



Current dynamics in the Xpert MTB/RIF assay pricing mechanisms

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WHO policy recommendations



- 1. Xpert MTB/RIF should be used as the initial diagnostic test in individuals suspected of having MDR-TB or HIV-associated TB. (Strong recommendation)**
- 2. Xpert MTB/RIF may be considered as a follow-on test to microscopy in settings where MDR-TB or HIV is of lesser concern, especially in further testing of smear-negative specimens. (Conditional recommendation acknowledging major resource implications)**

Remarks:

- These recommendations apply to the use of Xpert MTB/RIF in sputum specimens (including pellets from decontaminated specimens). Data on the utility of Xpert MTB/RIF in extra-pulmonary specimens are still limited;
- These recommendations support the use of one sputum specimen for diagnostic testing, acknowledging that multiple specimens increase the sensitivity of Xpert MTB/RIF but have major resource implications;
- These recommendations also apply to children, based on the generalisation of data from adults and acknowledging the limitations of microbiological diagnosis of TB (including MDR-TB) in children;
- Access to conventional microscopy, culture and DST is still needed for monitoring of therapy, for prevalence surveys and/or surveillance, and for recovering isolates for drug susceptibility testing other than rifampicin (including second-line anti-TB drugs).

Preferential pricing



Market prices:

Instrument: €40,000 – €45,000 (\$55,000 – \$62,000)

Cartridge: €40 – €60 (\$55 – \$82, country-specific)

Negotiated prices for the public sector in eligible countries (145):

Instrument: \$17,000 /\$17,500 (desktop/laptop) **>60% reduction**

Cartridge: \$16.86 **~75% reduction**

	FIND-negotiated price	FIND-negotiated price	FIND-negotiated price
Estimated annual global volumes (cartridges)	> 600,000	>1,700,000	>3,700,000
Estimated year	2011	2012	2014
Price (Ex Works)	US\$ 16.86	US\$ 14.00	US\$ 10.72

Preferential pricing and eligible 145 countries*



Afghanistan	Chile	Ghana	Libya	Pakistan	Sudan, South
Albania	China	Grenada	Lithuania	Palau	Suriname
Algeria	Colombia	Guatemala	Macedonia	Panama	Swaziland
Angola	Comoros	Guinea	Madagascar	Papua New Guinea	Syria
Antigua and Barbuda	Congo, Democratic Republic of the	Guinea-Bissau	Malawi	Paraguay	Tajikistan
Argentina	Congo, Republic of the	Guinea, Equatorial	Malaysia	Peru	Tanzania
Armenia	Costa Rica	Haiti	Maldives	Philippines	Thailand
Azerbaijan	Cote d'Ivoire	Honduras	Mali	Romania	Timor-Leste
Bangladesh	Croatia	India	Mauritania	Russia	Togo
Belarus	Cuba	Indonesia	Mauritius	Rwanda	Tonga
Belize	Djibouti	Iraq	Mexico	Saint Kitts and Nevis	Tunisia
Benin	Dominica	Jamaica	Micronesia, Federated States of	Saint Lucia	Turkmenistan
Bolivia	Dominican Republic	Jordan	Moldova	Saint Vincent & the Grenadines	Tuvalu
Bosnia and Herzegovina	Ecuador	Kazakhstan	Mongolia	Samoa	Uganda
Botswana	Egypt	Kenya	Montenegro	Sao Tome and Principe	Ukraine
Brazil	El Salvador	Kiribati	Morocco	Senegal	Uruguay
Bulgaria	Eritrea	Korea, North	Mozambique	Serbia	Uzbekistan
Burkina Faso	Estonia	Kosovo	Myanmar (Burma)	Seychelles	Vanuatu
Burundi	Ethiopia	Kyrgyzstan	Namibia	Sierra Leone	Venezuela
Cambodia	Fiji	Laos	Nauru	Solomon Islands	Vietnam
Cameroon	Gabon	Latvia	Nepal	Somalia	Western Sahara
Cabo Verde	Gambia, The	Lebanon	Nicaragua	South Africa	Yemen
Central African Republic	Gaza and West Bank	Lesotho	Niger	Sri Lanka	Zambia
Chad	Georgia	Liberia	Nigeria	Sudan	Zimbabwe



*as of 19.02.2011



Cost of implementation drivers



	Item	Cost	Comment	
A	Equipment	GeneXpert 4 module with laptop (Ex-Works price)	\$17,500	>60% price reduction compared to EU/US
B		Shipment	\$1,000	Depends on destination
C		UPS	\$500	Local purchase, depends on the market
D		Printer	\$200	Local purchase, depends on the market
E	Maintenance	Annual calibration costs	\$1,800	Highest price if done in Cepheid Toulouse, when web-based drops to 500USD
F	Consumables	Cost per cartridge	\$16.86	75% price reduction compared to EU
G		Number of working days per year	250	Number can vary depending on local context
H		Average number of tests per instrument /day	12	Number can vary depending on working hours
I		Number of tests/1 year/ full load 1 instrument	3000	G*H
J		Losses due to error/incorrect use (high estimate 10%)	300	10% of I
K	HR costs	Technician annual salary		Country-specific
L		Training and TA		Depends on the needs
M	Installation costs		\$19,200	A+B+C+D
N	Running costs (annual, 1 instrument)		\$57,438	E+F*(I+J)
O	GRAND TOTAL		\$76,638	N+M+L+K

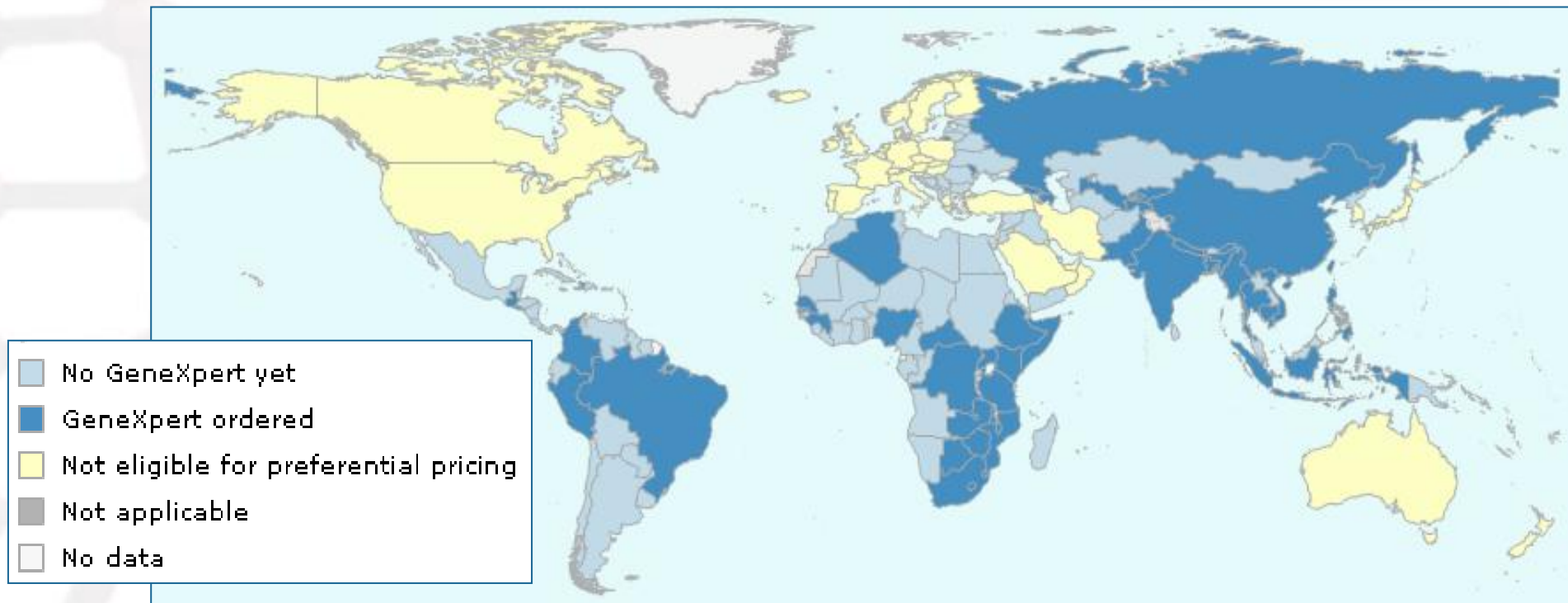
Depending on testing volumes

Cost of cartridges is driving the overall cost

Global roll-out of Xpert MTB/RIF



- 47 countries have procured at least one GeneXpert, as of Dec 2011



Data: FIND

- 460 machines (2401 modules) procured world-wide, as of Dec 2011

Historic sales and negotiated prices/volumes



Cumulative number of cartridges sold at preferential prices by 31 Dec 2011 – **591,450** (in addition to sales at commercial price)



Immediate future and negotiated volumes



	FIND-negotiated price	FIND negotiated price	FIND negotiated price
Estimated annual global volumes (cartridges)	> 600,000	>1,700,000	>3,700,000
Estimated year	2011	2012	2014
Price (Ex Works)	US\$ 16.86	US\$ 14.00	US\$ 10.72
Ave % reduction over EU*	75%	79%	84%

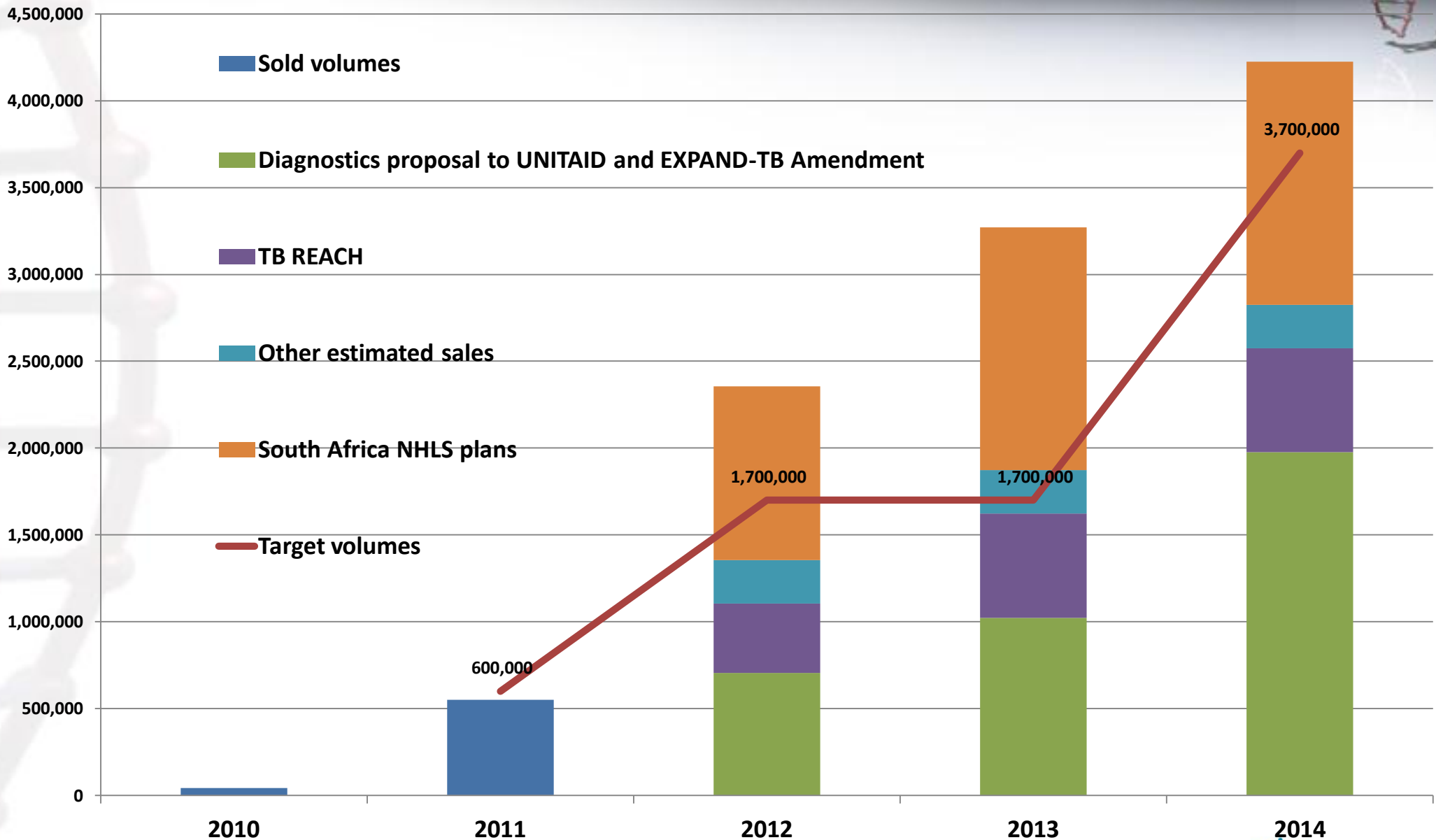
How do we get to the next estimated price drops?

Xpert MTB/RIF implementation, available estimates



Estimated cartridge numbers by year		2012	2013	2014
Expected	WHO-STP-FIND diagnostics proposal to UNITAID and EXPAND-TB project Amendment	705,760	1,022,120	1,975,520
	South Africa NHLS plans	1,000,000	1,400,000	1,400,000
	BMGF	Not available		
Started	TB REACH	400,000	600,000	600,000
	Xpert MTB/RIF implementation in EXPAND-TB project supported by Stop TB Partnership	76,610		
	MSF projects	Not available		
	USAID TB CARE I	Not available		
	PEPFAR	Not available		
	Other Private sector sales	250,000	250,000	250,000

Projections based on available estimates



Cartridge price in 2012-2014

\$16.86

- if no clear purchase commitments, may change in 2013, 2014

\$14

- if EXPAND-TB Amendment approved by UNITAID, project duration, for 27 countries

\$9.98

- if Diagnostics Proposal is approved by UNITAID, permanent, for 145 countries