



**Market-based approaches
in TB diagnostics**

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UNITAID's market impact framework

CASE FOR INTERVENTION

PATHWAY FROM MARKET TO PUBLIC HEALTH IMPACT



1

PUBLIC
HEALTH
PROBLEM

2

MARKET
SHORTCOMING

3

INNOVATIVE
MARKET
INTERVENTION

4

SUSTAINABLE
MARKET
IMPACT

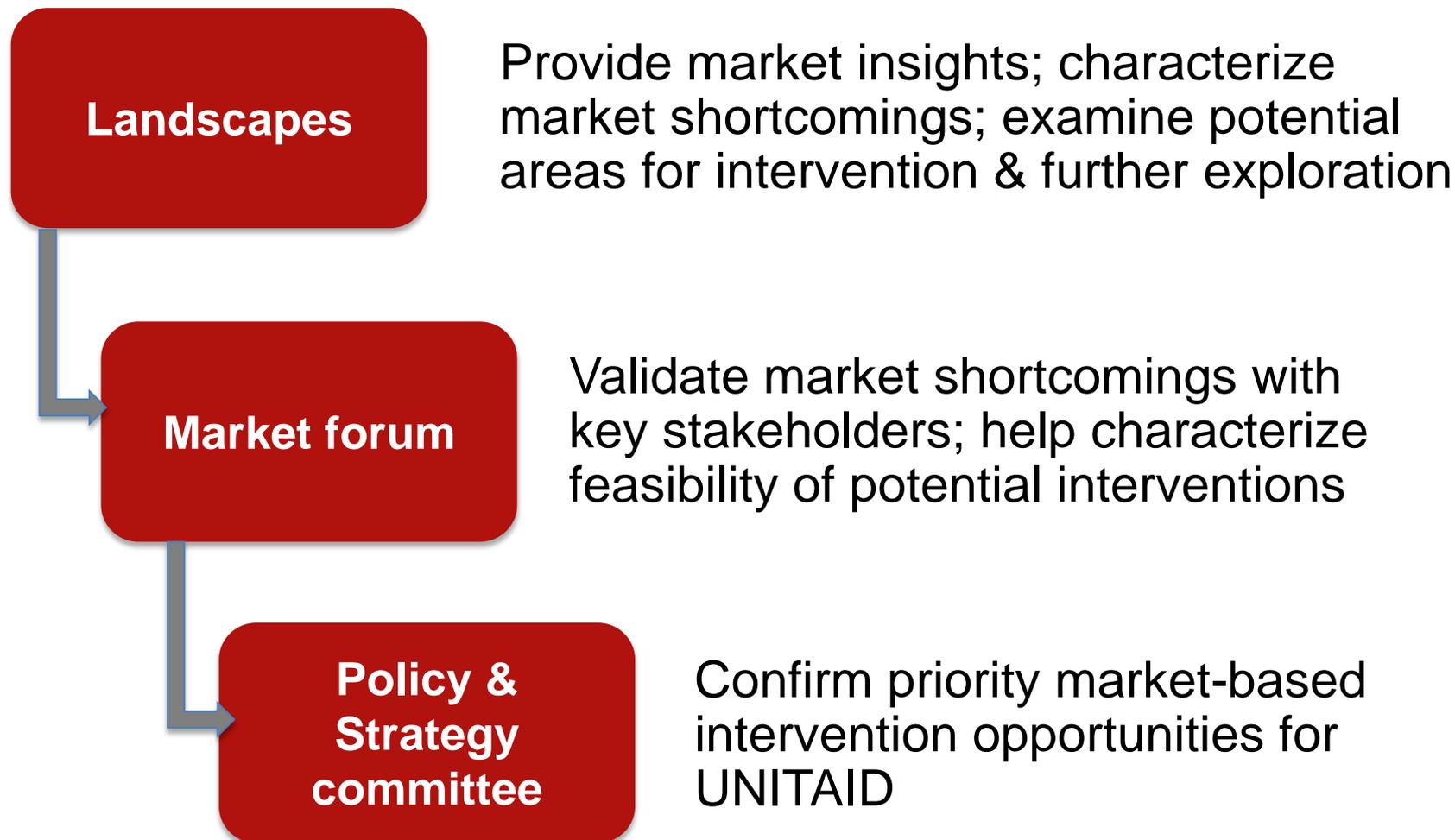
5

PUBLIC
HEALTH &
VALUE FOR
MONEY

Tools used to build case for intervention (1)

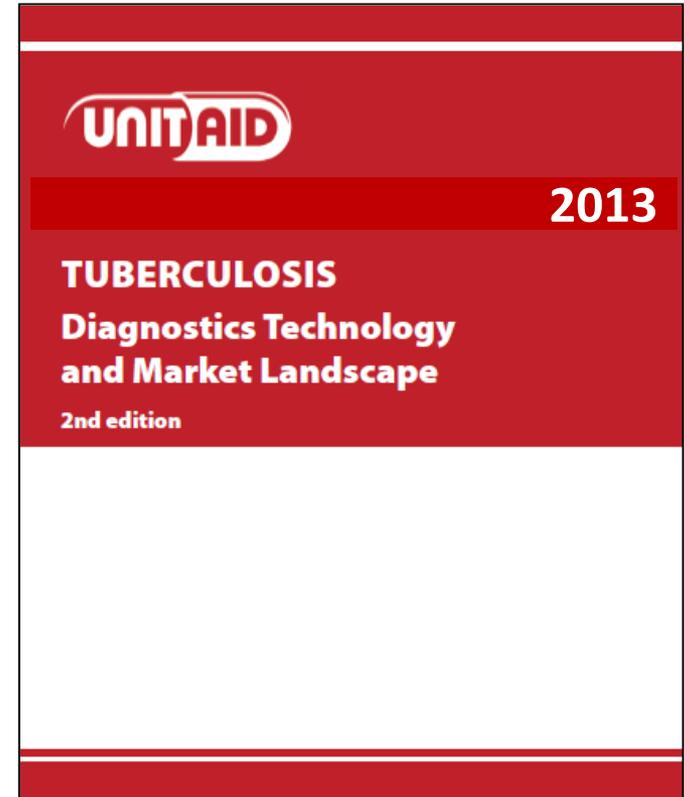


Tools used to build case for intervention (2)



2013 TB diagnostics landscape

- Public health problem & commodity access issue
- Technology landscape
- Market landscape
- Market shortcomings
- **Opportunities for intervention**
 - Should directly address market dysfunction – but opportunities, shortcomings not 1:1
 - Must be market-based, time-limited, with global impact (catalytic role of UNITAID)



2013 TB Market Forum

Market Dynamics dashboard

- Distils all UNITAID's landscape analyses into single-page, visual summary
- Facilitates ongoing discussion of issues across disease and product areas
- Provides high-level context and rationale for areas of intervention considered "ready" (or near-ready) for UNITAID support

M = Medicines D = Diagnostics P = Preventives	Product Sub-type	Access	Current Market Shortcomings*						Opportunity for Intervention***		
			Availability	Affordability	Quality	Acceptability/Adaptability	Delivery	Composite severity of all current market shortcomings†	Current (Apr 2013)	Over next 4 years	
Shortcomings (Apr 2013)											
HIV/AIDS	M	Adult first-line	54%	x	x	--	x	x		Med-High	High
		Adult second-line	~30%	x	xx	--	x	xx		Med	High
		Paediatric	28%	xx	xx	--	xx	xx		High†	High
		Viral hepatitis C co-infection	TBD	x	xx	x	xx	xx		Low	Med
	D	CD4	<60%	x	xx	xx	x	x		Med-High†	Med
		Viral load (VL)	<30%	xx	xx	xx	xx	xx		High†	High
		Early infant diagnosis (EID)	<30%	xx	xx	xx	xx	xx		High†	High
	P	Male circumcision devices	10% of target	x	xx	x	--	xx		Med	Med
		Female condoms	<1%	--	xx	--	xx	xx		Low	Low
		Microbicides	0%	xx	--	--	xx	--		Low	Low
Pre-exposure prophylaxis (PrEP)		<1%	--	--	--	xx	xx		Low	Low	
Tuberculosis	M	Adult first-line	66%	--	--	xx	xx	xx		Low	Med
		Adult second-line	19%	xx	xx	xx	xx	xx		Med†	High
		Paediatric	<50%	xx	x	xx	xx	xx		High†	High
	D	Near-POC or POC	40% TB Dx 19% MDR-TB Dx <5% DST	x	xx	x	xx	x		Med†	High
Malaria	M	Adult	<20% public <10% private	x	xx	xx	x	xx		Med†	High
		Paediatric	<20% public <10% private	x	xx	xx	xx	xx		Med†	High
	D	Rapid diagnostic tests (RDTs)	77% public Minimal private	x	x	xx	x	xx		High†	High
	P	LLINs	21%	xx	x	x	x	xx		Low	Med
		Indoor residual	~5%	x	xx	x	x	x		Low	Low

Access issues and market shortcomings focus and define market interventions

Access	Market shortcomings				
	Avail-ability	Afford-ability	Quality	Accept-ability / Adapt-ability	Delivery
40% TB Dx 19% MDR-TB Dx <5% DST	X	XX	X	XX	X

Commodity access issues

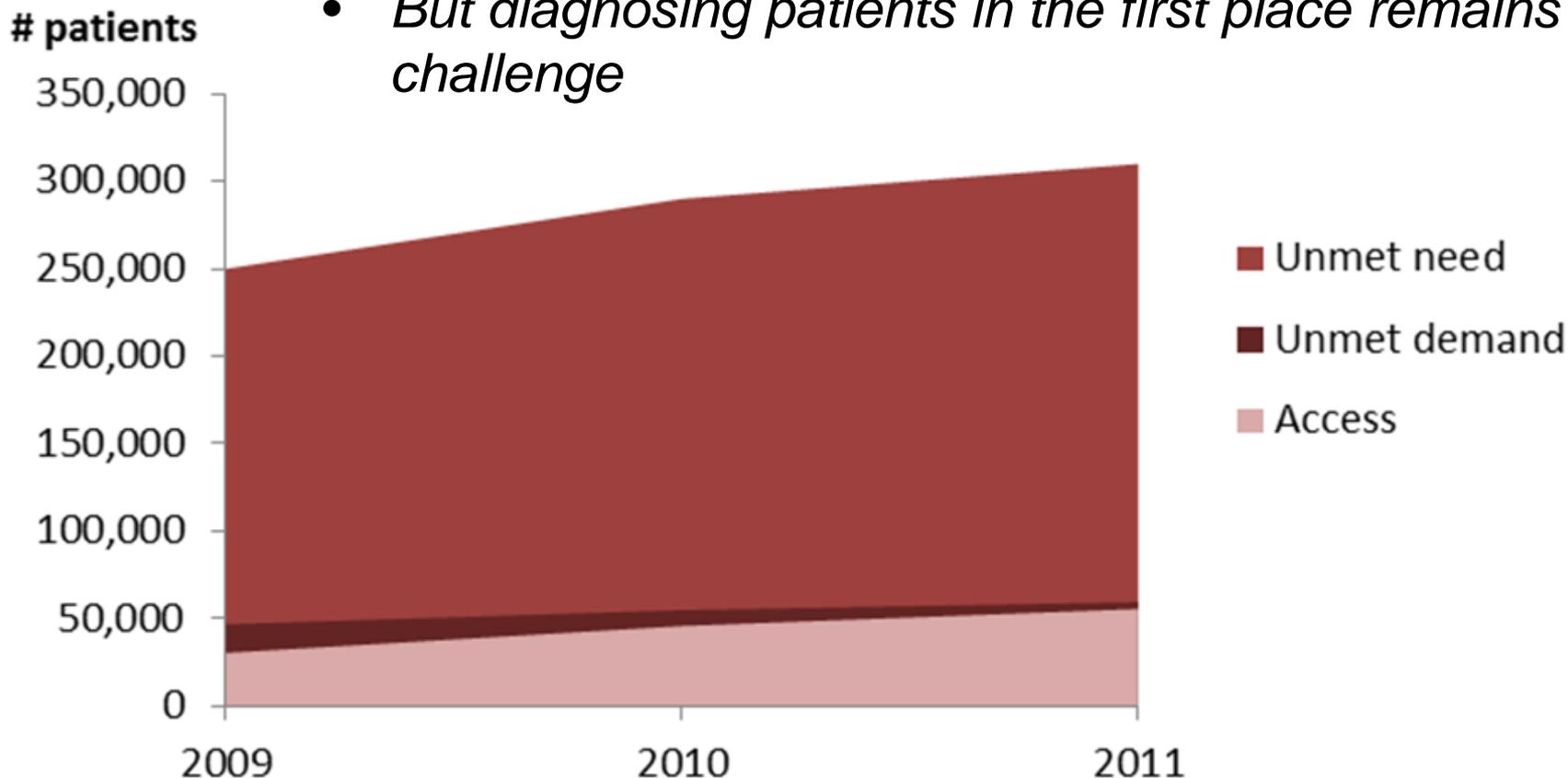
Access	Market shortcomings				
	Availability	Affordability	Quality	Acceptability / Adaptability	Delivery
	X	XX	X	XX	X

Gaps between patients who need these commodities, and those who have access to them

- Only 40% of TB cases are diagnosed: 2.9m with active disease (of 8.7m incident cases) were not diagnosed and notified in 2011
- Fewer than 1 in 5 MDR-TB cases are diagnosed
- Fewer than 1 in 20 smear-positive cases have access to DST

Trends in MDR-TB medicines need, demand & access

- *Most patients who are identified are treated*
- *But diagnosing patients in the first place remains a challenge*



Figures from the WHO Global TB Report 2012: need defined here as the number of estimated cases (among TB patients with pulmonary TB); demand, as the number of notified cases; and access, as the number of patients enrolled on treatment.

Availability

Access	Market shortcomings				
	Availability	Affordability	Quality	Acceptability / Adaptability	Delivery
	X	XX	X	XX	X

The needed product is not available at all (not developed)

- No true POC TB diagnostic test: GeneXpert still requires basic lab infrastructure

Reasons

- Significant technical challenges in developing a true POC product
- Unclear potential market and lack of clarity on available market share reduce developers' willingness to invest

Examples of market-based approaches: HIV market entry



Project	Partner
Accelerating access to innovative POC HIV diagnostics	CHAI, UNICEF
Implementation of CD4 and viral load testing in decentralized, remote and resource-limited settings	MSF
Market entry of HIV POC diagnostics	4 developers: 3 CD4; 1 VL/EID
Global network to improve access & quality of HIV monitoring technologies	LSHTM
Open Polyvalent Platforms for sustainable access to viral load testing in resource-limited settings	FEI

Affordability

Access	Market shortcomings				
	Availability	Affordability	Quality	Acceptability / Adaptability	Delivery
	X	XX	X	XX	X

Price is a barrier to access; unreasonable financial burden on governments, individuals or other payers

- New technologies are expensive: GeneXpert machine costs \$17,500 (4-module); each cartridge about \$10 to preferred buyers, or \$60+ in the private sector

Reasons

- High complexity of incorporating multiple reagents into a robust cartridge
- Monopolistic supplier

Xpert MTB/RIF assay

- Detects TB and RIF resistance in <2h
- Fully integrated (minimal user inputs, limited biosafety requirements vs. culture, DST)
- Higher sensitivity for detecting TB vs. microscopy, esp. in PLHIV
- Endorsed by WHO in 2010



Xpert MTB/RIF price decrease & scale-up

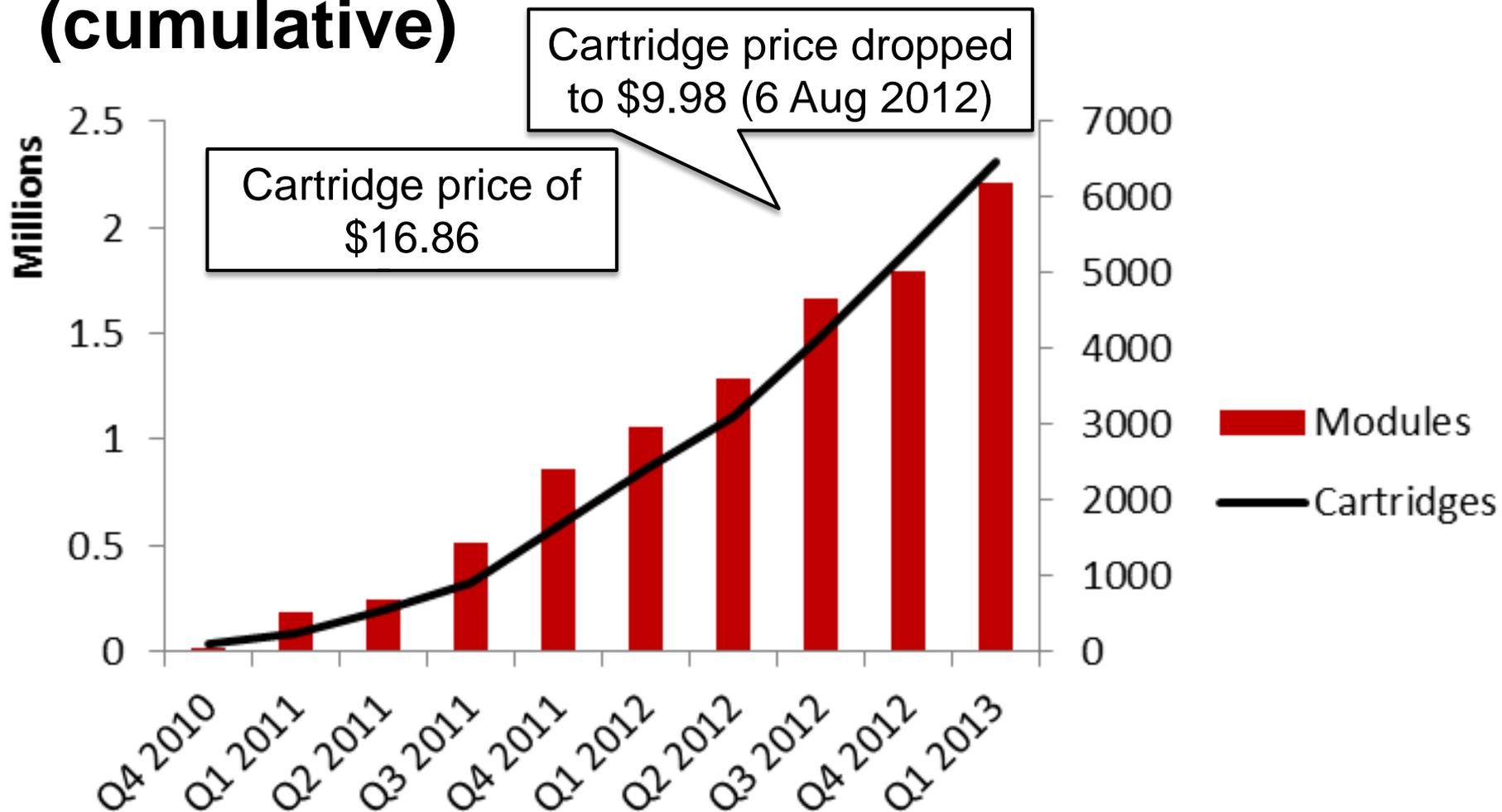
Price decrease

- June 2012: BMGF, PEPFAR, UNITAID, USAID announced agreement with Cepheid Inc. to reduce the cost of the test to \$9.98 per cartridge (from \$16.86)
- Price applies to >145 purchasers in low- and middle-income countries, effective Aug 2012

Scale-up

- UNITAID-funded TBXpert project supports scale-up in 21 high-burden countries
- Project will provide 1.4m cartridges and >200 instruments by 2015

Xpert instrument & MTB/RIF cartridges procured under concessional pricing (cumulative)



Quality

Access	Market shortcomings				
	Availability	Affordability	Quality	Acceptability / Adaptability	Delivery
	X	XX	X	XX	X

Problems with issues that individually or collectively influence product quality, including design & development

- Lack of information on quality of diagnostics to guide procurement
- Use of inappropriate tests, particularly in the private sector

Reasons

- Limited global quality assurance processes for TB diagnostics; reliance on ad hoc recommendations from WHO STAG-TB
- Limited in-country regulation of labs

Acceptability / Adaptability

Access	Market shortcomings				
	Availability	Affordability	Quality	Acceptability / Adaptability	Delivery
	X	XX	X	XX	X

Product is not acceptable to users, or not available in an appropriate format to enable effective use

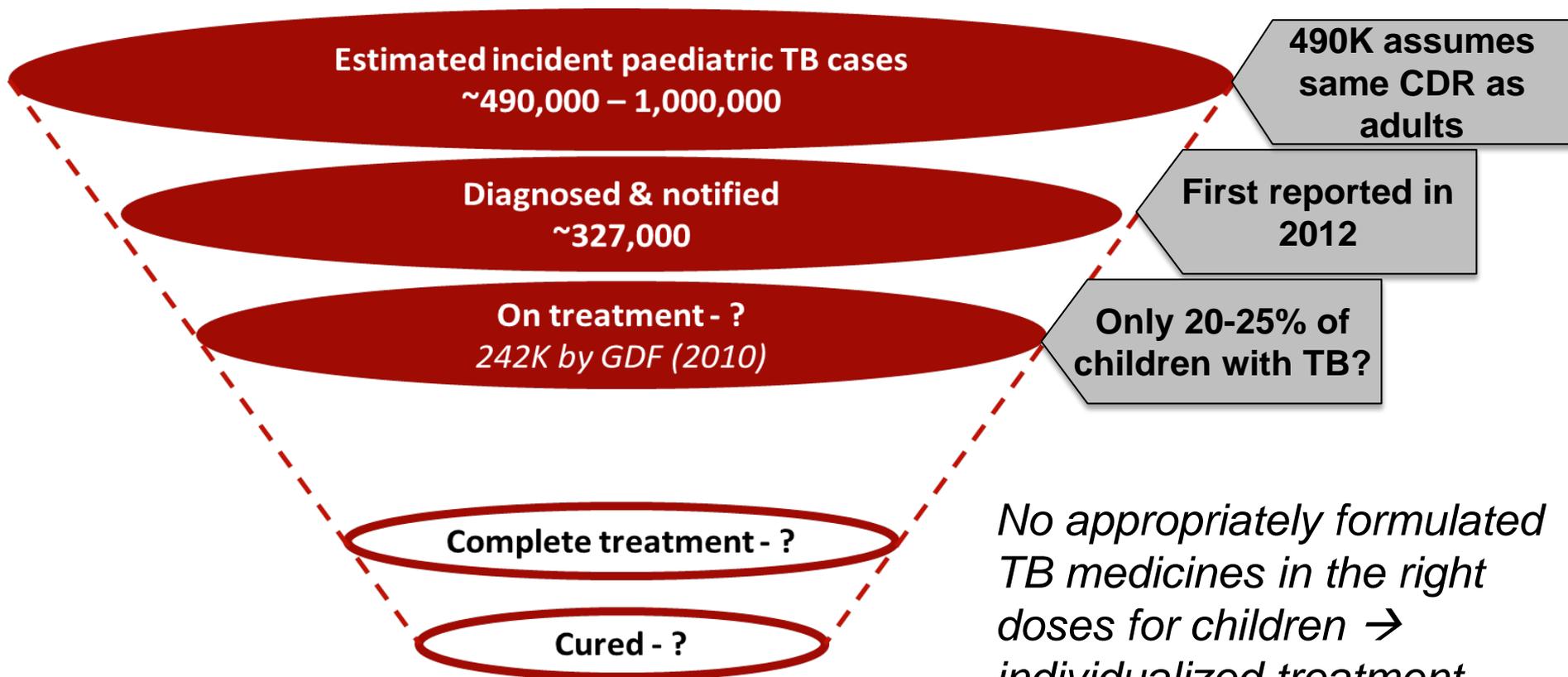
- Current diagnostics are not adapted for specific patient groups or decentralized healthcare settings – e.g.:
 - Children or others with paucibacillary sputum (PLHIV, EPTB)
 - Limited DST ability, multi-platform functionality

Reasons

- Technical difficulty in alternate specimen collection and other challenges presented by specific patient groups; identification of resistance a moving target (new drugs)

TB diagnostics for children

- Our starting point – the commodity access issue – is unclear



No appropriately formulated TB medicines in the right doses for children → individualized treatment approaches

Market & public health impact of lack of appropriate TB diagnostics for children

- Can treat patients effectively only when TB is detected
- Underdiagnosis reinforces uncertainty on disease burden, discouraging innovation (for both diagnostics and medicines for children)
- Individualized approaches deter comparison of methods and systematic reviews

Efforts to harmonize & generate evidence for TB diagnostics adapted for children

- Recently published Consensus on Standardized Clinical Case Definitions and Standardized Research Methods
- Updated guidance on use of Xpert in extrapulmonary TB and children (expected late 2013)
- Studies with alternate specimen types and approaches

Ongoing horizon-scanning by UNITAID to identify potential opportunities for intervention

Delivery

Access	Market shortcomings				
	Availability	Affordability	Quality	Acceptability / Adaptability	Delivery
	X	XX	X	XX	X

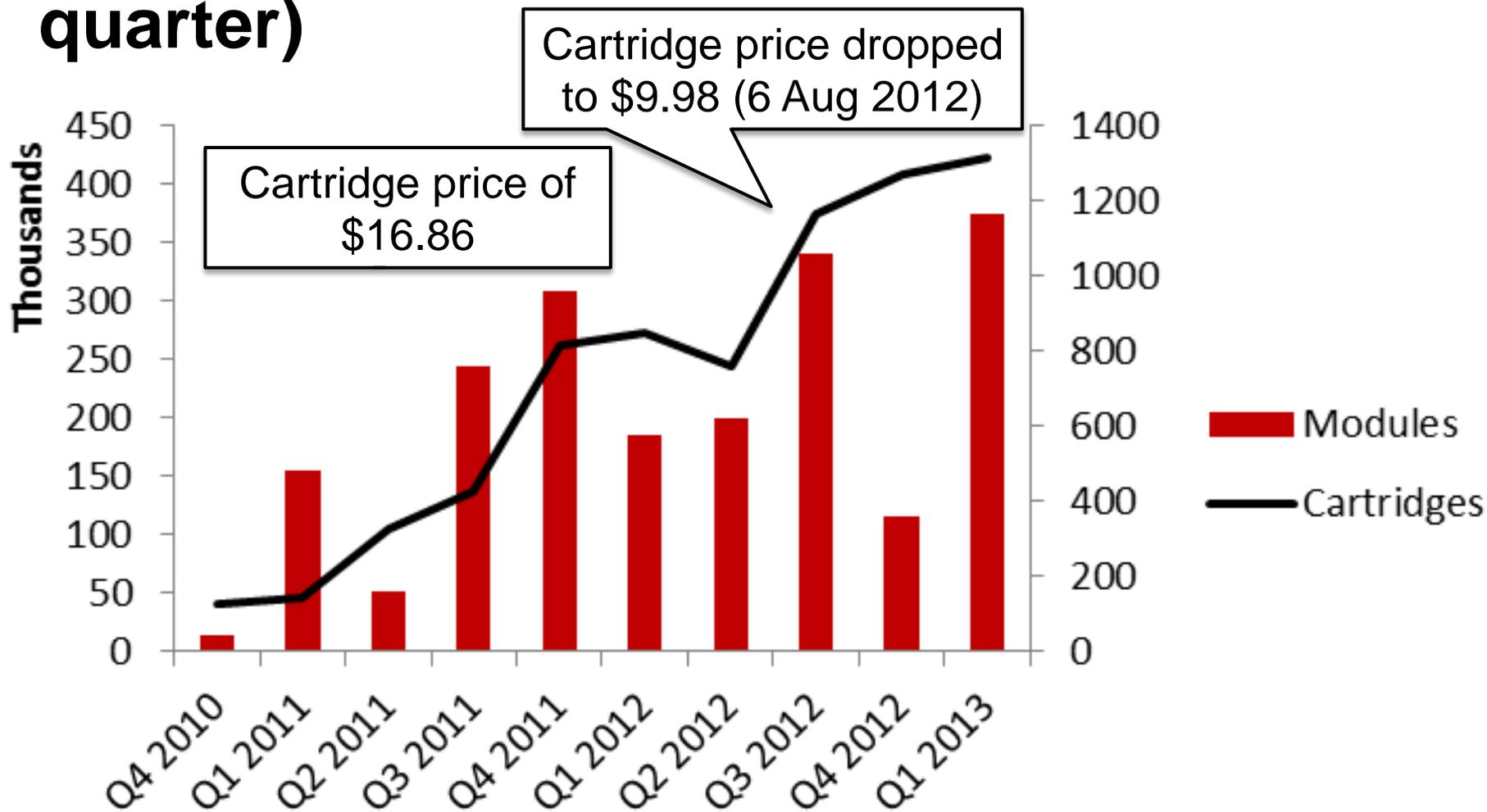
Shortcomings hinder provision of the right product to the right patient at the right time. Relates to selection, procurement, storage & distribution.

- Supply constraints affecting delivery of GeneXpert cartridges
- Barriers to adoption of novel innovative technologies hinder uptake

Reasons:

- Monopolistic market with limited production capacity. No alternative suppliers for purchasers to use
- Novel product types require extensive training and integration into diagnostic and clinical algorithms

Xpert instrument & MTB/RIF cartridges procured under concessional pricing (by quarter)



Acknowledgements

- Brenda Waning
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Call for Letters of Intent

UNITAID's 2013 Call is open to interventions supporting any of the 6 Strategic Objectives outlined in UNITAID's Strategy 2013-2016, with emphasis on interventions focused on treatments for HIV/AIDS, TB and malaria.

Additional details can be found at unitaid.org/calls

Closing date for submissions is **22 September, 2013**

