

<b>Institution: University of East Anglia</b>
<b>Unit of Assessment: 2 - Public health, health services research and primary care</b>
<b>Title of case study:</b> <b>Implementation of effective clinical practice in African primary care</b>
<p><b>1. Summary of the impact</b></p> <p>In order to reduce morbidity and mortality from HIV/AIDS, tuberculosis and other chronic diseases, effective and cost-effective interventions to strengthen primary care through in-service nurse training were put in place as standard practice throughout South Africa (population 50 million), based on our research. This programme has so far trained 1500 trainers in all 8 provinces, who in turn have trained 18,000 primary care professionals in 1900 of all 3500 clinics nationally. South Africa, with 5.8 million HIV+ people, and 500,000 newly infected with tuberculosis each year, based its Nurse Initiation and Monitoring of Antiretroviral Treatment policy on our training package and trials. These were landmark changes in primary health policy and provision in South Africa. The training methods and materials are also being used in Gambia, Malawi, Brazil and Portugal.</p>
<p><b>2. Underpinning research</b></p> <p>The research that led to the impact in this case study is the development and evaluation of educational methods to improve primary care in low and middle income countries. For over ten years this research provided evidence that these educational methods strengthen primary care in African countries, with particular focus on HIV/AIDS, tuberculosis and other chronic diseases.</p> <p><b>Practical Approach to Lung Health in South Africa (PALSA) (2000-2010):</b> UEA and South African researchers radically changed World Health Organisation (WHO) clinical practice guidelines and educational methods, aimed at integrating primary care of tuberculosis and other lung diseases. A large pragmatic cluster randomised trial showed that the PALSA education package, was effective, significantly increasing tuberculosis case detection and appropriate emergency referrals and asthma treatment, and was cost effective (research references 1-2).</p> <p><b>PALSA PLUS (2004-2011):</b> PALSA was expanded to cover HIV/AIDS and other sexually transmitted infections. A large pragmatic randomised trial (research reference 3) showed that PALSA PLUS improved the quality of HIV/AIDS care provided by primary care nurses. The research also showed that PALSA and PALSA PLUS increased tuberculosis cure and treatment completion rates and reduced patient dropout.</p> <p><b>Antiretroviral treatment (ART) expansion in South African primary care (2004-2011):</b> Novel statistical methods were used to evaluate ART effectiveness using patient cohort data (research reference 4). This provided the first rigorous evidence that ART in Africa could be highly effective even when implemented on a large scale. These studies also showed extremely high mortality rates among patients because of delays in their starting ART.</p> <p><b>Streamlining Tasks and Roles to Expand Treatment and Care for HIV/AIDS (STRETCH) (2007-2012):</b> The PALSA PLUS guidelines and training package was extended to cover initiation, monitoring and prescribing of ART, and nurse-led HIV/AIDS care which did not need doctors. This complex intervention was compared with South African standard of care in a MRC-funded pragmatic randomised trial (research reference 5). The trial showed that nurse-led ART was as effective as doctor-led ART in preventing deaths and in viral suppression, but was more effective in increasing patients' weight and immunity, detecting tuberculosis and improving treatment adherence. The cost effectiveness analysis (research reference 6) showed that STRETCH cost more than standard of care but was reasonably cost effective. Qualitative research identified barriers to implementation but showed how nurses were able to adopt this intervention.</p> <p><b>Integrated primary care of diabetes, hypertension, chronic respiratory disease and depression (Primary Care 101) (2010-2013):</b> The PALSA PLUS guidelines and training package was expanded to include diagnosis and treatment of these chronic diseases in adults and, diagnosis and treatment of depression in adults with chronic disease. This intervention was</p>

evaluated in a fourth NIH-funded pragmatic randomised trial, which currently is being analysed.

**UEA researcher involvement:**

**M Bachmann** - (Professor of Health Services Research, at UEA since 2003) has had lead roles in all the studies, especially trial design (PALSA, STRETCH, PC101), ART cohort studies, and economic evaluation (PALSA). He has supervised 5 South African PhDs based on this research.

**A Clark** - (Senior Lecturer in Medical Statistics, at UEA since 2005) had lead roles in developing statistical methodology for cluster randomised trials and economic evaluations.

**L Niessen** - (Professor of Public Health Economics & Public Health Modelling, at UEA since 2008) contributed to economic evaluation of PALSA.

**G Barton** - (Reader in Health Economics, at UEA since 2007) led the economic evaluation of STRETCH.

**3. References to the research**

*(UEA authors in bold)*

1. Fairall L, Zwarenstein M, Bateman, **Bachmann MO**, Lombard C, Majara B, Joubert G, English R, Bheekie A, van Rensburg D, Mayers P, Peters A, Chapman R  
Effect of educational outreach to nurses on tuberculosis case detection and primary care of respiratory illness: pragmatic cluster randomised controlled trial  
*BMJ* **2005** 331:750-754  
doi: 10.1136/bmj.331.7519.750
2. Fairall LR, **Bachmann MO**, Zwarenstein M, Bateman ED, **Niessen LW**, Lombard C, Majara B, English R, Bheekie A, van Rensburg D, Mayers P, Peters A, Chapman R  
Cost effectiveness of educational outreach to primary care nurses to increase tuberculosis case detection and improve respiratory care: economic evaluation alongside a randomised trial  
*Tropical Medicine and International Health* **2010** 15: 277–286  
doi: 10.1111/j.1365-3156.2009.02455.x
3. Zwarenstein M, Fairall LR, Lombard C, Mayers P, Bheekie A, English RG, Lewin S, **Bachmann MO**, Bateman E  
Outreach education for integration of HIV/AIDS care, antiretroviral treatment, and tuberculosis care in primary care clinics in South Africa: PALSA PLUS pragmatic cluster randomised trial.  
*BMJ* **2011** 342:d2022  
doi: 10.1136/bmj.d2022
4. Fairall LR, **Bachmann MO**, Louwagie G, Janse van Vuuren C, Chikobvu P, Steyn D, Staniland G, Timmerman V, Msimanga M. Seebrechts CJ, Boule A, Nhwatiwa R, Bateman ED, Zwarenstein MF, Chapman RD  
Effectiveness of antiretroviral treatment in a South African program: a cohort study  
*Archives of Internal Medicine* **2008** 168:86-93  
doi: 10.1001/archinternmed.2007.10
5. Fairall L, **Bachmann MO**, Lombard C, Timmerman V, Uebel K, Zwarenstein M, Boule A, Georgeu D, Colvin CJ, Lewin S, Faris G, Cornick R, Draper B, Tshabalala M. Kotze E, van Vuuren C, Steyn D, Chapman R. Bateman E  
Task shifting of antiretroviral treatment from doctors to primary-care nurses in South Africa (STRETCH): a pragmatic, parallel, cluster-randomised trial  
*Lancet* **2012** 380:889–898  
doi: 10.1016/S0140-6736(12)60730-2
6. **Barton GR**, Fairall L, **Bachmann MO**, Uebel K, Timmerman V, Lombard C, Zwarenstein M  
Cost-effectiveness of nurse-led versus doctor-led antiretroviral treatment in South Africa: pragmatic cluster randomised trial  
*Tropical Medicine and International Health* **2013** 18:769-77  
doi: 10.1111/tmi.12093

## Impact case study (REF3b)

**Key grants supporting this research:**

Bachmann (PI, grant awarded to UEA) "Streamlining tasks and roles to expand treatment and care for HIV: randomised controlled trial, economic evaluation and qualitative process evaluation (STRETCH)" £820,000 Medical Research Council (UK) 2008-10.

Fairall (PI, grant awarded to University of Cape Town; Bachmann co-applicant). "Evaluation of antiretroviral provision in Free State clinics" \$800,000 Canadian IDRC/CIDA 2004-7.

**4. Details of the impact**

South Africa has the largest number of HIV infections of any country. Out of a population of 50 million people, 5.6 million are HIV+. On World Aids Day in September 2009, South African President Jacob Zuma announced the most significant government-led interventions to stem the AIDS epidemic since its emergence more than 20 years ago, stating that extraordinary measures are needed. He said that "*In order to meet the need for testing and treatment, we will work to ensure that all the health institutions in the country are ready to receive and assist patients and not just a few accredited antiretroviral centres. Any citizen should be able to move into any health centre and ask for counselling, testing and even treatment if needed*". This research has had major impact on the health policy to achieve this. The policy developments are all landmarks in primary health policy and provision in South Africa, and have also been applied in Gambia, Malawi, Brazil, Mexico and Portugal.

Because our research had shown PALSA PLUS to be both effective and cost-effective, in 2010 the South African National Department of Health adopted PALSA PLUS as the primary method of in-service training for nurse practitioners in public sector primary care facilities throughout the country. To implement this policy it contracted our partner, the Knowledge Translation Unit at the University of Cape Town Medical School, to provide the training, clinical guidelines and training materials (see corroborating source C). By January 2013 the KTU had trained 1500 trainers in all 8 provinces in South Africa, who had in turn trained 18,000 primary care professionals in 1900 health facilities (of a total of 3500 nationwide). Supported by the STRETCH trial's evidence, in 2011 the South African National Department of Health adopted Nurse-Initiated Antiretroviral Treatment (NIMART) as national policy for the nationwide expansion of ART in primary care.

The research programme started in 2000 with a WHO initiative to improve tuberculosis control worldwide by increasing detection of infectious cases. WHO's Practical Approach to Lung Health (PAL) programme encouraged low and middle income countries to implement PAL guidelines for the diagnosis and treatment of chronic lung diseases among primary health care workers. In collaboration with WHO and South African health departments, and with local primary care doctors and nurses, the researchers completely redesigned the guidelines and educational methods and implemented them throughout one province as PALSA (corroborating source A). After the PALSA trial showed that the intervention was effective and highly popular, and that large scale expansion was feasible, it became standard practice in the Free State province from 2002 on. PALSA was then expanded, as PALSA PLUS, to cover nurse-provided care of HIV and sexually transmitted infections. After the second trial showed that PALSA PLUS was effective, it became standard practice in two provinces in 2009/10 and then nationally in 2011. Subsequently, the researchers were commissioned by the South African National Department of Health to expand the clinical guidelines and training to include diabetes, hypertension, chronic lung disease and depression, and started to evaluate it as the PC101 trial in the Western Cape. Preliminary evidence from PC101 and engagement with the National Department of Health led to it becoming the standard guidelines and educational method for primary care nursing in South Africa (corroborating source C).

Meanwhile the research programme addressed controversial policies on antiretroviral treatment (ART) for HIV/AIDS. KTU was contracted to monitor and evaluate the Free State's HIV/AIDS programme the programme, and to manage all electronic medical patient records. Our finding that 53% of patients died while awaiting ART but that when ART was received it reduced mortality by 87% increased pressure on South African authorities to accelerate ART roll-out and to initiate ART promptly in eligible patients. A key problem though was the lack of doctors to provide ART, which only doctors were authorised to prescribe. The researchers therefore developed and helped the Free State provincial Health Department to implement STRETCH - a radical breakthrough in

enabling primary nurses to treat HIV/AIDS by training and authorising them to prescribe ART, in the face of objections by the national Department of Health, HIV physicians, and the South African Nursing Council. This intervention was at first permitted only because it was implemented as a randomised trial (corroborating source B). Nurse Initiated ART (NIMART) became national policy within months of the end of the trial and is expected to greatly enhance access to ART in South Africa. Any nurse needs to complete our training to be authorised to prescribe ART. Between 2010 and 2011, 300,000 more people started ART. ART expansion will greatly reduce morbidity and mortality due to HIV/AIDS, and help control the rampant tuberculosis epidemic.

Our research has also had wider international impact. In 2010 the Malawian Ministry of Health began implementing PALM PLUS, a local adaptation of PALS PLUS. In 2011 the Gambian Department of Health & Social Welfare began to implement its adaptation of PALS PLUS, and in 2012 started implementing NIMART based on the STRETCH model. PALS PLUS guidelines and training materials are also being used in Brazil, Mexico and Portugal.

## 5. References to corroborate the contribution, impact or benefit

- A.** Practical approach to lung health. Manual on initiating PAL implementation  
 World Health Organisation (2008)  
[http://whqlibdoc.who.int/hq/2008/WHO\\_HTM\\_TB\\_2008.410\\_eng.pdf](http://whqlibdoc.who.int/hq/2008/WHO_HTM_TB_2008.410_eng.pdf)

This manual explains why PAL is a cornerstone of WHO TB policy. On pages 122 and 123 it cites the Practical Approach to Lung Health in South Africa (PALS) guidelines and supporting research (English et al 2004, Bheekie et al 2006, English et al 2006).

- B.** S-T-R-E-T-C-H! Streamlining Tasks and Roles to Expand Treatment and Care for HIV.  
 In: *Tried and Tested. In Models for the Scale Up for HIV Prevention, Treatment and Care from South Africa and Beyond.* (pp 208-212)  
 Department of Health (2010)  
[http://www.hst.org.za/sites/default/files/TriedandTested\\_ModelsforScaleUpHIVPrevention\\_Book.pdf](http://www.hst.org.za/sites/default/files/TriedandTested_ModelsforScaleUpHIVPrevention_Book.pdf)

This book, published online by the South African National Department of Health, describes exemplary evidence-based models for expansion of HIV/AIDS care, with a chapter advocating STRETCH (pp. 209-212).  
 It cites the STRETCH randomised trial as supporting evidence (Fairall et al., 2008, which is the study protocol for the trial described in reference 6 of underpinning research).

- C.** Knowledge Translation Unit, University of Cape Town Lung Institute  
<http://www.knowledgetranslation.co.za/index.htm>

This website describes the whole programme, including activity data on national implementation, guidelines, training methods and materials, and research publications. It confirms that:

“The Department [of Health] has supported the Knowledge Translation Unit to introduce rapid and effective training to all nurse practitioners and other health care providers in primary health care clinics in South Africa using the methodology of PALS PLUS. Legal provision for nurses to prescribe ART has been provided using Section 56(6) of the Nursing Act of 2005.” ... “PALS PLUS is now a national training requirement for any nurse prior to authorization to prescribe NIMART”

“The KTU has updated and revised the Primary Care 101 guideline for national use, following input from the Colleges of Medicine of South Africa, the Medicines Control Council, the South African Pharmacy Council, the South African Nursing Council and the National Department of Health Chronic Disease Cluster.”

- D.** Letter from the Deputy Director General (formerly Director of Primary Health Care) of the South African National Department of Health, confirming the impact of the research. He has been involved in national implementation on the basis of this research since the beginning.  
 (letter held on file at UEA)