time: Apr-Aug: 10%; Sept-Dec: 5%
- Sept-Dec: inconclusive results >5% in 7 projects

Types of inconclusive results
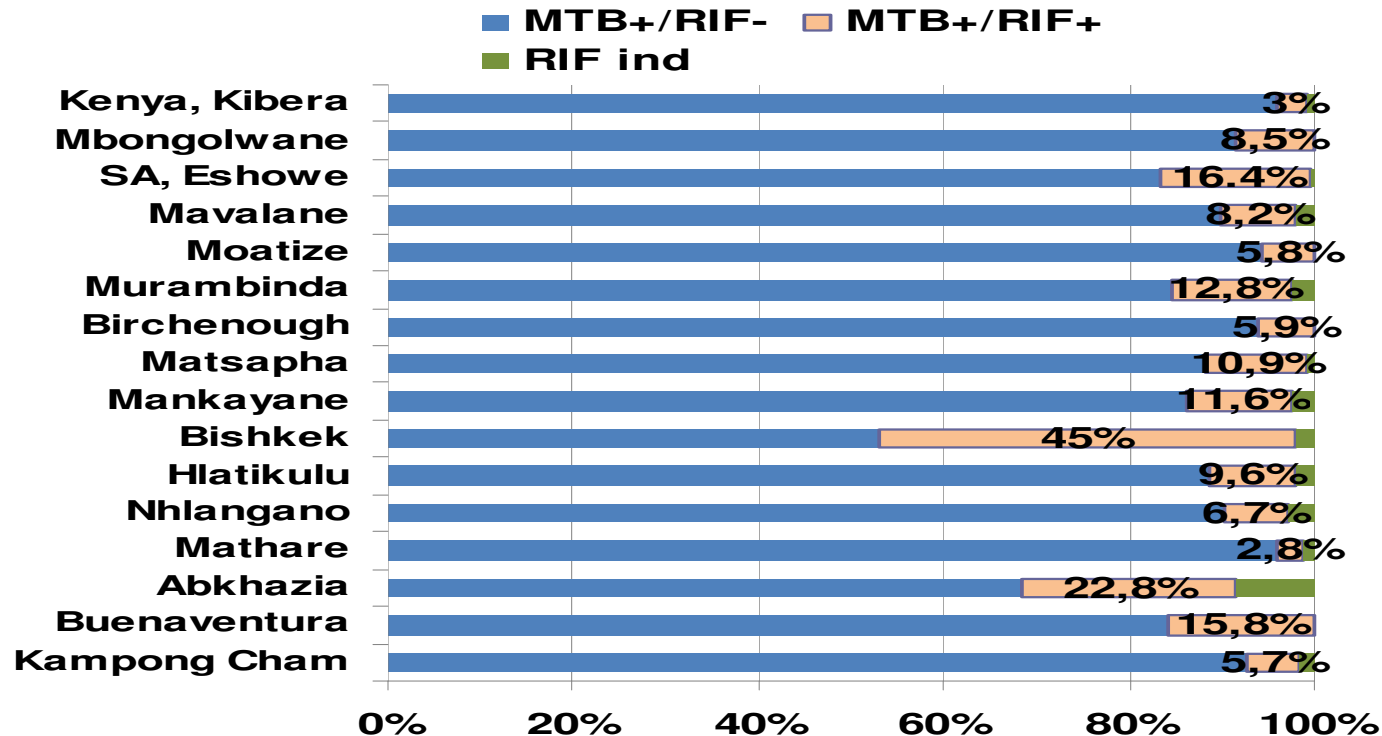
13 projects (Sept-Dec 2011)

Wide variations across projects

Error: 63% (20-100%), Invalid: 33% (8-71%), No result: 4% (0-40%)

Most common errors: 5011, 2127

RIF results

1,450 MTB+ specimens in 16 projects (Sept-Dec. 2011)

Legend: ■ MTB+/RIF- □ MTB+/RIF+ ■ RIF ind

Project	Value
Kenya, Kibera	3%
Mbongolwane	8,5%
SA, Eshowe	16.4%
Mavalane	8,2%
Moatize	5,8%
Murambinda	12,8%
Birchenough	5,9%
Matsapha	10,9%
Mankayane	11,6%
Bishkek	45%
Hlatikulu	9,6%
Nhlangano	6,7%
Mathare	2,8%
Abkhazia	22,8%
Buenaventura	15,8%
Kampong Cham	5,7%

Different detection strategies and Rif resistance prevalences

Proportion of RIF+ ranges 3- 45%

Average RIF indeterminate: 1.4%

Lessons from implementation

- **Relatively easy to use but not «plug and play» device**

- **Logistical and financial investment**
  - Devices and cartridges
  - Stable electricity power
  - Adequate conditions for operating procedures (temperature)

- **Limited decentralization**

- **Training is essential**
  - Specimen preparation
  - Diagnostic algorithms
  - MDR TB treatment
  - Proper data recording and reporting

- **Need for EQA reference laboratories for cultures and DST**

Conclusion

- **Significant increase in laboratory confirmation of TB**

- **Rapid screening of RIF resistant TB**

- **Real improvement in TB diagnostic**

- **High rates of inconclusive MTB results**
  - Still above 5% in 7/14 sites
  - Loss of confidence

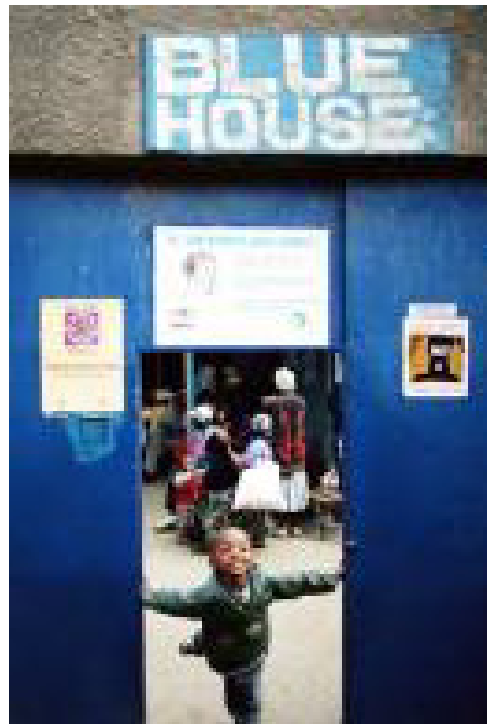## Cost is a major barrier

Recommendations

- **Need impact studies on patients outcomes**
  - Time to treatment initiation
  - Impact on case detection
  - Impact on case management

- **Need cost effectiveness studies**

Continue research for a non sputum based POC test

Thank you

Thanks to:
Emmanuel Fajardo
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Céline Lastrucci

Results by SSM techniques

From 7 projects after 4 months introduction phase

Fluorescence microscopy (5 projects)

FM	Xpert MTB+	Xpert MTB-	Not Interpretable	Total
SSM+	292	16 **5%**	23	331
SSM-	130	1204	130	1465
TOTAL	422	1220	153 **8%**	1796

Positivity rate   **Xpert : 23%**   **FM : 18%   (p<0.001)**

Relative increase vs. FM : 28 %

Ziehl Neelsen (2 projects)

ZN	Xpert MTB+	Xpert MTB-	Not Interpretable	Total
SSM+	49	3 **5%**	2	54
SSM-	34	296	32	362
TOTAL	83	299	34 **8 %**	416

Positivity rate   **Xpert: 20%**   **ZN: 13%   (p<0.001)**

Relative increase vs. ZN : 54 %