Idealith Research Foundation

bedrock policy analysis

Why don't the poor get essential medicines? Two stories.

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Why are these not available?

How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries?

Poverty, not patent policies, more often inhibits access to essential medicines in the developing world.

by Amir Attaran

ABSTRACT: This paper studies the relationship between patents and access to essential medicines. It finds that in sixty-five low- and middle-income countries, where four billion people live, patenting is rare for 319 products on the World Health Organization's Model List of Essential Medicines. Only seventeen essential medicines are patentable, although usually not actually patented, so that overall patent incidence is low (1.4 percent) and concentrated in larger markets. This and other results shed light on the policy dialogue among public health activists, the pharmaceutical industry, and governments that is often based on mistaken premises about how patents affect corporate revenues or the health of the world's poorest. Pragmatism and greater flexibility are urged, so that policy may better concentrate on the greater causes of epidemic mortality, which now pose unprecedented threats to global peace and security.

WHO Essential Medicines: patent situation (2003)

- WHO's *Expert Committee on the Selection and Use of Essential Medicines* chooses medicines based on medical criteria. Cost and patent status are not considerations.
  - *"[P]atent status of a medicine is not considered"*
  - *"[The] absolute cost of [a] treatment…[is] not…a reason to exclude a medicine"… from the essential medicine list.*

Source: WHO. The selection and use of essential medicines. Report of the WHO Expert Committee (including the 13th Model List of Essential Medicines. WHO Technical Report Series. Geneva: WHO; 2003

WHO Essential Medicines: patent situation (2003)

- There are 319 WHO Essential Medicines, of which only 17 are new enough to be patentable:
  - Antiparasitics: Lariam, Coartem
  - Antifungals: Diflucan
  - Antibacterials: Cipro; Zithromax
  - Antiretrovirals: AZT, 3TC, ddI, d4T, ABC, IND, EFV, NEV, RTV, SQV, NFV, LPV+RTV combination
- Sample size: 291 meds x 65 countries. n = 18,915
- Data relationships:
  - Overall patent coverage = 1.4%
  - LICs are different from MICs, and big countries are different from small countries ($p < 0.05$). The more people or money your country has, the more likely someone will patent there.

Source: Attaran (2004). Health Affairs.

WHO Essential Medicines: little future change

- There will at no time in the future likely be a large number of patented Essential Medicines: "Flux but little change."
- The anticipated "2016 watershed" when TRIPS introduces pharmaceutical patenting for Least Developed Countries will have little impact. Of 30 African LDCs, 28 already have pharmaceutical patenting, and have had for years or decades.
- There is a risk that manufacturing countries such as India will no longer be able to export patented medicines as they do now needs, but there are safety mechanisms in place to mitigate that also (e.g. Doha, price discounts, licensing, etc).

Source: Attaran (2004). Health Affairs.

WHO Essential Medicines: hyperbole on all sides

- Activists: patents are "a barrier in many [developing countries] to accessing affordable medicines"
- Industry: patents are "necessary to protect intellectual property rights on a global scale"

- Both are mistaken. Patents cannot cause essential medicines to be inaccessible in "many" developing countries because they do not exist 98.6 percent of the time; similarly, patents cannot be a "global" necessity of pharmaceutical business because companies forgo them 69 percent of their present day opportunities to get them.

Source: Attaran (2004). Health Affairs.

WHO Essential Medicines: a lingering worry I have

- Patents can, and do, interfere with some R&D that developing countries urgently need.

- Example: fixed dose combinations for HIV/AIDS. The current Indian debate:
  - Stavudine (BMS) - very few patents
  - Lamivudine (GSK) - many patents
  - Nevirapine (Boehringer Ingelheim) - many patents

- Patents and other intellectual property currently constrain:
  - Where the Indian coformulations can be sold.
  - Which companies can make this or similar coformulations.
  - Which companies can market a co-blister pack (a halfway house to coformulation).

- It currently appears the industry has done too little, too late to meet the public health needs of simplified AIDS therapy.

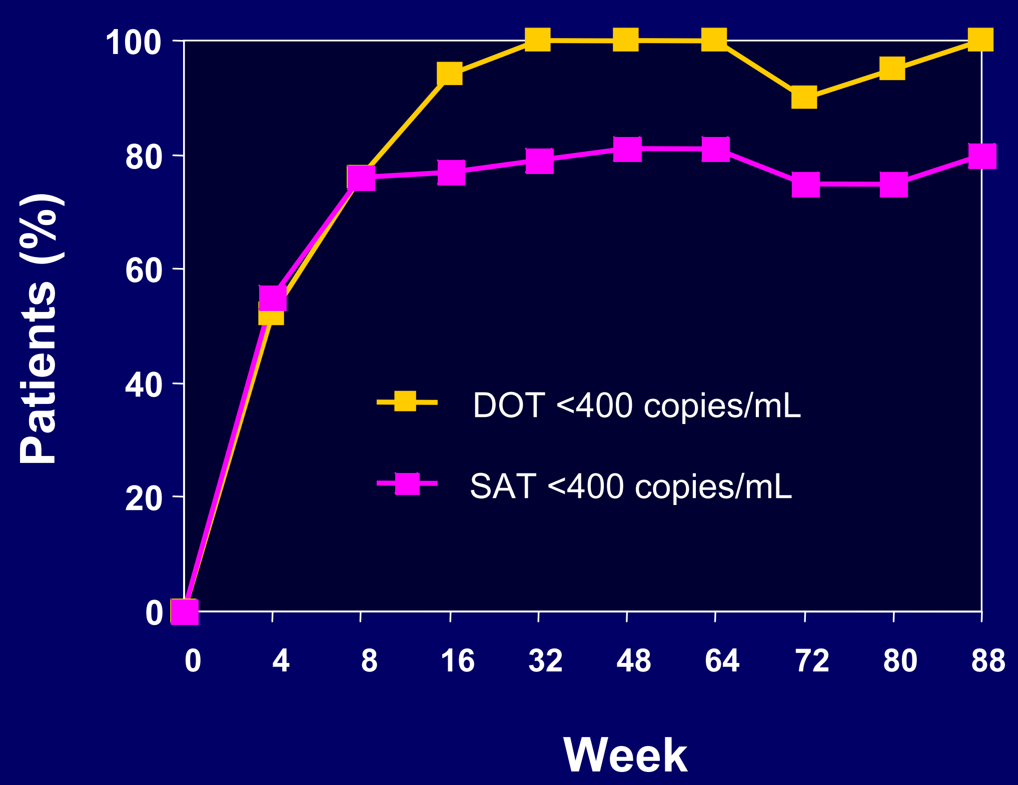
Source: Attaran (2004). Health Affairs.

Perfect Adherence Is Required for Better Virologic Outcomes (thanks to Dr. Anton Pozniak for this slide)

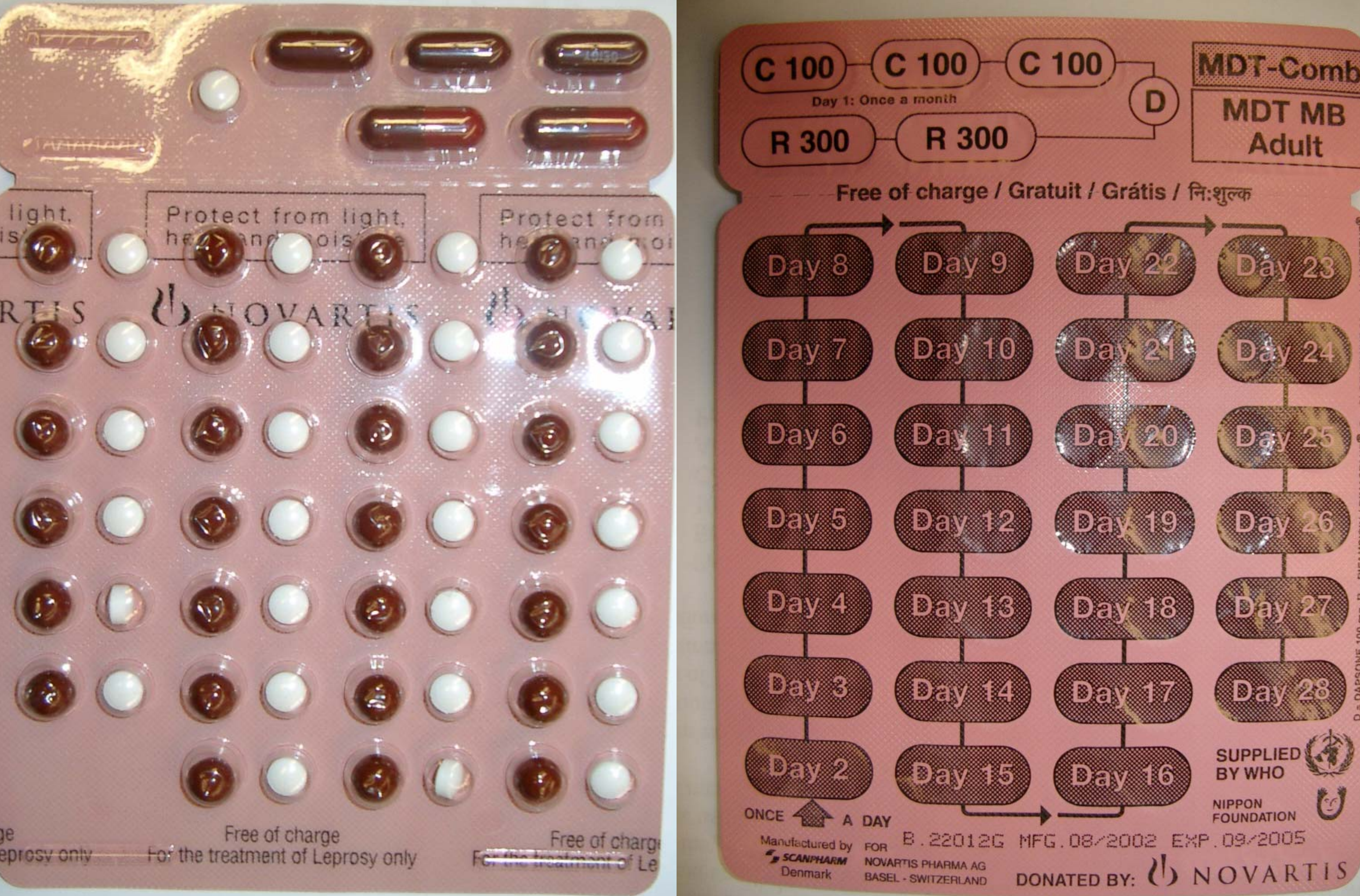
Impact of Directly Observed Therapy (DOT) and simplified therapy

Retrospective review of 100 ART-naïve patients on 3- or 4-drug HAART under DOT in prison or self-administered therapy (SAT) in trial unit

- **Conclusions**
  - **DOT group superior at all time points: adherence matters!**
  - **Within SAT group, 4-drug regimens had lowest response (57%)**



Fischl M, et al. Presented at 8th Conference on Retroviruses and Opportunistic Infections; February 4-8, 2001; Chicago, Ill. Abstract 528.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"Roll Back, Malaria"

WHO trends for malaria deaths and DALYs, 1998-2002

(% 1998 level)

150
140
130
120
110
100
90
80
70
60
50

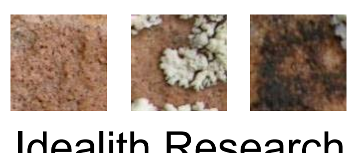
1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010

DALYs

Deaths

RBM promise

Data source: WHO, World Health Reports; 1999-2003
Authors' trend extrapolation.



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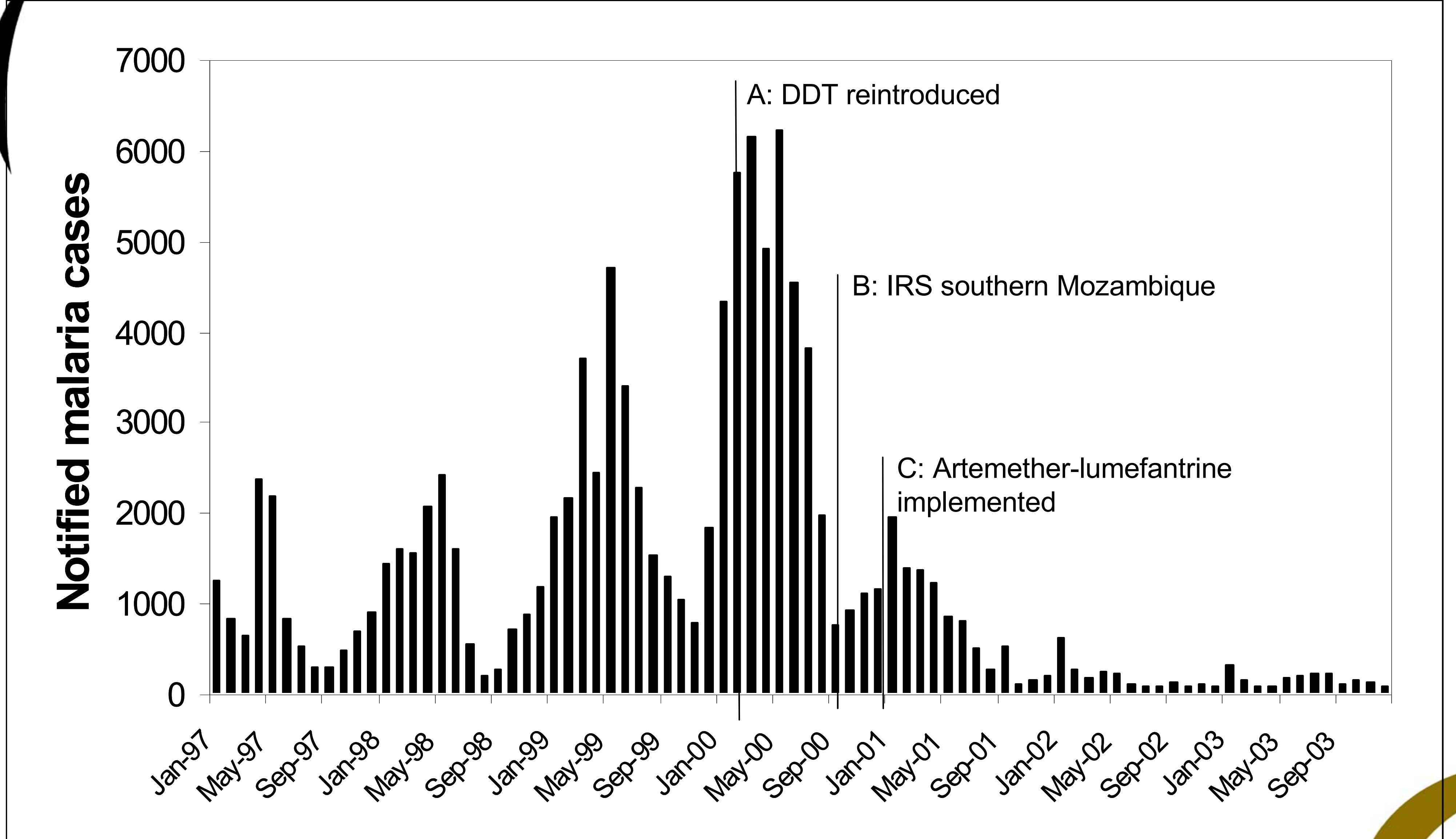
Number of malaria cases in KZN in relation to timing of significant malaria control interventions.



Source: South African National Department of Health, Notification Data. (Thanks to Dr. KarenBarnes)

Viewpoint

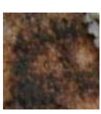
WHO, the Global Fund, and medical malpractice in malaria treatment

Amir Attaran, Karen I Barnes, Christopher Curtis, Umberto d'Alessandro, Caterina I Fanello, Mary R Galinski, Gilbert Kokwaro, Sornchai Looareesuwan, Michael Makanga, Theonest K Mutabingwa, Ambrose Talisuna, Jean François Trape, William M Watkins

In 1998, WHO launched a new, high profile campaign to Roll Back Malaria, with the stated goal to halve malaria deaths worldwide by 2010.[1] Achieving that goal requires preventive interventions (eg, insecticide-treated bednets, household insecticide spraying), but the main difference between life and death for malaria patients hinges on appropriate treatments. Simply, each malaria case must be promptly and accurately diagnosed, and treated with an effective malaria drug.

However, with nearly half the time to the 2010 deadline now past, progress on effective treatment is so inadequate doubled childhood malaria death risk, and in some sites, increased it up to 11-fold in the youngest children. In East and southern Africa, the proportion of children dying from malaria doubled as chloroquine and later sulfadoxine-pyrimethamine resistance took hold from the 1980s to the 1990s, even as deaths from other causes declined.[7] Elsewhere in Africa, chloroquine resistance increased the proportion of admissions to hospital and deaths from malaria by two-fold to four-fold.[8]

These links between drug resistance, treatment failure, and finally death are not controversial. WHO concurs that



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and supplied malaria medicines that don't work

- Where the old drugs don't work (and that's almost everywhere), childhood malaria deaths rise 2-11 fold.

	Parasitological failure (%)		Clinical failure (%)	
	CQ	SP	CQ	SP
Ethiopia	88 (82-94)	-	79 (51-93)	-
Kenya	71	23 (13-38)	64 (32-87)	8 (0-52)
Senegal	42 (24-59)	0	13 (10-16)	-
Uganda	41 (10-96)	17 (0-73)	28 (9-89)	10 (0-25)

Talisuna AO, Bloland P, D'Alessandro A (2004). History, dynamics and public health importance of malaria parasite resistance. Clin Microbiol Rev (in press)

The malaria treatment hall of shame

Artemisinin combination therapy (ACT) costs less than $1 for a child. The WHO and Global Fund are belatedly on the scene, but at least they now are trying. Who is still guilty of doing nothing?

- USAID – Has a $65 million malaria budget, but spends zero on malaria medicines of any kind.
- UNICEF – The world's leading child survival agency spends $3.7 million annually on malaria medicines, of which only $1 m is for ACT. That is a $1 million expenditure on treating the number one killer of children in Africa.
- World Bank – Claims it has loans of $300-500 million for malaria. The Bank's malaria head has refused to confirm or deny that it currently spends zero dollars on ACT.

This girl does not know when global health policy is right or wrong. <u>We do</u>. That is our blessing and our responsibility both.

Thank you.

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