Policy development process for introducing new malaria interventions in Tanzania: The case of Malaria vaccine RTS,S

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Dekan

Dedicated to the memory of my mother**;** late Kadidi Mukangara

for your love, patience and devotion

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SUMMARY

Global Health Initiatives (GHIs) originated in 1978 at the Alma Ata conference. The Alma Ata Declaration of Health for all by the year 2000 supported a comprehensive package of services to address child health, prevention and control of diseases and immunization against communicable diseases. In 1982, Comprehensive primary health care was replaced by UNICEF's Declaration of a Children's Revolution, which supported selective primary care and emphasized priority diseases, including malaria, and a package of cost effective interventions, such as immunization.

A key component of child health is availability and access to immunization. Traditionally, it takes years and decades for interventions and vaccines to become available and accessible to those most in need. Two major reasons for these delays are insufficient anticipation of the policy process and the absence of a framework to facilitate a comprehensive understanding of policy process required for decision making.

This thesis describes research into anticipated policy processes and develops a comprehensive framework for informing policy decisions about the RTS,S malaria vaccine in Tanzania. RTS,S is the most advanced of malaria vaccines in development and has shown to protect children 5-17 months when used in conjunction with other malaria control strategies such as insecticides treated nets (ITNs) and anti-malaria drugs.

National policy decisions for introducing new malaria interventions and vaccines are shaped by global health policies. This is the case for the malaria vaccine RTS,S will be implemented at national level after the approval of WHO global recommendations. The policy process is time consuming, involves several steps and consideration of several factors before settling on a decision. Early planning is essential to having a clear picture of decision making steps and the policy context in which a malaria vaccine might be implemented.

The goal of this study was to analyse the decision making and policy development process for introducing new malaria interventions in Tanzania, without any precedent of malaria vaccine use that might help to understand the context in which a malaria vaccine could be implemented. The goal was pursued using the following methods: a cross-sectional study, a qualitative approach and a synthesis approach. A cross-sectional study of 23 regions of Tanzania conducted during the Tanzanian Integrated Measles Campaign (IMC) survey in 2011 assessed awareness of and willingness to use a malaria vaccine among women aged 18 years or older with children under 11 months old. The main outcome measure was willingness to use a malaria vaccine. Document review and in-depth interviews with 20 key informants were conducted to assess malaria treatment policy changes in Tanzania and in other African RTS,S study countries. A comparative table and framework analysis was used as a practical guide to the steps of the decision making and policy process validated in

Tanzania and other African RTS,S study countries. Synthesis and analysis of the results obtained from those studies were used to propose practical recommendations for malaria vaccine implementation. The main findings were as follows:

- A high willingness to use the malaria vaccine, associated with a high level of knowledge of the benefits of vaccinating children under-five, high acceptance of the mode of administering the malaria vaccine (2-3 injected doses delivered in the same day according to the proposed schedule for receiving the malaria vaccine).
- The framework was developed and applied to RTS, S African countries with regard to its readiness for adoption of the forthcoming malaria vaccine. The rating implies that Tanzania ((12), very good), Burkina Faso ((10), Malawi (9), Kenya and Gabon (8), good) are prepared — with regard to policy promoting factors —to embark on adopting the forthcoming malaria vaccine, RTS, S. Ghana ((5), little) has few policy promoting factors in place and had not yet documented information on barriers to decision making. Mozambique ((1), weak) had hardly documented any promoting factors or barriers. The attempt to compare showed some "good" and "very good" rankings regarding policy promoting factors although these factors may be hindered by some mentioned and documented barriers.

According to the findings, implementing the RTS,S malaria vaccine in programme settings still requires guidance in the form of proposed recommendations:
In Tanzania, the malaria vaccine is expected to be delivered through Immunization and Vaccine Development (IVD), and implemented at facility level by health care providers in both private and public facilities. In order to support and propagate the policy, a number of activities are recommended. For example, awareness should be created through developing a package of information for the community, the consumers of the vaccine that is accessible and offered in user friendly settings. Different types of media could be used for vaccine adverts and advocacy. A partnership between IVD and Global Alliance on Vaccine Initiative (GAVI) would help to ensure that the vaccine is delivered on time. IVD should strengthen its storage capacity to accommodate the malaria vaccine. To prepare for financing the vaccine, co-financing levels should be incorporated into the national budget. Guidelines, documents and training materials for immunization services should be modified to include the malaria vaccine. Health care personnel involved in vaccination should receive necessary training and a special surveillance system should be established to monitor vaccine pharmacovigilance both at national and district levels.

Implementing RTS,S in programme settings still requires some research into: i) assessing the packaging of RTS,S and the storage capacity of IVD to accommodate the malaria vaccine; ii) assessing

vaccine pharmacovigilance in low and high transmission settings; iii) identifying the required numbers and skills of human resources iv) determining the additional workload for health care workers involved in vaccination.

This is the first report evaluating the policy and decision making process for introducing a malaria vaccine in Tanzania, without any precedent of malaria vaccine use. The results contribute to the growing knowledge that understanding people's perceptions of a new malaria vaccine and the availability of a comprehension framework to understanding the policy process could speed up the decision making process and shorten the time needed to make the vaccine available to those in need. However, RTS, S vaccine alone does not provide a definitive solution to preventing malaria. The vaccine should be integrated with other strategies to address the burden of malaria in malaria endemic countries in Africa. These findings would be useful for other African countries planning to embark on implementing the RTS,S malaria vaccine when global RTS, S policy recommends its use.

ZUSAMMENFASSUNG

Die Global Health Initiatives (GHIs) wurden im Jahr 1978 während der Alma-Ata Konferenz gegründet. Die Deklaration von Alma-Ata über „Gesundheit für Alle“ bis zum Jahr 2000 förderte ein umfassendes Packet von Leistungen fokussierend auf Gesundheit von Kindern, Prävention und Kontrolle von Krankheiten, sowie Impfungen gegen Infektionskrankheiten. Im Jahr 1982 wurde die flächendeckende Basisgesundheitsversorgung durch die „UNICEF Declaration of a Children‘s Revolution“ ersetzt, welche eine selektive medizinische Grundversorgung unterstützte, sich auf priorisierte Krankheiten, einschliesslich Malaria, konzentrierte und zahlreiche kostengünstige Interventionen, wie Immunisierung, förderte.

Ein Schlüsselelement in der Gesundheit von Kindern ist Zugang zu und Verfügbarkeit von Impfungen. Ehrfahrungsweise dauert es oft Jahre bis Jahrzehnte, bis solche Interventionen und Impfprogramme denen, die sie am dringendsten benötigen, zur Verfügung gestellt werden. Hauptgründe für diese Verzögerungen liegen oft bei ungenügender Planung im politischen Prozess und dem Fehlen von Rahmenbedingungen, welche die Entscheidungsfindung erleichtern würden.

Diese Dissertation beschreibt das Erforschen von antizipierten politischen Prozessen und entwickelt umfassende Rahmenbedingungen zur Information der Grundsatzentscheidung in Bezug auf den Malaria-Impfstoff RTS, S in Tansania. RTS,S ist der zur Zeit am weitesten entwickelte Impfstoff gegen Malaria. Tests zeigen einen wirkungsvollen Impfschutz bei Kindern im Alter von 5-17 Monaten, wenn die Impfung in Verbindung mit weiteren Malariakontrollstrategien, wie Insektizid-behandelten Moskitonetzen (ITNs) und Anti-Malaria Medikamenten, angewendet wird.

Nationale Grundsatzentscheidungen für die Einführung von neuen Malaria Interventionen und Impfstoffen basieren auf globalen Gesundheitsstrategien. Dies ist auch der Grund warum die Malaria-Impfung RTS,S nach der Zulassung durch die WHO auf nationaler Ebene eingeführt wird. Dieser politische Prozess ist nicht nur zeitintensiv, sondern beinhaltet auch mehrere Stufen bezüglich des Abwägens von verschiedenen Faktoren, bevor eine finale Entscheidung getroffen werden kann. Eine frühzeitige Planung ist daher entscheidend. Sie erlaubt es, ein klares Bild über den Entscheidungsfindungs-Prozess und den politischen Kontext zu erstellen, in welchen die Malaria-Impfung eingeführt werden soll.

Das Ziel dieser Arbeit war es, die Entscheidungsbildung und den Prozess der Strategie-Entwicklung für die Einführung von neuen Malaria Interventionen in Tansania zu analysieren, ohne vorangehende Anwendung einer Malaria-Impfung, was den Kontext besser verständlich machen könnte, in welchem die Malaria-Impfung eingeführt werden soll. Dieses Ziel wurde durch die Anwendung folgender Methoden angestrebt: Eine Querschnittsstudie, eine qualitative und eine darstellende

Methode. Die Querschnittsstudie wurde während der „Tanzanian Integrated Measles Campaign“ (IMC) Umfrage im Jahr 2011 in 23 Regionen Tansanias durchgeführt, um abzuschätzen, ob Mütter ab 18 Jahren oder älter mit Kindern unter 11 Monaten über eine derartige Schutzimpfung Bescheid wissen und zu bereit wären sich impfen zu lassen. Eine Dokumenten-Recherche und individuelle Interviews mit 20 Schlüsselpersonen wurden durchgeführt, um Entwicklungen der Malaria Behandlungsstrategien in Tanzania und anderen RTS,S-Studien Ländern in Afrika zu erheben. Als praktischer Leitfaden zu den Etappen der Entscheidungsfindung und den politischen Prozessen dienten eine Vergleichstabelle und die Analyse der Rahmenbedingungen, welche in Tanzania und anderen afrikanischen RTS,S Studien Ländern validiert wurden. Die Synthese und Analyse der Resultate, aus diesen Studien gewonnen, wurden angewendet, um praktische Befürwortung zur Einführung einer Malaria-Impfung zu erarbeiten. Im Folgenden werden die wichtigsten Ergebnisse aufgelistet:

- Es besteht eine große Bereitschaft zur Anwendung der Malaria-Impfung, assoziiert mit einem hohen Grad an Wissen um die Vorteile des Impfens von Kindern unter fünf Jahren und einer hohen Akzeptanz der Verabreichungsform von der Impfung (2-3 Injektionen an einem Tag, gemäß des empfohlenen Impfschemas).
- Im Hinblick auf die bevorstehende Einführung der Malaria-Impfung wurde das Rahmenprogramm für die afrikanischen RTS,S Länder angepasst und angewandt. Die Bewertung besagt, dass Tansania ((12), sehr gut), Burkina Faso ((10), Malawi (9), Kenia und Gabun (8), gut) - in Bezug auf Strategie-fördernder Faktoren - vorbereitet sind, um die Einführung der Malaria-Impfung RTS,S zu starten. Ghana (5), klein) konnte nur wenige Strategie-fördernden Faktoren vorweisen und es fehlt auch noch die Dokumentation der Hindernisse zur Entscheidungsfindung. Ebenso konnte Mozambique (schwach) noch keine entsprechende Dokumentation vorlegen. Der Vergleichs-Ansatz zeigte zwar einige „gute“ und „sehr gute“ Bewertungen bezüglich Strategie-fördernder Faktoren, jedoch könnten diese durch die oben erwähnten und dokumentierten Barrieren geschmälert werden.

In Übereinstimmung mit den Ergebnissen verlangt die Einführung der RTS,S Malaria-Impfung im Programm-Umfeld dennoch Richtlinien in der Form der hier vorgeschlagenen Empfehlungen:

In Tansania wird die Malaria-Impfung erwartungsgemäß über IVD (Immunization and Vaccine Development) geliefert und anschließend in staatlichen und privaten Gesundheits-Einrichtungen durchgeführt. Um dieses Vorhaben zu unterstützen und zu propagieren werden einige Tätigkeiten empfohlen. Zum Beispiel sollte die Bevölkerung durch ein Informationspacket aufmerksam gemacht werden, welches leicht zugänglich sein sollte. Verschiedene Medien sollten für die Ankündigung und Befürwortung der Impfung eingesetzt werden. Eine Partnerschaft zwischen IVD und GAVI wäre

hilfreich, um eine zeitgenaue Lieferung der Impfstoffe zu garantieren. Ebenso sollte IVD seine Lagerkapazität erhöhen. Für die Finanzierung der Impfung sollten im nationalen Budget co-Finanzierungslevels integriert werden. Richtlinien, Dokumente und Ausbildungsmaterialen für Impf-Dienstleister sollten entsprechend modifiziert werden und um die Malaria-Impfung ergänzt werden. Impfendes Gesundheitspersonal sollte die nötige Ausbildung erhalten und ein spezielles Monitoring-System sollte etabliert werden, um die Pharmakovigilanz auf Bezirks- und auf nationaler Ebene zu überwachen.

Die Einführung von RTS,S in Programm-Settings benötigt dennoch weitere Forschung: i) Abschätzen der Packungseinheit von RTS,S und der Lagerkapazität des IVD, welcher die Malaria-Impfung lagern wird; ii) Einschätzung der Pharmakovigilanz in Gebieten mit hohen und tiefen Übertragungsraten; iii) Ermittlung des Personalbedarfs und der notwendigen Fähigkeiten des Personals; iv) Abschätzen des durch die Malaria-Impfung entstehenden Mehraufwandes für das Gesundheitspersonal.

Dies ist der erste Evaluationsbericht über Strategieentwicklung und Entscheidungsfindungsprozesse für die Einführung einer Malaria-Impfung in Tansania, ohne vorangehende Anwendung einer Malaria-Impfung. Die Resultate tragen zum wachsenden Wissen über Verständnis und Wahrnehmung einer neuen Malaria-Impfung in der Bevölkerung bei und zeigen, dass die Verfügbarkeit von umfassenden Rahmenbedingungen zur Information und zum Verständnis der politischen Prozesse die Entscheidungsfindung beschleunigen, und die benötigte Zeit somit verkürzen, um die Impfung für die bedürftige Bevölkerung zur Verfügung zu stellen. Natürlich kann RTS,S alleine keine definitive Lösung zur Malariaprävention bieten. Deshalb sollte die Impfung in andere Strategien eingebunden werden, um die Krankheitslast durch Malaria in endemischen Ländern in Afrika zu minimieren. Diese Ergebnisse sind für weitere afrikanische Länder wichtig, welche den Start einer Malaria-Impfung mit RTS,S planen, wenn die globale RTS,S Strategie ihre Anwendung empfiehlt.

MUHTASARI

Harakati za kimataifa za afya zilianza mnamo mwaka 1978 katika mkutano wa Alma Ata. Azimio la Afya kwa wote ifikapo mwaka 2000 la Alma Ata liliunga mkono mipango mipana ya jumla ya huduma za kushughulikia afya ya mtoto, kinga na kudhibiti magonjwa na kinga dhidi ya magonjwa ya kuambukiza. Mnamo mwaka 1982, huduma ya afya ya msingi iliondolewa kupisha Azimio la UNICEF la Mapinduzi ya Watoto ambayo inaunga mkono huduma za msingi zilizochaguliwa na kusisitiza magonjwa ya kipaumbele yakiwemo malaria, na mpango wa jumla wa gharama halisi za utatuzi kama vile kinga.

Sehemu kuu ya afya ya mtoto ni upatikanaji na ufukiaji wa kinga. Kimazoea, huchukua miaka na miongo kwa mipango ya utatuzi na chanjo ili iweze kufikika kwa wale haswa wenye kuihitaji. Sababu kuu mbili kwa ucheleweshwaji huu ni upungufu wa dhana ya mchakato wa sera na kukosekana kwa mpangilio wa kuwezesha uelewa wa jumla wa mchakato wa sera unaohitajika kwa ufanyaji maamuzi.

Tasnifu hii inaelezea utafiti ndani ya dhana ya mchakato wa sera na kuendeleza mpangilio mpana kwa ajili ya kuelezea maamuzi ya sera kuhusu chanjo ya malaria ya RTS,S katika Tanzania. RTS,S chanjo ya malaria iliyopiga hatua katika maendeleo na imeonesha kukinga watoto kati ya miezi 5-17 inapotumika pamoja na mikakati mingine ya kudhibiti malaria kama vile vyandarua vilivyotiwa dawa (ITNs) na dawa za kutibu malaria.

Maamuzi ya sera ya taifa ya kuanzisha tatuzi (intervention) mpya za malaria na chanjo yanaongozwa na sera za afya za dunia. Hii ndivyo ilivyo kwa chanjo ya malaria. RTS,S itatekelezwa katika ngazi ya kitaifa baada ya kuidhinishwa kwa mapendekezo ya dunia ya Shirika la Afya Duniani (WHO). Mchakato wa sera hutumia muda mrefu, ikijumuisha hatua kadhaa na uzingatiaji wa sababu kadhaa kabla ya kufikia uamuzi. Mpango wa mapema ni muhimu ili kuwa na picha halisi ya hatua za ufanyaji uamuzi na maudhui ya sera ambayo chanjo ya malaria itakuwa inatekelezwa.

Lengo la utafiti huu ilikuwa ni kuchambua mchakato wa ufanyaji maamuzi na uendelezaji sera kwa ajili ya kuanzisha tatuzi mpya za malaria katika Tanzania, pasipo kutumia chanjo yoyote ya malaria iliyotangulia ambayo inaweza kusaidia kuelewa maudhui ambayo chanjo ya malaria itatekelezwa. Lengo lilishikiliwa kwa kutumia njia zifuatazo: utafiti wa mara moja, wa njia za kujieleza au simulizi na unganishi. Utafiti wa mara moja wa mikoa 23 ya Tanzania uliofanyika wakati wa utafiti wa kampeni ya pamoja ya surua (IMC) katika mwaka 2011 ukitathmini ufahamu wa, na utayari wa kutumia chanjo ya malaria miongoni mwa wanawake wenye umri wa miaka 18 au zaidi wenye watoto chini ya miezi 11. Matokeo makuu ilikuwa ni utayari wa kutumia chanjo ya malaria. Upitiaji nyaraka na mahojiano ya kina na watoa taarifa wakuu 20 yalifanyika kutathmini mabadiliko ya sera ya kutibu malaria katika Tanzania na nchi nyingine za utafiti wa RTS,S. Jedwali linganishi na mpangilio wa uchambuzi ulitumika kama mwongozo wa vitendo katika hatua za ufanyaji maamuzi na kuhalalisha au kuthibitisha

mchakato wa sera katika Tanzania na nchi nyingine za kiafrika za utafiti wa RTS,S. Uunganishaji na uchambuzi wa matokeo yaliyopatikana kutoka tafiti hizo yalitumika kupendekeza mapendekezo ya vitendo kwa utekelezaji wa chanjo ya malaria. Matokeo makuu yalikuwa kama ifuatavyo:

- Utayari wa hali ya juu wa kutumia chanjo ya malaria, ikihusiana na kiwango kikubwa cha ujuzi wa faida za chanjo kwa watoto chini ya umri wa miaka mitano, kukubalika kwa hali ya juu kwa muundo wa utoaji chanjo ya malaria (utoaji dozi 2-3 kwa siku moja kutokana na ratiba itakayopendekezwa ya upokeaji chanjo ya malaria)
- Mpangilio uliigwa na kufanyiwa mabadiliko na kutumika katika nchi za RTS,S kwa kuzingatia utayari wake wa kuiga chanjo ijayo ya malaria kama ilivyo. Ukadiriaji unaashiria kwamba Tanzania ((12), nzuri sana), Burkina Faso ((10), Malawi (9), Kenya na Gabon (8), nzuri) zinaandaliwa kwa kuzingatia sababu za undelezaji sera kuingia katika uigaji chanjo ya malaria ijayo, RTS,S. Ghana (5), kidogo) ina sababu za undelezaji sera chache zilizopo na haijaweka katika kumbukumbu taarifa kuhusu vikwazo katika ufanyaji maamuzi. Msumbiji ((1), dhaifu) ina kumbukumbu chache za sababu zozote za uendelezaji au vikwazo. Jaribio la kulinganisha imeonesha viwango vya “vizuri” na “vizuri sana” kuzingatia sababu za uendelezaji sera ingawa sababu hizi zinaweza kuzuiwa na baadhi ya vikwazo vilivyotajwa na vilivyopo katika kumbukumbu.

Kutokana na matokeo, utekelezaji wa chanjo ya RTS,S katika mpango ulioandaliwa, bado unahitaji mwongozo katika muundo wa mapendekezo yaliyopendekezwa

Katika Tanzania, chanjo hii ya malaria inatarajiwa kutolewa kupitia mpango wa Kinga na Uendelezaji chanjo (IVD) na kutekelezwa katika ngazi ya kituo cha tiba na watoa huduma katika vituo vyote vya binafsi na umma. Ili kuunga mkono na kuendeleza sera hii, baadhi ya shughuli zimependekezwa. Kwa mfano, ufahamu uanzishwe kupitia uendelezaji wa mpango wa jumla wa taarifa kwa jamii, watumiaji wa chanjo hii ambayo inafikika na kutolewa katika mazingira rafiki. Aina tofauti za njia zinaweza kutumika katika kutangaza na kuendeleza chanjo. IVD iimarishe uwezo wake wa kuhifadhi ili kukidhi chanjo hii. Ushirikiano baina ya IVD na Ushirika wa kimataifa wa mkakati wa chanjo (GAVI) utasaidia kuhakikisha kwamba chanjo hii inatolewa kwa wakati. Kuandaa utoaji fedha kwa ajili ya chanjo hii, ngazi za pamoja za utoaji fedha zitajumuishwa katika bajeti ya kitaifa. Miongozo, nyaraka na vifaa vya mafunzo kwa ajili ya huduma za kinga ziboreshwe ili zijumuishe chanjo ya malaria. Watumishi watoa huduma za afya watakaojumuishwa katika chanjo wapate mafunzo muhimu na mfumo maalumu wa ukusanyaji tarifa au takwimu za afya uanzishwe kufuatilia madhara ya chanjo katika ngazi ya wilaya na kitaifa.

Utekelezaji wa chanjo ya RTS,S katika mpango ulioandaliwa bado unahitaji baadhi ya tafiti katika i) kutathmini mpango wa jumla wa RTS,S na uwezo wa kuhifadhi wa IVD kukidhi chanjo hii ya malaria;

ii) kutathmini ufuatiliaji wa madhara ya chanjo katika mazingira ya maambukizi ya kiwango cha chini na katika kiwango cha juu; iii) kuainisha idadi inayotakiwa na ujuzi wa rasilimali watu iv) kuangalia ukubwa wa kazi ya ziada kwa watoa huduma wa afya waliojumuishwa katika chanjo.

Hii ni ripoti ya kwanza kutathmini sera na mchakato wa ufanyaji maamuzi kwa ajili ya kuanzisha chanjo ya malaria katika Tanzania, pasipo kutumia chanjo yoyote iliyotangulia. Matokeo haya yatachangia katika ukuzaji ujuzi wa kuelewa mtazamo wa watu katika chanjo mpya ya malaria na upatikanaji wa ufahamu wa mpangilio wa uelewa wa mchakato wa sera hii utaharakisha mchakato wa ufanyaji uamuzi na kufupisha muda unaohitajika kufanya chanjo hii kupatikana kwa wale wenye kuhitaji. Hata hivyo, RTS,S pekee haitoi ufumbuzi sahihi wa kukinga malaria. Chanjo hii ijumuishwe pamoja na mikakati mingine kutatua mzigo wa malaria katika nchi zenye malaria kwa muda mrefu katika Afrika. Matokeo haya yatafaa kwa nchi nyingine za kiafrika kupanga kuingia katika utekelezaji wa chanjo hii ya malaria ya RTS,S wakati sera ya dunia ya RTS,S ikipendekeza utumiaji wake.

LIST OF ABBREVIATIONS

ACT	Artemisinin Combination Therapy
AMANET	African Malaria Network Trust
ALu	Artemether Lumefantrine
BCG	Bacillus Calmette Guerin
BOD	Burden of Disease
CCHP	Comprehensive Council Health Plan
CDC	Centres for Disease Control and Prevention
CE	Cost Effective
COSTECH	Commission for Science and Technology
DALY	Disability Adjusted Life Year
DF	Decision Framework
DP	Development Partners
DPT	Diptheria Pertusis Tetanus
EPI	Expanded Programme for Immunization
GAVI	Global Alliance on Vaccine Initiative
GFATM	Global Fund to fight HIV/AIDS, Tuberculosis & Malaria
GHI	Global Health Initiatives
GMP	Global Malaria Programme
GOBI	Growth, Oral rehydration, Breast feeding , Immunization
HepB	Hepatitis B virus
Hib	Haemophilus influenza type b
HPV	Humman Pappiloma Virus
IHI	Ifakara Health Institute
IMC	Integrated Measles Campaign
ICC	Inter-agency Coordinating Committee
IRB	Institutional Review Board
IRS	Indoor Residue Spraying
ITN	Insecticide Treated Nets
IVB	Immunization Vaccines and Biologicals
IVD	Immunization and Vaccine Development
JTEG	Joint Technical Expert Group
LLITNs	Long Lasting Insecticide Treated Nets
MAP	Multi country AIDS Programme
MOFEA	Ministry of Finance and Economic Affairs (MOFEA)
MOHSW	Ministry of Health and Social Welfare
MPAC	Malaria Policy Advisory Committee
MSD	Medical Stores Department
MTEF	Medium Term Expenditure Framework
MUHAS	Muhimbili University of Health and Allied Sciences
MVI	Malaria Vaccine Initiatives
NIMR	National Institute for Medical Research
NMAC	National Malaria Advisory Committee
NMCP	National Malaria Control Program
MRDT	Malaria Rapid Diagnostic Test

OPV	Oral Polio Vaccine
PATH	Partnership in Appropriate Technology in Health
PCV	Pneumococcal Conjugate Vaccine
PERFAR	Presidents Emergence Plan for AIDS Relief
PHC	Primary Health Care
PMI	Presidents Malaria Initiative
PPP	Public Private Partnerships
PPS	Probability Proportion to Size
RBM	Roll Back Malaria
RCH	Reproductive and Child Health
SAGE	Strategic Advisory Group of Experts
SP	Sulphadoxine Prymethamine
SSA	Sub Saharan Africa
SWAp	Sector Wide Approach
TANAM	Tanzania NGOs Alliance against Malaria
TDHS	Tanzania Demographic and Health Survey
TFDA	Tanzania Food & Drug Authority
TEHIP	Tanzania Essential Health Intervention Project
TMVS	Tanzania Malaria Vaccine Secretariat
TT	Tetanus Toxoid
UNICEF	United Nations International Children's Emergency Fund
URT	United Republic of Tanzania
USAID	United State Agency for International Development
WG	Working Group
WHO	World Health Organization
WDR	World Development Report

1. Introduction

This chapter provides background information on the evolution of global health strategies and discusses how global health strategies shaped policy surrounding malaria interventions and its implications for implementation the forthcoming malaria vaccine.

1.1 Global Health Strategies

Global health strategies can be traced back to 1978, when the international conference on Primary Health Care (PHC) was held in Alma Ata. The conference expressed to the world the need to protect and promote the health of all people. The concept of Comprehensive Primary Health Care (PHC) was declared as a strategy to achieve "Health for All 2000" (WHO, UNICEF 1978)**.** The declaration supported the basic principles of PHC, based on universal access, equity, participation and an inter-sectoral approach (WHO, UNICEF 1978; Jong-wook 2003). The components of PHC targeted child health, prevention and control of diseases and immunization against communicable diseases, (WHO, UNICEF 1978; Osazuwa-Peters 2011)**.** In 1982, comprehensive PHC was replaced by UNICEF's Declaration of a Children's Revolution, which supported selective PHC, focussing on a package of low cost interventions including immunization. Immunization was perceived as a practical intervention that was easy to monitor and to evaluate. As a result of the declaration, global immunization coverage of children under 1 year increased from 20% in 1980 to 79% by 2006 and child survival was enhanced (Wisner 1988).

Among the key messages drawn from both the Alma Ata declaration (1978) and UNICEF's Children's Revolution (1982) initiatives, one is especially relevant to the current question of implementing the forthcoming malaria vaccine, and that is child health depends on the availability of and access to immunizations. The use of PHC methods, such as outreach and home-based service, is likely to increase access to RTS,S and make it affordable in terms of geographical accessibility by the target communities that need it most. The world Development Report (1993) emphasizes the need to address PHC and to strengthen health systems to reach people in need and improve health outcomes (World Bank 1993).

The World Development Report (1993) "Investing in Health" proposed that health investments are a viable strategy for achieving economic development, based on evidence from cost-effective interventions to address the burden of disease. The burden of disease (BOD) is estimated in terms of Disability Adjusted Life Years (DALYs) lost and the cost effectiveness of interventions is cost per DALY gained. To measure the BOD, the report uses the DALYs as a measure that combines healthy life years lost because of pre mature mortality with those lost as a result of disability (World Bank 1993)**.** Reducing the burden of infectious diseases such as malaria will increase workforce productivity that facilitates investment and enhance economic development (Savigny 2004).

The WDR 1993 suggested a minimum package of essential health and PHC interventions that have a significant impact on the existing burden of disease while maintaining cost effectiveness (World Bank 1993). To implement the report's recommendations, few studies embarked on health system strengthening, one of which yielded the Tanzania Essential Health Interventions Project (TEHIP) tool (Savigny 2004). The tool enabled district health planners to plan and set priorities using the BOD profile and cost-effectiveness analysis for resource allocation and expenditure targeting improved health systems delivery (Savigny 2004). The TEHIP tool was developed and tested in Rufiji and Morogoro districts in Tanzania and achieved various health outcomes, including reduction of child mortality by 40% and increased capacity to health systems in planning and prioritization of local burden of disease (Savigny 2004). Planning for the new malaria vaccine should take into account its cost effectiveness compared to other existing malaria interventions, to minimize government spending while addressing the disease in an efficient way. Including the malaria vaccine in health-related strategies and aligning policy to the global and national plans to address health-related Millennium Development Goals (MDGs) would offer a clear picture of the funding sources available.

1.1.1 GHIs Progress and Prospects

In 2000, the United Nations Millennium Declaration was signed to commits world leaders to combat poverty, hunger, disease, illiteracy, environmental degradation, and discrimination against women. The MDGs are derived from this Declaration, and all have specific targets and indicators (www.who.int/topics/millennium_development_goals/en). Eight MDGs were to be achieved by 2015. Five of the eight goals targeted health development, including MDG 1 to eradicate extreme poverty and hunger; MDG 4 to reduce child mortality by two thirds amongst children under five; MDG 5 to reduce maternal mortality by three quarters; MDG 6 to halt and reverse the incidence and spread of HIV/AIDS, Malaria and infectious disease; and MDG 8 for global partnership for development www.un.org/millenniumgoals/bkgd.shtml. To achieve health-related MDG targets, new actors were needed to deliver health care services, such as the private sector, philanthropic trusts, and civil society entities that worked together to create global public private partnerships (PPPs). Some of the private and philanthropic actors working in health include the Bill and Melinda Gates Foundation, the Clinton Foundation, the Rockefeller Foundation, the Ford Foundation and the WK Kellogg Foundation. These organizations worked alongside other disease-oriented global players such as the Global Alliance for Vaccines and Immunization (GAVI) and the Global Fund to fight HIV/AIDS, Tuberculosis (TB) and malaria (GFATM), World Bank Multi-Country AIDS Program (MAP), the US President's Emergence Plan for AIDS Relief (PERFAR), the US President's Malaria Initiative (PMI), the Stop TB Partnership, and the Roll Back Malaria Partnership among others (World Health Organization Maximizing Positive Synergies Collaborative Group et al. 2009; van Olmen et al. 2012). The GAVI focuses on childhood immunization while GFATM emphasizes disease-specific

programmes, including malaria. The PPPs fund malaria clinical trials and research and provide technical advice that is likely to influence malaria vaccine policy recommendations and its implementation at the national level.

1.1.2 Aid Effectiveness

GHIs established the international aid framework stipulated by the Paris Declaration on Aid Effectiveness (OECD 2005)**.** The framework sought to harmonize donor funds to maximize efficiency by mobilizing funds into one basket and allocating funds with a focus on a specific disease or intervention. The health outcomes expected from investment in disease-specific programmes or interventions depend on better alignment of targeted programmes with health services and integration into health systems that contribute to overall health system strengthening (van Olmen et al. 2012)**.** Harmonization of global health efforts can ensure that malaria vaccines are addressed in the global health agenda and are incorporated into global health plans and activities, thereby increasing funding opportunities for the malaria vaccine.

1.1.2.1 Contextualizing Aid Effectiveness in Tanzania

The Medium Term Expenditure Framework (MTEF), a budgetary instrument, was developed to incorporate planning and financing of the three year work programme for the Ministry of Health, for both recurrent and development activities, into one document. The Sector Wide Approach (SWAp) was developed as a mechanism by which to maintain sustainable relations with other service providers in health and with Development Partners (DPs). MTEF's achievement was the introduction of the Health Basket Fund, through which Councils receive funds for implementing health activities and interventions. The Comprehensive Council Health Plan (CCHP) was introduced as a management instrument to understand implementation of councils' health activities and interventions (Tanzania HSSP III 2008)**.** In Tanzania, a limited mechanism of accountability for donor funds exists, which monitors and evaluates performance of the funds. A planning tool using MTEF monitors fund allocations to ensure they are in line with budget targets. The procedures associated with the flow of funds from the Health Basket Fund to the government exchequer system and reallocation to the districts or councils could cause delays in malaria vaccine implementation and limit its access to those most in need. Availability of a specific framework would be useful for monitoring and evaluating donor contributions to implementing interventions. Policy decisions to introduce new malaria interventions require evidence-based information that is generated by research. The need for evidence-based decisions was stimulated by a Ministerial summit in Mexico.

1.1.3 Research and GHI progress

The Ministerial Summit on Health Research was held on November 16-20, 2004 and brought together health ministers or their representatives from governments in developed and developing countries. The summit also included intergovernmental organizations, the private sector, researchers and research councils, leaders and users of health research and civil society. Together, they discussed how health research could strengthen national health systems to achieve the health-related MDGs (WHO Ministerial Summit 2004). Among the key messages drawn from the summit were the needs to strengthen health systems and to translate scientific knowledge into evidence-based information to aid policy makers deliver targeted interventions to achieve specific health outcomes.

From a health systems thinking perspective, health systems research produces evidence-based information that helps to plan and evaluate interventions. The system involves linkages, relationships, interactions and behaviours among the elements that constitute the health systems' building blocks. Such building blocks include service delivery, the health workforce, information, medical products, vaccines and technologies, financing, and leadership and governance (stewardship). Analysing the root cause of the problem helps to show how the intervention will cause reactions in the system and how the system will respond to it. An intervention that targets one health system block will have an effect on other building blocks; this is also called a "system wide effect" or "system level interventions" (Savigny D; Adam T 2009). Applying this concept to the forthcoming malaria vaccine policy, malaria vaccination procedures need to be understood, immunization guidelines need to be revised and strategies to accommodate the malaria vaccine need to be developed. In turn, there will be a demand for in-service training (on revised immunization guidelines and strategies), a need to package and disseminate adequate and accurate information for the health workers and for users of the vaccine, and a way of funding these activities. In summary, addressing a health problem among children through malaria vaccine introduction poses concerns about service delivery, health workforce capabilities, information availability and financing.

Introducing new interventions involve interactions among multiple actors. Applying complex systems analysis would help policy makers to identify influential actors and to develop appropriate and timely strategies for addressing them.

1.1.4 Prospects of new technology and stakeholder involvement in the process

Various stakeholders influence the policy development process at each stage. These stakeholders are actors who drive the system through their participation as individuals or groups and their networks; their participation supports service delivery that aims to achieve specific health outcomes (Savigny D; Adam T 2009). Stakeholders are categorized into different levels: international/global, regional,

national, sectoral, district, health facility and community. For the case of RTS,S, the World Health Organization (WHO) is responsible for making global policy recommendations and the national regulatory authority assesses the vaccine according to the standards set for marketing authorization (Joint Technical Expert Group 2009). In Tanzania; Tanzania Food and Drug Authority (TFDA) is the regulatory authority that assesses the vaccine according to WHO standards. Other key actors include community members, health workers, managers, policy makers, research community representatives and funding partners (Tanzania HSSP III 2008). Identifying and understanding the key actors and their influence on policy decisions for malaria interventions will facilitate implementation of the forthcoming malaria vaccine. Understanding the status of malaria disease at the global and national levels will help to understand how the malaria vaccine can be integrated into other existing malaria interventions and strategies, which depend on the current malaria situation in a specific country.

1.2 Malaria World Wide

In 2014, the WHO estimated that global malaria mortality rates were reduced by 47% between 2000 and 2013. These substantial reductions occurred as a result of improved malaria intervention tools, increased political commitment and increased international and domestic financing (World Malaria Report 2014).

1.2.1 Malaria in Tanzania

Due to its geography and climate, Tanzania presents a wide range of malaria transmission levels. There are three malaria epidemiological strata in Tanzania. First, the arid central plateau (20% of the country) is characterized by unstable and seasonal malaria transmission. Second, the southern part of the country with one main rainy season (March –May), and the northern and western parts with bimodal rainfall (November –January) are characterized by stable malaria with seasonal variations in transmission. Third, the coastal fringe, southern lowlands and Lake Victoria regions are characterized by stable malaria with high transmission. Plasmodium falciparum accounts for 96% of all malaria infections in Tanzania (World Malaria Report 2012; PMI 2012). Some 31,900,000 people (73% of the population) live in high transmission areas. Approximately 11, 800,000 people (27% of the population) live in low transmission areas (World Malaria Report 2012). With nearly three quarters of the Tanzanian population living in high transmission zones, there is a need to introduce other interventions that contribute to the reduction of malaria transmission. This may be achieved if the measures target the source of transmission through malaria vaccines (Graves and Gelband 2006).

1.2.2 Malaria Control Strategies

Malaria control programmes implemented in malaria endemic countries have successfully scaled up existing malaria interventions and ultimately led to a decrease in malaria cases worldwide (WHO 2012), along with increased funding and political commitment (Ravishankar et al. 2009; Mendis et al.

2009; World Malaria Report 2011; PMI 2012). Interventions such as distributing insecticide treated nets (ITNs) — 145 million in 2010 and 66 million in 2012 — resulted in almost 60% of households owning a net and 33% of the population sleeping under a bed net. Indoor residual spraying (IRS) protects 10-12% of the population (World Malaria Report 2012). In most Sub Saharan Africa (SSA) countries, fewer than 50% of the at-risk population is protected by ITNs or IRS. Prompt diagnosis using rapid diagnosis tests (RDT) and efficient treatment with Artemisinin Combination Therapies (ACT) are efficient tools for reducing malaria. In 2009, 33 million RDTs were distributed, compared with 200,000 in 2005. In 2010, 229 million doses of ACT were procured worldwide, compared with 2.1 million in 2003 (World Malaria Report 2010). An efficient and strategic mix of malaria interventions have contributed to decreasing cases by 50% or more (WHO 2012).

1.2.3 Malaria Control Strategies in Tanzania

Between 2000 and 2010, reported mortality among children under five in Tanzania fell from 148 per 1000 live births in 1999 to 81 per 1000 live birth in 2010. In Ifakara, under five deaths were reduced from 25% in 2004 and 2005 to less than 5% in 2010 (World Malaria Report 2012; PMI 2012). The decline was associated with increased external resources; between 2003 and 2010, about USD 450 million were allocated to scale up malaria control programmes (World Malaria Report 2012; PMI 2012). The data indicates that Tanzania has been able to reduce the malaria burden due to the high coverage achieved by malaria control strategies. Some 18, 562 571 ITNs were distributed in the country between 2007 and 2010. Almost 63% of all households owned at least one ITN in 2010 compared with 23% in 2004 - 2005. Nearly 64% of all children under five and 56% of all pregnant women used ITNs before the 2010 survey. IRS expanded to almost 94% in 18 districts from 2007 to 2011. RDTs and ACTs were deployed to reach almost half of the population (World Malaria Report 2012; PMI 2012). To ensure continued high coverage, policies and strategies are needed to guide the future implementation of new malaria interventions, including the malaria vaccine.

1.3 The Need and Position for Policies and Strategies for Malaria

In 2011, The World Health Organization's Global Malaria Programme (WHO-GMP) established the Malaria Policy Advisory Committee (MPAC) to guide policy recommendations for malaria control and elimination In 2011 (Malaria Policy Advisory Committee 2012; World Malaria Report 2012). For the case of malaria vaccine RTS,S; the process of developing policy recommendations led to two departments, immunization Strategic Advisory Group of Experts (SAGE) and malaria (MPAC), jointly setting up a Joint Technical Expert Group (JTEG). The JTEG and MPAC will assess the evidence and MPAC and SAGE will review the report. If there is sufficient data to make a draft policy recommendation for malaria vaccines RTS, S, it will likely occur in 2015 (Mendis et al. 2009; Malaria Policy Advisory Committee 2012). Policy implications focus on the need for scientific evidence to

inform policy recommendations. MPAC highlights the need for timely and high quality information to guide malaria control policies and to effectively communicate evidence to policy makers. MPAC also encourages the involvement of various stakeholders in order to ensure that policy recommendations reflect the needs and concerns of stakeholders (Malaria Policy Advisory Committee 2012).

1.3.1 Tanzania National Malaria Advisory Committee's Role in Policy Implementation

Two separate ministries of health operate in the United Republic of Tanzania (URT), one each for the mainland and for Zanzibar. Each ministry has its own National Malaria Control Program (NMCP) and Malaria Strategy Plan. The mainland's NMCP has established committees to coordinate national malaria control policies and priorities. The National Malaria Advisory Committee (NMAC) is the body that provides policy direction for malaria control on the mainland. The NMAC links the various NMCP committees to the SWAp structures of the Ministry of Health and Social Welfare (MOHSW). The NMAC provides technical advice on malaria control to the NMCP (United Republic of Tanzania 2006; PMI 2011). The committee meets annually to discuss and assess problems resulting from implementation of malaria intervention policies (Makundi et al. 2007).

1.3.2 Malaria Vaccine Decision Making Framework (DMF)

In 2006, WHO's Africa Regional Office and PATH Malaria Vaccine Initiative (PATH MVI), in partnership with various multilateral and bilateral stakeholders, researchers, and several Ministries of Health, including Tanzania, developed a draft Decision Making Framework (DMF) to help identify evidence to support a policy decision to introduce the malaria vaccine within their national health systems. The DMF for the malaria vaccine outlines the data required from different levels (global and national), in different thematic areas (disease burden, other malaria interventions, impact, financial, efficacy, safety, programmatic, socio cultural) and at different periods (pre licensure, licensure and post licensure of malaria vaccine) (Wells and Brooks 2011; Brooks and Ba-Nguz 2012). The main objective for a DMF is to contribute to timely, evidence-based decisions about whether or not to introduce the malaria vaccine in a particular country or region. It has been noted that insufficient planning and lack of evidence-based information to inform the policy and decision making process is a reason for delays between development and availability of new interventions in low and mid income countries (Brooks and Ba-Nguz 2012). To overcome these challenges, the Tanzania Malaria Vaccine Secretariat (TMVS) was established to enable national authorities to obtain all necessary information surrounding the introduction of a new malaria vaccine in the health system.

1.3.3 Tanzania Malaria Vaccine Secretariat (TMVS)

The Tanzania Malaria Vaccine Secretariat (TMVS) was established in 2009 to coordinate the implementation of the national malaria vaccine DMF. TMVS generates information that will guide the policy process and aid national policy makers to identify critical data for deciding whether to introduce a new malaria vaccine. The following institutions are represented in TMVS: Ministry of Health and Social Welfare (MOHSW) Mainland and Zanzibar, Immunization and Vaccine Development (IVD), National Malaria Control Programme (NMCP), Tanzania Food and Drug Authority (TFDA), National Institute for Medical Research (NIMR), Ifakara Health Institute (IHI), African Malaria Network Trust (AMANET), Association of Private Practitioners, WHO IVD and Malaria departments, UNICEF IVD and Malaria departments, Development Partners Group (Health), Commission for Sciences and Technology (COSTECH), Muhimbili University of Health and Allied Sciences (MUHAS), and Tanzania NGOs Alliance Against Malaria (TANAM). The secretariat was endorsed by the Director of Preventive Services in the MOHSW. The TMVS will be operational until a decision is made about introducing the malaria vaccine. The TMVS coordinates collaboration between researchers, IVD and NMCP and other stakeholders to collect needed information for a timely and well-informed decision and to ensure that processes are in place for policy-decisions on introducing a Malaria vaccine in the Tanzanian health systems (TDHS 2010; PATH MVI 2008).

1.3.4 Malaria Vaccines: A New Tool for Malaria Control

Malaria endemic countries are consolidating their gains to enter the pre-elimination stage of malaria. Research and development initiatives are on-going to develop other interventions against malaria, such as a malaria vaccine. In Tanzania, the Ifakara Health Institute (IHI) and National Institute for Medical Research (NIMR) have been at the centre of clinical trial efforts towards developing the RTS, S vaccine, with support from the PATH Malaria Vaccine Initiative (MVI), through the Bill & Melinda Gates Foundation and in collaboration with the pharmaceutical company GlaxoSmithKline (GSK). Malaria vaccine RTS, S clinical trials have completed phase III and RTS,S is on track for registration. The malaria vaccine would complement existing interventions, such as ITNs, IRS and effective medicines. At the end of the on-going clinical trials for malaria vaccines, policy makers need to be provided with scientific advice on whether to adopt the vaccine or not. In this regard, early planning is essential. WHO has indicated that the malaria vaccine would be implemented in countries through Immunization, Vaccine and Biologicals (IVB) (Malaria Policy Advisory Committee 2012).

1.3.5 Immunization and Vaccine Development (IVD)

Most developing countries have adopted the WHO's guidelines for vaccinating children. According to those guidelines, children should receive the following vaccinations: Bacillus Calmette Guerin (BCG), Oral Polio Vaccine (OPV), Diptheria Pertusis Tetanus - Hepatitis B virus Haemophilus influenza type b (DPT-HepB-Hib), Measles, TT, Rotarix, Pneumococcal Conjugate Vaccine (PCV13) (TDHS 2010; Tanzania EPI Report 2010). The Immunization Programme in Tanzania is implemented by the MOHSW through IVD, which started in 1975. IVD aims to protect children from Vaccine Preventable Diseases. This is expected to be attained through high and effective vaccination coverage for all antigens, using quality vaccines (TDHS 2010; Tanzania EPI Report 2010). Therefore, there is a need to understand IVD programmatic feasibility, such as storage capacity, adequacy and skills of health personnel involved in immunization, surveillance system and guidelines for immunizations and feasibility considerations including scheduling and booster doses of malaria vaccine, in order to inform decision making for malaria vaccine introduction.

2. Goal, objectives and methods

The study goal, objectives and methods are presented in this chapter. The objectives are rooted in the need to prepare the groundwork for formulating and implementing the forthcoming malaria vaccine, RTS,S. A first step is to ensure that evidence-based information informs the policy process and decision making. There are a number of issues to be considered, such as the context in which the new vaccines are perceived (community perceptions), and the factors influencing different actors and the decision-making process in general. A framework to provide a comprehensive understanding of the policy process and steps involved along with recommendations and guidelines to advance the policy decision making process for the forthcoming malaria vaccine contributes to generating and sharing evidence-based information relevant to the needs of various stakeholders.

2.1 Goal

To analyse the decision making and policy development process for introducing new malaria interventions in Tanzania, in the absence of malaria vaccine use.

2.2 Objectives

Objective 1

To describe and analyse the Tanzanian population's awareness of and willingness to use malaria vaccines and to provide policymakers with evidence-based information about whether or not to adopt the forthcoming RTS,S malaria vaccine.

Objective 2

To describe and analyse comparatively the policy-making process for introducing new malaria interventions into Tanzania and to discuss it in relation to the situation in other RTS, S African countries.

Objective 3

To establish recommendations and guidelines for maximizing the effectiveness of the decision-making and policy process surrounding the introduction of a malaria vaccine in Tanzania.

2.3 Methods

2.3.1 Brief outline of the methods used to achieve each of the objectives

Objective 1

A large cross-sectional study of 23 regions of Tanzania (mainland Tanzania and Zanzibar) used randomly sampling probability to assess awareness of and willingness to use a malaria vaccine among women aged 18 years or older with children less than 11 months old.

Objective 2

Document review to RTS,S African countries and in-depth interviews with 20 key informants' were conducted at national level with government officials, bilateral and multilateral partners and other

stakeholders to assess malaria treatment policy changes in Tanzania and other RTS,S African countries. A comparative table and framework analysis was used as a practical guide to the steps of the decision making and policy process and validated in Tanzania and other RTS, S African countries.

Objective 3

The results obtained from Objectives 1 and 2 were synthesised and analysed to develop a practical guide (recommendations and guidelines) for malaria vaccine implementation.

Conclusion

This section provides a broad overview of the study methodology, including the study goal, study design and general methods used to achieve each study objective. Greater methodological detail is given in the following chapters.

3. Assessment of parental perception of malaria vaccine in Tanzania: A Case Study

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3.1 Abstract

Background: Clinical trials of the RTS,S malaria vaccine have completed Phase III and the vaccine is on track for registration. Before making decisions about implementation, it is essential to prepare the ground for introducing the vaccine by assessing willingness to use malaria vaccines. National decision makers need evidence-based information to decide about adopting the malaria vaccine in their respective countries.

Methods: In November 2011, as part of a large cross-sectional study of 23 regions of Tanzania (mainland Tanzania and Zanzibar) was conducted during Tanzanian Integrated Measles Campaign (IMC) survey. In this study, the variables of interests were awareness of and willingness to use a malaria vaccine. The main outcome measure was willingness to use a malaria vaccine. Logistic regression was used to examine the influence of predictive factors.

Results: A representative sample of 5,502 (out of 6,210) women, aged 18 years or older and with children under 11 months old, was selected to participate, using random sampling probability. Awareness of the forthcoming malaria vaccine, 11.8% of participants in mainland Tanzania responded affirmatively, compared to 3.4% in Zanzibar. The difference was highly statistically significant (p-value<0.001) However, 94.5% of all respondents were willing to vaccinate their children against malaria, with a slight difference between mainland Tanzania (94.3%) and Zanzibar (96.8%). The difference was statistically significant (p-value=0.02).

Conclusions: Although mothers were substantially had low awareness of the forthcoming availability of a malaria vaccine, their willingness to use the malaria vaccine was high. RTS,S will compliment other existing malaria interventions and it will be implemented through the Immunization, Vaccines and Biologicals (IVB) programme (formerly Expanded Programme on Immunization-EPI). The information generated from this study can aid policy makers in planning and setting priorities for introducing and implementing the malaria vaccine

3.2 Background

Malaria still remains a significant public health problem in Sub-Saharan Africa, including Tanzania, accounting for 10% of the observed burden of disease (World Malaria Report 2013). Recently, technical innovations to control malaria have contributed to a decline in the malaria burden, but the disease remains a significant threat due to persistent enabling environments, poverty and fragile health systems (World Malaria Report 2013). Therefore, additional strategies are needed to ensure a combination of interventions that target the various phases of the malaria life cycle, including malaria vaccination (Graves and Gelband 2006). Vaccines have contributed significantly to reducing as well as to eliminating the burden of disease due to vaccine preventable infections (Orenstein and Hinman 1999; Batt, Fox-Rushby, and Castillo-Riquelme 2004; de Timóteo Mavimbe et al. 2006; Larson et al. 2011; Bloom 2011; Murele et al. 2014; Burchett et al. 2012).

There are on-going efforts to deliver malaria vaccines as a means to achieving elimination. Malaria vaccine RTS, S is the most advanced candidate to undergo large scale Phase III evaluation in Africa. It has been tested in 11 African sites with varying degrees of malaria transmission. The study sites included: Nanoro in Burkina Faso; Kintampo and Agogo in Ghana; Lambarene in Gabon; Manhica in Mozambique; Lilongwe in Malawi; Kilifi, Siaya and Kombewa in Kenya; and Bagamoyo and Korogwe in Tanzania (RTS,S Clinical Trials Partnership 2014). The availability of RTS,S will contribute to a multi-intervention approach to controlling malaria that currently uses LLITNs, ITNs, IRS, and other means of disease reduction and effective drug treatment. Phase II and III clinical trials of RTS,S showed that the vaccine reduced the episodes of malaria among young children and infants in malaria endemic areas by half (Abdulla et al. 2008; Ojakaa et al. 2011; "A Phase 3 Trial of RTS,S/AS01 Malaria Vaccine in African Infants" 2012; RTS,S Clinical Trials Partnership 2014). Upon completion of the clinical trials, policy makers will need to make evidence-based decision on the best ways to engage communities to facilitate introduction of malaria vaccine in the national health systems using Tanzania as a case study.

Studies on vaccine adherence interventions and acceptance of vaccines recommended use of strategies that will enhance positive community knowledge and perceptions on vaccine effectiveness (Nuño, Chowell, and Gumel 2007; Vardavas, Breban, and Blower 2007). Effectiveness of vaccines rely on both clinical efficacy and on a community's perceptual factors (Murele et al. 2014). During vaccine promotion lack of community support due to poor knowledge and perceptions made community delay the uptake while others reject vaccines (Febir et al. 2013). Similar contexts existed when Polio vaccination programme was delayed in northern Nigeria (Wonodi et al. 2012; Yahya 2007). Another similar experiences was the community refection of deworming programme in Ghana (Dodoo et al. 2007; Febir et al. 2013).

Whereas Tanzania shares similar social cultural and economic contexts to those countries mentioned above there is a high likelihood that new of even current vaccines can be similarly rejected and thus undermining efforts to adopt new technologies to address the high burden of disease. Therefore it is crucial that community awareness of and willingness to use the malaria vaccine as well as community perceptions of its likely impact are well understood and used to highlight any community-based issues that need to be considered during policy deliberation and intervention planning (Brooks and Ba-Nguz 2012). The policy recommendations for introducing malaria vaccine RTS,S would be implemented in countries through the World Health Organization's IVB (formerly EPI) (D'Souza and Newman 2012). Based on this, the case study was initiated with the following objective: To describe and analyse the Tanzanian population's willingness to use malaria vaccines and to provide policymakers with evidence-based information on the best strategies to manage the introduction of new vaccine and in this case malaria vaccine.

3.3 Methods

Study design and setting

In November 2011, as part of a large cross-sectional study of 23 regions of Tanzania (mainland Tanzania and Zanzibar) was conducted during Tanzanian IMC survey. The study was designed to assess awareness of the forthcoming malaria vaccine and willingness to use malaria vaccine among women aged 18 years or older with children less than 11 months old.

Study sample size and sampling procedure

It was anticipated that the overall immunization coverage in the surveyed regions was estimated to be 85% (the desired precision is ±5% with 95% confidence). Thirty clusters were sampled (Immunization and Biologicals 2005)**,** and 9 women with children 0-11 months old per cluster were identified. A total of 6,210 women with children 0 – 11 months old were recruited. For the purpose of this analysis, only 5,502 women met the eligibility criteria and were included in the final analysis (n=5502).

The sampling procedure was based on 30-by-9 method and simple random sampling applied. The 30-by-9 method was a two-stage cluster sample. In the first stage, 30 clusters (corresponding to Enumeration Areas - EAs) were sampled by a Probability Proportion to Size (PPS) strategy using the CSurvey software. In the second stage of sampling, 9 eligible women with children 0-11 months old were selected within each EA.

Not all of the first 9 households visited had an eligible child; therefore, more than 9 households may have been visited. Similarly, fewer than 9 households may have been selected if there was more than one eligible child per household. A sample of 30 enumeration clusters (villages) per region was surveyed; the minimum sample size was 270 mothers in each region. In each region 30 clusters were visited and in each cluster, nine mothers with a child aged 0–11 months old were randomly selected and visited. The following steps were followed;

1. Within the regions, 30 EAs were selected using the PPS strategy.
2. In each EA, 9 eligible children were selected from households as follows:
    a. Go to the “centre” of the EA.
    b. Throw a pen to choose a random direction.
    c. Walk in that direction to identify the first household.
    d. Visit the first selected household and start to recruit the eligible children.
    e. After the first household visited, data collector moved to the “next household”, which was defined as the one whose front door was the closest to the just one visited.

f. This process was continued until all 9 eligible children were found/ reached.

Primary outcome and explanatory variables

The primary outcome variable was willingness to use a malaria vaccine; mothers were asked if they would like their children to receive malaria vaccine. The following explanatory variables of willingness to use a malaria vaccine were investigated: 1) Awareness of the forthcoming malaria vaccine; mothers were asked if they ever heard about malaria vaccine. 2) Knowledge of the health benefits of vaccinating under-five children, mothers were assessed if they know malaria vaccine can prevent children from getting malaria, reduced disease infection and death or enhance good health. 3) Mothers to accept the mode of administering the malaria vaccine (require 2-3 jabs to receive full benefit). 4) Mothers to agree proposed schedule of given malaria vaccine at the same health facility and at the same time as other childhood vaccines. Other explanatory variables were ITNs ownership, EPI and measles vaccination.

Data collection

Data was collected using structured questionnaires (Appendix 4) that assessed mothers of eligible children on their awareness of the forthcoming malaria vaccine, their willingness to use a malaria vaccine, their knowledge of the health benefits of vaccinating children under-five, their acceptance of the mode of administering the malaria vaccine and its proposed schedule. The study was limited due to lack of data collection on demographic data. Data on ITNs ownership, EPI and measles coverage generated from the Tanzania Demographic and Health Survey (TDHS) 2010.

Data management and analysis

Data were double entered from data collection forms into a computer data file using Data Management System for Clinical Trials Software (DMSys) (Sigma soft International, Cincinnati, USA) (http://www.sigmasoftintl.com/products.asp). Data were reviewed after the initial data entry to check for out-of-range responses, missing values, or inconsistent skip patterns; the original data collection sheets were reviewed to resolve any discrepancies or problems.

The data were analysed using STATA 11 standard edition software (StataCorp, Texas, USA). The data were summarized using frequency tables and cross tabulation. Cross tabulation was done to assess the association between knowledge of the benefits of under-five vaccination and awareness of the forthcoming malaria vaccine; and between knowledge of the benefits of under-five vaccination and willingness to use a malaria vaccine. Categorical data was reported with numbers and percentage and their associated p-values. Cross tabulation and Chi square was used to test association between variables in a two by two table. Fisher's exact test was used to compare proportions in two by two tables where expected value in a cell was less than five. Univariate logistic regression was used to

determine the magnitude of association for each exposure variable and outcome variable. Variables that showed association at a 0.25 significance level in univariate analysis were considered as candidates for the multivariate analysis. Multiple logistic regressions were used to determine the association between willingness and the primary exposure variable, while controlling for possible confounders. P-values of less than or equal to 0.05 were considered significant.

Ethical approval

The study was part of the Tanzanian IMC survey in November 2011 and received ethical approval from the Institutional Review Boards of Ifakara Health Institute. We obtained written informed consent from all participants prior to the start of the interviews.

3.4 Results

When asked about awareness of the forthcoming malaria vaccine, 11.8% of participants in mainland Tanzania responded affirmatively, compared to 3.4% in Zanzibar (Appendix 2). The difference was highly statistically significant (p-value<0.001) (Table 1). However, 94.5% of respondents were willing to take their children to get malaria vaccination, with a slight difference between mainland Tanzania (94.3%) and Zanzibar (96.8%) (Appendix 2). The difference was statistically significant (p-value=0.02) (Table 1).

Most (88.4%) of the respondents reported knowing the benefits of vaccinating children under-five, with 88.5% in mainland Tanzania and 87.9% in Zanzibar (Appendix 3). The difference was not statistically significant (p-value =0.7) (Table 1). The majority (81.3%) of respondents reported accepting the mode of administering the malaria vaccine (2-3 jabs), with a high proportion (82.6%) of acceptability among mainland Tanzanians than in Zanzibar (68.8%) (Appendix 3); the difference was statistically significant (p-value<0.001) (Table 1)**.** Most (86.7%) respondents would send their children for malaria vaccine according to the proposed schedule, with 86.7% of respondents in mainland Tanzania and 87.1% of respondents in Zanzibar (Appendix 3); the difference was not statistically significant (p-value=0.8) (Table 1).

The proportion of respondents with knowledge of malaria prevention, mainly ITN ownership, was 71.7% overall, and slightly higher in Zanzibar (73.1 %) as compared to mainland Tanzania (71.5 %); the difference was not significant (p-value=0.4, Table 1). Respondents whose children received EPI vaccines were 84 % overall and significantly higher (90.8%) in Zanzibar compared to mainland Tanzania (83.8 %). However, respondents whose children received EPI vaccines were statistically significant (p-value < 0.001, Table 1). Overall, 72.2 % of respondents whose children received measles vaccines, respondents whose children received measles vaccines were similar between Zanzibar (72.3%) and mainland Tanzania (72.2%). The difference was not statistically significant (p-value = 0.9, Table 1).

Table 1. Perceived indicators of RTS,S vaccine delivery and public interventions coverage in Zanzibar and Mainland, Tanzania

Perceived indicator	Zanzibar (%)	Mainland (%)	p-value
Willingness	96.8	94.3	0.02
Awareness	3.4	11.8	< 0.001
Benefit	87.9	88.5	0.7
Delivery mode	68.8	82.6	< 0.001
Proposed schedule	87.1	86.7	0.8
ITN ownership	73.1	71.5	0.4
Received EPI vaccines	90.8	83.8	<0.001
Received measles vaccines	72.3	72.2	0.9

Factors associated with willingness to use malaria vaccine

Willingness to use malaria vaccine was not associated with awareness of the forthcoming malaria vaccine. However, knowledge of benefits of vaccinating under-five children, acceptance of the mode of administering the malaria vaccine and proposed schedule were associated with willingness to use malaria vaccine. In multivariable analysis, mothers who reported to know the benefit of vaccinating under-five children were more likely to use malaria vaccine than those who didn't know (OR: 3.5; 95% CI: 2.57–4.75; $p < 0.001$). Mothers who reported to accept the mode of administering (2-3 jabs) malaria vaccine were more likely willing to use malaria vaccine than those who did not accept (OR: 16.78; 95% CI: 11.47–24.54; $p < 0.001$). Mothers who reported to agree with proposed schedule of the forthcoming vaccine were more likely willing to use malaria vaccine than those who did not agree (OR: 14.68; 95% CI: 10.51–20.51; $p < 0.001$) (Table 2).

Table 2. Factors affecting willingness to use malaria vaccine (N = 5502)

	Univariate analysis		Multivariate analysis	
Assessed indicators	**OR (95% CI)**	**p-value**	**OR (95% CI)**	**p-value**
Awareness				
No	1	0.2	1	0.7
Yes	1.3 (0.8 -1.9)		0.9 (0.5 - 1.5)	
Benefits of vaccination				
No	1	< 0.001	1	< 0.001
Yes	3.3(2.6 - 4.1)		3.5 (2.6 - 4.8)	
Mode of administering (2-3 injections)				
No	1	< 0.001	1	< 0.001
Yes	38.8 (27.5 - 54.8)		16.8 (11.5 - 24.5)	
Proposed Schedule				
No	1	< 0.001	1	< 0.001
Yes	39.6 (29.4 - 53.4)		14.7 (10.5 - 20.5)	

3.5 Discussion

The study was conducted to test awareness of and willingness to use a malaria vaccine which has not yet been propagated in a sample of women older than 18 years of age, with children less than 11 months, in 23 regions in Tanzania (21 regions in mainland Tanzania and 2 regions in Zanzibar -Unguja and Pemba). Information from this study can be used prepare ground for policy decisions and for intervention planning.

Understanding community perceptions can help to identify issues to guide policy decisions for introducing the malaria vaccine. These findings are similar to studies documenting the need for early planning for new interventions, essential for policy decision making; relevant information can speed up the efforts to facilitate its implementation (Brooks and Ba-Nguz 2012). Understanding community perceptions of a malaria vaccine also helps to inform country programme managers responsible for NMCP and IVD priority setting and planning.

Our results on the low (11%) level of awareness of the forthcoming malaria vaccine and high (94.5%) willingness to use a malaria vaccine were similar to those found by Colon-Lopez and others for HPV vaccination in Puerto Rico (Colón-López et al. 2012), which also indicated low (28.3%) level of awareness of and high (76.9%) willingness to use HPV vaccines. Both findings come from settings where none of the study participants had been vaccinated. This finding suggests that creating awareness of the malaria vaccine would be effective; currently understanding among respondents is low because the malaria vaccine is new and most people had not yet learned about it. Informing women about the malaria vaccine would likely increase women's interest in their willingness to use a malaria vaccine. Creating awareness could reveal policy-related issues that, once addressed, could support decisions for malaria interventions (Burchett et al. 2012) and child vaccinations (Dempsey et al. 2006).

Low awareness of the forthcoming malaria vaccine was compared to both willingness to use a malaria vaccine and knowledge of the benefits of vaccinating children under-five. This finding is consistent with others' findings in Kenya and Ghana that showed wide spread knowledge of childhood vaccinations (Ojakaa et al. 2011); in Ghana, over 90% of respondents understood that the malaria vaccine had benefits related to child vaccinations (Febir et al. 2013; Dempsey et al. 2006; Ojakaa et al. 2011; Bingham et al. 2012). Contrary to the study conducted when malaria vaccine efficacy results were not yet available, the level of willingness to use a malaria vaccine differed when respondents considered low efficacy results compared to other childhood vaccines (Febir et al. 2013; Olotu et al. 2013). Knowledge of existing routine immunization schedules and benefits increased the level of willingness to use a malaria vaccine. The structure of the immunization programme in

Tanzania is widely spread and accessible to the majority of Tanzanian women. As the malaria vaccine is expected to be delivered through the immunization programme, women would expect the vaccine's benefits to be in line with those of other routine vaccinations. Therefore, informing women about the benefits of vaccinating children under-five is likely to increase women's interest in the forthcoming malaria vaccine and their willingness to use it.

High acceptance of the mode of administering a malaria vaccine (2-3 jabs) according to the proposed schedule was similar to findings by Febir and others who showed that respondents were willing to receive vaccines in the form of injections, as most understood that "vaccines are injections given to children in their childhood to prevent occurrences of diseases" (Febir et al. 2013). Contrary to Parvez and others, immunization injections were perceived to be painful procedures (Parvez et al. 2010). The injection method becomes a challenge when increasing numbers of injections as women become less willing to take their children for malaria vaccination. After the end of routine vaccination, parents might not take their children for additional vaccinations for a variety of reasons, including mothers' competing priorities. Immunization clinics at health facilities and in informal areas (mobile clinics) can be good avenues for informing women about the malaria vaccine and for scheduling children for vaccination.

The strengths of the study include: larger sample size, representative sampling and combining data on awareness of the forthcoming malaria vaccine, willingness to use a malaria vaccine, knowledge of the benefits of vaccinating children under five, acceptability of the mode of administering the vaccine according to the proposed schedule, ITN ownership, and knowledge of EPI and measles vaccinations. The study had a number of limitations, including the difficulty in determining acceptance of a malaria vaccine that is not yet available. It is likely that there are other reasons not covered by this study that account for some women's lack of awareness of a forthcoming malaria vaccine and their unwillingness to use a malaria vaccine. For example, the vaccine may be accepted by the parents but still they do not take their children for vaccination due to distance, competing maternal priorities and lack of time.

Conclusions and recommendations

Although mothers were highly unaware of a forthcoming malaria vaccine, they were very willing to use a malaria vaccine. Identifying regions with both low awareness of a forthcoming malaria vaccine and low willingness to use malaria vaccines would allow appropriate advocacy strategies to be planned and communication strategies to be developed before introducing the malaria vaccine in Tanzania. Malaria vaccine RTS,S will complement existing malaria interventions and be implemented through the IVD. The information generated by this study can aid policy makers as they plan and set priorities for introducing and implementing the malaria vaccine

It is recommended that awareness of a potential malaria vaccine be created in the entire Tanzanian community, specifically among mothers who should be informed of both the benefits related to child vaccination and of the malaria vaccine. This could be accomplished by disseminating information to enhance maternal readiness for adopting malaria vaccination.

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4. Policy analysis for deciding on a malaria vaccine in Tanzania and implications for other African countries: case study

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4.1 Abstract

Background

Traditionally, it has taken decades to introduce new interventions in low-income countries. Several factors account for these delays, one of which is the absence of a framework to facilitate comprehensive understanding of policy process to inform policy makers and stimulate the decision-making process**.** In the case of the proposed introduction of malaria vaccines in Africa, a specific framework for decision making will speed up the administrative process and shorten the time until the vaccine is made available to the target population.

Methods: Document review and qualitative research tools were used as a basis for conducting key informant interviews, developing the Policy Analysis Framework and analysing stakeholders. 20 key informants at national level were assessed in Tanzania between July and August 2012. Interviews were conducted with government officials, bilateral and multilateral partners and other stakeholders. Semi-qualitative analysis applied to RTS,S African countries to assess malaria treatment policy changes and to draw lessons for malaria vaccine adoption.

Results: The framework was developed and applied to RTS, S African countries with regard to its readiness for adoption of the forthcoming malaria vaccine. The rating implies that Tanzania (12), very good), Burkina Faso (10), Malawi, (9), Kenya and Gabon (8) good) are prepared. Ghana scores poorly on policy promoting factors (5), little) and documented information on barriers. Mozambique also scores low on promoting factors and documented barriers ((1) weak).

Conclusion: The framework is a comprehensive tool that enables one to unpack the content and contextual factors surrounding the decision to introduce a potential malaria vaccine in African RTS, S countries. Furthermore, the framework provides an effective way to deepen our knowledge of the policy process and to inform the policy decision-making process for new malaria interventions, generally, and for the forthcoming malaria vaccine, specifically. It is an applicable and appropriate tool for African RTS,S countries and other low resourced settings. Lastly, the framework facilitates the synthesis of information in a coherent way, enabling a clearer understanding of the policy process, thereby speeding up the policy decision-making process and shortening the time until the forthcoming malaria vaccine becomes available. While we find the framework useful and applicable, we still feel that further validation is required.

4.2 Background

Introducing new technologies for diagnosis and treatment is often expensive and demands specific biological, medical and technical capabilities to use them (van Balen and Gerrits 2001; Bahamondes and Makuch 2014). They also require a certain level of infrastructure, effective health systems for example, to deliver high quality materials and services that make new technologies accessible and affordable (van Balen and Gerrits 2001; Frost and Reich 2009; Bahamondes and Makuch 2014). Creating access to new technologies requires understanding of the users' preferences, concerns and the context in which the new technologies are perceived. Successful delivery of new technologies depends on health system performance (van Balen and Gerrits 2001). The case of Norplant in Indonesia and the United States demonstrated how failure to consider the current state of a health system can hinder access. A new contraceptive implant technology required both insertion and removal by a trained provider. The providers were trained on how to insert the implants but they were not provided with removal skills, resulting in difficulties with implant removals (Frost and Reich 2009). Health systems' strengthening can also ensure that new products are designed to improve people's health in the context of their needs and preferences. Thus, people's needs have a role to play in access to new technology and, consequently, the effect and overall benefits of new technology. Availability of new technologies and interventions require policy makers and others to make decisions about whether or not to adopt them.

Even when a decision is made to adopt and implement a new health intervention in low and middle income countries (LMICs), it often takes years or decades before the benefits of the new interventions are realised (Kane and Brooks 2002; Bosman and Mendis 2007; Frost and Reich 2009; Levine, Knoll, et al. 2010; Brooks and Ba-Nguz 2012). This is due to delays in availability of new drugs, for example, due to cultural differences in perceptions of medical needs and costs (Berndt and Cockburn 2014). Delays in new vaccine adoption (Clemens and Jodar 2004; DeRoeck, Jodar, and Clemens 2007; Jacqueline Sherris et al. 2006) are commonly due to financial constraints, political obstacles (Clemens and Jodar 2004) and competing health priorities (DeRoeck, Jodar, and Clemens 2007), as well as absence of national disease burden data (Clemens and Jodar 2004), absence of vaccine efficacy data (Clemens and Jodar 2004; J. Sherris et al. 2005) and lack of sustainable supply mechanisms for the new vaccine (Mahoney 2004). As new interventions become available, it creates the need for greater understanding of the policy making process as it applies to technology adoption and implementation (DeRoeck 2004; Gericke et al. 2005; Bryson et al. 2010; Gessner et al. 2010; Grundy 2010; Levine, Hajjeh, et al. 2010; Victora 2010; Brooks and Ba-Nguz 2012; DeRoeck et al. 2005). Understanding evidence-based information helps in planning, priority setting and choosing from among the available alternatives (Ashford et al. 2006; Moree and Ewart 2004). Lack of understanding could also slow down the policy decision making process as it relates to introducing

new interventions (Ashford et al. 2006; Moree and Ewart 2004), as was the case with for both Haemophilus Influenzae type b (Hib) conjugate vaccine implementation (Hajjeh et al. 2010; Mitchell et al. 2005) and malaria treatment policy change implementation in Tanzania (Williams, Durrheim, and Shretta 2004; Mulligan et al. 2006; Amin et al. 2007; Bosman and Mendis 2007). Njau and others (2008) studied the influence of stakeholders in the decision to deliver ITNs. The authors critically analysed the stakeholders' interactions with one another and how they were influenced by the contextual factors (Njau et al. 2009). Elements of framework such as actors and context can facilitate understanding of evidence based information needed to make decisions.

Frameworks have been useful for identifying relationships among the elements that guide and inform health policy processes (Gill Walt et al. 2008). There are few frameworks used for policy analysis and the few that are available do not focus on specific policies to test the theory's application (Gilson and Raphaely 2008). Most frameworks available lack information which could be validated in the field (Wenger et al. 1999; Munira and Fritzen 2007; Piso and Wild 2009; Burchett et al. 2012). Various models and frameworks describe the policy process and though they are not mutually exclusive, several make specific contributions on which this study is built. These include the Policy Analysis Framework (G. Walt and Gilson 1994), the Kingdon model (Kingdon and Thurber 1984), Advocacy coalition' framework (Sabatier and Jenkins-Smith 1999), Street-level Bureaucrat's model (Lipsky 2010) and Reichs' political analysis (Reich 1995). Given the focus of the present study; two frameworks were chosen because of how they complement each other. Policy Analysis Framework (G. Walt and Gilson 1994) highlights ways of understanding policy processes through elements such as policy content, context, actors and processes involved in making and implementing policy (G. Walt and Gilson 1994). The Kingdon model of agenda setting (Kingdon and Thurber 1984) helps to explain how certain issues get onto the government policy agenda and suggests three related processes — the problem stream, the politics stream and the policies streams — that when brought together, create a window of opportunity and increase the chance of policy adoption. Advocacy coalition (Sabatier and Jenkins-Smith 1999) actors in policy communities form advocacy alliances that compete to influence specific policy objectives. Street-level Bureaucrats model examines what happens when policy is translated into practice; that is, policy implementation (Lipsky 2010). Reich's (Reich 1995) work on political mapping helps to explain why certain policies do not succeed and could help to develop strategies to address challenges for future policy implementation (Reich 1995). The above mentioned models and frameworks of policy making are likely to be more or less relevant depending on the specific circumstances and policy processes surrounding adoption of new technologies, like the malaria vaccine RTS,S.

In this study, we adapted a framework based on Policy Analysis Framework concepts to inform the policy making process for introducing the forthcoming malaria vaccine, RTS,S, in Tanzania. The framework analyses factors influencing the policy making process, such as content, context, actors and processes in order to establish a mechanism that will facilitate timely management of the stakeholders, thereby ensuring timely rollout of the vaccine. Specifically, the framework generates information on the positions, influences and preferences associated with the rollout, which ultimately leads to better and more efficient management of the stakeholders. By applying the proposed frameworks to existing policy processes for malaria interventions and vaccines in Tanzania, we are able to distil lessons learnt that will also serve to guide the forthcoming malaria vaccine policy formulation and implementation.

4.3 Methodology

Adapting Policy Analysis Framework

The malaria intervention specific framework was analysed based on identified policy analysis approaches and existing general frameworks for studying policy processes (G. Walt and Gilson 1994). It draws heavily upon Policy Analysis Framework (G. Walt and Gilson 1994) focus on (context, and content, context, actors and process). But also incorporates elements from the kingdon model as listed and described. The overall approach guides how elements influence the policy process and how issues get on the policy agenda (Kingdon and Thurber 1984) and the process through which policies are developed, formulated and implemented (G. Walt and Gilson 1994).

The framework guiding the analysis is presented in Table **3** and Figure 3. Table **3** presents the four elements of the framework (content, context, actors and process). Figure 3 describes the different stages of the policy process in Tanzania and describes how content, context, actors and process are determined. The analysis is presented in sections of this paper.

Study population

To better understand how various stakeholders engage in the policy making process for new malaria interventions and vaccines in Tanzania, qualitative methods were used, namely interviews with key informants. A sample of 20 key informants at the national level was assessed between July and August 2012. Participant categories included: international donors and public health stakeholders The US Agency for International Development (USAID), Presidents Malaria Initiative (PMI), World Health Organization (WHO), The United Nations Children Fund (UNICEF), Centers for Disease Control and Prevention (CDC); national and political institutions (Legislature, Members of Parliament); public health officials MOHSW; programme managers NMCP, IVD; regulatory authorities: TFDA; Ministry of Finance and Economic Affairs (MOFEA) and professional organisations, academia and research institutions: NIMR, IHI, AMANET & COSTECH. Key informants were selected based on their knowledge and involvement in the process of changing malaria treatment policy and adopting new vaccines in Tanzania. Interviews were open ended, with questions that aimed to analyse the existing policy process for new malaria interventions and vaccines in Tanzania and to draw out lessons learned that could be applied to the forthcoming malaria vaccine policy adoption and implementation process.

Data collection

The face-to-face semi-structured interviews began by soliciting verbal informed consent and permission to record the interviews. Interviews lasted between 40 — 60 minutes, depending on the level of detail offered by informants. Information gathered from the key informant interviews was used to map and analyse stakeholders in terms of interest and perceptions, capacity and motivation to adopt the policy and to determine possible actions for engaging stakeholders. Document review was conducted to RTS,S African countries

Data analysis

Interview notes were transcribed with the aid of recordings when available and uploaded and imported into MAXQDA 11 software for coding based on the themes derived from the interviews related to content, context, process and actors involved in the policy process. Interviews were analysed thematically to understand the experiences of different stakeholders and to describe policy change processes.

Document review to African countries where malaria vaccine RTS,S clinical trials were conducted to assess malaria treatment policy changes and to draw lessons for malaria vaccine adoption. Document review and qualitative research tools were used as a basis for conducting key informant interviews, developing the Policy Analysis Framework and analysing stakeholders. Policy Analysis Framework facilitated analysis of the steps of content, the actors involved in decision making, contextual factors influencing the policy and the process of how policy was initiated, formulated and implemented (G. Walt and Gilson 1994). Stakeholders analysis helped to specifically identify individuals and groups, assess their power, resources, policy positions and their perceptions of the problem (Roberts et al. 2008). Figure 2 outlined the stakeholder analysis. The Policy Analysis Framework and concepts from the Kingdon model (Kingdon and Thurber 1984), were used to illustrate and interpret results.

The study protocol, interview guide and consent for this study were reviewed and approved by the Institutional Review Board at the Ifakara Health Institute (IHI).

4.4 Results

Findings are presented according to the concepts drawn from Policy Analysis Framework (G. Walt and Gilson 1994): content (steps of content), context, actors and process (procedures)

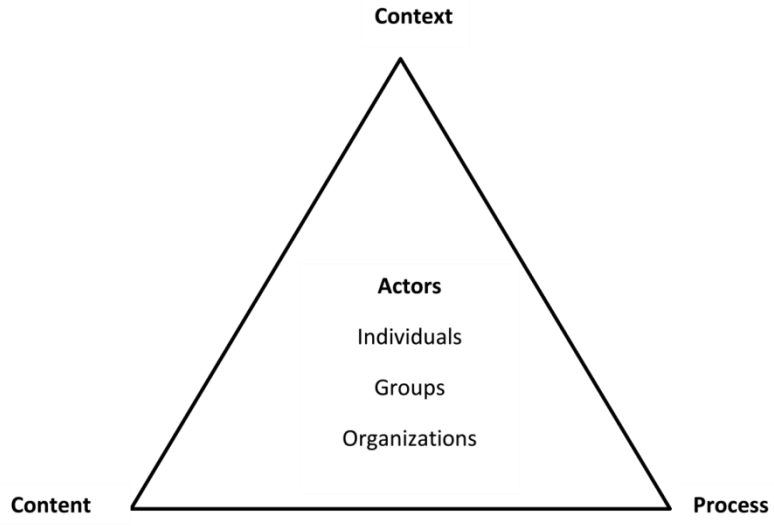

Figure 1. Policy Analysis Framework

Steps of content in decision making

In Tanzania, the process of making policy decisions for the introduction of malaria interventions involves several steps. Interview participants highlighted the steps of content as follows: i) reviewing the available evidence from different studies with consistent results and epidemiological data; ii) considering the availability of alternative interventions to replace the failing intervention, including the cost of the new intervention; iii) forming a task force or technical groups composed of doctors and bilateral and multilateral partners to get additional scientific inputs and correctly package the evidence in language that can be easily understood by policy makers; iv) getting feedback from the National Malaria Advisory Committee (NMAC), a technical body with the mandate to review technical evidence before it is made available to policy makers at the next level; v) presenting scientific evidence to the NMCP Manager to convince him of the need for the new intervention (NMCP is the secretariat to the NMAC). The NMCP secretariat prepares a brief summary, which, together with the recommendations from the NMAC, are presented to the Director of preventive services and to the Chief Medical Officer (CMO) of the MOHSW; vi) the Director of Preventive Services and the CMO present the findings to the MOHSW Senior Management team to get their buy-in, endorsement and approval. Normally this meeting would be held in the presence of the NMCP secretariat. The MOHSW Senior Management team comprises all Directorates (the Permanent Secretary, Director of Preventive services, Director of Curative Services, CMO, Director of Policy and Planning, Director of Human Resources and Director of Quality Assurance).

Interview participants also identified the steps in making policy decisions for the adoption of new vaccines in Tanzania: i) reviewing the available evidence on the disease burden and other epidemiological data pertaining to the vaccine (efficacy, safety and WHO–prequalification); ii) considering the availability of the intervention; iii) developing a concept paper or a proposal based on the latest epidemiological data; iii) consulting experts, researchers, health institutions and development partners in order to get additional scientific inputs for developing the proposal and presenting the evidence and epidemiological data to the Malaria Steering Committee (MSC), which replaces the NMAC in this case; iv) presenting the MSC's recommendations (via the NMCP secretariat) to the MOHSW's Senior Management team to get buy-in, endorsement and approval of the proposal; v) presenting the proposal to the Inter-agency Coordinating Committee (ICC) of the MOHSW's IVD unit so that the evidence is reviewed, and the cost analysis is discussed. The ICC can recommend that the proposal be submitted to GAVI to apply for funding to support the vaccine's roll out; vi) developing a comprehensive protocol for application for GAVI funds to introduce a new vaccine, including a detailed implementation plan, cost per annum (cMYP) and mechanisms for scaling up, among other details.

In Tanzania, the decision-making process for adopting malaria interventions and new vaccines in general takes years, involving several steps: meetings and presentations of scientific data from different studies with consistent results, packaging and disseminating evidence and getting approval for use by the MOHSW. Other steps include considering the availability of an intervention backed by scientific proof and assessed for efficacy and side effects; a task force packages and summarises scientific results, and is followed by stakeholder meetings, consensus building with the MOHSW management team for approval and adoption.

Context

The analysis of the context in which malaria policy decisions are made yielded various themes. Themes were broadly categorized into one of two major areas, promoting and barriers factors.

Promoting factors

According to interview participants, the major factors influencing the policy process for both malaria interventions and vaccines include:

Epidemiological and intervention characteristics

WHO recommends that policy decisions for introducing new interventions be based on established evidence of the epidemiology and burden of disease and on the safety, effectiveness and efficacy of the specific intervention to prevent the target disease.

The interventions should be of high quality but the question of how MOHSW can ensure quality assurance for new interventions remains open. “We need to set criteria for quality assurance, which we don’t have yet; the criteria to accept or not to accept the new interventions, which we do not have yet. It is an important observation you have noted”. (“MOHSW stakeholder”).

Country experiences of malaria treatment policy change

Mapping the country and looking at decisions adopted in neighbouring countries with similar settings (as Tanzania) such as Kenya, Botswana, and Malawi, can influence policy decision outcomes. In those countries, SP has replaced CQ as the first line drug and had they have already revised their national drug policy guidelines, accordingly (“NMCP stakeholder”).

Presentation and dissemination of evidence

Technical groups translate the evidence in a manner that is digestible and understandable to policy makers. The groups include the Medical Association of Doctors, bilateral and multilateral partners, and scientific bodies. There are lessons to be learned from past experiences. A scientific package was developed at the time that treatment policy changed from SP to ACT. The package included operation and orientation knowledge, an analysis of the costs and cost effectiveness of the new intervention and scientific proof that validated the intervention locally, in the field. When policy makers are well informed, they will get involved. The knowledge that the policy makers accumulate is important for adoption and approval decisions.

“You have to simplify the language and hit the message about replacement of the intervention” (“Bilateral & Multilateral partners stakeholders”).

“A package of the information reflects what you need to bring as a point of reference. The Prime Minister’s Office Local Government and Regional Administration (PMOLRAG) hire and fire employees, therefore packaging information brings those employees on board and gives them a policy level of understanding” (“Bilateral & Multilateral partners stakeholders”).

Coordination and harmonization of the process

Planning and harmonizing the policy process is done in collaboration with donors and other international stakeholders, from the conception stage to the final use of the findings. The process gives the opportunity from the outset to mobilize donor funding and to demonstrate to the donors and other partners the operational and other costs related to the policy adoption and implementation and to show that the policy is cost effective. When donors and partners are taken on board at the early stages of discussing the policy change, it gives an opportunity to strategies and leverage financial and technical support towards the aim,

thereby increasing the chance that the policy decision in question will be adopted ("Bilateral & Multilateral partners stakeholders").

Use of international scientific evidence

The use of international scientific evidence adapted to the local context is important for informing related policy decisions. Availability of an international person introduces another perspective and helps to clarify scientifically proven evidence, thereby increasing the chances that a policy decision and intervention will be adopted ("Bilateral & Multilateral partners stakeholders").

Of all the contextual factors promoting policy adoption, as identified by interviewees, the ones that were emphasised most included WHO recommendations related to safety, effectiveness and efficacy of interventions, the country's experience of malaria treatment policy change, the packaging, presentation and dissemination of evidence, coordination and harmonisation of the process and use of international scientific evidence and figures to engage positively in the dialogue.

Barriers factors

Interview respondents also identified factors that were barriers to decisions to adopt new malaria policy. These included:

Financial sustainability

The country cannot generate its own resources to sustainably fund new interventions from the national budget. Inadequate recurrent budgets have led to a dependency on donor funding. Sustainability of financing interventions is a challenge once when the donors withdraw their funding. For instance, there are inadequate funds for vaccine operations at national level; the government contributes 5.4% of costs of vaccines. Specifically, the government covers the full costs of BDG, Measles, OPV and TT, while co-funds DPT-HEPB-HIB vaccine (as reported by "IVD stakeholder").

Competing health and other priorities

Given its limited resources, the government must choose from among competing health priorities and other national and local priorities. Scientific evidence should justify the need for new interventions and be ranked as a priority in the MOFEA agenda, according to the Member of Parliament;

"It is important to understand why a particular intervention needs to be given priority, if there is treatment, prevention, larvicide, residual spraying and bed nets; all these are competing

interventions, they are competing for donor funding and donors have their own interests in funding" — ("Member of Parliament stakeholder").

Political will and bureaucratic procedures

Any new interventions take time (2 – 3 years) to be understood and then accepted. Thus, planning for new interventions should start early to explore opportunities for engaging the government and donors, to take them on board, and to advocate and lobby for adoption. This is especially important in the context of government allocations for the roll out of malaria interventions and vaccines ("Bilateral & Multilateral partners stakeholders")

Costs related to the adoption and implementations of interventions

All costs related to adopting and implementing interventions imply that large amounts of funds are spent on management activities rather than on actual implementation of interventions to achieve positive health outcomes ("NMCP Stakeholder").

Supply and distribution

In some instances, global supply does not meet the demand for the malaria interventions, Interview respondents reported distribution issues arising from the logistics of transporting interventions from the manufacturer to the users. Other issues of concern include: whether the interventions need special transport and storage, how they are stored, availability of vehicles to facilitate transportation, and user friendly packaging of vaccines to facilitate delivery. Another important element is training. New interventions require development and roll out of an appropriate training package for health facilities ("NMCP, Bilateral donor Stakeholders").

Professional compliance with antimalarial drugs

Access barriers related to affordability of interventions and competence of providers indicate that health infrastructure's capacity must be increased so that clinicians comply with the recommended national policy and guidelines ("NMCP stakeholder") These barriers are mostly influenced by: financial sustainability, competing priorities, political will and bureaucratic procedures, cost, supply and distribution and lack of compliance by users and health providers of the new malaria treatment policy.

Actors

With respect to the policy process for malaria interventions and vaccines, interview participants ranked stakeholders from most supporting to most opposing (Figure 2. Analysis of Key stakeholders interviewed below). In the process, different clusters of actors emerged, namely high supporters and

medium supporters, ranked as such on a scale of 0 – 8, where 0 is the lowest level of support. Analysis of key stakeholders interviewed indicated that the actors with the highest power and position to support malaria vaccine adoption ranged from 6 – 7, while users, customers and AMANET were in the medium support category, ranked around 4 (Figure 2. Analysis of Key stakeholders interviewed below).

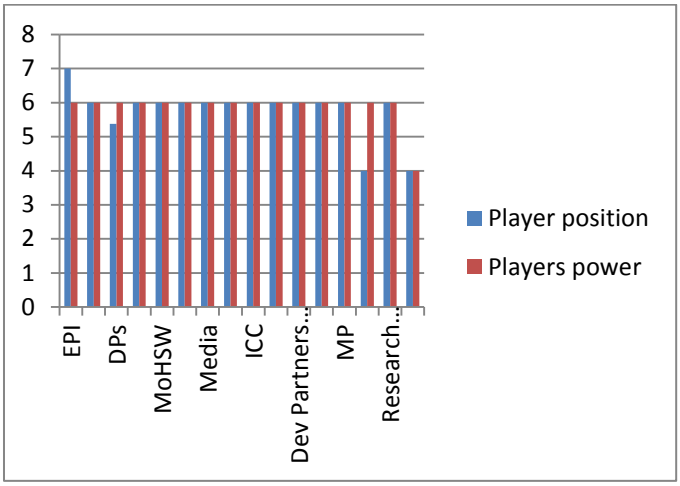

Figure 2. Analysis of Key stakeholders interviewed

Policy process

This section presents respondent's report on policy process for malaria interventions and vaccines. Findings are categorized into subthemes including: problem identification and policy formulation, agenda setting and partnership, policy implementation and operation and monitoring, evaluation and re adjustment.

Problem identification and Policy formulation

Sometimes, the problem is identified by researchers or specific task force related to the subject matter. When scientific evidence is collected and established, with scientific proof from different sentinel sites, the evidence has to be systematically reviewed by a number of researchers to support the process for a policy change. Technical consensus on evidence-based information is built in consultation, through the technical advisory group, task force, experts, WHO and other malaria donors and policy makers. Several stakeholder meetings were conducted and presentations were made by experts. A technical task force was formed as part of the process. The NMCP also engaged relevant stakeholders under the guidance of WHO to develop appropriate malaria treatment guidelines for the new policy ("NMCP, MOHSW, Bilateral & Multilateral partners stakeholders").

Agenda setting and Partnership

Politicians were more likely to introduce an issue into the policy agenda around a general election, when issues were compatible with other policy ideas, when there was a 'window of opportunity' (such as new or sudden availability of resources) and in times of crisis ("Bilateral & Multilateral partners stakeholders")

Policy implementation and operational

Planning for implementation begins when there is assurance of funding, therefore early identification and engagement of potential stakeholders to finance the new policy is important from the outset. Awareness and advocacy targeting the community who are the users of the intervention is advised. Relevant policy documents should be simplified so that they are understood by different groups of people. Service providers can sensitise users to interventions early to win support for relevant policy implementation ("NMCP, MOHSW stakeholders").

Monitoring, evaluation and re adjustment

Monitoring in policy development requires reviewing, planning and updating work on a regular basis and assessing whether activities are carried out as planned. For instance the IVD monthly progressive report on coverage, stock balance, surveillance sentinel sites and quarterly review meetings show the progress of implementation. These reports could be used as indicators against which to measure success in terms of process and health impact (IVD) ("IVD stakeholder").

Stages of policy development processes, simplified into four categories

The analytical framework explains the policy process setting that is selected, as shown in Figure 3 below. The framework explains the policy process for the forthcoming malaria vaccine and how stakeholders interact at different stages of the policy process. It describes how the stakeholders are involved and influence the policy process at each stage of the policy development process. The stages of policy process as identified in Figure 3 include: problem identification and policy formulation, agenda setting and partnership, policy implementation and operation and policy monitoring, evaluation and re adjustment. Stakeholder 'opinions vary and will shape the different stages of the policy process for the forthcoming malaria vaccine adoption and implementation in Tanzania.

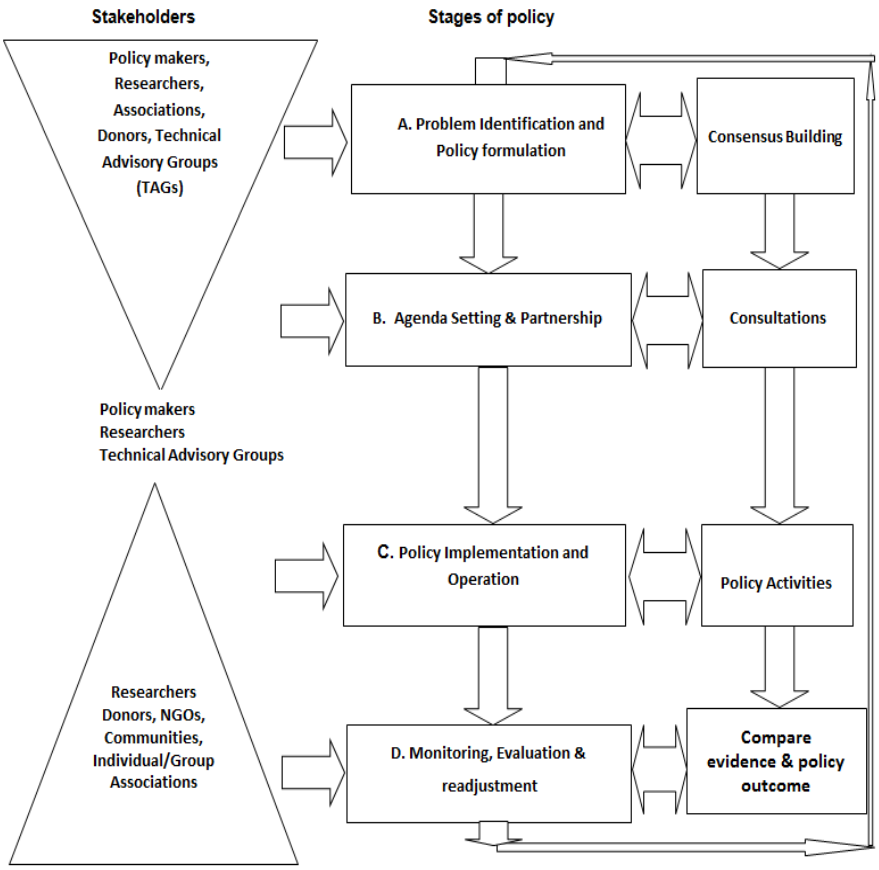

Figure 3. Stages of policy development processes, simplified into four categories

A. Problem identification and policy formulation
B. Agenda setting and partnership
C. Policy implementation and operation
D. Monitoring, evaluation and re adjustment

This practical result helps to construct the guideline (Chapter 6)

The elements of the policy process presented were further analysed and are presented in Table **3** below as they apply to policy change for new malaria interventions and vaccine adoptions in Tanzania. The study elements of the framework are; content, context, actors and processes. The elements are grouped according to the policy process to facilitate understanding.

Table 3. Key elements of policy process for malaria interventions and vaccine adoptions in Tanzania

Theme	Subtheme & content Malaria treatment	Subtheme & content Vaccine
Steps of content in decision-making		
Content	i) Availability of evidence ii) Availability of intervention iii) Formation of Task force/technical groups to synthesize the evidence; package and translate evidence and cost implication iv) Presentation to the NMCP manager to convince him/her about the scientific evidence and the need for new intervention v)Presentation to the Director of DPS and Chief Medical Officers vi) Presentation to the MoHSW management team for approval	i)Availability of evidence according to the (burden of disease and epidemiology data ii) Availability of intervention; Develop concept paper/ proposal iii) Scientific consultation with experts, researchers, health institutions and development partners iv) Presentation to MOHSW management v) Presentation to ICC vi) Development of a comprehensive protocol for GAVI application
Context	**Promoting factors**	
Epidemiological and intervention characteristics	WHO-prequalification and recommendations for efficacy, safety and quality	WHO-prequalification and recommendations efficacy, safety and quality
Country experience	Adoption of decisions in neighbouring countries with similar settings as Tanzania	adoption of decisions from neighbouring countries with similar settings as Tanzania
Packaging and dissemination of information	Translate the evidence in a manner that is digestible and understood to the policy makers.	Translate the evidence in a manner that is digestible and understood to the policy makers.
Coordination and harmonization of the process	Planning and harmonizing policy process among government bodies and donors	Planning and harmonizing policy process among government bodies and donors
Use of international scientific evidence	International stakeholders and donors take part in the dialogue from the onset and use their technical knowledge to clarify scientifically proven evidence in favour of the policy change	International stakeholders and donors take part in the dialogue from the onset and use their technical knowledge to clarify scientifically proven evidence in favour of the policy change
Barriers		
Financial sustainability	Affordability of operational costs; availability of domestic financing, external financing; dependence on donor funding during implementation of interventions and policies	Affordability of operational costs; availability of domestic financing, external financing; dependence on donor funding during implementation of interventions and policies
Competing priorities	Country's competing health and other priorities	Country's competing health and other priorities

Theme	Subtheme & content Malaria treatment	Subtheme & content Vaccine
Political will and bureaucratic procedures	It takes between two to three years to introduce new interventions	It takes between two to three years to introduce new interventions
Costs	Costs related to adopting and implementing interventions	Costs related to adopting and implementing interventions
Supply and distribution	Sometimes, global supply does not meet the demand of the new intervention	Sometimes, global supply does not meet the demand of the new intervention
Professional compliance with antimalarial drugs	Access barriers related to affordability of intervention and competence of providers	
Stakeholders		
Stakeholders	NMCP managers; Director of Preventive Services (DPS), technical working group, MOHSW, MOF, the media, Professional organisations, development partners, TFDA, MSD, NIMR and IHI	EPI managers, Director of Preventive Services (DPS), technical working group, MOHSW management team, MOF, the media, Professional organisations e.g MAT, development partners, GAVI, ICC, TFDA, MSD , NIMR and IHI
Policy process		
Problem identification and policy formulation	Understand the burden of disease and interventions to address burden of disease and the availability of alternatives Options and possible solutions are adopted	Understand the burden of disease and interventions alternative to address burden of disease and the availability of alternatives Options and possible solutions are adopted
Agenda setting	Opportunity for funding, for instance NMCP wrote a proposal to the GFATM to support the introduction of SP in Tanzania	Opportunity for funding, for instance GAVI opened window of opportunity to finance vaccine
Policy implementation and operation	Planning for implementation begins when there is assurance of funds; Policy activities are implemented	Planning for implementation begins when there is assurance of funds; Policy activities are implemented
Monitoring, evaluation and re adjustment	Assessment of outcome and impact – Tanzania HIV and Malaria Indicator Survey (THMIS), Demographic Health Survey (DHS)	EPI monthly progressive report on coverage, stock balance, surveillance sentinel sites and quarterly review meetings are used to assess the process and impact while the DHS assesses impact

The evidence drawn from elements of policy process and its importance based on review of literature:

Content

It is important to analyse the content of policy processes in the process of assessing policy options for introducing new interventions and their subsequent adoption. We paid attention to the steps involved in the process to adopt policy decisions in favour of malaria treatment policy change interventions and vaccines in Tanzania and other African RTS,S study countries. Several findings confirmed the importance of a careful assessment of the policy process which will facilitate the reform or policy change (Patton and Sawicki 1993; Green 2007).

Context

The contextual factors were analysed based on promoting factors and barriers for policy decision on new interventions. Promoting factors were; the characteristics of the interventions, packaging and dissemination of information, coordination and harmonisation of the process and use of scientific evidence. Barriers included; financial sustainability, competing priorities and political will and bureaucratic procedures. Several studies have identified barriers such as competing priorities and limited resources (Shiffman 2007), financial sustainability (G. Walt and Buse 2000) and political will (Munira and Fritzen 2007; Glassman et al. 1999; Reich 1995). The policy decision making process is dominated by political figures; their political will contribute to garnering political support for the policy decision to be made.

Actors

Interactions between actors and the other elements of policy process are given in Figure 3 above. In this study, we identified the key actors and mapped their position to identify which groups are mobilized to support and influence the policy process. Studies have confirmed similar findings, that identifying potential allies and opponents can help develop strategies for seeking support for policy decisions (Varvasovszky and Brugha 2000; Reich 1995; Schmeer 1999). Stakeholder analysis is one of the key tools used to facilitate policy decision making and eventual implementation (Brugha and Varvasovszky 2000).

Process

The policy process is divided into four stages; problem definition and agenda setting is when the issue comes to the attention of decision makers; formulation stage is when the policies are enacted; implementation stage is when policy activities are carried out; and the monitoring and evaluation stage assesses the impact (Gill Walt et al. 2008). The Kingdon model explains

how issues get on the policy agenda. Policy is made through problem streams, politics streams and policies streams. When all these factors come together, the issue can achieve high agenda priority and create a window of opportunity for policy adoption (Kingdon and Thurber 1984). Windows of opportunity for financial commitments from international organisations, availability of new interventions such as the forthcoming malaria vaccine, and the high political commitment in the country towards malaria control could attract the demand for policy adoption.

The elements of policy process considers the content of the policy, the actors involved in the process and the context in which the policy was developed and implemented, process is concerned about how the issue gained policy priority and how the actors influence the process.

Stakeholders were asked to reflect on the existing process of malaria interventions policy change and vaccines in Tanzania in order to identify key lessons learned for the forthcoming malaria vaccine implementation. The following list represents what stakeholders perceived were the most salient "lessons learned".

- The potential malaria vaccine is a first generation malaria vaccine with a high probability of success at the Phase III stage; it targets specific age groups of children and is given as a consolidated package with other IVD vaccines.
    - IVD has an established infrastructure which can potentially accommodate new vaccines;
    - Factors for consideration are programmatic issues needed for a new vaccine, cold chain, training health workers, cost of introduction, funding opportunities available for the vaccine (GAVI).
- Key concerns from the donor group and key questions generated
    - What are the operational costs of adding a new vaccine?
    - What are the potential sources of funding to deliver the vaccine?
    - How do you ensure supply meets demand for the vaccine?
    - How do you demonstrate operational and other costs to the donor partners?
- Package and disseminate information about the malaria vaccine
    - Develop a package for the community who are users of the vaccine to let them understand exactly what the vaccine is capable of achieving. Involves trainings and use of different types of media to facilitate adverts and advocacy.
- Lobbying and advocacy
    - Any new interventions takes time (2-3 years) to be understood and then accepted, thus lobbying for the malaria vaccine should start now

    - Advocacy should begin early enough as it takes time for people to understand and accept new interventions. Planning early will be important for the vaccine's success.
    - Explore opportunities such as the development of new strategies (government and donors) in which to include the malaria vaccine
- The vaccine should be understood as a complementary intervention to existing malaria control measures such as ITNs, ACTs and diagnostics
    - Integrate malaria vaccine with other opportunities such as child health day, malaria campaigns in general, and use of advocacy avenues
    - To secure enough funding and involve other stakeholders
- Planning, financing and implementation
    - There should be adequate analysis of the vaccine system in line with the introduction of the forthcoming malaria vaccine (storage, delivery, and packaging).
- Integration and complementarity
    - Attention should be paid to the documents or guidelines to show how the vaccine relates to and complements other ongoing malaria interventions.
    - Consider options for delivery at primary levels using existing interventions e.g. the delivery of a booster dose should be explored and documented in the implementation guidelines
- Involvement of front line implementers
    - Sensitisation of health workers has to begin early enough to improve on motivation and any negativity projected from them to community.
    - Involvement of health workers can be done through several, small gestures. For example, holding meetings between Council Health Management Teams (CHMTs) and health workers when they conduct supervision, informing and advising them to accept a new vaccine.
- Continuity and sustainability:
    - Have a clear plan of what the funding sources would be after GAVI support ends
    - Use opportunity to develop new health-related strategies to include the vaccine so that it is considered in funding
    - Ensure that there will be enough production so that procurement will not be affected by low production

The forthcoming malaria vaccine is viewed positively and the evidence accrued to date shows that it integrates well with the vaccine immunization programme. The introduction of a malaria vaccine has

no apparent negative impact on elements of the frameworks analysed. It is perceived as increasing opportunities to reach vulnerable children. The IVD programme is ready and capable of accommodating a new vaccine. The immunization programme has strategies for handling all related issues such as cold chain capacity, human resources, training, advocacy, revision of guidelines and reporting system on adverse events. Their preparedness enhances the value of ensuring all the groundwork is thoroughly reviewed before a malaria vaccine is introduced.

4.5 Discussion

The framework method has been developed and used widely in many countries and to address a variety of health policy concerns (Gilson and Raphaely 2008) The policy framework combines the concepts of content, context, actors and process to understand the policy process and to plan for effective implementation of interventions (G. Walt and Gilson 1994). The policy framework in this study built on the literature and was based on experiences and observations of the policy process and the factors influencing policy decisions in Tanzania. It was used to organise information in a way that explains the drivers of policy change and to gauge understanding and lessons learnt from the introduction of new malaria interventions through policy change. The framework also described the potential for introducing a malaria vaccine and other vaccines in the health system while critically observing policy formulation and implementation. The framework approach has its limitations. It highlights some information while minimising or excluding others (Coker et al. 2010). Here, we left out some parts of the framework or elaborated others to a lesser extent in order to focus on aspects that are relevant to the study context (Hercot et al. 2011).The framework may or may not be applicable to other low-income countries with similar contexts. Its applicability depends on whether the policy is appropriate to the needs of a specific country and is feasible in a low-resource settings (G. Walt and Gilson 1994).

The framework is feasible and can be used in the Tanzanian context. Although Tanzania has not yet introduced a malaria vaccine, the framework contributes to understanding a very complex and highly political subject – policy analysis. It assists in unpacking the national level discussion, involving evidence-based information, stakeholders' interactions, and political commitment; factors that are all important for planning the forthcoming malaria vaccine.

The framework was also applied to African countries that had conducted RTS,S malaria vaccine clinical trials. Among these are Burkina Faso, Ghana, Gabon, Mozambique, Malawi and Kenya (Table 4); none of these countries have introduced the malaria vaccine yet. The framework acknowledges the diversity of experiences across those countries. We have tried to analyse each country with regard to content and context, and we had to rate each country with regard to its readiness for adoption of forthcoming malaria vaccine. The reference for our ratings was previous malaria treatment policy change. We applied semi-qualitative ratings of health systems' readiness for malaria treatment policy change. Discussion is based on a summary of the content-and contextual-related steps in decision making (promoting and barriers factors: **Error! Reference source not found.**). It is interesting to note that Tanzania, Burkina Faso (Panisset et al. 2012); Gabon (Nsimba et al. 2008); Malawi (Malenga et al. 2009) and Kenya (Williams, Durrheim, and Shretta 2004; Amin et al. 2007;

Okungu and Gilson 2014) seemed to be well prepared with regard to content factors (agreed scientific evidence).

Promoting factors such as safety and efficacy, WHO protocol and decisions adopted in other countries were noted in Burkina Faso (Panisset et al. 2012; Kouyaté et al. 2007), Ghana (Duah et al. 2013), Gabon (Nsimba et al. 2008), Malawi (Malenga et al. 2009) and Kenya (Amin et al. 2007). Harmonization of the policy process across departments and collaboration between policy makers and scientists were identified in Burkina Faso (Panisset et al. 2012) and Malawi (Malenga et al. 2009). The importance of technical assistance from WHO and other interested donors were also identified in Burkina Faso (Panisset et al. 2012), Gabon (Nsimba et al. 2008), Malawi (Malenga et al. 2009) and Kenya (Amin et al. 2007). Among the identified barriers were the lack of sustainable financing in Burkina Faso (Kouyaté et al. 2007),Gabon (Nsimba et al. 2008) and Kenya (Amin et al. 2007); and non-adherence to treatment in Burkina Faso (Kouyaté et al. 2007), Mozambique (Cliff et al. 2010) and Kenya (Amin et al. 2007). Effective communication supporting the correct use of medicines can counteract non-adherence and use of in-effective medicines (Okungu and Gilson 2014; Mbofana, Machatine, and Moreira 2010). It can also be done through engaging the private sector and encouraging hospitals and pharmacies to adhere to national guidelines (Panisset et al. 2012).

The semi qualitative assessment (rating of malaria policy change) shows that most African RTS,S countries seemed to be ready for adoption of the forthcoming malaria vaccine. Tanzania seems to be well prepared with regard to both promoting factors ((12), very good) and well-documented barriers. It is interested to note that Burkina Faso seems to be well prepared with regard to content and policy promoting factors ((10), good). It does not, however, have well-documented information on barriers. Similarly, Malawi seems to be well prepared with regard to policy promoting factors ((9), good) but lacks documented information on barriers. Kenya and Gabon are also prepared with regard to policy promoting factors (++ (8), good) but neither have sufficient documented information on barriers. Ghana is also prepared with regard to policy promoting factors, scores poorly on policy promoting factors ((5), little) and on documented information on barriers and Mozambique also scores low on promoting factors and documented barriers ((1) , weak). The rating implies that Burkina Faso, Malawi, Kenya and Gabon are prepared to embark on adoption of the forthcoming malaria vaccines RTS, S. Ghana and Mozambique are not well prepared, which implies a need of study to understand those factors before a policy decision is made on RTS, S adoption. The attempt to synthetically compare all African RTS, S countries shows that a “good” or “very good” ranking on promoting factors may not automatically translate to action due to some mentioned and documented barriers.

Table 1. contextual factors influencing the introduction of RTS,S vaccine in different countries

RTS, S countries	Content	Context promoting factors (5)					
	Steps involved	Intervention characteristic	Package of information	Country experience	Coordination & harmonization	Use of international scientific evidence	Summary of promoting factors
Tanzania	Agreed scientific evidence (+)	Safety , efficacy & quality +++	Communication levels; i.e community & policy makers +++	Adopted decision from other countries ++	Scientists communities, policy makers & donors ++	Technical assistance WHO & interested Donors ++	Safety, efficacy& quality decision from other countries & collaboration between scientists & policymakers & donors technical assistance 12
Burkina Faso	Agreed scientific evidence (+)	Safety & efficacy +++	Communication levels; i.e community & policy makers	Adopted decision from other countries ++	Malaria &reproductive health department ++	Technical assistance WHO & interested Donors ++	Safety& efficacy, decision from other countries, collaboration between malaria & reproductive health department & technical assistance 10
Malawi	Agreed scientific evidence (+)	WHO protocol +++	No	Adopted decision from other countries ++	Scientists & policy makers ++	Technical assistance WHO & interested Donors ++	WHO protocol, decision from other countries & collaboration between scientists & policymakers & technical assistance 9
Kenya	Agreed scientific evidence (+)	WHO protocol +++	Communication levels; i.e community & policy makers +	Adopted decision from other countries ++	No	Technical assistance WHO & interested Donors ++	WHO protocol, decision from other countries & technical assistance 8
Gabon	Agreed scientific evidence (+)	WHO protocol +++	Communication levels; i.e community & policy makers +	Adopted decision from other countries ++	No	Technical assistance WHO & interested Donors ++	WHO protocol, decision from other countries & technical assistance 8
Ghana	No	WHO protocol +++	No	Adopted decision from other countries ++	No	No	WHO protocol decision from other countries 5
Mozambique	No	No	No	No	No	No	0

Rating of countries: 0 Not achievable (+) Weak + little ++ Good +++ Very good

Context Barriers factors (6)							
Financial sustainability	**Competing priorities**	**Political will & procedures**	**Costs**	**Supply & Distribution**	**Professional compliance**	**Summary of barriers**	**Summary of summaries; promoting &barriers**
Lack of sustainable financing 0	Competition from other priorities +	Understanding political procedures &timing of presentation +	Costs involved on adoption &implementation +	Logistics on distribution +	Non adherence to treatment/ Prescription +	Lack of financing & non adherence to treatment 5	Content ; Agreed evidence Promoting; Safety& efficacy, decision from other countries, collaboration between scientists , policy makers & donors & technical assistance Barriers; Lack of sustainable financing, competing priorities, understand political process, costs, logistics distribution & non adherence to treatment 18
Lack of sustainable financing 0	No	o	No	No	Non adherence to treatment/ Prescription +	Lack of sustainable financing & non adherence to treatment 1	Content ; Agreed scientific evidence Promoting; Safety& efficacy, decision from other countries, collaboration between malaria & reproductive health department & technical assistance Barriers; Lack of sustainable financing & non adherence to treatment 12
No	No	No	No	No	No	0	Agreed evidence, WHO protocol, decision from other countries & collaboration between scientists & policymakers & technical assistance 10
Lack of sustainable financing 0	No	No	No	No	Non adherence to treatment/ Prescription +	Lack of sustainable financing& non adherence to treatment 1	Agreed evidence, promoting: WHO protocol, decision from other countries & technical assistance Barriers; Lack of sustainable financing, & non adherence to treatment 10
Lack of sustainable financing 0	No	No	No	No	No	Lack of sustainable financing 0	Agreed scientific evidence WHO protocol, decision from other countries & 9
No	No	No	No	No	No	0	WHO protocol decision from other countries 5
No	No	No	No	No	Non adherence to treatment/ Prescription +	Non adherence to treatment 1	Non adherence to treatments 1

Conclusion and Recommendations

The framework is used at the national level, while overall policy recommendation is made at the global level. We can use the framework once the global policy is articulated and treat it as an operationalized statement. The framework is a comprehensive tool that enables one to unpack the content and contextual factors surrounding the decision to introduce a potential malaria vaccine in African RTS, S countries. Furthermore, the framework provides an effective way to deepen our knowledge of the policy process and to inform the policy decision-making process for new malaria interventions, generally, and for the forthcoming malaria vaccine, specifically. It is an applicable and appropriate tool for African RTS,S countries and other low resourced settings. Lastly, the framework facilitates the synthesis of information in a coherent way, enabling a clearer understanding of the policy process, thereby speeding up the policy decision-making process and shortening the time until the forthcoming malaria vaccine becomes available. While we find the framework useful and applicable, we still feel that further validation is required.

The framework is appropriate and recommended for various settings depending on the availability of content and contextual (promoting and barriers factors) information to inform the policy decision process. It can be useful as a step in the direction of research that supports better formulation and implementation of malaria interventions policies in African RTS, S countries.

Acknowledgements

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5. Discussion, Conclusions and Recommendations

5.1 Discussion

The thesis attempts to analyse policy issues that are especially relevant to policy decisions around intervention adoption. The analysis assessed parental perception of a malaria vaccine and policy analysis frameworks for deciding on a malaria vaccine in Tanzania, and considered implications for other African RTS,S countries. Detailed discussions of the findings are provided in their respective chapters. This section begins with detailed discussion of the methodology used and the lessons learnt. It is followed by a discussion of the main findings and its implications with reference to the objectives described in chapter 4. The thesis wraps up with policy recommendations and the main conclusions.

5.1.1 Methodology and study design

In undertaking this study, several approaches were used. A cross-sectional study was conducted during the Tanzanian Integrated Measles Campaign (IMC) survey, which provided a chance to document and reflects on future malaria vaccine adoption. One study assessed awareness of and willingness to use a malaria vaccine (Chapter 3). Another study documented the use of a policy analysis framework for deciding on malaria vaccine in Tanzania and its implications for other African RTS,S countries. Document review and qualitative research tools were used and the policy analysis framework was applied to African countries where malaria vaccine RTS,S clinical trials were conducted to assess malaria treatment policy changes and to draw lessons for malaria vaccine adoption (Chapter 4). Each of the methods used in the study had their strengths and limitations as explained in the paragraphs below.

Since the start of this study, three studies on community perceptions of malaria vaccines have been published, using different approaches. The studies are from Ghana (Febir et al. 2013), Mozambique (Bingham et al. 2012) and Kenya (Ojakaa et al. 2011). The method for selecting intervention and study areas was different in all three studies. In Ghana, the study (Febir et al. 2013) used qualitative and quantitative surveys, conducted in two districts. For the qualitative survey, participants were selected based on specific criteria included women and men whose children had or had not participated in RTS,S malaria vaccine trial. In total, 12 focus group discussions (FGDs) and 15 in-depth interviews (IDIs) were conducted. The quantitative survey involved 466 men and women from selected communities involved in the qualitative study. A systematic sampling method was used. Half of the respondents had been involved in the RTS,S malaria vaccine trial phase II. A structured questionnaire was developed based on the same themes and variables covered in the qualitative survey (Febir et al. 2013). The study in Kenya (Ojakaa et al. 2011) was a qualitative study, conducted in two malaria-endemic regions. Similar to the Ghana study, participants were selected based on

specific criteria. Study sites were selected based on malaria endemic and community support for the study. A total of 20 focus group discussions were held, with 234 participants; 22 in depth interviews and 18 exit interviews were also conducted (Ojakaa et al. 2011). The Mozambique study (Bingham et al. 2012) was a qualitative study, conducted in two malaria-endemic districts that did not host malaria vaccine clinical trials. The districts were accessible from Maputo during rainy season when the study was conducted and reflected geographic and cultural diversity. Participants were selected based on specific criteria, while sites were selected based on malaria endemicity and community support for the study. A total of 23 focus group discussions were held, with 250 participants; 26 in depth interviews were also conducted (Bingham et al. 2012).

The Kenya and Mozambique studies used similar qualitative study designs. The approach explores and seeks to understand the meaning that individuals attribute to a social or human problem (Creswell 2013; Driscoll et al. 2007). Such an approach is simple and cheap, and has the advantages of being able to define individual perceptions and attitudes. The conclusions are drawn from individually based data. It was convenient for the studies' small sample sizes. The study in Ghana used a mixed methods (qualitative and quantitative) approach. The advantage of this approach is that the qualitative data provides a deep understanding of responses, while statistical analysis provides a detailed assessment of patterns of responses. Combing the two methods can be time consuming and expensive, and usually requires reducing the sample size or limiting the time spent on interviews (Driscoll et al. 2007).

The current study was part of a large cross-sectional study using random sampling probability in 23 regions of Tanzania, with a study population of 5,502 women, aged 18 years or older and with children under 11 months old. The minimum sample size was 270 mothers in each region. The study benefited from being part of a big country-wide survey conducted during the Tanzanian Integrated Measles Campaign (IMC). The design increased the power of the study by using a large sample size. The survey evaluated the status of immunization coverage. It generated information on routine vaccination coverage that would be useful to predict the future uptake of malaria vaccine coverage, as the malaria vaccine is expected to be delivered through the immunization programme. It is a feasible study design with regards to the logistics needed to conduct a large study. It provides the opportunity to apply the lessons learnt from the study conducted in communities where RTS,S malaria vaccine trials were carried out, compared to the communities that did not participate in malaria vaccine trials as well as a comparison of the study regions with high malaria transmission and low malaria transmission. It helps to monitor adverse events in both low and high transmission areas.

5.1.2 Main findings and its implications

Understanding community perceptions of a malaria vaccine can help plan interventions and identify policy issues that could be hinder the introduction and implementation of a malaria vaccine (Febir et al. 2013). Our findings were similar to those found in Ghana and Kenya showing wide spread knowledge of the benefits related to childhood vaccinations (Febir et al. 2013; Ojakaa et al. 2011). Malaria vaccine was perceived to be a preventive tool against malaria (Febir et al. 2013; Ojakaa et al. 2011). Overall, our findings showed a low level of awareness and a high willingness to use a malaria vaccine. The malaria vaccine is new and many have yet to learn about it. There is no previous experience of using a malaria vaccine. The availability of evidence helps to make informed decisions about introducing a malaria vaccine within the Tanzanian health systems (Brooks and Ba-Nguz 2012). The policy process is complicated and involves different steps of decision making. Different factors influence or must be considered at each step.

5.2 Global policy recommendation

Policy recommendations for a malaria vaccine have been initiated at the global level, where the Joint Technical Expert Group (JTEG) serves as an evidence-assessment working group. The JTEG report will be reviewed by SAGE and MPAC, who will then make recommendations. JTEG recommended use of RTS,S malaria vaccine in children 5-17 months within all transmission settings. WHO has indicated that a policy recommendation advocating RTS,S malaria vaccine use would be implemented in countries through the World Health Organization's IVB (formerly EPI). SAGE comments on feasibility considerations, including scheduling and booster doses. JTEG recommends a booster dose administered between 15-18 months. The IVB schedule is already overburdened but there is a programmatic advantage to spreading out the booster schedule at that age because IVB routine vaccinations are completed by nine months. A booster dose is essential to increase vaccine efficacy and its feasibility must be considered when planning vaccine introduction with the aim of maximizing coverage. Countries should strengthen their pharmacovigilance systems, not only for febrile seizures and meningitis, but also for other adverse events occurring frequently. The feasibility of sub national vaccine implementation strategies depends on the capacity of the IVB programme. MPAC concerns are based on integrating the new vaccine with other malaria control strategies, that is to say that the introduction of a malaria vaccine should not affect the sustained coverage of other malaria control strategies. The NMCP should strengthen malaria surveillance prior to and in conjunction with the planned malaria vaccine introduction to allow for continued monitoring of malaria disease trends and of the vaccine's impact on coverage of malaria interventions. Cost effective analysis includes considerations such as age distribution of cases, cost of the vaccine and cost of new visits that may not support its use.

5.2.1 Implication of global recommendations to Tanzania

Malaria vaccine RTS,S is the first vaccine to show signs of protection and reduce episodes of clinical malaria by half among children 5-17 months old when used in conjunction with other malaria control strategies such as ITNs and anti-malarial drugs (Asante et al. 2011; Agnandji et al. 2011; Ojakaa et al. 2011; Abdulla et al. 2008). Therefore, a licensed vaccine has important potential to protect under five children. In Tanzania, the malaria vaccine is expected to be delivered through the IVD programme and implemented at facility level by health care providers in both private and public facilities. Although; IVD is a robust system capable of implementing the malaria vaccine, there are a number of challenges that need to be addressed, including weak vaccine pharmacovigilance, inadequate personnel and expansion of storage capacity. Currently cold room and storage capacity needs to be expanded at all levels (national, zonal, regional, district and facility) to accommodate malaria vaccine storage and transportation. Cold rooms are available at national, zonal and regional levels, while the cold chain is maintained by refrigerators at district and facility levels. At district level, refrigerators are electric, while those at facility levels are gas operated. Several facilities reported frequent shortages and hence a breakdown of the cold chain. There is a need to procure back-up power, such as generators and solar systems. Currently, the storage capacity at the national level is sufficient for six months' storage, with back up space for a 25% buffer stock. At the regional level, capacity is sufficient for four months' storage with back up space for a 25% buffer stock and 255 space capacities for storage of other drugs. At district level, storage is sufficient for three months. At facility level, they can maintain a monthly supply with two weeks' extra supply (Tanzania EPI Report 2010). Malaria vaccine delivery should be operationalized through technical staff at IVD. Lack of human resource is a problem throughout the health sector, especially in public services. At national level, only 35% of the required staffing levels have been filled. The inadequacy of human resources in both numbers and skill could be a key challenge to delivering the malaria vaccine through IVD services. Introduction of a malaria vaccine will add to the already burdened workforce, and the impact of this additional workload need to be analysed to develop a strategy to mitigate the situation (Tanzania EPI Report 2010). It is proposed to schedule the malaria vaccine at five, six and seven months and possible booster dose at 18 months together with second Measles vaccine. This strategy will lessen the workload as only one vaccine will be given on a single visit. Guidelines, documents and training materials should be modified to harmonize IVD programme and malaria vaccines and be made available for circulation to those working in immunization services. Public awareness and demand for safety of drugs and vaccine innovations need to be maintained both during trials and post licensure (Chen et al. 2001; Darwish 2000). Despite having been approved after undergoing clinical trials and post approval phase IV trials, monitoring systems need to be in place for continuous surveillance of adverse events. The IVD's vaccine pharmacovigilance is weak

(Tanzania EPI Report 2010), thus it should be strengthened in collaboration with the TFDA by establishing or strengthening reporting systems to give feedback on adverse events. Vaccines are considered cost effective interventions that are easy to administer, monitor and evaluate. The main determinant for implementing the malaria vaccine is its cost effectiveness compared with other existing malaria interventions. Cost effectiveness analysis provides information for identifying interventions that represent the best value for money, essential for setting priorities in low resourced settings (Goodman, Coleman, and Mills 1999). A documented study in Tanzania on the costs of introducing a malaria vaccine (Hutton and Tediosi 2006) estimated the cost of delivering a malaria vaccine through IVD programme as ranging from USD 1 -10 per dose; at a vaccine price of USD 1 per dose, the total annual cost of delivering malaria vaccines through IVD programme would be more than 35% of the current budget. When the vaccine price increases, the total annual cost would also increase (Hutton and Tediosi 2006). Additional resources should be mobilized and directed to the IVD programme to enable them to deliver the malaria vaccine in conjunction with other IVD vaccines.

5.3 General Conclusions

The main conclusions from the study were as follows:

1. Malaria is still a national priority that requires to optimal use of all malaria control tools available because it is still a public health problem.
2. There is a relatively high willingness among communities to use a malaria vaccine to complement other existing malaria interventions
3. The vaccine's acceptability matches the recently reinforced global strategy to promote policy recommendations in favour of malaria vaccine use.
4. Any introduction of a new intervention, in our case, has to follow a structured process of decision-making, as described in the framework, in order to succeed.
5. The prime steps are to answer questions of cost effectiveness, programmatic feasibility and potential integration with other malaria control strategies.
6. As malaria vaccine RTS,S is expected to be delivered through IVD programme, IVD services must be examined and made sufficiently robust to accommodate the malaria vaccine. IVD services appear capable of supporting malaria vaccine delivery; however IVD programme requires expansion of storage capacity, which can only be determined once the package of the malaria vaccine is known. IVD programme also needs capacity strengthening for health workers (immunization), revised guidelines and documents to harmonize the malaria vaccine with IVD services, and strengthened reporting system for any adverse events associated with the malaria vaccine.

7. Studies have documented RTS,S malaria vaccine is cost effective, more work is needed to determine its cost effectiveness.
8. Although the malaria vaccine is proven effective, a major challenge to policy adoption will be to obtain support from stakeholders particularly at the local and national levels.

5.4 Guideline for recommendations

1. In Tanzania, the malaria vaccine is expected to be delivered through Immunization and Vaccine Development (IVD) programme and to be implemented at facility level by health care providers in both private and public facilities.

2. Propagate the policy through awareness creation on the policy statement

- Advocate for increased resources to implement communication plan
- Develop a communication plan to demonstrate with evidence how the malaria vaccine will contribute to attaining public health outcomes
- Make information about the intervention accessible to target communities; it should be easy to read and understandable
- Deliver communication materials that show parents with their children to champion malaria vaccination.
- Use media to champion the malaria vaccination through accurate reporting on prominent stories related to the malaria vaccine.
- Use the IVD platforms (clinics, entertainments shows) to advocate for delivering a malaria vaccine.

3. Partnership can be created at the global, national and sub national levels.

- ❑ At the Global level
  - Make inquiries and agreements to build confidence that a global vaccine market and supply is assured, affordable and easily incorporated.
  - Liaisons between MSD clearing departments and IVD with GAVI to ensure that vaccine is delivered on time.
- ❑ At the national level
  - Advocate for increased resources to address programmatic limitations issues (expand storage and transportation capacity of IVD programme once the package of malaria vaccine is known).
  - Encourage IVD to procure more generators to ensure back up of power for cold rooms as a preparatory step towards accommodating the new malaria vaccine.
  - Plan early to incorporate co-financing levels into the national budget to prepare for financing malaria vaccine acquisition and distribution; it is still not known whether the malaria vaccine will be funding by government or GAVI co financing.

- Modify guidelines, documents and training materials for immunization services that show how IVD and malaria vaccines could be delivered together
- Operationalize the process through training technical staff at IVD on procedures and on identifying shortages.
- Training of health care personnel involved in vaccination to understand the intervention (malaria vaccine) in order to maintain quality of services delivered.
- Establish a special surveillance system to monitor vaccine pharmacovigilance. Based on the experience of this surveillance, adjust and modify operational guidelines as new issues arise.
- Identify where the vaccine will launch (districts, regions and zones); it will help to assess the side effects in areas with low and high malaria transmission.
- Establish adverse events plans, particularly monitoring febrile seizure and meningitis.
- Incorporate flexibility to adjust administration of booster dose to maintain vaccine efficacy.

❑ Sub national level

- Ensure partnership with IVD and district health services. The district is a very important level in the provision of health services in a decentralized system.
- Establish a special surveillance system to monitor vaccine pharmacovigilance.
- Strengthen the malaria surveillance system to allow for monitoring of malaria disease and vaccine impact.

5.5 Recommendations for future research

Operational research and evaluation

- Conduct a feasibility study to assess the required storage capacity of IVD and package of RTS,S malaria vaccine to accommodate malaria vaccine delivery.
- Carry out a situational analysis to identify the required numbers and skills of human resources
- Conduct workload analysis for health care workers involved in vaccination
- Conduct post licensure studies to follow up on safety, effectiveness and impact at sentinel sites with demographic surveillance systems linked to immunization
- Assess vaccine pharmacovigilance of malaria vaccine in low and high malaria transmission settings

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Appendix 1: Number of women with children 0 – 11 months interviewed

Country / Region	**Number**
TANZANIA	**5502**
ARUSHA	32
DAR ES SALAAM	239
DODOMA	306
IRINGA	291
KAGERA	243
KIGOMA	236
KILIMANJARO	253
LINDI	228
MANYARA	269
MARA	118
MBEYA	270
MOROGORO	242
MTWARA	237
MWANZA	283
PWANI	250
RUKWA	243
RUVUMA	262
SHINYANGA	250
SINGIDA	261
TABORA	280
TANGA	181
MAINLAND	**4974**
UNGUJA	298
PEMBA	230
ZANZIBAR	**528**

Appendix 2: Percentage distribution of all women, of perceived awareness of and willing to use malaria vaccine by country / region

Country / Region	Awareness	Willingness
TANZANIA	**11.0 (607/5502)**	**94.5 (5,201/5,502)**
ARUSHA	12.5 (4/32)	87.5 (28/32)
DAR ES SALAAM	2.9 (7/239)	97.1 (232/239)
DODOMA	4.3 (13/306)	89.5 (274/306)
IRINGA	0.3 (1/291)	89.0 (259/291
KAGERA	2.1 (5/243)	94.2 (229/243)
KIGOMA	5.9 (14/236)	95.8 (226/236)
KILIMANJARO	2.4 (6/253)	95.3 (241/253)
LINDI	6.1 (14/228)	94.3 (215/228)
MANYARA	68.4 (184/269)	83.3 (224/269)
MARA	33.1 (39/118)	90.7 (107/118)
MBEYA	3.7 (10/270)	97.4 (263/270)
MOROGORO	6.2 (15/242)	97.9 (237/242)
MTWARA	8.0 (19/237)	97.5 (231/237)
MWANZA	15.2 (43/283)	98.9 (280/283)
PWANI	6.8 (17/250)	97.2 (243/250)
RUKWA	16.5 (40/243)	97.9 (238/243)
RUVUMA	5.7 (15/262)	90.1 (236/262)
SHINYANGA	32.8 (82/250)	95.2 (238/250)
SINGIDA	11.1 (29/261)	98.1 (256/261)
TABORA	9.3 (26/280)	97.1 (272/280)
TANGA	3.3 (6/181)	89.0 (161/181)
MAINLAND	**11.8 (589/4974)**	**94.3 (4,690/4,974)**
UNGUJA	1.7 (5/298)	97.7 (291/298)
PEMBA	5.7 (13/230)	95.7 (220/230)
ZANZIBAR	**3.4 (18/528)**	**96.8 (511/528)**

Appendix 3: Percentage distribution of perceived benefits related to under-five child vaccinations, mode of administering malaria vaccine and perceived acceptance of sending the child for malaria vaccine on proposed schedule

Country / Region	Benefits	Delivery mode	Proposed schedule
TANZANIA	**88.4 (4,864/5502)**	**81.3 (4,473/5,502)**	**86.7 (4,772/5502)**
ARUSHA	75.0 (24/32)	62.5 (20/32)	87.5 (28/32)
DAR ES SALAAM	94.1 (225/239)	83.3 (199/239)	90.8 (217/239)
DODOMA	86.9 (266/306)	85.0 (260/306)	90.2 (276/306)
IRINGA	58.1 (169/291)	83.2 (242/291)	78.0 (227/291)
KAGERA	94.7 (230/243)	87.2 (212/243)	92.6 (225/243)
KIGOMA	86.4 (204/236)	88.1 (208/236)	96.2 (227/236)
KILIMANJARO	92.5 (234/253)	90.5 (229/253)	91.7 (232/253)
LINDI	95.2 (217/228)	90.4 (206/228)	93.4 (213/228)
MANYARA	72.9 (196/269)	75.8 (204/269)	77.0 (207/269)
MARA	89.0 (105/118)	85.6 (101/118)	86.4 (102/118)
MBEYA	97.0 (262/270)	90.0 (243/270)	93.0 (251/270)
MOROGORO	92.6 (224/242)	73.1 (117/242)	93.4 (226/242)
MTWARA	94.1 (223/242)	78.9 (187/237)	94.9 (225/237)
MWANZA	98.6 (279/283)	93.3 (264/283)	71.0 (201/283)
PWANI	92.0 (230/250)	88.0 (220/250)	82.0 (205/250)
RUKWA	97.5 (237/243)	97.1 (236/243)	95.9 (233/243)
RUVUMA	86.6 (227/262)	38.9 (102/262)	84.0 (220/262)
SHINYANGA	91.2 (228/250)	66.8 (167/250)	60.8 (152/250)
SINGIDA	90.4 (236/261)	83.9 (219/261)	92.7 (242/261)
TABORA	96.1 (269/280)	95.4 (267/280)	94.3 (264/280)
TANGA	63.5 (115/181)	81.2 (147/181)	76.8 (139/181)
MAINLAND	**88.5 (4400/4974)**	**82.6 (4,110/4,974)**	**86.7 (4,312/4,974)**
UNGUJA	88.6 (264/298)	75.2 (224/298)	86.6 (258/298)
PEMBA	87.0 (200/230)	60.4 (139/230)	87.8 (202/230)
ZANZIBAR	**87.9 (464/528)**	**68.8 (363/528)**	**87.1 (460/528)**

Appendix 4: Tool used to collect information on women's behavioural aspects related to vaccine and malaria Vaccine, Tanzania

A: General Information

District	|__|__|
Division	|__|__|__|__|__|__|__|__|__|__|__|__|__|
Ward	|__|__|__|__|__|__|__|__|__|__|__|__|__|
Village	|__|__|__|__|__|__|__|__|__|__|__|__|__|
Sub-village	|__|__|__|__|__|__|__|__|__|__|__|__|__|
Cluster number	|__|__|__|__|
Household Number	|__|__|__|
Date of last born child (Date / Month / Year)	|__|__|/|__|__|/|__|__|__|__|
Date of interview (Date / Month / Year)	|__|__|/|__|__|/|__|__|__|__|
Time to start: Hours: Minutes	|__|__|:|__|__|
Time to finish: Hours*: Minutes*	|__|__|:|__|__|

Respondent Number |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|

B: Status of the interview

1	What is the status of the interview?	(1) Complete	☐
		(2) Incomplete	☐
		(3) No interview	☐
2	If incomplete or no interview, why?	(1) Verbal Consent not given	☐
		(2) Verbal Consent refused	☐
		(3) Other	☐
		(4) Specify________________________	

C: GENERAL KNOWLEDGE

1	Apart from under-five child diseases with routine vaccination (TB, Polio, Measles and Hepatitis B, Diphtheria, Pertussis, Tetanus), which other health related problems do you consider to be serious in your community? (list up to five illnesses/diseases)	(1) ______________________________ (2) ______________________________ (3) ______________________________ (4) ______________________________ (5) ______________________________

2	Which illnesses/diseases you have mentioned above, do you propose them for vaccination?	(1) _____ (2) _____ (3) _____ (4) _____
3	Do you know of any benefits related to under-five child vaccination?	(1) Yes ☐ (2) No ☐
4	If yes, list them	(1) _____ (2) _____ (3) _____ (4) _____
5	What motivated you, for taking your child for vaccination?	

D: MALARIA

1	Do you know any malaria prevention strategies?	(1) Yes ☐ (2) No ☐	If **No** move to D3
2	If yes, list all methods of preventing malaria. *Please mention all that you can think of. (Check all that are mentioned). Which do you use at home?*		
	Methods of preventing malaria	**Mentioned**	**Home use**
	ITN (bed-nets) use for children		
	Residual spraying with insecticide		
	Intermittent preventive treatment (IPTi)		
	Drainage of mosquito breeding sites		
	Block mosquito entry inside homes		
	Plugging holes, closing windows/doors		
	Burn things to create smoke inside house		
	Cleaning environment around house		
	Other_____		
3	Have you ever heard about malaria vaccine?	(1) Yes (2) No	
4	If yes, where did you hear from?		
5	Suppose a malaria vaccine could soon become available for under-five children in your community. I am now going to give you some information about the vaccine. After I read each statement, please tell me the extent to which you agree with the statements.		

	A. Do you believe that malaria vaccination will bring any benefits related to under five child health? Yes/No/Not sure
	B. As Malaria vaccine will prevent cases of diseases; would you like your child to get the vaccine? Yes/No
	A. The vaccine can prevent many children from getting malaria. 5) Strongly agree 4) Agree 3) Not sure 2) Not agree 1) Strongly disagree
	B. The vaccine causes discomfort similar to other childhood vaccines 5) Strongly agree 4) Agree 3) Not sure 2) Not agree 1) Strongly disagree
	C. The vaccine will be given at the same health facility and at the same time as other childhood vaccines. 5) Strongly agree 4) Agree 3) Not sure 2) Not agree 1) Strongly disagree
	D. The malaria vaccine may require 2-3 jabs to receive full benefit. 5) Strongly agree 4) Agree 3) Not sure 2) Not agree 1) Strongly disagree
	E. Even though a child is vaccinated, s/he could still get malaria. 5) Strongly agree 4) Agree 3) Not sure 2) Not agree 1) Strongly disagree
	F. A vaccinated child who gets malaria will still need to receive treatment. 5) Strongly agree 4) Agree 3) Not sure 2) Not agree 1) Strongly disagree
	G. Even though a child is vaccinated, s/he still has to sleep under ITN. 5) Strongly agree 4) Agree 3) Not sure 2) Not agree 1) Strongly disagree
	H. The vaccine would prevent severe malaria in a vaccinated child. 5) Strongly agree 4) Agree 3) Not sure 2) Not agree 1) Strongly disagree

E: PNEUMONIA AND DIARRHOEA

1	Do you consider pneumonia is serious disease among under-five children in your community?	(1) Yes ☐ (2) No ☐
2	Do you suggest pneumonia vaccine to be provided too?	(1) Yes ☐ (2) No ☐ If **No**, then skip to E4
3	If yes, will you accept your child to be vaccinated with pneumococcal vaccine too?	(1) Yes ☐ (2) No ☐
4	Do you consider diarrhoea is serious disease among under-five children in your community?	(1) Yes ☐ (2) No ☐
5	Do you suggest diarrhoeal vaccine to be	(1) Yes ☐ If **No**, then Finish

	provided too?	(2) No ☐
6	If yes, will you accept your child to be vaccinated with diarrheal vaccine too?	(1) Yes ☐ (2) No ☐

Appendix 5: Interview Guides

Landscape Analysis of National Policy Decision Process for Adopting the RTSS vaccine – Tanzania

Interview guide for policy making with regard to policy processes of past malaria intervention and for the RTSS vaccine

Introduction

Ifakara Health Institute (IHI) and National Institute for Medical Research (NIMR) have been at the center of clinical trial efforts in the development of malaria vaccines. At the end of the on-going clinical trials for malaria vaccines; policy makers would need to be provided with scientific advice on whether to adopt the vaccine or not.

To achieve this, it was considered important to share the experience of the decision making process for adoption of other malaria interventions and vaccines in the country. Knowledge of the country's pathway for decision making on adopting vaccines will shed light on the implications for a malaria vaccine if a malaria vaccine is ultimately licensed.

(1) Over the last decades, scientists have made tremendous progress in the development of malaria vaccine and the world leading vaccine candidate – the GSK BIO RTS,S – has entered the last phase of clinical trials.
   What is the opinion of the Tanzanian Government on the development of malaria vaccine?
   Prompts
   - Does the Government consider it an appropriate intervention strategy?
   - What is the stand of the Government in terms of possible adoption?
   - What are the reservations the Government has regarding malaria vaccine

(2) What consideration is being given and what plan is the government making regarding possible adoption for the country?

(3) In the adoption of an intervention such as malaria vaccine, what are the issues and factors the government will like to be addressed or considered in the decision – making process towards possible adoption?

(4) What are the factors (challenges, facilitating factors, and opportunities) that can drive a future policy process for a malaria vaccine in Tanzania?

(5) The Tanzanian government adopted the use of ACT as 1st line drug for uncomplicated malaria could you highlight the decision- making process that informed its adoption.
   Prompt
   - Who were the stakeholders involved?
   - What is the line of communication?
   - What documents were referred to in the process
   - Who would you say were key to the decision making?
   - What is the process of dissemination of the decision?

(6) Is there is a specific guideline the government uses for decision- making for the adoption of new health interventions?
   - Who are the key players in the policy and decision making arenas
   - What is the role of these key players

(7) I would also like to know the decision making process for the decision making process for adopting interventions such as the - IPTp; ITN, HMM, AMFM,- in Tanzania.

(8) What is the current malaria control strategic plan and how are they integrated into the National health sector planning and budget?

(9) What are the lessons learnt from adopting these new interventions i.e that can help foresee possible enabling and constraints for a decision on the malaria vaccine – RTS,S.

Landscape Analysis of National Policy Decision Process for Adopting the RTSS vaccine – Tanzania

Interview guide for Division Vaccines and Immunization (DVI) [NPI]

Introduction

For the purpose of this interview, we will like to focus on the 2 major vaccines (newly) introduced/adopted in Tanzania –

Vaccine (1) Hib and PCV (2) CSM.

(1) In the adoption of this vaccine (1) & (2) what where the issues /factors considered in the decision-making process?
    a. What information will you require to assist in decision-making process to adopt any new vaccine?
(2) What is the adoption process for new vaccine (1) & (2) and the implications of this process for the RTSS malaria vaccine?
(3) What are the factors that influence adoption?
    a. In what ways does price/cost come into decision making?
    b. How does the vaccine schedule influence decision making e.g. through routine EPI schedules or non-EPI schedules
(4) Does the country have National Immunization Technical Advisory Group (NITAG)?
    a. Who is the contact person in this group? And how does this group influence the decision making for adoption of any new vaccine. How should they be involved?
(5) Is there a specific guideline the government uses for decision-making for the adoption of new vaccine?
    - Who are the key players in the policy and decision –making arena
    - What are the roles of the key players
(6) To what extent is the current immunization programme strategic plan integrated within the national health sector planning and budgeting?
(7) What in your opinion is the strength of the existing immunization programme vis a vis the adoption of new vaccine especially malaria vaccine
(8) The country is in the process of adopting HPV vaccine; could you describe the process so far, the challenges, facilitating factors and opportunities?
    - How does the programme plan to scale up the intervention?
(9) What do you think are the challenges, facilitating factors and opportunity that can direct a future policy process for a malaria vaccine?
(10) What would you advice should be considered or foreseen (enabling factors and constraints) for a decision on malaria vaccine – RTS, S?
(11) The government recently embarked on the process to adopt HPV vaccine for control of cervical cancer prevention in the Tanzania;
    - At what stage is the adoption process for HPV vaccine in Tanzania?
    - Could you share with us the adoption process so far and prior to actual pilot testing on going?
    - What is the strength given to WHO recommendation in the decision making process?
(12) How did the government come to decide to adopt the vaccine
    - What is the pathway for decision –making with regard to HPV vaccine?
    - What are the factors taking into consideration in the decision making process?
    - Explain in details each factors eg. For cost- in what ways does cost come into decision making; relativeness of price to other countries, same as GAVI, good price etc
    - Who are the key players in the decision-making process and what are their roles?
(13) What documents were key to initiating the process of considering HPV vaccine? E.g BOD data source and docs,
(14) What is the planned budget/finance and procurement mechanism?
(15) What it the consideration given to existing immunization programme in the decision-making for the adoption of HPV?

- Does the schedule of HPV fit into the existing routine immunization programme?
- What is the framework for decision-making on HPV vaccine, if there is any?

Landscape Analysis of National Policy Decision Process for Adopting New Malaria Control Intervention and New Vaccines – Tanzania

Interview guide for other stakeholder/policy maker [Policy unit WHO, UNICEF, Global fund, EU, other stakeholders]

1. What in your opinion do you think should be the pathway/framework for decision-making towards adoption of malaria vaccine by the country?
2. What is your contribution to /role in the decision-making process for adoption of vaccines [other health interventions] in Tanzania? – adoption and procurement of vaccines
3. What was your contribution to the recent adoption of Hib and PCV vaccines by Tanzania? Were you satisfied and how much more would you have liked to be involved and in what ways?
4. What in your opinion is the strength of the existing immunization programme vis a vis the adoption of new vaccine especially malaria vaccine? Eg is the structure strong enough? If yes why and if no what infrastructure need to be put in place?
5. Is there a specific guideline for decision-making you will like to suggest for the adoption of malaria vaccine?
6. What do you think are the challenges, facilitating factors and opportunities that can direct a future policy process for a malaria vaccine?
7. What would you advise should be considered or foreseen (enabling factors and constraints) for a decision on malaria vaccine –RTS,S?

Landscape Analysis of National Policy Decision Process for Adopting New Malaria Control Intervention and New Vaccines – Tanzania

Interview guide for other stakeholder/policy maker [stakeholders – Ministry of finance and procuring officers]

8. What in your opinion do you think should be the pathway/framework for decision-making towards adoption of malaria vaccine by the country?
9. What is your contribution to /role in the decision-making process for adoption of vaccines [other health interventions] in Tanzania? – adoption and procurement of vaccines
10. What was your contribution to the recent adoption of H. Influenza type b vaccine (Hib) and Pneumococcal conjugate vaccines (PCV) by Tanzania?
11. What is the consideration given to finance, budgeting and procurement in regard to adoption of new vaccines and other health interventions?
    a. State in what ways does each factor come into decision-making?
12. What is the budgeting and financing mechanism available for adoption on new vaccines in Tanzania?
13. What concern do you have on the sustainability especially with cost?
14. What threshold is used to judge whether any health intervention hold be funded e.g GDP per capita per DALY i.e specific cost-effectiveness threshold
15. What in your opinion is the strength of the existing immunization programme vis a vis the adoption of new vaccine especially malaria vaccine? Eg is the structure strong enough? If yes why and if no what infrastructure need to be put in place?
16. Is there a specific guideline for decision-making you will like to suggest for the adoption of malaria vaccine?

17. What do you think are the challenges, facilitating factors and opportunities that can direct a future policy process for a malaria vaccine?

CURRICULUM VITAE

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EDUCATIONAL QUALIFICATIONS

2015	PhD (Sandwich Program) in Epidemiology and Public Health at Swiss Tropical & Public Health, University of Basel, Switzerland: Thesis: Policy development process for introducing new malaria interventions in Tanzania: The case of malaria vaccine
2003	Masters of Arts in Development Management: Institute of Development Research and Development Policy, Ruhr University Bochum, Germany. Thesis: Problems in implementing decentralization of higher Education in Tanzania: The experience of University of Dar es salaam
2000	Bachelor of Arts with Education: Majoring in Political Science and Public Administration, University of Dar es Salaam, Tanzania

PROFESSIONAL TRAININGS

February 2013	Advanced Publication Workshop, Schoenstatt Training Centre, Cape Town, South Africa
March 2013	Knowledge Translation Workshop, Dar Es Salaam
Sept 2008	Macro-Economic Training Course, ARCADE & AFRODAD, Dakar, Senegal **(Certificate)**
Nov 2007	Development Cooperation and Conflict Management, Oslo, Norway **(Certificate)**
July 2007	Budget Analysis: Training for Civil Society Organization, REPOA, Dar Es Salaam (**Certificate)**
Dec 2006	Project Monitoring and Evaluation by the Students for Development/ Canada Corps Program, Saint Mary's University **(Certificate)**
August 2006	Regional Training on Gender in Macro Economics Policy, Planning and Budgeting, Dar es Salaam (C**ertificate)**
April 2006	Poverty-Environment Linkages in National Strategy for Growth & Reduction of Poverty (MKUKUTA) Implementation: Tanzania Natural resource Forum and WWF- Moshi, Kilimanjaro **(Certificate)**
Feb 2004	Web Course: Intergovernmental Fiscal Relations and Fiscal Decentralization Reforms, the World Bank Institute, Washington DC **(Certificate)**

WORK EXPERIENCE

Since 2010	Research Scientist**:** Ifakara Health Institute (IHI): Implementing PATH malaria vaccine Initiatives (PATH MVI) project to ensure available of critical data obtained to feed on Malaria Vaccine Decision-Making Framework (DMF)
2008–2010	Project Manager: Research and Policy Advocacy & Analysis: Tanzania Coalition on Debt and Development (TCDD), projects implemented: Research on Utilization of Forestry sector and Revenue Collection in Tanzania and Poverty Monitoring on Education and Health sectors Conducted Trainings on Public Expenditure Tracking Systems (PETs) & policy advocacy to Civil Society Organizations (CSOs) and Faith Based Organizations (FBOs)
2007-2008	Program Officer (Lobby & Advocacy): African Forum & Network on Debt & Development (AFRODAD) Harare –ZIMBABWE, tasked on Research, strategic development and management of policy and advocacy work. Researching and developing policy positions and advocacy strategies both pro-actively and in relation to AFRODAD's priority areas and ensuring that the experiences and views of poor people are taken into account in developing these strategies
2005-2006	Program Officer: Capacity Building & Policy Advocacy: Hakikazi Catalyst Non-Governmental Organization: supported local governance to institutionalize decentralized and participatory planning at villages and district level in Ngorongoro (Oxfam GB project)
Oct-Dec 2002	Intern: Center for International Development Policy and Capacity Building (InWent), Munich (GERMANY): Prepared the international conference on human rights and statistics organized by the INWENT and EUROSTAT in Brussels 27-29 November 2002. Wrote the working paper on the Impact of decentralization of health sector in Tanzania

RESEARCH EXPERIENCE

2012	Research & Policy Analysis for UNICEF End line Survey: Policy Review: incorporation of UNICEF thematic areas in the District Strategic Plans and Medium Term Expenditure Framework (MTEFs)
2009	Research & Policy Analysis for UNICEF Baseline Survey: Policy Review: incorporation of UNICEF thematic areas in the District Strategic Plans and Medium Term Expenditure Framework (MTEFs)
2007	Research & Policy Analysis on District Health Equity Analysis (Kilombero & Rufiji Districts) published on EQUINET Policy brief

2005	Research fellow: Gender Dimension Programme Committee at the University of Dar Es Salaam on the Barriers to the University Education, Retention and Graduate study for Women in Tanzania: The Case of University of Dar es Salaam
2005	Research assistant: Research & democracy in Tanzania (REDET). Study on Religious and Education Study in Dar es Salaam & Zanzibar
2004	Research fellow: Study on the Current situation of Professional Muslim Women in Tanzania**; Published on the web site:** www.imase.org
2004	Research fellow: The South African International Institute of Affairs (SAIIA) on Parliamentary engagement with Civil Society in Tanzania**;** led to a book: Daudi Mukangara (2005): Strengthening Parliamentary Democracy in SADC Countries: Tanzania Country Report. The southern African Institute of International Affairs
2000	Research assistant: SADC survey Team (Project on corruption and ethics)
2000	Research assistant: Research & democracy in Tanzania (REDET). Study on Religious and Education Study in Dar es Salaam & Zanzibar

PUBLICATIONS

2015	Assessment of parental perception of malaria vaccine in Tanzania: A Case Study (Manuscript submitted to Malaria Journal)
2015	Policy analysis for deciding on a malaria vaccine in Tanzania and implications for other African RTS,S countries: case study (To be submitted to Malaria Journal)

REFERENCES

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