Presentation to Montreal Advanced TB Diagnostic Research Course

Deployment of POC technologies: where, why and what impact?

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July 2012

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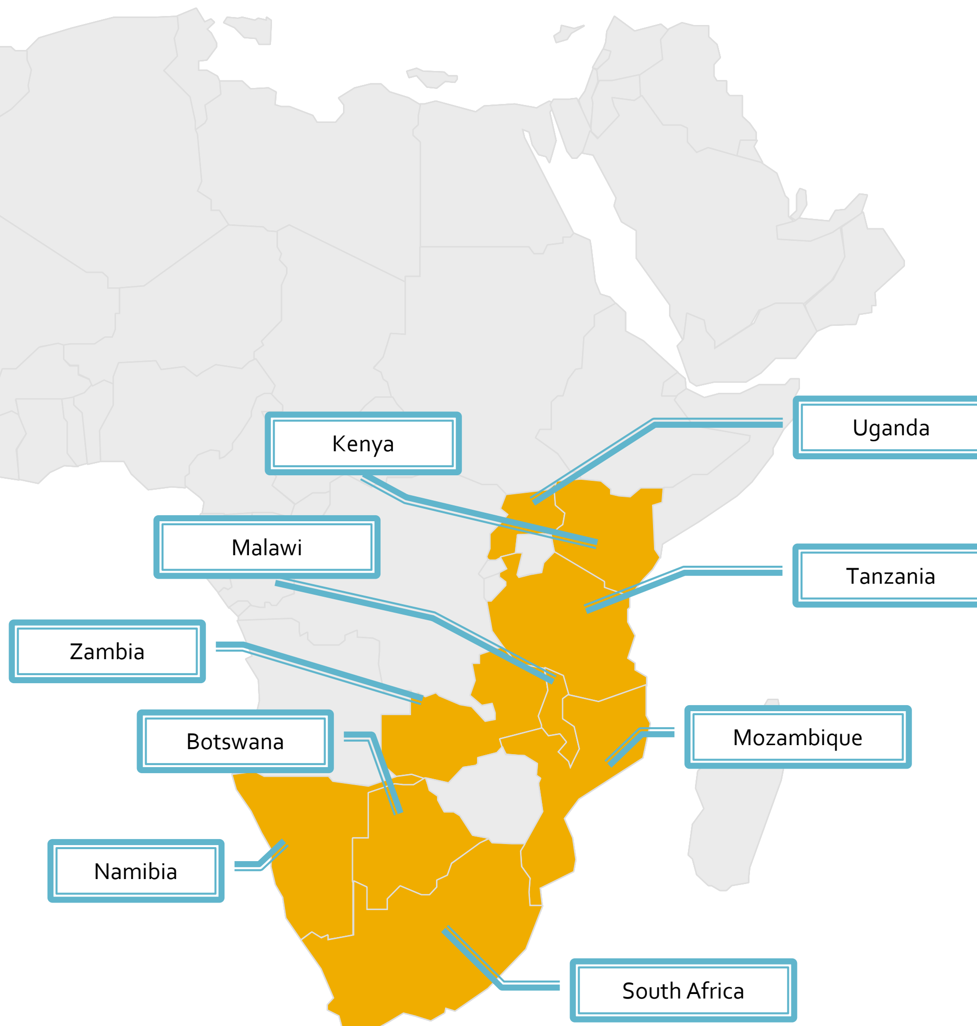


Key Questions

- What tests are needed?
- What tests are currently available and in what format?
- What platform format is appropriate?
- What is the expected frequency of testing?
- Who are the key stakeholders and what role do they play in technology adoption?
- What are the acceptable tradeoffs to these key stakeholders?

What tests are needed?

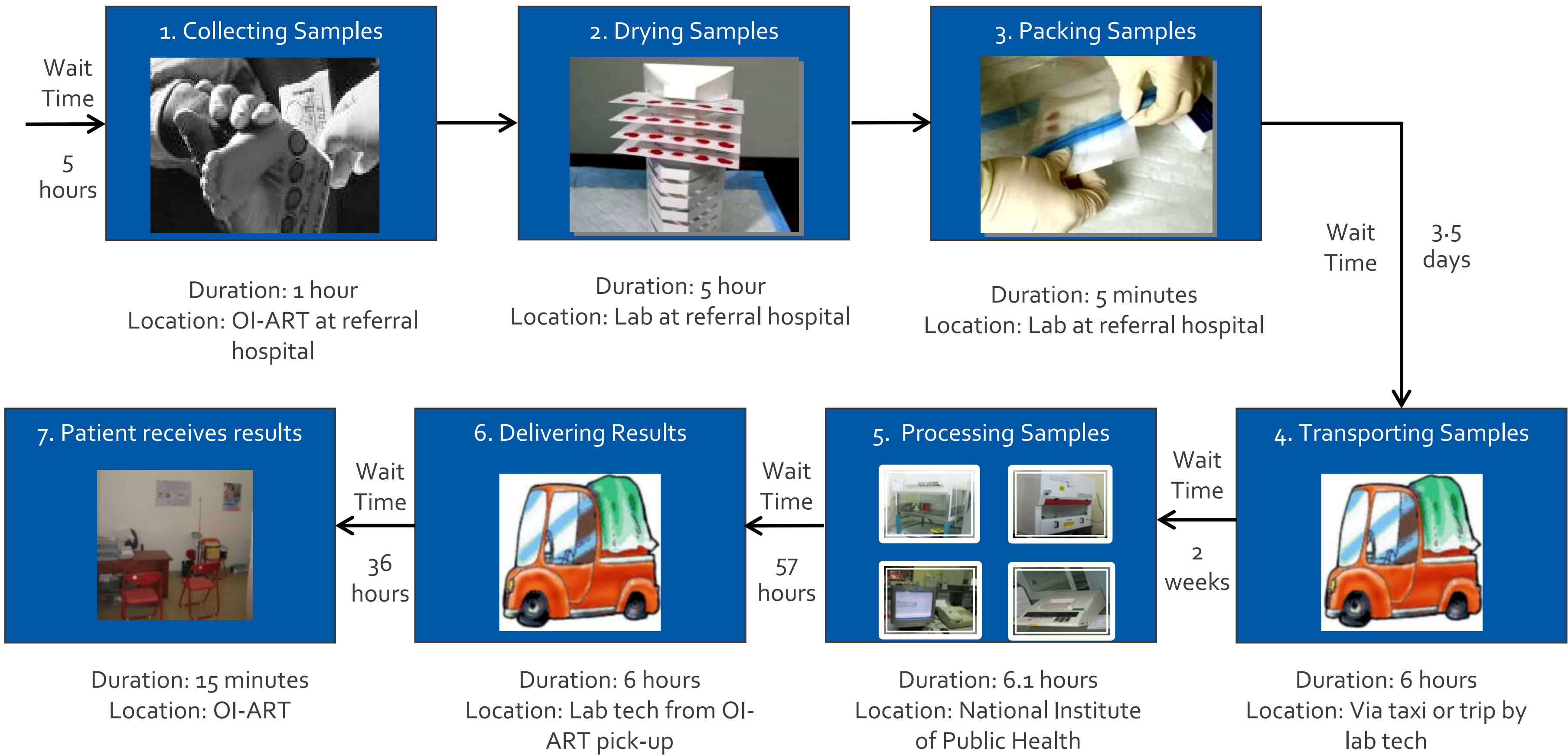
High Priority Assays

	Overall Rank
Rapid CD4 Test	1
Rapid Infant Diagnostic (DNA PCR or P24 ultra sensitive)	2
Rapid TB test	3
Rapid Viral Load Test	4
HIV rapid test allowing for earlier detection in adults (P24 antigen)	5
Other	6

Kwazulu-Natal, South Africa

Source: 2007 Kellogg field research

What tests are currently available and in what format? *Infant HIV Testing Example*

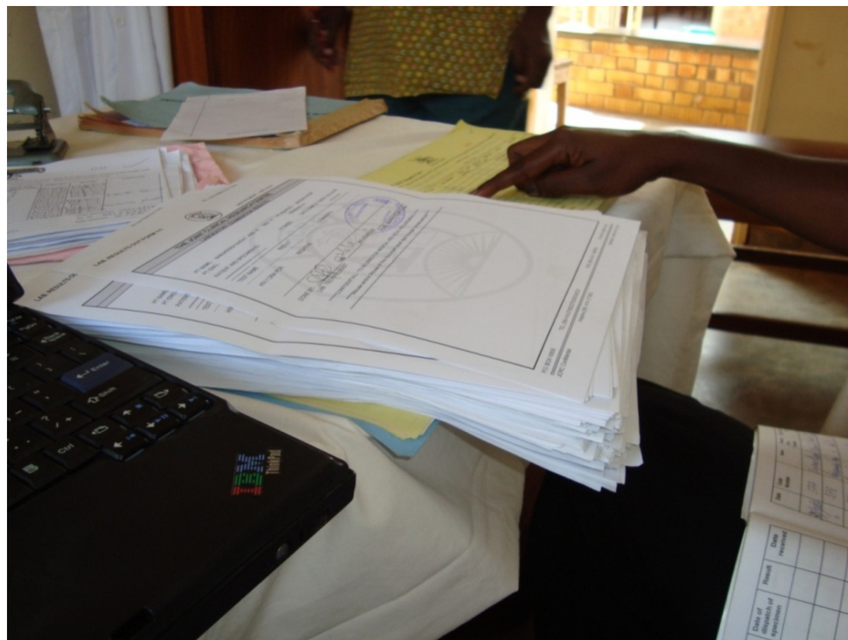


Source: 2008 Kellogg field research

What tests are currently available and in what format? *Infant HIV Testing Example*

The hurdles of getting the blood specimens to and from the DNA PCR equipped labs in a timely fashion poses sizable ongoing challenges, and many infant caretakers never return for results.

Countries	**~ Observed TAT**
Botswana	2-16 weeks
Cambodia	3 weeks
Mozambique	3 months or greater
Namibia	1-4 weeks
South Africa	1-3 weeks
Tanzania	N/A
Uganda	4-6 weeks

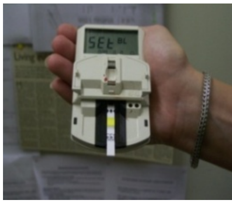


"Uncollected DNA PCR Results"

Source: 2008 Kellogg field research

What platform format is appropriate?

Qualitative Line	Control Line
Dark line = "+"	no line = invalid
No line = "-"	line = valid



National Measles Immunization Campaign
Ndola, Zambia

Who are the key stakeholders? What role do play in technology adoption? *Zambia Example*

	Introduction	Pilot	Approval	Ramp Up	Ongoing
Ministry of Health	R	A	R	R	R
NGOs	C	I	R	R	R
Hospitals	NA	R	NA	A	A
Clinics	NA	NA	NA	A	A
International Agency	C	I	C	NA	NA
Venture	R	R	I	R	R

Involvement Description

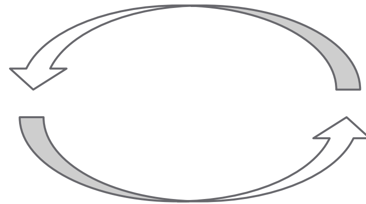
Responsible	Group holds ultimate responsibility for the success of the process step
Accountable	Group implements the process step and reports results and outcomes to the Responsible stakeholders
Consulted	Group provides input and expertise into the process step approach
Informed	Group is made aware of the ongoing process

Source: 2010 Kellogg field research

What are the acceptable tradeoffs?

Attributes

- Affordable
- Sensitive
- Specific
- User-friendly
- Rapid
- Equipment Free
- Delivered to those who need it



Key Stakeholder groups

Patients
Health Care Workers
Advisory International Agencies
Funding International Agencies
Governments
Distributors

Absent the "ideal" technology, tradeoffs must be made amongst attributes…

…but preferred tradeoffs can differ across stakeholder groups

Background

- Multi-Pathogen Diagnostic Cost Effectiveness Modeling in Uganda (CE Uganda) – McLaughlin-Rotman Centre for Global Health
  - The CE Uganda project quantified the cost effectiveness of three individual point-of-care (POC) multi-pathogen diagnostic testing algorithms (MPDx) to their respective gold standard algorithms in Uganda
- This type of cost effectiveness analysis, paired with a technical comparison to the gold standard, is a well-accepted methodology to evaluate the impact of a new diagnostic device on health outcomes
- If the device is deemed acceptable by the conventional cost effectiveness analysis and technical evaluation…

Where and how many?

- ...a decision maker then needs to decide where and how many of these devices need to be placed in their laboratory network

Background

South Africa

Source: Wendy Stevens, IAS 2011; *Taking the first steps Xpert MTB/RIF Implementation in public sector in South Africa: Lessons Learned*

Background

- Because devices cannot be implemented in all facilities, due to budget constraints, they most likely need to coexist with laboratory based testing in part of the network
- This implies that cost effectiveness of a device per se is not a relevant measure.

In most settings, devices cannot be implemented in all facilities, due to budget constraints. National Laboratory Managers often have to make make quick and tough decisions without adequate decision support tools and data.

	Uganda		Kenya	
Category	# facilities	% of total	# facilities	% of total
Hospitals	146	3%	12	0%
HC IV	188	4%	438	8%
HC III	1,182	23%	704	13%
Dispensary	3,517	70%	4,241	79%

…with similar facility distribution based on available data

Source: Uganda Facility Survey 2011 (provided by Mulago); Kenya Health Facilities List 2009 - http://www.publichealth.go.ke/index.php?option=com_docman&task=cat_view&gid=16&Itemid=94

Many facilities should be immediately ruled out since they do not have the infrastructure to support the diagnostic instrument.

		All client comfort amenities[1]	Regular Water Supply[2]	Regular Electricity or Generator[3]	Storage Conditions[4]	Two Qualified Staff[5]	Basic Lab Suppplies[6]
H	**Hospitals**	46%	64%	89%	59%	97%	88%
HCIV	**Health Center IV**	32%	52%	55%	46%	95%	66%
HCIII	**Health Center III**	42%	37%	29%	53%	61%	21%
HCII	**Health Center II**	42%	23%	14%	55%	20%	5%
HCI	**Health Center I**						
OR	**Outreach Programs**						

1 Functioning client latrine, waiting area protected from sun and rain, and basic level of cleanliness
2 Year-round water supplied in facility by tap or within 500 meters of facility
3 Electricity routinely available during service hours or a backup generator with fuel
4 Medicines stored in dry location, off the ground, and protected from water, sun, pests and rodents.
5 At least two qualified staff (Uganda specific) includes consultants/specialists (including surgeons, obstetricians/gynaecologists, paediatricians and physician specialists), medical officers, clinical officers, health educators, all nurses and nurse midwives, comprehensive nurses and public health nurses.
6 Refers to materials for anaemia test, including haemoglobinometer or calorimeter, centrifuge and capillary tubes for haematocrit, or any of the blotting paper tests.

Source: Ministry of Health (MOH) [Uganda] and Macro International Inc. 2008. *Uganda Service Provision Assessment Survey 2007. Kampala, Uganda: Ministry of Health and Macro International Inc.*

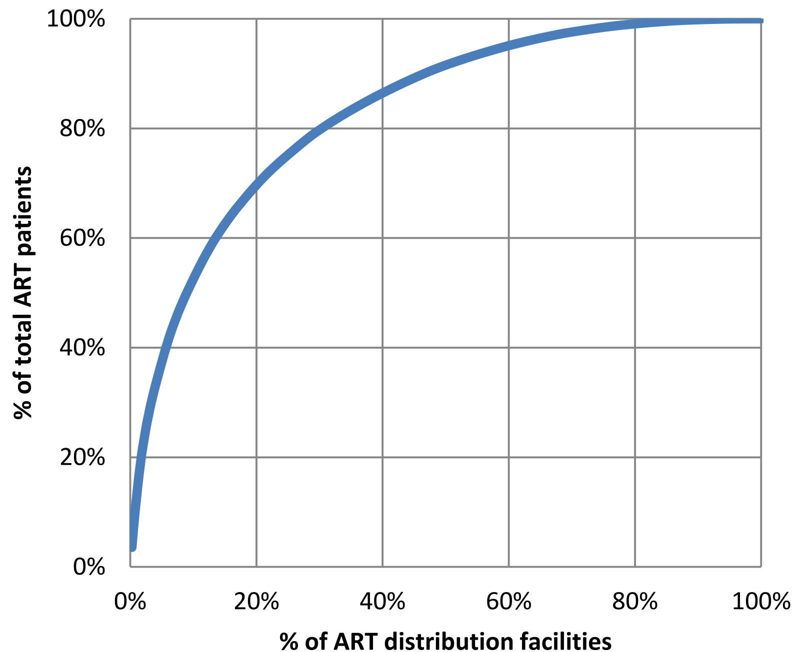
The same number of identical devices can have different aggregate health outcomes depending on the availability of services at the facilities they are placed in.

	HIV/AIDS			TB		Diarrheal disease[6]	Malaria[7]	Measles[8]	Neonatal[9]	Parasitic[10]
	Diagnosis[1]	Treatment[2]	Monitoring[3]	Diagnosis[4]	Treatment[5]					
H	79%	84%	52%	79%	87%	93%	81%	99%	65%	94%
HCIV	72%	52%	36%	70%	89%	85%	79%	99%	67%	53%
HCIII	20%	5%	30%	31%	81%	80%	35%	99%	51%	62%
HCII	6%	1%	93%	15%	44%	84%	11%	99%	12%	60%
HCI	N/A	N/A	N/A	N/A	N/A	N/A	N/A	99%	N/A	N/A
OR										

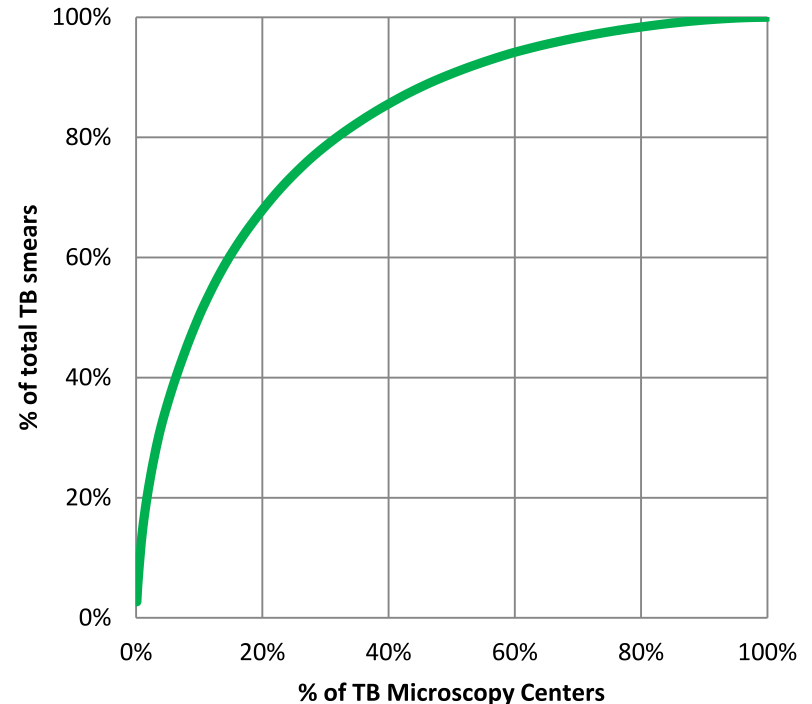
1 % of facilities where HIV testing (ELISA, Western Blot, Rapid test) in facility.
2 % of facilities with providers in the facility that prescribe ART and/or provide medical follow-up for ART clients
3 % of facilities with a laboratory in the facility conducts CD4, viral load, or total lymphocyte count (TLC) tests, or there is a system for sending blood sample for outside testing and receiving results
4 % of facilities with functioning microscope and glass slides plus all stains for AFB or Ziehl-Neelson test
5 % of facilities with any combination of pyrazinamide, rifampicin, ethambutol, and isoniazid or 4FDC.
6 % of facilities offering oral rehydration salts
7 % of facilities with functioning microscope, slides and stains available or rapid malaria test kit.
8 % of facilities with routine measles immunization services
9 % of facilities with offering antenatal care (ANC), post-partum care (PPC), and tetanus toxoid vaccine (TT),
10 % of facilities dispensing Metronidazole, tinidazole, Nalidixic acid, and cotrimoxazole

Source: Ministry of Health (MOH) [Uganda] and Macro International Inc. 2008. *Uganda Service Provision Assessment Survey 2007. Kampala, Uganda: Ministry of Health and Macro International Inc.*

The same number of identical devices can have different aggregate health outcomes depending on where patients present (or would present) for testing.



Based on 383 ART outlets & 195K ART patients

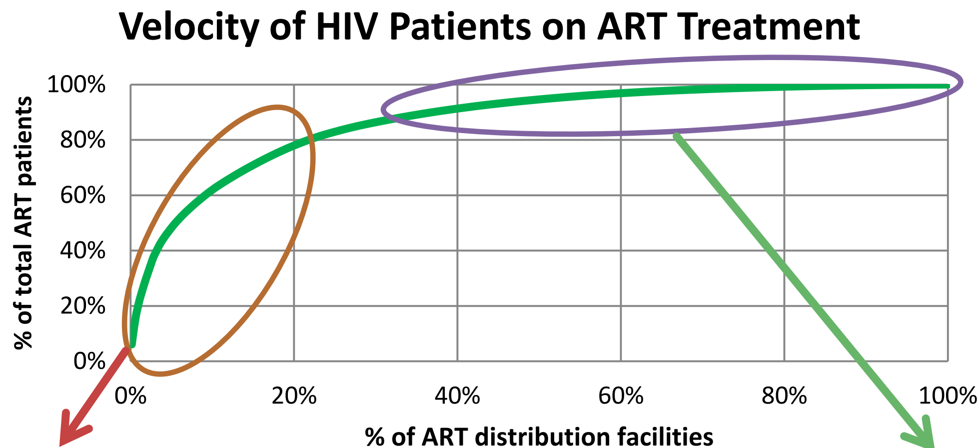


Based on 870 TB Smear Microscopy Sites & 236K Smears

In Uganda, for both HIV and TB, 20% of the facilities handle ~70% of the volume.

Source: ART, TB stats

High volume facilities may take first priority, but…



#1 High volume referral centers

2 Low volume HCs

This data has implications for the type of instrument that is developed and/or placed in EA settings.

…there are other variables to consider, including variations within the network

- Prevalence
- Patient loss-to-follow up
- Clinical staff
- Laboratory staff
- Existing laboratory network

Existing Laboratory Network

- Allocating POC device to one facility also alters the delays at facilities that remain within the laboratory network due to reduced load.
- When a POC device is less sensitive….
  - The impact of sensitivity is most pronounced when the laboratory capacity is large and the laboratory batch size is small. Conversely, The impact is the least when the laboratory capacity is very small and the laboratory batch size is large.
  - Lower accuracy of the device can be partly compensated by placing them in smaller clinics that have higher prevalence rates
- Largest volume heuristic is more effective when laboratory batch size is small and laboratory capacity is very tight

Source: Sarang Deo / Milind Sohoni - Indian School of Business; *Decentralization of Diagnostic Networks: Access vs. Accuracy Trade-off and Network Externality*

Next Steps

- There is a need for a model to both determine network-level cost effectiveness and assist with device placement decisions

Next Steps

Conceptual Framework for Placement Model: Example of GeneXpert

Identify improvements of GeneXpert vs. conventional device

Key improvements
1. Dx of sputum negative patient
2. Dx of MDR-TB
3. Reduced loss to follow-up

Identify relevant variations at health facility level

In Uganda, percentage of smear negative TB and HIV prevalence differs across health facilities, suggesting variable impact of GeneXpert by facility

Identify potential placement strategies

May place device in facilities that
1) provide ART
2) have high smear negativity rates
3) have high loss to follow up

Develop decision analytic model

Develop a model that integrates operational data for device placement and natural history of TB to project impact on life expectancy, cost

Next Steps

Data requirements for the model

Operations level data	Example	Source
Availability of diagnostics	National health facility map	MOH
Diagnostic capacity	AFB sputum workload	National laboratory
Diagnostic effectiveness	External Quality Assessment	National laboratory
Diagnostic referral network	Referral for drug susceptibility testing	Health facility
Laboratory process flow	Time from sample procurement to diagnosis	Health facility
Disease-related data		
Epidemiologic data	% multidrug resistant TB	National laboratory
Natural history data	Mortality of HIV by CD4	Literature

Acknowledgements

- Principal Investigator:
  - Dr. Achilles Katamba (Makerere University, Uganda)
- Key Project Personnel
  - Dr. Francis Bajunirwe (Mbarara University of Science and Technology, Uganda)
  - Sarang Deo – Indian School of Business, India
  - Mai Tuyet Pho –University of Chicago, USA
- Project Consultants
  - Moses Joloba
- Funders
  - McLaughlin-Rotman Centre for Global Health
  - Grand Challenges Canada