ACT Consortium
Framework for Evaluation of RDT interventions

This guidance document has been prepared by the ACT Consortium Core Science team. It is intended to aid the design of evaluation components and questions for controlled trial and country level evaluations.

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Introduction

The case for RDTs

Rapid diagnostic tests (RDTs) for malaria present an opportunity for parasite-confirmed diagnoses to patients in the remotest areas of malaria affected countries. The use of RDTs is hoped to contribute to two central goals for malaria control: improved case management of febrile illness and improved surveillance of malaria cases with confirmed parasitaemia.[1]

In the era of artemisinin combination therapy (ACT) for malaria, improved case management of fever, such that ACTs are only used for those who need them, is regarded as crucial not only for reduced cost for patients[2] and sustainability of subsidies but also for patient safety and identification and treatment of alternative causes of disease.[3] The World Health Organisation guidelines for case management have moved increasingly towards onwards parasitological confirmation prior to treatment: the 2006 guidelines for the treatment of malaria by the World Health Organisation[4] recommended restricting antimalarial treatment to parasite confirmed cases where possible in the population over 5 years, and the guidelines in 2010 extended this to all age groups where testing is available.

The global burden of malaria has changed in the past decade, with several countries experiencing significant decreases in the prevalence of malaria, while others continue to experience an enormous burden of the disease.[5] Accurate surveillance of malaria cases in the light of this epidemiological transition is essential and RDTs present an opportunity to monitor actual malaria cases, especially with investment in improved health information management systems.

In Africa, it is estimated that around 80% of fever cases are treated at home,[6] with much treatment purchased in the private sector. In order to have a significant impact on case management of fevers and on malaria surveillance, RDTs will need to be deployed across the public and private health systems.

The scale-up of RDTs

In order for RDTs to have the desired impact on health outcomes and accurate surveillance, there are a number of issues and processes which need to be considered. The tests need to be:

- Appropriate to the (epidemiological) situation
- Quality assured
- Procured in a timely manner
- Distributed to the point of care in a timely manner
- Transported and stored in appropriate conditions
- Monitored for accuracy
- Used where indicated clinically
- Used equitably across the population

- Used correctly and safely
- If sold to care-seekers, sold at an affordable price
- Prompting appropriate treatment or referral
- Recorded in registers as part of a wider health management information system

In addition to these points that relate directly to the procurement or use of the tests, there are wider potential impacts of the tests that may need to be addressed alongside widescale roll-out. These impacts, and methods to reduce negative impacts, need to be identified and fed-back into the roll-out of the tests if scale-up is to be managed effectively.

Concerns about RDT scale-up

Many questions remain about the roll-out of RDTs including issues concerning feasibility, cost and potential for negative impacts. These can be categorised as clinical, economic, logistical and social. Clinically, there are concerns that in the current context where access to ACTs is still inadequate, that emphasis on restricting use to those who have a positive blood test risks reducing access further. There is also still some concern about false negative results although much of this should be allayed by the RDT evaluation carried out by WHO/FIND/CDC. The consequences of not treating malaria are particularly severe in populations with poor access to re-treatment and in non-immune populations.[7] Further clinical implications arise if RDTs are rolled-out in the absence of the strengthening of skills, drug availability and referral mechanisms for managing alternative causes of symptoms, with the potential for under-treatment or under-referral of patients with non-malarial disease.[8] Additionally, there is evidence that even when RDTs are used, antimalarial treatment may be prescribed in spite of negative test results, with clinical, economic and social consequences.[9] Economically, RDTs are likely to be most cost-effective in areas with low malaria transmission[10]: in the absence of up-to-date information of local malaria epidemiology, the cost-effectiveness of using RDTs may be questionable.[7] Costs to patients may be increased with the introduction of RDTs, as well as increasing costs for health centres and for health insurance systems. In the private sector there will need to be sufficient incentive (financial and non-financial) for providers and patients if RDTs are to introduced successfully. Logistically, RDTs may lead to longer consultations which could lead to longer patient waiting times and dissatisfaction amongst clients as well as higher burden on providers.[11, 12] There are questions over RDT safety for patients being pricked and in the disposal and reuse of sharps. Additional challenges lie in quality control of tests.[13] In addition, the use of RDTs could change the market for microscopy and for skilled microscopists, reducing the availability of microscopy for checking for non-falciparum parasitaemia, parasite density and for quality control of RDTs in the public health sector and impacting on businesses and business models. Socially, increased costs associated with RDTs may alter perceptions of treatment seeking options and change behaviour in terms of choice of treatment or provider.[14] Associated with this and other supply and demand factors, RDTs may not be accessed equitably across the population, with some patients continuing to receive antimalarials presumptively.[15]

The need for evaluation

The potential advantages of the deployment of RDTs are clear. However, there are real concerns over the impact of RDTs on various levels in the scale-up of the tests. In order to assess the overall effect of the introduction of RDTs, operational research is needed to evaluate the impact of the tests on these different levels. Evaluations of the introduction of RDTs in the public sector are few, and even rarer in the private sector. The need for evaluation of some of the elements described above has been recognised, particularly in relation to the quality of the tests and safety of testing. A holistic evaluation framework that identifies potential impacts of RDTs on different levels, and methods for measurement of these is needed to guide researchers and policy makers who are appraising the deployment of RDTs.

The evaluation framework

This document is a work-in-progress that arose as a result of the recognition of the need for a comprehensive framework in which to frame activities planned within the ACT Consortium as well as in the greater global health community, particularly with regards to the implementation of RDTs.

Development of the framework

The development of this evaluation framework built on our own experiences with public health evaluation and involvement in assessing the implementation of RDTs as well as building upon established theory in intervention evaluation. We began formation of the framework with the specific aim of designing robust evaluations for ACT Consortium projects. Our goal was for the evaluations across these projects to both include the same key measurements while also recognizing the important impact that contextual and other project-specific factors have on intervention outcomes. Since we began developing the framework, it became clear that its use could be wider than the ACT Consortium, and our aim is to contribute to the design of operational research of RDT implementation and evaluation of national-level implementation of RDTs in public and/or private sectors. Through its use, we hope the framework can be refined and built upon. We welcome ongoing feedback and revisions to this initial framework.

The theoretical basis of the framework builds on the strong existing literature on intervention evaluation. We incorporate the widely used components of process, context and outcome evaluation, including proximal as well as more distal impacts on RDT and ACT use. (Please see the reference list at the end of this document for a selection of free-access evaluation literature).

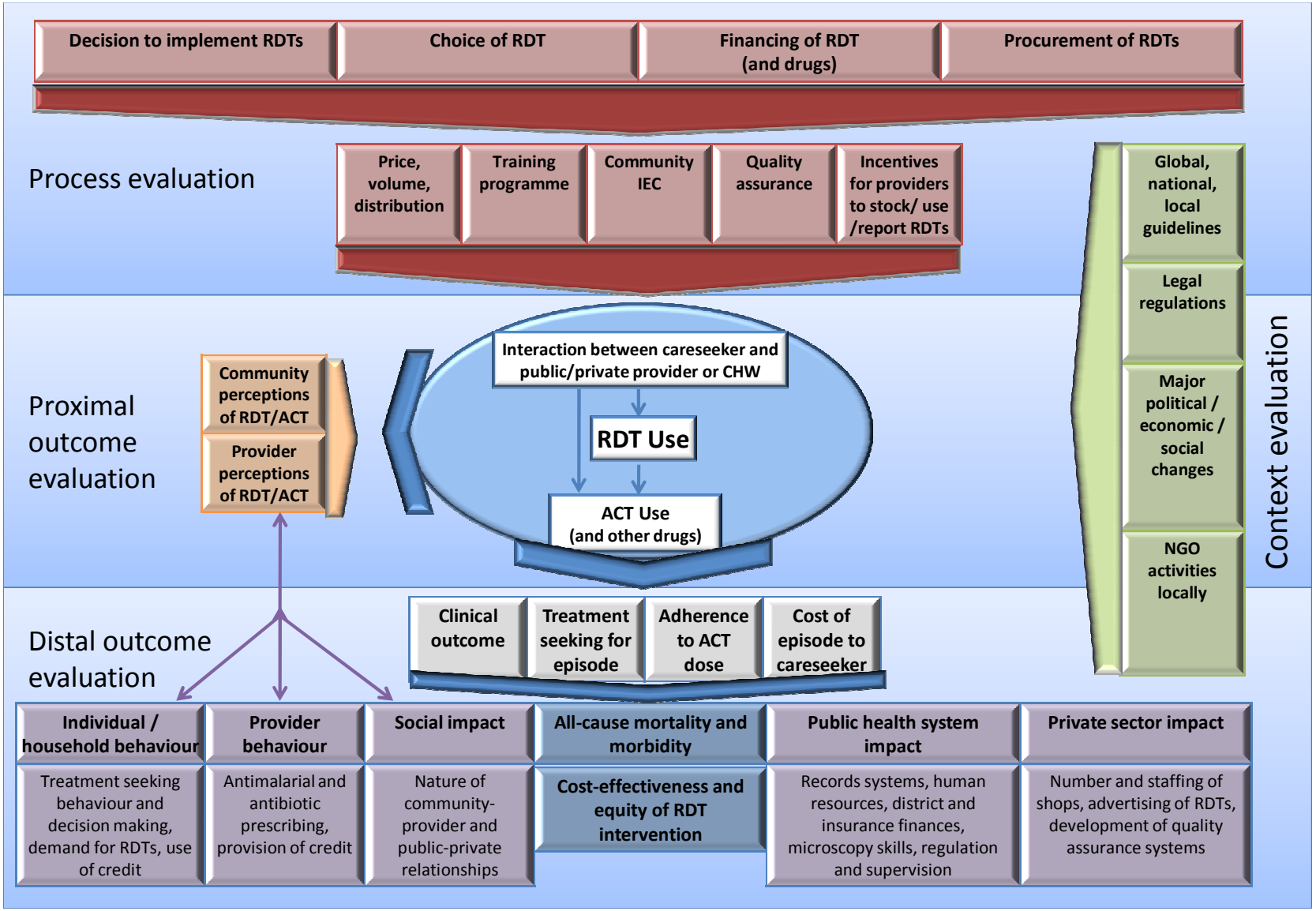
Overview

The framework consists of four evaluation components: process evaluation, proximal outcome evaluation, distal outcome evaluation and context evaluation. Through these four components, we attempt to capture factors feeding into and out of the implementation of RDTs in the public and/or private sectors. We have tried to capture and categorise the processes leading to RDT implementation from the inception and funding to training and information, education and communication about RDTs. We then break down the immediate, proximate, outcomes of RDT use by providers, including ACT use and perceptions of careseekers and providers around specific treatment seeking episodes. Next, we move to broader, distal, outcomes of RDT use. Here, we include the impact on the individual illness episode and aggregate measures of mortality, morbidity and cost impacts as well as wider impacts on the behaviour of community members, providers, and on the private sector and public health system at large. Finally, we include the analysis of the context of RDT implementation in a specific setting.

In order to gain a comprehensive insight into RDT implementation, we recommend all four components of the evaluation framework are conducted. The process and context evaluations will be particularly useful in understanding how and why the implementation of RDTs works as it does in a specific context. Lessons for improving implementation can then be learnt and comparisons drawn for implementation of other commodities or for RDT implementation elsewhere. The proximal outcome evaluation is often the central feature of operational research, but is usually a proxy for the desired impact of improved morbidity and mortality at a reasonable cost to individual careseekers, health systems and programme funders. These outcomes are captured in the distal outcome evaluation together with other important potential outcomes of the implementation of RDTs on communities, providers and systems. Understanding these wider outcomes is important for the assessment of the value of implementing RDTs, given the cost-effectiveness and wider consequences of implementation.

Given resource constraints, we have attempted to identify where variables are already being measured in current or potential new routine data sources, such as registers feeding into health management information systems, supervisory checklists, provider surveys (such as ACT Watch's outlet surveys and supply chain analyses), demographic and health surveillance surveys and malaria indicator surveys. We also identify methods for the assessment of domains not covered by existing data sources that could be undertaken as operational research activities.

Framework for evaluation of RDTs at public and/or private providers



Variables and data sources

We have identified variables for assessment of RDT implementation (in the public or private sectors) within each of the domains of the four components of the evaluation framework. For each variable, we have identified potential methods for data collection and have structured these by existing and additional data collection methods.

N.B. For brevity, we refer to public/private providers. Public providers may be at any level of the public health system from hospitals to health centres to community health workers. Private providers may be private hospitals, clinics, pharmacies or drug shops. 'Purveyors' refer to implementers: those delivering the RDTs or supporting packages.

Table 1. Process evaluation

Domain	Variable	Current or proposed routine source of data	Additional methods
POLICY ANALYSIS			
Decision to implement RDTs	• Which actor(s) responsible for decision to implement RDTs • What rationale used for decision to implement RDTs in the sectors/methods proposed	• Policy document review	• Interviews with policy makers
Choice of RDT	• Which actor(s) responsible for choice of RDT • What rationale used for choice of RDT in this setting	• Policy document review	• Interviews with policy makers
Financing of RDTs (and drugs)	• Which funder(s) responsible for financial support of RDTs (and drugs) at what stage of implementation: procurement, training, distribution, sustained/projected supply • Proposed vs actual stability and predictability of funding • New initiatives affecting procurement, cost, supply	• Funder documentation	• Interviews with country policy makers • Review of funding stability prior and during intervention period
Procurement of RDTs	• Methods for selection of supplier of RDTs, e.g. tender, convenience • Methods for procuring RDTs at national and lower levels • Existence and duration of agreement for continued supply	• Policy document review	• Interviews with policy makers • Interviews with purveyors

Domain	Variable	Current or proposed routine source of data	Additional methods
FIDELITY OF RDT PROGRAMME DELIVERED			
Training programme: • **Dose delivered** • **Reach** • **Dose received**	• Proportion of training sessions completed of those intended • Proportion of components of training completed of those intended • Proportion of intended participants attended • Barriers to participation • Extent of engagement of participants • Receptiveness of participants to use RDTs and follow results		• Purveyor log of training events • Purveyor record of target audience and attendance • Interviews with non-attendants • Observation or reflection of trainers • Interviews with attendants
IEC: • **Dose delivered** • **Reach** • **Dose received**	• Proportion of materials / activities delivered of those intended • Proportion of materials / activities delivered where intended • Proportion of intended recipient population reached • Proportion of intended recipient population engaged • Barriers to engagement • Extent of understanding of messages by recipient population • Extent of fit of messages with existing meanings of malaria, diagnosis, testing • Extent of engagement of participants with activities		• Purveyor log of materials /activities • Purveyor record of placement of materials/ activities • Purveyor record of number and characteristics of pop reached • Household survey • Purveyor record of number and characteristics of pop engaged • Interviews with cross-section of pop re (non-)engagement, understanding, fit with existing meanings
Price delivered through supply chain	• Match between intended price sold at different levels and price sold in reality	• ACT Watch supply chain survey	• Documentation of intended prices and changes over time • Interviews with

Domain	Variable	Current or proposed routine source of data	Additional methods
			wholesalers re mark-ups
Regulation and monitoring of RDT use	• Relationship between regulation and RDT practice • Frequency and nature of monitoring at wholesaler, district, provider levels • Impact of monitoring on actual use of RDTs	• Regulator/monitor records	• Records of wholesalers/providers re monitoring visits • Observation of monitoring visits • Interviews with regulators /monitors • Interviews with wholesalers/providers
Volume and distribution	• Official distribution & re-stocking mechanisms • Frequency and volume of RDTs distributed at all levels of RDT provider • Fit between distribution and needs	• District records • Provider stocking and request records	• Interviews with providers • Interviews with distributors
Quality assurance	• Official lot-testing mechanism • Frequency and volume of lot-testing • Frequency and timeliness of QA feedback to providers • Timeliness and mechanism for removal of faulty batches • Fit between lot-testing mechanism and needs	• Policy documents • District records • Wholesaler records	• Interviews with providers • Interviewers with QA personnel
Incentives for providers to stock and use RDTs	• Presence of financial or non-financial (e.g. accreditation) incentives for providers to stock RDTs • Presence of incentives for providers to use RDTs • Fit between incentives and provider priorities • Fit between those incentivised and those stocking and using RDTs	• MoH/district documentation	• Interviews with purveyors of incentives • Interviews with incentivised RDT providers • Interviews with non-incentivised RDT providers
Incentives for providers to report on RDT use	• Presence of financial or non-financial (e.g. capacity building) incentives for providers to report on RDT use • Fit between incentives and provider priorities	• MoH/district documentation	• Interviews with purveyors of incentives • Interviews with providers

Table 2. Proximal outcome evaluation

Domain	Variable	Current or proposed routine source of data	Additional methods
RDT USE			
Appropriate use of RDT	• RDT offered to all clients with fever in past X weeks • RDT not offered to clients with no history of fever • Referral if danger signs detected (according to local guidelines)	• Routine health facility register of all patients symptoms and whether tested • Introduction of registers in private sector of all patients symptoms and whether tested	• Observation, mystery client or exit interviews to assess which clients were offered/demanded and accepted/refused tests
Correct and safe use of RDT	• Expiry date checked • Gloves used • Finger cleaned with sterile swab and allowed to dry • Heel prick in infants • Sterile lancet used • Lancet discarded immediately in sharps container • Good technique used to obtain correct amount of blood • Blood placed in appropriate well • RDT placed flat on table and bottle held vertically to dispense buffer • Correct number of drops dispensed into appropriate well • Full number of minutes waited before reading result • Disposes of used materials correctly	• Supervisory visits to observe RDT operation with checklist	• Observation / mystery client to assess procedure
Who administers test	• Trained personnel only carrying out RDT • Level of personnel carrying out RDT	• Routine registers including identification of individual prescriber and index to prescriber characteristics	• Observation, mystery client or exit interview
Correct interpretation of RDT results (and given to client)	• Results read correctly • Results recorded correctly • Results given to client	• Supervisor checklist • Routine registers or patient cards with record of result	• Observation or mystery clients
Safety of storage	• RDTs stored at correct	• Routine supervision	• Observation or mystery

Domain	Variable	Current or proposed routine source of data	Additional methods
	temperature and humidity • Sharps and waste bins stored safely		clients
Procurement and supply of RDTs	• Appropriate RDT procured • Timeliness of supply throughout supply chain • Correct transport conditions • No stock-outs at peripheral level	• Existing supply management information systems • ACT Watch outlet survey • Supervision checklist	• Provider surveys • Interviews with providers • Interviews with procurement officers
Price sold through supply chain	• Price RDTs sold to MoH stores • Price RDTs sold to highest level importers and wholesaler • Price RDTs sold to mid-level wholesalers • Price RDTs sold to providers (different levels) • Price RDTs sold to clients	• ACT Watch supply chain survey	• Supply chain survey
ACT USE			
Appropriate provider use of ACT	• ACT prescribed/sold to RDT positive clients • ACT not prescribed/sold to RDT negative clients • ACT prescribed/sold to patients in absence of testing • Monotherapies not prescribed/sold	• Routine registers of client symptoms, whether tested, results and prescription	• Observation, mystery clients or exit interviews
Correct dose and storage of ACT	• ACT prescribed in correct dose for age (or weight) • ACT stored appropriately	• Routine registers including age/weight of client and dose	• Observation, mystery clients or exit interviews
Correct advice with ACT	• Rationale for adherence to full dose explained		• Observation, mystery clients or exit interviews
COMMUNITY PERCEPTIONS OF RDT/ACT			

Domain	Variable	Current or proposed routine source of data	Additional methods
RDT acceptability	• Careseeker attitudes toward RDT operation/process • Careseeker perception of local malaria treatment norms and the acceptability of RDT use within those norms • Careseeker attitudes toward referral if RDT negative		• Exit interviews • Community focus group discussions
Perceived advantages and disadvantages of RDTs	• Careseeker perceptions of usefulness of RDTs in gaining desired treatment • Careseeker rationale for use/non-use of RDT • Careseeker perceptions of accessibility of RDTs – location, type of provider, cost		• Community focus group discussions • Exit interview with RDT +, RDT -, and non-users
Perception of ACTs	• Careseeker perception of any link between RDTs and the use and dosing of ACTs, e.g. presence of parasites • Careseeker perception of why/ when to use ACTs vs other antimalarials • Careseeker perception of why/ when to use antimalarials vs other drugs, e.g. antibiotics		• Exit interview with RDT +, RDT -, and non-users • Community focus group discussions
PROVIDER PERCEPTIONS OF RDT/ACT			
Perceived advantages and disadvantages of RDTs	• Provider rationale for use/non-use of RDTs • Provider perception of accuracy of RDTs • Provider perception of relationship between RDT result and 'malaria' • Provider perception of client preference for RDT • Provider perception of the cost-benefit of using/selling RDTs with different clients • Provider preference for referral vs		• In-depth interviews with providers stocking and not stocking RDTs

Domain	Variable	Current or proposed routine source of data	Additional methods
	local treatment		
RDTs and prescribing	• Provider perception of restricting ACT to RDT negative clients • Provider perception of best way to convince clients to adhere to RDT results in treatment • Provider rationale for any perceived changes in their own dispensing behaviour • Provider perception of why/ when to use ACTs vs other antimalarials since RDT implementation • Provider perception of why/ when to use antimalarials vs other drugs, e.g. antibiotics since RDT implementation		• In-depth interviews with providers

Table 3. Distal impact of RDT implementation

Domain	Variable	Current or proposed routine source of data	Additional methods
ILLNESS EPISODE OUTCOME			
Impact on clinical episode outcome	• Resolution of symptoms by day X • Parasitological cure in patients with malaria by day X	• Routine registers of repeat consultations	• Cohort follow-up of symptoms and parasitaemia • Clinical effectiveness studies • Diary cards
Impact on treatment seeking	• Number and source of subsequent steps in treatment seeking	• ACT Watch household survey • DHSS Routine HIS data • Malaria indicator surveys	• Cohort follow-up of treatment-seeking since RDT • Household survey
Cost of illness episode to client	• Cost (financial, time, work lost) of each step to careseeker • Total cost of illness episode	• ACT Watch household survey	• Cohort follow-up of treatment-seeking since RDT • Household survey

Domain	Variable	Current or proposed routine source of data	Additional methods
Impact on adherence to ACT dose	• Complete dose taken • Doses taken at right times	• ACT Watch household survey	• Cohort follow-up of treatment-seeking since RDT • Household survey
Adverse events due to RDT	• Any adverse event associated with having an RDT conducted	• Routine registers of returning patients	• Diary cards • Cohort follow-up since RDT conducted
AGGREGATE CLINICAL AND COST OUTCOMES			
Impact on all-cause morbidity and mortality	• Absolute and relative numbers of illness episodes • Absolute and relative numbers of deaths	• Routine registers of attendance and case mix at all providers in an area • Death register	• Comparison with control areas or baseline data on malaria, fever, anaemia, etc. Rates • Household survey mortality rates
Overall cost of RDT implementation	• Cost of RDT strategy from different perspectives: government, providers and clients, relative to savings (including financial costs and time)	• Budget and expenditure records • ACT Watch outlet, supply chain and household survey	• Provider, supply chain and household survey
Cost-effectiveness of introduction of RDTs	• Cost-effectiveness of RDT strategy from different perspectives- taking into account cost of treating RDT negative patients		• Modelling • Cost-effectiveness studies along-side effectiveness studies
Equity of use	• Characteristics of population groups who have used/not-used an RDT (gender, age, SES, status in community) • Who places most value on RDTs within populations and within households (age, gender, SES, health status)	• ACT Watch household survey	• Household survey • Exit interview • Community focus group discussions
INDIVIDUAL/ HOUSEHOLD BEHAVIOUR			
Shifts in source of treatment for fever	• Order of providers consulted in fever cases (indexed to RDT	• ACT Watch household survey	• Household survey • Exit interview

Domain	Variable	Current or proposed routine source of data	Additional methods
	availability) • Proportion of cases using public vs. private providers • Number of treatment seeking steps before parasitological diagnosis	• Routine registers of attendance and case mix • Ministry of Health rates of use data • Malaria indicator surveys	
RDT uptake	• Use of RDT for each household case of suspected malaria prior to use of antimalarial drugs		• Household survey
Demand for RDTs	• Careseeker asks for an RDT from provider • The type of cases for which an RDT is sought (symptoms, type of patient)		• Observation or mystery client • Provider survey • Community focus group discussions • RDT sales data?
Referral advice followed	• Referral followed-up by careseeker	• Routine registers of referrals	• Cohort follow-up
How next steps decisions are made	• Who (in the family) makes decisions on if/how to proceed with treatment-seeking at each step • Effect of patient characteristics (status within family, gender, age, health symptoms) on referral adherence	• Linked registers from referring provider to referral centres including patient characteristics	• Community focus group discussion • Exit interview • Cohort follow-up
Impact on the use of other antimalarials (non-ACTs)	• Change in the frequency of use of non-ACT antimalarials by community members following the introduction of RDTs	• ACT Watch household survey	• Household survey • Exit interview
Impact on the use of antibiotics	• Change in the frequency of use of different types of antibiotics by community members following the introduction of RDTs	• ACT Watch household survey	• Household survey • Exit interview
Use of credit for RDT/ACT at provider	• Careseeker use of credit to purchase an RDT or ACT on credit • Impact of credit on provider choice	• Routine provider registers of credit and case mix	• Exit interviews • Household survey • Community focus group discussion
PROVIDER BEHAVIOUR			
Impact of RDT on diagnosis	• Careseeker receives diagnosis		• Exit interviews

Domain	Variable	Current or proposed routine source of data	Additional methods
	from provider post-RDT		• Observation or mystery clients
Impact of RDT on referral practices	• Referral or further advice from provider	• Routine provider registers	• Exit interviews • Observation or mystery clients
Impact on the use of other antimalarials (non-ACTs)	• Change in the frequency of sales/prescriptions of non-ACT antimalarials following the introduction of RDTs	• Routine sales/facility registers • Drug supply data • ACT Watch outlet survey	• Provider survey • Exit interview
Impact on the use of antibiotics	• Change in the frequency of sales/prescriptions of different types of antibiotics following the introduction of RDTs	• Routine sales/facility registers • Pharmacy drug supply records	• Provider survey • Exit interview
SOCIAL IMPACT			
Who administers RDTs (if at community level)	• Status of RDT provider in the community and impact on provider motivation and practices • Influence of provider over careseeker behaviour		• Observation (ethnographic) • Community focus group discussion • Interview with providers
Where are RDTs done (if at community level)	• Location where RDTs are performed, e.g. in the home • Influence of location of consultation on use of RDT • Influence of location on perceived safety of use	• Routine provider registers	• Observation (ethnographic) • Household survey • Provider survey • Community focus group discussion
RDT and provider-careseeker interaction	• Nature of provider-careseeker interaction during the RDT process and impact on trust and treatment outcome (current and future episodes) • Nature of provider advice • Nature of queries from careseeker to provider		• Observation (ethnographic) • Exit interview • Community focus group discussion
Use of credit	• Impact of credit for RDTs on provider-community relationships		• Community focus group discussions • Interviews with public and private providers • Observation

Domain	Variable	Current or proposed routine source of data	Additional methods
			(ethnographic)
Provider-community relationships	• Careseeker perceptions of public vs private providers in treating fevers since RDT implementation • Careseeker perceptions of any changes in relationship with public/private providers since RDT implementation • Public/private provider perceptions of any changes in relationship with community since RDT implementation		• Community focus group discussions • Interviews with public and private providers • Observation (ethnographic)
Public and private provider relationships	• Public provider opinions of the use of RDTs in the private sector • Private provider opinions of their relationship with public sector providers, e.g. for supplies, referrals, since RDT implementation • District health management officials perception of the nature of private-public provider relationships and the impact on appropriate RDT implementation		• Interviews with public and private providers • Interviews with district health management teams • Observation (ethnographic)
PUBLIC HEALTH SYSTEM IMPACT			
Impact on human resources of public health system	• Absolute and relative number of public sector individuals moonlighting in the private sector since RDT implementation • Absolute and relative number of individuals moving from/to the public and private sectors since RDT implementation • Job satisfaction of providers since RDT implementation	• Provider registers of staff	• Provider surveys • Interviews with providers • Interviews with in-charge at public facilities
Impact on regulation and supervision	• Changes to local/national regulation of diagnostics • Changes to supervision frequency and nature	• MoH documentation	• Interviews with district health management teams
Impact on public sector	• Number of skilled microscopists	• District records	• Interviews with district

Domain	Variable	Current or proposed routine source of data	Additional methods
microscopy (for QC, parasite density, vivax detection)	at health facilities • Number of RDT quality control centres with skilled microscopists		health management teams
Impact on health management information system records	• Changes to current data collection tools and reporting mechanisms	• Written registers • Electronic HMIS data	• Interviews with district health management teams
Supply chain through tiers (national dispensary → pharmacies → drug shops)	• Changes to existing drug/ equipment public sector supply chain	• ACT Watch supply chain survey	• Supply chain survey
Financial impact of RDT strategy to health system	• Cost of RDTs to district • Cost of RDTs to health facilities • Cost of RDTs to district insurance schemes	• District/facility/insurance records	• Interviews with district health management teams
Volume of RDTs used	• Total RDTs supplied/sold	• Central medical stores records	
Volume of ACTs used	• Total ACT doses supplied/sold	• Central medical stores records	
PRIVATE SECTOR IMPACT			
Private outlet sales of RDTs/ACTs	• Number of private outlets selling RDTs • Volume of RDTs sold (by type of outlet) • Number of private outlets selling ACTs • Volume of ACTs sold (by type of outlet)	• ACT Watch outlet survey • Sales registers	• Outlet survey
Staffing of private outlets	• Number of staff trained in RDTs per private outlet • Qualifications of staff conducting RDTs at private outlets		• Drug outlet surveys
Motivation of retailers to stock RDTs and keep register	• Reasons for stocking/not stocking RDTs • Reasons for recording/not recording/quality of recording RDT sales and client details in register		• Interviews with retailers
Impact on local advertising of RDTs/ ACTs	• Number of private outlets advertising RDTs	• ACT Watch outlet survey	• Outlet survey • Observation

Domain	Variable	Current or proposed routine source of data	Additional methods
	• Local development of visual advertising materials for RDTs • Presence and nature of any verbal advertisement of RDTs at private outlets		(ethnographic) • Interviews with retailers
Impact on private sector microscopy	• Number of private laboratories after RDT implementation • Number of laboratories providing quality control services after RDT implementation • What services provided by laboratories, e.g. routine diagnostic microscopy, parasite dentity, vivax detection • Quality of private microscopy services after RDT introduction	• ACT Watch outlet survey	• Outlet survey • Quality assessment of private laboratory microscopy

Table 4. Context evaluation

Domain	Variable	Current or proposed routine source of data	Additional methods
Global/national/ local guidelines	• Presence of supporting or competing initiatives including guideline changes, health systems changes, HMIS changes • Impact of additional initiatives on providers and clients	• Government documentation	• Review of concurrent government initiatives • Interviews with providers • Community focus group discussions
Legal regulations	• Presence of supporting or conflicting legal regulations regarding who can use RDTs and where RDTs can be used • Support for such legal regulations amongst policy makers and implementers • Impact on providers of competing legal and policy regulations	• Government documentation	• Interviews with regulators • Interviews with policy makers and implementers • Interviews with providers
Major political/ economic / social shifts concurrent with intervention period	• Presence of political change that affects RDT availability or implementation • Presence of economic change that	• Government documentation	• Interviews with policy makers • Interviews with district officials

	affects RDT availability or implementation • Presence of social change that affects RDT availability or implementation		• Focus group discussions with communities
NGO activities locally	• Presence of supporting nor competing NGO activities on local level • Impact of NGO activities on providers' and clients' perception and use of RDTs	• NGO documentation	• Interviews with NGO implementers • Interviews with providers • Focus group discussions with communities

Summary of current or adaptable routine data sources

- Provider (health facility, community health worker, private clinic or private outlet) patient registers, feeding into health management information system
- Provider (health facility, community health worker, private clinic or private outlet) stocking registers
- Provider (health facility, community health worker, private clinic or private outlet) sales, budget, expenditure records
- Supervisor (health facility, community health worker, private clinic or private outlet) checklist data
- Demographic and health surveillance system
- Malaria indicator survey
- Central medical stores records
- Death registers
- ACT Watch outlet survey
- ACT Watch supply chain survey
- ACT Watch household survey

Summary of additional data sources

- Outlet surveys (health facility, community health worker, private clinic or private outlet)
- Supply chain surveys (public and private)
- Household surveys
- Cohort follow-up of patients
- Exit interviews with patients
- Interviews with providers (health facility, community health worker, private clinic or private outlet)
- Community focus group discussions
- Observation (ethnographic) of communities, providers and interactions
- Interviews with district health management teams
- Interviews with policy makers
- Purveyor logs
- Clinical effectiveness studies
- Diary cards
- Modelling

For a description of qualitative methods, guidelines on how to develop qualitative protocols, and a list of resource guides on qualitative evaluation, please see Chandler, C.I.R. (2009). ACT Consortium Social Science Guidance. ACTC/CC/2009/SSGv04. Available online at http://www.actconsortium.org/pages/guidance-notes.html

Summary

We have outlined four components for the evaluation of malaria rapid diagnostic test implementation in public/private sectors of malaria endemic countries. These components are process evaluation, proximal outcome evaluation, distal outcome evaluation and context evaluation. We have identified domains for evaluation within each component and variables to assess within each domain. We have identified current, or proposed, routine sources of data as well as additional sources of data more suitable for collection in operational research. We hope to develop these data collection methods further into proposals for specific operational research activities where RDTs are being implemented in different settings.

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