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EVALUATION OF DFID-CHAI MARKET-SHAPING FOR ACCESS TO SAFE, EFFECTIVE AND AFFORDABLE HEALTH COMMODITIES

Final Report

e-Pact Consortium

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Acknowledgements

The evaluation of the DFID-CHAI 'Market-Shaping for Access to Safe, Effective and Affordable Health Commodities' programme was undertaken in three phases. This is the Final Report, reflecting work conducted in all phases.

The evaluation comprised wide-ranging data collection, including key informant interviews (KIIs) and country case studies, and analysis. As a result, we have drawn on staff at DFID and particularly at CHAI to identify key informants, access and share documents and data, and engage in detailed discussion about the programme under review.

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Disclaimer

Executive summary

1 Background to the evaluation

The UK Department for International Development (DFID) has commissioned an independent evaluation of its £35m programme of support to the Clinton Health Access Initiative (CHAI) entitled 'Market-Shaping for Access to Safe, Effective and Affordable Health Commodities'. The e-Pact consortium was engaged to deliver this evaluation through the Global Evaluation Framework Agreement (GEFA).

The DFID-CHAI Market-Shaping programme focused on increasing access to safe, effective and affordable commodities to support priority healthcare interventions in developing countries. At the logframe Impact level, the DFID grant was expected to contribute to the health-related MDGs by leveraging savings achieved towards increased testing and treatment for key conditions. At the Outcome level, the grant aimed to facilitate access to, and quality of, treatment of more patients within current funding levels. This was to be achieved by reducing the cost of health commodities and delivery, and increasing the availability of more affordable commodities (both number and amount procured) originating from low-cost, high-quality manufacturing environments such as China and India.

The DFID grant ran for three years (2012–2015) and supported CHAI's work in nine programme areas, five of which have been evaluated:

1. Maximising Value for Money and Ensuring Sustainable Supply of HIV Treatment
2. Accelerating Introduction and Scale-Up of Point-Of-Care (PoC) HIV Diagnostics
3. Maximising Value for Money of HIV Spending for Universal Access to Antiretroviral Therapy (ART) (known as "E2" and being reviewed separately)
4. Increasing Access to Long-Acting Reversible Contraceptives (LARCs)
5. Ensuring Rapid and Sustainable Scale-Up of Supply of Quality Malaria Treatments

1.1 Evaluation approach

The evaluation was undertaken in three phases: an Inception Phase, an Interim Findings Phase and a Final Report Phase. The Inception Report was delivered in December 2014, and the Interim Findings report in June 2015. This is the Final Report for the evaluation. Separate reports have been prepared for E2, which was subject to a separate review process aligned with the main evaluation, and for LARCs due to data sensitivities.

The Evaluation Terms of Reference (ToR) specified that programme theory should form the basis of the conceptual framework for this evaluation. A theory-based approach can help identify the intended change, the process through which change is expected to happen, how the intervention will contribute, how changes will be measured, and any contextual factors that could explain variations in observed performance. The extent to which observed outcomes conform to or deviate from theoretical expectations can then be assessed. Central to such an approach is the use of Theory of Change (ToC).

The evaluation developed generic and programme area-specific ToCs, using as a starting point CHAI's 'model of change' and the ToC from the DFID Business Case. These ToCs were presented and agreed with CHAI and DFID during the Inception Phase. A framing structure links these ToCs to the evaluation questions, supporting a consistent approach to data collection and analysis, and aiding the identification of generalizable lessons. This framing structure is based around three key areas of evaluative enquiry: is CHAI doing the right things … in the right way … to generate the right results?

2 Evaluation Findings

The evaluation has comprised fifteen months of activity overall, focused on data collection across the five programme areas above. Data collection comprised wide-ranging document review, 124 global key informant interviews (KIIs), 15 country case studies (eight visited and seven remote), and a stakeholder survey.

The evaluation findings draw on CHAI's own assessment of programme activity and achievements, and reflect the evaluation team's programme area specific and cross-cutting analyses of the data collected, with reference to the evaluation framework. This report focuses on three programme areas: HIV treatment, HIV

PoC diagnostics, and malaria treatment. The E2 and LARCs components are subject to a separate reporting process.

2.1 Programme area findings summary

We have used *Healthy Markets for Global Health: A Market Shaping Primer* (USAID, 2014) as a reference point for this evaluation, in order to contextualise CHAI's market-shaping interventions. The *Primer* is a useful tool as it draws on wide-ranging expertise and input from key market-shaping actors including CHAI. For each of the programme areas evaluated, we have looked at where CHAI is focusing its efforts alongside those of other market-shaping actors, along the pharmaceutical value chain set out in the *Primer* – research and development (R&D), manufacturing, procurement, distribution, service delivery and user adoption – and along the continuum from catalytic market-shaping work through to programmatic health systems work.

Set in the context of global market-shaping efforts with reference to the *Primer*, it is clear that **CHAI has deployed a discrete set of market-shaping interventions and tools, across an increasing range of product areas**. Its approach to the supply-demand interface focuses on demand creation and demand transparency, with supply-side price negotiations based on that characterisation of demand. On the demand-side, CHAI is increasingly involved in programmatic work at country-level. Here we summarise CHAI's activities under the DFID grant and our assessment of them.

HIV Treatment

Almost £8.7m was spent on this programme area, against an original grant allocation of £6.9m. CHAI's objective was to sustain reduced prices, ensure stable market supply, and scale up use of the most effective ARVs, generating NPV savings of $561 million to $1.1 billion between 2012 and 2020. To do this, CHAI proposed to simultaneously engage with ARV drug manufacturers and with the key stakeholders involved in product selection and purchasing decisions in five to seven focus countries.

During the grant period, CHAI made major contributions to the process of product transitioning within countries, providing data and evidence to underpin national policy and decision-making, and facilitating the many implementation activities required. CHAI also provided targeted support to country-level procurement and widened its scope of support to health systems strengthening (HSS) activities, focused on getting products to patients. On the supply side, the work of CHAI's lab team has focused on reducing production costs and bringing to market safer formulations with fewer side effects. CHAI also engaged in license brokering work, where intellectual property barriers required navigation. CHAI continued to contribute to information transparency through its forecasting and price ceiling work, and to host global supplier-buyer meetings.

Demand has now coalesced around a limited number of first-line optimised formulations. For both first and second line, prices have reduced. Supply capacity is now in line with demand for the targeted regimens, although there were some periods of adjustment during the grant timeframe. Attribution to CHAI – for the market-shaping successes and the challenges experienced – is difficult, given the significant role played by normative agencies and global buyers in this sector. There has also been a growth in capacity globally for work to increase information transparency and license brokering; CHAI no longer uniquely contributes here.

HIV PoC Diagnostics

£4.3m[1] was spent on this programme area, in line with the original grant allocation of £4.4m. CHAI proposed to decrease prices, hasten regulatory approvals of new products, and support governments to increase the uptake of PoC devices. The focus of CHAI's work was to support countries in the increased adoption, and effective use, of PoC CD4 technologies. CHAI's initial uptake expectations were extremely high, and would have required rapid market penetration; these expectations were likely bolstered by a complementary UNITAID grant that allowed for commodity purchase, with imminent expectations that the supply base would broaden.

[1] The EvT requested data on POC CD4 only expenditure, or approximate percentage of total Output spend on CD4 PoC. Given CHAI's matrix structure and financial systems, CHAI was not able to provide this, thus this figure includes expenditure outside the grant scope, including on viral load. (Ref: Email discussions with CHAI from February 10-22, 2016.)

During the grant period, to support product introduction and transition management, CHAI engaged in normative, regulatory and particularly implementation work with selected countries. For example, CHAI supported training, quality assurance, M&E, and supply chain improvements related to PoC CD4 introduction. CHAI also introduced operational innovations and solutions, in part to improve the functionality of PoC CD4 devices installed prior to the DFID grant. However, the supply pipeline did not mature as expected and a mid-2013 change in World Health Organization (WHO) Guidelines, which prioritised viral load over CD4 as the method for monitoring patients on treatment, had significant implications for CHAI's work. As a result, DFID and CHAI renegotiated the uptake targets in November 2014.

The reduced target for testing volumes was nearly achieved by 2015. Although price reduction targets were not achieved, CHAI has been able to negotiate some overall reductions, which vary across countries. The savings achieved (against the cost of lab-based CD4) were significantly lower than anticipated pre-grant.

Malaria Treatment

Almost £2m was spent on this programme area, against an original grant allocation of £2.7m. CHAI aimed to promote rapid product introduction to stave off artemisinin resistance, ensure patients have access to the best treatments, and mitigate the risk of supply disruptions. CHAI proposed to introduce generic products (focused on DHA-PQP and AS-PY) to enhance competition and drive down prices, and to engage in country-level capacity building. For severe malaria, CHAI aimed to promote generic entry of injectable artesunate to increase competition and potentially drive down prices, and to engage in demand-side work to ensure WHO guidance translated into rapid adoption at country level. To promote supply stability, CHAI aimed to actively identify sources of supply disruptions and collaborate with stakeholders across the malaria community to mitigate risks.

During the grant period, CHAI focused on programmatic interventions at country level, specifically service delivery and user adoption activities related to injectable artesunate in focus countries. Indeed, these countries, especially those also benefitting from a related UNITAID grant, have seen significant scale-up of injectable artesunate, replacing quinine as the preferred treatment for severe malaria. CHAI has also worked with a number of manufacturers aiming to expand the supplier base and support new entry into the market, specifically for injectable artesunate and DHA-PQP. However, CHAI's work has not yet led to market entry of new oral ACTs or new suppliers of injectable artesunate, nor has it achieved significant price reductions.

2.2 Cross-cutting findings summary

Here, we draw out key findings across the three programme areas above – and also the E2 and LARCs programme areas – from our cross-cutting analyses of the 15 country case studies and the stakeholder survey data. This section is structured around the three areas of evaluative enquiry – right things, right way, right results – with reference to the evaluation questions (EQs). Key findings are identified by the use of bold text.

Did CHAI do the right things?

CHAI is well-aligned with national and global priorities, through its demand-side work. CHAI has supported country governments to follow global normative recommendations and guidelines, and there is strong evidence from the evaluation country case studies that CHAI's interventions are relevant and aligned to country needs, policies and plans. It is also true that CHAI's close proximity to government can affect perceptions of CHAI by other stakeholders, for example in relation to perceived transparency and neutrality.

CHAI has demonstrated robust, criteria-based processes for deciding in which markets to intervene. However, processes for assessing how to intervene, against counterfactual options, are sub-optimal. CHAI's pre-intervention appraisal and risk assessment processes do not yet fully assess the feasibility of proposed interventions, or the potential longer-term effects of an intervention on the relevant market. Engineering an assessment that takes into account both short and longer-term considerations is particularly important when CHAI is entering a new product area.

Overall, CHAI has identified intervention areas where its core skills will add value. CHAI has developed a 'comparative advantage' at country-level through its data handling and analytical capability (particularly in relation to costing and forecasting), and its supply-side knowledge, commercial acumen and understanding

of business. Better documentation of CHAI's experience and contribution in these areas would further strengthen CHAI's position in the market-shaping field, and influence broader understanding and practice.

Did CHAI work in the right way?

CHAI strives to be collaborative, according to its values and mission statements. **In practice, there is evidence of CHAI being both disruptive and collaborative in its market-shaping efforts.** CHAI has collaborated most evidently and productively with MoHs at country-level. CHAI has also worked effectively with key global health agencies. Disruption has occurred productively through CHAI's game changing interventions (e.g. the VG for contraceptive implants that triggered a dramatic price reduction), and less productively where CHAI has moved into areas outside its 'comparative advantage' or where CHAI's urgency has generated tensions among stakeholders.

We found evidence of limited transparency across all programme areas, which in turn weakens CHAI's sharing of lessons and contribution to global public goods. There is widespread agreement that CHAI could do more to proactively communicate information about its activities. CHAI's stakeholders indicated a lack of understanding of CHAI's role, mandate, strategy, workplan (e.g. within a particular country), and funding sources. CHAI has recently published a list of its donors and several case studies from its market-shaping activity, which is a promising start, but the opportunity remains for CHAI to offer more, taking the mantle of 'thought leader' and influencing wider market-shaping practice.

CHAI is an organisation with well-recognised capability. Stakeholders highlighted areas such as the commitment, creativity, competence and technical skill of CHAI's staff, though concerns were raised about rapid staff turnover and CHAI's tendency to engage many younger staff with limited experience. At country-level, CHAI's use of embedded technical assistance and secondments is widely valued, as is CHAI's flexible and responsive approach.

There is strong evidence that CHAI has contributed to sustainability – e.g. transferring skills, tools, process knowledge to others, contributing to institutional change – although the outcomes of capacity building are not always clear. There is also widespread concern about whether progress can be sustained without ongoing CHAI intervention and country-level support, particularly as CHAI has not yet articulated clear exit strategies for its supply- or demand-side work.

Did CHAI achieve the right results?

The outcome measures tracked in this grant relate to aggregate cost savings and new supplier entry. **The aggregate outcome indicators for the grant have been achieved.**

Across the grant as a whole, CHAI has estimated overall cost savings to date of $766m (non-discounted).[2] Through to 2020, savings of $2.5–$3.4 billion (low case–high case, non-discounted) are estimated. This equates to NPV $1.9 - $2.6 billion, compared to the NPV expectations from the business case of $1.45–2.53 billion. However, the majority of the savings to date derive from price reductions in the HIV Treatment and LARCs programme areas, and the EvT could not corroborate CHAI data on first-line ARV prices and volumes in 2015.[3]

The other outcome indicator tracked across the grant relates to new supplier entry, which facilitates competition. The indicator measures the number of products from Indian, Chinese or South African manufacturers gaining SRA approval: CHAI reported 21 approvals secured with direct CHAI support, greatly exceeding the original target of 5–10. This outcome is very impressive, but it is worth noting that all the products are ARVs or MDR-TB drugs, and support to the listed products and companies would have had varying degrees of relevance to meeting a market gap or company need. In addition, not all the companies involved confirmed receipt of direct support from CHAI. CHAI cites progress made on the development of some diagnostics and vaccines, but not yet with a similar rate of approvals.

[2] CHAI annotated logframe at end-of-grant

[3] The evaluation timeframe coincided with the end of grant in September 2015 whereas the final 2015 treatment volume data is not available until end of Q1 2016. The pricing issue is dealt with in detail within the report.

The aggregate outcome measures thus mask significant variation in the outcomes achieved across the different markets being shaped by CHAI. This will translate into variable public health impacts across different areas of communicable disease, child health and reproductive health. The aggregate impact estimates calculated by CHAI (800,000 additional patients tested, and 7.7m additional patients treated with optimal products) do not reflect this diversity.

Looking at each programme area in turn, **CHAI has achieved, and in some cases significantly exceeded, four of the outputs anticipated under the DFID grant, but has made limited progress against two others (2.1 and 6.2). Across the three remaining outputs, good progress has been made but the outputs achieved have fallen short of end-of-grant targets**. In three instances, targets had been revised during the grant period in response to shifting market conditions (which had the effect of making them more easily achievable), though none had been fully achieved by September 2015. This mixed picture is evident in the following summary table. It sets out the output targets defined as part of the grant agreement between DFID and CHAI, alongside a summary of the CHAI reported performance achieved by the end of the grant (September 2015).

Programme area	Output indicator for 2015	CHAI reported performance at end Sept 2015
HIV treatment	1.1 1st line regimen cost reduction to $104 PPPY *(revised up from $90 PPPY after AR 2014)*	Achieved $108 PPPY[4]
	1.2 2nd line regimen cost reduction to $250 PPPY	Achieved $237 PPPY
	1.3 Cost savings for 1st and 2nd line regimens in 4 SADC countries (excl. South Africa) totalling $92m-$199m	Achieved $73m over lifetime of grant
	1.5 Increased no. (10 by 2015) of SRA approved HIV and MDR-TB products from Indian / Chinese / SA sources	Achieved 21
HIV PoC Diagnostics	2.1 30-60% reduction in cost per test for 2-3 PoC CD4 products	Reported 16% (actual 10%) cost reduction (45% reduction in 3 major markets)
	2.2 1.9m PoC tests conducted p/a in countries of CHAI operation, of which 1.1m in SADC countries *(revised down from 7.7m and 5.6m respectively mid-grant)*	1.86m tests conducted in 2014/15 of which 1.2m SADC
Malaria treatment	6.2 Four to six manufacturers undertaking bioequivalence testing for Injectable Artesunate, DHA-PQP or SP-AQ *(revised down at AR 2013)*	Three new supply sources being tested but with limited CHAI involvement
	6.3 15m vials of Injectable Artesunate procured in four to six focal countries *(added at AR 2014)*	11.7m procured by Sept 2015
	6.4 $200m savings on malaria commodities *(added at AR 2014)*	Facilitated $240m savings 2013-2015

In some areas, a lack of progress can be explained by a detailed assessment of how the market evolved and an unpacking of how this differed from what was expected. In other instances, output targets for 2015 have been 'missed' simply because CHAI's original expectations were too optimistic. As a result, the original VfM calculations for several of the programme areas also proved overly optimistic.

Translating these grant outputs into objectively verifiable market outcomes and broader public health impacts is challenging. A key issue is that the grant did not require CHAI to systematically track indicators of baseline and changing market structure (e.g. market size, market shares) other than prices and volumes of selected products. Neither did the grant require CHAI to collect relevant public health indicators (such as data showing increasing rates or timelines of ART initiation or reduced patient loss, or improved targeting of testing and treatment), which could actually demonstrate a translation from grant outputs to broader outcomes of market efficiency and health impact.

In summary, **CHAI performance during the grant period has varied significantly** across each programme area and output indicator, ranging from good progress in line with original expectations for several indicators to very little progress elsewhere. Several indicators have been changed during the grant period (as noted in the table above). Where outputs have been achieved, **it is not always possible to determine whether grant outputs have translated into market and health outcomes and impact**, particularly in situations where many stakeholders contribute towards the outcomes or where data to verify impact are not in the public

[4] NB: $108 is the CHAI reported progress, however, the EvT team has questioned the appropriateness of this value.

domain, for example procurement savings or public health impact, although **CHAI models indicate that anticipated outcomes, in terms of aggregate cost savings and new supplier entry, have been achieved**. It is clear that the flexibility of the DFID grant has been welcomed by CHAI, and may have helped accelerate progress in some output areas or countries, although this does have some downsides for DFID (making grant management and accountability more challenging) and for CHAI (obscuring CHAI's core mission and mandate, and possibly reducing the transparency of its work).

3 Conclusions and Recommendations

Here we summarise our conclusions related to the programme as a whole, and make recommendations to both DFID and CHAI. The conclusions relate to four themes that have emerged strongly from the evaluation:

1. Grant management and accountability
2. Co-ordination of market-shaping interventions
3. Planning for market-shaping intervention
4. Collaboration for market-shaping intervention

Through both the conclusions and the recommendations, we aim to support DFID to develop an effective next phase of partnership with CHAI, to strengthen the management of market-shaping interventions and other adaptive programmes, and to enhance the role that DFID plays within the broader field of market-shaping for global health.

3.1 Conclusions

Grant management and accountability: We conclude that CHAI has achieved good progress against many output indicators under this grant. However, it has proven difficult for DFID to hold CHAI accountable for both inputs and outputs, due to the extent of CHAI's market-shaping activities in a crowded and busy field and due to specific features of the DFID grant including its M&E system. DFID's approach towards 'adaptive programming' was appropriate and necessary for this grant, but it must be recognised that this brings challenges, including limitations in accountability.

Coordination of market-shaping interventions: We conclude that there may be a lost opportunity to optimise market-shaping if different funders and implementers do not co-ordinate their approaches and choice of interventions, and/or if there is not a cohesive approach to all ends of the value chain. Both DFID and CHAI have a role to play in ensuring strong coordination for greater impact.

Planning for market-shaping intervention: We conclude that CHAI appropriately identifies areas of market-shaping need, to which CHAI can bring useful and sometimes unique skills and insights. However, CHAI needs to strengthen its design and appraisal of proposed market-shaping interventions, to assess and appropriately manage risks and trade-offs, to ensure that the full economic and systems costs of an intervention are accounted for, and to plan for impact monitoring over time.

Collaboration for market-shaping intervention: We conclude that CHAI expresses an intent to collaborate in its market-shaping activity and to balance the needs of beneficiaries, government priorities, donors' accountability requirements, and private sector incentives. However, CHAI must ensure that all relevant stakeholders are adequately consulted and engaged in the design and implementation of market-shaping interventions.

3.2 Recommendations to DFID

This evaluation has identified a range of lessons and recommendations for DFID, which relate to the management of its grants to CHAI and potentially other similar, adaptive programmes. DFID has already opted to continue its support to CHAI, initially through a cost-extension to the existing grant until end March 2018. This will entail a shift into additional programme (or product) areas. We anticipate that the recommendations below will be immediately relevant to this new phase of DFID support to CHAI's market-shaping activity.

Recommendation A1: Join up with other funders

- Consider working with others to create a "funders' forum" or similar co-ordination mechanism, which would bring together the major funders of market-shaping initiatives. Its purpose could include joint market

assessments, joint evaluations, peer review and lesson learning, and strategic co-funding (of single or complementary initiatives). This would also help CHAI, as there would be fewer principal-agent relationships to manage and a considerable reduction in the burden of reporting. The funders' group for Product Development Partnerships (PDPs), in which DFID has participated for over 10 years, provides an interesting comparator model and precedent.

- Depending on the product sector, there may be need for real-time monitoring of supply-demand alignment through a dedicated mechanism. This would reduce information asymmetry and improve transparency, as well as being more efficient than any one party, such as CHAI or the GFATM, acting as an information 'broker'.

Recommendation A2: Develop new adaptive planning and monitoring tools and frameworks

- Develop planning and monitoring tools and frameworks to support adaptive programmes, including market-shaping interventions, which can nevertheless provide assurance through DFID systems. (These tools and frameworks could be developed collaboratively with members of the "funders' forum" above.) A 'balanced scorecard' approach could be used to enable consideration of a broader set of metrics during planning, monitoring and evaluation.

Recommendation A3: Improve accountability – project monitoring tools need further disaggregation and transparency

- Logframe and VfM indicators should be accompanied by notes outlining the assumptions behind the targets, with estimates disaggregated by country, and explanations of the methodology and comments on feasibility. Bundling of measures should be avoided. This will enable a more robust dialogue about objectives, timescales, and risk management, enabling the monitoring tools to better serve their purpose. It also needs to be clear from where the data will come, and how feasible it is for CHAI to gather data and for an evaluator to gain access to data for the purposes of independent validation.
- There is also a need for improved transparency externally regarding what DFID is supporting CHAI to do. At a minimum, the logframe and business case should be well publicised by DFID to country government and global partners.

Recommendation A4: Require market-shaping grantees to report data on baseline, mid-cycle and end-of-project market structure

- DFID should require reporting on market structure indicators at baseline and throughout any market-shaping grant, and the provision of both public health and market-shaping ToCs at programme area (product) level. Grantees should also justify the selection of specific demand and supply-side interventions – clarifying how they will shift or limit risk, reduce transaction costs or correct information asymmetries – against counterfactual options. (Oversight of this process could be provided by the "funders' forum" proposed above).

Recommendation A5: Narrow CHAI grant scope but incentivise sharing, for broader impact

- Consider narrowing the product and geographical scope of DFID's grant to CHAI, to sharpen the focus, streamline project reporting and oversight, and ease communication between DFID HQ and country offices/programmes. (This narrowing could be coordinated with members of the "funders' forum" to ensure that different grants to CHAI are complementary and provide appropriate support to CHAI's operations, avoiding gaps or duplication.)
- Incentivise CHAI to share lessons (successes and failures) and contribute to market-shaping knowledge as a global public good (GPG). Incentives might include funding streams triggered by GPG activities, GPG process and output milestones and performance indicators, and DFID hosted learning events (engaging the "funders' forum", as above).

3.3 Recommendations to CHAI

This evaluation has generated several cross-cutting recommendations to CHAI, which would assist in improving the transparency, accountability and sustainability of CHAI's interventions and in doing so should increase the impact of CHAI's market-shaping activity. These would be relevant to many areas of CHAI's programming, including those beyond the work funded by DFID.

Recommendation B1: Enhance CHAI project cycle management

- Develop a more explicit project cycle that includes pre-intervention research and market assessment, consultation, design, appraisal, implementation, monitoring and evaluation.
- Develop project management systems and processes that support this cycle.

Recommendation B2: Fully consider both the short- and long-term

- During the design and appraisal process, evaluate several market-shaping options, taking an industry wide perspective and evaluating short-term and long-term impacts, risks and trade-offs. CHAI should dedicate greatest analytical resource to any interventions that have the potential to narrow the supplier base. External expertise, oversight and QA should be engaged in these situations. Robust discussion in a "funders' forum" (see above) would be merited.

Recommendation B3: Communicate and collaborate

- Communicate and collaborate from the outset, to test ideas, aid learning, align and co-ordinate with others.
- Ensure attention to the balancing of government and global priorities, thinking about how to leverage lessons across countries and how to promote efficiency rather than simply champion government wishes (where these may be in conflict).
- Take responsibility to ensure that other partners at country level are adequately consulted on CHAI plans and any implications that has for their work or budgets. This is part of seeing CHAI's work through to impact. It cannot be assumed that governments will do this for CHAI.
- Promote market-shaping knowledge as a global public good. Share both successes and failures, and support CHAI partners to do the same – locally, nationally, regionally and globally. Getting CHAI's knowledge and best practice into the public domain should be an integral part of intervention design.

Contents

Acronyms

3TC	Lamivudine
ACT	Artemisinin-based Combination Therapy
AIDS	Acquired Immune Deficiency Syndrome
AL	Artemether-lumefantrine
AMDS	AIDS Medicines and Diagnostics Service
API	Active pharmaceutical ingredient
ART	Antiretroviral therapy
ARV	Antiretroviral
AS	Artesunate
ASAQ	Artesunate-amodiaquine
ASLM	African Society for Laboratory Medicine
AS-PY	Artesunate-Pyronaridine
ATV/r	Atazanavir-ritonavir
BMGF	Bill and Melinda Gates Foundation
BMS	Bristol Myers Squibb
CDC	Centers for Disease Control
CHAI	Clinton Health Access Initiative
CIFF	Children's Investment Fund Foundation
CN	Concept Note
CPHL	Central Public Health Laboratory
CYP	Couple year of protection
DALY	Disability-Adjusted Life Year
DFID	Department for International Development
DHA-PQP	Dihydroartemisinin-Piperaquine Phosphate
EFV	Efavirenz
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
EID	Early infant diagnosis
EMA	European Medicines Agency
EQs	Evaluation Questions
ERP	WHO Expert Review Panel
EvT	Evaluation Team
FDA	United States Food and Drug Administration
FDC	Fixed-dose combinations
FIND	Foundation for Innovative New Diagnostics
FLD	First-line drugs
FP	Family Planning
GFATM	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Good manufacturing practice
HCW	Healthcare Workers
HIV	Human immunodeficiency virus
HSS	Health system strengthening
HRH	Human resources for health
ICAI	Independent Commission on Aid Impact
IP	Intellectual property
IUD	Intrauterine device
KII	Key informant interview
LARC	Long-acting reversible contraceptive
LDC	Least developed country
LIC	Low-income country
LLIN	Long-lasting insecticide-treated net
LMIC	Low- and middle-income countries
LPV/r	Lopinavir/ritonavir
LSHTM	London School of Hygiene and Tropical Medicine
LTFU	Loss to follow up
M&E	Monitoring and Evaluation

MDG	Millennium Development Goals
MDR	Multi-drug resistant
MMV	Medicines for Malaria Venture
MoH	Ministry of Health
MoHSW	Ministry of Health and Social Welfare
MoU	Memorandum of understanding
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
NACO	National AIDS Control Organisation
NCD	Non-communicable Disease
NCHADS	National Centre for HIV/AIDS Dermatology and STDs
NDoH	National Department of Health
NGO	Non-governmental organisation
NHLS	National Health Laboratory Services
NMCP	National Malaria Control Programme
NMS	National medical stores
NPV	Net Present Value
O&G	Other and government
PATH	Program for Appropriate Technology in Health
PDP	Product Development Partnerships
PEPFAR	US President's Emergency Plan for AIDS Relief
PMI	US President's Malaria Initiative
PMTCT	Prevention of mother-to-child transmission (of HIV)
PoC	Point-of-care
PPMR	Procurement Planning and Monitoring Report
PSM	Procurement and Supply Management
pppy	per person per year
PQ	Prequalification
PVI	Price Volume Intervention
RDT	Rapid diagnostic tests
RFI	Request for information
RH	Reproductive health
RHSC	Reproductive Health Supplies Coalition
RSA	Republic of South Africa
SADC	Southern African Development Community
S&M	Service and maintenance
SLD	Second-line drugs
SP-AQ	Sulphadoxine/pyrimethamine-amodiaquine
SRA	Stringent Drug Regulatory Authority
SSA (1)	Semi-synthetic artesunate
SSA (2)	Sub-Saharan Africa
TA	Technical assistance
TB	Tuberculosis
TDF	Tenofovir disoproxil fumarate
TEE	TDF with efavirenz and emtricitabine
TLE	TDF with lamivudine and efavirenz
TL	Team Leader
ToC	Theory of Change
ToR	Terms of Reference
TWG	Technical working groups
UNCoLSC	UN Commission on Life-Saving Commodities for Women and Children
VfM	Value for money
VG	Volume guarantee
VL	Viral Load
WHO	World Health Organization

1 Introduction

1.1 Overview of the evaluation

The UK Department for International Development (DFID) has commissioned an independent evaluation of its £35m programme of support to the Clinton Health Access Initiative (CHAI) entitled Market-Shaping for Access to Safe, Effective and Affordable Health Commodities.

The e-Pact consortium has been engaged to deliver this evaluation through the Global Evaluation Framework Agreement (GEFA). Itad are the e-Pact consortium lead for this evaluation and put together the evaluation team (EvT) for this assignment. As the lead organisation, Itad are responsible for the overall delivery of the evaluation products against the Terms of Reference and for ensuring the high quality of the products according to both Itad and e-Pact standards.

DFID's Terms of Reference (ToR) set out the following objectives for the evaluation:

1. Examining if outputs in the programme's Theory of Change (ToC) are being effectively translated into the desired outcomes.
2. Exploring which indicators, using the start of the current programme as a baseline, have been met, which are in progress, and which may have fallen behind.
3. Providing a stronger contextual understanding behind any progress made towards achieving the indicators.

The DFID-CHAI Market-Shaping programme focused on increasing access to safe, effective and affordable commodities to support priority healthcare interventions in developing countries. The DFID grant ran for three years (September 2012 to September 2015) and supported CHAI's work across nine programme areas. Of these areas, five (highlighted in bold below) have been studied in detail during this evaluation:

- **Maximising Value for Money and Ensuring Sustainable Supply of HIV Treatment**
- **Accelerating Introduction and Scale-Up of Point-Of-Care HIV Diagnostics**
- **Maximising Value for Money of HIV Spending for Universal Access to ART (E2)**
- Improving Pricing and Supply Security for High-Quality MDR-TB Drugs
- Accelerating Market Entry of Highly Accurate and Lower-Cost New Diagnostic Products
- **Increasing Access to Long-Acting Reversible Contraceptives**
- Improving Vaccine Market Dynamics for Price Negotiations
- Ensuring Rapid and Sustainable Scale-up of Supply of Malaria Rapid Diagnostic Tests
- **Ensuring Rapid and Sustainable Scale-up of Supply of Quality Malaria Treatments**

Due to the sensitivity of quantitative and qualitative data handled by the E2 ("E Squared") programme area, this has been reviewed separately from the other programme areas. The EvT has delivered a separate Interim Findings Report for the E2 review, and will do the same for the Final Report due at the end of 2015. These E2 reports are confidential and are not being published.

The evaluation commenced later than was originally planned by DFID, and its formative potential in relation to the 2012–2015 DFID-CHAI grant was therefore limited. However, the Interim Findings report was delivered in time to shape DFID thinking regarding its market-shaping activities in the health sector and its ongoing support to CHAI within this context. DFID has recently opted to extend its grant to CHAI through to March 2018 and has drawn on the evaluation's interim findings to inform the next phase of this work. However, the evaluation has maintained its focus on the grant as originally designed, covering a three-year period from September 2012 to September 2015.

The full set of deliverables from this evaluation comprises the following:

- An Inception Report
- Two Interim Findings Reports – one for the main evaluation, and one for the E2 review
- Two Final Reports – one for the main evaluation, and one for the E2 review
- One set of PowerPoint "decks" covering the key evaluation findings, aimed principally at DFID and CHAI staff
- One journal article and one learning note, both for external audiences.

1.2 Objectives and scope of the Inception Phase

The Inception Phase of the evaluation was undertaken between September and December 2014, by core EvT members with guidance from the Project Director. During the Inception Phase, the aims and objectives of the EvT were to:

- Develop an understanding of the parameters of the DFID-CHAI market-shaping programme;
- Confirm the scope of the evaluation and refine the evaluation framework;
- Refine the Theories of Change for each programme area, as core evaluative tools;
- Establish clear contact points and lines of communication with DFID and CHAI;
- Hold introductory calls and meetings with core staff at DFID and CHAI;
- Gather core programme documents and begin to review them;
- Plan for the Interim Findings Phase of the evaluation, particularly with a view to undertaking country case study visits;
- Identify additional evaluation team members to be engaged, including country consultants;
- Develop a list of key informants and a core questionnaire for semi-structured interviews.

The Inception Report was delivered to DFID in December 2014. In line with the Inception Phase objectives, it set out the EvT's understanding of the programme being evaluated, and outlined the approach and process to be followed during the Interim Findings and Final Report phases. The Inception Report was reviewed by the Evaluation Reference Group and feedback was given to the EvT in January 2015.

1.3 Objectives and scope of the Interim Findings Phase

The Interim Findings phase of the evaluation ran from January to May 2015 and had several objectives:

- To gather data about the CHAI market-shaping activities supported by the DFID grant (principally in the five programme areas under scrutiny), and the context in which they take place;
- To refine the analytical approach used by the evaluation;
- To inform plans for the Final Report phase of the evaluation;
- To set out some initial findings to DFID and CHAI, to inform their activities over the remaining period of the DFID grant;
- To inform discussions within DFID, and with external partners including CHAI, about potential follow-up work on market-shaping as the grant period draws to a close.

The Interim Findings phase therefore comprised five months of activity, focused on data collection across the five programme areas under review, and an initial analysis of quantitative and qualitative data with reference to the evaluation framework. Country case studies conducted during this phase included country visits to Tanzania, South Africa (RSA), Uganda and Zambia, and remote case studies (two of which extended into the Final Report phase) covering work in Cambodia, Cameroon, Mozambique, Rwanda (E2 only), Swaziland and Zimbabwe.

The interim findings were largely drawn from qualitative data gleaned from document review, country case studies and global key informant interviews (KIIs). The findings reflected CHAI's own assessment of programme activity and achievements, as well as the perspectives of many different stakeholders. Most of these stakeholders had worked closely with CHAI, while a few had a more strategic perspective on CHAI's role within the broader market context.

In the Interim Findings report, the EvT endeavoured to draw out the issues and questions that emerged most clearly across the data sources including KIIs, and to make recommendations to CHAI and DFID on this basis. The Interim Findings report also set out the approach and process that would be followed in the Final Report phase. The draft report was discussed in detail with DFID, CHAI and the Evaluation Reference Group, and a series of written comments were also received by the EvT. The report was then revised and submitted to DFID.

1.4 Objective and scope of the Final Report Phase

The Final Report phase of the evaluation ran from June to November 2015. It focused on exploring the themes and answering the questions identified in the Interim Findings phase through additional data collection, as well as undertaking a full analysis of these data. Where appropriate and useful, modelling work was also undertaken.

Data collection during the Final Report phase included:

- Further document review, particularly relating to the country-level activity that CHAI is engaged in across the five programme areas being evaluated.
- Country case studies in 5 countries: Ethiopia, Kenya, Malawi, Nigeria and (remotely) India.
- Completion of outstanding KIIs with global-level stakeholders.
- An electronic survey of stakeholders, to triangulate feedback from KIIs at both global and country levels.

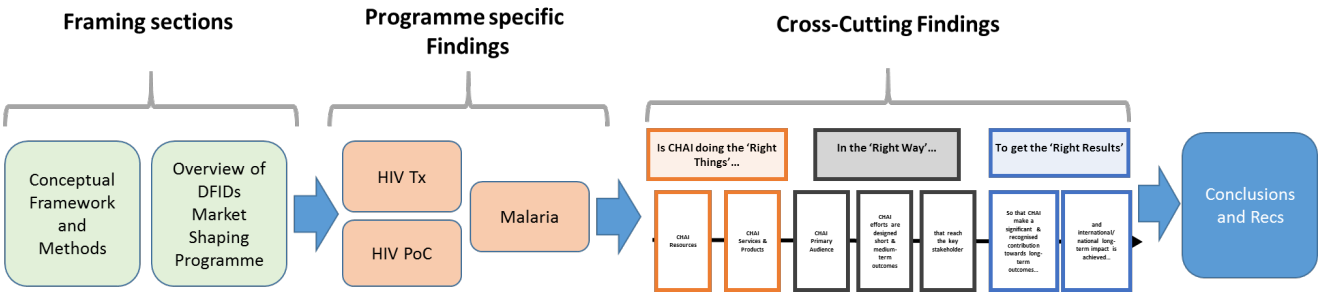
1.5 Structure of the Final Report

The aim of this Final Report is to synthesise all data and analyses, draw conclusions, and make recommendations to both DFID and CHAI. The structure of the report includes:

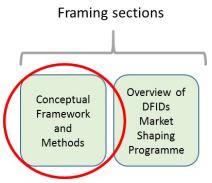
- An explanation of the conceptual framework and methodology employed for this evaluation;
- An overview of the market-shaping programme supported by the DFID grant to CHAI;
- A set of findings based on in-depth analyses of three programme areas supported by the DFID grant, set within the context of the markets they intended to shape – HIV Treatment, HIV PoC Diagnostics, and Malaria Treatment;
- A set of cross-cutting findings answering the evaluation questions (EQs), drawing on the programme area specific analysis, as well as a strategic issues analysis and cross-cutting analyses of the country case studies and the stakeholder survey;
- The overall conclusions of the evaluation and a set of recommendations for DFID and CHAI, including some recommendations related to specific markets (or programme areas) in Annex K;
- Additional detail and background information is provided in Annexes A to J.

Figure 1 summarises this structure and will be used to aid navigation across the report.

Figure 1: Summary of report structure



2 Conceptual Framework and Methodology



2.1 Introduction

The evaluation Terms of Reference (ToR) specified that programme theory should form the basis of the conceptual framework for this evaluation (see Annex A). A theory-based approach can help to identify the intended change, the process through which change is expected to happen, how the intervention will contribute, how changes will be measured, and any contextual factors that could explain variations in observed performance. It can then be used to assess the extent to which observed outcomes conform to or deviate from theoretical expectations, and to assess the validity of the change model. Central to such an approach is the use of a Theory of Change (ToC).

In this section, we outline the conceptual framework for the evaluation based on the ToC for the DFID-CHAI market-shaping programme. We then detail the evaluation methodology, including the approach we have taken to data collection, analysis and triangulation, and any key limitations and ethical considerations that have affected the evaluation. Specifically, we explain how the report will use the dominant logic of market-shaping practice, as set out in *Healthy Markets for Global Health: A Market Shaping Primer*, to contextualise CHAI's market-shaping interventions and to assess the extent to which they follow good practice.

2.2 Theory of Change

The evaluation developed programme area-specific ToCs. These used as a starting point CHAI's 'model of change' and the ToC from the DFID Business Case, which were overall grant-level ToCs applicable to all nine programme areas. The programme area-specific ToCs were developed by examining the resources and strategies that CHAI offers, their key stakeholders, and the expected results of their market-shaping activities. They recognise that CHAI's anticipated outcomes are outside its direct control and that working with (and through) relevant stakeholders and partners is critical to CHAI's success. The programme area ToCs were presented and agreed with CHAI and DFID during the evaluation Inception Phase, and are included in Annex D.

We identified a framing structure that helped to ensure the ToCs clearly link to the evaluation questions, enabled consistency across evaluation workstreams, and offered the potential to identify generalizable lessons. This framing structure is based around three key areas of evaluative enquiry: is CHAI doing the right things … in the right way … to generate the right results?

Figure 2: Key areas of evaluative enquiry

The Interim Findings report gave detailed feedback to CHAI and DFID based on document review and key informant perspectives in relation to each programme area, framed by the respective ToCs and the overarching questions above. In this Final Report, we present key findings drawn from the analysis of data, which were collected to explore issues underpinning CHAI's theory of change and its application in practice. In doing so, we reflect on the extent to which the ToC has been useful and can be strengthened going forward.

2.3 Evaluation questions

A set of evaluation questions (EQs) were developed in response to the DFID ToR (see Annex A). During the Inception Phase of the evaluation, these were grouped into the areas of evaluative enquiry above, then refined further during the Interim Findings phase. As data collected during the Interim Findings phase were analysed, several themes emerged that were not captured in the original EQs. The EQs were modified to capture these issues, though the overarching structure of the EQs remained unchanged. The final version is included at Annex C.

The EQs have been used to frame both data collection and evaluation findings. They were used to develop the interview guide for KIIs, at Annex E, and to develop the stakeholder surveys (see Annexes H and I). We also used the EQs to interrogate data and generate findings across each programme area being evaluated. In Section 5 of this report, we use the EQs as an organising framework to report a synthesis of findings from the evaluation.

2.4 Overview of methodological approach

This section describes the overall approach that the EvT has employed to meet the objectives of the evaluation ToR and answer key evaluation questions. Table 1 provides an overview of the data collection tools and analytical methods that the EvT has applied across the course of the evaluation.

Table 1: Use of data collection tools and analytical methods

Programme Area	Data collection tools	Analytical methods
HIV treatment HIV PoC Diagnostics Malaria treatment LARCs (reported separately)	• Document review • Global key informant interviews (KIIs) • Country case studies	• Coding and synthesis of KIIs • Trend analysis • ToC Analysis • Counterfactual modelling and analysis (HIV Diagnostics and LARCs only) • VfM analysis • Market-shaping stakeholder/interventions mapped against USAID Healthy Markets Primer
Cross-cutting	• Country case studies • Stakeholder survey	• Synthesis of country case studies • Analysis of survey data

The sampling of information has been largely determined by DFID. For example, the evaluation ToR specified the five programme areas (including E2, not listed above) that were to be the focus of the evaluation. Together these five areas make up more than 50% of DFID's funding to CHAI's market-shaping work. Similarly, the choice of country case studies, a key method of data collection described below, was initially set out in the ToR though this has been adjusted slightly over the course of the evaluation.

2.5 Data collection methods

We have used a range of structured data collection tools, as noted in Table 1 above and detailed below. In addition, the EvT has held in-person meetings in London and New York with CHAI, as well as phone calls and email exchanges with relevant programme leads. Regular discussions have been conducted with the DFID lead for the evaluation as well. These discussions have enabled CHAI and DFID to share and assess data with the EvT, and to discuss and contextualise emerging findings.

2.5.1.1 Document review: literature and CHAI data

The EvT has reviewed a large volume of literature initially provided by CHAI and DFID during the Inception Phase, as well as a wide range of additional documentation and data during the Interim and Final Report phases, including materials on the programmes and projects of other stakeholders working on issues and

activities related to market-shaping.[5] The EvT has also reviewed data from CHAI, including budget data, ceiling price lists, resource mapping related to the E2 component, and value for money (VfM) analysis.

A synthesis of reviewed documentation, drawing out key theories to test, was prepared for each programme area prior to country visits and global KIIs.

2.5.1.2 Key Informant Interviews

Key Informant Interviews (KIIs) have been conducted either face to face, by telephone or by Skype.[6] Up to 30 key external stakeholders for each programme area were interviewed, largely during the Interim Findings Phase, with outstanding interviews conducted during the Final Report Phase with a focus on issues emerging from interim findings. Country case studies included further key informant interviews, typically 15 to 25 per country.

Approximately 60% of the key informants for each programme area or country were identified by CHAI and/or DIFD; the remaining 40% were identified by the EvT using its networks to supplement CHAI and DFID lists. Stakeholders were chosen to include those that have a clear understanding of the design or implementation of CHAI's activities under the project (including as recipients of CHAI's services), as well as those who have not had direct dealings with CHAI but are knowledgeable about health and market-shaping needs. The mix and quality of respondents were analysed in real time, adding in further stakeholders (to add more data points) where there was disagreement or lack of clarity in responses, and ensuring an appropriate distribution to inform on the variety of interventions CHAI has implemented.

KII objectives were to deepen EvT understanding of CHAI's work in context and to address relevant EQs. Importantly, the KIIs also supported the formative aspects of the evaluation, providing important stakeholder perceptions, data and feedback to CHAI and DFID during the three-year grant period. A detailed assessment against the EQs, drawing on stakeholder feedback, was set out in the Interim Findings report and discussed with CHAI, DFID and members of the Evaluation Reference Group.

All key informants were sent an email request for an interview, attaching DFID's introduction letter to the evaluation. This gave an overview of the grant objectives and described the output areas most relevant to each informant. Interviews were semi-structured and based on comprehensive topic guides, to help ensure systematic coverage of questions and issues by team members conducting interviews. An example is included in Annex E. The topics were developed from the EQs, but grouped and targeted according to the individual being interviewed. The semi-structured approach allowed interviewers to explore unforeseen avenues of enquiry as issues arose.

The interviews during the Interim Findings phase were open-ended and explorative. They enabled the EvT to form interim conclusions about whether CHAI is doing the right things, in the right way, with the right results. In the Final Report Phase, we tested and refined these conclusions through additional remote and face-to-face interviews.

2.5.1.3 Country case studies

Through this evaluation, the EvT has reviewed 15[7] out of 25 (60%) of CHAI's country programmes through country case studies. Eight of these were conducted in person and seven were conducted remotely. This reflects a slight adjustment to the approach proposed in the Inception Report, in response to our data collection experience during the Interim Findings phase: specifically, no case study was merited in China given that all supply-side interviews could be conducted by Skype or telephone.

[5] Specifically, we have reviewed all available materials related to DFID grant documentation and progress reporting, CHAI formal reporting to DFID, CHAI strategy and programme summary presentations, UNITAID landscape analyses, situational analyses, peer-reviewed literature, press releases, meeting notes including of supplier-buyer summits, documentation on normative guidelines, analyses of markets, case studies and relevant health strategic plan and programme review documents for country case studies.

[6] Phone interviews proved appropriate as the evaluation team already had an extensive professional network across the relevant programme areas.

[7] Liberia was included in the evaluation ToR but omitted from the list of countries to be visited from the outset, due to disruption to CHAI's programming resulting from the Ebola outbreak.

The country case studies were undertaken through a combination of document review, telephone interviews and country visits, ensuring effective and representative data collection but with value for money considerations in mind.

- **Desk review:** Prior to a country visit or telephone interviews, the team reviewed relevant documentation and a list of potential KIs from CHAI, and in some cases held a preparatory call with the CHAI country office. Areas to explore through KIIs were identified based on this desk review, the ToCs (Annex D), the EQs (Annex C) and the KII questionnaire (Annex E).
- **Country data collection**: Remote data collection and document review were conducted by the core team in liaison with the CHAI office concerned (and in-country DFID advisers where applicable). For countries that were visited, a local consultant with appropriate knowledge and networks supported the relevant core team member, and facilitated additional data collection locally.
- **Telephone interviews**: KIIs with country-level stakeholders were conducted by telephone or Skype where no visit was conducted, or as a follow-up to a visit (e.g. where a stakeholder was not available to meet in-country, or where a further discussion was merited). We undertook remote interviews to complete the following case studies during the Interim Findings phase: Cambodia, Cameroon, Mozambique, Rwanda (E2 only), Swaziland and Zimbabwe. Remote interviews were conducted for India during both the Interim Findings and Final Report phases.
- **Country visits**: The EvT visited four countries during the Interim Findings Phase: South Africa, Tanzania, Uganda and Zambia. A further four countries – Ethiopia, Kenya, Malawi and Nigeria – were visited during the Final Report Phase.

2.5.1.4 Stakeholder survey

During the Final Report Phase, two online surveys were administered as part of the data collection for this evaluation – one was designed for industry stakeholders only, and the other was targeted at national government representatives and other stakeholders (O&G i.e. other and government). Both closed (multiple choice) and open-ended questions were included in the surveys, structured around the three areas of evaluative enquiry ('right things', 'right way' and 'right results'). The question set was shared with CHAI in draft and then refined based on their feedback, to maximise the potential for CHAI to glean valuable lessons from the survey. Prior to full distribution, the surveys were piloted with a limited number of respondents (one for the Industry survey and five for the O&G survey) and minor amendments made.

The two surveys were administered through Survey Monkey during the period 14th August to 4th September 2015. The Industry survey was distributed to 50 stakeholders, of which 16 responded (32% response rate), while the O&G survey was distributed to 401 stakeholders, of whom 98 responded (24% response rate). All stakeholders received reminder emails prior to the survey closing, in an effort to increase response rates.

2.6 Analysis methods

Data collected for the evaluation has been analysed using a range of approaches, some by programme area and others across the grant as a whole.

Programme area-specific analyses:

- **KII analysis.** A synthesis of stakeholder perceptions has been generated through detailed qualitative analysis using the KII guide. Global KIIs were coded thematically against the EQs, using a coding structure and Dedoose online software. Coding was undertaken by two evaluation team members to ensure consistent interpretation of key terminology. Emerging themes were highlighted and new codes added to capture these as appropriate. Robust synthesis of country-level data was supported through use of a clear structure for the case study reports to facilitate synthesis. A brief executive summary for each country case study is included at Annex I.
- **Analysis of Interim Findings report.** A further review of the key findings and evidence presented in the Interim Findings report was conducted, using the evaluation questions. The purpose was to identify gaps that still needed to be filled through data collection and/or analysis in the Final Report phase. The interim findings were coded by one member of the evaluation team, as a further basis for triangulation.
- **Theory of Change analysis.** A Theory of Change (ToC) approach has been central to the evaluation, including through informing the evaluation questions, data collection tools and therefore all analysis. More

specifically, the programme-specific ToCs have been prominent in the analysis presented for each programme area and have helped identify a number of areas in which ToC assumptions could be reviewed.

- **Trend analysis.** We have collected and analysed comparable data on indicators that show change over the lifetime of the programme. This information has been analysed in the context of the ToC, recognising not only CHAI's influence on the indicator but also the influence of confounding variables and contextual changes. The primary focus of this work has been on routine project reporting, specifically the ongoing assessment of CHAI's performance against logframe indicators.
- **Market Impact analysis:** For the Final Report, the EvT was asked to prioritise the analysis of CHAI's market impact. The most robust way to assess market impact would be through market-effect studies. This means setting up controlled trials where a control group has no CHAI influence and a test group has CHAI influence, with longitudinal data collected on the change in market structure, controlling for other variables. Such market-effect studies have not been conducted by others, and even if it were the remit of this evaluation to conduct such studies, confounding variables would make interpretation difficult. The DFID grant was not structured to require CHAI to assess baseline, interim or final market structure, so the data that have informed CHAI's market-shaping objectives are not available within DFID project documentation. The EvT has consequently been required to undertake wider data collection and analysis – including reference to proposals and reports CHAI has produced for other donors and shared with DFID – on supply and demand market features at baseline and end of grant. The market impact analysis has been combined with the other methods of analysis to draw conclusions about CHAI's contribution to any changes in market structure that emerged during the grant period.
- **Counterfactuals.** The EvT has explored counterfactual scenarios where possible. During the Interim Findings phase we established that some potential comparators were not relevant. The evaluation has looked specifically at counterfactuals for LARCs and HIV Diagnostics, where CHAI might have used counterfactual (i.e. different) market-shaping tools to influence producers' risks and incentives. Both models take an industry-wide and dynamic perspective. The LARC model examines the actual impact of the volume agreement CHAI negotiated on industry structure. By contrast, the HIV Diagnostics model is a theoretical model (Annex J) that examines the factors most likely to influence the impact of a price-volume intervention on industry structure. The aim of both models is to inform discussions about the process of analysis CHAI undertakes before pursuing an intervention and to inform discussions about risks and benefits of interventions that seek to influence price and volumes.
- **Value for Money (VfM) analysis.** Our VfM analysis has been informed by Itad's VfM Diagnostic Framework,[8] which focuses on evaluating monetary, quantitative and qualitative indicators according to standalone, trend and benchmark measures. Starting with the quantitative value for money indicators reported by CHAI in DFID project documents, the EvT has analysed trend progress during the course of the grant, and against expectations at grant initiation. The EvT has also benchmarked these quantitative indicators against comparable achievements by others, where possible. Most importantly, the EvT has examined the context to draw qualitative conclusions about the relevance of CHAI's actions, and therefore possible attribution of impact to CHAI. The monetary savings arising from CHAI's VfM results have also been recalculated and compared with expectations at the start of the grant.
- **Stakeholder and intervention mapping**. We have used *Healthy Markets for Global Health: A Market Shaping Primer* (Box 1) as a reference point for this evaluation, in order to contextualise CHAI's market-shaping interventions.[9] The *Primer* is a useful tool as it draws on wide-ranging expertise and input from key market-shaping actors including CHAI. For each of the programme areas evaluated, we have looked at where CHAI is focusing its efforts alongside those of other market-shaping actors; and for HIV treatment, HIV PoC Diagnostics and Malaria treatment we have mapped CHAI and others' interventions along the pharmaceutical value chain set out in the *Primer*.

Box 1: *Healthy Markets for Global Health: A Market Shaping Primer*

Market-shaping interventions in health are increasingly varied, but in general they are designed to disrupt specific practices or more broadly transform the way a market operates, in order to improve the affordability and accessibility of medicines and other commodities. This might involve correcting information asymmetries,

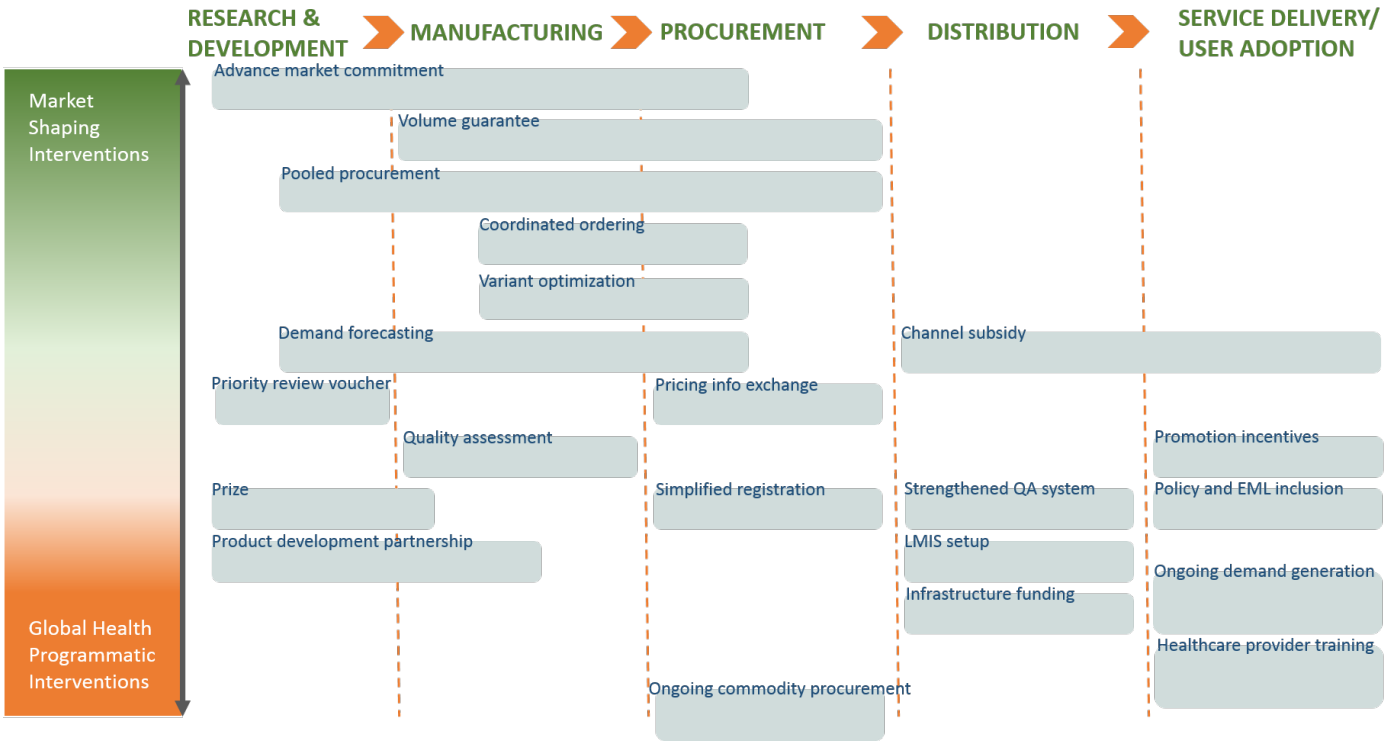
[8] http://www.itad.com/wp-content/uploads/2014/11/Itad-VFM-paper-v21.pdf

[9] As highlighted in the limitation section, it is important to note that we have this supports our evaluation of CHAI's work in context; but we have not evaluated that broader context.

reducing transactions costs or rebalancing risks, including by using the purchasing power of procurers in catalytic ways to stimulate the supply side of the market. USAID coordinated the development of *Healthy Markets for Global Health: A Market Shaping Primer* (revised in late 2014) that summarises the field and sets out recognised good practice.

Figure 3, adapted from one in the Healthy Markets primer, plots a range of market-shaping and related interventions along the pharmaceutical value chain. Those towards the top of the figure are more catalytic and short-term, focused on interactions between buyers and suppliers. Those towards the bottom of the figure are longer term and focused more on how products are distributed, prescribed, dispensed and used within developing country health systems; this demand-side activity can send important signals to suppliers, and market-shaping actors can play a role in highlighting or amplifying those signals through their interactions with buyers and suppliers.

Figure 3: Market-shaping and related interventions along the value chain



The Healthy Markets primer also sets out a five-step pathway for the selection, development, implementation and monitoring of market-shaping interventions. Each of these steps is designed to answer key questions, as follows:

- *Observe Market Shortcomings*: How does the market compare to an optimal, healthy market? Where does the market fall short in delivering health outcomes?
- *Diagnose Root Causes*: Which analytical tools can provide a better understanding of these shortcomings? What interplay of transaction costs, available information, or relative risk is producing the observed shortcomings?
- *Assess Market Shaping Options*: Theory of change – how does the intervention work? What are the benefits, drawbacks, and implementation constraints?
- *Implement Customized Intervention*: Who should be engaged and how? What trade-offs will be required? How will unintended consequences be minimised? How will ongoing and sustainable results be ensured?
- *Measure Results*: How will changes be tracked across market characteristics, public health outputs, and public health impact? What feedback loops will enable real-time adaptations? How will the evaluation process include stakeholders? How will evaluation findings be shared?

Cross-cutting analyses:

- **Country case study analysis.** The case study reports from 13 countries[10] were coded against the EQs. This was done by three members of the evaluation team to ensure consistency of interpretation. Consistency of coding was checked by one member of the evaluation team during a process of synthesis. Synthesis was undertaken to enable the evaluation to highlight the number of countries in which a particular issue had been raised during country case studies and as a means to triangulate findings from other data sources.
- **Survey analysis.** Prior to the survey analysis, the data sets were cleaned.[11] Then the responses of the pilot respondents were combined with the main data sets, creating an overall sample of N = 17 for the Industry survey and N = 98 for the O&G survey. The multiple choice data were analysed in Excel[12] and are presented in summary tables in Annexes H and I. The four open-ended questions were analysed through a process of reading across the responses for each question and drawing out the themes being mentioned in each response – these are also presented in the survey annexes, with details of the number of respondents who commented on the issue, whether positively or negatively.

2.7 Triangulation

To ensure the evaluation is evidenced-based, objective and independent, we have used a triangulation process drawing on a variety of data sources and approaches to confirm similar results, including:

- comparing document review and semi-structured interviews, to help us identify whether information is evidence-based vs a more singular perception;
- reviewing a diverse range of documentation, including sources of information external to CHAI;
- reviewing National Health Strategic Plans prior to country case studies, in order to inform EvT conclusions on whether CHAI is doing the "right things", addressing strategic concerns;
- interviewing stakeholders who are independent of CHAI, and conducting an analysis of KIIs (using Dedoose) to generate a robust synthesis of views;
- undertaking document review prior to country visits to refine a list of specific issues to explore at country level;
- modelling to test and verify the data and results that CHAI has reported, and to explore counterfactual scenarios, for selected programme areas;
- comparing the findings from synthesis of key informant interviews, country case studies and a stakeholder survey to check for corroboration or contradictory evidence.

2.8 Limitations

There are some important limitations to this evaluation. In relation to its scope, the evaluation has placed CHAI's market-shaping activity in context and explored the extent to which CHAI's work complements and adds value to the work of others. It has also used counterfactuals to assess CHAI's impact on the market for key health commodities. However, it is important to stress that this is not a comparative study. We have evaluated CHAI's work in context. We have not evaluated that broader context.

The KIIs were exhaustive: 129 global and 304 country-level informants. Based on the EvT's extensive knowledge of the market-shaping architecture, we are confident we have gleaned insights from all the relevant stakeholders. However, the response rate from the survey (32% for industry and 24% for O&G) means that the emerging data should be treated with caution.

[10] Cambodia, Cameroon, Ethiopia, India, Kenya, Malawi, Mozambique, Nigeria, South Africa, Swaziland, Tanzania, Uganda and Zimbabwe. Zambia was not available for synthesis, and Rwanda relates to E2 only.

[11] Firstly, the data from five respondents were removed from the denominator for the O&G survey. These five people completed only the background information and then stopped without responding to any of the actual survey questions; therefore, there was little value in retaining them in the sample. For all other respondents, where questions had been skipped or left blank, the text "no response given" was inserted.

[12] For some questions, data were disaggregated by the characteristics of the respondent – namely, in which programme area they had interacted with CHAI (LARCs, Malaria, HIV treatment, HIV diagnostics, HIV financing, Multiple, or Other) and, for the O&G survey, the type of stakeholder they were (Aid recipient or government employee, Donor, Programme implementer or technical assistance provider, or Other).

Within the scope of the DFID grant itself, is important to note that the Annual Reviews of the CHAI programme, specifically that in October 2014 (end of Year 2 of the grant), triggered changes and additions to a significant number of logframe indicators, milestones and targets. This is challenging from the perspective of an external evaluator. In order to ensure that the evaluation accurately reflects the scope of the DFID market-shaping grant to CHAI and its evolution over time, we have attempted to use both the original logframe and any subsequent amendments to frame our assessment of each programme area.

As anticipated, we have encountered challenges in attributing market outcomes to CHAI initiatives. We have dealt with this challenge by focusing on contribution, and the plausibility that CHAI has contributed to observed results. The programme areas ToCs have informed this assessment.

2.9 Ethical considerations

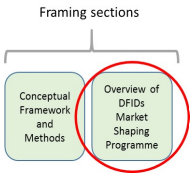
The evaluation has been conducted in line with DFID's Ethical Principles for Evaluation and Research, which state that "evaluations should usually be independent of those implementing an intervention or programme under study". Organisational independence ensures that the evaluators are not under the influence or control of those who have decision-making responsibility for the activities being evaluated and that evaluators have full access to the information they need to fulfil their mandate.

To facilitate the EvT's access to data deemed by CHAI to be confidential, the EvT signed a Non-Disclosure Agreement to give CHAI assurance that confidentiality would be respected.

The evaluation involved primary data collection from key stakeholders, mostly in the form of key informant interviews. The EvT also handled a large amount of secondary data, which required adherence to ethical standards. The key ethical issues relating to this data collection process are listed below, along with the approach taken by the EvT to mitigate ethical risks:

- **Voluntary participation**: Identified key informants were contacted by email with an interview request, which included information about the DFID grant to CHAI and the evaluation approach. At the start of each key informant interview, respondents were asked for verbal consent to the EvT member taking notes of the discussion. They were also informed about the background and the objective of the interview.
- **Confidentiality**: During the process of consenting, the respondents were assured of their anonymity and informed that EvT feedback to DFID and CHAI would be generalised and not attributable to any specific stakeholders.
- **Data safety and security:** The evaluation has had access to a large volume of secondary data, much of which is not open access and some of which is confidential. Only team members who are directly involved in the evaluation have had access to these data through a secure Dropbox. Data related to the separate review of the E2 component has been kept separate, with even tighter restrictions on EvT access.

3 Programme Overview



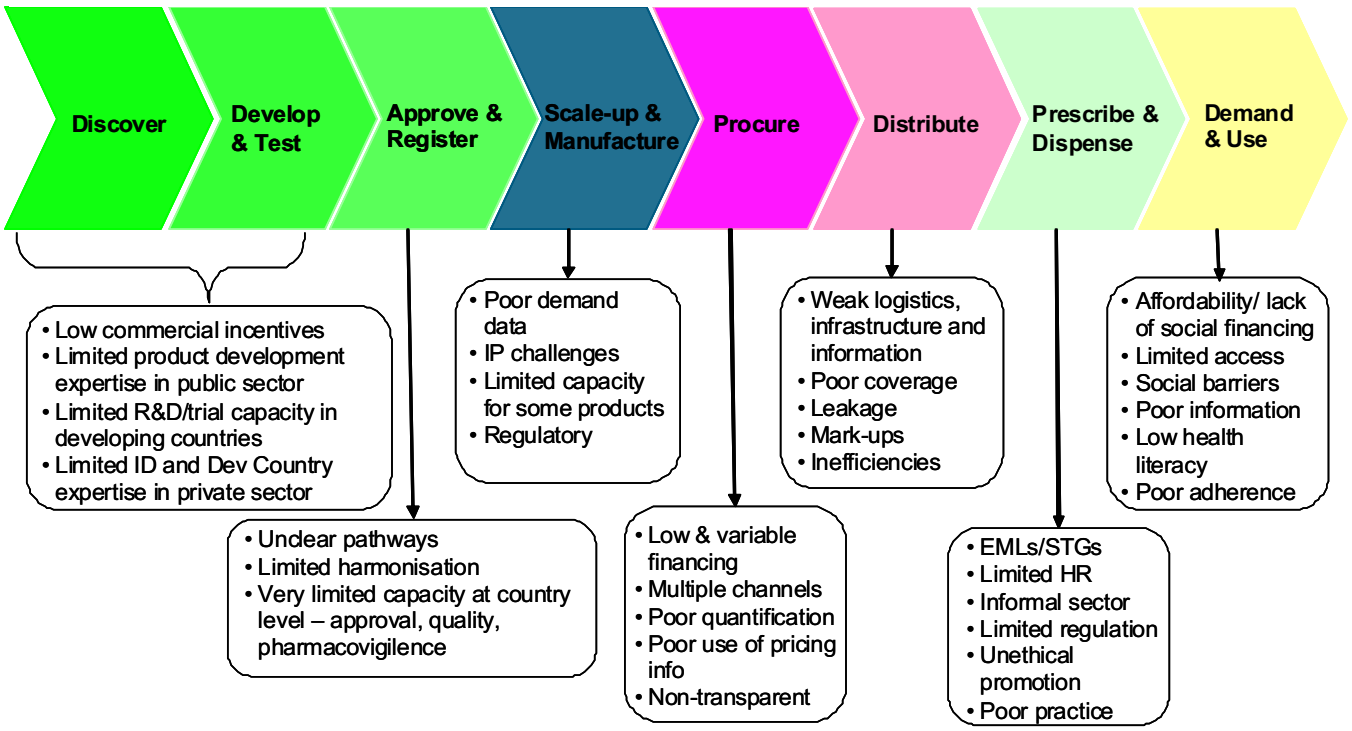
3.1 Introduction

In this section we discuss a number of contextual factors influencing DFID's decision to fund CHAI's work on market-shaping for access to medicines, including the policy and political context. We explore briefly why DFID is interested in access to medicines, and in market-shaping as a strategy; we consider why DFID chose to fund CHAI and why the programme took the shape that it did. These together highlight the expectations that DFID and CHAI appear to have held at the start of the grant in 2012. The following section then looks at how these expectations were met (or not) as the programme was implemented, for each of the focal programme areas for the evaluation.

3.2 DFID interest in access to medicines

DFID has a longstanding policy and programming engagement on issues affecting access to medicines in low- and middle-income countries (LMICs). The UK government has supported a wide range of initiatives designed to address bottlenecks along the value chain from the initial discovery of new drugs and other technologies through to their distribution and use, many of which are highlighted in the graphic below.

Figure 4: DFID Access to Medicines framework



Source: DFID market-shaping grant Business Case (June 2012)

As highlighted in the Business Case for the CHAI grant, DFID recognises the strategic importance of better access to safe, effective and affordable medicines, vaccines and other health commodities for faster progress towards the health and other Millennium Development Goals (MDGs).

3.3 DFID interest in market-shaping

The use of market-shaping interventions in global health is now well established. Examples of different interventions are provided in
Box 1. By engaging in market-shaping activity, DFID hopes to address some of the bottlenecks identified above (Figure 4), to enable the market to operate more efficiently, and thereby secure greater value from the billions of dollars that donor and developing countries spend annually on health commodities. The DFID Business Case for the market-shaping grant to CHAI asserted that "coordinated market-shaping on both the supply- and demand-side, such as facilitating the entry of new generic suppliers, improving the process chemistry for priority compounds, aggregating demand and using pro-active procurement tactics, can transform the functioning of markets to deliver much lower prices, better quality products and greater security of supply, so allowing for greater availability of quality assured essential medicines for the poor."

This emphasis on market-shaping is consistent with the broader policy direction in DFID in recent years, which asserts that developing the private sector in a country is central to its economic development, to poverty reduction, and to graduating from dependency on aid. To support work in this area, DFID plans to spend £1.8 billion on economic development in 2015–16, more than doubling the amount spent in 2012–13.[13] Within this focus has been a consistent recognition of the importance of market solutions. The UK Independent Commission on Aid Impact (ICAI) noted that in 2011, DFID stated its aims for private sector development (PSD) as being 'to make markets function better and with greater fairness…[to] enable poor people to find their own way out of poverty'.[14] [15]

There is some evidence to suggest that the potential to leverage the contribution of emerging powers to the access to medicines agenda was also at play in DFID's decision to focus on market-shaping.[16] The "emerging powers" or the BRICS[17] group of countries is particularly important given its impact on both demand for medicines (e.g. for HIV treatment, where South Africa has the largest number of people living with HIV globally) and supply (where India and China in particular are major players in the production of generic medicines). There is evidence that when the CHAI grant was developed, the emerging powers agenda was high profile, including at a senior level within DFID,[18] [19] possibly in the context of the Busan Partnership for Effective Development Cooperation (Dec 2011)[20] that highlighted the changing landscape of aid with the emergence of new players.

3.4 DFID decision to support CHAI

At the time of DFID's decision to fund CHAI, work on market-shaping for access to medicines was gathering pace. DFID had supported a number of programmes and initiatives, such as MeTA[21] and SARPAM;[22] and multilateral efforts were at various stages of advancement in areas such as pooled procurement[23] and advance market commitments.[24] [25] Arguably, CHAI's work on HIV treatment in the early 2000s pioneered the approach, but there are now many forces that directly or indirectly shape markets for global health commodities. Stakeholders with significant influence include the World Health Organization (WHO), the Global Fund to Fight AIDS TB and Malaria (GFATM), UNITAID, the Bill and Melinda Gates Foundation (BMGF), the Medicines for Malaria Venture (MMV), and the US Government (e.g. through PEPFAR, PMI, and associated

[13] http://icai.independent.gov.uk/report/dfids-private-sector-development-work/
[14] http://icai.independent.gov.uk/wp-content/uploads/ICAI-PSD-report-FINAL.pdf
[15] Private Sector Development Strategy: Prosperity for all: making markets work, DFID, 2008, http://www.enterprise-development.org/page/download?id=1727.
[16] *DFID market-shaping grant Business Case, June 2012*
[17] The BRICS are Brazil, Russia, India, China and South Africa.
[18] https://www.gov.uk/government/speeches/emerging-powers
[19] The Emerging Powers and the Changing Landscape of Foreign Aid and Development Cooperation. Public Perceptions of Development Cooperation. Summary Paper 1: China
http://r4d.dfid.gov.uk/Output/189428/
[20] http://www.oecd.org/development/effectiveness/busanpartnership.htm
[21] http://www.medicinestransparency.org/
[22] http://www.sarpam.net/
[23] http://www.medicinespatentpool.org/
[24] http://www.who.int/immunization/newsroom/amcs/en/
[25] http://www.gavi.org/funding/pneumococcal-amc/

implementing partners). These major players were increasingly focused on access to medicines and market-shaping, including through the creation of UNITAID in 2006. However, there was evidence at that time that more was needed to accelerate work in this area[26] [27] and that successful market intervention could not be secured by Global Health Initiatives (GHIs) alone.[28]

The DFID Business Case considered the option to implement a range of market-shaping interventions through contracting one or more organisations with relevant expertise through a DFID-managed mechanism to coordinate and communicate across different implementing entities. However, in view of the high degree of specialisation required for market-shaping across the proposed commodity areas, and in view of the market-shaping landscape at that time, DFID took the view that there were insufficient organisations with the specialist skills to make this option implementable (although it is an objective of DFID's market-shaping engagement to develop the landscape in this direction). At the same time, the Business Case noted that CHAI had the "experience, technical capacity, presence on the supply- and demand-side, track-record of results, commitment and shared objectives necessary to implement the proposed intervention"; this view was formed based on advice from DFID policy leads and in-country health advisers, as well as independent consultants.

CHAI had been an important partner for DFID in its work on market-shaping for global health since the mid-2000s. DFID provided an initial £9 million grant to CHAI for market-shaping work, which ran from 2008 to 2011. This covered work on improving access to selected HIV and malaria medicines in developing countries. It was subject to an independent evaluation in 2011, from which key findings included that DFID support had "helped to improve the affordability, availability and quality for AIDS and Malaria drugs…, and increased capacity in African countries to access these drugs... through negotiating pricing, increasing competition through reducing entry barriers for new producers, facilitating reduction in costs through improving production processes, and improving demand forecasting and the flow of market information more generally" (DFID Business Case). It also noted that CHAI's supply-side work was often seen as the primary catalyst of cost savings, the denominator in the Value for Money (VfM) equation of economy, efficiency and effectiveness, and essential from a VfM perspective.[29]

By 2012, it was recognised that market-shaping interventions had contributed significantly to the 95% decline in prices for first-line antiretrovirals (ARVs) for HIV over the previous decade, and to an 80% decline in malaria treatment prices.[30]

3.5 DFID's 2012–2015 grant to CHAI

DFID agreed a second market-shaping grant to CHAI. This had a much larger allocation, of £35 million, and covered a broader range of interventions in nine programme areas, as set out in Section 1 above.

This broader range of interventions was supported in order to cover the priority health commodities in which DFID invests significant resources – through both bilateral and multilateral channels – as well as to offer the potential to seize opportunities for other commodities as they emerge. Efficiency of HIV spending (or "E2") was included in order to translate some of the principles of market-shaping to HIV financing.[31]

An Accountable Grant was signed on 23 July 2012, for a programme of activity spanning the three-year period from September 2012 to September 2015. The impact, outcome and output targets from the original project logframe are set out in Box 2. The original budget allocations for the grant are set out in Table 2 in Section 4.

[26] The *DFID market-shaping grant Business Case (June 2012)* case notes that Global Health Initiatives (GHIs) are developing strategies to move from a relatively passive "market taking" position (ensuring efficient procurement within the current market structure) to an active "market shaping" approach.
[27] GAVI Supply Task Team (unpublished) "Vaccine Supply and Procurement Strategy - Inception Report"
[28] *DFID market-shaping grant Business Case, June 2012*
[29] Ibid
[30] Global Fund (2010) Press Release: Agreements Reduce Prices of Malaria Medicines by up to 80%.
[31] Conversation with James Droop, DFID

Box 2: DFID-CHAI Programme impact and outcome statements and measures (original logframe)

Impact
Significant increase in ability to advance health-related Millennium Development Goals (MDGs) – Goal 4 on child mortality, 5 on maternal health, 6 on HIV/AIDS and other diseases:
- Saving generated will allow 2.3–2.8 million additional patients to be reached (HIV, TB, malaria, contraceptives).
- Savings on new diagnostic products allow for an additional 550,000 patients to be tested (HIV, malaria, TB).

Outcomes
Facilitate access to, and quality of, treatment of significantly more patients using the funding that is currently available, by reducing the cost of healthcare commodities and delivery. In addition, increase availability (both number and amount procured) of more affordable commodities originating in low-cost, high-quality manufacturing environments such as China and India.
- Net present value (NPV) of total global savings on medicines of US$1.45 billion by 2020
- Between 10 and 15 new products originating from India, China and South Africa approved by a stringent drug regulatory authority (SRA)

Outputs
Optimal drugs for HIV/TB
- 45% reduction in prices for WHO-preferred HIV first-line and second-line HIV regimens (specific focus on hyper-endemic countries in Southern Africa)
- Up to 50% reduction in lowest prices for quality-assured MDR-TB treatment
- 3 additional SRA-assured HIV and MDR-TB products supplied from India & SRA sources

Lower-priced, high-quality diagnostics
- Up to 30% reduction in cost per test result received (over and above price reduction through UNITAID) for at least 2–3 point-of-care (PoC) CD4 products
- Scale up usage of PoC testing for HIV in hyper-endemic countries in Southern Africa
- 3 new SRA approved PoC diagnostic products from China or India

Lower-priced, high-quality contraceptives
- More than 35% reduction in cost of LARCs in low and middle-income countries

Increased availability and supply of malaria diagnostics and treatments
- Significant reduction in prices of malaria rapid diagnostic tests (RDTs)
- Up to five new malaria treatments from India and China submitted to a SRA

The grant was expected to generate NPV savings of $380 to $598 million by 2015, through cost savings multiplied by the scale-up in volumes predicted for key health commodities. Taking cost savings through to 2020 into account, total NPV savings were estimated at between $1.45 billion and $2.53 billion.[32]

The DFID appraisal of the grant included cost-benefit and return on investment analyses. It found the Internal Rate of Return (IRR) to be between 228% (assuming no increase in global access over the project period) and 305% (based on a dynamic trajectory) through to 2020. The grant was also assessed as having a positive return on investment (ROI), paying for itself through savings in DFID health commodity expenditure. Specifically, it was calculated that UK expenditure on antiretroviral therapy (ART) through GFATM and UNITAID alone would give the intervention an ROI of at least 5% a year.

At the impact level, DFID and CHAI calculated that the projected cost savings and scale-up in volumes would allow 2.3–2.8 million additional patients to be reached with safe and effective health commodities and an additional 550,000 additional patients to be tested for HIV, malaria and TB.

A number of contextual factors are likely to have contributed to the particular shape and focus of this grant, compared with its predecessor. Since 2010, DFID has undergone significant changes in the volume of its resources and in the way these resources are programmed and monitored. This has created pressure to develop larger programmes (in terms of financial commitments) in response to increasing programme funds and decreasing administrative resources. However, DFID's budget increases have happened at the same time as major cuts in most other UK Government departments, which has resulted in increased scrutiny on

[32] DFID Business Case p.28 'Summary of NPV Calculation'

the results DFID achieves. As noted in the recent ICAI report on "DFID's approach to delivering impact", this appears to have led to a focus on short-term results at the expense of long-term, sustainable impact.[33]

At the same time, DFID, and indeed the development sector more broadly,[34] has been grappling with how best to implement adaptive programmes that enable effective responses to complex problems (e.g. see the ICAI report highlighted above,[35] and DFID's smart guide on logical frameworks).

At the initial evaluation meeting with CHAI at DFID (21 November 2014), the EvT learned that the CHAI programme has been characterised by adaptation. As discussed in more detail within each programme area in the key findings section, we have indeed found clear evidence of adaptation to implementation experience as the grant has progressed. There have been changes to the overall funding amounts allocated to each programme area, the portion allocated to global vs country-level activities, the countries to which funding has been allocated, and the activities conducted with the funding. There has also been significant iterative adaptation of logframe and VfM targets.

In summary, contributing to global savings was the key expectation of the DFID grant to CHAI, as well as:

- that it would contribute to progress on the health MDGs through improving access to medicines and other health commodities;
- that this would be done through market-shaping activities that would also leverage the potential of market actors in the BRICS countries; and
- that a set of specific and measurable results and targets would be achieved through flexible and adaptive programming.

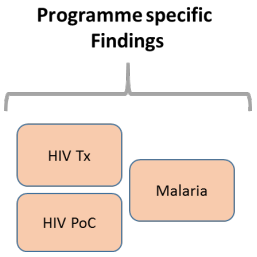
The extent to which these expectations were met is discussed in the remainder of this report, focusing on four programme areas in turn as proxies for the DFID grant as a whole, and then drawing out cross-cutting findings and more generalizable lessons.

[33] http://icai.independent.gov.uk/wp-content/uploads/ICAI-report-DFIDs-approach-to-Delivering-Impact.pdf

[34] The issue of adaptive programming was discussed in a blog by the deputy head of Deputy Head of DFID's DRC office https://dfid.blog.gov.uk/2013/10/21/adaptive-programming/ and has been the subject of much debate in a range of high profile international forums and publications, including for example: *Aid on the Edge of Chaos* (Ramalingham, 2013); a series of three blogs by the Centre for Global Development (http://www.cgdev.org/blog/complexity-adaptation-and-results) and in the Doing Development Differently agenda (http://www.odi.org/events/4147-doing-development-differently).

[35] http://icai.independent.gov.uk/wp-content/uploads/ICAI-report-DFIDs-approach-to-Delivering-Impact.pdf

4 Programme Area Findings



4.1 Introduction

This section of the report sets out the evidence gathered through data collection and analysis, in relation to three specific programme areas, and the key findings that have emerged from this. As indicated previously, assessments of CHAI's E2 intervention and the LARCs programme area are the subject of separate and confidential reports.

Table 2 below is taken from the most recent CHAI data shared with the EvT (November 2015), reflecting grant status at the end of its planned three-year timescale. Column A provides the original grant allocation across programme areas, and column B shows actual expenditure across the grant period (to end September 2015), both in pounds sterling.

Columns C and D show the original low and high case anticipated NPV savings. The three columns to the right (E, F, G) reflect CHAI's estimates of cost savings achieved, forming the basis of CHAI VfM calculations. All cost savings figures are in US dollars. Within the programme area sections of this report, the EvT has detailed, and in some cases questioned, the assumptions that form the basis of the estimates below.

The five programme areas that are focused on in this evaluation are shaded green in the table.

Table 2: Grant Budget and VfM Summary – 2012 forecasts, 2015 actuals, and 2020 scenarios

	Programme area	*Budget*		*Expected NPV Savings*		*CHAI reported achieved savings (non-discounted)*		
		A Original proposed grant allocation £	B Actual expenditure, September 2015 £	C Original anticipated NPV cost savings low case through 2015 $	D Original anticipated NPV cost savings high case through 2015 $	E CHAI reported cost savings through September 2015 $	F Low case cost savings scenario through 2020 $	G High case cost savings scenario through 2020 $
1	Maximising Value for Money and Ensuring Sustainable Supply of HIV Treatment	6,940,000.00	8,688,560.75	153,200,000	267,300,000	271,567,882	994,096,134	1,428,478,592
2	Accelerating Introduction and Scale-Up of Point-Of-Care HIV Diagnostics	4,430,000.00	4,281,233.38	99,700,000	99,700,000	18,183,443	211,940,593	211,940,593
3	Maximising Value for Money of HIV Spending for Universal Access to ART (E2)	3,040,000.00	3,279,657.41	73,000,000	177,000,000	66,460,542	357,445,705	679,289,514
4	Improving Pricing and Supply Security for High-Quality MDR-TB Drugs	2,020,000.00	763,621.29	39,000,000	39,000,000	--	--	--
5	Accelerating Market Entry of Highly Accurate and Lower-Cost New Diagnostic Products	4,100,000.00	1,340,542.37	--	--	--	--	--
6	Increasing Access to Long-Acting Contraceptives	780,000.00	343,290.80	14,600,000	14,600,000	234,299,739	511,951,539	511,951,539
7	Improving Vaccine Market Dynamics for Price Negotiations	1,590,000.00	991,130.91	--	--	164,319,295	395,140,480	457,897,268
8	Ensuring Rapid and Sustainable Scale-up of Supply of Malaria Rapid Diagnostic Tests	3,560,000.00	3,959,286.39	--	--	3,038,804	16,604,250	23,288,346
9	Ensuring Rapid and Sustainable Scale-up of Supply of Quality Malaria Treatments	2,860,000.00	1,978,881.92	--	--	--	--	--
10	Private Market TB Initiative: IPAQT	-	557,143.74	--	--	7,937,674	51,346,288	51,346,288

	Other: SLL, NMO, Liberia	1,370,000.00	4,244,294.58	--	--	--	--	--
TOTAL		**£ 30,690,000.00**	**£ 30,427,643.54**					

Note: Total grant overhead is GBP 4,426,442, or equivalent to 5% of funds spent on sub-contracts and 15% of all other direct programmatic amounts.

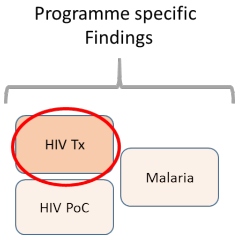
The data in the table raise several important points:

- There have been several shifts in the allocation of resources to different programme areas, and some additional initiatives (which were not highlighted in the evaluation ToR) have been included, beyond the original 9 programme areas.
- It should be noted that the DFID grant to CHAI included resources from two DFID HQ departments and three DFID country programmes (India, Southern Africa and Uganda). The resources from DFID Uganda (Sept 2013-Jun 2015, $1.8 million; funding included in overall figures above) included support to a Health System Strengthening (HSS) component supporting activities conducted in other programme areas.
- Two of the five focal programme areas for this evaluation (LARCs and Malaria treatment) have been subject to significant reductions in resources, based on a comparison of actual expenditure in September 2015 and the original proposed grant allocation; while the HIV treatment area has spent approximately US $13 million instead of the US $11 million originally allocated.
- Accepting CHAI's assumptions, overall cost savings are reported to have exceeded those set out in the DFID Business Case, by a significant margin if total projections are included (rather than those that are comparable with the bases for projected savings at the outset of the grant).
- It should be noted that in the table above CHAI has provided reported savings achievements (columns E, F, G) in non-discounted figures, while original expectations (columns C, D) have been reported on an NPV (discounted) basis. Thus the achieved savings will appear to be inflated when compared to the discounted expectations. For information, column E recalculated for programme area 1 (HIV treatment) on an NPV basis would be $231 million (vs. $271 million non-discounted) and column F NPV savings would be approximately $780 million (vs. $994 million non-discounted).
- Aggregate figures mask variations in performance across the five focal programme areas. Significant overachievement in LARCs cost savings makes up for significant underachievement relative to expectations for PoC diagnostics and E2; no savings have been recorded for malaria treatment because the basis for the VfM calculations related to an area outside the evaluation scope (see Section 4.4 for more detail).

Further, with respect to all CHAI expenditure data cited in this report, CHAI has requested that the following is noted: "Due to CHAI's matrix operating structure, the budget does not perfectly align with the organisation of the grant logframe. For the purposes of the evaluation and in an effort to to provide the data in the format requested by the EvT, financial data allocations have been categorised to align with the logframe, which requires some interpretation. Thus, the allocations within [CHAI financial] reports, while largely accurate, should be considered indicative."

In this section of the evaluation report, we look at how the DFID grant allocations were used across three programme areas – HIV treatment, HIV PoC diagnostics, and malaria treatment. For each programme area, we start by looking at the context pre-grant in terms of the public health need and state of the market. Then we examine CHAI's market-shaping interventions that aimed to respond to that need, and the results that this work has generated across the grant period.

4.2 HIV Treatment



CHAI's work to shape the market for HIV treatment is analysed in this section according to its process (the activities in which CHAI engaged), and its impact (what CHAI achieved). CHAI's activities, and those of other stakeholders, are plotted using a key framework from the Healthy Markets Primer (see Box 1 above), to consider the degree to which its 'dominant logic' explains the process by which CHAI approached its market-shaping work in this programme area. CHAI's impact is analysed in terms of market changes – as indicated by pricing, uptake volumes and competition – before and after the grant timeframe, and the contribution of CHAI to those changes is evaluated.

4.2.1 Market context pre-grant

4.2.1.1 What was the public health need?

In 2012, there were approximately 35 million people living with HIV (PLHIV) in low- and middle-income countries (LMICs), with 26m eligible for treatment and 9.7m on treatment. However, this still only represented 65% of the "15 million by 2015" target agreed by UN Member States in June 2011 at the General Assembly High-Level Meeting on AIDS in New York. Many countries had large financing gaps to fill, to meet their National Strategic Plans (NSPs) and to align with WHO Guidelines, while donor funding was expected to remain static. The DFID grant to CHAI was conceived within this context of growing resource needs within a limited resource envelope, and a consequent need to achieve efficiencies in spending.

Early on in the grant, the World Health Organization (WHO) 2013 HIV treatment guidelines made a recommendation for the use of tenofovir disoproxil fumarate (TDF) in combination with lamivudine and efavirenz (TLE), or TDF with efavirenz and emtricitabine (TEE), and a discontinuation of stavudine (d4T) in first-line regimens. As this transition involved nearly 1 million patients on d4T-based regimens, and a gradual shift of between 2,000,000 and 3,800,000 patients on zidovudine (AZT) regimens to TLE or TEE, it was recognised as a significant undertaking.

4.2.1.2 What was the market need?

Newer ARVs presented challenges with regard to accelerating uptake, reducing prices and, in some cases, navigating intellectual property (IP) barriers. With established ARVs, volumes and competition were higher, and lowering costs through process innovations offered high potential for expanding access to treatment. In both second-line drugs (SLDs) and first-line drugs (FLDs), there has been a reliance on a small number of manufacturers to supply the entire market, given barriers to entry[36] in both sectors. Domestic funding for ARVs had increased prior to 2012, but not all agencies had demonstrated good procurement practice. Global purchasers were buying more strategically, and systems for capturing market intelligence and pricing information were improving.

First-line drug market

Market interventions to influence first-line regimens began prior to the DFID grant to CHAI. In 2006, Gilead independently arranged for 15 companies to have tenofovir licenses, while UNITAID and CHAI intervened to incentivise market entry and competition for tenofovir (TDF)-based regimens. The Medicines Patent Pool (MPP)'s work enabled wider market eligibility and a reduction (eventually elimination) of royalty fees. By 2012, nine manufacturers were selling TDF eligible for donor-funded procurement and 3.9 million patients were on TDF-based formulations (46% of all adult patients). However, only Mylan had secured WHO prequalification (PQ) on the fixed-dose combination (FDC) formulation for most of 2012. Due to a price premium on the Mylan product, uptake of the FDC was slow initially. The median price per person per year (pppy) in 2012 was $146[37] for the TDF FDC while the CHAI ceiling price, and baseline price used in the VfM calculations for the grant,

[36] Barriers may include a lack of economies of scale, challenges in accessing APIs, different manufacturing cost structures or tender practices that award all volumes to one or two large manufacturers. For second-line drugs, barriers may also be posed by intellectual property.

[37] The UNITAID Market Landscape notes even lower prices: "By 2012, nine manufacturers sold TDF eligible for donor-funded procurement. Three manufacturers sold the one-tablet full-regimen TDF/3TC/EFV at a cost of less than US$ 140 per person per year."

was $159. Using the CHAI ceiling price as the basis for price monitoring, CHAI had expected pricing to evolve as in Table 3 below, taken from CHAI's VfM projections. The top row shows the baseline and expectations due to market forces without CHAI's intervention, and the bottom line predicts the price trajectory factoring in CHAI's influence.

Table 3: CHAI's forecast price reductions for 1st line, WHO-preferred HIV regimens

	2012	2013	2014	2015
Baseline TDF+3TC+EFV price pppy (counterfactual price evolution)	$159	$150	$140	$130
CHAI TDF+3TC+EFV price pppy	$149	$130	$110	$90

Second-line drug market

At the start of the grant, atazanavir-ritonavir (ATV/r) had a market share of less than 5% of second-line patients and lopinavir/ritonavir (LPV/r) more than 90%. CHAI expected to increase uptake of formulations containing ATV/r and to reduce pricing. Again using the CHAI ceiling price as the basis for price monitoring, CHAI had expected pricing to evolve as in Table 4 below, taken from CHAI VfM projections. The top row shows the baseline and expectations due to market forces without CHAI's intervention, and the bottom line factors in CHAI's interventions.

Table 4: CHAI's forecast price reductions for 2nd line, WHO-preferred HIV regimens

	2012	2013	2014	2015
TDF+3TC+ATV/r baseline price pppy(counterfactual price evolution)	$394	$389	$365	$350
CHAI price pppy	$377	$330	$266	$250

4.2.2 CHAI intervention

For this programme area, CHAI was allocated $11.1 million (approximately £7m) of the DFID grant, and CHAI expected to generate NPV savings of $561 million to $1.1 billion between 2012 and 2020.[38]

CHAI's objective was to sustain reduced prices, ensure stable market supply, and scale-up use of the most effective ARVs. CHAI proposed to simultaneously engage ARV drug manufacturers and key stakeholders involved in product selection and purchasing decisions in 5–7 focus countries, specifically:

- Reformulating an existing drug to further reduce the cost of ARV therapy;
- Accelerating uptake of currently available, more cost-effective ARVs;
- Facilitating cost reduction and widespread uptake of critical new ARVs; and
- Promoting the long-term sustainability of the ARV market.

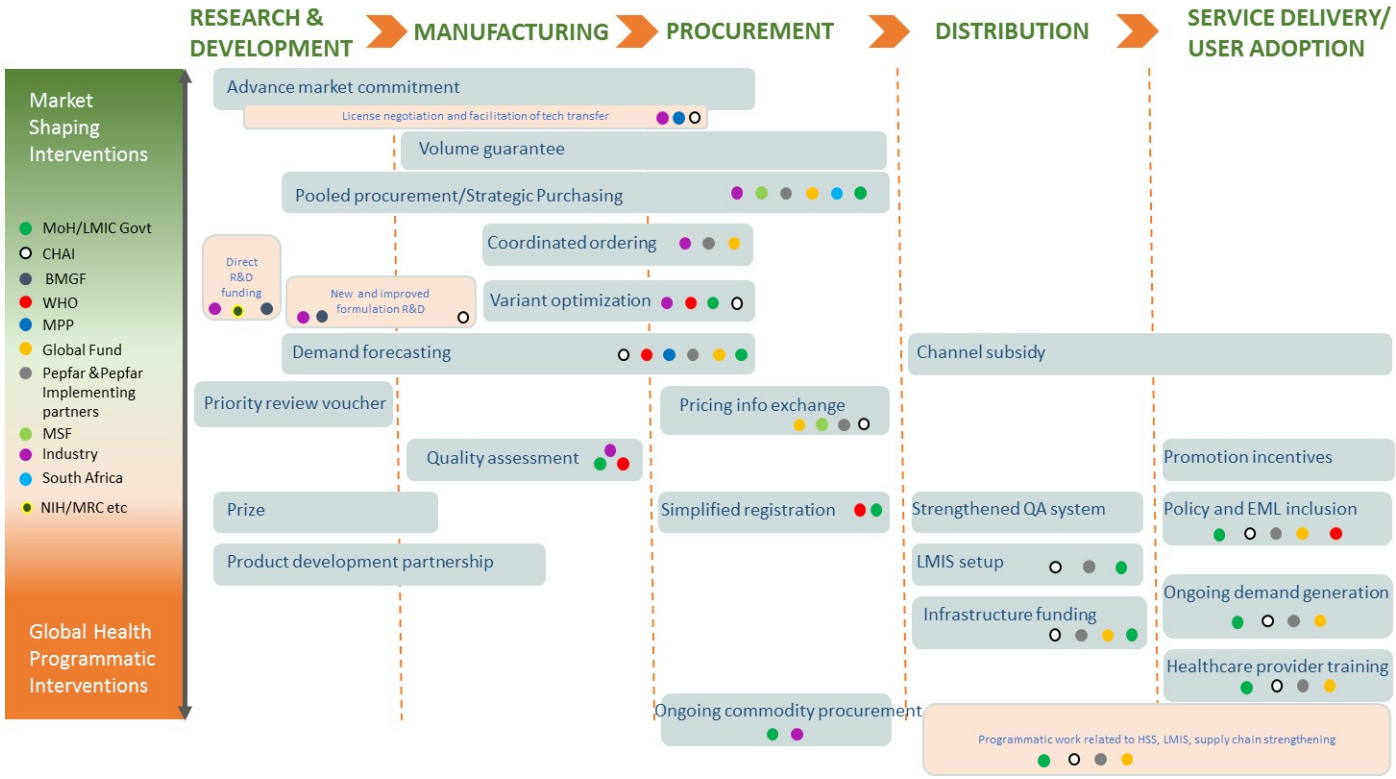
At the time the grant was being developed, CHAI's market-shaping priorities were to improve tendering practices globally and in focus countries, and to increase information transparency around prices and supply throughout the supply chain from intermediates and active pharmaceutical ingredients (APIs) through to formulations. CHAI expected to facilitate licensing of patented products, and to find ways to decrease costs through, for example, process chemistry innovations and dosage reduction. There was also a focus on decreasing the prices of quality-assured products by expanding the supply base, particularly focusing on Chinese, Indian and South African suppliers. CHAI's country focus – according to the DFID Business Case, the VfM calculations, and Annex E of Evaluation ToRs (Feb 2014)[39] – was consistent: Kenya, Nigeria, South Africa, Swaziland, Uganda, Zambia, Zimbabwe.

[38] Market Shaping for Access to Safe, Effective and Affordable Health Commodities, DFID Business Case, June 2012
[39] These were the countries defined as having "Direct DFID funded engagement"

4.2.2.1 What were others doing?

The EvT has plotted the landscape of implementation activity influencing the ARV market, using a key figure from the Healthy Markets Primer. The Primer positions activities in terms of their fit on a technology development and implementation value chain (horizontal placement) as well as the degree to which the intervention is more catalytic vs programmatic, as defined by its time-bound nature and potential for exit (vertical placement).

Figure 5: Market-shaping implementation landscape for HIV treatment



Starting at the upper left hand side of the diagram, publicly funded national research bodies such as the US National Institutes for Health (NIH) and the UK Medical Research Council (MRC) fund upstream R&D into new ARVs. Similarly, BMGF funding is focused on supporting new technology R&D and process innovations to reduce cost or to improve safety, efficacy or tolerance of formulations. UNITAID had funded earlier work, including through CHAI and the Medicines Patent Pool (MPP), to shape the markets for FLDs and SLDs; this shaping was being further leveraged during the period of this grant. UNITAID, DFID, SIDA, and the Children's Investment Fund Foundation (CIFF) are all funding work in this space; however, they are not shown in the diagram – only the agents they fund are shown, due to the difficulty in distinguishing which funder is behind certain interventions, particularly as there is significant overlap. The MPP negotiates licences with patent holders and has a transparent and systematic process by which it makes those licences (and technology transfer where relevant) available to generic manufacturers. CHAI has also been engaged in licence brokering work, as detailed later in this section.

USAID/PEPFAR is one of the major funders of HIV prevention and treatment programmes in numerous LMICs, and their work (directly and through partners) spans the entire value chain. Similarly, the GFATM is the largest funder of ARVs in the developing world. GFATM and PEPFAR used the same procurement agent, the Partnership for Supply Chain Management (PfSCM), during part of the grant period and this allowed a degree of coordinated ordering. Given that 75% of the purchasing is controlled by GFATM, PEPFAR and South Africa together, major market influence is coming from these stakeholders, with spending on ARVs in excess of $1 billion per year. The GFATM Voluntary Pooled Procurement (VPP) programme marked the start of a more strategic market-shaping role, and in 2013 this evolved into GFATM's new Procurement for Impact

(P4i) initiative.[40] Under this shift, the GFATM has an increased strategic purchasing role, including direct selection and contracting of manufacturers.[41]

Ministries of Health (MoHs) in developing countries fund an increasing portion of the commodities and programmatic work, especially in South Africa. Médecins Sans Frontières (MSF) runs its own service delivery facilities in least developed countries (LDCs), procures for its programmes, and works to increase information transparency in the ARV market. The WHO PQ programme, along with stringent drug regulatory authorities (SRAs) such as the US Food and Drug Administration (FDA), regulate the quality of ARVs and influence what can be bought with public funds. The WHO influences market size and allocation, through recommendations on treatment eligibility and preferred regimens. WHO recommendations have in recent years increasingly coalesced around a dominant set of regimens, towards "variant optimisation". This insures against inefficient demand fragmentation or the use of sub-optimal regimens, insofar as LMIC governments (often with the support of CHAI and WHO in country) can align national policies and guidelines with WHO global recommendations. Demand forecasting is done by a variety of partners. ARV producers are involved throughout the value chain, as shown in Figure 5 above.

Mapping stakeholders and interventions onto the Primer figure enables several observations. Work spans all areas of the value chain and it encompasses catalytic as well as programmatic work. However, there are many stakeholders involved in implementing these different activities, and there is potential for gaps at the interface between them. There are also a few new tools being used to shape this market now, which were not used even 5 years ago. Navigating IP protection and process chemistry innovations are fairly recent developments. Strategic purchasing has been used to diversify the supply base, for example CHAI's UNITAID funded work, which shaped the market for LPV/r. The three large buyers have also taken a more strategic and coordinated approach to purchasing in recent years; they are communicating better although not fully coordinating orders.

CHAI is present, to varying degrees, in many areas of the ARV value chain. CHAI advises and supports manufacturers in the development of optimal ARV formulations, works on process chemistry innovations to reduce the cost of production, engages with Chinese and Indian sources of APIs to broaden the supply base, facilitates licensing agreements between patent holders and generic firms, provides data to support evidence informed decision-making around which regimens to prioritise at country level, and supports LDC governments in the development of their policies, plans, financing and implementation when transitioning from older regimens or formulations to optimised regimens. CHAI also reduces risks for purchasers and manufacturers by improving ARV demand forecasting, advises on procurement practice and supports good procurement process in some countries, and supports mechanisms for information exchange and lesson sharing, including around market intelligence systems. CHAI is relatively less active in the middle section of the figure; influence on product regulatory approvals at national or global level has not been an emphasis of CHAI, nor has CHAI been a buyer of adult ARVs during the grant period. In addition to the above-mentioned activity – which fits neatly into the Primer framework – the light orange area in the lower right-hand corner has been added to reflect CHAI's more programmatic technical assistance (TA), where it has flexibly filled gaps in government funding or has extended the work of other partners into new geographic or product areas. A final observation is that the diagram does not facilitate reflection on the emphasis within CHAI's work: for example, CHAI engages heavily in data and dialogue in support of "Policy and EML inclusion" of optimised regimens, which is not apparent from the small white dot under that heading.

4.2.2.2 Review of CHAI activities under DFID grant

The Primer allows us to illustrate the range of CHAI's market-shaping work in HIV treatment, which spans nearly every aspect of the value chain through catalytic as well as programmatic support. CHAI's specific activities are further detailed below, grouped into two main sections: i) demand-side, in-country work; and ii) supply-side and global-level work.

[40] http://www.who.int/hiv/amds/07_GF-procurement-and-funding.pdf
[41] The Global Fund-PEPFAR ARV Supplier Conference. Dubai: The Global Fund to Fight AIDS, Tuberculosis and Malaria; 24–25 June 2015.

i) Demand-side, in-country work

In support of WHO recommended product transitions, CHAI has supported work from policy to systems levels showing a holistic approach, focusing on influencing how products are bought, the product mix, and how the products get to patients. Beyond these more catalytic activities focused on product transitions, CHAI is engaged in a large amount of more programmatic TA focused on supporting general access to medicines, including supply chain work, and this is not limited to HIV.

Procurement practice

The tendering practices of GFATM and PEPFAR have evolved during the grant period independently of CHAI, although CHAI is supportive of new GFATM sourcing approaches and was engaged prior to the grant timeframe in the GFATM market-shaping strategy and Market Dynamics Committee. However, there were two significant examples observed during EvT country visits where CHAI is influencing country-level procurement strategies and processes.

In Malawi, CHAI is supporting the Central Medical Stores Trust (CMST) to improve its data management and particularly quantification to support procurement, warehousing and distribution. The aim is to strengthen the core government procurement and supply chain systems, build trust in CMST among donors and funders, and ultimately reduce the operation of parallel systems and increase efficiency.

CHAI has been supporting South Africa's tendering capacity development for many years. In the 2015–2017 tender, CHAI support resulted in significant savings of $260 million, $190 million of which came from savings on TEE. For the first time, this is a three-year tender, providing opportunities for cost savings and product optimisation. Even though the South African National Department of Health (NDoH) now has its own advanced systems for gathering supply-side intelligence, decision-makers confirmed in KIIs that CHAI continues to make major contributions to South Africa's tender savings, through its business intelligence and ability to provide a second opinion. CHAI has also been working on documenting and building the systems for tender management. The NDoH also values CHAI support to procurement over the years: "More and more, CHAI's methods have become our way of doing business, so that's a success story in terms of TA transferring skills and methods to local partners" (Government official).

Product mix

The evaluation country case studies validated CHAI efforts to support country-level product optimisation decisions in relation to HIV treatment. However, these efforts were not universally successful. In all countries where it operates, CHAI works in an advisory capacity in terms of product selection and procurement decisions, presenting data to help countries analyse the cost-benefit of optimal ARV regimens. CHAI models the costing implications of switching to new regimens, analysing different scenarios for phased introduction. CHAI helps translate choices into procurement decisions, with drug specific costing and quantification work, as well as advocacy to include new regimens in GFATM procurement and supply management (PSM) plans and in ARV tenders. In Zambia, CHAI leveraged data from across countries and provided access to global expertise to help decision-makers understand that TLE and TEE were interchangeable, while in Zimbabwe, CHAI provided data that facilitated the government's decision to change to a single pill a day TLE. Decision-makers in South Africa appreciated that CHAI had used its networks with Chinese firms to helpfully determine whether there was sufficient efavirenz (EFV) capacity to support South Africa's move to TEE.

CHAI was also credited in several countries with having a significant role in motivating inclusion of ATV/r as a second-line option on their new HIV treatment guidelines. For example, Malawi experienced one of the most rapid and successful transitions of second-line patients from LPV/r to ATV/r. Nearly all second-line patients (97–99%) were on ATV/r at the end of 2014. However, CHAI's objective to work with urgency can sometimes cause tensions. For example, in Kenya, CHAI presented a cost-benefit analysis as a rationale for change of policy and wanted the government to adopt ATV/r immediately. However, the National AIDS and STIs Control Programme (NASCOP) insisted on a consultative process to consider all options, as well as a formal change in guidelines, before initiating procurement. Now that ATV/r has been incorporated into the Kenya national ART guidelines, CHAI has supported its inclusion in GFATM procurement plans.

ATV/r product registration timelines have also been a challenging area. CHAI was active and successful in supporting speedy ATV/r registration of the single ATV/r supplier in Malawi, although CHAI was not able to have impact with the Medicines Control Council (MCC) in South Africa. In-country registration as well as global WHO PQ or approval by another SRA is required for new products and new formulations,[42] and thus product approvals are important in terms of enabling a broad supply base of quality producers. However, weak competition in global ATV/r supply was a source of price rigidity, as well as supply insecurity, for ATV/r during the grant period. At a global level, there was only one supplier of ATV/r until March 2015, as the second-to-market supplier of ATV/r was working on satisfying additional data requirements of the US FDA. A company representative from this second to market supplier stated that CHAI was not involved in resolving these additional data requirements, except as a recipient of information; this supplier kept CHAI, GF, and PEPFAR abreast of developments in their exchange with the FDA and problems were eventually resolved between the supplier and the FDA. [43]

Global supply capacity in relation to second-line product transition has also been an issue. During late 2014, there were global ATV/r shortages, as demand picked up more quickly than supply capacity. When Nigeria placed an order for ATV/r recently, this caught the single supplier by surprise and highlighted the need for improved real-time communication and coordination of orders. As of mid to late 2015, the two main ATV/r suppliers continued to see this as an unmet need. CHAI is no longer a buyer of second-line ARVs and this appears to have reduced its ability to facilitate communication about supply and demand alignment in relation to real-time ordering.

Product transitions

The smooth transition to TDF-based regimens, recommended in the 2013 WHO HIV treatment guidelines, was an important global priority. In all countries where it operates, CHAI has been key to supporting the process of transitioning: participating in expert advisory committee meetings, supporting new guideline drafting and the development of clinical support tools to aid smooth transitions, and changing clinical algorithms. For example, in Ethiopia, CHAI developed the national switch algorithm. CHAI funds meetings and the printing of new guidelines, as well as related provider training. In Uganda and Nigeria, CHAI has worked with PEPFAR partners to host continuing medical education (CME) and to support other mechanisms for gleaning provider support to product transition. CHAI has also analysed the budget impact of new products, provided data and analysis in support of GFATM concept notes (and therefore facilitated access to funding), and supported adaptation of supply systems, including data management for forecasting and quantification as well as supply chain alterations. With the August 2015 publication of CHAI's work on ATV/r,[44] CHAI has started to better document and share its experiences in supporting the process of new product introduction.

CHAI also draws on its cross-country experience and leverages tools developed in one country for others – e.g. the online database tool in South Africa (Box 3 below). Good examples of contributing to sustainability are provided by South Africa and Uganda, among others. In Uganda, CHAI was credited with strong process management, which results in gradual ownership by MoH employees and the government once they see the benefits of key initiatives such as the forecasting tool.

However, product transitions were not without challenges, a principal one being security of supply, i) globally (as previously explained) and ii) within countries. Supply challenges within South Africa with the transition to TEE were well documented, with weaknesses in operational management and implementation criteria that resulted in stock-outs.[45] Zambia's introduction of Option B+ was similarly riddled with difficulties, including drug stock-outs, even though CHAI led the business plan development process including drug quantification.

[42] Registration in the home market (e.g. India for Indian suppliers) is also required and this has reportedly become more challenging as of late.

[43] Note that in CHAI's Mar 31 2015 quarterly report, CHAI states that "For second-line treatment, CHAI's efforts have focused on increasing access to and lowering the price of atazanivir/ritonavir (ATV/r), but capacity constraints from current suppliers during late 2014 and early 2015 threatened to halt the positive trends in uptake and hinder further price reductions. In response, CHAI worked with the suppliers, global procurement bodies, and the U.S. Food and Drug Administration (USFDA) to resolve the problem". The text implies that CHAI had a role in this process. CHAI was not able to provide any further information to validate its specific role in support of ATV/r dossier submissions or exchange of data requirements between global regulators and suppliers. The EvT's interview with subsequent ATV/r market entrant does not validate CHAI's reporting of its activity and influence.

[44] http://www.clintonhealthaccess.org/case-study-atvr-uptake/

[45] See (for example) Bekker et al., Provision of anti-retroviral therapy in South Africa, the nuts and bolts. *Antiviral Therapy* 2014, 19 Suppl 3: 105–116.

It would be difficult to blame CHAI for systemic problems that pre-dated the FDC roll-out (in the case of South Africa) or for issues exacerbated by major institutional change (in the case of Zambia).

Box 3: Getting to the root cause of ARV stock-outs in South Africa

Analysis of reports from the Stop Stock-outs campaign[46] showed that 20% of ARV stock-outs were due to manufacturers' failure to supply and 80% due to poor facility demand planning. CHAI is getting to the root cause of the issue by supporting work on an online commodity management tool, which simultaneously helps the NDoH to more accurately forecast and quantify its requirements as well as to track and monitor the performance of suppliers. The aim is to improve efficient stock management but also to discipline suppliers who default on lead times. The database project is the first of its kind in Sub-Saharan Africa and CHAI plans to take it to other countries.

CHAI's programmatic TA

There is a certain amount of health systems and supply chain work that is required for product introduction and transitions. CHAI's work in support of access to HIV-related medicines is not limited to catalytic support, but extends into longer-term cross-disease programmatic efforts. For example, in Kenya, CHAI has helped develop systems for tracking ARV use; in Ethiopia, CHAI is supporting Integrated Pharmaceutical Logistics System (IPLS) work to help extend PMTCT (Prevention of mother-to-child transmission of HIV) reach to more rural areas; and in Zimbabwe, CHAI works closely with the MoH on forecasting, procurement and supply planning. In Malawi, as noted previously, CHAI is working to strengthen supply chain management systems for all health commodities, not just ARVs.

CHAI's HIV systems support work has thus served as a platform for moving into more programmatic TA. This may be appealing to CHAI as an organisation and attractive to individuals within CHAI, as well as to governments who appreciate CHAI's ability to flexibly and quickly fill TA gaps. However, this has sometimes presented challenges for CHAI in terms of comparative advantage, the need for collaboration, and effectiveness in execution. Specifically, this work often has a focus at sub-national level and requires effective collaboration with PEPFAR partners and others. Programmatic TA may also dilute CHAI's focus on catalytic or strategic issues. This was seen for example in Zambia, where CHAI seized an opportunity to support a decentralised pharmacy mentoring programme focused on supply chain strengthening, but with finite resources was not able to work on catalytic supply chain impact at more central levels. Ongoing, less catalytic TA also takes CHAI outside the scope of the DFID market-shaping grant.

In addition to the fact that the range of HIV treatment activities covered by the grant has been wider than originally intended, the range of countries supported has expanded. CHAI's country focus – according to the DFID Business Case, the VfM calculations and Annex E of Evaluation ToRs (Feb 2014)[47] – was consistent, shown in bold type in Table 5. However, with the agreement of DFID that adding countries was an option, 8 further countries (non-bold in Table 5) eventually received DFID funding for this programme area. This may indicate flexibility to respond to needs, and with only 75% of country allocations going to the original seven countries, it also reflects a highly adaptive programme.

Finance allocations and expenditure directed to global as well as country level activities are provided in Table 5. It has been challenging for CHAI to provide this information, given CHAI's matrix operating structure, and a budget which does not perfectly align with the organization of the grant logframe. For the purposes of the evaluation, CHAI categorised allocations to align with the logframe, requiring some interpretation. Thus, the allocations below, while largely accurate, should be considered indicative. Allocations also have shifted within the evaluation timeframe due to refinement of the interpretation of the classifications and in latter years, to reflect actual expenditure rather than budget figures.

[46] http://stockouts.org
[47] These were the countries defined as having "Direct DFID funded engagement"

Table 5: Finance allocations for HIV treatment (Original countries highlighted in bold)

HIV Treatment Team	DFID Access 2 (£)	DFID Access 2$
Global	£ 3,708,665	$ 5,886,914
Cambodia	£ 122,020	$ 196,709
Ethiopia	£ 283,126	$ 453,290
India	£ 224,278	$ 356,690
Kenya	£ 307,503	$ 488,777
Lesotho	-£ 2,578	$ (4,015)
Malawi	£ 331,182	$ 531,691
Myanmar	£ 282,392	$ 456,824
Nigeria	£ 779,226	$ 1,241,925
South Africa	£ 480,401	$ 762,348
Swaziland	£ 666,081	$ 1,060,687
Tanzania	£ 72,208	$ 115,397
Uganda	£ 507,509	$ 808,444
Zambia	£ 536,479	$ 856,726
Zimbabwe	£ 390,069	$ 624,221
Grand Total	**£ 8,688,561**	**$ 13,836,627**

ii) Supply-side and global-level activity

During the grant period, other partners have developed their capacities and systems for procurement, for market intelligence gathering, for licence brokering, and for managing product transitions. In response to these developments, CHAI has broadened its disease areas, its services and its partnerships, in line with evolving market-shaping needs. However, there remain opportunities to exit, alter or bolster other interventions.

With UNITAID funding prior to the current DFID grant, CHAI had been a strategic purchaser of second-line ARVs, and was key in shaping this market. This role was transitioned to the GFATM and PEPFAR during the current DFID grant. Suppliers and other procurers, as well as CHAI, acknowledge that CHAI's access to real-time information on purchase trends has consequently lessened in these markets. The aforementioned challenges with ATV/r highlight a continued need to manage the timing of guideline changes, tenders and orders at country level – and across countries – in relation to supply-side regulatory approvals and capacity. CHAI and the rest of the global community will need to bolster the mechanism for managing demand and supply alignment, especially during product transitions and with the expectation of several new ARVs entering the market by 2017.

CHAI has deepened its work in the lab, not only working on process chemistry innovations as it had done before, but also working on targeting new formulations and dose reductions that have the potential to provide less expensive, better tolerated ARVs. Under the current grant, CHAI is supporting work on a lower dose formulation of TDF intended to increase bioavailability and reduce costs, with the support of Aurobindo and a Canadian contract manufacturing firm. This work could be expected to save one-third of API costs on first-line treatments worldwide. CHAI is also recognised by many global stakeholders, including generic companies, as a key partner to consult as the next generation of FDCs are developed, given CHAI's understanding of country needs as well as process chemistry. While there was consensus among key informants on the usefulness of CHAI's work on low-dose TDF, and CHAI's potential role in informing new FDC combinations, the value of the work on low-dose EFV is not universally accepted. Although the BMGF has pulled the funding on the work – with a view that the cost-benefit no longer justifies it – CHAI continues to be optimistic on its prospects, it has been discussed favourably every year since 2013 at the annual Conference on Retroviruses and Opportunistic Infections (CROI) meeting. Subsequent to the grant end, EFV400 has been included in the 2015 WHO Guidelines. Mylan is also putting money into its development, expecting to reduce by 10% the cost of treating 90% of the first-line patients taking FDCs containing EFV, with additional benefits of a smaller pill with fewer side effects.

CHAI's work to increase competition, by facilitating market entry, has always been strong in India. During the current grant, CHAI strengthened its work with Chinese firms, focusing on the largest API and intermediate manufacturers, and in areas where there have been supply shortages in the past. WHO identified the need for API capacity tracking for certain products, so CHAI and others are responding to this need.[48] Chinese companies working with CHAI appreciate CHAI's market summaries as well as bilateral meetings to update companies on trends (WHO guidelines and uptake patterns) in their current product areas and likely emerging product areas. CHAI has connected these companies with Indian customers and has explained how to gain WHO PQ – this help has resulted in a more diverse supply base for existing ARVs for products like zidovudine and EFV. These companies are now branching into making WHO-prequalified API for other ARVs as well as hepatitis C virus APIs. Chinese companies interviewed expressed interest in forward integrating into finished product production and conveyed their need for TA in several domains: knowing which products have good potential (i.e. where additional suppliers are needed), developing good manufacturing practice (GMP) capacity, preparing regulatory dossiers for WHO PQ and registering the product in recipient countries, and understanding how to bid for tenders. The Chinese firms interviewed by the EvT conveyed a large appetite for continued and expanded TA from CHAI.

Under this grant, CHAI also facilitated bilateral licences between originators and generic firms, for example convincing Bristol Myers Squibb (BMS) to extend its licensees for ATV/r and catalysing a deal between ViiV and Aurobindo on dolutegravir. In the latter example, CHAI was involved as a broker between ViiV and Aurobindo during Phase 2 studies: CHAI aided ViiV in a process of choosing a manufacturing partner early on, while MPP was working on negotiating a broader licensing deal in parallel. Subsequently in Phase 3, ViiV has agreed that all dolutegravir licensees will be routed through MPP except the license of Aurobindo, with whom ViiV has a sourcing relationship.

However, there are several disadvantages of CHAI's continued involvement in licensing. First, an alternative to MPP may lessen MPP's negotiating leverage with originators, particularly where CHAI's confidential bilateral deals offer terms preferred by an originator over the public terms offered by MPP, with wider geographical eligibility or reduced royalty rates. Second, the contract terms MPP has negotiated – e.g. eligible geographies – have proven to be superior to the ones negotiated bilaterally. This issue is now coming to a head in a dispute between BMS and an ATV/r licence it negotiated prior to MPP. MPP has also established efficiencies and systems when negotiating licences for several companies at once; these have the additional benefit of being transparent and in the public domain. CHAI therefore has an opportunity to exit ARV licence brokering and focus on areas where it has a comparative advantage – providing information on market needs and size, and the likely uptake curve of new ARV formulations.

Market intelligence and information transparency is supported through CHAI's market reports, ceiling prices and forecasting work. CHAI's annual ARV Market Report provides a global perspective on the ARV marketplace across LMICs and outlines CHAI's expectations on how the market will evolve over the next five years. The report is available online and shared widely with suppliers and buyers. During the grant period, CHAI continued to negotiate ceiling prices on selected ARVs. CHAI ceiling prices have been available to the 77 countries participating in the CHAI Procurement Consortium, representing the maximum levels at which participating suppliers may price their products when selling or communicating price quotes to members of the CHAI Procurement Consortium. Price competition and transparency with ARVs have improved considerably and large tenders set the international market prices now, thus limiting the audience and value of the CHAI ceiling prices. There may be some continuing interest in using the ceiling prices for certain products with more limited competition, by certain countries that are less well integrated into information networks; however, even in these situations, it would be preferable to share price information that is reflective of the full market, not just prices offered by participating suppliers. Subsequent to the grant end, and on the basis of feedback from multiple stakeholders, CHAI has shifted away form ceiling prices and now publishes a CHAI Reference Price instead.[49]

CHAI also contributes to information exchange and lesson learning through publications and meetings. As mentioned, CHAI's experiences with regard to new product introduction and transitioning were shared in a recently published ATV/r case study,[50] although this publication could be stronger if it also spoke to the difficulties and lessons learned in the transition process. CHAI also hosts an annual Supplier-Buyer meeting,

[48] http://www.who.int/hiv/amds/04_API-production-capacity.pdf?ua=1
[49] http://www.clintonhealthaccess.org/2015-chai-arv-reference-price-list-2/
[50] http://www.clintonhealthaccess.org/case-study-atvr-uptake/

which brings together Least Developed Country (LDC) governments, major buyers, and Indian and Chinese suppliers. Chinese suppliers value this meeting, given its relative novelty to them and their desire to build their networks and learn about the global marketplace. However, partly as a result of the transition of major buyers who now have established fora to communicate with suppliers, CHAI's annual meeting is no longer a unique opportunity for participants to discuss challenges facing the ARV market. Meetings hosted by WHO such as annual forecasting meetings, and the June 2014 GFATM and PEPFAR ARV supplier conference in Dubai, have overlapping content and participants. In addition, some LDC governments expressed that the Supplier-Buyer meeting agenda is too globally focused, lacking relevance to their needs. In response, CHAI will be hosting a regional level meeting in Africa, tailored more towards domestic and regional supply issues.

CHAI's expertise in ARV forecasting is well recognised. CHAI's forecasts carry a great deal of weight due to CHAI's relationships at country level, knowledge of decision-makers, and insight into the trajectory of change. Suppliers appreciate CHAI's scenarios, and like to know the detail behind the assumptions: what is actual, and what is estimated or assumed. Other partners also provide forecasts, such as WHO's AIDS Medicines and Diagnostics Service (AMDS), the MPP, and selected consulting firms. Differences between forecasts – not discussed prior to meetings – have caused some tensions among partners. CHAI has shown responsiveness to this feedback, which was provided in the evaluation Interim Findings report, and has made recent efforts to better coordinate with others and improve transparency.[51]

4.2.3 CHAI impact

CHAI's impact has been evaluated by examining the change in market structure, CHAI's reported progress against logframe and VfM indicators – focused on volumes, prices and new market entry – and the EvT's assessment of this reported progress and its attribution to CHAI.

4.2.3.1 Current market context

By mid-2014, 13.6 million people in LMICs were receiving treatment, up from 9.7 million at the start of the grant.[52] Several factors influenced this increase, as well as the market for TDF specifically, early in the grant period. WHO Guidelines in July 2013 changed the CD4 threshold level for ARV treatment initiation to 500 cells/mm^3, and recommended lifelong ART for all pregnant and breastfeeding women regardless of CD4 cell count. This made an additional 9.2 million patients eligible for treatment, although the translation of WHO guidance into country-level policy has proceeded at a different pace for different countries.

As previously mentioned, the 2013 WHO Guideline Revision also included recommendation of a once-daily FDC of TLE or TEE for all adolescents and adults, including pregnant women. This represented a major consolidation of regimens compared with 2006, when up to 24 regimes were included in recommendations for adults. The ARV market remains concentrated on the supply side and the demand side, with 96% of demand represented in 10 products (2014) and 75% of purchasing for LDC markets by three buyers. With regard to TLE regimens specifically, there is now a diverse supply base; Mylan has lost its monopoly on the TLE FDC, as Hetero became eligible for donor-funded procurement by the end of 2012 and Aurobindo by the second quarter of 2013.

As a result of this expansion in the supply base and countries transitioning national guidelines to align with WHO recommendations, the number of people on the triple TDF regimens, including the TDF FDC, increased rapidly in 2013. While in 2012, 46% of adult patients – 3.9 million patients – were on TDF formulations, in 2013 there were 5.9 million patients, or 57% of adult patients, on TDF-based regimens. This represented a 51% increase in the number of patients in only one year; therefore, much of the progress on the grant was achieved that year.

At the end of 2015, CHAI estimates that over 10 million patients will be on TDF formulations, of which approximately 5 million will be on TLE, 4 million on TEE (mostly in South Africa) and about 1 million on TDF+3TC+NVP.[53] Of the patients taking TLE, more than 90% are taking the FDC. Pricing of the FDC has

[51] http://www.slideshare.net/MedicinesPatentPool/forcasted-demand-for-current-and-new-arv-medicines-in-low-and-middle-income-countries
[52] Fast-Track: Ending the AIDS Epidemic by 2030. Geneva: UNAIDS; December 2014.
[53] Actual patient numbers for 2015 will not be known until 2016

dropped from $159 at baseline in 2012 to $108 at present.[54] The market for TDF-based regimens is healthy at present, with predictable ongoing demand and aligned supply capacity.

The size of the second-line market in LMICs is estimated at 700,000 at present, or roughly 5% of all people on ART. There has been a growth in patients on ATV/r regimens, from 6% of second-line patients in 2012 to approximately 30% in 2015, with approximately 80,000 in volume. Pricing has gone from $454 to $237 for the combination tracked in the CHAI logframe TDF+3TC+ATV/r.[55] During the majority of the grant timeframe ATV/r prices remained high and, as a result, the uptake of ATV/r was lower than CHAI expected. LPV/r pricing has also reduced significantly, from $448 to $303; given that four times as many patients are on LPV/r, this represents a major saving. Progress with further uptake and price reductions was hampered by the capacity constraints of current suppliers during late 2014 and early 2015. A major source of disruption during the grant period has been countries ordering at unpredictable points and without knowledge or consideration of existing demand in the market. For countries with a high demand the manufacturers will react; however, smaller countries can find it difficult to get orders fulfilled quickly. A second supplier came online in March 2015, backlog orders have just now been resolved, and as of the end of 2015, suppliers report that there is excess supply capacity in relation to orders. One additional manufacturer has a dossier pending with the WHO PQ Programme, and several others have filed drug master files (DMFs) with the US FDA for APIs containing ATV.

4.2.3.2 CHAI reported progress against logframe indicators

The objective set out by CHAI in the area of Output 1 is "Improved and sustainable supply, pricing and stability of high quality, clinically optimal drugs". The progress against milestones and targets is provided in the tables below against the original logframe targets and the current logframe targets.

Output indicator 1.1: Price reductions for 1st line, WHO-preferred HIV regimens

Table 6: Progress against logframe output indicator 1.1

	Baseline	Milestone Y1	Milestone Y2	Target (2015)
Original logframe targets (remained the same in Nov '14 logframe)	$169[56]	$140	$115	$90 PPPY by 2015
Current logframe targets (changed sometime after Nov '14)	$169	$140	$115	$104 PPPY by 2015
Achieved		$131	$129 for triple FDC	$108[57]

Output indicator 1.2: Price reductions for 2nd line, WHO-preferred HIV regimens

Table 7: Progress against logframe output indicator 1.2

	Baseline	Milestone Y1	Milestone Y2	Target (2015)
Original logframe targets	$454	$380	$300	$250 PPPY by 2015
Achieved		$306	$279	$237

Output indicator 1.3: Achieve annual cost savings for 1st and 2nd line, WHO-preferred HIV regimens in 4 Southern African Development Community (SADC) countries (excluding RSA), totalling between $92 million to $199 million

[54] NB: Baseline price is a CHAI ceiling price whereas CHAI has changed their methodology as of October 2015, and no longer provides ceiling prices. This is further explained below.
[55] NB: This combination represents approximately 56,000 patients out of 80,000 on an ATV/r containing regimen.
[56] NB: The 2011 price of $169 is used as the baseline in the logframe while the 2012 price of $159 is used in the VfM calculations. The grant began in mid-2012.
[57] CHAI has used a $108 "reference price". Whether this is appropriate is discussed subsequently.

Table 8: Progress against logframe output indicator 1.3

	Baseline	Milestone 1	Milestone 2	Target (2015)
Original logframe targets	0	$18 million over life of grant	n.a.	$92 million
Achieved		$25 million	$26 million to date	$73m to date; $292–429M by 2020

Output indicator 1.4: TB focused, therefore out of scope

Output indicator 1.5: Increase in number of SRA approved HIV and MDR-TB products supplied from Indian, Chinese and RSA sources

Table 9: Progress against logframe output indicator 1.5

	Baseline	Milestone 1	Milestone 2	Target (2015)
Original logframe targets	Active market monitoring to proactively identify potential products	3 additional SRA approved products from Indian, Chinese or RSA supplier	5 additional SRA approved products from Indian, Chinese or RSA supplier	10 additional RSA products from Indian, Chinese or RSA suppliers
Achieved		23 (o/w 5 new formulations) in total	15 with direct CHAI support	21 with direct CHAI support

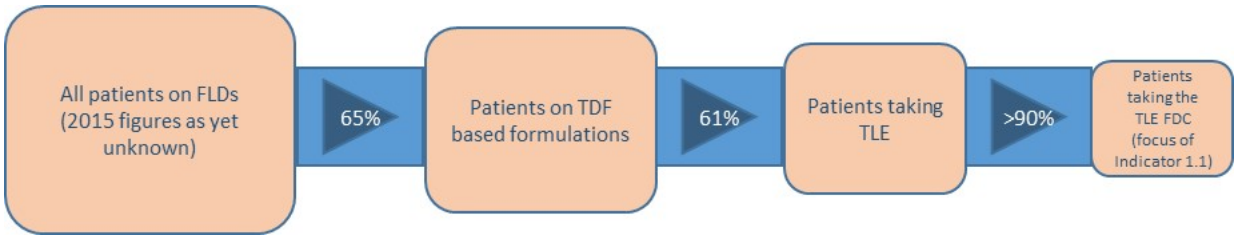
4.2.3.3 EvT assessment of progress

The key findings under each logframe indicator are provided below, with a summary sentence in bold.

Output 1.1: Price reductions for 1st line, WHO-preferred HIV regimens

Although the target price has not been achieved, the market for TLE is healthy, with sufficient ongoing predictable demand and a broad supply base. Market entry on low dose efavirenz and dolutegravir has been delayed relative to CHAI expectations.

Output indicator 1.1 focuses on the FDC TLE with a baseline price of $169 per person per year (pppy) in 2011 and an end of project target price of $90 pppy with CHAI intervention. The logframe was changed in November 2014 with a revised end of project target of $104 pppy for TLE, rather than $90. As the majority of first-line patients taking TDF-based combinations take TLE,[58] and more than 90% of patients taking TLE take the triple FDC, this is an important price to influence.



At the end of grant, CHAI reports the TLE FDC price as $108 pppy as compared with the target of $90 (or $104). Whereas the logframe and VfM measures had intended to use the CHAI ceiling prices, representing the highest price a CHAI consortium country should expect to pay, the $108 comes from the 2015 reincarnation of the CHAI ceiling price list, which will now be called the CHAI reference price list, and which was due to be published on 20 November 2015. The CHAI reference price used for 2015 is the same of that achieved by GFATM as of October 2015, reflecting the market power of GFATM. Even allowing for using prices achieved subsequent to the grant end of $108, price, the DFID logframe target has not quite been achieved. Table 10 below is an extract from CHAI's reference price list.

[58] Exception is South Africa, where TEE is the norm.

Table 10: Extract from CHAI's reference price list

	CHAI Reference Price 2015	GF Pricing October 2015	SCMS price May 2015	Kenya tender price awarded 2014	2013–2014 GPRM weighted avg price	MSF July 2014
Adult products, prices in USD						
TDF (300) + 3TC (300) + EFV (600)	108	107.88	119.88	126	129.84	133.92

CHAI has offered two possible reasons for missing the target:

- CHAI has explained that the TLE FDC price has remained higher than logframe targets throughout the grant due to the scale-up of TLE happening faster than the rate at which capacity was installed. According to CHAI, the scale-up happened quickly, for a time Mylan was the only supplier of triple TLE and "many suppliers have been operating at maximum capacity for the triple FDC due to increase in demand for EFV, thus there is limited incentive to reduce prices."

  The evaluation's analysis does not support CHAI's explanation. While it is correct that Mylan was the only WHO prequalified supplier during 2012, there have been at least 4 TLE triple suppliers with SRA approval since October 2013, and today there are five quality-assured TLE suppliers (see Table 11 below). There are also eight generic TEE suppliers (plus three originators with different agreed geographies).[59]

Table 11: Quality-assured TLE suppliers – SRA approval dates

	WHO PQ	FDA
Mylan	2010	2009
Cipla	2015	2013
Aurobindo		2013
Hetero		2012
Macleods		2014

  During the early months following the 2013 changes to the WHO treatment guidelines, it is accurate that demand increased and, with a lack of coordination between countries, supply was constrained resulting in extending delivery times. However, WHO AMDS noted in March 2014 that the approved suppliers of TLE and TEE FDCs had sufficient production capacity relative to expected demand, due to production capacity being brought on line in 2013. Given the fact that buffer stocks held by countries that switched to TDF-based first-line treatment had not yet been established, short-term supply constraints were resulting in lead times of 4–8 months on average.[60] Additional production capacity was made available by the main suppliers to meet the demand, and lead times normalised by mid-2014. Since then, there has been good capacity in the market for these products. There has also been some constraint in the market for efavirenz API due to environmental regulations in China. This has had more of an impact on single dose formulations of EFV, whereas the EFV-containing FDCs in high demand (and in almost constant production) have not been problematic. Thus, for over one year now, the TLE market appears to have the hallmarks of a healthy market, with sufficient ongoing predictable demand and sufficient competitive supply, and, theoretically, this market should be reaching a competitive equilibrium with prices approaching marginal cost of production.

- A second reason offered by CHAI for not meeting the price targets relates to the assumption that one or both new products (lower dose efavirenz or dolutegravir) would have been available to replace the efavirenz 600 in TLE, bringing the overall price down. CHAI posits that efavirenz 400 could reduce the price of first-line by up to $12 pppy and dolutegravir by up to $19 pppy. This is a plausible explanation and, as we know, the market entry of these products has been delayed. However, there is no way for the evaluation team to validate whether the assumptions behind the $90 had included the replacement of the

[59] See: http://www.theglobalfund.org/documents/psm/PSM_ProductsHIVAIDS_List_en/
Approval dates can be found at
· http://apps.who.int/prequal/default.htm
· http://www.fda.gov/internationalprograms/pepfar/ucm119231.htm
[60] http://apps.who.int/iris/bitstream/10665/104449/1/WHO_HIV_2014.4_eng.pdf

EFV 600 with alternatives, because neither the model itself nor any accompanying materials make reference to detailed assumptions behind the price evolution from $169 to $90 pppy. A November 2011 CHAI presentation to the WHO[61] supports to some degree this second explanation for not meeting the price targets. In this presentation, CHAI predicted that the price of TLE would come down by 30% between 2015 and 2017 to a price of $100 pppy based on developments launched in 2015: TDF process optimisation, TDF reformulation, and EFV dose optimisation.

Output 1.2 Price reductions for second-line WHO-preferred HIV regimens.

The price reduction target has been met, supported by CHAI-enabled uptake, licence deals negotiated bilaterally and subsequently by MPP, with improved access terms, and competition from AbbVie.

For second-line regimens, CHAI had the objective to influence prices of second-line WHO-preferred HIV regimens, in particular the price of TDF+3TC+ATV/r.

The baseline price of TDF+3TC+ATV/r was $409 pppy in 2011 and CHAI forecast a 2015 price of $250 with CHAI intervention. The notes behind this price evolution state that this "assumes majority of price reduction is contingent on aggressive demand generation and potentially bringing additional suppliers to market, which are unlikely to materialise without CHAI intervention". The evaluation country case studies found that ATV/r uptake can indeed be attributed to CHAI. In fact, CHAI had to work harder than expected to "sell" the benefits of ATV/r, given the unexpected aggressiveness with which AbbVie defended their competing product LPV/r.

There was a momentum behind the supply-side licensing deals from BMS to generics before CHAI became involved, and CHAI's work to accelerate uptake was one factor that subsequently contributed towards that momentum. MPP can be credited with negotiating global licenses with improved access terms. The result is a 2015 CHAI reported price for TDF/3TC/ATV/r of $237, below the 2015 target of $250. CHAI's implied ToC is that by encouraging uptake of ATV/r and supply-side competition through new generic entry, prices would come down. However, it would seem that the only manufacturer with a quality-assured product up until March 2015 has priced ATV/r just below the price of LPV/r. As the price of LPV/r decreased, Mylan also decreased its ATV/r price. Improved pricing for the Boc-hydrazine intermediate was also a factor contributing to reductions in API costs.

Output 1.3 Achieving annual cost savings for first- and second-line WHO-preferred HIV regimens in 4 SADC countries (Malawi, Swaziland, Tanzania, Zambia) excluding RSA, totalling $92 million.

At the end of the grant, **CHAI reports that $73m has been saved to date, short of the $92 million target. The indicator measures theoretical savings; CHAI was able to provide some evidence of actual procurement savings.**

This indicator was designed at the request of DFID SA for the DFID GDPP program so that the SA office could measure the impact of its investment. It served a specific, rather than general, purpose.

The indicator is assessed by taking the patient number projections from CHAI forecasts and multiplying by the ceiling price trends already being captured in Outputs 1.1 and 1.2. The indicator thus is another expression of data reported in indicators 1.1 and 1.2. and it is therefore sensitive to the same variables, namely the price of TLE and its volumes. Appropriately, the savings from Output 1.3 are not included in CHAI VfM totals, so as to avoid double counting.

The indicator would offer more value if it provided an actual snapshot into procurement prices achieved through tenders, to show that CHAI's work translates into realised savings. Despite efforts, the evaluation team was not able to get actual procurement savings data on ATV/r and TLE from the countries visited. The data belongs to the countries and an established relationship and trust is requested to gain access, and CHAI has a policy of not sharing confidential partner information. These factors make procurement savings a problematic indicator for an external evaluator to validate. At the EvT's request, CHAI was able to leverage its partner relationships in-country to obtain a number of mostly confidential reports (invoices, pipeline reports,

[61] Addressing Challenges to Scale-Up of ART: Strategic Issues Facing Generic Suppliers, World Health Organization, Geneva November 1, 2011: http://www.who.int/hiv/amds/clinton_oct2011.pdf

contract excerpts), in order to validate reported savings in Zambia of $10 million in 2014 by procuring 3TC and ATV/r instead of previously used products. In Swaziland, CHAI reports that $2 million annually has been saved through tender support provided by CHAI. In Malawi, roughly 2,700 patients had been transitioned to ATV/r by the end of 2014. Using 2013 CHAI ceiling prices, Malawi saved approximately $162,000 in 2014 using ATV/r instead of LPV/r. Specific savings for Tanzania were not reported by CHAI.

Output 1.5 An increase in number of SRA approved HIV (and MDR-TB) products supplied from Indian, Chinese and RSA suppliers.

CHAI reports that it has exceeded this target by a large measure, with 21 suppliers being directly supported by CHAI. This measure bundles together highly dissimilar product types and supplier types, and is challenging to validate, given the confidentiality of CHAI's upstream work.

The objectives under this indicator are three additional SRA approved products from Indian, Chinese or RSA suppliers by 2013, 5 additional SRA approved products from Indian, Chinese or RSA suppliers by 2014, and 10 additional SRA approved products from Indian, Chinese or RSA suppliers by 2015.

This measure bundles together different types of products from a variety of sources and with difficulty in attributing how much contribution CHAI has made towards SRA approval. There is not much granularity in the wording with regard to the level of innovation in the product of interest – e.g. New Drug Applications (NDAs), new formulations, or minor incremental variations to existing formulations.

CHAI has provided names of suppliers supported under this Output (Table 12). These companies have been active suppliers of ARVs for over a decade and clearly have the ability to attain SRA approval and negotiate licences with originators, directly or via MPP.

Table 12: Suppliers supported under Output 1.5

Product	Product Type	Strength + Form	Supplier	Date Qualifie	Adult or P	Approval
ABC/3TC	Dual FDC	Tablets 120mg / 60mg (dispersible)	Mylan	23/10/2014	Peds	FDA
ABC/3TC	Dual FDC	Tablets 60mg / 30mg (dispersible)	Mylan	23/10/2014	Peds	FDA
ATV/r	Dual FDC	Tablets 300mg / 100mg	Emcure	17/03/2014	Adults 2L	FDA
AZT/3TC + ATV/r	Co-pack	Tablets 300mg / 150mg co-packaged with 300mg / 100mg	Mylan	04/09/2014	Adults 2L	FDA
AZT/3TC/NVP	Triple FDC	Tablets 60mg / 30mg / 50mg (Dispersible & Scored)	Strides	21/09/2012	Peds	FDA
AZT/3TC/NVP	Triple FDC	Tablets 60mg / 30mg / 50mg (Dispersible & Scored)	Cipla	16/10/2012	Peds	FDA
AZT/3TC/NVP	Triple FDC	Tablets 60mg / 30mg / 50mg (Dispersible)	Strides	24/10/2014	Peds	WHO PQ
TDF/3TC/EFV	Triple FDC	Tablets 300mg / 300mg / 600mg	Hetero	08/11/2012	Adults 1L	FDA
TDF/3TC/EFV	Triple FDC	Tablets 300mg / 300mg / 600mg	Aurobindo	26/06/2013	Adults 1L	FDA
TDF/3TC/EFV	Triple FDC	Tablets 600mg / 300mg / 300mg	Cipla	30/12/2013	Adults 1L	FDA
TDF/3TC/EFV	Triple FDC	Tablets 300mg / 300mg / 600mg	Macleods	14/08/2014	Adults 1L	FDA
TDF/FTC/EFV	Triple FDC	Tablets 300mg / 200mg / 600mg	Aurobindo	02/04/2013	Adults 1L	FDA
TDF/FTC/EFV	Triple FDC	Tablets 300mg / 200mg / 600mg	Hetero	31/10/2013	Adults 1L	FDA
TDF/FTC/EFV	Triple FDC	Tablets 300mg / 200mg / 600mg	Emcure	06/02/2015	Adults 1L	FDA
TDF/FTC/EFV	Triple FDC	Tablets 300mg / 200mg / 600mg	Macleods	17/11/2014	Adults 1L	WHO PQ
TDF/FTC/EFV	Triple FDC	Tablets 300mg / 200mg / 600mg	Macleods	28/11/2014	Adults 1L	FDA
TDF/FTC/EFV	Triple FDC	Tablets 300mg / 200mg / 600mg	Ranbaxy	24/10/2014	Adults 1L	WHO PQ
TDF/FTC/EFV	Triple FDC	Tablets 300mg / 200mg / 600mg	Strides	12/12/2014	Adults 1L	WHO PQ

In the EvT team's assessment, CHAI's involvement in supporting the approval of these products with these suppliers has largely been indirect, through CHAI's demand side, forecasting or other enabling environment work. Most of the suppliers listed above were interviewed, as were others from China and South Africa. It was possible to establish that Chinese companies highly value CHAI's provision of market intelligence which helps them prioritise the right products to develop. Conversely, Indian and South African based companies were not able to confirm direct CHAI support during this grant period. While Indian companies did acknowledge an important role CHAI could play in helping them decide which future FDC combinations to develop, they were not able to confirm that CHAI has had any substantial, direct role in supporting SRA approval situations requiring licence brokering or where regulatory data challenges presented an issue (e.g. with second-to-market suppliers of ATV/r).

4.2.3.4 CHAI reported results against VfM indicators

CHAI's VfM projections factored in estimations of scale-up and reduced pricing for more cost-effective ARVs, with an objective to generate NPV savings ranging from $561 million to $1.1 billion with a DFID investment of $11.1 million.

Whereas the logframe output indicators focus on prices only, the VfM targets factor in uptake volumes multiplied by the difference in prices with and without CHAI. The basis for the value for money thus becomes the difference in prices on TLE for first-line and ATV/r for second-line multiplied by increasing patient numbers. The majority of the overall savings for Output 1 were originally expected to be derived from the first-line savings on TLE, with a smaller contribution from ATV/r (given relative patient numbers on FLD vs SLDs, and thus model sensitivity to FLD savings). Subsequently LPV/r savings were added to the VfM calculations, as explained below.

First-line

The original NPV savings expectations were derived from the difference between the counterfactual price without intervention (CHAI's predictions of market price evolution due naturally to increases in volume and competition) and the ceiling price CHAI expected to negotiate, given its work under the grant. The price difference was then multiplied by the projected patient treatment numbers (actuals from previous years, CHAI forecasts for current and future years) to arrive at the NPV savings. Rather than tracking the actual prices paid by countries in tenders, the basis CHAI uses for evaluating whether these targets have been achieved has been the CHAI negotiated price ceilings. The basis for the prices was amended in 2015, as CHAI has now used its "reference price" of $108.

With regard to volumes,
Table 13 shows CHAI's expectations as proposed in the VfM projections.

Table 13: CHAI's expectations as proposed in VfM projections

	2012	2013	2014	2015
Original VfM calculations (from 2012)				
TDF+3TC+EFV – baseline projections[62]	1,617,968	2,255,632	2,867,765	1,780,230 (conservative) 3,425,544 (baseline)
Current VfM calculations (revised in 2014)				
TDF+3TC+EFV – baseline projected	2,179,730	2,089,900	3,389,307	4,363,148 (conservative) 5,365,170 (baseline)
Achieved as reported in Oct 2015 spreadsheet	2,179,730	2,089,900	3,358,324	Exact figures not yet known.

As compared to original 2012 TLE projections of between 1.7 and 3.4 million patients, estimates for 2015 are that somewhere between 4.3 and 5.3 million patients are actually on this regimen as of 2015. CHAI uses the "conservative" patient number estimates in the conservative NPV future savings projections and uses their "baseline" patient numbers in the baseline NPV future savings projections. Savings estimates for previous years use actual numbers. This leaves a question about which numbers to use for 2015, as there is a lag in accessing data on actual number of patients on TLE. CHAI has assumed 5.3 million patients are on TLE in 2015 for their own projections of VfM savings to 2015. Given the very large increase from 3.3 to 5.3 million patients, and the lack of evidence on which this is based, the EvT team has used the more conservative volume of 4.3 million as the basis for VfM calculations.

The drivers of the NPV savings are the increase in patient numbers, and the reduced price achieved as compared with the counterfactual; the counterfactual price is in turn influenced by the assumed price at the start of the grant and assumptions about how price would evolve without CHAI's involvement. According to CHAI's assumptions or 5.3 million patients and a reduced price to $108, $191 million has been saved between 2012 and 2015 on TDF+3TC+EFV. Using the more conservative 4.3 million patient number, the EvT calculates that $169 million has been saved between 2012 and 2015.

[62] All generic-accessible (GA) adults; linear scale-up

Second-line

ATV/r: With regard to volumes on SLDs, Table 14 shows CHAI's achievements for the TDF+3TC+ATV/r regimen as used in the VfM projections. As with first-line, the VfM projections calculate the difference between the counterfactual versus achieved price and multiply this difference by the number of patients on this therapy (actuals to 2014 and estimated projections 2015–2020).

Table 14 shows that uptake volumes on TDF+3TC+ATV/r are lower than CHAI had expected. Although increased access to viral load testing has translated to more patients on SLDs, lower than expected uptake of TDF+3TC+ATV/r was partly due to the fact that there was a single manufacturer with a quality-assured product up until March 2015 and supply shortages at certain points. Also, the aggressive pricing of the LPV/r contributed to strong continued sales growth of this competing product, including in South Africa, where CHAI was not able to influence uptake of ATV/r.

Table 14: CHAI's volume expectations and achievements for TDF+3TC+ATV/r regimen

	2012	2013	2014	2015
Original VfM targets (from 2012)				
TDF+3TC+ATV/r – volume projections[63]	28,370	60,846	95,394	131,318
Current VfM targets (revised in 2014)				
TDF+3TC+ATV/r – volume projections	12,489	30,733	55,373	78,951
Actual volumes, as reported in Oct 2015 spreadsheet and used in VfM calculations	12,489	30,733	44,104	Exact figures not yet known. Baseline = 56,871 Conservative = 56,409

Savings between 2012 and 2015 on initiation of patients to ATV/r amount to $13 million.

LPV/r: A price reduction objective for the most commonly used second-line ARV, TDF+3TC+LPV/r, was not included in the logframe, nor was it included in the original value for money calculations. It was added during 2014 revisions to the VfM calculations. The assumption was that LPV/r price would be reduced from a baseline of $449 in 2012 to a target of $351 in 2015. This assumption remained the same up until the September 2015 VfM projections. The October 2015 end of project logframe and VfM calculations show that $303 is the achieved price for LPV/r containing regimens and this was used in the VfM calculations.

The difference between the baseline $449 and target/achieved price $303 represents the "savings" and it is multiplied by number of patients on this regimen to generate the majority of the savings under Output indicator 1.2.

Table 15: CHAI's volume expectations and achievements for TDF+3TC+LPV/r regimen

	2012	2013	2014	2015
October '15 end of project spreadsheet				
TDF+3TC+LPV/r volume projections	92,194	225,233	212,231	188,932
Estimates in both the Nov '14 spreadsheet and the Sept '15 spreadsheet				
TDF+3TC+LPV/r volume projections	92,194	225,233	230,346	229,131
Actual volumes as reported in Oct 2015 spreadsheet	92,194	225,233	212,231	188,932

CHAI's rationale for adding LPV/r to the VfM calculations was "Our efforts on ATV/r had an unanticipated secondary effect on reducing LPV/r pricing as well." Volumes and prices for LPV/r have evolved as shown in Table 16. Obviously given there are three times as many patients on LPV/r versus ATV/r regimens, price changes to LPV/r will have major effects on VfM savings.

[63] All generic-accessible (GA) adults; linear scale-up

Table 16: CHAI's price expectations and achievements for TDF+3TC+LPV/r regimen

	2012	2013	2014	2015
Current VfM calculations				
TDF+3TC+LPV/r - volumes	92,194	225,233	212,231	188,932
Counterfactual price per patient per year	$449	$449	$449	$449
CHAI price per patient per year	$448	$366	$351	$303
Achieved price	$303			

Savings between 2012 and 2015 on prices of LPV/r amount to $67 million.

In summary, savings in 2012–2015 under CHAI's price assumptions ($108) total $169 million, of which approximately 70% comes from FLD savings, and 30% comes from SLD savings (of which 5% comes from ATV/r).

Using the $108 price assumption of CHAI, the more conservative TLE patient numbers of 4.3 million, and allowing for the increased expenditure (from $11 million to $13 million), the conservative NPV savings to 2020 come to $778 million as opposed to the $561 million (conservative scenario) that had been expected at grant initiation. 85% of the total NPV value arises from 2015 to 2020, which can be explained by the fact that savings from expected price reductions have been delayed – only partially realised in the last few months, the volumes are expected to continue scaling up, and the discount rate is fairly low. 80% of the value comes from Output 1.1 and 20% from Output 1.2. Output 1.1 is influenced heavily by this year onwards, given the forecasted increase of more patients on TLE than expected (with continued volume growth post-2015), and the switch to CHAI reference prices. The 20% overall value arising from Output 1.2 is split with LPV/r savings contributing 75% and ATV/r savings 25%.

4.2.3.5 EvT assessment of progress

The use of CHAI ceiling prices at baseline and throughout the grant period, switching to CHAI reference "market" prices at the grant end, represents a shift in methodology which makes attaining the objectives more within reach. In the Interim Findings report, the EvT made the point that CHAI ceiling prices are not representative of the diversity of this market – for example, only Mylan and Hetero, of five eligible suppliers of the TLE FDC, have elected to participate in the CHAI ceiling price list. This made CHAI ceiling prices an inferior measure for judging the state of the market and it was suggested to use different measures subsequently. However, to switch to the methodology within the grant is overly favourable to the VfM calculations. Similarly, the starting price for TDF+3TC+EFV of $159 in 2012 (which is then used as the basis for the counterfactual price projected forward) can also be questioned, given that the market price in 2012 was between $140 and $146.[64] So the assumptions around baseline and end of grant price, as well as those around volumes, require discussion. The table below illustrates the range of (non-discounted) savings on first-line ARVs for Indicator 1.1, which arise given scenario analysis around the main value drivers.

Table 17: Savings range with varying volumes and prices

	Savings to 2015 assuming 4.3 m patients	Savings to 2015 assuming 5.3 m patients
CHAI $108 pppy price	$169.3 m	$191.3 m
SCMS price $120 pppy	$116.9 m	$126.9 m
Kenya price $126 pppy	$90.7 m	$94.8 m

Obviously such large differences in near term savings estimates, when projected forward under the same assumptions, result in wide-ranging NPV estimates.

If we remodel the overall Output 1 NPV savings, keeping the $159 starting price for TDF+3TC+EFV – and using the May 2015 SCMS price of $120 pppy as the end of grant price – the resulting NPV savings are $480 million, and if we remodel using the 2014 Kenya price of $126 pppy (the EvT suggests that this price range would be more comparable to the "highest price a country should expect to pay" trajectory used throughout this grant) then the NPV savings comes to $331 million. This compares with the overall NPV savings to 2020 of $778 million using the $108 pppy price.

[64] UNITAID Market Landscape: "By 2012, nine manufacturers sold TDF eligible for donor-funded procurement. Three manufacturers sold the one-tablet full-regimen TDF/3TC/EFV at a cost of less than US$ 140 per person per year."

At the start of the grant, CHAI had expected to generate a NPV savings in the range of $561 million (conservative scenario) to $1.1 billion. The EvT team has highlighted the difficulty with determining appropriate patient volumes and prices. If more conservative assumptions are modelled, then the NPV savings result – although positive – is below expectations.

4.2.4 Conclusions

For this programme area, CHAI was allocated $11.1 million of the DFID grant and CHAI expected to generate a NPV saving of $561 million to $1.1 billion between 2012 and 2020. Savings projections to 2020 have now been recalculated, factoring in the higher expenditure of $13 million, and an expected range of NPV savings between $333 and $778 million. Approximately 85% of the HIV treatment programme area NPV savings is expected to happen post-grant. There were many changes to the logframe targets and indicators throughout the duration of the grant, including an addition of LPV/r to the model and a last minute change in the price source used for the end of project price, which is used in the VfM calculations from 2015 to 2020.

CHAI's projections for first-line pricing – which were the basis for the expected NPV savings and VfM projections in the DFID Business Case – were extremely ambitious and not achieved, whereas CHAI's volume projections were significantly lower than the actual volumes realised. Changes in treatment eligibility for first-line had an elevating effect on numbers of patients, while expanded access to viral load testing had an elevating effect on patient numbers for second-line, although this did not fully translate into ATV/r projected uptake numbers.

Over the time period of the grant, demand has coalesced around a limited number of first-line optimised formulations, prices have reduced, and supply capacity is now in line with demand. However, there were some periods of adjustment during the grant timeframe – a temporary misalignment for TLE, which quickly resolved and some issues with ATV/r supply capacity playing catch up as demand took off. These misalignments revealed some continuing weaknesses in the global system for managing product introductions and transitions.

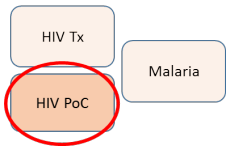
Attribution to CHAI – for the successes and the challenges – is difficult. As previously mentioned, the 2013 WHO Guideline revision caused demand to centre on a concentrated number of recommended regimens CHAI's work on pricing and supply improvements during the timeframe of the previous DFID grant contributed to the feasibility and realisation of these recommendations. The GFATM P4i[65] initiative started within the grant period and counts among its achievements a long-term agreement with manufacturers underwritten with pooled procurement mechanism volumes and a savings of $340 million on health products through global tenders on artemisinin-based combination therapy (ACTs), bednets and ARVs. The capacity of partners to develop products to SRA standards, broker licenses, and improve information transparency has improved, with implications for the degree of CHAI inputs now required.

As illustrated previously, through the Primer mapping and in sections describing CHAI's work, CHAI has played a role in this market development and this role started well before the current grant for example including CHAI's role in shaping the WHO Guidelines. However, there has also been substantial direct influence from major buyers wielding the power of nearly $2 billion in annual ARV procurement funds, WHO helping to shape the usage of those funds, and MPP's work in licensing. CHAI's influence during this grant period has been primarily at the country level, providing TA to governments in an effort to smooth product introductions and transitions. CHAI's lab-focused work in support of process chemistry innovations and new formulations has important potential, but it has not yet come to fruition.

[65] http://www.who.int/hiv/amds/07_GF-procurement-and-funding.pdf

4.3 HIV PoC Diagnostics

Programme specific Findings



CHAI's work to shape the market for HIV point-of-care (PoC) diagnostics is analysed in this section according to its process (activities in which CHAI engaged), and its impact (what CHAI achieved). CHAI's activities, and those of other stakeholders, are plotted using a key framework from the Healthy Markets Primer, to consider the degree to which its 'dominant logic' explains the process by which CHAI approached its market-shaping work in this programme area. CHAI's impact is analysed in terms of market changes – as indicated by pricing, uptake volumes and competition – before and after the grant timeframe, and the contribution of CHAI to those changes is evaluated.

4.3.1 Market context pre-grant

4.3.1.1 What was the public health need?

In 2012, there were approximately 35 million people living with HIV (PLHIV) in LMICs. Tests for treatment staging and monitoring were expensive and lab based, requiring infrastructure investment and relatively skilled technicians. These factors limited the potential for decentralised placement. There had been an expansion in the number of sites performing CD4 testing between 2003 and 2011, and most countries had increased testing capacity relative to need. However, that capacity was concentrated in urban areas inaccessible to many patients. The result was long turnaround times for test results, high rates of patient loss to follow up (LTFU), and wastage of test results that did not reach the patient.

CHAI's DFID project was approved based on a ToC and expectation that expanding point-of-care (PoC) technology would solve the problems experienced with more centralised, lab-based solutions, with the benefits of reducing patient loss, decreasing time to ART initiation, increasing rate of ART initiation, and eliminating wastage of conventional test results not received.

4.3.1.2 What was the market need?

CHAI was not required by DFID to provide details on the market structure at baseline or throughout the grant, nor was it asked to provide a programme-specific ToC, or counterfactuals for its selected market-shaping interventions. The EvT has consequently been required to piece together snapshots of the market structure at various points in time.

The market for conventional, lab-based CD4 test devices was dominated by three products, two of which were from the same supplier – Becton Dickinson – commanding a 60% share of LDC markets.[66] There were three suppliers with different CD4 PoC technologies: PointCare NOW, Partec CyFlow miniPOC, and Alere Pima. All three had obtained SRA certification but only Pima had achieved WHO PQ status. It was estimated that Pima had gained a 5% share of the overall CD4 market since its entry in 2009.

Partly as a result of the market dominance of a few suppliers, overall CD4 test pricing had remained stagnant since 2003, despite increases in volume. Pricing at baseline was approximately $7 per test for PoC CD4. For lab-based CD4 testing, price per test ranged from $3.50 to $10, plus $1–$2 per test for sample collection consumables. At the time of DFID grant initiation, it was expected that at least 2–3 new CD4 PoC technologies would enter the market by early 2013 and compete with Pima.

In 2010 CHAI estimated the CD4 testing need in LMICs to be 29 million tests, with 17.5 million tests estimated as the actual market size (indicating around 60% coverage).[67] CHAI assumed a 14% growth in CD4 testing need, based on growth in ARV programmes, which would have translated into a CD4 testing market size of

[66] Non-LDC figures not available. However, interview informants indicated this is small in proportion as non-LDC countries had earlier moved to viral load for staging and monitoring

[67] CHAI estimates based on the number of patients enrolled in HIV care and treatment, and assuming national guidelines for both pre-ART staging and ART monitoring. CHAI and UNICEF proposal to UNITAID, Dec 2011, shared with DFID. This estimate seems high in retrospect; however, this estimate was made prior to the WHO change to recommend viral load for monitoring.

49 million by 2014 and 56 million by 2015. The EvT has developed a counterfactual theoretical model using CHAI's assumptions above, to examine what could have been expected at this time, with or without CHAI's interventions. Under the assumption of continued 60% coverage of need, the counterfactual market size in 2015 would be estimated at 33 million CD4 tests. Assuming Pima retained its 5% share of this market, Alere's total market size without a CHAI intervention would have been 1.7 million tests.

Table 18: Pre-intervention world (What was expected to happen with and without CHAI)

	w/o Chai	with Chai				
Assumed growth in CD4 test need	14%	14%				
CD4 coverage	60%	80%				
PoC market share of total CD4 market	5%	30%				
Chai suported countries as fraction of total demand	40%	57%				
w/o Chai interverventions	2010	2011	2012	2013	2014	2015
CD4 test need	29	33.1	37.7	43.0	49.0	55.8
Actual market size CD4 tests (at 60% coverage)	17.5	19.8	22.6	25.8	29.4	33.5
PoC market size	0.9	1.0	1.1	1.3	1.5	1.7
PoC market size in Chai supported countries	0.4	0.4	0.5	0.5	0.6	0.7
with Chai Interventions	2010	2011	2012	2013	2014	2015
CD4 test need	29	33.1	37.7	43.0	49.0	55.8
Actual market size CD4 tests (moving from 60 to 80% coverage)	17.5				39.2	44.7
PoC market size	0.9				11.8	13.4
PoC market size in Chai supported countries					6.8	7.7

With CHAI's interventions, CHAI expected to grow CD4 coverage to 78% (rounding up, 80% used in calculations).[68] Assuming the 12 CHAI-supported countries (those supported by UNITAID as well as DFID) represented approximately 40% of total global demand for CD4 at baseline – growing to 57% of total demand by 2015 – and knowing that CHAI intended to grow the PoC market size in CHAI-supported countries to 7.7 million tests by 2015, this would imply a total PoC CD4 market size of 13.4 million PoC tests in 2015, or a 30% market share of PoC in total CD4 demand.[69] The overall market growth projections for CD4 test scale-up, and PoC share growth, were extremely ambitious, and should have raised questions about feasibility.[70]

4.3.2 CHAI intervention

For this programme area, CHAI was allocated $8.3 million of the DFID grant (reduced 15% subsequently to $7.1 million, as explained below) and CHAI expected to generate NPV savings of $427 million between 2012 and 2020.[71]

In CHAI's concept note to DFID, CHAI emphasised the public health need. In order to meet that need, CHAI proposed a plan to decrease prices, speed regulatory approvals of new products, and support governments to increase uptake of PoC devices. CHAI did not provide baseline market data to DFID, a ToC for how its interventions would shape that market,[72] or a vision of what a healthy market would look like at the end of the grant period. The work was expected to support uptake, as well as to draw on CHAI's ability to negotiate down prices by 30–60% from baseline.

Counterfactual responses to this market-shaping intervention could have been (a) various options for negotiating a commitment to price reduction from Alere, (b) for CHAI or other partners to work more closely with near-to-market developers, with deliberate "push" interventions tailored to addressing their specific needs and/or (c) to improve utilisation and operations of existing lab-based CD4 test capacity, for example through

[68] CHAI proposed an increase from 60% to 78%.
[69] This seems like a large growth increase in PoC testing in a few years. Competitors were expected to enter the market imminently and thus the PoC CD4 market scale-up was expected to accelerate due to these competitors serving different market segments from those suited for Pima. Scale-up in testing volume would have also been more likely if the anticipated price reductions were realised.
[70] Chai's estimates of the CD4 market size at the start of the DFID grant were also larger than market size actuals subsequently provided in a 2015 AMDS publication:
http://apps.who.int/iris/bitstream/10665/179864/1/9789241509169_eng.pdf?ua=.1
[71] Market Shaping for Access to Safe, Effective and Affordable Health Commodities, DFID Business Case, June 2012
[72] Only a few sentences were provided in the concept note were provided as the ToC

the use of improved sample transport. DFID's business case development process did not require CHAI to provide a counterfactual analysis of programme areas within the overall grant.

In October 2012, a major development was a new UNITAID grant award of $95 million to CHAI and UNICEF for PoC CD4 market-shaping. Like the DFID project starting about the same time, this was a demand-side project focused on programmatic work to support uptake and rational deployment. In addition, the UNITAID grant provided for a market shaping component and for UNICEF to purchase PoC commodities from 2013 to 2016 for seven Sub-Saharan African countries. Given overlaps between the two grants, with regard to geographic scope and implementation support, CHAI proposed to reduce the proposed budget to DFID by 15%. CHAI also proposed shifting the country focus as indicated in the table below.

Table 19: Evolution of country focus for HIV PoC diagnostics

	Lesotho	South Africa	Swaziland*	Malawi	Mozambique	Uganda	Zimbabwe	Ethiopia	Kenya	Tanzania	Zambia	India	Nigeria
CHAI work supported by DFID Business Case		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
CHAI work supported by UNITAID (Oct 2012)	✓	✓	✓	✓	✓	✓	✓						
Annex E of the ToRs for DFID Evaluation (Feb 2014)[73]		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
CHAI communication with EvT re: country selection for direct DFID engagement (Nov 2014)[74]	✓	✓	✓		✓			✓	✓		✓	✓	

Subsequent to the agreement on revised country focus of the DFID grant, there continued to be a lack of clarity around country inclusion during the evaluation, as a result of the disconnect between the business case, evaluation ToRs, subsequent communications from CHAI, and also the financial expenditure data produced during the evaluation. For example, Malawi was included according to the ToR and the expenditure data; however, CHAI clarified prior to the case study visit in June 2015 that it was not a DFID-supported country, as DFID funding had only been used to bridge the gap between two UNITAID grants. Similarly, Lesotho and Swaziland were added subsequent to business case approval and the development of the EvT TORs, while Uganda, Zimbabwe, and Tanzania have been dropped from the programme.

In the UNITAID grant, CHAI's specific role was to lead on demand forecasts, in-country evaluations, operational research, and catalytic implementation of in-country systems and processes. UNICEF was to lead on strategic procurement and would work together with CHAI at the national level to support national planning, policy and strategy development with regard to PoC CD4, as well as implementation. Both organisations were to engage with supply side market shaping and advocacy for the strategic use of PoC and near-PoC testing at both the national and international level, and for wider use of diagnostic testing in general.

CHAI and the implementing partner Program for Appropriate Technology in Health (PATH)[75] had also submitted a different grant proposal to UNITAID focused on supporting new product developers of HIV diagnostic tests, which would have potentially overlapped with Output 2.4 of the DFID grant. This second proposal to UNITAID was unsuccessful. CHAI reported that its supply-side engagement with DFID funds was moved even further upstream in response. Output 2.4 is focused on Indian and Chinese suppliers, thus implying an upstream focus, as no Indian or Chinese developers were near to market in 2012; CHAI clarified that this work was focused on TB and viral load (VL) PoC developers. It not entirely clear from the project documentation what interaction CHAI was planning to have with near-to-market CD4 developers. In a memo CHAI sent to DFID just after the UNITAID PoC grant request was successful, CHAI clarified that "UNITAID

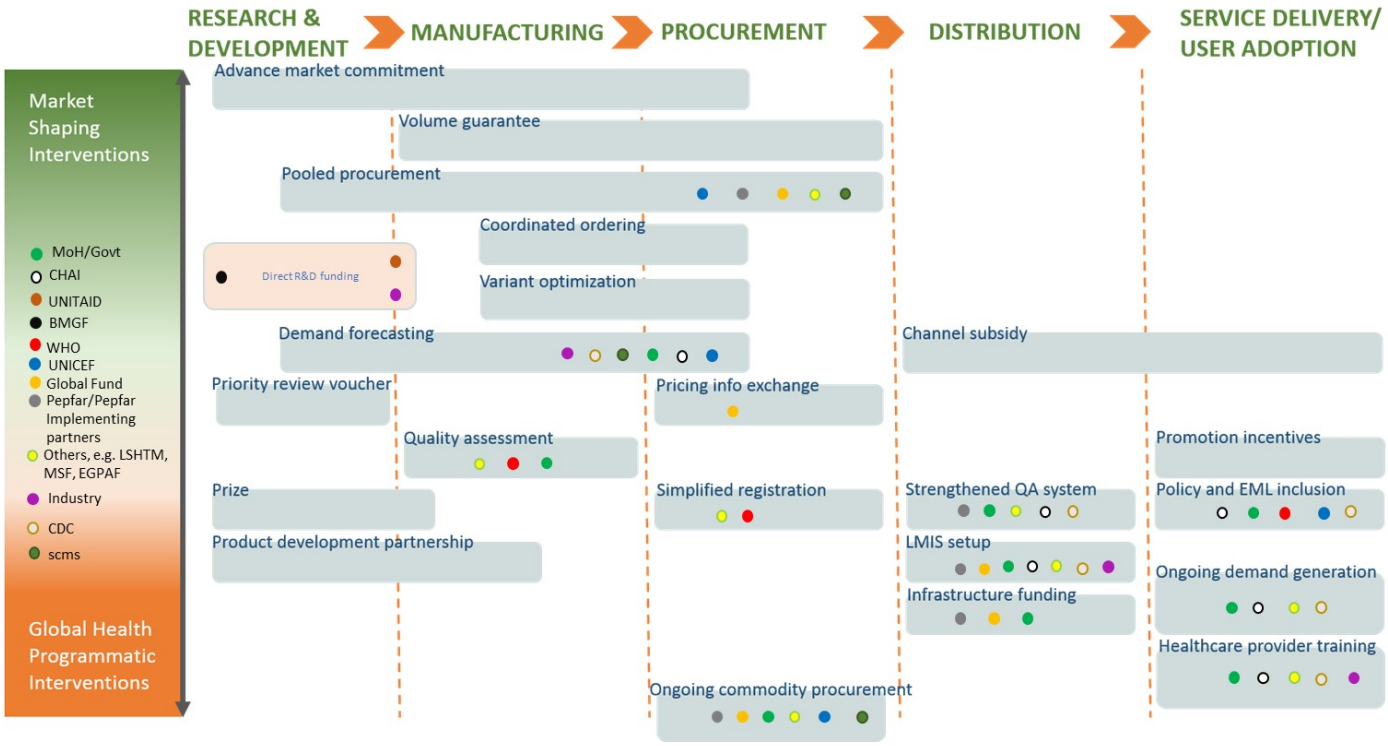
[73] These were the countries defined as having "Direct DFID funded engagement"
[74] CHAI has clarified that this selection of countries has remained the same from October 2012 until now, although the TORs for this evaluation were presumably drawn from the list of countries in the DFID Business Case from June 2012.
[75] http://www.path.org

support will cover engagement with current suppliers of PoC tests[76] and the DFID support can augment that with support for engagement with suppliers who have PoC tests in development but not yet commercialised."[77]

4.3.2.1 What were others doing?

The Healthy Markets Primer figure below was used to map implementation activity influencing the PoC CD4 market. As mentioned previously, the Primer positions activities in terms of their fit on a technology development and implementation value chain (horizontal placement) as well as the degree to which the intervention is more catalytic vs programmatic, as defined by the time-bound nature and ability to exit (vertical placement).

Figure 6: Market-shaping implementation landscape for HIV PoC CD4



The BMGF support to PoC CD4 work under the CD4 Initiative is noted, as is private investment. UNITAID issued grants of between $3 million and $10 million to fund a portion of the commercialisation work of the four most promising near-to-market PoC CD4 developers. UNITAID had also earlier funded a significant amount of Pima pilot and introduction work under its paediatric programme (under grants implemented by CHAI which officially ended in 2015). The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) is an important implementer of Early Infant Diagnosis (EID) programmes and has also been involved in Pima piloting and deployment, including with UNITAID funding. USAID/PEPFAR is one of the major funders of HIV prevention and treatment programmes (including VL, CD4 and EID commodities) in numerous LMICs, especially Malawi, Mozambique, Uganda, Zimbabwe and Kenya. The US Centers for Disease Control and Prevention (CDC) has also been a major funder of PoC CD4 testing in several countries, working on Pima evaluations (including in collaboration with CHAI in Tanzania) and largely via PEPFAR funding. Also with funding from PEPFAR, the Supply Chain Management System (SCMS) is responsible for diagnostics procurement in several countries including Ethiopia and is an important partner in integrating new PoC products into routine procurement lists in-country. Médecins Sans Frontières/Doctors Without Borders (MSF) was also funded by UNITAID to do similar work to CHAI but within its own service delivery facilities in seven countries: Lesotho, South Africa, Swaziland, Malawi, Mozambique, Uganda, and Zimbabwe. GFATM is the largest funder of HIV diagnostics in the developing world, while MoHs in developing countries fund an increasing portion of the commodities and programmatic need as well, especially in South Africa.

[76] This would have referred to UNICEF's engagement with Alere, the only supplier during the most of the grant period.
[77] This could have applied to the single upstream PoC CD4 developer CHAI supported under Output 2.4 (who ultimately exited the market) or it could have been interpreted as applying to nearer to market CD4 PoC developers.

Due to a lack of consistent standards for comparing product quality and performance in the diagnostic market, UNITAID has been funding efforts by the WHO diagnostics prequalification programme as well as the London School of Hygiene and Tropical Medicine (LSHTM) to harmonise around common performance and design standards. This work has been in collaboration with CHAI, the Pan-African Harmonization Working Party (PAHWP) and the African Society for Laboratory Medicine (ASLM), and supports efficiency gains made possible if MoH partners and regulatory agencies wish to use the results of product evaluations from other countries to grant regulatory approval, accelerating the time it takes for countries to approve and introduce new products. The roles of CHAI and UNICEF under their new UNITAID grant were previously explained and have been plotted accordingly in the figure. Finally, WHO has an important normative role in issuing guidance which has major effects on policies, plans and guidelines within countries and therefore affects the demand and supply of health technologies.

The value of the Healthy Markets Primer framework is that it was developed through a consultative process, with experts agreeing on norms, or "dominant logic" as is referred to in the Primer text, of interventions that shape markets. It is noteworthy that CHAI did not propose to intervene at the pre-market level. There had been early stage R&D funding by BMGF, and UNITAID was providing small late stage development funds to the most promising technologies as well as a large purchase fund. Most funding and interventions, including CHAI's efforts, were focused on the "pull" or post-market side. This emphasis of effort may have been due to the fact that market entry of new PoC CD4 competitors was expected imminently and some stakeholders were of the view that near-to-market firms had the capacity to deal with investment risks independent of donor intervention.

4.3.2.2 Review of CHAI activities under DFID grant

As mentioned, there were several changes to country inclusion for this programme area. End of grant expenditure data show that $6.4 million was spent (intended allocation $7.1 million) and 85% of country allocations went to the eight DFID focus countries (Table 20). It is understood that some of the remaining 15% was used to bridge gaps between two UNITAID grants.

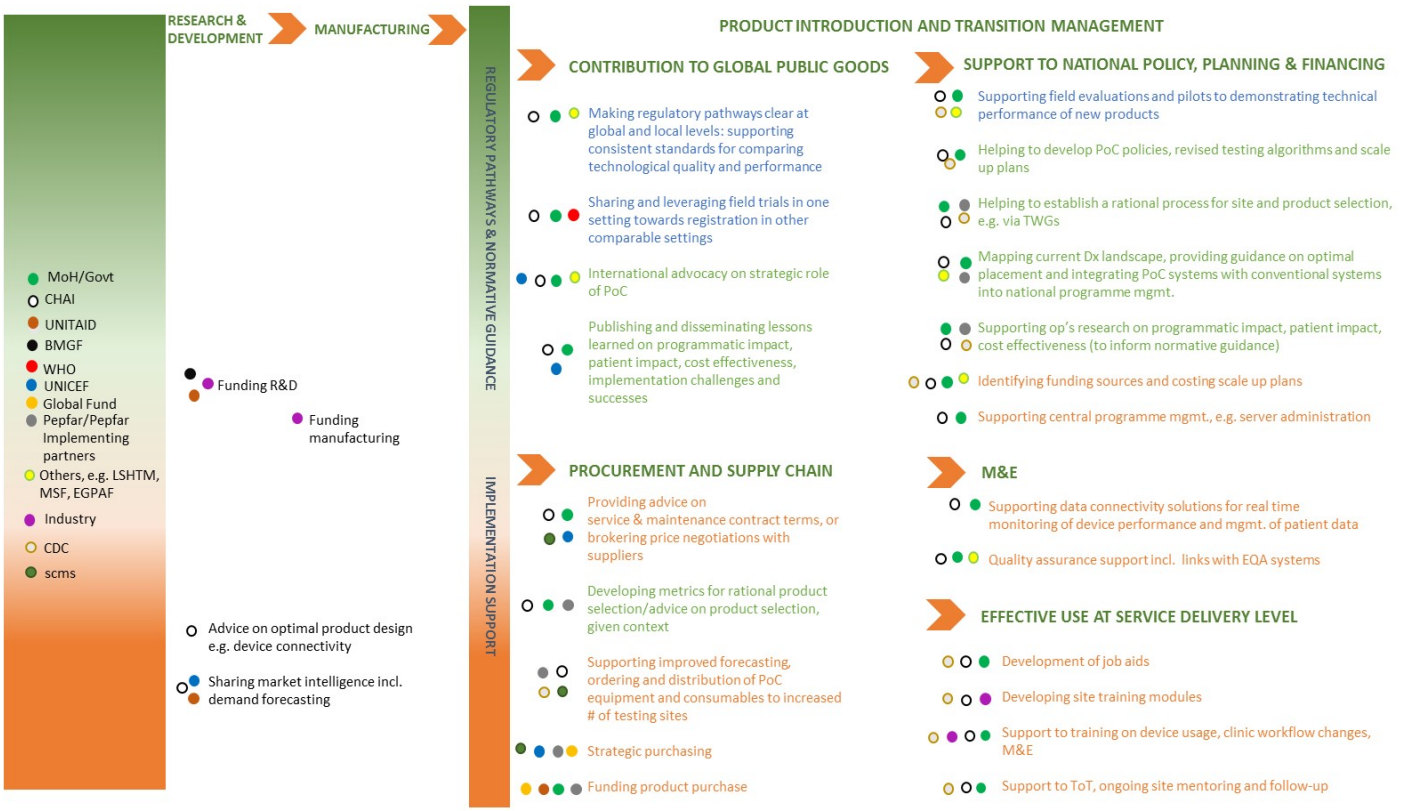
Table 20: Total expenditure and country focus for HIV PoC diagnostics
(DFID focus countries highlighted in bold)

POC Diagnostics		
Team	**DFID Access 2 (£)**	**DFID Access 2$**
Global	£ 2,173,414	$ 3,433,148
South Africa	£ 405,155	$ 641,932
Zambia	£ 313,577	$ 496,079
Mozambique	£ 219,552	$ 347,524
Swaziland	£ 214,582	$ 340,583
Lesotho	£ 200,184	$ 317,183
India	£ 181,760	$ 289,500
Ethiopia	£ 132,807	$ 210,525
Kenya	£ 127,485	$ 200,859
Zimbabwe	£ 86,133	$ 134,394
Malawi	£ 74,569	$ 116,922
Tanzania	£ 65,545	$ 102,158
Uganda	£ 58,189	$ 91,578
Nigeria	£ 28,282	$ 44,276
Grand Total	**£ 4,281,233**	**$ 6,766,660**

Within countries, the Healthy Markets Primer has been adapted to explain CHAI's activity. The original figure does not allow us to adequately reflect the emphasis of CHAI's work; therefore, we have exploded the right-hand side where the emphasis of activity took place (Figure 7). This side has been renamed "Product introduction and transition management" with subheadings to reflect main areas of work, falling along a

continuum of relatively more catalytic work at the top and relatively more programmatic work towards the bottom.[78] CHAI's more catalytic regulatory and normative work is difficult to capture in the Primer headings; we have captured this work under two headings "Contribution to Public Goods" and "Support to National Policy, Planning and Financing". Similarly, the value-chain style headings at the top of the Healthy Markets Primer do not fit well with CHAI's relatively more programmatic implementation work, which has been categorised in the adapted diagram under the headings "Procurement and Supply Chain", "M&E" and "Effective Use at Service Delivery Level". CHAI's specific activities under these categories are further detailed below.

Figure 7: Adapted Primer figure



Regulatory work (in blue type)

On the regulatory side, CHAI has helped 15 countries evaluate and pilot Pima. Most of this work was funded under a previous grant from UNITAID to CHAI that ended in 2015.[79] CHAI also supported full field evaluations of Zyomyx in Mozambique and Kenya, and of BD FACSPresto in Kenya, Ethiopia, Tanzania, Zimbabwe and India (ongoing). Product developers acknowledged CHAI as a good source of information about which labs to go to – those with strong personnel, infrastructure and systems.

CHAI's original plans on the regulatory side had been more ambitious and catalytic. CHAI expected to help make regulatory pathways clearer, support work on more consistent standards for comparing technology quality and performance, publish and disseminate results of evaluations, and leverage the initial evaluations to facilitate rapid registration in additional countries. In most of the CHAI-supported countries, regulatory pathways have indeed been identified for new product approval either through national regulatory agencies or Technical Working Groups (TWGs) for new technologies; in Kenya and Uganda CHAI's influence was most noted in this regard. In India, CHAI is working with the National AIDS Control Organisation (NACO) to harmonise processes for regulatory licensing and programme evaluation, thereby requiring fewer rounds of evaluations for a new product. This will not only enable earlier adoption of the PoC EID and VL technologies in future, but will also reduce NACO's reliance on partners for a vendor independent evaluation. However, the

[78] NB: The way that an intervention is implemented has a considerable effect on its vertical placement. Catalytic activities can turn into programmatic activities if government capacity is not built and/or lessons learnt are not documented and widely disseminated, and, conversely, implementation support can become catalytic if systems, processes and skills are built.
[79] Last orders were placed at the end of 2014

coordination between CHAI, LSHTM and WHO has been sub-optimal and CHAI could have worked better with stakeholders to clarify the challenges to launch effectiveness, explain to developers what the process is for different countries, and make clear what the regulatory process lacks.

Partly as a result of having fewer than expected technologies become ready for evaluation, CHAI was not able to fully realise its ambitions in building MoH capacity to conduct independent evaluations. It was similarly more difficult than expected to encourage countries to accept the results from other countries; in many countries, e.g. Zambia, it remains the case that new diagnostic products will be evaluated in the country in order to obtain regulatory approval, leading to duplication of efforts, and delaying adoption and uptake. This is an area where global efficiency objectives may conflict with country-level plans, with CHAI caught in the middle.

Normative influence (in green type)

CHAI's work to influence normative guidance at global and national levels had some catalytic elements. For example, to select products for evaluations or pilots, CHAI helped countries establish an evidence-based, transparent, multi-stakeholder process for product and site selection, mostly through TWGs. CHAI also helped countries develop PoC policies, revise testing algorithms and develop scale-up plans. To varying degrees in different countries, CHAI helped countries understand total comparative costs of PoC vs lab-based tests, although the evidence base for some of CHAI's cost assumptions needs to be improved, as discussed subsequently. In order to clarify the role of CD4 testing, CHAI, WHO and others authored a major publication[80] that clarified the continuing need and role for CD4.

Under the UNITAID grant, CHAI conducted operational research to understand the impact of PoC introduction on programmes and patients. MoH capacity to conduct operational research independently, and to analyse and interpret results, has not yet been built. CHAI's productivity in publishing and disseminating operational research is a key weakness, which will be discussed subsequently.

CHAI worked with governments to map existing diagnostic capacity, segment the market and choose PoC placement based on rational criteria, integrating PoC into national programmes. In Mozambique, this process was very detailed, involving 30 criteria across four categories: technology attributes (including capital cost) – 30% weighting; testing method and procedures – 40%; reagents, consumables and supplies – 20%; and other company information – 10%. In India, CHAI is supporting NACO in drawing up rational scale plans, to complement the existing conventional CD4 testing network. CHAI has mapped all 500 ART centres, along with their patient loads, to inform site selection for further PoC CD4 placement. In Ethiopia, a rational allocation process undertaken by the Technical Working Group was amended when regional health bureaus, an important stakeholder in service delivery, shifted allocations for site selection.

It is fair to assume that – through CHAI's support and modelling of a rational decision-making process – government capacity has been built for subsequent product introductions. However, CHAI was less successful in building skills and systems, or documenting and disseminating results and lessons in a way which would facilitate its exit from TA provision. This limits CHAI's contribution to global public goods and makes its interventions more programmatic than catalytic.

Implementation support (in orange type)

CHAI also supported in-country operations needed to effectively implement PoC testing, including support to training, quality assurance, service and maintenance, data management, procurement, supply chain and M&E systems. On procurement and supply chain, CHAI was able to negotiate innovative deals on service and maintenance, for example, in Ethiopia. CHAI's tactics in these negotiations were shared with other CHAI colleagues but not publicly. CHAI had mixed success with building government systems and capacity to forecast, order and distribute reagents and consumables. In several countries, CHAI worked on the supply chain systems to ensure distribution of PoC equipment and consumables to an increased number of testing sites. In Zambia, CHAI worked with district MoH staff to improve supply chain and stock management and with clinics to adapt workflow for improved patient management and reduced LTFU.

[80] Ford et al., The future role of CD4 cell count for monitoring antiretroviral therapy, *Lancet*, Feb 2015

In Ethiopia, recent programmatic reviews have identified that a high proportion of diagnostic devices are either non-functional or are underutilised (especially in rural areas). During the EvT country visit, one factor identified was the government's difficulties with distributing reagents to government sites equipped with Pima machines, including to sites with Pimas financed by UNITAID (via CHAI) as well as Pimas financed by PEPFAR (where ICAP provides support). There has been reciprocity between partners to address this systemic issue. The need for solid communication between CHAI, MoH, other government partners, and international donors will become even more essential globally, as PEPFAR and GFATM become more important funders of new diagnostics and will need to coordinate arrangements for ongoing maintenance and reagent purchase.

CHAI has helped governments cost scale-up plans and identify funding sources, not only for PoC CD4 but also for viral load. In India, the Pima pilot's success has led to plans for further scale-up of PoC and CHAI has supported NACO in budgeting for procurement of 300 additional devices under a GFATM grant. In Swaziland, CHAI conducted two PoC CD4 forecasting and procurement training courses with government and ensured PoC CD4 was included in the GFATM grant application.

CHAI has also supported quality assurance mechanisms, for example the enrolment of all Pima sites in Zambia in an External Quality Assurance programme. Similarly, CHAI supported training-of-trainers (TOT) and mentorship packages and site training modules, both for technical device use and operational training for effective PoC implementation. Lessons learned from this training have not yet been published for the benefit of countries outside of CHAI's support scope.

CHAI has supported effective use of Pima devices where capacity was installed prior to this grant, especially where devices were not placed or used optimally, or did not have modems for connectivity and/or service and maintenance contracts. CHAI has been working on optimising the use of these fleets, through training, and additional purchase of auxiliary commodities (like modems). CHAI has introduced operational innovations such as a dashboard – an online tool allowing real-time monitoring of devices in the field. For example, in Swaziland, CHAI's global mHealth team supported installation of a modem on each device so it would be possible for the supervisor and national manager to see progress in real time on a dashboard by logging in. This has greatly reduced expense and logistical difficulty. CHAI also supports mobile connectivity solutions in Kenya, which transmit PoC testing data, improving data management. This work is highly valued in Kenya, though it is referred to as the "CHAI dashboard"; government still relies on CHAI to manage the server and to help them interpret the meaning of the data arising from it. The data generated and uploaded on the national dashboard allows oversight of device and user errors and enables stock management. However, determining patient impact requires CHAI to conduct parallel studies (required by UNITAID) because the dashboard does not connect with patient electronic records. CHAI is now exploring potential interoperability, which would help determine if diagnostics are being used in the right time and right place. CHAI's experiences with PoC CD4 data management have not been documented and shared, which is a missed opportunity. This is currently being addressed through a Connectivity Case Study and a broader Data Management Case Study, which will be shared in 2016.

Some of the implementation challenges that were highlighted during country visits include issues with device utilisation, such as placement of each technology to maximise utilisation as well as gap coverage, dealing with service and maintenance problems, or issues with distribution systems not delivering a secure reagent supply. Challenges with maintenance and reagent supply can contribute to shaking provider confidence, limiting use of the device or causing providers to duplicate PoC testing with confirmatory lab-based CD4 tests. Catalytic vs programmatic impact has not yet been achieved in most countries with respect to building government capacity to conduct training, maintain the machines[81] and ensure adequate reagents, manage data, and control quality, as well as to publish and disseminate experience. Continued technical assistance will be required.

The DFID PoC funding did not include any commodity procurement. Even in the UNITAID countries, the amount of procurement that CHAI contributed directly has been modest compared with the total scale-up achieved. This is evidence of the catalytic effect that CHAI intended to have through the DFID and UNITAID grants from the outset. For example, of the 113 PIMA devices that have been deployed in Kenya, 57 of these were purchased through the CHAI-UNITAID grant and deployed in April 2015, and Pimas purchased earlier

[81] A function not only of government capacity but also of funders' willingness to fund service contracts

by PEPFAR were deployed by CHAI at the pilot stage to develop a strategy for PoC prior to UNITAID devices arriving in the country.

Nonetheless, scale-up has been slower than CHAI expected through the project. The WHO Guideline change influenced potential scale-up, so CHAI and DFID agreed to adapt targets accordingly. However, as recently as 6 months ago, more than a year after the guidelines changed, CHAI was still extremely bullish on targets. For example, Kenya was predicted to conduct 268,000 tests during 2015, whereas it has only done 132,000. CHAI reports that this is due to a quicker than expected migration to viral load. Similarly, Ethiopia and India are well behind recent targets. In Ethiopia, CHAI stated that "It took two years to complete the evaluation results, then guidelines needed to be written up before scale-up, and to write the guidelines, there had to be a consensus building workshop. The procurement process with UNICEF also took a while." In India, uptake has been much slower than CHAI had anticipated due to leadership changes at NACO and staff changes at Alere, as well as initial difficulty in agreeing an acceptable Pima price. Zambia was also slow, as it took a lot of time to develop government comfort with the PoC concept, to field test within the country and then to prepare the health system for roll-out. By the time there was agreement, B+ had been rolled out, lessening the need for CD4. Several countries are now moving towards 'test and treat', which will further reduce the need for CD4 testing. Although uptake within many countries has been lower and slower than CHAI expected, CHAI has helped countries approach the exercise logically and address access challenges related to diagnostics.

Although outside the scope of this evaluation, it should be mentioned that CHAI is involved in lab strengthening above and beyond PoC focused work. This shows a holistic approach, meeting country needs. There were also many examples of CHAI staff working across countries, and global and country staff working well as a team. For example, in Ethiopia, CHAI gets involved in quantification processes for reagents and consumables (provision of Forlab training), and is engaged in dry blood spot (DBS) piloting. CHAI also led work on costing of options for alternative sample transport systems, not only for HIV but also for TB. This is important because Ethiopia's new GFATM grant will allow for 19 new VL devices to be purchased, so there will be a heightened need for sample transport. Based on CHAI's analysis, informed by work with CHAI staff in Lesotho, Rwanda and the UK, a decision was made to use the postal service on a contractual basis. This will be integrated for all disease sample transport in the future, showing health system strengthening rather than vertical thinking. CHAI India is also doing some innovative work outside of PoC, actively working on a cost-benefit analysis, looking at different models of viral load testing scale-up, including public vs private options. This team is also supporting NACO's study to see whether DBS can be used instead of plasma for VL, which would ensure ease of scale-up through simplified sample transport and reduced cost. There are many more examples such as these.

4.3.3 CHAI impact

4.3.3.1 The changing market context

Several events occurred that together changed expectations of the scale-up potential of CD4 PoC, and consequently expectations for the project. The product pipeline ended up being less mature than anticipated. Multiple product developers experienced technical and financial challenges and halted their product development programmes, and the second product, BD FACSPresto, only received WHO PQ in September 2014. Consequently, donors concerned about entrenching a monopoly situation limited the amount of funding invested in Pima. For example, while the UNITAID grant to CHAI and UNICEF was originally expected to amount to $95m, only $20m was made available initially. After 18 months and another proposal process, CHAI was awarded an additional $35m, for a total of $55m.

Prices also failed to come down, perhaps influenced by reduced funds for procurement and an absence of emerging competition. Funding shortages at GFATM meant that countries were less bullish on diagnostic uptake, preserving scarce finance for maintaining treatments. The final, most significant factor was a change in WHO Guidelines in July 2013, which prioritised viral load over CD4 as the method for monitoring patients on treatment. The WHO guideline change exacerbated the market uncertainty for PoC CD4 developers, and finally CHAI, WHO and others authored a key publication[82] that clarified the continuing need and role for CD4.

[82] Ford et al., The future role of CD4 cell count for monitoring antiretroviral therapy, *Lancet*, Feb 2015

Unfortunately, the publication came in February 2015, which was 6 months too late to prevent one of the leading follow-on developers from going bankrupt because they were unable to raise funds in the insecure uptake environment. Meanwhile, many countries have been moving to Option B+ during the grant timeframe, and more recent considerations of test and treat for the wider population continue to send signals of a potentially contracting market for CD4 testing.

Consequently, during the 2014 DFID Annual Review, it was agreed to revise Output indicator 2.2, reducing the 2015 target number of CD4 PoC tests from 7.7 to 1.9 million in countries of CHAI operations (the 12 countries that are funded by DFID and UNITAID). This corresponds to 0.8 million tests as the volume in the 8 DFID-supported countries alone (the 0.8 million is to be used for the VfM calculations).[83]

Table 21: Post-intervention world (what actually happened)

	2014	2015
Total CD4 million tests new projections (theoretical need)	34.7	
Total CD4 actual tests were 19.5 according to CHAI (which matches with coverage of about 56%)	19.4	
Portion of previous row which is just PoC (from CHAI VFM spreadshseet)*	4.00	5.00
Portion of previous row /PoC which is in CHAI supported 12 countries	1.40	1.90
and portion of previous row which is from the DFID supported CHAI countries	0.46	0.84
Implied PoC market share as % of total CD4 market (4/19.5)	0.21	
*Based on CHAI POC forecast - starting assumption is # of peds & adults on ART from DAT Global ARV forecast		

If we compare the expectations at the start of the grant against the 2014 impact, the following can be observed:

CD4 tests (millions)	Actual 2010	2014 expectations		Actual 2014
Comparison of CD4 overall		w/o CHAI	with CHAI	
CD4 test need pre	29	49	49	34.7
actual CD4 market size	17.5	29.4	39.2	19.4
		2014 expectations		
Comparison of PoC specifically	2010	w/o CHAI	with CHAI	Actual 2014
POC market size	1	1.5	11.8	4.00
portion of PoC which is in chai 12 countries		0.6	6.8	1.40
and portion of total PoC which is the dfid countries				0.8
implied PoC market share as % of total CD4 market		5%	30%	21%

The estimated need for CD4 tests,[84] forecast by CHAI in 2012 before the change in WHO guidelines, was 49 million for 2014. CHAI expected the actual market size to be 30 million tests without the CHAI intervention and 40 million with the intervention. After the WHO guideline change, the 2014 CD4 test need estimated by CHAI was 34.7 million.[85] Actual CD4 market size in 2014 was 19.5 million.[86] So against original expectations, the need for CD4 tests reduced by approximately one-third from ~50m to ~35m (based on changes to WHO recommendations), but the actual market size against expectations (with CHAI intervention of ~40m) was reduced by one-half to ~20m. The overall CD4 market between 2010 and 2014 has remained fairly stagnant – 17.5 million in 2010 vs 19.4 million in 2014. The growth of 2 million tests seems to have arisen from CD4 tests conducted on Pima devices and given the overall growth in Pima volumes to 4 million tests and growth in market share from 5 to 20%, it would appear that some of the previous volumes arising from lab-based CD4 tests have now been shifted to Pimas. From these numbers, we can see that test volumes did not evolve as expected during the grant and this is only partly explained by the change in WHO Guidelines.

[83] When the targets were lowered, a new indicator was added to respond to the new landscape. This indicator was focused on reducing the cost of centralized VL testing to respond to the new WHO guidelines and achieve VfM targets via a new opportunity (NB: Evaluation of CHAI's VL work was outside of review scope).

[84] Estimated based on the number of patients enrolled in HIV care and treatment, and assuming national guidelines for both pre-ART staging and ART monitoring. CHAI UNICEF proposal to UNITAID October 2012, shared with DFID

[85] "Accelerating Access and integration of innovative point of care HIV technologies in national diagnostics programmes, Phase 2b. Annex 1: Project Plan. CHAI and UNICEF, Aug 2015, shared with DFID

[86] Accelerating Access and integration of innovative point of care HIV technologies in national diagnostics programmes, Phase 2b. Annex 1: Project Plan. CHAI and UNICEF, Aug 2015, shared with DFID

On the supply side, new supplier entry did not happen as expected and it appears that the expansion in test volume has arisen entirely from Pima devices. There is a risk that high switching costs may act as a barrier to the adoption of new products. However, differentiating features, if advantageous, may be the reason for making the investment in switching costs. Pathways to market are possibly clearer now, given the fact that governments have been through the process of Pima introduction and have built systems and processes to consider the next generation. This should decrease market entry investment cost. However, PoC pricing remains opaque[87] and purchase costs continue to look high to a government viewing the situation purely from an acquisition cost standpoint, rather than overall economic cost-benefit.

Even without the challenges arising from the supply side, and the many changes in context, CHAI found several aspects of implementation to be more difficult than anticipated. CHAI learnt the following key lessons, as reported to DFID[88]:

- finding the balance between conventional and PoC is challenging but critical to improving patient outcomes and maintaining cost-effectiveness
- countries may prioritise sites for PoC using a variety of different criteria based on country priorities and country context
- effective PoC testing requires integration of many different systems, which can take years to build
- sites need to make fundamental changes to adapt to new technologies and ensure linkage to care and treatment
- working directly with MoHs is critical to ensure lasting results and sustainability, and
- working with partners on global and national level has been critical to reach scale.

It is encouraging to see CHAI reflect on lessons learnt with an emphasis on health impact, as the EvT similarly view this as a key priority going forward. The recognition of the value of a cost-effective balance between lab-based and PoC devices is also noteworthy; with the expected shift towards a "Treat All" approach in the upcoming 2015 WHO ART Guidelines, the need for CD4 testing can be expected to decline gradually, providing a strong case to responsibly and gradually downsize CD4 testing in CHAI-supported countries, and to make the best use of existing lab-based as well as PoC capacity.

4.3.3.2 CHAI reported results against logframe indicators with EvT assessment

The objective set out by CHAI in the area of HIV PoC Diagnostics (Dx) is to "accelerate market entry, adoption, and uptake of innovative, affordable and high-quality PoC CD4 diagnostics" resulting in the following quantitative results:

- Output indicator 2.1: 30–60% reduction in cost per test result received for at least 2–3 PoC CD4 products
- Output indicator 2.2: 7.7m PoC tests conducted per year in countries of CHAI operations (revised down to 1.9m mid-grant)
    - Also Output indicator 2.2: 5.6m tests conducted in SADC countries (revised down to 1.1 m mid-grant)
- Output indicator 2.4: 3+ products from Indian or Chinese companies approved by a SRA by June 2015 (not specifically related to the PoC CD4 market)

Output indicator 2.3 is TB focused, therefore out of scope.

Output indicator 2.5: "Decrease in the cost of conventional viral load testing for HIV (to support faster implementation of 2013 WHO guidelines)" was added to the logframe and VfM in November 2014 in response to the changing WHO guidelines in 2013, the heightened importance of VL, and changing nature of the PoC CD4 market. It also would allow acknowledgement of the global access prices CHAI had negotiated in September 2014 with the leading supplier of lab-based viral load tests. As this work is not PoC specific, CHAI and DFID deemed it was out of the evaluation scope, although the EvT inevitably gleaned insights into CHAI's work in viral load as context to CHAI's work in HIV diagnostics more generally.

[87] In addition, PEPFAR has different requirements for bundling service and maintenance vs deals CHAI has negotiated so there is purchaser fragmentation with regard to requirements

[88] Slide 8, DFID External Evaluation: HIV Point of Care Diagnostics New York, NY April 21, 2015

Each of the logframe targets within the evaluation scope is discussed in turn, with the key finding highlighted in bold.

Output 2.1: 30–60% reduction in cost per test result received for at least 2–3 PoC CD4 products, as compared with a baseline of the current market price for equipment and per test price for leading laboratory-based CD4 and PoC CD4.

CHAI did not achieve the Year 3 target of 30–60% price reduction for 2–3 products; however, as of 2015, CHAI reported that a 16% overall price reduction had been achieved, with a 45% reduction in 3 major markets. (Actual achievement = 10% reduction)

The baseline all-in price per test for Pima was calculated by CHAI to be $11.81 in 2011 and $11.54 in 2012. The baseline price per test was amended in subsequent spreadsheets to $11.96 based on refined cost assumptions. Using $11.96 per test as the baseline, a 10% reduction from baseline has actually been achieved with a price of $10.80 by end of grant.

This was reduced from $11.40 in August 2015, following a deal on bundled service and maintenance (S&M) and reagent cartridges with Alere and a reduced sample collection kit with Lasec for 3rd party consumables.[89] CHAI has attempted to negotiate a global access price from Alere multiple times throughout the grant period, and reports that a deal should be finalised by Q1 2016 which will result in a further reduction to $10.02 price per test.. CHAI has also pursued negotiations with Becton Dickinson (BD), focusing on the market entry price for the second-to-market BD FACSPresto.

CHAI provided the EvT with a detailed break-down of the components of the "all-in" costs for Pima as compared with lab-based CD4 tests. The cost per test assumptions factor in more than a dozen different cost categories and divide by the expected average utilisation rate of 1400 tests per year to arrive at a cost per test. Cost per test on both existing laboratory diagnostic equipment and PoC devices will vary depending on the utilisation rate, with a lower cost per test achieved at full capacity. As explained below under logframe indicator 2.2, Pima devices are on average being used at less than one-quarter of their potential capacity. The assumption of 1400 tests per year assumes 5.6 tests are performed per day (250 work days per year). The EvT has calculated actual average usage (detailed further below) as 3.7 tests per day, 928 per year, which would increase the price per test. The EvT has remodelled the price per test using 928 tests per device per year instead of 1400. This makes the current price per test $11.70. If we recalculate the baseline price assuming 928 tests per year, then the baseline Pima price becomes $13.40 and compared to the $11.70, this represents a 15% price reduction.

The implication of this discussion is that cost per test relies heavily on assumptions about device utilisation as well as cost categories which are not based on public information. This makes it a challenging indicator to validate.

Output 2.2: 7.7m PoC tests conducted per year in countries of CHAI operations (revised down to 1.9m mid-grant) AND 5.6m tests conducted in SADC countries (revised down to 1.1m mid-grant).

Having been delayed in reaching the (lower, revised) targets throughout the grant period, the test volume targets have now nearly been met as of 2015 for CHAI countries and for DFID focus countries. The targets have been exceeded in SADC countries.

Indicator 2.2 aggregates demand projections from several different countries; the approach to this scope of work was to work across a portfolio of countries varying from high to low risk. The country inclusion was

[89] Evidence of price reductions on extended Pima warranty: Service and maintenance (S&M) for a period of six years was reduced from $6,000 to $2,400. Originally the Pima device came with a free one-year warranty and S&M cost $1200 per year each subsequent year. Now the Pima device comes with a free two-year warranty and S&M costs $1,200 per year for Years 3 and 4, and Alere provides a new swap-out device at the end of Year 4 with another free two-year warranty for Years 5–6. In Mozambique, this has been further reduced from $1,200 for Years 3 and 4 to $900. CHAI was able to provide evidence of these reductions through:
- an Invoice for Zimbabwe at $1,200 for 1 year (based on the old model): This translates into $6,000 for 6-year coverage (1-year original warranty + 5 years of annual extended warranty);
- an invoice for Ethiopia at $2,400 for 4 years: This translates into $2,400 for 6-year coverage (2-year original warranty + $2,400 for 2 years of extended warranty and a new devices w/ 2-year original warranty);
- an invoice for Mozambique at $900: A reduction from $1,200 on annual extended warranty.

renegotiated, and spending does not line up with the countries selected. If not for the aggregation, earlier attention might have been drawn to the delays in Zambia, India, Ethiopia and Kenya, so that interventions could have been adapted or dropped altogether if deemed no longer appropriate. In the absence of such detail and with changes to the indicators and to the entire scope of the programme area[90] – the logframe was not fully serving its purpose as a planning and performance monitoring tool, but rather it became a performance tracker.

Table 22: CHAI reported device placement and tests performed

	Number of devices				Number of tests		
	Baseline 2012	Aug-13	Aug-14	Aug-15	Aug 2013 Reported	Aug 2014 Reported	Aug 2015 Reported
Ethiopia		**59**	**104**	**104**	**16000**	**33470**	**53000**
India		**0**	**20**	**20**	**0**	**0**	**31500**
Kenya		**77**	**77**	**113**	**15700**	**18539**	**46700**
Lesotho		**30**	**42**	**68**	**19875**	**19875**	**38200**
Malawi		43	126	135	22300	36800	101000
Mozambique		**132**	**141**	**168**	**300700**	**242479**	**329400**
South Africa		**-**	**-**	**0**	**86,900**	**86,900**	**86,900**
Swaziland		**63**	**77**	**79**	**39750**	**48356**	**63388**
Tanzania		445	450	550	183133	270000	260000
Uganda		303	315	315	271305	320000	515600
Zambia		**50**	**68**	**103**	**7100**	**7100**	**120000**
Zimbabwe		276	336	349	255500	280620	214401
TOTAL	**1194**	**1478**	**1756**	**2004**	**1218263**	**1364139**	**1860089**
(of which DFID)		411	529	655	399,125	369,819	682,188
DFID countries target (CHAI VfM)						*457,000*	*769,000*
and SADC countries						992,130	1,213,289

The testing volumes are actual reported country volumes averaging 3.7 tests per device per day, as shown in Table 23 below.

Table 23: Pima testing volumes

	Tests per device per year for 2015	Tests per device per day for 2015*
Ethiopia	509.6	2.04
India	1,575.0	6.30
Kenya	413.3	1.65
Lesotho	561.8	2.25
Malawi	748.1	2.99
Mozambique	1,960.7	7.84
South Africa		0.00
Swaziland	802.4	3.21
Tanzania	472.7	1.89
Uganda	1,636.8	6.55
Zambia	1,165.0	4.66
Zimbabwe	614.3	2.46
TOTAL	928.2	3.71
	*assume 250 working days/year	

Although Pima has a theoretical throughput of 15–20 tests a day based on its processing time, this would require a constant patient flow, a healthcare worker dedicated to running a Pima instrument and clinics being open during morning and afternoon hours. While these conditions may be met in some facilities, in other facilities one healthcare worker might be responsible for patient triage, conducting the test, and counselling patients, or the Pima might be one of several tests being conducted by lab technicians. In addition, clinics may only be open for a portion of the day.

[90] Including diagnostic focus (additional of viral load), country focus (see Table 20) and pipeline stage focus (going further upstream in support to developers)

Output indicator 2.4: 3+ products from Indian or Chinese companies approved by a SRA by June 2015.

Work in this area is undertaken by CHAI's New Diagnostics Project (NDP) team and has included PoC and non-PoC products for TB and HIV, with CHAI providing advice on product design optimisation tweaks (e.g. device connectivity solutions) and other launch considerations (e.g. regulatory and policy approvals, distribution options). NDP had previously engaged with an Indian firm on their work to develop a CD4 test, but that firm's work was discontinued in 2014 to focus on other products. Strictly speaking, therefore, this indicator has moved beyond the scope of this evaluation; however, it is included for context.

CHAI's remaining work has focused on working with several Indian and Chinese upstream developers in support of 4 EID and VL PoC products, and the earliest to market has a possible launch date of 2017. These developers credit CHAI with reducing their learning time, and helping them to avoid mistakes with regard to product design and commercialisation. CHAI was not able to share the criteria or process by which it selects firms to support.

4.3.3.3 CHAI reported results against VfM indicators

The VfM under Output 2 is derived from i) price reduction, comparing counterfactual price with the price CHAI achieved, multiplied by number of tests and ii) savings from reduced wastage of lab-based CD4 tests.

Savings from price reduction

With regard to price reductions, CHAI expected the test price without intervention (counterfactual price) to reduce by approximately 3.5% annually, based on historical price trends seen with conventional CD4 products. As mentioned previously, the counterfactual price per test and target price per test used in CHAI's VfM spreadsheet were quite dynamic, as were the resultant savings expectations (also a function of test volumes), as shown below.

Table 24: Changes to M&E baseline and targets during grant: counterfactual price, target price and resultant savings

	2012	2013	2014	2015
Original 2012 VfM spreadsheet				
Counterfactual price	$11.54	$11.27	$11.01	$11.01
CHAI price	$11.05	$10.28	$9.52	$9.52
Savings	**$0.7 m**	**$2.9 m**	**$6.5 m**	**$8.3 m**
Nov '14 VfM spreadsheet				
Counterfactual price	$11.81	$11.54	$11.27	$11.01
CHAI price	$11.81	$11.24	$11.24	$9.52
Savings	**0**	**$0.1 m**	**$0.05 m**	**$2.7 m**
Sept '15 VfM spreadsheet				
Counterfactual price	$11.96	$11.69	$11.42	$11.16
CHAI price	$11.96	$11.47	$11.40	$11.40
Savings	**0**	**$0.1 m**	**0**	**0**
Oct '15 VfM spreadsheet				
Counterfactual price	$11.96	$11.69	$11.42	$11.16
CHAI price	$11.96	$11.47	$11.40	$10.80
Savings	**0**	**$0.1 m**	**$0.01 m**	**$0.27 m**

As mentioned previously, the assumptions behind the cost per test are challenging to validate and the EvT has observed that the assumed tests per device do not match with field reported data. Given these challenges and the fact that this component contributes a small amount to the overall savings, the EvT has not included this component in its VfM calculations but has relied on the two primary drivers of value: i) savings based on service and maintenance (S&M) negotiations and ii) savings on wastage.

CHAI reports that the total savings from S&M in 2015 were approximately $500k from 135 devices being purchased with the new lower S&M price. Since the start of the grant through to August 2015, there have been $1.4m additional savings on pricing of S&M, assuming a price reduction from $6,000 to $2,000 for S&M for all new devices purchased (discussed above under logframe indicator 2.2), which applies to 284 devices

purchased in 2013 and 118 devices purchased in 2014. Therefore, a total of approximately $2 million has been saved on pricing to date.

Savings from wastage reduction

Since the start of the grant through to August 2015, CHAI reports that $12.8m has been saved from reduced wastage. Underpinning the wastage rates calculation, there are several assumptions: conventional test price per test (influenced by assumptions on conventional test volumes per device) and assumed wastage rates on conventional vs PoC CD4 tests, as well as (as above) PoC price per test (as a function of utilisation). The savings on wastage assumes constant all-in costs of $10.50 for lab-based CD4 and $11.96 for PoC CD4 (including commodities, HR, sample transportation, site overhead, etc.) and assumes a reduction in wastage from 45.7% with lab-based CD4 to 5% for PoC CD4. The 45.7% was calculated from a weighted average of three countries before the start of the project (Mozambique, Malawi and South Africa) where CHAI had data on wastage for lab-based CD4.[91] There have been no publications since mid-2012 showing more recent device wastage rates. The 5% wastage rates for Pima have been estimated before the start of the project; CHAI has since found that actual wastage for PoC CD4 is 0–3% in most countries.[92]

Total savings calculations are thus as follows:

$ millions USD	2012	2013	2014	2015	2016	2017	2018	2019	2020
$ savings wastage	1.03	3.28	3.08	5.19	6.49	8.11	10.1	10.1	10.1
$ savings pricing (reagents/consumables/devices)	0.00	0.11	0.01	0.27					
$ savings pricing (S&M)		1.02	0.43	0.59					
Total savings	1.03	4.41	3.52	6.05	6.49	8.10	10.13	10.13	

As compared with the conservative savings estimates at grant initiation of $427 million to 2020, the revised NPV savings to 2020 using the aforementioned figures, and factoring in the total grant expenditure of $6.4 million, comes to $42.5 m. The majority of this stems from savings on wastage. Given the fact that this saving assumes a doubling in testing volume by 2018, it may be more appropriate to focus on the NPV savings to date. As against expectations of $100 million NPV savings to 2015 (end of grant), factoring in the expenditure of $6.4 m, the EvT calculates a programme NPV savings of $7.4 m,[93] assuming we accept CHAI's assumptions with regard to price per test and wastage rates.

4.3.3.4 CHAI reported results against key indicators of success

CHAI was also reporting against indicators of success "Increase in proportion of patients with access to on-site CD4 testing from approximately 50% to 75% in focus countries."[94] CHAI's most recent reporting shows the following figures: Ethiopia 74%, India 78%, Lesotho 51%, Swaziland 100%, Zambia 78%. This is defined as the percentage of patients (requiring CD4) who are enrolled at a site that offers on-site CD4 testing, either through lab-based CD4 or PoC CD4. The numerator is the number of CD4 tests required **for patients enrolled at sites** with either lab-based CD4 or PoC CD4 (4,646,542). The denominator is the number of total CD4 tests required for all patients in the focus countries (8,063,632). In both cases, this assumes 2 CD4 tests per patient per year, in accordance with the national guidelines of each of the focus countries.

Two issues with this indicator should be noted: (i) The title of the indicator implies that it is a measure of allocative efficiency – i.e. whether the location of PoC placement is filling a gap in coverage, thereby improving access. However, the indicator is not sensitive to evaluating increased access by virtue of PoC CD4 installation because it measures change in access to PoC as well as lab-based CD4 testing. It measures the number of CD4 tests required for patients **enrolled at a site**, so countries with a heavy urban bias to the epidemic and to available lab-based testing (e.g. Addis/Ethiopia) will have a higher number. (ii) The data on which the indicator is based is not easily available. During the country visit to Ethiopia, the EvT attempted to

[91] CHAI provided the additional references on wastage at the EvT team's request, however these all rely on pre-grant data (i.e. data from before mid-2012)
[92] The calculation has not been adjusted to reflect the latest data on wastage, but applies the original estimates to total PoC CD4 testing volumes in the focus countries.
[93] NB: In Table 1, CHAI provides savings to date of $14.8 million. Consistent with the methodology used in the DFID Business case, the EvT factors in the grant investment to arrive at an NPV savings.
[94] This was included as a tab in CHAI's reporting spreadsheet and CHAI updated DFID on these figures in their reports to DFID

validate the specific country figures reported in the 2014 CHAI progress report to DFID; however, the CHAI country team was not able to provide the (government owned) data and it is not based on public information.

4.3.3.5 EvT assessment of CHAI performance

Health impact

It is clear that PoC devices have been deployed, albeit at a slower than expected pace, and the share of the tests conducted by PoC devices versus conventional CD4 devices has increased.

There is no information to show that CHAI has achieved allocative efficiency between countries and within countries. The major contribution to testing volumes reported on the DFID logframe comes from Zimbabwe, Uganda, Tanzania and Mozambique – countries which already had Pimas prior to the DFID grant, primarily from earlier PMTCT (Prevention of mother-to-child transmission of HIV) programming. This is not to downplay the important contribution that CHAI has made in these countries – prior to the current DFID grant, and then during the grant – to ensure the effective use of these devices. Similarly, the EvT requested, but was not able to obtain access to, data on within country distribution. Approximately 15% of CD4 need for pre-ART staging is at the provincial hospital level and 27% is at the district hospital level, both of which are largely covered with on-site testing at centralised CD4 laboratories, while 58% of need is at the health centre level. All facilities are theoretically served by centralised CD4 laboratories. Whether sites are hospitals or health centres, non-POC sites would rely on sample transport which the work sought to minimise by expanding the percentage of patients with access to on-site CD4.Programme reviews in Ethiopia, corroborated by EvT interviews, indicate that Pimas were placed where there was already existing but underutilised lab capacity, indicating sub-optimal placement; however, CHAI reports that none of the 87 Pimas supported by CHAI were placed in a facility that already had a conventional platform.

Similarly, the public health contribution of the devices has not been validated during the grant period. Publicly available data on PoC CD4 impact includes a widely cited 2011 Mozambique study, co-authored by CHAI prior to the grant, showing that PoC CD4 testing cut loss to follow up (LTFU) between HIV diagnosis and ART initiation from 64% to 32%, reduced the time to ART initiation from 48 to 20 days (including the time allotted for adherence counselling and other steps in the ART initiation process), and increased ART initiation by 85%.[95] Another study that CHAI co-authored,[96] relied on this same data from Mozambique as well as other published data to estimate realistic values for various input parameters into a theoretical model. It was estimated that PoC was cost-effective compared with the laboratory-based test over a wide range of input parameter values reflecting Mozambique and several other resource-limited settings. Again, this work did not capture empirical data on health impact from work conducted under the grant.

Reduced test turnaround time and time to ART initiation have been reported at International AIDS Society (IAS) meetings since 2011.[97] In 2011, Hatzold et al. found that PoC device integration with testing and care in Zimbabwe reduced the time from diagnosis to ART initiation from 60 to 24 days. In Tanzania, Mwanja et al. found the time between diagnosis and ART initiation reduced from 60 to 25 days with the introduction of the Pima; however, testing errors were high at 20%, highlighting the importance of healthcare worker (HCW) training. In Uganda, Brouillette et al. found that Pima increased access to CD4 testing in some centres, while in others it had a minimal effect. HCW documentation of results was weak, with 11 of 18 health centres documenting less than 60% of test results in patient files. The study concluded that major determinants influencing the impact of the tests are facility-level practice (e.g. venous vs pinprick blood drawing methodology) and placement of devices based on patient volume and facility capacity. The Wynberg systematic review[98] analysed 15 studies and concluded that “point-of-care CD4 testing can increase retention in care prior to starting treatment and can also reduce time to eligibility assessment, which may result in more eligible patients being initiated on ART.”[99]

[95] Jani I, et al., September 2011 (*Lancet*).
[96] Hyle et al. (*PLOS Medicine*, 2014)
[97] Mwanja et al. (*IAS*, 2013); Brouillette et al. (*IAS*, 2013); Hatzold et al. (*IAS*, 2011).
[98] Wynberg et al. (*JIAS*, 2014)
[99] The majority of studies were carried out in southern Africa, including eight in South Africa, two in Mozambique and two in Zimbabwe. Overall, the quality of included studies was considered to be low to moderate.

In reporting to DFID, CHAI states that CD4 test turnaround times were reduced, the time to ART initiation was reduced, and the percentage initiated on ART was increased where Pima has been deployed. For example, CHAI Ethiopia reported that numbers initiated on treatment went from 3% to 30% where Pima was available. The EvT asked to see the data during the country visit but was told that it was collected for UNITAID reporting and the CHAI team did not feel comfortable sharing it. Similarly, CHAI Kenya reported that the average time to treatment initiation at Pima sites was reduced by 16 weeks (from 18 weeks to 2 weeks). In both countries, there were sensitivities in enabling the EvT to validate the data, which has not been published. The India team was, however, able to share some data from the Pima pilot to show that turnaround time was reduced, frequency of testing increased, dependence on sample transport was reduced, and the skill requirement of health personnel was reduced.

CHAI is making recent improved efforts to work on disseminating results and lessons from PoC implementation. Lessons learned and best practice will be useful to the decisions about PoC EID and VL device scale-up. It is important for countries to understand what conditions are likely to make the Mozambique results translatable (or not) in different settings; similarly, impact studies are needed that focus not only on the advantages provided by PoC devices but also on the challenges and lessons with PoC experience.

Market Impact

The Healthy Markets primer states that “Market shaping is about accelerating the market to a more optimal equilibrium point in terms of improved health outcomes and sustainability…. a market shaping intervention requires a thorough inventory of the benefits, trade-offs, and unintended consequences from multiple perspectives in the market.” One of the perspectives to consider was that of the near-to-market firms who had been counted on to enter the market. CHAI states that its market-shaping work was not focused on directly working with these firms; rather, CHAI saw itself as a neutral broker, providing a level playing field to CD4 PoC suppliers. However, the baseline playing field was not level to start with, given the power imbalance between established diagnostic suppliers who were first and second to market, versus the follow-on start-up firms, some of which arose out of the BMGF CD4 Initiative. Smaller, less well-capitalised firms would have required an even stronger push or pull – or a combination of the two – to enable their market entry. The size and credibility of the purchase funds here, in the context of uncertainty arising from the WHO change in guidelines and late messaging from the global community about the continued role of CD4, proved to be insufficient. One could blame the donors for a faulty conceptualisation of a programme, to which CHAI responded. However, CHAI had quite a bit of flexibility in how it responded to the challenge. Could CHAI or others have worked more tightly with one or two near term PoC developers – backing them more fully, altering the risk sharing equation and facilitating access to capital? Could CHAI have influenced the global and donor community by recommending a different way of supporting near-to-market firms, e.g. larger amounts of push funds and TA, or contractually binding purchase agreements linked to meeting pre-determined targets? Given what was known in 2012, would it have been good for longer-term market health to secure a global access price from Alere at that stage? These questions were not a focus of CHAI when approaching the PoC CD4 market. Annex J provides an illustrative modelling exercise, which reflects the kind of analysis in which we would have expected to see CHAI engage as it approached this space with market- shaping responsibility.

4.3.4 Conclusions

For this programme area, CHAI was allocated $7.1 million of the DFID grant and CHAI expected to generate a NPV savings of $427 million out of the total NPV grant savings of between $1.3 and $2.1 billion (conservative vs linear scale-up) between 2012 and 2020. The EvT has recalculated savings projections to 2020 as $42.5 million.

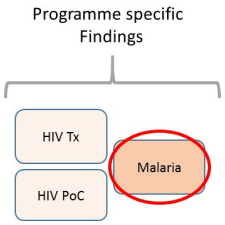
CHAI’s projections for overall CD4 testing market growth, and for PoC share growth, which were the basis for the expected NPV savings and VfM projections in the DFID Business Case, were extremely ambitious. Scale-up has been slower than CHAI expected throughout the project and this can only be partially explained by the change in WHO Guidelines.

A synergistic UNITAID grant approved at the start of the DFID grant should have increased the chances of achieving the project’s objectives, however, CHAI’s plans for regulatory, normative and implementation work were only partially realised. CHAI has been successful in helping governments create processes and systems

to approach technology uptake in a more logical way. However, the evidence base is weak with regard to optimised (between and within country) placement and utilisation of devices, and public health impact in terms of improved case-finding, ART initiation, and retention in care. Better public dissemination is required of the data and impact, allowing for peer-review. This should include lessons showing the devices' impact on operational efficiency, important as countries consider the role of PoC for EID and VL.

CHAI has helped make the pathways to market clearer now; governments have been through the process of Pima introduction and have built systems and processes to consider the next generation of technologies. This should decrease risk and market entry investment cost for follow-on PoC CD4 entrants, as well as EID and VL PoC suppliers. However, the second-to-market arrived two years later than expected and the market remains concentrated; pricing remains opaque and had reduced only by 10% at grant end. Buying behaviour remains fragmented; and high switching costs may act as a barrier to adoption of new products. The characteristics of new products may allow countries to target different market segments for placement; however, fixed government budget envelopes will work against this. Although CHAI's scope of work was substantial (Figure 7) and engagements within countries have been appreciated and impactful, we nonetheless can see that CHAI limited itself to a narrow part of the market-shaping continuum (Figure 6), as conceptualised in the Healthy Markets Primer, focusing on creating an enabling environment to pull through new entrants. Evaluation of this programme area has highlighted weaknesses in the architecture and the process by which decisions are made about market shaping interventions – which markets should be shaped, (in particular) how should they be shaped, and what are the roles of various actors. There were some process gaps in terms of peer-reviewing assumptions, producing a detailed ToC, analysing counterfactual options, and charting an agreed path forward with relevant stakeholders.

4.4 Malaria Treatment



CHAI's work to shape the market for malaria treatment will be analysed according to its process (activities in which CHAI engaged), and its impact (what CHAI achieved). CHAI's activities, and those of other stakeholders, will be plotted using a key framework from the Healthy Markets Primer, to consider the degree to which its 'dominant logic' explains the process by which CHAI approached its market-shaping work in this programme area. CHAI's impact will be analysed in terms of market changes before and after the grant timeframe, and CHAI's contribution to those changes will be evaluated.

4.4.1 Market context pre-grant

4.4.1.1 What was the public health need?

In 2012, there were an estimated 207 million cases of malaria across 99 countries globally. Africa has the highest burden, with 80% of total cases in 2012 and 90% of deaths. Malaria mortality primarily impacts children, with 77% of cases occurring in children under five years old. Even though significant progress had been made in scaling up access to artemisinin-based combination therapies (ACTs) since they were recommended in the 2006 WHO Guidelines, widespread access to quality-assured ACTs remained an issue. There was limited access to appropriate diagnostic testing and treatment, and irrational and inappropriate use of ACTs was rampant, with both overtreatment and poor treatment seeking behaviour in cases of febrile illness.

It is estimated that, each year, approximately 8 million cases of uncomplicated malaria progress to severe malaria. Although this represents only a minority of cases worldwide, reducing severe malaria is critical to reducing malaria mortality. In 2012, quinine was the predominant treatment for severe malaria, and uptake and implementation of injectable artesunate, recommended by the WHO in 2010 as the preferred alternative to quinine, was still low.

4.4.1.2 What was the market need?

By 2012, quality-assured ACT delivery volumes had increased from 11 million treatment courses in 2005 to 278 million courses in 2011, largely due to scaled-up investments from international donors, increased procurement from public sector programmes, and the Affordable Medicines Facility-malaria (AMFm), which accounted for almost half of all procurement. It was estimated that ACT deliveries would decline from a peak of 331 million treatment courses in 2012, to 319–334 million treatment courses in 2013.[100] The ACTs were mostly funded by international donors: in Africa, which accounts for 97% of the donor-funded market, 64% of ACTs were procured by GFATM/UNITAID/UNICEF and 17% by PMI, while national governments financed 9%.

The quality-assured ACT market was highly concentrated around two medicines: 77% of ACTs delivered were artemether-lumefantrine (AL: 255 million courses), and 22% were artesunate-amodiaquine (ASAQ: 73 million courses). Multiple WHO-prequalified products existed for both AL and ASAQ, from both innovator (Novartis, Sanofi) and generic (Guilin, IPCA, Strides, Cipla, Ajanta) manufacturers.

Mid-2012, a total of 15 ACTs from six manufacturers were prequalified by WHO, all AL or ASAQ besides one artesunate+sulfadoxine-pyrimethamine (AS-SP; Guilin). Medicines under assessment for WHO prequalification for quality and safety/efficacy included dihydroartemisinin-piperaquine (DHA-PQP) as an alternative oral ACT option, as well as AQ-SP for seasonal malaria chemoprevention. DHA-PQP (Sigma-Tau) and AS-PY (Shin Poong) obtained European Medicines Agency (EMA) approval in 2011 and 2012, respectively, but restrictions on its use were issued (see also Table 25).

For severe malaria, less than 2 million vials of injectable artesunate (roughly 400,000–625,000 treatments for children under 5 years old) were procured in 2011, out of an estimated 48–50 million vials that would have

[100] World Malaria Report, 2013

been needed to treat global annual cases.[101] There was only one WHO-prequalified injectable artesunate product (60mg powder for injection) on the market, at approximately $1.48 per vial (VPP negotiated price, February 2012).

Reasons identified for the low uptake of injectable artesunate included slow incorporation of WHO recommendations into national guidelines, limited funding for injectable artesunate procurement, unfamiliarity with the product, provider preference, a higher price than that for parenteral quinine, and buyer concerns about a sole prequalified supplier. Although the average treatment course cost of injectable artesunate is higher than quinine ($3.30 compared with $1.30), total costs are found to be equivalent. In particular, when considering the cost of administering the two drugs and the management of side effects, artesunate is found to be cost-effective.[102]

Artemisinin markets were volatile and reached an almost record-high price of $1000/kg towards the end of 2011, up from $300/kg in 2009, while prices dropped again in early 2012. There were serious concerns about the highly fluctuating prices and about possible artemisinin shortages. At the start of the grant, semi-synthetic artemisinin (SSA), which could help stabilise the artemisinin market, was not yet prequalified by the WHO for the manufacturing of APIs or finished products.

In the UNITAID 'malaria medicine landscape' report that was issued after the start of this grant (December 2013), a number of market needs were identified. These included, but were not limited to: the lack of prequalified rectal artesunate for pre-referral treatment of children with severe malaria (*availability*); the high ACT retail price in non-AMFm countries and the high price difference between ACTs and non-artemisinin treatments (*affordability*); low market share and availability of quality-assured ACTs, and high quality-control failure rates of non-WHO/SRA-prequalified antimalarials (*quality*); risk of supply shortages for artemisinin and public sector stock-outs of prequalified ACTs; irrational use of all antimalarials, especially in the private sector; low uptake of injectable artesunate for severe malaria; and unpredictable future demand (*delivery/design, awareness*).

4.4.2 CHAI Intervention

In its ToC, CHAI aimed to promote rapid product introduction in order to stave off artemisinin resistance, ensure patients have access to the best malaria treatments, and mitigate the risk of supply disruptions. CHAI proposed introducing generic products (focused on DHA-PQP and AS-PY) to enhance competition and drive down prices, and engaging in country capacity building. For severe malaria, CHAI aimed to promote generic entry of injectable artesunate to increase competition and potentially drive down prices, and to engage in demand-side work to ensure normative guidance from the WHO is translated to rapid adoption in country. To promote supply stability, CHAI aimed to work to actively identify sources of supply disruptions and collaborate with stakeholders across the malaria community to mitigate these risks. It should be noted that CHAI's work on the introduction of malaria rapid diagnostic tests (RDTs) also contributes to patients having access to the best (and most appropriate) malaria treatment. This work is included under the DFID grant to CHAI, but is not assessed through this evaluation.

A total of £1.98 million has been spent under Malaria Treatment component of Output 6, revised down from £2.86 million in the originally proposed grant allocation. Of this, £740,000 (38%) went towards global-level activities, and the majority of the remaining £1.2 million (62%) towards activities in the five focal countries: Uganda, Nigeria, Malawi, Zambia and Cameroon.[103] Allocation to these countries varied from £179,000 (Uganda) to £277,000 (Nigeria) over the grant period, and funding was primarily spent on demand-side work on the adoption and implementation of injectable artesunate. In addition, some funding was used in Tanzania (£65k), Cambodia (£23k) and Liberia (£14k), although it is not clear which malaria treatment-related activities these can be linked to.

[101] Based on estimate of 8.0 million severe malaria cases per year and weighted average range of 6.0–6.3 vials per severe malaria case.
[102] Lubell, Y. et al. 'Cost-effectiveness of parenteral artesunate for treating children with severe malaria in sub-Saharan Africa' *Bulletin of the World Health Organization* 2011; 89:504–512.
[103] In Cambodia, limited work on malaria treatment was conducted during Year 1 only: budget $38,000.

A total of £4 million has been spent on ensuring rapid and sustainable scale-up of supply of malaria rapid diagnostic tests (mRDT). Complementary programmatic funding for Output 6 (malaria diagnosis and treatment) is reported by CHAI as $7.027m (£4.6 million) through to end-2014, which is made up of contributions from 17 donors, including UNITAID and BMGF.[104]

As outlined in the original market-shaping proposal (May 2012), CHAI's activities under the DFID grant are aimed at accelerating access to affordable, high-quality antimalarial drugs and commodities in malaria-endemic settings and improving market stability. CHAI's work on the malaria treatment component consists of four key objectives, addressing a number of the market shortcomings outlined above:

1) Accelerate adoption and uptake of injectable artesunate for the treatment of severe malaria
2) Expand access to new, high-quality, low-cost ACTs and developing in-country distribution infrastructure to enable rapid roll-out
3) Identify opportunities and undertake targeted interventions to provide ACT market stability
4) Identify additional opportunities to utilise CHAI's market approach in malaria markets.

In August 2012, UNITAID approved a proposal from MMV (Improving Severe Malaria Outcomes project; US$34M; 2013–2016), with CHAI and the Malaria Consortium responsible for in-country programme implementation, and the latter also for implementation research. The grant was based on the DFID-funded experience and lessons learned in early adopter countries (Nigeria and Uganda). The main objective of this proposal was to help catalyse uptake of injectable artesunate, create a sustainable market with multiple WHO-prequalified manufacturers, and reduce prices by up to 30–35%. These objectives thereby overlap substantially with the ones outlined under the DFID-funded market-shaping grant. It is not always clear which CHAI activities are funded through DFID vs UNITAID in the four countries where both grants are operational. UNITAID covers largely the same countries as the DFID grant: Kenya was selected over Zambia, as Kenya had already updated their national guidelines, whereas the other four countries (Uganda, Nigeria, Cameroon, Malawi) are supported by both the DFID and UNITAID grants. In countries covered by both grants, CHAI proposed to shift DFID resources to provide general programmatic funding, whereas the UNITAID grant is used for procurement of commodities and some programmatic expenses.

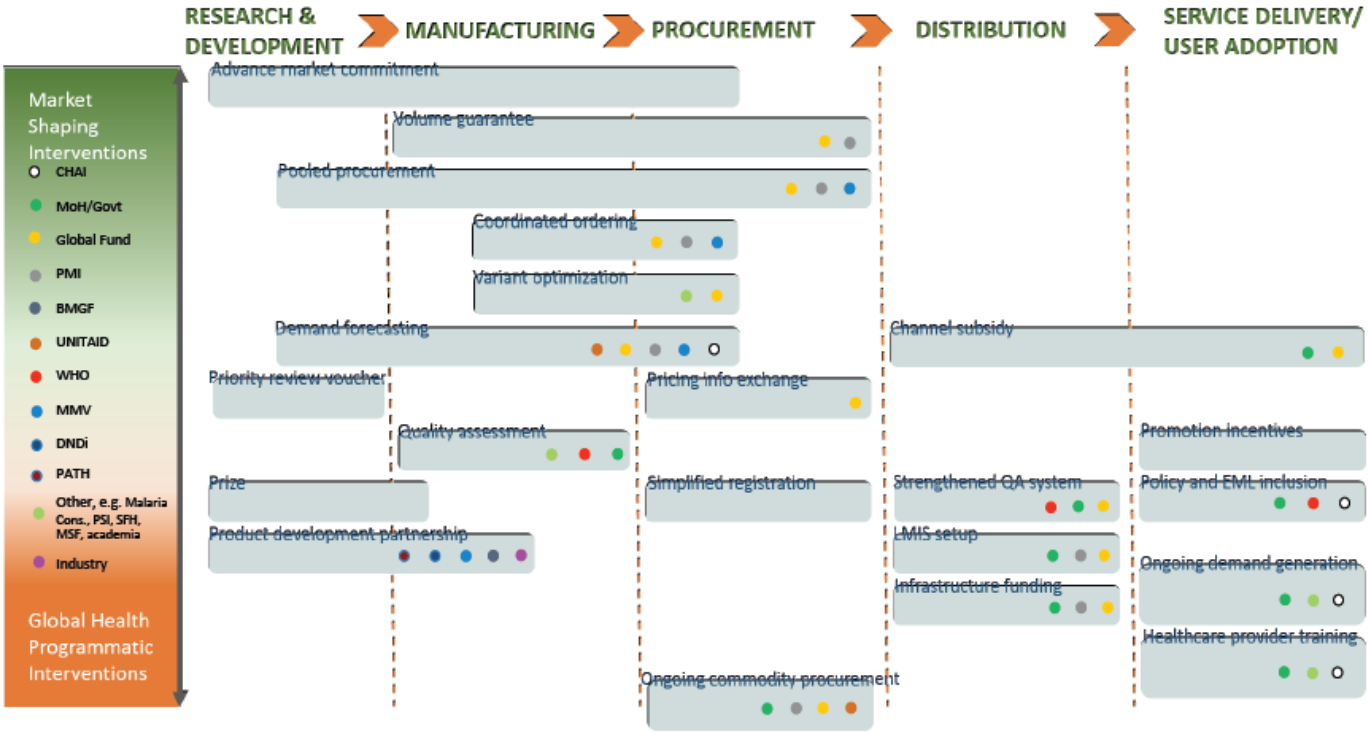
CHAI also collaborates with PATH on a BMGF-funded grant to stabilise the artemisinin market. This project has as objectives to assess the potential impact of strategic reserves of artemisinin and define appropriate operating parameters of potential reserves, assist quality-assured API and ACT producers in registering SSA, and provide oversight of the commercialisation of SSA by Sanofi. Contingent on the outcome of the first objective, artemisinin will be purchased to create an initial reserve. This project was said to build upon and extend initial work conducted under the DFID-funded grant.

4.4.2.1 What are others doing?

The Healthy Markets Primer was used to map the landscape of funding and implementation activity influencing the antimalarial market. CHAI's activities outlined are those funded by DFID and (co-)funded by other donors over the past three years.

[104] CHAI 'Schedule of Complementary Funding for the DFID Access Grant: for the period of July 2012–December 2014'

Figure 8: Market-shaping landscape for antimalarials



The US President's Malaria Initiative (PMI) and the Global Fund remain the key funders of antimalarial commodity procurement. Through the Procurement for Investment (P4i) initiative, the organisations aim to influence the market through joint demand forecasting, coordinated ordering, pooled procurement and volume guarantees. For instance, two-year framework contracts have been established with allocated and committed volumes of ACTs with a group of nine selected suppliers.

As noted in their 2014 Annual Report, BMGF spent 18% of their Global Health portfolio, or $200 million, on malaria, a large part going towards R&D for new antimalarials through Product Development Partnerships (PDPs), including funding of the development of SSA – the PATH/Sanofi project – to stabilise artemisinin markets. The Drugs for Neglected Diseases initiative (DNDi) has also been active in PDPs for malaria drugs, notably with the fixed-dose combination of artesunate+mefloquine (ASMQ) together with Cipla.

In order to increase access to ACTs, UNITAID was the largest funder of the AMFm hosted by the Global Fund. The AMFm aimed to shift the business model for ACTs from "low-volume, high-margin" to "high-volume, low-margin", negotiating a discounted price, and then paying a proportion of this reduced price directly to manufacturers, in the form of a subsidy or co-payment (channel subsidy). In addition, it aims to increase the proportion of facilities stocking quality-assured ACTs instead of artemisinin-based mono-therapy (variant optimisation).

In order to support the production of global ACT forecasts, UNITAID supported a grant on Artemisinin and ACT Demand and Supply Forecasting (2009–2013); and a new UNITAID consortium on medium- to long-term ACT forecasting led by CHAI (with other members being IMS Health and UCSF Global Health Group) started early 2015 for a duration of three years.

UNITAID has also published two malaria medicines landscape reports (2013, 2015), to describe and monitor the landscape for malaria commodities, identify market shortcomings and underlying reasons, and propose interventions to address these.

Specific to severe malaria, and as mentioned above, UNITAID approved a proposal from MMV to help catalyse uptake of injectable artesunate, create a sustainable market with multiple WHO-prequalified manufacturers, and reduce prices of injectable artesunate. This includes demand forecasting of injectable artesunate, as well as in-country work conducted by CHAI and the Malaria Consortium focusing on policy change, demand generation and healthcare provider training.

MMV's additional market interventions include managing R&D through PDPs, supporting introduction of newly registered medicines, and gathering market intelligence to ensure timely availability of key market data. MMV has worked with a number of manufacturers to bring new antimalarials and formulations to market, including DHA-PQP (Sigma-Tau, 2011) and the fixed-dose combination of AS-PY (Shin Poong, 2012), with new market entries expected in the near future.

WHO has an important normative role in issuing policy guidance, and supporting quality assurance through its PQ programme and its essential medicines list. This affects demand and supply of new antimalarials.

Governments/MoHs in malaria-endemic countries are the key players at service-delivery level, in charge of national-level policy-making, quality assurance, ongoing commodity procurement, logistics management information systems (LMIS), infrastructure, training and ongoing demand generation. AMFm participating countries also are involved in the channel subsidy and, through its requirement to disallow artemisinin mono-therapies, variant optimisation.

The Primer allows us to see where CHAI has been working, but it does not fully reflect the emphasis of activities deployed. In addition, the figure is used to reflect all work on malaria commodities, and does not distinguish between medicines for uncomplicated and severe malaria or different medicines with their specific indication, which are affected by different market shortcomings and require different market-shaping approaches.

4.4.2.2 Review of CHAI activities under DFID grant

As shown in the Primer framework, CHAI's activities in this area have concentrated mainly on programmatic interventions at country level, specifically service delivery/user adoption activities mostly related to the adoption of injectable artesunate in focus countries. CHAI has been less active in upstream market-shaping work. In Nigeria, CHAI also worked on the private sector co-payment mechanism (extension of AMFm channel subsidy) and supported the set-up of a LMIS in selected States.

CHAI's activities in the malaria treatment programme area are reported according to the four key objectives set out in the grant.

i) Injectable artesunate

Country-level work

CHAI's country-level work[105] has focused on providing support to national policy, planning and financing, and implementation support including procurement and supply chain management and promoting effective use at service delivery level. This work was an extension from earlier pilot projects in Uganda and Nigeria (funded under the previous DFID market-shaping grant), and a project with MMV to scale up activities in Nigeria to State-specific programmes.

CHAI selected countries for adoption and implementation of injectable artesunate based on a series of assessments in seven countries [106] with credible selection criteria, including current uptake status, counterfactual (what would happen without CHAI's involvement), and CHAI's potential role in accelerating uptake. Even though only two of the five countries selected are listed in the top 12 countries by malaria mortality burden (Nigeria, where 10 of the 37 States are targeted, and Uganda), the assessments conducted suggest that CHAI's potential impact in this area is maximised by a focus on these five countries.

CHAI's influence on national healthcare policy has come through its support of data for decision making, management and support of the implementation process, and in some countries, leveraging UNITAID-funds for commodity purchase. At the policy level, National Malaria Control Programmes (NMCPs) are guided by the WHO recommendations issued in 2010. However, in all targeted countries CHAI was said to have

[105] In Uganda, Nigeria, Cameroon, Malawi and Zambia

[106] Cameroon, Ethiopia, Kenya, Liberia, Malawi, Tanzania, Zambia. Pilot projects on injectable artesunate were conducted in Uganda and Nigeria under the previous DFID grant, hence these countries were included in the selection from the start.

contributed to changes in policy by providing valuable background information and documentation on effectiveness and cost-effectiveness of injectable artesunate vs quinine, as well as 'international data' and evidence from other countries, and also supporting the NMCP to make cost calculations. CHAI's role in mobilising funding, especially from GFATM and UNITAID, was seen as crucial to enable the country to shift from quinine to the more expensive injectable artesunate. CHAI also funded meetings and workshops bringing all stakeholders together, enabling everyone to discuss the evidence and present it to key decision makers. Once the decision was made, CHAI supported the drafting, launch and printing of the new guidelines and education materials.

CHAI's support to policy implementation has ranged from supply chain management to promoting effective use at service delivery level. CHAI has supported commodity management and national forecasting of (new) antimalarial drugs; this information in turn informed global-level demand forecasting. Stakeholders said that national quantification has benefited greatly from CHAI's assistance, even though in Uganda an overstock of injectable artesunate was only narrowly avoided. In Zambia, forecasting has been led by other implementing partners in the case management working group. In addition, CHAI has supported the development of training materials and job aids, cross-fertilising experience across countries, while the actual training was financed primarily from other sources. Stakeholders in Zambia and Nigeria said that CHAI's focus on the monitoring and evaluation of uptake of injectable artesunate had been limited, and in the case of Zambia this was seen as a key weakness in CHAI's role. Key indicators related to severe malaria are not yet included in national routinely collected data in any of the five intervention countries, while this information is crucial to measure health outcomes and potential unintended consequences of new product introduction.

Global-level work

At the global level, demand for injectable artesunate is increasing as countries in Sub-Saharan Africa include it in their national guidelines. CHAI has sought to catalyse the market by providing commodity financing (through UNITAID), to incentivise additional suppliers to enter the market, and to improve quantification to support market stabilisation.

Although CHAI's proposal to DFID originally envisaged CHAI's engagement in the more upstream work on injectable artesunate – supplier negotiations, additional entry into market – MMV took the lead on this as part of the UNITAID grant. CHAI foresaw the need to: benchmark and audit injectable commodity costs to understand the potential floor price; engage in cost-plus negotiations with Guilin on the basis of projected costs and expected volumes plus a modest but sustainable profit margin; and launch a modified open tender when additional suppliers enter the market. Initial analysis indicated that price reductions of up to 30–35% compared with 2012 levels could be absorbed while still ensuring a sustainable profit margin for manufacturers in this space. Even though CHAI was said to have a good overview of the manufacturer's landscape, its predictions for potential price reductions turned out to be too optimistic and were described (by key informants to the evaluation) as "disconnected from reality". Negotiations based on volume-linked price discounts under the UNITAID programme with the single prequalified manufacturer have not resulted in lower price per vial.

CHAI has come with different forecasts of market size of injectable artesunate: one based on potential global demand (i.e. theoretical need), and another based on funding committed and theoretical need in selected countries. The first forecast sets global theoretical demand at approximately 50 million vials per year.[107] CHAI also developed a three-year (2014–2016) injectable artesunate demand forecast based on country and donor plans for 12 high-burden malaria countries which account for 60% of all severe malaria deaths. The forecast distinguishes between funding committed to procure injectable artesunate (approx. 18 million vials in 2015 and 2016) and the theoretical need in these countries (approx. 32 million and 38 million vials in 2015 and 2016 respectively).[108] Both forecasts were shared with prospective manufacturers in an effort to encourage market entry, but to date the product remains single source. Reasons for this include uncertainties around the actual size of the market for injectable artesunate, unpredictable donor funding, questions around uptake of the product especially in the private sector, and the significant capital investment needed in sterile manufacturing facilities for production of injectable formulations.

[107] Based on an estimated 8 million cases of severe malaria worldwide annually and an average severe malaria treatment of 6.3 vials of injectable artesunate
[108] CHAI Presentation Buyers Suppliers Summit, Nov 2014

ii) ACTs

In order to expand access to new, high-quality, low-cost ACTs and develop in-country distribution infrastructure to enable rapid roll-out, CHAI's focus on new ACTs aimed to increase available supply options and help stave off resistance to artemisinin. Activities in this area originally focused on two key products in the ACT pipeline: DHA-PQP and AS-PY.

On DHA-PQP, CHAI initially focused on proactive engagement with potential manufacturers on the development and production of DHA-PQP. This strategy was re-evaluated in October 2014. CHAI consequently concluded that given the limited market potential, and Sigma-Tau's commitment to ongoing production, as well as imminent market entry expected from a second generic supplier (supported by MMV), CHAI's activities would be limited to supporting additional generic entry on a light touch basis – meaning provision of market information and any technical or regulatory support if required. If this market analysis had been conducted at an earlier stage, this might have enabled CHAI to better target its efforts vis-à-vis suppliers.

CHAI's work on AS-PY initially intended to focus on demand-side activities to support roll-out in South-East Asia, but was discontinued at an early stage.

CHAI attributed the shift in strategy related to both of these products to EMA warnings, which would delay market entry of supply sources and make it unlikely that countries would adopt this treatment. However, these warnings for DHA-PQP and AS-PY were issued in June 2011 and February 2012 respectively (before the start of this grant) and seem to only partially explain the story. A Cochrane review (2014) reported that use of DHA-PQP is generally safe,[109] the product recently received WHO prequalification, and new generic entry is expected in the near future. Unlike DHA-PQP, AS-PY is not yet included in WHO guidelines, and, as it is also relatively expensive, a scale-up of this product is not expected in the near future.

iii) ACT market stability

CHAI's work under this area has focused on the potential of semi-synthetic artemisinin (SSA) to stabilise the artemisinin market. Here, CHAI produced an analysis on SSA, which was said to be a good analytical and intellectual output on the possible options and ways forward. This paper was shared with selected stakeholders, and CHAI was credited with bringing the potential of licensing for SSA technology to the attention of other potential manufacturers, prequalified Indian generic formulators and API producers.

However, external factors beyond CHAI's control have impeded progress in this area, notably the intellectual property (IP) landscape of SSA. Also, the price of artemisinin currently lies below the Sanofi agreed 'no profit/no loss' price of SSA, which in the short run makes SSA less interesting for manufacturers. Overall, there is still no consensus on the approach to SSA going forward. CHAI's work in this area has therefore been limited to knowledge dissemination, and is followed up through the PATH/BMGF grant.

iv) Additional malaria market-shaping work

Under this area, CHAI has worked with the Global Fund procurement team as part of the P4i initiative to help realise cost savings for essential malaria commodities, and reports having done initial assessments on the insecticide market for indoor residual spraying. On the former, CHAI's contribution is further expanded upon in Section 4.4.3.2 under the relevant logframe indicator; CHAI has conducted an assessment of potential priority interventions for insecticides, and done some costing on organophosphates (limited documentation is available on activities in this area). Lastly, CHAI also reports conducting work on sulphadoxine/pyrimethamine-amodiaquine (SP-AQ) for seasonal malaria chemoprevention, supporting MMV to assess a Request for Information (RFI) to identify suppliers interested in developing SP-AQ. Key informants described this support as useful but limited.

[109] Zani B, Gathu M, Donegan S, Olliaro PL, Sinclair D. Dihydroartemisinin-piperaquine for treating uncomplicated Plasmodium falciparum malaria. Cochrane Database Syst. Rev. 2014;1: CD010927

4.4.3 CHAI Impact

4.4.3.1 Market context post-grant

ACTs

The donor-funded portion of the ACT market initially increased but then started to decrease in 2014 (278 million in 2011, 332 million in 2012, 392 million in 2013, and 346 million in 2014). A demand forecast for ACTs made in 2013 estimated that ACT deliveries would already decline in 2013 to 319–334 million treatment courses,[110] which shows the high level of uncertainty around ACT demand forecasting. However, in South-East Asia and the Western Pacific Region, volumes of prequalified ACTs procured with donor funding continued to increase.

In 2013, of the 392 million ACTs, the AMFm delivered 129 million treatments to the private and 15 million to the public sector. In 2014, AMFm was integrated into the GFATM core grant mechanism, and 2015 is the first year of approved GFATM grants through the New Funding Model (NFM). The NFM has allocated $4,300m for malaria from 2015–2017;[111] based on historical trends around 16% of this will be used for ACT procurement, information that contributes to more reliable demand forecasts based on funding committed.

The market share of ACT volumes procured in the donor-funded market remains highly concentrated on AL and ASAQ, capturing 74% and 24% of the market respectively (2014 data). Since mid-2012, WHO prequalified an additional 18 ACT formulations: apart from more generic versions (including paediatric formulations) of AL and ASAQ, this included two formulations of ASMQ developed by DNDi and Cipla. After gaining EMA approval in 2011, Sigma-Tau's version of DHA-PQP also gained WHO prequalification in October 2015. However, the market share of these other ACTs remains negligible: 0.2% for AS+MQ, and 1.2% for DHA-PQP.

For severe malaria, Guilin also had two new formulations of injectable artesunate (30mg and 120mg) prequalified by WHO, but procurement of these formulations remains negligible compared with the 60mg version.

Table 25: WHO-prequalified antimalarials, uncomplicated and severe malaria (2004–2015)

		Formulation	Strength	Applicant	Date of PQ
	Uncomplicated malaria				
Pre-grant	AL	tab	20mg+120mg	Novartis	2004-Apr-26
	AS+AQ	tab	150mg+50mg	Guilin Pharm	2007-Aug-30
	AQ	tab	150mg	Guilin Pharm	2007-Aug-30
	AS+AQ	tab	153mg+50mg	Ipca	2008-Apr-23
	AS+PY	tab	60mg+180mg	Shin Poong	*EMA art. 58*
	AS+AQ	tab	153mg+50mg	Cipla	2008-Nov-11
	AS+AQ	tab	67.5mg+25mg	Sanofi-Aventis	2008-Oct-14
	AS+AQ	tab	135mg+50mg	Sanofi-Aventis	2008-Oct-14
	AS+AQ	tab	270mg+100mg	Sanofi-Aventis	2008-Oct-14
	AL	tab	20mg+120mg	Ipca	2009-Dec-15
	AL	disp. tab	20mg+120mg	Novartis	2009-Feb-27
	AL	tab	20mg+120mg	Cipla	2009-May-22
	AS+AQ	tab co-blister	153mg+50mg	Strides Arcolab	2011-Dec-22
	AL	disp. tab	20mg+120mg	Ajanta Pharma	2012-Dec-19
	AS+SP	tab	50mg+[500+25mg]	Guilin Pharm	2012-May-24
	AS+AQ	tab	67.5mg+25mg	Ipca	2012-Jun-01
	AS+AQ	tab	135mg+50mg	Ipca	2012-Jun-01
	AS+AQ	tab	270mg+100mg	Ipca	2012-Jun-01
During grant	AS+MQ	tab	25mg+50mg	DNDi/Cipla	2012-Sep-12
	AS+MQ	tab	100mg+200mg	DNDi/Cipla	2012-Sep-12
	AS+AQ	tab	67.5mg+25mg	Guilin Pharm	2012-Nov-16
	AS+AQ	tab	135mg+50mg	Guilin Pharm	2012-Nov-16
	AS+AQ	tab	270mg+100mg	Guilin Pharm	2012-Nov-16

[110] UNITAID. Demand Forecast for Artemisinin-based Combination Therapies (ACTs) in 2013–2014. Q2–2013 Update (unpublished draft), 2013
[111] Global Fund Suppliers Meeting Sept 2015

	AS+AQ	tab	67.5mg+25mg	Ajanta Pharma	2013-Jul-10
	AS+AQ	tab	135mg+50mg	Ajanta Pharma	2013-Jul-10
	AS+AQ	tab	270mg+100mg	Ajanta Pharma	2013-Jul-10
	AL	tab	20mg+120mg	Strides Arcolab	2013-Jun-24
	AL	tab	20mg+120mg	Macleods	2013-Oct-21
	AS+AQ	tab	25mg+67.5mg	Cipla	2014-Apr-08
	AS+AQ	tab	50mg+135mg	Cipla	2014-Apr-08
	AS+AQ	tab	100mg+270mg	Cipla	2014-Apr-08
	AL	tab	20mg+120mg	Mylan Labs	2014-May-16
	AL	tab	40mg+240mg	Mylan Labs	2014-May-16
	AL	tab	20mg+120mg	Ajanta Pharma	2014-Oct-06
	AQ+SP	tab co-blister	150mg+[500+25mg]	Guilin Pharm	2014-Oct-20
	AL	tab	80mg+480mg	Novartis	2015-Jul-15
Post-grant	DHA-PQP	filmcoat tab	160mg+20mg	Sigma-Tau	2015-Oct-09
	DHA-PQP	filmcoat tab	320m+40mg	Sigma-Tau	2015-Oct-09
	Severe malaria				
Pre-grant	Artesunate	tab	50mg	Guilin Pharm	2005-Dec-21
	Artemotil	sol. inj.	50mg/ml	Artecef BV	2006-Mar-01
	Artemotil	sol. inj.	150mg/ml	Artecef BV	2006-Mar-01
	Artesunate	powder inj.	60mg	Guilin Pharm	2010-Nov-05
During grant	Artesunate	powder inj.	30mg	Guilin Pharm	2013-May-23
	Artesunate	powder inj.	120mg	Guilin Pharm	2013-May-23

A key change in the ACT market has been the reform of the GFATM procurement model, Procurement for Impact (P4i). P4i was established to increase access to health products by fundamentally changing the way the GFATM works across the supply chain. Key elements of the new model for malaria include: (i) joint ACT forecasting between the GFATM and PMI and two-year forecasts for suppliers; (ii) longer-term contracts with suppliers established through a tender process; and (iii) volume guarantees for suppliers. Framework agreements for the procurement of ACTs were set up with suppliers in 2014, and achievements related to long-lasting insecticide-treated nets (LLINs) include greater visibility in demand, long-term framework agreements with LLIN suppliers, diversity in supplier panel, price stability, local manufacturing supported, engagement with suppliers, and improved supplier performance.

Injectable artesunate

The market for injectable artesunate for the treatment of severe malaria has seen large growth over the past year: whereas less than 2m vials (equating to approx. 317,000 treatments) of the prequalified version were supplied in 2011, this figure increased to around 12m vials (approx. 1.9 million treatments) in 2014. Compared to a theoretical need of 50m vials, this represents an impressive increase in coverage from 4% to 25% over the 3-year period. Procurement by the UNITAID/MMV/CHAI project accounted for a considerable share of this increase hence was partially within CHAI's influence; CHAI also advocated for other donors in its focus countries to prioritise the procurement of injectable artesunate. Reasons mentioned to explain this large increase include adoption of injectable artesunate in national guidelines, availability of funding (among others by UNITAID and GFATM), and training and advocacy to increase awareness and acceptance of this new product.

SSA

Semi-synthetic artemisinin (SSA) was prequalified by the WHO in May 2013, and the first delivery of ACTs produced with SSA to endemic countries occurred in 2014. The total production capacity of SSA is approximately 60 tonnes per year, which is currently not being fully utilised due to the lack of ACT manufacturers (beyond Sanofi, the manufacturer of SSA) that have gone through the WHO PQ process needed to supply SSA-based ACTs. Current IP rights may further limit widespread scale-up and use of SSA. The market price of natural artemisinin is currently below the no profit/no loss price of US$350/kg, making use of SSA a less attractive option.

4.4.3.2 CHAI reported results against logframe indicators with EvT assessment

During the timeframe of the grant, CHAI reported the following key results:[112]

- On injectable artesunate, CHAI expanded its work in Uganda and Nigeria to include Malawi, Cameroon and Zambia. All countries had updated their national guidelines to injectable artesunate as the preferred treatment by April 2014, have secured funding from multiple donors for procurement of this drug in 2015–2016, and have established quantification committees to ensure that sufficient commodity is ordered to meet demand. The pilot work conducted under the previous DFID grant informed the design of the UNITAID/MMV project.
- On the supply side, CHAI worked with fully integrated suppliers (i.e. API production and fill) as well as standalone API manufacturers of injectable artesunate, and developed and shared forecasts.
- On SP-AQ, CHAI supported the evaluation of an initial RFI for this drug, and provided input into the new RFI for a dispersible formulation.
- CHAI engaged with the GFATM P4i initiative to provide support with the development of an understanding of market dynamics, and with structuring and evaluation of the relevant tender, resulting in considerable savings on ACTs and bednets.
- In addition, a CHAI 'white paper' on the potential of SSA to stabilise this market has been drafted and shared with selected stakeholders.

CHAI also reported a number of lessons learned during the grant:

- Suppliers require evidence of a more developed market before investing in newer malaria compounds (e.g. DHA-PQP), more so than for other disease areas like HIV.
- Setting proper expectations with stakeholders regarding quantifying orders is critical. While regular quantifications and forecasts are important practices to establish, variation from the forecasted amount should be expected during the period of transition to a new drug.
- It remains important to partner with other groups doing similar work to avoid duplication and build on each group's strengths.

CHAI's work in malaria treatment under the DFID grant is aimed at facilitating new market entry, accelerating new product uptake and contributing towards savings in procurement, with three specific indicators. The progress against milestones and targets is provided in the table below against the original logframe indicators and the current logframe indicators (i.e. as amended during the grant period).

Table 26: CHAI performance against logframe indicator milestones and targets

	Baseline	Milestone Y1	Milestone Y2	Target (2015)
6.2 Number of manufacturers undertaking bioequivalence (or equivalent), with exhibit batches in stability testing for submission of regulatory dossiers for injectable artesunate, DHA-PQP and SP-AQ (original logframe: *number of regulatory dossiers submitted to an SRA)*				
Planned current logframe	2	3	4	4–6
Achieved		**None**	**None**	**3 in stability testing**
6.3 Aggregate number of vials of superior treatment for severe malaria (injectable artesunate) procured in 4–6 focal countries				
Planned current logframe	*Indicator inserted as part of 2014 Annual Review*			15 million
Achieved				**11.7 million**
6.4 Aggregate savings on essential malaria commodities facilitated through CHAI support to global procurers				
Planned current logframe	*Indicator inserted as part of 2014 Annual Review*			US$ 200 m
Achieved				**US$ 240 m**

Output indicator 6.2: "Number of manufacturers undertaking bioequivalence (or equivalent), with exhibit batches in stability testing for submission of regulatory dossiers for injectable artesunate, DHA-PQP and SP-AQ", with a 2015 target of 4–6 manufacturers.

This indicator was revised down following the Annual Review 2013, from 5–7 supply sources at the beginning of the grant. In addition, the initial indicator stipulated that dossiers should be submitted, which was changed to manufacturers undertaking a bioequivalence study – which is approximately 6–9 months prior to submission

[112] DFID-CHAI malaria grant update presentation to DFID 150417; DFID-CHAI Annual Review Supplement 2015

of dossiers. Also, the indicator was expanded to include new supply sources of artemisinin-based APIs and new formulations of existing antimalarials that may be useful in future elimination efforts, such as low-dose primaquine.

Despite these revisions, which should have made it easier to achieve the intended goals, **CHAI's work on promoting new market entry and a broader supplier base for new antimalarials has not achieved its target.** As reported by CHAI, different manufacturers are conducting stability testing for three new supply sources of DHA-PQP and injectable artesunate. However, the imminent expansion of the supplier base cannot be attributed to CHAI: CHAI's work on DHA-PQP has been minimal, while MMV has played a major role in liaising with the manufacturers to expand the supply sources of these antimalarials.

Overall, CHAI's contribution to expanding the market for these products, including understanding of the likelihood of suppliers to enter, has been limited. The degree of market development needed to entice new suppliers was highlighted as a newfound insight, which CHAI will factor into its timelines for future engagement with malaria suppliers. Early market landscape analyses on these products could have helped to set realistic goals; CHAI did conduct an analysis on the DHA-PQP market towards the end of 2014, showing limited potential for CHAI's involvement in this area, but this came too late to influence the DFID grant.

Overall, CHAI activities in this area have not led to increased availability and supply of, or reduced prices for, new antimalarials, and the assumption that the introduction of additional quality-assured suppliers for new ACTs will lead to price competition and supply security is therefore not applicable.

Output indicator 6.3: "Aggregate number of vials of superior treatment for severe malaria (injectable artesunate) procured in 4–6 focal countries" with a target of 15 million vials by 2015.

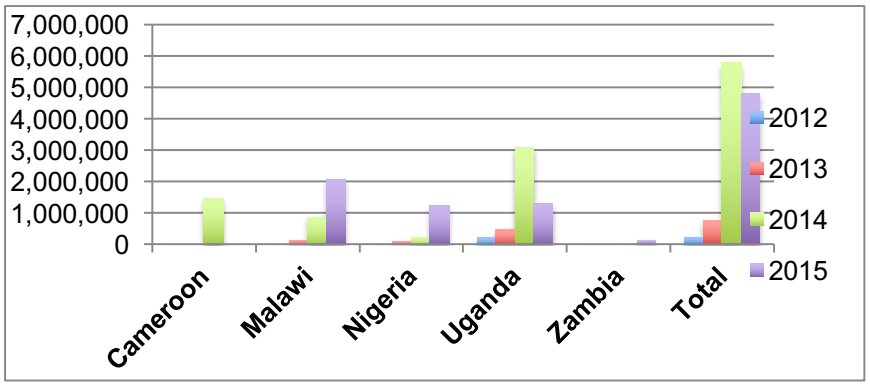
This indicator was added following the 2014 DFID Annual Review, at which time activities in this area were well under way. **By September 2015 (end of grant), focal countries had procured 11.7 million vials of injectable artesunate, below the envisaged 15 million target** (see Table 27, and Figure 9 below). The quantity of vials procured increased rapidly during the first three years of the grant – from less than 300,000 to around 5.8 million in 2014 and appears to be holding at about the same level in 2015 (4.8 million vials procured in the first 3 quarters of 2015). CHAI projects that the five countries will meet the 15 million target within the next six months, and procure 19.5 million vials by the end of 2016.

Table 27: Vials of injectable artesunate procured, by focal countries 2012–2015

	2012	2013	2014	2015*	Total
Cameroon	0	0	1.493.181	0	**1.493.181**
Malawi	0	163.000	896.000	2.092.500	**3.151.500**
Nigeria	30.700	108.416	261.770	1.283.461	**1.664.347**
Uganda	238.500	513.000	3.116.693	1.328.406	**5.196.599**
Zambia	0	0	20.400	150.000	**170.400**
Total	**269.200**	**784.416**	**5.788.044**	**4.834.367**	**11.676.027**

** 2015 includes Q1-Q3, up to the end of Sept 2015*

Figure 9: Vials of injectable artesunate procured, by focal countries 2012–2015*



** 2015 includes Q1-Q3, up to the end of Sept 2015*

Of the total quantity, almost half was procured by GFATM, while UNITAID and PMI funded 20% and 18%, and the Chinese and national/state governments 8% and 6%, respectively (Table 28).

Table 28: Number of vials of injectable artesunate procured, by donor 2012–2015

	2012	2013	2014	2015*	Total
GFATM	0	0	2.523.874	3.175.461	**5.699.335**
PMI	0	0	911.900	1.150.000	**2.061.900**
UNITAID	0	0	1.909.810	440.000	**2.349.810**
Chinese government	238.500	403.000	240.000	0	**881.500**
Nat'l/State government	30.700	381.416	202.460	68.906	**683.482**
Total	**269.200**	**784.416**	**5.788.044**	**4.834.367**	**11.676.027**

** 2015 includes Q1-Q3, up to the end of Sept 2015*

A few observations can be made. Firstly, the total quantity of injectable artesunate procured in 2015 is lower than in the previous year, allowing for the fact that Q4 2015 data are not included in this overview. The quantity of product procured in Malawi, Nigeria and Zambia has been steadily increasing (with Zambia being much delayed), while in Cameroon and Uganda, significantly less (or no) injectable artesunate has been procured in 2015 than in the year before. Each country has its unique dynamics: Uganda changed its guidelines earlier than the other countries, and provides injectable artesunate free of charge to all hospitals and higher-level health centres (quinine is not being supplied anymore). Here, more than 70% of all patients treated with severe malaria receive injectable artesunate instead of quinine in 2015, whereas this figure remains low in Cameroon (<25%) and Zambia. In Cameroon, uptake is driven by the demand of health workers and patients, with training and awareness creation still ongoing, and is therefore expected to happen at a much slower pace. Zambia has been relying on PMI annual commitments of funds for commodity purchase, and is gradually phasing in injectable artesunate to specific provinces and health facilities in order to avoid quinine stock wastage and ensure effective training and health systems adaptation. In Malawi, the NMCP said that coordination between different partners procuring injectable artesunate is a challenge, which can result in over- or under-stock at facility level.

A steadily increasing procurement of product may indicate effective demand-creating activities – or alternatively, it may point to a lack of information on uptake from the lower levels. Reduction in procurement quantities from the year before, as observed in Cameroon and Uganda, suggests that future orders had to be revised down or cancelled in order to prevent an overstock of injectable artesunate in the country.

It should be noted that this indicator talks about orders placed, and not commodities delivered in-country (typically around 6 months later) nor actual uptake by patients. Assumptions underpinning the quantity of injectable artesunate to be ordered seem very optimistic,[113] and actual uptake of procured injectable

[113] Total number of severe malaria cases in the five focal countries is estimated at 7 million and 7.7 million in 2014 and 2015 respectively. The percentage of patients with severe malaria treated in the public sector is set at 100% (75% in Nigeria), and uptake

artesunate in countries may in effect be much slower than envisaged. Unfortunately, actual uptake and treatment of patients with severe malaria is not reported on, and this information is currently only to a limited extent collected through routine data collection systems. It can therefore not be established to what extent the ordered injectable artesunate has translated into improved patient outcomes or public health impact.

A second observation is that procurement of injectable artesunate in Zambia is minimal. This is the only DFID focus country not covered by the UNITAID grant, and suggests that results achieved under this indicator may be dependent on parallel activities conducted by CHAI and Malaria Consortium under the UNITAID grant (including the assurance of catalytic funds for commodity procurement).

In terms of quantified health impact, CHAI expected that accelerating adoption of injectable artesunate in the five focal countries would save 20,000–50,000 lives over the duration of the grant, with the number of lives saved being based on the quantity of vials supplied.[114] Using the figures above and assuming quantity ordered equals uptake of product – which may be an unrealistic assumption – a total of 45,000 lives have been saved until the end of the grant period. This meets expectations of 20,000–50,000 lives saved across the duration of the grant.

Output indicator 6.4: "Aggregate savings on essential malaria commodities facilitated through CHAI support to global procurers", with a target of $200 million by 2015.

This indicator was also only added towards the end of 2014 (following the 2014 DFID Annual Review), at which time GFATM's new procurement model was already well under way. The GFATM announced in a November 2013 press release[115] that its new framework to reduce base prices of mosquito nets through the use of large-scale purchasing power resulted in an immediate cost saving of US$51 million, and projected overall savings of US$140 million for GFATM over two years. In June 2014, the GFATM and partners reported [116] they had achieved a way to maximise transition funding for a private sector co-payment mechanism for ACTs, the driving factor in projected savings of over $100 million through price reductions over two years. **Aggregate savings on essential malaria commodities** (bednets and private sector co-payments for ACTs) **over a two-year period therefore come to US$ 240 million, which exceeds the end of grant target of US$200 million target.**

The GFATM has achieved these savings working together with a range of partners, comprising WHO, DFID, the US PMI, UNITAID, UNICEF, the Roll Back Malaria Partnership and the UN Special Envoy for Financing the Health MDGs and for Malaria, and CHAI. CHAI was said to have made a valuable contribution in providing intelligence on the ACT market and developing models for the evaluation of tenders, including scoring and allocation to suppliers. This contribution was felt in ACTs, but less so in bednets where CHAI was said to have limited experience. Even though cost savings have been achieved, these can only to a limited extent be attributed to CHAI.

4.4.3.3 CHAI reported results against key indicators of success

CHAI also reported to DFID against 'indicators of success' to reduce the global burden of malaria, by ensuring rapid and sustainable scale-up of supply of malaria RDTs (outside the scope of this evaluation) and quality malaria treatments. As highlighted above, there were **no additional supply sources** that submitted regulatory dossiers for new malaria treatments to a SRA or WHO (4–5 projected), while no suppliers exited from the ACT marketplace during the grant. **Adoption of injectable artesunate has indeed been accelerated in 5 high-burden countries**. There has been no entry of new supply sources hence no impact on savings. **Improved patient outcomes may have been achieved**, assuming vials procured have translated into uninterrupted patient access to injectable artesunate. However, patient outcome cannot be verified due to little to no reliable data on severe malaria morbidity and mortality.

of injectable artesunate (instead of quinine) in 2015 varies between 75% and 100%. According to these calculations, a total of 21 million vials of injectable artesunate are needed to treat these patients, of which two-thirds would have actual access.

[114] Data from the AQUAMAT study on the mortality rates for quinine and artesunate (10.9% and 8.5%) shows that one life is saved for every 41.7 patients that are treated with Inj AS over quinine. At 6.3 vials per treatment that means that one life can be saved for every 262.5 vials of Inj AS supplied.

[115] http://www.theglobalfund.org/en/news/2013-11-05_Breakthrough_on_Procurement_to_Save_USD_140_Million/

[116] http://www.theglobalfund.org/en/news/2014-06-24_New_Framework_on_Malaria_Drugs_to_Save_$100_Million/

Table 29: CHAI indicators of success – malaria programme component

Reduce Global Burden of Malaria	Ensuring Rapid and Sustainable Scale-up of Supply of Malaria Rapid Diagnostic Tests	*Outside the scope of this evaluation*	
	Ensuring Rapid and Sustainable Scale-up of Supply of Quality Malaria Treatments	• Submission of regulatory dossiers for new malaria treatments to a stringent regulatory authority or the WHO by 4–5 additional supply sources and no supplier exits from ACT marketplace during grant • Accelerated adoption in 4–6 high-burden countries of injectable artesunate and/or new antimalarial treatments	**Savings Impact:** Future price reductions enabled, market sustainability supply security enhanced and uninterrupted access to effective antimalarial treatment ensured by facilitating entry of 4–5 new supply sources of more effective treatment **Patient Outcome:** Uninterrupted patient access to affordable high-quality antimalarial treatments facilitated through improved market stability

No VfM indicator was developed or tracked by CHAI for this programme area.

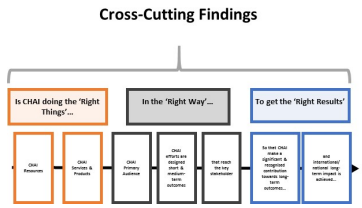
4.4.4 Conclusions

For this programme area, CHAI was allocated $3.0 million of the DFID grant. As in other programme components, there have been a number of changes to the logframe during the grant, with the original indicator being revised down and two new indicators added following the Annual Reviews in 2013 and 2014, respectively.

CHAI's activities have been primarily focused on and successful in its more programmatic activities at country-level related to the adoption of injectable artesunate for the treatment of severe malaria in five focal countries. The focal countries, and especially those also targeted by the UNITAID grant, have seen a large scale-up of injectable artesunate replacing quinine as the preferred treatment for severe malaria. The achievements in this area can at least partially be attributed to the UNITAID grant, with DFID funding playing a catalytic role. The quantity procured in these countries is below the original target set out under this grant (11.7 million vs the 15 million vials target). The total quantity of injectable artesunate procured has the potential to save 45,000 lives – meeting the target of 20,000–50,000 lives saved. However, the lack of reliable data on severe malaria morbidity and mortality means that actual health impact of this programme area cannot be verified.

On the supply side, expanding access to new high-quality affordable malaria products remains a priority. Over the grant period, CHAI has worked with a number of manufacturers aiming to expand the supplier base and support new entry into the market, specifically for injectable artesunate and DHA-PQP. However, CHAI's work has not led to market entry of new oral ACTs or new suppliers of injectable artesunate, nor has it achieved price reductions; other players like MMV seem to have been more successful in this area. CHAI's analysis of the SSA market was regarded as useful, and will be followed up through other grants.

5 Cross-cutting Findings



5.1 Introduction

In the Programme Area Findings section above, we looked in depth at three programme areas within the DFID market-shaping grant to CHAI: HIV Treatment, HIV PoC Diagnostics, and Malaria Treatment. In this section, we draw out key findings across these programme areas, from a strategic issues analysis and from cross-cutting analyses of the 15 country case studies (summarised in Annex I) and the stakeholder survey data (summarised in data tables in Annexes H and I).[117] We also draw on findings from the E2 and LARCs evaluations in this section.

Several cross-cutting issues and questions were identified by the EvT during the Interim Findings phase. Some strategic questions about market-shaping more generally are addressed in 5.2 below, as is the link between CHAI's market-shaping work and the emerging powers' contribution to global public goods, an issue specifically highlighted by DFID at the onset of the evaluation.

The remaining part of this cross-cutting section is structured around the three areas of evaluative enquiry – right things, right way, right results – with reference to the evaluation questions (EQs) articulated in the ToR and elaborated by the EvT. To answer the question 'Did CHAI work in the right way?', the themes of collaboration and communication, capability, and sustainability are explored. Under 'Did CHAI achieve the right results?', we examine both CHAI's performance under the DFID grant and its potential for long-term impact. Key findings are identified by the use of bold text.

5.2 Strategic questions

Through the Interim Findings phase of the evaluation, the EvT identified a series of strategic questions related to market-shaping in global health, which were to be explored further during the Final Report phase. The evaluation has yielded some evidence and lessons that can assist us in answering these questions, as summarised below.

1. ***When is the best time to enter and exit a market-shaping intervention? What are the market conditions that determine this?***

Although this question speaks to market-shaping generally and market conditions generally, in practice it must be answered for each intervention specifically, considering the match between i) available tools and ii) the situations to which they are applied. The short answer is that there is a limited time frame in which market-shaping tools apply to certain situations.

As illustrated in the Healthy Markets Primer figure, certain interventions can be suitably applied to technologies at specific stages of the product lifecycle. An extreme example to illustrate the point: a market-shaping intervention focused on preparing the ground for new product uptake would not be appropriately applied to a situation where the focus technology is still in early stage research, as this would be reducing market risk when the pressing problem is scientific risk – amounting to a temporal mismatch and inefficient use of resources. We would expect such demand-side interventions to have greater impact once the developer has a plausible product and market calculations start to weigh more heavily than scientific risk.

By implication, if a "market-shaper" is more comfortable with a dominant set of market-shaping intervention tools (for example, R&D funding for upstream projects, strategic procurement, price-volume intervention (PVI) negotiations or advance market commitments, or supporting downstream readiness for uptake and effective use) then the usefulness of that actor will be limited to the lifecycle situations to which their tool best applies.

[117] The case studies and survey findings are presented separately, as the survey (which was discussed and agreed with CHAI) was not organised by evaluation question. Instead we have pulled out the survey findings that relate most closely to the EQs that are relevant to each section.

The larger a market-shaper's toolbox of interventions, the greater capacity there is for them to shape markets throughout the product lifecycle[118].

Much of CHAI's work under the DFID grant has been undertaken at country level, creating conditions for uptake. This needs to match with the lifecycle stage of the product. In the CD4 PoC space, $6.4m was spent on CHAI staff, with a focus on market preparation and product adoption/implementation, with no new products to take up. In other words, the intervention chosen – PoC CD4 country preparatory and product adoption/implementation work – was too early to take advantage of a robust pipeline. In other respects, however, CHAI's PoC CD4 work under the UNITAID and DFID grants[119] was too late, as there was already a mounting momentum towards viral load, Option B+ and 'test and treat'. CHAI is "responsibly transitioning" this work now, ensuring that recurrent costs for existing devices are included in GFATM grants and focusing its work across a range of technologies (including PoC CD4 where required) and lab strengthening efforts. This is an appropriate exit from PoC CD4, though one might argue that such a strategy reorientation could have happened earlier, if not at the beginning of the DFID grant. (See the Kenya and Ethiopia case studies in Annex I for details.)

One question on which we are now able to offer some insight is whether CHAI can still be as effective in encouraging uptake when it is not able to purchase: the answer is that it depends. In HIV treatment, CHAI has not had procurement funds during this grant period. However, in PoC CD4 and injectable artesunate CHAI had the ability to draw on procurement funds in certain countries covered by the UNITAID grant. Why is the ability to purchase important? On the supply side, it gives the "shaper" access to proprietary information on cost structure, capacities and ordering,[120] which gives the shaper power and the ability to influence firm investment behaviour, if applied strategically. Shaping the supply side – in particular securing affordable prices and secure supply, offered by a broad supply base – is an important factor, which in turn encourages uptake.

The ability to purchase new technologies with catalytic donor funds can encourage uptake decisions at country level, especially for more novel products with more limited impact data or where GFATM grants cannot rapidly be leveraged. Relative to other product sectors, it has been easier for CHAI to support ARV product transitions because countries already have ongoing GFATM grants with funds programmed for first- and second-line ARVs; there is still much adaptation to be done, but the money is there and the transition less challenging than in some of the other programme areas reviewed.

In the case of injectable artesunate, most countries fund quinine domestically and a transition to injectable artesunate means (in budgetary terms) a threefold increase in cost. To encourage this, one or more of the following helps: i) external funding, at least temporarily until budgets can be reprogrammed and impact can be seen, and ii) attention to providing very good impact data, to reassure countries that the investment (which one way or another will fall on domestic budgets eventually) is worth it.

This logic applies to some degree to HIV diagnostics as well. In diagnostics, governments may be hesitant to take up new technologies unless/until funding is also secured for the devices (during this grant period, GFATM budgets have been insufficient in many countries to cover existing ARV needs, let alone new product uptake). Governments will also want to secure funds for the consumables (e.g. reagents) and complementary infrastructure required to install the device and keep it well utilised. In LARCs and diagnostics, there are also the complementary training costs, which can be substantial.

The corollary is that – in cases where the device/medicine funding, or complementary or recurrent funding, is high, and not already programmed into GFATM grants or covered by others (at least temporarily), or where impact data are not clear – uptake may not happen. In the EvT's assessment, this dynamic was highlighted

[118] There are other considerations besides lifecycle stage that are important in choosing the right intervention tool, such as the nature of the market failure/risks, as discussed below.

[119] However, it should be noted that CHAI was heavily involved in the POC CD4 market from 2008, before any products became available and before funding became available from DFID or UNITAID.

[120] When CHAI was a buyer under the UNITAID programme, it engaged in a three-phased tender process, which enabled access to cost information. Phase 1: Invite all companies (signatories and non-signatories to previous CHAI agreements who are willing to become signatories) Phase 2: Make a choice whether to provide an outright offer or to participate in the cost plus model. The latter is subjected to a cost audit, where CHAI studies yields, processes, source, and cost of key intermediates and give the company a fixed margin. The advantage of the cost plus model is that companies are given a second chance to bid after the first tender offer. This arrangement voluntarily incentivised companies to share their costs. Phase 3: Companies who offered the outright price did not get a second chance to bid during the third phase.

in the case of Zambia, which fell outside of UNITAID funding for both injectable artesunate and PoC CD4 device funding, and where uptake was slower and lower than expected. On the one hand, it can be argued that the issue is not so much whether CHAI itself has procurement funds, but whether there are consolidated donor funds for procurement that can be deployed to support market-shaping interventions. However, the point is that – under the set of circumstances outlined above, such as was found with injectable artesunate and PoC CD4 diagnostics – CHAI's leverage to shape the market may be limited in the absence of the power provided by procurement funds.

2. When can 'market-shaping' become anti-competitive?

According to the Healthy Markets Primer, market-shaping interventions increase information flow and transparency, reduce transaction costs, or alter risk allocation.[121] The first two of these intervention types are relatively benign and would be unlikely to raise barriers to market entry. The exception might be if the information flow were brokered by a market-shaper who held onto that information to its own advantage or to the advantage of certain firms.

The third type of market intervention – altering risk allocation – is by design intended to disrupt an existing equilibrium, and to create a new equilibrium more aligned with long-term public health objectives. Risk reallocation in market-shaping can alter the power relationship between purchasers and suppliers, shifting this power to produce desired behaviour. More power can be given to purchasers, for example if demand and purchasing are aggregated. If there is too much power on the purchasing side, suppliers' margins can be unsustainably squeezed and market exit may be the result – i.e. reduced competition.

Annex J explores in detail another type of risk altering intervention that CHAI engaged in during this grant: bilateral price negotiations intended to alter both prices and volumes. These price-volume interventions (PVIs) will also affect the power balance between competing firms; this can be a problem if it results in a narrowing of the supply base of competitors with the potential to provide comparable or superior products – i.e. reduced competition. The likelihood of this happening is a function of three things: (a) the baseline power balance between firms; (b) the baseline characteristics of the demand, and (c) the nature of the intervention and its effect on (a) and (b).

a) The power balance between firms is a function of factors such as relative market shares in the focus product sector, cost advantage (via scale economies, access to API), firm size, product or geographic diversification, and access to capital markets. Micro-level differences such as each firm's strategic positioning, pricing policy, goals, and portfolio opportunities can also be relevant.
b) Relevant characteristics of demand include the overall market size and growth (including how this compares in donor-influenced segments vs other segments) and switching costs.
c) The power of the intervention to influence (a) and (b) will be a function of how it affects market growth, how it affects the market share of each supplier, how it affects price, and the duration of its effect.

The optimum approach is to ensure that a PVI offers the best alternative, relative to counterfactual approaches, and to structure the approach so as to maximise public health benefit and VfM while minimising risks.

This evaluation revealed a mixed picture with regard to how well CHAI contributes to information flow. CHAI does indeed contribute, but needs to improve its emphasis on documenting and disseminating lessons learned and impact data, and (although impeded by its lack of information on ordering in absence of a buyer role) CHAI needs to contribute more effectively to supply-demand alignment in HIV treatment product transitions. With regard to price negotiations, CHAI has a good understanding of the economics and incentives affecting individual firms with which it negotiates; however, CHAI was not able to demonstrate a focus on overall industry economics and a process for deciding how to intervene and how to structure a risk altering intervention, considering the factors detailed under a) to c) above.

[121] We suggest this is an incomplete conceptualisation as "altering risk allocation" doesn't fully capture the idea of an intervention which alters the bargaining power between buyers and sellers, as described in this early work for DFID: http://hdrc.dfid.gov.uk/wp-content/uploads/2012/08/273801_UK_-_Assessing_the_Market_Impact_of__GHI_on_Neglected_Disease_Health_Commodity_Markets_Report.pdf

3. What are the transaction costs arising from the disruption of markets, e.g. for health systems? Who bears these costs, and how?

Market-shaping activities, particularly if they aim to disrupt established suppliers, can generate costs for health policy-makers, planners, funders and regulators, as well as for healthcare workers (HCWs). Two illustrative (but not exhaustive) examples from the CHAI market-shaping activities supported by DFID include:

- LARCs – significant global training requirements arising from the introduction of a new implant, the costs of which must be borne by LIC/MIC governments or donors; prior to CHAI's market intervention, manufacturers made greater contributions to this. A need for bespoke training may also act as a barrier to entry for competitor products.
- HIV PoC Diagnostics – the introduction of CD4 Pimas tied MoHs and providers into service contracts and the need to purchase consumables such as reagents, as well as some training costs and health systems adaptations. This has been funded by UNITAID for an interim period but will eventually be transitioned to governments, or to GFATM grants where applicable. The training and health systems costs are to some degree tied to the product and thus will need to be funded again when follow-on technologies become available. This represents a switching cost, which may serve as a barrier to entry or disincentive for governments to adopt a new technology. Multipurpose technologies (e.g. multiplex diagnostic technologies) may have greater longevity and streamline patient care, resulting in fewer transaction costs and greater VfM overall.

It is important that the market participation or system costs are assessed and factored into any market-shaping activity, in order to understand full economic costs. For example, in PoC CD4, CHAI has been working on costing per test for PoC vs lab-based devices, factoring in all costs related to the device: reagents, consumables, service and maintenance, distributor margins, etc. Total economic costs would also include the costs borne by LIC/MIC governments (for example, training HCWs) and the donor funds given to CHAI to support governments in product introduction. As donor funding to CHAI comes from several sources, an assessment of the full economic or total system costs of new product introduction is not possible from an external viewpoint.

4. What is the role of 'emerging powers' in market-shaping for global health?

The increasingly important role of 'emerging powers' (middle-income countries such as India and China) in the global pharmaceutical and healthcare products markets – and therefore in improving access to medicines – was highlighted in the DFID Business Case for the market-shaping grant and again to the EvT during the Inception Phase of the evaluation.

Emerging powers are important to both supply and demand for many of the health commodities covered by the DFID grant to CHAI:

- Much of the world's artemisinin is grown and processed in China and India, and a significant manufacturing base for antimalarials has developed as a result. There is also high and growing demand for antimalarials in South East Asia, whereas in other regions demand is stable. (CHAI has funding from another donor to work towards malaria elimination in Asia, especially in the Greater Mekong Sub-region.
- There are many large generic manufacturers of ARVs and other essential medicines in India in particular, with a large and growing portfolio of WHO-prequalified products. South African companies also produce ARVs and China is an important source of API.
- Demand in large emerging power and low-income country (LIC) markets such as India, South Africa, Nigeria and Ethiopia is significant for HIV commodities and increasingly significant for non-communicable disease (NCD) commodities. The large volumes of medicines consumed in these countries provides a market stability and contribution margin, which enables suppliers to have the confidence to install capacity, further develop their businesses, and (in a competitive environment) reduce prices.
- China is the base of a LARC implant manufacturer that could challenge the two dominant players in this market. Indonesia could be the base of further entrants.
- To the degree that emerging power companies can also supply the UK, Europe and US, the result may be increased competition and downward pressure on prices to the benefit of UK patients as well.

CHAI's market-shaping work supports the emerging powers' contribution to global public goods. The references to the role of emerging powers in the grant Business Case and logframe focus on CHAI's supply-side role with firms in MICs, particularly in encouraging new entrants to the marketplace, in increasing

competition between manufacturers, and in developing and introducing new technologies. CHAI's work – as well as increased donor funding – has been highly focused on helping the demand in LICs to materialise. Firms have responded to this, and their businesses have grown and developed. CHAI is now extending its scope to, for example, NCD and/or Hepatitis C drugs (as planned for the next phase of the DFID grant to CHAI), which are important products in both established and emerging markets. This may strengthen the business case for firms to adopt a 'high volume low margin' approach to the development, introduction and sale of new products across all markets, which has the potential for wide-ranging public health impact.

5.3 Did CHAI do the right things?

The EQs under this heading explored whether CHAI identified interventions that were high impact, feasible, aligned to country needs and global priorities, and using skills or perspectives that were unique to CHAI. A further EQ asked whether CHAI's ToC articulated programme logic, assumptions and risks, and how it could be improved. Related to CHAI's ToC, and prompted by the evaluation's Interim Findings, we also explored whether and how CHAI's approach is differentiated according to the market being shaped.

As set out in 5.2 above, when choosing a market-shaping intervention, one needs to consider the lifecycle pipeline stage of the focus technology as well as other supply and demand characteristics. Market-shaping interventions that increase information transparency and reduce transaction costs are more easily applied to a range of lifecycle stages, firm and technology types; they have less capacity to create perverse effects. At the same time, reducing transaction costs and increasing information flow can be an insufficient means to gain the desired behaviours, if more significant risk reallocation is required (for example where there are higher investment costs, higher scientific risk, or a less secure market awaiting the successful market entrant).

Set in the context of global market-shaping efforts, it is clear that **CHAI has deployed a discrete set of market-shaping interventions and tools, across an increasing range of product areas**. This is clearly seen in the market-shaping landscape figures for HIV PoC CD4 and Malaria Treatment (Figure 6 and Figure 8). In LARCs, CHAI's intervention was very targeted (and we did not attempt to map this within the broader landscape). In HIV Treatment (Figure 5) CHAI worked on a relatively expanded range of interventions on the upstream side as well as the downstream, more programmatic side. However, in all programme areas, **CHAI has a consistent 'comfort zone' in its approach to the supply/demand interface, focusing on demand creation, demand transparency, and supply-side price negotiations based on that characterisation of demand**. The intervention emphasis varies according to the product sector, but the toolbox remains relatively consistent. However, the evidence gathered for this evaluation indicates that this core toolbox of interventions alone is not sufficient to shape the market for some products and/or some types of firms. In such cases, effective market-shaping requires CHAI to expand the scope of its intervention or to work with other actors in the lead – as happened in the case of MMV taking the lead in support of new antimalarial market entry.[122]

With regard to CHAI's supply-side PVI negotiations in the programme areas covered in this evaluation, these consistently took the form of bilateral PVIs, always negotiated with a dominant firm(s) in the market (e.g. LARCs, PoC CD4 Pima and now viral load).[123] Interventions that alter risks – such as PVIs – can have more profound effects on risk allocation, and positive effects, if well structured and matched to the right market context. In terms of CHAI's process, CHAI was not able to demonstrate to the EvT sufficient rigour to its process for matching the intervention to the situation, including thinking from an industry wide and dynamic perspective, and considering counterfactual options, risks and trade-offs. Annex J is illustrative of *one type* of analysis we were expecting to see, for example when CHAI approached the PoC diagnostics, injectable artesunate, and LARCs programme areas.

At global level, CHAI's new market opportunities (NMO) team assesses new project ideas for impact and strategic fit. Ideas for new projects originate from synergies with existing work, from CHAI teams, and from external sources such as current global health priorities. CHAI staff with an idea need to generate buy-in from senior management and country directors. Senior leadership meetings are held every 2–3 months and CHAI

[122] The EvT is aware that CHAI has been recently been awarded a new UNITAID grant for work to help bring to market new FDCs for HIV treatment. The interventions proposed in this grant are an innovative departure from CHAI's comfort zone and will require advanced deal-structuring skills.

[123] Outside of the evaluation scope, the EvT is aware that CHAI's work on second line ARVs represents an exception to the approach of negotiating price with a dominant market leader. In this case, strategic purchasing by CHAI, paying a premium for a time period, enabled market entry of near-to-market generic producers of LPV/r.

staff must present ideas to this group of 10; this group will press the presenter and play devil's advocate. Once the idea has survived that, it gets a further vetting from the CHAI planning team. The ideas need to survive several levels of vetting and there has to be a quantitative analytical component. At these various levels, the idea proponent(s) will be asked "have you considered this counterfactual"?

- Example 1: hepatitis consideration by new market opportunities team. Pros and cons were considered. It is a MIC issue; the product will still be expensive even once CHAI has become involved. However, on the positive side, there is a willing originator company and a pathway for generic companies, it is an HIV co-infection, and the scope (differential between cost and prices) is there for price negotiation. (It costs $84,000 for 84 pills and it cures hepatitis). The team needed to strengthen their argument, they came back and presented a second time to management, and then it was accepted. At this stage, it is worked into a donor proposal.
- Example 2: male circumcision (MC). Reduces risk of HIV by 60%. There are devices that make it easier to do MC. During the vetting process, the main issue identified was driving uptake at country level. CHAI could not bring money to the table for procurement. The primary barrier is demand and building demand for a preventative intervention (market campaign, messaging) is something easily within expertise of other organisations. CHAI decided that this intervention would not be the most appropriate use of its skills.

At country level the process is different. CHAI has a three-year strategic planning process related to its grant cycle management. Country teams build their programmes and annual work plans based on grants. Annual work programmes are built around standard list of questions. *"At country level, the way it works is MoH asks us to do something. We look at whether there are pathways, i.e. is there infrastructure or other players needed and willing to drive this forward, what is the funding landscape? Do we have enough mandate, political capital, financial capital? (This would increase the success of this intervention). Is there return on investment sufficient to warrant our involvement?"*

There are two possible ways for projects to originate at country level and to get approval:

- Global team may develop a project proposal and they loop in the country teams. *"Global comes to us and says there's funding for this – can you check and see if government is interested? These are projects in the $70–100K range – they do not go to the planning team. This is an example of when the global team secures the funding and then they look for countries. Usually the access team sources the money and then they come to us. Less than $1 million – these are small programmes."*
- Alternatively, a country-specific proposal emerges, the concept note (CN) is developed locally (sometimes with global team assistance) and approval is sought from HQ. Approval for large projects goes through the process previously outlined. Country teams report that most of the time, HQ approve the CNs, and then the country team further develops the proposal. Smaller projects (e.g. opportunistic infection or HCV work in Ethiopia) do not have to go through the vetting process described above.

With regard to sustainability, the country teams are developing more and more project proposals for government to submit to donors. If CHAI has funding for a three-year project, then in the last year of the project, CHAI may develop the CN and MoH takes that and tries to convince donors to extend the work.

We conclude that at the country level and for smaller projects, CHAI is relatively less analytical in its choice of projects, though it always requires approval and cooperation from the government. At global level, CHAI has a rigorous process for evaluating new market opportunities and the areas where CHAI will work are assessed for impact and strategic fit. However, once CHAI decides to work in an area, there is a weakness in the process of deciding how to intervene, or which interventions to choose. As discussed under the strategic issues above, CHAI is missing an industrial economics perspective that focuses not just at the single firm level but at the level of the entire industry and on how to construct an overall healthy market.

We also found that CHAI does not have a formal project management cycle. This means that approved interventions are not subject to a standardised design and appraisal process. CHAI shared a summary risk assessment from the LARCs VG Concept Note, but we have not seen evidence of a systematic approach to risk assessment and mitigation. Neither have we seen evidence of CHAI's internal project M&E, though clearly CHAI is producing regular monitoring reports for numerous donors.

To address some of the gaps highlighted above, CHAI has recently advertised a new post of Project Management Director for its Access Program. The postholder will develop and implement a new project

management system, but in the meantime CHAI has introduced Smartsheet (an online tool for collaborative project management) to an initial group of staff.

There is evidence of CHAI being well-aligned with national and global priorities, through its demand-side work. Across the programme areas evaluated, CHAI has consistently helped national governments to follow recommendations from global health agencies and to adopt and implement WHO guidelines. For example, CHAI has specifically helped to draft national treatment guidelines, fund their printing and dissemination, and support related training and mentoring. Further evidence can be found in the country case studies and stakeholder survey:

- There is strong evidence from country case studies that CHAI's interventions are relevant and aligned to country needs, policies and plans. In Cameroon, CHAI's agenda was overambitious initially but then scaled back at government request. CHAI works particularly closely with national government ministries, and above all MoHs. It is important to note that this alignment can lead to questions about whether CHAI is supporting or more proactively setting the MoH agenda – as raised by several key informants in Swaziland, for example. A close proximity to government also has implications for CHAI visibility (which in turn may have implications for perceptions of transparency) and can compromise perceptions of neutrality.
- Among respondents to the stakeholder survey, CHAI is perceived to be well-aligned with country government priorities in general. However, several stakeholders expressed concern about CHAI's expanding scope and whether it can achieve impact across all the markets it is engaged in. Several stakeholders commented that a tighter, more strategic focus would be better.

There is clear evidence that **CHAI has selected interventions that (can) have impact, but there appears to be some tension – evidenced in LARCs, HIV PoC diagnostics and HIV treatment – between short-term market and health impacts and longer-term considerations**. As noted above, there is evidence that CHAI's pre-intervention appraisal and risk assessment processes do not yet fully assess the feasibility of proposed interventions (e.g. obstacles to scale up), or the potential longer-term effects of an intervention on the relevant market. For example, we found evidence that CHAI had conducted some pre-intervention risk assessment for LARCs,[124] yet the potential impact of the selected intervention (a volume guarantee with two suppliers) on competing suppliers seems to have been under-estimated. For malaria treatment, market assessments for several target products came too late (2014) to influence the selection of interventions under this grant. Further evidence related to CHAI's intervention choice can be found in the country case studies and stakeholder survey:

- **There is mixed evidence from country level that CHAI has been able to identify the areas of highest impact in which to engage.** There is good evidence from some country case studies, for Kenya and Uganda for example, that CHAI has chosen strategic and high impact interventions. In Tanzania and Swaziland, key informants highlighted CHAI's use of previous work and other evidence to guide intervention choice. However, in some countries, we found CHAI could have supported additional interventions that would have had significant impact e.g. HIV labs in Nigeria, and central PSM in Zambia. CHAI provides some ad hoc support to governments (often at their request) that may not be high impact, though it may improve CHAI's contextual understanding, strengthen government perceptions of CHAI's responsiveness, and build trust.
- **There is mixed evidence that CHAI has been able to identify interventions with a high feasibility of success.** The feasibility of many of CHAI's interventions can be inferred from evidence of output and outcome level results, but the feasibility of specific interventions was questioned by a significant number of key informants in three countries.[125] We found evidence of CHAI taking steps to establish the feasibility of interventions in four countries,[126] where the use of pilots helped to establish feasibility, and/or feasibility assessments were undertaken.
- **There is strong evidence from the survey that stakeholders believe CHAI identifies the areas of highest impact in which to engage**. The majority of both industry and government/other (O&G) respondents either strongly or somewhat agreed that CHAI identifies the areas of highest impact in which to engage. Stakeholders were asked specifically if they found CHAI supplier-buyer meetings and price

[124] This was summarised in the 2012 'Contraceptive Implants Volume Guarantee: Concept Note' drafted by CHAI.
[125] e.g. in South Africa seeking to understand the feasibility of working with NHLS could have saved wasted energy; in Tanzania, concerns were expressed by KIs about CHAI's ability to work on demand creation, and on achieving the best procurement prices; in Uganda, CHAI's work with the private not for profit (PNFP) sector by designing a co-payment mechanism for AS inj in PNFP facilities proved irrelevant once a large donation of free AS inj was received from PMI.
[126] Mozambique, South Africa, Tanzania, Zimbabwe

ceilings useful. Most did, although some concerns were expressed about the impact that price ceilings have on, for example, scope for negotiation, consideration of factors other than price during procurement, and new supplier entry.

Further examples where CHAI showed country alignment and high impact intervention choice include:

- Among the priorities in Ethiopia's HIV Investment Case 2015–2020 are the extension of PMTCT services and improved detection of ART failure. Towards the former, CHAI has helped the government extend PMTCT sites from 1000 to 2500, and towards the latter, CHAI has contributed data and analytics to improve sample transport and scale up viral load diagnostics.[127]
- Among the priorities in India's National Strategic Plan (NSP) for HIV is the objective to decentralise and extend diagnostic and treatment services. CHAI has supported the uptake of PoC CD4 devices as a means to reduce LTFU and extend the reach of ART services. CHAI is also helping government evaluate different models of viral load scale up, including public vs private options. Towards preventing ARV stock-outs, CHAI designed a bar-code-enabled web-based Inventory Management System (IMS) that provides real-time visibility of ARV inventory levels. This will be extended to other commodities and facilities beyond ART sites.
- CHAI is involved in lab strengthening, beyond PoC-focused work, in nearly every country evaluated (Nigeria is an exception). This shows a holistic approach, aligned with country needs. For example, in Ethiopia, CHAI supported the technical working group to prepare a detailed viral load scale-up plan, costing for the scale-up and negotiation of cost per test. CHAI supported laboratory technologist training and supplied SMS printers. CHAI provided Forlab training for quantifying reagents and consumables and is engaged in DBS piloting. CHAI also led work on costing options for alternative sample transport systems, not only for HIV but also for TB.

We found that CHAI has core skills and expertise in specific areas, particularly data handling and analytic work, and that CHAI has identified areas where these skills will add value. For example, in LARCs, CHAI skills have improved global implant forecasting capacity. There are also examples of CHAI applying these skills outside its 'comfort zone'. This was the case for malaria treatment, although it was not apparent that CHAI had sufficiently assessed the market-shaping gap and its comparative advantage prior to its work on DHA-PQP specifically. We identified a number of areas where **CHAI could enhance its unique contribution and added value through better documentation of its experience** (e.g. in HIV Treatment, where CHAI experience is extensive), as discussed below. Further evidence can be found in the country case studies and stakeholder survey:

- In four countries where evidence relevant to CHAI's 'unique contribution' was reported,[128] CHAI appears to have a clear role and there were no concerns about overlap with others. However, in five other countries,[129] questions were raised about CHAI's niche and potential overlap with others. In South Africa, Zambia and Nigeria, it was suggested that CHAI could be intervening in additional areas of market-shaping based on its skill set but is not yet doing so. CHAI has recognised and valued skills and experience (a 'comparative advantage') in the following areas: bringing a business perspective, supply-side knowledge useful for procurement, data analysis on cost and forecasting, and being responsive and flexible.
- In the survey, nearly three quarters of O&G stakeholders either strongly or somewhat agreed that CHAI considers its skill set and comparative advantage relative to others when choosing its areas of work.

In summary, CHAI has developed a core set of market-shaping interventions focused on demand creation, demand transparency, and supply-side price negotiations, which make good use of CHAI's strong analytical capability. It has aligned its work well with global and national priorities, and has focused its demand-side work on supporting governments to increase uptake of key products recommended in normative guidelines. In doing so, it has pursued a mix of strategic and ad hoc activities, though not all activities have demonstrated feasibility and impact. CHAI has missed some opportunities to intervene in potentially high impact areas, and could have even greater impact by documenting and sharing its experience.

[127] Sample transport is important because the country's new GFATM grant allows for the funding of 19 new VL devices, so there will be a heightened need for sample transport.
[128] Cambodia, Cameroon, Ethiopia, Mozambique
[129] Kenya, South Africa, Tanzania, Uganda, Zambia

5.4 Did CHAI work in the right way?

5.4.1 Communication and collaboration

In the following paragraphs, in line with relevant EQs, we look at whether CHAI has managed to balance being collaborative with being disruptive, and at how CHAI has established a clear and complementary mandate and credibility with relevant stakeholders. We also explore a range of issues related to CHAI's communication, including how transparent CHAI is about its mission, projects, competencies and funding sources, whether CHAI shares lessons and contributes to global public goods, and also whether CHAI's products are technically sound and peer reviewed.

CHAI strives to be collaborative in its work, according to its values and mission statements. **In practice, there is evidence of CHAI being both disruptive and collaborative in its market-shaping efforts.** CHAI has collaborated most evidently with MoHs at country-level. CHAI has also worked effectively with global health agencies such as GFATM and UNITAID, though the emphasis is on regular interaction and coordination rather than the development of a more explicit partnership. There is mixed evidence on the clarity of CHAI's mandate, particularly where CHAI has moved into areas outside its 'comparative advantage' (e.g. CHAI's support to the GFATM on bednets). Further evidence of collaboration (and occasional disruption) can be found in the country case studies and stakeholder survey:

- **Across all country case studies, examples were found of positive collaboration by CHAI.** However, in South Africa and Tanzania a need for further collaboration was specifically highlighted in the country case study report, and in the Ethiopia and Tanzania case studies concerns were reported about outcomes in spite of collaboration. In some cases, **disruption may result from a sense of urgency and a perceived lack of consultation, as much as from the type of intervention pursued**. Pushing too fast may cause tensions with stakeholders, as was seen when CHAI wanted to push ATV/r uptake in Kenya based on its costs and benefits, while government insisted on a standard consultative process. Similarly, the Kenya diagnostics dashboard could have been more useful if donors and other implementers had been consulted more fully on their data needs prior to its development. If LTFU data had been linked to subsequent treatment initiation, this would have allowed policy makers to understand whether the right diagnostic was being used in the right place at the right time.
- **There is some evidence that CHAI has sought to establish a clear, complementary mandate and credibility with relevant stakeholders at country level.** In Cambodia and Nigeria, CHAI's role as a neutral technical adviser was highlighted, and CHAI's coordination and convening role was specifically highlighted in three countries.[130] In Malawi, key informants suggested CHAI's convening power was specifically linked to the CHAI country director's gravitas. CHAI has engaged very experienced and credible country directors in several other countries, such as Ethiopia and Nigeria.
- Survey respondents tended to agree that CHAI works collaboratively and seeks to coordinate with others. There was slightly less agreement that CHAI balances being collaborative with being disruptive to catalyse change, that CHAI consults appropriately when designing interventions, or that CHAI's interventions are innovative. Several respondents noted that CHAI collaborates most closely with government partners.

We found evidence of limited transparency across all programme areas, which in turn weakens CHAI's sharing of lessons and contribution to global public goods. There is widespread agreement that CHAI could do more to proactively communicate information about its activities and, for example, it has only recently started sharing externally the lessons learned across certain product areas. In the area of HIV PoC diagnostics and in CHAI's forecasting work, concerns were expressed about the lack of external peer review and QA of CHAI's products, and the limited opportunity partners have to input into, or build off, CHAI's products. Further evidence can be found in the country case studies and stakeholder survey:

- **There is strong evidence that CHAI shares only limited information about its range of projects, funding sources, mission, core competencies and limits.** Eight country case studies[131] highlighted specific issues related to transparency, which included a general sense of secrecy, a lack of information about CHAI's role and mandate, and a lack of understanding about CHAI's funding sources,[132] preferred

[130] Cambodia, Kenya, Uganda
[131] Cameroon, Ethiopia, Kenya, Mozambique, Nigeria, South Africa, Tanzania, Uganda.
[132] Since feedback provided in the EvT's Interim Findings report, CHAI has published the following:
A list of donors to CHAI http://www.clintonhealthaccess.org/content/uploads/2015/10/CHAI-Donor-List_September-20151.pdf

approaches and methodologies. CHAI's limited external communication was specifically highlighted in five country cases studies.[133] For example, in Malawi, many key informants said they had no insight into CHAI's strategy or work plan and would like to understand this better. In several countries, CHAI's lack of desire to take credit was cited as a reason for not communicating externally.[134] Four country case studies[135] noted a perceived lack of consultation and/or a rush to implement by CHAI.

- **There is good evidence that CHAI is now doing more to share best practice.** CHAI's efforts to share best practice and useful data were specifically reported in five country case studies.[136] Other examples of CHAI's sharing of lessons include: sharing experiences across different CHAI country offices,[137] and supporting regional learning.[138] Effective internal communication was noted in the example of the CHAI Ethiopia team working with other CHAI staff on sample transport cost modelling, and also sharing lessons from its negotiations of innovative service and maintenance deals with suppliers, which was presented at an internal CHAI summit meeting. However, sharing outside of CHAI could be strengthened; evidence was reported of opportunities and/or interest in strengthening lesson learning in three countries.[139] In some country case studies, it was noted that there are few incentives for CHAI to publish lessons currently.[140]
- **Survey data has generated a mixed picture of stakeholders' understanding of CHAI.** Most survey respondents believe they have a good understanding of the range of work that CHAI does. Industry stakeholders felt more secure in their understanding of CHAI's core values and mission than O&G stakeholders. Both groups of stakeholders demonstrated rather less confidence in their understanding of CHAI's funding sources.
- Survey respondents seemed uncertain that CHAI's product choices are "neutral" and "evidence-based", with many not answering this question. Almost half the O&G stakeholders did not agree that CHAI offers neutral, evidence-based perspectives, or said it is variable. Nevertheless, the vast majority of stakeholders said CHAI's own tools and products are technically sound, and they have confidence that they have been peer reviewed or quality assured prior to release.
- There were mixed views on whether CHAI effectively shares experiences across countries and globally to support lesson learning, with about half of O&G stakeholders reporting that CHAI performance was variable or not adequate.

In summary, **CHAI appears committed to the principle of collaboration, but its practice is limited by several factors, including weak external communication and a perceived lack of transparency or willingness to share.** The implications of CHAI's performance on transparency, lesson learning and external communications are likely to be felt in terms of its leverage, levels of trust among its partners, and the credibility of its products – in other words, on CHAI's ability to influence partners. Conversely, greater public dissemination would facilitate peer review of CHAI's data and analyses. This would support evidence-informed decision-making at country and global levels, and ease DFID's monitoring burden and help validate CHAI reports, as more expert eyes will have reviewed the data. It may also facilitate an earlier exit by CHAI from programmatic or brokering work, as understanding and capacity are built elsewhere.

And a consolidated financial report: http://www.clintonhealthaccess.org/content/uploads/2015/10/2014-Consolidated-Financial-Statements.pdf

[133] Ethiopia, Kenya, Malawi, Tanzania, Uganda
[134] e.g. Kenya, Uganda
[135] Ethiopia, Kenya, Nigeria, Tanzania
[136] Cameroon, Ethiopia, Mozambique, Swaziland, Tanzania
[137] Mozambique, Swaziland, Tanzania
[138] Mozambique
[139] Ethiopia, Kenya, Mozambique
[140] Ethiopia, Uganda

5.4.2 Capability

With respect to CHAI's capability, we have looked at whether CHAI has the right staff with the right skills, the right structure and systems, and the right style and values to be effective as an organisation working on market-shaping.

This area was explored in detail through the evaluation Interim Findings report. A range of attributes were reported in relation to CHAI staff and their skills. Positive attributes were highlighted, such as commitment, technical skills, creativity, competence, and an understanding of business. Some concerns were raised about CHAI engaging staff with limited experience, including when moving into new areas of market-shaping activity such as LARCs. In discussions with key informants, we recorded positive and negative comments about the same attributes – for example, on CHAI's understanding of local context – which suggests that CHAI's capability varies across different programme areas and countries.

Within the country case studies, there is good evidence that CHAI staff provide skills and capacity that are both relevant and valued locally. In Cameroon, Nigeria and Uganda in particular, a positive overall assessment of CHAI staff capacity was reported. Across twelve country case studies,[141] the following specific positive attributes of CHAI staff were reported: supportive and/or responsive staff; good use of secondments; commitment, dedication, hard work, enthusiasm, professionalism; experience; understanding context and/or using national staff; linking well with CHAI and other global expertise; and strong technical skills. Conversely, feedback included the need to strengthen CHAI's national staff complement and technical skills, and concerns about rapid staff turnover.

The feedback from CHAI stakeholders expressed through the survey reinforces the evidence set out above:

- The majority of stakeholders agree that CHAI staff have appropriate skills and experience, and are politically astute. Slightly fewer stakeholders believe CHAI provides market knowledge that could not be found elsewhere.
- A significant number (almost half of O&G stakeholders) feel staff turnover affects CHAI's impact to some degree. Industry stakeholders were not so concerned with this.
- The majority of stakeholders believe CHAI has appropriate management and internal communications systems in place.

5.4.3. Sustainability

The issue of sustainability covers a wide range of EQs, related to the breadth of CHAI's interventions and the extent to which CHAI builds capacity and systems or contribute to institutional change. To a degree, it also covers CHAI's own management of change, and specifically whether CHAI has been able to adapt interventions to new information or contextual shifts to help ensure their ongoing relevance.

While CHAI's overall approach to market-shaping is quite narrowly focused, **there is good evidence that CHAI's demand-side activities are sufficiently broad.** In all country case studies, CHAI was reported to be implementing a broad range of activities, including developing plans/guidelines, [142] health system strengthening activity, [143] supporting human resources for health (HRH), [144] and supporting management information and M&E systems.[145] There are many examples of CHAI bridging from its HIV specific work to support HSS more generally, to the benefit of other disease areas, such as the sample transport system design in Ethiopia and the IMS extension beyond ART centres in India. It is not clear, though, to what extent this breadth of programming is driven by sustainability considerations or by the need to address more immediate obstacles to achieving market-shaping impact without creating disease-specific parallel systems.

Based on implementation performance, CHAI's effectiveness in managing and influencing change appears to be mixed: questions were raised about CHAI's political influencing capacity (especially in HIV PoC). The main factors that appear to influence CHAI's performance in this area include (on the positive side) CHAI's neutral data-driven approach, its close relationship with government, its ability to convene, and (on

[141] Cambodia, Cameroon, Ethiopia, Kenya, Malawi, Mozambique, Nigeria, South Africa, Swaziland, Tanzania, Uganda, Zimbabwe
[142] Cambodia, Cameroon, Ethiopia, India, Mozambique, Uganda
[143] Ethiopia, Kenya, Mozambique, Nigeria, South Africa, Swaziland, Tanzania, Uganda, Zimbabwe
[144] India, Kenya, Mozambique, South Africa, Swaziland, Tanzania
[145] India, Kenya, Mozambique, South Africa, Swaziland, Tanzania, Uganda, Zimbabwe

the negative side) its lack of documentation and the speed at which it tries to work. Further evidence can be found in the country case studies and stakeholder survey:

- **There is some evidence that CHAI is effective in influencing and managing change.** Specific examples of CHAI exerting influence were reported in seven country case studies.[146] Factors that have increased CHAI's influence include: UNITAID funding[147] (although the removal of UNITAID funding has also been linked to reduced CHAI influence); trust – i.e. CHAI is a trusted partner and so is influential;[148] and CHAI's focus on data, analysis and evidence to inform decision-making.[149] CHAI's speed and flexibility and ways of working more generally were noted as factors facilitating CHAI's influence,[150] although in Kenya one of CHAI's interventions was too focused on speed, which would have been at the expense of the normal consultative processes required to influence policy. The influence of President Clinton was noted in at least one country.[151] In Cambodia, it was observed that CHAI is attempting to strengthen its influence.
- **There is good evidence that CHAI has course corrected, based on new information and/or changes in context.** In six[152] countries adaptation was recorded on the following bases: responding to experience of implementation, responding to need, responding to changed circumstance/context, and adaptation as part of CHAI's offer. In Tanzania, questions were raised about the basis for CHAI's adaptation, which was done with limited consultation, although it was also reported that CHAI had adapted due to changed circumstance.
- Among survey respondents, CHAI is generally seen as adaptable, with a significant majority of stakeholders saying CHAI course corrects in response to new data or changes in context.

There is widespread evidence to illustrate how CHAI is taking action to support capacity building at country level. This includes attention to skills transfer to government staff, through joint working with key individuals and group training. The balance CHAI has struck between driving work forward and building systems is somewhat unclear: there are examples of the pace of CHAI's work being both welcomed (e.g. in Malaria Treatment) and criticised (e.g. in LARCs), and as highlighted above more could be done to support long-term change (e.g. through sharing lessons). It seems clear that the tension between short- and long-term goals is not straightforward to resolve, given different capacity requirements and different views of stakeholders. Further evidence is found in country case studies and the results of the stakeholder survey:

- **There is mixed evidence that CHAI has found the right balance between driving things forward quickly vs building up systems and bringing people along in a way that might be more conducive to long-term systemic change.** In four countries[153] no concerns were raised about the balance between speed and building systems, and CHAI's work to build capacity was highlighted. In Ethiopia specifically, we found that CHAI had achieved balance between pace and systems development. In three countries[154] concerns were raised by a range of stakeholders around this issue. These included not bringing people along,[155] and not focusing on longer-term considerations.[156]
- **There is strong evidence that CHAI has contributed to capacity building – e.g. transferring skills, tools and process knowledge to others, contributing to institutional change – although the outcomes from this are not always clear.** In 10 countries,[157] CHAI has contributed to sustainability through capacity building. In three of these,[158] there is compelling evidence of and/or potential for success. Factors that related to sustainability are reported as: working with partners to promote sustainability;[159] incorporating interventions into national plans and promoting strong country ownership;[160] and hiring local staff.[161] In three countries[162] the importance of working with governance structures was highlighted.

[146] Cambodia, Cameroon, Kenya, Nigeria, Tanzania, Uganda, Zimbabwe.
[147] Highlighted in Cameroon
[148] In Cambodia
[149] Cameroon, Kenya, Nigeria, Tanzania, Uganda, Zimbabwe
[150] Nigeria
[151] Uganda
[152] Cameroon, Kenya, Mozambique, Swaziland, Tanzania, Uganda
[153] Cambodia, Ethiopia, South Africa, Swaziland
[154] Kenya, Mozambique, Tanzania
[155] Kenya, Tanzania
[156] Mozambique, Tanzania
[157] Cambodia, Cameroon, India, Kenya, Nigeria, South Africa, Swaziland, Tanzania, Uganda, Zimbabwe
[158] South Africa, Uganda, Zimbabwe
[159] Kenya
[160] Cameroon, India, Nigeria, South Africa, Zimbabwe
[161] Cambodia, Uganda
[162] Kenya, Tanzania, Zimbabwe

Several country case studies captured concerns raised by stakeholders, such as a dependence on CHAI support,[163] and limited country capacity.[164] In Kenya, for example, it was reported that CHAI had not adequately ensured buy-in from partners who would eventually be responsible for taking over a CHAI-led health systems intervention. In Cambodia and Tanzania, the lack of a clear exit strategy was highlighted.

- Through the survey, around half of O&G stakeholders strongly or somewhat agreed that CHAI has built capacity among implementing partners that could sustain progress, with 12% disagreeing and 26% saying CHAI's track record is variable. A notable number of respondents were unsure or disagreed that the outcomes CHAI has contributed to will be sustained without ongoing CHAI support.
- Overall, respondents were less likely to agree with statements related to CHAI's success in capacity building than those related to quantifiable impacts (e.g. reducing stock-outs, securing donor resources). In addition, **several O&G stakeholders made substantive comments about sustainability through the survey, emphasising the importance of capacity building at country-level.** Other suggestions by respondents included: i) the need for CHAI to give greater consideration to long-term sustainability and exit strategies at the project planning and initiation stages, ii) the increased use of pilots when it is not clear whether an initiative can be sustained, iii) the need to engage more local personnel in CHAI projects (and offices), and iv) providing longer-term arm's length assistance as CHAI exits, such as mentoring and M&E support.

In summary, while there are some concerns about the balance between CHAI's sense of "urgency" and its attention to longer-term systems development and capacity building, CHAI is taking action to support sustainability. This includes work to transfer skills to country government staff, in particular. However, the outputs generated by these activities are not always evident. It is clear that there is scope for improvement – for example in CHAI's articulation of exit strategies – and the survey feedback includes some useful suggestions from CHAI's stakeholders on how it strengthen its approach.

5.5 Did CHAI achieve the right results?

5.5.1 CHAI performance under the DFID grant

In this section, reflecting the EQs, we examine to what extent CHAI has delivered the outputs anticipated under the DFID grant, and the contribution made towards broader market and health outcomes. We also consider the methods and data used in CHAI reporting, the specific contribution of DFID funding and the leverage potential of the DFID-CHAI partnership.

Output targets were defined as part of the grant agreement between DFID and CHAI, and specific output targets were articulated for each programme area. As such, the outputs delivered across the grant timescale have been discussed in depth in the programme area findings above. An overview of these findings is presented here in summary form.

Table 30: Summary of CHAI outputs over the grant period (2012–2015)

Programme area	Output indicator for 2015	CHAI reported Performance at Sept 2015
HIV treatment	1.1 1st line regimen cost reduction to $104 PPPY *(revised up from $90 PPPY after AR 2014)*	Achieved $108 PPPY
	1.2 2nd line regimen cost reduction to $250 PPPY	Achieved $237 PPPY
	1.3 Cost savings for 1st and 2nd line regimens in 4 SADC countries (excl. South Africa) totalling $92m-$199m	Achieved $73m over lifetime of grant
	1.5 Increased no. (10 by 2015) of SRA approved HIV and MDR-TB products from Indian / Chinese / SA sources	Achieved 21
HIV PoC Diagnostics	2.1 30–60% reduction in cost per test for 2–3 PoC CD4 products	Reported 16% (actual 10%) cost reduction (45% reduction in 3 major markets)
	2.2 1.9m PoC tests conducted p/a in countries of CHAI operation, of which 1.1m in SADC countries *(revised down from 7.7m and 5.6m respectively mid-grant)*	Achieved 1.86m tests conducted in 2014/15 of which 1.2m SADC

[163] Cambodia, India, Kenya, Nigeria, Zimbabwe
[164] Kenya, Nigeria, Zimbabwe

Malaria treatment	6.2 4–6 manufacturers undertaking bioequivalence testing for Inj AS, DHA-PQP or SP-AQ *(revised down at AR 2013)*	3 new supply sources being tested but with limited CHAI involvement
	6.3 15m vials of Inj AS procured in 4–6 focal countries *(added at AR 2014)*	11.7m procured by Sept 2015
	6.4 $200m savings on malaria commodities *(added at AR 2014)*	Facilitated $240m savings 2013–2015

This summary table presents a very mixed picture: **CHAI has achieved and in some cases significantly exceeded the outputs anticipated under the DFID grant, but has made little or no progress against others. Still other outputs show good progress but fall short of end-of-grant targets**. In three instances, targets had been revised during the grant period (which had the effect of making them easier to achieve), though none had been fully achieved by September 2015.

The analysis in Section 4 sheds light on why certain outputs have not been achieved. In some areas, a lack of progress can be explained by a detailed assessment of how the market evolved and an unpacking of how this differed from what was expected. For example, with respect to HIV PoC diagnostics, there was delayed device uptake, delayed market entry, delayed and limited price reduction, and a shifting of priorities due to a change in WHO Guidelines. Similarly, with injectable artesunate, there was no new market entry and prices did not evolve as expected. Procurement did not evolve as expected either, although this made less of a difference. In other instances, targets for 2015 have been 'missed' simply because CHAI's original expectations were too optimistic. This is the case across several programme areas, for example, for calculations of initial PoC CD4 market size (and continued over-estimations of uptake rate through the grant) and for the price reduction that could be achieved for Pima; for rates of ATV/r uptake; for the price trajectory for TLE; and for the price reductions sought for injectable artesunate. As a result, the VfM calculations for most programme areas – which supported the DFID Business Case and ultimately grant approval – also proved to be overly optimistic.

Translating the grant outputs into market outcomes and broader public health impact is challenging. The data on outcomes that were produced by CHAI and made available to the EvT reflect this challenge, but also highlight where significant caution is required in relation to claims of outcomes achieved. The grant scope did not require CHAI to track market indicators other than price and volume, nor was CHAI required to collect relevant public health data, which could actually demonstrate a translation from grant outputs to broader outcomes or impacts.

In relation to VfM as an outcome measure, the EvT identified some specific concerns. Across the grant as a whole, CHAI has estimated overall cost savings to date of $766m (non-discounted). [165] Through to 2020, savings of $2.3–$3.4 billion (low case–high case, non-discounted) are estimated. This equates to NPV of $1.8 - $2.6 billion, which can then be compared to the NPV expectations to 2020 from the business case of $1.65–2.53 billion. However, as seen in Table 2 in Section 4.1 the majority of the savings to date derive from price reductions in the HIV Treatment and LARCs programme areas, with most other programme areas underperforming on this measure. Also, as detailed in Section 4.2, the HIV treatment savings may be overestimated due to questionable assumptions about first-line ARV prices and volumes in 2015.

The other outcome indicator tracked across the grant relates to new supplier entry, which facilitates competition. The indicator measures the number of products from Indian, Chinese or South African manufacturers gaining SRA approval: CHAI reported 21 approvals secured with direct CHAI support, greatly exceeding the original target of 5–10. This outcome is very impressive, but it is worth noting that all the relevant products are ARVs or MDR-TB drugs and not all the relevant companies confirmed receipt of direct support from CHAI. CHAI cites progress made on the development of some diagnostics and vaccines, but not yet with a similar rate of approvals.

The outcome measures for the grant thus mask significant variation in the outcomes achieved across the different markets being shaped by CHAI. This will translate into variable public health impacts across different areas of communicable disease, child health and reproductive health. However, as noted above, CHAI was not required to collect or analyse public health data. The impact data reported by CHAI appear to be calculated by CHAI, based on outcome measures also calculated by CHAI: at the end of the grant, CHAI estimated that

[165] CHAI annotated logframe at end-of-grant

7.7m additional patients were being treated with optimal products, and 800,000 additional patients had been tested (for HIV, TB and malaria), as a result of efficiencies generated through grant activity.

A reliance on modelling impact, rather than gathering and analysing public health data, can mask the effects of market-shaping activity on the experience, choices and behaviours of healthcare providers and beneficiaries. For example, there is a need for published data on how PoC CD4 scale-up has impacted health systems and patients and for a better understanding of whether LARC implants have reached new users or displaced other (more cost-effective) LARCs, such as IUDs.

At country level, CHAI reports progress made in activities and against the output indicators under the grant. However, as at the global level, **it is not clear that country data are being collected, which could help determine whether activities and outputs have led to desired outcomes, or which could help CHAI reorient its interventions or improve coordination with others, as necessary**. For example, output indicator 6.3 tracks vials of injectable artesunate procured, but we found little evidence that CHAI monitors uptake at country level (this was flagged as a key issue by stakeholders in Zambia). Similarly, in Malawi, key informants highlighted the challenge of managing the volume of injectable artesunate procured, as it comes through different agents. The savings estimated under HIV treatment are not confirmed by procurement data, even on a sample basis. Wastage rates averted on lab-based CD4 tests are not confirmed, and nor are reductions in LTFU or increases in rates of treatment initiation. This lack of data on the output to outcome continuum is a key concern illustrated by the fact that in a large number of countries we found that data related to disease burden (e.g. the severe malaria burden) were not being routinely collected or analysed. Related to this issue is the fact that there seems to be a lack of reliable data on the impact of CHAI's interventions on health systems. Further evidence can be found in the country case studies and stakeholder survey:

- The country case study reports documented wide ranging outputs from the DFID grant, for example: optimisation,[166] price reductions, changes in the enabling environment such as regulation or political will,[167] reduced turn-around times,[168] increased forecasting capacity,[169]and health systems strengthening.[170]
- Examples of outcomes were also cited in some country case study reports including: cost savings,[171] increased supplies,[172] and increased availability or access.[173]
- Several country case study reports identify issues regarding the data used by CHAI to measure and report results.[174] In some cases, the lack of source data was the concern, whereas in others data were reported to be available but were not published. It is important that CHAI can cite specific data from reliable sources when reporting results. We recognise that this is a challenge where data belong to government ministries, but CHAI has missed opportunities to encourage governments to put more data into the public domain. This translates into a missed opportunity to help correct information asymmetries and thereby support market-shaping efforts, as well as to improve accountability at both national and global levels.
- The feedback from CHAI stakeholders expressed through the survey indicates that the majority believe CHAI has given advice that has resulted in cost savings (though quite a few stakeholders did not respond to these questions). There is less agreement among stakeholders that CHAI helps achieve improved value for money overall.
- Interestingly, O&G respondents to the survey were slightly more likely to say CHAI has increased access to medicines in the short-term, whereas industry stakeholders agreed more strongly that CHAI works to increase access to medicines in the longer-term. Stakeholders were also more likely to agree that CHAI has accelerated the pace of change than broadened the scale of change. Around 1/3 of O&G stakeholders either strongly or somewhat agreed that CHAI overstates its role in achieving results, and a similar number disagreed with the converse statement that CHAI underplays its role. More than 50% of industry respondents strongly or somewhat disagreed that CHAI underplays its role.

With respect to the added value of the DFID-CHAI partnership**, we found that DFID support has been important to CHAI in both strategic and operational ways**. For example, DFID's agreement to procure

[166] Cameroon, India, Nigeria, Tanzania, Uganda
[167] India and Swaziland
[168] India, Tanzania
[169] India, Mozambique, South Africa, Swaziland
[170] Mozambique, Nigeria, South Africa, Swaziland, Uganda
[171] In six countries: Cambodia, Kenya, Nigeria, South Africa, Swaziland,
[172] In two countries: Kenya and Nigeria
[173] In six countries: Ethiopia, India, Kenya, Mozambique, Swaziland, Uganda
[174] Cambodia, Ethiopia, Kenya, Uganda

products has bolstered CHAI's effectiveness in the LARCs sector. There is also strong evidence that the flexibility of DFID funding has enabled CHAI to respond to emerging needs and priorities, although as discussed elsewhere this has implications for the robustness of the grant accountability framework and also for clarity around CHAI's role and mandate.

- Country case study reports indicate that DFID funding has enabled CHAI to achieve specific outputs. Influential factors include: complementing other funding;[175] flexibility in DFID funding, which has allowed CHAI to fill gaps;[176] use of DFID funds to cover core staff costs.[177] The Kenya report noted that DFID funds allowed the expansion of CHAI's work, and the Tanzania report noted that DFID funds enabled the piloting of catalytic work. The flip side of DFID funding flexibility is reported in three country case studies,[178] and relates to a lack of clarity about what DFID has funded.
- **There is good evidence that the DFID-CHAI partnership has resulted in leverage of (a) additional support and (b) complementary activities**, although our ability to distinguish between (a) and (b) is limited**.** In seven country case study reports,[179] evidence was cited of leverage of additional funds. The main source of leverage has been through CHAI support to GFATM proposal writing;[180] other funds have been leveraged from DFID in Nigeria, from the government in Zimbabwe, from the government of India (which will fund the roll-out of the IMS system CHAI supported to date), and from other sources.[181] Mechanisms that appear to have influenced CHAI's leverage include: CHAI's use of piloting and catalytic funding;[182] working with the private sector on co-payments, which was highlighted in two country case studies;[183] and using the grant as a springboard for complementary grants, also reported in two country case studies.[184]

In summary, **CHAI performance during the grant period has varied significantly** across the four programme areas and across each output indicator. Several indicators have been changed during the grant period (as noted in Table 34 above), including some less than 12 months before the end of the grant. Where outputs have been achieved, **it is often not possible to determine whether grant outputs have translated into market and health outcomes and impact.** It is clear that the flexibility of the DFID grant has been welcomed by CHAI, and may have helped accelerate progress in some output areas or countries, although this does have some downsides for DFID (making grant management and accountability more challenging) and for CHAI (obscuring CHAI's core mission and mandate, and affecting perceptions of transparency).

5.5.2 Potential for longer-term impact

In the following paragraphs, we consider the likelihood of the outcomes from this grant being sustained, both through the capacity that CHAI has built among implementing partners – particularly at country level, but also globally – and CHAI's development of best practices that can be applied in other contexts.

The main findings on longer-term impact from CHAI's capacity building efforts are presented in the sustainability section above. In short, CHAI has engaged in some capacity building activities, but the extent to which these have resulted in increased capacity and improved sustainability is, at this time, unclear.

There is some evidence that programme outcomes will be sustained, but this is highly variable across programme areas and country contexts. Mechanisms that CHAI has used to promote sustainability of activities and their long-term impact were reported in several country case studies, and include capacity building, partnership working, incorporating market-shaping and related interventions into national plans, and promoting country ownership more generally. Several factors that could limit the potential for longer-term impact were also cited in country case studies. These included governance issues that had not been

[175] Cambodia and Kenya
[176] Cambodia, Kenya, Uganda, Zimbabwe
[177] Cameroon, Ethiopia, Kenya, Uganda
[178] Cameroon, Ethiopia, Kenya
[179] Cameroon, India, Mozambique, Nigeria, Swaziland, Uganda, Zimbabwe
[180] Cameroon, India, Malawi, Nigeria, Uganda
[181] Swaziland and Uganda
[182] Nigeria, Uganda, Zimbabwe
[183] Nigeria and Uganda
[184] Mozambique and Zimbabwe

addressed,[185] continued dependence on CHAI,[186] limited country-level capacity,[187] and CHAI's lack of a clear exit strategy.[188]

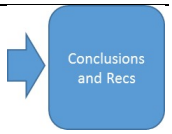
There is evidence from our assessment of CHAI's market-shaping work that a lack of coordination and accountability for results in the short-term can weaken the potential for longer-term impact. For example, we found that in the market-shaping of HIV PoC CD4, there was a patchwork approach to interventions, with donors and implementers not joined up. Although small firms did receive some financial support from donors, they nonetheless had remaining needs which were not adequately addressed, and they exited the market. No single agency or implementer owned the PoC CD4 Diagnostics space, so no one was accountable for failures. Similarly, when CHAI entered into negotiations with HIV diagnostic suppliers, there was no clear sponsor to whom CHAI was accountable, nor any source of external oversight and quality assurance, to help CHAI explore counterfactual options and consider the risks of various deals to long-term market outcomes. Ultimately, the market for HIV diagnostics has moved on, with a greater emphasis on other technologies and approaches besides PoC CD4. The consequence is that the impact of CHAI's work on PoC CD4 is likely to be only short- to medium-term from a systems and market perspective; although if PoC scale-up proves to show increased HIV diagnosis and ART initiation, then the health impact will be long lasting.

There is some evidence that best practices will be applied across other areas of the health sector, countries and contexts. However, as noted above, CHAI's sharing of best practice for others to draw on is in an early phase, and as yet it is underutilised as a strategy to maximise impact. CHAI has recently developed several case studies, which have been published (between August and November 2015), on injectable artesunate uptake,[189] ATV/r uptake,[190] and expanding access to contraceptive implants.[191] The utility and potential impact of these case studies could not be assessed by this evaluation, as they were published after KIIs and country case studies had been concluded.

In summary, CHAI has more work to do on institutional capacity building and preparing for exit across the programme areas covered by this evaluation. Increased coordination and collaboration in the short-term could make it easier for CHAI to gradually step away from an intervention over the longer term. CHAI has not yet maximised the potential for impact through sharing of best practice, although promising activity is now under way in this area.

[185] Nigeria, Swaziland, Tanzania
[186] Reported in India, Mozambique, and Zimbabwe
[187] Reported in Kenya, Nigeria and Zimbabwe
[188] In Tanzania
[189] http://www.clintonhealthaccess.org/content/uploads/2015/08/Case-Study_Inj-AS-Uptake.pdf
[190] http://www.clintonhealthaccess.org/content/uploads/2015/08/Case-Study_ATVr_Uptake.pdf
[191] http://www.clintonhealthaccess.org/content/uploads/2015/08/Case-Study_LARC.pdf

6 Conclusions and Recommendations



6.1 Introduction

The evaluation of the DFID-CHAI 'Market-Shaping for Access to Safe, Effective and Affordable Health Commodities' programme has been carried out over a period of 15 months. It has gathered evidence through a review of key data and documentation, 124 global key informant interviews (KIIs), 15 country case studies and a stakeholder survey, with a particular focus on four areas within the DFID-CHAI programme. Our programme area-specific and cross-cutting analysis has enabled us to generate findings that answer three overarching questions: did CHAI do the right things, in the right way and with the right results?

In this section, we draw conclusions related to the programme as a whole, and make recommendations to both DFID and CHAI. The conclusions relate to four themes that have emerged strongly from the evaluation:

- Grant management and accountability
- Coordination of market-shaping interventions
- Planning for market-shaping intervention
- Collaboration for market-shaping intervention

Through both the conclusions and the recommendations, we aim to support DFID to develop an effective next phase of partnership with CHAI, to strengthen the management of market-shaping interventions and other adaptive programmes, and to enhance the role that DFID plays within the broader field of market-shaping for global health.

6.2 Evaluation Conclusions

6.2.1 Grant management and accountability

We conclude that CHAI has achieved good progress against many output indicators under this grant. However, it has proven difficult for DFID to hold CHAI accountable for both inputs and outputs, due to the extent of CHAI's market-shaping activities in a busy field and due to specific features of the DFID grant including its M&E system.

Key issues are:

- *The busy implementation space: a*s illustrated in the Healthy Markets Primer figure and detailed in accompanying text, there are many stakeholders influencing, funding and/or implementing market-shaping objectives in each programme area. It is difficult to isolate CHAI's activity and to attribute changes in market structure to it; in turn, this makes it difficult to hold CHAI accountable for results.
- *The mix of funders and principals to whom CHAI is accountable:* there are multiple donors funding CHAI for the same programme areas. In addition, different parts of DFID are funding CHAI for related work (e.g. Zambia DfE topping up CMS work, parallel funding from DFID Malawi for supply chain work). There has been sub-optimal coordination across funding streams when several donors support similar CHAI activities or complementary work in one product area.[192] Further, there has been a tendency for CHAI to use DFID funding for work others have declined to support.[193] CHAI at the same time has multiple principals – multiple donors funding the same areas – and each donor influences the scope and scale of interventions. CHAI is also accountable to LMIC governments; this is yet another principal/agent relationship. At the country level, different parts of government only know about CHAI's work in their own area. In addition, non-government partners in countries are often unclear about CHAI's mandate. Overall the situation

[192] The Ethiopia data on Pima impact is one example where there was CHAI discomfort in sharing data, collected and analysed for UNITAID, with DFID.

[193] In the past this happened when CHAI tendered for upstream artemisinin work for UNITAID, but lost to A2S2, although CHAI proceeded with the work anyway using DFID's funds. Another more recent example happened when CHAI/PATH was not successful in securing a UNITAID grant for upstream CD4 POC work; however, CHAI has proceeded with the work using DFID funding. DFID also continues to fund CHAI's development of low dose EFZ, although BMGF has pulled funding.

resembles the story of the blind men and elephant in the room[194] and the consequent risk (of this lack of clarity) is that partners may not be able to engage effectively with CHAI, or hold CHAI fully accountable for activities or results.

- *Features of the DFID grant*: The scope of CHAI's work is wide and DFID's contribution to CHAI country offices is a small fraction of the overall country funds. There has been significant evolution of the programme and its M&E indicators. The DFID funding to CHAI is more flexible than other donors' in that it has not been restricted to the intended countries or activities. Rather, it has been reprogrammed each year, allowing CHAI to adapt their plans. From an appreciative perspective, this flexibility has enabled CHAI to respond rapidly to emerging needs and deliver adaptive programming in response to a rapidly changing context. The disadvantage of this situation is that the repeated changes can have the effect of lessening accountability and follow-through to the original grant intent. The diversity and degree of change would certainly make it difficult for DFID staff to manage the level of detail and this has presented some challenges for evaluators as well.
- *Features of the M&E system:* Overall there is an issue relating to information asymmetry, with the principal (DFID) having less information than the agent (CHAI) and this is apparent when looking at M&E indicators:
  - Outputs/results indicators aggregate many dissimilar categories (e.g. uptake volumes for several countries, market entry across a wide landscape of product types);
  - Outputs/results indicators are not sensitive/linked to the impact of the intervention (e.g. the key success indicator that measures on-site access to CD4 testing, measuring uptake volumes without any measure of allocative efficiency);
  - Some of the measurement data cannot be collected by an independent evaluator, because data are owned by government (e.g. Pima impact data) or are time consuming for government to obtain (e.g. teasing out procurement data for a target product). This challenge is exacerbated by the fact that DFID contribution share to CHAI country offices is small, so labour intensive M&E would not be aligned with the share of investment.
  - Some of the data presented in CHAI reports or used as assumptions in VfM modelling cannot be easily verified, such as price per test for Pima vs lab-based CD4 tests or market size assumptions. (DFID did not require baseline or end-of-project indicators of market structure.)
  - Full costs – including those born by governments and those covered by other donors – are not accounted for, so determining the overall cost-effectiveness of CHAI's market-shaping interventions is challenging.
  - Outcome and impact data are calculated or modelled by CHAI; public health data are not routinely collected and analysed, and are not reflected in grant M&E frameworks.

As a related point, CHAI's assumptions, reporting, tools and products receive very little external quality assurance (QA). There are confidentiality issues – with data from both countries and manufacturers – so CHAI presents data in an aggregated way, but the risk is that there is insufficient external vetting of the quality and technical accuracy of CHAI's work. Greater scrutiny and oversight are merited, given that large grants are being approved based on CHAI assumptions, country plans and decisions are being guided by CHAI tools, and some important market-shaping deals are being negotiated by CHAI staff.

6.2.2 Coordination of market-shaping interventions

We conclude that there may be a lost opportunity to optimise market-shaping if different funders and implementers do not co-ordinate their approaches and choice of interventions, and/or if there is not a cohesive approach to all ends of the value chain. Both DFID and CHAI have a role to play in ensuring strong coordination for greater impact.

Key issues are:

- *Choice of intervention and approach:* In market-shaping of PoC CD4 Diagnostics, we found a patchwork approach to interventions, with donors and implementers not joined up. Market entry of near-to-market firms was not facilitated by the market-shaping 'toolbox' supported by donors. No single agency or implementer owned the PoC CD4 space, so no one was accountable for results (successes or failures). The viral load negotiations have also proceeded with no particular donor as a sponsor.

[194] It is a story of a group of blind men (or men in the dark) who touch an elephant to learn what it is like. Each one feels a different part, but only one part, such as the side or the tusk. They then compare notes and learn that they are in complete disagreement. (Source: Wikipedia)

- *Cohesive approach to all ends of the value chain:* CHAI's role historically has been to fill gaps in market-shaping cohesiveness. Before the GFATM evolved to its current, more active market-shaping approach, CHAI negotiated annual ceiling prices on first-line ARVs and subsequently shaped the market for second-line and paediatric ARVs with UNITAID funds. Before MPP was up and running, CHAI negotiated license deals. Wherever licensing is not joined up with procurement, or procurement is not joined up with forecasting, or forecasting is not joined up with demand creation, there is a role for CHAI. The challenge is when the leadership of these different functions (licensing, procurement, forecasting, demand creation) sits with different agents and communication is insufficient. This seems to have been at the root of issues with ATV/r, where CHAI did not have access to real-time information on orders and was not able to contribute fully to supply and demand alignment.

6.2.3 Planning for market-shaping intervention

We conclude that CHAI appropriately identifies areas of market-shaping need, to which CHAI can bring useful and sometimes unique skills and insights. However, CHAI needs to strengthen its design and appraisal of proposed market-shaping interventions, to assess and appropriately manage risks and trade-offs, to ensure that the full economic and systems costs of an intervention are accounted for, and to plan for impact monitoring over time.

Key issues are:

- *Funding and incentives:* CHAI does not have its own funding. It relies on external financing in the form of core support or project-specific funding, often secured by pitching a new idea or conveying past success to maintain an existing donor relationship. This may create incentives to exaggerate the scale of existing market challenges or the impact CHAI could have. There may be incentives at an organisation or individual level to showcase short-term market accomplishments, rather than focusing on longer-term market health and a healthy price-volume trajectory, or to prioritise work that can be more easily quantified and attributed to CHAI. There may also be incentives to engage in business development, with a preference for longer-term, larger grants that are not tied to specific activities. CHAI could end up following the funding, even where this may be in conflict with what needs to be done. Donors need to recognise these incentives facing CHAI (but not unique to CHAI) and to help CHAI manage them through its budgeting, project management and M&E framework.
- *Criteria for intervention:* CHAI needs criteria-based decision tools to guide where it works, especially within countries. At global level, and when entering major areas of work, CHAI has a relatively more formal and criteria-based process for deciding whether to engage. At country level, the situation is more fluid and opportunistic; government agreement and donor funding are often sufficient rationale for entering new areas of work. Referring to the Healthy Markets Primer, we see that CHAI is engaging in more programmatic interventions as opposed to catalytic or transformative interventions.[195] This may be attractive from the perspective of CHAI as an organisation, or specific individuals within CHAI. However, this shift has implications for CHAI's management systems, structures, funding requirements, and the timescale for return on donor investment. If CHAI is being funded primarily as a catalytic market-shaper, this shift may detract from that funded mandate. A further consideration is CHAI's comparative advantage relative to those with many years of experience in HSS work at country level.
- *Moving fast while planning well:* There is a tension between planning and being deliberate vs reacting quickly and being flexible. One of CHAI's core principles is that it acts with urgency, and indeed CHAI is widely recognised as an organisation that gets things done without wasting time. However, the EvT observed that CHAI is missing out on important steps in planning, design and appraisal, as well as the lesson learning and dissemination that could make CHAI's work more effective and allow it to be better leveraged by others. For example, CHAI needs to dedicate sufficient analytical resources to ensuring there is a market-shaping gap and that CHAI is well placed to fill it. There is also a need to plan for impact monitoring from the outset. In the desire for urgency, this may be overlooked.

[195] For example, see question set 6 under the EQs, which describes HSS work being conducted within countries with the DFID grant.

6.2.4 Collaboration for market-shaping intervention

We conclude that CHAI expresses an intent to collaborate in its market-shaping activity and to balance the needs of beneficiaries, government priorities, donors' accountability requirements, and private sector incentives. However, CHAI must ensure that all relevant stakeholders are adequately consulted and engaged in the design and implementation of market-shaping interventions, consistent with the principle of "collaborate from the start" (step #1 in the Healthy Markets primer).

A key principle at the heart of CHAI's strategic approach is that LMIC governments are CHAI's foremost partner. This is appropriate and the benefits are obvious. However, there are risks with this approach.

CHAI's prioritisation of government as a partner may increase risk when:

- *there are agency problems*: for example, if the priorities of those with whom CHAI works do not match with strategic priorities for the country; in cases where the government does not necessarily speak for clinicians or patients who may have different views on priorities, and where wider engagement with civil society may be beneficial; in cases where the government or its systems are not functioning well; or in cases where the government is not using evidence to inform their decision-making.
- *government priorities are at odds with global priorities*: for example, if the government wants higher volumes or lower prices for a specific technology, this may not necessarily be in the best long-term interest from a global market-shaping perspective. Similarly, governments may want to spend donor funds inefficiently, for example by conducting unnecessary field evaluation studies.
- *other partners are not adequately consulted or engaged,* or if CHAI relies on government to do so and the consultation is sub-optimal. This is a particular issue when other partners are needed to cover recurrent costs, support supply chain management, or provide complementary investment.

6.3 Key points from E2 Review and LARCs Report

Long-Acting Reversible Contraceptives (LARCs)

CHAI and other stakeholders identified two aims for the LARCs market: to achieve affordable and sustainable prices, and to broaden the supplier base. Each was seen as likely to improve access to LARCs. CHAI pursued a reduction in the manufacturers' price of the two leading implant products (Jadelle and Implanon), and also undertook to reach an agreement with an Indian or Chinese manufacturer (though the nature of this was not specified). CHAI did not propose any country-level distribution or service delivery activities, although it did obtain a substantial grant from another donor to address these areas.

During the grant period, in agreement with donors, CHAI pursued a Volume Guarantee (VG) with the two WHO-prequalified implant suppliers to give them the assured demand that would lead to them accepting a lower price. CHAI entered longstanding discussions between suppliers and major stakeholders, and the VG was agreed in two stages, with Bayer and then Merck.

The target was to achieve a price reduction of greater than 35%; ultimately a price reduction of 53% was agreed for the period 2013-2018. A support agreement was signed in 2014 with Dahua, the manufacturer of Sino-Implant, building on support from another NGO. However, by this time sales of Dahua's product had collapsed, due in part to it not yet receiving WHO prequalification, which reduced donor procurement. Also, the VG eliminated Sino's price advantage and encouraged some major buyers towards Jadelle and Implanon. Sales of Jadelle have been so strong that there is now a shortage, with a long waiting list. Modelling undertaken for the evaluation illustrated the trade-offs between the VG agreed price and security of supply. A key concern is that no data were collected regarding the extent to which the increased Jadelle and Implanon shipments went to new users or substituted other contraceptives, including highly cost-effective IUDs.

£343,000 was spent on this programme area, against an original grant allocation of £780,000. However, a range of donors contributed much larger sums to ensure increased procurement and delivery of implants. CHAI also acted to improve coordination of all implant stakeholders.

E2

£3,279,657 was spent on this programme area, against an original grant allocation of £3,040,000. Through the E2 initiative, CHAI aimed to "create the fiscal space for 3 to 5 countries to reach universal access to treatment within their existing or planned funding envelopes, and leverage tools and benchmarks to catalyze change in other countries". CHAI provided technical assistance (TA) to MoHs and other government agencies in 5 focus countries: Ethiopia, Malawi, Rwanda, South Africa and Zambia. This TA focused on helping CHAI partners to: quantify their resource needs, principally by updating their National Strategic Plans (NSPs) for HIV treatment and care; quantify the resources available, from both the government's budget and development partners, and identify gaps and inefficiencies; optimise spending on HIV treatment, by reducing non-commodity costs and by allocating the available resources efficiently.

The E2 Review found that:
- CHAI has provided some valued TA, support and advice to government agencies in 5 focus countries;
- Some useful tools have been developed through the E2 initiative, e.g. for 'resource mapping', which have potential for wider use;
- There is a need to focus on further integrating these tools with core government processes and the preparation of National Health Accounts, and on developing domestic analytical capability (within and outside government);
- E2 has contributed to the evolution of government policies on HIV treatment and has helped governments mobilise resources to support this e.g. from GFATM;
- However, anticipated cost savings have not yet been secured. Institutional weaknesses in CHAI partner agencies have been an important factor (especially in South Africa). Pre-intervention appraisal, including capability assessments of partner institutions, could help CHAI target its resources, identify and mitigate risks, and adapt TA over time.

6.4 Recommendations to DFID

This evaluation has identified a range of lessons and recommendations for DFID, which relate to the management of its grants to CHAI and potentially other similar, adaptive programmes.

DFID has already opted to continue its support to CHAI, initially through a cost-extension to the existing grant until end March 2018. This will entail a shift into additional programme (or product) areas. We anticipate that the recommendations below will be immediately relevant to this new phase of DFID support to CHAI's market-shaping activity.

Recommendation A1: Join up with other funders

- Consider working with others to create a "funders' forum" or similar coordination mechanism, which would bring together the major funders of market-shaping initiatives. Its purpose could include joint market assessments, joint evaluations, peer review and lesson learning, and strategic co-funding (of single or complementary initiatives). This would also help CHAI, as there would be fewer principal/agent relationships to manage and a considerable reduction in the burden of reporting. The funders' group for Product Development Partnerships (PDPs), in which DFID has participated for over 10 years, provides an interesting comparator model and precedent.
- Depending on the product sector, there may be need for real-time monitoring of supply/demand alignment through a dedicated mechanism. This would reduce information asymmetry and improve transparency, as well as being more efficient than any one party, such as CHAI or the GFATM, acting as an information 'broker'.

Recommendation A2: Develop new adaptive planning and monitoring tools and frameworks

- Develop planning and monitoring tools and frameworks to support adaptive programmes, including market-shaping interventions, which can nevertheless provide assurance through DFID systems. (These tools and frameworks could be developed collaboratively with members of the "funders' forum" above.) A 'balanced scorecard' approach could be used to enable consideration of a broader set of metrics during planning, monitoring and evaluation.

Recommendation A3: Improve accountability – project monitoring tools need further disaggregation and transparency

- Logframe and VfM indicators should be accompanied by notes outlining the assumptions behind the targets, with estimates disaggregated by country, and explanations of the methodology and comments on feasibility. Bundling of measures should be avoided. This will enable a more robust dialogue about objectives, timescales, and risk management, enabling the monitoring tools to better serve their purpose. It also needs to be clear from where the data will come and how feasible it is for CHAI to gather that data and for an evaluator to gain access to that data for purposes of independent validation. (More difficult where data is country owned, time consuming to collect or protected by confidentiality agreements.)
- There is also a need for improved transparency externally regarding what DFID is supporting CHAI to do. At a minimum, the logframe and business case should be well publicised to country government and global partners (NB the current logframe and business case is very difficult to find via Google).

Recommendation A4: Require market-shaping grantees to report data on baseline, mid-cycle and end-of-project market structure

- DFID should require reporting on market structure indicators at baseline and throughout any market-shaping grant, and the provision of both public health and market-shaping ToCs at programme area (product) level. Grantees should also justify the selection of specific demand and supply-side interventions – clarifying how they will shift or limit risk, reduce transaction costs or correct information asymmetries – against counterfactual options. (Oversight of this process could be provided by the "funders' forum" proposed above.)

Recommendation A5: Narrow CHAI grant scope but incentivise sharing, for broader impact

- Consider narrowing the product and geographical scope of DFID's grant to CHAI, to sharpen the focus, streamline project reporting and oversight, and ease communication between DFID HQ and country offices/programmes. (This narrowing could be coordinated with members of the "funders' forum" to ensure that different grants to CHAI are complementary and provide appropriate support to CHAI's operations, avoiding gaps or duplication.)
- Incentivise CHAI to share lessons (successes and failures) and contribute to market-shaping knowledge as a "global public good". Incentives might include funding streams triggered by GPG activities, GPG process and output milestones and performance indicators, DFID hosted learning events (engaging the "funders' forum", as above).

6.5 Recommendations to CHAI

This evaluation has generated several cross-cutting recommendations to CHAI, which would assist in improving the transparency,[196] accountability and sustainability of CHAI's interventions and in doing so should increase the impact of CHAI's market-shaping activity. These generalised recommendations would be relevant to many areas of CHAI's programming, including beyond the work funded by DFID and beyond the scope of this evaluation. (Some programme area or market-specific recommendations are outlined in Annex K.)

Recommendation B1: Enhance CHAI project cycle management

- Develop a more explicit project cycle that includes pre-intervention research and market assessment, consultation, design, appraisal, implementation, monitoring and evaluation.
- Develop project management systems and processes that support this cycle.

Recommendation B2: Fully consider both the short- and long-term

- During the design and appraisal process, evaluate several market-shaping options, taking an industry wide perspective and evaluating short-term and long-term impacts, risks and trade-offs. CHAI should dedicate greatest analytical resource to any interventions that have the potential to narrow the supplier base. External expertise, oversight and QA should be engaged in these situations. Robust discussion in the "funders' forum" (see above) would be merited.

[196] Transparency is not an end or objective in itself, but is a means to achieving greater accountability or trust and collaboration of others.

Recommendation B3: Communicate and collaborate

- Communicate and collaborate from the outset, to test ideas, aid learning, align and coordinate with others.
- Ensure attention to the balancing of government and global priorities, thinking about how to leverage lessons across countries and how to promote efficiency rather than champion government wishes (where these may be in conflict).
- Take responsibility to ensure that other partners at country level are adequately consulted on CHAI plans and any implications that has for their work or budgets. This is part of seeing CHAI's work through to impact. It cannot be assumed that governments will do this for CHAI.
- Promote market-shaping knowledge as a global public good. Share both successes and failures, and support CHAI partners to do the same – locally, nationally, regionally and globally. Getting CHAI's knowledge and best practice into the public domain should be an integral part of the design for each workstream – an active process before an investment is made into a tool or an intervention, considering which target audience would be interested in the tool or lessons from an intervention, who needs to be involved in its development, and how tools or deliverables will be disseminated to ensure they are transferred into policy and practice.

Annex A Evaluation Terms of Reference

(*As drafted by DFID for procurement purposes, excluding annexes*)

Evaluation of DFID-CHAI Market-Shaping for Access to Safe, Effective and Affordable Health Commodities

Introduction

The Department for International Development (DFID) leads the UK's work to end extreme poverty. We are ending the need for aid by creating jobs, unlocking the potential of girls and women and helping to save lives when humanitarian emergencies hit.

This project is to evaluate DFID's £35m programme entitled 'Market-Shaping for Access to Safe, Effective and Affordable Health Commodities' that is implemented by the Clinton Health Access Initiative (CHAI). The project began in July 2012 and will run until September 2015.

The project aims to make markets for key health commodities for HIV/AIDS, TB and malaria, as well as for vaccines and contraceptives, work more effectively through both supply and demand-side interventions. Better-functioning markets support enhanced access to health commodities for the poor as well as increasing value for money for donors, governments and other funders. A particular focus of the programme is to increase the supply of commodities from high-quality, lower-cost suppliers.

CHAI aims to, in general, increase access to critical, safe, affordable and effective health products while achieving good value for money through the DFID-CHAI Market-Shaping for Access to Safe, Effective and Affordable Health Commodities programme. CHAI aims to maximise impact in each of the individual programmes that make up this grant by selecting the appropriate mix of supply and demand-side interventions to achieve targeted outcomes. The strategies, outputs and outcomes for this grant can be found in Annex A. Specific logframe indicators for the programme areas to be evaluated and/or reviewed will be provided to the selected evaluator.

Although there are more than nine areas in this programme, this evaluation will be limited to a sample of four programme areas and a review of one. Budgets for these five areas collectively comprise at least 55% of the total grant budget (excluding global overhead). Findings and learnings from this evaluation and review will be applied, in general, to the grant as a whole but will be done so with appropriate considerations and caution. Value for money findings will be considered at an aggregate grant level, as defined by metrics in the Business Case.

Objective

CHAI carries out their work in a number of programme areas; four of these will be assessed as part of this evaluation and one will be included in this body of work but will be handled as a separate review (this is due to data sensitivity issues). For each programme area being tackled, the aim is to: Identify to what extent CHAI's strategies are relevantly addressing marketplace needs by:

- Examining if outputs in the programme's Theory of Change are being effectively translated into the desired outcomes.
- Exploring which indicators, using the start of the current programme as a baseline, have been met, which are in progress and which may have fallen behind.
- Providing a stronger contextual understanding behind any progress made towards achieving the indicators. This contextual analysis will be framed by the 'Proposed Evaluation Questions' set out later in this document and will form a major part of the evaluation.

Outputs

The key outputs of this evaluation which are to be delivered by the Service Provider are:

Output 1: Delivery of a baseline data report whereby the supplier will set out how data (whether it is quantitative or qualitative) will be collected and validated, how assumptions will be tested at relevant time periods required and how data from multiple sources will be pulled together.

To support the delivery of this output the successful bidder will have access to qualitative data, such as routine reports and updates produced by CHAI, to the extent that it does not compromise confidentiality agreements and/or jeopardise working partnerships held by CHAI. The data detail CHAI's approach to the work and to an extent, progress against outputs.

Agreement on how data is to be disaggregated will be discussed following contract agreement.

Output 2: Delivery of an 'interim findings' report that will help inform programme activities and priorities for the remainder of the CHAI grant period. The precise scope and timing of the interim report will depend on the sequencing and approach to the evaluation agreed with the successful bidder.

Output 3: Delivery of an end of grant evaluation report which covers the programme areas evaluated/reviewed, tailored presentations for CHAI and DFID.

Output 4: An end of grant document that addresses the lessons learned during the evaluation which can be published in an academic or policy journal and a learning note for dissemination across the market dynamics community.

Recipient

The primary recipients of the evaluation are DFID and CHAI, to be shared with both headquarters and country offices. The evaluation will contribute to DFID's oversight of this programme and also contribute to strengthen and adjust approaches that CHAI is deploying in this programme as necessary. Further the evaluation is also intended to contribute to better understanding, decision-making and tools among the broader set of players active in market dynamics for health commodities through the identification of best practice and other lessons learned.

The Scope of Work

The programme has nine thematic components:

6. Maximising Value for Money and Ensuring Sustainable Supply of HIV Treatment
7. Accelerating Introduction and Scale-Up of Point-Of-Care HIV Diagnostics
8. Maximising Value for Money of HIV Spending for Universal Access to ART (E2)
9. Improving Pricing and Supply Security for High-Quality MDR-TB Drugs
10. Accelerating Market Entry of Highly Accurate and Lower-Cost New Diagnostic Products
11. Increasing Access to Long-Acting Contraceptives
12. Improving Vaccine Market Dynamics for Price Negotiations
13. Ensuring Rapid and Sustainable Scale-up of Supply of Malaria Rapid Diagnostic Tests
14. Ensuring Rapid and Sustainable Scale-up of Supply of Quality Malaria Treatments

This evaluation will include a detailed evaluation of four key programme areas and a separate review to tackle the E2 programme on maximising value for money in HIV spending. These areas were selected on the basis of (i) the weight of their contribution to the inputs, outputs and outcomes; (ii) the potential of an evaluation to shed light on key strategic and tactical market-shaping issues and (iii) the presence of innovative elements in the theory of change. The E2 programme will be handled in a separate review as the results would include sensitive data that cannot be published as it may jeopardise the programme. All of the final products for the evaluation will be published. The separate review will cover similar questions but will not be publicly available.

The evaluation will use the theory of change which aims to select an appropriate mix of supply and demand-side interventions.

For evaluation:

Programme Area to be Evaluated / Reviewed	High-Level Model of Change
• HIV Treatment	• Sustain reduced prices and ensure stable market supply
• Point-of-Care (PoC) HIV Diagnostics	• Accelerate market entry and scale-up
• Malaria Treatment	• Ensure rapid scale-up and sustainable supply
• Lower global prices of Long-Acting Contraceptives in order to increase uptake (evaluation)	• Lower global prices in order to increase uptake

The models of change for these specific programmes are expanded in Annex D.

Reporting and governance arrangements

The successful bidder will report and coordinate directly with the Evaluation Steering Committee. When resources and information are required by the evaluator, a point of contact within the Evaluation Steering Committee will provide a liaison with the Reference Group who will have an appointed a member to assist.

The Evaluation Steering Committee will oversee the technical assessment of all bids for the evaluation, liaise directly with the contract holder, and have the final say on quality assuring the evaluation design and outputs. The evaluators will report to the Evaluation Steering Committee.

The Evaluation Reference Group will comprise all members of the Evaluation Steering Committee and CHAI members, as well as additional external expertise. This Reference Group will input into the evaluation throughout the process. To safeguard independence, the Reference Group has an advisory role, and will be chaired by DFID.

The Evaluation Steering Committee primary point of contact will be the lead adviser of the CHAI grant, James Droop.

Reporting will be a key part of demonstrating progress under this contract. The Service Provider will set out how and what they plan to provide to DFID in their technical proposal. Final reporting requirements will be agreed upon contract signature though minimum requirements will include outputs noted on page 2, quarterly financial reports and summaries of progress against work plan deliverables and any anticipated changes in deliverables.

The primary point of contact at DFID for this evaluation will be the lead adviser of the CHAI grant, James Droop.

Timing

The CHAI programme started on 6 July 2012, to be finalised in August 2015, with a final end date of 30 September 2015. We want the successful bidder to give an indicative timeline in order to meet the specification, but require the Final Report on 31 October 2015.

There will be a formal break point in the contract after the Interim Findings report is submitted.

DFID reserves the right to scale up/back this programme in response to changing requirements. DFID may also choose to extend the contract by up to 6 months in the case of unforeseen circumstances.

Budget

The budget range for this evaluation is between £400,000 to £600,000. Bidders are reminded that they should be demonstrating good value for money as part of their bid.

Performance monitoring

The Service Provider will be contracted on an output basis where payment is made against the outputs listed above. Due to the relatively short duration of this contract, the technical bid must include a detailed work plan for the entire contract duration. The financial plan should show payments proposed against work plan deliverables. Payment will be made on verification of the deliverables to DFID's satisfaction.

The Service Provider must also propose and implement project performance measures such as the quality and timeliness of deliverables, management, personnel performance and relationships with key stakeholders. Project performance management measures (key performance indicators – KPIs) will be finalised and agreed at the start of the contract.

DFID will evaluate the performance of the Service Provider throughout the project and formally conduct quarterly reviews. It is expected that the Service Provider takes a proactive approach to notifying DFID of any matters which may require immediate attention.

Methodology

The Service Provider is expected to propose their methodology for the evaluation as part of the technical bid. As this is a *process* evaluation the programme theory of change should form the basis of the conceptual framework; DFID welcomes bids that will use a broad but robust and appropriate range of qualitative and

quantitative methods. Experimental and quasi-experimental designs are not feasible for this study. It is envisaged that the methodology should include but not be limited to the following:

- Bidders must consider how to handle results on all five programme areas in this scope of work. This will include details of how bidders plan to keep the E2 programme as a separate review to the evaluation.
- A clear analytical framework for selecting stakeholders for interview and how to involve these stakeholders.
- A proposed approach to country engagement.
- A plan for internal results dissemination within CHAI and DFID as well as a more general communications plan which should include a minimum of one peer-reviewed academic article.

Proposed evaluation questions

Below are proposed evaluation questions. DFID welcomes additions or amendments to these questions if the spirit of the guidance is maintained.

Question 1: On a general level, to what extent are the strategies aligned with country needs and global priorities?

Question 2: To what extent has CHAI achieved the desired activities and outputs?

4. For each programme area identified for the evaluation, comment on the extent to which CHAI has been able to deliver each designed activity and output. (See Annex D for programme briefs) – see Annual Review.

Question 3: What confidence do we have that CHAI outputs and approach will achieve the desired outcomes?

5. To what extent have activities within each programme area evaluated contributed to their desired outcomes?
6. To what extent is CHAI's collaborative approach effective in achieving the programme's desired outcomes?

Question 4: How sound was CHAI's programme design (problem identification and approach to a solution). Can this design be improved and if so how?

7. Were CHAI able to identify the areas of highest impact in which to engage? (Bidders will be expected to clearly state their definition of key terms used in measurement such as 'highest impact.')
8. Were lessons learned in the early stages of the programme successfully integrated to course-correct and refine the approach?
9. How well does the current Theory of Change conceptualise and articulate programme logic, outputs and outcomes?
10. To what extent can the current Theory of Change be improved and how?

Question 5: Is the programme providing value for money at an aggregate grant level and what key factors have contributed to this?[197]

In addition to the aforementioned evaluation questions, the evaluation should also look to answer the following three complementary questions.

Complementary question 1: What confidence do we have that progress instituted by CHAI will be sustained at both global and country levels?

11. What is the likelihood of outcomes and benefits from the programme being sustained beyond the end of the project?

[197] Note that aggregate grant level calculations for this include the following programme areas: HIV Treatment, PoC HIV Diagnostics, LARCs, Value for Money of HIV Spending and MDR-TB Drugs, as noted in value for money references of the Business Case.

12. To what extent has CHAI built capacity among implementing partners at global, regional and/or national levels to sustain progress made?
13. How could proof of best practices be applied across other health priorities, countries and contexts following completion?
14. To what extent has engagement with emerging powers affected the performance of the programme?

Complementary question 2: How did the programme adapt its strategies to changing contexts? What were the unintended consequences, if any?

15. Looking at the unintended consequences of market-shaping, have changing context threatened the programme outcomes? How did CHAI respond to this and what were the subsequent results?

The final list of evaluation questions will be agreed with DFID prior to contract award.

Skills and qualifications

A highly qualified team with demonstrable experience of delivering quality evaluations will be required. Particular importance will be attached to knowledge of market dynamics of global health commodities and associated interventions, as well as pharmaceutical supply issues, regulatory and licensing frameworks, procurement, demand forecasting, product introduction and supply chains. It may be acceptable for bidders to form consortia to ensure availability of this expertise. If the consortium members are outside of those already declared as framework partners, then permission should be sought from the Contract Officer during the tender process. The use of local consultants in the CHAI countries is desirable.

The evaluators will have:

- Strong evaluation expertise and track record of evaluating complex programmes, including demonstrated expertise in the design and conduct of program evaluation studies.
- Extensive experience in conducting programme evaluations using qualitative and quantitative methods, particularly in the health sector.
- Experience of evaluating access to medicines interventions, particularly market-shaping programmes.
- Knowledge of market dynamics of health commodities, pharmaceutical supply issues, regulatory and licensing frameworks, procurement, demand forecasting, product introduction and supply chains.
- Knowledge and understanding of the different challenges and impacts of access to medicines for different commodities, diseases (HIV and malaria preferred), countries and communities (at global country levels).
- Excellent interpersonal skills, including the ability to function in a team setting, to lead or facilitate meetings, and to communicate effectively and sensitively with government and stakeholder staff and higher-level administrators.
- Superior oral and written communication skills, including experience in writing technical, analytic and evaluation reports, and critical interviewing skills while being affable and unbiased.
- Ability to discreetly handle sensitive data and/or conversations.
- Strong research and analytical skills, including quantitative and qualitative data collection and analysis, and policy and program outcome analysis.
- Experience with conducting studies related to international programs or services preferred.

Logistics and procedures

The selected evaluation provider is expected to supply their own logistic plans including travel, transport, communications and work space.

The selected evaluation provider will be expected to manage the evaluation with no logistical support from DFID or CHAI. This will include independently recruiting staff, designing the evaluation, collecting evidence and producing outputs as required. Bidders will be expected to reference how they intend to maintain objectivity and independence while working with the implementing partner being evaluated (CHAI).

Both DFID and CHAI will provide information, contacts and programme data where needed. The selected evaluator will have the support of CHAI country offices in undertaking the evaluation but will be expected to log and report on all interaction with the programme implementing partner (CHAI).

It is expected that bids will clearly set out how the evaluation will adhere to ethical protocols in particular when dealing with community health information. The evaluation must conform to the OECD-DAC principles of accuracy and credibility which can be provided if necessary.

Bidders will be expected to illustrate how they intend to design the evaluation around the DFID ethical principles (see Annex C).

The selected evaluator will be responsible for publishing the Final Report, sharing data sets with stakeholders, approaching journals and producing learning outputs. All products of the evaluation must be made publicly available in line with DFIDs Open Access Policy. The review will be provided to DFID but will not be publicly available.

Duty of Care

The Supplier is responsible for the safety and well-being of their Personnel (as defined in Section 2 of the Contract) and Third Parties affected by their activities under this contract, including appropriate security arrangements. They will also be responsible for the provision of suitable security arrangements for their domestic and business property.

The Supplier is responsible for ensuring appropriate safety and security briefings for all of their Personnel working under this contract and ensuring that their Personnel register and receive briefing as outlined above. Travel advice is also available on the FCO website and the Supplier must ensure they (and their Personnel) are up to date with the latest position.

The Supplier is responsible for ensuring that appropriate arrangements, processes and procedures are in place for their Personnel, taking into account the environment they will be working in and the level of risk involved in delivery of the Contract (such as working in dangerous, fragile and hostile environments etc.). The Supplier must ensure their Personnel receive the required level of training and safety in the field training prior to deployment.

Tenderers must develop their Tender on the basis of being fully responsible for Duty of Care in line with the details provided above and the initial risk assessment matrix developed by DFID see Annex 2 of this ToR. They must confirm in their Tender that:

- They fully accept responsibility for Security and Duty of Care.
- They understand the potential risks and have the knowledge and experience to develop an effective risk plan.
- They have the capability to manage their Duty of Care responsibilities throughout the life of the contract.

If you are unwilling or unable to accept responsibility for Security and Duty of Care as detailed above, your Tender will be viewed as non-compliant and excluded from further evaluation.

Acceptance of responsibility must be supported with evidence of capability and DFID reserves the right to clarify any aspect of this evidence. In providing evidence Tenderers should consider the following questions:

a. Have you completed an initial assessment of potential risks that demonstrates your knowledge and understanding, and are you satisfied that you understand the risk management implications (not solely relying on information provided by DFID)?
b. Have you prepared an outline plan that you consider appropriate to manage these risks at this stage (or will you do so if you are awarded the contract) and are you confident/comfortable that you can implement this effectively?
c. Have you ensured or will you ensure that your staff are appropriately trained (including specialist training where required) before they are deployed and will you ensure that ongoing training is provided where necessary?
d. Have you an appropriate mechanism in place to monitor risk on a live / ongoing basis (or will you put one in place if you are awarded the contract)?
e. Have you ensured or will you ensure that your staff are provided with and have access to suitable equipment and will you ensure that this is reviewed and provided on an ongoing basis?
f. Have you appropriate systems in place to manage an emergency / incident if one arises?

UK Government approved hostile environment training course is known as SAFE (Security Awareness in Fragile Environments). The course should be booked through DFID and factored into the commercial tender.

For further information on specific countries, please see the Risk Assessments which are located at Annex E of this Terms of Reference.

Background

The Clinton Health Access Initiative (CHAI) was launched by President Clinton in 2002 and began as the Clinton HIV/AIDS Initiative. The programme was designed to increase access to treatment for those living with HIV/AIDS and strengthen health systems. It has now expanded its work to include the provision of treatment and diagnostic tests for a range of other diseases, by reducing the cost of healthcare commodities and delivery.

There are no other donors to the Market-Shaping for Access to Safe, Effective and Affordable Health Commodities. DFID is the sole donor. However, several donors provide support to CHAI for activities related to market dynamics, access to medicines and global health more broadly. These include bilateral, multilateral agencies, and private foundations. DFID and CHAI will engage these partners as appropriate throughout the process and make the evaluation available to them.

DFID's first grant to CHAI began in 2008 and adopted this market-shaping model. The new CHAI 2012 – 2015 programme aims to optimise patient outcomes while achieving value for money targets. Six priority areas are being targeted:

- Maximising value for money in the fight against HIV
- Maximising value for money in the fight against TB
- Accelerating access to accurate, lower-cost diagnostics
- Improving maternal and child health
- Reducing the global burden of malaria, and
- Sharing lessons learned and evaluations of new products.

Under the current 2012 – 2015 programme, DFID will provide up to £35 million for work on a series of market-shaping initiatives across an expanded range of priority health commodities including: antiretrovirals, antimalarials, diagnostics, vaccines, contraceptives and TB treatments. The theme which draws these initiatives together is CHAI's approach of working on both the supply and demand sides of the marketplace, leveraging its knowledge of both sides to achieve results in each which are larger than could be achieved in working on one or the other exclusively. The programme is led by DFID's Policy Division, with funding from Human Development Department and DFID India and DFID South Africa (through the Global Development Partnership Programme). Other DFID departments may also join the programme.

An assessment undertaken in 2011 to evaluate a previous grant to CHAI stated that; 'DFID support has helped to improve the affordability, availability and quality for AIDS and Malaria drugs provided by Indian and other manufacturers, and increased capacity in African countries to access these drugs. This has been done through negotiating pricing, increasing competition through reducing entry barriers for new producers, facilitating reduction in costs through improving production processes, and improving demand forecasting and the flow of market information more generally. By helping to increase the number of people in poor countries who can access these drugs, DFID support has directly contributed to achievement of MDG targets on communicable disease and access to medicines.' Some specific results associated with the first grant are set out in Annex A.

The previous assessment noted the limitations of an evaluation of this type of programme given that many of the activities – brokering relationships, contributing data to discussions, influencing decisions – contribute to outcomes alongside other interventions, is difficult to attribute to a single partner and may yield long-term gain that is not captured in the short-term.

The previous assessment offered several recommendations that can provide greater context during the design phase of this current evaluation:

- To make connections between activities, outputs and impact (i.e. the theory of change) more tangible and explicit.
- To consider systemic approaches in addition to transactional approaches. For example, finding global or regional solutions to registration problems versus getting one-off registration waivers for specific products; patent pool approaches to intellectual property versus individual license brokering; building wider forecasting systems versus building forecasting tools for one commodity type versus; working within official

channels, in synergy with partners and building capacity versus working in parallel or on a "project" basis due to urgency.

- To consider sustainability and capacity building (e.g. the extent to which good market-shaping practice and capacity could be transferred into relevant actors at the global, regional, and national levels.
- To optimise the balance of public access to information (e.g. maximising publicly available quality information without compromising commercial confidentiality requirements).
- To enhance the coordination and information-sharing with DFID offices in countries where activities are being supported under the programme. This serves to enhance programme oversight and help ensure opportunities for synergy with other DFID interventions were exploited.

Strategies on both the supply and demand sides include:

Supply-Side:

- Accelerate uptake of currently available, more cost-effective products
- Reduce prices to enable widespread uptake of products (new and existing)
- Determine unmet market demand of new product opportunities (validate product need)
- Increase market capacity to maintain structural process gains

Demand-Side:

- Accurately forecast demand for new products (assist governments in quantifying magnitude of unmet need)
- Build capacity to support product introduction and ensure interventions are sustained
- Assist with prioritisation of health outcomes within existing financial resources

The programme aims to add value to the investments DFID makes in health commodities and results through other channels. For example, DFID finances significant quantities of health commodities through global partnerships such as: The Global Fund for AIDS, TB and Malaria, the GAVI Alliance, UNFPA and UNITAID. DFID's bilateral programmes also finance a significant volume of health commodities, both directly and indirectly. More effective markets for these health commodities (i.e. markets that better support public health goals) will deliver savings for DFID and add to results. Equally, on the upstream side, DFID's Research and Evidence Division supports research and development into new vaccines, medicines and diagnostics through Product Development Partnerships (PDPs). More effective markets, with clear regulatory pathways to market and clear demand visibility will accelerate entry of new commodities to market and their contribution to health outcomes.

The programme is one of a number of programme and policy interventions that DFID supports to (i) add value and impact to the wider DFID health portfolio and (ii) strengthen the overarching access to medicines system/value chain to deliver better outcomes for the poor. These interventions include the Medicines Transparency Alliance (MeTA), the Access to Medicines Index, the Global Medicines Regulatory Harmonisation initiative and the Industry-Government Forum on Access to Medicines (IGFAM).

Market-shaping model

A number of key principles underpin the DFID approach to market-shaping in the CHAI grant. These are:

- Firstly, interventions are undertaken with full support and buy-in of developing country authorities and in coordination with the relevant international stakeholder partnerships active in the respective disease or commodity area.
- Second, supply and demand interventions are well coordinated and tailored to the specific features of individual health commodity markets, based on robust market assessments.
- Third, sustainability is mainstreamed into all work. This means working to build market-shaping capacity, whether in developing country Ministries of Health or in global partnerships and communities.
- Fourth, where appropriate, the approach focuses supplier engagement on key 'emerging power' suppliers, such as India, China and South Africa, given their transformative market potential. Indian companies supply over 85% of the drugs used to treat AIDS in Africa, and up to 70% of vaccines procured by UN agencies.
- Fifth, where appropriate, interventions complement other interventions that DFID supports in market-shaping and access to medicines. This includes investments in multilaterals such as UNITAID, GFATM and GAVI, as well as in-country programmes such as the South Asia Regional Programme for Access to Medicine (SARPAM).

- Finally, where appropriate, market-shaping interventions have sufficient scope to cover the priority health commodities in which DFID invests significant resources, both through bilateral and multilateral channels, as well as offering the potential to seize opportunities for other commodities as they emerge.

Patient impact

The desired patient impact of the programme is improved health outcomes for patients. Specifically, for the programmes that are being evaluated, this includes:

High-Level Patient Impact	Programmes to be Evaluated and/or Reviewed under Grant
• Increased number of patients treated with safe and high-quality HIV and malaria drugs	• HIV Treatment • Malaria Treatment • Value for Money of HIV Spending
• Decreased loss in patients between testing and treatment initiation for HIV	• PoC HIV Diagnostics
• Decreased number of new HIV infections	• Value for Money of HIV Spending
• Decreased number of unwanted pregnancies and maternal deaths	• LARCs (Long-Acting Contraceptives)
• Reduction in infant and adult mortality	• HIV Treatment • Malaria Treatment • PoC HIV Diagnostics • Value for Money of HIV Spending • LARCs (Long-Acting Contraceptives)

However, given that this is a *process* evaluation, evaluating patient impact will be out-of-scope.

Outcomes of the current project

The overarching desired change of the programme is *increased access to critical, safe, affordable and effective health products while achieving good value for money*. Outcomes for the various programmes that are being evaluated and/or reviewed may include an impact, effect, behaviour change, knowledge or skills, which result from the respective programme outputs. This translates into the following:

Supply-Side
- Global financial savings on improved HIV treatment access
- Procurement strategies, practices and mechanisms that cut across multiple geographies (to find, evaluate and engage appropriate suppliers; reveal process efficiencies; and fulfil unmet demand)
- Stakeholder mechanisms and structures for ongoing negotiations and agreements
- Replicable interventions across health priorities or geographies
- Proof of concept for best practices

Demand-Side
- Availability of drugs at clinical level
- Country ownership of processes to forecast, procure and adopt products (for new product introduction, rapid scale-up, and/or sustained uptake)
- General health system benefits from program outcomes

Background: Outputs of the current project

Outputs for each programme to be evaluated and/or reviewed will be defined by specific Indicators of Success and Logframe Indicators. Outputs for this evaluation may include products, activities, processes or services, such as:

Supply-Side
- Price reductions (on WHO-preferred HIV and malaria regimens; HIV, TB and/or malaria diagnostic products; LARCs) such as:
  - Price reductions for first-line, WHO-preferred regimens, available at under $90 PPPY by 2015 (~45% price reduction from 2012 baseline)

  - Price reductions for second-line, WHO- preferred regimens, available at under $250 PPPY by 2015 (~45% price reduction from 2012 baseline)
  - Achieve annual cost savings for 1st and 2nd line, WHO-preferred HIV regimens in 4 SADC countries (excluding RSA), totalling between $92 million to $199 million
  - Price reductions of 30–60% compared to current baseline for at least 2–3 PoC CD4 products (at least 30% reduction in cost per test result for PoC CD4 tests)
  - 35% decline in market prices of Implanon and Jadelle (LARCs)
- Stable prices
- Increased number of drugs and diagnostics accessible to country governments (for HIV, TB and malaria) e.g.,
  - Increase in number of SRA-assured approved HIV products supplied from Indian, Chinese and South African sources
- Increased number of suppliers entering the market (for HIV, malaria, vaccines, LARCs) e.g.,
  - Number of agreements reached with Indian and Chinese manufacturers for LARCs
  - Submission of regulatory dossiers for new malaria treatments to a stringent regulatory authority or the WHO by 4–5 additional supply sources and no supplier exits from ACT marketplace during grant
- Stable supply
- Market assessments for new opportunities
- Higher quality products in the marketplace

Demand-Side

- Accurate forecasts (for HIV and malaria treatment) e.g.,
  - Accelerated adoption in 4–6 high burden countries of injectable artesunate and/or new antimalarial treatments
- Increase in on-site access to CD4 testing e.g.,
  - Increase in proportion of patients with access to on-site CD4 testing from ~50% to 75% in focus countries
  - Scale-up usage of PoC testing in countries, monitoring results in individual countries, with particular focus on potential scale of SADC (including RSA)
- Lower cost of ART service delivery e.g.,
  - An estimated 20% reductions in the unit cost of ART service delivery relative to current benchmark
  - Reduction in the non-commodity unit costs that together reduce the aggregate cost of treatment in 3–5 focus countries by $150M+
- Government budget reallocations to higher impact interventions e.g.,

1. Funding re-allocated to 3–5 highest priority interventions, including ART, PMTCT and MC

Background: Existing information sources

- Business Case (June 2012): DFID-CHAI Market-Shaping for Access to Safe, Effective and Affordable Health Commodities. Publicly available on http://projects.dfid.gov.uk/.
- Updated logframe and first programme Annual Review: To be provided to selected evaluator
- Waning et al. (Globalisation and Health, 2010) 'Intervening in global markets to improve access to HIV/AIDS treatment: an analysis of international policies and the dynamics of global antiretroviral medicines markets'
- Cheri Grace, HLSP (November 2010) 'A Value for Money Perspective Applied to Global Health Initiative Market-Shaping Activities'
- UNITAID market impact framework (available at www.unitaid.eu)
- DFID's approach to Value For Money, DFID (July 2011)

Bidders will be encouraged to search for these and additional sources of background information and DFID programme documents will be made available as necessary.

Annex B Evaluation Team

The Evaluation Team is set out in the table below. The core team has remained constant throughout the evaluation. Itad analysts and administrators have been engaged to support this core team as appropriate, and country consultants were also engaged to support country case study visits.

Position	**Name**
Project Director	Sam McPherson
Team Leader and E2 Reviewer	Emma Back
Technical Team Leader and HIV Lead	Cheri Grace
Core Team Member and Malaria Treatment Lead	Kashi Carasso
Core Team Member and LARCs Lead	Dan Whitaker
Core Team Member and Evaluation Adviser	Tim Shorten
Analyst	Emma Newbatt
Analyst	Jon Cooper
Administrators	Michelle Kay Susannah Bartlett Grace Elliott Giada Tu Thanh
Country Consultants	Aarti Patel Patrick Mubangizi Violet Kabwe Sosten Chilumpha Yegilenesh Habte Ramso Babatunde Ipaye

The **Country Consultants'** ToR included country data collection, conduct of KIIs (alone where necessary and appropriate, or with a core team member), and logistical support to country visits by core team members.

Annex C Evaluation Questions

Evaluation questions		*Indicator*	*Source*	*Tools & Methods*
Is CHAI doing …				
… the right things	*Is CHAI's intervention relevant and aligned to country needs and global priorities?*	*CHAI strategies use & reference global/national targets & indicators*	*CHAI strategies* *Key informants*	*Document review* *KIIs*
	Was CHAI able to identify the areas of highest impact in which to engage?	*High impact areas have been selected*	*CHAI strategies* *Key informants*	*Document review* *KIIs*
	Was CHAI able to identify interventions with a high feasibility of success?	*Interventions with high feasibility of success have been selected*	*CHAI strategies* *Key informants*	*Document review* *KIIs*
	Does CHAI choose interventions where it can contribute a unique skill set or perspective relative to others?	*CHAI can offer a unique skill or perspective relative to others*	*CHAI strategies* *Key informants*	*Document review* *KIIs*
	How well does the current ToC conceptualise and articulate programme logic, assumptions and risks? To what extent can the current ToC be improved and how?	*Gaps do/don't exist in results chain logic*	*CHAI & DFID reports* *Key informants*	*ToC Analysis*
… in the right way	*Is the intervention sufficiently broad – for example, does it cover healthcare systems work? Does it consider short as well as long-term impact?*	*CHAI interventions includes relevant health system strengthening (HSS) activities*	*CHAI and DFID project documents* *Key informants*	*Document review* *KIIs*
	To what extent has CHAI course corrected based on new information or changes in context?	*Strategies and plans were revised periodically*	*CHAI and DFID project documents* *Key Informants*	*Document review* *KIIs*
	Is CHAI transparent – what are its range of projects, who funds those, what is its mission, what are its core competencies, what are CHAI's limits?	*CHAI publishes/makes available information on its role, approach, methods etc.*	*CHAI and DFID project documents* *Key informants* *CHAI website*	*Document review* *KIIs*
	How well does CHAI share lessons and contribute to global public goods?	*CHAI publishes/makes available results and information on approaches/methods*	*CHAI and DFID project documents* *Key informants* *CHAI website* *Peer-reviewed literature*	*Document review* *KIIs* *Literature review*

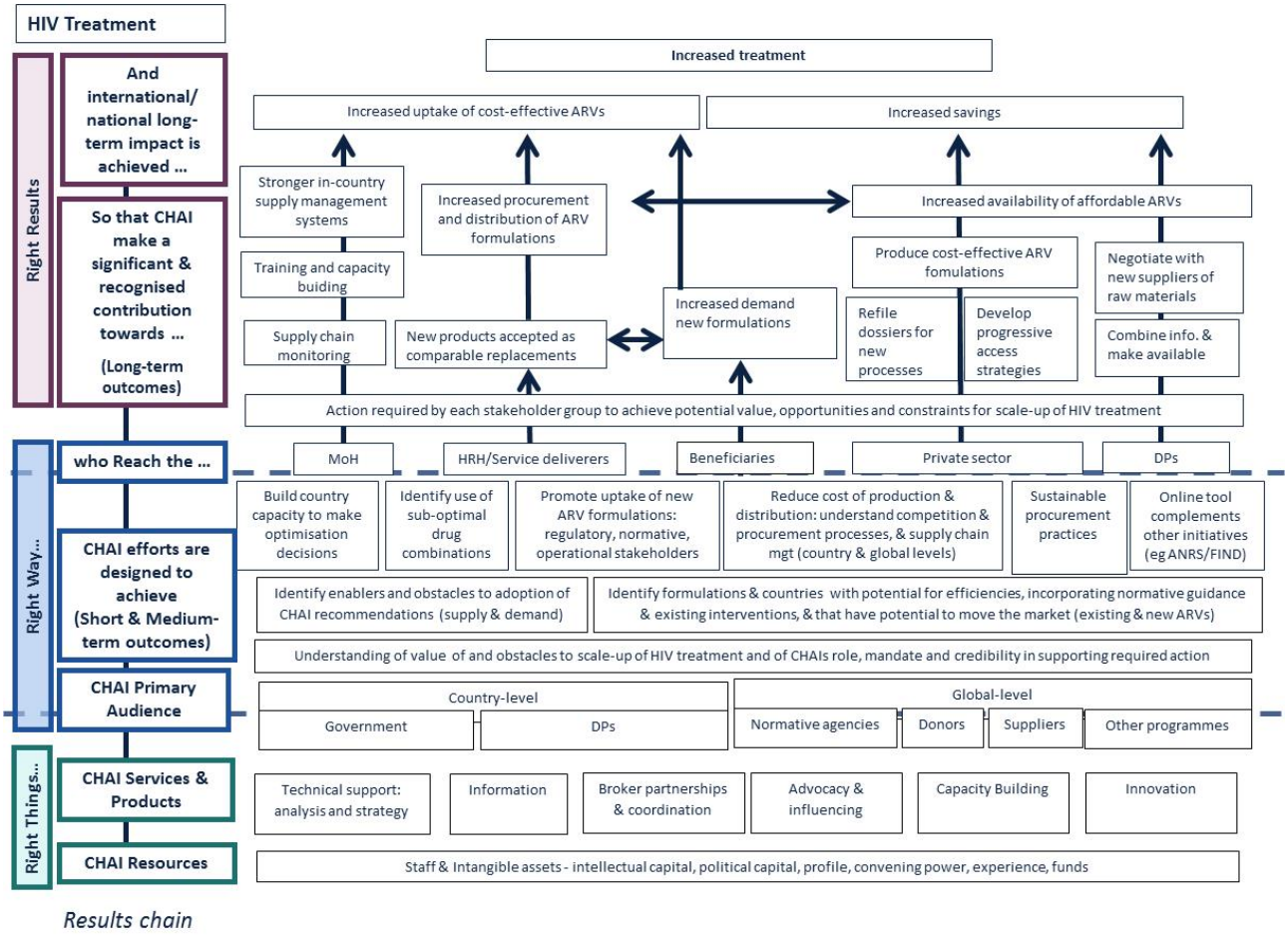
	How effective is CHAI in influencing and managing change?	*CHAI has influenced and managed change effectively*	*CHAI and DFID project documents* *Key Informants*	*Document review* *KIIs*
	Are CHAI's products technically sound and peer-reviewed by internal and external expertise?	*CHAI's products are technically sound and peer-reviewed by internal and external expertise*	*CHAI and DFID project documents* *Key Informants*	*Document review* *KIIs*
	Has CHAI found the right balance between driving things forward quickly vs building up systems and bringing people along in a way that might be more conducive to long-term systemic change	*Partners concerns about the pace and focus of CHAI's programme implementation*	*CHAI and DFID project documents* *Key Informants*	*Document review* *KIIs*
	Has CHAI found the right balance between being collaborative and being disruptive (the "right" balance might be defined as the one that succeeds in driving progress/achieving intended impact)	*Partners feel that progress has been optimised*	*CHAI and DFID project documents* *Key Informants*	*Document review* *KIIs*
	In what ways did CHAI seek to establish a clear, complementary mandate and credibility with relevant stakeholders?	*Partners acknowledge CHAI credibility*	*Key informants*	*KIIs*
	Does CHAI have the right staff with the right skills, the right structure and systems, the right style and shared values to be effective in its work?	*CHAI has relevant staff skills & experience available*	*Document review* *CHAI & DFID reports* *Key informants*	*Document review* *KIIs*
	How well has CHAI contributed to sustainability - e.g. transferring skills, tools, process knowledge to others – contributing to institutional change?	*CHAI has contributed to transferring skills, tools, process knowledge to others*	*CHAI and DFID project documents* *Key informants*	*Document review* *KIIs*
	Does CHAI have effective internal and external communication?	*CHAI staff and partners have information they need and want on CHAI's programmes*	*CHAI project documents* *Key informants*	*Document review* *KIIs*
… with the right results	*To what extent has CHAI delivered the desired outputs?*	*As per logframe indicators 1.1–1.5, 2.1, 2.2, 2.4, 3.1, 3.2, 4.1, 4.2, 6.2.*	*DFID reports* *CHAI reports* *Key informants*	*Modelling* *KIIs* *Document review*
	To what extent have these outputs contributed to desire outcomes?	*As per logframe indicators OI1 and OI2*	*DFID reports* *CHAI reports* *Key informants*	*ToC analysis*
	To what extent have these outcomes contributed to desired impact and broader health outcomes?	*As per logframe indicators I1 and I2*	*DFID reports* *CHAI reports* *Key informants*	*ToC analysis*
	To what extent are reported results based on valid methods and reliable data?	*Results can be replicated; stakeholders do not raise concerns about credibility of results*	*Modelling based on CHAI data triangulated against benchmarks and expert advice*	*Modelling*

	To what extent do results represent value for money against international norms?	*Performance on VFM indicators is comparable with results of relevant bodies/programmes (e.g. on cost per test result achieved)* *VFM indicators developed by CHAI*	*CHAI reports* *DFID reports* *Key Informants*	*VFM analysis* *Document review*
	To what extent has DFID support enabled CHAI to achieve these outputs?	*Could CHAI have achieved comparable results without DFID support?*	*Key informants*	*KIIs*
	To what extent has the DFID-CHAI partnership leveraged (a) additional support to CHAI and (b) complementary initiatives/actions by others to shape the overall market?	*New/additional funding to CHAI agreed after DFID grant.* *Increased action by partners in targeted areas*	*CHAI reports* *Key informants*	*KIIs* *Document review*
	What is the likelihood that programme's outcomes will be sustained beyond the end of the programme?	*Projected savings are maintained*	*Models*	*Modelling*
	To what extent has CHAI built capacity among implementing partners at global, regional and national level to sustain progress made?	*Logframe indicator 7.1*	*CHAI reports*	*Document review*
	To what extent will proof of best practices be applied across other health priorities, countries and contexts following completion?	*Best practices are documented in CHAI future planning*	*CHAI & DFID reports* *Key informants*	*Document review* *KIIs*

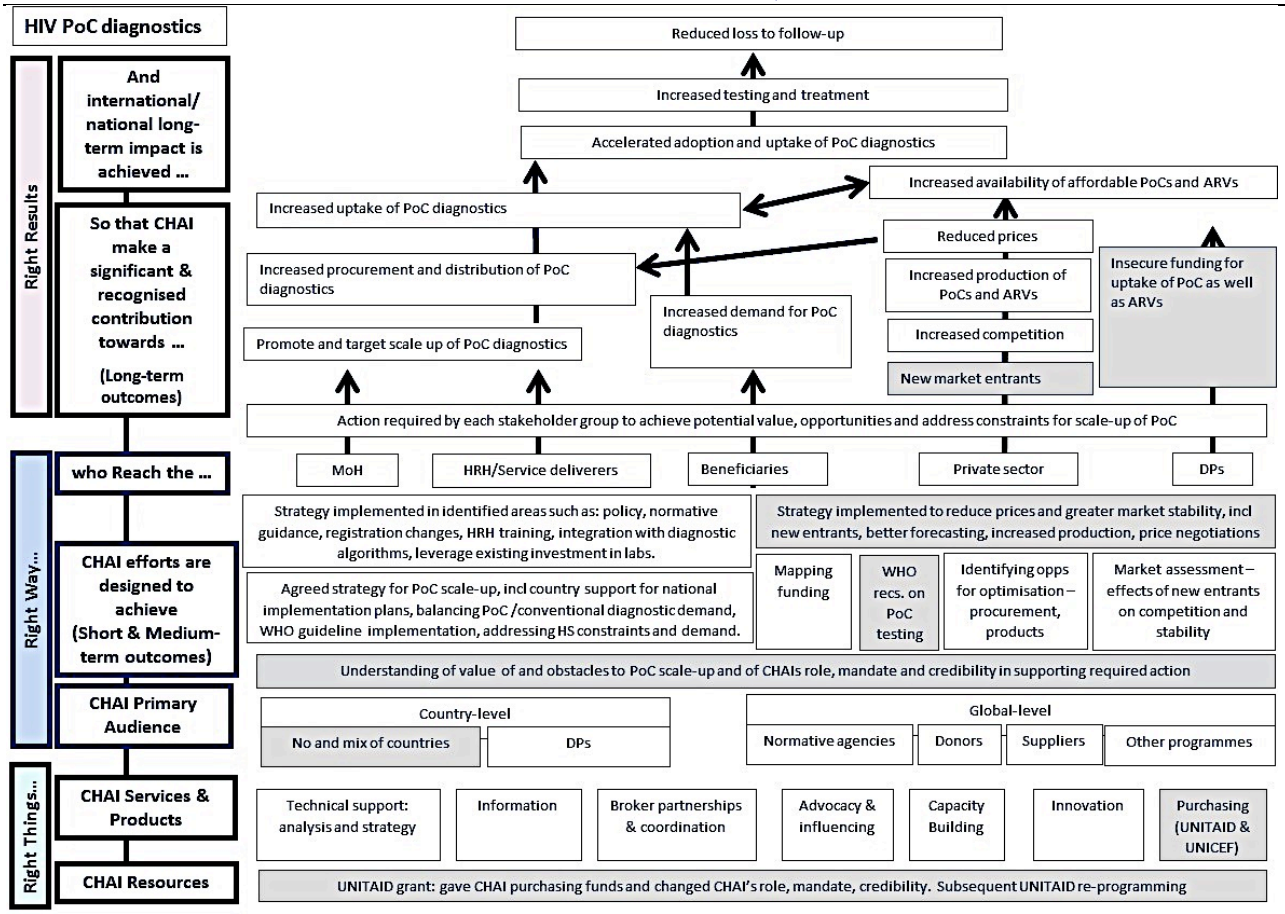
Annex D Theory of Change Diagrams

The ToCs that we have used for this evaluation were developed using CHAI's 'model of change' and the overarching ToC from the DFID Business Case for the grant. Given the diversity and complexity of the five different programme areas, we developed a more detailed ToC for each. These were presented and agreed with CHAI and DFID during the evaluation Inception Phase. The four ToCs relevant to the programme areas covered in this Final Report are set out below.

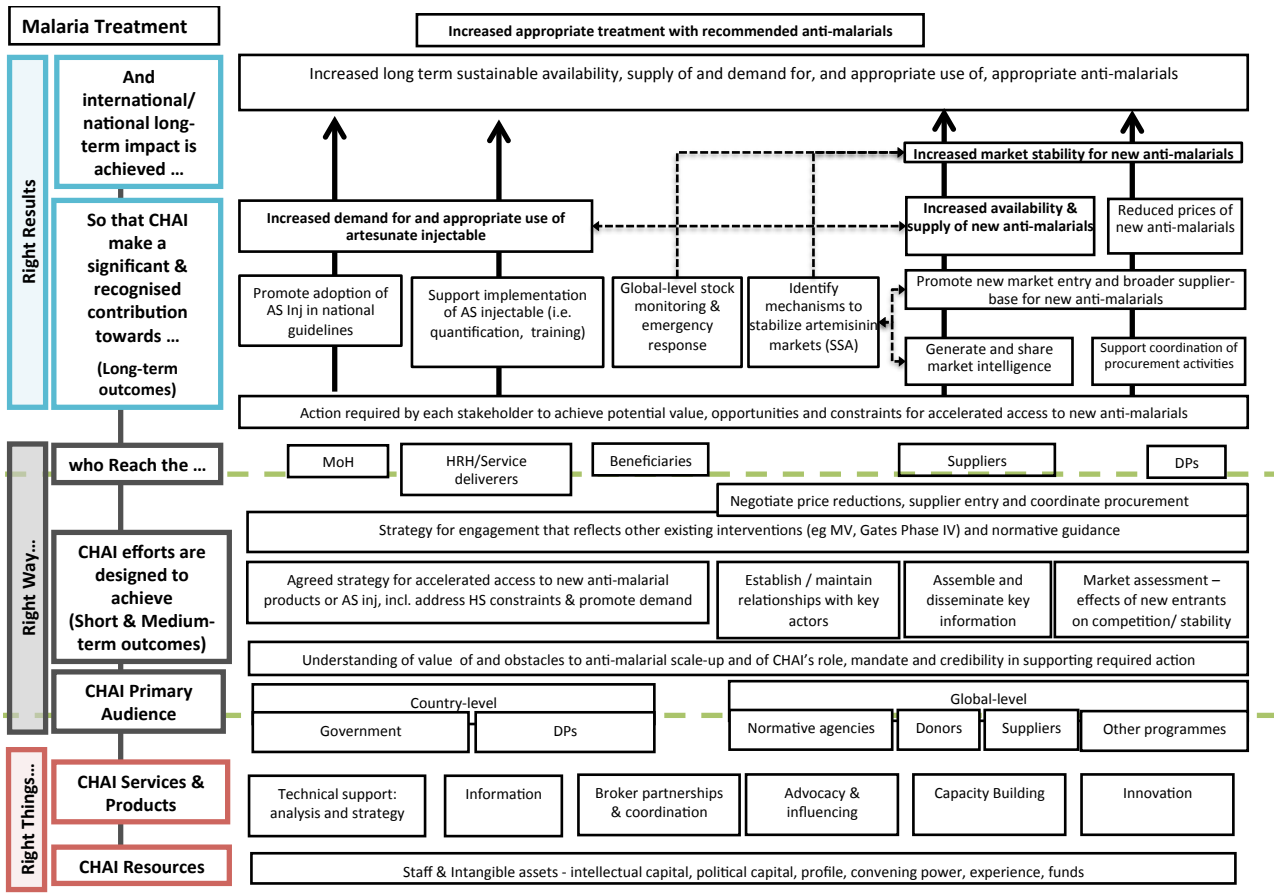
Programme Area ToCs



Results chain



Results chain



Results chain

Annex E Interview Guide

Respondent: _____

Organisation: _____

Email:

_____

Relationship with CHAI:

_____

Internal[198] ☐ Connected[199] ☐ External[200] ☐ Suggested by: CHAI ☐ e-Pact team ☐

Date: _____

Interviewer: _____

Recorded: Y/N
Consent obtained to record/write up a note of the conversation: Y/N
Permission to quote (with broad categorisation): Y/N

Question 0: Background – people interview, organisation, general comments about interview etc.

Record response

Question 1:[201] *What specific services and products CHAI has contributed, with which audience in mind? Is CHAI's strategy clear and relevant (e.g. to addressing market challenges)? To what extent are CHAI strategies aligned to country needs and global priorities? Were CHAI able to identify the areas of highest impact in which to engage?*
Country or thematic examples:

Record response

Indicative sub-questions:

1. *Is strategy sufficiently broad – for example, does it cover healthcare systems work?*
2. *How sound was CHAI's programme design (problem identification and approach to a solution). Is it based on sound contextual and situational analysis? Are judgements about feasibility sound? Can this design be improved and if so how?*

Responses

Question 2: *How has CHAI sought to influence decisions? In what ways did CHAI seek to establish a clear, complementary mandate and credibility with relevant stakeholders? Does CHAI have the right (7S) strategy, skills, staff, structure, systems, style and shared values for doing what it needs to do?*

[198] **Internal** = CHAI staff, i.e. those that CHAI has direct control over;
[199] **Connected** = 'partners' with whom CHAI is directly engaging, and who therefore have direct experience of working with CHAI, i.e. those that CHAI has direct influence over
[200] **External** = stakeholders that are expected to be influenced by CHAI and CHAI partners to achieve expected outcomes, i.e. those that CHAI has indirect influence over
[201] The results from this section will help us refine the survey tool – in which activities did CHAI engage?

Country or thematic examples:

Record response

Indicative sub-questions:

- *How did the programme adapt its strategies to changing contexts? What were the unintended consequences, if any?*
- *Were lessons learned in the early stages of the programme successfully integrated to course-correct and refine the programme?*
- *Are there any examples of CHAI contributing to sustainability - e.g. transferring skills, tools, process knowledge to others – contributing to institutional change?*

Responses

Question 3: *To what extent has CHAI delivered the desired outputs and outcomes? Will the impact be sustained, and capacity built, beyond the programme? (For supply-side informants, in what way has CHAI helped enable risk reduction, volume increases, cost reduction, etc.?)*

Country or thematic examples:

Record response

Indicative sub-questions:

1. What confidence does the informant have that CHAI's work has contributed to this? What other factors have influenced the relevant outcomes?
2. Are the market outcomes subject to reversal? Will the impact be sustained, and capacity built, beyond the programme?

For CHAI/DFID/other global informants (as appropriate)

3. *To what extent has DFID support enabled CHAI to achieve these outputs? Could CHAI have achieved comparable results without DFID support?*
4. *To what extent has the DFID-CHAI partnership leveraged (a) additional support to CHAI and (b) complementary initiatives/actions by others to shape the overall market?*

Responses

Question 4: *Strategic level questions, largely for global/industry interviews.*

Question(s):

1. For stakeholders operating at a global more strategic level (and possibly also some supply-side informants), headings A-C should pick up on the role of CHAI (and DFID as funder of CHAI) within the global architecture, i.e. whether (compared to other actors in this space) CHAI is doing the right things the right way with the right results. Possible topics to explore may be:
    - the changing role of emerging power (BRIC) suppliers and CHAI's/DFID's interface with them compared to others influencing them
    - the changing availability of donor funds in a world where LDCs are shrinking – what this implies for CHAI's business model
    - the dynamic of (on the one hand) more interest/activity in the market-shaping space while (on the other hand) possible inefficiencies in this space – and where CHAI fits - and should fit – into the space

- the need for CHAI's involvement in mature vs new markets – how long should a donor intervene and how should the intervention shift as the market matures?
- the validity of CHAI's assumption, based on experience of and/or observation of the effects of CHAI's work, that disrupting markets leads to positive outcomes?
- have transaction costs been created elsewhere in the system, born by whom, how have these been managed?

Responses

Question 5: A*dditional questions that are relevant to the evaluation and which emerge during the interview.*

Question(s):

- In the informant's view, what would be the (counterfactual) current situation if CHAI had not been involved?
- Does the informant have a view as to how CHAI might improve effectiveness, for example redirecting their focus to other priorities, contributing different services or products or contributing in a different way?

Responses

Annex F List of global stakeholder organisations

A list of the organisations providing global-level key informants for the evaluation is below. In many cases, more than one individual was interviewed at an organisation, particularly where the organisation works on a wide range of health issues and products. In some cases, an interview covered more than one programme area. It should also be noted that many of the global stakeholders have country-level insights into CHAI's demand-side work and were able to comment to this effect; equally, some of the key informants for county case studies were aware of and able to comment on CHAI's supply-side activity.

Suppliers (existing products or products in development) – 31 interviews across all programme areas
World Health Organization WHO
The Bill and Melinda Gates Foundation BMGF
The Global Fund to Fight AIDS TB and Malaria GFATM
Medicines Patent Pool (MPP)
SCMS
UNITAID
PATH
African Society of Laboratory Medicine (ASLM)
UNICEF
London School of Hygiene and Tropical Medicine (LSHTM)
Médecins Sans Frontières MSF
US Centres for Disease Control CDC
Medicines for Malaria Venture MMV
University of Michigan
PSI
IDA
IPCA
FHI360
Marie Stopes
Reproductive Health Supplies Coalition RHSC
UNFPA
USAID

Annex G Survey data – Industry stakeholders

Right things

Question	Number of respondents (%) a. Strongly agree	b. Somewhat agree	c. Variable	d. Somewhat disagree	e. Strongly disagree	f. N/A	No response given	Grand Total
Q3. CHAI has identified the areas of highest positive impact in which to engage	11 (64.7%)	5 (29.4%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	17 (100%)
Q4. CHAI appropriately considers its skills and comparative advantage relative to others when choosing its areas of work.	7 (41.2%)	9 (52.9%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	17 (100%)
Q5. CHAI conducts a comprehensive situation analysis, identifying root causes of problems, before proposing possible solutions or interventions.	9 (52.9%)	4 (23.5%)	3 (17.6%)	0 (0%)	0 (0%)	1 (5.9%)	0 (0%)	17 (100%)
Q6. CHAI considers the long-term implications of the interventions it supports.	10 (58.8%)	4 (23.5%)	1 (5.9%)	1 (5.9%)	0 (0%)	1 (5.9%)	0 (0%)	17 (100%)
Q7. CHAI's Supplier/Buyer meetings are useful to us.	11 (64.7%)	2 (11.8%)	1 (5.9%)	0 (0%)	0 (0%)	3 (17.6%)	0 (0%)	17 (100%)
Q8. CHAI price ceilings continue to be useful.	3 (18.8%)	4 (25%)	2 (12.5%)	1 (6.3%)	2 (12.5%)	4 (25%)	0 (0%)	17 (100%)
Q9. Please enter below any additional comments on the degree to which CHAI is or is not doing what you deem to be the right things	A total of four stakeholders (two from the field of HIV diagnostics, one from malaria medicines and one from multiple program areas) commented on this question. The use of the term "ceiling price" for viral load testing was reported by one industry stakeholder to have been a problem. The pricing that was agreed to with CHAI leaves no further room for negotiation One stakeholder noted that global CHAI teams were willing to work with industry to drive prices down over time in a sustainable way, whereas local (country) teams insisted on immediate lowest pricing, even if that means losing significant amounts of money per product sold. Another stakeholder noted that sometimes CHAI country level staff seem to lose sight of the policy aspect of their work and focus on implementation. While at times they might need to engage in pilots or start-ups there needs to be clear understanding that the goal is for scale up and sustainability. Some country programs have too much vested in their own implementation to be able to clearly assess the impact – for example, the POC work was not a success in several countries yet the teams were highly invested in making it work. That both drove out more appropriate technologies and also limited competition even when it was clear that the provider was not able to deliver quality services.							

Similarly, another stakeholder commented on the issue of longer term considerations, noting that while CHAI has the ability to analyse a situation and to identify the cause of problems often the conclusion or suggested solution take into consideration the long term perspective.

Right way

Question	Number of respondents (%)							
	a. Strongly agree	b. Somewhat agree	c. Variable	d. Somewhat disagree	e. Strongly disagree	f. N/A	No response given	Grand Total
Q10. I have a good understanding of CHAI's core values and mission.	8 (47.1%)	8 (47.1%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	17 (100%)
Q11. The skills and experience of CHAI staff are appropriate to the job they need to do.	12 (70.6%)	3 (17.6%)	2 (11.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	17 (100%)
Q12. CHAI's has appropriate management systems and internal communication to support its work.	9 (52.9%)	6 (35.3%)	1 (5.9%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	17 (100%)
Q13. The CHAI staff with whom I have interacted are politically astute/sensitive.	11 (64.7%)	4 (23.5%)	0 (0%)	0 (0%)	0 (0%)	2 (11.8%)	0 (0%)	17 (100%)
Q14. The impact of CHAI's work is reduced by turnover of its staff.		3 (17.6%)	3 (17.6%)	6 (35.3%)	2 (11.8%)	3 (17.6%)	0 (0%)	17 (100%)
Q15. The quality of the CHAI staff with whom I have worked has been consistently good.	13 (76.5%)	3 (17.6%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	17 (100%)
Q16. CHAI offers country partners a neutral, evidence based perspective when it comes to making product choices (for example choosing ARV regimens and making diagnostic decisions).	5 (29.4%)	1 (5.9%)	2 (11.8%)	2 (11.8%)	0 (0%)	7 (41.2%)	0 (0%)	17 (100%)
Q17. CHAI course corrects/changes approach in response to new data or changes in context.	4 (23.5%)	7 (41.2%)	2 (11.8%)	1 (5.9%)	0 (0%)	3 (17.6%)	0 (0%)	17 (100%)
Q18. CHAI's interventions are innovative in addressing the need/problem.	6 (35.3%)	8 (47.1%)	2 (11.8%)	0 (0%)	0 (0%)	1 (5.9%)	0 (0%)	17 (100%)
Q19. I am confident that the products and tools CHAI develops are technically sound.	12 (70.6%)	4 (23.5%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	17 (100%)
Q20. I am confident that the products and tools CHAI develops are peer-reviewed or quality checked before presentation to others.	8 (47.1%)	5 (29.4%)	2 (11.8%)	0 (0%)	0 (0%)	2 (11.8%)	0 (0%)	17 (100%)
Q21. When involved in new technology introduction, CHAI ensures that the	6 (35.3%)	5 (29.4%)	3 (17.6%)	0 (0%)	0 (0%)	3 (17.6%)	0 (0%)	17 (100%)

technology is appropriate to the country's needs.								
Q22. When involved in new technology introduction, CHAI works to ensure the technologies can be effectively utilised (e.g. ensuring that training is conducted or complementary commodities can be funded).	3 (17.6%)	7 (41.2%)	3 (17.6%)	0 (0%)	0 (0%)	4 (23.5%)	0 (0%)	17 (100%)
Q23. In my experience with CHAI, CHAI inflates/overstates its role or influence on the results achieved.	1 (5.9%)	2 (11.8%)	3 (17.6%)	3 (17.6%)	7 (41.2%)	0 (0%)	1 (5.9%)	17 (100%)
Q24. In my experience with CHAI, CHAI underplays/doesn't take enough credit in its role in the results achieved.	0 (0%)	2 (11.8%)	6 (35.3%)	4 (23.5%)	3 (17.6%)	1 (5.9%)	1 (5.9%)	17 (100%)
Q25. CHAI seeks to co-ordinate its work with relevant stakeholders.	9 (52.9%)	6 (35.3%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	1 (5.9%)	17 (100%)
Q26. When modelling data to support decision making, CHAI's assumptions are realistic and feasible.	4 (23.5%)	9 (52.9%)	1 (5.9%)	1 (5.9%)	0 (0%)	1 (5.9%)	1 (5.9%)	17 (100%)
Q27. When modelling data to support decision making, CHAI's assumptions are transparent.	7 (41.2%)	8 (47.1%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)	1 (5.9%)	17 (100%)
Q28. I have a good understanding of the source of CHAI's funding.	5 (29.4%)	6 (35.3%)	4 (23.5%)	2 (11.8%)	0 (0%)	0 (0%)	0 (0%)	17 (100%)
Q29. I have a good understanding of the range of work CHAI does.	9 (52.9%)	6 (35.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (11.8%)	17 (100%)
Q30. I am easily able to get the information/data I need from CHAI.	9 (52.9%)	8 (47.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	17 (100%)
Q31. CHAI manages data confidentiality appropriately.	11 (64.7%)	4 (23.5%)	0 (0%)	0 (0%)	0 (0%)	1 (5.9%)	1 (5.9%)	17 (100%)
Q32. There is a transparent process for CHAI's selection of industry partners with which it engages.	6 (35.3%)	5 (29.4%)	2 (11.8%)	1 (5.9%)	0 (0%)	3 (17.6%)	0 (0%)	17 (100%)
Q33. I am comfortable sharing confidential information with CHAI.	8 (47.1%)	7 (41.2%)	1 (5.9%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	17 (100%)
Q34. CHAI has market knowledge that we cannot get from other sources and partners.	6 (35.3%)	5 (29.4%)	5 (29.4%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	17 (100%)
Q35. Please enter below any additional comments on the degree to which CHAI is or is not approaching its work in what you deem to be the right way.	Two stakeholders commented on this question – one from the field of HIV diagnostics and another who had worked with CHAI in a number of different areas: • One stakeholder felt that CHAI try to adhere to high ethical standards at country level but that country teams lack transparency and consistency.							

- One stakeholder noted that CHAI had done a good job in supporting introduction of second line ARVs and influencing country teams.

Right results

Question	Number of respondents (%)							
	a. Strongly agree	b. Somewhat agree	c. Variable	d. Somewhat disagree	e. Strongly disagree	f. N/A	No response given	Grand Total
Q36. We have refined the profile or characteristics of our products in development as a result of input from CHAI.	5 (29.4%)	5 (29.4%)	1 (5.9%)	3 (17.6%)	0 (0%)	2 (11.8%)	1 (5.9%)	17 (100%)
Q37. CHAI has helped streamline or clarify the global or country level regulatory pathway for new products.	4 (23.5%)	4 (23.5%)	3 (17.6%)	1 (5.9%)	1 (5.9%)	3 (17.6%)	1 (5.9%)	17 (100%)
Q38. CHAI has helped us understand/navigate the regulatory pathway for product introductions.	6 (35.3%)	2 (11.8%)	4 (23.5%)	2 (11.8%)	0 (0%)	2 (11.8%)	1 (5.9%)	17 (100%)
Q39. CHAI has accelerated field evaluations of new products.	4 (25%)	3 (18.8%)	2 (12.5%)	3 (18.8%)	0 (0%)	3 (18.8%)	1 (6.3%)	17 (100%)
Q40. CHAI helps maintain a broad supplier base.	5 (29.4%)	3 (17.6%)	3 (17.6%)	1 (5.9%)	0 (0%)	4 (23.5%)	1 (5.9%)	17 (100%)
Q41. CHAI helps us manage our capacity in relation to demand.	2 (11.8%)	2 (11.8%)	4 (23.5%)	2 (11.8%)	0 (0%)	6 (35.3%)	1 (5.9%)	17 (100%)
Q42. CHAI works effectively together with global partners (e.g. Global Fund, UNICEF, UNITAID, WHO)	6 (35.3%)	7 (41.2%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)	3 (17.6%)	17 (100%)
Q43. CHAI continues to have a major influence on pricing.	3 (17.6%)	7 (41.2%)	3 (17.6%)	1 (5.9%)	0 (0%)	2 (11.8%)	1 (5.9%)	17 (100%)
Q44. CHAI has an important influence on buying practices of major purchasers.	2 (11.8%)	7 (41.2%)	5 (29.4%)	0 (0%)	0 (0%)	1 (5.9%)	2 (11.8%)	17 (100%)
Q45. CHAI has important insight into demand and supply alignment.	8 (47.1%)	4 (23.5%)	3 (17.6%)	0 (0%)	0 (0%)	1 (5.9%)	1 (5.9%)	17 (100%)
Q46. CHAI contributes positively to healthy market dynamics.	9 (52.9%)	6 (35.3%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)	1 (5.9%)	17 (100%)
Q47. CHAI has helped us reduce costs.	1 (5.9%)	2 (11.8%)	4 (23.5%)	1 (5.9%)	1 (5.9%)	8 (47.1%)	0 (0%)	17 (100%)
Q48. CHAI has helped us reduce risks (e.g. of over/under production).	1 (5.9%)	5 (29.4%)	4 (23.5%)	3 (17.6%)	0 (0%)	4 (23.5%)	0 (0%)	17 (100%)
Q49. CHAI is effective at sharing its experiences across countries and globally, in support of overall learning of stakeholders.	7 (41.2%)	6 (35.3%)	3 (17.6%)	0 (0%)	0 (0%)	0 (0%)	1 (5.9%)	17 (100%)

Q50. The outcomes to which CHAI has contributed will be sustained without continuing CHAI support.	2 (11.8%)	3 (17.6%)	6 (35.3%)	3 (17.6%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	17 (100%)
Q51. In the absence of CHAI's support, change towards desired outcomes would have moved at a slower pace.	6 (35.3%)	8 (47.1%)	2 (11.8%)	0 (0%)	0 (0%)	0 (0%)	1 (5.9%)	17 (100%)
Q52. In the absence of CHAI's support, change towards desired outcomes would have been at a smaller scale.	5 (29.4%)	7 (41.2%)	3 (17.6%)	0 (0%)	1 (5.9%)	0 (0%)	1 (5.9%)	17 (100%)
Q53. CHAI has successfully increased access to health commodities in the short term.	5 (29.4%)	7 (41.2%)	2 (11.8%)	1 (5.9%)	0 (0%)	1 (5.9%)	1 (5.9%)	17 (100%)
Q54. CHAI works in a way which helps increase access to health commodities over the longer term.	7 (41.2%)	5 (29.4%)	3 (17.6%)	0 (0%)	0 (0%)	1 (5.9%)	1 (5.9%)	17 (100%)
Q55. Please enter below any additional comments on the degree to which CHAI is or is not achieving what you deem to be the right results.	Two stakeholders commented on this question, one from the field of HIV diagnostics and one from Malaria medicines: • One felt that the impact of CHAI's work since 2012 is not clear and that "short term gains seem to take precedence over long term sustainable markets." • Another highlighted the issue of quality in the ACT market. They felt that the focus of CHAI has been to have a quick impact on price, and there had not been sufficient consideration of the fact that ACTs are "high tech" products and so price has implications for quality. The stakeholder noted that manufacturers may decrease quality control to remain competitive.							
Q56. For those areas in which you believe CHAI can improve its practices, please provide suggestions.	Five stakeholders made comments in this area: • One stakeholder noted that CHAI sometimes overstates the influence it has on other stakeholders. • One suggested that CHAI could work more closely with buyers (donors) to purchase more qualified contraceptive products for women in developing countries. • One noted that CHAI had improved its analysis since 2010 and tried to draw on more expertise from industry with good transparency. This was felt to be something CHAI should continue, in terms of drawing on key experts from the private sector. • One suggested that CHAI should get more regular funding to strengthen its projects and continue its "good work". • One informant recommended that CHAI increase the frequency of its supplier meetings, and should also ensure that country teams understand the main goals and the needs of key partners.							

Annex H Survey data – Government and Other Stakeholders

Right things

Question	Number of respondents (%) a. Strongly agree	b. Somewhat agree	c. Variable	d. Somewhat disagree	e. Strongly disagree	f. N/A	No response given	Grand Total
Q4. CHAI has identified the areas of highest positive impact in which to engage.	45 (45.9%)	39 (39.8%)	10 (10.2%)	0 (0%)	4 (4.1%)	0 (0%)	0 (0%)	98 (100%)
Q5. CHAI appropriately considers its skills and comparative advantage relative to others when choosing its areas of work	33 (33.7%)	37 (37.8%)	18 (18.4%)	8 (8.2%)	0 (0%)	0 (0%)	0 (0%)	98 (100%)
Q6. CHAI conducts a comprehensive situation analysis, identifying root causes of problems, before proposing possible solutions or interventions.	31 (31.6%)	39 (39.8%)	18 (18.4%)	6 (6.1%)	0 (0%)	2 (2%)	1 (1%)	98 (100%)
Q7. CHAI considers the long-term implications of the interventions it supports.	32 (32.7%)	37 (37.8%)	20 (20.4%)	6 (6.1%)	0 (0%)	0 (0%)	1 (1%)	98 (100%)
Q8. CHAI works in transformative/catalytic rather than programmatic areas.	30 (30.6%)	33 (33.7%)	25 (25.5%)	3 (3.1%)	0 (0%)	1 (1%)	3 (3.1%)	98 (100%)
Q9. CHAI works in time-bound areas with a clear start and end versus areas requiring relatively longer term support.	29 (29.6%)	29 (29.6%)	26 (26.5%)	8 (8.2%)	0 (0%)	3 (3.1%)	0 (0%)	98 (100%)
Q10. CHAI's Supplier/Buyer meetings are useful to us.	27 (27.6%)	14 (14.3%)	14 (14.3%)	4 (4.1%)	0 (0%)	31 (31.6%)	2 (2%)	98 (100%)
Q11. CHAI price ceilings continue to be useful.	40 (40.8%)	19 (19.4%)	11 (11.2%)	4 (4.1%)	0 (0%)	19 (19.4%)	2 (2%)	98 (100%)
Q12. Please enter below any additional comments on the degree to which CHAI is or is not doing what you deem to be the right things.	Comments about **CHAI's work with government** were broadly positive, particularly in terms of the extent to which CHAI work on joint solutions. • CHAI support is based on gaps and a jointly agreed work plan (aid recipient/government employee); another positive comment about the extent to which they work with governments to identify joint solutions (implementer of technical assistance provider) • CHAI is flexible when handling priority guidance from MOH • They should be helping government make allocation decisions across interventions or diseases, rather than working within them (donor)							

There were more mixed views on CHAI's work in **capacity building:**

- One stakeholder noted that CHAI's support to national Technical Assistance is commendable (aid recipient/government employee); another made a similarly positive comment about the way that CHAI works with government and build capacity of government staff (aid recipient/government employee)
- However, there was a negative comment about the extent to which CHAI build capacity of government to use the systems they design. (implementer or TA provider)

Sustainability and long term change was noted as an area that required more focus:

- One recommended that an exit strategy should be discussed before the start of the CHAI programme in a country (aid recipient/government employee)
- Another suggested that CHAI need to focus on longer term health of markets, not only quick wins (donor).
- One stakeholder commented that sustainability is CHAI's biggest challenge

In terms of the areas in which they are engaging, and whether they are doing the **right things,** there were various comments and specific examples given:

- One respondent felt that CHAI are doing the right things (aid recipient/government employee)
- They have been critical in stimulating innovative approaches in HIV interventions in Nigeria
- They played an important role in developing/revising ART treatment guidelines towards global standards (implementer or TA provider)
- CHAI do many things right but could improve (donor)
- Sometimes what they do is helpful, but at other times they could do better at delivering on their commitments (donor)
- CHAI have been acting at a strategic level and negotiating with suppliers – both have been to a high standard although attribution is difficult. (donor)
- One respondent recommended that they should be more deeply engaged in communities
- Another recommended that CHAI focus on hot spots of high prevalence in HIV
- There were mixed views on the extent to which CHAI should be involved in areas like healthcare worker training. One respondent suggested they should support capacity building of HCW, whereas another (specifically in reference to LARCs) questioned whether this was the right role for CHAI or whether they should be operating at more of a strategic, planning and use of data level.

There were a number of suggestions that CHAI might focus more on **fewer, or more high impact areas:**

- One commented that CHAI seem to be in business development mode rather than impact mode – they seem to be focusing on less high priority interventions. They have become less strategic (Donor)
- One flagged that it is not clear the extent to which, in malaria, supply side activities have value add for manufacturers or the extent to which their activities have catalysed new entrants
- One respondent felt that CHAI does not prioritize target areas where support might be needed the most, but tries to engage in a wide range of things, which might not be needed or appropriate; similarly, another felt that CHAI could be a "great force" if they defined their role and didn't try to be everything.

Two respondents mentioned CHAI's **price negotiations:**

- In terms of price negotiations, it was noted by one implementer/TA provider that sometimes CHAI's price negotiations don't help the country because the criteria for procurement decisions are not based on purchasing the cheapest drugs
- However, another noted that the prices negotiated by CHAI have increased access

Four respondents commented negatively on the **quality of their analyses:**

- The quality of their analysis that lead to interventions have declined in recent years (donor)
- On the volume guarantee for 1-rod implants, manufactured by Merck, a more in-depth analysis, including on price and transition to the new NXT version, and forward looking, long-term analysis of risks would have been able to anticipate, mitigate current problems with the transition as well as better estimate impact on generic manufacturers and post-volume guarantee pricing issues. (donor)
- One stakeholder (implementer or TA provider) made a negative comment on the depth to which CHAI carries out its work
- One stakeholder noted that they are good at gathering and presenting information but that they need a more scientific appraoch to evidence generation.

There were comments on the capacity of CHAI staff, or issues with the staffing model or policies:

- In terms of individuals, one respondent noted that while some CHAI colleagues advance a CHAI agenda others are clear that they are supporting government priority areas (aid recipient/government employee)
- One respondent felt that CHAI has not fully aligned its skills mix with its mandate (aid recipient/government employee). Similarly, another (implementer or TA provider) made a negative comment on CHAI's choice of resources (human or financing). Two others felt that the quality of their in country consultants is very variable – with one noting that there is insufficient management oversight and support, and another noting that this negatively impacts their ability to have the "right results"
- It was noted by one respondent that there are no firewalls between staff working to benefit industry and those influencing government policy. There are also no employment policies with regards to ex-CHAI staff working at companies who have benefited from CHAI intervention

Six respondents commented on CHAI's approach to **working with external stakeholders**, with regards to issues such as **collaboration and transparency**:

- In terms of transparency, one respondent noted that there is no transparency on CHAI's principles of engagement, i.e. how they select the suppliers they work with. Another (a donor) noted that CHAI could be more productive if they worked more collaboratively, were more transparent, and coordinated with others better, and another donor felt that a willingness to collaborate, share information and tools, etc. are critical and welcomed, although did not make a specific comment on the current situation. One implementer/TA provider similarly said that collaboration would help ensure success of roll out (implementer or TA provider)
- Another donor flagged that CHAI have lately been more open to sharing the global agreements which previously were apparently held confidential, and that this had improved relations with stakeholders.
- One respondent noted that CHAI's strategy for stakeholder engagement is good but did not elaborate any further.

Right way

Question	Number of respondents (%) a. Strongly agree	b. Somewhat agree	c. Variable	d. Somewhat disagree	e. Strongly disagree	f. N/A	No response given	Grand Total
Q13. I have a good understanding of CHAI's core values and mission.	24 (24.5%)	40 (40.8%)	18 (18.4%)	8 (8.2%)	0 (0%)	4 (4.1%)	2 (2%)	98 (100%)
Q14. The skills and experience of CHAI staff are appropriate to the job they need to do.	31 (31.6%)	33 (33.7%)	20 (20.4%)	5 (5.1%)	0 (0%)	2 (2%)	3 (3.1%)	98 (100%)
Q15. CHAI's has appropriate management systems and internal communication to support its work.	22 (22.4%)	34 (34.7%)	10 (10.2%)	6 (6.1%)	0 (0%)	18 (18.4%)	4 (4.1%)	98 (100%)
Q16. The CHAI staff with whom I have interacted are politically astute/sensitive.	25 (25.5%)	38 (38.8%)	19 (19.4%)	5 (5.1%)	0 (0%)	2 (2%)	4 (4.1%)	98 (100%)
Q17. The impact of CHAI's work is reduced by turnover of its staff.	13 (13.3%)	17 (17.3%)	15 (15.3%)	25 (25.5%)	0 (0%)	11 (11.2%)	4 (4.1%)	98 (100%)
Q18. The quality of the CHAI staff with whom I have worked has been consistently good.	40 (40.8%)	26 (26.5%)	22 (22.4%)	4 (4.1%)	0 (0%)	1 (1%)	2 (2%)	98 (100%)
Q19. CHAI offers a neutral, evidence based perspective when it comes to making product choices (for example choosing ARV regimens and making diagnostic decisions).	30 (30.6%)	1 (1%)	31 (31.6%)	14 (14.3%)	2 (2%)	10 (10.2%)	3 (3.1%)	98 (100%)
Q20. CHAI course corrects/changes approach in response to new data or changes in context.	27 (27.6%)	39 (39.8%)	15 (15.3%)	3 (3.1%)	0 (0%)	7 (7.1%)	6 (6.1%)	98 (100%)
Q21. CHAI can be held accountable by partners for the effectiveness of its work.	23 (23.5%)	35 (35.7%)	14 (14.3%)	12 (12.2%)	0 (0%)	7 (7.1%)	3 (3.1%)	98 (100%)
Q22. CHAI's interventions are innovative in addressing the need/problem.	35 (35.7%)	1 (1%)	36 (36.7%)	15 (15.3%)	0 (0%)	2 (2%)	3 (3.1%)	98 (100%)
Q23. I am confident that the products and tools CHAI develops are technically sound.	37 (37.8%)	37 (37.8%)	14 (14.3%)	5 (5.1%)	0 (0%)	1 (1%)	2 (2%)	98 (100%)
Q24. I am confident that the products and tools CHAI develops are peer-reviewed or quality checked before presentation to others.	27 (27.6%)	36 (36.7%)	18 (18.4%)	4 (4.1%)	0 (0%)	5 (5.1%)	3 (3.1%)	98 (100%)

Q25. CHAI sees its work through until sustainable change has been achieved or another donor/implementer takes over the work.	16 (16.3%)	32 (32.7%)	26 (26.5%)	10 (10.2%)	0 (0%)	10 (10.2%)	2 (2%)	98 (100%)
Q26. CHAI builds in appropriate mechanisms to monitor impact and results of the interventions it supports.	20 (20.4%)	35 (35.7%)	17 (17.3%)	7 (7.1%)	0 (0%)	10 (10.2%)	6 (6.1%)	98 (100%)
Q27. When involved in new technology introduction, CHAI ensures that the technology is appropriate to the country's needs.	27 (27.6%)	36 (36.7%)	14 (14.3%)	6 (6.1%)	0 (0%)	9 (9.2%)	4 (4.1%)	98 (100%)
Q28. When involved in new technology introduction, CHAI works to ensure the technologies can be effectively utilised (e.g. ensuring that training is conducted or complementary commodities can be funded).	34 (34.7%)	31 (31.6%)	13 (13.3%)	5 (5.1%)	0 (0%)	11 (11.2%)	3 (3.1%)	98 (100%)
Q29. In my experience with CHAI, CHAI inflates/overstates its role or influence on the results achieved.	11 (11.2%)	23 (23.5%)	8 (8.2%)	23 (23.5%)	0 (0%)	3 (3.1%)	5 (5.1%)	98 (100%)
Q30. In my experience with CHAI, CHAI underplays/doesn't take enough credit in its role in the results achieved.	2 (2%)	16 (16.3%)	12 (12.2%)	33 (33.7%)	0 (0%)	4 (4.1%)	6 (6.1%)	98 (100%)
Q31. CHAI consults stakeholders appropriately when designing interventions.	24 (24.5%)	35 (35.7%)	17 (17.3%)	13 (13.3%)	0 (0%)	0 (0%)	6 (6.1%)	98 (100%)
Q32. CHAI seeks to co-ordinate its work with relevant stakeholders.	33 (33.7%)	35 (35.7%)	15 (15.3%)	7 (7.1%)	0 (0%)	0 (0%)	5 (5.1%)	98 (100%)
Q33. CHAI has been collaborative in attaining the desired outcome.	32 (32.7%)	37 (37.8%)	17 (17.3%)	5 (5.1%)	0 (0%)	0 (0%)	5 (5.1%)	98 (100%)
Q34. CHAI balances being collaborative with being disruptive of the status quo to catalyse change.	17 (17.3%)	38 (38.8%)	23 (23.5%)	6 (6.1%)	0 (0%)	3 (3.1%)	5 (5.1%)	98 (100%)
Q35. When modelling data to support decision making, CHAI's assumptions are realistic and feasible.	20 (20.4%)	39 (39.8%)	19 (19.4%)	6 (6.1%)	0 (0%)	2 (2%)	6 (6.1%)	98 (100%)
Q36. When modelling data to support decision making, CHAI's assumptions are transparent.	22 (22.4%)	38 (38.8%)	16 (16.3%)	8 (8.2%)	0 (0%)	1 (1%)	6 (6.1%)	98 (100%)

Q37. I have a good understanding of the source of CHAI's funding.	12 (12.2%)	23 (23.5%)	26 (26.5%)	17 (17.3%)	0 (0%)	7 (7.1%)	5 (5.1%)	98 (100%)
Q38. I have a good understanding of CHAI's mandate.	13 (13.3%)	40 (40.8%)	23 (23.5%)	9 (9.2%)	0 (0%)	3 (3.1%)	8 (8.2%)	98 (100%)
Q39. I have a good understanding of the range of work CHAI does.	18 (18.4%)	36 (36.7%)	25 (25.5%)	9 (9.2%)	0 (0%)	3 (3.1%)	6 (6.1%)	98 (100%)
Q40. I am easily able to get the information/data I need from CHAI.	30 (30.6%)	33 (33.7%)	17 (17.3%)	6 (6.1%)	0 (0%)	2 (2%)	5 (5.1%)	98 (100%)
Q41. CHAI manages data confidentiality appropriately.	32 (32.7%)	28 (28.6%)	11 (11.2%)	4 (4.1%)	0 (0%)	13 (13.3%)	7 (7.1%)	98 (100%)
Q42. There is a transparent process for CHAI's selection of industry partners with which it engages.	10 (10.2%)	23 (23.5%)	15 (15.3%)	8 (8.2%)	0 (0%)	28 (28.6%)	9 (9.2%)	98 (100%)
Q43. I am comfortable sharing confidential information with CHAI.	32 (32.7%)	22 (22.4%)	16 (16.3%)	6 (6.1%)	0 (0%)	8 (8.2%)	6 (6.1%)	98 (100%)
Q44. CHAI has market knowledge that we cannot get from other sources and partners.	20 (20.4%)	35 (35.7%)	22 (22.4%)	10 (10.2%)	0 (0%)	3 (3.1%)	6 (6.1%)	98 (100%)
Q45. CHAI works effectively together with global partners (e.g. Global Fund, UNICEF, UNITAID, WHO)	31 (31.6%)	38 (38.8%)	10 (10.2%)	3 (3.1%)	0 (0%)	0 (0%)	9 (9.2%)	98 (100%)
Q46. Question for government partners only: CHAI only finances the work – we design, implement and evaluate the intervention.	4 (4.1%)	11 (11.2%)	6 (6.1%)	5 (5.1%)	0 (0%)	29 (29.6%)	38 (38.8%)	98 (100%)

Q47. Please enter below any additional comments on the degree to which CHAI is or is not approaching its work in what you deem to be the right way.

Two respondents made comments that were related to CHAI's allocation of **resources:**

- CHAI has the ability to harness domestic resource – from the private sector – for National Programmes (aid recipient or government employee).
- CHAI does not only finance the work but also involved in design, implementation and evaluation of the work. Noted that it is rare for them (implementers or TA providers) to design activities and just request funding from CHAI.

Linked to this, there were mixed comments about the **alignment** of CHAI support with country level needs:

- One aid recipient or government employee commented that CHAI sometimes come with ideas and try to convince country teams to adopt the intervention without considering the country context. However, another noted that CHAI "listen to the opinion of MOH"
- One respondent highlighted that CHAI support to harmonization of the training materials on severe malaria case management had been good although that the process had been a bit delayed.

Areas for improvement were noted in relation to CHAI's **collaboration with partners** other than the MOH:

- One (donor) noted that, in Kenya, CHAI tends to work more alone with the MOH and could improve its approach to collaboration with other partners.

- One (donor) felt that collaboration had improved over time, perhaps as a result of the traditional players engaging with the agenda. The same respondent also felt that the balance of collaboration/disruption etc. varies by country and by context.
- One felt that CHAI are highly competitive in nature – and for example, will take on a new idea from another partner and not collaborate but instead go alone when they should work together with partners. The respondent felt that this means that CHAI end up undermining other people's work.
- A specific comment was made about CHAI Kenya, who were flagged as technically strong, but less politically savvy and that individual staff members could be pushy with partners.

Four respondents made comments about particular aspects of CHAI's work:

- CHAI's work in **price negotiations** was flagged by one stakeholder to have been very welcome and catalytic. However, the same respondent also noted that in CD4 or VL, short term wins had been prioritised over longer term gains and that this had resulted in reduced innovation and perhaps a sub-optimal product.
- One respondent flagged that the **demarcation of supply side and demand side work** is blurred.
- In terms of the market, one respondent noted that CHAI favours certain suppliers over others and can **skew the market –** meaning that some players get cornered out of the market.
- One flagged that CHAI has not facilitated for the consistent supply of PCR consumables and reagents for EID and VL – they have assumed leadership but **performed poorly.**

General comments were positive, but not elaborated:

- "CHAI is approaching its work in the right way"
- "CHAI have become an increasingly good and dependable partner."

Right results

Question	Number of respondents (%) a. Strongly agree	b. Somewhat agree	c. Variable	d. Somewhat disagree	e. Strongly disagree	f. N/A	No response given	Grand Total
Q48. CHAI helps achieve improved value for money (i.e. benefit from the services provided per the resources invested).	35 (35.7%)	1 (1%)	33 (33.7%)	17 (17.3%)	2 (2%)	1 (1%)	7 (7.1%)	98 (100%)
Q49. CHAI is effective at sharing its experiences across countries and globally, in support of overall learning of stakeholders.	32 (32.7%)	1 (1%)	39 (39.8%)	11 (11.2%)	2 (2%)	3 (3.1%)	6 (6.1%)	98 (100%)
Q50. CHAI has built capacity among implementing partners to sustain progress made.	14 (14.3%)	33 (33.7%)	25 (25.5%)	12 (12.2%)	0 (0%)	7 (7.1%)	6 (6.1%)	98 (100%)
Q51. The outcomes to which CHAI has contributed will be sustained without continuing CHAI support.	12 (12.2%)	21 (21.4%)	33 (33.7%)	21 (21.4%)	0 (0%)	2 (2%)	6 (6.1%)	98 (100%)

Q52. CHAI has helped partner countries to avoid stock-outs.	22 (22.4%)	31 (31.6%)	21 (21.4%)	7 (7.1%)	0 (0%)	8 (8.2%)	7 (7.1%)	98 (100%)
Q53. In the absence of CHAI's support, change towards desired outcomes would have moved at a slower pace.	28 (28.6%)	33 (33.7%)	22 (22.4%)	7 (7.1%)	0 (0%)	0 (0%)	6 (6.1%)	98 (100%)
Q54. In the absence of CHAI's support, change towards desired outcomes would have been at a smaller scale.	25 (25.5%)	29 (29.6%)	20 (20.4%)	11 (11.2%)	0 (0%)	0 (0%)	9 (9.2%)	98 (100%)
Q55. We are able to operate the tools or models CHAI has built without ongoing CHAI support.	13 (13.3%)	25 (25.5%)	18 (18.4%)	11 (11.2%)	0 (0%)	19 (19.4%)	8 (8.2%)	98 (100%)
Q56. CHAI has successfully increased access to health commodities in the short term.	29 (29.6%)	38 (38.8%)	16 (16.3%)	4 (4.1%)	0 (0%)	0 (0%)	7 (7.1%)	98 (100%)
Q57. CHAI works in a way which helps increase access to health commodities over the longer term.	24 (24.5%)	39 (39.8%)	20 (20.4%)	4 (4.1%)	0 (0%)	0 (0%)	6 (6.1%)	98 (100%)
Q58. CHAI has helped secure resources from major donors such as the Global Fund for AIDS, TB and Malaria.	25 (25.5%)	24 (24.5%)	12 (12.2%)	8 (8.2%)	0 (0%)	19 (19.4%)	9 (9.2%)	98 (100%)
Q59. CHAI's interventions build systems and capacity across disease areas where possible and appropriate.	25 (25.5%)	32 (32.7%)	15 (15.3%)	11 (11.2%)	0 (0%)	7 (7.1%)	7 (7.1%)	98 (100%)
Q60. CHAI has helped streamline or clarify the regulatory pathway for new products.	18 (18.4%)	27 (27.6%)	17 (17.3%)	9 (9.2%)	0 (0%)	14 (14.3%)	7 (7.1%)	98 (100%)
Q61. CHAI has accelerated field evaluations of new products.	19 (19.4%)	28 (28.6%)	16 (16.3%)	3 (3.1%)	0 (0%)	22 (22.4%)	8 (8.2%)	98 (100%)
Q62. CHAI is doing a good job of facilitating market entry of new products.	21 (21.4%)	25 (25.5%)	23 (23.5%)	4 (4.1%)	0 (0%)	0 (0%)	8 (8.2%)	98 (100%)
Q63. CHAI has given advice on product selection which has resulted in important savings.	23 (23.5%)	22 (22.4%)	23 (23.5%)	2 (2%)	0 (0%)	19 (19.4%)	8 (8.2%)	98 (100%)
Q64. CHAI has given advice on procurement process which has resulted in important savings.	25 (25.5%)	19 (19.4%)	26 (26.5%)	2 (2%)	0 (0%)	16 (16.3%)	8 (8.2%)	98 (100%)

Q65. Please enter below any additional comments on the degree to which CHAI is or is not approaching its work in what you deem to be the right way. Please enter below any additional comments on the degree to which CHAI is or is not achieving what you deem to be the right results	Three stakeholders commented about **specific achievements** in relation to CHAI's work: • One aid recipient/government employee highlighted the introduction of atazanavir/ritonavir as something CHAI had done. • Another respondent (implementer or TA provider) noted that CHAI had supported the inclusion of severe malaria indicators into DHIS. • One stakeholder noted that sometimes volumes are just not attainable – and that savings are negotiated after it has been agreed what the company needs to make in profit. **Alignment** was referenced positively by one respondent (a recipient/government employee), who noted that CHAI work with MOH on every decision. Three respondents commented on issues of **sustainability** in relation to CHAI's work with government: • CHAI is strongest in their country portfolios - supporting countries with registration/introduction of new products, concept note development, and TA to ministries. However, it is not clear that these changes are sustainable. • CHAI should consider long term sustainable models at the start of program support. • Sustainability is limited where CHAI do the work without building the capacity of the MOH to do the work. Two stakeholders made comments about CHAI's work with **partners:** • CHAI is selective about working with partners and could be more effective if they engaged critical partners earlier. • With reference to work in Kenya, one program implementer/TA provider noted that a lot of the achievements in Kenya are a result of a team effort between CHAI and partners. Two respondents made recommendation for **new areas of work** for CHAI: • One aid recipient/government employee noted that CHAI would need more funding to be able to do activities in other countries (Nigeria was identified as a malaria endemic example). • One programme implementer/TA provider recommended strongly that CHAI should bring its skills to TB/MDR-TB and HCV the same way it did for HIV.

Q66. For those areas in which you believe CHAI can improve its practices, please provide suggestions.	**Various recommendations were made by survey respondents, in relation to CHAI's work. These have been grouped below:**
	
	Selection of interventions
	• Two respondents commented on the process by which CHAI selects its interventions. One noted that CHAI should do stronger analysis before it selects its interventions, and vet those analyses with others, and another flagged that CHAI should be clearer on how it selects areas of work in country, and how this links up to supply side work on market shaping.
	• Two respondents suggested they be more focused and selective in areas of work, with one other noting that they should focus less on high profile and more on high impact programs. Similarly, three others suggested they have a defined work plan and specific area of support/mandate or be clear on their objectives
	• One respondent noted that CHAI need to deliver when they commit – "less on the talk more on the walk"
	• Various stakeholders flagged new areas of work for CHAI:
	  ○ Malaria: commodity support in severe malaria and seasonal chemoprophylaxis intervention
	  ○ Evaluation of non-HIV diagnostics POCs
	  ○ Work with a broader community to ensure a healthier market across product groups

- CHAI should look across health areas to support allocation decisions by government
- Support to areas of laboratory accreditation and strengthening systems
- More support for academics interested in research
- CHAI technical and financial support at regional hubs and branch offices

Collaboration

- Seven stakeholders directly talked about increasing collaboration with partners, for example to cross pollinate or increase synergy. One noted that there should be more collaboration, transparency and coordination of activities with donors and implementing partners, and another specifically highlighted that this should be without preselection. Another flagged stakeholders in access to medicines and civil society specifically.
- Two raised the issue of collaboration with government or end users, with one recommending that CHAI need to collaborate more with government authorities. Another noted the issue of introduction of new technologies and suggested that CHAI could be less forceful and more collaborative when it is introducing new products or technologies, and ensure that people are consulted.

Technical competence and other issues related to CHAI staff

- Various respondents raised the issue of CHAI competence or skills and the match with the tasks they are working on. Two flagged issues of the match of skills/expertise/capacity to tasks. Another recommended that CHAI should hire competent staff as much as possible and yet another noted that the skills of CHAI staff are highly variable. Similarly, another stakeholder flagged the need for CHAI to recruit the appropriate expertise and not just to rely on students to do the work for them – it was felt that this might increase a collaborative and system wider approach to their work. One person recommended that CHAI hire "*more senior home-grown, technologically competent, context knowledgeable staff from the host country."* They noted that too much of a presence of foreign staff may limit acceptance by local governments.
- It was recommended by one stakeholder that CHAI should have a more nuanced political skill set among CHAI staff – for example, recruiting leaders that are coalition builders and relationship managers. One other respondent just flagged "leadership and management" as a recommendation without further details
- There were some personality issues raised by a couple of respondents. One noted that some CHAI staff are seen as too pushy and indeed noted that turnover of staff could be a good thing in that case. Another noted that it could "*avoid the difficulties other NGOs face when working with Government by reducing its degree of arrogance and insensitivity*" (aid recipient, government employee)
- Two people commented that CHAI should work to prevent high staff turnover and retain good staff. Although one noted that this has improved over the past couple of years, they still flagged that CHAI had lost good people and suggested higher pay, promotion potential and other incentives to keep people at CHAI.

Confidentiality/transparency

- Eight respondents specifically raised transparency as an issue – for example, one suggested there could be more transparency in the way that savings are achieved, about CHAI's relationship with industry or about the intended use of the information. One noted that there should be a separation or "ring fence" of CHAI's work with the private sector from public sector interaction. Others just suggested that CHAI could "be more transparent" or similar, with no further details given.
- However, one informant noted that CHAI need to maintain confidentiality with sensitive information they get from governments. Similarly, another noted that CHAI's independence and willingness to stay as a quiet partner is one of the reasons it is trusted by governments

Sustainability

- Four respondents recommended improvements to CHAI's approach to capacity building – for example, that they should have more, longer term technical assistants to build capacity locally, should improve capacity of host country to own and sustain CHAI technological interventions, or should simply increase their focus on capacity building of governments as a priority. One further respondent noted that CHAI need to be more sensitive to the needs of governments rather than focusing on achieving CHAI milestones.
- In terms of specific areas for capacity building, one respondent talked specifically about building capacity in the area of supply chain – they felt that the support from CHAI currently, vis-a-vis the gaps and areas of need, is too little. Another noted that CHAI need to build capacity of government officials in the areas that they are strong in – such as analytics and data mining. Another recommended they do occasional mentoring, monitoring and evaluation when they leave to improve sustainability
- Others talked more broadly about sustainability issues. One flagged the need for proper exit plans and consideration of sustainability issues – focus on a system approach and work within existing regulatory framework. Another respondent similarly highlighted the need for greater consideration of sustainability at the onset of CHAI's interventions – limited life of CHAI interventions was highlighted as a current challenge. One respondent highlighted that CHAI should strengthen the national framework prior to roll out of its activities, and another noted that some grown innovations are needed.
- In terms of pilots, one respondent noted that where CHAI's intervention is not sustainable, it needs to be introduced as a pilot but with a long term plan, a priori, that is signed up to governments. Another flagged that pilots need to be done in multiple regions, and regions that are different to one another, so that when scaled up they can suit the whole country.
- One informant (donor) noted that CHAI does work towards sustainable outcomes and that where this is not achieved, this may not be in CHAI's hands

Lesson learning and sharing

- One respondent noted that having a decentralised, loose organisational structure means opportunities for knowledge sharing and cross fertilisation are missed. Another felt that CHAI could share experience and lessons learned and document good practice.

Annex I Country Case Studies

Introduction

During the evaluation's Interim Findings phase (January to May 2015) the evaluation team conducted 10 country case studies. Four of these centred around visits to the countries concerned: South Africa, Tanzania, Uganda and Zambia. Six were conducted remotely: Cambodia, Cameroon, Mozambique, Rwanda, Swaziland and Zimbabwe. During the Final Report phase (June to October 2015) a further 5 country case studies were conducted, 4 through visits (Ethiopia, Kenya, Malawi and Nigeria) and 1 remotely (India).

All of these case studies are summarised in this Annex, with the exception of Rwanda (which relates to the E2 component only, and is therefore covered in the separate E2 review reports).

Case study matrix

Geographic Distribution	*HIV Treatment*	*PoC HIV Diagnostics*	*Malaria Treatment*	*LARCs*	*VFM of HIV Spending (E2)*	*Visit plan*
Cambodia	•					N/A
Cameroon	•		✓	•		N/A
China						N/A
Ethiopia	•	✓		•	✓	Phase 2
India	•	✓				N/A
Kenya	✓	✓				Phase 2
Liberia						N/A
Malawi	✓	•	✓		✓	Phase 2
Mozambique	•	✓		•		N/A
Nigeria	✓		✓			Phase 2
Rwanda					✓	N/A
South Africa	✓	✓			✓	Phase 1
Swaziland	✓					N/A
Tanzania	•	✓		•		Phase 1
Uganda	✓	✓	✓			Phase 1
Zambia	✓	✓	✓		✓	Phase 1
Zimbabwe	✓	✓				N/A

Cambodia: remote country case study summary

Introduction

Data collection methods for the Cambodia case study included a desk review of key documentation (although this was very limited), and remote interviews with key informants at country-level. A total of seven people representing six organisations were interviewed, and the interviews were transcribed and analysed against the questions of interest.

CHAI's Market-Shaping Activity and DFID Support

CHAI has been working in Cambodia since 2005, and has a staff of 8 (including 3 Cambodian nationals). DFID funding during the period 2012–2015 was for a total of $232,786, of which $196,709 was allocated to HIV treatment;[202] therefore, this was the focus of the case study (Cambodia also received a small allocation of funding to malaria treatment in 2012).

[202] CHAI spreadsheet 'DFID2 Funding – Country Allocations – 02.02.16 Update'

Findings

The National Centre for HIV/AIDS, Dermatology and STDs (NCHADS)[203] is the key government counterpart for CHAI's work on HIV treatment in Cambodia. CHAI Cambodia is working with NCHADS on a number of different streams of work which are generally considered to be relevant to the needs of the organisation.

Much of the engagement with NCHADS in Cambodia seems to be centred on a technical assistance and capacity building function. The particular DFID-funded areas that were highlighted by the CHAI team were the scale-up of appropriate HIV treatment and second-line treatment optimisation – for example, supporting the shift to atazanavir/ritonavir.

CHAI has been supporting the government in the skills and tools for forecasting of need for antiretrovirals, and the capacity of the government to do this has reportedly increased over time; however, there is a continued perceived need for CHAI support. CHAI's work with the logistics unit of NCHADS is aimed at strengthening capacity in procurement and supply chain management (PCSM) – for example, through designing training.

CHAI is performing a TA function with the malaria programme – for example, working on the concept note development process, and is working together with other partners in the malaria space, acting as the technical agency in conjunction with implementing partners such as PSI as the Cambodia programme is working towards its goals of controlling malaria and eliminating artemisinin resistance. Other activities undertaken by CHAI include support to the launch of a nationwide public-private partnership for malaria (including a network of registered providers for drugs and diagnostics and case surveillance mechanisms).

Cambodia has a small (and shrinking) number of development partners and a reported absence of agency politics. A number of partners are engaging with CHAI, and noted that CHAI performs a coordination function among the development partners. Those interviewed were universally positive in their reflections on working with CHAI in Cambodia – their role is seen as complementary and non-overlapping to other development partners. CHAI is perceived to be a "trusted and valued partner" for NCHADS and indeed CHAI sees itself as a "thought partner" in terms of its advocacy function. While there were some areas for possible improvement identified (for example, a perceived lack of national staff), there were a number of comments on the responsiveness and capacity of CHAI staff, and the flexibility of their funding was highlighted as a positive and useful contribution.

Key successes in the field of HIV treatment include the scale-up of coverage of ART, and the more recent shifts in regimens to optimise treatment and phase out toxic products such as d4t. CHAI has supported the government to take a more evidence-based approach to HIV treatment, facilitating the operationalisation of WHO guidelines and providing training and support to healthworkers. They have contributed to the successful phasing out of suboptimal treatment regimens in a manner that avoids significant wastage, with associated reported cost savings.

Given the reducing development partner presence and funding in Cambodia, sustainability is a critical issue in Cambodia. While there are some reports that capacity is being built among the government, it is not completely clear how the positioning and close engagement of CHAI international staff are informing a longer-term exit strategy.

Cameroon: remote country case study summary

Introduction

Data collection methods included a desk review of key documentation, as well as a series of interviews with key informants at country-level. A total of 9 stakeholders representing 7 organisations working in malaria were interviewed; of these one was internal, three were connected stakeholders, and 5 were external partners. Phone interviews were conducted between 20 March and 27 April 2015 by the evaluation team's lead on malaria, partially in French.

[203] The body within the Ministry of Health (MoH) with responsibility for the health sector response to HIV in Cambodia

CHAI's Market-Shaping Activity and DFID Support

CHAI has operated in Cameroon since 2011. The current 3-year DFID market-shaping grant to CHAI Cameroon is $1,366,697 of which the majority is spent to support CHAI's work on malaria diagnostics (not covered by this evaluation) and to a lesser extent on malaria treatment. In 2014 the DFID market-shaping grant comprised 15.6% of CHAI Cameroon's overall budget; other donors are SIDA (health financing), BMGF (vaccines and LARCs), MoH using US Government funds (PMTCT), CBCHB using USG funds (PMTCT PoC CD4, paediatric ART, supply chain) and UNITAID (implementation of injectable artesunate).

CHAI has provided technical support with respect to the adoption of the new WHO guidelines for the preferred treatment of severe malaria by providing evidence from other countries and cost-analyses of the implication of switching to injectable artesunate for Cameroon; brokered partnerships and facilitated coordination between partners and the MoH/NMCP by funding and organising meetings; and in the process has likely transferred skills and built capacity of the government.

Findings

CHAI was credited with having a good understanding of value of and obstacles to antimalarial scale-up and of their own role, and having the mandate and credibility to conduct the activities they are involved in. They are seen as providing technical and financial assistance, but were said to sometimes get involved in areas that are not their expertise, i.e. procurement, M&E and communication. One important driver of adoption of injectable artesunate in Cameroon is creating demand among health staff and communities, as uptake is fully demand driven (as opposed to the case in Uganda, for instance). CHAI has been involved in training of health workers, but communication and awareness campaigns are not directly CHAI's mandate. Overall, they have established and maintained relationships with key actors from the government and development partners, and assembled and disseminated key information. They have shown a strategy for engagement that reflects other existing interventions, mainly the UNITAID MMV grant as CHAI is the key implementer in Cameroon. However, the provision of information on CHAI's own activities – in terms of work plans or country strategy – was described as lacking transparency, and both the NMCP and partners expressed the need for CHAI to strike a balance between fully supporting the government with its activities vs sharing, agreeing upon and monitoring annual work plans to ensure accountability and avoid duplication of activities.

CHAI has played a role in the adoption of injectable artesunate for the treatment of severe malaria in the national guidelines, and influenced this change in policy with data and evidence, mobilisation of funding – UNITAID (funding conditional on policy change), drafting the Global Fund Concept Note – training materials, and training of health workers.

The implementation of injectable artesunate is described as slow, and still very few patients with severe malaria benefit from the more effective treatment. If new purchase orders scheduled for later this year are postponed, the target figure of 1.6m vials of injectable artesunate procured in Cameroon by the end of the project will not be reached.

Ethiopia: country case study summary

Introduction

The Ethiopia case study was conducted through a country visit between July 13th and 17th 2015. The EvT reviewed relevant documents, and collected quantitative and qualitative data from secondary sources and interviewed 22 KIIs representing 9 organizations, including 5 from CHAI and 1 from DFID.

CHAI's market-shaping activity and DFID support

CHAI Ethiopia has 7 programmes funded by a variety of donors and has received $1,283,645 under the DFID grant to work on 3 areas covered by this evaluation – HIV treatment, HIV PoC diagnostics and HIV financing (E2) – and MDR TB. This work is relatively limited for CHAI Ethiopia, compared to other much larger grants, for example BMGF support to immunisation work.

Findings

CHAI has provided valuable support to the Ethiopian Health system in its HIV/AIDS related diagnosis and treatment plans as it moves from treating 375,000 to 500,00 patients within the context of a 25–40% funding gap for its strategic plan.

- The DAT program has supported introduction of ATV/r, supported capacity development of the PFSA system, supported expansion of PMTCT from 1000 to 2500 sites, supported access of diagnostic and treatments for cryptococcus meningitis treatment for PLHIV, and implemented IPLS system capacity building. DAT has also done business development work under the DFID grant, focused on schistosomiasis control, viral hepatitis and pharmacy mentoring. As part of E2, CHAI has undertaken resource mapping and costing of the HIV program and has supported the case for funding reallocations.
- The HIV diagnostics team (well respected) has distributed 87 UNITAID funded PIMA POC diagnostics machines, 36 of which arrived in March 2015. CHAI helped with rational approach to site selection (overridden by regional health bureaus, against TWGs recommendation), helped to develop the CD4 testing guideline with other TWG partners like EPHI and CDC, conducted onsite Master TOT trainings and cascade trainings at regional and facility levels, supplied cartridges and supported connectivity solutions. CHAI has provided a useful negotiating partner to government in dealing with suppliers, and has facilitated new product entry through supporting field evaluation of second to market BD FACS Presto. There is some evidence that Pimas are have not been functioning, especially in rural areas. Reagent distribution issue flagged – "rescue" reagents being provided by PEPFAR partners. Strong momentum towards VL, already high access to lab based CD4, and recent field testing of second to market BD product call into question wisdom of March 2015 placement of 36 additional Pimas.
- CHAI is heavily involved in lab strengthening beyond PoC focused work: quantification processes for reagents and consumables (provision of Forlab training), DBS piloting, and costing of options for alternative sample transport systems (for both HIV and TB).

Conclusions

CHAI is achieving the project objectives and is also extending into health system strengthening work more generally (PFSA, IPLS) and leveraging DFID funds towards grants from other funders. Many innovations and lessons learned in Ethiopia could be useful to other countries (sample transport system, negotiations with diagnostic suppliers, data management system being developed for equipment maintenance, Pima impact data). CHAI has only shared this internally or with UNITAID; this limits efficiency of the overall global health system. CHAI's work is not always visible outside its tight inner circle, leading to some ambiguity as to its role and mandate as well as its funders. CHAI should clarify its mandate and its funders with important leaders and other stakeholders.

India: remote country case study summary

Introduction

An epidemiologically important country India, the second largest country in the world, has the third highest HIV burden (2.1 million PLHIV) in the world. Present coverage of ART for adults and children is 67% (CD4 < 350) and the country is moving to the new 2013 WHO guidelines. The current National Strategic Plan for HIV (NACP IV) prioritizes appropriate key areas for India including: 1) preventing new infections, especially among key populations; 2) PPTCT; 3) demand generation for HIV services: 4) comprehensive care, support and treatment; 5) reducing stigma and discrimination; 6) de-centralization of services; 7) building NGO and civil society capacity; and 8) integrating HIV services with health systems in a phased manner.

CHAI's market-shaping activity and DFID support

DFID provided £723,664 during this grant to support CHAI India's demand side support of NACO in two of the programme areas, 'Accelerating Introduction and Scale-Up of Point-Of-Care HIV Diagnostics' and 'Maximizing Value for Money and Ensuring Sustainable Supply of HIV Treatment', as well as a small amount of DFID funding for market-shaping work for MDR TB. The EvT was also told of funding for CHAI India's supply side work (GBP 211,790) though this is not included in the market-shaping grant breakdown.

Findings

In HIV diagnostics, CHAI presented data and advocated with national leaders and stakeholders to consider PoC testing as a means to reduce LTFU and extend the reach of ART services. CHAI subsequently supported

the implementation and monitoring of a 20-site pilot with Pima. The Pima devices were bought with UNITAID funds under the paediatric project which ended in 2010.204 CHAI shared data with the ET to show that the pilot reduced TAT, increased the frequency of testing, reduced dependence on sample transport and reduced the skill requirement of health personnel. CHAI headquarters estimates that at present 22,000 tests are conducted per year with the 20 Pimas (against an expectation for this year of 31,500). While original CHAI projections for specific countries have not been provided to the evaluation team, it is probable that uptake has been much slower than Chai had anticipated. GoI agrees that uptake was slow at first and attributes this to staff changes at Alere and at NACO as well as initial difficulty getting an acceptable price from Alere. Given the pilot's success, CHAI has successfully advocated for further scale up of PoC and has supported NACO in budgeting for procurement of 300 additional devices under GFATM grant. CHAI is supporting NACO in drawing up rational scale plans, to complement the existing conventional CD4 testing network. CHAI has mapped all the 500 ART centres, along with their patient loads, to inform site selection for further PoC CD4 placement. CHAI expects to support the evaluation of additional, near to market PoC CD4 devices for regulatory licensing, so as to inform adoption of the most efficient option. CHAI is also assisting NACO in drafting technical specifications requirements for PoC procurement which will inform the tendering. Towards sustainability, CHAI is working with NACO to harmonize processes for regulatory licensing and program evaluation, thereby requiring fewer rounds of evaluations for a new product. This will not only enable earlier adoption of the PoC EID and VL technologies in future, but will also reduce NACO's reliance on partners for a vendor independent evaluation.

CHAI's viral load work is out of the evaluation scope, however as context, CHAI has been actively working on a cost benefit analysis, looking at different models of scale up, including. public vs. private options. VL scale up has been slow in India; according to stakeholders, this has been due to lack of funds, and previously high price of devices. However, given the new VL global access price announced (CHAI negotiated) and the start of India's new GF grant in October (CHAI supported the budgeting for the concept note), scale up plans are in motion. CHAI is also supporting NACO's study to see whether DBS can be used instead of plasma for VL, which would ensure ease of scale up through simplified sample transport and reduced cost. CHAI has also supported NACO in drafting the Request for Proposal (RFP) for inviting bids and drafting of national guidelines for VL testing. Given the need to co-ordinate and optimise VL and CD4 capacity, CHAI is developing site level patient load based projections for the number of VL and CD4 tests that would be required in the future to help make a capacity utilization based case for platform selection for both tests at each facility.

CHAI's HIV treatment work has focussed on strengthening the supply chain and getting more paediatric patients under the treatment net. Towards the latter, CHAI has supported NACO in planning scale up of the number of patient touch points. Mother-baby pairs have to travel greater distances for testing, which is a large barrier to access. CHAI's data driven advocacy demonstrated high concordance between DBS and WB testing and led to revision of the EID testing algorithm in March 2015, so that DBS is being used for confirmatory testing as well; this reduces the number of visits for mothers and is expected to lead to reduction in LTFU. CHAI also conceptualised, developed and implemented an information management system to facilitate tracking of infants and improve retention in care. The system also helps to dynamically monitor the program and identify bottlenecks. At present, CHAI is working on delivering test reports digitally to reduce the Turn-around Time to ART initiation for infants through reducing time for report delivery from several days to minutes. Furthermore, CHAI supported NACO in developing a national plan for rollout of WHO option B+, as well as supporting the initial training of trainers across the country.

NACO runs one of the largest programs in the world and manages an extensive supply chain. Yet, the systems used to manage the supply chain were manual and paper-based resulting in large scale wastages, stock-outs, and issues with tracking and validating supplies from suppliers, which in turn delays payments to suppliers. CHAI analysed of NACO supply chain and designed a bar-code-enabled web-based Inventory Management System (IMS) that provides real-time visibility of inventory levels for all centrally procured commodities at all levels of the distribution and service delivery system. The ART management system supported by Chai is ART specific; this is appropriate given the fact that the facilities are HIV specific, however MoH has directed that IMS be implemented for the national TB and malaria programme as well. An internal

[204] This was not part of the UNITAID PoC grant. India was a part of the UNITAID paediatric project in 2010. Within the UNITAID paediatric project, CHAI had commodity funding to support scale up of drugs and diagnostics needed for paediatric HIV treatment. CHAI was able to evaluate and pilot the use of POC CD4 under the UNITAID paediatric project in a number of countries using the commodity budget to purchase PIMAs.

evaluation with higher authorities in NACO made 3 recommendations 1/ Move IMS from CHAI management onto the GoI server 2/ Scale IMS to other facilities (currently 300) to 500 ART centres, and subsequently to 10,000 testing centres. 3/ Scale IMS to other diseases e.g. TB. GoI will fund these next steps. CHAI is providing an important contribution to the GoI's national objectives to decentralise and extend diagnostic and treatment services, and has demonstrated innovation in its approach to TA.

Conclusions

In support of the NACP IV aims to reduce new infections by 50% and provide comprehensive care, support and treatment to all people living with HIV by 2017, CHAI has made particularly important contributions towards demand generation for HIV services, comprehensive care, support and treatment; de-centralization of services; and integrating HIV services with health systems in a phased manner.

Kenya: country case study summary

Introduction

The current Kenya Strategic framework (KASF 2014–2019) includes a significant shift from a general population response towards a key population and geographically targeted response, and strategies to increase PMTCT uptake and increase coverage in HIV treatment and care, in line with adoption of the WHO eligibility criteria of CD4 <500 coverage.

CHAI's market-shaping activity and DFID support

The total amount from the DFID grant allocated to CHAI's work in Kenya was $1,133,911. The relevant areas for this evaluation are CHAI Kenya's HIV treatment and PoC CD4 diagnostics work, to which DFID has provided $689,636 during the 3-year grant (75% for HIV treatment).

Findings

In HIV treatment, CHAI has supported normative and policy work at central levels, providing cost effectiveness data to the government in support of regimen choices for first and second line ARV treatment. CHAI has supported programme management activities in the transition to new regimens – supporting drafting of revisions to policies and guidelines. Towards supply security, CHAI staff have tried to ensure alignment of supply and demand during a phased transition, however CHAI staff report a reduced insight into the supply side, and communications with suppliers, now that CHAI is no longer buying. CHAI has also supported the operational side of transition to new regimens - ARV forecasting tools used in Kenya have been developed by CHAI, and CHAI has also financed and contributed technically to logistics management, dosing charts and development/piloting of an ART dispensing tool. This work has been largely transitioned to government now.

CHAI's overall diagnostic work has focused financial and technical support on a wide range of activities supporting new product introduction at a country level. CHAI liaised with the regulatory authorities to ensure that new diagnostics are registered in the country for use and supported new product evaluation of three new POC CD4 products and one PoC VL product. CHAI provided financial and technical support to policy and guideline drafting. CHAI supported rational decision making about product uptake and placement choices of Pima and advocated with county officials to secure political will to allow sites to be used. A total of 113 PIMA devices that have been deployed in the country, 57 these that were purchased through the CHAI-UNITAID grant and deployed in April 2015 and earlier Pimas purchased by PEPFAR which were deployed by Chai at the pilot stage to develop a strategy for POC prior to UNITAID devices arriving in the country. CHAI has provided operational support to introduction, such as technical analytical support for the establishment of harmonized HIV lab procurement system through tracker, financing health worker training on new PoC use, financing the data connectivity solutions to allow better information management and performance accountability. A process of integration of the Laboratory Information System (LIS) with the CHAI-financed and managed data connectivity solution (called a dashboard) is being worked on, to ensure that the dashboard is fully owned by the government. CHAI reports that the average time to treatment initiation at Pima sites was reduced by 16 weeks (from 18 weeks to 2 weeks) although the evaluation team was not provided with any data to validate this statistic and there are no publications.

CHAI uses data and information to aid decision making in policy committees at the ministry, facilitates discussion between suppliers of laboratory reagents and diagnostics with the government officials, and brings on new information about the global prices of diagnostics and regimens. By supporting the product evaluations

of other diagnostics, CHAI has enhanced competition and has increased supplies to all government facilities. The next challenge will be to facilitate wider use of these evaluations beyond Kenya, in order to improve overall efficiency of the global evaluation system. Several stakeholders thought that CHAI staff would benefit from a deeper technical understanding when working on TWGs. CHAI has appropriately adjusted its approach and is working more with technical managers of different programs, which has enhanced coordination, acceptability and implementation of activities. CHAI presented a cost benefit analysis as a rationale for change of policy LPV/r to ATV/r, and wanted the government to move faster to change treatment based on the cost rationale. However, NASCOP insisted on the normative consultative process, including exploring all options with the wider stakeholder group.

CHAI does not prioritize having its logos included on projects towards which it has contributed, preferring for the MoH to take full ownership and credit. CHAI also has a reputation for effective transfer of activities over to government, as was seen for example with regard to the transfer of paediatric ARV procurement management. CHAI also has more flexible funds which have been creatively used by Nascop to plug the gaps that are not supported by other partners. As opposed to CHAI's way of working in other countries in the region, CHAI Kenya does not have seconded staff to different government departments. Instead, CHAI coordinates its work within the office providing ad hoc support to the MOH programs as and when needed most especially through the TWGs. CHAI also works effectively with implementing partners of PEPFAR, including at county level where Chai has trained staff and placed different PoCs within CHMTs. CHAI's approach to work is on the whole well appreciated by all stakeholders. CHAI is engaged in many activities but this causes some stakeholders to be unclear about CHAI's mandate. Three independent stakeholders raised a concern in relation to Chai developing tool prototypes without adequate consultation,205 and then expecting others to implement these. This highlighted a challenge which can arise when MoH gives Chai a mandate to do something and Chai proceeds, with less emphasis on consulting with other stakeholders who will be affected by an intervention. Similarly, Chai does not have a strong direct linkage or strong working relationship with KEMSA, the government body in charge of procurement of commodities. This means that some of the good work supported by CHAI through NASCOP might not effectively translate to better commodity management especially given the fact that KEMSA will be assuming a larger mandate in the procurement and supply of ARVs, diagnostics and other supplies with the exit of Kenya Pharma.

CHAI continues to operate the dashboard on behalf of the Nascop and it is sometimes referred to as the 'CHAI dashboard'. While demonstration of the dashboard's value has already resulted in PEPFAR indicating a willingness to continue meeting the costs of maintaining the systems and infrastructure, different partners expressed concerns about its sustainability in terms of government's ability to manage and continue to develop the platform as well as their ability to fully analyse and interpret the data arising from it. Consultation around the dashboard's development was also criticized from country as well as global level stakeholders, who observed that it could have been much more useful if donors and support partners had been consulted on what data would be useful, for example LTFU data linking diagnostics to a subsequent visit. The data systems were not structured to get that LTFU data, so cannot verify if the programme is achieving right place, right time diagnosis.

At national level, significant achievements have been made in the area of HIV treatment and diagnostics; the particular contribution of CHAI and attribution is a challenge. Data was not available on the contribution of Pimas to the overall CD4 testing volume in the country. There are 113 Pima devices in Kenya and 18,112 tests have been performed on those devices between Jan and Sept 2015, which is well below the target provided by CHAI headquarters of 268,000 by August 2015. It is estimated that $300,000 is being saved each month from the switch to ATV/r for second line, or $3.6 million per year. The evaluation team was not able to verify with procurement agency that these savings are actually being achieved.

Conclusions

CHAI's work appears to be successful in chipping away at the big, strategic problems in Kenya such as scaling up coverage, in particular among paediatric patients. CHAI is helping to save funds, for examples through

[205] CHAI responds that it does not develop tools of its own volition, it is based on an identified need, usually by MoH. Most times, CHAI actually takes existing tools and improves them as part of a wider consultation. CHAI can't develop its own tools because we don't work at facility level an important fact to recognize. In the same way that Kenya Pharma is no longer a contractor of the US government today CHAI is alive to the fact that anything developed in isolation gets lost with every transition. The only difference is that CHAI is willing to on occasion move faster that other partners with the sole objective to meet the treatment targets and objects that have been agreed upon for example those highlighted in the opening paragraphs of this document.

price savings on SLDs and diagnostics. CHAI is also supporting efficiency gains, example by consolidating regimens and avoiding waste by improved link of testing to treatment. CHAI has not documented and disseminated lessons learned from its significant successes and innovations in the diagnostics field; this is a missed opportunity to contribute to global public goods.

Malawi: country case study summary

Introduction

The Malawi case study for this evaluation was conducted in June and July 2015. Following an initial review of CHAI documentation, a country visit was undertaken over 5 days, and this was supplemented with follow-up interviews as appropriate. 24 individual key informants were interviewed, some from the same institution or department. The majority of key informants were 'connected' to CHAI and worked directly with them.

CHAI's market-shaping activity and DFID support

The areas of CHAI Malawi's work supported by the DFID market-shaping grant, and covered by this evaluation, are: HIV Treatment, which was allocated $531,691; HIV PoC Diagnostics, allocated $116,922; E2 (i.e. HIV Financing), allocated $640,189; and Malaria Treatment, allocated $330,143.

Findings

- A lot of people, including CHAI's principal partners, are unclear about what CHAI is doing and what its strategic priorities are. There is a sense that many of CHAI's interventions are short-term – their target is met and then they move on.
- CHAI staff are seen as generally rather young, energetic, smart, and hard working, but not always experienced. Turnover is perceived as very rapid. CHAI skills in using Excel and in crunching numerical data are seen as being exceptionally strong. CHAI is perceived as adding value to work on quantification, forecasting and costing. The CHAI Country Director role has recognised gravitas, strengthening CHAI's convening power, though not all stakeholders feel adequately consulted or engaged by CHAI.
- Some stakeholders perceive a tendency for CHAI to put pressure on the MoH to do things that might not be high priority or appropriate at the time. This may be the flip side of CHAI's sense of "urgency".
- Support to development of Guidelines (for e.g. PoC diagnostics, malaria case management) and related training is valued, as is CHAI's strong focus on strengthening information systems (e.g. labs, logistics).
- CHAI costing and drafting input to the Global Fund Concept Notes appears to have helped Malawi secure vital funding. However, concerns remain about the NSP costing methodology, whether plans are feasible (e.g. 90-90-90 targets, test and treat), and the loss of focus on HIV prevention. There's a need for broader costing and modelling work, to establish longer-term costs and impacts.
- CHAI has provided business strategy and management systems support to the Central Medical Stores Trust (CMST) through the HIV Treatment programme area. Stakeholders already perceive positive change, though recognise that full reform may take some time.
- Several people questioned the approach taken to rolling out CD4 PoC (Pima) – site selection, balance of investment in this vs other diagnostics interventions (particularly sample transport) – and there is a desire to learn from this as PoC technologies for EID and VL monitoring are rolled out.
- When products are procured by CHAI, it's not always clear how broader system issues are going to be handled e.g. service contracts and consumables for diagnostic machines, warehousing and distribution for malaria treatments (Inj AS).

Conclusions

Recommendations to CHAI

- To help increase the sustainability of CHAI's work in Malawi, consider recruiting additional Malawian graduates/postgraduates – to boost CHAI's local networks, understanding of local context, and continuity for partners; and seek to identify and strengthen teams at MoH (or elsewhere) that could be future custodians of databases and analytical tools; also Malawian institutes that could provide long-term analytical support to MoH (including assistance in using complex Excel spreadsheets.
- To stimulate local innovation and increase impact from CHAI's (and DFID's) investment, explore opportunities to link people and initiatives across programme areas.

- To help local development partners understand CHAI, and to build mutual trust and accountability, develop a website (or at least a series of pages on the CHAI corporate website) to outline CHAI's goals and activities in Malawi, and a brief factsheet about CHAI's programme strategy and current activities.

Recommendations to DFID:

- Strengthen communication flows between DFID HQ and DFID Malawi, to ensure the co-ordination of different funding streams and activities undertaken with CHAI.
- Facilitate country-level feedback to triangulate the reporting of results by CHAI in Malawi. CHAI Malawi and DFID Malawi could meet (with DFID HQ joining by telephone if feasible) every six months to improve understanding and alignment.

Mozambique: remote country case study summary

Introduction

CHAI's market shaping activity in Mozambique was studied remotely, by telephone and email. The EvT conducted a literature review and approached key informants (KIs) recommended by the local CHAI and DFID country offices, as well as others suggested by those KIs. CHAI supplied its Country Program Summary for 2014-15.

CHAI's market-shaping activity and DFID support

CHAI has been active in Mozambique since 2002 and currently works on five themes: commodities and equipment; new technologies; information systems and connectivity; mentoring and service integration; and the supply chain (including with Coca-Cola). The work is focused on five patient life stage, all within the maternal-child health (MCH) continuum, rather than by disease area: family planning; ante-natal care; birth; post-natal care; 0-5 years. Under the DFID grant, HIV PoC Diagnostics work in Mozambique has been allocated $347,524.

Findings

- CHAI has focused well on severe challenges to the health sector;
- There is close interaction with MoH at national, provincial and district level, though without secondment, as used in other countries by CHAI;
- HIV diagnostics has been the area where CHAI has made the most impact, where point of care (PoC) technologies have transformed capabilities;
- CHAI has supported the scale-up of paediatric HIV treatment, with this activity closely linked to the diagnostic programmes;
- CHAI has addressed health system issues which represented a challenge to the distribution (initially of HIV diagnostics but then more widely) in a systematic way;
- There is significant contribution by CHAI in Mozambique to CHAI's global logframe output indicators.

Conclusions

In conclusion, CHAI has acted in a dynamic fashion to define and address key obstacles to the use of relevant health care commodities in Mozambique. Impressively, this has in turn led CHAI to seek to address some of the severe health system strengthening issues encountered in this process. CHAI's Involvement with MoH has been effective, even if relations with other development partners are more varied. PIMA (HIV diagnostic), in particular, represents a successful piloting/scale-up cycle, delivered jointly by CHAI and the national public health institute. While CHAI has certainly contributed to improved outcomes, attribution is as always a challenge. CHAI has also shown itself to be a useful and collaborative regional stakeholder.

Nigeria: country case study summary

Introduction

The Nigeria case study was conducted through a country visit between July 5–11, 2015. Data collection methods included a desk review of key documentation and interviews with key informants. A total of 51 stakeholders representing 20 organizations were interviewed, including 7 from different CHAI teams and 1 DFID health advisor.

CHAI's market-shaping activity and DFID support

DFID's market-shaping grant for CHAI Nigeria was $2,005,627 for the 3-year period. Of this, $373,537 was used to fund activities on malaria treatment, $1,241,925 on HIV treatment, and $44,276 on HIV diagnostics (the remainder was for MDR TB and malaria diagnostics, not included in this evaluation).

Findings

Overall, CHAI's work in malaria and HIV can be characterized by providing TA to the government, focused on general coordination and operational support, resource mobilization and commodity management, through activities aligned with national priorities and strategies.

CHAI has played a leadership role in supporting the adoption and roll-out of injectable artesunate as the preferred treatment for severe malaria. The drug is procured by both government and donors (and included in national and state EMLs) demonstrating national ownership, with training (funded by UNITAID) in several high-burden states. In terms of impact, the 3 million vials procured during the grant period would save a total 11,500 lives, assuming drug availability, uptake and patient access. There are some concerns around uptake, as the new medicine is scaled up very rapidly.

For HIV treatment, CHAI has focused on the change in guidelines from LPV/r to ATV/r for second-line treatment. Since the guideline change in early 2013, uptake of ATV/r has gradually increased, and a third of all patients on second-line ARV treatment now use ATV/r, with cost-savings of around $0.5m. The uptake has been slower than expected due to shortages of ATV/r towards the end of 2014.

CHAI has done very limited work on HIV diagnostics, despite its extensive experience in this area following the implementation of the UNITAID lab commodities grant. The lab system was described as 'being in shambles' and as the 'Achilles-heel of the HIV program', and it seems like a missed opportunity for CHAI not to have devoted more resources and attention to it.

Overall, CHAI was very positively perceived by almost all partners, and said to have improved its way of working over recent years. It is seen as a neutral partner, which facilitates collaboration with government and partners alike. It was found to balance being collaborative and being disruptive, and to share information and methodologies with partners.

Conclusions

Recommendations to CHAI:

- Prioritize activities focused on supporting the national HIV-laboratory system, including but not limited to reinvigorating the HIV Laboratory Technical Working Group
- Support the monitoring & evaluation and supervision of uptake and quality implementation of injectable artesunate, incl. inclusion of relevant indicators in the DHIS and rational use
- Consider embedding CHAI staff within the Ministry of Health offices at national and state level
- Set up a more systematic way of capacity building and skills transfer activities (i.e. quarterly trainings on commodity management)
- Focus not only on technical but also political stakeholders by further engaging State Governors in CHAI's activities to ensure increased ownership and contribute to sustainability
- Expand CHAI's work on the LMCU to other states beyond Nasawara and Cross River
- Involve State Ministries of Health in design, implementation and monitoring of CHAI's work plans
- Maintain a healthy balance between branding of CHAI while ensuring not to over-claiming credits
- Apply the CHAI model to activities promoting the adoption of medicines for patients suffering from hepatitis

Recommendations to DFID:

- Clarify lines of communication and reporting between CHAI Nigeria, DFID Nigeria and DFID HQ
- Continue and expand funding to CHAI to extend TA and/or implement activities in areas identified

South Africa: country case study summary

Introduction

The field visit to South Africa took place from 1st February to 7th February 2015, mostly in Pretoria and Johannesburg. The methodology consisted of a desk review of relevant documents, interviews with key informants (n= 29) as well as visits to CHAI-SA office, DFID Southern Africa office, National Department of Health, National Treasury and the offices of partners. Key informants were identified by CHAI-South Africa, the internally connected informants as well by the evaluation team, the externally connected informants.

CHAI's Market-Shaping Activity and DFID Support

CHAI started work in SA in early 2000 and resumed activities back in 2010. No formal country work plan was made available to the evaluation team. CHAI's initial support in SA was focused on HIV treatment and access to ARVs. CHAI's approach was seconding staff to assist NDoH, strategically and technically, with price negotiations. Having succeeded in their initial work, CHAI, in the current phase, is moving away from the secondment model towards providing focused, technical support to the government. With DFID funding, CHAI supports SA in three areas of work: Drug Access, HIV Financing, and Laboratory Services, including HIV Diagnostics. The total allocation from DFID is $2,257,700 from 2012–2015, apportioned as follows: $762,348 HIV treatment, $830,251 E2, $641,932 PoC, $23,170 MDR TB.

DFID SA has no business case or logframe indicators for the CHAI work in SA. DFID SA is also moving away from supporting TA activities in South Africa.

CHAI appears to be doing the right things by focusing on access to ARVs and diagnostics and contributing to health systems strengthening. They work in the right way by either seconding senior staff to strategic offices like the offices of the Deputy Director General (Health), Chief Executive Officer (NHLS) as well as in operations (NHLS); and by providing targeted technical support to the Directorate of Procurement. CHAI also acts as a convener by bringing together partners to discuss key issues around access to HIV treatment and diagnostics. Selected key successes of CHAI include:

- Assisting the NDoH to achieve a savings of ~ $260 million in the 2015/2017 ARV tender.
- Improving quantification and forecasting tools thus allowing NDoH to put in place a three-year tender for their latest ARVs.
- Assisting NDoH with monitoring supplier performance by leading the development of an online scorecard where suppliers are obliged to put in data regarding the status of their supplies.
- Assisting the NHLS bid adjudication committee during the latest tender for diagnostics. Working with the government of SA and Roche Diagnostics to bring down the price of VL tests from around $30 per test to less than $10/test. For SA, the price is even lower, at $7/test.
- Contributing data and analysis towards major institutional reforms, such as change in institutional status of NHLS and introduction of National Health Insurance
- Contributing data and analysis to better understand HIV financing needs (HIV Strategic Plan, costing work in Gauteng province), better understand what resources are available (Annual Plan and Resource Map, DHER) and improve efficiencies at the facility level

CHAI has made considerable contributions to the bullet list above; however, many implementing partners as well as capable technicians and policy makers within government also contribute to the overall results seen in the country. Therefore, while CHAI has contributed to the success, specific attribution to CHAI is difficult to explicitly account for.

CHAI works well with government, especially at the national level with the Department of Health. With a country team of 27 (programme and support staff combined) within such a large country, CHAI needs to make careful strategic choices about the most catalytic value of its chosen interventions. In its health systems work, CHAI needs to strengthen its partnership with other PEPFAR partners and civil society organisations that operate more in provinces and districts and have greater numbers of staff for greater results.

CHAI also needs to engage more proactively with DFID-SA. As partners are starting to exit SA, including DFID-SA support for technical assistance, CHAI needs to develop its own exit strategy and foster stronger transfer of skills to its counterparts in the government structures so that the technical capacity CHAI has helped to build and establish remains to benefit the people of SA.

Swaziland: remote country case study summary

Introduction

For Swaziland, data collection primarily focused on: 'Maximising Value for Money and Ensuring Sustainable Supply of HIV Treatment', and 'Accelerating Introduction and Scale-Up of Point-Of-Care HIV Diagnostics'. Data collection methods included a desk review of key documentation, and remote interviews with key informants at country-level. Initially, the CHAI offices in Swaziland were contacted in order to obtain suggestions on key informants as well as background documentation if available, while others were identified by key informants. A total of eight people representing four organisations were formally interviewed. Interviews took place from 12 March to 9 April 2015, and were conducted by an evaluation team member.

CHAI's market-shaping activity and DFID support

Since 2012, DFID has provided $1,477,459 support to CHAI's work in the following areas: HIV treatment, PoC Diagnostics and MDR TB. This has focused on health system strengthening to ensure a consistent supply of high-quality ARVs and essential medicines, accelerating the uptake of ARVs to increase the number of adults and children alive and receiving optimal ARVs at the right time, providing access to point-of-care diagnostics, and increasing the efficiency and cost-effectiveness of health commodity and medicines procurement and tendering processes.

Findings

- CHAI has undertaken a credible analysis of the barriers to achieving Swaziland's HIV targets, being principally weak coordination and management and inefficient supply chain practices. Its activities appear to have been correctly targeted to overcome these barriers.
- Its work to roll out PoC CD4, developing a transition plan for its continuity, while preparing the country for VL PoC is a well recorded success, and was welcomed by government.
- CHAI's work with the government to identify the most promising places to put devices, training nurses, utilising 'mHealth' innovation to improve M&E, and its focus on building a strong mentoring program for clinical staff was the right way to provide support to development of the CD4 PoC programme.
- Creation of a CHAI staffed data management unit in the MoH is applauded by government and has improved the utilisation of data in order to ensure continuous supply of ARVs and to eliminate stock-outs at the national level. It is also slated to become financed by government so promoting its sustainability.
- CHAI is reported as making steady progress on improving forecasting, quantification, stock monitoring and laboratory systems through technical assistance so removing key bottlenecks in the supply chain.
- Its practice of seconding staff to the MoH, and then planning with government to include those positions in fiscal health budgets is worthy and self-reported as successful.
- There is some suspicion that CHAI can tread a fine line between influencing and supporting as opposed to manipulating the government's agenda, through its 'behind the scenes' influence on policy development through TWGs etc. However, there is limited evidence of tension with other development partners.
- CHAI's planning appears to be deliberately flexible, to allow for adaptive programming, often to enable prompt response to government demands. There is a possibility borne out by external comments that this can lead to some duplication of effort and confusion.

Conclusions

- In summary, CHAI assesses its own approach to the issues as strategic, adaptive and unique. It also demonstrates in each successive DAT proposal a methodical building on previous activities to achieve its own strategic and grant objectives year on year.
- The CHAI agenda and the MoH agenda appear to be intertwined. Connected and external stakeholders tend to agree, with some minor concern that there is a fuzzy line sometimes between setting the MoH agenda and supporting it, demonstrated by the CHAI practice of drafting material for MoH employees to present in TWG meetings.
- Certainly CHAI appears to undertake its work on the basis of careful and sound analysis of context and data. A sound VFM analysis accompanies each of the annual DAT proposals (2014 and 2015), which informs strategic choices.
- CHAI clearly sees that it builds on its successes and learns from challenges, while adapting to MoH requirements year on year. It sees a clear logical progress in terms of its 'bedrock' indicators, while preserving and valuing its flexibility (as facilitated by DFID).
- CHAI appears to be aware of potential scrutiny of its predominantly young, smart expat staff, and has taken steps to employ more locals. This is reflected in the views of external stakeholders. There was a

slight feeling that CHAI can be a little 'quickfire' in its approach to problem solving, and should adapt more to the pace of the MoH.
- CHAI Swaziland reports that it has performed well, achieving its own targets, and it sees itself as a prototype CHAI office. Overall, all stakeholders agreed that without CHAI issues would still have been progressed, but much more slowly.

Tanzania: country case study summary

Introduction

For Tanzania, the focus was primarily on CHAI's activities relating to HIV diagnostics and treatment, with a secondary focus on LARCs insofar as it shed light on CHAI's global level work. A list of key informants was developed, with input from CHAI and DFID. Two members of the evaluation team carried out interviews in Tanzania between 26 January and 7 February 2015. Supporting documentation was retrieved wherever possible.

CHAI's Market-Shaping Activity and DFID Support

CHAI has been active in Tanzania since 2003, when it began with work on HIV. It is currently active in four areas additional to the three focus areas, one of which cuts across all CHAI activity – Human Resources for Health. DFID funding for this was $1,778,671 over 2012–15 (though most of this is on malaria diagnostics). Areas covered by this evaluation include HIV treatment and PoC Diagnostics.

Findings

- CHAI has acted dynamically to determine and address key obstacles, including health system strengthening issues.
- Engagement of CHAI with MoHSW has been impressive, with initial consultations followed by secondment of CHAI staff.
- However, this has led to CHAI acquiescence in questionable MoHSW policies – e.g. the restriction of access to the emerging streams of health management information.
- CHAI has engaged in successful cooperation with a number of DPs also working closely with MoHSW, but engagement with other stakeholders has been variable.
- CHAI's rapid facilitation (or imposition) of evolving WHO and supplier guidance is both a virtue and a danger, ensuring guidance is enacted quickly, but with very little consultation.
- It is likely that global calculations underestimate the cost of adaptation to new products.
- CHAI's involvement across multiple therapeutic areas offers important opportunities for economies of scope and scale in its activities.
- HIV and LARCs outcomes in Tanzania are positive, but attribution is a challenge.
- There is some demand in Tanzania for CHAI to focus on a wider definition of family planning than just implants.
- Between country and global level, there is potential for useful regional (i.e. African) level activities by CHAI.

Conclusions

- CHAI is continuing what has proven an effective strategy.
- Better coordination is needed between CHAI and stakeholders beyond MoHSW, though some promising partnerships are emerging.
- At the global level, CHAI and DFID should push Merck to ensure that countries have some say over the timetable for the introduction of the LARC Implanon NXT.
- Efforts should be made to disseminate valuable lessons learned in Tanzania, e.g. staff embedded with MoHSW.
- CHAI should engage in the development of an exit strategy for Tanzania.

Uganda: country case study summary

Introduction

Data collection methods in Uganda included a desk review of key documentation, and a series of interviews with key informants at country-level. A total of 41 stakeholders representing 16 organisations were interviewed; of these 17 were internal, 10 were connected stakeholders, and 14 were external partners.

Country-level interviews took place from 1 to 6 February 2015, and were jointly conducted by an international and a national consultant. Data collection focused on malaria treatment, HIV treatment and HIV diagnostics programmes.

CHAI's Market-Shaping Activity and DFID Support

CHAI has operated in Uganda since 2008, and its office has grown rapidly, to 48 FTE in February 2015. The 3-year DFID market-shaping grant to CHAI Uganda was $3,613,095, which combined the DFID Human Development Department (HDH) grant and the contribution from DFID Uganda (Jan 2014–Sept 2015). The DFID market-shaping grant comprises approximately 15–20% of CHAI Uganda's overall budget, with the remainder coming from UNITAID (severe malaria, PoC CD4), BMGF (vaccines) and ELMA (paediatric HIV).

For all programme areas, CHAI has focused on supporting national policy change following best available evidence and/or WHO guidelines. Under the previous DFID grant, their work in malaria treatment concentrated on supporting the policy change from quinine to injectable artesunate, and the current grant has supported the implementation of this new national policy. Similarly, CHAI has supported the MoH to change national guidelines based on the new WHO Guidelines for ART (2013), which guided their work in both HIV treatment (increased eligibility for ART, provision of lifelong ART for all HIV+ pregnant and breastfeeding women, and introduction of "test and treat' for all children under 15 years of age) and HIV diagnostics (use viral load as the preferred monitoring approach to diagnose and confirm ARV treatment failure). In terms of policy implementation, CHAI has supported the MoH in gathering and analysing data, using global-level intelligence to inform on prices and best practices, conducting cost-analyses to calculate the financial implications of introducing a policy change, and use of evidence for decision-making. CHAI has played an important role in the successful Global Fund Concept Notes (2015–2017) for HIV/TB, malaria and HSS, and secured UNITAID funding for procurement of injectable artesunate for severe malaria and PoC CD4.

CHAI has also played a role in supporting the commodity management needed to implement the policy change, and support transition to new protocols. This includes quantification and forecasting of need, and preventing expiry and stock-outs of old/new products. However, an ambitious forecast of injectable artesunate requirements for the UNITAID program almost led to an overstock in the country, though this was ultimately averted.

CHAI has also supported the programmes to develop training material and job aids, and conduct trainings (though trainings on severe malaria have mostly been funded through UNITAID), and supportive supervision/monitoring. Importantly, CHAI was said to have facilitated general coordination and communication between the different government programmes and entities (NMCP, ACP, CPHL, QPPU and NMS) and between the MoH and implementing partners, and provided operational support to the MoH.

CHAI's strategy was considered clear and relevant – using global recommendations to support the MoH to adopt best evidence, which in the end should improve access to medicines and save lives – and fully aligned to the country's need. As the activities outlined above are all instrumental to enable the smooth implementation of a new policy, it seems that CHAI has been able to identify the areas of highest impact in which to engage.

Overall, CHAI seeks to influence decisions through "data and dialogue". CHAI Uganda has credibility with stakeholders and was highly regarded by almost all people interviewed. CHAI's mandate is clear to most but not all, as they are primarily a provider of technical assistance but also function as a donor through their role in the UNITAID donation of paediatric and second-line ARVs. Some external stakeholders said they are not always aware of what CHAI does. CHAI does not have an annual work plan, or has one that is flexible to change. CHAI has staff seconded to the MoH, and they work closely with MoH staff to ensure skills transfer and promote sustainability and ownership – which seems to be successful.

The Uganda-specific logframe indicator focuses on the transition from quinine to injectable artesunate in the public sector. Both Milestone 1 (2013) and 2 (2014) were achieved: a procurement and distribution plan for injectable artesunate was completed; training of health workers has started in 2014 funded by the GF, PMI and UNITAID; funding for the procurement of injectable artesunate was secured, including through the successful malaria Global Fund Concept Note 2015–2017, as well as through PMI; and injectable artesunate has been rolled out over the past two years.

For HIV treatment, milestones 1 and 2 have been reached: within the CMP low stock levels of ARVs are flagged by order cycle, and CHAI assists the Pharmacy Division/QPPU to use data from CMP's NMS to inform AMC, national quantification and procurement of ARVs. No indicator was included for HIV VL work. HSS-related work also needs to be assessed towards the end of the program (September 2015).

It is difficult to determine attribution, especially as CHAI's work mostly pertains to providing technical assistance to the Uganda MoH. CHAI's impact was especially felt in their work with CPHL on HIV lab commodities (EID, CD4 network), and CHAI's role in working with NMS was highly commended by stakeholders. As CHAI works very closely together with MoH and there is a high level of ownership within the MoH, it seems likely that the impact achieved will be sustained while CHAI is present.

The main recommendations to CHAI include finding a balance between fully supporting the MoH and not being 'seen' as a separate partner, vs communicating to external partners about CHAI's work and activities. CHAI should consider using and sharing an annual work plan. DFID could communicate more about CHAI's activities with other partners (i.e. during donor meetings), and ensure harmonisation of work between DFID-supported programmes, such as WHO's and CHAI's, and collaboration with MSH work on commodities.

Zambia: country case study summary

Introduction

The evaluation team's visit to Zambia took place from 8th February to 14th February 2015. The methodology consisted of a desk review of relevant documents, interviews with key informants (n= 26) as well as visits to the CHAI Zambia office. Key informants were identified by CHAI-Zambia and supplemented with additional informants identified by the evaluation team.

CHAI's Market-Shaping Activity and DFID Support

CHAI Zambia did not share a formal country work plan with the evaluation team. They were able to provide selected examples of the outputs or products of their work as well as short summaries of their work under each of the DFID-funded programme areas. The total funding under the DFID grant for Zambia is $2,237,897 from 2012–2015, apportioned as follows: $856,726 HIV treatment, $356,501 Malaria treatment, $528,591 E2, $496,079 PoC Diagnostics.

Findings

- HIV Treatment: CHAI has worked under the optimisation agenda to show the benefits of ATV/r and TLE. CHAI funded new ARV guideline development, printing of the guidelines and training of CHWs in the new guidelines. CHAI has also funded the pharmacy mentoring programme, conceived and initiated by government, and designed to improve management of stocks at hospital level; this was not an area of CHAI specific expertise, nor was it highly catalytic and impactful. During the evaluation team's visit there were press-worthy reports of stock-outs at the very same facilities that had been included in the mentorship programme. The mentorship programme needs to be implemented into an ongoing system for training, with follow up opportunities for skill transfer and refresher training.
- There are significant unmet needs at the central medical stores for supply chain management strengthening, which would offer a strategic, catalytic opportunity for reducing stock-outs. CHAI has done very limited work on procurement and supply chain management in Zambia. Several stakeholders cited this as a missed opportunity to get to the root of supply access problems.
- With regard to the pharmacy mentoring programme, an evaluation just after the intervention showed that it had improved medicines management practices, however the longer term impact and sustainability of this is initiative is not clear. There were several weaknesses in the execution of this programme, which should have been identified with better planning at the start, and although it was a government initiated intervention (good for sustainability and ownership) it may not have been the most strategic use of CHAI's time and resources.
- CHAI's influence has resulted in government's inclusion of TLE and ATV/r as options in the new guidelines. CHAI was able to draw on global expertise to explain the value of ATV/r, countering aggressive marketing of LPV/r by Abbvie.
- HIV Diagnostics: CHAI's global team provided data from Mozambique and Ethiopia to show the value of PoC and financed evaluation studies when the first devices were piloted. CHAI also financed the

workshops to develop the guidelines and paid for them to be printed: the guidelines gave the PoC tests credibility and helped stakeholders to realise that the government supported PoC based on an evaluation of the evidence. CHAI has financed modems to enable connectivity, which will allow the test data to be better analysed for impact.

- The Zambian government moved at an extremely protracted pace in introducing PoC devices. There was a common view that CHAI staff were in the best position to influence government, but lack of influencing skills might have impeded their ability to have more impact to move things along.
- Malaria: CHAI has been supporting the introduction of injectable artesunate, taking a lead facilitator role in the case management working group: Through CHAI's process modelling, it was felt that the MoH is learning how to manage product introductions. CHAI met the cost for guidelines development (printing, launch) as well as orientation activities. CHAI was credited with being a strong partner to PMI. A missed opportunity is that the impact monitoring was not completely thought through at the start.
- Apart from 1 person, no informant was able to identify the main funders of CHAI; most thought CHAI was primarily funded by Bill Clinton or the Clinton family.
- Several stakeholders said that CHAI staff transitions in Zambia had been a problem.
- "CHAI positions themselves well – the right skills and the right committees. I like the commitment of the CHAI staff. They worked around the clock on the GF application."
- CHAI compensates for weak health economics expertise, weak HMIS… but how will these issues be resolved longer term?"
- "CHAI spreads itself too thin. You can hug one tree or hug three trees. You'll get a better grip if you just hug one."

Zimbabwe: remote country case study summary

Introduction

For Zimbabwe, data collection primarily focused on: 'Maximizing Value for Money and Ensuring Sustainable Supply of HIV Treatment', and 'Accelerating Introduction and Scale-Up of Point-Of-Care HIV Diagnostics'. Data collection methods included a desk review of key documentation, and remote interviews with key informants at country-level. Initially, the CHAI offices in Zimbabwe were contacted in order to obtain suggestions on key informants as well as background documentation if available, while other stakeholders were identified by key informants. A total of eight people representing four organisations were formally interviewed by an evaluation team member. It is noted that we were unable to arrange an interview with a DFID representative in Zimbabwe, and only limited documentation was made available to the team.

CHAI's Market-Shaping Activity and DFID Support

Since 2012, DFID has provided grant support totalling $758,614 to CHAI's work in Zimbabwe, in the following areas: HIV treatment and PoC Diagnostics. This has included work on health system strengthening to ensure a consistent supply of high-quality ARVs and essential medicines, accelerating the uptake of ARVs to increase the number of adults and children alive and receiving optimal ARVs at the right time, providing access to point-of-care diagnostics and increasing the efficiency and cost-effectiveness of health commodity and medicines procurement and tendering processes.

Findings

- While CHAI's annual work plans are aligned to the government agenda, it appears to deliberately factor in capacity for adaptive programming, often to enable prompt response to changing government demands.
- CHAI has undertaken a credible analysis of the barriers to achieving Zimbabwe's HIV around technical capacity gaps in government (such as costing and analysis) and an inefficient supply chain. Its activities appear to have been appropriately targeted to overcome these barriers.
- Its work to roll out PoC CD4, developing a transition plan for its continuity, while preparing the country for VL PoC appears to have been welcomed by government.
- CHAI's work with the government appears to have accelerated development of the PoC CD4 programme, for example to test CD4 devices as part of an operational research project, identify the most promising places to put devices, its training of nurses coupled with a strong mentoring program for clinical staff, as well as the utilisation of mHealth innovations to improve M&E.

- CHAI seems to have fulfilled a valuable role supporting the government to prepare for the implementation of the new WHO guidelines related to the use of VL, for example in costing an implementation plan, convening partners and identifying capacity gaps.
- CHAI is reported to have made steady progress towards improving government health systems, including forecasting, quantification, stock monitoring and laboratory systems (predominantly through targeted technical assistance), so removing perceived 'bottlenecks' in the supply chain. Its support to 'sustainable' data management systems in particular (such as validation tools predicting treatment demand).
- CHAI operates a model akin to consulting, with a lot of (mostly young) staff working long hours to provide focused technical support to government, while engendering a culture of urgency. Individual skills are not necessarily always allied to a broader programmatic and public health understanding.
- CHAI appears to have a mutually beneficial relationship with partners such as Elizabeth Glazer, JSI and MSF, although tension seems to have arisen in some instances from the discontinuity of CHAI's work. That appears to be because not all partners appear to understand the CHAI model of 'build, operate and transfer', which means CHAI will withdraw from piloted initiatives without going to scale.
- It is apparent that given CHAI's integrated programming and multiple funding sources, it is difficult to attribute many of the activities and outcomes to a particular donor. Certainly, there is no evidence of CHAI being held to account for any particular national deliverable by the local DFID office.

Conclusions

- The CHAI agenda and the MoH agenda appear to be closely linked. For the most part the things it does are significantly aligned to government strategy, and perceived best practice.
- CHAI's approach is dictated by its model and the relatively modest ACCESS funding. CHAI does not aspire to implement at scale, but rather to pilot an approach and mobilise support for its adoption, so catalysing change through its skills and technical knowledge.
- Certainly CHAI appears to undertake its work on the basis of careful and sound analysis of context and data, effected by a relatively young team (which CHAI reported are all local hires), bringing a diverse set of skills and experience – but not necessarily in public health/development programming.
- The evidence available suggests a degree of complementarity with development partners, and limited tension.
- CHAI reports that it has performed well, achieving its own targets, and it sees itself as a prototype CHAI organisation. Overall, there is some consensus that without CHAI, work in the areas of HIV treatment and diagnostics (which has been significant at a national level) would have progressed but much more slowly (although it is difficult to determine attribution).
- The sustainability of CHAI's work is open to question, due to the capacity issues in government and the necessarily technical nature of the support CHAI provides, often as part of a pilot rather than a sustained intervention.

Annex J Modelling industry dynamics

Introduction

The Healthy Markets Primer presents a normative paradigm for how to approach market-shaping interventions and advises market-shapers to assess market-shaping options and to implement a customised intervention. One of the ways that counterfactual intervention options can be assessed is by developing theoretical models to explore how different interventions might be expected to alter investment decisions of relevant firms, given a set of plausible assumptions about industry economics.

We have constructed such a spreadsheet-based model (snapshot provided below) where we consider a market with Firm A and Firm B, where Firm A is already in the market and Firm B is considering entering the market. The objective of the model is to analyse the factors that would influence firm response to a bilateral negotiation intended to accelerate market maturity - reducing prices and increasing volumes. Hereafter, this intervention will be called a PVI (for price/volume intervention). The PVI can be modelled to resemble several different CHAI PVIs, or attempted PVIs, during the grant period: a global access price agreement (viral load diagnostics), a negotiation for specific markets (as was done with CD4 Pima in selected countries), a volume guarantee as was done with LARCs, or the negotiations CHAI attempted for injectable artesunate. Price reductions resulting from competitive procurements are outside the focus of this analysis.

Objective

Our central research question: what are the conditions that influence the market impact on Firm B of a PVI negotiated with Firm A? We are interested in testing if Firm B can still enter the market and under what conditions. Or, in other words, under what conditions does the PVI become anti-competitive? Can we predict this so that we can tailor our intervention?

Assumptions

We have modelled a situation where the market is split between 2 segments, D (donor funded segment) and ND (non-donor funded segment). D is the more significant market (80%) and ND represents 20% of the market. It was assumed that there are only two suppliers – Firm A and Firm B, with Firm A holding a dominant position with 100% of the D market and 90% market share of the ND market at the outset. Without any intervention, it is assumed that both segments will grow at 5% (in real terms) per annum. We have also assumed that an intervention in the form of a PVI negotiated with Firm A over the limited period of 4 years would lead to a substantially increased market growth in this period in segment D. The model assumes it is uneconomic (or not contractually possible) for Firm B to enter the PVI-influenced D market segment during this 4-year period.

We evaluated how this increased growth resulting from the PVI would affect the incentives for Firm B to enter segment D after 4 years to compete against Firm A. We assumed that, once Firm B is able to enter the D market, Firm A's market share in the competitive segment would decline by 5% per annum. It was also assumed that in the non-PVI portion of segment D, Firm A would lose its market share at the same attrition rate, whereas in the PVI portion of the segment, it would not lose its market share during the period of the PVI. In the ND market, it was assumed that the rate of market share loss for Firm A would be the same as in the non-PVI portion of segment D (i.e. 5%).

With the above assumptions, we have calculated the expected revenue increases for Firm B in each of the market segments. The variation of assumptions relating to the growth in the PVI affected segment of D market over the PVI period and the percentage portion of segment D affected by the PVI would not affect Firm B's expectations with regard to its growth in the ND segment.[206]

[206] We assume these are discrete markets for simplicity, although we know that the contribution margin provided by large volume increases on donor markets can indirectly allow price reduction and increased uptake for non-donor markets, potentially exacerbating any advantage Firm A gains from the PVI

Key findings

Using the model, we are able to establish that Firm B's expectations with regard to its growth in D segment will be significantly influenced by two factors: i) the percentage portion of the market that is influenced by the PVI as well as ii) the overall market growth in segment D that will be expected to be caused by the PVI.

If the PVI results in D market growth at the annualised rate of 15% (resulting in a 75% increase over the 4-year PVI period) and the PVI affected portion of segment D is 50%, then Firm B would expect an increase of the revenue growth multiple over 10 years of 18.1x vs. 33.7x without a PVI. If the PVI affected segment is higher than 70%, the resultant expectation would be even lower (17.9x). The higher the PVI affected segment percentage, the lower are Firm B's expectations.

If the market D were to grow at 10% per annum resulting in a 50% increase in the market during the PVI 4-year period, with a 50% portion of the market affected, then the multiple would be 17.1x vs. 18.1x if the growth is 15% p.a. Conversely, if we assume a higher segment D growth of 19% per annum resulting in a 100% increase over the 4-year period, Firm B's expectation would grow; however, the only growth scenario which takes Firm B into the range of revenue it would have otherwise in the absence of a PVI (33.7x) is a PVI enabled market growth higher than 49% per annum.

Another key factor influencing market impact of the PVI is the extent of the price drop enabled by the PVI. It has been assumed that during the PVI period of 4 years the annualised price decline negotiated with Firm A would be 20.5% resulting in 60% decline in the overall price during the 4 years. Under these assumptions, if there is no PVI, in 10 years Firm B would expect to increase its total sales by 33.7x. However, with the PVI in place, resulting in the above-mentioned product price decline (60% over 4 years), Firm B's expectation would decrease to 18–19.1x depending on the percentage portion of D affected by the PVI with Firm A (assuming that the market during the 4-year period doubles, i.e. 19% annualised growth over 4 years).

Dropping price will not benefit Firm B under these assumptions, even though market size increases 100% over 4 years, and even assuming Firm B can tap into that larger market immediately after 4 years, gaining 5% market share per annum.

Firm B would expect a 33.7x sales increase in 10 years, which under the scenario with a PVI in place, can only be matched and exceeded with the overall PVI influenced market starting at 80% or higher of segment D and growing at 49% per annum (equivalent to 390% growth over period of the PVI) or higher.

A PVI which halves prices and doubles the market over 4 years would leave Firm B in a worse off position in relation to revenue increase vs. if no PVI is negotiated, the market grows more slowly and prices do not drop substantially.

Discussion

The model finds that the market impact of the PVI is a function of the relative size of D/ND, market growth in general, market growth as a result of the PVI, size of the price drop associated with the PVI, the percentage of D market Firm A is assured as a result of the PVI, and the time period of this assurance.

If the PVI results in a large enough additional growth, the price drop is not too severe[207], and Firm B can erode some of that increased market growth from Firm A, then the intervention can be good for Firm B.. The importance of the D segment within the overall market is a significant factor. If there is a substantial enough ND market, then Firm B might be able to enter anyway, bolstered by the ND market sales.

There are other factors that would need to be considered from Firm B's perspective:

- The model does not consider whether B has the cost structure to enter market D under new prices negotiated under the PVI nor does it consider (if it cannot profitably supply at the new prices) whether Firm

[207] "Too severe" in relation to Firm B's cost structure – this is discussed in the first bullet of the subsequent paragraph

B has the capital base[208] to temporarily suffer a loss upon market entry competing with the new pricing negotiated under the PVI.

- Switching costs, especially important in diagnostics as well as reproductive health products, are a determinant in whether Firm B can actually capture any of the market after the PVI has concluded, or whether Firm A's position will become further entrenched. Product agnostic trainings and clinical algorithms can be developed in such a way as to facilitate swapping out, but to some degree the training will be tied to the product, user confidence will have been built, and a reluctance to switch may have developed.
- Our ability to predict and to tailor a PVI intervention will be a function of our confidence about the assumptions driving our modelling and scenarios. For example, how confident we are in the data with regard to the demand side: Is the market growing, what was the original market size of D and ND, whether Firm B would be able to get volumes from elsewhere or cross-subsidise, or will Firm A get all of the growth of D market, or only some of it (this could be a function of contract terms, size of the price cut, interchangeability)?
- The model assumes full elasticity of demand, which may not be appropriate for all product sectors – i.e. whether it is appropriate to say that reducing price by half will result in a doubling of demand. It may be necessary to think about whether there be trained health workers to administer the products, as well as what will be the timeframes required by countries to adapt policies, guidelines, and alter health systems.
- Firm B would lack certainty of being able to build market share, whereas Firm A has secured certainty through the PVI negotiation. Thus, Firm B's expected cash flow will be lower due to lack of this certainty (affecting probability of realising the cash flow). This reduces the expected monetary value of the future cash flows.
- The fact that a deal has been negotiated with a dominant firm may have important signalling effects on Firm B; it may send perceptions that the market is not open to competition and this can also influence Firm B's expectations and behaviours.
- Start-up capital cost to enter market D is not factored into the model. Higher capital investment requirements may imply a higher need for a contractual intervention with suppliers, in order to assure capacity. [209] At the same time, the more scale-dependent the industry, the higher the potential for a predatory impact from interventions that foster gains in market share to one firm at the expense of other firms.[210] .

A useful future exercise for CHAI would be to model the market impact of a PVI implemented with a non-dominant Firm B, to better understand the drivers of impact, risks and situations in which this may be of benefit from an industry-wide, dynamic perspective. This would be applicable (hypothetically) to counterfactual options CHAI might have pursued with second-to-market injectable artesunate, LARCs or HIV diagnostics product developers.

Why do we care about market impact on Firm B?

As public health market shapers, we are not primarily driven by industrial development objectives but by health impact objectives. Thus, market structure – and impact on market structure – is only important as a means of achieving competitive and sustainable pricing, stable supply and innovation, which in turn enhance consumer welfare and provide donors with value for money.

[208] A function of factors such as whether Firm B is large and/or diversified in its geographic or product mix, whether Firm B has access to capital markets

[209] See Owen Barder and Ethan Yeh, Centre for Global Development Working Paper No 80, January 2006. "The Costs and Benefits of Front-Loading and Predictability of Immunization." The paper illustrates the option value of waiting for better (but never complete) information before making capacity production increases. It also uses a game-theoretic approach to model bargaining power between producer and purchaser under different scenarios of capacity investment.

[210] See Grace, C and Gehl Sampath, P. Third International Conference for Improving Use of Medicines, Antalya Turkey 2011. http://www.inrud.org/ICIUM/ConferenceMaterials/969-grace- a.pdf.
This work concludes that the economic effect of differential pricing or donations (a differential price with price set at zero) may be akin to predatory pricing, depending partly on the market characteristics of the market sector and partly on the size, duration and structure of the offer itself.

The model presented here shows that a PVI with Firm A, who is in a dominant market position, can have an effect akin to predatory pricing.[211] It can facilitate market share capture by Firm A, inducing adoption or switching to the PVI service/product. Under certain conditions discussed above, and where the competing firm(s) have no way of raising prices or recouping the lost volume through other markets, then the response may be the same as it would be in a predatory pricing situation – that is, any of the following:

- A reduction in output,
- A rise in prices,
- Supplier exit from the product line, or
- (where competition does not yet exist) suppliers deciding not to enter the market.

A PVI with some firms can exacerbate demand uncertainty for other (non-PVI) firms, which can lead to supply insecurity, since industry typically produces to conservative estimates of all possible demand projections in order to conserve capital and avoid wastage. This dynamic is accentuated in product sectors where lead times between investment and product availability are longer (e.g. ACTs) or where capital investments are higher (e.g. vaccines).

A negative impact on competing firms is obviously only of concern if the consequence is negative impact to consumer welfare. For example, donors may implement a policy decision that drives away products with sub-optimal public health benefits – like chloroquine in areas where there is chloroquine resistance or artemisinin monotherapies (which can confer resistance to the artemisinin-based combination therapies). In these examples, the market exit of producers from the product segment is actually beneficial from a public health standpoint. However, in the case of quality products with public health benefits, policy makers should support a pro-competitive environment, as evidence shows that this is supportive of price reduction, supply security and increased innovation, in turn enhancing consumer welfare. Evidence on the entry of generic drugs in general tells us that the number of generic entrants affects the degree of price competition[212] and positively correlates with market size and expected profits.[213] Evidence specifically from medicines in low- and middle-income countries (LMICs) shows that differential prices have been less effective than generic competition in achieving lowest sustainable prices. This has been shown in ARVs[214] as well as in ACTs, TB medicines, and vaccines.[215]

Nonetheless, this is not to say that PVIs should never be used. As with any market shaping tool, one must consider whether this is the best strategy compared to alternatives by analysing the a) the market conditions and b) the PVI design (e.g. price, duration, population eligibility). For example, Barder and Yeh216 produce

[211] We do not assume that predatory or otherwise anti-competitive behaviour is the intent of any producer engaging in a PVI. The nature of this model is to look for risks, weaknesses in the competitive supply structure and potential negative scenarios. We only analyse what is possible, under several probable industry conditions.

[212] Frank, RG and Salkever, DS. Generic entry and pricing of pharmaceuticals. J Econ Manage Strategy. 1997; 6: 75–90
Hudson, J. Generic take-up in the pharmaceutical market following patent expiry: a multi-country study. Int Rev Law Econ. 2000; 24: 103–112

[213] Rudholm, N. Entry and the number of firms in the Swedish pharmaceutical market. Rev Ind Organ. 2001; 19: 351–364
N. Entry and the number of firms in the Swedish pharmaceutical market. Rev Ind Organ. 2001; 19: 351–364
Bae, J. Research on pharmaceutical drug development, use, and outcomes: drug patent expirations and the speed of generic entry. Health Services Res. 1997; 32: 87–101
Morton, F. Entry decisions in the generic pharmaceutical industry. RAND J Econ. 1999; 30: 421–440
Saha, A, Grabowski, H, Birnbaum, H, Greenberg, P, and Bizan, O. Generic competition in the US pharmaceutical industry. Int J Econ Bus. 2006; 13: 15–38
Hudson, J. Generic take-up in the pharmaceutical market following patent expiry: a multi-country study. Int Rev Law Econ. 2000; 24: 103–112

[214] In a review of more than 7,000 developing-country purchase transactions from 2002-07, Waning et al. found that the tiered prices for 15 of 18 antiretroviral drugs were 23-498 percent higher than the generic price:
http://www.scielosp.org/scielo.php?script=sci_arttext&pid=S0042-96862009000700013&lng=en&nrm=iso&tlng=en
Similarly, a 2014 analysis of publicly announced ARV prices found that of the 22 products for which both originator tiered prices and WHO quality-assured generic prices were listed, the generic price was lower for 19 products (86 percent). Generic prices were frequently as low as one-eighth to one-fifth of tiered prices: http://msfaccess.org/sites/default/files/MSF_UTW_17th_Edition_4_b.pdf

[215] http://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-7-39

[216] The paper uses a game-theoretic approach to model bargaining power between producer and purchaser under different scenarios of capacity investment. The model predicts that there would be scope for significant benefits to both buyers and sellers if demand and prices were agreed to before production investment takes place through some type of commitment mechanism. Owen Barder and Ethan Yeh, Centre for Global Development Working Paper No 80, January 2006. “The Costs and Benefits of Front-Loading and Predictability of Immunization”.

a game-theoretical model to show how a PVI implemented in the early days of pentavalent vaccine introduction might have resolved some of the capacity constraints and enabled faster scaling up.

Modelling such as demonstrated here can help inform decisions about when is the best time (in terms of dynamic efficiency of the market) for a bilateral pricing deal or a volume guarantee, with which firms is such a deal best negotiated and under what conditions will this encourage beneficial long-term shifts in market structure?

Initial Situation - MARKET SHARE:

%	Firm A	Firm B	%
Revenue D	80	-	80
Revenue ND	18	2	20
Total Market (D + ND)	**98**	**2**	**100**

RELATIVE MARKET SIZE	-	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*
D Market With PVI	40.0	47.6	56.5	67.2	79.9	83.9	88.1	92.5	97.2	102.0	107.1
D Market Outside the PVI	40.0	42.0	44.1	46.3	48.6	51.1	53.6	56.3	59.1	62.1	65.2
Total D Market	80.0	89.6	100.6	113.5	128.6	135.0	141.7	148.8	156.3	164.1	172.3
ND Market	20.0	21.0	22.1	23.2	24.3	25.5	26.8	28.1	29.5	31.0	32.6
Total D + ND Market	100.0	110.6	122.7	136.7	152.9	160.5	168.5	177.0	185.8	195.1	204.9
D Market Growth With PVI		19%	19%	19%	19%	5%	5%	5%	5%	5%	5%
General Market Growth		5%	5%	5%	5%	5%	5%	5%	5%	5%	5%
D Market Shares %											
PVI segment											
Firm A	50.0	50.0	50.0	50.0	50.0	47.5	45.1	42.9	40.7	38.7	36.8
Firm B	-	-	-	-	-	2.5	4.9	7.1	9.3	11.3	13.2
Non-PVI segment											
Firm A	50.0	47.5	45.1	42.9	40.7	38.7	36.8	34.9	33.2	31.5	29.9
Firm B	-	2.5	4.9	7.1	9.3	11.3	13.2	15.1	16.8	18.5	20.1
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Implied Market Share of the PVI portion of D market + Non-PVI D Market:											
Firm A	100.0	97.5	95.1	92.9	90.7	86.2	81.9	77.8	73.9	70.2	66.7
Firm B	-	2.5	4.9	7.1	9.3	13.8	18.1	22.2	26.1	29.8	33.3
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	Assume market share loss by Firm A in normal conditions:										
Firm A D MS Loss (PVI segment)		0%	0%	0%	0%	5%	5%	5%	5%	5%	5%
Firm A D MS Loss (Non_PVI segment)		5%	5%	5%	5%	5%	5%	5%	5%	5%	5%
ND Market Shares %											
Firm A	90.0	85.5	81.2	77.2	73.3	69.6	66.2	62.9	59.7	56.7	53.9
Firm B	10.0	14.5	18.8	22.8	26.7	30.4	33.8	37.1	40.3	43.3	46.1
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Firm A ND MS Loss		5%	5%	5%	5%	5%	5%	5%	5%	5%	5%
IMPLIED TOTAL MARKET SHARES (UNITS)											
D Market											
Firm A	80.0	87.3	95.7	105.4	116.6	116.3	116.1	115.8	115.5	115.2	114.9
Firm B	-	2.2	4.9	8.1	11.9	18.6	25.7	33.1	40.8	48.9	57.4
	80.0	89.6	100.6	113.5	128.6	135.0	141.7	148.8	156.3	164.1	172.3
ND Market											
Firm A	18.0	18.0	17.9	17.9	17.8	17.8	17.7	17.7	17.6	17.6	17.6
Firm B	2.0	3.0	4.1	5.3	6.5	7.7	9.1	10.5	11.9	13.4	15.0
	20.0	21.0	22.1	23.2	24.3	25.5	26.8	28.1	29.5	31.0	32.6
Total D + ND Market	100.0	110.6	122.7	136.7	152.9	160.5	168.5	177.0	185.8	195.1	204.9
Firm A (D+ND)	98.0	105.3	113.7	123.3	134.5	134.1	133.8	133.5	133.1	132.8	132.5
Firm B (D+ND)	2.0	5.3	9.0	13.4	18.4	26.4	34.8	43.5	52.7	62.3	72.4
	100.0	110.6	122.7	136.7	152.9	160.5	168.5	177.0	185.8	195.1	204.9
Firm B $ Sales	D Market										23.0
	ND Market										15.0
											38.0
Firm B Increase in Sales in 10 Years											19.0 x
D Market											
Firm A	80.0%	79.0%	78.0%	77.1%	76.3%	72.5%	68.9%	65.4%	62.1%	59.0%	56.1%
Firm B	0.0%	2.0%	4.0%	5.9%	7.8%	11.6%	15.2%	18.7%	22.0%	25.1%	28.0%
ND Market											
Firm A	18.0%	16.2%	14.6%	13.1%	11.7%	11.1%	10.5%	10.0%	9.5%	9.0%	8.6%
Firm B	2.0%	2.8%	3.4%	3.9%	4.2%	4.8%	5.4%	5.9%	6.4%	6.9%	7.3%
	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Firm A (D+ND)	98.0%	95.2%	92.6%	90.2%	88.0%	83.6%	79.4%	75.4%	71.6%	68.1%	64.7%
Firm B (D+ND)	2.0%	4.8%	7.4%	9.8%	12.0%	16.4%	20.6%	24.6%	28.4%	31.9%	35.3%
	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Scenarios:

Assume PVI	1
Assume no PVI	0
Assume D Market (PVI Segment) annual growth (over 4 years) with PVI:	19%
PVI as % of the Total D Market	50%

Assume price decline per annum in the PVI period:	20.5%
Total price decline in the PVI period:	60.0%

	1.2	*1.46*	*1.7*	*2.0*	*2.4*	*4.9*

Firm B Revenue Increase (times) 10 years

		PVI Segment market growth (p.a. first 4 years)									
	19.0	5%	10%	15%	19%	24%	29%	34%	39%	44%	49%
	0%	17.981	17.981	17.981	17.981	17.981	17.981	17.981	17.981	17.981	17.981
	10%	17.626	17.832	18.069	18.277	18.575	18.911	19.289	19.711	20.182	20.704
	20%	17.270	17.669	18.126	18.527	19.102	19.751	20.480	21.295	22.203	23.211
	30%	16.914	17.491	18.152	18.731	19.562	20.500	21.553	22.731	24.044	25.501
PVI	40%	16.558	17.298	18.147	18.890	19.955	21.158	22.510	24.021	25.705	27.574
Segment as	50%	16.202	17.091	18.110	19.002	20.282	21.726	23.349	25.164	27.186	29.431
% of D Market	60%	15.847	16.869	18.042	19.069	20.542	22.204	24.072	26.161	28.488	31.071
	70%	15.491	16.633	17.942	19.089	20.735	22.591	24.677	27.010	29.609	32.494
	80%	15.135	16.382	17.812	19.064	20.861	22.888	25.166	27.713	30.551	33.701
	90%	14.779	16.117	17.650	18.993	20.920	23.094	25.537	28.269	31.313	34.691
	100%	14.424	15.837	17.457	18.877	20.912	23.210	25.791	28.679	31.895	35.465

Firm B Market Share % in D Segment in 10 Years

		Annual market share loss by Firm A under normal (i.e. no PVI) conditions:									
	33.3%	1%	2%	3%	4%	5%	6%	7%	8%	9%	10%
	0%	9.6%	18.3%	26.3%	33.5%	40.1%	46.1%	51.6%	56.6%	61.1%	65.1%
	10%	9.2%	17.6%	25.3%	32.3%	38.8%	44.6%	50.0%	54.8%	59.3%	63.3%
	20%	8.8%	16.9%	24.3%	31.2%	37.4%	43.1%	48.3%	53.1%	57.5%	61.5%
	30%	8.4%	16.2%	23.4%	30.0%	36.0%	41.6%	46.7%	51.4%	55.7%	59.6%
PVI	40%	8.1%	15.5%	22.4%	28.8%	34.7%	40.1%	45.1%	49.7%	53.9%	57.8%
Segment as	50%	7.7%	14.9%	21.5%	27.6%	33.3%	38.6%	43.5%	48.0%	52.1%	56.0%
% of D Market	60%	7.3%	14.2%	20.5%	26.4%	31.9%	37.1%	41.8%	46.2%	50.4%	54.2%
	70%	7.0%	13.5%	19.6%	25.3%	30.6%	35.6%	40.2%	44.5%	48.6%	52.3%
	80%	6.6%	12.8%	18.6%	24.1%	29.2%	34.0%	38.6%	42.8%	46.8%	50.5%
	90%	6.2%	12.1%	17.7%	22.9%	27.9%	32.5%	36.9%	41.1%	45.0%	48.7%
	100%	5.9%	11.4%	16.7%	21.7%	26.5%	31.0%	35.3%	39.4%	43.2%	46.9%

	At start	In 10 Yrs	Market Growth
Total D Market	80.0	172.3	115%
	At start	In 10 Yrs	Market Growth
Total ND Market	20.0	32.6	63%

	PVI YES(1), NO(0)	
	19.00	0	1
	5%	33.66	18.13
	10%	33.66	18.28
	20%	33.66	18.53
	30%	33.66	18.73
PVI	40%	33.66	18.89
Segment as	50%	33.66	19.00
% of D Market	60%	33.66	19.07
	70%	33.66	19.09
	80%	33.66	19.06
	90%	33.66	18.99
	100%	33.66	18.88

Annex K Market-specific recommendations

HIV Treatment

Recommendation C1: Increase focus on real-time communication to align supply and demand

- The supply/demand misalignments which happened during the grant period have highlighted some weaknesses in the system. With large countries and large suppliers in particular, CHAI should be leveraging its relationships on the supply and demand side, working with global buyers and other stakeholders to support real-time communication of demand trends and tender timing, as well as forecasting ahead to allow suppliers to increase capacity well before products are purchased. It will be increasingly important for CHAI, GFATM, PEPFAR and the South African government to closely communicate on supply-demand alignment as new ARVs such as dolutegravir, darunavir, low-dose EFZ and TAF come to market.
- CHAI can play an important role at the interface between country and global levels, understanding which countries are transitioning to which products and at what rate. Within countries, CHAI is well positioned to help monitor the ongoing rate of uptake, factor this into procurement advice in terms of lead times and stock levels, help to align this to global supply capacity and avoid stock-outs during transition to new regimens. This advice was communicated in the Interim Findings report and since then CHAI has developed a procurement issues tracker, which is used to monitor issues arising in countries as well as with suppliers.

Recommendation C2: Document and disseminate evidence of impact and lessons learned

- CHAI now has a vast amount of learning that should be shared, improving the efficiency and effectiveness of the entire system to deal with these challenges. Some initial ideas of HIV Treatment lessons to share, just to further illustrate this point, include:
  1. Product introduction and transitions. Pros/cons of pilots and field tests of new products; choices in how to ration – e.g. by facility type, patient type – pros and cons and lessons learned with different choices; preventing stock-outs while scaling up – options and lessons learned; options for tapping into global intelligence on which products to scale up when in relation to global supply capacity;
  2. Lessons learned with forecasting – pros and cons of different types of forecasts and using different types of assumptions; how to deal with uncertainty in assumptions;
  3. Procurement best practice – lessons learned over the years and across contexts.

  These suggestions were made in the Interim Findings report and since then CHAI reports that it has authored and disseminated a white paper on tendering and procurement best practices. CHAI also reports that it has been working on a toolkit to guide countries through new ARV introductions. This is expected to be rolled out in Q1 2016. The EvT recommends that such resources are peer reviewed externally and should be made widely available, not limited to MoHs and partners with which CHAI works closely.

Recommendation C3: Exit, alter or bolster selected interventions, to ensure continued relevance and increase impact

- With regard to new product introduction and transitions, this will continue to be an important area for CHAI, but the emphasis will need to shift. CHAI should increase emphasis on documenting the difficulties and lessons learned in the process of transitioning to new products, shifting to a catalytic role. Many countries now have substantial experience with new product introductions and transitions and no longer need to rely on CHAI for ongoing direct assistance.
- On the supply side, CHAI should step up efforts to support Chinese firms, given agreement by global stakeholders on the need for API supply tracking and given the clear need to shift CHAI support to third tier firms, where capacity is lower, and where CHAI's support can have greater impact. ARV licence brokering was valuable before the establishment of MPP; however, now CHAI should shift focus on areas where it has a comparative advantage – providing information on market needs, market size and the likely uptake curve of new ARV formulations.
- CHAI's price ceiling work is soon to be adapted, refocusing on reference pricing and product information sheets. CHAI could usefully extend its price transparency work into new product sectors, for example untangling the opaque pricing that goes along with diagnostics, or increasing price transparency with regard to NCD medicines.
- CHAI's annual meeting is no longer the unique opportunity it once was for participants to discuss challenges facing the ARV market, and CHAI has recently innovated to a regional approach.

- CHAI has also shown responsiveness to EvT feedback about transparency around forecasting, and has made recent efforts to better coordinate with others.

HIV PoC Diagnostics

Recommendation D1: Fully assess market-shaping options.
Annex K provides an illustrative approach of a process that CHAI should follow before starting to negotiate price deals; this approach looks at pricing dynamically and from an industry-wide perspective, rather than from a static and single firm perspective.

Recommendation D2: Collaborate from the start.
CHAI needs to collaborate better with other implementers with presence at the service delivery level (e.g. MSF, EGPAF and PEPFAR partners) who can provide the necessary information on the impact of PoC devices on operational efficiency and clinical workflow. CHAI should also better align with GFATM and PEPFAR partners to ensure harmonisation of quality assurance requirements, purchase terms, and reagent supply chains. This has been problematic in some countries to date. On the regulatory side, CHAI could do more to coordinate with LSHTM and WHO, helping to define a vision for an improved regulatory path to market, and supporting developers to better understand the market entry process in different countries.

Recommendation D3: Document and disseminate evidence of impact and lessons learned.
Under the UNITAID grant, CHAI and UNICEF have been asked to produce a number of deliverables or tools. These are tools of global relevance to many countries, including those supported under the current DFID grant. CHAI has been asked to produce the following under the current UNITAID Phase 2A grant.

i) Tools and guidelines for market sizing, segmentation, site and product selection
ii) Training guidance document and training materials
iii) Guidance document on in-country quality assurance framework
iv) Product profiles for each PoC or near-PoC product that becomes available
v) Generic national PoC strategy document and implementation guidelines

In addition, CHAI has introduced operational innovations around data capture and quality assurance which are globally applicable and should be shared. There is also a need for peer-reviewed, published evidence to show the impact of the PoC CD4 experience on programmes and patients, specifically in relation to test turnaround time, loss to follow up between HIV diagnosis and ART initiation, and time to ART initiation. Other areas for study include how PoC introduction has translated into improved case-finding, ART initiation and retention in care, and the devices' impact on operational efficiency and clinical workflow.

Recommendation D4: Improve information transparency
CHAI should share its knowledge with regard to diagnostic pricing, and contracting options (purchase vs leasing equipment with service and maintenance). GFATM has just done this, with a tool[217] explaining HIV diagnostic contracting options and their pros and cons, so that governments are less reliant on TA in perpetuity and are more empowered to make independent decisions.

Malaria Treatment

Recommendation E1: Focus on improving data availability in order to measure impact on severe malaria.
Poor data availability and accuracy for key severe malaria metrics present a key risk to the successful implementation of injectable artesunate roll-out across all countries. In particular, there is consistent under-reporting of in-patient data, and little to no reliable data on severe malaria morbidity and mortality. This paucity of information negatively affects quantification and forecasting efforts, in turn undermining optimal order placement and distribution. Further, poor data limit the ability to properly assess the public health impact of this intervention, and monitor potential unintended consequences of overuse or inappropriate use of injectable artesunate. Even though the groundwork on injectable artesunate has been done (in terms of policy change, transition commodity management, securing funding for procurement, and training), monitoring and evaluation of uptake, especially through routinely collected data, is still a highly underdeveloped area requiring significant attention. Even though CHAI will continue its work on severe malaria in four target countries (apart from Zambia) until 2016 as part of the UNITAID grant, it is surprising that no activities related to severe malaria have been included as part of the extended DFID market-shaping grant (2016–2018).

[217] http://www.theglobalfund.org/en/p4i/

Recommendation E2: Indicators to monitor a DFID grant should be specific to CHAI's work funded by DFID.
The uptake of injectable artesunate (indicator 6.3) has been particularly high in countries covered by both UNITAID and DFID, and much less in the country only funded by the DFID grant. Also, CHAI was said to have played a minor role in achieving cost savings under the new GFATM procurement model (indicator 6.4), even though this was used as a key indicator to measure CHAI's performance.

Recommendation E3: Detailed assumptions underpinning indicators and statements should be provided at the beginning of the grant.
For severe malaria, these assumptions were obtained at a late stage during the evaluation, and enabled the reviewers to assess the feasibility of targets set by linking caseload per country, uptake in public vs private sectors, uptake of injectable artesunate, and number of cases treated with this new commodity. Under the new grant, CHAI's claims made – for instance, reducing production costs of SSA by 40% and saving $26–43 million through 2023 – should be well founded and backed up by numbers that are shared with DFID.

Recommendation E4: Clearly show how the activities proposed under the planned DFID grant extension fall within the wider antimalarial landscape.
CHAI should demonstrate how its planned interventions fit with activities conducted by others (i.e. IVCC/UNITAID on IRS, PATH and CHAI/BMGF on SSA) and with the funding CHAI receives from other donors, to ensure complementarity and to avoid duplication and double-funding of activities. In its extended DFID grant (2016–2018), CHAI proposes to work on a new generation of insecticides used for resistance management in indoor residual spraying (IRS) by facilitating entry of new suppliers to increase competition, lower prices, and drive product uptake, and will support the transition to a synthetic market for artemisinin. In addition, CHAI proposes to provide TA to improve quantification, procurement, distribution, and information collection systems to increase availability of ACTs and injectable artesunate, which is an area where a number of other partners are active as well.