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Diagnostic Testing in the Retail Private Sector: Lessons Learned

Report meeting of the RBM - Case Management Working Group

Meeting held in London, 29-30th April 2013

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Contents

1	Welcome and introductions	5
2	Project presentations	6
2.1	Increasing access to parasitological malaria diagnosis in the private sector: a discussion of the literature to date. <i>Nora Petty, CHAI</i>	6
2.2	A framework for RDT programme evaluation. <i>Shunmay Yeung, ACT Consortium</i>	7
2.3	Evaluation of interventions to support the introduction of RDTs in Nigeria. <i>Obinna Onwujekwe (University of Enugu, ACT Consortium) & Lindsay Mangham-Jefferies (LSHTM, ACT Consortium)</i>	7
2.4	The impact of RDTs in the Ugandan private sector. <i>Anthony Mbonye, Ministry of Health Uganda, ACT Consortium</i>	8
2.5	Experience with referrals from the Ugandan private sector. <i>Sian Clarke</i>	8
2.6	Evaluation of RDTs in the private sector: a cluster randomised trial in Ghana. <i>Evelyn Ansah</i> ,	9
2.7	Findings from a programmatic evaluation in Cambodia. <i>Shunmay Yeung, LSHTM, ACT Consortium</i> 10	
2.8	Process and qualitative considerations in a programmatic evaluation. <i>Clare Chandler, LSHTM, ACT Consortium</i>	11
2.9	Experience with RDTs in three outlet types in Myanmar. <i>Tanya Shewchuck, PSI</i>	11
2.10	Establishing malaria case management services in private sector medicine stores serving city slums – Early lessons from Monrovia, Liberia. <i>Richard Allen, MENTOR</i>	12
2.11	Increasing access to malaria diagnosis and treatment in Zambia. <i>Elizabeth Streat, Malaria Consortium</i>	13
2.12	Testing the feasibility and uptake of subsidised RDTs in Uganda and Zanzibar. <i>Nora Petty</i>	14
2.13	Prevalence of malaria parasitaemia and purchase of Artemisinin-based combination therapies among drug shop clients – Tanzania, 2012. <i>Melissa Briggs, Malaria Branch CDC</i>	15
2.14	Scaling-up low cost RDTs: early experiences from Tanzania. <i>Nora Petty</i>	16
2.15	Experiences from RDTs in the private sector in Nigeria. <i>Jennifer Anyanti & Ernest Nwokolo, SFH</i> ..	17
3	Panel discussion with Country Representatives.....	18
3.1	National Malaria Control Programme, Tanzania. <i>Fabrizio Molteni</i>	18
3.2	National Malaria Control Programme, Uganda. <i>Agaba Bosco</i>	19
4	Synthesis of Q&A and panel discussions: common emerging themes.....	20
4.1	Ensuring availability and support for affordable, quality assured RDTs to be scaled-up sustainably in the private market.....	20
4.2	Ensuring safe practices in RDT use	21
4.3	Supporting uptake of RDTs and adherence to results by providers.....	21
4.4	Encouraging population demand for RDTs.....	23
4.5	Contextual factors not easily amenable to change	23
4.6	Next steps.....	24
4.7	Concluding remarks.....	24

Executive Summary

On April 29–30, 2013, the Roll Back Malaria Case Management Working Group (CMWG) Diagnosis Work Stream convened a meeting of researchers and subject-matter experts to:

- To share the results of research activities and early pilot interventions to introduce diagnostic testing for malaria into the retail private sector;
- To extract lessons learned and identify key bottlenecks and success factors from operational research and limited experiences to inform the future design of pilot projects for deploying diagnostic testing in the private sector in malaria endemic countries; and
- To provide the RBM Board with preliminary guidance on potential approaches to improving quality of care of malaria in the private sector, including quality diagnostic testing.

At this meeting, the results of more than a dozen small-scale studies and pilots from eight countries in Africa and Southeast Asia were reviewed. Many of the results presented were preliminary or have not yet been published. Their methodologies, targets, and objectives also differed to varying degrees.

Nonetheless, some common experiences, findings, and challenges emerged during the two days of deliberations. All the studies and pilots demonstrated that targeted private sector providers (which were mostly licensed or accredited drug vendors, such as patent medicine vendors and licensed chemical sellers) were willing to incorporate diagnostic testing for malaria with rapid diagnostic tests (RDTs) into their businesses, although to varying degrees. Many believed that adding malaria RDTs to the services they provided would be good for business, as it would increase the status of their business by enabling them to provide a definitive diagnosis to their patients.

Furthermore, in most studies, clients seeking treatment for fever were reported to be willing to accept diagnostic testing before receiving treatment. Many reported that they appreciated being able to determine whether or not their fever was caused by malaria.

External assessments found that drug shop staff could be trained to perform and interpret the tests with a high level of accuracy, particularly when training and periodic technical supervision was provided.

Adherence to the test result was variable from study to study, with from 11% to 49% of those with a negative test result for malaria still being prescribed malaria treatment. It was noted, though, that these results were similar to or possibly even better than those seen in public sector facilities. Identifying methods to improve adherence to test results was seen as a priority area for further investigation in ongoing and future studies and pilots.

The price that consumers paid for a diagnostic test also varied widely among the studies and pilots. Most studies, though, did not directly test out different pricing schemes, but rather set a recommended retail price based on formative research, such as willingness-to-pay assessments, prior to the launch of these studies and pilots. The meeting participants agreed that further investigation in this area was needed, but acknowledged that an acceptable pricing level would likely vary among countries and even within countries (e.g. urban vs. rural settings).

The participants agreed that three of the greatest challenges to achieving large-scale implementation of such private sector strategies were existing regulatory barriers and weak referral systems. In most countries, the providers targeted in these studies and pilots were licensed dispensers who, by law, could dispense

medications to persons with a prescription, but were not permitted to make a diagnosis, perform a diagnostic test, or prescribe antimalarials and antibiotics. Such regulatory restrictions would have to be eased before this strategy could be fully scaled-up.

In almost all settings, referral systems from private retail outlets to public facilities were non-existent. In those studies where drug sellers were encouraged to refer patients with severe illness and those where a clear diagnosis could not be made, patients often reported poor or incorrect management at the receiving facility. Some public sector providers dismissed the private sector providers as frauds or quacks, undermining the referral process. The success of any private sector intervention will depend on changing perceptions and supporting new practices of providers at referral facilities.

Finally, participants drew a sharp distinction between implementation of Affordable Medicines Facility for Malaria (AMFm) and strategies that incorporated diagnostic testing prior to treatment. While the former focused on making affordable ACTs widely available in targeted countries, strategies for expanding malaria diagnosis and treatment to the private sector required delivery of a comprehensive health service. Such a service would require good training, supervision and quality-assurance, monitoring and evaluation, appropriate referral systems, and safe management of biohazardous waste, in addition to making testing affordable and financially attractive to the private retailers.

These preliminary findings will be presented to the RBM Board at their upcoming meeting in May 2013. The participants agreed that a subsequent meeting in late 2013 or early 2014 to review additional findings from ongoing studies and additional planned pilots, including those funded by UNITAID and PMI, would be warranted to develop more definitive recommendations for countries on best practices for scaling-up comprehensive fever case management in the private retail sector.

1 Welcome and introductions

Dr Lawrence Barat, PMI, focal point of the RBM CMWG diagnostics work stream & Dr Shunmay Yeung, LSHTM, deputy director of ACT Consortium

Larry Barat opened the meeting and welcomed participants. Apologies were conveyed from David Schellenberg.

The objectives of the meeting were:

- To share the results of research activities and early pilot interventions to introduce diagnostic testing for malaria into the retail private sector.
- To extract lessons learned and identify key bottlenecks and success factors from operational research and limited experiences to inform the design of pilot projects of deploying diagnostic testing in the private sector in malaria endemic countries
- To provide the RBM Board with preliminary guidance on potential approaches to improving quality of care of malaria in the private sector, including quality diagnostic testing.

The preliminary nature of the findings from many studies was noted, and the need for checking with investigators before including any unpublished findings in any written format was made clear. LB suggested ranges or aggregates of data may be used in order to move forward discussions within RBM but the report would be circulated for comment. Any participants who anticipate using data should contact the investigators prior to final inclusion in any circulated or published document.

2 Project presentations

2.1 Increasing access to parasitological malaria diagnosis in the private sector: a discussion of the literature to date. *Nora Petty, CHAI*

Nora Petty from CHAI presented results from a draft literature review describing availability, price, use and acceptability of RDTs in the for-profit private sector, including evaluations of controlled experiments. The findings were from published, unpublished, and grey literature. The full review was noted as not for further circulation beyond the meeting group at the time of the meeting. Of 354 initial search results 49 were included in the review. Findings:

- **Availability.** Formal outlets (hospitals, clinics, pharmacies) were more likely to stock RDTs than informal outlets (drug shops). Urban areas were more likely to stock RDTs than rural areas.
- **Pricing.** Small sample sizes, but median price range was \$0-4.29. Prices reported were higher in formal outlets compared to informal outlets. Median prices were noted to be higher in the market place than clients had reported that they were willing to pay.
- **Perceptions.** Qualitative studies suggested positive perceptions of RDTs from both end-users and providers, although in many cases people were unfamiliar with RDTs. People felt RDTs could assist in determining the true causes of fever and could save time and money compared with laboratory testing. Challenges included perceived high cost of the test and fears that the test could be used to test for HIV/AIDS. However in controlled experiments where subsidized RDTs were introduced into the market, the attraction of the tests did not necessarily result in high uptake.

Experimental studies. The controlled experiments varied in design, but most were conducted in low-level retail outlets (e.g., drug shops), most included training and supervision activities, and some type of demand generation activities. They all incorporated a subsidy levels (albeit at varying levels). These are preliminary findings and are subject to further analysis of pricing and the context of the studies.

- In all of the studies, end-user prices were higher than recommended retail prices;
- Uptake was mixed, ranging from 16-72% patients with fever getting RDTs, which could potentially be related to level of guidance provided in the different settings;
- Performance of the dispensers conducting the tests was mixed, potentially also related to supervision;
- Adherence to test results was also mixed ranging from 2-49% receiving antimalarials with negative test results.

Nora concluded that experiences to date show that retail outlets can safely perform the RDT but training and supervision is needed. Significant challenges remain with regards to the dispensers recommending and performing the test and adhering to negative test results. Nora suggested that further research was required to understand the private sector supply chain in terms of stocking behaviors and cost of transport/business; to understand country regulations for where RDTs can be done; to determine willingness to pay in practice (not through contingent evaluation methods); to compare the cost-effectiveness of different training, supervision and demand generation activities; and to better inform how to link positive RDTs to ACTs and negative RDTs to the correct treatment for non-malarial febrile illnesses.

2.2 A framework for RDT programme evaluation. *Shunmay Yeung, ACT Consortium*

Shunmay Yeung reviewed the rationale for introducing RDTs and the work of the ACT Consortium in this area. A framework was developed for the evaluation of RDTs by the Consortium in 2009, this is available on their website at www.actconsortium.org

The evaluation framework outlines:

- Proximal outcomes: beyond the uptake of RDTs and their adherence, the framework emphasises clinical outcomes, treatment seeking, adherence to ACT dose and cost of episode to the careseeker, also community perceptions and provider perceptions
- Process evaluation: the framework identifies various aspects of how RDTs are introduced including price, volume, distribution, training programme, community engagement, quality assurance of tests, incentives for providers to stock/use/report RDTs
- Distal outcome evaluation: the framework draws attention to the wider impact of RDTs, including on all-cause mortality and morbidity, cost-effectiveness and equity of RDT intervention, impacts on household behaviour, provider prescribing eg. Antibiotics, social impacts in terms of positioning of providers, public health system impact and also impact on other private sector actors.

A decision-tree model was shown which can incorporate findings from studies along a series of decision points, from diagnostic done, treatment prescribed to subsequent treatment seeking and cost, health outcomes.

2.3 Evaluation of interventions to support the introduction of RDTs in Nigeria. *Obinna Onwujekwe (University of Enugu, ACT Consortium) & Lindsay Mangham-Jefferies (LSHTM, ACT Consortium)*

Objective: Lindsay Mangham-Jefferies outlined a 3-arm cluster randomised trial 'REACT' based in South-East Nigeria where the project aimed to understand what interventions would be most useful to support the planned introduction of RDTs in both the public and private sector. The providers targeted in the project were pharmacies and patent medicine dealers (PMDs) as well as public health facilities.

Context: Formative research was the start point for the project in 2010. At this point, the project found few patients were tested for malaria before treatment, and only 23% of cases of febrile illness received an ACT (most got SP). At medicine retailers <1% clients had a malaria test. In this setting, demand by clients was for either a specific drug or for advice on a drug rather than for a diagnostic process.

Interventions: The interventions were designed to tackle both provider knowledge, skills and confidence and demand from community members for RDTs and for ACTs. RDTs were provided for free to providers. The provider intervention components were training, job aids and supervision. The community oriented intervention was school-based, using a hands-off approach, whereby school teachers were invited to hold events in their communities such as health talks, drama, dance. Peer educators were also invited to participate, given a framework for activities within schools. The approach was pragmatic, to mimic a real-life setting: a 'real world' evaluation.

Evaluation: A logic model for the intervention and evaluation was shown, showing the intended pathways of effect from each intervention component to the outcomes intended. Each item on the intended pathway of

change was measured in the project's evaluation where possible. Evaluation took place after 3 months after the intervention was offered. The primary outcome was 'treatment according to guidelines', composed of whether patients were tested and whether results were adhered to, and the type of antimalarial prescribed.

Findings: preliminary, not for citation.

Country context (Ernest Nwokolo): RDTs are not officially allowed to be used by PMDs and policy change on this is hoped for by bringing evidence on ACT use through the private sector. Malaria prevalence is going down and this clashes with health provider expectations and raises challenges with what to do with case-negative patients, clashes with microscopy results which are ambiguous saying 'one plus'.

2.4 The impact of RDTs in the Ugandan private sector. *Anthony Mbonye, Ministry of Health Uganda, ACT Consortium*

Objective: Anthony Mbonye presented preliminary results from a cluster randomised trial in Uganda. The primary objective was to evaluate the impact, cost-effectiveness and availability of RDTs in registered drug shops on the proportion of patients receiving appropriate ACT treatment for malaria at those shops.

Intervention: The project started with formative research and liaison with other stakeholders to design the intervention package. The intervention consisted of: interactive training (in RDTs, case management, communication with patients), job aids, supervision (visiting shops at the start of the intervention), MoH logo on price lists and certificates, record keeping, rectal artesunate, community sensitisation through district health educators and village health teams, including leaflets ('get tested', 'RDTs available at some drug shops', 'ACTs will be sold at small price after testing'). Some drug shop vendors decided to put up roadside signs to advertise their RDTs. In control arm shops, interactive training was also carried out, without the RDT related component. In both arms, providers were trained to take reference blood slides, to keep records and were supplied with free ACTs. The intervention activities were rolled out from October 2010.

Findings: The evaluation was from Jan-Dec 2011 with 65 drug shops. Found more patients attending in the RDT arm in absolute numbers. Majority of patients had an RDT in the intervention arm (98%), 40% RDTs were reported as positive with some variation with seasonality. Adherence to RDT results was 92% overall, among negative RDT results 89.4%. Much fewer ACTs sold in the RDT arm (59% given ACT) compared with presumptive (98% given an ACT). Referral reported was higher in the RDT arm (12% compared with 4%). More referrals were for negative than positive RDT results. Acceptability was high, few refused. Lot testing of RDTs showed they were good quality.

2.5 Experience with referrals from the Ugandan private sector. *Sian Clarke*

Objective: Sian Clarke presented a qualitative evaluation of the Mbonye Ugandan trial (above) including a referral form. This qualitative study focused on understanding the process of introducing RDTs to drug shop vendors (DSVs), including how RDTs are perceived and used and how RDTs impact on referral processes of clients. 22 focus group discussions were conducted towards the end of the trial with DSVs in each arm, public health workers and with community members who had visited the DSVs.

Context: The trial targeted registered drug shops in an environment where the shops are highly regulated. More than half of vendors had health training and the remainder had experience through working in health facilities. Only 40% had previously received any training in malaria, and only 43% were aware that ACTs were the first line treatment for malaria in Uganda. Formative research showed that these shops were in a 'liminal space', both legitimate and illegitimate, both shops and clinics, both trusted and distrusted. They are at the boundary of formal and informal system. Maintaining authority and legitimacy is based on social proximity to communities as well as borrowing institutional legitimacy through association with formal sector.

Findings: The trial enabled enhanced legitimacy for DSVs through the paraphernalia of gloves, swabs, lancets, kits, registers. DSVs perceived greater attendance and felt the project had increased their standing as health practitioners. Patients showed a desire for diagnostic process and for improved quality of services. They showed increased trust in shops and appreciated endorsement of DSVs by Ministry of Health. The low price of RDTs was important. Positive RDT results were well received but negative results were problematic, calling into question the DSV's skills and potential for loss of income through referring. DSVs managed negative results through making an alternative diagnosis and treating the illness (often with injections and multiple treatments, according to patients), arranging a second test (although problematic if the result conflicted), or using a referral form (although this was a threat to health workers in public facilities who feared inclusion of DSVs in formal sector, and this had a negative impact on DSVs via patients).

Conclusions: The process of testing was highly acceptable, with supporting message focused on adherence to results. Low price of RDTs was important. Guidelines for dealing with RDT negatives are needed (antibiotic use, referral). Securing legitimacy for private providers was important, through Ministry of Health approval and the appropriation of biomedical paraphernalia, in increasing trust and raising perceptions of status. The role of MoH as a gatekeeper could have promoted compliance, in order to retain endorsement and access to commodities.

2.6 Evaluation of RDTs in the private sector: a cluster randomised trial in Ghana. *Evelyn Ansah,*

Objective: Evelyn Ansah presented a cluster randomised trial Ghana that aimed to test the impact of the introduction of RDTs for malaria on the dispensing behaviour of chemical sellers (drug outlets). Results were preliminary and incomplete at the time of the meeting.

Context: Currently chemical sellers aren't allowed to test and should not be selling antibiotics. Formative research included a census of shops, qualitative studies, a household survey to understand perceptions of this idea and a baseline survey and set of direct observations in shops. At baseline 61% said their first option with fever was to go to a chemical seller. Around two thirds of sellers had received formal training in medicine. The direct observations showed that sometimes the person attending the shop was not the patient. Most often drugs were sold without asking any questions, mostly only documented the business parts of the transactions. Occasionally attendants took the temperature or did an injection.

Intervention: Community sensitisation was carried out in 30 communities, using two films with RDTs vs no RDTs. Training of chemical sellers for 4 vs 3 days, covering malaria case management, SOPs for the study, good sample taking and RDTs (intervention arm only), certificates (showing NMCP and pharmacy council). Safety boxes were given to shops, linked to the local health facility for disposal via a fieldworker. Did not supply ACTs, RDTs were provided for free.

Design: cluster randomised trial comparing those shops with RDTs versus standard practice. Research slides were taken in both arms. 28 day follow-up of all slide positive clients. Mystery client visits to every shop. Triplicate client record form to document test results, treatment, referral. A number of sub-studies were added to the trial, looking at careseeking for malaria at chemical sellers, health outcomes, referrals, impact of AMFm on availability and cost of ACTs, performance of RDTs under routine conditions, prevalence of malaria at shops.

Findings: No data on primary outcomes yet. Broadly, chemical sellers felt that clients were happy with the RDT, they liked the certificates (makes regulatory visits faster), and said they learned that not every fever was malaria. Very high referrals in the RDT arm (around three quarters of negative RDTs) compared with the control (only 1 referred). Refusals were high in the control arm where reference tests were taken with no immediate result given. Results of the test were delivered to the shop three days later and did not influence the chemical sellers' dispensing decisions. Variations were apparent by shop.

Challenges arising: rapid turnover of shop attendants meant frequent re-training was necessary; some sellers did not want to test before dispensing; some patients found positive results on re-testing in health facilities where they had been referred on account of negative tests for further assessment; there was a shortage of subsidized ACTs for adults during the trial; Discussions with chemical sellers at the closure of the trial on how this can be implemented outside trial conditions brought up the issue of who will pay for gloves and other logistics such sharps bins etc.

2.7 Findings from a programmatic evaluation in Cambodia. *Shunmay Yeung, LSHTM, ACT Consortium*

Context: Cambodia mixed malaria epidemiology in terms of transmission intensity and species of plasmodium. The programme of ACTs and RDTs started 10 years ago, when no ACT was commercially available, there were fake drugs and there were inaccurate malaria diagnoses. Village Malaria Workers are seen as key to deliver malaria interventions but challenges persist in accessing these VMWs, and in what they can do when test is negative, in 80% presenting cases. The private sector intervention uses subsidized socially marketed RDTs and ACTs with various supporting interventions including medical detailers. Currently run by PSI. Wholesale price of RDTs was dramatically reduced in 2009 to try to increase uptake of tests.

Objective: The Good Use of ACTs and RDTs in Drug shops (GUARD) study was designed to understand multiple aspects of how RDTs were deployed, performed, used in case management and perceived by providers. Included a census, RDT user assessment, mystery client study, FGDs, quality control of RDTs, temperature and humidity monitoring of RDTs.

Findings: of 217 outlets, half stocked RDTs, being bought and sold for consistently higher prices than intended by PSI; median price \$0.73. In mystery client visits, 42% were offered a test, half of whom offered to perform it themselves. Higher uptake of RDTs was observed in the West (Pailin and around) and by formally trained providers. Performance of tests was good, although difficulty was found with blood pipette, only about 40% waited for the full 20 minutes, only 16% disposed of sharps into sharps box (most wrapped and put into a plastic bottle). For negative tests, providers said typhoid was the most common cause, about a third said they would treat with antibiotics. FGDs suggested providers saw themselves either as simple sellers of drugs or providers of treatment, which would involve diagnosis. RDTs did not fit well into either practice. Quality assurance of RDTs showed they were good. Found that having RDTs in the private sector can improve surveillance of malaria – in 2012 >100,000 RDTs have been collected.

Conclusions: RDTs can be rolled out in the private sector as part of an overall strategy but may not be appropriate at all provider types. Ongoing supportive supervision and behaviour change communication are needed and incentives are important to consider.

2.8 Process and qualitative considerations in a programmatic evaluation. *Clare Chandler, LSHTM, ACT Consortium*

Clare Chandler presented some lessons learned from ACT Consortium RDT projects including in developing interventions and in evaluation of the impact of RDTs.

The term ‘complex intervention’ was applied to RDTs, first reflecting on the need for RDT interventions to change behaviour known to be well-established, second in terms of the complex settings RDTs are incorporated into especially with the ambiguous role of private providers in health systems, and third in terms of the need to take into account this complexity in the evaluation of RDT interventions, wherever designs sat on the spectrum of proof-of-principle to effectiveness study. The point was made that complexity did not only refer to technological and logistical issues, but also to social complexity – every component of a programme to scale-up RDTs has a social side, such as the symbolism of the paper of the referral form in Sian Clarke’s presentation.

The ACT Consortium projects invested significant resources in designing interventions around RDT introduction, based on formative research (qualitative and quantitative), theory, literature and with stakeholders. These typically involved provider-oriented and consumer-oriented behaviour change methods. One ‘lesson learned’ was the importance of mapping out the underlying hypotheses in the intended pathways of change from intervention delivery to outcomes being measured. This enabled the projects to tighten the interventions and evaluate pathways of impact. To do this, another ‘lesson learned’ by ACT Consortium projects was to undertake process evaluations to document the delivery (fidelity, dose, reach) of their interventions as well as to understand the process of change through qualitative and quantitative methods, in order to establish whether change (or no change) could be plausibly attributed to different components of the interventions delivered. An example was given of the GUARD study in Cambodia where provider interpretations of their roles helped to understand the relatively low use of RDTs. Finally, another ‘lesson learned’ in ACT Consortium projects was the need to document and consider context of trials or pilots in terms of variation (differences between clusters), attribution (how the mechanism of change occurred and what else might have affected the change observed) and generalisability (what was specific to this context that supported/hindered change and how it might be recreated elsewhere).

2.9 Experience with RDTs in three outlet types in Myanmar. *Tanya Shewchuck, PSI*

Context: PSI works across Myanmar and is in a unique position to work across many different townships. Mixed transmission in the country with artemisinin resistance containment activities ongoing. Renewed focus on diagnosis and treatment at scale with related BCC support.

Intervention: Case management activities working with GPs and village health workers as a PSI social franchise, not a closed franchise (i.e. allowed to work with others outside of PSI). This method intends to improve quality of care, provide ACTs and RDTs along with other treatments. For GPs, activities involve branding (SUN Quality Health), training with opportunities to network (with no incentives), monthly

reporting on services supported by PSI (not all providers report well), collecting used RDTs and cross-checking these with monthly reports. For VHWs, give ACTs and RDTs for free, and encourage to refer into the SUN Health system.

Findings: Reports from GPs suggest high adherence to malaria test results, but figures don't necessarily present treatment given. An alternative method might be useful to evaluate this, e.g. mystery client or exit interviews. For VHWs, assessment of case management used observed simulated consultations using a mannequin. Results showed improvement in case management by VHWs although not as good as GPs. Country wide results using ACT Watch survey methods showed availability of diagnostics were highest among health workers and private health facilities, where PSI works.

Upcoming: A pilot project is about to start, with the aim to compare effectiveness and cost-effectiveness of interventions to improve RDT use. 3 arm study: (1) RDTs only, (2) RDTs including free RDT for every 5 (3) as above with intensive support supervision. Training across study arms in the form of on-the-job training. Challenges include trying to design training, including adapting IMCI; supervising medical detailers who are visiting the shops to give the training; working in the regulatory environment.

2.10 Establishing malaria case management services in private sector medicine stores serving city slums – Early lessons from Monrovia, Liberia. *Richard Allen, MENTOR*

Context: Richard Allen presented a project to introduce RDTs at medicine stores in Liberia. In Liberia, 23% fever cases are treated in the private sector. In this study, introduced in densely populated areas of informal housing, suspect >50% fevers treated in private sector.

Design: The project involved mapping, training, supplies & accounting, monitoring & supervision, IEC/BCC, waste management, operational research (annual cross sectional household survey of treatment seeking, 3 monthly mystery shopper and exit interview, annual HAI and ACT Adherence studies). Training involved training up 'master facilitators' to train dispensers and registered shops in malaria and differential diagnosis, data recording, counselling of clients to increase awareness of optimal malaria treatment and convince patients to accept RDT and adhere to results. The project involves careful management of the supply chain by MENTOR with a plan to hand over to partners in country. RDT price retailed at \$0.27, ACT adult dose \$0.47 and child dose \$0.33 but the plan is to increase price in the future to help achieve sustainability. The intention is to increase demand for diagnosis and response to RDT results. 40 community volunteers are disseminating key messages and supporting referrals.

Implementation: To date, 126 trained dispensers from 97 registered medical stores and pharmacies (MS/Ps) enrolled and having purchased stock. MS/Ps are able to sell a wide range of over the counter drugs and antibiotics under licence. Dispensers are obliged to only sell subsidised ACT after a positive RDT result. According to protocol customers with negative RDT results are meant to be referred to a public facility, validation of this will be provided during mystery shopper surveys. Project subsidized RDTs and ACTs are provided by the manufacturer in different packaging to MoH supplied formulas so that leakage can be tracked. IEC/BCC activities are due to start imminently. Branding includes 'I have malaria; how do you know?' and a "get tested before treatment.' Funding for the pilot is due to continue until March 2014. Three legislative changes have been made to enable RDTs to be used in the private sector, and the project feels there is strong governmental support for the initiative beyond this pilot.

Findings: RDT usage since September 2012: rapid increase since start, fluctuating seasonally. 29.9% RDT positivity rate, with 94.9% going on to purchase a subsidized RDT, 3.1% of customers opted for a different

antimalarial. 53% of customer base is adult with 23% U5, mostly evening trade. Few treatments to children <1 year, interpreted as going to public facilities. Data from the baseline HAI study covering all sale points for malaria medicines in Monrovia and Kakata district. Most widely available is amodiaquine (89%) and ASAQ (65%) at ~\$0.88 leaked from MoH, few artemisinin monotherapies are available and RDTs were available for purchase in 17% of sale points.

2.11 Increasing access to malaria diagnosis and treatment in Zambia. *Elizabeth Streat, Malaria Consortium*

Context: Elizabeth Streat presented experiences of introducing RDTs at drug dispensers in Zambia. In this context, there have been low rates of diagnosis and treatment; many fever cases seek treatment in private and informal outlets (20%). Malaria Consortium are part of the 'ZAAI': Zambia Access to ACTs Initiative, funded by DfID and World Bank, to improve access and uptake of ACTs through the distribution of subsidized ACTs and RDTs in private, public and community sectors. This talk based on accredited drug dispensing outlets in hard to reach districts. The project was implemented in 4 districts over one year.

Design: ACTs and RDTs were subsidised at the wholesaler level and drug dispensers purchased these through normal distribution channels (most dispensers went to Lusaka to get their supplies) to sell at a recommended retail price. Pharmacies, drug shops and grocery stores underwent training and accreditation. ACTs were intended to be overbranded to prevent cross-over between public and private sectors. The intervention also included community sensitisation. The evaluation consisted of exit interviews, mystery shopping (4 scenarios: adult presenting with fever, in a hurry, with financial constraints, on behalf of someone else) and household surveys on health seeking behaviour.

Implementation: 63 outlets were trained and accredited, with 58 functioning. Most were close to district town. The programme contrasted with Tanzania's ADDO project, where staff had longer training and more commodities were available. In Zambia, staff at shops were different, with a rapid turn over, and only a few over the counter drugs could be sold. Overbranding was difficult; the project added detailed printed instructions to packs of ACTs instead. BCC activities were carried out in 2 districts including promotional materials, branding shops and on radio shows, dramas, community dialogues. Branding included 'the health shop' and a focus on 'test before treating.'

Findings: Evaluation of BCC suggested it had an impact: recognition of shops by poster, sign or sticker, recognition of 'test before treat' message. Evaluation of shop practices: 5.6% were overpaying for ACTs, 18% overpaying for RDTs, 35% overpaid ACTs with prior RDT, 72% overpaid ACT without prior RDT. Differences were found between exit interview and mystery client methods. Dispenser questionnaire: 99% got supplies from Lusaka, most customers came from within a 5km range, most reported an increase in revenues from RDTs. 95% said they had stock outs over 1week for ACTs. Many said the ZAAI programme increased profitability, customer satisfaction, provider knowledge and attracting customers. Challenges for dispensers: record keeping, workload, convincing customers, profitability especially in having no alternative medicines available for treating RDT negative cases. Additional challenges: stockouts of ACTs and RDTs; referrals: the original plan was to refer patients to public sector but drug dispensers treated rather than referring. This was interpreted to be due to public workers not being aware of the programme.

2.12 Testing the feasibility and uptake of subsidised RDTs in Uganda and Zanzibar. *Nora Petty*

Context: Nora Petty described two trials undertaken by CHAI in Uganda and Zanzibar to introduce RDTs to private outlets. The two settings are extremely different in terms of malaria epidemiology, with Eastern Uganda being high transmission and Zanzibar very low transmission, and access to public health facilities.

Uganda

Design: The goal of the study was to investigate the feasibility and impact of the distribution of RDTs through private drug shops. CHAI sold RDTs at a subsidised price to a distributor in Kampala who then agreed to sell to eligible drug shops in the intervention area through their local wholesaler at a set price. The intervention also included training of all the participating drug shops and BCC in randomly assigned villages 5 months after training. The evaluation assessed availability and price of RDTs, adherence to test results, and quality of RDTs in the shops. The methods included household surveys, exit interviews and monthly monitoring visits. In total, there were 58 treatment villages (with 92 registered shops enrolled) and 36 control villages.

Findings: There was a big variation in uptake of RDTs between the different drug shops: many shops did not procure any RDTs after being given the first free box, while six shops accounted for over a third of all procurements. Their level of interest in RDTs was also markedly different, e.g. one wrote a sign on the shop advertising the availability of testing while others seemed disinterested. Further analysis will be undertaken to see what factors may have incentivised stocking and selling RDTs. Customers reported \$0.40 as the most common price paid for RDTs, which was similar to the price paid for microscopy in private sector. Among RDT positive patients, more than 80% received any antimalarial, but only around a third received an ACT. RDT negative patients were significantly less likely to receive any antimalarial. Provider performance of RDTs was good (e.g., glove use, accurate interpretation of tests), but may have been reinforced by the monthly monitoring visits. Data are pending on impact of the BCC campaign on fever diagnosis, RDT sales and appropriate treatment, as well as the community-level impact of RDTs on confirmatory diagnosis rates. Some challenges included access to the RDTs by drug sellers in the district, which led to many of the drug shop owners purchasing RDTs from other shops locally at a marked up price. Additionally, there were a large number of unregistered shops in the intervention area that could not participate in the project, which may reduce the overall community-level impact if consumers continued to seek treatment in the shops without diagnosis.

Zanzibar:

Design: The goal of the study was to evaluate the introduction of subsidized RDTs in the private sector, combined with stricter regulations, on ACT targeting. In this study, only higher-level facilities were allowed to participate. CHAI trained selected staff in these facilities how to perform RDTs. There was no BCC or advertised RRTs. The RDTs were subsidized and distributed through one of the AMFm first-line buyers. ACTs were reclassified from over the counter (OTC) to prescription only. The Zanzibar Food and Drug Board (ZFDB) enforced the removal of all antimalarials from OTC shops through a series of inspections, and CHAI paid them a performance-based incentive. The pre- and post- evaluation assessed the proportion of suspected malaria patients receiving a test, RDT availability and pricing, treatment seeking, and availability of antimalarials at OTCs. Methods included household surveys, mystery client surveys, and health facility surveys. Unguja Island was the intervention while Pemba Island was the control .

Findings: The findings presented were from a mid-line survey conducted six-months after the start of the intervention. Sales records from the first-line buyer indicated an increase in subsidised RDT sales over time. Additionally, two rounds of regulatory visits had been conducted by the midline survey; a significant decline

in stocking of antimalarials by OTC shops was found by both ZFDB visits and the mystery client survey. However, the proportion of suspected malaria patients accessing care at OTC shops was unchanged at the midline survey. There was no evidence that the proportion of health facilities using RDTs had increased by the midline. Mean retail price decreased between the baseline and midline surveys, but was still significantly higher than RRP. At the midline, results from the household survey indicated that there was an overall decrease in the use of diagnostic testing, which was interpreted as potentially due to a stock-out in the public sector where testing significantly decreased at the time of the survey. Results from the endline should be available in mid-2013.

2.13 Prevalence of malaria parasitaemia and purchase of Artemisinin-based combination therapies among drug shop clients – Tanzania, 2012. *Melissa Briggs, Malaria Branch CDC*

Context: Melissa Briggs presented findings from a survey of patients at drug shops in Tanzania. In 2010, less than a third of children under 5 received ACT within one day of fever onset. Careseeking is around 41% to private sector facilities or drug shops, 19% to government health facilities. A study in 2004 found 42% malaria prevalence in children presenting with fever at drug shops. Tanzania was part of the AMFm beginning in 2010, and the Accredited Drug Dispensing Outlet programme had been rolled out in 15 of 21 regions at the time of this study in 2012.

Study design: Cross-sectional drug shop malaria prevalence study in Mtwara and Mwanza. AMFm was available nationwide. ADDOs existed in Mtwara, but not Mwanza. RDTs were available in the public sector, but not in drug shops at the time of the study. Data collection occurred during the rainy season, March-May 2012. Patients were sampled from all registered shops, including ADDOs in Mtwara and non-ADDOs in Mwanza. Methods included a survey of drug shop attendants; and assessment of clients exiting the shops including exit interview, a physical examination and testing for malaria (RDTs and microscopy, PCR for discordant results). 777 clients were enrolled from 73 shops.

Findings: 100% of shops in Mtwara stocked ACTs, 75% in Mwanza. Most providers had completed secondary school. Of clients attending, >60% were >15 years. Mostly, no prior treatment had been taken before coming to the drug shop. Some had gone to the public sector where they were diagnosed and were told to come to the drug shop to purchase drugs. There were drug stockouts in the public sector at the time of this study. 20% of patients purchased ACTs, three quarters of which were subsidised. Reference blood slides showed 14% of patients had malaria, with a higher prevalence in the 5-14 age group than other ages. Of those who purchased ACTs, 80% were malaria negative. Children under 5 were more likely to receive an ACT, and ACTs were more likely to be purchased if the client had visited a health facility first or if the provider had >5 years of experience. Paracetamol and antibiotic purchase had a negative association with ACT purchase. Clients with malaria parasitemia were more likely to purchase an ACT in Mtwara than in Mwanza. The study was unable to assess the impact of the ADDO program because this was correlated with region. In the Independent Evaluation of AMFm Tanzania saw improved availability of ACTs, increased market share, but amongst those seeking fever at household level no change in number getting ACTs overall.

2.14 Scaling-up low cost RDTs: early experiences from Tanzania. *Nora Petty*

Context: CHAI is in the process of helping the Tanzanian NMCP to scale-up access to RDTs in formal private outlets (e.g., hospitals, clinics and dispensaries) nationwide and Accredited Drug Dispensing Outlets (ADDOs) in a pilot region. The impetus for the project is the declining prevalence of malaria in Tanzania, which has resulted in over-treatment of malaria. Data from the AMFm Independent Evaluation shows limited availability of RDTs in the private for-profit sector.

Intervention: At the start of the project, CHAI discovered that private for-profit importers were procuring RDTs for a significantly higher price than the global median public sector price. There are several reasons why this was the case (e.g., small volumes, lack of market information, higher risks). To address the issue, CHAI negotiated 50-75% price reductions for *Plasmodium falciparum* RDTs for the Tanzanian private sector market with five of the major RDT suppliers. The agreement stipulates that the manufacturers will lower their prices for the period of the one-year pilot, while CHAI will work with in-country partners to maintain low margins and promote the products. In order to access this preferred pricing, in-country distributors have also signed MoUs with CHAI committing to low margins.

For the national rollout (only formal facilities), CHAI is working with the NMCP and JHU to design and rollout a consumer marketing campaign to increase knowledge and demand for RDTs. The campaign includes the promotion of a 'quality' logo (which will also be located on the participating RDT boxes), a national level radio campaign, a launch event, and community-level activities. This will correspond with the roll out of a national campaign for the promotion of public sector RDTs. Additionally CHAI is co-hosting with the participating distributors a voluntary one-day training for formal facilities in urban centres in four regions in Tanzania. The training will include information on how to perform RDTs with refresher training on appropriate treatment following diagnostic results. This will also be an opportunity for the co-hosting distributor to promote their particular RDT brand.

In the pilot districts in Morogoro region, CHAI will look at whether ADDOs can safely and effectively use RDTs, and the comparative uptake of RDTs in low-cost (~1000Tsh) versus subsidized (~500Tsh) regions. CHAI will provide an in-depth two-day training for all of the participating ADDOs. Only ADDOs that successfully complete the training will be able to buy RDTs from local wholesalers. Additionally CHAI may include additional local demand generation activities, although the pilot region is expected to benefit from the national-level activities.

Findings: The following is preliminary findings from the baseline survey. At this time, most people seeking care for febrile illnesses in ADDOs were found to be using these shops as their first point of treatment. Despite a strong feeling from patients that they should be tested for malaria, almost half of the patients reported that they feel that they should still take an antimalarial after a negative test result. Even for a positive test, very few ADDO dispensers knew the correct dose of ACTs for different age-weight bands. The reported median willingness to pay for an RDT and subsequent treatment is about the same as the current median cost for all the treatments that patients purchase. Cost could be a potential barrier to RDT uptake particularly if the cost of an ACT (the most popular antimalarial) increases post-AMFm.

2.15 Experiences from RDTs in the private sector in Nigeria. *Jennifer Anyanti & Ernest Nwokolo, SFH*

Context: The Nigerian NMCP aims to abolish presumptive treatment of malaria. However, there are other policies that need to change, for this to happen. Most people go to patent proprietary medicine vendors (PPMVs) as their first port of call, which are supposed to sell over-the-counter drugs. PPMVs are either trained through informal apprenticeship over around 7 years or PPMVs are opened by village health worker or nurses, working at a government or private facility in the day and near their homes they have shops. They are registered either by the pharmacist council or the state government. They can be regulated by either, meaning they have a risk of being closed down and arrested if selling anything deemed inappropriate by either body who monitoring their shop.

Study design: To determine the feasibility of lower level health workers, mainly PPMVs to perform malaria RDTs and comply with guidelines. Project was in 6 states, one from each geopolitical zone. Quantitative (provider survey, reference slides and exit interviews) and qualitative evaluations (FGDs).

Intervention: SFH have distributed 3 million RDTs through private and community based providers. PPMV training focused on identification of malaria using RDT, counselling skills, preparing blood slides for research purposes. RDTs were provided for free, no ACTs were provided. PPMVs were chosen to have already worked with SFH, particularly on ACT training. Legally, PPMVs are not supposed to take blood, so the project got permission but only for adults to be tested, not children.

Findings: Contrary to the expectation that PPMVs are illiterate, the qualitative study revealed that most are literate and know how to refer. Most clients purchasing antimalarials had headache (81.4%), then fever (62.5%). Most came after 1 day of onset of symptoms. Noted that many people know how to recite symptoms of malaria and in spite of test results want to take antimalarials. Interpretation of results was good, although interpreting negative result 72.3%. Good performance was observed in carrying out the tests and taking safety precautions. Of those presenting with symptoms, 18% tested positive for malaria. Clients who were negative were supposed to be referred to the health facilities but only 18 referral cards were retrieved from facilities. Mostly they said that there was no point in going for the referral with a negative result. 71% got an ACT. PPMVs and clients both preferred the plastic covered lancets to the metal ones. The hypothesis was posed that RDTs may demystify malaria in the population.

Additional study: The 'REMEDI' pilot study with UCSF funded by Exxon Mobil in an urban area of Oyo state, Nigeria. RDTs were introduced at PPMVs (39%) and pharmacies (61%). Exit interviews were carried out with adults who had purchased malaria medication and a short follow-up survey was done. Only 4% of patients who already purchased ACTs were positive for malaria. Found >60% were willing to pay \$3.30 for an RDT. At follow-up, of those who had been RDT negative, 72% said they did not take the drug but would keep for another time.

3 Panel discussion with Country Representatives

Due to visa problems, several country representatives were unable to attend. Tanzanian and Ugandan country representatives were asked to respond to the question, 'after this meeting, what information would it take for countries to scale up diagnostics in the private sector?'

3.1 National Malaria Control Programme, Tanzania. *Fabrizio Molteni*

Fabrizio Molteni outlined the private sector projects with RDTs starting up in Tanzania and outlined implications and further challenges. Reflecting on the presentations in the meeting, he noted that the projects have used a lot of resources, particularly human resources. It is important to not think about the private sector without thinking about the public sector first. It has taken 4 years to scale up RDTs in the public sector in Tanzania. In the private sector, two initiatives are starting: CHAI's (described above) and a recently signed UNITAID project. Beyond this, a further 35% private facilities will need to be reached. The aim is for AMFm phase 2 aim to cover 100% formal private facilities. Key implications for Tanzania in the scale-up of RDTs in the private sector were outlined as follows:

Operational. The operational implications of scaling up RDTs in the private sector include the magnitude of this sector, with >6000 ADDOs and >900 formal providers and bottlenecks in procurement and supply management that have led to stock-outs. The cost of RDTs went down three times in the last year which gives more hope for sustainability. One important issue that wasn't discussed in depth during this meeting was quality assurance. The logistical challenge of trying to scale-up a scheme through districts which would have to expand to the private sector was noted. Want to introduce RDTs in urban areas where the intervention can be maximised as 75% facilities are based there. The plan would be to start in lower transmission areas, where introduction of diagnostics has the greatest potential to reduce over-diagnosis and over-treatment of malaria. A training package needs to be developed, working with CHAI on this, as well as BCC. Challenges also arise in variation in willingness to pay across the country and in setting up monitoring & evaluation efforts.

Policy. Regulatory framework and boards restrict efforts to deliver RDTs, especially to more peripheral settings. A waiver given for the CHAI project introducing RDTs and the hope is that this will create a case for further discussion for the Laboratory Board. The private sector is featuring as high level in new strategic plan with the hope that this can influence regulatory boards. By end of the pilot phase the NMCP hopes to be able to re-discuss whole package and the informal private sector, including certification of those performing tests.

Equity. Around 20% of the country cannot afford or access malaria treatment. The private sector cannot reach all sectors as ADDOs are primarily in urban areas and formal private facilities are only in three cities. Community involvement is also needed to reach these areas. Need to integrate public, private and community initiatives to address equity issues.

Logistical implications. Logistics in terms of ordering, quantification etc are a challenge, although there is already a mature first-line buyer. Final integration of the AMFm mechanism into the country grant requires good monitoring of a sector used to dealing with goods not services – need to learn experiences of this, e.g. through mobile phones, of how to scale-up quickly. Intend not to overburden the district system but support it by contracting out.

Challenges and gaps. It will be a challenge to maintain retail prices of low-cost RDTs. Need to address issue of what to do with negative results, especially in the informal sector. High turnover of staff in private sector so need to set up frequent training and supervision.

3.2 National Malaria Control Programme, Uganda. *Agaba Bosco*

Agaba Bosco reflected on implications for the Ugandan NMCP of projects presented at the meeting. He noted that many malaria endemic countries' health systems are focused on the public sector while a significant number of patients seek treatment in the private sector. But, some improvements in quality of care and increased availability of commodities has increased treatment seeking in the public sector. It was noted that in the current uncertain and unpredictable donor funding, it would be important to design interventions and approaches that are cost-effective and feasible that can be easily implemented by health systems/Governments in malaria endemic countries. A good proportion of governments are still struggling to fund their public health systems in the public health sector, for long-term sustainability plans it's important to understand how far such limited governments funding can be overstretched to fund their private sectors as well including the scale-up Rapid Diagnostics Tests.

During panel discussion, he identified the following Critical issues that were not adequately addressed by the studies presented:

- Non-malaria febrile illnesses: availability of clear referral systems from peripheral lower facilities and private drug outlets to higher level facilities/hospitals will be important, equipment of higher level facilities to be able to investigate NMFI and availability of alternative treatment options to treat NMFI. This should not be an issue for NMCP alone so should bring in other players in the health system.
- Most data presented by malaria endemic countries comes from the public sector and this may not provide a true malaria picture. Data collection and reporting systems from private sector needs to feed into the current public health sector data (HMIS etc) if the clear country picture of interventions is to be well understood.
- All studies/Projects presented were done in an ideal 'project mode' where everything is flowing excellent, resources etc. It will be different when thinking of a national public health systems with all the well known operational and systems challenges. The studies don't give good evidence for how governments can easily and very soon take over these programmes.
- Donor funding required. Currently there is uncertain donor support. One year no-cost extension from AMFm but then what? Risk of another policy that is going to be shelved.
- Wide variation in private sector policies across countries.
- How much should we subsidize RDTs?
- Need to consider distribution systems in a scalable sense, rather than the project-specific methods for bringing in RDTs. Each of the studies presented had its own way of managing its RDTs supplies and distribution working outside the national distribution system. We need to understand how Private sector supply chains will work and this most importantly the fact that the AMFm supply systems has been leaping with gross challenges.

- Supporting interventions exist in public system needs to be replicated for private system, how much will this cost and is it affordable? This cost should not just be computed on the RDTs commodity subsidy alone but the whole package.
- Studies have generated good evidence but not yet strong and concrete enough for policy change/shift, with several gaps and questions yet to be addressed.

4 Synthesis of Q&A and panel discussions: common emerging themes

The findings presented by the various partners attending this meeting demonstrated the potential for RDTs to be procured, subsidized, used safely, sold to clients, used to guide antimalarial dispensing and to be appealing to customers. The mixed findings from across studies, which used different interventions as well as different evaluation methodologies, provided an opportunity for rich discussion of the factors driving and hindering successful implementation of RDTs. The following summary points were agreed:

- The presentations represented a spectrum of studies from proof of principle to effectiveness, skewed towards more the former.
- There were many small scale studies, mainly in African countries.
- Much is preliminary data.
- Most were short term studies with a large amount of human resource support for implementation
- Study outcomes were targeting ACT treatment rather than management of febrile illnesses.
- Most were based on the model of RDTs subsidised at country level in a context of subsidised ACTs.

The preliminary nature of evidence presented during the meeting meant that clear definitions of best practices for the scale-up of RDTs in the private sector could not be made. However, many lessons learned in these pilots were shared and these led to agreement on issues to consider as potentially important in supporting the scale-up of RDTs in the private sector as well as identification of gaps for further thinking and research. These can be grouped under the following headings:

- (1) Ensuring availability for affordable, quality assured RDTs to be scaled-up sustainably in the market**
- (2) Ensuring safe practices in RDT use**
- (3) Supporting uptake of RDTs and adherence to results by providers**
- (4) Encouraging population demand for RDTs**
- (5) Contextual factors not easily amenable to change**

4.1 Ensuring availability and support for affordable, quality assured RDTs to be scaled-up sustainably in the private market

Procurement and supply chain. CHAI shared experiences of procurement of low-cost RDTs for Tanzania. This required a complex web of agreements with importers and distributors. There was varied, but limited, experience with RDTs in the supply chain; most projects had introduced RDTs more directly to providers themselves. CHAI's experience in Uganda suggested that drug sellers would not travel to get centrally located RDTs. In Zambia, Malaria Consortium experience was that most sellers got supplies from one wholesaler in Lusaka. The cost of stocking, transport and profit margins through supply chains require further consideration. Methods to monitor subsidies was identified as an area for further research.

Affordability. A wide range in prices paid/charged for RDTs was apparent across the presentations. CHAI's literature review suggested prices paid/charged for RDTs were consistently higher than in willingness to pay studies. Further studies were said to be needed to identify willingness to pay in practice, alongside costs of ACTs, to inform countries on pricing structures.

Quality of RDTs. Some projects incorporated quality testing of RDTs, or replacing tests found to be faulty by drug sellers. However, no systematic quality control scheme was reported as piloted. FIND is carrying out a study on positive control wells (PCWs) which may help to test batches of RDTs to give confidence in quality. Tanzania is considering scaling up a quality assurance of tests system through district health teams. This will require a responsive system, including troubleshooting, that may have challenges for feasibility, but will also be required for public health systems rolling out RDTs.

RDT ancillary items. Gloves, buffer solution, sharps and so on all require supply chains, and potentially to be purchased by customers in addition to the test. Potentially bundling of these items, with single-use buffer droppers could be trialled to improve uptake and affordability.

Governmental support. It was noted a number of times that support of governments and professional bodies (i.e. medical and pharmacy boards and societies) is essential for such an initiative, to help with regulations and policies as well as to have ownership over the initiative to integrate it and ensure funding support for its various supporting requirements in a sustainable way.

Longer term effects. The longer term and broader effects of introducing RDTs into drug shops was identified as requiring consideration and potentially research.

4.2 Ensuring safe practices in RDT use

Regulation. The challenges of regulations not allowing blood testing, or clinical diagnosis, or the dispensing of other drugs at drug shops, were discussed at length. These appear to differ between countries and between provider types within the private sector. Professional bodies also control the ability to introduce RDTs outside of laboratories and formal health facilities. The involvement of regulators in an oversight capacity was suggested to be important to support future integration of RDTs and MNCP policies into regulatory changes.

Training and accreditation/certification. The importance of training, and re-training, providers was noted. With high turn-over of staff at drug shops, the feasibility of re-training to ensure safe RDT use is a challenge outside of 'project mode.' Monitoring visits could provide opportunities to re-train providers.

Monitoring. Mechanisms for monitoring safety of RDT use were not clear, beyond 'project mode.' Could be linked to quality control of RDTs. Methods for data recording to monitor RDTs in the private sector was also considered important, and ideally linked to public HMIS. The cost-effectiveness of different models of this was identified as an area for research.

4.3 Supporting uptake of RDTs and adherence to results by providers

Training. Training was a core component in most pilot studies presented. Adherence to results was a focus of messaging in some, alongside building knowledge, skills and confidence to diagnose malaria and non-malarial cases. Incentives to participate in training were discussed: in the Uganda (Mbonye) study,

participation was high without formal incentives, although this may have been due to the project being affiliated with the MoH. Elsewhere, poorer uptake of training affected ability of the projects to implement RDTs effectively.

Supervision. This was considered a key component of some interventions, although the nature of supervision required to support RDT uptake and adherence remains unclear. Further studies to compare the cost-effectiveness of different training and supervision packages were suggested.

Incentives. Financially, the importance of profit margins for providers if RDT scale-up was to be sustainable was discussed. This might also be achieved through service fees. It was noted that for providers who sell other drugs beyond antimalarials, the negative result may not decrease profitability, but where no other drug could be sold, RDTs could result in a loss for the provider. Research into co-packaging ACTs and RDTs was suggested. Non-financially, alignment with health professionals and the legitimacy this conferred to drug sellers appeared to be an incentive to use RDTs. The high adherence to results in the Uganda (Mbonye) study may have been in part a means of maintaining alignment with the MoH, and the potential to continue to secure resources and legitimate status.

Trust in test results. Several projects reported provider concerns over the accuracy of RDTs, particularly negative results. This was related in part to perceptions of malaria epidemiology, with negative results being unexpectedly common, reflecting expectations of higher malaria prevalence. It was also related to conflicting results from microscopy, which was sometimes carried out subsequent to RDTs, with a positive result conflicting with a negative RDT. Meeting participants discussed the need to assure the quality of RDTs through quality control, the need to communicate to populations about declining malaria prevalence and also the need to improve standards of microscopy at public and private facilities, where false positives seem common. Without microscopy improvements, it was argued that RDT programmes (in the private or public sector) could be undermined.

Ability to treat negative results, and referrals. For providers who had alternative medicines to dispense, treating negative RDT cases appeared simpler than for those who had no alternative treatment. A key challenge was the action to recommend to providers who were not allowed to treat beyond malaria in the case of RDT negative patients. Most projects recommended referral into the public system, but this was problematic in a majority of cases, with referral being infrequently carried out (except in Ghana, noted below). The meeting participants discussed the need for alternative guidelines for dealing with RDT negative cases, such as to use the iCCM algorithm for diarrhoea and pneumonia for children, and potentially to ask adults with fever only to return in 24 hours, on the basis that most fevers are self-resolving. Further research on non-malarial febrile (and non-febrile) illnesses was identified as a priority, to feed into guidelines for practice for private providers. The conflict between regulation and practice was noted, however, with many providers selling drugs they were not officially allowed to do. Regulation therefore also plays a role in dealing with RDT negative cases.

Public health system characteristics. A number of health systems characteristics were identified as having the ability to support or hinder RDT programmes in the private sector. Related to issues discussed above, the quality of microscopy had the potential to undermine RDT results and the strength of public sector quality control, training and supervision is likely to affect ability to scale-up such measures to the private sector. Beyond this, the ability and willingness to respond to referrals from private providers was identified as a major issue. In terms of ability, when fever case management at public facilities relied on presumptive malaria treatment, this was found to undermine trust in RDTs and drug shop abilities. In terms of willingness, public health workers were identified as being unwilling to react to referrals from drug shops, either due to not recognising/knowing about the programme or due to reluctance to recognise drug sellers as part of the formal health system, considering them outside of the system. In Ghana, however, a different situation was

found, with high levels of referral from chemical sellers. Here, the health insurance system can be seen as linking private and public systems, with referral forms a legitimate link that formalises the seller's role. This may in part explain the difference seen in this setting.

Careseeker characteristics. A major challenge identified across different settings in encouraging RDTs for clients was that the care seeker was not the patient, but a representative, often a parent or child. In these cases (a reasonable proportion in some settings), RDTs could not be performed. In other cases, the patient may be present but refuse an RDT. Guidelines need to take into account these cases, and provide alternative recommendations to the RDT.

4.4 Encouraging population demand for RDTs

Behaviour change communication (BCC). BCC was discussed frequently during the meeting. It was a component of most interventions, and appeared to vary in its nature from branding commodities and shops, to advertising, to educational approaches through community officers and leaflets. No studies reported comparing BCC approaches, which does not enable us to interpret the potential success of RDTs without patient-oriented communication. However, most presenters interpreted BCC efforts as important to success. Key messages suggested were 'test before treating', 'not everything is malaria', 'RDTs could save time and money', 'RDTs find the true cause of fever.' Further research on the need for, nature of and comparisons between BCC efforts was called for.

Treatment seeking. Where people seek care for fevers, and where antimalarials are purchased was recognised as central to the issue of improving fever case management and targeting ACTs through the use of RDTs. Studies presented suggested that many of those purchasing ACTs did not have malaria, and often did not even report fever, but also that many with malaria parasites had not purchased antimalarial drugs even in an AMFm setting. This suggests that further work is needed to improve both access to ACTs and to improve targeting of ACTs. The possibility of treatment seeking shifting according to availability of different commodities was noted, with hypotheses posed that RDTs could either attract or discourage treatment seeking to shops offering and promoting the tests. Further research into the characteristics of individuals seeking care at different sources and rationales for these choices is required to target messages for improved fever (and headache, joint pains) case management, particularly for adults who consume the majority of ACTs unnecessarily.

4.5 Contextual factors not easily amenable to change

Epidemiology. The prevalence of malaria formed an important backdrop to the results as well as implications for scale-up. Low endemicity areas may be most cost-effective to use RDTs in order to reduce ACT use but in this setting results suggest RDT results may be less trusted if expectations of malaria endemicity is not in line with true prevalence.

Timeframe. Experience shared from RDTs in the public sector suggested acceptability of RDTs and their results may increase over time. Early pilots may show lower adherence than scaled-up programmes. A suggestion was made for policy analysis work to identify ways to speed up the process of change, as was done between first-line treatment for malaria. A long-term commitment would be needed for RDT scale-up, drawing on examples of the AMFm pilot and RDTs in the public sector.

Project effect. Attention was drawn to the need to interpret results in the context of projects, which have greater resources and can deliver more intense interventions as well as altering behaviour by virtue of affiliation with a project, e.g. run by the MoH. This leaves a gap in knowledge for sustainability. For example, projects could retrain new staff during the project period, but at scale the rapid turnover of drug shop staff could be more difficult to manage. Projects working with the same group or area over time may also produce results that are less replicable beyond that intensive setting.

Provider types. The number of different provider types and their ability to be a part of an RDT programme will affect coverage of an RDT intervention to the population. Many projects were working with registered shops that were more than equalled in number by unregistered shops providing different and competing services. An understanding of these providers, as well as of treatment seeking, will help to project whether investments in RDTs and a system to support them will be cost-effective.

Functionality of the wider health system. On a broad scale, there were frequent references to the need for a strong health system to support the scale-up of RDTs in the private sector.

4.6 Next steps

Based on the information presented at this meeting, the participants recommended the follow-up actions listed below:

1. For those studies/pilots that have not yet been published, the group encouraged the investigators to complete their analyses and pursue publication as soon as possible.
2. The preliminary findings of this meeting will be presented to the RBM Board at their upcoming meeting in June 2013.
3. There was an agreement that a follow-up meeting would be needed, possibly early in the next year, to review further results from some studies and pilots that were ongoing, as well as the UNITAID-funded pilots and other pilots that were to be scheduled to begin in the near future. The goal of such a meeting would be to draw additional and more definitive information on lessons learned, best practices, and major bottlenecks for scaling-up case management services, including diagnostic testing for malaria, in the private retail sector.

4.7 Concluding remarks

Dr Lawrence Barat thanked participants for coming together, for their knowledge and commitment and for sharing findings and ideas. Thanks were made to the organising committee both present and in his absence David Schellenberg and Rebecca Tremain for organising the logistics. Thanks to RBM for cocktail party and for support for travel expenses for country participants.

Later this year or early 2014 it may be appropriate to come back together to hear experiences from UNITAID pilot and final analyses from the studies presented here.

Jan van Erps thanked participants, on behalf of the RBM Secretariat, for attending and sharing.

List of Participants

No.	Name	Organization
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2	David Schellenberg	ACT Consortium
3	Sian Clarke	ACT Consortium
4	Anthony Mbonye	MOH Uganda/ACT Consortium
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6	Lindsay Mangham-Jefferies	ACT Consortium
7	Shunmay Yeung	ACT Consortium
8	Clare Chandler	ACT Consortium
9	Evelyn Ansah	Malaria Capacity Development Consortium
10	Tanya Shewchuck	PSI
11	Elizabeth Streat	Malaria Consortium
12	Grace Nakanwagi	Malaria Consortium
13	Sylvia Meek	Malaria Consortium
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15	Nora Petty	CHAI
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19	Jennifer Anyanti	SFH
20	Edmund Rutta	MSH
21	Jason Lane	DfID
22	Sandra Incardona	FIND
23	Ian Boulton	AMFm Task Force
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25	Katie Eves	Mentor
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27	Agaba Bosco	NMCP Uganda
28	Melissa Briggs	CDC
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