

MARKET ASSESSMENT FOR MALARIA VACCINES

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THE BOSTON CONSULTING GROUP

ACKNOWLEDGEMENTS

Malaria market assessment study sponsored by



With funding from



TABLE OF CONTENTS

Project overview

Endemic country findings

- **Malaria burden**
- **Public market**
- **Private market**

Travelers and military findings

Demand model methodology

Predicted vaccine market size

Implications and next steps

Appendix

OVERALL STUDY OBJECTIVE: ACHIEVING BETTER UNDERSTANDING OF THE DEMAND FOR MALARIA VACCINES

Project objectives

Connect stakeholders

Create platform of knowledge that connects scientists, industry leaders, and donors with end users in countries afflicted by malaria

- Critical to ensure that what gets developed is what countries want
- Make need for vaccine concrete in eyes of industry donors

Inform decisions

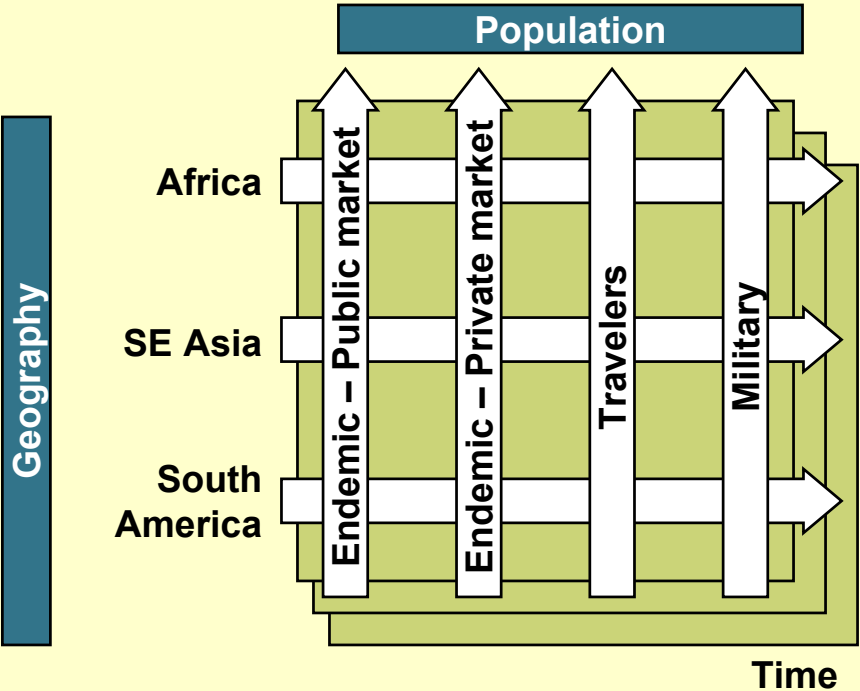
Obtain more complete information about the need for a malaria vaccine to inform decision making and throw light on the decision-making “black-box”

- Understand hurdles and constraints to enable most rapid uptake possible
- Evaluate key risks and uncertainties
 - manufacturing capacity and capital investments required
 - design of clinical trials
 - “fair value” agreements
 - portfolio management
 - how to attract biopharma companies to invest in malaria vaccine R&D

Project stems from MVI’s mission to accelerate the development of promising malaria vaccine candidates and to ensure their availability in the developing world

INCLUDES PUBLIC AND PRIVATE MARKETS IN MALARIA-ENDEMIC AREAS OVER TIME AND ACROSS DIFFERENT POSSIBLE PRODUCTS

Project scope covers broad range of populations and endemic geographies from 2010 to 2025



Flexibility built into design so that project broadly relevant for malaria vaccine community

Analysis for malaria vaccines in general, not for any one specific vaccine

- Overall evaluation of demand drivers and adoption hurdles
- Includes demand forecasting and “tipping points” for various product profile scenarios (e.g., duration, efficacy, cost)

Market assessment conducted at one point in time, but structure allows ongoing insights to be developed as new information becomes available

- Attributes of a vaccine
- Attitudes with respect to particular product profile requirements
- Funding available for malaria

PROJECT DRIVEN BY DEMAND LEAKAGE FRAMEWORK



Description

Number of people who would benefit from a malaria vaccine

Number of people for whom this vaccine suitable

Number of people with access to medical care and able to pay for vaccination

Number of people likely to get vaccinated given government/personal stance and vaccination strategies

Example factors

- Size of population with significant malaria mortality and disease burden
- Size of traveler population
- Size of relevant military population

- Species (*P. falciparum* or *P. vivax*)
- Pediatric indication

- Country healthcare expenditure per capita
- Infrastructure, e.g., beds per 1000 people
- Percent of children under 12 vaccinated for measles

- Government support of current prevention and treatment
- Individual compliance with current prevention and treatment

DEMAND LEAKAGE FRAMEWORK IMPLEMENTED VIA THREE-PHASED APPROACH

Conducted Across Both Endemic Countries and Special Populations



Objective

Situation analysis for endemic countries and select populations

Evaluation of demand drivers and barriers

Model future demand for vaccine, including scenarios analysis and key sensitivities

Key activities

- Review secondary sources for endemic countries (e.g., malaria burden, EPI uptake, demographics)
- Identify and study analogs
- Perform cluster analysis to segment countries
- Generate product profile for primary research

- Primary research in 8 endemic countries
- Primary research with travel medicine specialists and military experts
- Primary research with donors, policymakers, and KOLs

- Conduct additional interviews as necessary
- Synthesize findings
- Develop interactive model to estimate vaccine demand
- Run scenarios and sensitivities on model output

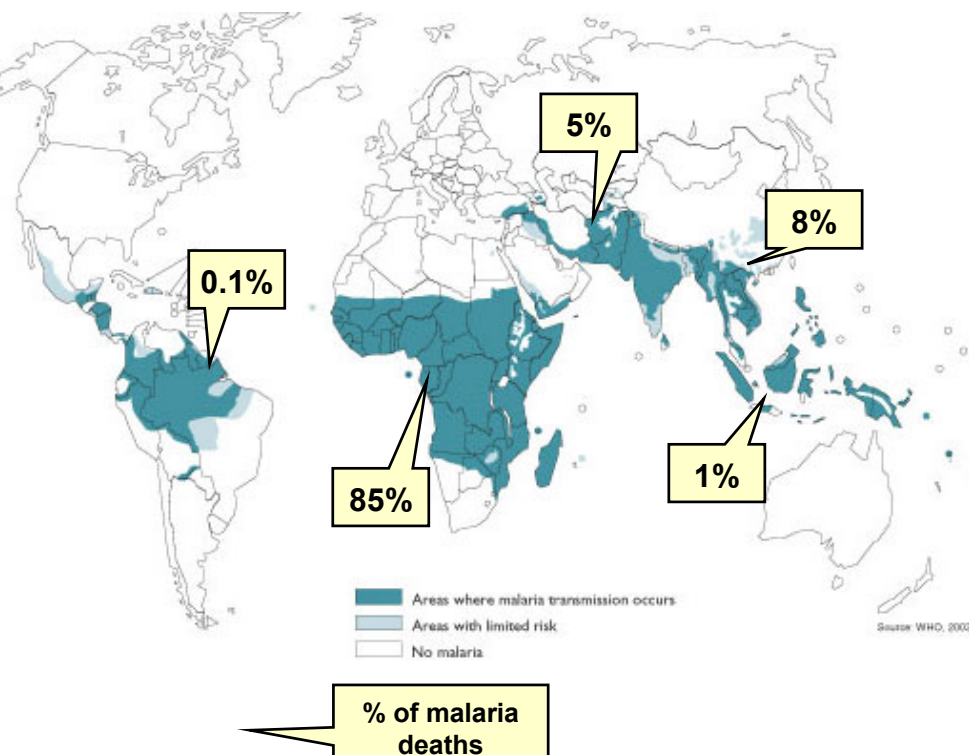
Project completed over 20 weeks in 2004-5

PRIMARY INTERVIEWS FOCUSED ON MALARIA-ENDEMIC REGIONS ACROSS THE GLOBE

Included Both *P. vivax* and *P. falciparum* Endemic Regions

Malaria-endemic regions are geographically concentrated

P. falciparum of increasing importance in Africa and SE Asia



Africa dominated by *P. falciparum*

- 5 to 10% of cases are *P. vivax*
- Increasing drug resistance to this more severe species makes *P. falciparum* a focus area

Growing importance of *P. falciparum* in India

- 20% of cases in 1980 to 45% in 2000

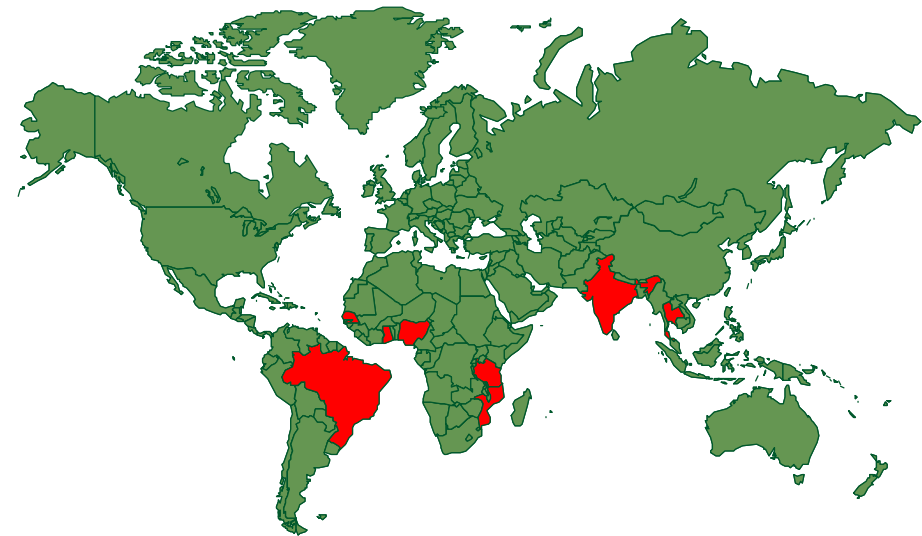
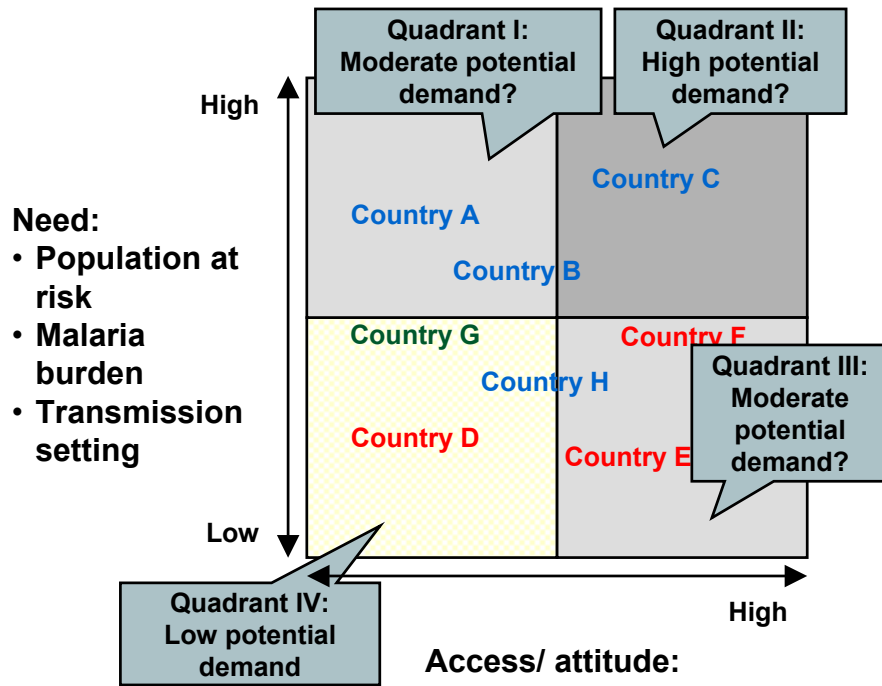
P. falciparum accounts for nearly 80% of cases in the Mekong region of SE Asia

Eastern Europe, Caucasus, and Brazil predominantly *P. vivax*

EIGHT LOCATIONS CHOSEN TO MAXIMIZE EXPOSURE TO NEED, ACCESS, AND ATTITUDES OF MALARIA-ENDEMIC COUNTRIES

Countries chosen to balance selection across key criteria

Over 200 interviews conducted



Brazil

Ghana
Mozambique
Nigeria
Senegal
Tanzania

India
Thailand

 Primary research countries

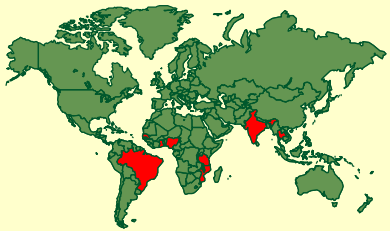




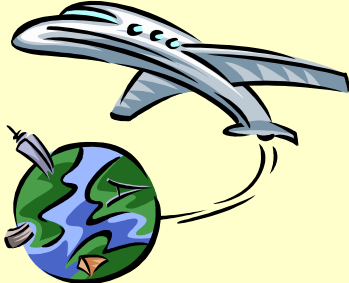
P. falciparum predominant

P. vivax and *P. falciparum* predominant

P. vivax only predominant

Note: Complete list of interviewees can be found in the appendix
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IN ADDITION, PRIMARY RESEARCH CONDUCTED WITH DONORS, POLICYMAKERS AND MILITARY AND TRAVELERS EXPERTS

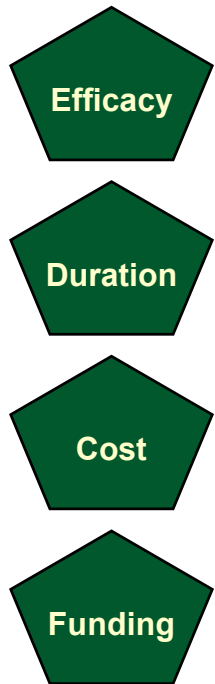
Sample endemic country interviews	Sample donor and policymaker interviews	Sample military interviews	Sample travelers interviews
<p>Ministry of Health</p> <p>Ministry of Finance</p> <p>WHO</p> <p>Academic researcher</p> <p>Hospitals</p> <p>Director of Health, Multi-national corporations</p> 	<p>Senior Technical Advisor for Immunization, USAID</p> <p>Health Advisor, DFID</p> <p>Senior Health Specialist, World Bank</p> <p>Secretariat, Roll Back Malaria</p>   	<p>Science Director, Walter Reed Army Institute of Research (WRAIR)</p> <p>Director, Army Malaria Vaccine Program</p> <p>Former Director, Division of Communicable Diseases and Immunology (WRAIR)</p> <p>Walter Reed Army Institute of Research</p> 	<p>Senior Lecturer, London School of Hygiene and Tropical Medicine</p> <p>Director, Travel Clinic, Massachusetts General Hospital</p> <p>Director, Center for Travel and Tropical Medicine (Toronto)</p> 

More than 200 in-country and 30 global interviews conducted

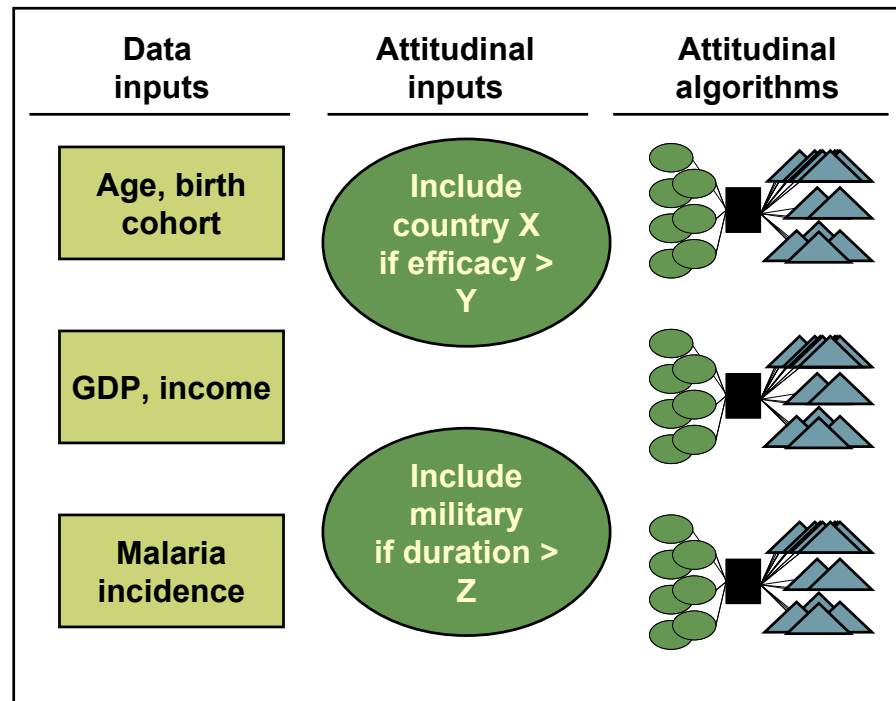
FINDINGS INCORPORATED INTO AN ADAPTIVE MODEL USED TO PREDICT VACCINE DEMAND

Sample Information Flow – Does Not Represent Full Scope of Model

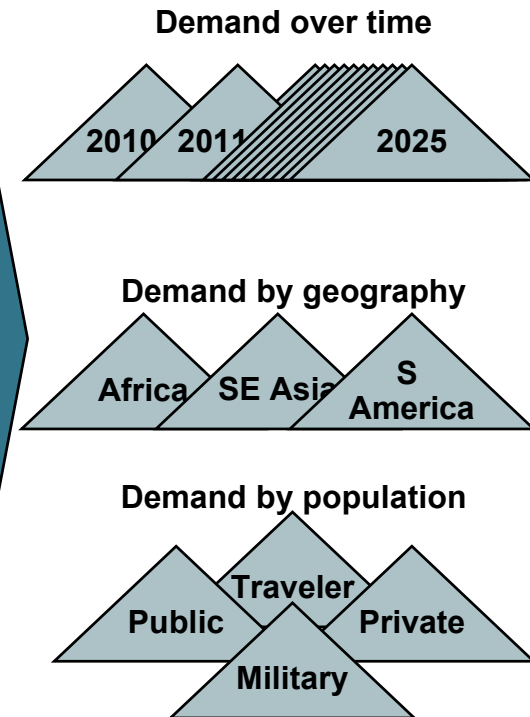
Scenario drivers



Model logic



Modular outputs



Model has flexibility to accommodate changes in vaccine landscape and country characteristics over time

TABLE OF CONTENTS

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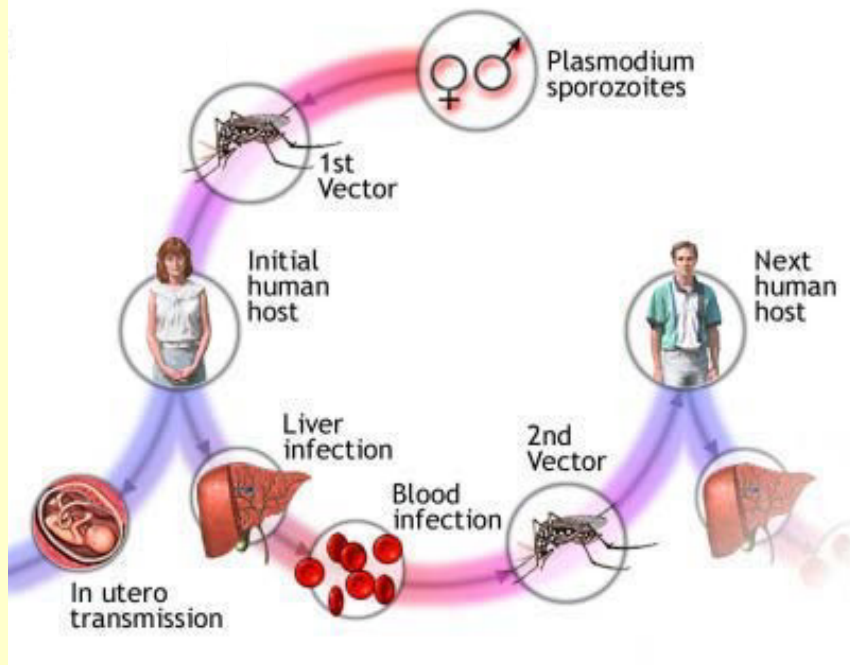
Predicted vaccine market size

Implications and next steps

Appendix

MALARIA IS ONE OF THE WORLD'S MOST COMMON AND MOST DEADLY PARASITIC DISEASES

Malaria transmission cycle



Basic facts

Population at risk – malaria is endemic in 117 countries; 2.5 B people are at risk (40% of world's population)

Morbidity – malaria infects a minimum of 300 to 500 MM people per year

Mortality - between 1 and 2 MM people die annually from malaria, mostly children under 5 in rural areas

Health care – at least 10% of hospitalizations and 20-60%⁽¹⁾ of doctor visits in Africa are caused by malaria

Costs – real costs in Africa are \$1.8 B annually; lost GDP of \$12 B per year due to malaria

(1) WHO estimates 20-30%, but in-country primary research cites 40-60%

Source: WHO 2002

PRIMARY MALARIA BURDEN DRIVEN BY P. FALCIPARUM AND P. VIVAX

P. falciparum Increasing Its Impact Across Both Asia And Africa

Plasmodium characteristics

P. falciparum

- Responsible for most Malaria deaths, especially in Africa
- Infection can develop suddenly and produce several life-threatening complications
- Almost always treatable if treatment started promptly
- Infects RBCs in all stages of development

P. vivax

- Geographically widest spread, yet mostly found in the tropics, especially throughout Asia
- Produces less severe symptoms
- Relapses for up to 3 years possible, and chronic disease is debilitating
- Infects only young RBCs
- More likely to affect both adults and children

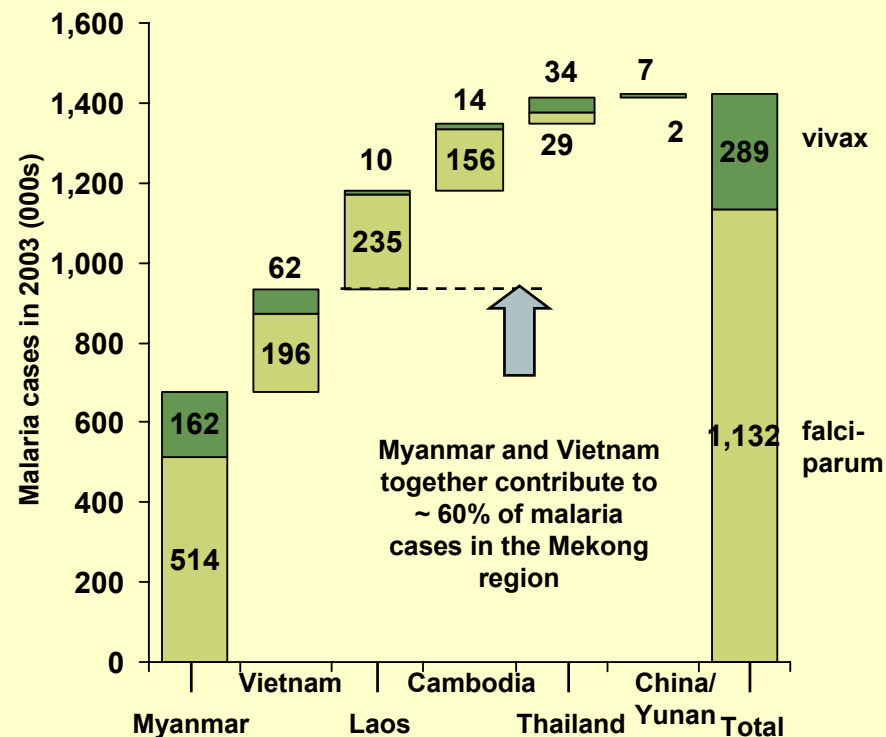
P. malariae

- Wiped out from temperate climates, but still in Africa

P. ovale

- Rare, and generally occurs in West Africa

In addition to its prevalence in Africa, P. falciparum also dominates in Mekong region of SE Asia



P. falciparum of growing concern in both Africa and Asia due to increasing drug resistance

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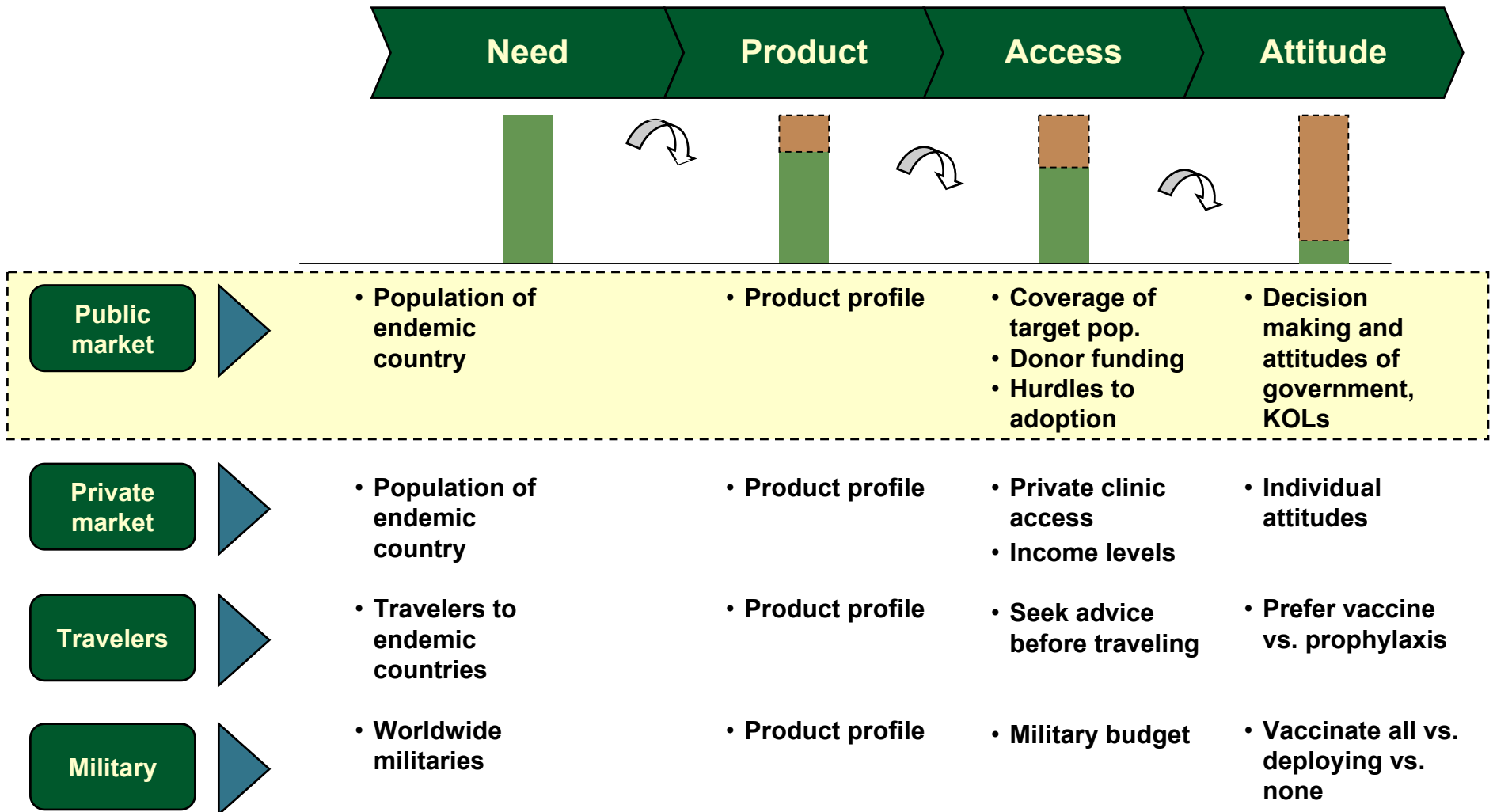
Demand model methodology

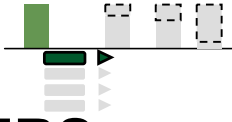
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ENDEMIC COUNTRY DEMAND LARGELY DRIVEN BY PUBLIC MARKET





THROUGHOUT OUR PRIMARY RESEARCH, STAKEHOLDERS RECOGNIZED THE SIGNIFICANT IMPACT OF MALARIA

Malaria is...

...a primary health issue

“...one of the most important vector borne diseases in Thailand” – MoPH Thailand

“...the most important vector borne disease from a public burden perspective in India” - NVBDCP

“...the primary public health crisis in Senegal” – BASICS Senegal

...a high cost burden

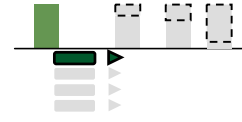
“...estimated to result in productivity loss of 1 – 3 % of GDP” – Ghana MoH

“...estimated to cost US\$ 1 Bn per year to the country in terms of economic productivity” – Nigeria Dept of Public Health

...a huge problem - Mozambique MoH

Note: NVBDCP stands for National Vector Borne Disease Control Program

Source: BCG interviews, BCG analysis
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THE UBIQUITOUS NATURE OF THE DISEASE IN AFRICA PRESENTS A UNIQUE SET OF ISSUES

Malaria is so common in Africa that it can lead to complacency

- Frequency of deaths desensitizes the population
- Long history of the disease results in health workers feeling it is routine

“People accept it as part of life” –DFID

“The frequency of child deaths is so high that it is commonplace” – World Vision Senegal

Those hardest hit by malaria in Africa, are often disenfranchised

- Infants, young children, and pregnant women, who lack semi-immunity of adults, are most affected
- These groups have the smallest voice in health policy

“Children, who are worst affected by malaria, do not have a voice in the political system” – Ghana Health Service

“Malaria primarily targets children and pregnant women, who are not the decision-makers” – Mozambique MoH

Malaria is being overshadowed by HIV, particularly in East Africa

- HIV/AIDS hits adults much harder than malaria
 - though malaria is often the cause of death
- HIV/AIDS receives a greater share of health funds

“A lot of money is being poured into HIV/AIDS” – World Bank Tanzania

“There’s a limited pot of money for healthcare, and HIV is attracting the resources” – UNICEF Moz.

As a result, malaria can lack the human capital, financial resources, and political energy it might warrant based on its impact



IN COUNTRIES SUCH AS INDIA, THAILAND AND BRAZIL, THE IMPACT OF MALARIA IS MORE CONTAINED

Malaria is a problem in India, though high burden areas are geographically concentrated

“~10 – 15% of the population is at sufficient risk from malaria to warrant intensive control programs” – WHO

“Malaria control is the oldest and largest national vertical health program in the country” – MoHFM India

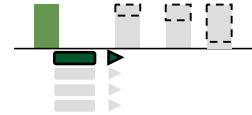
Malaria also a problem in Thailand and Brazil, but morbidity is now low and the disease burden has been restricted to border areas

“We saw malaria incidence rising in the 1990s, so in 1999 we decided to make this a priority” – MOH, Brazil

“Reported malaria cases were close to 500,000 cases in 1980s, but now are less than 30,000 a year” – Trop. Med. Thailand

“Malaria in Thailand is now well-controlled, except in the Thai-Myanmar and Thai-Cambodia border regions” – Trop. Med. Thailand

But the concentration of malaria in border or remote locations in these countries can create a different set of political challenges for diagnosis, prevention and treatment



CURRENT INTERVENTIONS COMBINE PREVENTION AND TREATMENT

Prevention includes spraying, environmental cleaning, ITNs and IPT



Spraying: outdoor and indoor based on vector resting location



Environmental clean-up: removal of standing water; seeding of larvivorous fish



ITNs: insecticide treated bed nets for children < 5 and pregnant women



IPT: intermittent presumptive treatment for pregnant women, IPTi for infants

Treatment focuses on early recognition and accurate diagnosis and treatment

Early recognition: Educate patients to recognize symptoms early and promptly seek treatment

- Education in schools, health facilities
- Home info packets



Accurate diagnosis: Ensure correct diagnostic techniques are available

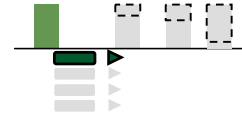
- Increasing access to health facilities (clinics, ambulances, pharmacies)



Accurate treatment: Drug therapy according to resistance of the region and plasmodium species

- CQ often limited by resistance
- SP often first-line, but facing growing resistance
- ACT use increasing, but facing supply problems

Portfolio approach to intervention likely to continue



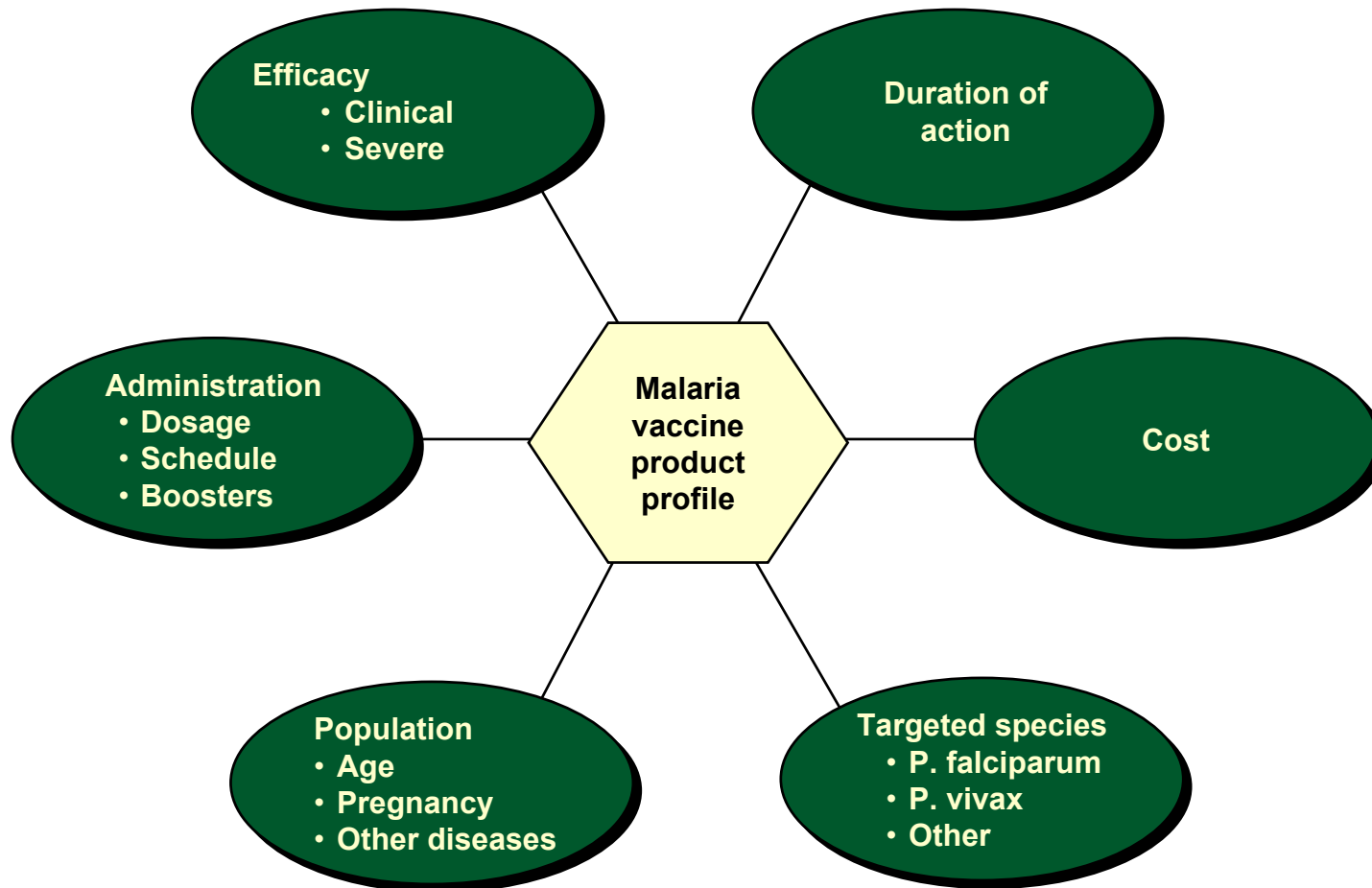
FOCUS ON PREVENTION VS. TREATMENT VARIES BY GEOGRAPHY

Most African Countries Emphasize Prevention while More Developed Countries Promote Early Diagnosis and Treatment

Area \ Strategy	Population at risk and attitude	Donor perspective	Prevention	Diagnosis and treatment
Africa	<ul style="list-style-type: none"> • Children under 5 and pregnant women most vulnerable • Majority of country • Common disease: part of daily life 	<ul style="list-style-type: none"> • Some funds for subsidized ITN, IPT, ACT, etc 	<ul style="list-style-type: none"> • ITN subsidies • IPT with SP piloted • Lower focus on spraying and clean-up 	<ul style="list-style-type: none"> • First line varies (CQ, SP and Amodiaquine) facing resistance • Shift to ACTs • Limited diagnostic equipment
SE Asia	<ul style="list-style-type: none"> • Adults and children • Biggest problem in border areas • Focus of local govt 	<ul style="list-style-type: none"> • Wealthier countries less reliant on donor support 	<ul style="list-style-type: none"> • Residual spraying in selected districts • Use of larvivorous fish to control vector 	<ul style="list-style-type: none"> • Rapid diagnosis / presumptive treatment based on geography • High resistance; some must use ACT first line
South America	<ul style="list-style-type: none"> • Adults and children • Biggest problem in border areas • Perceived to be “under control” 	<ul style="list-style-type: none"> • Wealthier countries less reliant on donor support 	<ul style="list-style-type: none"> • Spraying & clean-up in high risk/border areas • No ITN, indoor spray due to outdoors-resting vector 	<ul style="list-style-type: none"> • Faster response from diagnostic facilities • Species specific treatment • Goal: treatment within 24 hours

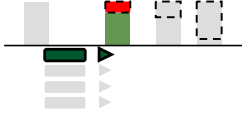
Difficulty in controlling malaria burden, especially in Africa

SIX CHARACTERISTICS OF PRODUCT PROFILE ARE KEY DEMAND DRIVERS



PUBLIC MARKET VACCINE MUST BE COST EFFECTIVE, FINANCIALLY SUSTAINABLE, AND EASY TO ADMINISTER

Attribute	Impact on demand	Details	Comments
Efficacy	High	<ul style="list-style-type: none"> Minimum efficacy desired against clinical disease vary from 30% in W Africa to 50% in E Africa to 80% in SE Asia 	<p>Countries will compare efficacy against ITNs and other preventative tools</p>
Duration	Medium	<ul style="list-style-type: none"> Duration factors into cost effectiveness <ul style="list-style-type: none"> minimum of 1 year 	<p>Benefit of protecting children early in life, until they develop partial immunity</p> <p>Duration impacts cost</p>
Cost	High	<ul style="list-style-type: none"> Cost/efficacy needs to compete with existing interventions May require donor funding, but countries need sustainable solution 	<p>Financial sustainability a huge issue</p>
Species	High	<ul style="list-style-type: none"> <i>P. falciparum</i> most important in Africa and Asia vs. <i>P. vivax</i> in Brazil 	<p>We're most concerned about <i>P. falciparum</i>—it is the most deadly</p>
Population segment	Low	<ul style="list-style-type: none"> Relevant to infants, children, and pregnant women in Africa vs. adults in SE Asia, S America 	<p>Pregnant women and under fives are highest priority</p>
Administration	High	<ul style="list-style-type: none"> Prefer to give vaccine with existing EPI schedule 	<p>Only realistic way to implement vaccine is through EPI schedule</p>



STAKEHOLDERS ACROSS COUNTRIES AGREE ON REQUIREMENTS FOR CERTAIN PRODUCT PROFILE CHARACTERISTICS

Malaria Endemic Countries

Duration

Most stakeholders agree that ~1 year minimum acceptable

- Yearly boosters acceptable, but bring significant concerns for costs and compliance in rural and border populations
 - booster frequency will impact cost/benefit assessment
 - extending duration to 2 years could significantly increase coverage and reduce costs

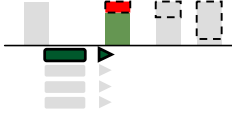
Administration

Almost universal view that vaccine should be included in EPI program

- Most prefer adhering to existing EPI timing
 - some openness to changing schedule for efficacious vaccine
- Vaccination campaigns may be used in Thailand and Brazil to reach adult target population
- Injection not an issue, although oral is preferred and would increase compliance

Safety

Across all countries, safety universally important but also “assumed”



VACCINE RELEVANT FOR HIGH-RISK POPULATIONS IN AFRICA VS. TOTAL POPULATION IN HIGH-RISK AREAS IN SE ASIA / S AMERICA

Population

Africa

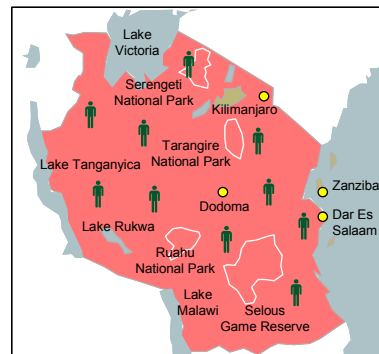
- Entire countries considered malaria-endemic
- Adults develop partial immunity to disease
 - children under five and pregnant women in greatest need
 - government cover for adults unlikely
- HIV positive adults priority in some countries

SE Asia / S America

- In Brazil, Thailand, India, etc, malaria only present in border areas
- Vaccine considered relevant and appropriate for all age groups in India and Brazil and primarily adults in Thailand

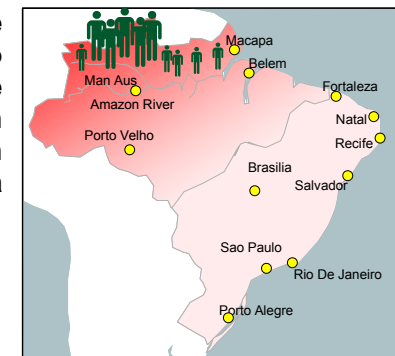
Tanzania

Vaccine relevant to children under 5 throughout country



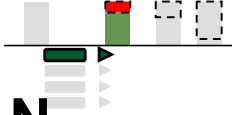
Brazil

Vaccine relevant to all age groups in Amazon area



Note: SE Asia / S America represented in interviews by India, Thailand, and Brazil

Source: BCG interviews, BCG Analysis
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EFFICACY AND COST HURDLES DIFFER FOR AFRICAN COUNTRIES VS. SE ASIA / S AMERICA

Africa Typically Has Lower Efficacy Requirement and Higher Cost Sensitivity

Africa

SE Asia / S America

Efficacy

- Impact on clinical disease critical
- Impact on severe disease may not influence introduction decisions
- RTS,S data viewed as promising
- W. Africa hurdle: ~30% against clinical and ~50% against severe disease
- E. Africa hurdle: ~50% against clinical

- Impact on clinical disease very important
 - Thailand focused on severe disease efficacy due to increasing drug resistance
- P. falciparum more important to India and Thailand; P. vivax more important to Brazil
- Hurdle: ~80-90% against clinical disease

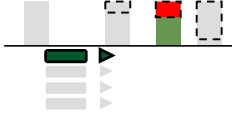
Cost

- Population expects vaccine to be free
 - majority of population cannot afford even \$1-3/dose
- Governments will evaluate cost effectiveness of vaccine vs. malaria control portfolio
- Donor funding critical
- Some countries will refuse upfront financing without clear path to sustainability

- Wealthier governments expected to purchase vaccine; donors important in poorer nations
 - Thailand: \$10-20 / dose affordable
 - India: cost of rolling out to even high risk groups would be prohibitive
- Governments will evaluate cost/benefit of vaccine vs. malaria control portfolio
- Some countries will refuse upfront financing without clear path to sustainability

Note: SE Asia / S America represented in interviews by India, Thailand, and Brazil

Source: BCG interviews, BCG Analysis
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ENDEMIC COUNTRIES' ABILITY TO PURCHASE VACCINE IS HEAVILY CORRELATED WITH DONOR FUNDING

Developing economies rely heavily on donor funding for health programs

- Many African and SE Asian countries fund a majority of their budgets with donor support
- High disease burden in these countries translate to large amounts of funding dedicated towards the health budget

“The general funds that the Senegal MoH uses to fund its operations can come from international donors like the World Bank or the EU”

“~ 50% of our overall budget and more than 50% of health spending is donor-funded”



More developed economies receive (and need) less donor support

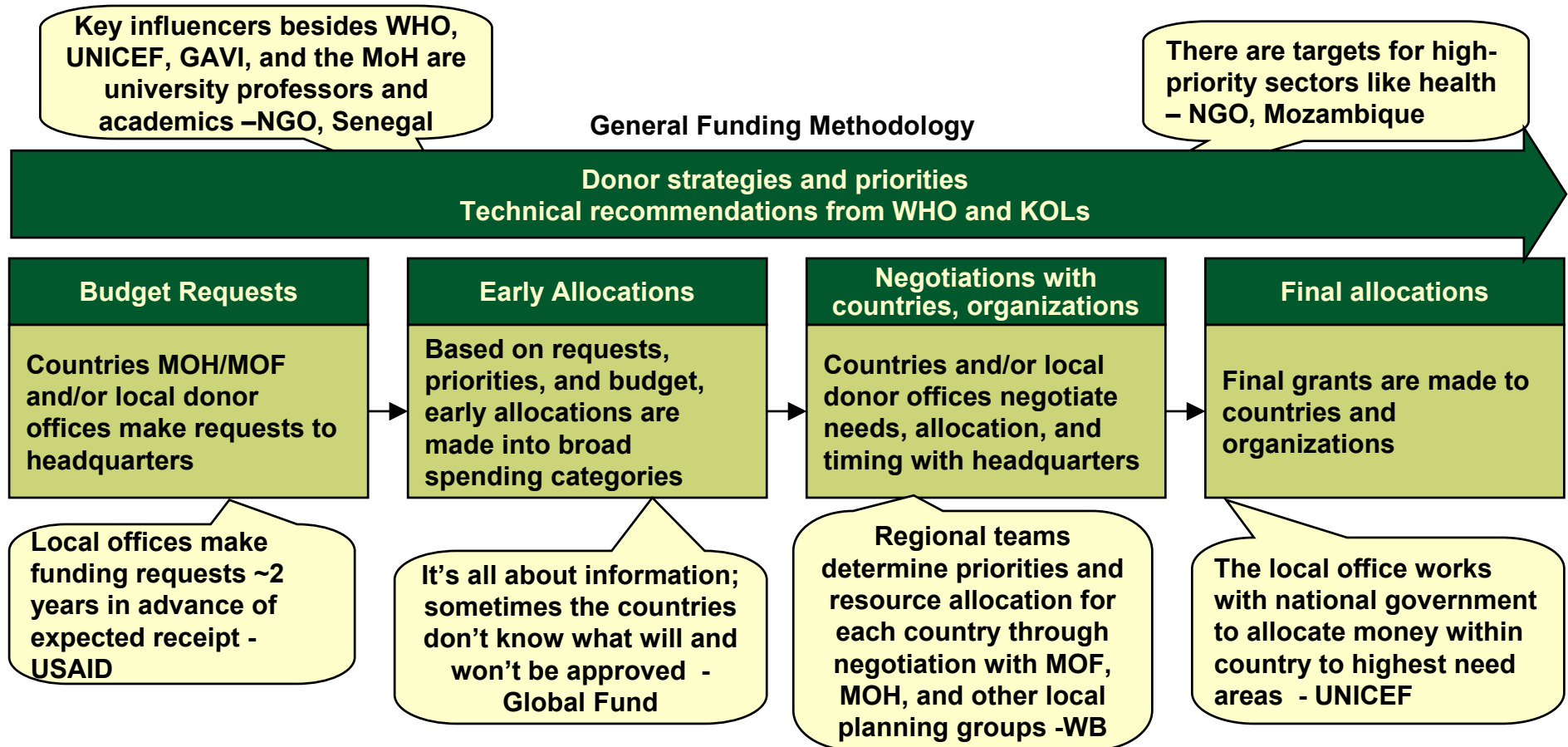
- Developed economies cover most of their budgets with internal funds
- Organizations such as the World Bank are less likely to give low-cost loans to developed economies

“Thailand is now considered a well established economy and ‘too rich’ to need outside support” – NSTDA

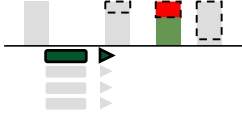
“In India, NGOs and donor organizations have a very limited role in malaria control; less than 5% of expenses for malaria are from donors”

Funding sustainability will drive demand for less wealthy countries

FUNDING DECISIONS MADE VIA ITERATIVE PROCESS, OFTEN BASED ON WHO GUIDELINES AND KOL RECOMMENDATIONS



Highly collaborative approach translates to donors making few independent evaluations of new technologies or interventions



MALARIA VACCINE SEEN AS PROMISING, BUT WOULD SHARE AVAILABLE DONOR RESOURCES WITH EXISTING INTERVENTIONS

Donors are highly interested in a vaccine...

- Donors routinely cite a vaccine as a very exciting possibility
- Donors fund significant amounts of vaccine R&D

“DFID maintains an active interest in vaccine research” - DFID

“A vaccine will be a very attractive investment for the donor community” -USAID

...but total funding unlikely to increase drastically

- Total malaria and vaccine funding may not change with partial efficacy vaccine

“There is only one pot of money for all healthcare interventions” -UNICEF

“USAID dollars given to the Vaccine Fund will likely not increase in response to a new malaria vaccine” -USAID

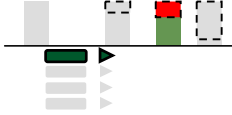
..and current solutions are unlikely to disappear

- Current tactic of portfolio approach to malaria unlikely to disappear with vaccine introduction

“No one measure is a magic bullet—need to work with what we have” -USAID

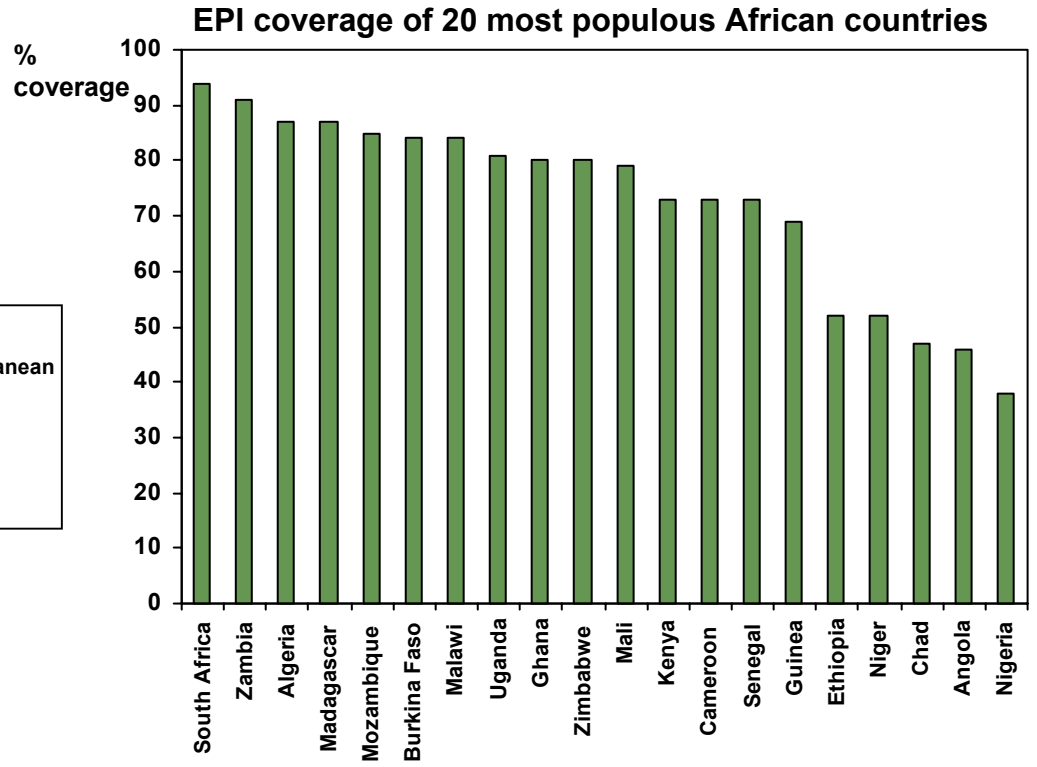
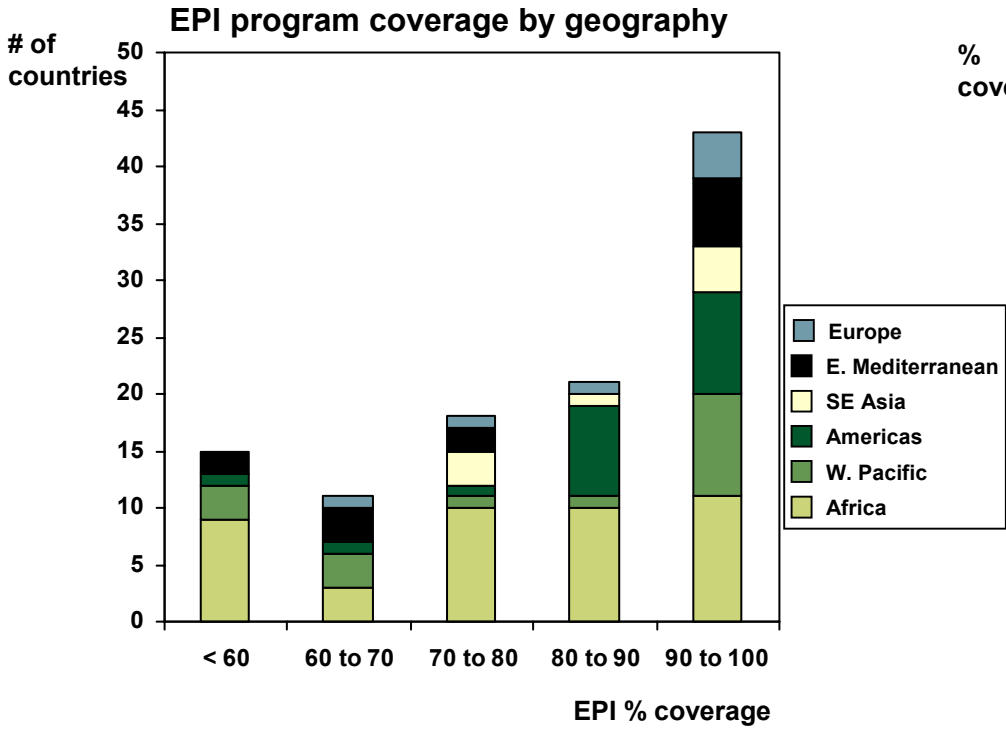
“We would not want to see a vaccine hindering the use of ITNs; the world has worked so hard to get people to use them” -USAID

Allocation of funding within prevention and control portfolio likely to be determined by vaccine product profile



EXISTING EPI COVERAGE SHOWS NUMBER OF PEOPLE POTENTIALLY VACCINATED

EPI Program Is An Effective Tool For Reaching Vaccine Recipients



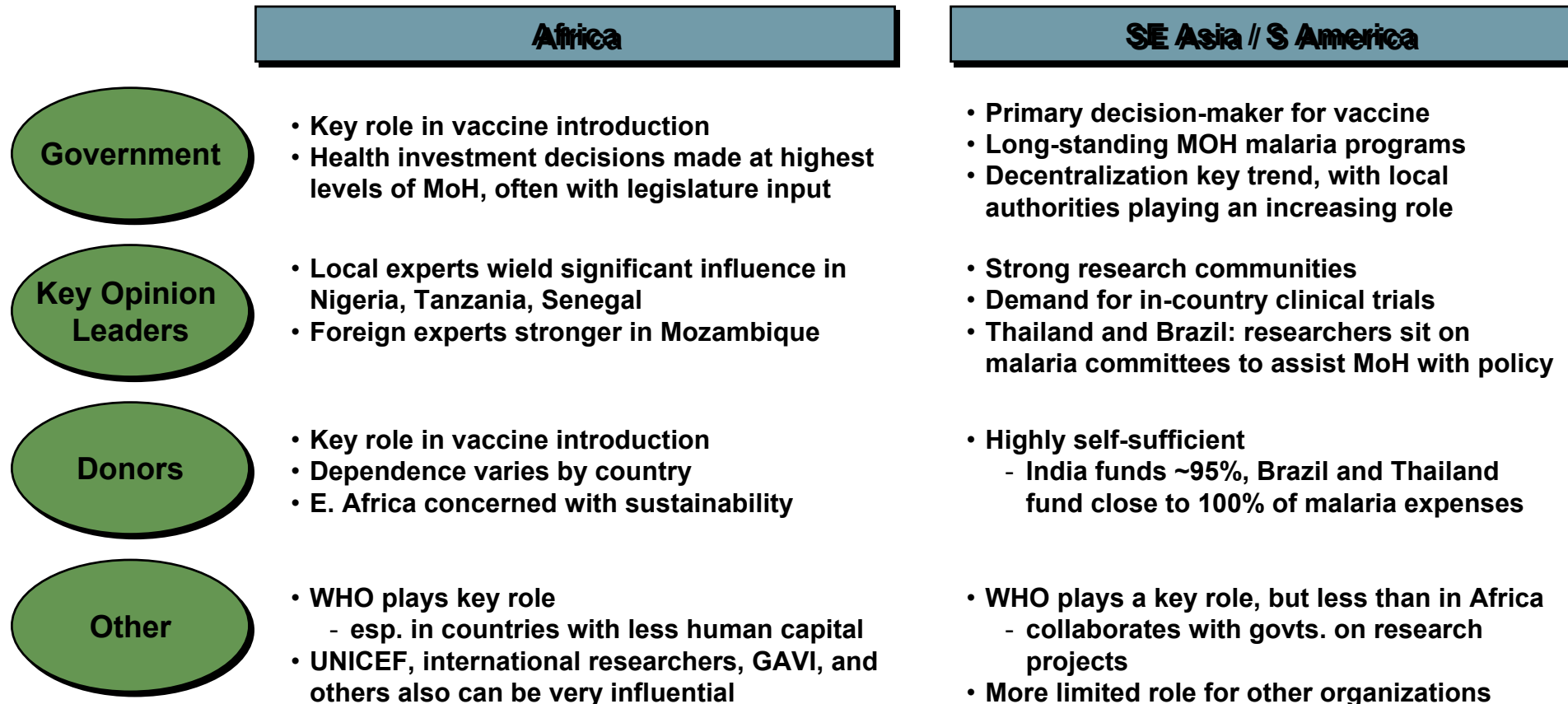
EVEN WITH DONOR FUNDING, SOME CONCERN ABOUT KEY STAKEHOLDERS WILLINGNESS TO ACCEPT A MALARIA VACCINE

8 Reasons Commonly Cited

Reasons for Reduced Interest	Rationale	Relevant Geographies
1 No need for a vaccine	Countries with better control over malaria may view need for a vaccine as less urgent	Brazil, Thailand
2 Do not trust vaccine due to prior failure	Community may be less willing to support a new malaria vaccine based on history of SPF66	Thailand; Africa—high awareness, but less impact due to high burden
3 Inadequate infrastructure	Pragmatic concerns regarding ability to reach population, i.e. staff training, cold chain needs, etc.	Mozambique, Tanzania, Nigeria; likely an issue throughout Africa
4 Do not want to spend for non-nationals	Government unlikely to unilaterally spend money on malaria control for migrants and refugees	
5 Need local data to prove effectiveness	Some countries emphasize importance of testing the vaccine in-country	Most countries
6 Difficult decision making	States or regions highly autonomous in decision-making, particularly regarding health interventions	Nigeria, India
7 Partial efficacy vaccine may decrease credibility	Vaccinated people who contract malaria could decrease credibility of entire immunization program	Most countries
8 Partial efficacy vaccine complicates messaging	Must communicate benefit of partial efficacy in promotion materials and to trainers	Most countries

Most hurdles can likely be addressed through effective pre-launch planning, proactive stakeholder management, and communication

INFLUENCE OF GOVERNMENT, KOLS, DONORS, AND NGOS DIFFERS BETWEEN AFRICA AND SE ASIA / SOUTH AMERICA



Coordinating influencers across geographies key to maximizing intervention supply

Note: SE Asia / S America represented in interviews by India, Thailand, and Brazil

Source: BCG interviews, BCG Analysis
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KEY TAKEAWAYS

Public Market

Significant need for malaria vaccine in public market. Despite breadth of existing alternatives for prevention and treatment, control perceived to be insufficient in most countries

- **Growing need for response to *P. falciparum* in non-African countries**

Minimum product profile varies by geography, however consistent focus on importance of *P. falciparum*, one year duration, and safety

- **Efficacy requirement highest for clinical disease in SE Asia (80%); lowest in W Africa (30%)**
- **Cost important as governments often do not have ability to pay for vaccine**
 - **and public often expects vaccine to be free of charge**

Current vaccination infrastructures could support significant uptake – but, donor funding will be needed to finance vaccine purchase and infrastructure enhancement requirements in African countries

- **Increasing focus on long-term sustainability of donor supported programs**
- **Wealthier SE Asian / South American countries willing to do more alone**

African country governments and donors rely heavily on recommendations from global scientific community and WHO when making decision about vaccine introduction

- **In wealthier SE Asian / South American countries, government and local stakeholders key**

Hurdles vary across geographies, but include perception of need, perceptions of vaccines, communication and credibility issues for partial effective vaccines and desire for local clinical data

TABLE OF CONTENTS

Project overview

Endemic country findings

- Malaria burden
- Public market
- Private market

Travelers and military findings

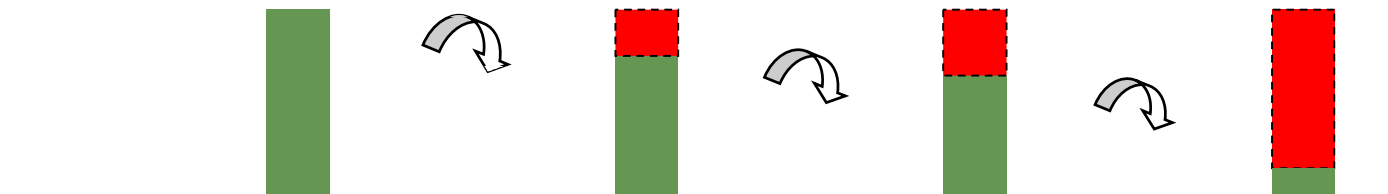
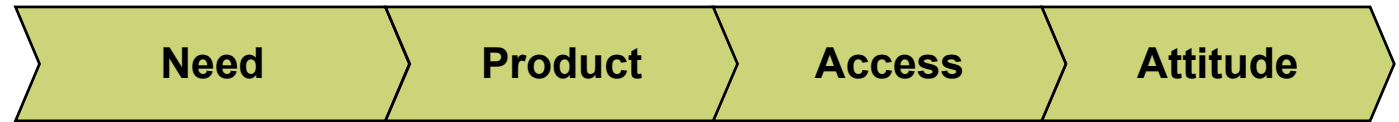
Demand model methodology

Predicted vaccine market size

Implications and next steps

Appendix

PRIVATE MARKET ALSO RELEVANT IN ENDEMIC COUNTRIES



PUBLIC MARKET

- Population of endemic country

- Product profile

- Coverage of target pop.
- Donor funding
- Hurdles to adoption

- Decision making and attitudes of government, KOLs

PRIVATE MARKET

- Population of endemic country

- Product profile

- Private clinic access
- Income levels

- Individual attitudes

TRAVELERS

- Travelers to endemic countries

- Product profile

- Seek advice before traveling

- Prefer vaccine vs. prophylaxis

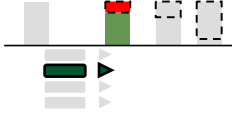
MILITARY

- Worldwide militaries

- Product profile

- Military budget

- Vaccinate all vs. deployed vs. none

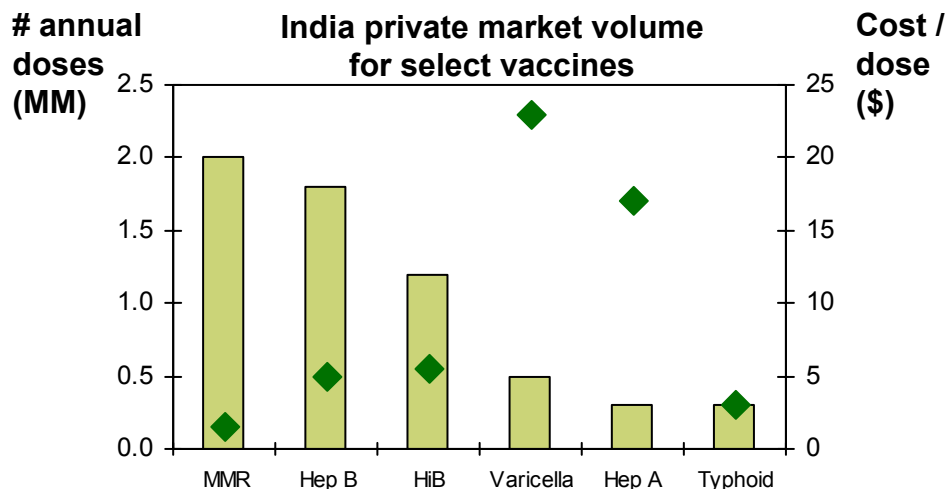


PRIVATE MARKET MOST CONCERNED THAT VACCINE BE HIGHLY EFFICACIOUS

Attribute	Impact on demand	Details	Comments
Efficacy	High	<ul style="list-style-type: none">• Most important factor given need to proactively seek out vaccine; efficacy has to warrant the time and money invested	Private market acceptance likely with high efficacy
Duration	Medium	<ul style="list-style-type: none">• Minimum one year	
Cost	Medium	<ul style="list-style-type: none">• Cost less of an issue than in public market for wealthy individuals, but still significant for groups choosing among interventions	Cost of vaccine would have to be comparable to current interventions for use in the private market
Species	High	<ul style="list-style-type: none">• Vaccine for <i>P. falciparum</i> more important given severity of disease	
Population	Medium	<ul style="list-style-type: none">• Private market vaccine applicable to adults as well as other high risk groups	
Administration	Low	<ul style="list-style-type: none">• Individuals seeking a vaccine in the private market are more likely to comply with multiple doses / boosters	

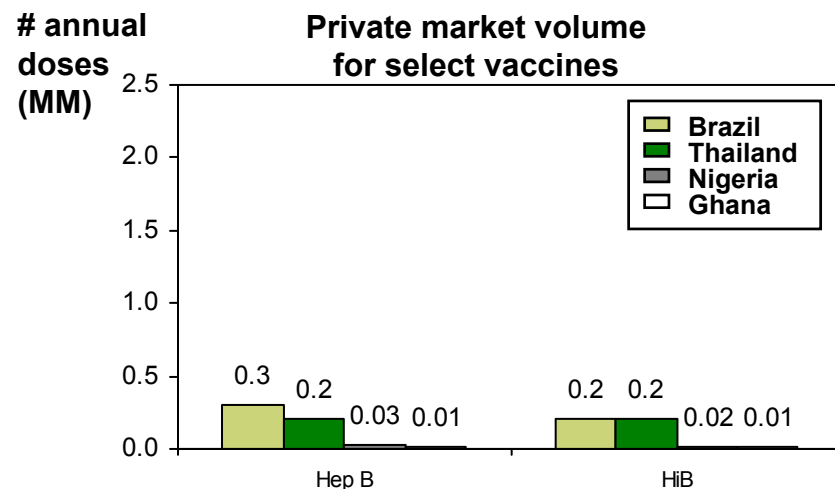
PRIVATE MARKET LIKELY SMALL, EXCEPT IN MORE WEALTHY AND POPULOUS COUNTRIES SUCH AS INDIA

Extensive private market for vaccines in India



70% of health care spend from private market;
2004 private vaccine market estimated at \$65 MM

Private market for vaccines appears limited in other countries



Private purchase of vaccines limited to the very high income class who prefer private facilities

Private market in African countries for a malaria vaccine likely to be small

HURDLES INCLUDE INADEQUATE INFRASTRUCTURE, LIMITED CLINIC ACCESS, AND REGULATIONS

Infrastructure

- Africa: private vaccination services obtained through private clinics often in large urban areas
- Brazil and Thailand regions limited to border areas with less private health care infrastructure
- Private shops selling pharmaceuticals exist in all primary research countries except Mozambique
 - usually do not distribute vaccines; may have more limited access to cold chain

Access

- Clientele of private clinics tends to be wealthy and urban, typically much less than 10% of total population

Regulation

- Regulations in several countries may impact viability of private vaccination markets
 - Mozambique: regulations limit sale of drugs/vaccines to select health facilities and pharmacies
 - Tanzania: regulations prevent private clinics from charging for EPI schedule vaccines

Nigeria likely to have the most robust private market of the African countries researched

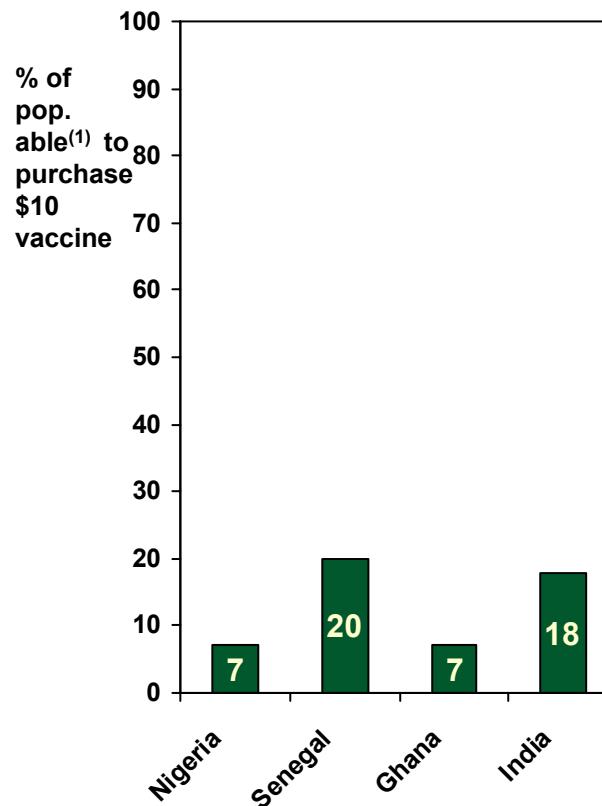
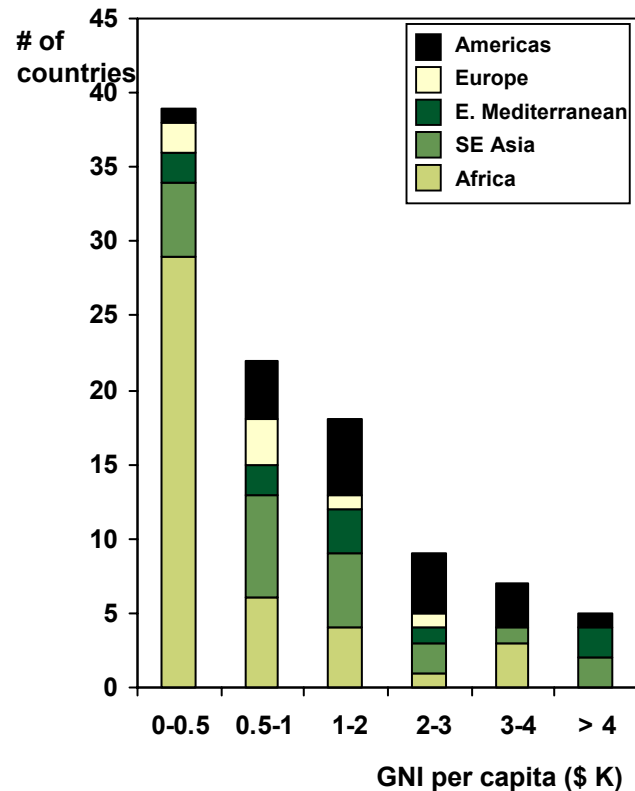
- **Even there, infrastructure challenges would need to be addressed to maximize reach**

PRIVATE MARKET ALSO LIMITED IN MANY MALARIA ENDEMIC COUNTRIES BY AFFORDABILITY AND EFFICACY CONSTRAINTS

Per capita GNI indicates country wealth...

...and ability of individuals to purchase a vaccine

While efficacy requirements are high across countries



- Efficacy hurdles for private market uptake likely to be higher than for public market
- Majority of private market likely to opt for alternative prevention over an expensive, low efficacy vaccine
- Wealthiest segment may purchase all available interventions
 - even expensive ones, such as residual spraying

1) Able to purchase vaccine defined as 2 weeks of annual income, based on country per capita levels and income distribution

Source: BCG interviews, BCG Analysis

INDIVIDUAL ATTITUDES FURTHER LIMIT PRIVATE MARKET OPPORTUNITY EVERYWHERE EXCEPT INDIA

In Brazil, Thailand, Africa, cultural expectation is to obtain health services from government...

In primary research countries, standard vaccines are provided free of charge by the government

- Similarly, malaria-related interventions are often also government-funded

In countries with a socialist history, private market for health services is relatively new

- Paying for health services, or paying more for better service, has not been completely absorbed into the culture

For Brazil and Thailand, private health services are more common in higher-income areas; however, income levels in malaria endemic regions very low

- Rely heavily on health services provided by government
- Unlikely to be able to afford high-cost vaccines

...Whereas in India, private market is increasing

Emergence of urban malaria means higher socio-economic class is seeking private prevention and treatment for malaria

Large proportion of health care in India provided by private sector

- Vaccines often obtained via private sector

Government health care infrastructure considered poor quality and inefficient

Indian middle and upper socio-economic strata (SEC A & B) primarily accesses health care from private sector

- accounts for ~ 200 - 250 Mn people
- annual birth cohort of ~ 5.5 – 6.5 MM

Significant uptake of vaccine in private market likely in India if efficacy hurdles can be met

KEY TAKEAWAYS

Private Market

Product profile varies from public market requirement

- **Higher efficacy threshold given availability of alternatives (minimum 50%)**
- **Administration restrictions lower due to routine doctor visits**
- **Cost less sensitive than for public market**

Access and wealth constraints limit private market to subset of populations

- **Wealthiest segment of population likely to purchase all relevant interventions**
 - **i.e. residual spraying along with ITNs, a vaccine, and ACT purchases**
- **Only small fraction of remaining population can afford typical vaccine costs and this group will likely have to decide among interventions**
 - **i.e. only 0.03% of Nigeria privately purchases \$12 Hep B vaccines**
- **However, small fraction of large country is still a substantial population (~600,000 Indian citizens purchase Hep B)**
- **Proximity to clinics and regulations on private sales of vaccines also limit demand**
 - **many countries have <300 clinics able to administer a private vaccine**

Cultural expectation of publicly-provided health services translates to some individuals not seeking private vaccination, even if they can afford it

TABLE OF CONTENTS

Project overview

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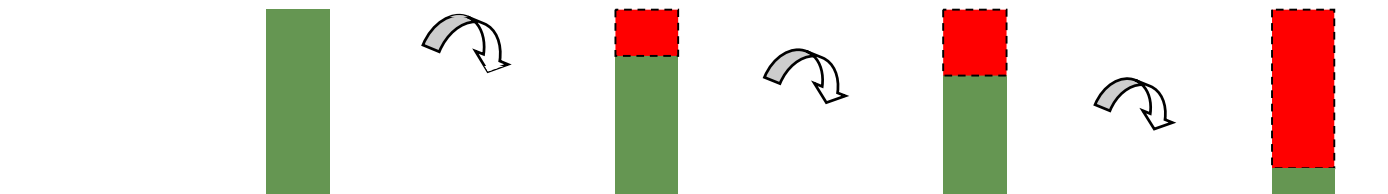
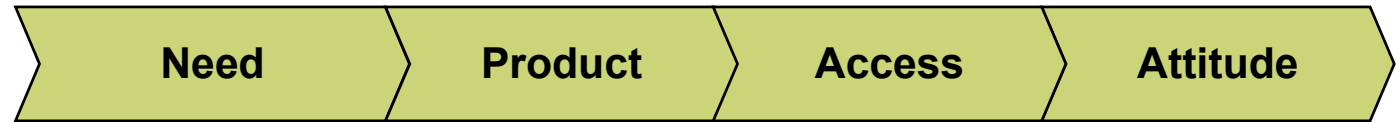
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TRAVELERS MARKET HAS EXTREMELY HIGH PRODUCT REQUIREMENTS



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- Product profile

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- Hurdles to adoption

- Decision making and attitudes of government, KOLs

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TRAVELERS

- Travelers to endemic countries

- Product profile

- Seek advice before traveling

- Prefer vaccine vs. prophylaxis

MILITARY

- Worldwide militaries

- Product profile

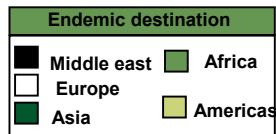
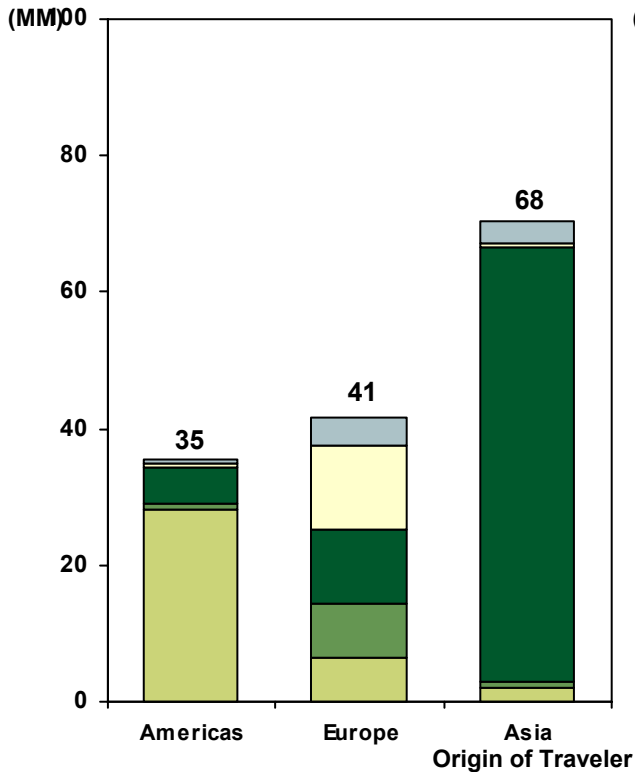
- Military budget

- Vaccinate all vs. deployed vs. none

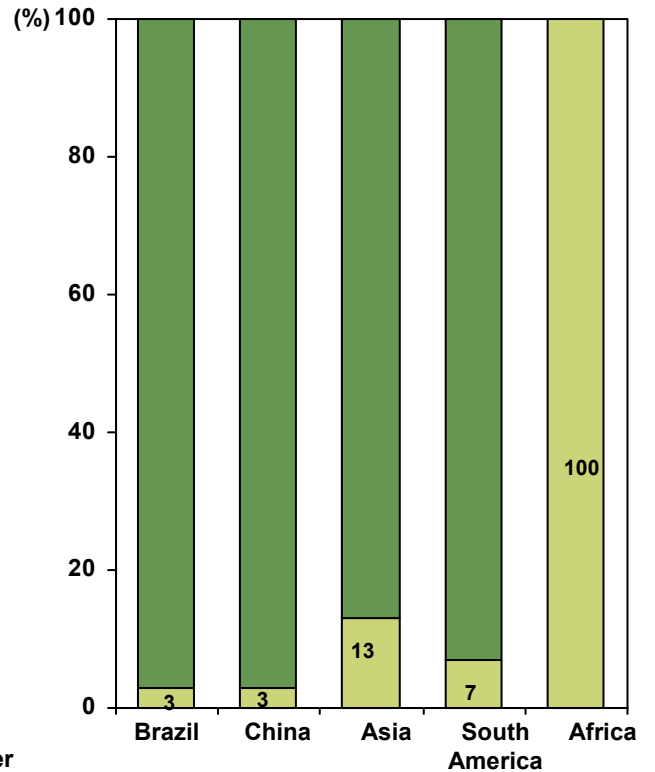
~147 MM TRAVELERS TRAVEL TO MALARIA ENDEMIC REGIONS

22MM of These Are At-Risk For Malaria

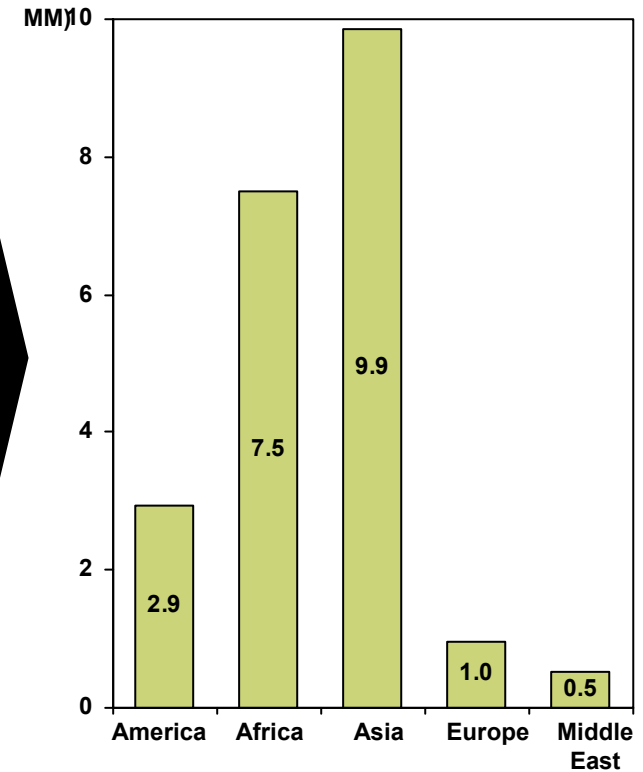
International tourist arrivals
2002



Percent of travelers at-risk⁽¹⁾
within endemic countries



Travelers affected in malaria
endemic countries



(1) Countries clustered depending on traveler mobility within country (rural areas, jungle/bush, provinces with high indices of malaria)

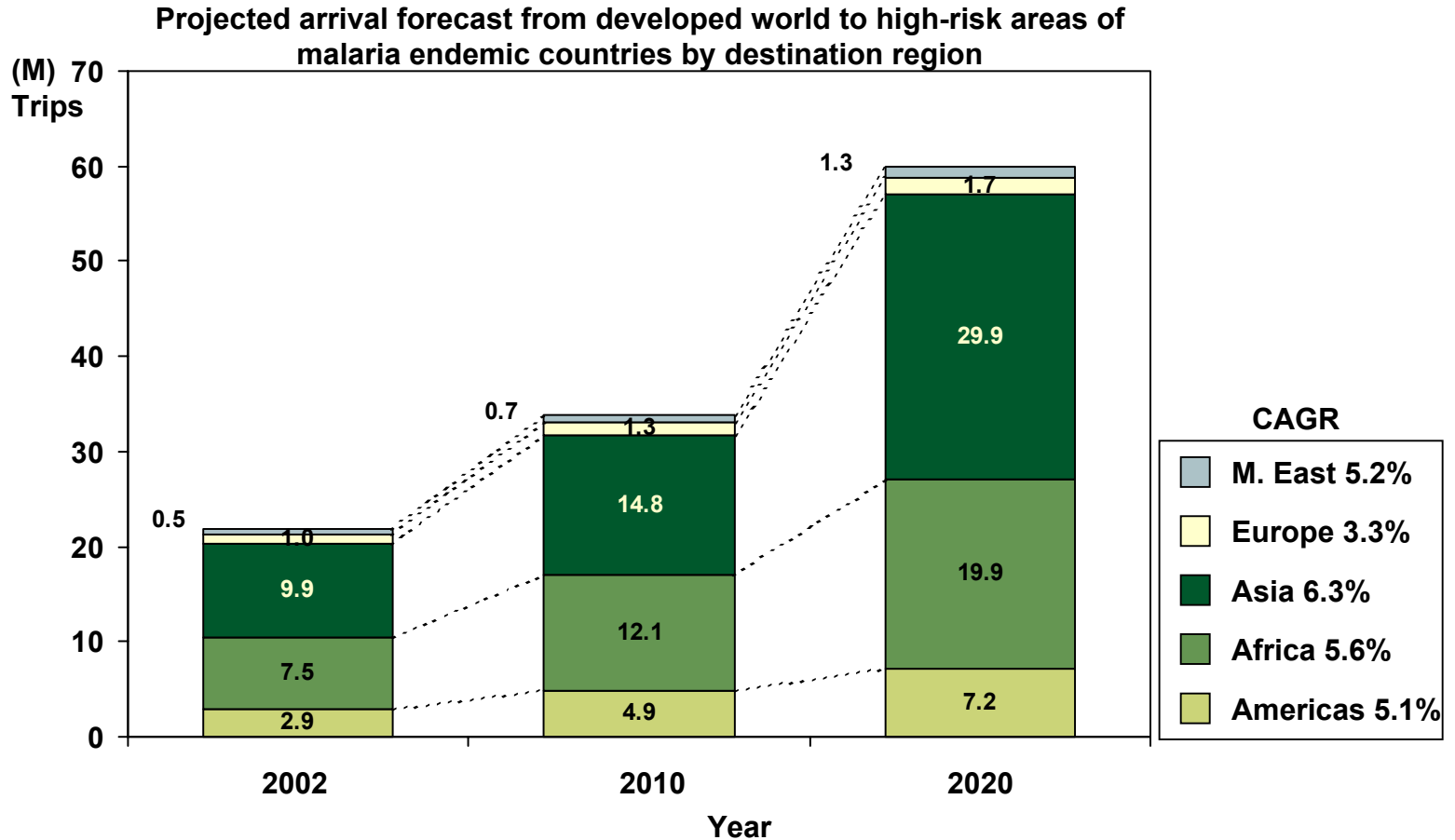
Note: Malaria endemic countries defined by WHO, 'developed world' refers to travel from the Americas (South, Central, Caribbean, North America), Europe (Northern, Western Central/Eastern, Southern, East Mediterranean Europe) and Asia (North-East Asia, South-East Asia, Oceania, South Asia) as defined by WTO. It is important to note that not all travelers to malaria endemic countries will be traveling to regions with high malaria incidence within them.

Source: World Tourism Organization "World Overview and Tourism Topics" 2003 edition

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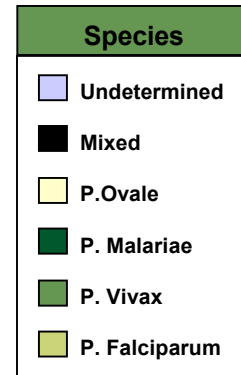
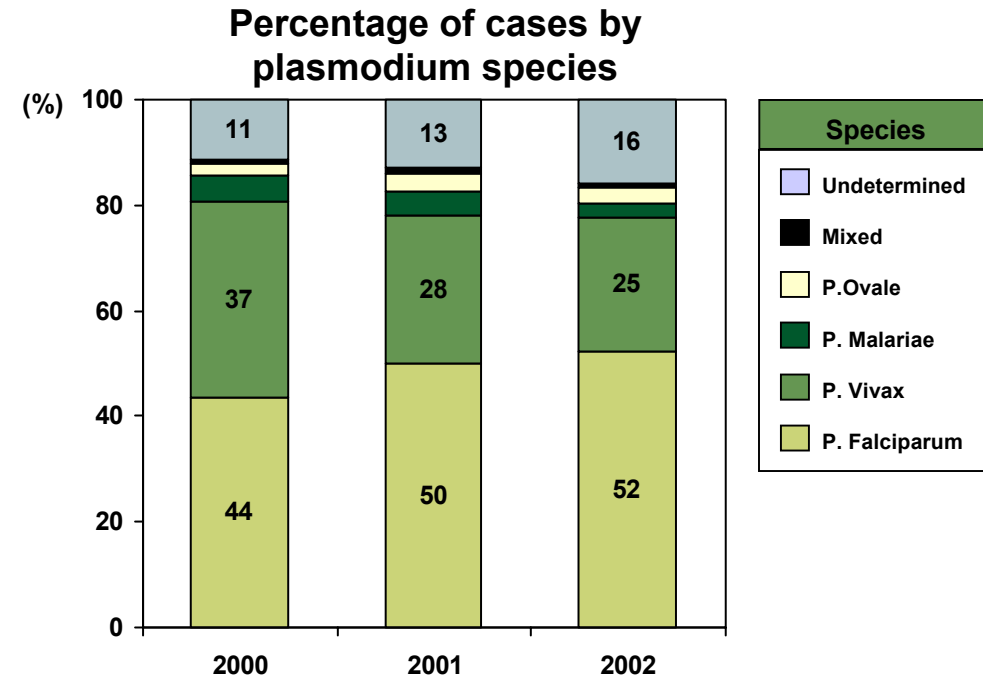
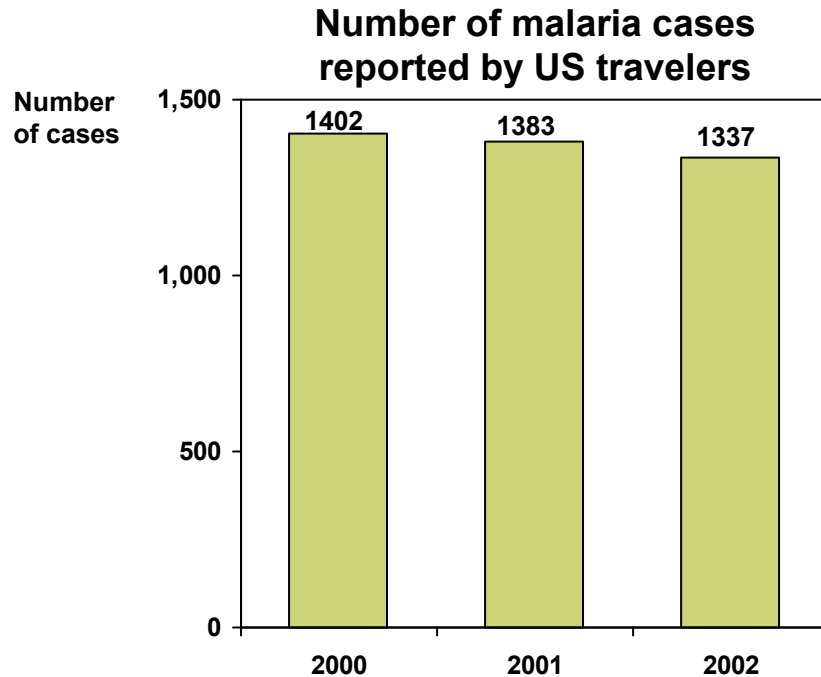
INTERNATIONAL TOURISM TO ENDEMIC REGIONS PROJECTED TO INCREASE OVER THE NEXT 15 YEARS



Note: Malaria endemic countries defined by WHO, 'developed world' refers to travel from the Americas (South, Central, Caribbean, North America), Europe (Northern, Western Central/Eastern, Southern, East Mediterranean Europe) and Asia (North-East Asia, South-East Asia, Oceania, South Asia) as defined by WTO.

Source: World Tourism Organization "World Overview and Tourism Topics" 2003 edition; BCG analysis

MALARIA CASES AMONG U.S. TRAVELERS ARE DECREASING BUT INCIDENCE OF FALCIPARUM STRAIN IS INCREASING



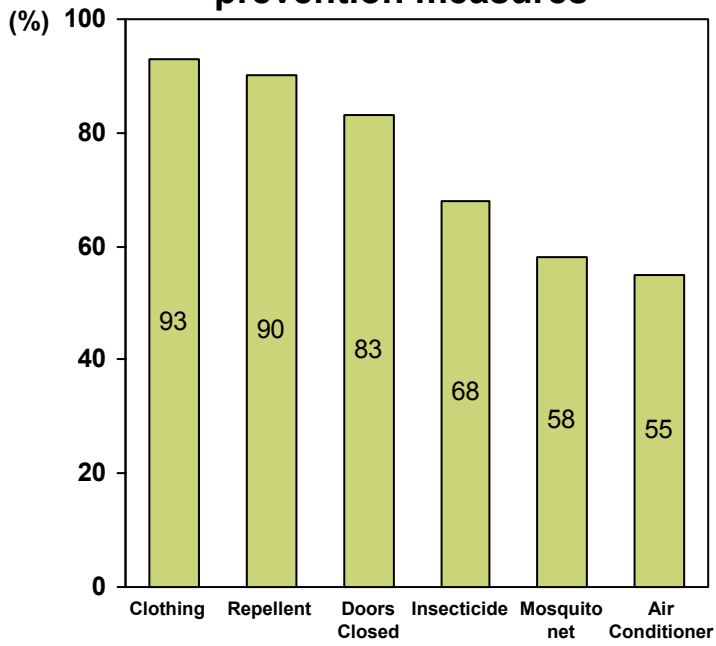
Note: Malaria cases confirmed by blood film are reported to local and state health departments by health-care providers or laboratory staff; number of cases probably underreported; "Imported malaria" refers to malaria acquired outside the U.S. and its territories

Source: CDC Malaria Surveillance Report 2002

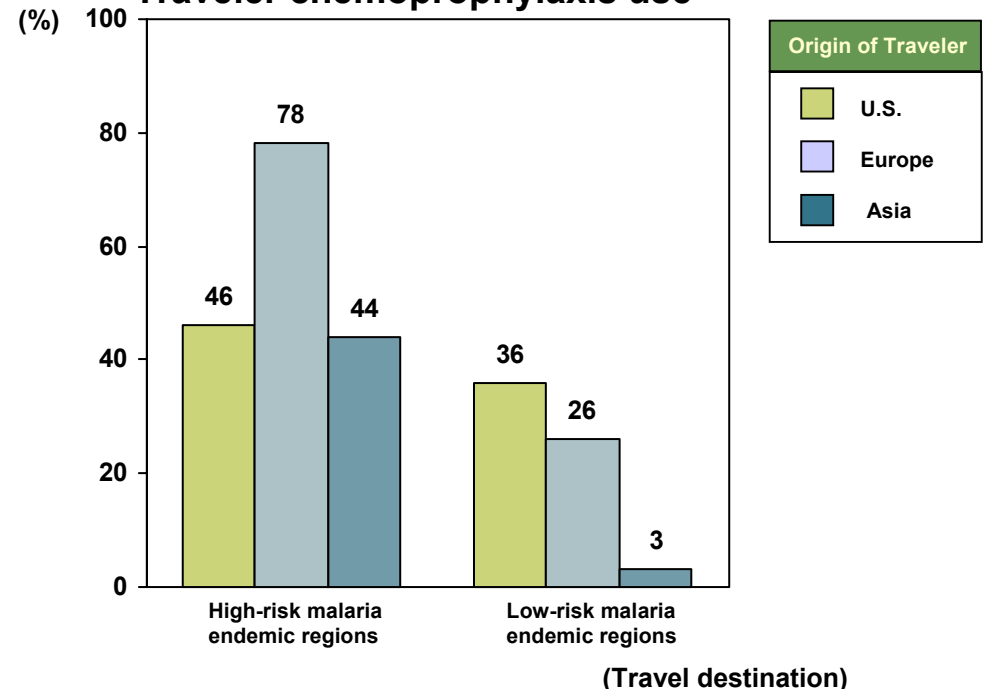


GENERAL MALARIA PROTECTION IS HIGH AMONG TRAVELERS TO ENDEMIC REGIONS BUT MANY DO NOT TAKE CHEMOPROPHYLAXIS

Traveler general malaria prevention measures⁽¹⁾

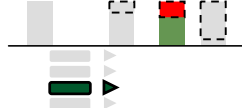


Traveler chemoprophylaxis use⁽²⁾



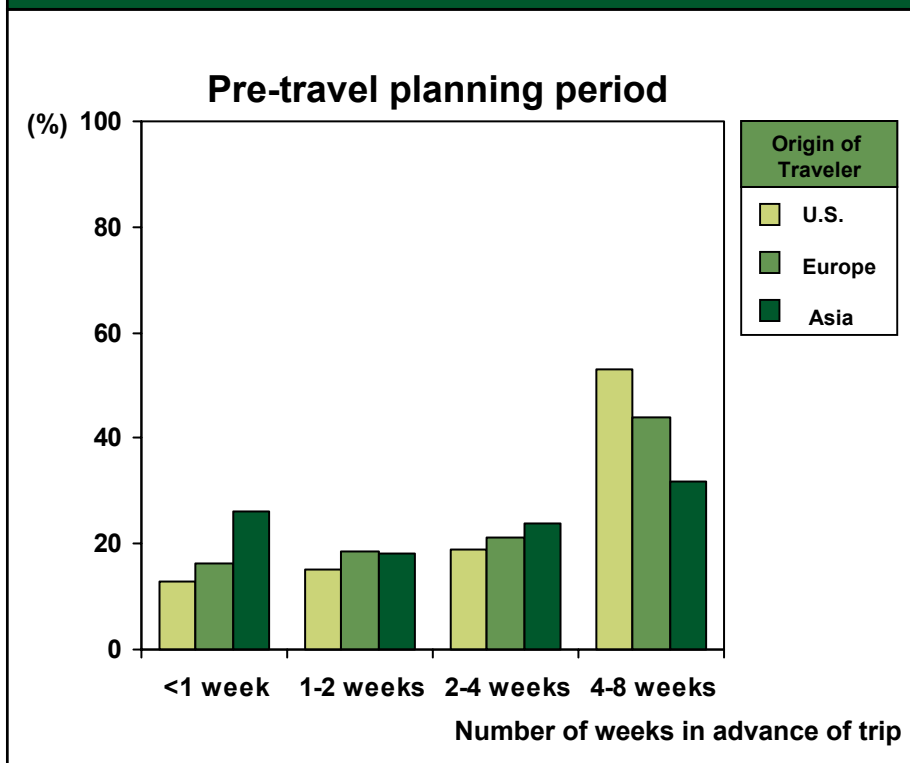
(1) Journal of Travel Medicine, Volume 11, Issue 01, 2004, January "Travelers' Knowledge, Attitude and Practices on the Prevention of Infectious Diseases". Interviews conducted in Johannesburg Airport, Inclusion Criteria: European residents on intercontinental flights. High-risk malaria destinations were tropical Africa, Papua New Guinea and the Solomon Islands with regional and seasonal exceptions. Low-risk malaria regions were endemic regions in Latin America, Asia and Southern Africa. 219 malaria and 200 vaccine preventable questionnaires were available for analysis.

(2) Journal of Travel Medicine, "Travel Health Knowledge, Attitudes and Practices among U.S. travelers" 404 respondents, interviews conducted in JFK airport among travelers going to target destination country identified as high risk. High risk countries for malaria were Ghana, Nigeria, Liberia, Tanzania and Kenya. Low-risk were: rural areas with known risk of malaria such as Brazil, Ecuador, DR, China, The Philippines, Thailand, Guyana and El Salvador. "Travelers Knowledge, Attitudes and Practices on Prevention of Infectious Diseases: Results from a Pilot Study" 609 responses from European travelers boarding flights to developing countries (Africa, Asia, excluding Japan and Singapore, and Latin America) "Travel Health Knowledge, Attitudes, and Practices among Australasian travelers" 21011 surveys conducted at five airports in Australasia, distributed to passengers from flights to countries in Asia, Africa, and South America. High risk malaria areas were all rural/jungle areas in Asian Countries except for Northern China, Singapore, Taiwan and Japan and all Sub-Saharan countries.

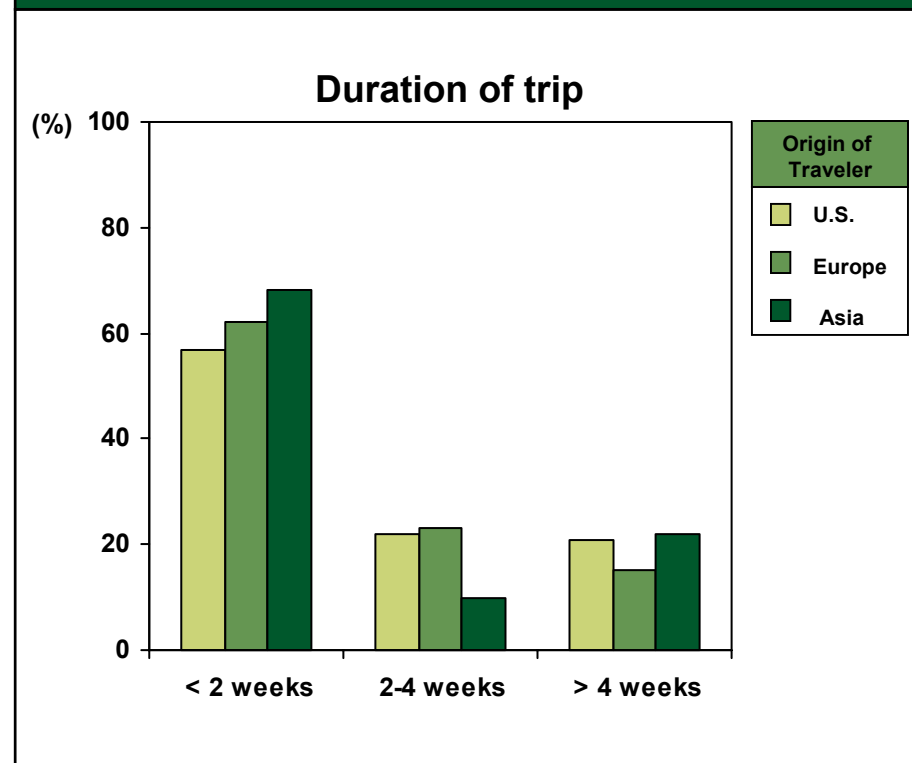


TIMING OF IMMUNIZATION AND DURATION OF TIME IN COUNTRY IS CRITICAL FOR A POTENTIAL MALARIA VACCINE

Only 30-50% of travelers plan at least 4-8 weeks in advance



Most travelers remain in destination < 2 weeks

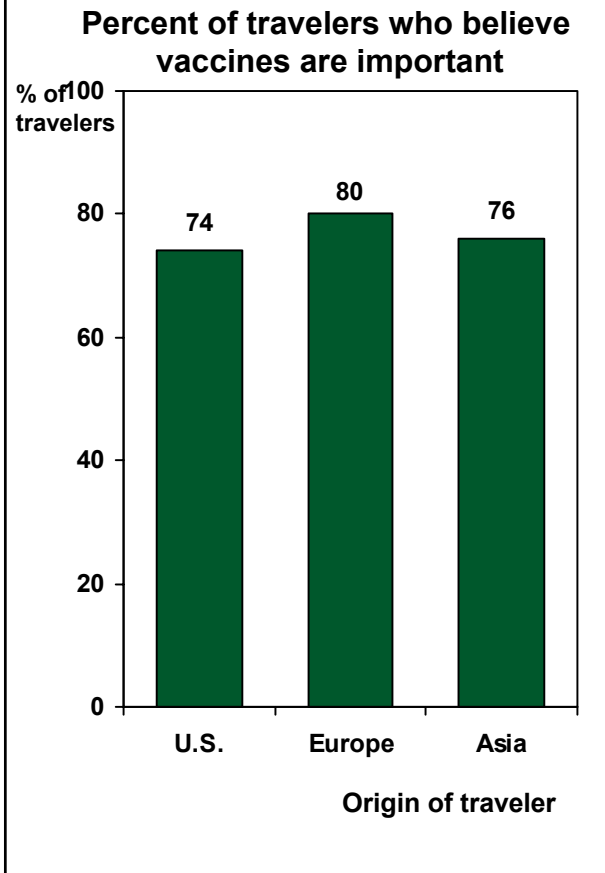


Depending on profile, vaccine most useful for travelers who plan in advance and/or take long trips

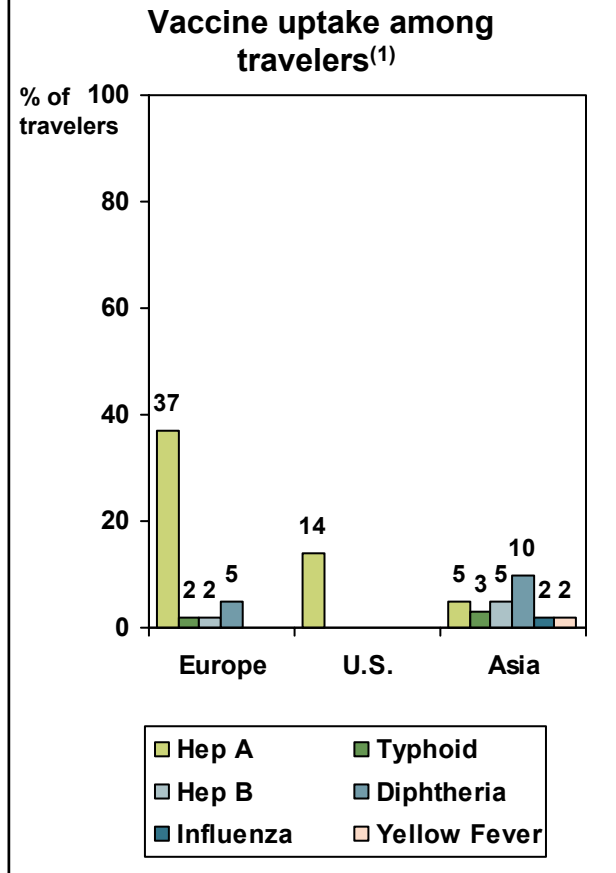
Source: Graph I and II from combined studies (U.S., Europe, and Australasia traveler) Journal of Travel Medicine "Travel Health Knowledge, Attitudes and Practices among U.S. travelers", "Travelers Knowledge, Attitudes and Practices on Prevention of Infectious Diseases", "Travel Health Knowledge, Attitudes and Practices among Australasian travelers"

ALTHOUGH TRAVELERS THINK HIGHLY OF VACCINES, FEW USE THEM TO PROTECT AGAINST INFECTIOUS DISEASES

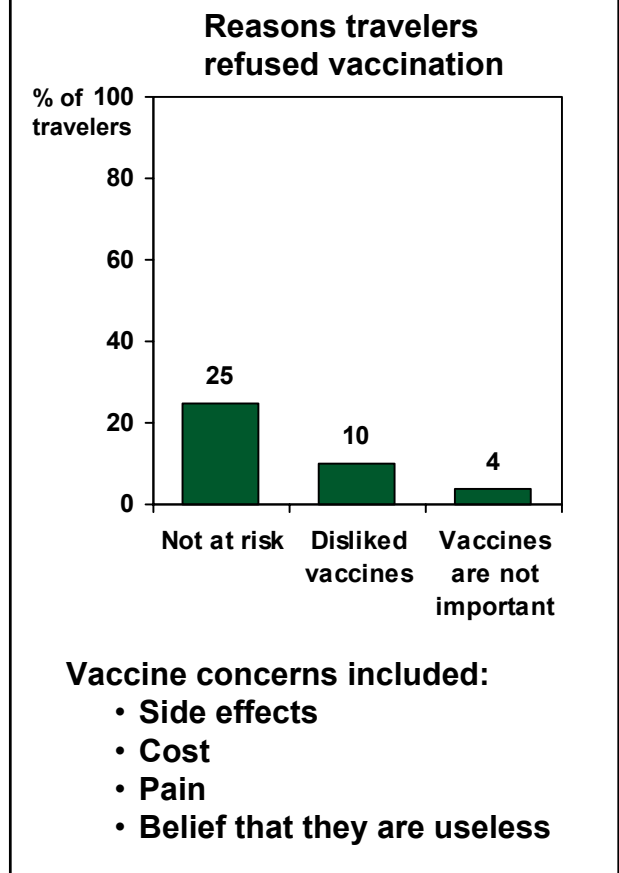
Vaccine opinion rate high among travelers ...



...but Hep A uptake is low



Variety of reasons drive low uptake



(1) Vaccine uptake information not available for all countries

Note: Hep A protection surveyed among travelers at risk of contracting the disease in country of destination, study methodologies in backup slides

Source: Journal of Travel Medicine: Volume 11, issue 01, 2004, "Travel Health Knowledge, Attitudes, and Practices among U.S. travelers"; Volume 10, Issue 02, 2003, "Travelers Knowledge, Attitudes and Practices on Prevention of Infectious Diseases"; Volume 11, issue 01, "Travel Health Knowledge, Attitudes and Practices among Australasian travelers"



TRAVELER VACCINE UPTAKE DEPENDS ON ITS PROFILE

Attribute	Impact on demand	Details	Comments
Efficacy	High	<ul style="list-style-type: none"> • Would need to be at least as efficacious as prophylaxis (98%) • Potential risk of misuse of standby treatment with lower efficacy • Previous low efficacy vaccine (cholera) had low uptake 	<p>“From a public health perspective, there is very low tolerance for risk with travelers”- CDC</p>
Duration	Low	<ul style="list-style-type: none"> • Short nature of “average trip” decreases importance of long duration vaccine 	<p>“A 30% efficacy vaccine is too low. It would be a hard sell”- Canadian KOL</p>
Cost	Medium	<ul style="list-style-type: none"> • Price sensitivity may depend on health-care system and drug coverage in home country • Cost relative to chemo-prophylaxis will likely drive demand • Travelers seem less price-sensitive if side effects of chemo-prophylaxis could be avoided 	<p>“Cholera vaccine has been highly ineffective”- CDC</p> <p>“Cost of treatment is a hurdle for a lot of people”- CDC</p>
Species	Medium	<ul style="list-style-type: none"> • Falciparum primary requirement for travelers • However, lack of vivax efficacy could hurt vaccine credibility or generate negative impressions 	
Administration	High	<ul style="list-style-type: none"> • Time required between administration and departure will be key driver in vaccine usefulness given wide variation in planning habits observed 	<p>“There is a general public dislike to taking tablets- U.K.” KOL</p>
Education	High	<ul style="list-style-type: none"> • Increasing population that seek pre-travel medical advice could heavily influence number that can receive vaccine • Traveler attitudes towards vaccines vs. tablets also important 	<p>“People are still afraid of needles”- KOL</p>

KEY TAKEAWAYS

Travelers Market

Frequency of international travel to high-risk malaria areas is growing

- **22 MM arrivals in 2002 and 60 MM projected in 2020**

Traveler behavior varies significantly in chemoprophylaxis use, pre-travel planning habits, duration of trips, and attitudes toward vaccines

- **78% of European travelers to high-risk malaria areas take prophylaxis vs. 46% of American travelers to high-risk malaria areas take prophylaxis**
 - however, in low risk areas, prophylaxis use by Europeans lower than by Americans
- **30-50% of travelers plan trips 4-8 weeks in advance**
- **> 50% of travelers spend less than 2 weeks in destination region**

Key demand drivers are efficacy, timing of immunization, education, duration of trip

- **Vaccine must be as effective as available prophylaxis (~98%)**
- **Vaccine most useful if effective within a month of travel due to travel planning habits**
- **Market likely limited by number of people who seek pre-travel health advice from a physician**
- **Vaccine most useful for people who remain in destination for long periods of time (over 1 month)**

Ultimate demand will depend on product profile trade-offs with available prophylaxis options

MILITARY MARKET ALSO HAS SPECIFIC PRODUCT REQUIREMENTS



Public market



- Population of endemic country

- Product profile

- Coverage of target pop.
- Donor funding
- Hurdles to adoption

- Decision making and attitudes of government, KOLs

Private market



- Population of endemic country

- Product profile

- Private clinic access
- Income levels

- Individual attitudes

Travelers



- Travelers to endemic countries

- Product profile

- Seek advice before traveling

- Prefer vaccine vs. prophylaxis

Military

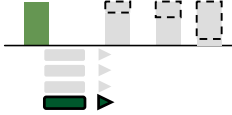


- Worldwide militaries

- Product profile

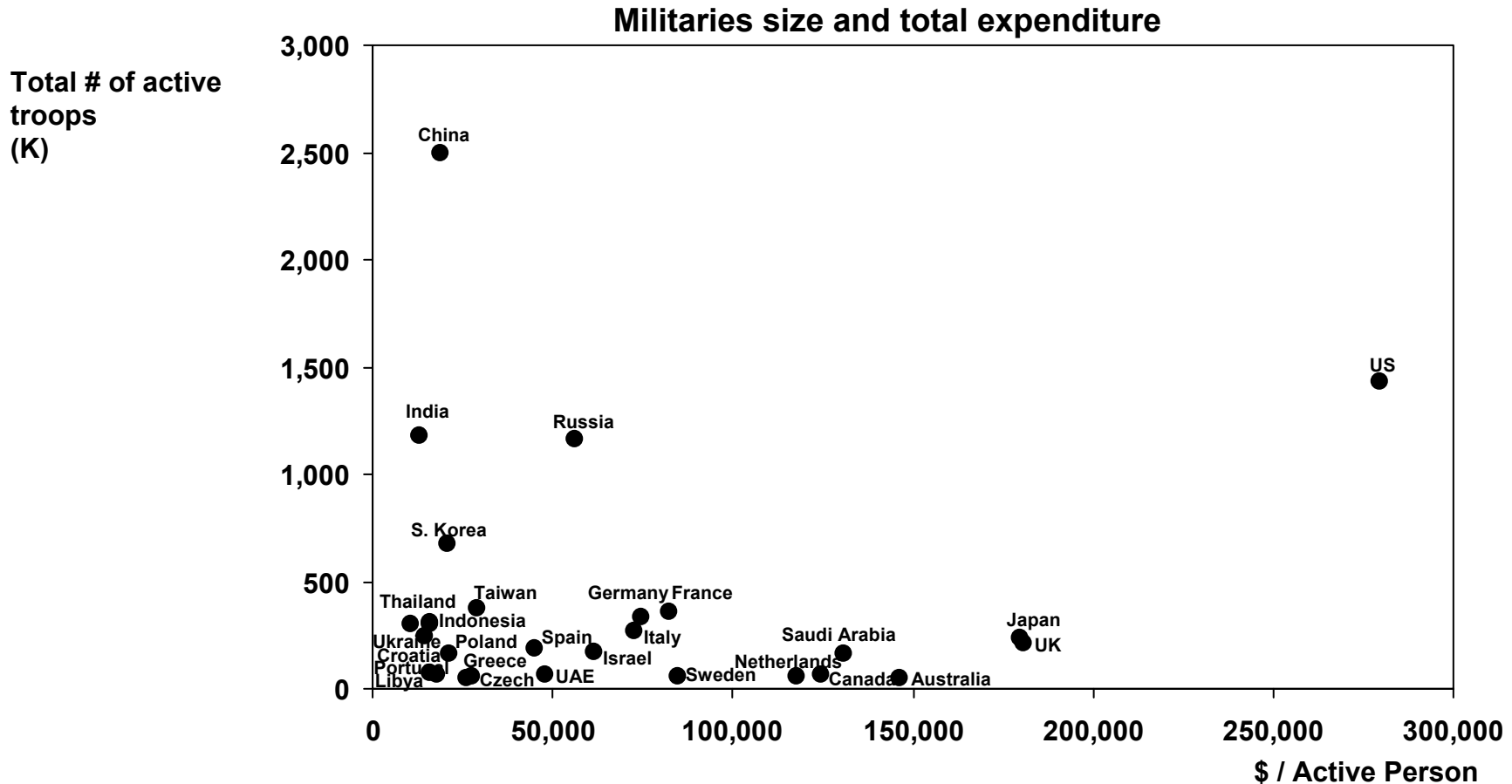
- Military budget

- Vaccinate all vs. deployed vs. none



OVER 18 MM PEOPLE SERVE IN MILITARIES WORLDWIDE

US Leads In Military Spending



Note: Includes only militaries with over 50,000 active members and over \$10,000 / member

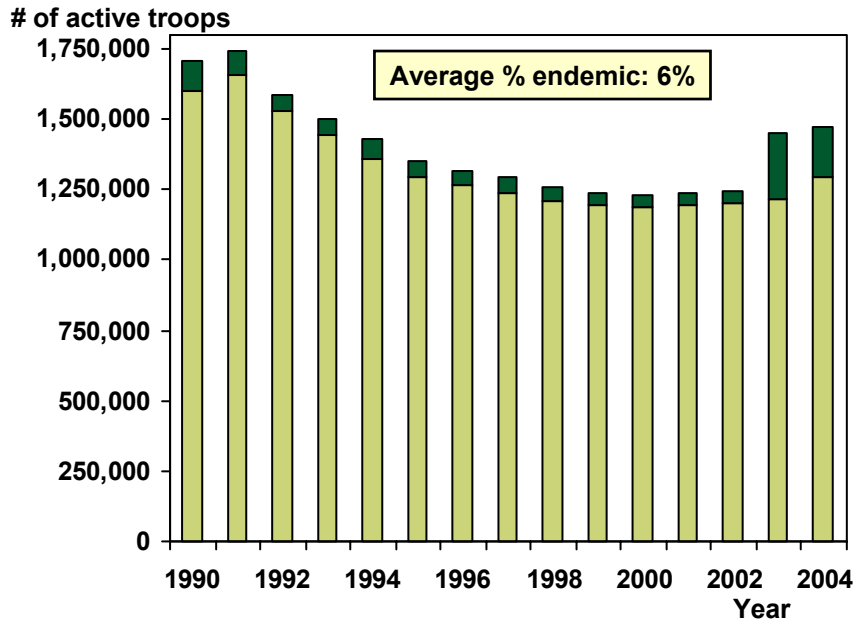
Source: US Dept. of Defense, IISS "Military Balance," World Military Expenditures and Arms Transfers" Bureau of Arms Control, Center for Disease Information

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TROOPS ARE CONTINUALLY DEPLOYED TO MALARIA-ENDEMIC REGIONS

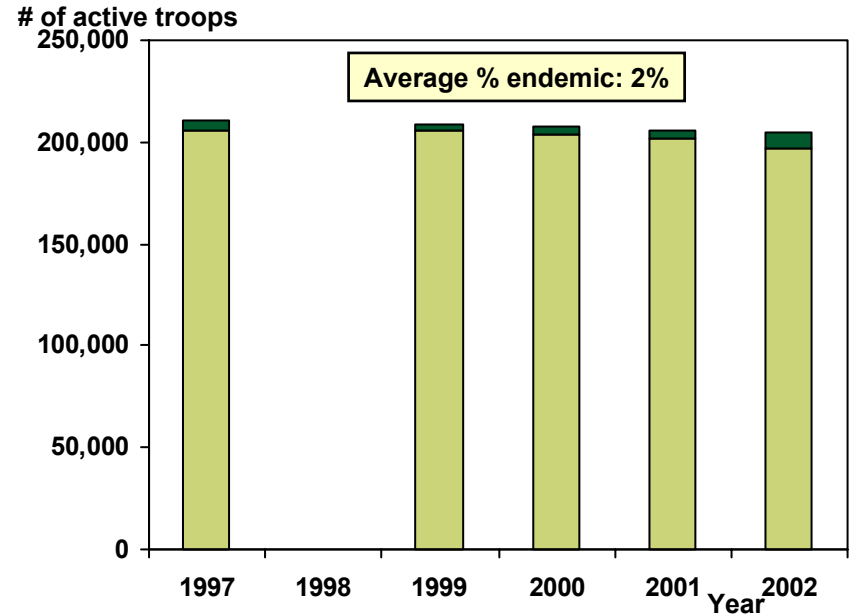
US military deployments (1990-2004)



Average length of deployment 110 days

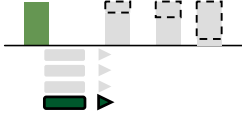


UK military deployments (1997-2002)



Average length of deployment 180 days

- Of US troops deploying to non-US locations from 1990-2004, 26% were sent to malaria endemic regions
- % of troops exposed to malaria endemic regions higher due to deployment cycles



MILITARIES FOCUS ON READINESS AND PREVENTING ILLNESS

Malaria Vaccine Has Potential To Maximize Both

“Once military personnel is sick, they are useless for a mission” -WRAIR

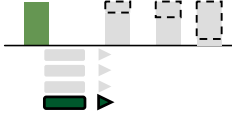
“The military’s main concern and what a vaccine would be mainly used for is to prevent illness” -KOL

“Focus is to prevent malaria, full-stop” – British Forces

“Soldiers need to be prepared to be deployed anywhere, if need be” – WRAIR

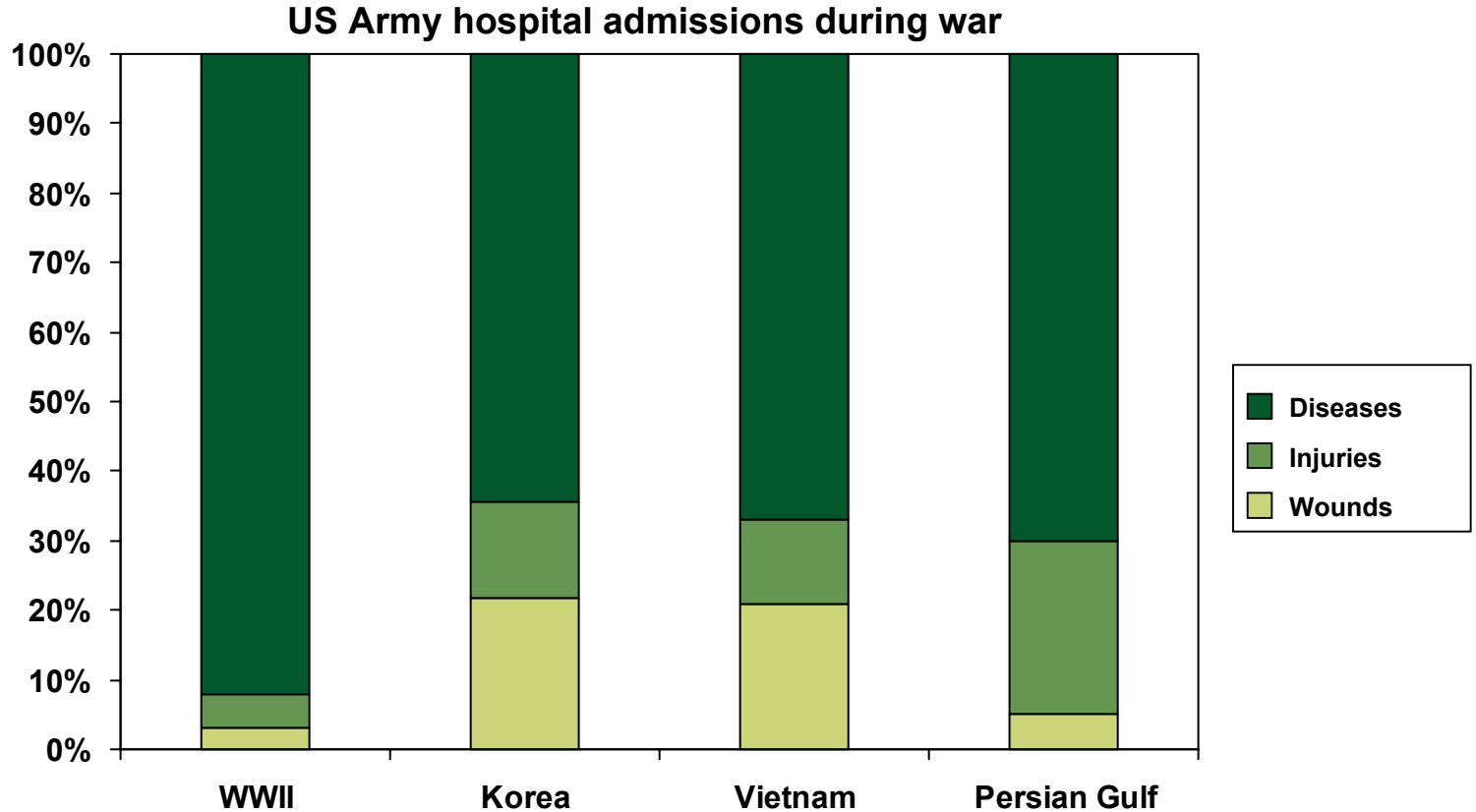
“Troops becoming unwell will affect operational capabilities...this is unacceptable” –British Forces

“Malaria control is seen as a fundamental performance metric of battalion commanders” - Indian Army



ILLNESS IS A SERIOUS ISSUE FOR MILITARIES

More Soldiers Die From Diseases Than from Wounds and Injuries



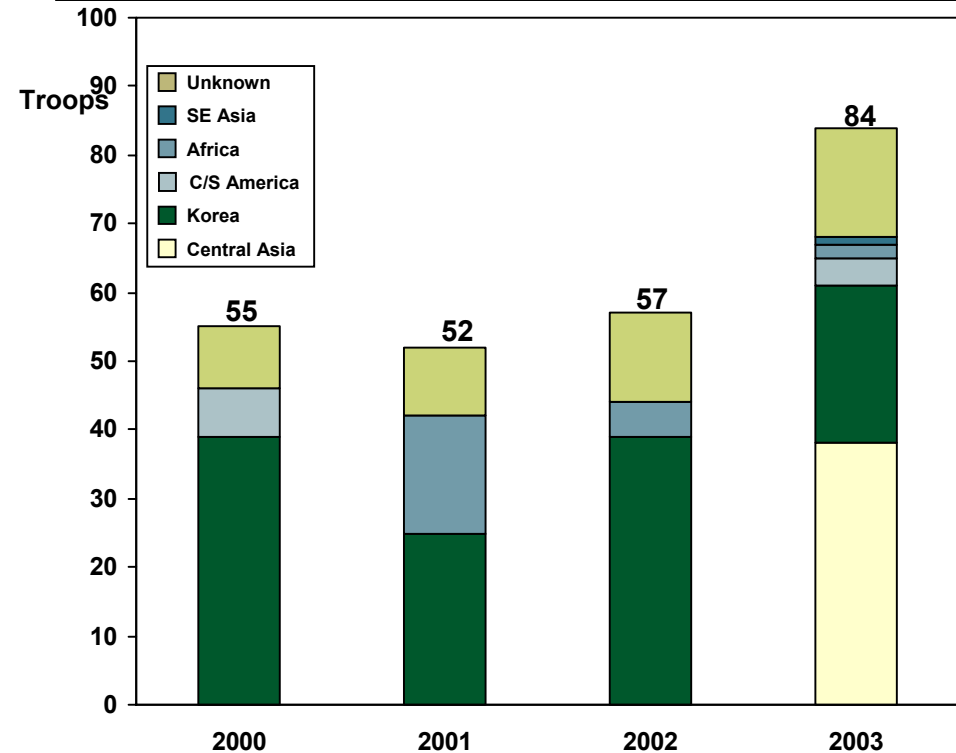
In Somalia and Operation Restore Hope, malaria was the No. 1 cause of casualties

CURRENT TACTICS FOCUS ON PREVENTION, BUT COMPLIANCE ISSUES MEAN THAT MALARIA IS STILL A CONCERN

Three key preventative actions in US military

- 1 Personal Prevention**
 - DEET
 - Uniform repellent
 - Protective clothing
- 2 Chemoprophylaxis**
 - Chloroquine
 - Mefloquine
 - Doxycycline
 - Primaquine
- 3 Unit Protection**
 - Bulk repellent
 - Camp selection
 - Mosquito surveys
 - Insecticides
 - Early diagnosis

US military malaria incidence (2000-2003)



Compliance drops largely due to long deployment times
- US deployments average 110 days, UK deployments average 180 days

MILITARIES ACTIVELY VACCINATE THEIR TROOPS

All troops receive

United States

Influenza
Measles
Meningococcal
(A,C,Y,W-135)
Mumps
Polio
Rubella
Tetanus
Diphtheria
Hepatitis A

United Kingdom

Meningococcal C
Polio
Tetanus
Diphtheria
Yellow Fever
Hepatitis A
Typhoid
TB

“The military currently gives Hep A vaccine to all its soldiers. They made major purchases in recent years and the only reason they did so was because Hep A was a major problem in North Africa during World War II” –KOL

Troops deploying to high risk areas receive

United States

Yellow Fever
Typhoid
Japanese Encephalitis

Occupational Risk:
Hepatitis B
Plague
Rabies
Varicella
Small Pox
Anthrax

United Kingdom

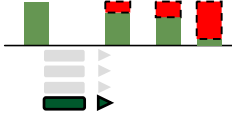
Meningococcal A
Japanese Encephalitis
Rabies
Encephalitis (tick)

Occupational Risk:
Hepatitis B
Rubella

“Soldiers deployed to Korea had to take the anthrax vaccine, those travelling to Kuwait took the small pox vaccine, those going to Kenya received the yellow fever vaccine and some going to Asia received the JE vaccine” -WRAIR

Comfort with vaccination as a prevention technique could drive demand for a potential malaria vaccine

- **“The most efficient, cost-effective and easiest way to prevent any infectious disease is with a vaccine” –Naval Medical Research Institute**



MILITARY DEMAND HINGES ON VACCINE PROFILE

Unique Set of Challenges For Military Markets

Attribute	Impact on Demand	Details	Comments
Efficacy	High	<ul style="list-style-type: none">• Efficacy against clinical disease most important<ul style="list-style-type: none">- 50-80% threshold mentioned	<p>“A malaria vaccine needs to be very effective for troops in the field” -KOL</p>
Duration	Medium	<ul style="list-style-type: none">• Duration will drive whether some or all troops receive a vaccine<ul style="list-style-type: none">- 4-6 month minimum mentioned	<p>“It needs to be highly effective for 4-6 months at least” -WRAIR</p>
Cost	Split High/Low	<ul style="list-style-type: none">• Cost not an issue for high expenditure forces• Cost an issue for lower budget forces	<p>“Price/cost of the vaccine is not an important issue” -WRAIR</p>
Species	Low	<ul style="list-style-type: none">• Military cannot afford to have anyone sick<ul style="list-style-type: none">- species of disease not important- military affected by all species	<p>“A large section would have to be inoculated...this is unlikely to be cost effective” - Indian army</p>
Administration	Medium	<ul style="list-style-type: none">• 6 month window to reach recruits• 1 month window to reach deploying troops	
Safety	High	<ul style="list-style-type: none">• Safety a big issue; must not hinder ability to train or fight	<p>“Safety is a huge issue” -WRAIR</p>

KEY TAKEAWAYS

Military Market

Preparedness is essential to maintaining an alert force

- **Malaria incidence is problematic for militaries**
 - largely due to low chemoprophylaxis compliance from extended deployments

Vaccine used regularly as preventative tool

Demand will hinge on vaccine characteristics

- **Safety is key**
 - troops must be able to train and fight without side effects or risks
- **Militaries will immunize segments of personnel based on vaccine profile**
 - All troops vs. troops deploying to high-risk areas
- **Efficacy against clinical disease is critical**
 - militaries cannot afford illness; “a sick soldier is a useless soldier”
 - vaccine must compete with prophylaxis compliance levels (50-80%)
- **Cost not an issue for militaries with high expenditures (i.e. US, UK, Japan), but may significantly affect demand from militaries with smaller budgets**

TABLE OF CONTENTS

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Implications and next steps

Appendix

MALARIA VACCINE DEMAND MODEL NEEDS TO BE FLEXIBLE AND TRANSPARENT DESPITE INHERENT COMPLEXITY

Key model attributes

Realistic

Base demand estimate logic on well-established and reliable data and reasonable assumptions

Transparent

Build user-friendly, logical model without a “black box” component

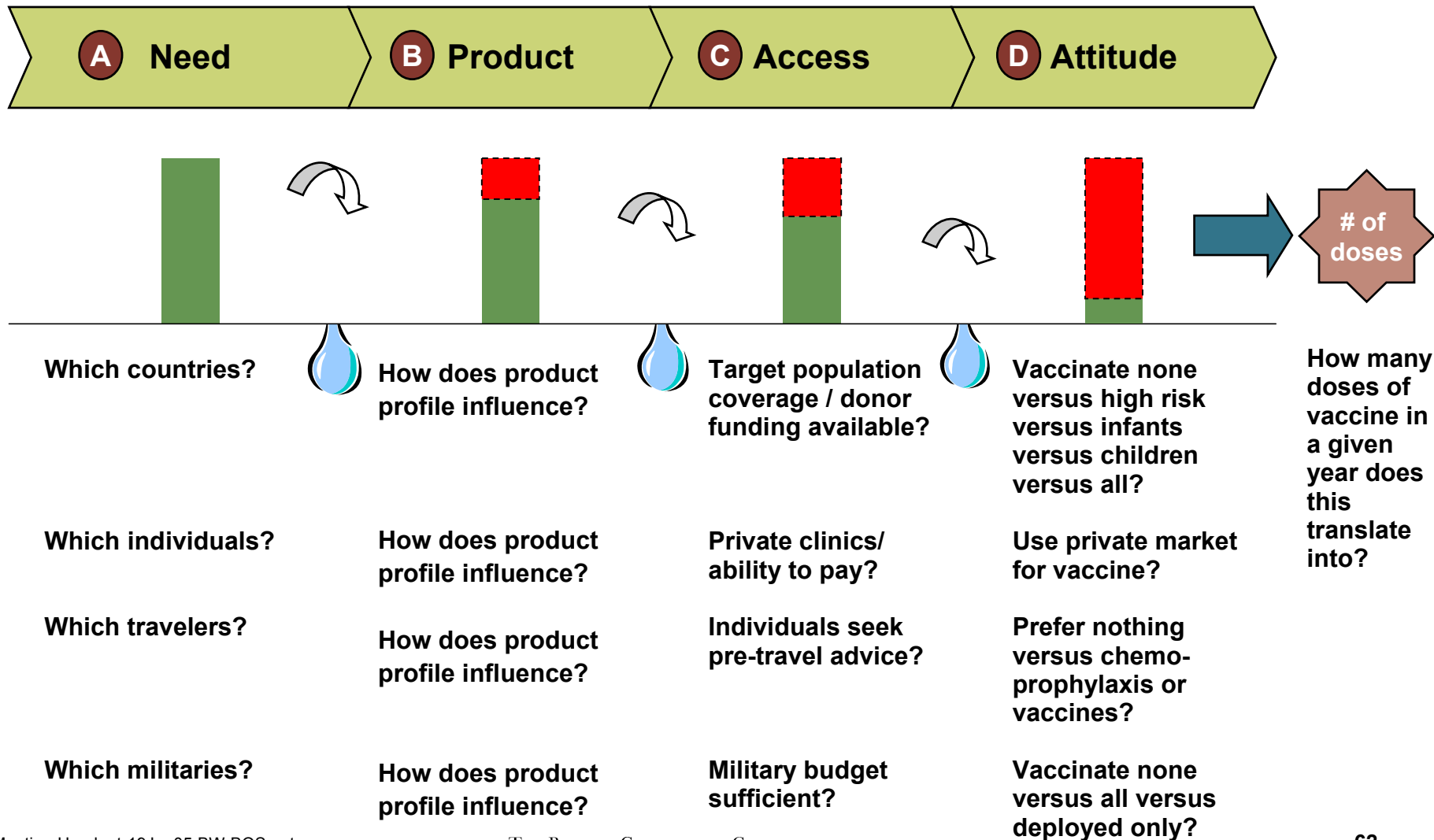
Flexible

Allow MVI to improve quality of estimates through future research and model adaptation

Concrete

Generate actual demand forecast ranges and sensitivities that are as accurate as possible given current data availability

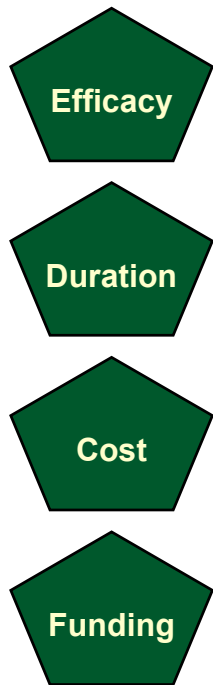
MODEL FOLLOWS THE DEMAND LEAKAGE FRAMEWORK FOR ASSESSING MARKET POTENTIAL



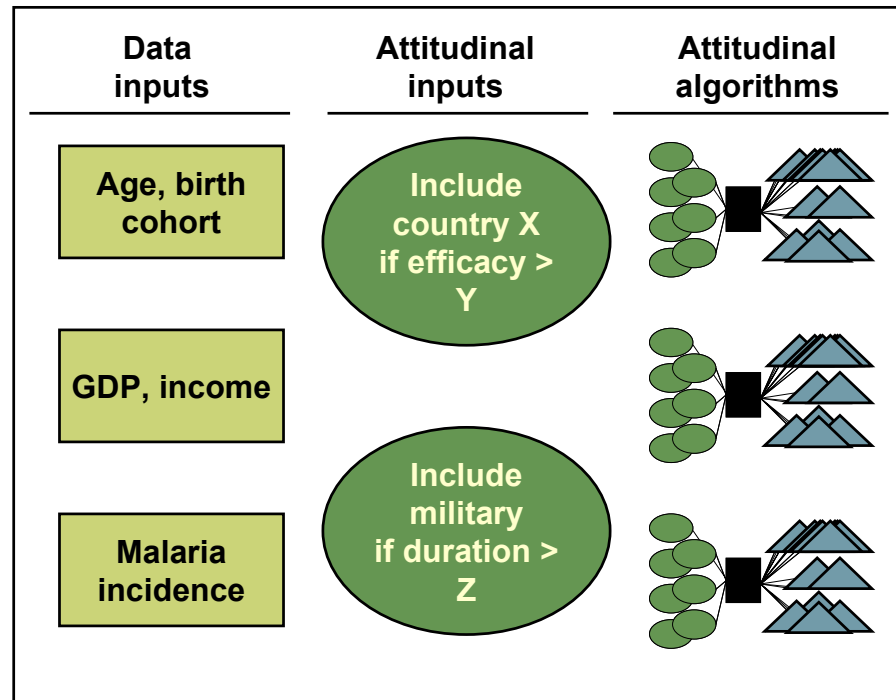
DEMAND MODEL USES SCENARIO DRIVERS, DATA INPUTS, AND ATTITUDINAL ALGORITHMS TO FORECAST DEMAND

Sample Information Flow – Does Not Represent Full Scope of Model

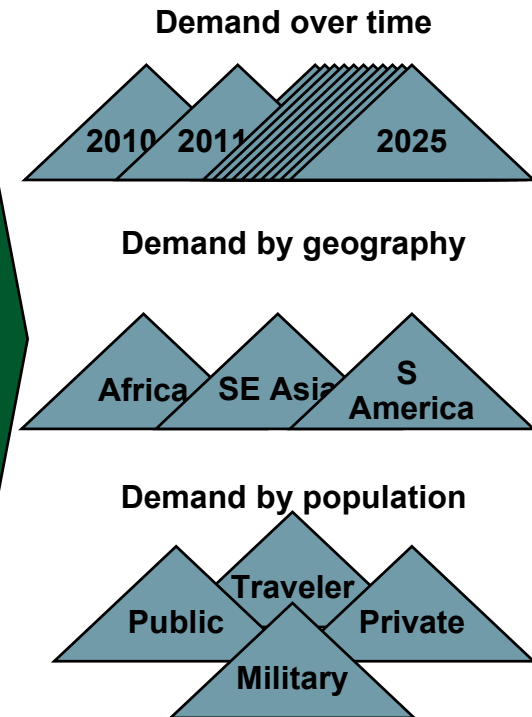
Scenario drivers



Model logic



Modular outputs



Model has flexibility to accommodate changes in vaccine landscape and country characteristics over time

INPUTS AND ALGORITHMS BASED ON FINDINGS FROM PRIMARY AND SECONDARY RESEARCH

Including Extensive Interviews In Eight Endemic Countries

Data inputs based on primary and secondary sources

Secondary data from sources such as:

- WHO/RBM
- World Bank
- UN
- Global Fund
- OECD
- Journal of Travel Medicine
- US Department of Defense

Primary data from interviews

- Data sourced from reports and books published by in-country interviewees

Attitudinal inputs incorporate learnings from country research

Sample algorithms include:

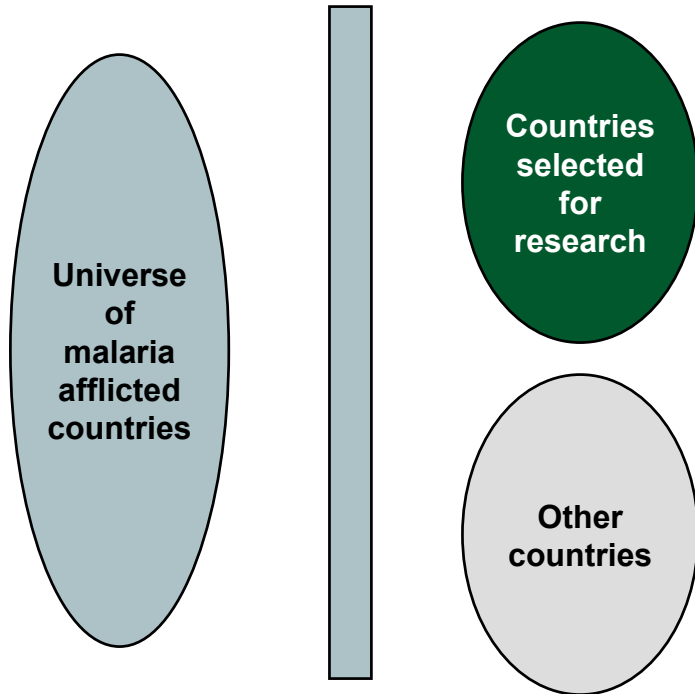
- Product profile threshold to introduce vaccine
- Use of vaccine vs. other components of intervention portfolio
- Attitude of government and donors with respect to demographic and regional targeting of vaccine
- Funding scenarios for the vaccine
- Military criteria for vaccinating all troops vs. deployed troops only
- Travelers choice of chemo-prophylaxis or vaccine

Complete list of sources included in appendix

PRIMARY RESEARCH FINDINGS WERE EXTRAPOLATED TO ALL ENDEMIC COUNTRIES VIA CLUSTERING METHODOLOGY

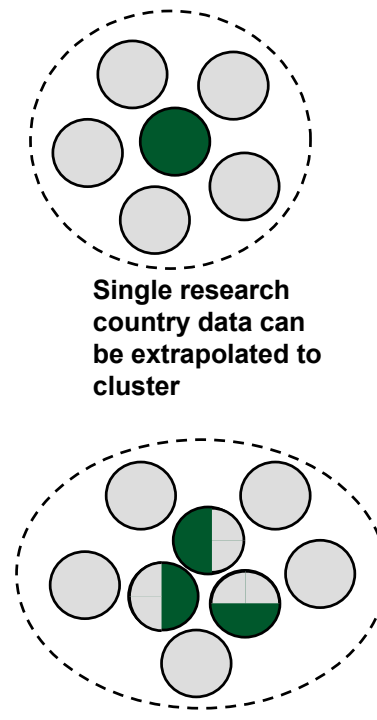
Clustering methodology

Country segmentation and selection for research



Based on need and access/attitude

Country mapping



Based on similarity of malaria related characteristics

Combination of research country data can be extrapolated to cluster

Application in model

Model minimizes the need to cluster to increase accuracy

- Majority of model inputs are objective and specific to countries
- Few inputs based on cluster extrapolation

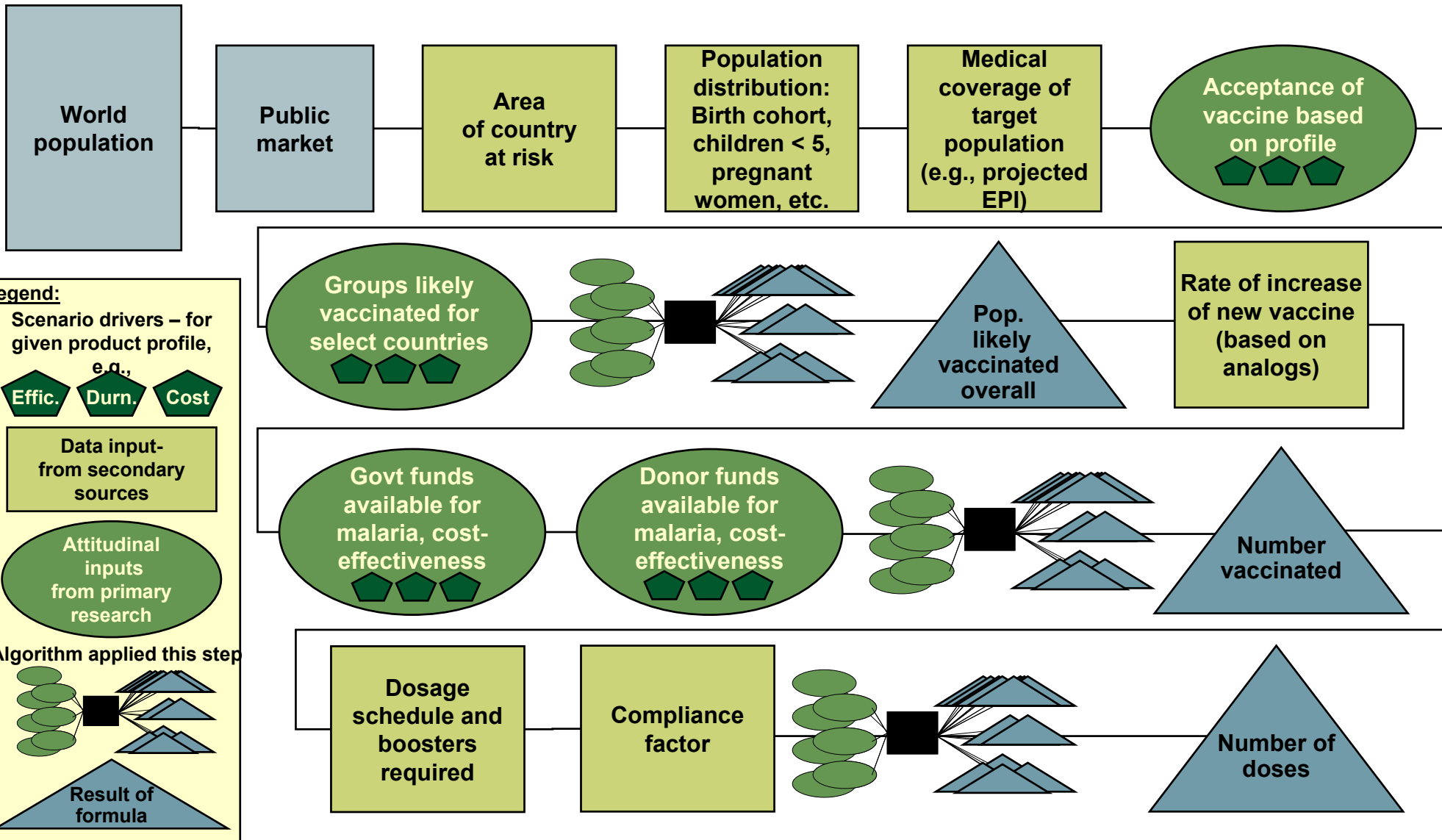
Country specific inputs include:

- Population size
- GDP/income data
- Health care infrastructure
- Access and coverage data

Cluster specific inputs include:

- Product profile levels at which vaccine likely to be accepted
- Attitude of governments with respect to segment of population covered (e.g., infants vs. high risk areas)
- Segments likely to have access to private market

DETAILED INFORMATION FLOW OF PUBLIC MARKET MODULE



METHODOLOGY TO GENERATE UPTAKE SCENARIOS FOR EACH COUNTRY

Define upper threshold for coverage

Run scenarios around upper threshold

Define rate of uptake

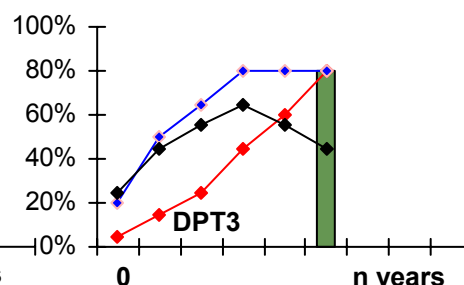
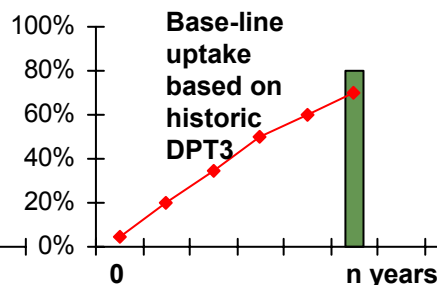
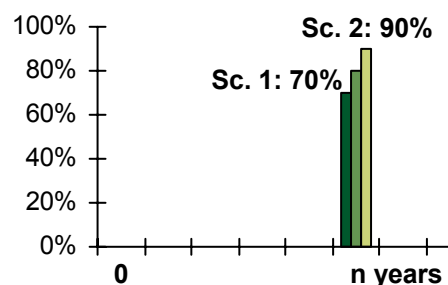
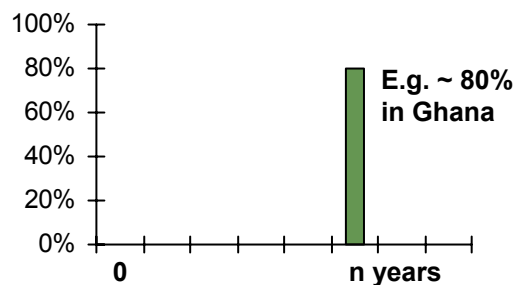
Run scenarios around uptake

- For each country individually
- Based on historic EPI data
 - for different vaccine coverage, e.g. DPT3 as base-line coverage, HepB as high coverage where implemented, others

- Based on progress in economic and health care indicators
- Using regression analysis, e.g. EPI coverage as influenced by GDP/cap
- Using specific scenarios

- Based on historic EPI data
- Baseline defined as uptake of DPT3 average for region

- Based on vaccine analogues
 - e.g. baseline: DPT3 average for region, fast: HepB average where implemented
- Based on scenarios around funding availability, sustainability planning, etc.



INPUTS TO MODEL

Scenario drivers	Data inputs (i)	Data inputs (ii)	Attitudinal algorithms
<ul style="list-style-type: none"> • Efficacy against clinical and severe disease • Duration of action • Cost per dose • Doses required • Boosters required • Plasmodium target <ul style="list-style-type: none"> - P. falciparum - P. vivax • Population <ul style="list-style-type: none"> - Infants - Children < 5 - Pregnant women - HIV positive • Donor funding • Timing of vaccine licensure <ul style="list-style-type: none"> - By age-group - For pregnant women • Post-licensure lag in uptake <ul style="list-style-type: none"> - Due to regulatory and policy development requirements 	<ul style="list-style-type: none"> • Population by country • Population at risk • Projected birth cohort • Projected children < 5 • Historical vaccine uptake by country per vaccine • Projected EPI coverage • Projected peak coverage and rate of increase of coverage for vaccines • Compliance estimates • GNI, per capita and house-hold income distributions • Physicians / capita • Urban vs. rural • Malaria burden per country <ul style="list-style-type: none"> - Incidence - Deaths - Others 	<ul style="list-style-type: none"> • Active military troops per country • % deployed to malaria-endemic regions • Deployment length • Average annual turnover • Budget per soldier • Travelers to developed world from developing • Percent who seek pre-travel advice • Advance window for seeking advice • Percent who take chemo-prophylaxis • Length of trip • Product uptake curves in private, military and travelers markets 	<ul style="list-style-type: none"> • Product profile required for entry in public market • Government view of which populations to vaccinate <ul style="list-style-type: none"> - Age-groups - Regions / states • Product profile required in private market • Attitude toward vaccination in private market • Product profile required in military market • Militaries' likelihood to vaccinate troops • Product profile required in travelers market • Fraction of travelers likely to get vaccine

MODEL ALLOWS US TO RUN SCENARIOS AND SENSITIVITIES AROUND PREDICTED DEMAND

Also Creates Flexible Tool That Can Be Updated Over Time

A flexible and adaptable tool

Model uses base case to incorporate primary research findings and predict demand

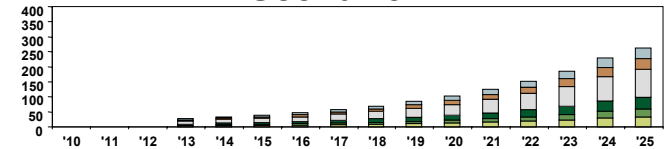
- Inputs are variable and inter-relationships have been built across variables

Therefore, can develop and test complex scenarios around:

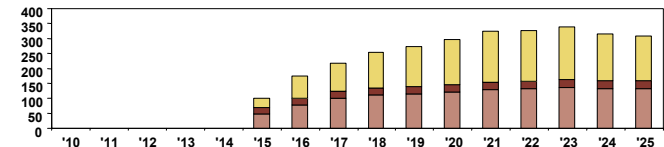
- Product profile
- Country-specific inputs
- Attitudes
- Other

Can also conduct sensitivity analyses around any single variable by changing it incrementally vs. other variables

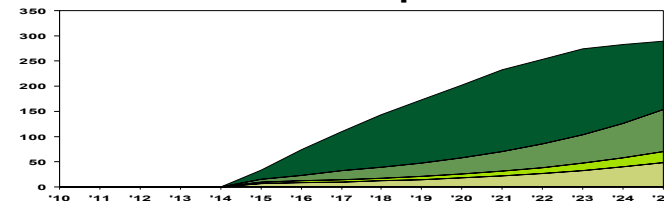
Scenario 1



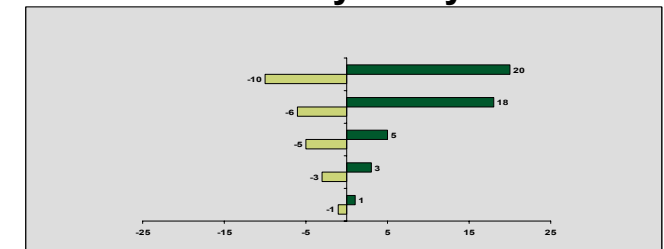
Scenario 2



Scenario Comparison



Sensitivity Analysis



SUMMARY OF MODEL METHODOLOGY

Model needs to be flexible and transparent despite inherent complexity

- **Needs to be realistic, transparent, flexible and concrete**

Model follows the demand leakage framework for assessing market potential

- **Need, Product, Access and Attitude**

Demand model uses scenario drivers, data inputs, and attitudinal algorithms to forecast demand

Inputs and algorithms based on findings from primary and secondary research

- **Including extensive interviews in eight endemic countries**

Primary research was used to understand impact of demand drivers related to attitudes of key stakeholders where secondary data was unavailable

- **Findings from primary research extrapolated to all endemic countries via clustering methodology**

Four key modules in the model project demand for public, private, military and travelers markets

Model allows us to run scenarios and calculate sensitivities around predicted demand

- **Creates flexible tool that can be updated over time**

TABLE OF CONTENTS

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- **Public market**
- **Private market**
- **Travelers market**
- **Military market**

Implications and next steps

Appendix

PUBLIC MARKET DEMAND SCENARIOS

Base Case

Sensitivity

Efficacy

Time of Introduction

Market Uptake

Cost

BASE CASE DEFINITIONS FOR THE PUBLIC MARKET

Base case definition

Product profile of vaccine

- Strain of vaccine: Falciparum
- Efficacy of vaccine: 50% against clinical and 50% against severe disease
- Age-groups: Protection at all age-groups except in pregnancy
- Duration of action: > 1 year
- Dosage: Three doses followed by annual booster
- Cost: US\$ 7 / dose and US\$ 5 incremental delivery cost per course; similar pricing in all malaria afflicted countries

Funding availability

- Donor organizations support malaria programs at current level, ~ US\$ 300 Mn / year
- Funding of vaccine based on cost-effectiveness trade-offs with existing interventions
 - 30% of malaria dedicated funds used to provide vaccines
 - 10% of immunization funds used to provide a malaria vaccine
- Future growth of funds at donor country GDP growth
- Priority given to countries with highest need

Timing of introduction

- Vaccine registered for children < 5 years in 2010, for children > 5 in 2011 and in adults in 2012
- Post-licensure lag 5 years in Africa, 3 – 4 years ROW

Uptake in markets

- Maximum coverage based on EPI performance on DPT projected into the future
- Change in coverage based on past experience with new vaccine introduction

PUBLIC MARKET FOR A MALARIA VACCINE IN 2025 LIKELY TO BE ~70 MM PEOPLE

For a 50% Efficacious Vaccine, Unconstrained by Funding

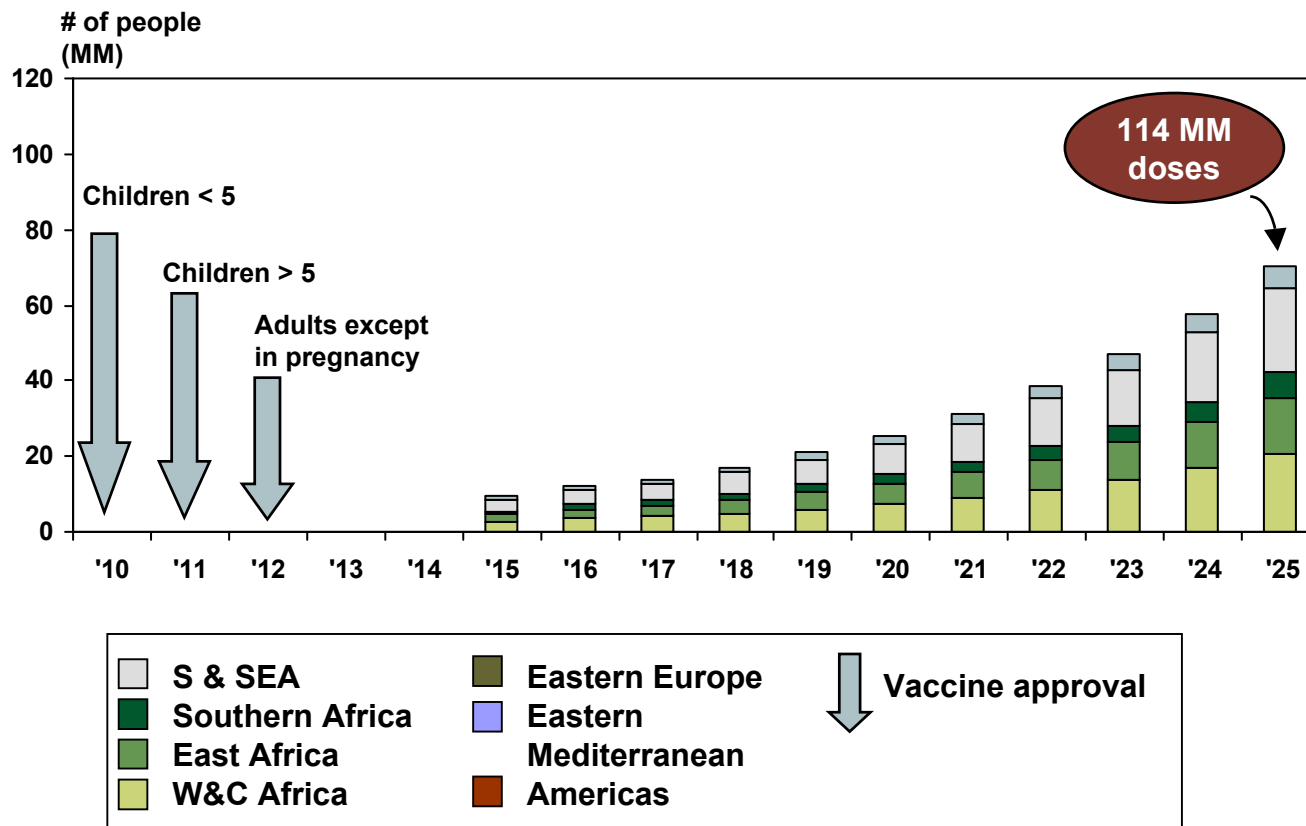
Estimated vaccine demand with no funding constraints (2010-2025)

Key messages

Due to post-licensure introduction lag, uptake only begins 5 years after vaccine approval

Majority of demand from Africa due to lower efficacy levels of vaccine

Demand estimate assumes sufficient funding is available to fund all doses that can be delivered



LEADING TO A MARKET SIZE IN 2025 OF 114 MM DOSES

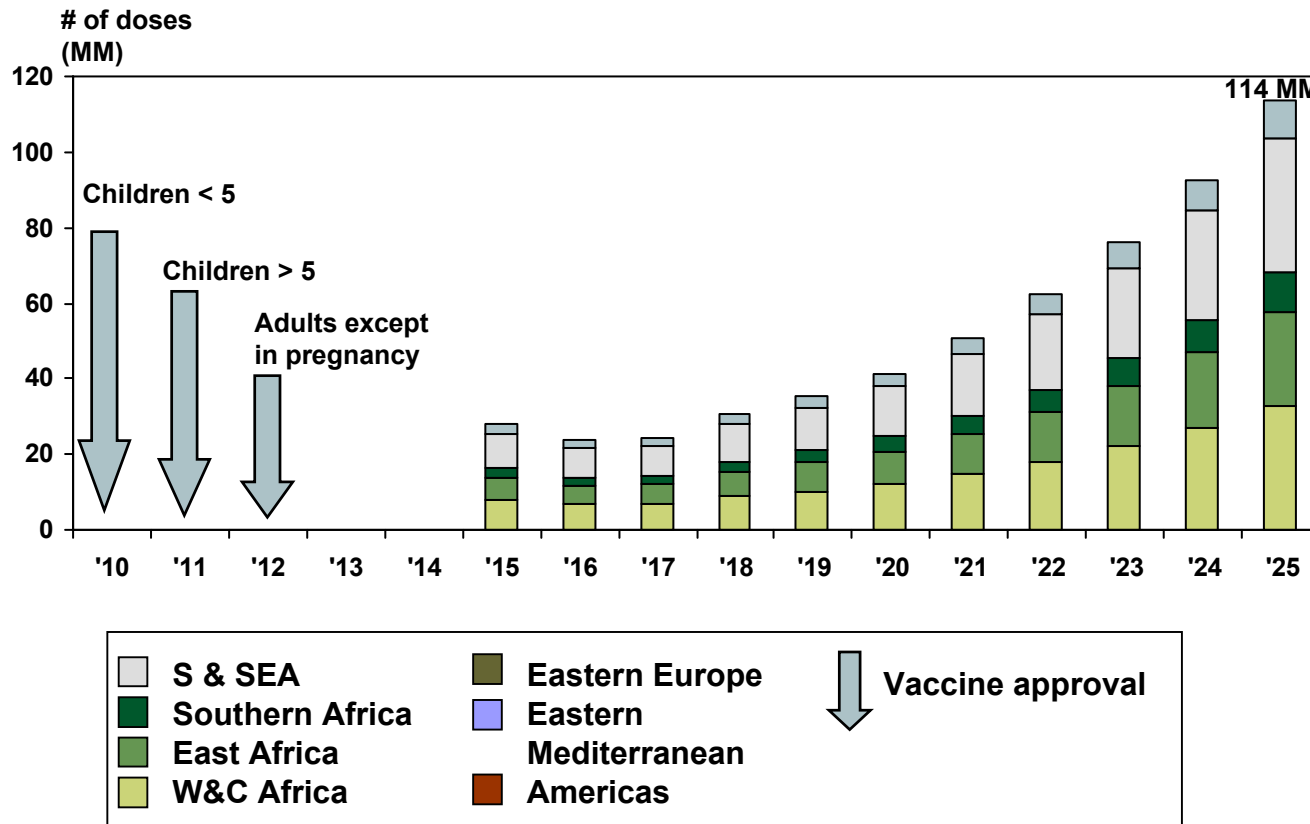
For a 50% Efficacious Vaccine, Unconstrained by Funding

Estimated vaccine demand with no funding constraints - Doses (2010-2025)

Key messages

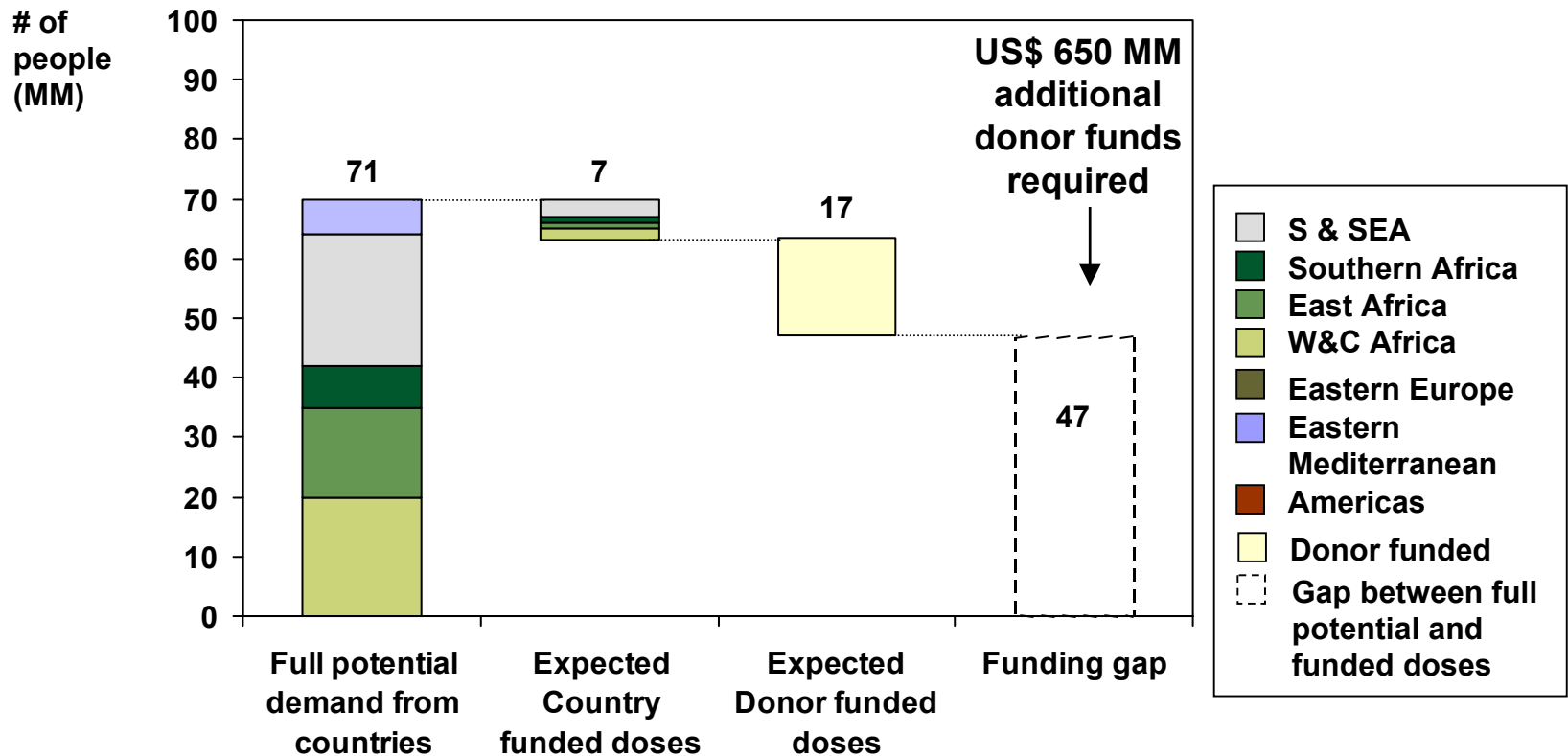
Conversion of number of vaccinated people to doses depends on

- Age profile of populations
- Boosters required by vaccine
- Compliance rate



HOWEVER, ONLY 35% OF FULL POTENTIAL DEMAND IS LIKELY TO BE FUNDED AT CURRENT DONOR ACTIVITY LEVELS

Comparison between full potential demand and funds likely to be available (2025)



Donor activity at the current level insufficient to fund full potential demand, 47 MM additional people could be protected with full funding

Note: Assuming current levels of donor activity in the future

Source: BCG analysis
70685-02-DC Meeting-Handout-19Jan05-BW-BOS.ppt

FUNDING GAP INCREASES OVER TIME FROM 1 MM PEOPLE IN 2019 TO 47 MM PEOPLE IN 2025

Vaccine demand likely to be funded at current donor activity levels (2010-2025)

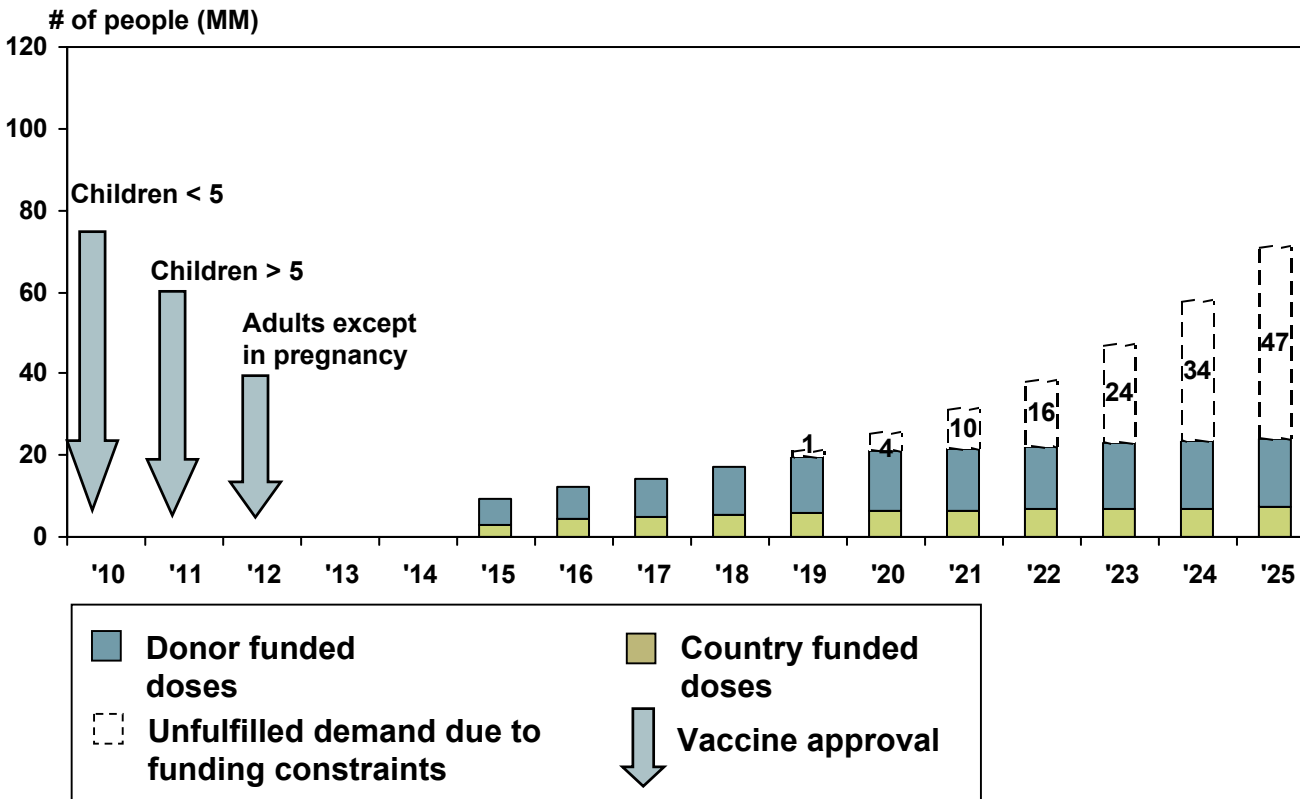
Key messages

Countries unable to fully self-fund demand

- As majority of demand for a 50% efficacious vaccine is from high burden, low income countries

Donor activity at current levels insufficient to vaccinate all people who could be reached

Gap increases over time as potential coverage increases faster than ability to fund a vaccine



Note: Assuming current levels of donor activity in the future

Source: BCG analysis

70685-02-DC Meeting-Handout-19Jan05-BW-BOS.ppt

PUBLIC MARKET DEMAND SCENARIOS

Base Case

Sensitivity

Efficacy

Time of Introduction

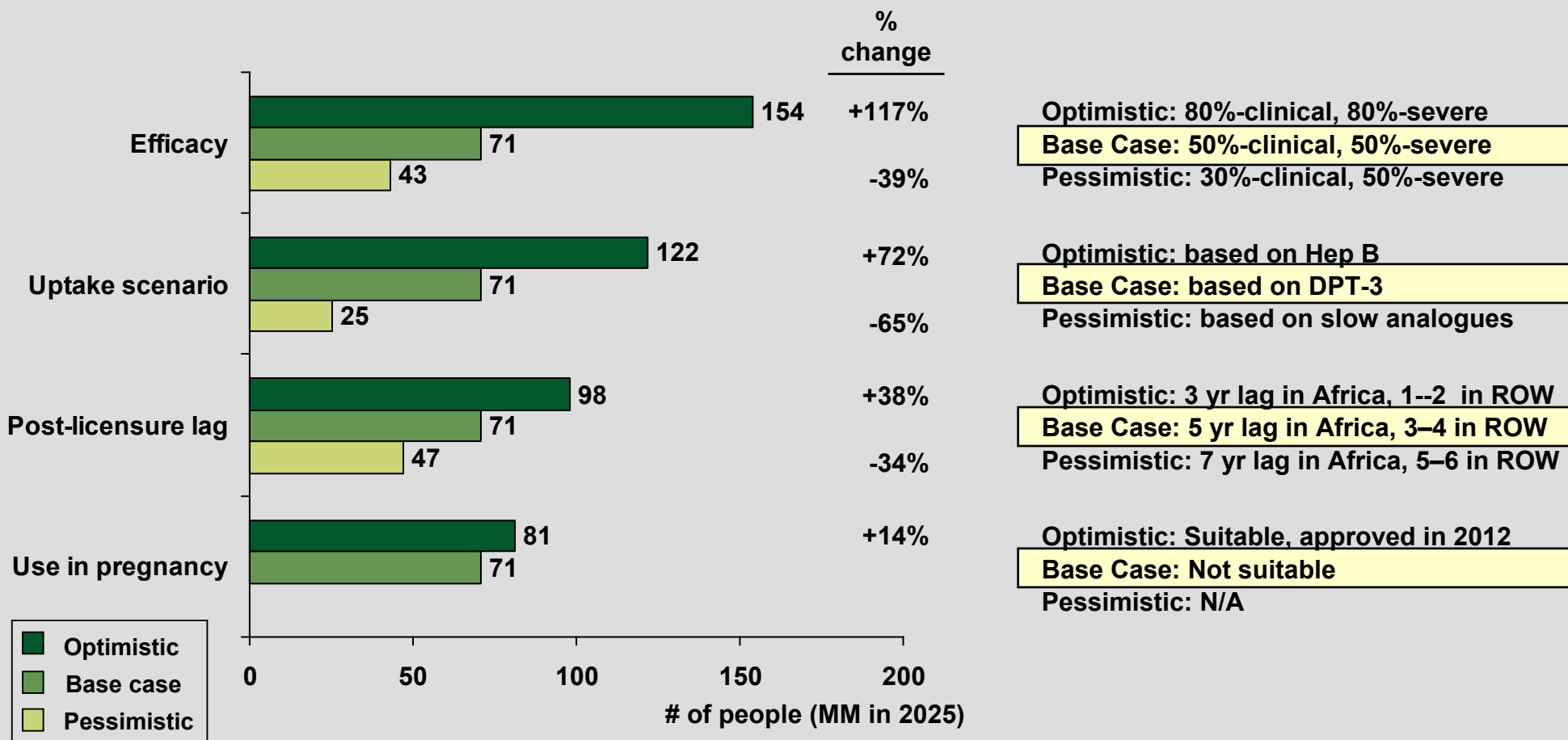
Market Uptake

Cost

DEMAND FOR A MALARIA VACCINE MOST SENSITIVE TO EFFICACY AND UPTAKE SCENARIOS

For Demand Unconstrained By Funding Availability

Sensitivity of funding unconstrained demand to model inputs (MM of people IN 2025)



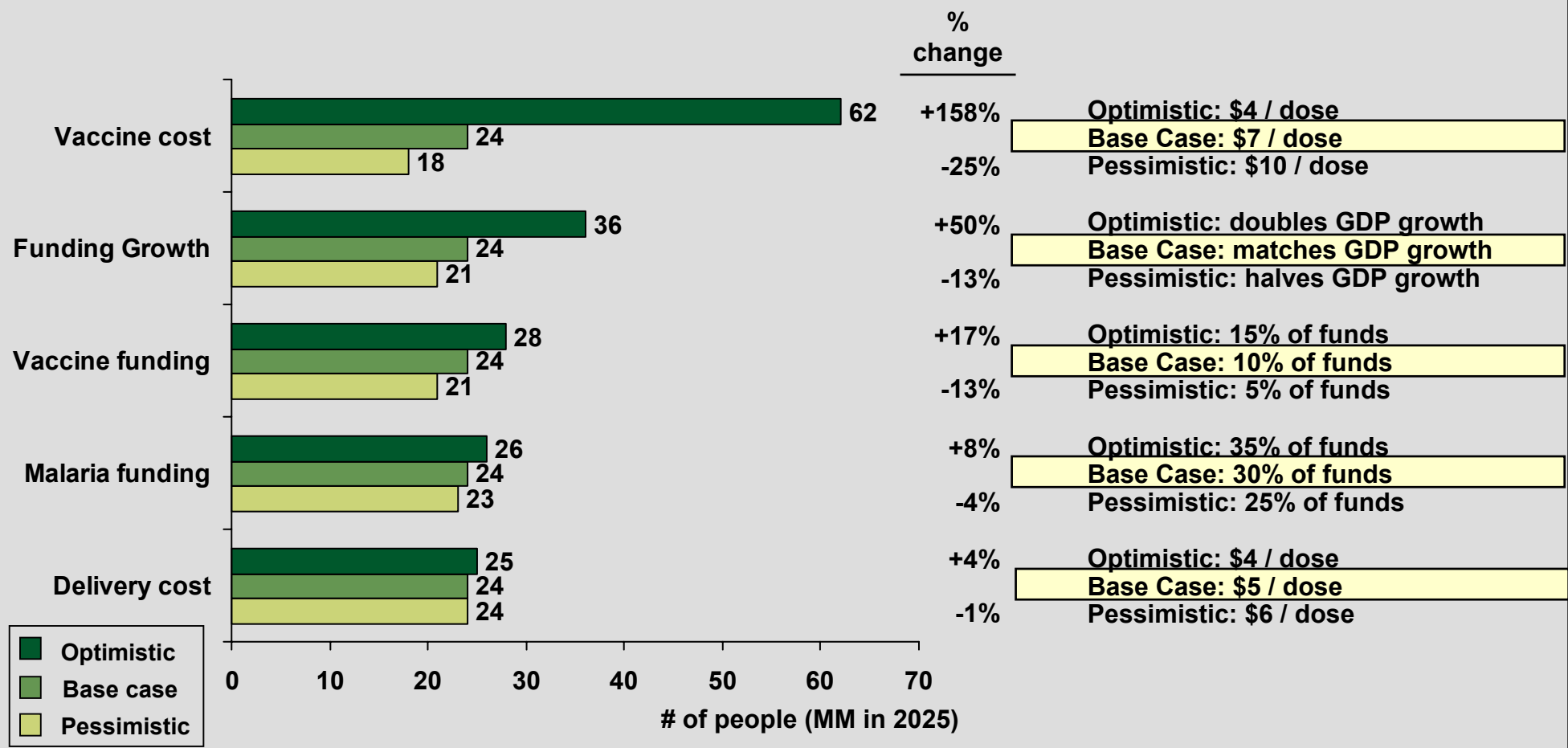
Note: Sensitivity to demand drivers keeping all other variables constant at base-case levels; ROW: Rest Of the World

Source: BCG analysis
70685-02-DC Meeting-Handout-19Jan05-BW-BOS.ppt

DEMAND FOR A MALARIA VACCINE MOST SENSITIVE TO COST AND FUNDING GROWTH

At Current Funding Levels

Sensitivity of funded demand for 2025 to model inputs (MM of people)



Note: Sensitivity to demand drivers keeping all other variables constant at base-case levels

Source: BCG analysis
70685-02-DC Meeting-Handout-19Jan05-BW-BOS.ppt

PUBLIC MARKET DEMAND SCENARIOS

Base Case

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Efficacy

Time of Introduction

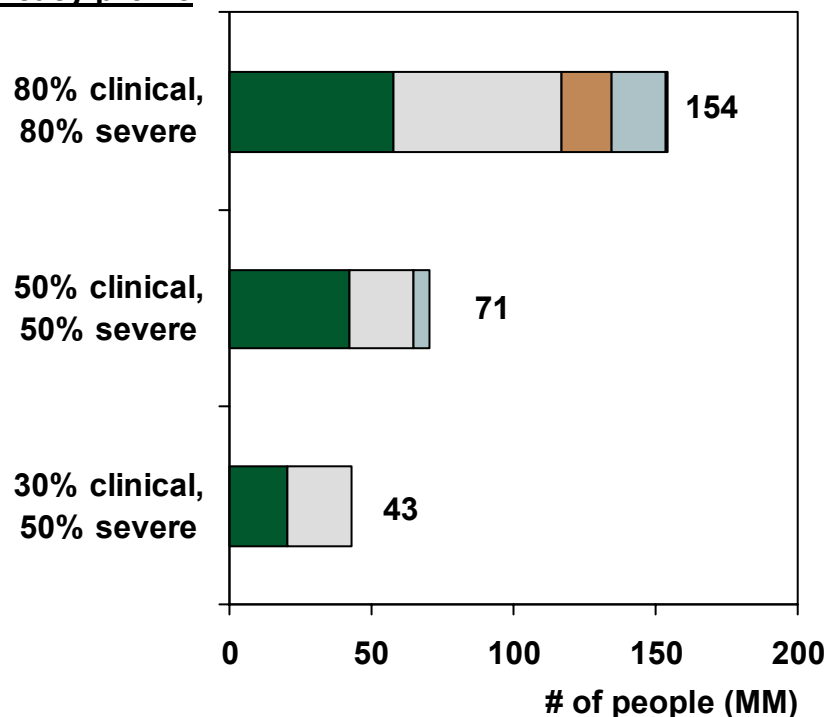
Market Uptake

Cost

DEMAND FOR AN 80% EFFICACIOUS VACCINE AS HIGH AS 154 MM PEOPLE IN 2025 WITH UNCONSTRAINED FUNDING

Funding unconstrained demand for varying vaccine efficacy levels (2025)

Efficacy profile



Key messages

Efficacy has a significant impact on vaccine demand

- Funding unconstrained demand for highest efficacy vaccine considered is 300% that of the lowest efficacy vaccine considered

60% of demand for a 50% efficacious vaccine from Africa

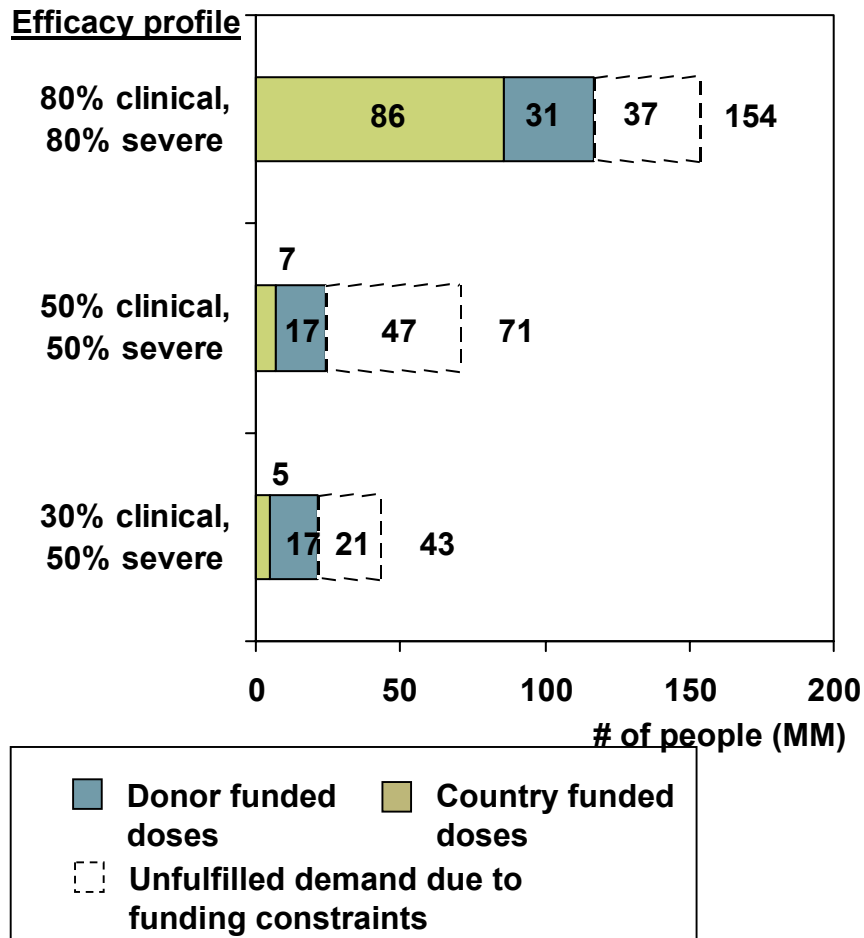
- However, at 80% efficacy significant uptake (63% of demand) outside of Africa

Uptake driven by a combination of factors

- Efficacy thresholds at which vaccine is accepted in a country
 - e.g., uptake in Thailand requires 80% efficacy
- Attitude of governments with respect to population segments targeted, both demographic and geographic
- Ability of country to reach target population

76% OF DEMAND FOR AN 80% EFFICACIOUS VACCINE LIKELY TO BE FUNDED IN 2025 AT CURRENT DONOR ACTIVITY LEVELS

Funded demand for varying vaccine efficacy levels (2025)



Key messages

Portion of donor and country funds committed to a malaria vaccine increases at higher efficacy levels

- 50% of donor and country malaria funds dedicated to a vaccine at 80% efficacy
- 30% of donor and country malaria funds dedicated to a vaccine at 50% efficacy

Higher efficacy results in a higher proportion of full potential demand being funded

- 76% of funding unconstrained demand fulfilled for 80% efficacy vaccine
- 34% for a 50% efficacy vaccine

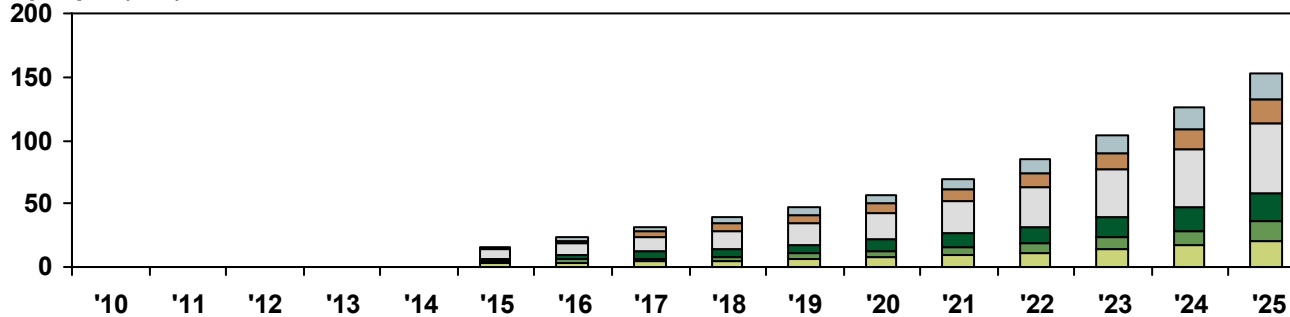
Countries contribute towards a larger proportion of funding at higher efficacy levels

- As richer countries, with lower malaria, burden are willing to take up vaccine
- However, ability of poorer countries to fund vaccine is limited

DEMAND FOR 80% EFFICACIOUS VACCINE IN ANY GIVEN YEAR MORE THAN TWICE THAT FOR A 50% EFFICACIOUS VACCINE

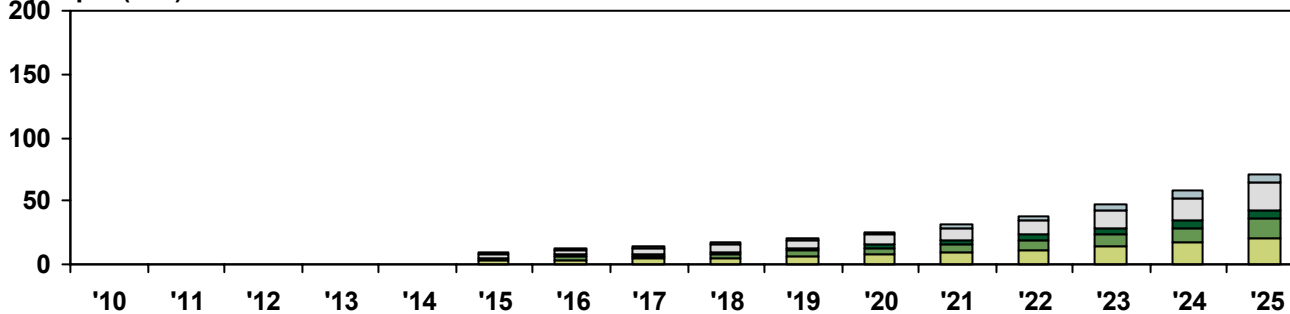
Demand unconstrained by funding for varying efficacy levels - People (2010-2025)

of people (MM)



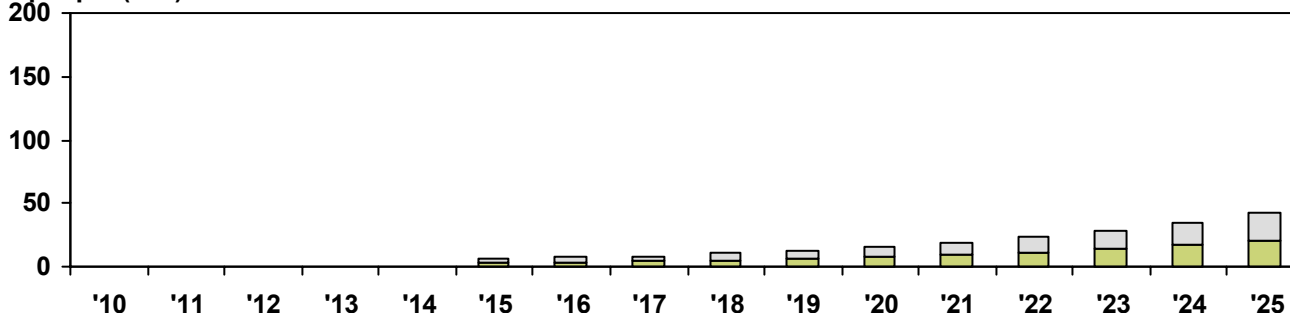
Demand for 80% clinical, 80% severe vaccine

of people (MM)



Demand for 50% clinical, 50% severe vaccine

of people (MM)



Demand for 30% clinical, 50% severe vaccine



PUBLIC MARKET DEMAND SCENARIOS

Base Case

Sensitivity

Efficacy

Time of Introduction

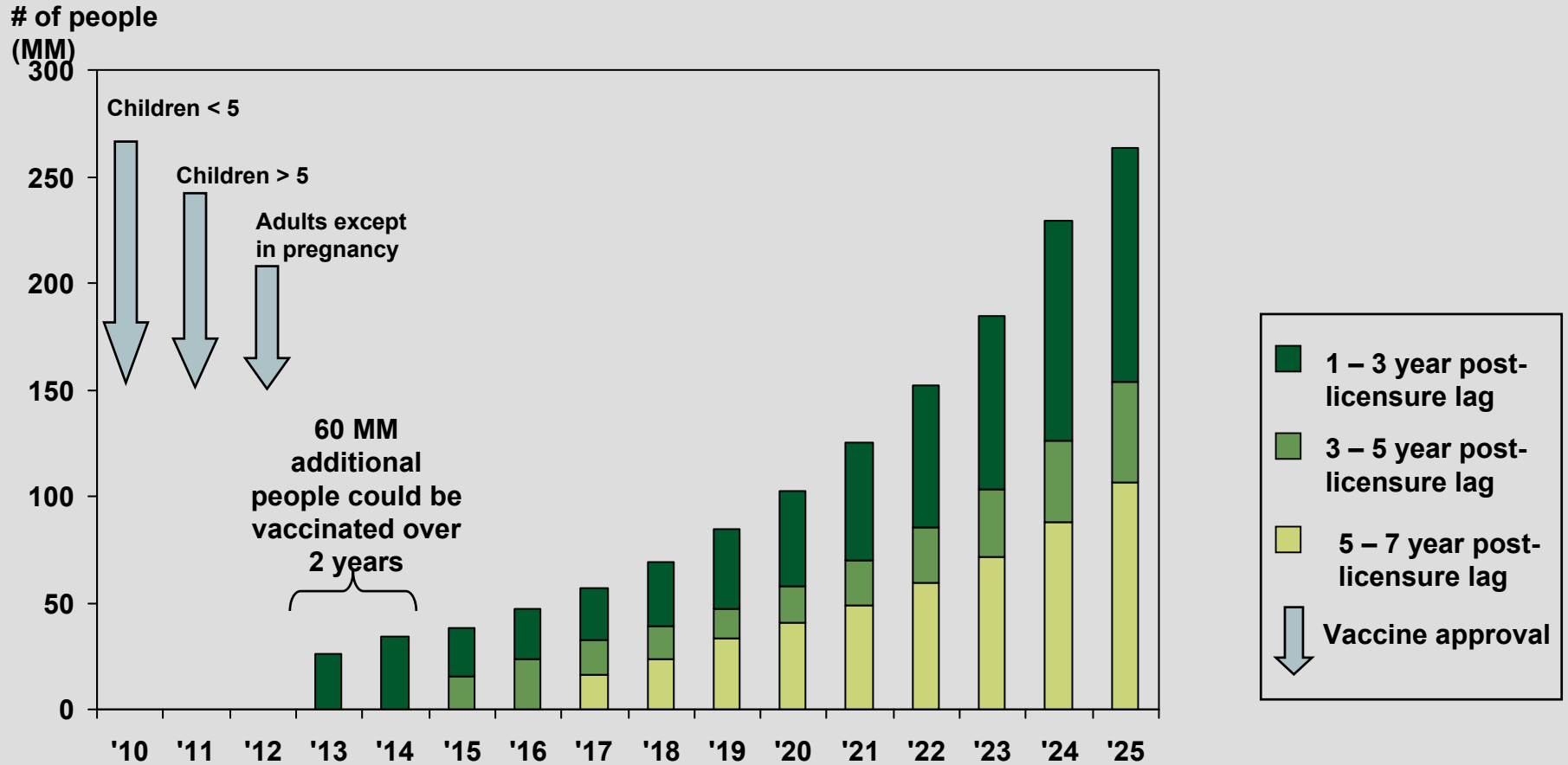
Market Uptake

Cost

REDUCING THE POST-LICENSURE LAG BY 2 YEARS COULD LEAD TO 60 MM MORE PEOPLE BEING VACCINATED

For An 80% Efficacious Vaccine

Funding unconstrained demand for an 80% efficacious vaccine - People (2010-2025)



PUBLIC MARKET DEMAND SCENARIOS

Base Case

Sensitivity

Efficacy

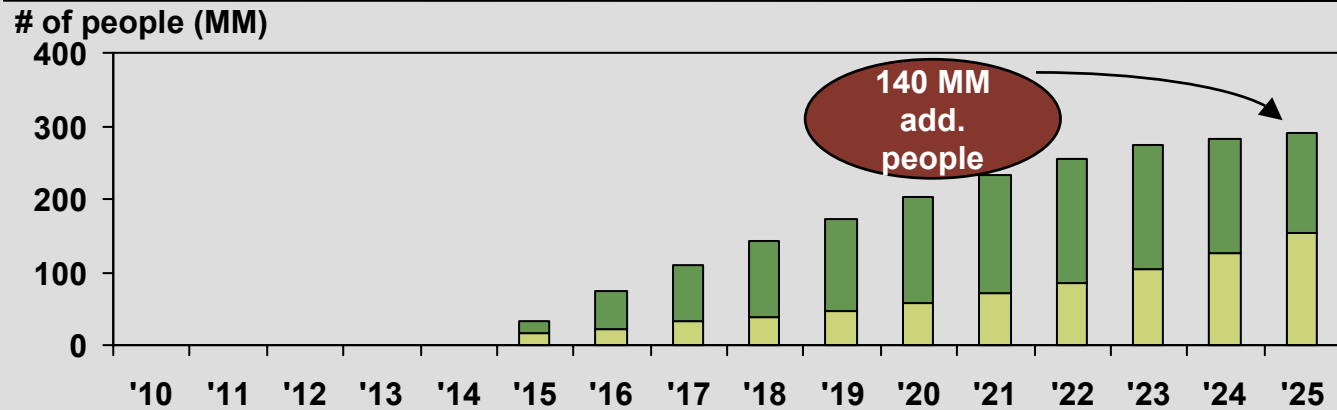
Time of Introduction




Market Uptake

Cost

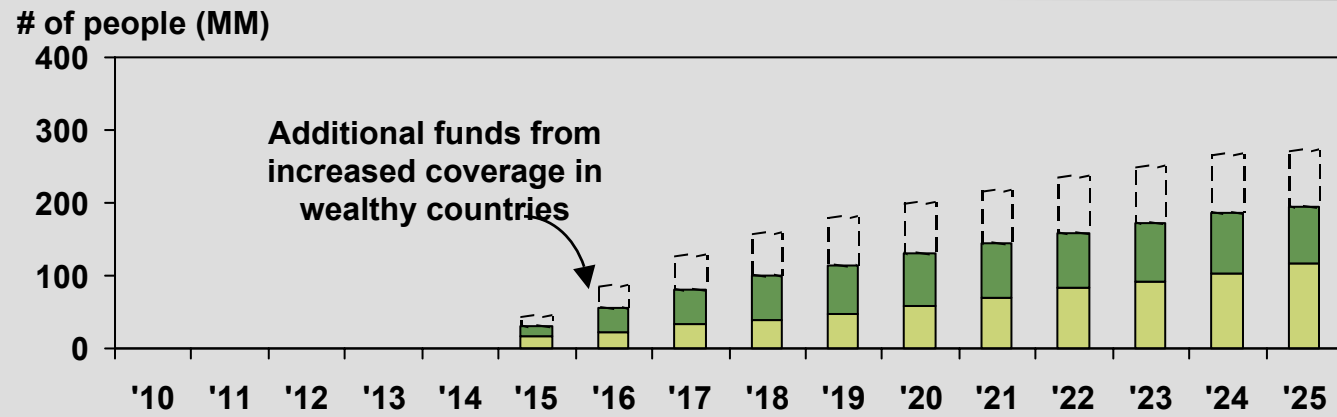
ADVOCACY AND IMPLEMENTATION SUPPORT FROM DONORS COULD LEAD TO 140 MM MORE PEOPLE VACCINATED IN 2025

Demand for an 80% efficacious vaccine unconstrained by funding - People (2010-2025)



-  Unfulfilled demand due to funding gap
-  Additional uptake assuming Hep B coverage levels
-  Uptake based on DPT coverage levels

Demand at current funding levels for an 80% efficacious vaccine – People (2010-2025)



Note: Assuming current levels of donor activity in the future
Source: BCG analysis
70685-02-DC Meeting-Handout-19Jan05-BW-BOS.ppt

PUBLIC MARKET DEMAND SCENARIOS

Base Case

Sensitivity

Efficacy

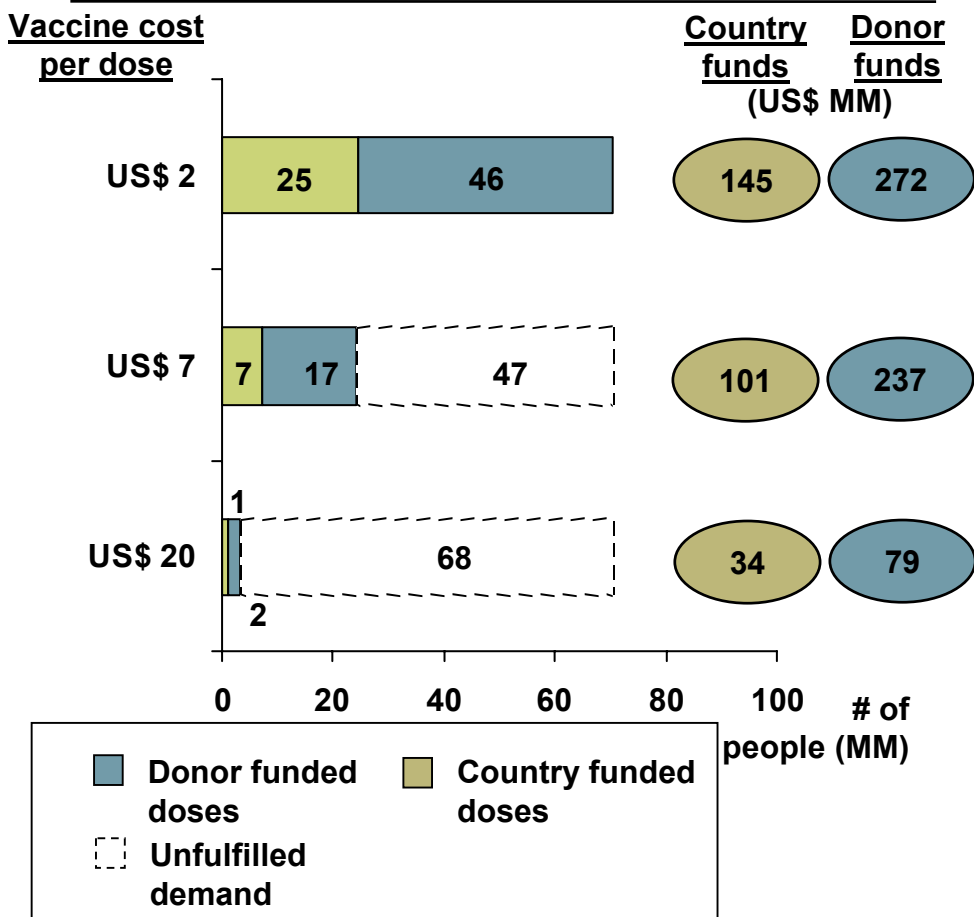
Time of Introduction

Market Uptake

Cost

FOR A US\$ 2 / DOSE VACCINE, ALL OF DEMAND COULD BE FUNDED AT CURRENT DONOR ACTIVITY LEVELS

Funded demand for varying cost levels of a 50% efficacious vaccine (2025)



Key messages

Countries and donors would consider adding a malaria vaccine to existing portfolio of interventions

Cost-effectiveness of the vaccine in comparison to existing interventions affects:

- Willingness to fund vaccine
- Proportion of funds allocated to vaccine

Proportion of funds committed to a malaria vaccine increases at lower cost levels

Results in a higher proportion of full potential demand being fulfilled at lower cost, assuming current funding levels

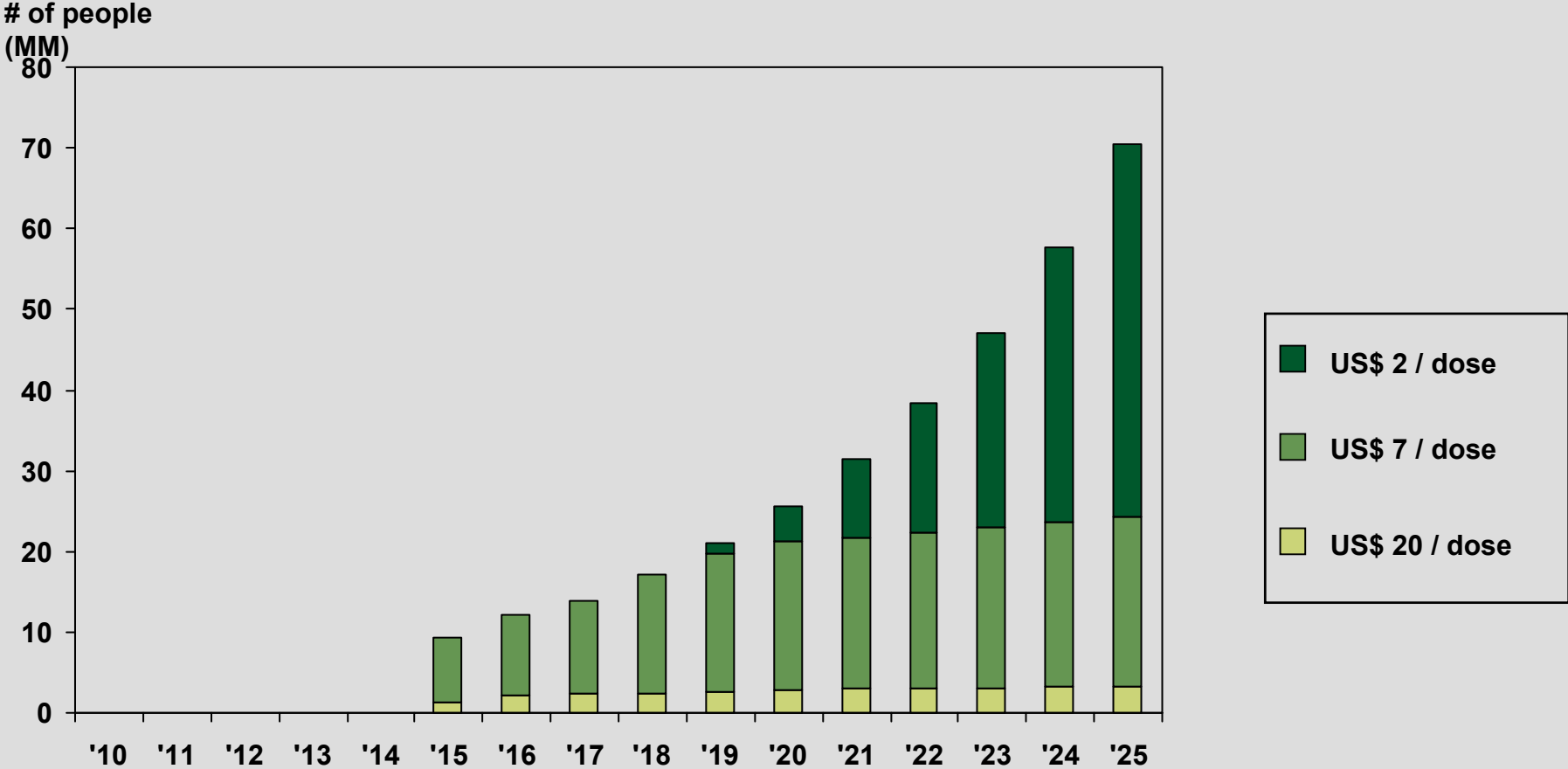
- 100% of potential demand fulfilled for a US\$ 2 / dose vaccine
- Only 5% of potential demand fulfilled for a US\$ 20 / dose vaccine

Note: All cost scenarios assume similar incremental vaccine delivery cost of US\$ 5 / course, all US\$ values refer to 2003 US\$

Source: BCG Analysis

US\$ 7 VACCINE CAN BE FULLY FUNDED TILL 2019, US\$ 2 VACCINE CAN BE FULLY FUNDED THROUGHOUT At Current Funding Levels

Funded demand for varying cost levels for a 50% efficacious vaccine - People (2010-2025)



Note: All cost scenarios assume similar incremental vaccine delivery cost of US\$ 5 / course, all US\$ values refer to 2003 US\$

Source: BCG Analysis

SUMMARY OF PUBLIC MARKET DEMAND

Base Case

70 MM people could receive a 50% efficacious vaccine priced at US\$ 7 / dose in 2025 if sufficient funding is available

- However, only 35% of full potential demand is likely to be funded at current donor activity levels
- Number of people unable to be vaccinated at current donor activity levels increases from 1 MM people in 2019 to 47 MM people in 2025

Efficacy

Demand for an 80% efficacious vaccine as high as 154 MM people in 2025 with unconstrained funding

- 76% of demand for an 80% efficacious vaccine likely to be funded in 2025
- Demand for 80% efficacious vaccine in any given year more than twice that for a 50% efficacious vaccine

Time of introduction

Reducing the time lag between approval of vaccine and implementation in country by 2 years could lead to 60 MM more people being vaccinated, for an 80% efficacious vaccine

Market uptake

Advocacy and implementation support from donors could lead to 140 MM more people vaccinated in 2025

- By affecting fundamental access issues and improving government's ability to deliver vaccines

Cost

With a low cost vaccine, full potential demand for a 50% efficacious vaccine could be fulfilled

- US\$ 7 vaccine can be fully funded till 2019, US\$ 2 vaccine can be fully funded throughout

Sensitivity

Demand estimates most sensitive to efficacy, cost, funding growth and market uptake rates

TABLE OF CONTENTS

Project overview

Endemic country findings

- **Malaria burden**
- **Public market**
- **Private market**

Travelers and military findings

Demand model methodology

Predicted vaccine market size

- **Public market**
- **Private market**
- **Travelers market**
- **Military market**

Implications and next steps

Appendix

PRIVATE MARKET DEMAND SCENARIOS

Base Case

Sensitivity

Efficacy

Time of Introduction

Affordability

Cost

BASE CASE DEFINITIONS FOR THE PRIVATE MARKET

Base case definition

Product profile of vaccine

- **Strain of vaccine: Falciparum**
- **Efficacy of vaccine: 50% against clinical and 50% against severe disease**
- **Age-groups: Protection at all age-groups except in pregnancy**
- **Duration of action: > 1 year**
- **Dosage: Three doses followed by annual booster**
- **Cost: US\$ 15 / dose and US\$ 5 delivery cost per course; similar pricing in all malaria afflicted countries**

Vaccine affordability

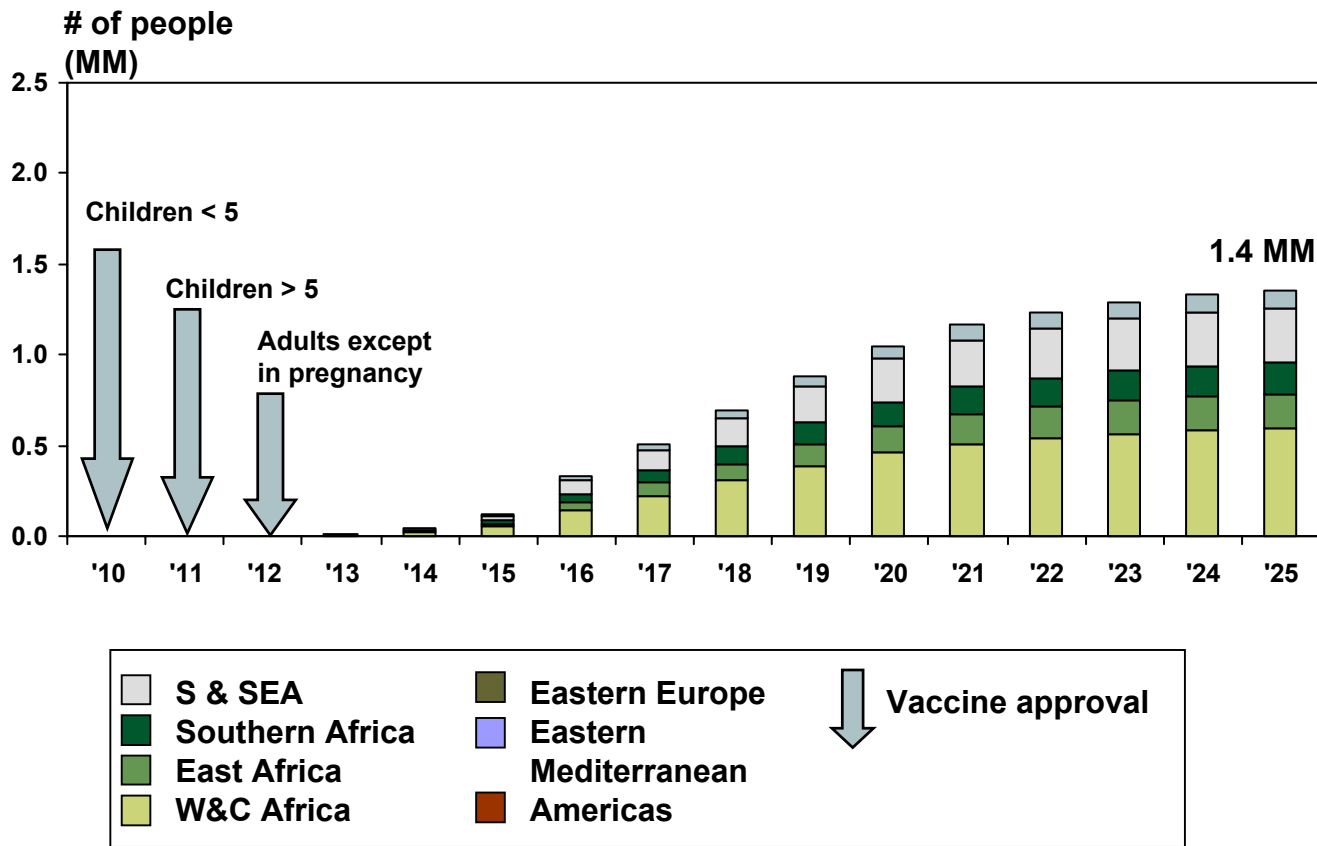
- **Families are willing to spend upto 2 weeks of annual household income to vaccinate household members**

Timing of introduction

- **Vaccine registered for children < 5 years in 2010, for children > 5 in 2011 and in adults in 2012**
- **Post-licensure lag 2 years in Africa, 1 – 2 years ROW**

1.4 MM PEOPLE LIKELY TO BUY A 50% EFFICACIOUS VACCINE, 70% FROM AFRICA

Estimated vaccine demand by geography - People (2010-2025)



Key messages

Post-licensure lag may be shorter in private market

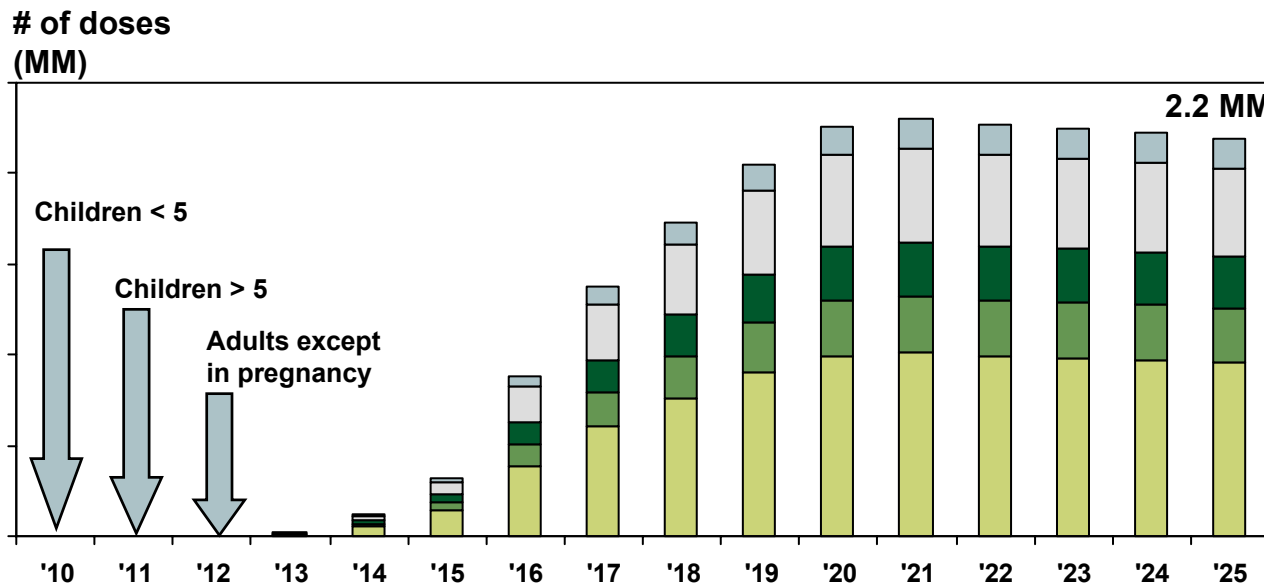
- As Govt. vaccine adoption and funding constraints typically delay public market uptake

Majority of demand from Africa due to lower efficacy levels of vaccine

LEADING TO A MARKET SIZE IN 2025 OF 2.2 MM DOSES

For a 50% Efficacious Vaccine, Costing US\$ 15 / dose

Estimated vaccine demand by geography - Doses (2010-2025)



Key messages

Conversion of number of vaccinated people to doses depends on

- Age profile of populations
- Boosters required by vaccine
- Compliance rate

PRIVATE MARKET DEMAND SCENARIOS

Base Case

Sensitivity

Efficacy

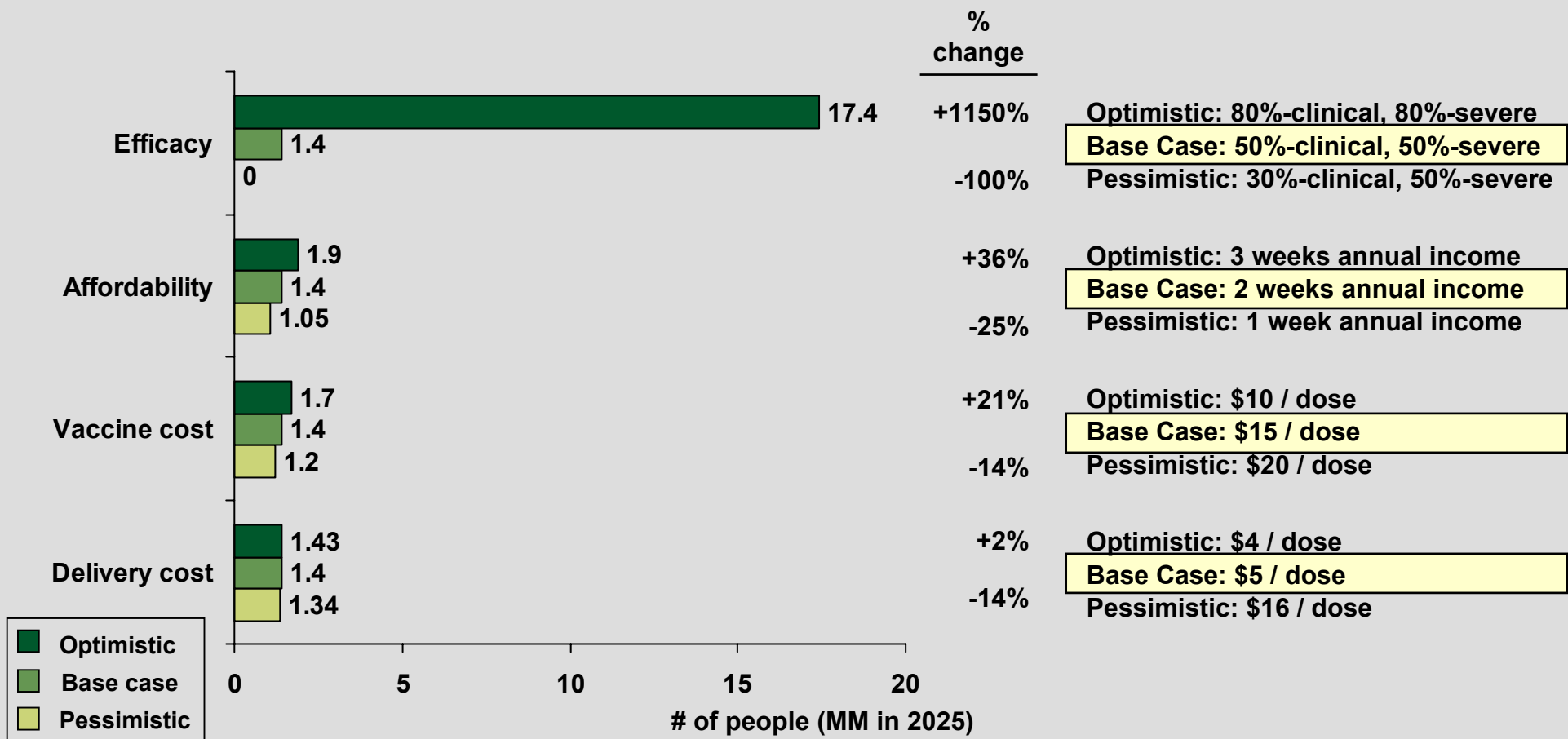
Time of Introduction

Affordability

Cost

PRIVATE MARKET DEMAND FOR A MALARIA VACCINE MOST SENSITIVE TO EFFICACY

Sensitivity of private market demand for 2025 to model inputs (MM of people)



PRIVATE MARKET DEMAND SCENARIOS

Base Case

Sensitivity

Efficacy

Time of Introduction

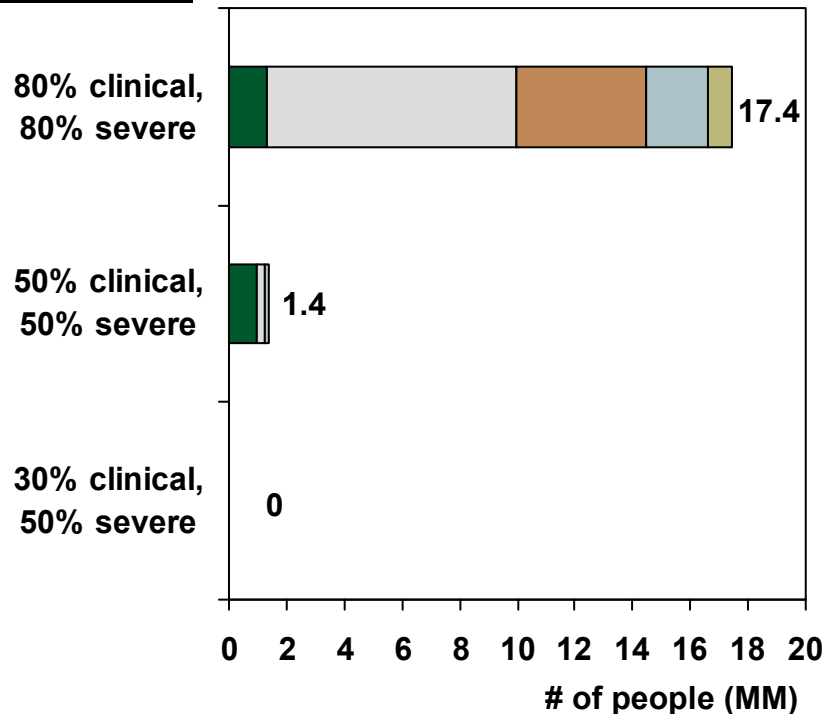
Affordability

Cost

DEMAND FOR AN 80% EFFICACIOUS VACCINE AS HIGH AS 17 MM PEOPLE IN 2025

Private market demand for varying vaccine efficacy levels (2025)

Efficacy profile



Key messages

Efficacy has a significant impact on vaccine demand

- Demand for 80% efficacious vaccine is more than 10 times that for a 50% efficacious vaccine

Uptake driven by a combination of factors

- Efficacy thresholds at which vaccine is accepted in a country
 - e.g., uptake in Thailand requires 80% efficacy
- Affordability of vaccine to country populations based on projected income distributions
- Population size of countries

Majority of demand for 80% efficacious vaccine from outside Africa

PRIVATE MARKET DEMAND SCENARIOS

Base Case

Sensitivity

Efficacy

Time of Introduction

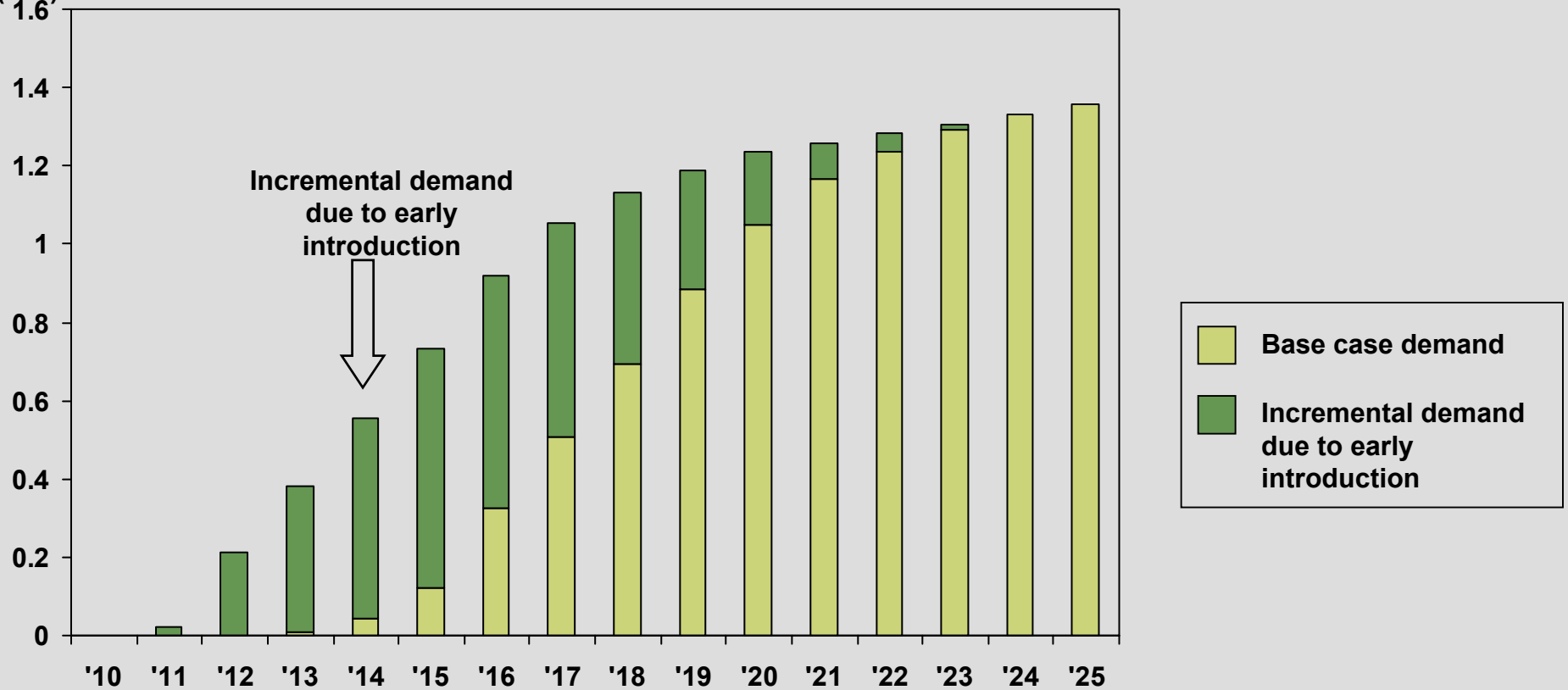
Affordability

Cost

EARLY APPROVAL AND INTRODUCTION COULD INCREASE DEMAND BY 3.9 MM PEOPLE BETWEEN '10 AND '25

Private market demand for a 50% efficacious vaccine - People (2010-2025)

of people
(MM)



PRIVATE MARKET DEMAND SCENARIOS

Base Case

Sensitivity

Efficacy

Time of Introduction

Affordability

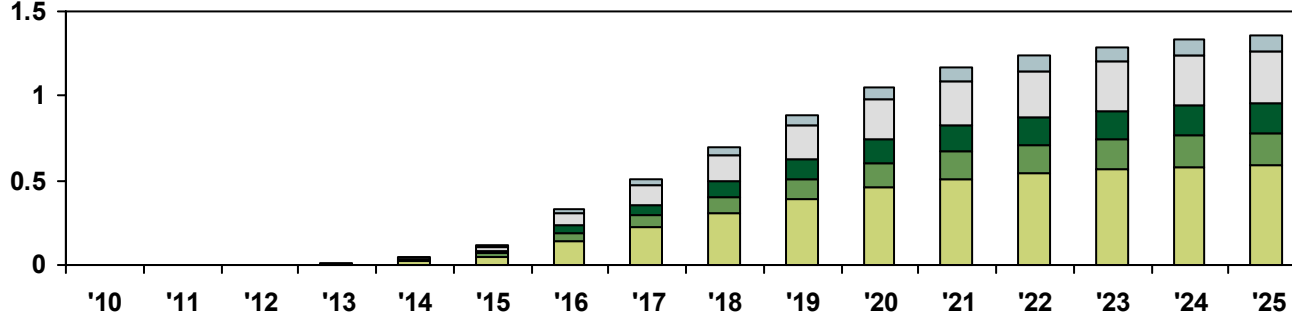
Cost

AS FEW AS 0.7 MN PEOPLE MAY BUY VACCINE IF THEY ARE WILLING TO SPEND 1% OF ANNUAL INCOME

For A 50% Efficacious Vaccine

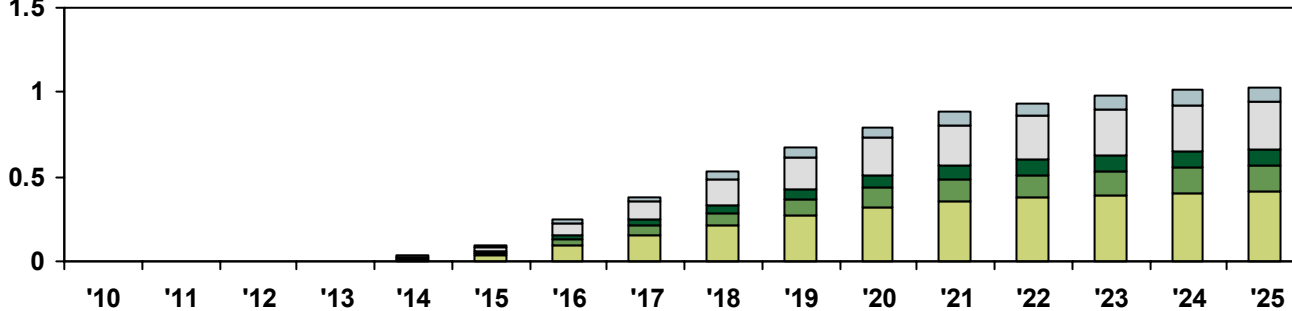
Private market demand at varying affordability levels for a 50% efficacious vaccine - People (2010-2025)

of people (MM)



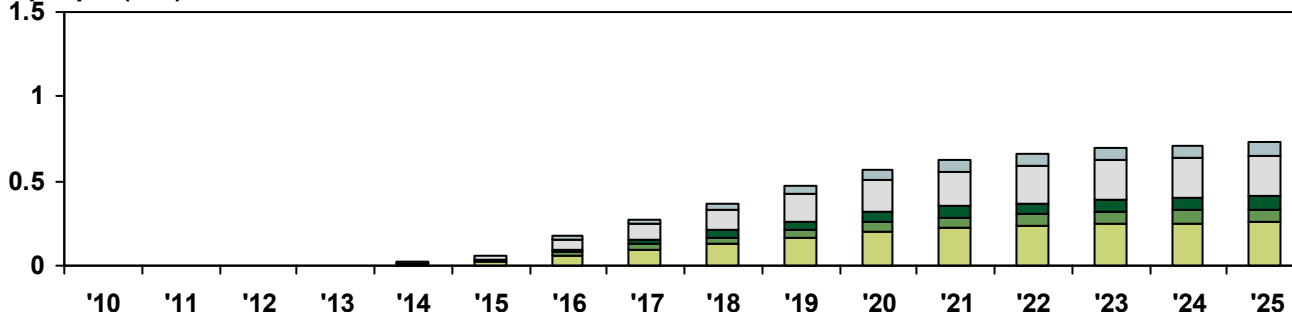
Demand at 2 weeks of annual income

of people (MM)



Demand at 1 week of annual income

of people (MM)



Demand at 1% of annual income



PRIVATE MARKET DEMAND SCENARIOS

Base Case

Sensitivity

Efficacy

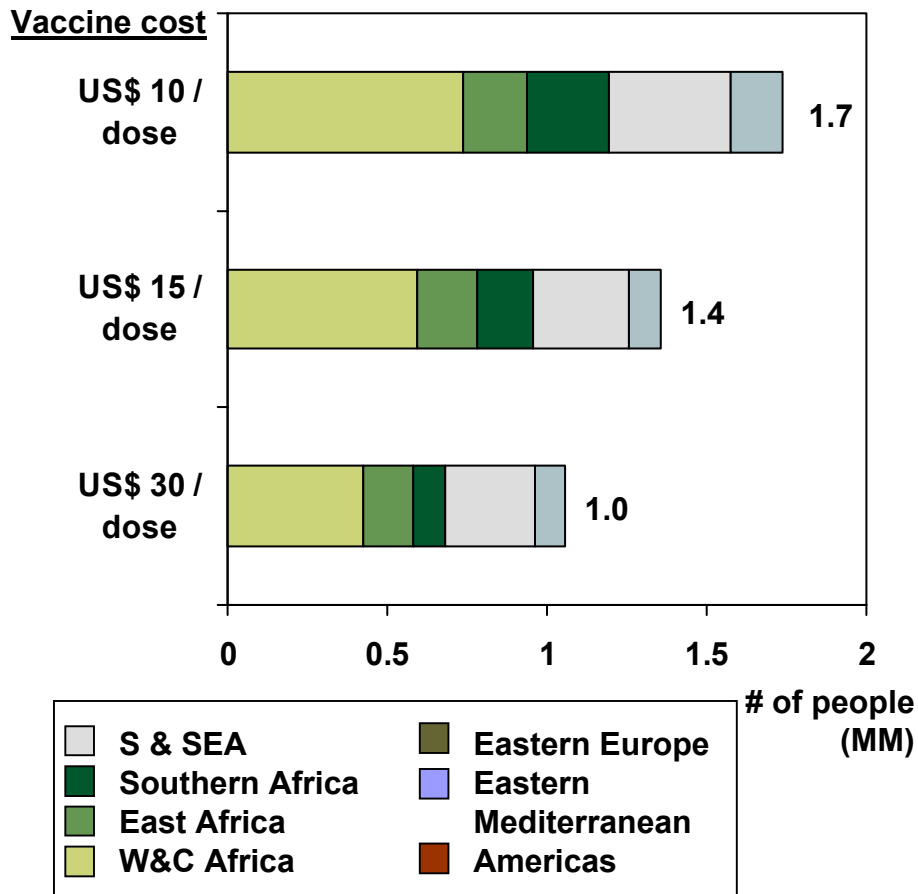
Time of Introduction

Affordability

Cost

DEMAND RANGES BETWEEN 1.7 MM TO 1.0 MM PEOPLE FOR A PRICE RANGE OF US\$ 10 TO 30 PER DOSE

Funded demand for varying cost levels of a 50% efficacious vaccine (2025)



Key messages

Private market demand driven by two sub-segments of the high income population in countries

- A very high income group which is relatively price insensitive
- A relatively lower income group with sufficient discretionary income to afford a vaccine, but which is sensitive to price

Results in relatively low price sensitivity when compared to the public market

Majority of demand for a 50% efficacious vaccine comes from Africa across cost levels

Note: All cost scenarios assume similar incremental vaccine delivery cost of US\$ 5 / course, all US\$ values refer to 2003 US\$

Source: BCG Analysis

70685-02-DC Meeting-Handout-19Jan05-BW-BOS.ppt

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SUMMARY OF PRIVATE MARKET DEMAND

Base Case

- 1.4 MM people likely to buy a 50% efficacious vaccine, 70% from Africa
 - Uptake likely to begin 3 years after approval
 - Limited uptake from regions outside Africa where higher efficacy needed

Efficacy

- Demand for an 80% efficacious vaccine as high as 17 MM people in 2025
 - Efficacy has a significant impact on vaccine demand
 - Demand for 80% efficacious vaccine is more than 10 times that for a 50% efficacious vaccine
 - Majority of demand for 80% efficacious vaccine from outside Africa
 - Uptake driven by a combination of factors
 - Efficacy thresholds at which vaccine is accepted in a country
 - e.g., uptake in Thailand requires 80% efficacy
 - Affordability of vaccine to country populations based on projected income distributions

Time of introduction

Early approval and introduction of vaccine, within 1 year of vaccine approval, could increase demand by 3.9 MM people between 2010 and 2025

Affordability

0.7 MM people may buy vaccine if they are willing to spend 1% of annual income, as compared to 1.4 MM people if they are willing to spend 2 weeks of annual income

Cost

- Demand ranges between 1.7 MM to 1.0 MM people for a price range of US\$ 10 to 30 per dose, as compared to 1.4 MM people for a US\$ 15 per dose vaccine
 - Private market demand driven by two sub-segments of the high income population in countries
 - A very high income group which is relatively price insensitive
 - A relatively lower income group with sufficient discretionary income to afford a vaccine, but which is sensitive to price

Sensitivity

Demand estimates most sensitive to efficacy

TABLE OF CONTENTS

Project overview

Endemic country findings

- **Malaria burden**
- **Public market**
- **Private market**

Travelers and military findings

Demand model methodology

Predicted vaccine market size

- **Public market**
- **Private market**
- **Travelers market**
- **Military market**

Implications and next steps

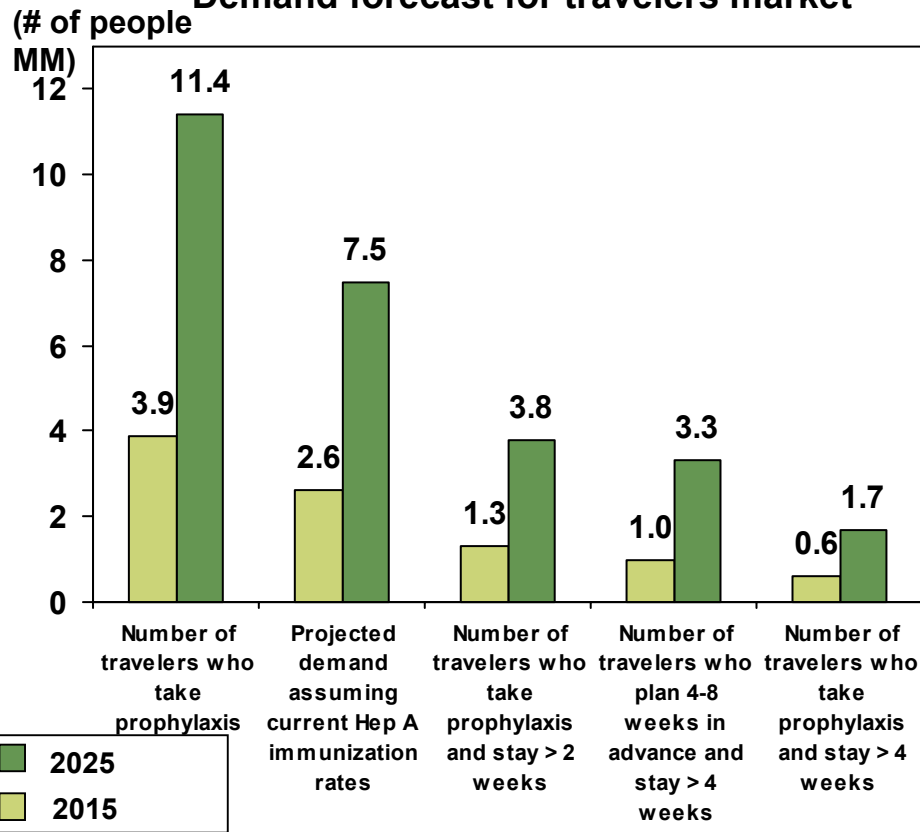
Appendix

TRAVELERS MARKET LIKELY TO RANGE BETWEEN 1.7 AND 3.3 MM PEOPLE IN 2025

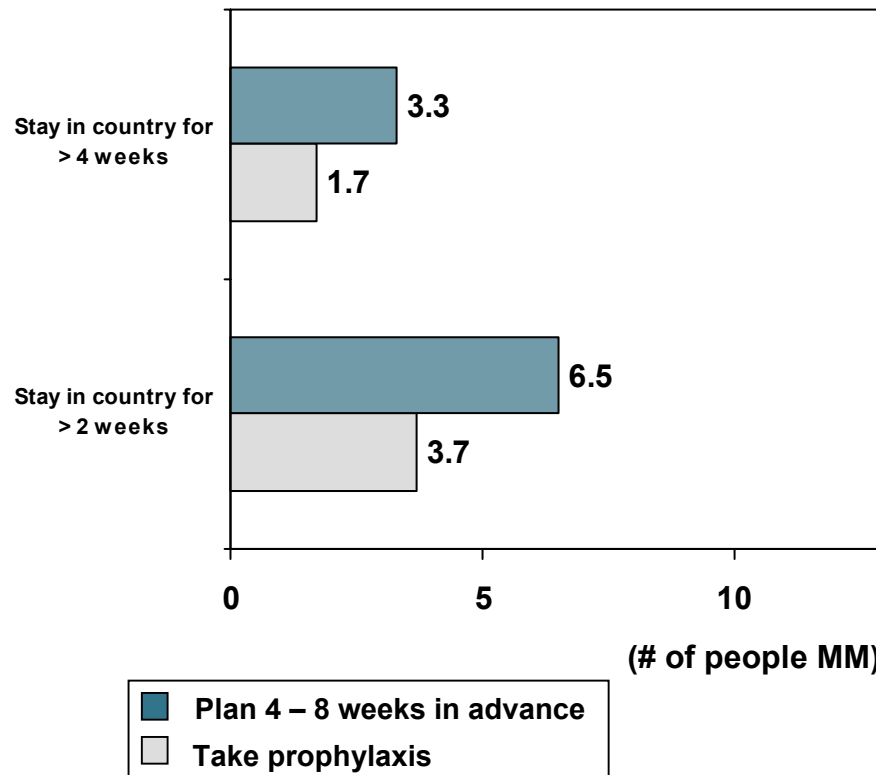
Demand ranges from 1.7 MM to 3.3 MM people in 2025

Demand sensitivity highest to time in-country required to generate interest in vaccine

Demand forecast for travelers market



Sensitivity analysis for travelers market (2025)



Peak demand likely to be in the range of 1.7 and 3.3 MM people in 2025

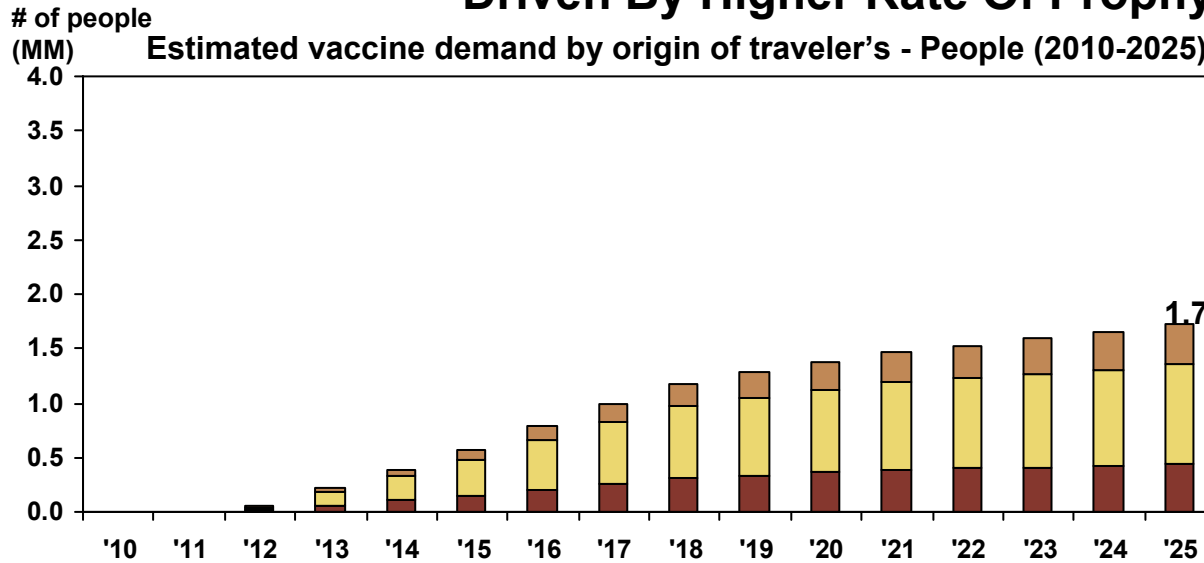
- However close to 100% efficacious vaccine required
- Sensitive to in-country stay assumptions, cost and administration schedule

Note: Assuming one arrival per traveler per country per year

Source: BCG analysis
70685-02-DC Meeting-Handout-19Jan05-BW-BOS.ppt

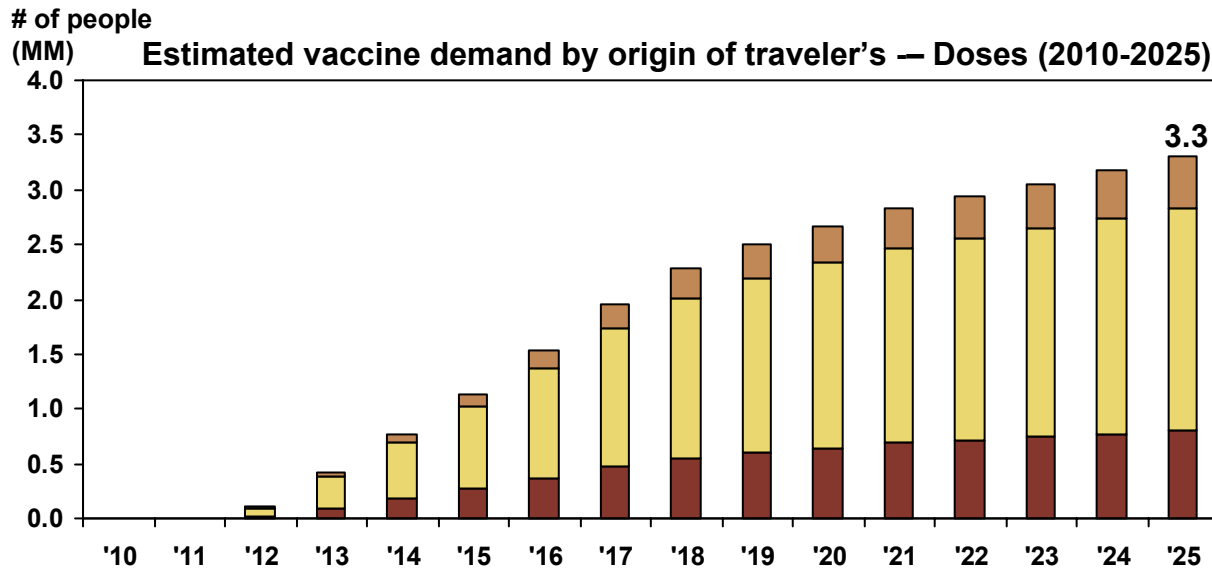
60% OF DEMAND IN TRAVELERS MARKET LIKELY TO BE FROM EUROPEAN TRAVELERS

Driven By Higher Rate Of Prophylaxis Use



Base Case

Demand based on travelers who take prophylaxis for malaria and stay longer than 4 weeks in country



Demand based on travelers who plan 4-8 weeks in advance and stay > 4 weeks

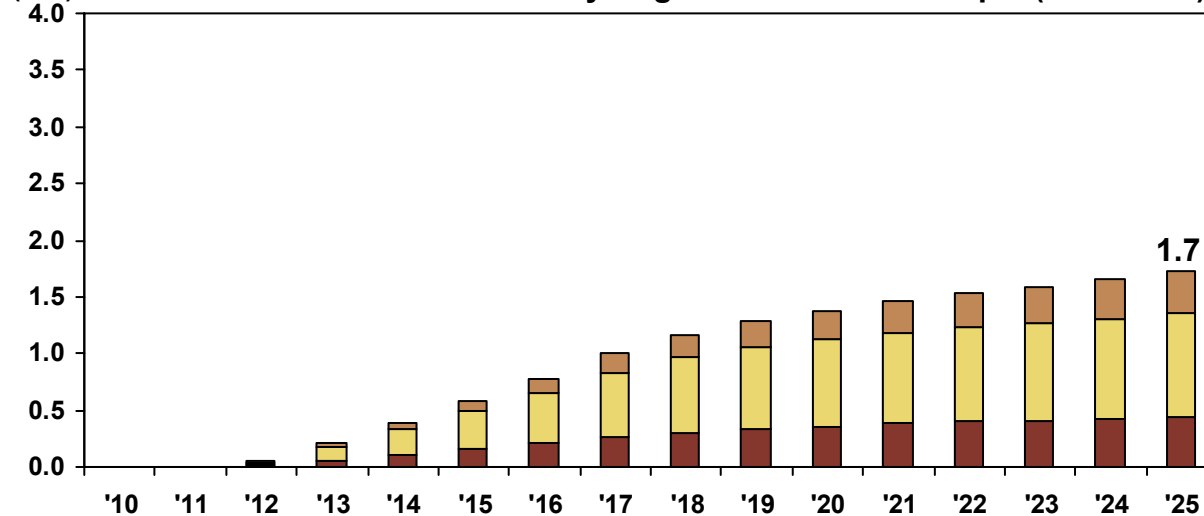


Note: Assuming one arrival per traveler per country per year

Source: BCG analysis
70685-02-DC Meeting-Handout-19Jan05-BW-BOS.ppt

DEMAND FOR A VACCINE IN THE RANGE OF 1.2 MM IF 10% ARE FREQUENT TRAVELERS WITH 3 ARRIVALS / YEAR

of people (MM) Estimated vaccine demand by origin of traveler's - People (2010-2025)

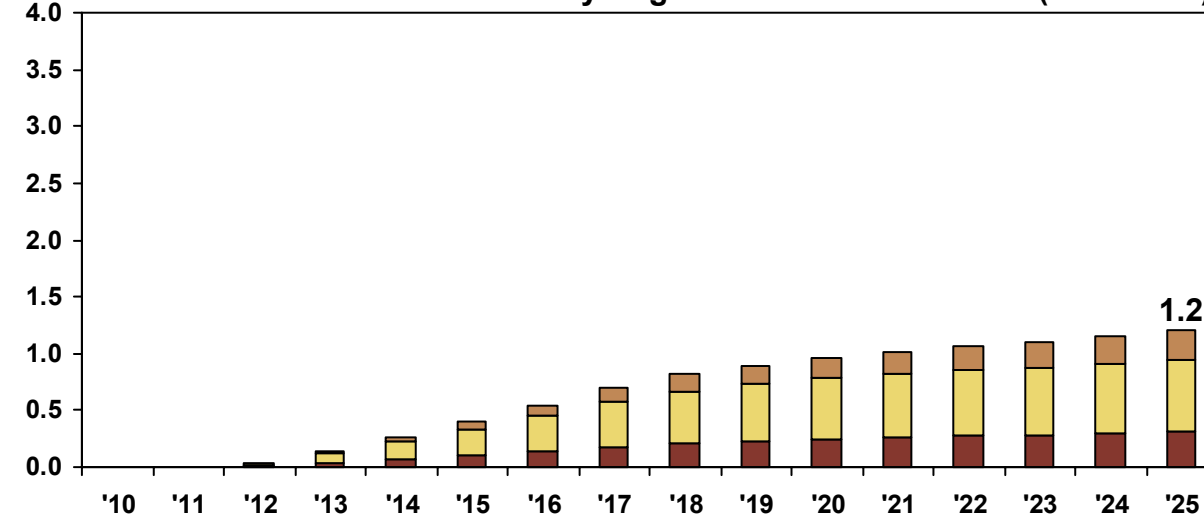


Base Case

Demand based on travelers who take prophylaxis for malaria and stay longer than 4 weeks in country

100% of travelers arrive once / year / country

of people (MM) Estimated vaccine demand by origin of traveler's — Doses (2010-2025)



Demand based on travelers who take prophylaxis for malaria and stay longer than 4 weeks in country

90% of travelers arrive once / year / country, 10% of travelers arrive 3 times / year / country



TABLE OF CONTENTS

Project overview

Endemic country findings

- **Malaria burden**
- **Public market**
- **Private market**

Travelers and military findings

Demand model methodology

Predicted vaccine market size

- **Public market**
- **Private market**
- **Travelers market**
- **Military market**

Implications and next steps

Appendix

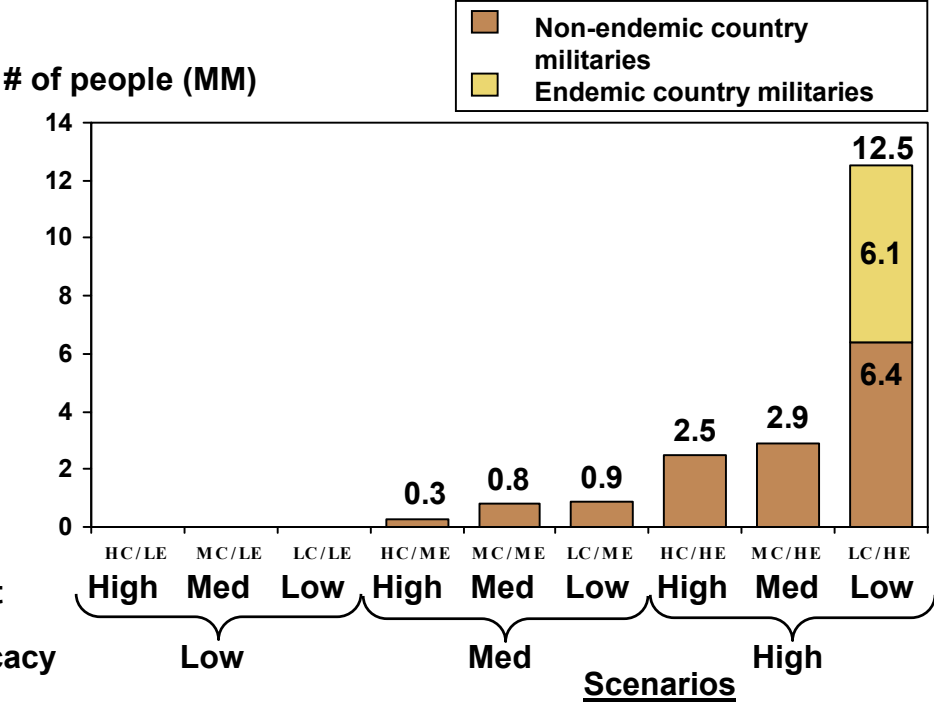
PEAK ANNUAL DEMAND FOR A MALARIA VACCINE IN THE MILITARY RANGES FROM 0-13 MM THROUGH 2025

2025 Scenarios

Efficacy Against Clinical Disease

> 80%	12.5MM	2.9MM	2.5MM
50- 80%	0.8MM	0.8MM	0.3MM
< 50%	0	0	0
	<\$20	\$20-\$100	>\$100
	Total Vaccine Cost		

Significant impact of efficacy on demand



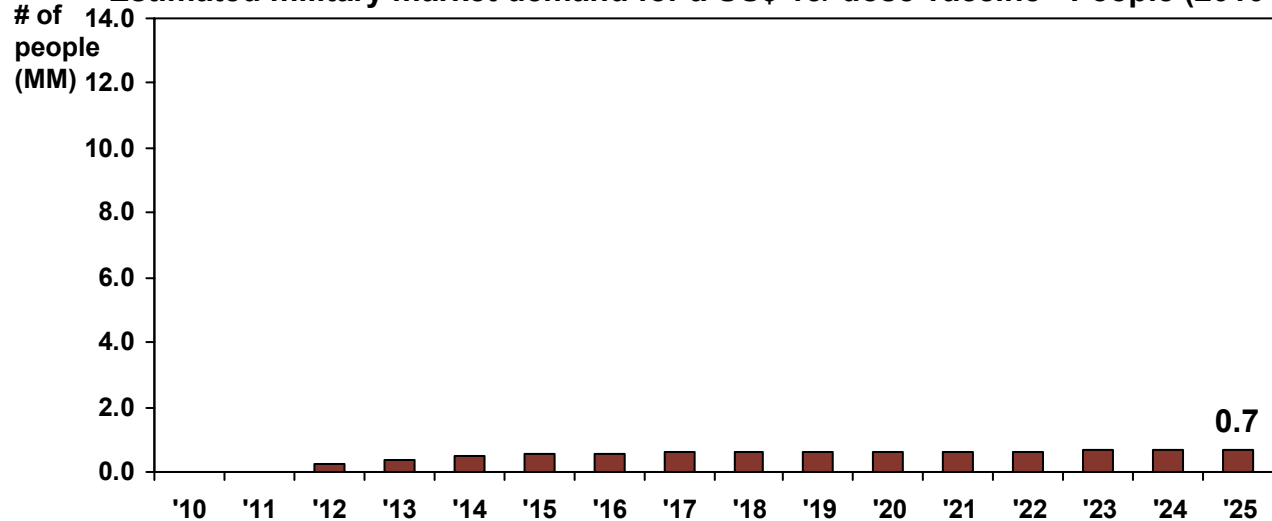
Key:
 Cost: Low - < \$ 20, Med - \$ 20 – 100, High - > \$ 100
 Efficacy: Low - < 50%, Med – 50 – 80%, High - > 80%

Military demand sensitive to efficacy and cost

EFFICACY OF VACCINE HAS SIGNIFICANT IMPACT ON MARKET

12.5 MM People Likely to Receive a 80% Efficacious Vaccine

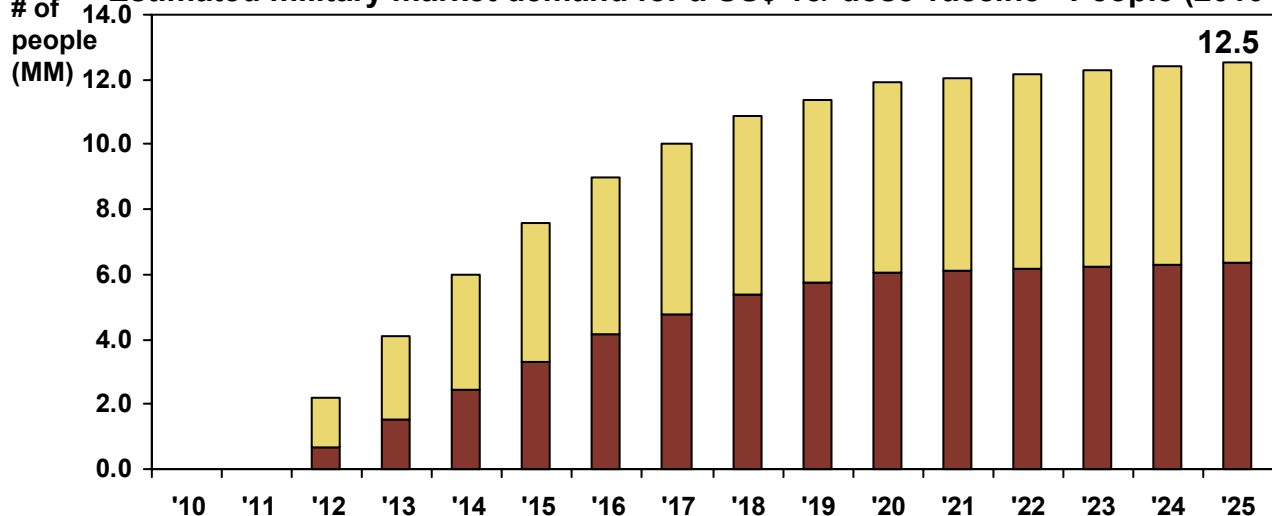
Estimated military market demand for a US\$ 15/ dose vaccine - People (2010-2025)



Vaccine efficacy:

50% against clinical and 50% against severe disease

Estimated military market demand for a US\$ 15/ dose vaccine - People (2010-2025)



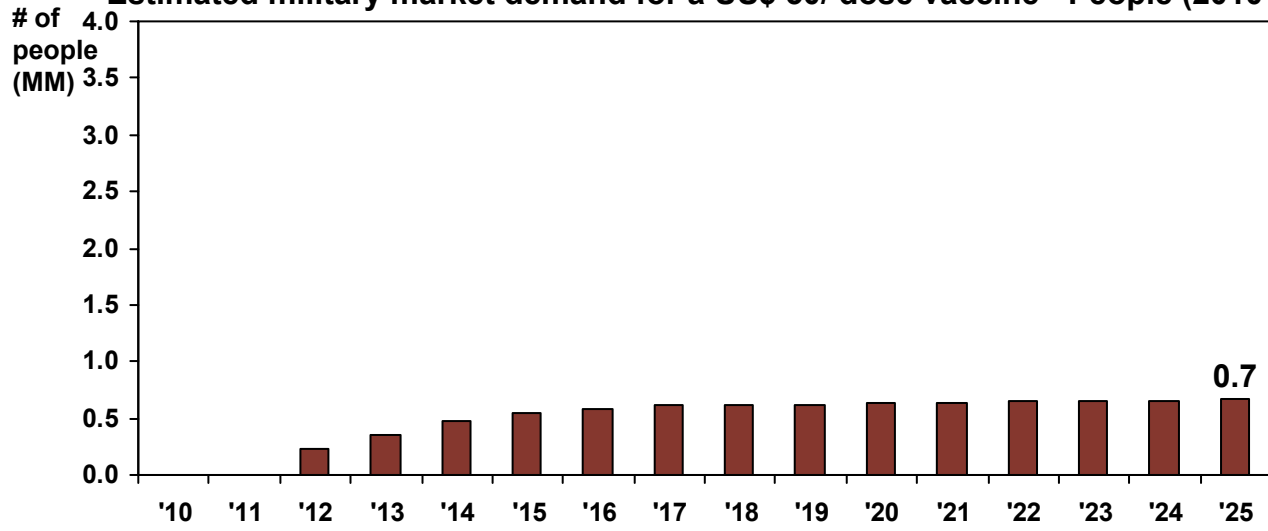
Vaccine efficacy:

80% against clinical and 80% against severe disease



DEMAND FOR A US\$ 50 / DOSE VACCINE LIKELY TO BE RESTRICTED TO NON-ENDEMIC COUNTRY MILITARIES

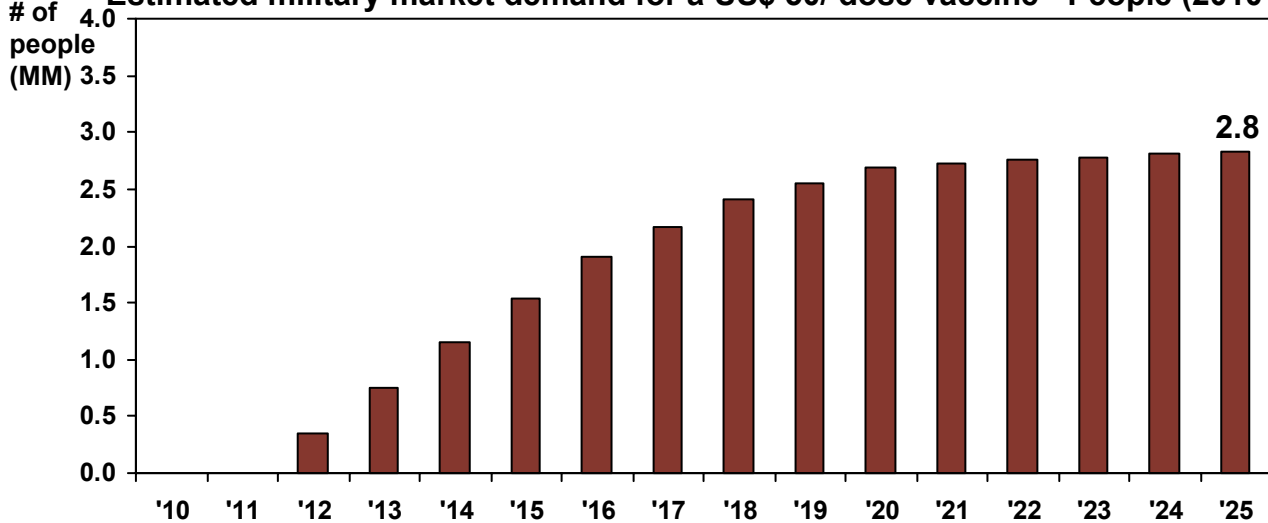
Estimated military market demand for a US\$ 50/ dose vaccine - People (2010-2025)



Vaccine efficacy:

50% against clinical and 50% against severe disease

Estimated military market demand for a US\$ 50/ dose vaccine - People (2010-2025)



Vaccine efficacy:

80% against clinical and 80% against severe disease



SUMMARY OF TRAVELERS AND MILITARY MARKET DEMAND

Travelers market

Travelers market likely to range between 1.7 and 3.3 MM people in 2025

- **However efficacy needs to be close to 100%, similar to existing chemoprophylaxis**
- **Only travelers who stay longer than 2 - 4 weeks and who plan at least 4 weeks in advance likely to consider a vaccine**
- **Demand is sensitive to assumptions around average number of trips per person per year**

60% of demand in travelers market likely to be from European travelers

Military market

Military market likely to be in the range of 0.7 MM people in 2025 for a 50% efficacious vaccine costing US\$ 15 / dose

- **Demand likely only from non-endemic country militaries at 50% efficacy levels**
- **Demand for a US\$ 50 / dose vaccine likely to be restricted to non-endemic country militaries**

Higher efficacy of vaccine has significant impact on military market

- **12.5 MM people likely to receive a 80% efficacious vaccine at US\$ 15 / dose as compared to only 0.7 MM people for a 50% efficacious vaccine**

Cost of vaccine impacts demand for the vaccine, especially from armies with relatively lower health care budgets

- **Number of people receiving an 80% efficacious vaccine would reduce from 12.5 MM to 2.8 MM people (in 2025) if cost of vaccine was US\$ 50 / dose instead of US\$ 15 / dose**

TABLE OF CONTENTS

Project overview

Endemic country findings

- **Malaria burden**
- **Public market**
- **Private market**

Travelers and military findings

Demand model methodology

Predicted vaccine market size

Implications and next steps

Appendix

BASE CASE DEVELOPED USING BEST CURRENT KNOWLEDGE Can Become More Specific As Vaccine Candidates Progress Toward Licensure

Model structure has been developed to allow it to be an adaptable, living tool

- **Inputs and assumptions can be dynamically changed**

Assumptions for data and attitudes will continue to be refined as new information is obtained over time

As we learn more about the emerging product profile of a specific vaccine candidate, we will be able to more accurately predict expected demand

Although we cannot pinpoint a single specific demand “answer”, there are common themes that we believe will continue to most heavily drive demand over time

FOUR CENTRAL THEMES EMERGED ACROSS MARKETS

Substantial need/potential demand exists across all four markets examined

Specific requirements for product profile exist and vary significantly by country

- **Efficacy thresholds**
- **Minimum duration to be considered**
- **Species of malaria**

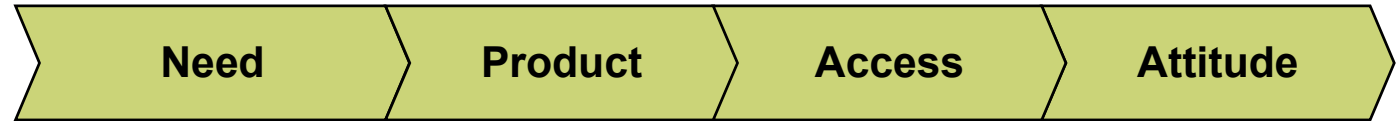
Ease of access will drive uptake, especially EPI program suitability

Third parties play an influential role

- **Donor community**
- **Local and global scientific communities**

KEY FINDINGS BY MARKET

Given Development Timelines, Important to Focus On Developing Desired Product Profile And Influencing Public Market Attitudes



PUBLIC MARKET

- Burden high throughout Africa, in border areas elsewhere

- There is role for partial efficacy
- W Africa 50% vs. E Africa 80%
- Duration > 1 yr
- Cost critical

- Desire for administration through EPI program

- Use of portfolio approach to fight malaria
- WHO support
- Donor funding
- Need for local clinical data

PRIVATE MARKET

- Burden high throughout Africa, in border areas elsewhere

- Efficacy of 50% due to alternatives
- Duration > 1 yr

- Limited by individual income, access to clinics

- Willingness to pay for private health services

TRAVELERS

- Travelers to malaria endemic regions increasing

- Must have efficacy greater than or equal to prophylaxis

- Relevant for travelers who seek pre-travel advice

- Will likely prefer vaccine over prophylaxis for longer trips

MILITARY

- Low prophylaxis compliance and desire for readiness gives high need

- Mission comes first, need high clinical efficacy
- No side effects
- Min duration 4-6 mo

- Reach during basic training or before deployment

- Vaccinate if helps mission

THREE FACTORS MOST INFLUENCE FUTURE SUCCESS OF MALARIA VACCINE

Product profile

Product profile has the strongest influence on demand, as the vaccine must reach stated thresholds to have any uptake

- Efficacy and cost are key drivers, demand in the public market expected to be:
 - 71 MM people with clinical and severe efficacy of 50%, growing to 154 MM at ~80%
 - 50 MM additional people could be funded if cost of vaccine was lowered from \$7 to \$2 per dose
- P. falciparum component and one year duration are important minimum requirements

Funding

Donor funding can drive demand by stimulating early markets and enabling less wealthy countries' purchase and administration of vaccine

- Public markets will rely heavily on sustainable funding to introduce vaccine
 - uptake only 7 MM people in base case scenario without donor funding
- With strong donor advocacy and implementation support, demand in the public market could reach 290 MM people with clinical and severe efficacy of 80%
- Private markets likely to lag public markets since they do not “turn on” until higher efficacy level reached
 - unlikely to be achieved in first generation vaccine

Influencer support

Support of WHO, academics, and standards-setting organizations are key to vaccine's introduction and credibility

- Support of key third-party organizations can influence lag between licensure and introduction
- Countries and donors both both rely on key opinion leaders and WHO recommendations in deciding on which interventions to support

TABLE OF CONTENTS

Project overview

Endemic country findings

Travelers and military findings

Demand model methodology

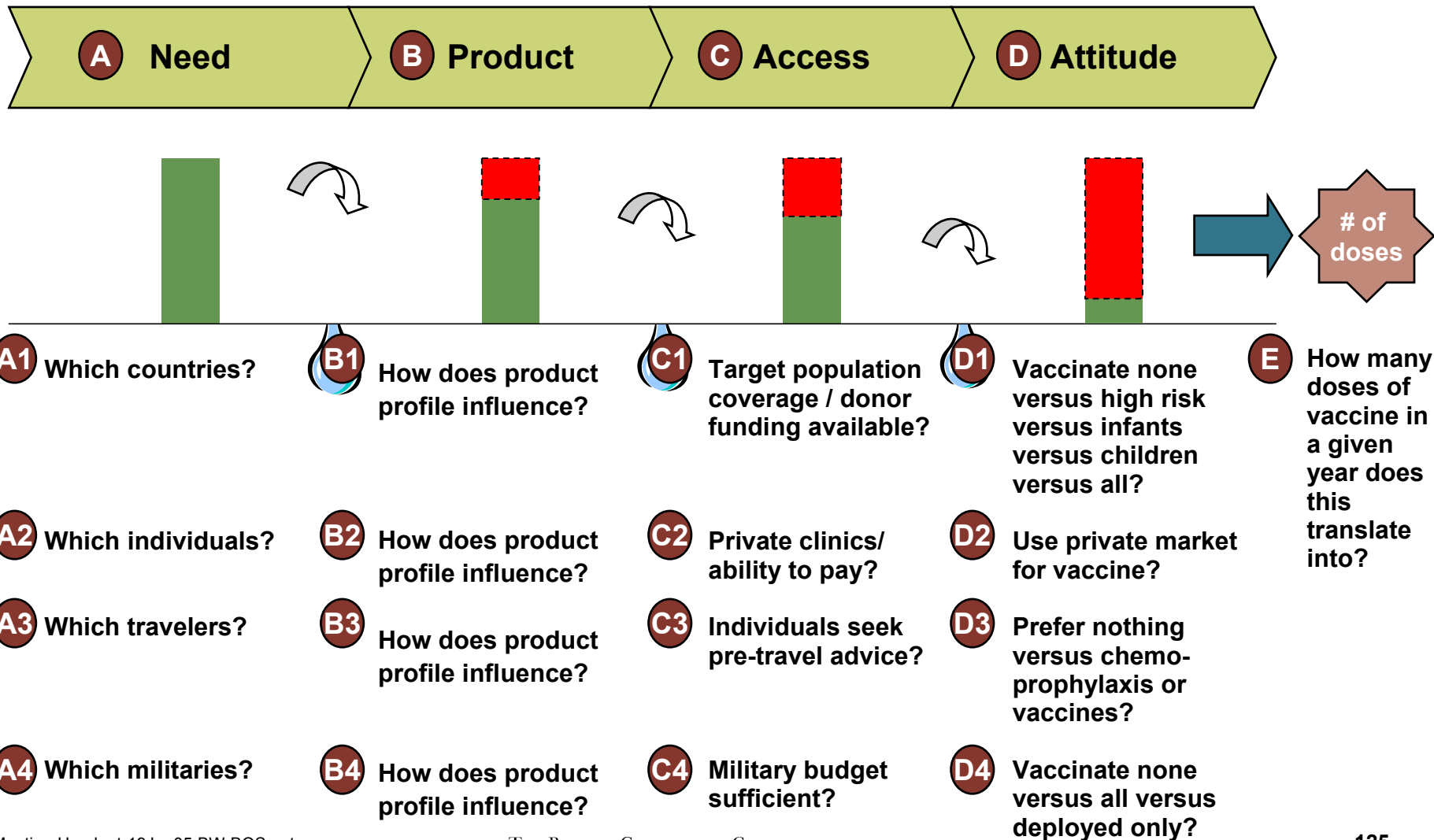
Predicted vaccine market size

Implications and next steps

Appendix

- **Detailed description of demand model**
- **Primary research sources**
- **Secondary research sources**
- **Contact information**

MODEL FOLLOWS THE DEMAND LEAKAGE FRAMEWORK FOR ASSESSING MARKET POTENTIAL



QUESTION **A1** WHAT COUNTRIES ACROSS THE WORLD NEED A MALARIA VACCINE?

- Model contains a master country data sheet
- Lists all countries in the world
- Selects those that are endemic to malaria
- Contains detailed data on
 - Economic profile and development
 - Population profile and growth
 - Malaria related statistics
 - Health care statistics

Region	Country	MALARIA	Population	Birth cohort (Es	Population < 5 (Est	GDP CAP
America Andean	Bolivia	1	8,586,443	214,661	1,073,305	2,370
America Andean	Colombia	1	41,662,073	1,041,552	5,207,759	6,519
America Andean	Ecuador	1	13,710,234	342,756	1,713,779	3,905
America Andean	Peru	1	28,409,897	710,247	3,551,237	4,888
America Andean	Venezuela	1	24,654,694	616,367	3,081,837	6,402
America Brazil	Brazil	1	182,032,604	4,550,815	22,754,076	7,537
America Mexico	Mexico	1	103,718,062	2,592,952	12,964,758	8,903
Americas	Belize	1	266,440	6,661	33,305	5,351
Americas	Guyana	1	702,100	17,553	87,763	4,046
Americas	Suriname	1	435,449	10,886	54,431	4,217
Central Africa	Cameroon	1	15,746,179	393,654	1,968,272	1,269
Central Africa	Central African Republic	1	3,683,538	92,088	460,442	1,289
Central Africa	Chad	1	9,253,493	231,337	1,156,687	656
Central Africa	Congo	1	2,954,258	73,856	369,282	1,036
Central Africa	Equatorial Guinea	1	510,473	12,762	63,809	5,239
Central Africa	Gabon	1	1,321,560	33,039	165,195	5,514
Central Africa	Sao Tome and Principe	1	175,883	4,397	21,985	954
Central America	Costa Rica	1	3,896,092	97,402	487,012	7,838
Central America	El Salvador	1	6,470,379	161,759	808,797	4,701
Central America	Guatemala	1	13,909,384	347,735	1,738,673	4,144
Central America	Honduras	1	6,669,789	166,745	833,724	2,510
Central America	Nicaragua	1	5,128,517	128,213	641,065	2,027
Central America	Panama	1	2,960,784	74,020	370,098	6,524
Central Africa	Democratic Republic of th	1	56,625,039	1,415,626	7,078,130	346
East Africa	Burundi	1	6,096,156	152,404	762,020	529
East Africa	Eritrea	1	4,362,254	109,056	545,282	629
East Africa	Ethiopia	1	66,557,553	1,663,939	8,319,694	382
East Africa	Kenya	1	31,639,091	790,977	3,954,886	1,452
East Africa	Rwanda	1	7,810,056	195,251	976,257	799
Eastern Mediterrar	Afghanistan	1	28,717,213	717,930	3,589,652	660
Eastern Mediterrar	Djibouti	1	457,130	11,428	57,141	1,288
Eastern Mediterrar	Egypt	1	74,718,797	1,867,970	9,339,850	3,901
Eastern Mediterrar	Iran (Islamic Republic of)	1	68,278,826	1,706,971	8,534,853	6,673
Eastern Mediterrar	Iraq	1	24,683,313	617,083	3,085,414	2,997

All information on this sheet is based on data and fixed with respect to the model

QUESTION **B1** HOW DOES POTENTIAL PRODUCT PROFILE DRIVE DEMAND? (I)

- Sheet captures a matrix that defines a product profile
- All parameters on the matrix are variable, allowing demand to be estimated for a wide range of profiles
- Matrix captures the interplay between
 - Efficacy
 - Duration of action
 - Target population
 - Clinical manifestation
 - Dosage
 - Schedule
 - Cost of vaccine

Species of malaria	Disease target	Age-group	Duration of action					
			1	2	3	4	5	6
			50% < 6 months	50% 6 months	50% > 6 months to < 1 y	50% 1 year	50% >1 to 5 year	50% > 5 years
Falciparum	Clinical	Infants	50%	50%	50%	50%	50%	50%
Falciparum	Clinical	Children 1 - 5 years	50%	50%	50%	50%	50%	50%
Falciparum	Clinical	Children 5 + years	50%	50%	50%	50%	50%	50%
Falciparum	Clinical	Adults	50%	50%	50%	50%	50%	50%
Falciparum	Clinical	Pregnant women	50%	50%	50%	50%	50%	50%
Falciparum	Severe	Infants	50%	50%	50%	50%	50%	50%
Falciparum	Severe	Children 1 - 5 years	50%	50%	50%	50%	50%	50%
Falciparum	Severe	Children 5 + years	50%	50%	50%	50%	50%	50%
Falciparum	Severe	Adults	50%	50%	50%	50%	50%	50%
Falciparum	Severe	Pregnant women	50%	50%	50%	50%	50%	50%
Vivax	Clinical	Infants	0%	0%	0%	0%	0%	0%
Vivax	Clinical	Children 1 - 5 years	0%	0%	0%	0%	0%	0%
Vivax	Clinical	Children 5 + years	0%	0%	0%	0%	0%	0%
Combined	Severe	Children 5 + years						
Combined	Severe	Adults						
Combined	Severe	Pregnant women						

Dosage chart	
Dosage	# of
Initial dosage	3
Gap between doses 0 & 1 (months)	1
Gap between doses 1 & 2 (months)	1
Gap between doses 2 & 3 (months)	
Gap between doses 3 & 4 (months)	
Gap between doses 4 & 5 (months)	
Frequency of booster doses (once every _ months)	12
Applicable during pregnancy	Yes
Dosage during pregnancy	3

Cost of vaccine	Cost A	Cost B	Cost C
Cost per dose in public market (US\$)	2	10	20
# doses in initial administration	3	3	3
Need for annual booster	Yes	Yes	Yes

All inputs on this sheet are variables

QUESTION **B2** HOW DOES POTENTIAL PRODUCT PROFILE DRIVE DEMAND? (II)

- Product profile – Entry sheet captures research findings on minimum threshold required to enter market
- Establishes whether vaccine will enter market based on assumed product profile
- Captures information at the level of clusters

Cluster Id	Country / Cluster	Product profile parameter	Minimum required to enter market type				Result for market type	
			Public market	Private market	Public	Private	Public market	Private market
1	Ghana cluster	Efficacy / effect	30%	50%	TRUE	TRUE	Yes	Yes
	Ghana cluster	Duration of acti	12	12	1	1		
	Ghana cluster	Age-group	All	All				
	Africa cluster 1	Cost of vaccine	5	5				
2	Nigeria cluster	Efficacy / effect	30%	50%	TRUE	TRUE	Yes	Yes
	Nigeria cluster	Duration of acti	12	12	1	1		
	Nigeria cluster	Age-group	All	All				
3	Senegal cluster	Efficacy / effect	30%	50%	TRUE	TRUE	Yes	Yes
	Senegal cluster	Duration of acti	12	12	1	1		
4	Brazil cluster	Efficacy / effect	80%	80%	FALSE	FALSE	No	No
	Brazil cluster	Duration of acti	12	12	2	2		
	Brazil cluster	Age-group	All	All				
5	Tanzania cluster	Efficacy / effect	50%	60%	TRUE	FALSE	Yes	No
	Tanzania cluster	Duration of acti	12	12	1	2		
	Tanzania cluster	Age-group	All	All				
6	Mozambique cluster	Efficacy / effect	50%	60%	TRUE	FALSE	Yes	No
	Mozambique cluster	Duration of acti	12	12	1	2		
	Mozambique cluster	Age-group	All	All				
7	India cluster	Efficacy / effect	80%	80%	FALSE	FALSE	No	No
	India cluster	Duration of acti	12	12	2	2		
	India cluster	Age-group	All	All				
8	Thailand cluster	Efficacy / effect	80%	80%	FALSE	FALSE	No	No
	Thailand cluster	Duration of acti	12	12	2	2		
	Thailand cluster	Age-group	All	All				

All inputs on this sheet are variables

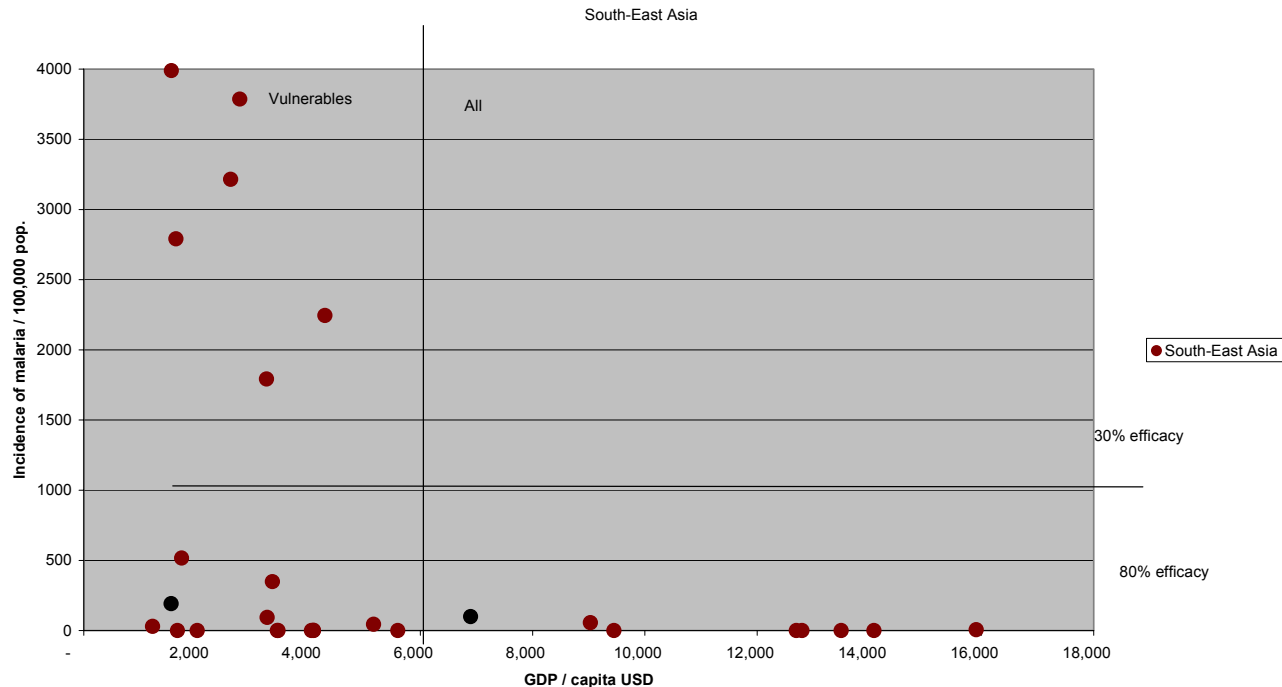
QUESTION **B2** HOW DOES POTENTIAL PRODUCT PROFILE DRIVE DEMAND? (III)

		Public market									
Cluster Id	Country / Cluster	% of population that will be considered	Donor funding availability (1 = Government to self-fund, 2 = Full availability of funds from donors, 3 = Partial funding available from donors)	% of total health expenditure likely to be spent on malaria	% of malaria spend likely on vaccine	Intent to vaccinate children < 1	Intent to vaccinate pregnant women	Intent to vaccinate children 1-5	Intent to vaccinate children > 5	Intent to vaccinate adults	Annual Compliance rate to boosters
1	Ghana cluster	100%	1	30%	30%	Yes	Yes	Yes	No	No	70%
2	Nigeria cluster	100%	1	30%	30%	Yes	Yes	Yes	No	No	50%
3	Senegal cluster	100%	1	30%	30%	Yes	Yes	Yes	No	No	70%
4	Brazil cluster	10%	1	10%	30%	Yes	Yes	Yes	Yes	Yes	80%
5	Tanzania cluster	100%	1	30%	30%	Yes	Yes	Yes	No	No	60%
6	Mozambique cluster	100%	1	30%	30%	Yes	Yes	Yes	No	No	50%
7	India cluster	15%	1	15%	30%	Yes	Yes	Yes	No	No	60%
8	Thailand cluster	5%	1	10%	30%	Yes	Yes	Yes	Yes	Yes	80%
9	Americas HI	10%	1	10%	30%	Yes	Yes	Yes	Yes	Yes	80%
10	Americas LI	10%	1	10%	30%	Yes	Yes	Yes	No	No	80%
11	East Africa	100%	1	30%	30%	Yes	Yes	Yes	No	No	60%
12	Eastern Mediterranean HI,LI	15%	1	30%	30%	Yes	Yes	Yes	Yes	Yes	60%
13	Eastern Mediterranean LI,LI	15%	1	30%	30%	Yes	Yes	Yes	No	No	60%
14	Eastern Mediterranean LI,HI	100%	1	30%	30%	Yes	Yes	Yes	No	No	60%
15	Europe LI,LI	5%	1	10%	30%	Yes	Yes	Yes	No	No	80%
16	SEA HI,LI	15%	1	10%	30%	Yes	Yes	Yes	Yes	Yes	80%
17	SEA LI,HI	100%	1	15%	30%	Yes	Yes	Yes	No	No	60%
18	SEA LI,LI	15%	1	15%	30%	Yes	Yes	Yes	No	No	60%
19	Southern Africa HI,LI	100%	1	30%	30%	Yes	Yes	Yes	Yes	Yes	60%
20	Southern Africa LI,LI	100%	1	30%	30%	Yes	Yes	Yes	No	No	50%
21	Southern Africa LI,HI	100%	1	30%	30%	Yes	Yes	Yes	No	No	50%
22	West and Central Africa	100%	1	30%	30%	Yes	Yes	Yes	No	No	60%

- Clustering methodology used to extrapolate in-country research findings, especially attitudinal parameters, to the malaria afflicted countries around the world
- Methodology based on malaria burden and country income levels

All inputs on this sheet are variables

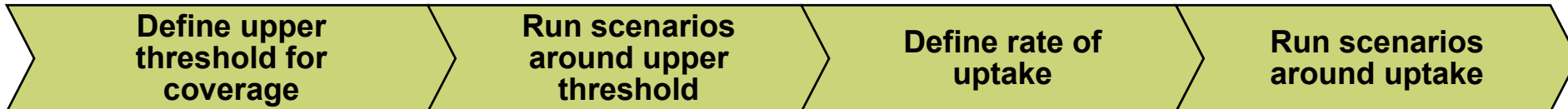
QUESTION **B2** HOW DOES POTENTIAL PRODUCT PROFILE DRIVE DEMAND? (IV)



- Methodology based on malaria burden and country income levels
- Findings form in-country research segmented on the basis of above parameters
- Findings extrapolated to non-research countries

All inputs on this sheet are variables

QUESTION C1 IN THE PUBLIC MARKET, WHAT PROPORTION OF POPULATION IS LIKELY TO HAVE ACCESS TO THE VACCINE?

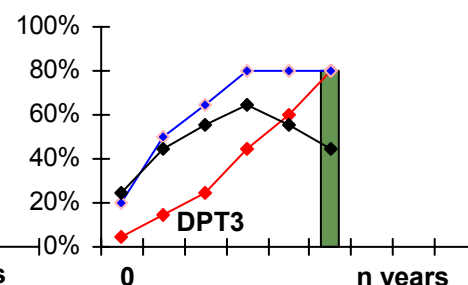
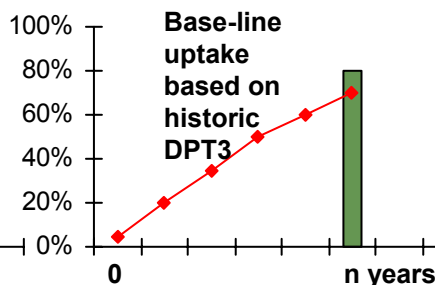
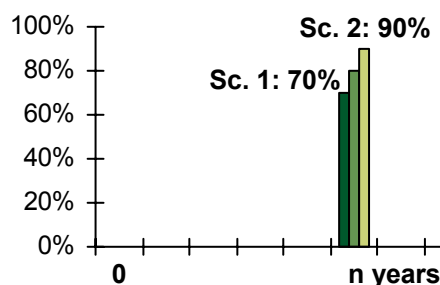
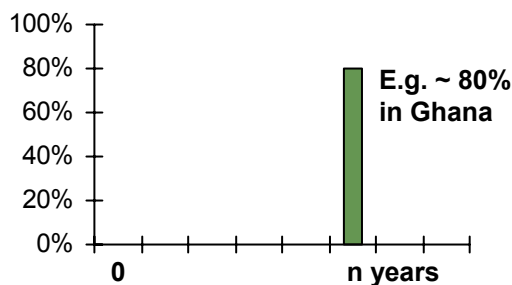


- For each country individually
- Based on historic EPI data
 - for different vaccine coverage, e.g. DPT3 as base-line coverage, HepB as high coverage where implemented, others

- Based on progress in economic and health care indicators
- Using regression analysis, e.g. EPI coverage as influenced by GDP/cap
- Using specific scenarios

- Based on historic EPI data
- Baseline defined as uptake of DPT3 average for region

- Based on vaccine analogues
 - e.g. baseline: DPT3 average for region, fast: HepB average where implemented
- Based on scenarios around funding availability, sustainability planning, etc.



EPI inputs are fixed, all others are variables

QUESTION **D1** BASED ON ATTITUDE OF GOVERNMENTS, WHAT PROPORTION OF POPULATION WILL BE TARGETED?

- **Regional profile:**
Population that will be considered by government to be targets for the vaccine
 - E.g. Africa countries 100%, Brazil 10%, Thailand 5%
- **Demographic profile:**
Age-groups and demographic profiles considered by the government for public market
 - E.g. Africa: <5s and pregnant women, Thailand all age-groups

		Public market					
Cluster Id	Country / Cluster	% of population that will be considered	Intent to vaccinate children < 1	Intent to vaccinate pregnant women	Intent to vaccinate children 1-5	Intent to vaccinate children > 5	Intent to vaccinate adults
1	Ghana cluster	100%	Yes	Yes	Yes	No	No
2	Nigeria cluster	100%	Yes	Yes	Yes	No	No
3	Senegal cluster	100%	Yes	Yes	Yes	No	No
4	Brazil cluster	10%	Yes	Yes	Yes	Yes	Yes
5	Tanzania cluster	100%	Yes	Yes	Yes	No	No
6	Mozambique cluster	100%	Yes	Yes	Yes	No	No
7	India cluster	15%	Yes	Yes	Yes	No	No
8	Thailand cluster	5%	Yes	Yes	Yes	Yes	Yes

All inputs on this sheet are variables

QUESTION **D1** BASED ON ATTITUDE OF GOVERNMENTS AND DONORS, WHAT PROPORTION OF FUNDING WILL BE AVAILABLE FOR A MALARIA VACCINE?

- **Cost-effectiveness in comparison with other interventions used to estimate proportion of donor and country funding that could be dedicated to a malaria vaccine**
- **Based on interview findings donor organizations and country Ministries of Finance**

Cost-Effectiveness Profiles

Parameter	Cost of vaccine compared to ITNs	Notes	Efficacy of vaccines compared to ITNs	Notes
Vhigh	20	More than 2 X ITN cost	90%	> 90%
High	15	More than 1.5 X ITN cost	60%	More than 2X of ITNs
Medium		Within 50% of ITN cost		Less than 2X of ITNs
Low	7.5	Less than 50% of ITN cost	30%	Less than ITNs

Parameter (Cost)	Parameter (Efficacy)	Concatenate	Result
Low	Low	LowLow	10%
Medium	Low	MediumLow	10%
High	Low	HighLow	0
Vhigh	Low	VhighLow	0
Low	Medium	LowMedium	50%
Medium	Medium	MediumMedium	30%
High	Medium	HighMedium	20%
Vhigh	Medium	VhighMedium	10%
Low	High	LowHigh	60%
Medium	High	MediumHigh	50%
High	High	HighHigh	40%
Vhigh	High	VhighHigh	30%
Low	Vhigh	LowVhigh	80%
Medium	Vhigh	MediumVhigh	80%
High	Vhigh	HighVhigh	70%
Vhigh	Vhigh	VhighVhigh	60%

Product profile	
Efficacy lookup	50.0%
Cost lookup	8.67

Donor /country funding factor			
Cost result	Efficacy result	Concatenate result	Funding result
Medium	Medium	MediumMedium	30%

All inputs on this sheet are variables

QUESTION **E1** HOW MANY DOSES OF VACCINE IN A GIVEN YEAR DOES THIS TRANSLATE INTO?

Parameters	Year A	Year B	Year C	Year D	Year E
Birth cohort & pregnant women	$A_1 \times N_i$	$B_1 \times N_i$	$C_1 \times N_i$	$D_1 \times N_i$	$E_1 \times N_i$
Children aged 1 – 5 years	$\sum A_{2-5} \times N_i$	$\sum A_{2-5} \times N_{IB} \times CF_1$ $(B_{2-5} - A_{2-5}) \times N_i$	$\sum A_{2-5} \times N_{IB} \times CF_2$ $(B_{2-5} - A_{2-5}) \times N_{IB} \times CF_1$ $(C_{2-5} - B_{2-5}) \times N_i$	$\sum A_{2-5} \times N_{IB} \times CF_3$ $(B_{2-5} - A_{2-5}) \times N_{IB} \times CF_2$ $(C_{2-5} - B_{2-5}) \times N_{IB} \times CF_1$ $(D_{2-5} - C_{2-5}) \times N_i$	$\sum A_{2-5} \times N_{IB} \times CF_4$ $(B_{2-5} - A_{2-5}) \times N_{IB} \times CF_3$ $(C_{2-5} - B_{2-5}) \times N_{IB} \times CF_2$ $(D_{2-5} - C_{2-5}) \times N_{IB} \times CF_1$ $(E_{2-5} - D_{2-5}) \times N_i$
Children > 5 and adults	Same as children 1 – 5, except progression does not stop after 5 th year				

Compliance factor, number of initial and booster doses are variables.

A_i = Population of age i in year A
 CF_n = Compliance factor for cluster / country for n^{th} year
 N_i = Number of initial doses
 N_{IB} = Number of booster doses / year

QUESTION **A2** WHAT COUNTRIES ACROSS THE WORLD NEED A MALARIA VACCINE?

- Model contains a master country data sheet
- Lists all countries in the world
- Selects those that are endemic to malaria
- Contains detailed data on
 - Economic profile and development
 - Population profile and growth
 - Malaria related statistics
 - Health care statistics

Region	Country	MALARIA	Population	Birth cohort (Es	Population < 5 (Est	GDP CAP
America Andean	Bolivia	1	8,586,443	214,661	1,073,305	2,370
America Andean	Colombia	1	41,662,073	1,041,552	5,207,759	6,519
America Andean	Ecuador	1	13,710,234	342,756	1,713,779	3,905
America Andean	Peru	1	28,409,897	710,247	3,551,237	4,888
America Andean	Venezuela	1	24,654,694	616,367	3,081,837	6,402
America Brazil	Brazil	1	182,032,604	4,550,815	22,754,076	7,537
America Mexico	Mexico	1	103,718,062	2,592,952	12,964,758	8,903
Americas	Belize	1	266,440	6,661	33,305	5,351
Americas	Guyana	1	702,100	17,553	87,763	4,046
Americas	Suriname	1	435,449	10,886	54,431	4,217
Central Africa	Cameroon	1	15,746,179	393,654	1,968,272	1,269
Central Africa	Central African Republic	1	3,683,538	92,088	460,442	1,289
Central Africa	Chad	1	9,253,493	231,337	1,156,687	656
Central Africa	Congo	1	2,954,258	73,856	369,282	1,036
Central Africa	Equatorial Guinea	1	510,473	12,762	63,809	5,239
Central Africa	Gabon	1	1,321,560	33,039	165,195	5,514
Central Africa	Sao Tome and Principe	1	175,883	4,397	21,985	954
Central America	Costa Rica	1	3,896,092	97,402	487,012	7,838
Central America	El Salvador	1	6,470,379	161,759	808,797	4,701
Central America	Guatemala	1	13,909,384	347,735	1,738,673	4,144
Central America	Honduras	1	6,669,789	166,745	833,724	2,510
Central America	Nicaragua	1	5,128,517	128,213	641,065	2,027
Central America	Panama	1	2,960,784	74,020	370,098	6,524
Central Africa	Democratic Republic of th	1	56,625,039	1,415,626	7,078,130	346
East Africa	Burundi	1	6,096,156	152,404	762,020	529
East Africa	Eritrea	1	4,362,254	109,056	545,282	629
East Africa	Ethiopia	1	66,557,553	1,663,939	8,319,694	382
East Africa	Kenya	1	31,639,091	790,977	3,954,886	1,452
East Africa	Rwanda	1	7,810,056	195,251	976,257	799
Eastern Mediterrar	Afghanistan	1	28,717,213	717,930	3,589,652	660
Eastern Mediterrar	Djibouti	1	457,130	11,428	57,141	1,288
Eastern Mediterrar	Egypt	1	74,718,797	1,867,970	9,339,850	3,901
Eastern Mediterrar	Iran (Islamic Republic of)	1	68,278,826	1,706,971	8,534,853	6,673
Eastern Mediterrar	Iraq	1	24,683,313	617,083	3,085,414	2,997

All information on this sheet is based on data and fixed with respect to the model

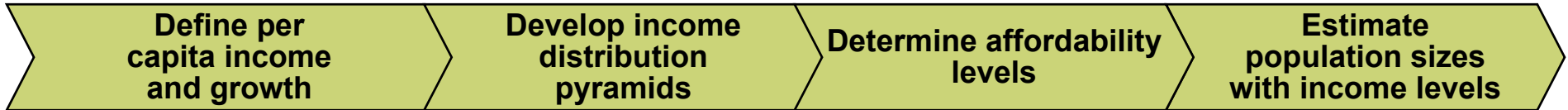
QUESTION **B2** HOW DOES POTENTIAL PRODUCT PROFILE DRIVE DEMAND? (II)

- Product profile – Entry sheet captures research findings on minimum threshold required to enter market
- Establishes whether vaccine will enter market based on assumed product profile
- Captures information at the level of clusters

Cluster Id	Country / Cluster	Product profile parameter	Minimum required to enter market type				Result for market type	
			Public market	Private market	Public	Private	Public market	Private market
1	Ghana cluster	Efficacy / effect	30%	50%	TRUE	TRUE	Yes	Yes
	Ghana cluster	Duration of acti	12	12	1	1		
	Ghana cluster	Age-group	All	All				
	Africa cluster 1	Cost of vaccine	5	5				
2	Nigeria cluster	Efficacy / effect	30%	50%	TRUE	TRUE	Yes	Yes
	Nigeria cluster	Duration of acti	12	12	1	1		
	Nigeria cluster	Age-group	All	All				
3	Senegal cluster	Efficacy / effect	30%	50%	TRUE	TRUE	Yes	Yes
	Senegal cluster	Duration of acti	12	12	1	1		
4	Brazil cluster	Efficacy / effect	80%	80%	FALSE	FALSE	No	No
	Brazil cluster	Duration of acti	12	12	2	2		
	Brazil cluster	Age-group	All	All				
5	Tanzania cluster	Efficacy / effect	50%	60%	TRUE	FALSE	Yes	No
	Tanzania cluster	Duration of acti	12	12	1	2		
	Tanzania cluster	Age-group	All	All				
6	Mozambique cluster	Efficacy / effect	50%	60%	TRUE	FALSE	Yes	No
	Mozambique cluster	Duration of acti	12	12	1	2		
	Mozambique cluster	Age-group	All	All				
7	India cluster	Efficacy / effect	80%	80%	FALSE	FALSE	No	No
	India cluster	Duration of acti	12	12	2	2		
	India cluster	Age-group	All	All				
8	Thailand cluster	Efficacy / effect	80%	80%	FALSE	FALSE	No	No
	Thailand cluster	Duration of acti	12	12	2	2		
	Thailand cluster	Age-group	All	All				

All inputs on this sheet are variables

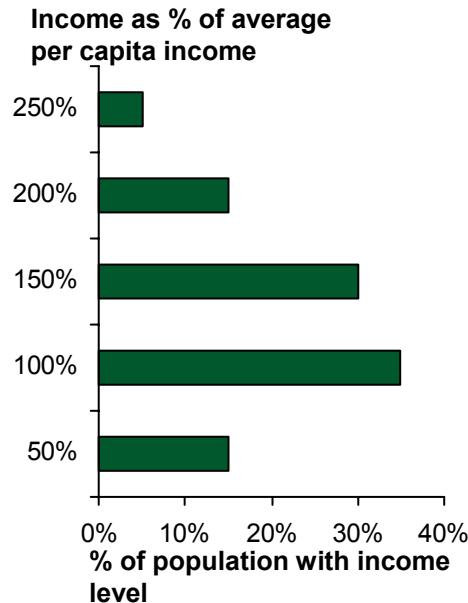
QUESTION C2 IN THE PRIVATE MARKET, WHAT PROPORTION IS LIKELY TO BE ABLE TO AFFORD THE VACCINE? (I)



- For each country individually
- Determine per capita income and growth rates

COUNTRY_NAME	Growth rate	2003 GNI
Albania	15.7%	1740
Algeria	5.3%	1890
Angola	14.5%	740
Antigua and Barbuda	2.4%	9160
Armenia	10.8%	950
Australia	0.9%	21650
Austria	0.6%	26720
Azerbaijan	9.2%	810
Bahamas, The	1.6%	15110
Kingdom of Bahrain	3.7%	11260
Bangladesh	2.0%	400
Barbados	1.7%	9270
Belarus	3.0%	1590
Belgium	0.7%	25820
Belize	1.9%	3190
Benin	3.1%	440
Bhutan	8.9%	660
Bolivia	-2.6%	890
Bosnia and Herzegovina	5.6%	1540
Botswana	3.3%	3430
Brazil	-8.7%	2710

- For geographic regions
 - E.g. Sub-Saharan Africa, East Africa, etc.

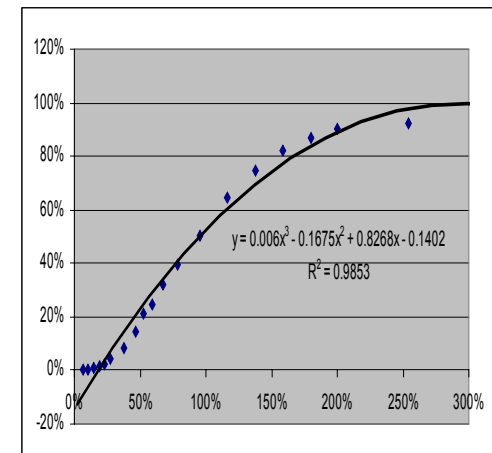


- Based on interview findings
- Determine affordability levels

- What % of per capita income likely to be spent on malaria vaccine
- E.g. 2 weeks income, 1% of annual income, etc.

- Develop scenarios for various cost levels of the vaccine

- Develop regression model to estimate % of population with a level of income high enough to purchase vaccine

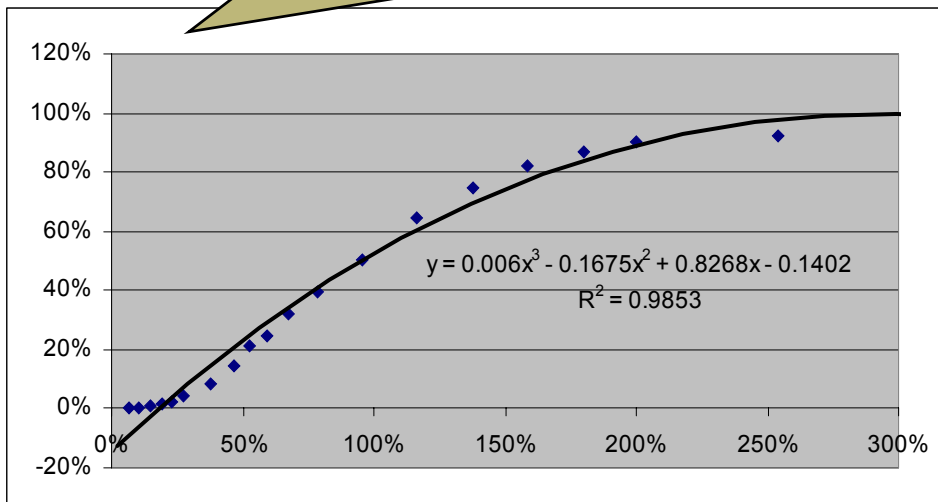


Income levels and growth are fixed, income pyramids and affordability inputs are variables

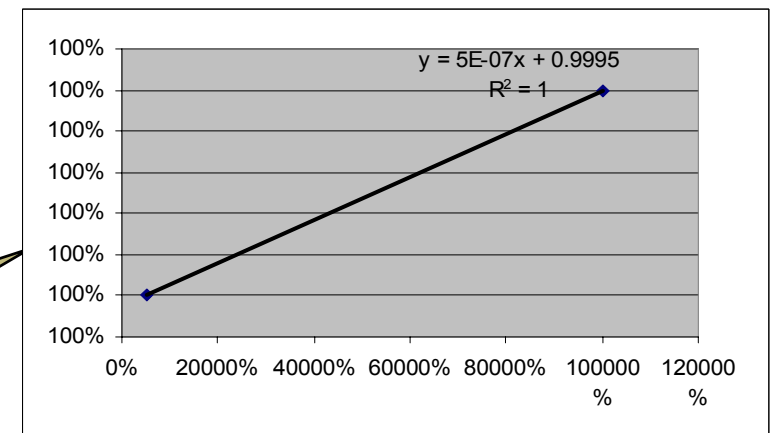
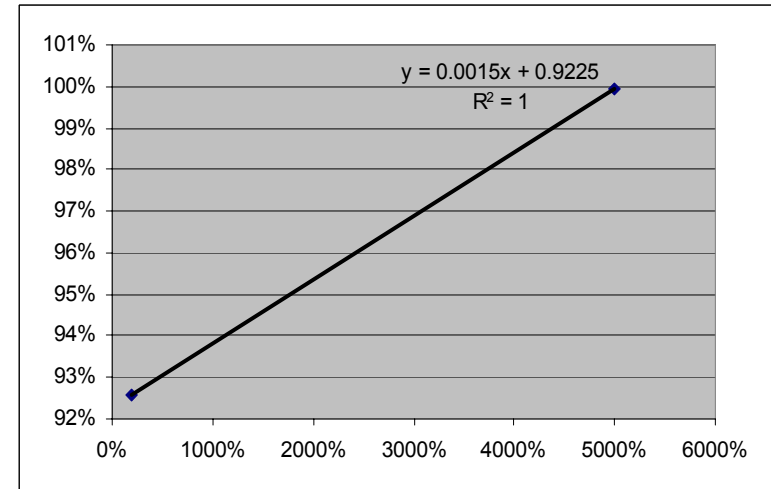
QUESTION C2 IN THE PRIVATE MARKET, WHAT PROPORTION IS LIKELY TO BE ABLE TO AFFORD THE VACCINE? (II)

Affordability model for private sector uses multiple regression equations

3rd degree polynomial regression equation used to model affordability till 3 X of average income



Linear equations used to model affordability > 3 X of average income



QUESTION **D2** BASED ON ATTITUDES IN PRIVATE MARKET, WHAT PROPORTION OF POPULATION WILL BE TARGETED? (II)

- Population likely to need vaccine given distribution of malaria and attitudes
- Given coverage by public market, portion that will procure vaccine in private market
 - Adjustments made for high-income families who prefer private vaccination
- Portion of population with access to private vaccination

		Private market					
Cluster Id	Country / Cluster	% of population that will be interested	Uptake likely from private market for children < 1	Uptake likely from private market for pregnant women	Uptake likely from private market for children 1 - 5	Uptake likely from private market for children > 5	Uptake likely from private market for adults
1	Ghana cluster	100%	No	No	No	Yes	Yes
2	Nigeria cluster	100%	No	No	No	Yes	Yes
3	Senegal cluster	100%	No	No	No	Yes	Yes
4	Brazil cluster	10%	No	No	No	Yes	Yes
5	Tanzania cluster	100%	No	No	No	Yes	Yes
6	Mozambique cluster	100%	No	No	No	Yes	Yes
7	India cluster	100%	No	No	No	Yes	Yes
8	Thailand cluster	5%	No	No	No	Yes	Yes

All inputs on this sheet are variables

QUESTION E2 HOW MANY DOSES OF VACCINE IN A GIVEN YEAR DOES THIS TRANSLATE INTO?

Parameters	Year A	Year B	Year C	Year D	Year E
Birth cohort & pregnant women	$A_1 \times N_i$	$B_1 \times N_i$	$C_1 \times N_i$	$D_1 \times N_i$	$E_1 \times N_i$
Children aged 1 – 5 years	$\sum A_{2-5} \times N_i$	$\sum \frac{A_{2-5} \times N_{IB} \times CF_1}{N_i}$	$\sum \frac{A_{2-5} \times N_{IB} \times CF_2}{N_{IB} \times CF_1}$	$\sum \frac{A_{2-5} \times N_{IB} \times CF_3}{N_{IB} \times CF_2}$	$\sum \frac{A_{2-5} \times N_{IB} \times CF_4}{N_{IB} \times CF_3}$
Children > 5 and adults	Same as children 1 – 5, except progression does not stop after 5 th year				

Compliance factor, number of initial and booster doses are variables. CF separate for public and private markets

A_i = Population of age i in year A
 CF_n = Compliance factor for cluster / country for nth year
 N_i = Number of initial doses
 N_{IB} = Number of booster doses / year

METHODOLOGY AND ASSUMPTIONS FOR TRAVELERS MARKET

A3

Traveler market need determined by WTO international tourism statistics from the developed world to malaria endemic regions as defined by the WHO

- **To determine the number of travelers at risk for malaria, countries were clustered depending on rate of traveler mobility to high-risk malaria regions (rural areas, jungle/bush, provinces with high indices of malaria)**

B3

Model assumes minimum product profile requirements/thresholds for vaccine adoption

- **Assumptions include: efficacy requirement of 98%, 5 week malarone cost of \$200, and a vaccine that requires three doses**

C3

Pre-travel medical advice and prophylaxis use drawn from traveler behaviour studies from the Journal of Travel Medicine

D3

For purpose of scenarios travelers were grouped by planning and duration habits

- **Travelers who take prophylaxis**
- **Projected uptake based on current Hep A immunization rates**
- **Travelers who take prophylaxis and stay in destination for over 2 weeks**
- **Travelers who plan 4-8 weeks in advance and stay in destination for over 4 weeks**
- **Travelers who take prophylaxis and stay in destination for over 4 weeks**

D3

Uptake of vaccine assumed to be similar to private market uptake curve

E3 TRAVELER MARKET TRIANGULATION

Hep A Proxy

Travelers from developed world to high-risk areas in malaria endemic countries	22 M
% of American travelers that get Hep A vaccine	14%
% of European travelers that get Hep A vaccine	37%
% of Asian travelers that get Hep A vaccine	5%
Total travelers from developed world that got Hep A vaccine in 2002	4.5 M

Malarone Sales

Total global prophylaxis sales in 2004	\$290 M
Total global malarone sales in 2004	\$78 M
Average duration of travel	18 Days
~ Cost of malarone per day	\$5
Total number of travelers that took malarone in 2004	.9 M

(1)Travelers to areas where they are at risk of contracting Hep A, 'developed world' refers to travelers from Asia, Europe, and the Americas as defined by WTO

(2)Duration of travel based on Journal of Travel Medicine studies covering Asian, U.S. and European travelers

MILITARY NEED SEGMENTED INTO NUMBER OF TROOPS LIKELY TO RECEIVE VACCINATION

A4 **Militaries need vaccinations to maximise troop readiness and avoid illness**

Three primary options for choosing a population to vaccinate:

- 1) All troops**
- 2) No troops**
- 3) Troops deployed to malaria-endemic regions**

Snapshot: Deployment sizing in the model

Sample: Countries without malaria: ~5% deployed	Sample: Countries w/ malaria: same % as pop. at risk are deployed
Belgium	Algeria
Canada	Cambodia
Japan	Djibouti
Poland	Ethiopia
UK	Malaysia
US	Saudi Arabia

VACCINE COST AND EFFICACY INFLUENCE MILITARY DEMAND, SAFETY AND DURATION ACT AS THRESHOLD CRITERIA

B4

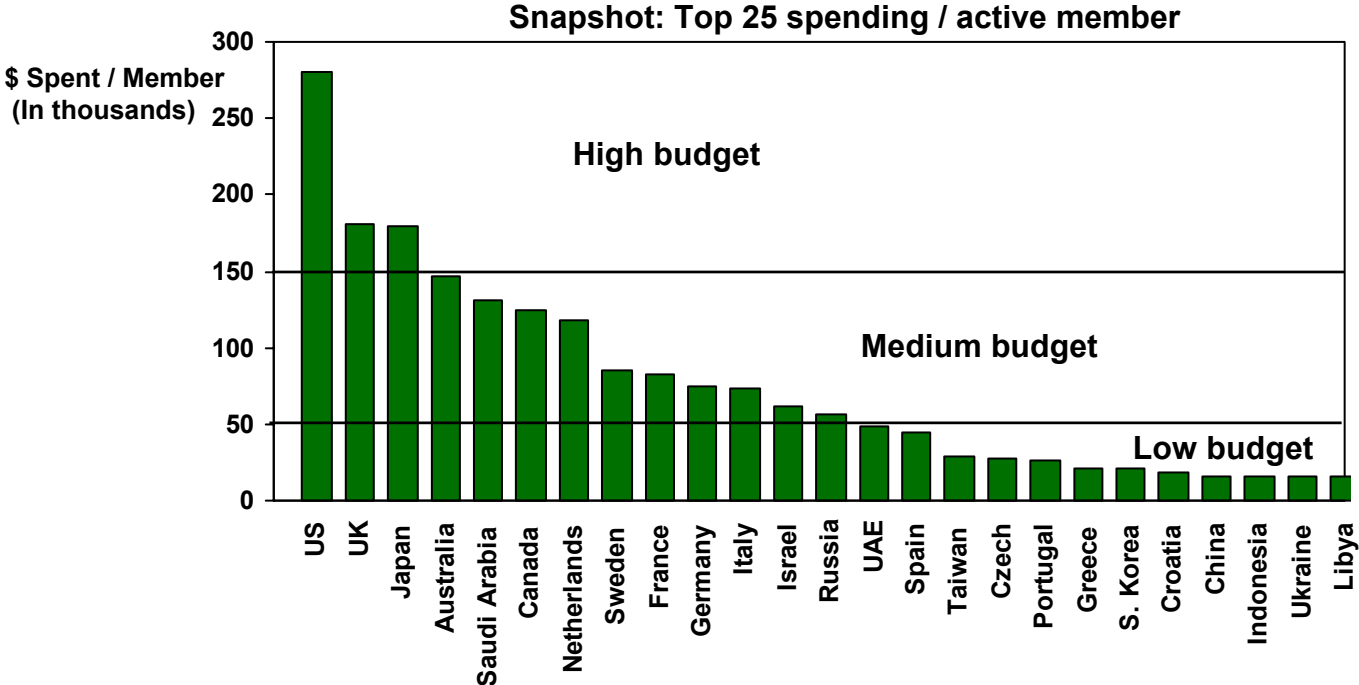
Vaccine efficacy and cost are key demand variables and were segmented into three tiers

<u>Vaccine Efficacy (Clinical)</u>	<u>Vaccine Cost (total)</u>
Low (<50%)	Low (< \$20)
Medium (50-80%)	Medium (\$20-\$100)
High (>80%)	High (>\$100)

Duration and safety are threshold criteria—militaries are unlikely to accept a vaccine that lasts <6 months or one with serious side-effects

MILITARY BUDGETS DRIVE ABILITY TO PAY FOR VACCINE

C4 Military expenditure levels segmented into three tiers



US DOD spends ~\$15-17B each year for the Defense Health Program, or ~\$6,000/person

D4

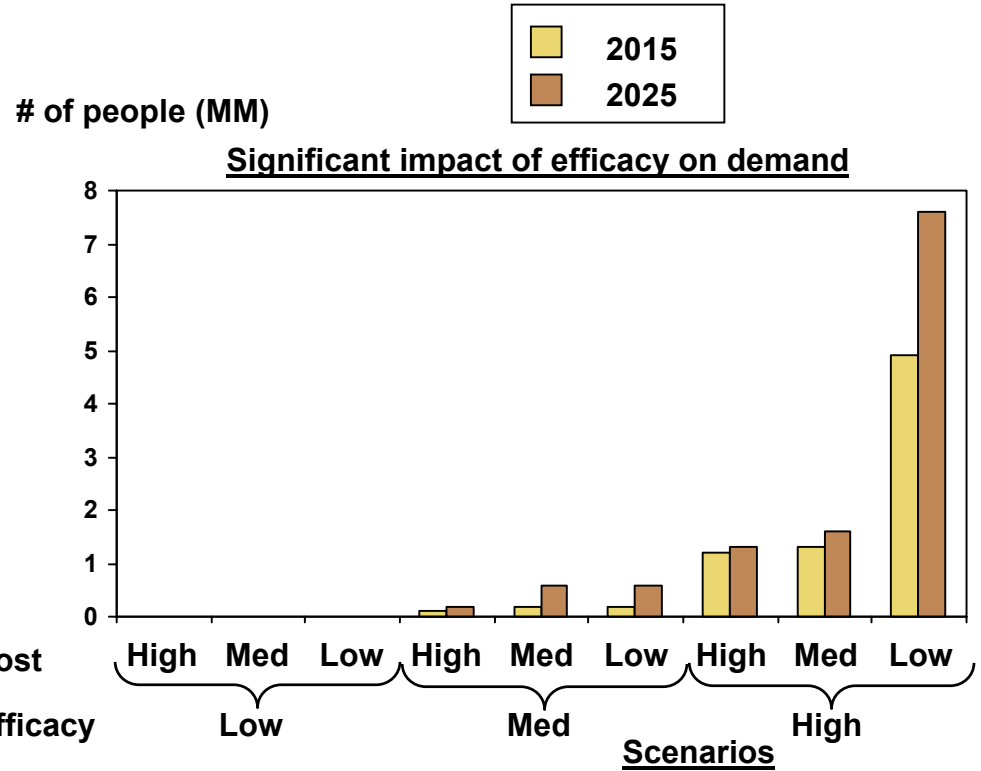
PEAK ANNUAL DEMAND FOR A MALARIA VACCINE IN THE MILITARY RANGES FROM 0-13 MM THROUGH 2025

2015 Scenarios

Efficacy Against Clinical Disease	> 80%	7.7MM	1.6MM	1.3MM
	50- 80%	0.5MM	0.5MM	0.2MM
	< 50%	0	0	0
		<\$20	\$20-\$100	>\$100
		Total Vaccine Cost		

2025 Scenarios

Efficacy Against Clinical Disease	> 80%	12.5MM	2.9MM	2.5MM
	50- 80%	0.8MM	0.8MM	0.3MM
	< 50%	0	0	0
		<\$20	\$20-\$100	>\$100
		Total Vaccine Cost		



Key:
 Cost: Low - < \$ 20, Med - \$ 20 – 100, High - > \$ 100
 Efficacy: Low - < 50%, Med – 50 – 80%, High - > 80%

Military demand sensitive to efficacy and cost

E4

ASSUMPTIONS: TIERING OF VACCINE EFFICACY AND COST, MILITARY BUDGETS AND DEPLOYMENT

Tiering of Scenarios

Military Budget	Vaccine Efficacy (Clinical)	Vaccine Cost (total)
Low (<\$50,000 / Active Member)	Low (<50%)	Low (< \$20)
Medium (>\$50,000 / Active Member)	Medium (50-80%)	Medium (\$20-\$100)
High (>\$150,000 / Active Member)	High (>80%)	High (>\$100)

Average Deployment Time: 120 days
% Newly Deployed in A Cycle: 40%

Snapshot: Variables in military model

Country	Budget Segmentation	Efficacy Segmentation	Price Segmentation	Malaria Risk (1-Yes, 0-No)	% Deployed to Malarial	% Used (1-All, 0-None)	Potential New Vaccines
Albania	Low	High	Low	0	5%	2	6,828
Algeria	Low	High	Low	1	100%	2	128,281
Argentina	Low	High	Low	1	10%	2	0
Armenia	Low	High	Low	1	5%	2	5,222
Australia	Medium	High	Low	0	5%	1	53,795
Austria	Low	High	Low	0	5%	2	5,184
Azerbaijan	Low	High	Low	1	5%	2	7,814

Scenario Uptake Levels

Military Budget Segmentation	Vaccine Efficacy Segmentation	Vaccine Cost Segmentation
Low	Low	Low
Low	Low	Medium
Low	Low	High
Low	Medium	Low
Low	Medium	Medium
Low	Medium	High
Low	High	Low
Low	High	Medium
Low	High	High
Medium	Low	Low
Medium	Low	Medium
Medium	Low	High
Medium	Medium	Low
Medium	Medium	Medium
Medium	Medium	High
Medium	High	Low
Medium	High	Medium
Medium	High	High
High	Low	Low
High	Low	Medium
High	Low	High
High	Medium	Low
High	Medium	Medium
High	Medium	High
High	High	Low
High	High	Medium
High	High	High

Troops deploying to endemic regions
 All active troops

TABLE OF CONTENTS

Project overview

Endemic country findings

Travelers and military findings

Demand model methodology

Predicted vaccine market size

Implications and next steps

Appendix

- **Detailed description of demand model**
- **Primary research sources**
- **Secondary research sources**
- **Contact information**

BRAZIL INTERVIEWS

Amazon Tropical Medicine Foundation (5 people)

FIOCRUZ (4 people)

Ministry of Health (3 people)

Hospital das Clinicas/University of Sao Paulo (3 people)

INPE– National Institute of Space Research

World Bank

WHO/PAHO

USAID

GHANA INTERVIEWS

Ministry of Health (6 people)
Noguchi Memorial Institute (2 people)
GSK Ghana (2 people)
Food & Drugs Board
EPID Researcher
USAID
MEDEX
NPO-Malaria, WHO
Dodowa Health Research Institute
Malaria Consortium Office
National Malaria Control Office
Health Research Unit, Ghana Health Service
National Malaria Control Programme
DFID
HACI-Ghana
Ghana Social Marketing Foundation

INDIA INTERVIEWS

GSK, India (3 people)

Ministry of Health (2 people)

NVBDCP (2 people)

Epidemic Diseases Hospital and MRC (2 people)

UNICEF

WHO India

WHO SEARO

ICGEB

Ex Director, NAMP

National Institute of Health and Family Welfare

Universal Program of Immunization

Sir Dorabji Tata Center for Research in Tropical Diseases

Manipal Hospital

Vidarbha Hospital

Sangeetha Nursing Home

MOZAMBIQUE INTERVIEWS

Ministry of Health (5 people)
World Vision (3 people)
UNICEF (2 people)
CISM (2 people)
Ministry of Planning and Finance (2 people)
National Malaria Control Programme
Universidade de Eduardo Mondlane
Health Alliance International
Malaria, PSI
DFID
Save the Children
USAID
Ilha de Josina Community
WHO Mozambique
WHO AFRO
Child Survival Program, World Relief
Government health official, Maputo Province
Project Hope
Bethesda Clinic (private), Maputo
World Bank, Mozambique

NIGERIA INTERVIEWS

NIPRD (8 people)

Iso General Hospital (5 people)

FMOH (4 people)

Zankli Medical Center (3 people)

House of Representatives, Committee on Health (3 people)

Lagos State Ministry of Health (3 people)

NAFDAC (2 people)

Lowanson Community Partners for Health (2 people)

Federal Capital Territory, Dept. of Public Health

Health Department, Gwagwalada Local Government

Universal Gaskiya Pharmacy Ltd.

National Programme of Immunization

GSK, West & Central Africa

Gwagwalada Local Government

National Assembly Clinic

Nigerian Medical Association

NIMR

RBM, WHO

UNICEF

USAID

DFID

Hope for AIDS and Life Outreach

SENEGAL INTERVIEWS

Ministry of Health (3 people)

Bambey District Health Centre (2 people)

Fann Hospital (2 people)

PATH (2 people)

WHO (2 people)

BASICS

DERF

GSK

Hopital Aristide le Dantec Service au Pediatrie

UNICEF

USAID

World Vision

TANZANIA INTERVIEWS

Ministry of Health (8 people)

St. Francis Hospital, Ifakara (5 people)

World Health Organization (3 people)

USAID (2 people)

National Malaria Control Programme

National Institute for Medical Research

Ministry of Finance

Africa Region, World Bank

Muhimbili University School of Public Health

DFID

Tanzania FDA

African Malaria Network Trust

Ifakara Health Research & Development Centre, LSHTM

HealthScope Tanzania

Project Manager, Reproductive and Child Health, African Medical and Research

Ifakara Research and Development Centre

AAR (Tanzanian Health Insurance Provider/Private Clinic Operator)

THAILAND INTERVIEWS

Faculty of Tropical Medicine , Mahidol University (4 people)

MoPH (3 people)

Biogenetech Co. Ltd. (2 people)

Shoklo Malaria Unit, Mae Sod, Tak province

National Science and Technology Development Agency

Wellcome Trust Unit Bangkok

Department of Immunology & Medicine, AFRIMS

The Global Fund

Wellcome Trust Unit Bangkok

WHO SAE

Faculty of Tropical Medicine, Mahidol University

TRAVELER INTERVIEWS

Centers for Disease Control and Prevention (3 people)

**Tropical & Geographic Medicine Ctr., Division of Infectious Diseases,
Massachusetts General Hospital**

**Infectious and Tropical Disease Dept., London School of Hygiene and Tropical
Medicine**

Center for Travel and Tropical Medicine, Toronto General Hospital

London School of Hygiene and Tropical Medicine

MILITARY INTERVIEWS

WRAIR (3 people)

Sir Dorabji Tata Center for Research in Tropical Diseases

Consultant Public Health Physician, British Forces

GSK, former WRAIR

DONOR AND POLICYMAKER INTERVIEWS

GSK (7 people)
PATH (5 people)
WHO (3 people)
CDC (3 people)
DFID (3 people)
RBM (2 people)
USAID (2 people)
World Bank (2 people)
UNICEF (2 people)
JICA
Netherlands Ministry
GAVI
Global Fund
WHO AFRO
Initiatives on PPP for Health
NIH
Ifakara
STI
MMV
MIM

INTERVIEW TOPICS VARIED BY TARGET GROUP

Target	Government Officials	Physicians/KOLs	Private market	Donors and policymakers
Topics	<p>Overview of current malaria situation and approach to prevention and treatment</p> <p>Current funding for malaria interventions</p> <p>Process/rationale for resource allocation</p> <p>Unmet needs</p> <p>Reactions to potential product profile attributes and ranges</p> <p>Assessment of private market</p> <p>Key influencers and other factors that will impact demand</p>	<p>Overview of current malaria situation</p> <p>View of current malaria interventions and unmet needs</p> <p>Methods by which patients access malaria care and treatment</p> <p>Reactions to potential product profile attributes and ranges</p> <p>Assessment of private market</p> <p>Key influencers that will impact demand</p>	<p>Experience with malaria in household</p> <p>Impact of malaria on productivity and other metrics</p> <p>Interventions currently used</p> <p>Amount of money currently spent on malaria interventions and other drugs/vaccines</p> <p>High-level reactions to potential product attributes</p>	<p>Overview of current malaria situation</p> <p>Interventions that are funded/supported and rationale</p> <p>Unmet needs</p> <p>Reactions to potential product profile attributes and ranges</p> <p>Assessment of private market</p> <p>Key influencers and other factors that will impact demand</p>

TABLE OF CONTENTS

Project overview

Endemic country findings

Travelers and military findings

Demand model methodology

Predicted vaccine market size

Implications and next steps

Appendix

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- **Secondary research sources**
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SECONDARY SOURCES

Brazil Ministry of Health Datatus

Case study on the costs and financing of immunization services in Ghana (Abt Associates)

Center for Disease Information, Bureau of Arms Control “World Military Expenditures and Arms Transfers”

CDC Malaria Surveillance Report 2002

Countrywatch

DASA

DFID “Developing a Sustainable ITN Market in Mozambique” RFP, May 2004

DHS (1997 data)

Food and Agriculture Organization of the United Nations (2002 data)

GAVI

Ghana EPI Financial Sustainability Plan (GAVI)

Ghana Health Report

Heritage

IMS (2003 data)

India Ministry of Health Datatus

Institute of Medicine of Natural Sciences

Journal of Travel Medicine, “Travel Health Knowledge, Attitudes and Practices among US Travelers”

Journal of Travel Medicine, “Travelers Knowledge, Attitudes and Practices on Prevention of Infectious Diseases: Results from a Pilot Study”

Journal of Travel Medicine, “Travelers Knowledge, Attitudes and Practices on the Prevention of Infectious Diseases”

SECONDARY SOURCES

LSHTM

Malaria Foundation International

MARA Technical Report (1998)

MICS data (1998-2001)

Mozambique Financial Stability Plan (GAVI)

National Malaria Control Program Health Facility and Community Survey 2004 (2003 data)

Naval Medical Research Institute

NIC (2000)

PAHO

Project Hope: A Study to Describe Barriers To Childhood Vaccination in Mozambique

Roll Back Malaria (Abuja criteria)

Survey of basic vaccine coverage in Thailand (2003)

Tanzania Ministry of Health

Thai Ministry of Public Health

The Africa Malaria Report (WHO/UNICEF 2003)

The Global Fund

The Southeast Asian Journal of Tropical Medicine and Public Health, Vol. 34, (4), 2003

U.S. Department of Defense

UK Department of Trade and Investment

UNICEF

SECONDARY SOURCES

US Census Bureau

US Department of Defense, IIS “Military Balance”

USAID

Virtual Naval Hospital

WHO: Life expectancy and infant mortality (2003)

WHOLIS

WHOSIS

World Bank

World Tourism Organization, “World Overview and Tourism Topics” (2003)

TABLE OF CONTENTS

Project overview

Endemic country findings

Travelers and military findings

Demand model methodology

Predicted vaccine market size

Implications and next steps

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CONTACT INFORMATION

MIV, PATH Central Number: 206-285-3500

Contact: Patricia Atkinson Roberts

BCG Central Number: 617-973-1200

Contacts: Wendy Woods, Dave Matheson