Institution:
UNIVERSITY OF LIVERPOOL and LIVERPOOL SCHOOL OF TROPICAL MEDICINE

Unit of Assessment:
UOA1 - Clinical Medicine

Title of case study:
Building and implementing a replicable model for HIV Testing and Counselling

1. Summary of the impact

Research at the Liverpool School of Tropical Medicine (LSTM) has developed a successful approach to the rapid scale-up of HIV Testing and Counselling (HTC) services in high prevalence countries, a vital component of the global HIV response. The model combines comprehensive quality assurance with operational research and has led to HTC expansion in mobile, home and facility-based settings. It has also allowed for responsiveness to local needs leading to post rape care services linked to HTC, services for the deaf and HTC for men who have sex with men (MSM) and other hidden populations in Africa. The global impact of this model is reflected in WHO policy, Ministry of Health HTC guidelines in numerous countries in Africa, the on-going work of an indigenous Kenyan NGO and expansion of HTC through community outreach in the UK.

2. Underpinning research

Through a range of collaborations in Africa, Asia and the UK, LSTM has led research in the development and scale-up of quality assured, complex interventions to increase diagnosis of HIV, prevent transmission and improve HIV outcomes especially in generalised HIV epidemic areas and amongst adolescents and marginalised groups. LSTM staff who conducted this body of research has included Charles Gilks (Prof 1995 – 2002), Gillian Arthur (Clinical Lecturer 1999 - 2002), Miriam Taegtmeyer (Senior Clinical Lecturer 2001 - present), seconded to Kenya in 2001 - 2004 where she founded a local NGO, Liverpool Voluntary Counselling and Testing (LVCT), David Lalloo (Dean of Clinical Sciences 1999 – present) and Sally Theobald (Reader in Social Science 2001 - present).

HTC services using rapid diagnostic (20 minutes) HIV tests have helped millions of people learn their HIV status, and for those testing positive, learn about options for long term care and treatment. These rapid tests are highly sensitive and specific, they can be performed with a finger-prick blood sample; they do not require electricity or laboratory machines and can be performed by a health care worker or trained lay counsellor, making them suitable for use outside of health facilities. Confirmation through a second rapid test can provide immediate and final results, allowing onward referral and linkage to other services. LSTM conducted a DfID-funded pilot project in 1999 assessing the feasibility, acceptability and cost of integrating these newly available rapid tests into three primary health centres in Kenya. Integration was found to be both acceptable and feasible, to be associated with behaviour change and significantly reduced cost. It represented a significant improvement on previous practice where deferred results led to 47-66% of persons tested not receiving results [1].

Research headed by Taegtmeyer during her time in LVCT, led to the first published descriptions of translating these pilot studies into the scale-up of HTC services in high prevalence countries, a vital component of the global HIV response. Firstly describing expansion to 350 sites in Kenya [2], and how this was accompanied by a robust quality assurance system [3]. Additional operational research compared costs of mobile and stand-alone HTC services provided to 62,173 clients [4], discussed human resource implications and informed choices in mass media promotion for HTC that underpinned policymaker decisions to diversify models for HTC in Kenya from 2004 onwards as mobile services were found to be cost effective, lay counsellors to provide accurate results through a task shifting approach and media promotion that directly mentioned HIV positive results to be more successful than that which did not. The demand of services from vulnerable groups led to further studies on best approaches to deliver HTC services for post-rape care [5], for the deaf [6] and for men who have sex with men [7] in Africa as well as on improving linkages to HIV care among newly diagnosed positives, for example through home initiation of services.

Qualitative studies in the UK indicated acceptability and feasibility of similar approaches to point of care testing for HTC, although impact data was required before commissioners in the UK would make this part of routine HIV services. LSTM therefore conducted a pilot study in 2009- 2010 in

Liverpool using similar training, community entry, supervisory methods and radio interview outreach as done in Kenya. This brief 2009 pilot resulted in 953 tests and 17 new positives diagnosed and linked to care and treatment, an approach that is now funded by commissioners and integrated at the Royal Liverpool University Hospital.

3. References to the research

1. **Arthur GR**, Ngatia G, Rachier C, Mutemi R, Odhiambo J, **Gilks CF**. The role for government health centers in provision of same-day voluntary HIV counseling and testing in Kenya. (2005) Acquir Immune Defic Syndr. Nov 1; 40(3):329-35. Citations: 15 Impact Factor: 3.871

2. Marum E, **Taegtmeyer M**, Chebet K. Scale up of voluntary HIV counselling and testing in Kenya. (2006) JAMA. 296:859-62. Citations: 41 Impact Factor: 23.175

3. **Taegtmeyer M**, **Doyle V**. Quality Assurance Resource Pack for Voluntary Counselling and Testing Service Providers. Nairobi: Liverpool VCT Centre. (2003)

4. Grabbe KL, Menzies N, **Taegtmeyer M**, Emukule G, Angala P, Mwega I, Musango G, Marum E. Increasing access to HIV counselling and testing through mobile services in Kenya: strategies, uptake and cost-effectiveness**.** (2010) J Acquir Immune Dedic Syndr. Jul 1; 54 (3):317-23 Citations: 29 Impact Factor: 4.262

5. Kilonzo N, **Taegtmeyer M**, Molyneux C, Kibaru J, Kamonji V, **Theobald S**. Engendering health sector responses to sexual violence and HIV in Kenya: results of a qualitative study. (2008) AIDS Care. Feb; 20 (2):188-190. Citations: 8 Impact Factor: 1.466

6. **Taegtmeyer M**, Hightower A, Opiyo W, Mwachiro L, Henderson K, Angala P, Ngare C, Marum E. Responding to the Signs: A peer-led VCT programme for the Deaf in Kenya. (2009) Disability and Rehabilitation. 31 (6): 508-14 Citations:11 Impact Factor: 1.555

7. **Taegtmeyer M**, Davies A, Mwangome M, van der Elst EM, Graham SM, Price MA, Sanders EJ. Challenges in providing counselling to MSM in highly stigmatized contexts: results of a qualitative study from Kenya. (2013) PLoS One. Jun 7;8(6) Citations: 0 Impact Factor: 3.730

Key Research Grants

2013–2014 (1 year). **Bill and Melinda Gates Foundation**. Operational Characteristics of HIV self-test prototypes in lay users in sub-Saharan Africa. $187,000. **Miriam Taegtmeyer.** (PI)

2013 – 2017 (4 years). **FP7 Framework for Health.** REACHOUT – close to community services. €5.8 m. **Miriam Taegtmeyer**. (PI)

2010 – 2015 (5 years). **CDC.** Institutional collaboration between LSTM and CDC and Prevention on Malaria and HIV. $1.8 m. **Miriam Taegtmeyer**. (PI)

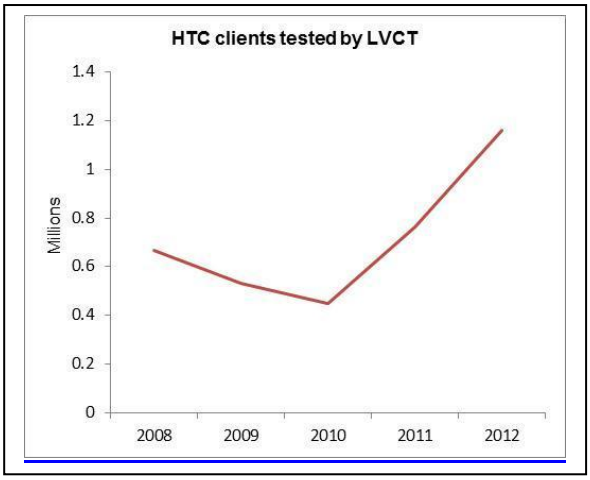
2001 – 2003 (2 years). **DFID**. VCT scale-up in government health facilities in Kenya.. £320,000. **Miriam Taegtmeyer** (PI)

2012 – 2015 (3 years). **Wellcome Trust**. ES Postdoctoral Research Fellowship - The social impact of HIV self-testing: reconstructing knowledge and re-framing risks associated with HIV prevention. £443,455. **David G Lalloo & Robert Heyderman** (PI's)

4. Details of the impact

HIV presents a significant health burden in Kenya with an estimated 104,000 infected children and 1,192,000 persons living with HIV infection in 2012 [8]. Early treatment has been associated with a

96% reduction in onwards transmission of HIV and theoretical modelling has shown that testing scale-up accompanied by treatment could lead to the eradication of HIV within a decade. LSTM's research has increased testing, both directly through the changes in policy and systems in Kenya and indirectly through the scalable quality assured services delivered in institutions like LVCT.



Health Impact

LVCT was founded by Dr Taegtmeyer to exploit the LSTM research findings on best practice for the delivery of quality assured HTC. The finding shaped the NGO's practice and is maintained today through methodologies documented by Taegtmeyer and referenced within the Kenya National Voluntary Counselling and Testing (VCT) guidelines in 2010 [9]. LVCT has grown into an internationally acclaimed indigenous Kenyan organisation (t/o US$ 9.2m pa). Dr. Kilonzo, Director of LVCT, completed her PhD at LSTM. LVCT continues to have a direct reach in HTC services in Kenya, as shown in the graph and supports post rape care services in 84 health facilities in 2012. The principles established in the early research have enabled rapid scale-up including mobile, outreach and home-based testing. A sound quality basis has facilitated adaptations to enable services for the deaf and other vulnerable groups including MSM and post-rape cases. The LVCT annual report [10] documents delivery of quality assured HIV and counselling to 1,159,970 clients, with 223,645 children, couples, MSM, persons with disabilities and sex workers in 2012. Levels of HIV testing have increased with 72% of adults aged 15 to 64 years in 2012 reporting ever having been tested for HIV, a significant increase from 34% in 2007. HIV prevalence among adults aged 15 to 64 years decreased nationally from 7.2%, to 5.6% in 2012, as indicated in the Kenya AIDs Indicator Survey [8].

The methodology documented by Taegtmeyer and LVCT was rolled out in 2008 onwards in other African countries and multiplied through WHO policies and guidelines. Partner agencies include the Ministries of Health in Ethiopia (focus on access to disadvantaged populations), Cote d'Ivoire (home testing) and Botswana and Tanzania [11] (quality assurance). The 2012 CDC/WHO handbook for planning, implementing and monitoring home-based HTC in high prevalence countries, was developed by Taegtmeyer and is globally available [12].

Policy Impact

Kenya: Dr Taegtmeyer was part of the editorial team of the first national guideline for VCT in Kenya. This was used as the basis for the updated guidelines in 2007 and the later second edition in 2010 [9] with a focus on provider initiated counselling and testing, quality improvement systems and inclusion of the option for HIV self-testing. The guideline changed practice and the approach to HTC with the establishment of a QA taskforce that developed a QA strategy for HTC linked to the new guidelines. The initial Kenyan quality assurance resource pack published in 2003 has been the basis of the 2012 National Quality Management Guidance Framework [13] for HIV testing and counselling in Kenya 2012.

International: LSTM research findings on HTC have gained considerable attention of international policy makers and significantly impacted policy on HTC in the WHO and at the US government's Centres for Disease Control (CDC). Taegtmeyer was a member of the PEPFAR counselling and testing team from 2007 – 2012. Taegtmeyer was the primary writer of WHO's Handbook for Improving HIV Testing and Counselling Services, published in 2010, translated into French and Mandarin [14]. Taegtmeyer also led the writing of a Practical Handbook on Planning, Implementing and Monitoring Home-based HTC [12], and was part of the core writing group of the Operational and Service Delivery Guideline Development Group for the WHO ART guidelines in 2013 [15]. Recommendations from the WHO on HIV re-testing were published in 2010 in French and English [15] and Taegtmeyer led on the expert consultation on acute HIV infection in Atlanta which was the basis of these recommendations. LSTM initiated the first ever international

symposium on self-testing for HIV, Taegtmeyer and Theobald contributed to the consensus statement agreed by UNAIDS, WHO, and the Brocher Foundation in April 2013 [17, page 33], on the legal, ethical, gender, human rights and public health implications of HIV self-testing scale up. Special acknowledgements were made to Taegtmeyer in the meeting report. [17, page 34]

UK: The research in 2009 led the Liverpool Centre for Sexual Health to adopt point of care testing as a direct consequence of the pilot and it is now in routine clinical use for HIV same day testing service, (730 POCT in 2012) targeting at risk individuals and was presented in a national forum that saw the beginning of the scale-up of point of care services in a range of sexual health clinics in the UK [18].

5. Sources to corroborate the impact

Each source listed below provides evidence for the corresponding numbered claim made in section 4 (details of the impact).

8. Kenya AIDS Indicator Survey 2012, Preliminary Report, http://nascop.or.ke/library/3d/Preliminary%20Report%20for%20Kenya%20AIDS%20indicator%20survey%202012.pdf

9. National Guidelines for HIV Testing and Counselling in Kenya, 2nd Edition, October 2010. http://nascop.or.ke/library/HTC/National%20Guidelines%20for%20HTC%20in%20Kenya%202010.pdf

10. LVCT Annual Report 2011/12 http://www.lvct.org/images/pdf/annual%20report%202012-2013.pdf

11. Tanzania Standard Operating Procedures for HIV Testing and counselling services. http://www.jica.go.jp/project/tanzania/001/materials/pdf/vct_10.pdf

12. Home-based HIV counselling and testing: CDC and WHO Practical Handbook for planning, implementing and monitoring home-based HTC in high prevalence countries (2012) http://www.cdc.gov/globalaids/Resources/prevention/docs/HomeBasedHIVTestingAndCounsellingHandbook.pdf

13. National Quality Management Guidance Framework for HIV Testing and Counselling in Kenya (2012) http://nascop.or.ke/library/HTC/National%20QMG%20Framework%20Final.pdf

14. WHO Handbook for improving HIV testing and counselling services Nov 2010. Taegtmeyer, LSTM first author http://www.who.int/hiv/pub/vct/9789241500463/en/index.html

15. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (2013) http://www.who.int/hiv/pub/guidelines/arv2013/en/

16. Delivering HIV results and messages for re-testing and counselling in adults (2010) (French and English). http://whqlibdoc.who.int/publications/2010/9789241599115_eng.pdf

17. Report with consensus statement, on the first international symposium on self-testing for HIV April 2013. http://apps.who.int/iris/bitstream/10665/85267/1/9789241505628_eng.pdf

18. Contact: Lead Nurse, Liverpool Centre for Sexual Health, Directorate of Sexual Health & HIV Medicine, Royal Liverpool and Broadgreen University Hospitals, can confirm numbers of Point of Care HIV same day testing, now in routine clinical use since 2009.