Institution: University of Liverpool

Unit of Assessment: 19 – Business and Management Studies

Title of case study: Evaluating Health Technologies for Health Policy and Clinical Practice

1. Summary of the impact

Health Technology Assessment (HTA) is a systematic approach to evaluating the safety, clinical and cost effectiveness of a drug/medical intervention into the NHS. Research and practice of HTA enabled Liverpool University to significantly impact and influence national and international health policy by optimising NHS decision-making on drug adoption and other clinical interventions, as well as disseminating HTA expertise and application around the globe. Reach is both geographical and organizational, spanning the UK NHS, the European, African and Asian healthcare systems, as well as with members of the Pharmaceutical industry. Numerous populations, from patients of the UK NHS, to world-citizens, benefit as a consequence of the application of health economics research.

2. Underpinning research

Rooted in Health Economics, HTA research at Liverpool grew out of a national programme of research aimed at optimising drug utilisation within the NHS. Prior to 1999, the introduction of new drugs into the NHS was the responsibility of hospital-based drug-formulary committees who would decide independently whether to introduce new drugs for hospital use. Different committees frequently made contradictory decisions implying that a fundamental NHS principle (equal access for patients in equal need) was replaced by a postcode lottery. Health Economics-informed research led by Professor Walley and Dr Haycox led to a number of articles (see for example Section 3.1) arguing for the establishment of a single evaluative body that would centralise expertise and undertake HTA on behalf of the entire NHS - in essence the National Institute for Clinical Excellence (NICE) which was established in 1999. Professor Walley has worked at Liverpool since 1990, and is also Director of the National Institute of Health Research Evaluations Trials and Studies Unit. Dr Haycox has worked at Liverpool since 1995 and is now Director of the Liverpool Health Economics Group.

Under the Directorship of Dr. Haycox, the Liverpool Review and Implementation Group was forged; one of seven independent academic units funded by NHS to undertake economics cost-benefit research with a specific aim to inform the policy decisions of NICE. University of Liverpool Management School staff aligned with the unit, who undertook key research underpinning the impact, included Dr A Haycox (2004-present); Prof T Walley (1986-1997); Dr R Hill (1954-1997); Prof A Baghust (2004-2008); Dr R Mujica-Mota (2007-2010). Health Economics research has been undertaken in a wide range of therapeutic areas including Thrombolysis (Section 3.2), Insomnia (Section 3.3), Coronary Artery Stents (Section 3.4) and Pemetrexed for the treatment of malignant Pleural Mesothelioma (Section 3.5). Specifically, the comparative value of surgery (Coronary Artery Bypass Grafting) and Stenting (performed by Interventional Radiologists) was a source of great controversy. This research (Section 3.4) provided an evidence base to ensure the utilisation of optimum treatment pathways for different sub groups of patients in this therapeutic area. The impact of each individual research project, on subsequent national healthcare policy and guidance resulting from the research, is outlined in section 5.

HTA research at Liverpool attained international recognition, facilitating further collaborations that extend the reach of this research-based approach beyond the UK. In particular, international collaborations were established to assist in the development of research and policy strategies in parts of the world in which healthcare systems were changing rapidly. The first collaboration (the Piperska Alliance) was established in 2008 between researchers at Liverpool led by Dr Haycox, the Karolinska Institute (Stockholm) and the Mario Negri Institute (Milan). This multidisciplinary network of researchers was established to develop research networks in order to undertake research aimed at informing national healthcare policy in the countries of Central and Eastern

Europe (CEE). Such countries had limited experience of either health research or health policy formulation in a market based environment and so a supportive research network was established in Liverpool to develop research skills and directly undertake research in such countries. Piperska now coordinates and collaborates with over twenty CEE countries in undertaking research to inform national policies and to optimise resource use in their healthcare systems (Section 3.6).

Other international collaborations have been established which emphasise the impact and international reach of Liverpool-based research. In particular, Liverpool has been preeminent in developing research infrastructures and 'roadmaps' for the establishment of HTA systems in South East Asia (SEA) and North Africa, both in supporting the establishment of universal systems of healthcare provision and in promoting the establishment of systems of HTA to optimise healthcare resource utilisation. A research-based structure of HTA is a pre-eminent need for the establishment of Universal healthcare coverage and, as a direct consequence of its research expertise, Liverpool is at the forefront of developing such research-based structures of HTA particularly in Indonesia and in Egypt.

3. References to the research

1. **Walley, T**., **Haycox, A**., Barton, S. Drug rationing in the UK NHS: current status and future prospects. Pharmacoeconomics, 1997. Vol 12, No. 3, pp 339-350. This article was published in the highest impact journal in its field. Impact Factor of 3.44
2. Boland, A., Dundar, Y., **Bagust, A., Haycox, A**., **Hill, R**., **Mujica-Mota, R**., **Walley, T**., Dickson, R. Early thrombolysis for the treatment of acute myocardial infarction: a systematic review and economic evaluation. Health Technology Assessment NHS R&D HTA Programme, 2003. Vol 7, No 15.
3. Dundar, Y., Boland, A., Strobl, J., Dodd, A., **Bagust, A**., **Haycox, A**., Bogg, J., Dickson, R., **Walley, T**. Newer hypnotic drugs for the management of insomnia: a systematic review and economic analysis. Health Technology Assessment, 2004, June. Vol 8, No 24.
4. **Hill, R**., **Bagust, A**., Bakhai, A., Dickson, R., Dundar, Y., **Haycox, A**., **Mujica-Mota, R**., Reaney, A., Roberts, D., Williamson, P., **Walley, T**. Coronary artery stents: a rapid systematic review and economic evaluation. Health Technology Assessment, 2005. Vol 8; iii-iv: 1-242.
5. Dundar Y, **Bagust A**, Dickson R, Dodd S, Green J, **Haycox A**, **Hill R**, McLeod C, **Walley T**. Pemetrexed disodium for the treatment of malignant pleural mesothelioma: a systematic review and economic evaluation. Health Technology Assessment. 2007.
6. Garattini S, Bertele V, Godman B, **Haycox A**, Wettermark B, Gustafsson LL. Enhancing the rational use of new medicines across European healthcare systems – A Position Paper. Eur Jn Clinical Pharmacology 2008; 64:1137–1138. This publication summarises the impact and international reach within the European context of the Liverpool co-founded Piperska Alliance.

Key grant awards:

- Haycox. *To develop and implement health needs assessment and predictive modelling using statistical and epidemiological methodologies in conjunction with existing HEU staff.* NHS North West. £72,135.78. 2010-2012
- Haycox. *Economic Evaluation of Public Health Interventions in Wirral.* Wirral Primary Care Trust. £236,057.75. 2012-2014
- Haycox. *The impact of the Liverpool Care Pathway on Care at the End of Life*. Department of Health. £592,879.63. 2010-2013
- Haycox. *Induction of labour in pre-eclamptic women: a randomised trial comparing balloon catheter with oral misoprostol.* Medical Research Council. £610,720.80. 2012-2015

4. Details of the impact

Research into Health Technology Assessment (HTA) undertaken at Liverpool has led to significant impacts at the local, national and global levels.

Local Level Impact. Liverpool provides Health Economics support to the Liverpool Clinical Trials Unit (LCTU), the largest CTU in the North West. Each proposal for clinical research, submitted to LCTU, is assessed in terms of the quality of its Health Economics content and, in appropriate circumstances, the health economics research component is improved or added to the trial design. Through this work, as well as relationships with local providers and commissioners of healthcare, Liverpool research has optimised resources allocated to a wide range of therapeutic areas. These areas extend from evaluating the Liverpool care pathway in end of life care to a range of research projects with Liverpool Women's hospital in the fields of paediatric and neonatal medicine. The corroboration offered by Wirral Primary Care Trust (Wirral PCT), a healthcare commissioner with whom Liverpool researchers have worked particularly closely, is evidence of Liverpool research directly impacting on the optimisation of healthcare resource allocation for local populations, both in terms of the optimisation of local commissioning and the provision of care in a wide range of particular patient groups and therapeutic areas (section 5.2).

National Level Impact. HTA research at Liverpool has played an important role is establishing the policy and practice of drug adoption in the NHS. As an independent academic unit funded by NHS R&D, and working directly with NICE, the research that it undertakes has a direct and significant impact on healthcare provision within the UK. Each of the research projects identified in section 2, has led directly to a change in national policy (Section 5.1) in order to enhance the provision of health care in a range of therapeutic areas, including thrombolysis, treatment of insomnia, malignant mesothelioma and coronary artery disease. For example, by identifying the optimal relationship between resource allocation and clinical pathways and outcomes, for patients suffering a heart attack, the research emphasised the importance of providing patients with access to Thrombolysis during the one hour period (the 'golden hour') following the attack. Additionally, the research into treatment for insomnia (Section 3.3) identified that new drugs (the 'Z' drugs) were found to be of limited clinical effectiveness and did not provide 'value for money' for the NHS. As a consequence of his international reputation as a research leader, Dr. Haycox was invited to join the NICE Appraisal Committee in 2008, and his role in NICE has been crucial in extending the impact of the research undertaken at Liverpool globally.

International Level Impact. Liverpool has contributed substantially to International Healthcare Policy; specifically research in South East Asia, North Africa and Central Eastern Europe, facilitating the implementation of structures and skills of HTA that optimise the introduction of new drugs into national healthcare systems. Many of the health systems of low to middle income countries are in flux with regard to the nature and structure of their healthcare systems. HTA research at Liverpool has impacted on health systems in countries of North Africa and South East Asia favouring a move towards universal health coverage rather than a more 'market' oriented approach. In support of universal coverage, Liverpool research has been helped to champion the use of structures of Health Technology Assessment as a 'rationing' device to maintain healthcare expenditure within sustainable levels. Health technologies that are introduced into a health system that provides universal coverage serve all of the population and not just the rich, so HTA provides a mechanism by which to allocate scarce healthcare resources. To facilitate this, Liverpool developed research-based guidance concerning optimal structures of HTA to support the establishment of universal health coverage in Indonesia and Egypt. Another crucial element of such guidance was to identify the skills and expertise that must be developed within national research-based academic groups to support the establishment of effective systems of HTA. The contribution of Liverpool to research-based policy and skills development is widespread, with exemplars to demonstrate the impact and reach of the research in three areas: Central and Eastern Europe (CEE), South East Asia (specifically Indonesia) and North Africa (specifically Egypt).

The impact and reach of HTA research at Liverpool has been extended through collaborative relationships with Pharmaceutical Companies. A particularly close collaborative partnership with

Novartis (the second largest drug company in the world), at both the national and global level, has been instrumental to diffusing the Liverpool HTA research to inform policy and practice in North Africa and South East Asia (Section 5.5). Also, optimising the management of new medicines is a particular challenge for countries in CEE, given their limited experience of market-based healthcare provision. The Piperska alliance, led by Liverpool, has developed research-based collaborations between leading academics and policy makers from Poland, the Czech Republic, Slovakia, Slovenia, Latvia, Lithuania, Estonia, Serbia, and Turkey. This has led to enhanced HTA research structures being established in many CEE countries leading to greater control on the introduction of new drugs and a consequent improvement in resource allocation and population health (for further details see Section 3.6; Section 5.5).

The principal beneficiaries of the impacts are:

- Patients in the UK, through the use of research-based HTA to target resources on interventions of proven clinical and cost effectiveness;
- Healthcare practitioners, both managerial and clinical, in the UK, through the establishment of optimal structures of healthcare provision based entirely on research-based evidence;
- Pharmaceutical companies through joint research-based HTA projects which independently evaluate the clinical and cost effectiveness of new drugs;
- Patients in SEA, North Africa and CEE, through the optimisation of healthcare provision to support the establishment of universal healthcare coverage;
- Health services within SEA, North Africa and CEE through joint research and training initiatives.

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

1. The Chief Executive of NICE can be contacted to attest that the guidelines issued by NICE on thrombolysis; insomnia; malignant mesothelioma; and coronary artery disease, were directly informed by assessment reports provided by Liverpool as sources of evidence (Appendix B in all cases), and are being currently applied.

2. The previous Director of Performance (Wirral PCT) and now Director of Pubic Health (Wirral Borough Council) can be contacted to attest to the impact of Liverpool research in optimizing the provision of local healthcare for the benefit of the local population and treatment afforded to particular patient groups.

3 The former Dean of the School of Public Health at the Centre for Health Economics and Policy Analysis (CHEPS), Universitas Indonesia, has provided a testimonial attesting to the 'fundamental and significant impact' that Liverpool has exerted on health research and policy in Indonesia and South East Asia.

4 The Manager of the Minister's Technical Office, Ministry of Health and Population in Egypt, has provided a testimonial attesting to the impact of research at Liverpool on the development of universal healthcare coverage and developing the skills and knowledge necessary to develop HTA expertise in Egypt - "We see Liverpool as being a preeminent research based group that has significantly influenced health research and policy in Egypt".

5 The Head of Market Access and External Affairs for Novartis Turkey. Until recently he was Director of Novartis in the AMAC region (Asia, Middle East and Africa). He has provided a testimonial attesting to the ' significant impact that the collaborative research undertaken between the Liverpool Health Economics team and Novartis pharmaceuticals has exerted on a global level'.