

Institution: University of York		
Unit of Assessment: 16 - Economics and Econometrics		
Title of case study: Estimating Health Opportunity Costs		
Period when the underpinning research was undertaken: 2008-2020		
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:
Karl Claxton	Professor	1989-present
Nigel Rice	Professor	1994-present
Stephen Martin	Senior Research Fellow	1989-present
Period when the claimed impact occurred: 2014-2020		
Is this case study continued from a case study submitted in 2014? No		
<p>1. Summary of the impact (indicative maximum 100 words)</p> <p>Research at York has estimated the health effects of changes in health care expenditure. <u>First</u>, these estimates inform all impact assessments conducted by the UK Department of Health and Social Care (DHSC). They have informed negotiation with the UK Treasury during spending reviews, the reform of the cancer drugs fund, how new vaccines are commissioned, and how health benefits are discounted in national accounts. They have also contributed to the negotiation of substantial rebates paid by pharmaceutical manufacturers to the NHS. <u>Second</u>, the research has inspired similar work in other countries and has directly informed national policy on pharmaceutical pricing in Norway and Canada. It has also informed the discounts required by health insurers and state-funded Medicaid programmes in the United States. <u>Third</u>, applying a similar approach to country level data has provided estimates of health opportunity costs for low and middle income countries (LMICs). This has led the World Health Organization (WHO) and the World Bank to change how they make recommendations about the cost-effectiveness of health care interventions, informed prioritisation at the Bill and Melinda Gates Foundation (BMGF) and has directly informed the development of the health benefits packages of the Ministries of Health in Malawi and Ghana.</p>		
<p>2. Underpinning research (indicative maximum 500 words)</p> <p>Research at York has estimated the marginal productivity of NHS expenditure or the shadow price of the NHS budget constraint. This indicates the health opportunity costs associated with additional NHS costs and how the cost-effectiveness of interventions and policies can be judged. It is central to a range of resource allocation decisions. Output [A] demonstrated how national data, which identifies expenditure by broad programmes of care, can be linked to mortality outcomes and used to estimate the relationship between changes in expenditure and health outcomes, while addressing issues of endogeneity by identifying and testing suitable instruments. This work was further developed through MRC/NIHR funded research to estimate expenditure and outcome equations across all 23 programmes of NHS care; capturing the effects of changes in expenditure on length and quality of life [B].</p> <p>This research also identifies where (by disease area) and what types of health outcomes (mortality and quality of life effects) are likely to be gained (lost) as a consequence of increases (decreases) in NHS expenditure and for whom (by age and gender). It provides the analytic and evidential foundation to incorporate a range of values that can be attached to different types of health effects (gained or displaced), as well as the associated wider consumption effects (supported by other York published research). Since 2014 the DHSC (Department of Health until 2018) has funded the development of this work as part of the Economic Evaluation Policy Research Unit (EEPRU) with analysis of subsequent waves of expenditure and outcome data [E], examination of the effect of the scale of budget impact and adopting an alternative approach to identification based on exogenous elements in funding allocations [C]. This research was conducted with close oversight by the DHSC and the Health & Care Alignment Working Group. The key insight was that the cost per Quality Adjusted Life Year (QALY) gained through changes in NHS expenditure is likely to be less than GBP15,000 per QALY, which is substantially less than the norms used to judge the cost-effectiveness of new health technologies. The DHSC renewed EEPRU</p>		

funding (2019) with estimation of health opportunity cost identified as a key priority area and extended the analysis to consider public health [F] and social care expenditure.

This work has been extended in a number of directions by researchers at York. The implications that these estimates might have for other countries was explored using estimates of income elasticity of demand for health and assumptions about the relative 'underfunding' of publicly funded health care. Work funded by the Bill and Melinda Gates Foundation (BMGF) applied estimated elasticities of health expenditure on mortality, survival and morbidity, using country level data, to country specific measures of: infrastructure, donor funding, population distribution, mortality rates, conditional life expectancies (by age and gender), disability burden of disease and total health care expenditure. This work provides estimates of country specific cost per Disability Adjusted Life Year (DALY) averted of changes in health expenditure in 93 low and middle income countries (LMICs) [D]. The key insight is that cost per DALY averted of changes in health expenditure is likely to be substantially lower than the norms widely used by global bodies which make recommendations, purchase health technologies or prioritise the development of new ones as well as decision makers in LMICs. Published York research showed that an assessment of the health opportunity costs of expenditure, and how it is likely to evolve over time, is an important consideration in the appropriate discounting of health and health care costs. The work was extended to cover LMICs, contributing to the BMGF reference case for benefit cost analysis. The research has also inspired similar work in other countries (Spain, Australia, Netherlands, Sweden, South Africa, China and Indonesia) with the advice or collaboration of York researchers.

3. References to the research (indicative maximum of six references)

[A] (2008) Martin S, Rice N, Smith PC "Does health care spending improve health outcomes? Evidence from English programme budgeting data" *Journal of Health Economics* 27(4):826–42 <https://doi.org/10.1016/j.jhealeco.2007.12.002>

[B] (2015) Claxton K, Martin S, Soares M, Rice N, Spackman E, Hinde S et al. "Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold" *Health Technology Assessment* 19(14):1-542 <https://doi.org/10.3310/hta19140> (Pub. as 2013 working paper, CHE RP 81)

[C] (2018) Claxton K, Lomas J, Martin S "The impact of NHS expenditure on health outcomes in England: Alternative approaches to identification in all-cause and disease specific models of mortality" *Health Econ* 27(6):1017-1023 <https://doi.org/10.1002/hec.3650>

[D] (2018) Ochalek J, Lomas J, Claxton K "Estimating health opportunity costs in low-income and middle-income countries: a novel approach and evidence from cross-country data" *BMJ Global Health* 3(6):1-11 <http://dx.doi.org/10.1136/bmjgh-2018-000964> (Pub. as 2015 working paper, CHE RP 122)

[E] (2019) Lomas JRS, Martin S, Claxton KP "Estimating the marginal productivity of the English National Health Service from 2003 to 2012" *Value in Health* 22(9):995-1002 <https://doi.org/10.1016/j.jval.2019.04.1926> (Pub. as 2018 working paper, CHE RP 158)

[F] (2020) Martin S, Lomas J, Claxton KP "Is an ounce of prevention worth a pound of cure? A cross-sectional study of the impact of English public health grant on mortality and morbidity" *BMJ Open* 10(10):1-12 <http://dx.doi.org/10.1136/bmjopen-2019-036411> (Pub. as 2019 working paper, CHE RP 166).

[A]-[F] Peer reviewed publications; [B]-[F] Funded by MRC, NIHR, BMGF.

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

UK Impact: Research at the University of York on health opportunity costs was described (by the former DHSC Chief Analyst) as "*the single most important piece of work*" being done for the DHSC [1a]. Since 2014 DHSC routinely uses GBP15,000 per QALY as an empirical estimate of health opportunity costs based on the findings of York research. Since 2014 this ongoing programme of research has been funded by DHSC (through EEPUR). Progress and findings are regularly presented by York researchers and discussed at frequent meetings with policy makers and analysts at DHSC and the Health & Care Alignment Working Group (a cross departmental group tasked with aligning how economic evaluations are undertaken) [1a][1b]. **This research has changed the way policy analysis undertaken by the DHSC is conducted** and "*the results of the work are being used in internal Impact Assessments at DHSC*", which are a mandatory requirement for all new policies introduced across

government. Since 2014, DHSC has undertaken 23 impact assessments using the GBP15,000 per QALY estimate, considering policies ranging from the regulation of dental charges to accelerated access to new medical technologies [1c]. These assessments reported a total financial impact of GBP1.9 billion. However, the health opportunity costs associated with these policies, which were not routinely considered prior to the York research, were estimated to be 125,846 QALYs, which the DHSC values at GBP7.5 billion.

York research on the marginal productivity of NHS expenditure has, at the request of DHSC, been extended to public health and more recently social care expenditure. These estimates have informed negotiations between HM Treasury and DHSC during periodic spending reviews and the role of public health and prevention in the strategic plan for the NHS. The findings of York research have been described (by the Chief Economist at Public Health England) as, *“the central message to HMT in relation to public health spending, and I believe was influential in securing a better funding settlement than in previous years”* [1b]. More recently these findings have also, *“been fed directly into the deliberations of the Health & Social Care Taskforce, a jointly-run group between HMT and No.10”* [1b]. York research has also had an impact on proposed reforms by DHSC and the Joint Committee on Vaccination and Immunisation (JCVI) regarding how new vaccines are commissioned, and how changes to existing national immunisation programmes are considered. An estimate of GBP15,000 per QALY was recommended to judge the cost effectiveness of immunisation programmes [1d]. The DHSC supported this recommendation, which *“should deliver a positive impact on overall population health through the better allocation of health resources,”* although, to date, this has not been taken up by the Government.

Research at York on health opportunity costs has also been central to the question of how much the NHS can afford to pay for the benefits offered by new pharmaceuticals. The importance of an empirical assessment of opportunity cost (‘displacement’) was evident in the terms of reference DHSC gave to National Institute for Health and Care Excellence (NICE) for developing value based assessment for pharmaceutical pricing [2a]. Claxton was a special advisor to the NICE Methods Working Party on value based assessment, and evidence of opportunity costs (‘displacement’) based on York research was presented, and informed the briefing papers [2a]. The scheme ultimately proposed by NICE in 2014 did not, however, reflect likely opportunity costs, and, as a consequence, was withdrawn following consultation, which included a critical submission from York [2b]. With evidence from York research, that the cost per QALY of NHS expenditure was likely to be lower than the norms used by NICE [2b], the DHSC was able to negotiate national rebates, based on caps on total branded pharmaceutical expenditure as part of the 2014 Pharmaceutical Price Regulation (PPRS) agreement. A new voluntary scheme was agreed, following confidential negotiations in 2018, where evidence from this body of research, indicating that the cost per QALY remains less than GBP15,000, was vital in securing continued rebates payments from 2019 to 2024 (GBP841,000,000 was repaid to the NHS from manufacturers in 2019) [3]. Researchers from York were involved in detailed discussions about rebate mechanisms with key stakeholders in preparation for these negotiations (e.g., ABPI May 2016, Janssen Dec 2017 and March 2018, DHSE and NHSE, May 2017 and March 2018).

York research has also informed other policies. For example, in 2015 the National Audit Office (NAO) investigated the Cancer Drugs Fund and requested evidence from York researchers. This showed that the health opportunity costs of the fund far exceeded possible health benefits. Following the NAO’s critical report, which cites this evidence [4], the Cancer Drugs Fund was reformed, removing the possibility of budget overruns (GBP136,000,000 in 2014/15), removing less cost effective drugs, and collecting more adequate evidence of benefit. The Office of National Statistics (ONS) commissioned an external review of discounting national accounts including health benefits where an empirical assessment of health opportunity costs is important. The review, co-authored by York researchers, drew heavily on the underpinning research and provided transparency and validation of how ONS discounts QALY gains [5] which informs the evaluation of a range of health policies.

Shaping Public Debate: As well as direct impact on a range of national policy and expenditure decisions in the UK, the research has generated broader public debate about funding and access to health care. This is evidenced by invitations to address a range of stakeholders including: devolved UK administrations (All Wales Medicines Strategy Group, Jan 2019); regulators (Association of Competition Law Judges & the European Commission, June 2018); health policy stakeholders (e.g. Westminster Health Forum Keynote Seminars Jan/Sept 2015, Jan 2016 & July 2017); clinical communities (e.g., Society of British Neurosurgeons Sept 2015, UK Oncology Forum June 2016 & June 2019, Academy of Medical Sciences June 2017); and the pharmaceutical and health insurance sector (e.g. FT Global Pharmaceutical and Biotechnology Conference Nov 2015, WPA Group Sept 2018). The impact on public debate is evidenced by interviews for TV ('[Trust me I'm a Doctor](#)' BBC2 2018), radio (e.g. BBC Radio 4 [Today Programme](#) Feb 2015) and coverage in print media (e.g. [The Times](#), [Financial Times](#), [The Guardian](#), Feb 2015) as well as invitations to address lay audiences (e.g., Stopaids Oct 2016 & April 2019, *Cafe Scientifique* March 2017, Rotary Club April 2018).

International Impact: The research has also had a direct impact on national policy on pharmaceutical pricing in Norway and Canada and discounts to list prices in the USA. Researchers at York were invited by The National Council for Quality Improvement and Priority Setting in Health Care to present the UK research to members of the Norheim Commission (Oslo, March 2014). This public enquiry recommended that the Ministry of Health and Care Services adopt a cost per QALY 'threshold' founded on evidence from York research [6]. These recommendations were adopted by the Norwegian Medicines Agency (NoMA) in 2015. Researchers at York were invited to present their research and its implications for pharmaceutical pricing to members of the Canadian Patented Medicines Price Review Board (PMPRB) (Banff, June 2017). PMPRB commissioned researchers at York to conduct an analysis of the likely cost per QALY for the Canadian Provinces, founded on the underpinning research, to inform their reforms to pharmaceutical pricing (Ottawa, May 2018). Following unsuccessful legal challenges, these reforms require potentially substantial discounts to list prices based on a cost per QALY threshold which draws on the results of this work [7a][7b]. The US Institute for Clinical and Economic Review (ICER) evaluates the clinical and economic value of prescription drugs. It has become known as the nation's independent watchdog on drug pricing, reporting 'health-benefit price benchmarks' that inform the discounts required by private health insurers as well as the state funded Medicaid programmes. Informed by York research, the ICER updated its value assessment framework which lowered its 'benchmark prices', following an invitation to present a series of ICER Webinars (June 2019) [8]. It has also inspired recent US research (with York researchers) that further strengthens the case that substantial discounts are often required.

Impact on LMICs: The Gates Foundation has funded research at York to apply a similar approach using country level data to provide estimates of health opportunity costs for LMICs. Following presentation of this work to the Foundation (Seattle, June & September 2016) this evidence has been integrated into how the Foundation undertakes health impact and cost effectiveness analyses for most product development projects in the BMGF portfolio [9a]. This analysis informs the executive board when prioritising product development decisions (York researchers presented to members of executive board, April 2019). The key insight from this research was that the cost per DALY of changes in health expenditure is likely to be substantially less than the 1 to 3 GDP *per capita* per DALY averted, which had become a widely used norm to make recommendations and inform decisions in LMICs. Following a presentation of these findings to key stakeholders in Global Health (June 2015) and at WHO (Geneva, March 2016) the WHO distanced itself from these norms [9b]. In September 2020 Claxton was appointed to the WHO working group for the Fair Pricing Forum and this work is informing proposals for tiered pricing mechanisms. Disease Control Priorities (DCP) is an influential resource published by the World Bank which guides global organisations, donors and LMICs in identifying essential packages of related and cost-effective interventions. Researchers at York were invited to discuss their research with DCP authors (Seattle, June 2016). The third edition of DCP rejects the previous norms as too high, and instead uses

criteria based on evidence from York research to identify those interventions which are likely to be cost-effective in different settings [9c].

This work has informed which interventions should be included in publicly and donor funded packages of care. The Ministry of Health (MoH) of Malawi invited researchers at York to assist in developing the Health Sector Strategic Plan and identify an essential health benefit package (HBP) based on evidence of health opportunity costs. Researchers at York worked closely with the MoH developing analysis which was presented to stakeholder workshops (Lilongwe, June 2016), which included the Minister of Health, senior civil servants, politicians and donors. This provided the MoH with a transparent, evidence based approach to informing the content and scale of the HBP with existing resources, identifying interventions that should be prioritised and the value of implementation efforts [10a][10b]. This HBP is recognised as an example of how universal coverage might be achieved with a more affordable package that almost doubles the DALYs averted in Malawi, evidenced by the Minister of Health being invited to address the plenary opening of the 71st World Health Assembly in Geneva about the Malawian HBP [10c][10d]. York Researchers also provided advice during the development of the health benefits package for Ghana, which took a similar approach, based on evidence of health opportunity costs from York research [10e]. **In summary, by informing policy and practice in relation to decisions on the use of health care resources the research, as whole, has contributed to maximising the health gains achieved from limited resources both nationally and internationally.**

5. Sources to corroborate the impact (indicative maximum of 10 references)

- [1] **DHSC:** (a) Testimonial from Former Chief Analyst, DoH (2013-16) 23 July 2020; (b) Testimonial from Chief Economist, PHE, 11 November 2020; (c) DHSC Impact Assessment Example Report - Accelerated Access Collaborative for health technologies (23 in total, all using the GBP15,000 threshold based on [B], see, p.10); (d) (May, 2018) Consultation on the Cost-Effectiveness Methodology for Vaccination Programmes and Procurement (CEMIPP) Report (p.14 cites working paper for [B])
- [2] **NICE:** (a) (March 2014) Centre for Health Technology Evaluation: Consultation Paper, Value Based Assessment of Health Technologies; (b) (Sept. 2014) Value Based Assessment proposal, Director, Centre for Health Technology Evaluation (Cites working paper [B] p.11)
- [3] PMLive Article – Chair, Ethical Medicines Industry Group EMIG. Comment: the new UK pricing deal. “Government has threatened the industry during every recent PPRS negotiation with a reduction in the standard NICE cost-effectiveness threshold.”
- [4] (Sept. 2015) NAO ‘Investigation into the Cancer Drugs Fund’ ([B] cited, p.27)
- [5] Testimonial from Deputy Chief Economist, 4 June 2018
- [6] **Norway** - *Åpent og rettferdig – prioriteringer i helsetjenesten* (Open and fair priority setting in the health service). Official Norwegian Reports 2014:12 (21 York citations)
- [7] **Canada:** (a) (July 2019) PMPRB, Steering Committee on Modernization of Price Review Process Guidelines Final Report; (b) Testimonial from Director, Policy & Economics Analysis Branch, PMPRB, 30 November 2020
- [8] **USA:** Testimonial from President, ICER, 6 December 2020 with attached report
- [9] **LMICs:** (a) Testimonial from Deputy Director of Data and Analytics, Global Development, and Strategy Planning, BMGF, 30 November 2020; (b) Testimonial from former Economist, Dept. of Health Systems Governance & Financing, WHO, 27 November 2020; (c) (2017) World Bank ‘Disease Control Priorities: Improving Health and Reducing Poverty: 3rd Ed.’ (Ch.7, cites [B], York work also cited in Chs. 3 & 9)
- [10] **Malawi:** (a) Government of the Republic of Malawi. Health Sector Strategic Plan II 2017-2022. Towards Universal Health Coverage (cites [D], pp. 33,35); (b) Testimonial from the Secretary for Health, Ministry of Health, 2 February 2017; (c) Testimonial from Team Leader, Human Capital Team, Foreign, Commonwealth and Development Office, 26 October 2020; (d) (July 2018) Malawi expanding health care provision, Muluzi tells World Assembly. Malawi Nyasa Times; (e) (2018) Ministry of Health, Republic of Ghana. An Economic Evaluation Considering the Benefits Package of The National Health Insurance Scheme in Ghana (cites 5 York papers)