Demystifying Medicine Lecture Series

Scientific Discovery and Malaria Interventions for Global Health

Thomas E. Wellems, MD, PhD
National Institute of Allergy and Infectious Diseases
Bethesda, MD
The Millennium Development Goals (MDGs)

At the United Nations Millennium Summit in September 2000, world leaders committed to work together to mobilize the energy and capacity of the international community, to meet a series of targets to reduce poverty and inequality and named these the Millennium Development Goals (MDGs). The goals are to:

1. Eradicate extreme poverty and hunger
2. Achieve universal primary education
3. Promote gender equality and empower women
4. Reduce child mortality
5. Improve maternal health
6. Combat HIV/AIDS, malaria, and other diseases
7. Ensure environmental sustainability
8. Develop a global partnership for development

These goals are linked to measurable targets, such as cutting in half the proportion of people living in extreme poverty, halving the proportion of people without access to safe drinking water, and reducing by two thirds the mortality rate of children under five - all by 2015.
Global Under-5 Mortality Rate, 1970-2013

Wang et al. (2014) Lancet PMID: 24797572
## Contributions to Change in Under-5 Deaths, 1990 vs. 2013

<table>
<thead>
<tr>
<th>Factor</th>
<th>Change in Deaths (thousands)</th>
<th>Contribution</th>
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<tbody>
<tr>
<td>Fertility</td>
<td>1,424</td>
<td>+24.6%</td>
</tr>
<tr>
<td>Maternal education</td>
<td>-2,224</td>
<td>-38.5%</td>
</tr>
<tr>
<td>Income</td>
<td>-902</td>
<td>-15.6%</td>
</tr>
<tr>
<td>Secular trend*</td>
<td>-4170</td>
<td>-72.1%</td>
</tr>
<tr>
<td>Unexplained</td>
<td>+58</td>
<td>+1.0%</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>+32</td>
<td>+0.6%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>-5782</strong></td>
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* Secular trend includes: development assistance for health initiatives, health care system and public health policy improvements, new technologies (vaccines, drugs, ITNs, diagnostics)

Lozano et al. (2012) Lancet 380: 2095-2128
Malaria Deaths and Human Development Index in Africa

Cumulative probability of malaria death per 1000 children aged 0-5 years

Human development index for income and education

$R^2 = 0.3311$
$p = 0.000$

Tusting et al. (2013) Lancet 382: 963-72
Malaria Death Rates in the 20th Century

Changes in Malaria Endemicity between 1900 and 2007

Malaria Transmission by *Anopheles*

Ronald Ross (1857-1932)

Battista Grassi (1854-1925)

Low, Sambon, & Terzi in the Roman Campagna, 1900

*Anopheles gambiae*
Attacking Malaria Deaths in Italy

“Unum facere et alterum non omittere”
Angelo Celli (1906)

“Alms for the poor, struck down in the Campagna. 1694.”
Success in the Panama Canal

- Mosquito control and quinine distribution program (40,000 doses/day)
- Reduction of malaria incidence from 800/1000 (1906) to 16/1000 (1916)
- Control of yellow fever

*Ancon* in the Culebra Cut, 1914

William C. Gorgas (1854-1920)
Impact of the 1955-1969 Malaria Eradication Campaign

“For the first time it is economically feasible for nations ... to banish malaria completely from their borders.”
(P.F. Russell, Man’s Mastery of Malaria, 1955)
Breakdown of the GMEP and Resurgent Malaria

Malaria Incidence in India

Millions of Cases

The Route to Chloroquine

- Quinine and pre-chloroquine synthetic drugs
  - Quinine
  - Methylene blue, 1891 (Paul Ehrlich)
  - Pamaquine, 1926
  - Mepacrine, 1931 (atebrin; quinacrine)
- Chloroquine named antimalarial-of-choice (1945)
  - Chloroquine, 1936 (Resochin; SN-7618)
Malaria Death Rates in the 20th Century

- Chloroquine introduced
- Chloroquine resistance spreads in Africa

Deaths (annual per 10,000)

- Sub-Saharan Africa
- Outside sub-Saharan Africa
Percentage Pediatric Deaths from Malaria, Mama Yemo Hospital

Chloroquine-resistant strains enter area

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tr>
<td>1955</td>
<td>8&lt;sup&gt;th&lt;/sup&gt; World Health Assembly adopts Global Malaria Eradication Program, “vertical” strategy with heavy reliance on DDT spraying for aggressive mosquito control. Program ended in 1969 (WHA resolution 22.39).</td>
</tr>
<tr>
<td>1978</td>
<td>31&lt;sup&gt;st&lt;/sup&gt; World Health Assembly adopts a redefined control strategy based on measures adapted to local epidemiological conditions and resources available (“stratification”).</td>
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<tr>
<td>1992</td>
<td>Revised Global Malaria Control Strategy endorsed by Health Ministers in Amsterdam. Emphasizes disease control based on decentralized, tailored use of anti-transmission measures and antimalarial treatments; capacity and infrastructure strengthening; political commitment; community partnership.</td>
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<tr>
<td>1998</td>
<td>WHO, UNICEF, UNDP and World Bank establish the Roll Back Malaria (RBM) partnership to scale-up resources and coverage by key interventions.</td>
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<tr>
<td>2008</td>
<td>Malaria Eradication Research Agenda (malERA) convened following Gates Foundation Malaria Forum. RBM releases Global Malaria Action Plan.</td>
</tr>
<tr>
<td>2014</td>
<td>WHO Global Malaria Program (GMP) is developing a Global Technical Strategy for 2016-2025, to be the foundation for RBM Global Malaria Action Plan 2.</td>
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Integrated Approaches of Today’s Malaria Control Programs

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Effective Malaria Programs Requires Multiple Tools (Interface of Molecular Parasitology and Global Health)

Mosquito Transmission Control

Effective Treatments Everywhere

Rapid Diagnostic Tests

Malaria Vaccines
**P. Falciparum** Chloroquine Resistance


**P. vivax** Chloroquine Resistance

Institute of Medicine Report 2004 recommendation:

a sustained global subsidy of artemisinins coformulated with other antimalarial drugs (ACTs)
Increasing Use of ACTs for Malaria Treatment

ACT deliveries from manufacturers to the public and private sectors, by drug and presentation, 2005–2013

ACT, artemisinin-based combination therapy; AL, artemether-lumefantrine; AMFm, Affordable Medicine Facility–malaria; AQ, amodiaquine; AS, artesunate; Co-B, co-bilster; FDC, fixed-dose combination; MQ, mefloquine; SP, sulfadoxine-pyrimethamine

Source: ACT deliveries (2005–2013*), data provided by eight companies eligible for procurement by WHO/UNICEF.

Estimated proportion of children aged under 5 years with confirmed *P. falciparum* malaria who received ACTs, sub-Saharan Africa, 2002–2013

Source: Household survey data modelled by Tulane University and University of California, San Francisco

World Malaria Report (2014)
Dihydroartemisinin-Piperaquine Failure in Cambodia

Marker of Delayed Clearance after Artemisinin Treatment in SE Asia

KELCH PROPELLER MUTATIONS

[Map showing distribution of KELCH propeller mutations in SE Asia with pie charts for different regions like Thailand, Cambodia, and Vietnam.]
Public-private partnerships work. They are cheap, effective and the best outcome for public health.

**HOW PUBLIC-PRIVATE PHARMACEUTICALS PARTNERSHIPS WORK**

- **Expertise.** PPPs – using employees and advisers with both industry and non-profit backgrounds – can help provide funding, focus and assistance in clinical trials in developing countries, and subsequent registration and distribution.
- **Collaboration.** Ot her pharmaceutical companies may be willing to share expertise or compounds through PPPs, which they would not offer to direct competitors.
- **Agility.** Smaller companies may have sufficiently low overheads, or a desire to market one or two late-stage products, to produce neglected disease drugs commercially.
- **Challenges.** PPPs’ main weakness is that they are under-funded, and still largely supported by charitable organisations, while governments have focused on alternative inappropriate incentives and provided little money to date.
- **Future incentives.** The work of PPPs could be further boosted through co-operating to cut costs, a reduction in patent fees, start-up funding, a prize for companies carrying out the neglected disease research and international donations to help countries purchase and distribute such drugs once developed.
### MMV Supported Projects, 4Q 2014

#### Research

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<th>Novartis</th>
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<td>Campinas</td>
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<td>Daichi-Sankyo</td>
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<td>Eisai</td>
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<td>Drug Discovery</td>
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<td>MMV</td>
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<td>15 Projects</td>
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#### Translational

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<th>Project</th>
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<tr>
<td>P218 DHFR</td>
<td>DSM265 NIH/Takeda</td>
</tr>
<tr>
<td>SJ733 St Jude</td>
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<td>KAE609 Novartis</td>
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<td>PA92 Drexel/UW/GNF</td>
<td>KAF156 Novartis</td>
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<td>MMV253 AstraZeneca</td>
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<td>GSK030 GSK</td>
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#### Development

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<th>Under review</th>
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<tr>
<td>OZ439/PQP Sanofi</td>
<td>Tafenoquine GSK</td>
<td>Rectal Artesunate CIPLA/Strides/TDR</td>
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<td>OZ439/FQ Sanofi</td>
<td>DHA- Piperaquine Paediatric Sigma-Tau</td>
<td>Pyronaridine Artesunate Paediatric Shin Poong/Iowa</td>
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<tr>
<td>KAE609 Novartis</td>
<td>KAF156 Novartis</td>
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#### Access

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<td>Artemether- Lumefantrine Dispersible Novartis</td>
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<td>Artesunate for injection Guilin</td>
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<td>Pyronaridine Artesunate Shin Poong/Iowa</td>
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<td>Artesunate- Mefloquine CIPLA/DNDi</td>
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<tr>
<td>Sulfadoxine Pyrimethamine- Amodiaquine Guilin</td>
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</table>

* First review or approval by WHO Prequalification, or by regulatory bodies who are ICH members or observers

† Included in MMV portfolio post approval

1. Brand name: Coartem® Dispersible
2. Brand name: Artesun®
3. Brand name: Eurartesim®
4. Brand name: Pyramax®
5. Brand names: Coarsucam™, ASAQ/Winthrop®
“The impact of continuous cultivation of *P. falciparum* was phenomenal. It spawned a renaissance of research on the immunology, cell biology and molecular biology of this parasite.”

Sherman and Simpson (2013) *National Academy of Sciences* 
“You can’t study something you can’t grow” (W. Trager)

- *P. vivax* is a pathogen of major global impact
- Drug screening and vaccine discovery depend upon non-human primate and human infections for parasite material
- Until *in vitro* cultivation is solved, molecular and genetic progress on *P. vivax* will be slow and limited
Fake Medicines and Malaria

Malaria is a disease that can be prevented and treated... when using the right medicines

- Genuine malaria medicines make a difference between life and death
- WHO recommends treatment with quality-assured artemisinin-based combination therapies (ACTs)
- Genuine ACTs are rapidly and reliably effective, curing more than 90% of malaria cases
- 50 countries are on track to reduce their malaria cases by 75% by 2015
- The strides achieved so far have in large part rested on improving access to effective treatment for correctly diagnosed cases, long lasting insecticidal nets for prevention and raising awareness among communities
- Let’s keep fake medicines from undermining these efforts!

1/3 of antimalarials in Africa are fake

In sub-Saharan Africa - where the burden of malaria is the greatest - the prevalence of fake medicines can be even higher

In Ghana and Cameroon: up to 40% are fake
In Nigeria: up to 64% are fake

Case studies

- In 2005, a 23 year old man died in Eastern Myanmar from cerebral malaria after being given fake medicine, bought in good faith by his local hospital. When the village committee discovered the cause of this needless death, they were sufficiently angry to collect all packs of these fake antimalarials they could find in local shops and burn them in front of the whole village.

- In 2009, Nigeria intercepted a consignment of nearly 700,000 doses of fake antimalarials. This quantity of fake medicines, if not intercepted, would have been sufficient to give ineffective or dangerous "medications" to hundreds of thousands of pregnant women and children.

- In 2012, in Angola, 14 million packets of fake malaria medicines were found in a container from China, hidden inside a shipment of loudspeakers. The fake pills contained no active ingredient. Instead, they were made of calcium phosphates, fatty acids and yellow pigment. The fakes — enough to treat more than half the country’s annual malaria cases, had they been genuine — are part of a proliferation of bogus malaria drugs in Africa that threaten to undermine years of progress in tackling the disease. A large international investigation is now underway.

Recommendations

- Always buy WHO prequalified antimalarial medicines from a reputable source where medicines are stored properly.
- Always check the packaging carefully:
  - Check the expiry date and if the dosage is correct.
  - Check if the patient information leaflet is in the correct language.
- Closely examine the appearance of your medicines:
  - Check if the pills are cracked or chipped.
- Make sure you have a malaria diagnostic test before taking an antimalarial.
- Antimalarial doses must be taken within three days to be effective.
- Recovery should be rapid and complete by day three of treatment if the antimalarial medicine is genuine.
- Speak with your doctor or pharmacist if you have unusual side-effects after taking your medicines.
- If you have any concerns about the quality of your medicines, and/or if you notice an anomaly on the packaging, instructions, blister pack, or pills, contact your health authority or the medicine manufacturer and retain packaging and any tablets for testing.
Tremendously Expanded RDT use:

“The number of RDTs distributed by national malaria control programmes in the public sector has increased from less than 200,000 in 2005 to more than 108 million in 2012. Manufacturers surveyed by WHO for the World Malaria Report 2013 reported a total of 205 million RDT sales in 2012. Data received from countries reveal that most RDTs (78%) were used in the WHO African Region, followed by the South-East Asia Region (16%).”

http://www.who.int/malaria/areas/diagnosis/rapid_diagnostic_tests/en/
Neglected tests for neglected patients


World Malaria Report (2014)
Malaria Diagnostic Tests/Distributed ACTs, Africa 2006-2013

More tests than ACTs

Fewer tests than ACTs

ACT deliveries from manufacturers to the public and private sectors, by drug and presentation, 2005–2013

ACT, artemisinin-based combination therapy; AL, artemether-lumefantrine; MMFm, Affordable Medicine Facility–malaria; AQ, amodiaquine; AS, artesunate; Co-B, co-blisters; FDC, fixed-dose combination; MQ, mefloquine; SP, sulfadoxine-pyrimethamine

Source: ACT deliveries (2005–2013*), data provided by eight companies eligible for procurement by WHO/UNICEF
Malaria Rapid Diagnostic Test Performance

Summary results of WHO product testing of malaria RDTs: Round 1-5 (2008-2013)

Figure S3: Panel detection score of malaria combination RDTs, meeting WHO procurement criteria for false-positive and invalid rates, in phase 2 of rounds 2-5 against wild-type (clinical) samples containing *P. falciparum* and *P. vivax* at low (200) parasite density (parasites/μL).

Panel detection score - A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.
2014: GSK Applies for RTS,S/AS01 Vaccine Regulatory Approval

From X-irradiated Sporozoites to the CSP Vaccine (1967-2014)

letters to nature
Nature 216, 160 - 162 (14 October 1967); doi:10.1038/216160a0

Protective Immunity produced by the Injection of X-irradiated Sporozoites of Plasmodium berghei

R. S. NUSSENZWEIG, J. VANDERBERG, H. MOST & C. ORTON
Department of Preventive Medicine and Department of Radiology, New York University School of Medicine.

Ruth Nussenzweig
Risk of Infection, Malaria and Death from *P. falciparum* in African Children

- 400 bitten by infected mosquitoes
- 200 bloodstream infections
- 100 symptomatic infections
- 100 asymptomatic parasitemia
- 200 uncomplicated malaria
- 1 death
Attacking the Complexes Critical to Erythrocyte Invasion


Srinivasan et al. (2014) 111: 10311-10316
Annual Mosquito Entomological Inoculation Rate (EIR) and Proportion of Individuals Infected with *P. falciparum*

- decreasing EIR from 200 to 100 reduces infection prevalence by 4%
- decreasing EIR from 100 to 1 reduces infection prevalence from 70% to 30%

Mean density observed Mean A. gambiae s.l. density/house

Wet Season (June – October)  Dry Season (November – May)

Wet-Dry Season Ecology of Malaria Mosquitoes

P. falciparum Can Suppress Midgut Nitration and Evade Mosquito Immunity

Science 24 May 2013:
Vol. 340 no. 6135 pp. 984-987
DOI: 10.1126/science.1235264

The Human Malaria Parasite Pfs47 Gene Mediates Evasion of the Mosquito Immune System
Alvaro Molina-Cruz¹, Lindsey S. Garver¹, Amy Alabaster¹, Lois Bangiolo¹, Ashley Haile¹, Jared Winikor¹, Corrie Ortega¹, Ben C. L. van Schaijk², Robert W. Sauerwein², Emma Taylor-Salmon¹, Carolina Barillas-Mury¹,*

Carolina Barillas-Mury
“Men and women were sick because they were poor; they became poorer because they were sick and sicker because they were poorer”

Winslow (1951) *WHO Monograph Series* No. 7
International Bill of Rights

Universal Declaration of Human Rights
Article 27
(1948)

International Covenant on Civil and Political Rights
(1966)

International Covenant on Economic, Social and Cultural Rights
Article 15
(1966)

ICESCR commits parties to work toward economic, social, and cultural rights for individuals, including labor rights and the right to health, the right to education, and the right to an adequate standard of living.

Socioeconomic development as an intervention against malaria: a systematic review and meta-analysis

Lucy S Tusting, Barbara Willey, Henry Lucas, John Thompson, Hmooda T Kafy, Richard Smith, Steve W Lindsay

Summary

Background Future progress in tackling malaria mortality will probably be hampered by the development of resistance to drugs and insecticides and by the contraction of aid budgets. Historically, control was often achieved without malaria-specific interventions. Our aim was to assess whether socioeconomic development can contribute to malaria control.

Methods We did a systematic review and meta-analysis to assess whether the risk of malaria in children aged 0–15 years is associated with socioeconomic status. We searched Medline, Web of Science, Embase, the Cochrane Database of Systematic Reviews, the Campbell Library, the Centre for Reviews and Dissemination, Health Systems Evidence, and the Evidence for Policy and Practice Information and Co-ordinating Centre evidence library for studies published in English between Jan 1, 1980, and July 12, 2011, that measured socioeconomic status and parasitologically confirmed malaria or clinical malaria in children. Unadjusted and adjusted effect estimates were combined in fixed-effects and random-effects meta-analyses, with a subgroup analysis for different measures of socioeconomic status. We used funnel plots and Egger’s linear regression to test for publication bias.

Findings Of 4696 studies reviewed, 20 met the criteria for inclusion in the qualitative analysis, and 15 of these reported the necessary data for inclusion in the meta-analysis. The odds of malaria infection were higher in the poorest children than in the least poor children (unadjusted odds ratio [OR] 1.66, 95% CI 1.35–2.05, p<0.001, I²=68%; adjusted OR 2.06, 1.42–2.97, p<0.001, I²=63%), an effect that was consistent across subgroups.

Interpretation Although we would not recommend discontinuation of existing malaria control efforts, we believe that increased investment in interventions to support socioeconomic development is warranted, since such interventions could prove highly effective and sustainable against malaria in the long term.

Funding UK Department for International Development.
Malaria Death Rates in the 20th Century

Control of Malaria in PR China

- Primary health care nets
- Community Participation
- Official commitment at all levels
- Integrated antimalarial measures
- Widely available microscopical stations and treatment
- Provincial and regional intersectorial programs
- Scientific research, drug discovery

Urbanization and the Global Decrease of Malaria Transmission

Movie generated from data and software at the Gapminder web site: http://www.gapminder.org/
Breaking the Health-Poverty Trap

The benefits of investing in malaria

The economic gain from ending malaria in Africa would be $332 BILLION

Malaria alone costs the African continent $12 billion per year and is an economic drain on families, communities, and nations. But current investments are already shrinking the malaria map and improving the health and financial well-being of countries across the African continent. In fact, every $1 invested in malaria prevention and treatment delivers a return of $20.

A New Class of Consumers Grows in Africa

Market on Par With China’s and India’s

By PETER WONACOTT May 2, 2011

Buying In
Africa’s middle class has risen to 34% of the population, expanding to 313 million people.

SHARE OF AFRICA'S POPULATION, BY CLASS

- Rich: More than $20/day
- Middle class: $2-$20
- Poor: Less than $2

SHARE OF COUNTRY THAT IS MIDDLE CLASS

- Over 66%
- 32-66%
- Under 33%

The Economist
October 20, 2012
5 Reasons Why 2013 Was The Best Year In Human History

BY ZACK BEAUCHAMP  Posted on December 11, 2013 at 3:34 PM Updated: December 12, 2013 at 10:55 AM

Between the brutal civil war in Syria, the government shutdown and all of the deadly dysfunction it represents, the NSA spying revelations, and massive inequality, it'd be easy to for you to enter 2014 thinking the last year has been an awful one.

But you’d be wrong. We have every reason to believe that 2013 was, in fact, the best year on the planet for humankind.

1. Fewer people are dying young, and more are living longer.
2. Fewer people suffer from extreme poverty, and the world is getting happier.
3. War is becoming rarer and less deadly.
4. Rates of murder and other violent crimes are in free-fall.
5. There’s less racism, sexism, and other forms of discrimination.

http://www.telegraph.co.uk/history/11310456/Goodbye-to-one-of-the-best-years-in-history.html