Institution: BRUNEL UNIVERSITY (H0113)

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

Title of case study: Informing the policy and implementation of screening for abdominal aortic aneurysms (AAA)

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

Abdominal aortic aneurysms (AAAs) affect more than 4% of British men aged 65-74 and are responsible for over 6,800 deaths annually. The MASS trial showed that screening could reduce AAA-related mortality by 42%, and the Health Economics Research Group (HERG) demonstrated, through the MASS trial, that AAA screening was cost-effective. HERG thus helped inform the policy announced by UK ministers in 2008 to introduce a national screening programme for all men reaching 65. By Spring 2013 it was fully introduced in England - offering screening to 300,000 men annually; the latest Annual Report (2011-12) claimed an uptake rate of 75%. In 2008 the DH estimated the health gain from a screening programme would be at least 130,000 QALYS over 20 years. Internationally, MASS is the most significant trial of AAA screening, and provides the most robust evidence-based model of its cost-effectiveness. It extensively influenced AAA screening guidelines, policies and services, including in the USA and Europe.

2. Underpinning research (indicative maximum 500 words)

In November 1993 Professor Martin Buxton, then Director of the Health Economics Research Group (HERG) at Brunel University, was a co-applicant to the MRC for the Multi-centre Aneurysm Screening Study (MASS). He had already started working on the costs and cost-effectiveness of AAA screening with Alan Scott's leading clinical team at Chichester. For the MASS application, the initial collaboration was expanded to include trialists and statisticians at the MRC Biostatistics Unit in Cambridge and the Psychology and Genetics Research Group at the United Medical and Dental School. The comprehensive aims of the MASS trial included: estimating the reduction in mortality from rupture of AAA that could be achieved by population based screening; assessing the impact of the screening programme and treatment criteria on NHS costs, and on patients' quality of life; and producing data to allow assessment of the potential for a national screening programme.

The trial was funded in 1996. Buxton was a co-applicant and also a member of the Trial Steering Committee. A population based sample of 67,800 men aged between 65-74 was recruited from Jan 1997-May 1999, with an initial four-year follow-up period. During the stream of work, Buxton and colleagues at HERG (principally Stirling Bryan, a named applicant, until 1997; Helen Campbell,1998-2002; Mathew Glover, 2010-) were responsible for analysing the detailed cost data. Buxton was an author on the main clinical effectiveness paper, published in Nov 2002 in the Lancet (1), which provided 'reliable evidence of benefit' from AAA screening aimed at reducing the 6,800 annual deaths in England and Wales alone. Buxton was lead author on the BMJ cost-effectiveness paper published simultaneously. It stated: 'Even at four years the cost effectiveness of screening for abdominal aortic aneurysms is at the margin of acceptability according to current NHS thresholds. Over a longer period the cost effectiveness will improve substantially, the predicted ratio at 10 years falling to around a quarter of the four year figure.' (p.1135) (2)

A 2007 Cochrane review included four studies; the MASS study contributed 67,800 of the 127,891 men. Findings from the Chichester study, one of the other three studies, were published in 1995 and described as the first ever report of an RCT of a screening programme for AAA; the HERG team led on a paper assessing costs to patients (3). The Cochrane review concluded that there was significant reduction in mortality from AAA in men who undergo ultrasound screening and the cost effectiveness may be acceptable but needed further expert analysis. Buxton and Campbell were also co-authors on subsequent papers developing Markov modelling of the cost-effectiveness of screening, and using the cost data collected in the original study (4,5). The continuing follow-up work retained the aim of supplying data for a national screening programme – but increasingly helping inform its implementation. The 13-year, and final, follow-up paper on the effectiveness shown in the MASS trial, was published in 2012 with Buxton as a co-author. It reported 'a 42 (95 per cent confidence interval 31 to 51) per cent reduction' in the AAA-related mortality rate by screening men aged 65-74 years (p.1649) (6). Research to assist in refinement of the policy has continued with HERG's cost-effectiveness modelling of potential alternative recall intervals (7).

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

1) Scott RAP, Ashton HA, Buxton M, Day NE, Kim LG, Marteau TM, Thompson SG, Walker NM (on behalf of the Multicentre Aneurysm Screening Study Group) (2002) The Multicentre Aneurysm Screening Study (MASS) into the effect of abdominal aortic aneurysm screening on mortality in men: a randomised controlled trial. *Lancet,*360:1531-9 http://dx.doi.org/10.1016/S0140-6736(02)11522-4 Scopus: 522 citations.

2) Buxton M, Ashton H, Campbell H, Day NE, Kim LG, Marteau TM, Scott RAP, Thompson SG (2002) Multicentre aneurysm screening study (MASS): cost effectiveness analysis of screening for abdominal aortic aneurysms based on four year results from randomised controlled trial. *BMJ,* 325:1135-8. DOI: http://dx.doi.org/10.1136/bmj.325.7373.1135 Scopus: 150 Citations.
An accompanying editorial in the *BMJ* described the trial as 'a job well done.'

3) Bryan S, Buxton MJ, McKenna M, Ashton H, Scott A (1995) Private costs associated with abdominal aortic aneurysm screening: the importance of private travel and time costs. *J Med Screening,* 2:62-6 http://msc.sagepub.com/content/2/2/62

4) Kim L, Thompson S, Briggs A, Buxton M, Campbell H (2007) How cost-effective is screening for abdominal aortic aneurysms? *J Med Screening*,14:46-52.
http://dx.doi.org/10.1258/096914107780154477

5) Campbell HE, Briggs AH, Buxton M, Kim LG, Thompson SG (2007) The credibility of health economic models for health policy decision-making: the case of population screening for abdominal aortic aneurysm. *J Health Serv Res Policy*, 12:11-7
http://dx.doi.org/10.1258/135581907779497594

6) Thompson SG, Ashton HA, Gao L, Buxton MJ, Scott RAP on behalf of the Multicentre Aneurysm Screening Study (MASS) Group (2012) Final follow-up of the Multicentre Aneurysm Screening Study (MASS) randomized trial of abdominal aortic aneurysm screening. *Brit J Surg*, 99:1649-56.
http://dx.doi.org/10.1002/bjs.8897

7) Thompson, S. G., L. C. Brown, M. B. Sweeting, M. J. Bown, L. G. Kim, M. J. Glover, M. J. Buxton, J. T. Powell (2013) Systematic review and meta-analysis of the growth and rupture rates of small abdominal aortic aneurysms: implications for surveillance intervals and their cost-effectiveness. *Health Technol Assess,* 17:41. http://dx.doi.org/10.3310/hta17410

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

The assessment of cost-effectiveness, primarily undertaken by Buxton and colleagues, was a major part of the evidence provided by the MASS trial. This underpinned policies and guidelines that introduced and promoted AAA screening in the UK and internationally. AAAs affect more than 4% of British men aged 65-74 and are responsible for over 6,800 deaths annually. The MASS trial showed that screening could reduce AAA-related mortality by 42%. Implementation of the NHS AAA screening programme in started in 2009. It was fully implemented in England by Spring 2013, offering 'screening to around 300,000 men every year during the year they turn 65' (1). Uptake in the 2011-12 cohort of men invited for screening was 75%, according to the latest report (1). In 2008 the Department of Health's (DH's) Impact Assessment considered policy options for AAA screening and estimated that each would provide a gain of at least 130,000 quality adjusted life years (QALYS) over a 20 year period, and that the net value of the option adopted was £3,884million over 20 years, valuing the health benefit at a social value of £40,000 per QALY gained (p.3) (2).

The ministerial commitment to introduce a national AAA screening policy was announced in 2008 as part of a statement by the UK Prime Minister on the changes that would be made in what was the sixtieth year of the NHS (3). The timescales throughout the UK varied slightly. The decision to introduce a national screening programme in England had to be subject to an Impact Assessment produced by the DH, and signed off by the relevant minister (2). Published in July 2008 it explored the options and explained why the preferred option was a screening policy for all men aged 65. Major evidence references used in the Impact Assessment were the four RCTs included in the Cochrane review, but especially the findings from the MASS trial. The DH's Impact Assessment's analysis of costs relied heavily on work primarily led by HERG in the MASS study: Buxton et al (2002), Kim et al (2007). Highlighting the importance of MASS, the Impact Assessment stated:

'The main elements of the cost analysis are therefore based on the outputs and subsequent analysis from MASS….The unit costs for screening and elective and emergency surgery operations are based on MASS trials….An alternative cost base … was also considered. However, the MASS unit costs are more comprehensive and reliable, and are based on a detailed bottom-up costing, taking into account patient-specific costs.' (paras 44, 48) (3).

Further evidence to support the importance of the MASS study, and HERG's contribution, in the policy decisions to set up a national screening programme comes from the DH and MRC. The DH sent a letter on 15 June 2011 congratulating HERG on the work for Policy Research Programme: 'This has made a significant contribution to strengthening the evidence-base for policymaking through a range of applied economic research. This has included important contributions to the consideration of abdominal aortic aneurysm (AAA) screening;' (DH, Head of Policy Research Programme) (4). In 2010 the MRC reported on findings from its first collection of data on research impacts. The impact of the MASS stream of work on the introduction of the national AAA screening programme was one of just eight examples of policy impact that the MRC highlighted (5).

To get to the position in 2008 where ministers announced the decision to introduce the screening policy, Buxton and other MASS team members had undertaken extensive dissemination of the findings, both to the National Screening Committee, which analysed the data and options in detail, and also to relevant clinicians. Following the contribution made by Buxton to the AAA screening decision, he was invited to become a member of the UK National Screening Committee from 2009. On 31 March 2004 Buxton and others addressed many stakeholders at a meeting, 'Aneurysm Screening: The Facts and the Future' called by the Vascular Surgical Society of Great Britain and Ireland. It was widely covered by UK TV and print media, and the proceedings were published (6).

In addition to documented evidence of influence on health policy, and cost-effective, improved health services and clinical outcomes in the UK, the MASS trial also had extensive international impact on advisory committees, guidelines, and policies and helped generate improvements in both publicly and privately funded healthcare services. This includes in the USA and Europe.

A 2009 practice guideline from the US Society for Vascular Surgery drew on the same four studies as the Cochrane review, and so again the MASS study, contributing 67,800 of the 127,891 men included, had the most influence. The guideline stated: 'We recommend one-time ultrasound screening for AAA for all men at or older than age 65' (p.11S). It described the level of recommendation as 'Strong' and the quality of evidence as 'High' (7). AAA screening is now widely available in the USA. Many of the policies and practices in the period from 2008 drew on a key 2005 evidence synthesis and Recommendation Statement from the US Preventive Services Task Force in its public advisory role. The MASS study's importance was highlighted in both the recommendation and the synthesis, which have remained in place throughout 2008-13. The latter stated: 'the detailed micro-costing approach used in the MASS CEA… justified a "good" quality rating.' (p.3) (8). That review formed the basis both for the legislation under which Medicare has offered AAA screening throughout the 2008-13 period, and for clinical policy statements issued by the healthcare companies, such as Aetna which for its 22 million members says: 'Aetna considers one-time ultrasound screening for abdominal aortic aneurysms (AAA) medically necessary for men 65 years of age or older.' (8). Originally published in 2005 the policy was reviewed annually and republished, the last time being in December 2012, and continues to inform healthcare practice.

In Sweden, health policy is decided by counties. An assessment by the Swedish Council on Health Technology Assessment (SBU) in 2008 came after some counties had introduced screening. But it strongly recommended screening and drew heavily on 'The largest study, the MASS study' (p.2), showing over 50% of the men in the review came from the MASS study (9). Screening was later adopted by most counties. The 2011 European Society for Vascular Surgery guidelines also drew on the four studies in the Cochrane study, with the MASS study the largest. It supported population screening of older men to reduce 'aneurysm-related mortality by almost half'. (p.S5) (10).

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

1) The NHS AAA Screening Programme's web site provides data about the programme being fully introduced in England by Spring 2013 with around 300,000 men annually being offered screening, and considerable progress in the rest of the UK: http://aaa.screening.nhs.uk/questions The latest Annual Report (2011-12) showed a 75% uptake: http://aaa.screening.nhs.uk/annualreport

2) The DH formal analysis of the benefits from the introduction of AAA screening and the ministerial sign-off of the introduction of the policy came in the *Impact Assessment of a national Screening Programme for Abdominal Aortic Aneurysms.* July 2008, Department of Health. http://webarchive.nationalarchives.gov.uk/20080726153931/http://dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_086050 (Key references to MASS, paras: 44,48)

3) The Prime Minister made a speech to celebrate the 60th anniversary of the foundation of the NHS; in that he made various commitments, including on the introduction of AAA screening. Reference: Prime Minister's health speech 7 January 2008 accessed online at: http://webarchive.nationalarchives.gov.uk/20090114000528/number10.gov.uk/page14171

4) DH recognition of the major importance of HERG's role in informing policy development in AAA screening is contained in a letter to Professor Buxton on 15 June 2011 from Dr Sandra Williams, Head of Policy Research Programme, DH. Pdf available from Brunel University.

5) The MASS study was highlighted in the MRC's impact report: *MRC: outputs, outcomes and impact of MRC Research: Analysis of MRC e-Val Data 2010,* but because it related to funding that came after the main MRC-funding, the reference here was to the MRC Biostatistics Unit part of the MASS collaboration who had recently received some continued funding for part of the research. http://www.mrc.ac.uk/Achievementsimpact/Outputsoutcomes/MRCe-Val2009/Policy/index.htm

6) The Vascular Surgical Society of GB and Ireland's report on the 2004 meeting addressed by Buxton and other MASS team members highlighted the range of stakeholders attending, including the PM's health advisor, and the media coverage. Pdf available from Brunel.

7) In the USA the Society for Vascular Surgery 2009 guidelines drew heavily on the four trials in the Cochrane review, but in the relevant text named only the MASS study. It recommended screening and stated: 'Level of recommendation: Strong; Quality of evidence: High' (p.11S). Chaikof EL et al. The care of patients with an abdominal aortic aneurysm: the Society for Vascular Surgery practice guidelines. J Vasc Surg 2009;50: 2S-49S (October 2009 Supplement). doi:10.1016/j.jvs.2009.07.002 http://www.jvascsurg.org/article/S0741-5214(09)01368-8/fulltext

8) The US Preventive Services Task Force published a review in 2005 that has influenced the policies and practices of a wide range of healthcare providers throughout the 2008-13 period. It contains several elements including: *Screening for Abdominal Aortic Aneurysm: Recommendation Statement.* http://www.uspreventiveservicestaskforce.org/uspstf/uspsaneu.htm and *Cost-Effectiveness Analyses of Population-Based Screening for Abdominal Aortic Aneurysm. Evidence Synthesis.* http://www.uspreventiveservicestaskforce.org/uspstf05/aaascr/aaacost.htm . Both use the same four trials as the Cochrane review, with the MASS trial, 'A good-quality RCT' (p.3), providing half the participants. The cost-effectiveness analysis in MASS was influential because of its quality: the Task Force's recommendation remained the official public advice throughout 2008-13. The AAA screening policy of Aetna, a major US healthcare provider, is regularly updated. The review in December 2012 repeated the strong recommendation for screening, based on the Task Force review above. Clinical Policy Bulletin: Abdominal Aortic Aneurysm Screening. Number 0702, last reviewed 11/29/2012. http://www.aetna.com/cpb/medical/data/700_799/0702.html Similarly, the Screening Abdominal Aortic Aneurysms Very Efficiently (SAAAVE) Act that introduced screening into Medicare's services in 2007 was based on the MASS-informed Preventive Services Task Force Recommendation and has been in force throughout the 2008-13 period with all new entrants to Medicare who meet the criteria being eligible for screening.

9) In Sweden the strong recommendation for AAA screening in the SBU Report 2008-04 drew heavily on MASS: http://www.sbu.se/en/Published/Alert/Screening-for-Abdominal-Aortic-Aneurysm/

10) The European Society for Vascular Surgery guidelines also drew on the 4 studies included in the Cochrane review, with MASS therefore the largest, and concluded: 'Population screening of older men for AAA, in regions where the population prevalence is 4% or more, reduces aneurysm-related mortality by almost half within 4 years of screening, principally by reducing the incidence of aneurysm rupture. Level 1a, Recommendation A.' (p. S5) Reference: Moll FL et al.; Management of abdominal aortic aneurysms clinical practice guidelines of the European Society for Vascular Surgery. *Eur JVasc Endovasc Surg* 2011; 41(Suppl):S1-S58. http://dx.doi.org/10.1016/j.ejvs.2010.09.011