Marta Soares

Edward Cox



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| Unit of Assessment: 2 - Public Health, Health Services and Primary Care            |                           |                                       |
| Title of case study: Using Economics to Inform Budget Allocation in Global Health. |                           |                                       |
| Period when the underpinning research was undertaken: 2014-2019                    |                           |                                       |
| Details of staff conducting the underpinning research from the submitting unit:    |                           |                                       |
| Name(s):                                                                           | Role(s) (e.g. job title): | Period(s) employed by submitting HEI: |
| Paul Revill                                                                        | Professor                 | May 2011- present                     |
| Mark Sculpher                                                                      | Professor                 | Nov 1997 - present                    |
| Jessica Ochalek                                                                    | Research Fellow           | Oct 2014 - present                    |
| Beth Woods                                                                         | Senior Research Fellow    | Jan 2014 - present                    |
| Karl Claxton                                                                       | Professor                 | Oct 1989 - present                    |
| Simon Walker                                                                       | Senior Research Fellow    | Oct 2006 - present                    |

Sep 2007 - present

Sep 2017 - present

Period when the claimed impact occurred: 2014 – 2020

**Research Fellow** 

Is this case study continued from a case study submitted in 2014? N

Senior Research Fellow

1. Summary of the impact (indicative maximum 100 words)

Health economics research at York has led to health sector resource reallocations (within and across disease programs) by governments and intergovernmental organizations, resulting in improved and more equitable population health outcomes; particularly in Malawi/east Africa and in respect of HIV. Changes in national and global policies relate to: (i) prioritizing interventions for funding (through health benefits package design) in Malawi; (ii) informing best practice regionally in the East, Central and Southern Africa Health Community (iii) changing the criteria by which the World Health Organization (WHO) determine cost-effectiveness and thus prioritize interventions; (iv) HIV policy formulation by WHO leading to the adoption of life-saving interventions; and (v) investments in innovative HIV product development (e.g. HIV self-testing) by the Bill and Melinda Gates Foundation (BMGF).

2. Underpinning research (indicative maximum 500 words)

University of York methods and applied research, coupled with York researchers' support for policy uptake, has guided decisions on the organization and funding of healthcare in low-income countries (LMICs). Central to this research has been demonstrating how 'opportunity costs' can be understood in the complex environment of global health, assessing their likely magnitude (i.e. by estimating the benefits through alternative uses of limited budgets) and estimating the population health consequences of different policy choices. York's work has concentrated on guiding policy decisions in relation to national health systems in Malawi and other east and southern African countries; both by informing national (e.g. Ministry of Health) policymakers and those in international organizations - for instance, the WHO - whose policies affect healthcare globally but especially in LMICs.

An important tool to prioritize limited health budgets is a health benefits package (HBP). This defines the content of publicly subsidised healthcare on the path towards the Sustainable Development Goal (SDG) of Universal Health Coverage (UHC). In the past, HBP design has failed to consider the constraints faced by health systems (e.g. healthcare budgets, infrastructure and restrictions in the use of donor funding), because they were based on aspiration rather than reality, meaning they have rarely been fully implemented (because resources were not available) and vulnerable populations have lacked access to even the most valuable interventions. Research from York has provided an analytic framework and associated analyses for the design, development and ongoing use of HBPs, initially for Malawi and also for application in other settings [A]. The research estimated population-wide health consequences of prioritizing spending on many different health interventions and implementation priorities. covering all major diseases. It used a metric of "net health benefit" that shows the health gains from spending on one intervention compared to other possible uses of limited resources (i.e. net of health opportunity costs) to enable policymakers to maximize gains from their available budgets, make informed decisions on implementation priorities and health systems strengthening, negotiate with donors as to where additional funding would be most beneficial and decide trade-offs between maximizing health and meeting other valid social objectives (e.g. improving equity).



Using similar economic concepts and methods, based upon assessment of health opportunity costs, a second stream of research [B] has aided understanding of and calculated cost-effectiveness thresholds (CETs), which are benchmarks invoked to assess value-for-money from healthcare in applied analyses. Our research has produced empirical estimates of health opportunity costs for countries across the world that can be used even in the absence of such thorough assessments as was provided for Malawi's HBP. The WHO had previously deemed any intervention with a cost less than 1-3 times GDP per capita (pc) for every healthy life year (measured as a disability-adjusted life years (DALY) averted) as cost-effective. This was based on an approach, which could be described as an aspirational "demand side" notion, that sought to immediately and directly address unmet health needs. In direct contrast, our "supply side" estimates are based upon assessing the consequences of budget availabilities and capacities of health systems. Our study demonstrated that, given the resource constraints, the CETs of low and middle income countries (LMICs) should in reality be much lower than 1-3 times GDP per capita (eg. for Malawi, a CET of 0.01–0.51 GDP pc; and Kazakhstan, 0.33–0.59 GDP pc). This led to a focus on scaling up provisions of lower cost and highly productive health care to those in need, thus leading to 'more health for the money' from available budgets.

A similar methodological approach has been applied to guide the formulation of international HIV policies. As members of the HIV Modelling Consortium, York researchers have contributed to epidemiological and economic analyses to inform WHO HIV Guidelines in 2016, 2017 and 2019; all demonstrating how limited HIV funding can be used to its greatest effect. The approach also demonstrates how any additional funding made available can most impactfully be used. One study, undertaken for the 2016 Guidelines, showed how a simplified form of monitoring patients receiving HIV treatment (known as *viral-load-informed differentiated care*) would be cost-effective in sub-Saharan Africa, reducing burdens on clinics and making care more easily accessible for patients [C]. In a simulated model for Zimbabwe, over 20 years, the CD4 count monitoring strategy, previously recommended by WHO, was estimated to avert 540,000 Disability Adjusted Life Years (DALYs) compared with no monitoring and cost USD500,000,000, whereas the proposed approach of viral-load-informed differentiated care was estimated to avert 1120,000 DALYs compared with no monitoring and cost USD361,000,000.

Further economic analyses have informed the 2017 WHO HIV Guidelines on interventions for those beginning HIV treatment with advanced HIV disease, defined as having CD4 cell count <200cells/mm3. An initial cost analysis was included in the REALITY clinical trial paper of prophylaxes against the major causes of the estimated 690,000 annual HIV deaths **[D]**. The study found that 3 lives would be saved for every 1000 patients treated and our analysis showed this was affordable. Our initial analysis did not assess the determinants of cost-effectiveness in all settings, but this was evaluated in later research which highlighted the importance of reducing drug prices to generate greater health benefits **[E]**.

Finally, our research has also guided investments in new early-stage products. One such study showed the beneficial population health impacts likely to result from the development and availability of HIV self-testing, as an alternative approach to facility-based HIV testing **[F]**. It estimated that in Zimbabwe 7,000 DALYs would be averted at modest cost, with similar impacts also expected in other African countries. We recommended the commitment of funding to bring HIV self-testing to market and make its availability widespread.

**3. References to the research** (indicative maximum of six references) All references are peer reviewed and have resulted from peer reviewed research funding. They are reflective of a much broader body of work. York authors are named in bold.

**A.** J. Ochalek, P. Revill, G. Manthalu, F. McGuire, D. Nkhoma, A. Rollinger, **M. Sculpher** and **K. Claxton**, "Supporting the development of a health benefits package in Malawi," *BMJ Global Health,* vol. 3, no. 2, p. e000607, 2018. <u>http://dx.doi.org/10.1136/bmjgh-2017-000607</u>.

**B. B.** Woods, P. Revill, M. Sculpher and **K.** Claxton, "Country-level Cost-Effectiveness Thresholds: Initial Estimates and Need for Further Research," *Value in Health,* vol. 19, no. 8, pp. 929-935, 2016. <u>https://doi.org/10.1016/j.jval.2016.02.017.</u>

**C.** Phillips, A. Shrouti, L. Vojnov, ..., **S. Walker**, T. Hallett and **P. Revill**, "Sustainable HIV treatment in Africa through viral-load-informed differentiated care," *Nature*, vol. 528, no. 7580, pp. 68-76, 2016. <u>https://doi.org/10.1038/nature16046</u>.



**D.** J. Hakim, V. Musiime, A. Szubert, ...**S. Walker**, ... and D. Gibb, "Enhanced prophylaxis with antiretroviral therapy for advanced HIV in Africa", *New England Journal of Medicine*, vol.377, no.3, 233-245, 2017. <u>https://www.nejm.org/doi/10.1056/NEJMoa1615822</u>.

**E. S. Walker, E. Cox, P. Revill,** V. Musiime, M. Bwakura-Dangarembizi, J. Mallewa, P. Cheruiyot, K. Maitland, N. Ford, D.M. Gibb, A.S. Walker, and **M.O. Soares**, "The cost-effectiveness of prophylaxis strategies for individuals with advanced HIV starting treatment in Africa", *Journal of the International Aids Society*, vol. 23, no. 3, 2020. https://onlinelibrary.wiley.com/doi/full/10.1002/jia2.25469.

**F.** V. Cambiano, D. Ford, T. Mabugu, S. N. Mavedzenge, A. Miners, O. Mugurung, F. Nakagawa, **P. Revill** and A. Phillips, "Assessment of the Potential Impact and Cost-effectiveness of Self-Testing for HIV in Low-Income Countries," *The Journal of Infectious Diseases,* vol. 212, no. 4, pp. 570-577, 2015. <u>https://doi.org/10.1093/infdis/jiv040</u>.

4. Details of the impact (indicative maximum 750 words)

Our research has been geared towards impact at various levels: **1**. <u>National</u>, especially in Malawi; **2**. <u>Regional</u> adoption of the HBP work in Malawi as best practice; and **3**. <u>Global</u> policymaking. The thread that brings these impact areas together is that the outcome of decisions made at higher levels can only be fully understood by determining impacts on those countries ultimately intended to be the beneficiaries of international health decisions.

## (1) Designing the Essential Health Package (EHP) of interventions to be prioritized for funding in Malawi (national level)

Like many countries, Malawi has chosen to prioritize spending by developing a health benefits package (which in Malawi is referred to as an Essential Health Package; the EHP). York methods and applications have been incorporated into Malawi's plans for healthcare provision through sustained engagement between the Ministry of Health (MOH) and York researchers, including an initial health economics workshop with the MOH and other Government departments held in June 2016 [5.1a] and annual meetings since 2016. In July 2017, Malawi published its medium-term strategic health plan for 2017-2022 with a chapter on EHP that is underpinned by York research [5.1b]. As the Deputy Director - Planning Department in the MOH puts it: "CHE's research has impacted on Malawian policy development in two ways: by providing an analytic framework which enables robust determination of the EHP around which the health budget is formulated; and by providing new estimates of Cost-Effectiveness Thresholds which allow us to prioritize those interventions which deliver health gains at lower costs" [5.1c; A, B]. The strategic health plan notes that previous EHPs could not be implemented partly because "the cost-effectiveness threshold that was used for determining whether an intervention would be included in the EHP did not reflect the opportunity cost of health spending in Malawi" [5.1b, p. 33]. Instead, the plan cites York research (including earlier work that was subsequently published as [A]) as providing more appropriate benchmarks [5.1b, pp. 33-5]. As a result, the revised EHP costs 31% less than the cost of providing its predecessor package, and less per DALY averted: "while implementing the previous package would have cost USD7.91 per DALY averted, with the revised EHP it only costs USD5.97 per DALY averted" [5.1b, p. 40]. York research has thus contributed significantly to a revised EHP which "provides better value for money than the previous package" [5.1b, p. 40].

As well as informing the allocation of Malawi's USD247million revised EHP, York's analytic framework and cost-effectiveness thresholds are also used by the Foreign, Commonwealth and Development Office (FCDO, formerly DFID) to guide allocation of funds in FCDO's Umoyo-Wathu Health Systems Strengthening Programme, which provides GBP130,000,000 funding for health assistance in Malawi. The FCDO Team Leader of the Human Capital Team describes the Umoyo-Wathu programme as *"firmly grounded on the EHP"* and explains that the programme 'focuses on scaling up access and impact of the EHP, and makes use of York's research to inform and guide investments in cost-effective health services" [5.1d].

## (2) Regional adoption of the HBP work in Malawi as best practice

York's analytic framework and cost effectiveness benchmarks developed for Malawi **[A, B]** subsequently influenced health policy regionally in the East, Central and Southern Africa Health Community (ECSA-HC) - the regional intergovernmental organization representing all Ministries of Health in its 9 member states (Kenya, Lesotho, Malawi, Mauritius, eSwatini, Tanzania,



Uganda, Zambia, Zimbabwe). As confirmed by the Director of Programmes, ECSA-HC formally recognises the Malawian EHP as best practice [5.1e]. As he writes: "The revised benchmarks on cost-effectiveness developed by York's Centre for Health Economics enable more focused and effective spending, providing better value for money and improved health outcomes" [5.1e]. In 2018, at their annual meeting, the 9 ECSA-region Ministers of Health wrote a regional Ministerial Resolution on Priority Setting and Health Benefits Package Design (HMC67/R2) [5.1f]. The resolution reflects the principles of the York research by proposing methods that reflect the realities of resource constraints, particularly the need to consider the supply side constraints to HBP implementation, and is now adopted as policy throughout the region. Following this, training on HBP design was provided by York researchers to MOH representatives and academic partners from 9 ECSA states (4-6 February, 2019, Lilongwe, Malawi). As a result, other countries in the region, including Uganda, Zambia and Kenya, have embarked upon efforts to revise their health benefits packages [5.1e]. York's approach to HBP design has also influenced health planning in Ghana, a country of 29,000,000 people and annual health insurance expenditure of ~USD250,000,000. In 2018, the MOH commissioned an economic evaluation of the national health insurance scheme. That evaluation notes that "the research methods were inspired by research in which an EHP was developed for Malawi)" [5.2, p.14; A].

The York approach to EHP design has also been adopted as an example of best practice by the UK FCDO. As the Team Leader in the Human Capital Team at FCDO Malawi explains: *"the Malawi example of the EHP is part of the FCDO Best Buys guidance to country offices, for helping develop effective health services"* **[5.1d]**. This document is provided to all FCDO incountry health leads.

## (3) Global health policy-making and prioritization

In June 2015, the WHO announced that it would stop recommending the use of 1-3 times the GDP per capita benchmark in its guidance **[5.3a]**. Through sustained engagement with the WHO **[5.3b]**, research from York on the most appropriate benchmarks to use to evaluate the cost-effectiveness of health interventions in LMICs influenced this decision (earlier work, subsequently published as **[B]**). A WHO Economist at this time notes the York research was: *"instrumental in shifting thinking about economic evaluation at WHO' and 'directly influenced a series of decisions at WHO to clarify its position about cost-effectiveness thresholds for LMICs...and enabled in turn the increased prioritization and scale-up of interventions that could deliver higher health gains for lower cost" [5.3c].* 

York methods research has also influenced recommendations by WHO clinical departments, especially in HIV. Our research (with the HIV Modelling Consortium, for which we lead economic analyses), has been incorporated into the last 3 HIV Treatment Guidelines and major updates [5.4a-c, 5.5a]. One study [C] argued for the adoption of a differentiated care approach to monitoring patients on HIV treatment and this was incorporated into the 2016 WHO HIV Treatment Guidelines [5.4a], leading to the approach now being available for the majority of the 17,000,000 people receiving HIV treatment worldwide. The Director of the HIV Modelling Consortium states: "The policy changes have reduced the frequency of visits required by patients to see healthcare providers, and led to increased health gains at a lower overall cost than previous treatment models used" [5.5b]. Differentiated treatment approaches have also been emphasised in the new UNAIDS HIV targets which will guide global HIV responses between 2020 and 2025 [5.6]. Additional research [D][E] has informed the 2017 WHO Advanced HIV Disease Guidelines recommendation for an enhanced package of care to those living with HIV and presenting at clinics with advanced disease [5.4b]. An independent review of the Joint Global Health Trials Scheme, funded to GBP138,800,000 in rounds 1-9, included the REALITY trial study [D] as its first example of impact and policy influence [5.7].

The Portfolio Holder for Advanced HIV Disease at WHO summarises: "The 2013 Consolidated HIV Guidelines included for the first time extensive disease modelling, costeffectiveness analysis and emphasised a public health approach to providing care to people living with HIV...UoY researchers (had) a major input to (the) policy shift towards providing ART for all people living with HIV in 2016...UoY has continued to provide important inputs into HIV guidelines processes (including) differentiated care, enhanced prophylaxis for advanced HIV disease, and changes in drug regimens" [5.5a]. Since then, there has been a major shift in the



emphasis placed on economic analysis: "Economic analysis is now recognized as being a critical component for Guidelines development. The work of the Centre for Global Development and the international working group convened by (CGD) and co-chaired by Paul Revill ...provided WHO and other international health agencies with recommendations for the use of economic analysis in health policy formulation" [5.5a].

The approaches that York has developed to economic analysis have additionally informed investments in health technologies of the future, especially by the BMGF who fund development of many products tailored for LMICs. York researchers have assessed the likely impacts of new HIV diagnostics, in particular. One example is the research on the potential of HIV self-testing **[F]**, if it were to come to market and become widely available. This led to investment in continued product development by the BMGF **[5.5b]**. The research also acted as a catalyst for further research. Most notably, research on feasibility and implementation was conducted through the HIV Self Testing in Africa (STAR) initiative, funded by UNITAID with support from the BMGF and others **[5.8a]**. York researchers' work on self-testing also led to a positive recommendation in the 2016 WHO Guidelines on HIV Self Testing Supplement **[5.8b]**, in which **[F]** was cited, and its availability was subsequently scaled-up **[5.5b]**. By July 2018, HIV self-testing was used by an estimated 4,700,000 people, with the global market expected to reach 20,000,000 annually by the end of 2020 **[5.8c]**.

5. Sources to corroborate the impact (indicative maximum of 10 references)
5.1. Informing Malawi's healthcare provision plans and further impact in the ECSA region. a) Modelling and health economics workshop, 8-10/6/2016, Lilongwe, Malawi; b) Government of the Republic of Malawi. Health Sector Strategic Plan II 2017-2022. Towards UHC 2017; c) Testimonial, Deputy Director - Planning Department, MOH, Malawi; d) Testimonial, Team Leader, Human Capital Team, FCOD-Malawi; e) Testimonial, Director of Health Programmes, East, Central and Southern Africa Health Community (ECSA); f) Resolutions of the 67th Ministers Conference, Zimbabwe, 12-14/11/2018.

**5.2.** Informing health benefits packages in Africa (outside the ECSA region) Vellekoop H, Odame E. (2018). <u>An Economic Evaluation Considering the Benefits Package of</u> <u>The National Health Insurance Scheme in Ghana</u>. MOH, Republic of Ghana.

**5.3.** Changing WHO cost-effectiveness thresholds. a) International Decision Support Initiative meeting 2015; b) Meetings relating to WHO benchmarks: For example, Workshop on health economics within the WHO Value-for-Money theme (Geneva 3/2016); c) Testimonial, former WHO Lead Economist.

**5.4.** Informing WHO international HIV guidelines. a) WHO, "<u>Consolidated Guidelines on</u> the Use of Antiretroviral Drugs for Treating and Preventing HIV Infectious: Recommendations for a Public Health Approach - 2nd Edition", 2016. [3.3] is cited as ref 4 (Working Group), p.477; b) WHO, "<u>Guidelines for managing advanced HIV disease and rapid initiation of</u> antiretroviral therapy" 2017. The REALITY trial [3.4] is summarised, pp.7-8, and a presentation of work subsequently published as [3.5], as well as [3.4], is summarised in the section *Cost and Cost-effectiveness*, p.10; c) WHO, "<u>Update of recommendations on first- and second-line</u> antiretroviral regimens", 2019. Ref 15 p.14, includes York researchers.

**5.5.** Expert testaments on HIV policy impacts. a) Testimonial, Portfolio Holder for Advanced HIV Disease, WHO; b) Testimonial, Director of the HIV Modelling Consortium on HIV product development.

**5.6.** Informing global HIV targets. UNAIDS. "World Health Day Report 2020: Prevailing against pandemics by putting people at the centre" 2020.

**5.7.** Influencing WHO on the response to advanced HIV disease. Case study summary 1: The REALITY trial (Gibb), p.2., in <u>Technopolis Group</u>, <u>Review of the Joint Global Health Trials</u> funding scheme: Final report, 2019.

**5.8.** Guiding the development and implementation of HIV self-testing. a) <u>The STAR</u> programme website ; b) WHO, "<u>HIV Self Testing and Partner Notification Supplement to</u> <u>Consolidated Guidelines on HIV Testing Services</u>"</u> December, 2016. [3.6] is summarised in section 2.2.4 Cost and Cost-effectiveness, pp. 26-28, as ref 164; c) Unitaid, WHO, <u>Market and technology landscape</u>: <u>HIV rapid diagnostic tests for self-testing</u>, 4th edition, 2019 (accessed 27/12/2020).