



NHLS, Cost Minimisation Case Studies – Malaria RDT

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Overview

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Cost minimisation analysis

- Cost-minimisation analysis (CMA): a determination of the least costly among alternative interventions that are assumed to produce equivalent health outcomes [1].

1. Drummond et al. (2015) Methods for the Economic Evaluation of Health Care Programmes. Fourth Edition. Oxford, Oxford University Press

Background

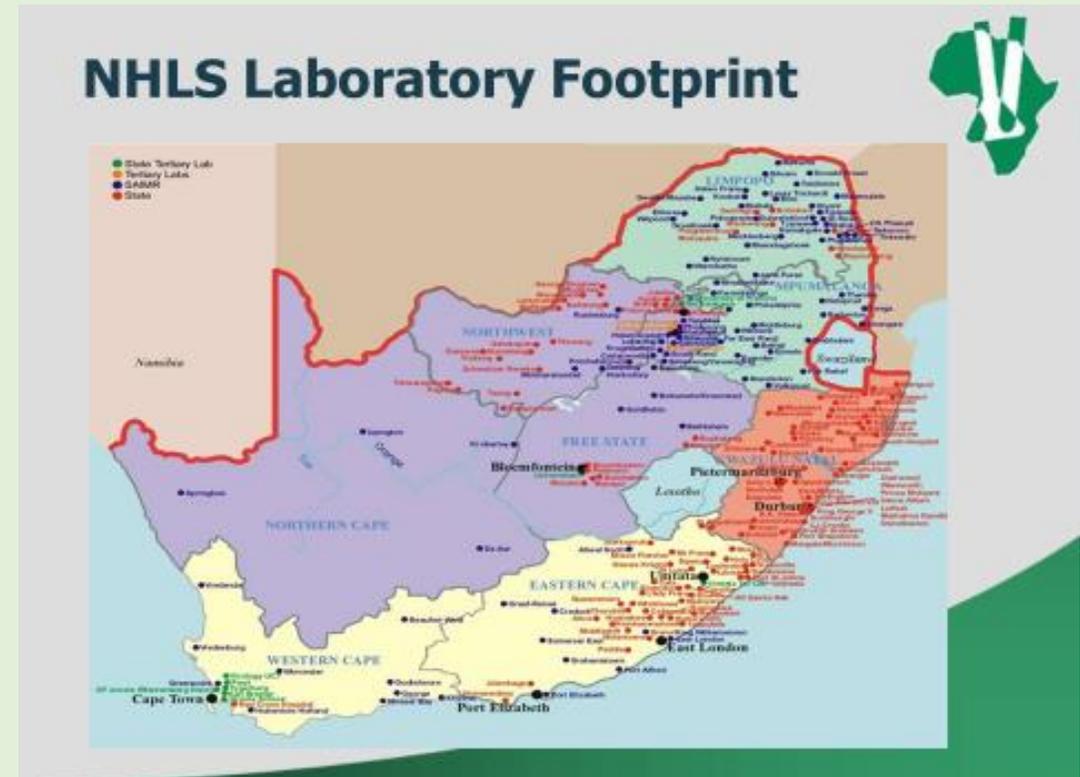
Malaria is a vector-borne infection; WHO estimates that half the world's population is at risk of malaria.

In 2012, there were an estimated 207 million cases and an estimated 627 000 deaths. Approximately 90% of all malaria deaths occur in sub-Saharan Africa.

Four *Plasmodium* species cause malaria in humans in Africa, i.e. *Plasmodium falciparum*, *P. ovale*, *P. malariae* and *P. vivax*. South Africa has 3 malaria endemic areas; in parts of KwaZulu-Natal, Limpopo and Mpumalanga Provinces.

The NHLS pathology services comprises of 268 testing laboratories of which 136 laboratories provide malaria testing for the public sector.

FREAN, J et al. Case management of malaria: Diagnosis. *South African Medical Journal*, [S.l.], v. 103, n. 10, p. 789-793, aug. 2013. ISSN 2078-5135. Available at: <http://www.samj.org.za/index.php/samj/article/view/7442/5463>.



Objectives

To review the different malaria antigen-detecting rapid diagnostic tests (RDT) that were procured by the National Health Laboratory Services (NHLS) during the period 2013-2014.

To provide parasite-based diagnosis in areas where good quality microscopy cannot be maintained.

To make informed decisions on procurement and implementation of the national malaria programme in South Africa.

Methodology

1. Create list of malaria Pf and Combo RDT kits used by NHLS.
2. Review the performance of these kits on the WHO/Find performance tests and remove kits that perform poorly.
3. Negotiate pricing with suppliers of the remaining RDT kits and remove costly RDT kits based on a predetermined price threshold set by the NHLS.
4. Reference laboratory (NICD) to evaluate one RDT kit of each of the remaining kits after the price negotiations and select the best RDT kit based on technical performance (sensitivity/specificity) for NHLS use
5. Mandatory for all laboratories to use the RDT kits that met the technical criteria and was inexpensive
5. Ongoing: Reference laboratory will conduct lot/batch testing of these kits for NHLS to ensure the quality assurance of the product.
6. The RDT selection procedure will be reviewed every 3/5 years.

Comparison of RDT Kits used by NHLS Laboratories

1. Kits used by NHLS Laboratories

<i>P. falciparum</i> only			
Kit name	Manufacturer	Supplier	Oracle number
1. First response	Premier Medical	Armada Health	To be loaded
2. ParaHit	Span Diagnostics	Biomed Healthcare	P01b6886
3. ICT	ICT International	ICT Diagnostics	P01i0106
4. SD Bioline	Standard Diagnostics	Pantech	P01a2112
5. Makromed		Omnimed	Not evaluated by WHO
6. Assure			Only used by 1 lab

<i>P. falciparum</i> and other species			
Kit name	Manufacturer	Supplier	Oracle number
1. First Response	Premier Medical	Armada Health	Special order – currently, minimum volume of 72 kits
2. ParaHit	Span Diagnostics	Biomed Healthcare	P01b6887
3. ICT	ICT International	ICT Diagnostics	Ordered by quote
4. BinaxNow		Alere Scarborough	P06m0177
5. OptiMal	Diamed	BioRad	P04o0012
6. Visitect			Only used by 1 lab

2. Kits used by NHLS Laboratories & evaluated by WHO/Find

<i>P. falciparum</i> only			
Kit name	Manufacturer	Supplier	Oracle number
1. First response	Premier Medical	Armada Health	To be loaded
2. ParaHit	Span Diagnostics	Biomed Healthcare	P01b6886
3. ICT	ICT International	ICT Diagnostics	P01i0106
4. SD Bioline	Standard Diagnostics	Pantech	P01a2112

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3. ICT	ICT International	ICT Diagnostics	Ordered by quote
4. BinaxNow		Alere Scarborough	P06m0177
5. OptiMal	Diamed	BioRad	P04o0012
*6. SD Bioline	Standard Diagnostics	Pantech	To be loaded

*Not currently used by NHLS but requested by one lab to be added.

Technical Performance Evaluation

2. WHO Product Evaluation

<i>P. falciparum</i> only				
Kit name	Manufacturer	Supplier	PDS* (2012)	PDS* (2013)
1. First response	Premier Medical	Armada Health	100 (100)	95 (100)
2. ParaHit	Span Diagnostics	Biomed Healthcare	85 (100)	85 (100)
3. ICT	ICT International	ICT Diagnostics	87 (98)	87 (98)
4. SD Bioline	Standard Diagnostics	Pantech	98 (99)	95 (99)

<i>P. falciparum</i> and other species				
Kit name	Manufacturer	Supplier	PDS^ (2012)	PDS^ (2013)
1. First Response	Premier Medical	Armada Health	84 + 75	85 + 74
2. ParaHit	Span Diagnostics	Biomed Healthcare	85 + 82	85 + 82
3. ICT (ML03)	ICT International	ICT Diagnostics	79 + 60	93 + 40
4. BinaxNow	Inverness	Alere Scarborough	91 + 10	Not done
5. OptiMal	Diamed	BioRad	51 + 97	51 + 97
6. SD Bioline	Standard Diagnostics	Pantech	94 + 91	94 + 91

Red text = remove from list due to unacceptable performance

PDS = panel detection score, must be ≥ 75

*For Pf at 200p/ μ l (2 000p/ μ l)

^For Pf at 200p/ μ l + Pv at 200p/ μ l

- Panel Detection Score(PDS) is a measure of inter-test and inter- lot consistency, as well as the ability to detect antigen.
- All kits PDS ≥ 75 %
- Parasite samples diluted to parasite density
 - *For Pf at 200p/ μ l (2 000p/ μ l)
 - ^For Pf at 200p/ μ l + Pv at 200p/ μ l

Results of Malaria RDT Kits

3. Pricing of kits

<i>P. falciparum</i> only					
Kit name	Supplier	From Oracle iProcurement			Final price from supplier
		Price per kit	No. of tests	Price per test	
1. First response	Armada Health	R 206.25**	25	R 8.25	
2. ParaHit	Biomed Healthcare	R 202.00	25	R 8.08	
3. ICT	ICT Diagnostics	R 185.00	25	R 7.40	
4. SD Bioline	Alere (05KF50)	R 185.00**	25	R 7.40	

<i>P. falciparum</i> and other species					
Kit name	Supplier	From Oracle iProcurement			Final price from supplier
		Price per kit	No. of tests	Price per test	
1. First response	Armada Health	R 281.25 */**	25	R 11.25	
2. ParaHit	Biomed Healthcare	R 268.00	25	R 10.72	
3. SD Bioline	Alere (05KF60)	R 360.00	25	R 14.40	

*Minimum order 72 kits at a time **From Quote = to load onto iProcurement (Alere health has a minimum order amount for free delivery, other suppliers?)

Analysis

***P. falciparum* only**

- 4/6 were recommend for use
- Price range : R7.40 – R28.68 per test (25 tests per RDT kit)
- Two of the RDT kits used by the lab were not recommend by WHO/FIND the cost of these tests were R12.14 and R28.68 per test

***P. falciparum* and other species**

- 3/6 were recommend for use
- Price range: R10.72 -29.80 per a test (25 tests per a RDT kit)
- Three RDT kits excluded; price ranged from R15,82, R17.10 and R29.80 per test

Discussion

- Although, malaria is seasonal in South Africa the total spend for malaria testing within the NHLS was R220 000 - R250 000 per month (for the period 2013-2014).
- The clinical performance of the malaria RDTs used was comparable, accurate and reliable.
- A review of the laboratory test kit usage indicated that 25% of the laboratories were using the most expensive kit and 57% of the laboratories were using the cheapest option.

Conclusion & Recommendations

- Determine the level of standardisation for diagnostic tests within the NHLS.
- The flexibility of choice as per laboratory category.
- Recommending a five year mandatory period for current systems.
- To determine a baseline for lifespan of instruments currently in place.
- Adopt a mechanism for new technology to be evaluated at a centralized point: NHLS – Health Technology Assessment Unit.
- To develop a program to assess efficiencies with the technologies utilising a multidisciplinary team (i.e. technical, financial and SCM staff).

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LABORATORY SERVICE

The End

Thank you
Ke a Leboga
Ndo Livhuwa
Ndza Khensa
Asante Sana
Ngiyabonga
E Nkosi
Dankie
Merci beaucoup
Grazie
Obrigado

