Institution: London School of Hygiene & Tropical Medicine (LSHTM)

Unit of Assessment: UoA2 – Public Health, Health Services & Primary Care

Title of case study: Expanding access to effective antimalarial treatment through the private sector

1. Summary of the impact

Research carried out by LSHTM made a fundamental contribution to the creation of the Affordable Medicines Facility – malaria (AMFm), a financing mechanism initiated to improve access to effective antimalarials through subsidies and price negotiations with drug manufacturers. Drawing on LSHTM research showing the importance of the private sector in supplying antimalarial medicines, the scheme was proposed by the US Institute of Medicine (IOM) and piloted in Kenya and Tanzania. After its 2009 launch, a subsequent evaluation by LSHTM and others using LSHTM methodological innovations led to AMFm's integration into ongoing funding streams.

2. Underpinning research

Effective medicines to treat malaria exist, but access to them remains low. As recently as 2008, only about 16% of febrile children under 5 (the population group most at risk of dying from malaria in high transmission settings) received an artemisinin-based combination therapy (ACT), the recommended drug for malaria case management. Research by LSHTM established the importance of the private sector in treating malaria, in many settings exceeding 50% of care-seeking for fever.

Catherine Goodman (then Research Fellow, now Senior Lecturer) started her PhD in 2000, supervised by Anne Mills (Professor of Health Economics and Policy), on the nature of the private retail market for antimalarial medicines in rural Tanzania. Kara Hanson (then Lecturer, now Professor of Health System Economics) joined them in leading research on the role of the private sector in delivering malaria medicines, supported by Research Fellows/Lecturers Benjamin Palafox, Edith Patouillard, Sarah Tougher (from 2008), and Sergio Torres Rueda, Barbara Willey and Andrea Mann (from 2011). All were based at LSHTM throughout their research involvement.

The research fell into three main areas. First, an investigation into the use of the private sector for malaria case management and the conditions under which medicines are supplied.[3.1] Research in 2000–2002 explored the retail market for antimalarials from both a supply and demand perspective, using qualitative and quantitative methods. The results showed that antimalarial medicines were widely available from retail outlets, which provided easier access to the drugs than health facilities, and were widely used by the population. The research highlighted the importance of these private retail providers, but also the weaknesses of drug sales regulation. The same research examined competition in the antimalarial medicine market,[3.2] identifying the effects of market concentration in rural Tanzania as having a significant impact on the price of antimalarials. LSHTM also contributed to research in 2009–2010 showing the widespread market penetration of artemisinin monotherapies in some countries[3.3] via surveys of outlets in Benin, the Democratic Republic of the Congo (DRC), Madagascar, Uganda and Zambia.

Second, the development and strengthening of methods for collecting data on the characteristics and practices of private sector drug retailers. For example, a standardised metric was developed for comparing quantities of antimalarials – the Adult Equivalent Treatment Dose – and retail audit methods were developed to capture the range of antimalarials available in an outlet, their prices and mark-ups, and volumes sold. Many of these methods were subsequently extended and adapted through the multi-country ACTwatch project.[3.4]

Third, research studies which evaluated the impact of subsidies and interventions. These were carried out at sub-national (pilot) scale, using a cluster randomised controlled trial in Kenya (2008–2009)[3.5] and a controlled before-and-after study design in Tanzania (2007–2008). Finally, a mixed-method, multi-country study was conducted in 2010–2012 to evaluate ACT subsidies at a national scale in Ghana, Kenya, Madagascar, Niger, Nigeria, Uganda and Tanzania (including Zanzibar).

Subsidies and supporting interventions were shown to have been effective in improving availability, affordability and market share in the majority of settings.[3.6]

3. References to the research

3.1 Goodman, C, Kachur, SP, Abdulla, S, Mwageni, E, Nyoni, J, Schellenberg, JA, Mills, A and Bloland, P (2004) Retail supply of malaria-related drugs in rural Tanzania: risks and opportunities, *Tropical Medicine and International Health*, 9(6): 655–663, doi: 10.1111/j.1365-3156.2004.01245.x. Citation count: 46

3.2 Goodman, C, Kachur, SP, Abdulla, S, Bloland, P and Mills, A (2009) Concentration and drug prices in the retail market for malaria treatment in rural Tanzania, *Health Economics*, 18(6): 727–742, doi: 10.1002/hec.1473. Citation count: 6

3.3 O'Connell, KA, Gatakaa, H, Poyer, S, Njogu, J, Evance, I, Munroe, E, Solomon, T, Goodman, C, Hanson, K, Zinsou, C, Akulayi, L, Raharinjatovo, J, Arogundade, E, Buyungo, P, Mpasela, F, Adjibabi, CB, Agbango, JA, Ramarosandratana, BF, Coker, B, Rubahika, D, Hamainza, B, Chapman, S, Shewchuk, T and Chavesse, D (2011) Got ACTs? Availability, price, market share and provider knowledge of anti-malarial medicines in public and private sector outlets in six malaria-endemic countries, *Malaria Journal*, 10(326), doi: 10.1186/1475-2875-10-326. Citation count: 16

3.4 O'Connell, KA, Poyer, S, Solomon, T, Munroe, E, Patouillard, E, Njogu, J, Evance, I, Hanson, K, Shewchuk, T and Goodman, C (2013) Methods for implementing a medicine outlet survey: lessons from the anti-malarial market, *Malaria Journal*, 12(52), doi: 10.1186/1475-2875-12-52. Citation count: 0

3.5 Kangwana, BP, Kedenge, SV, Noor, AM, Alegana, VA, Nyandigisi, AJ, Pandit, J, Fegan, GW, Todd, JE, Brooker, S, Snow, RW and Goodman, C (2011) The impact of retail-sector delivery of artemether-lumefantrine on malaria treatment of children under five in Kenya: a cluster randomized controlled trial, *PLoS Medicine*, 8(5): e1000437, doi:10.1371/journal.pmed.1000437. Citation count: 13

3.6 Tougher, S, ACTwatch Group, Ye, Y, Amuasi, JH, Kourgueni, IA, Thomson, R, Goodman, C, Mann, AG, Ren, R, Willey, BA, Adegoke, CA, Amin, A, Ansong, D, Bruxvoort, K, Diallo, DA, Diap, G, Festo, C, Johanes, B, Juma, E, Kalolella, A, Malam, O, Mberu, B, Ndiaye, S, Nguah, SB, Seydou, M, Taylor, M, Rueda, ST, Wamukoya, M, Arnold, F and Hanson, K (2012) Effect of the Affordable Medicines Facility – malaria (AMFm) on the availability, price, and market share of quality-assured artemisinin-based combination therapies in seven countries: a before-and-after analysis of outlet survey data, *Lancet*, 380(9857): 1916–1926, doi: 10.1016/S0140-6736(12)61732-2. Citation count: 10

Key grants

Goodman, Economic Analysis of the Markets for Antimalarials in Rural Africa, Wellcome Trust, 1/10/2000–31/12/2004, £174,011.

Hanson, Antimalarial Drugs: Market and Supply Chain Research and Policy Recommendations (ACTwatch), Bill & Melinda Gates Foundation (LSHTM contracted by PSI), 1/9/2007–28/2/2013, $987,024.

Hanson, Independent Evaluation of the Affordable Medicines Facility – Malaria (AMFm), The Global Fund to Fight AIDS, Tuberculosis and Malaria (LSHTM subcontracted by ICF International), 15/2/2010–31/12/2012, $890,000.

Goodman, Evaluation of the Impact of Retail Sector Delivery of ACT on Effective Malaria Treatment of Children Under Five in Kenya, DFID, through a grant to Population Services International, 1/4/2008–30/6/2010, $411,783.

4. Details of the impact

LSHTM research was pivotal both in shaping the design of the AMFm, an initiative launched in 2009 seeking to enable countries to increase the provision of affordable, quality-assured ACTs through the public, private not-for-profit and private for-profit sectors; and subsequently influencing the 2012 decision to integrate the AMFm into the core funding mechanism of the Global Fund to fight AIDS, Tuberculosis and Malaria.

In 2004, the US IOM committee suggested a subsidy of ACT administered at the top of the supply chain, and available through public and private sectors, to increase access to effective antimalarials and reduce the risk of artemisinin resistance. LSHTM research on the size of the private market and on private sector antimalarial prices was one of the few pieces of empirical evidence available. This evidence underlined the need to include the private sector in the subsidy mechanism, and was used to estimate the magnitude of price reduction needed to crowd out non-artemisinin therapies.[5.1, 5.2] Hosted and managed by the Global Fund, the AMFm was implemented in 2009 at national scale in eight African countries as a result of the IOM proposals, which were championed by the Roll Back Malaria partnership (which implements coordinated action against malaria).

The hypotheses that a subsidy programme would increase access to ACT and reduce the availability of artemisinin monotherapies which can encourage the spread of artemisinin-resistant strains of malaria, were tested in pilot antimalarial subsidy programmes in Kenya and Tanzania in 2008–2010, for which LSHTM researchers provided key methodological guidance[5.3] and which also informed the design of the AMFm.

The working groups designing the AMFm made direct reference to LSHTM work and LSHTM researchers were consulted on aspects of the design.[5.4] LSHTM research was also included among the evidence used to establish the success metrics against which AMFm would be assessed in the 2010–2012 independent evaluation[5.5] which would guide future board decisions.

LSHTM researchers (Hanson, Goodman and Tougher) were key members of the (competitively selected) AMFm independent evaluation team, and led the design and analysis of the outlet survey in the eight AMFm countries in Africa. LSHTM researchers also designed the qualitative case studies which generated data used to interpret and attribute programme impact. AMFm countries started ordering subsidised ACT in mid-2010, and by the end of 2012 over 292m doses of subsidised ACT had been ordered, of which 56% were paediatric.[5.6, 5.7] The independent evaluation showed that purchases of quality-assured ACT increased substantially in all but two countries, with ACT market share increasing from 16 to 40%. Subsidised antimalarials were reaching rural and remote areas and drug affordability was substantially improved, with price reductions observed in rural as well as urban areas.[5.7]

The research methods developed by LSHTM for studying retail antimalarial medicine supply have subsequently been adapted and used on a much larger scale by ACTwatch, a consortium including LSHTM and funded by Gates to monitor programme implementation in 2008–2013 and provide evidence on how to improve ACT availability and reduce private sector prices. ACTwatch adapted the tools of Goodman et al. for more than 30 nationwide surveys of retail outlets in 10 developing countries across Africa and Southeast Asia. Methodological innovations included sampling outlets where no sampling frame exists; ways to question informal medicine suppliers; metrics for comparing volumes across different antimalarial classes and formulations; methods for measuring sales volumes; and approaches for documenting the distribution chain. ACTwatch helped stimulate funding for new research and policy advocacy. The data have also been used for policy advocacy at country level, contributing, for instance, to the decision in Zanzibar to strengthen regulation to remove oral artemisinin monotherapies from drug selling outlets.[5.8]

The independent evaluation ultimately led to the integration of AMFm into core Global Fund processes in 2012. The note of the Global Fund board decision explicitly recognised the independent evaluation.[5.9, 5.10] In future, countries will be responsible for allocating resources to expand access to malaria diagnosis and treatment through the private sector from their overall

Global Fund grants.

Research team members Hanson and Tougher were cited in a range of media, including US National Public Radio, *Nature*, the *Irish Journal*, *BBC News*, *Science*, *The New York Times* and *News Medical*, helping to increase understanding of AMFm and the underpinning research among the general public.

5. Sources to corroborate the impact

5.1 University of Washington School of Public Health, Professor of Global Health.

5.2 Arrow, KJ, Panosian, CB and Gelband, H (eds) (2004) *Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance*. Washington, DC: National Academies Press, http://www.nap.edu/openbook.php?isbn=0309092183 (accessed 8 October 2013) (Box 3-1 summarises work by Goodman et al. on retail antimalarial markets in Tanzania; the AMFm, implemented in 2009, was proposed by this report; hence it is cited here although it predates the impact period; note also that the report cites Goodman et al. and Coleman et al. on evidence of cost effectiveness of ACT, reflecting earlier research).

5.3 Clinton Health Access Initiative former Executive Vice President.

5.4 AMFm Task Force, Roll Back Malaria Partnership (2007) *Affordable Medicines Facility – Malaria (AMFm): Technical Design*, http://www.rbm.who.int/partnership/tf/globalsubsidy/AMFmTechProposal.pdf (accessed 10 October 2013) (references to LSHTM work on pp. 32, 45 [ref. 54], 46 [refs 75, 99]).

5.5 Schäferhoff, M and Yamey G (2011) *Estimating Benchmarks of Success in the Affordable Medicines Facility – Malaria (AMFm) Phase 1*. Report submitted to the Global Fund to Fight AIDS, Tuberculosis and Malaria by the Evidence to Policy Initiative (E2Pi), Global Health Group, San Franciso, CA, http://www.theglobalfund.org/Documents/amfm/E2PI_EstimatingBenchmarksInAMFm_Report_en/ (accessed 8 October 2013) (LSHTM research referred to pp. 14, 15, 48 [x 2], 63 [note 1], 64 [note 51].

5.6 Global Fund to Fight AIDS, Tuberculosis and Malaria (2013) *Affordable Medicines Facility – Malaria (AMFm): Summary Report on Co-paid ACTs* (AMFm orders database), http://portfolio.theglobalfund.org/ReportLibrary/AMFm/Summary (accessed 8 October 2013).

5.7 Tougher, S et al. (2012) (see 3.6 above).

5.8 Zanzibar Malaria Control Programme, AMFm Coordinator.

5.9 Global Fund to Fight AIDS, Tuberculosis and Malaria (2012) Board approves integration of AMFm into core global fund grant processes, press release, 15 November, http://www.theglobalfund.org/en/mediacenter/newsreleases/2012-11-15_Board_Approves_Integration_of_AMFm_into_Core_Global_Fund_Grant_Processes/ (accessed 10 October 2013) (Global Fund minute refers to the Independent Evaluation report as guiding the decision, and the evaluation report was co-authored by LSHTM: see http://www.theglobalfund.org/en/amfm/independentevaluation/, accessed 10 October 2013).

5.10 Specialist, Monitoring, Evaluation and Implementation Research, Global Fund to Fight AIDS, Tuberculosis and Malaria.