Institution: University of Sheffield

Unit of Assessment: 2 - Public Health, Health Services and Primary Care

Title of case study: A new measure for assessing the cost-effectiveness of health care interventions: the SF-6D

1. Summary of the impact

The decision about whether to fund new health care interventions is increasingly being informed by evidence of cost-effectiveness in terms of the cost per Quality Adjusted Life Years (QALY). The SF-6D health index is widely used internationally for calculating QALYs from patient reported health outcomes collected in clinical trials and other surveys. It contributes to *health system efficiency* from being used by health technology agencies around the world (including Australia, Canada, England, Scotland, Ireland and Norway) to calculate QALYs to facilitate decisions about the most efficient use of limited health care resources. The SF-6D is freely available to non-commercial bodies, including researchers and policy makers. *Commercial benefits* come from the licensing of the measure to pharmaceutical companies, health insurers and others to assess the cost-effectiveness of their products with 460 licenses being sold since 2008. A further 521 licenses are distributed on a non-commercial basis to academic researchers, public sector and charitable organisations.

2. Underpinning research

The SF-6D health index is a measure used in assessing the cost-effectiveness of health care interventions. The main project was undertaken between 1999 and 2002 at the University of Sheffield's School of Health and Related Research (ScHARR) by John Brazier (1989-), Jennifer Roberts (1997-2003) and Mark Deverill (1995-2002), funded by a grant from GlaxoWelcome (R1).

The SF-6D was derived from the SF36 (www.sf-36.org), a widely used patient reported measure that assesses health across 8 dimensions. The SF-36 does not enable trade-offs between them (e.g. pain vs. physical functioning), or between quality and length of life and so could not be used to assess cost-effectiveness. The SF-6D index was developed in order to overcome these limitations.

The main project (1999-2001) involved 3 stages:

1) Revising the SF-36 using psychometric methods to a 6 dimension classification (physical functioning, role limitation, social functioning, pain, mental health and vitality) amenable to valuation.
2) Obtaining population preferences for the 6 dimensions for a sample of states via face-to-face interviews with a representative sample of the UK general population (n=836) using standard gamble, a choice based method for measuring preferences under uncertainty.
3) Estimating values for all 18,000 health states defined by the SF-6D using econometric modelling techniques.

The resulting algorithm generates an index for health anchored at 0 (equivalent to being dead), and 1 (full-health), with negative values denoting states worse than being dead. This algorithm shows how much value people place on different health limitations and how they trade-off between them (e.g. how much vitality they will sacrifice for a reduction in pain).

The main research was published in 2002 (R2) and since then the SF-6D has become widely used around the world. The SF-6D has a number of advantages over the previously used main health valuation measure the EQ-5D: it has a richer descriptive system (with 18,000 states as opposed to only 243 for the EQ-5D), it is more sensitive to health changes particularly for milder states (R3) and it covers a broader range of health dimensions by including role limitations, social functioning and vitality. The SF-36 is often used in clinical studies and so this algorithm enables QALYs to be estimated without the need for additional data collection.

There have been 4 main extensions to increase impact: 1) The development of an algorithm for the SF-12 (a reduced version of the SF-36), thus increasing the reach of the work (R4). 2) The development of an improved algorithm using Bayesian methods (R5), allowing decision makers to take better account of differences across patients. 3) The development of valuation algorithms for SF-6D in other countries including Japan (R6), Brazil, China (Hong Kong), Australia, Portugal and Spain. It has also been used to derive an index from the VR-12 for use in Medicare data sets in the USA. 4) The development of algorithms for condition specific measures of health, extending the reach to health problems and trials where generic measures have not been used or are not appropriate.

3. References to the research

Main grant:

R1. Brazier J, Deverill M, Roberts J. Estimation of a utility based algorithm for the SF-36, *Glaxo-Welcome*, 1997-99

Main journal paper:

R2. Brazier J, Roberts J, Deverill M (2002) The Estimation of a Preference-Based Measure of Health from the SF-36 *Journal of Health Economics*, 21(2) 271-292. doi: 10.1016/S0167-6296(01)00130-8 **[930]** [Awarded the 2002 *International Society for Quality of Life* Prize for ''Outstanding contribution to the study of health related quality of life''. Andrew Oswald (2009), in his Warwick Economics Research Paper (No.887) "World-leading research and its measurement", notes this paper as among the top most cited economics papers in the world.

Other key papers arising from this research:

R3. Brazier J, Roberts J Tsuchiya A, Busschbach J. (2004) A comparison of the EQ-5D and SF-6D across seven patient groups *Health Econ.* 13(9) 873-884 doi: 10.1002/hec.866 **[247]**

R4. Brazier J, Roberts J (2005) Estimation of a preference-based index measure of health for the SF-12 & comparison to the SF-36 preference-based index *Medical Care*, 42(9), 851-859 **[271]**

R5. Kharroubi SA, Brazier J, Roberts J, O'Hagan A. (2007) Modelling SF-6D health state preference data using a non-parametric Bayesian method. *Journal Health Econ.* 26(3): 597-612 doi: 10.1016/j.jhealeco.2006.09.002 **[31]**

R6. Brazier J, Fukuhara S, Kharroubi SA, Roberts J, (2009) Estimating a preference-based index from the Japanese SF-36 *Journal Clinical Epidemiology* 62(12): 1323-1331 doi: 10.1016/j.jclinepi.2009.01.022 **[11]**

4. Details of the impact

The development of the SF-6D contributes to *public policy and services* around the world and has *commercial benefits* in the UK. The health system efficiency improvement arises from the use of SF-6D data in the assessment of the cost-effectiveness of health care interventions by health services and regulatory agencies around the world. Commercial benefits come from the licensing of the measure to pharmaceutical companies and others who need to demonstrate the cost effectiveness of their products to these agencies.

Achieving impact

Dissemination of the SF-6D was initially targeted at the funders (GlaxoWelcome) and to key decision makers (e.g. Department of Health). The work was presented at conferences attended by potential end users including: pharmaceutical companies (International Society for Pharmacoeconomics and Outcomes research), HTA agencies (International Society of Technology Assessment in Health Care, 1999), Australian policy makers (the Australian Health Outcomes Collaboration in 1999), and US policy advisors (Institute of Medicine, USA in 2004). Information about the SF-6D and other measures developed in ScHARR is advertised at user conferences

(e.g. ISPOR, ISOQOL). The team has continued to promote the SD-6D through publishing research showing how well it performs compared to other instruments in terms of psychometric properties and across different conditions (R3).

To maximise access, the SF-6D is supplied in easy to use software including excel, SPSS and SAS programs accessible to a wide a range of users. These programs can be run on SF-36 (version 1 or 2) and SF-12 datasets to estimate the SF-6D index on the zero to one scale for calculating QALYs. Guidance and instructions on how to use the programs are provided at the sf-6d website (see http://www.sheffield.ac.uk/scharr/sections/heds/mvh/sf-6d). Access to the SF-6D is through either a license for commercial applications from the University's commercialisation partner in the UK, Fusion IP, or from Quality Metric in the US who supply the software for a charge. Non-commercial applications covering all public sector and charitable applications are free of charge and copies of the software can be obtained through ScHARR; 521 non-commercial licenses have been distributed since 2008.

International public policy and services (HTA regulatory authorities)

An important impact of the SF-6D has been its use by HTA regulatory bodies around the world for assessing the cost-effectiveness of health technologies. The SF-6D is recommended for use by Health Technology Assessment (HTA) agencies in Ireland **(S1)** and China **(S2)**; it is explicitly named as an accepted measure in Australia **(S3)**, Belgium, Canada **(S4)**, Norway **(S5),** South Korea and Thailand; it also meets the specific guideline requirements of HTA agencies in 21 other countries whose guidelines are available via the ISPOR website(www.ispor.org/PEguidelines/index.asp) and thus can be used for health care decision making in those countries. It is also featured in the European Network for Health Technology Assessment (eunethat) Guideline on health-related quality of life and utility measures **(S6)**.

The SF-6D has been used in decision making in the UK by NICE, SMC and AWMSG. It has been used as the main health utility measure in important assessments such as pharmacological treatments for Alzheimer's (NICETA217), gout (NICESTA118301), low platelet count (NICESTA088101) and peripheral arterial disease (NICETA223), and has been used alongside other measures in many other appraisals.

Commercial benefits

The main commercial users of the SF-6D have been pharmaceutical companies and consultancy companies working on their behalf who wish to examine the cost-effectiveness of new drugs and make submissions to regulatory authorities. It is available through Fusion IP, a company specialising in marketing IP owned by the University. The selling of the SF-6D has also been subcontracted to Quality Metric (www.qualitymetric.com) a US based company specialising in measuring health outcomes who also distribute other SF products including SF-36 and SF-12. Since 2008 they have together sold over 460 licenses to pharmaceutical and consultancy companies including Novartis, Roche, Pfizer, Novo Nordisk, Astellas, Merck, Sanofi and BMS. Other important commercial users have been health care insurers and providers in the USA.

The companies benefit because an accepted generic health measure administered in their clinical trial (the SF-36 or SF-12) can be directly, and easily, translated into a preference based measure that can be used in economic evaluation. The SF-6D enables them to estimate the health related quality of life benefits of their technology in terms of QALYs, which is a requirement for a submission to regulatory bodies around the world.

5. Sources to corroborate the impact

Regulatory agencies around the world recommend and/or accept use of the SF6D as demonstrated by the HTA guidelines. Examples include the following:

S1 Guidelines of the Health Information and Quality Authority in Ireland state :

*"Use of an indirect preference-based measure, such as the EQ-5D or **SF-6D**, is recommended for the reference case as these measures have widespread availability, are easy to use and interpret and because they are based on preferences of the general public."* p31.

www.hiqa.ie/publication/guidelines-economic-evaluation-health-technologies-ireland

S2. The Chinese HTA guidelines states:

*"The recommended measuring instrument of health utility mainly includes Standard Gamble (SG), Time Trade-off (TTO), Visual Analogue Scale (VAS), EuroQol-5 Dimensions (EQ-5D), Short-Form Six-Dimensions (**SF-6D**), Health Utility Index (HUI) and Quality Well Being (QWB)" p8* (translated from Chinese).

www.pe-cn.org/en/pe_guidelines/index.asp

S3. The Australian HTA guidelines state:

*"Acceptable MAUIs are the Health Utilities Index (HUI2 or HUI3), the EQ5D ('EuroQol'), the **SF-6D** (a subset of the Short Form 36, or SF-36) or the Assessment of Quality of Life (AQoL) instrument." p78*

http://www.pbs.gov.au/industry/listing/elements/pbac-guidelines/PBAC4.3.2.pdf

S4. The Norwegian HTA guidelines state:

*"The main rule is that QALY-outcomes are to be calculated using multi-attribute utility instruments that evaluate both the physical and psychological condition of the patient as well as his/her social functioning. Some examples of such instruments are EQ-5D, **SF-6D** and 15D*". p16

www.ispor.org/PEguidelines/source/Norwegian_guidelines2012.pdf

S5. The Canadian Agency for Drugs and Technologies in Health states:

*'Analysts are encouraged to use indirect measurement instruments, because they are easy to obtain, compare, and interpret. … Some widely used instruments in this category are the Health Utilities Index (HUI), the EQ-5D, the **SF-6D**, and the 15D.'*

http://www.cadth.ca/media/pdf/186_EconomicGuidelines_e.pdf

S6. EUNEHTA is an agency representing HTA bodies around Europe that has produced a guideline that includes the SF-6D and appends a list of country specific guidelines.

Endpoints used for REA of pharmaceuticals: health related quality of life and utility measures. European Network for Health Technology Assessment. 2012

http://www.eunethta.eu/sites/5026.fedimbo.belgium.be/files/Health-related%20quality%20of%20life.pdf