Professor Tony Culyer

CURRICULUM VITAE

Professor Anthony John (Tony) Culyer, CBE, BA, Hon DEcon, Hon FRCP, FRSA, FMedSci

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last update: November 2011

Personal background

Present Status
Ontario Research Chair in Health Policy & System Design, University of Toronto
Professor of Economics, University of York, England
Adjunct Scientist, Institute for Work and Health, Toronto
Chair, WSIB Research Advisory Council (to March 2010)
Founding Co-Editor, *Journal of Health Economics*

Date of Birth
1 July 1942

Addresses
(Home, England): "The Laurels", Main Street, Barmby Moor, York, Y042 4EJ, UK
Tel. (0)1759-307177
E-mail: tonyandsiegi@btinternet.com

(Home, Canada): 80 Front Street East Suite 804, Toronto, Ontario, M5E 1T4, Canada
Tel: 416 369-9973
E-mail: tonyandsiegi@sympatico.ca

(University, Canada): Department of Health Policy, Management and Evaluation, University of Toronto, Faculty of Medicine, University of Toronto, Health Sciences Building, 155 College Street, Suite 425, Toronto, Ontario M5T 3M6
Tel: 416 978 7340
Fax: 416-978-7350
E-mail: tony.culyer@utoronto.ca

(University, England): Department of Economics & Related Studies, University of York, Heslington, York Y010 5DD, England
Tel: (0)1904-321420
Fax: (0)1904-433759
E-mail: ajc17@york.ac.uk

Web page: http://www-users.york.ac.uk/~ajc17

Marital Status
Married from 1966 to 2011 to same partner Siegi, with son and daughter, four grandchildren. Now widowed.

Secondary Education
Sir William Borlase's School, Marlow
The King's School, Worcester

University Education
Graduated Exeter University in 1964 (2(i)) in Economics, Exeter University

Leo T. Little Prize for best graduating student in Economics 1964.
1964-5 Graduate Student and Teaching Assistant at the University of California at Los
Angeles (plus Fulbright Travel Scholarship).

Degrees
B.A. (Hons), (Exeter) (1964)
Doctor of Economics, honoris causa (Stockholm School of Economics) (1999)

Honours
Founding Fellow of the Academy of Medical Sciences (1998)
Commander of the British Empire (CBE) (1999)
Fellow of the Royal Society of Arts (1999)
Doctor of Economics, honoris causa (Stockholm School of Economics) (1999)
Honorary Fellow of the Royal College of Physicians of London (2003)

Fellowships of Academies
Founding Fellow of the Academy of Medical Sciences (1998)
Fellow of the Royal Society of Arts (1999)
Honorary Fellow of the Royal College of Physicians of London (2003)

University Career

1964-65	Teaching Assistant, University of California at Los Angeles
1965-66	Tutor in Economics, University of Exeter
1966-69	Assistant Lecturer in Economics, University of Exeter.
1969-72	Lecturer in Economics, University of York
1971-79	Assistant Director, Institute of Social & Economic Research, University of York
1972-76	Senior Lecturer in Economics, University of York
1976-79	Reader in Economics, University of York
1976	Senior Research Associate at the Ontario Economic Council Visiting Professorial Lecturer at Queen's University, Kingston, Canada
1979	William Evans Visiting Professor, University of Otago, Dunedin, New Zealand Visiting Fellow, Australian National University, Canberra, Australia
1979-82	Deputy Director, Institute of Social and Economic Research, University of York
1979-	Professor of Economics, University of York (since 1982 in Department of Economics & Related Studies)
1983-84	Director of the Graduate Health Economics Programme, Department of Economics & Related Studies, University of York
1985-86	Visiting Professor, Trent University, Canada
1986-01	Head of Department of Economics & Related Studies, University of York
1989-94	Visiting professor, Department of Health Administration, University of Toronto
1990-91	(Oct-Feb) Visiting Professor, Institut für Medizinische Informatik und

	Systemforschung (Gesellschaft für Strahlen-und Umweltforschung), Munich, Germany
1991	(Apr-Sep) Visiting Professor, Department of Health Administration, University of Toronto
1991-94	Pro-Vice-Chancellor, University of York, England
1994-97	Deputy Vice-Chancellor, University of York, England
1995-96	Director, School of Politics, Economics & Philosophy, University of York
1996	(November) Visiting Professor, Central Institute of Technology, New Zealand
1997-01	Director of Health Development, University of York
1999-01	Director (Board Member) of York Health Economics Consortium
2001-03	Chair, Board of York Health Economics Consortium
2003-07	Visiting Professor, Department of Health Policy, Management & Evaluation, University of Toronto
2003-06	Chief Scientist, Institute for Work & Health, Canada
2006-07	Senior Scientist, Institute for Work & Health, Canada
2006-07	Senior Economic Adviser, Cancer Care Ontario
2006-10	Chair, Research Advisory Council of the Workplace Safety & Insurance Board (Ontario)
2007-	Ontario Research Chair in Health Policy and System Design, University of Toronto
2007-	Adjunct Scientist, Institute for Work & Health, Toronto

Affiliations

Academy of Medical Sciences, Health Economists' Study Group, International Health Economics Association, Royal Economic Society, Royal Society of Arts, Royal College of Physicians (London), Royal School of Church Music, Royal School of Church Music (Canada).

Journal Editing

1996-70	Acting Editor, Assistant Editor, Editorial Board member (various times), *Social and Economic Administration*.
1982-	Founding Co-editor, *Journal of Health Economics*
1984-85	Founding Editor, *Nuffield/York Portfolios*
1986-96	Advisory Editor, *Social Science and Medicine*
1976-84	Member, Editorial Board, *Bulletin of Economic Research*
1983-93	Founding Member, Editorial Panel, *The Economic Review*
1992-2002	Member, Editorial Board, *Medical Law International*
1994-2001	Member, Managing Committee, *Journal of Medical Ethics*
1995-2000	Member, Editorial Board, *British Medical Journal*
1996-2007	Founding Member, International Advisory Board, *Clinical Effectiveness in Nursing*
1998-2001	Member, Editorial Advisory Board, *Handbook on Research Methods for Evidence Based Health Care*
1999-2005	Member, Editorial Board, *Zeitschrift für die gesamte Versicherungswissenschaft*
2001	Guest Editor, *Journal of Medical Ethics* (Vol. 27, No. 4).
2009-	Editor in Chief, The Elsevier on-line Encyclopedia of Health Economics,

External Academic Advisory Boards

1989-92	Member, Methodological Advisory Group on Non-economic Loss, Ontario Workers' Compensation Board
1992-98	Member, Advisory Committee of the Canadian Institute for Advanced Research (Population Health Program)
1992-2001	Member, Advisory Committee for Centre for Health and Society, University College, London
1990-94	Member, Research Advisory Committee of the Institute for Work and Health (Toronto, Canada)
1997-2002	Member, Research Advisory Committee of Canadian Institute for Health and Work
1997-2003	Member, Research Advisory Committee of the Institute for Work and Health (Toronto, Canada)
2000-03	Trustee, The Canadian Health Services Research Foundation, Ottawa
2001	Member, International Scientific Advisory Committee, Unit of Health Economics and Technology Assessment in Health Care, Budapest University of Economics
2006-10	Member, International Advisory Board, Alberta Bone & Joint Institute
2006-10	Chair, Research Advisory Council, Workplace Safety and Insurance Board (Ontario)
2006-10	Member, Advisory Board, Centre for Research Expertise in Musculo-Skeletal Diseases, University of Waterloo
2006-10	Member, Advisory Board, Centre for Research Expertise in Occupational Disease, University of Toronto
2006-10	Member, Advisory Board, Centre for Research Expertise in Improved Disability Outcomes, University Health Network, Toronto

Professional Groups

1970-86	Founding Organiser, Health Economists' Study Group (HESG)
1970-	Member, HESG
1975-76,	Member, Scientific Committee of the International Institute of Public Finance
1975-90	Honorary Adviser to the Office of Health Economics
1977-85	Member, Organising Committee of International Seminar in Public Economics
1979-85	Founding Course Coordinator for the Health Economics option, Corporate Management Programme of King's Fund College, London
1980-82	Convenor, SSRC European Workshop in Health Indicators (for report, see publications)
1982-83	Member, Scientific Committee of the International Institute of Public Finance
1983-84	Director, York MSc. Programme in Health Economics
1987-88	Member, Institute of Health Service Management Working Party on Alternative Funding and Delivery of Health Services (for reports see publications).
1987-2001	Member, Conference of Heads of University Departments of Economics (CHUDE)
1988-93	Member, Standing Committee of CHUDE
1989-92	Member, College Committee of the King's Fund College, London,

1990-97	Member of Editorial Policy Committee, Office of Health Economics
1990-97	Member, Editorial Board, Office of Health Economics
1991-93	Member, Economics Association National Development Group on economics curriculum development
1991-92	Council member, Royal Economic Society
1992	World Health Organisation Adviser (economics of schistosomiasis control in Kenya)
1992	Member, Canadian Institute of Advanced Research (Review Panel on Population Health)
1992-97	Member, Kenneth J. Arrow Award in Health Economics (Prize Committee)
1992-92	Member, Institute of Health Services Management's "Future Health Care Options" Working Party
1994	President, Section F (Economics), British Association
1996	Member, ESRC Training Board Economics Area Panel
1996-2003	Member, Academic Advisory Council, University of Buckingham
1997	Member of World Health Organisation two-person mission to Kazakhstan on the privatisation and reform of health care services, February
1997-2001	Vice Chair, Office of Health Economics
1997-	Chair, Office of Health Economics Editorial Board
1988-93	Member, Standing Committee of CHUDE
2001-	Chair, Office of Health Economics Policy Board
2002-07	Member, Governing Board, International Health Economics Association
2004-	Chair, Office of Health Economics Management Committee
2004-06	Adviser, Canada Health Council
2005	Member, Ontario Health Technology Advisory Committee
2006-07	Senior Economic Advisor, Cancer Care Ontario
2006-07	Economic Advisor, Ontario Ministry of Health and Long Term Care
2006	Member, Ontario Ministry of Health and Long Term Care Equity Editorial Board
2006-08	Canadian Institutes for Health Research Michael Smith Prize in Health Research Committee
2007-	Member, Ontario Ministry of Health and Long Term Care Career Scientist Relevance Review Panel
2007-	Member, Ontario Ministry of Health and Long Term Care Health Research Advisory Council
2009-	Member, Hall Foundation Board (Canada)
2009-	Member Advisory Committee, NICE International
2009-	Member, Department of Health Policy Research Units Commissioning Panel
2009-	Member, Ontario Ministry of Health and Long Term Care, Health System Strategy Division, External Advisory Group
2009-	Member, Ontario Ministry of Health and Long Term Care Advisory Group on Productivity
2009-	Member, Ontario Ministry of Health and Long Term Care Steering Committee for Partnerships for Health System Improvement (CIHR project)
2010- 11	Member, Ontario Health Quality Council Advisory Committee

Principal Lectures

1976	Plenary Lecture, First Canadian Health Economics Symposium, Kingston
1980	Plenary Lecture, First Australian Conference of Health Economists, Canberra
1986	Woodward Lecturer, University of British Columbia
1986	Plenary Lecture, Third Canadian Conference on Health Economics, Winnipeg
1990	Perey Lecturer, McMaster University
1990	Champlain Lecturer, Trent University
1994	Francis Fraser Lecturer (British Postgraduate Medical Federation, London).
2001	Plenary Lecture Canadian Health Economics Study Group, Vancouver
2006	Sinclair Lecturer, Queen's University, Kingston
2005	Plenary Lecture, Canadian Health Economics Study Group, Toronto

University (outside my Department) Management

1991-94	Pro-Vice-Chancellor, University of York
1994-97	Deputy Vice-Chancellor
1994-99	Member, Health Sector Group of the Committee of Vice-Chancellors and Principals
1997-2001	Director of Health Development, University of York

At various times Representative of University of York on Court and Council of Leeds University, 1978-85, member of Council, Nominations Committee, General Academic Board, Professorial Board, Member or chair of: Staff Committee, Finance Committee, Secretarial and Clerical Committee, Joint Negotiating Committee (Joint chair), Court, Council, Appointments to Court and Council, Vacancies Review Panel, Planning Committee, Administrative Planning Committee, Policy and Resources Committee, Equipment Subcommittee (minor spenders), VC's Advisory Group, VC's advisory committees on Academic Plan, Discretionary Salary Awards; Promotions Committee, Premature Retirement Committee, Leave of Absence Committee, Research Committee (chair), Awards Sub-Committee (chair), Health Liaison Group (chair), Board for Graduate Schools (chair), Undergraduate Admissions Committee (chair), Special Cases Committee (chair), Medical Services Committee (chair), Library Advisory Committee (chair), Joint Committee with AUT (chair), Heslington Lectures Committee (chair), University Committee (chair), King's Manor Resources Group (chair), Disciplinary Advisory Committee, IT Strategy Committee, Panel for Admin Library Computing and Other Related Staff (chair), Post-1995 Institutional Planning Group, Careers Advisory Group (chair), Alcuin Collaboration Group (chair), Alcuin Project Development Group (chair), Alcuin Project Steering Group (member), CVCP (in lieu of VC), Search Committee for new VC (1992), chair of any of the above chaired by VC in his absence, University and University College of Ripon & York St John Health Collaboration Steering Group (co-chair).

Principal Canadian Connections

1976	Senior Research Associate at the Ontario Economic Council and

	Visiting Professor, Economics Department, Queen's University
1985-6	Visiting Professor, Trent University, Canada
1986	Woodward Lecturer, University of British Columbia
1989-90	Visiting Professor, Department of Health Administration, University of Toronto
1989-92	Member, Methodological Advisory Group on Non-economic Loss, Ontario Workers' Compensation Board
1990	Commissioned to write paper on Equity in Health for Ontario Premier's Council on Health, Well-Being and Social Justice
1990	Perey Lecturer, McMaster University
1990	Champlain Lecturer, Trent University
1991	(Apr-Sep) Visiting Professor, Department of Health Administration, University of Toronto
1990-4 and 1997-02	Member, Research Advisory Committee, Institute for Work and Health, Toronto
1992-02	Member, Advisory Committee of the Canadian Institute for Advanced Research Population Health Program
2000-3	Trustee, Canadian Health Services Research Foundation, Ottawa
2002-3	Member, Scientific Advisory Committee, Institute for Work and Health
2003-7	Visiting professor, Department of Health Policy, Management & Evaluation , University of Toronto
2003-6	Chief Scientist, Institute for Work & Health, Toronto
2003-4	Member, External Research Review Team for Cancer Care Ontario
2005-7	Adviser, Canada Health Council
2005-6	Member, Ontario Health Technology Advisory Committee (OHTAC)
2005-7	Member, CIHR Michael Smith Prize in Health Research Committee
2005-	Member, Scientific Committee, Alberta Bone & Joint Health Institute
2006-	Member, International Advisory Board, Alberta Bone & Joint Institute
2006-7	Senior Scientist, IWH, Toronto
2006-	Advisor to MOHLTC on Citizens' Council
2006-	Chair, WSIB Research Advisory Council
2006-7	Senior Economic Advisor, Cancer Care Ontario
2007	Chair, External Review Panel of Centre for Health Service Policy Research, UBC
2006-10	Chair, Research Advisory Council, Workplace Safety and Insurance Board (Ontario)
2006-10	Member, Advisory Board, Centre for Research Expertise in Musculo-Skeletal Diseases, University of Waterloo
2006-10	Member, Advisory Board, Centre for Research Expertise in Occupational Disease, University of Toronto
2006-10	Member, Advisory Board, Centre for Research Expertise in Improved Disability Outcomes, University Health Network, Toronto
2006	Member, Ontario Ministry of Health and Long Term Care Equity Editorial Board
2007-	Member, Value for Money Committee, Health Council of Canada
2007-	Member, Ontario Ministry of Health and Long Term Care Career Scientist Relevance Review Panel

2007- Member, Ontario Ministry of Health and Long Term Care Citizen's Council Advisory Committee
2007- Member, Ontario Ministry of Health and Long Term Care Health Research Advisory Council
2008- Chair, Advisory Committee to CCO Pharmaceutical Economics Unit
2008- Member, Advisory Committee, Toronto Health Economics and Technology Assessment (THETA) Collaborative
2008- Member, Clinical Standards, Guidelines and Quality Committee of the Board of Cancer Care Ontario
2009- Member, Interim Scientific Committee, Occupational Cancer Research Centre, Toronto
2009- Member, Ontario Ministry of Health and Long Term Care, Health System Strategy Division, External Advisory Group
2009- Member, Ontario Ministry of Health and Long Term Care Steering Committee for Partnerships for Health System Improvement (CIHR project)
2010- Member, Ontario Health Quality Council Advisory Committee

Current other roles

Co-editor, Journal of Health Economics
Chair, Office of Health Economics (London, England)
Adjunct Scientist, Institute for Work & Health, Toronto
Trustee and Council member, Royal School of Church Music
Director, Royal School of Church Music, Canada
Member, Citizens' Council Committee, NICE
Member, Advisory Committee, NICE International
Member, MOHLTC Advisory Committee on Citizens' Council
Member, MOHLTC Advisory Committee on R&D
Member, editorial boards of several other journals
Member, International Advisory Board, Alberta Bone & Joint Institute
Member, Advisory Board, Royal School of Church Music
Member, Board of Directors, Royal School of Church Music (Canada)

External Assessor for Chairs etc.

Durham (economics), Leeds (health economics), London School of Economics (social policy), London School of Hygiene & Tropical Medicine (health economics) (twice), Newcastle (health sciences), Oslo (health economics), Toronto (health economics), Southampton (health policy), UBC (economics) (twice)Northallerton Health Authority (Chief Executive), Office of Health Economics (deputy director), King's Fund (Chief Executive), National Institute for Clinical Excellence (Director of Appraisals), North Yorkshire Health Authority (Director of Primary Care), Director of R&D (NICE).

External Reviews of Departments

1989 Economics Department, McMaster University
1993 London Special Health Authorities (member of Thompson Committee)
1998 Wessex Institute and the Institute of Health Policy, Southampton University (with Charles Florey) 1

1999	McMaster University Centre for Health Economics and Policy Analysis (CHEPA)
2007	UBC Centre for Health Services Policy Research

National Health Service (England) Appointments

1975-84	Member, DHSS Research Liaison Groups (several)
1982-90	Member, Northallerton Health Authority
1990-92	Non-executive member, Northallerton Health Authority
1991-2001	Member, Central Research and Development Committee (CRDC) for the National Health Service
1992-93	Member, Central R&D Committee Mental Health National Steering Group (Goldberg Committee)
1992-94	Member, Yorkshire Health Research and Development Committee
1992-97	Member, CRDC Standing Group on Health Technology
1993-97	Chair, CRDC Health Technology Assessment (HTA) Methodology Panel
1992-93	Member, Review Advisory Committee on the London Special Health Authorities. (The "Thompson Report", Special Health Authorities: Research Review, London, HMSO, 1993, chaired by Sir Michael Thompson)
1993-94	Chair, NHS Research Task Force on R&D to Review the Funding and Support of Research and Development in the NHS, (The "Culyer Report"): *Supporting Research and Development in the NHS: A Report to the Minister of Health*, London, HMSO, 1994
1994-99	Deputy Chair and non-executive member, North Yorkshire Health Authority (reappointed to new Authority in 1996), (chair and member of several subcommittees of the Board)
1995-2001	Member, Northern & Yorkshire Regional Research Advisory Group
1995-2001	Member, Northern and Yorkshire Regional Universities Group for R&D
1995-99	Special Adviser, High Security Psychiatric Services Commissioning Board (HSPSCB)
1995-1999	Member, R&D Committee of the HSPSCB
1995-99	Member, R&D Commissioning Sub Group of the HSPSCB
1996	Member, Central R&D Committee Sub-Group on the Strategic Framework
1996-97	Member, National Working Group on R&D in Primary Care ("Mant Committee")
1997-98	Chair, Department of Health Expert Workshop on DH Guidelines for Pharmaco-economic studies
1997-98	Adviser, Department of Health Comprehensive Spending Review Group on "Non front-line services"
1997-99	Special Adviser to NHS Director of R&D
1997-98	Chair, Central R&D Committee Sub-Group on Budget 1 Allocations to Trusts
1998-2002	Member, Healthcare Sector Group, Department of Trade and Industry and Department of Health Overseas Trade Services
1998-2000	Member, NHS R&D Exceptional Cases Advisory Group
1998-2000	Member, NHS R&D Strategic Review Sub Group
1998-2000	Member, NHS R&D Evaluation Strategy Steering Group

1999-2003	Vice Chair (and non-executive director), National Institute for Clinical Excellence
2007-10	Chair, NICE Research & Development Committee
2007-	Member, NICE Citizens' Council Committee
2008-	Member, NICE International Advisory Committee
2008	Member, Department of Health Value Focus Group on the cost and benefit perspective of NICE

Other Government roles

1983-87	Member, Comac-HSR Committee of the European Commission
1995-97	Member, British Council Health Advisory Committee
1997-98	Member, Department of Trade and Industry Advisory Committee on Exports of Health-related Products
2005-07	Member, Economics Advisory Panel, Home Office

Recent publications (2007-10)

2007

Culyer A J. "Need - an instrumental view" in Richard Ashcroft, Angus Dawson, Heather Draper and John McMillan (Eds.) *Principles of Health Care Ethics*, 2nd Edition, Chichester: Wiley, 2007, 231-238.

Culyer A J. "When and how cancer chemotherapy should be privately funded," *Oncology Exchange*, 2007, 6: 47.

Culyer A J, McCabe C, Briggs AH, Claxton K, Buxton M, Akehurst RL, Sculpher M and Brazier J. "Searching for a threshold, not setting one: the role of the National Institute of Health and Clinical Excellence", *Journal of Health Service Research and Policy*, 2007, 12: 56-59.

Robson LS, Clarke J, Cullen K, Bielecky A, Severin C, Bigelow P, Irvin E, **Culyer AJ**, Mahood Q. "The Effectiveness of Occupational Health and Safety Management System Interventions: A Systematic Review", *Safety Science*, 2007, **45**: 329-353.

Culyer A J "Merit goods and the welfare economics of coercion" in Wilfried Ver Eecke (Ed.) *Anthology regarding Merit Goods. The Unfinished Ethical Revolution in Economic Theory*. West Lafayette: Purdue University Press, 2007, 174-200 (reprinted from *Public Finance*, 1971, 26: 546-572.

Claxton K and **Culyer A J,** "Rights, responsibilities and NICE: A Rejoinder to Harris" *Journal of Medical Ethics*, 2007, 33: 462-464.

Culyer A J, "NICE misconceptions" *The Lancet*, September 11 2007, on-line at http://www.thelancet.com/journals/lancet/article/PIIS014067360761321X/comments

Culyer A J, "Equity of what in health care? Why the traditional answers don't help policy - and what to do in the future" *HealthcarePapers*, 2007, 8(Sp): 12-26.

Culyer A J, McCabe C, Briggs A, Claxton K, Buxton M, Akehurst R, Sculpher M, Brazier J, "Searching for a threshold - Not so…", *Journal of Health Services Research and Policy*, 2007, 12: 190-191. (letter: reply to G Mooney, J Coast, S Jan, D McIntyre, M Ryan and V Wiseman).

Culyer A J, "Resource allocation in health care: Alan Williams' decision maker, the authority and Pareto", in A Mason & A Towse (eds.) *The Ideas and Influence of Alan Williams: Be Reasonable –Do it My Way!* Oxford, Radcliffe Publishing, 2007, 57-74.

2008

E Tompa, **A J Culyer**, R Dolinschi (Eds.) *Economic Evaluation of Interventions for Occupational Health and safety: Developing Good Practice*, Oxford: Oxford University Press, 2008, pp. xvi + 295.

Chalkidou K, **Culyer A J**, Naidoo B, Littlejohns P "Cost-effective public health guidance: asking questions from the decision-maker's viewpoint", *Health Economics*, 2008, 17: 441-448.

Claxton K, Briggs A, Buxton M, **Culyer A J**, McCabe C, Walker S, Sculpher M J "Value based pricing for NHS drugs: an opportunity not to be missed?" *British Medical Journal*, 2008, 336: 251-254.

Brouwer W B F, **Culyer A J**, Job N, van Exel A, Rutten F F H. "Welfarism vs. extra-welfarism", *Journal of Health Economics*, 2008, 27: 325–338.

J Hurley, D Pasic, J Lavis, **A J Culyer** C Mustard and W Gnam, "Parallel payers and preferred access: how Canada's Workers' Compensation Boards expedite care for injured and ill workers", *HealthcarePapers*, 2008, 8: 6-14.

J Hurley, **A J Culyer**, W Gnam, J Lavis, C Mustard and D Pasic, "Response to commentaries", *HealthcarePapers*, 2008, 8: 52-54.

K Chalkidou, T Walley, **A J Culyer**, P Littlejohns, and A Hoy. "Evidence-informed evidence-making", *Journal of Health Services Research & Policy*, 2008, 13: 167-173.

K Claxton and **A J Culyer "**Not a NICE fallacy: A reply to Dr Quigley", *Journal of Medical Ethics* 2008, 34: 598-601.

A J Culyer, B Amick and A LaPorte. "What is a little more health and safety worth?" in E Tompa, **A J Culyer**, R Dolinschi (Eds.) *Economic Evaluation of Interventions for Occupational Health and safety: Developing Good Practice*, Oxford: Oxford University Press, 2008, 15-35.

A J Culyer and M Sculpher. "Lessons from health technology assessment" in E Tompa, **A J Culyer**, R Dolinschi (Eds.) *Economic Evaluation of Interventions for Occupational Health and safety: Developing Good Practice*, Oxford: Oxford University Press, 2008, 51-69.

A J Culyer and E Tompa. "Equity", in E Tompa, **A J Culyer**, R Dolinschi (Eds.) *Economic Evaluation of Interventions for Occupational Health and safety: Developing Good Practice*, Oxford: Oxford University Press, 2008, 215-231.

E Tompa, A J Culyer and R Dolinschi "Suggestions for a reference case", in E Tompa, **A J Culyer**, R Dolinschi (Eds.) *Economic Evaluation of Interventions for Occupational Health and safety: Developing Good Practice*, Oxford: Oxford University Press, 2008, 235-244.

C McCabe, K Claxton and **A J Culyer** "The NICE cost effectiveness threshold – what it is and what that means," *PharmacoEconomics*, 2008, 26: 733-744.

K Chalkidou, **A J Culyer**, P Littlejohns, P Doyle, A Hoy. "Imbalances in funding for clinical and public health research in the UK: can NICE research recommendations make a difference?" *Evidence and Policy*, 2008, 4: 355-369.

J Hurley, D Pasic, J Lavis, C Mustard, **A J Culyer**, W Gnam. "Parallel lines do intersect: interactions between the workers' compensation and provincial publicly financed health care systems in Canada." *HealthCare Policy*, 2008, 3: 100-112.

2009

Chalkidou K, **A J Culyer**, B Naidoo, P Littlejohns "The challenges of developing cost-effective public health guidance: a NICE perspective", in S Dawson and Z S Morris (eds.) *Future Public Health: Burdens, Challenges and Opportunities*, Basingstoke: Palgrave Macmillan, 2009, 276-291.

A J Culyer, *Deliberative Processes in Decisions about Health Care Technologies: Combining Different Types of Evidence, Values, Algorithms and People*, London: Office of Health Economics, 2009, pp. 1-20.

A J Culyer "How Nice is NICE? A Conversation with Anthony Culyer", Health Care Cost Monitor, Hastings Centre Blog, 2009.

M. J. Dobrow, R. Chafe, H. E. D. Burchett, **A J Culyer,** L. Lemieux-Charles *Designing Deliberative Methods for Combining Heterogeneous Evidence: A Systematic Review and Qualitative Scan. A Report to the Canadian Health Services Research Foundation*, Ottawa: Canadian Health Services Research Foundation, 2009, pp. 24 + 30, ().

2010

Cookson R, **A J Culye**r. "Measuring overall population health - the use and abuse of QALYs", in Killoran A, Kelly M (eds). *Evidence Based Public Health: Effectiveness and Efficiency*, Oxford: Oxford University Press, 2010, 148-168.

A J Culyer, *The Dictionary of Health Economics*, Cheltenham: Edward Elgar, 2010.

A J Culyer "Perspective and desire in comparative effectiveness research - the relative unimportance of mere preferences, the central importance of context", *Pharmacoeconomics*, 28: 1-9.

2011

K Claxton, M Paulden, H Gravelle, W Brouwer, **A J Culyer**. "Discounting and decision making in the economic evaluation of health-care technologies", *Health Economics*, 2011, 20: 2-15.

R Chase, **A J Culyer**, M Dobrow, P Coyte, C Sawka, S O'Reilly, K Laing, M Trudeau, S Smith, J Hoch, S Morgan, S Peacock, R Abbott, T Sullivan. "Access to Cancer Drugs in Canada: Looking Beyond Coverage Decisions", *Healthcare Policy*, 2011, 6: 27-35.

A J Culyer. "UK report: NHS 'reforms'", *Health Care Cost Monitor*, 2011, 1-2. The Hastings Centre, on-line at http://healthcarecostmonitor.thehastingscenter.org/anthonyculyer/u-k-report-nhs-reforms.

P Tso**, A J Culyer**, M Brouwers, M J Dobrow. **"**Developing a decision aid to guide public sector health policy decisions: A study protocol", *Implementation Science*, 2011, 6:46.

Current grants

Strengthening the health system through improved priority setting. Canadian Institutes of Health Research (Sustainable Financing, Funding and Resource Allocation), Co-investigators: Dr. Andreas Laupacis (PI), Dr. Doug Martin (Co-PI_, Dr. W. Evans, Dr. W. Levinson, Dr. T. Sullivan, Dr. S. Pearson, Dr. A. Hudson. $159,805 per year for 5 years, 04/2005 to 09/2010.

Dynamics of Parallel Systems of Finance: Interactions Between Canada's Worker Compensation Systems and Public Health Care Systems; Canadian Institutes of Health Research. Co-investigators: Dr Jerry Hurley (PI), Dr William Gnam, Dr John Lavis, Dr Cameron Mustard, Dr Emile Tompa. $75,000 for 1 year, Reference #: PPG-74820.

Several grant applications to CIHR with M Dobrow (Cancer Care Ontario) and others are currently being considered.

Recent grant

Conceptualising and Combining Evidence for Health System Guidance, Canadian Institutes of Health Research, Co-investigator Dr Jonathan Lomas, 2005.

Teaching Experience

Graduate

At various times have given lectures and seminars in Advanced Economic Theory (micro and macro), the Economics of Human Resources, the Economics of Social Policy, Health Economics, Social Policy Analysis, and given graduate classes on Social Policy to students of Social Administration. Supervised MSc, MPhil and DPhil

thesis students. PhD external examiner at various Universities in the UK and overseas.

Undergraduate
At various times have given first year introductory lectures in Economics; second year lectures in Price Theory, Welfare Economics, Macroeconomics, and Investment Appraisal; third year lectures and seminars in Economics of the Social Services, Economics of Human Resources, Health Economics, Applied Economics, and Advanced Economic Theory. External examining.

Listed in

At various times:
Who's Who in Economics: A Biographical Dictionary of Major Economists 1700-1981 (ed. Blaug and Sturges), Wheatsheaf, 1983 (and subsequent editions)
Who's Who
Who's Who in Education
Who's Who in America
Who's Who in the World
The Academic Who's Who
The Universities' Who's Who
The International Authors' and Writers' Who's Who
People of Today

Recreation and other

Church music: Emeritus Organist and Choir Director in an Anglican rural parish church in England, Chair of the York District of the Royal School of Church Music 1983-95, Chair of North East Area Committee of the Royal School of Church Music 1995-2003, member RSCM Advisory Board 2002-4, Member of Council and Trustee RSCM, 2003-. Board Director of Royal School of Church Music (Canada) 2008-. Member of the York Diocesan Liturgy and Music Advisory Group 1995-99. Various roles in local Church of England (at various times Parochial Church Council member, Lay Chair of Parochial Church Council, Sometime Deanery Financial Adviser, Sometime Member York Diocesan Church Urban Fund, etc.). Amateur composer. Music generally. Gardening when time, weather and low back problems permit. DIY when time and LBP permit and urgency insists.

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Current articles

Hic sunt dracones: The future of Health Technology Assessment – one economist's perspective
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All effective treatment must be free

"Here be dragons" may not have actually appeared on any known early map of the world but it is on the 'Lenox Globe' of 1510 in the New York Public Library, and monsters, giant horned men, and other similarly terrifying beasts were certainly sketched in early maps of the remoter and mostly unexplored regions of the world. One may draw an analogy between such maps and the current state of Health Technology Assessment (HTA). There is a large terrain of well-researched and largely well-understood methods—economic, biostatistical, and epidemiological—on which most researchers are engaged in what is aptly called 'normal science' (Kuhn 1972). There are many important research topics, both applied and methodological, that customarily fill the pages of journals such as this and that are also 'normal' in the Kuhnian sense of operating within the conventional optimising paradigm of most cost-effectiveness analysis as illustrated by Drummond et al. (2005) and Gold et al. (1996), and many others. I do not intend to dwell here on research falling into this category. Nor do I intend, however, to devalue it by implying that it is somehow unadventurous or merely conventional. On the contrary, HTA is a living example of the intense creativity that is possible within a paradigm, and HTA is not at all normal in respect of the amazing bridging that has taken place across conventional disciplinary (and faculty) lines, between clinical, statistical, and philosophical disciplines as well as social sciences, and it seems to me a considerable and highly unusual achievement that there should be so little misunderstanding between these disciplines. Indeed, an eavesdropper on a conversation between its practitioners would be hard-pressed to tell from language alone whether a speaker was an epidemiologist, a statistician, a clinician, an ethicist or an economist. This is what I imagine people may have in mind in making a distinction between multidisciplinarity and interdisciplinarity.

Fascinating though such an interdisciplinary story would be, that is not what I want to draw to your attention. My concerns about HTA relate to the fact that, when applied, it inevitably has a political context. It is political both with a large 'P' and a small one. The large 'P' relates to the political ideology of health services and springs from the notion of a public interest element of health services. This is an interest that can be cast in many languages for, example, in political language, 'solidarity'; or, in Marxian language, 'from each according to their ability; to each according to their need';' or, in neoclassical economic language, 'public goods' and 'caring externalities'. It finds particular expression in the idea, which I think can be first attributed to Archie Cochrane (Cochrane 1972), that the only health care warranting public financing or public delivery is health care that is demonstrably effective. Cochrane's slogan, which I have stolen as the sidehead for this section, was "All effective treatment must be free" (Cochrane 1972). It is, of course, perfectly possible to argue that it would be a rather good marketing strategy for any private health insurance agency to claim that the only services it would cover would be those in which one could have confidence that they were truly effective, even cost-effective, for there must be a substantial fraction of any population for whom that would be an attractive bundle to purchase, whether privately or through taxes, since there seems little point, at least from a consumer's point of view, in having to purchase services of no value. Fascinating though this tack would be, like the interdisciplinary story I shall set it aside in order to

dwell on the 'small p' political context. This is the context in which the political creator of NICE, Frank Dobson, when asked as Secretary of State for Health whether he thought it would work, said "probably not, but it's worth a bloody good try." Applied HTA is 'political' both in the sense that it inherently embodies value judgments, including ones about equity, or fairness, and in the sense that the identification and acceptance of value judgments of any kind requires a process within the body politic, one, moreover, that needs to have particular characteristics if it is to lead to acceptable decisions.

An economist's angle

I ought to make plain the purpose of HTA and the key questions that it addresses – or ought to address. HTA exists to help public decision makers make evidence-informed choices at the level at which formulary, insurance coverage, and clinical guideline decisions are taken so as to advance the public's health. HTA ought to be seen as an aid to thought; never a substitute for it. It is a tool and, as such, ought to be useful, credible and fit for purpose. It is not a chisel to be used as a screwdriver, nor a screwdriver to be used as a chisel. It should reveal what we do not know as well as what we do, what sort of confidence we may have in the available information, and be capable of indicating what other kinds of information would further aid decision makers. It ought to help decision makers integrate different kinds of information and expose the values that ought to underpin all such decisions. Regarding key questions, the main ones are very familiar: does an intervention (or 'health technology') 'work'? For whom does it work? How well does it work? Relative to what alternatives? At what cost? Is it worthwhile? Can it be introduced (or withdrawn) and used in fair ways? What values are embodied in the answers to the foregoing? And what is the legitimate source of those values?

Even though many other disciplines provide crucial inputs, especially empirical inputs, to answer these question, it is economics that has provided the overall analytical framework for Comparative Effectiveness Research (CER) and Cost-Effectiveness Analysis (CEA) in HTA. Economics has specifically prescribed a broadly utilitarian type of 'optimization' (constrained maximization), though the stipulation of 'health' rather than 'utility' as the maximand is a significant departure from utilitarianism as normally practised. HTA's long-standing concern over the way in which this maximand is distributed over a jurisdiction's population is another departure, such distributional concerns being of sublime indifference to strict utilitarians. Economics has also specified the general character of the evidence required to determine probable cost-effectiveness (clinical of course, but also other evidence, especially that related to costs, non-clinical outcomes and outcomes affecting third parties). It is economists who insist on the separate roles of 'science' and 'social value judgments' and who have emphasized that what qualifies one to make judgments about the former rarely also qualifies one to make judgments about the latter. Economics has introduced the HTA world to some of its own vocabulary, which has been quickly understood and absorbed into the conventional practice of HTA: words (and the inevitable acronyms) like incremental cost-effectiveness ratio (ICER); 'publicness', in the sense of a benefit whose enjoyment by one person does not diminish enjoyment for another; 'opportunity cost', in the sense of the most highly valued alternative use of the resources undergoing investigation; 'social welfare function' (SWF), in the sense of how the satisfied preferences of many individuals are

linked or added up; 'externality', in the sense of the impact on others of one's behaviour[1]. Economics has also brought some of its own techniques to the table: Quality-adjusted Life-years (QALYs) and other outcome concepts; discrete choice experiments (DCE) and other experimental methods (many in association with cognitive psychology); time preference and discounting. Indeed, it would be a challenge to find any method in use today that remains uniquely the property of any one discipline, including economics. A short list of such core disciplines ought to include anthropology, biostatistics, cognitive psychology, decision theory, epidemiology, ethics, ethnography, management, mathematics, political science, public administration, qualitative research, and social policy.

Despite this rich multi-disciplinary input, it remains the case that the current guidance, whether from institutions like NICE and OHTAC or academic textbooks and articles, fails to deal with equity, in the sense of fairness, with anything like adequacy. This brings me to the dragons that I think need slaying which, like sleeping dogs, have been left to lie but which, if aroused, are capable of more mischief and destruction than any dog.

Two dragons

The first dragon is equity and, in particular, how one may embody equity considerations into HTA. By 'equity' I mean interpersonal fairness in the receipt of health care and the distribution of its consequences. Economists have a well-developed corpus of theory, both for describing the characteristics of a first-best allocation of resources to production and the fruits of that production to final consumers. They also have a well-developed set of principles for putting that analysis to work in a second-best world. Complementing those principles is an impressive array of empirical tools. It is all adaptable to the circumstances of the public sector as well as the private. And it has been, moreover, adapted to the circumstances of health care and health.

What economists have never been able satisfactorily to do is develop any analysis of equity of comparable sophistication, comparable applicability and comparable mutual agreement. Nor, alas, has the vacuum been filled by anyone else, though Johri and Norheim's review (2009) is a useful beginning. The consequence is that the committees that make recommendations about the adoption and funding of new health care interventions, or disinvestment in old ones, do not know how to address matters of equity. Nor do they know how to integrate such considerations into efficiency analyses. Economists are strong on what *not* to do. Do not identify equity with equality, nor health with welfare, nor need with priority. Do not assume that equity trumps efficiency, nor that efficiency trumps equity. The list may readily be prolonged. The trouble is that these prohibitions are nearly always what people *do* tend to ignore That is not surprising given that economists, along with ethicists and other social analysts, have failed to stipulate what it is that one do instead. By the same token, the aforesaid failure has, again not surprisingly, left an empirical void which stands in marked contrast to the evidential base that exists for efficiency studies, so that even if we suddenly knew what it is that we should do with respect to equity, we would hardly be able, as a practical matter, to do it. As it happens, I think

[1] These definitions are somewhat loose; tighter ones can be found in Culyer 2010.

there is a solution that will banish this dragon to even further reaches of our known landscape, but before revealing this I must turn to the second dragon.

The second dragon is associated with the first and, unless this dragon is also slain, or at least banished, it will make it mightily difficult to dispose of dragon number one. Dragon number two is our ignorance as to the character of a process that might enable us to integrate equity in HTA. Specifically, the challenge is that we are short of an adequate understanding of the processes necessary for combining different types of evidence, evidence about different kinds of thing (monetary and non-monetary, qualitative and quantitative), and for articulating concepts that are not themselves evidential (such as equity). It is not merely that processes can have characteristics that appeal in and of themselves -- characteristics like transparency, citizen engagement, openness, deliberation and contestability -- it is that characteristics such as these are to be valued for more than their intrinsic merits. They are, in short, necessary for the proper accomplishment of the tasks of HTA and, in particular, they are essential to the major task of merging equity satisfactorily with efficiency.

Philosophy, political science and social policy all address equity and, in the case of philosophy, have done so for many centuries. Administrative science, the law and management science have all addressed 'processes'. But none of these disciplines has concerned itself deeply with HTA (with the exception of the sub-discipline of bioethics) and, typically, none has made the theory and practice of HTA their daily business. This accounts, I conjecture, for two unfortunate phenomena. The first is that the question whether the methods of HTA ought to be more intimately linked to the processes of real-world decision making has gone unaddressed. The two are treated as essentially unrelated activities. As a consequence, HTA – or at least the conventional practice within HTA of cost-utility analysis – has been described as a "perversion of science as well as of morality" (Harris 2005). Powers and Faden (2000) call attention to its "moral flaws", an unfortunate judgment that hinges on the implausible proposition that those who use HTA methods, and CUA in particular, are moral morons wedded to the uncritical use of a single decision tool. The charge is a triple one: that the tool is a poor one, that it is used uncritically, and that it is the only one they use[2]. The other unfortunate phenomenon is that, despite these centuries of study, no one yet has come up with usable tools that would assist decision makers and those who advise them to integrate the two great criteria of efficiency and equity and to devise effective (even cost-effective) processes for doing so.

It seems to me that the way forward is for those of us who are, as it were, HTA 'insiders' should grasp the challenges ourselves, perhaps in collaboration with some of the aforesaid colleagues from other disciplines (including the critics), but at any rate not in deferment to them, and set in motion a new research program designed to get to the heart of these matters. That is what I propose to try to boost in the rest of this paper.

Process

"Arguably the biggest threat to our public health care system is not our ability to pay for the increasing cost of care, but rather a loss of public confidence." (Chase et al.

[2] A more sympathetic critic, but one who nonetheless tends to think that HTA practitioners regard CEA as *the* rather than merely *a* tool is Brock (e.g. Brock 2000).

2010). While this loss of confidence parallels a general scepticism about the adequacy and fairness of public decisions across the board, health care has evidently not escaped it. For many (e.g. Mendelberg 2002, Petts 2004) the solution is citizen engagement and other processes of more direct democracy. I have much sympathy with sentiments such as these. However, that is not where I want to lay the emphasis here. I want, instead (or, perhaps, 'as well') to suggest that better processes would be useful not only for re-establishing confidence in general, but also for offering ways in which better decisions are likely to result. A better process might be better in the sense that it is more 'transparent' and confidence-building on that account. Those are the *intrinsic* merits of a good process and are embodied in 'accountability for reasonableness' (Daniels 2000, Daniels and Sabine 2008). But it may also be a better process by virtue of the fact that it embodies more complete evidence, or more deeply investigated evidence, or by its better combining of many elements -- some evidential and others not, or through enabling a more complete addressing of equity and of its consideration alongside efficiency. By 'process' I mean the steps that are taken, and their organisation and management, from the earliest inception of an HTA ("what 'technology' is to be assessed?") through its further scoping and refinement; selection of comparator technologies, identification of primary and secondary research; critical appraisal of the evidence; stakeholder comment, consultation and further deliberation; through draft guidance, recommendations or decisions; appeals; conclusions, recommendations and dissemination[3].

The processes that I particularly have in mind are: the possibility of external comment in order that interested parties may see what there is to comment upon; consultation, through which external parties are invited both to engage with decision makers and their advisers and to enter into discussion about whatever aspects of the process may be under way at the time, which includes assumptions, comparators, model building, literature review and matters to do with the intrinsic process itself; and finally, the most complete form of engagement, deliberation, in which relevant stakeholders actually participate in the decision making itself -- though probably excluding the final 'determination' or conclusion of the process, for which responsibility necessarily lies with those appointed to decide.

Issues that require resolution would be determined at a 'high' level, such as through the board of an organisation, or at ministerial or even cabinet level. Examples of such issues include: specifying the objective (health maximisation?), the available budget, the 'threshold' (lintel?) ICER, the discount rate(s) to be used, whether sophisticated programming or simple CEA is to be used, whether Multi-criteria Decision Analysis is an approved method, the choice of technologies to evaluate, and the comparators and equity requirements. Occasionally some of these might be determined at a 'lower level', which I take to be the level of the decision making agency or advisory committee. These lower level issues would generally include all of the following: testing the concept validity of outcome measures, assessing the quality of the science on a particular subject intervention and its comparators, interpreting and combining both qualitative and quantitative evidence (systematic reviews, other reviews, meta-analyses), linking, if possible, internal and external validity, weighing uncertainty, identifying absent information and deciding what to do in its absence, assessing 'feasibility' and manageable time lines, trading off conflicting desiderata and, finally,

[3] This is broadly the sequence of processes used by NICE.

making recommendations or issuing guidance through (preferably tried and tested) Knowledge Translation methods.

A good many technologies do not easily 'fit' into the customary methods of HTA. Consider public health: its complex interventions, diversity of responsibility for the vectors of delivery (communities, schools, hospitals, prisons,…), heterogeneity of outcomes (better health, but also reductions in teenage pregnancies, reduced crime, reduced *fear* of crime, …), long time horizons (especially when the interventions involve culture change or challenge cherished beliefs) and programmatic character (prevention, screening). Or consider the simplifying assumptions, such as constant returns to scale, non-diminishing marginal value of QALY, or the simple additivity of outcomes, that are so often merely taken for granted rather than tested for their appropriateness. Also consider the character of evidence, especially when one widens the notion of 'technology' beyond pharmaceuticals: the greater dependence on multivariate observational studies and econometrics, the use of cheaper experimental methods than RCTs, and the kind of evidence required on value questions such as the value to be placed on a unit of outcome or the measurement of changes in 'equity'. Then too consider what might be best regarded as a potential by-product of HTA: the possibilities it affords for raising the public understanding of risk and uncertainty, the reasons why one thing rather than another has been chosen, and the enhancement of the general credibility of guidance.

The 'process' has three important aspects. One is to ensure that divergent views are properly represented to minimize the chances that any one particular interest group should unfairly 'capture' the process. Another is to enable the wisdom and experience of other decision makers to be brought to the table. Their judgments, especially about value-laden and possibly controversial issues such as quality of science or the meaning of 'equity', may be wiser than those of the 'official' participants. A third is that the process itself is a means by which evidence is generated or at least brought before decision makers. Such evidence might relate to matters of 'feasibility' and 'manageability', where the experience of practical managers amongst the decision makers may be a useful input; to matters of external validity, where specific knowledge on the environments into which an intervention might be introduced may be essential; or to the appraisal of outcomes, where the fit of the outcome measures used in research studies with the experience of actual patients and their carers can be tested and possible biases identified and adjustments made on account of them. (Culyer 2009, Dobrow et al. 2009)

I have just *listed* some 'issues' and asserted *some* better ways of addressing them. My selection is not evidence-based, save in a somewhat experiential and necessarily partial way. Nor is it founded on any well-developed theory of 'good' decision making. It is therefore ad hoc. Most of the literature on these topics, such as it is, is assertive rather than analytical, ideological rather than scientific, strong on advocacy but weak on evidence. It is also written by the practitioners of many different disciplines and appears in places that seem very remote from any HTA concern[4].

Equity

[4] For example, who would think of looking in *Trends in Parasitology*, for the useful article by Lavery et al. (2010) with its tips on successful community engagement in research?

Much the same applies, I fear, to the treatment of equity. Of course, equity, in its major sense of distributive justice and 'fairness' has been a central concern of moral philosophy since the days of classical Greece. Its modern students are well-practised in the business of typology (utilitarian – several varieties, deontological – again several varieties, theological, consequentialist, etc. etc.) but they have, with a few fine exceptions. (such as Daniels (2000) and Daniels and Sabin (2008) on decision processes, been quite extraordinarily bad at providing tools for the use of practical decision makers such as the practitioners and users of HTA

Even the most elementary 'tools', such as a typology of characteristic equity issues to form an 'agenda' for discussion at various stages of an HTA process, would be an advance on what we currently have. Such a typology might focus deliberation on such matters as the *domains* of equity. For example, there are equity issues regarding the use and distribution of health care inputs, the processes that determine who gets what, the evaluation of outcomes, and on the priority that ought to be attached to different diseases, or to prevention versus cure. Decision makers need to reflect on the appropriateness of the criteria used in respect of any of these, their inclusiveness, the relative weight to attach to each, and so on. Some red flags are provided in some jurisdictions by statute, as when there is a legal obligation to guard against discrimination by age, gender, disability, other demographics, workplace, education, institutionalized discrimination. However, not all jurisdictions cover all possible issues and matters of equitable concern may lie hidden in the depths of an HTA. There are also a number of 'top level' issues, such as whether there may be some principles on which all would agree as minimal requirements for equity, whether it is possible to enunciate some axiomatic statements that define what an 'increase' in equity might mean and how it might be recognised empirically, and there is always a need to establish the applicability of any such principles in the context in question.

Some of the 'hidden' equity biases that are likely always to need surfacing include *embedded inequity* – through which possible unfairness is 'built in' to concepts (e.g. omitted dimensions of outcome measure that discriminate against those for whom such outcomes are important), or *framing effects* in experimental approaches that bring in social class bias, or unfairness that is inherent in the intervention (e.g. a threat to autonomy through the removal of choice, as with some public health measures). There are also *institutional biases***,** inequities resulting from practices in jurisdictional scope (e.g. health consequences not taken into account by some faith-based provider institutions, school boards or workplace managements) and the degree of concern many jurisdictions have with the distribution of consequences (health or not-health). There is also *implicit stereotyping* the use, often in all innocence, of definitions and concepts that exclude individuals or aspects of health-related welfare that have differential impact on individuals, and that make untested assumptions about what does and does not 'matter' to the people for whom the intervention exists.[5] Particular contexts (e.g. geography) may disadvantage some relative to others. Minimally, surely, one ought to test to see whether any of the following could affect the balance of advantage across different groups: the setting of care (e.g. home or institution), language, education or SES of clients, religious beliefs, stigma, or multiple deprivations.

[5] Reutzel et al (1999) provide an interesting example of unwarranted assumptions made about the hearing needs of deaf people.

Decision makers ought to ask, for example, whether the processes in HTA itself are biased by denying representation to people with a legitimate interest. Whether the interests of *absentee* stakeholders are properly considered – for example, those anonymous individuals for whom services will not be provided as a consequence of implementing the recommendations. Participants in HTA need to be self-aware and self-critical regarding their own procedures. Processes in delivery of the care under evaluation can be prejudicial to technologies for some types of client (e.g. those of low SES) and can favour those adept at negotiating their way through processes, or impose differential burdens on some clients (e.g. wage versus salary earners).

Then there are special claims such as claims of need (e.g. low initial health status?), of deservingness (e.g. choosing life styles that are hazardous to health?), of history (e.g. past endurance of ill-health, past receipt of the intervention), of desperation (e.g. 'last chance'), of unfair innings (lived only a short life-span), of non-health consequences (other welfare effects), of willingness to pay (e.g. top-up payments). Sometimes the beneficiary is identified as a member of a group or even by name as is often the case with spectacular acts of medical – or other – rescue. Ought cases of extreme need be given special favour (Hope 2004 ch 3, Cookson et al. 2008)? What weight ought to be given to such claims either in general or in the context of a specific HTA? What weights actually are given (e.g. Cropper 1994, Johannesson and Johanson 1997, Johanson-Stenman and Martinson 2008)? Cumulative effects may escape proper attention, for example, cumulative past disadvantages or effects that might be relevant in assessing benefit or cost or their distribution across patients and other affected groups.

The point of these examples is that in the process of discussion and deliberation about a technology decision, all of these hidden problems need to be deliberately "surfaced" because ignoring them (being unaware of their existence, or aware but doing nothing about them) leads to a bad decision. My suggestions are merely illustrative and are certainly not exhaustive. But who better to complete the list, maintain it through casuistry and careful recording of the reasons for decisions, and synthesize and consolidate it over time, than those involved in the process of HTA? Through such casuistry may we not build up case-based precedents to help decision-makers achieve consistency across interventions and over time, perhaps, eventually create a systematic 'ethics of HTA'?

Deliberation

The slaying of both my dragons HTA requires, I conjecture, deliberation, with an emphasis on: process, from scoping a topic through evidence generation and synthesis to delivering guidance; consultation with legitimate stakeholders (usually also a source of evidence); and facilitated discussion. These all weak points in the current state of HTA, and they are all Cinderella research topics (but see Lomas et al. 2005, Culyer 2009, Dobrowe et al. 2009) with multidisciplinary concerns.

I believe the ultimate product and measure of success would be the increase in confidence of participants, stakeholders and the public. This would be achieved by their understanding of the processes and knowledge that the best evidence was used, that the appropriate 'experts', lay and professional, had contributed, that *all* relevant evidence had been searched and considered, that *all* relevant stakeholders had their say and been heard, that key concepts (e.g. 'outcomes') had been tested for construct

validity, that *all* relevant cost and benefits had been weighed and included in calculations, that fair comparisons had been made (both between interventions and between individuals), that all relevant conceptual and empirical biases had been eliminated, and that the main risks had been assessed and undue risks not taken. I suppose, taken as a group, such outcomes might constitute evidence of a 'good' process.

To realize this ultimate product, however, HTA would be wise to broaden its horizons, turning away from what is largely just an algorithm to find ways to take seriously the myriad value and ethical issues which currently still have the unfortunate appearance of afterthoughts, tacked on to, but essentially excluded from, the core decision logic, and to develop an empirical program to rival, mutatis mutandis, that of CEA and CER. After all, non-monetary values, though less easily measured perhaps than monetary ones, are still subject to empirical estimation and the values that individuals actually cherish ought at the least to *inform* decision makers' values. This is not merely a matter of expanding the algorithm but also, as I have tried to show, a matter of developing suitable processes that generate information through the participation of stakeholders while also facilitating the thoughtful assessment of what is known, combining it with revealed values, and producing multiple solutions to problems that are not uniquely soluble, like those on which there are deep divisions of principle in the community. To participate both in such processes and in the accompanying research program must surely be one of the more exciting prospects confronting today's HTAers.

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An equity checklist: a framework for health technology assessments

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Introduction

A challenge was recently presented to Health Technology Assessment (HTA) practitioners to address equity better in their analyses [1]. In this paper we attempt to meet that challenge, at least in part. HTA is the systematic evaluation of the consequences of the use of a health care intervention (henceforth 'technology'). Its principal purpose is to inform decision-making. Ethical considerations and non-economic social consequences were included in early general formulations of HTA [2]. However, it is only recently that attempts have been made to develop frameworks for considering methods of integrating ethics and a wider set of social consequences into HTA [3-7]. A comprehensive attempt to give practical guidance is that of the National Institute for Health and Clinical Excellence (NICE) in England and Wales [6]. One important ethical consideration is equity. Despite the significance of equity ideas in the design of many health care systems, pragmatic tools for integrating them into the efficiency categories of cost-effectiveness in HTA remain under-developed [8]. We attempt here a first step towards a pragmatic solution by providing a framework of equitable considerations of potential relevance in HTA decision making, giving examples of the ways in which such considerations might arise, and providing a summarized checklist which may itself be used as a decision tool by HTA decision makers or which could be further abbreviated as a desk-top aide-memoire. The framework is primarily intended for high-level decision makers who specify the criteria to be used by HTA advisory committees. The checklist if offered as a first approximation to a practical tool for use by such advisory committees.

Equity has many meanings in both academic and lay contexts [9-12]. The absence of an agreed theory of equity arises out of the absence of a general or monist theory of morality. There are moral theories that claim to be general, such as utilitarianism,

though utilitarianism in its classical form is not directly concerned with equity. Non-utilitarian theories hold, variously, that the equitable distribution of health care resources is that which is to the advantage of the least advantaged person - so-called maximin theory. Deontological theory posits that an equitable distribution arises out of the duty each has to provide for others. Entitlement theory holds that an equitable distribution is the outcome of an equitable economic and social system (for a review of rival approaches see Veatch [13]). We do not attempt the Sisyphean tasks of selecting from or reconciling rival philosophies but suggest instead that equity issues concerning the use of health care resources in a decision-making context are best considered explicitly as pluralist. Rather than defining a priori what 'equity' is, we draw on a multidisciplinary literature and our own practical experience, to create an eclectic list of equity issues, which, if left unaddressed by decision makers, could be deemed by a reasonable person to be unfair or to lead to unfairness in the adoption, diffusion or consequences of a health technology.

Two domains of equity are especially relevant in HTA. One is fairness of the *procedures* used in the conduct of HTAs. The other is equity as a *decision criterion*, like efficiency, for *ranking health care interventions.* Equity in the first sense has, at least in part, been conceptualized as 'accountability for reasonableness' [10, 14-16] and has been adopted by some agencies (e.g. NICE 2008). Equity in the second sense is a statutory requirement in several jurisdictions and is likely to be increasingly required: illegal discrimination will need to be addressed in all jurisdictions, such as the UK, where such legislation exists. However, such imperatives typically address only a subset of the concerns for equity that can arise in HTA. Unfortunately, there exists no substantive body of principled thinking that can serve as a sure, or even moderately agreed, foundation for a more comprehensive treatment of equity in HTA [11].

Equity in the sense of fairness in the way health care is financed, produced and distributed has been a founding principle of many health care systems throughout the world, and has resulted in systems that broadly fund activity according to ability to pay and distribute it according to need (especially in middle and high income countries). It would therefore seem appropriate for HTA equity criteria in such jurisdictions to be at least consistent with these broader ideals of health care. Unfortunately there are major differences between definitions of 'need', measures of it and its application in HTA decisions [12] and it is far from clear what a criterion of need would require over and above the criteria of effectiveness and cost-effectiveness.

The standard approach to equity within HTA seems to operate at two distinct levels. The first is general, such as being aware of the difference between horizontal and vertical equity (noting that only the former involves attempting to achieve equity through the equality of something [9, 17]) or having an equal respect for everyone. Since not all inequalities are inequitable, nor all equalities equitable, we agree with Whitehead (1991) in making equity and inequity the focus of our attention rather than

equality or inequality [18]. The second is specific, such as the application of differential weights to costs and benefits according to particular equity-related characteristics of those likely to be affected by the decision [19-27]). While there is merit in this outcome-based approach, in practice decision makers have difficulty in identifying circumstances in which departures from strict equality in the value of units of outcome could be justified, with the possible exception of end-of-life benefits which NICE, for example, explicitly treats as warranting special weights, but without specifying them in quantitative terms, and which others, such as Ontario's Committee to Evaluate Drugs (CED), favour - though only implicitly[6]. Equity-focused 'impact assessments' are examples of procedures that have a focus specifically on the distribution of outcomes (e.g. Kemm et al 2006 [29]).

There is little guidance concerning what, justly, *ought* to constitute either the characteristics in question or the size of the weights. Some gather evidence regarding the public's preferences, stakeholders' perspectives or experts' advice on either of these matters [26, 27, 30-36]. Empirical efforts to discover what 'the public' thinks about appropriate ways of trading-off benefit with cost also raise the fundamental ethical question of the extent to which HTA *ought* to embody such values, even when participants are well-informed. It is possible that preferences may be unstable or that the values elicited change according to the amount of information that is given, the technology considered, whether the health state in question is merely anticipated or actually experienced. Even when all such confounders have been taken into account it is possible for there to be considerable variance around population means and the distribution of ethical values need not have a single mode. Ethicists might raise the objection that what is just or fair is not to be determined by populist vote, while others might contend that the preferences of elected representatives of the community in question should count rather than the preferences of those who elected them. Other methods have sought generalizable trade-offs between equity and efficiency [37, 38]. However, not all equity issues involve trade-offs with efficiency[7] [40] and none of these approaches addresses what *ought* to be done nor attempts to address the many other dimensions of equity that ought to be taken into account. The dimensions of equity typically considered (at least by health economists) are quite restrictive, being mostly concerned with distributive fairness and focused on health, the geography of

[6] In the UK the Department of Health's recent call for proposals regarding value-based pricing for pharmaceuticals explicitly invites proposals regarding weights (see [28]).

[7] Equity is commonly perceived as in conflict with efficiency. The existence of any trade-off hinges, however, on the concept of 'efficiency' employed. If being efficient is to maximise aggregate population health with *fixed* weights for its members' health states (say, equal weights), then any such weights are potentially inequitable, and could generate a clash (say, on grounds of neglecting previous histories of ill-health, or of treating a given health gain as of equal social value regardless of the starting health state of individual members). But this clash is between different approaches to weighting health states, and less to do with efficiency. If, on the other hand, efficiency is of the conventional kind in economics (e.g. Barr 2004 [39]) – a state of affairs in which no one's health can be increased without the necessity of reducing someone else's, then there is a virtually unlimited set of differently weighted combinations of members' health states, any one of which is efficient but only a few equitable. The real trade-off is again between rival conceptions of what it means to be equitable.

health care, and income. Further, irreconcilable differences in values are glossed over, hidden stereotyping happens and reliance, save in the case of legislated requirements, is almost entirely upon intuition.

We propose the creation of a pluralist [41] 'checklist', that might be expanded and developed in the light of experience, consultation, deliberation and the transparency that ought to accompany it. In any specific decision context, not all the items in the checklist will be relevant – and perhaps none will be – but the intent is to minimize the risk of overlooking considerations of equity that might be relevant by ensuring that minds are open to matters that can easily be overlooked or, if not overlooked, that may be difficult to articulate, appraise or measure.

A proposed initial checklist

We propose a practical and adaptable initial framework (the 'equity checklist'), as the basis for the development of a more comprehensive typology[8]. It is practical because it is intended as a sequence of 'red flags' to alert decision makers – and the designers of the systems within which they work – to matters of equity that might warrant integration into the usual efficiency analysis of HTAs. It is adaptable because the checklist as it currently stands is intended only as an initial step and what may be added is currently unknowable (at least, by us).

The checklist is an initial framework to inform discussion and decision at a relatively high level, to set criteria, and ensure that lower tier decisions – and the reasons for them – are incorporated into minutes and notes of the meetings at which they are taken, thereby enabling a dynamic process of comparison and consolidation as cases accumulate. In our approach, what is equitable or inequitable is less a matter for *a priori* definition than for discovery and subsequent categorization by those appointed by legitimate means to make such decisions. We hope that the checklist will help the process of discovering whether a consensus does exist and, where it does not, what the nature of the conflict may be and how it might most appropriately be dealt with. Although the exercise is not intended to generate a consensus, establishing that there is no consensus on some of these questions is as important as seeking one [45]. While it may be possible to develop a consensus over time in a jurisdiction, or at least a consistency in the way equity matters are considered, it seems unlikely that such a consensus would ever be achieved across jurisdictions, where prevailing standards, cultures and political values could vary greatly.

The object instead is to enable all potentially relevant factors to be clarified and considered, along with any evidence pertaining to them, including any evidence

[8] It is intended to complement rather than supplant other checklists such as those being developed by the Campbell and Cochrane Equity Methods Group (Ueffing et al. [42] and Tugwell et al. [43]). It could also be used as a complement to audits of equity such as that operated in England by the Department of Health [44]).

generated in the actual process of consultation and deliberation. The process is intended to affect both the procedures of the HTA as well as the 'final appraisal determination'.[9] It may also be used by agencies to determine the scope of equitable issues to be considered by advisory committees, with the consequence that some of the matters identified in the list would not in practice be open for discussion.

We propose that the equity checklist should: (a) be used as part of the process through which advisory bodies are given their terms of reference, (b) form a part of the scoping agenda prior to the selection of a candidate intervention and its comparators for HTA, (c) accompany the usual efficiency-related statistical and analytical, research and background briefing for decision makers, including systematic and other reviews, incorporating any anticipated equity issues in the scoping stage; and (d) where appropriate (e.g. when equity issues of sufficient weight are identified to warrant detailed consideration) help to structure the discussion and composition of multi-disciplinary, multi-professional and 'lay' advisory groups during the assessment process.

We anticipate that the checklist will be developed in a variety of ways. One is through academic research and discussion, which will in turn inform the methodological guidance of HTA agencies. Others, which we have previously characterised as casuistry, are through the gradual building up of case studies of actual decisions, their reasoning, and their eventual analysis, synthesis and consolidation into statements of good practice at various levels of the decision making process. This will normally require digging deeper than the mere on-line consultation of the recommendations and decisions of advisory committees. In this fashion, we expect to see an accumulation of case-based precedents that will help decision-makers achieve consistency across interventions, constantly remind them of factors that might otherwise be overlooked, together with suggestions of how they could be handled.

Elements of the Checklist

Equity versus equality

Decision makers may need reminding that equity and inequity are not the same as equality or inequality. When, however, inequalities are linked with postulated causes as when, for example, a concentration curve links health or ill-health to income, an inequality might be judged as also inequitable. Some inequalities are actually equitable as when, for example, someone with an urgent need to treatment receives it before another who is a less urgent case. In all cases, however, it is worth asking 'equality (or inequality) of what?' Common candidates include: need; deservingness or responsibility; capacity to benefit or be harmed; degree of incapacity or current health state; history of past health or ill-health; prognosis with and without the

[9] This is the term used by NICE to describe the recommendation or final product of its evidentiary review process: the guidance of its Technology Appraisal Advisory Committee.

technology; health outcome - quality of life; and dependents (e.g. care-giving responsibilities). The ethical element derives from the postulated cause of the health inequality. Empirical causes judged to be ethically relevant commonly include income and wealth; social class; social deprivation; and life-style and behaviour. While the solution to inequity is likely to require addressing the underlying causes, an assessment of their mutability and the balance of cost and benefit in changing them, the range of remedies in HTA is typically narrower, lying within health care and typically within a rather small subset of health care technologies.

The language of equality and inequality is explicitly quantitative and it is always worth seeking empirical and quantitative information about *how equal or unequal* the relevant factors, outcomes or causes are and how equal or unequal it is felt they ought to be. Major unjust inequalities may rightly be perceived as more important to remedy than minor ones, though the relative costs or redress ought normally also to be taken into account. In all cases a judgement should be made as to whether the evidence on equity warrants any significant departure from the implications of the efficiency analysis, such as recommending the use of an intervention when its incremental cost-effectiveness ratio is above that normally deemed to be the maximum allowable, or not recommending one that is below that threshold, on grounds of its inequitable consequences.

Domains of equity

The matters for discussion under this category of the checklist relate to the appropriate focus on equity, for example, whether it should relate to health care inputs, processes or outcomes; whether it is the direct or indirect (perhaps unintended) consequences of the use and diffusion of the health technology that matter; whether there should be a disease focus, with patients being classified by, say, diagnostic group, or in some other way (say, by socio-economic status (SES)). If the identification of subgroups within a larger class of individuals could generate inequities, these should be explored. It is at this stage that some groups who might be affected by a technology can be (innocently but mistakenly) overlooked, as might be the case in interventions for parents that have significant side-effects on children. Such an omission would, of course, also bias an efficiency analysis as well as raising potentially significant equity issues [46]. For example, if we consider a screening technology that distinguishes between cancer patients who would benefit from a particular treatment from those who would not, then one domain of equity pertains to the consideration the implications for both sub-groups: not only the sub-group that benefits but also those who are disappointed.

Legal Obligations

Most jurisdictions will specify statutory requirements to consider justice and equity and there may be further administrative obligations placed on agencies by higher tier organizations or their own governing bodies. Anti-discrimination legislation may be

quite specific in requiring specific factors to be taken into account and may go so far as to specify how and the discretion that is permitted the decision makers. Legal obligations may be absolute, in the sense that any inequality of the sort in question is illegal, or relative in the sense that discretion may be exercised regarding the extent to which a given inequality violates a principle of equity. Common dimensions include discrimination by age, religion, gender, disability, ethnicity, race, socio-economic status, nationality, language and sexual orientation. Other dimensions may have regulations we cover under other headings.[10]

General principles

Despite the difficulty in obtaining universal assent to specific ethical principles, it is always worth establishing whether some (probably simple) principles would in fact be agreed for all cases or in the context of the case under consideration. Some may be of inherently broadly applicable and become embodied as standard in the consideration of equity. Principles that might be worth discussing could include:

(a) The domain of equity shall be 'current and prospective health' not past health.

(b) Equity requires either the attainable equality of something or else its fair inequality.

(c) Fair inequalities in treatment exist when the inequality arises from a fair claim for being treated differently, such as an accepted claim of higher need.

It may also be possible to agree specific axioms relating to equity, such as the following cockshies:

> Weak equity axiom 1: 'if person A has a worse state of health than person B, then in determining the equitable allocation of an intervention having a given impact on a population including A and B the equitable solution ought to increase A's health more than B's, or reduce it less'.

or

> Weak equity axiom 2: 'if person A has a worse state of health than person B, then in determining the equitable allocation of a budget for interventions on a population including A and B the solution ought to include only interventions that on average increase A's health more than B's, or reduce it less'.

[10] NICE has gone further than most agencies in identifying groups of people for whom special treatment may in some circumstances be appropriate. They are: race (ethnicity) only when clinical effectiveness cannot be identified in any other way; disability, especially where there are obstacles to their benefitting from a technology; age, sex or sexual orientation, if they are an indicator of benefit or risk or clinical effectiveness cannot be identified in any other way; stigma, to the extent that it affects behaviour and the probability of benefit; behaviour-dependent conditions only if continuing behaviour affects the probability of benefit; socio-economic status only if effectiveness is linked to status or there is a legal requirement to favour this group [47].

Embedded inequity

By embedded inequity we mean inequities arising from inherent characteristics of the analysis or intervention. This might arise from the use of specific concepts or tools. For example, it is generally recognised that the use of EQ-5D might discriminate unfairly against clients with cognitive impairment or with sensory deficits for whom it is not well-designed. Unfairness might also arise in the detail of the measurement process –. EQ-5D may omit significant dimensions and thereby unfairly discriminate against patients for whom the omitted factors are key outcomes, such as relief of fatigue for people living with rheumatoid arthritis or anaemia. Time costs may not properly reflect opportunity costs for different social/employment groups, as when salary earners do not lose income when attending a clinic compared with the self-employed. Practical measurement and experimental methods may contain inequitable framing biases, or measures of inequality may over or underweight the extremes of a distribution of benefits or harms [48] or exclude relevant dimensions [49].

The systematic exclusion of vulnerable groups from clinical trials/research can lead to an absence of evidence on effectiveness in those groups, which in turn can result in inequitable denial of access. A now classic case of this bias is the exclusion of women from cardiovascular clinical trials despite the prevalence rate of cardiac disease amongst them (see Kim et al. 2009 [50]).

Embedded inequity might also arise from the inherent character of an intervention, such as denial of choice that can arise in some interventions such as water fluoridation, population-screening programs or (healthy) fixed school lunch menus, where the affront to freedom may bear more heavily on some than on others, such as those with religious dietary restrictions. The commonly made assumption that a quality-adjusted life year is of equal social value to whomever it accrues is an embedded assumption that may need modification if it is thought that the value (weight) placed on a QALY gain for one who is currently very sick ought to be higher than for one less sick [23].

Inequity may arise when the valuation basis of health outcomes is variable as when, for example, those who have actually experienced a condition (and its treatment) value its avoidance less than those who anticipate but have not experienced it [51]. More generally, if the prevalence of unstable valuations of outcomes is related to other characteristics, such as education or social class, then a suitable precaution might be to discover the views of those most directly affected by the intervention in question. There is a great deal of evidence of the considerable variability of preferences and valuations, and their susceptibility to framing and other effects, in the literature of cognitive psychology and experimental economics (e.g. Kahnemann and Tversky 2000 [52]).

Institutional bias

Institutional biases are those that are also embedded but in organizations rather than analytical methods or interventions. The equity issue here is whether the jurisdictional scope of agency or of its parent organization causes any costs or benefits that might be significant for equity to be omitted or distorted. For example, if major outcomes include effects such as reductions in teenage pregnancies or a reduction in the frequency of j-walking, these may not be a part of a Ministry of Health's remit, belonging instead to a Ministry of Social Work or the Ministry of Transport. Conversely, the jurisdictional scope of 'partner' agencies or ministries might cause significant costs or benefits for health equity to be omitted or distorted (such as impacts on life expectation).

Other skews may exist in the distribution of the costs and benefits of interventions across 'stakeholders' that create inequity, as when workplace interventions have costs that fall mainly on owners and benefits that fall mainly on workers [53]. Institutional biases may cut across a myriad of domains, including the highest institutional levels such as health ministries, within agencies conducting technology appraisals, in provider institutions, in workplaces and other locations of care or intervention.

Implicit stereotyping

Implicit stereotyping occurs when assumptions are made about a condition and the desirability of treating it so as to ascribe those living with that condition as 'abnormal' or 'undesirable' [54]. For example, individuals who are deaf like to consider themselves as a group distinguished not only by deafness but also by a language (Sign) and resist the descriptor 'disabled' on the grounds that deafness is, in effect, a socially-constructed 'disability', and therefore need not be 'treated'. Implicit stereotyping is especially likely when the culture of the 'patient' differs from that of the analyst. A dramatic example of the way in which 'disease' can be socially constructed is pinta (dyschromic spirochaetosis). This skin disease produces distinctive rose-coloured spots on the skin, which some Indians in South America once believed to be a sign of being healthy, and which was so prevalent among some tribes that the few single men *not* suffering from it were regarded as pathological to the point of being excluded from marriage [55][11]. To treat it therefore according to concepts of disease which are external to that culture is likely to imply that the value of treatment thus estimated would conflict with a value based on local Indian concepts and values. The danger for HTA in implicit stereotyping is that the externally perceived health gain relative to that perceived by the patient can be substantially different, and subsequent implementation becomes patronising or even stigmatizing.

Implicit stereotyping may be particularly expected for congenital and other chronic conditions. A check is actually to ask the target populations concerned through consultation and deliberation whether the measure or conceptualization of the health

[11] This interpretation is not uncontroversial, see Frankel (1986) pp 2-3 [56], but the social construction remains.

benefit or state is biased – or whether there may some members of the target group for whom this might be the case.

Contexts, behaviours and circumstances
This category includes aspects of the context of technology use that could, at least in principle, disadvantage some people relative to others (e.g. traveling from a remote home to a clinic or hospital) and thereby render an intervention cost-effective for one group but not for another (e.g. [31]). Any of the following circumstances could affect the balance of negative and positive consequences: demographics (age, sex, ethnicity, socio-economic status (SES)), location of delivery of care (e.g. home or institution), language, religious beliefs, sexual orientation, or multiple deprivation.

Some effects occur in unanticipated ways. For example, it was found in Rich et al. (1976) that the reliability of self-administered dipslide measures of bacteriuria taken at home by girls without symptoms varied significantly with the age and socio-economic status of the children performing the tests compared with costlier supervised sampling of the same girls [57]. In such cases, the cost-effectiveness of an intervention that is in all other respects the same will be higher for the younger and/or lower SES children.

There is considerable evidence that differential behavioural responses to public health measures according to SES may actually contribute in an unintended way to inequity, especially when utilization of an intervention is lower among more disadvantaged and 'hard-to-reach' populations or by ethnic minorities [8]. It can be all-pervading, for which the term 'staircase effect' was coined by Tugwell et al. [58]. Unintended inequality-widening interventions have been termed 'intervention generated inequalities' [59]. These are widespread phenomena and have been found to exist, for example, in many preventive interventions [60, 61]. There is also, needless to say, abundant evidence that many interventions also generate greater health equality [58].

More generally, equity concerns may arise whenever a particular technology is cost-effective for some subgroups of clients but not others [38] whether for behavioural or other reasons, depending again on the social and economic characteristics of the subgroups.

Processes in HTA
Anticipated equity effects that require adaptation of the usual review processes of the agency need to be considered and addressed as early as possible in the HTA, including the scoping stage. Thus, all questions concerning rights of different groups to be consulted, represented or to participate in decision making processes should be considered not only in terms of the expertise, knowledge and understanding that they may bring to the process but also with regard to fairness. For example, if a manufacturer or a patient group may be affected for good or ill by the HTA process, it is likely that fairness would at least require their right to participate to be considered.

If the outcome measure of choice may not be valid for some patients, perhaps because some aspect of health benefit is not included among the dimensions of the measure, then the *procedure* should ensure that decision makers have access to patients and informal carers with experience of the condition and its treatment to enable the construct validity of the measure to be assessed and, if necessary, to enable appropriate adjustments. This approach was employed recently by the Medical Advisory Secretariat in Ontario during their scoping stage of an HTA, where they sought patient input on the research questions to ensure that they captured relevant patient outcomes in their evidentiary review [31].

Hidden opportunity costs

These are costs imposed on those affected by the intervention and anonymous people who are affected through consequential changes in the distribution of resources. The identity of the individuals who lose may not be known. The weight to be attached to any such opportunity cost might vary according to what is known about who are most likely to lose compared with those directly affected by the intervention. One group of stakeholders that is almost invariably omitted from the deliberative processes is the 'ordinary' or *potential* consumer of health care – that is, members of the public (as distinct from representatives of specific patient advocacy organisations). By definition, these are anonymous individuals whose stakeholder status arises from the fact that their taxes or premiums fund health care budgets, and if some of these budgets are spent on one intervention, those parts are not available for others including interventions for these ordinary and potential consumers. While this opportunity cost provides the underpinning argument for using a test incremental cost-effectiveness ratio (ICER) and is a conventional part of the efficiency element of an HTA, the possibility arises that there may also be equity considerations. For example, when the beneficiaries of a proposed new intervention are relatively privileged or underprivileged members of the community (or few in number) compared with the 'ordinary' consumer. Similarly, the 'ordinariness' of those who bear the opportunity costs of newly introduced interventions ought to be tested. Empirical ways in which this might be done are, however, very much at the research stage.[12]

Processes in the delivery of care

Processes in the delivery of care might have inequitable consequences even in the absence of institutional bias of the type already outlined. For example, the way in which care is delivered may be demeaning or unduly revealing, as when a patient enters an HIV or STD clinic having a sign publicly indicating its purpose. There may be processes at local delivery sites that deny opportunities for patients to reveal equity-related factors. For example, it is commonly charged that middle class clients

[12] The topic is being investigated by a group led by Karl Claxton and Mark Sculpher at York (UK) researching value-based pharmaceutical pricing.

of health care systems are more adept at managing their way through administrative processes and hence of receiving effective health care [62]. A flagrant breach of equity arises when health care providers select out patients deemed to be less financially advantageous to the organisation by virtue, for example, of the chronicity of the disease or their insurance status.

Special claims

There is a range of frequently heard specific equity claims that ought to be anticipated and appraised both in the scoping of an HTA and at subsequent stages. A position should be taken as to what categories of claims will be entertained. Commonly met claims include: claims of need, such as low initial health status; claims of responsibility, which may be positive if, say, the likely beneficiaries are deserving by virtue of their roles as, for example, parents, or negative if, say,the likely beneficiaries are deemed 'undeserving' by virtue of behaviour such as pursuing life styles hazardous to health; claims of history, such as past endurance of ill-health or previous receipt of the intervention; claims of desperation, as when the intervention in question represents a 'last chance' for a cure; claims of unfair innings, such as a short already-lived life-span [63]; claims related to non-health consequences (other effects on welfare) or on multiple deprivations; claims of willingness to pay such as a willingness to 'top-up' to compensate the provider for providing care that is less cost-effective than the third party payer's threshold requires.

Special claims and possible inequity may arise in connection with individuals who are not themselves patients. While it is commonplace in efficiency studies to recognize the importance of taking account of the impact of technologies on informal carers, carers too may have circumstances or characteristics that warrant special consideration on grounds of equity, especially if they have carried very heavy physical and emotional burdens while caring [64]. It is important not to be misled by spurious special claims from interest groups but it is equally important not to allow the strongest of special claims to go unappraised or to overlook the interests of those who are not organized or equipped to ensure that their claims are.

Cumulative effects

The consideration of cumulative past disadvantages or advantages that might be relevant in assessing benefit or cost or their distribution across affected parties would enable a broad view to be taken and help to ensure that the 'whole' was not taken uncritically to be merely the sum of the individual 'parts'. The accumulation might be across many equity categories, or over time, or both. The possibility ought to be considered that such accumulation strengthens any case for redress.

These categories are summarized in the following 'checklist', in which we have included 'prompts' to stimulate discussion and the assessment of the relevance of the category in question.

Table 1 about here

Conclusions

We have provided a framework for developing a checklist of equity considerations to complement the standard efficiency calculus of HTA. It is intended be used as part of the process through which advisory bodies are given their terms of reference; the scoping of the agenda prior to the selection of candidate interventions and their comparators for HTA; the accompanying background briefing for decision makers, including systematic and other reviews; and as a tool to help to structure the discussion and composition of professional and 'lay' advisory groups during the assessment process. Its effective development and implementation depends upon the creation of an on-going research program that identifies omissions and on HTA processes that provide, through appropriately detailed minuting and note-taking, accounts of decisions taken by decision making agencies that can be interpreted as precedents and analyzed retrospectively to promote consistency and to understand the reasons why apparently similar cases have been adjudicated differently on different occasions. Periodic reviews and updating guidance for decision makers are also recommended. In these ways, it may be hoped that equity will be more systematically and fully considered and implemented in both the procedures and decisions of HTA.

Table 1 A Checklist of Equity Considerations for Health Technology Assessment

Domain	Elaboration	Questions
1 Equity and equality	There can be fair inequalities and unfair equalities. Equity ought not to be equated with equality (of something) but, if it is, the ethical 'weight' to be attached to the 'something' needs consideration. 'Equality' and 'inequality' imply a degree of quantification (minimally an order of states of 'more' or 'less'). Check on empirical research for quantified measures of inequity. In the absence of good quality research, identify other sources such as 'expert opinion' but be alert to the possibility of 'expert prejudice'.	Equality (or inequality) of what? Common candidates include: need, deservingness or responsibility, capacity to benefit (or be harmed), degree of incapacity or current health state, history of past health or ill-health, prognosis with and without the technology; health outcome - quality of life; and dependents (care-giving responsibilities). Need to seek empirical and quantitative information about *how equal or unequal* the relevant factors are
2 Adequacy of the domains of equity	The focus of the analysis of equity. This could be on health care inputs, processes, direct outcomes, indirect outcomes, disease patterns, patient types, subgroups. The desired focus is likely to be context-dependent and may depend on the rulings of a higher tier authority.	Should the domain of equity relate to health care inputs, processes or outcomes? Might there be unintended consequences that raise equity issues? Should the domain of analysis be disease focused; or should some other basis for differentiating individuals and subgroups be used? What are the equity-related consequences of this categorization?
3 Legal obligations	Common offences include discrimination by age, gender, disability, ethnicity, race, nationality,	Have the relevant local legal obligations concerning age, gender, disability, ethnicity, race, nationality, language,

	language, sexual orientation, in the workplace, in education; there are also institutionalized discrimination, implicit and indirect discrimination.	sexual orientation, etc. been considered? Are there any legislative requirements concerning institutionalized, implicit or indirect discrimination, in the respective jurisdiction?
4 General principles	Minimal requirements for 'equity', axiomatic statements, applicability of such principles in current context	Have a set of guiding principles or axioms been established concerning what constitutes equality (or fair inequalities) in the current context? Is it possible to infer specific equitable guidance in the current context from the general guidance? Are their precedents that could guide in the present context?
5 Embedded inequity	Possible unfairness 'built in' to concepts (e.g. omitted dimensions of outcome or cost), framing effects in experimental approaches, possible unfairness inherent in the intervention (e.g. threat to autonomy).	Are there inequities in the measurement or methodological processes informing the HTA? For example, does the outcome measure omit significant dimensions and thereby differentially exclude key outcomes for some groups? Are the standard weights attached to gains and losses affecting different people (usually but not necessarily, unity) deemed suitable in the current context? Do the measures of inequity weight distance from the average in an acceptable way? Are there any aspects of the intervention, in addition to the direct effects, that may raise equity concerns?
Institutional bias	Inequity resulting from jurisdictional scope in clinical practices, provider institutions, workplaces, or in the distribution of consequences.	Do any of the following cause particular costs or benefits to be omitted or distorted: the agency's parent organization, the culture of the HTA agency itself, provider institutions, workplaces?
7 Implicit stereotyping	Definitions and concepts that exclude or prejudice individuals. Aspects of the effects of the intervention that have differential impact on individuals, or which	Is the measure or conceptualization of the health benefit or cost or state biased? Have assumptions about what 'matters' been tested by consulting those affected? Is the current

	make in untested assumptions about what does and does not 'matter', or are stigmatizing.	context one in which there are likely to be marked differences in culture between analysts and client groups that could give rise to implicit stereotyping? Are there people who might be affected but whose interests have not been taken into account?
8 Contexts and circumstances	Aspects of the context that could disadvantage some relative to others (e.g. geography, culture), tests for whether any of the following could affect the balance of advantage: Usual demographics (age, sex, ethnicity, SES), location of delivery (e.g. home or institution), language, education of clients, religious beliefs, sexual orientation, stigma, multiple deprivation. Aspects of the context that render the proposed methods of HTA inappropriate (e.g. methods used in a high-income country being applied in a low-income country, 'western' values being applied in an aboriginal or 'first nations' context).	Do any of the following circumstances affect the balance of negative and positive consequences: geography, demographics (age, sex, ethnicity, socio-economic status), location of delivery of care (e.g. home or institution), education, language, religion, sexual orientation, or multiple deprivation? Are methods developed in one culture being appropriately applied in another?
9 Processes in HTA	Process that deny suitable representation to people with a legitimate interest, processes that deny consideration of the interests of absentee stakeholders.	Has the scoping of the HTA caused a bias in the processes through which information germane to equity is gathered or considered? Is the current guidance devoid of any implicitly biasing elements, such as the exclusion of relevant consultation groups, in the current context? If not, can the matter be addressed and rectified? Are the appropriate health outcomes measures and stakeholders included in the HTA process (including patients and members of the public)?

10 Hidden opportunity costs	These refer to costs inflicted on those affected indirectly by the intervention and those anonymous people who are affected through consequential changes in the distribution of resources if the recommendations of the HTA were implemented. The identity of the individuals who lose may not be known. It may also be that the weight to be attached to any such opportunity cost might vary according to what is known about those most likely to be losers relative to those directly affected by the intervention.	Has due regard been had to the interests of the anonymous clients of the health care system from whom resources will be removed as a consequence of the implementation of the recommendation of the HTA? Do those most likely to be affected in this way have distinctive characteristics suggesting that differential weights ought to be attached to the impacts on them? Are there any empirical estimates of any such relevant effects?
11 Processes in delivery of care	Processes in the delivery of care that are prejudicial to, demeaning of or embarrassing for some who are affected. Some processes favour those adept at managing their way through complex or unfamiliar processes. Thus, other inequities for those lacking such social skills or that impose differential costs/burdens on some clients and stakeholders relative to others might not be known or even revealed.	Are there processes in the delivery of care, apart from those that are embedded in institutions, that discriminate unfairly? Are any of the likely delivery processes prejudicial to, demeaning of or embarrassing for some clients relative to others? Is there a 'middle class' bias that favours those with skills at dealing with receptionists, bureaucrats, professionals and other unfamiliar groups of people?
12 Special claims	Claims such as claims of need (e.g. low initial health status?), claims of responsibility (e.g. life styles hazardous to health), claims of history (e.g. past endurance of ill-health, past receipt of the intervention), claims of desperation (e.g. 'last chance'), claims of unfair innings (lived life-span), claims of non-health consequences (other welfare	What, if any, special claims ought to be considered? Are there claims or interests not being heard but deserving of voice? Are their claims that are not ethically significant? Can the claims that might carry weight bear empirical testing for their veracity and size? Are there precedents for dealing with claims of the sort in the current context? How do special claims compare to the putative claims of those not

	effects), claims of willingness to pay (e.g. top-ups).	represented in the HTA process?
13 Cumulative effects	Consideration of cumulative past disadvantages or advantages that might be relevant in assessing benefit or cost or their distribution across affected parties.	Has a holistic perspective been taken, or merely the sum of the individual 'parts'? Have historical disadvantages been considered? Are there any other respects in which the cumulative experience or the combination of experiences of those affected may be of equitable concern?

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PET: a Practical Equity Tool for health technology assessments

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Abstract

Equity refers broadly to fairness and provides an ethical underpinning for many of the top level resource allocation principles of health care system design. While equity is increasingly being considered by both theorists and practitioners, it remains largely under-developed in health technology assessment (HTA). We advance our previously developed framework on incorporating equity considerations into health technology assessments by suggesting the use of a table-top decision aid which we call PET: a Practical Equity Tool for HTA decision makers.

Equity refers, broadly speaking,to fairness, and provides the ethical underpinning for many of the top level resource allocation principles of health care system design. While equity in health and health care is increasingly being considered by both theorists and practitioners, it remains largely under-developed in health technology assessment (HTA). In two recent papers [1, 2] we developed a framework intended to help decision makers and their advisers to consider the implications for equity that the introduction (or withdrawal) of health care interventions, both clinical and non-clinical, might have. The idea was that systematic consideration of the various elements in the proposed framework might enable judgments that were hitherto based solely on budgetary and health or service outcome information, or even on sophisticated variations on the 'reference case' recommended by the Washington Panel [3], to be modified by explicitand systematic consideration of equity. In principle, the modification could cut both ways – interventions judged not to be cost-effective for a specific subgroup may nonetheless be recommended on grounds of their equity consequences, while interventions judged to be cost-effective might not be recommended on account of their adverse equity affects. Such bold steps, however, require a more secure footing than any currently recommended methods prescribe. To this effect, we present a table-top decision aid which we call PET: a Practical Equity Tool for HTA decision makers.

The detailed framework is not described here. Instead we present a summary of the arguments of the earlier two papers in the form of a short checklist suitable for encapsulation (lamination) as a table-top decision aid for HTA decision makers. The summary presented here should be seen as a prototype. It is likely that there are some aspects of equity which we have overlooked and which would need to be incorporated in specific other contexts. It is also virtually certain that in some contexts and jurisdictions one or more of the included categories will either prove irrelevant or need substantial amplification. These developments ought to be accompanied by adequate minutes and other records that explain the grounds for such decisions which may then become casuistical precedents for subsequent decisions as a 'cases' build up. We hope, nonetheless, that at a broad level of generality, the decision aid in its current form includes most aspects that are likely to arise. We expect that it will require least modification at the highest levels of decision-making, for example at the level at which a Ministry is instructing an agency as to the categories to be considered, or at which an agency is instructing its advisory committees. At lower levels, the tool would omit categories that were not deemed appropriate and it might contain more elaborate expensions of aspects deemed to be of particular ethical significance.

There are several ways in which the tool could be used. Possibilities include: help to manufacturers in anticipating some aspects of the equitable impact of their products, enabling them to provide agencies with information supplementary to their usual cost-

effectiveness material; inclusion as part of the process through which advisory bodies are given their terms of reference; the identification at an agency's scoping stage of a technology appraisal those aspects of equity that might lend themselves to empirical research (quantitative and qualitative) and that might be undertaken prior to any formulary-type decision; and where appropriate (as when equity issues of sufficient weight are identified to warrant detailed consideration) to help structure the discussion and composition of multi-disciplinary, multi-professional and 'lay' advisory groups during the appraisal process. How evidence, or opinion, about equity ought to be set against, or weighed up alongside, the effectiveness and cost-effectiveness evidence is a matter for deliberation between the decision makers and those whom they consult. Again, however, good records of such processes and their outcomes would help to generate a body of 'cases' and provide evidence about the nature of the trade-offs considered and the conclusions reached about them.

The most effective use of PETdecision aid will depend on the quality of the prior training of the participating stakeholders. Untrained and unprepared deliberators, skilled though some of them may be in other aspects of HTA, will be less effective than those for whom PET will prompt a recollection of more complete arguments and other applications of equity principles, and a like recall of facilitated simulations in training sessions. The items in the tool are therefore also prompts, which may help those who design training and guidance material.

PET: A practical equity tool for HTA decision makers

Guiding Questions:

1 **Are we concerned with fairness related to equality or to fair inequality?**
[*Equality (or inequality) of what? Need, deservingness, responsibility, capacity to benefit (or be harmed), degree of incapacity or current health state, history of past health or ill-health, prognosis with and without the intervention; health outcome -- quality of life; and dependents (care-giving responsibilities)? Do we need quantitative information on any aspect? If there is any inequality of treatment or outcome, for example, by giving some groups a priority status, is it an acceptable inequality? What is the case for it? Is there any evidence base?*]

2 **Have all possible and relevant aspects of equity been taken into account?**
[*Should the focus of equity relate to health care inputs or costs, to processes or to outcomes? Might there be unintended consequences of an intervention that raise equity issues? Should the focus be disease or should some other basis for differentiating individuals and subgroups be used? Have equity aspects of the likely ways in which the interventions will be delivered been addressed? Have the Board's (or equivalent) equity requirements been met? Is there any evidence base?*]

3 **Have legally required factors been addressed?**
[*Have the relevant local legal obligations concerning age, gender, disability, ethnicity, race, nationality, language, sexual orientation, etc. been considered? Are there any legislative requirements concerning institutionalized, implicit or indirect discrimination?*]

4 **Are there any general principles of equity that ought to be taken into account?**
[*Have a set of guiding principles or axioms been established concerning what constitutes equality (or fair inequalities)? If so are they applicable in the current context? Is it possible to derive specific ways of proceeding from the general guidance? Are there any precedents from earlier decisions that we could draw upon?*]

5 **Are there any inequities embedded in our methods of analysis?**
[*Are possible inequities built into our concepts (such as omitted dimensions of outcome or cost), have there been biasing framing effects in experimental data, is there possible unfairness inherent in the intervention (such as a threat to some individuals' autonomy)? Are the standard weights attached to gains and losses affecting different people (usually but not necessarily, unity) suitable in the current context? Do the empirical measures of inequity (if any) weight distance from the average in an acceptable way? Are there any indirect consequences of the intervention that may raise equity concerns?*]

6 **Is there any possibility of institutional bias?**
[*Do any of the following cause particular costs or benefits to be omitted or distorted: our parent organization, the culture of the manufacturers of the interventions, the culture of specific patient advocacy groups, the culture of the HTA experts and their institutions, provider institutions likely to deliver the intervention, workplaces*?]

side one

7 **Is there any possibility of implicit unfair stereotyping?**
[*Are we using definitions and concepts that inherently exclude or prejudice anyone? Do any aspects of the effects of the intervention have differential impact on individuals, or make untested assumptions about what does and does not 'matter', or stigmatize? Have assumptions about what 'matters' been tested by consulting those affected? Are there people who might be affected but whose interests have not been taken into account?*]

8 **Could the current context and circumstances lead to inequity?**
[*Do any of the following circumstances affect the distribution of negative and positive consequences: geography, demographics (age, sex, ethnicity, socio-economic status), location of delivery of care (such as home or institution), education, language, religion, sexual orientation, or multiple deprivation? Are measures developed for one culture being appropriately applied in another (such as methods used in a high-income country being applied in a low-income country, or 'western' values being applied in an aboriginal or 'first nations' context?*]

9 **Are our HTA processes fair?**
[*Has the scoping of the HTA caused a bias in the processes through which information about equity has been gathered or considered? Is our procedure devoid of implicitly biasing elements such as the exclusion of relevant consultation groups? Have the appropriate stakeholders been included in the HTA process (including patients and members of the public)? Is anyone likely to have felt excluded?*]

10 **Have hidden opportunity costs been neglected?**
[*Has due regard been given to the interests of the anonymous clients of the health care system who are not the direct beneficiaries of the technologies being considered but from whom resources will be diverted as a consequence of the implementation of the recommendation of this HTA? Do those most likely to be affected in this way have distinctive characteristics suggesting that differential weights ought to be attached to the impacts on them? Are there any empirical estimates of any such relevant effects?*]

11 **Are the processes of delivery of the technologies equitable?**
[*Are there processes in the delivery of care, apart from those embedded in institutions, that discriminate unfairly? Are any of the likely delivery processes prejudicial to, demeaning of or embarrassing for some clients relative to others? Is there a 'middle class' bias favouring those with skills at dealing with receptionists, bureaucrats, professionals and other unfamiliar groups?*]

12 **Are there any special claims that should be addressed?**
[*Are there interests such as people with needs that are not being heard? Do children, people near death require special consideration? Are their claims ethically significant? Can any claims that might carry weight bear empirical testing for veracity and size?*]

13 **Do cumulative effects matter?**
[*Has a holistic perspective been taken of people, or merely separate individual aspects? Have historical disadvantages been considered, especially multiple ones? Are there any other respects in which the cumulative experience or the combination of experiences of those affected may be of equitable concern?*]

Side two

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The NICE Cost Effectiveness Threshold – what it is and what that means.

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Abstract

NICE has been using a cost effectiveness threshold range between £20,000 and £30,000 for over 7 years. What the cost effectiveness threshold

represents and what the appropriate level is for NICE to use, and what the other factors are that NICE should consider, have all been the subject of much discussion. In this paper we briefly review these questions, provide a critical assessment of NICE's utilisation of the ICER threshold to inform its guidance and suggest ways in which NICE's utilisation of the ICER threshold could be developed to promote the efficient use of health service resources.

Section 1: Background

The National Institute for Health and Clinical Excellence (NICE) is charged with considering both the effectiveness and cost effectiveness of treatments and then with making recommendations as to their provision within the National Health Service (NHS). Cost Effectiveness Analysis (CEA) assesses two or more alternative courses of action in terms of their costs and benefits. The comparison is summarised using the expected Incremental Cost Effectiveness Ratio (ICER). This is a measure of the additional cost per additional unit of health gain produced by one intervention compared to another. NICE's preferred form of cost effectiveness analysis uses the Quality Adjusted Life Year (QALY) to describe the outcome of each intervention. By extension, the preferred form of ICER is the Cost per QALY gained. Within the NICE appraisal process, the ICER for each technology is compared to a threshold value; generally accepted as having an upper limit of £30,000; to establish whether the technology represents an efficient use of limited NHS resources.

The objective of this paper is to review the current state of knowledge regarding the cost effectiveness threshold, the principles of its use in health care resource allocation decisions and any arguments for and against changing the threshold from the current range of £20,000 to £30,000.

Section 2 summarises the current statements in the methods guide regarding the value and of use of the cost effectiveness threshold. Section 3 reviews the relevant literature on the use of the cost effectiveness threshold in resource allocation decision making. Section 4 draws key implications of using an ICER threshold to promote population health gain from the NHS budget. Section 5 considers the issue of whether the NICE threshold should change; and Section 6 attempts to summarise the key observations of the paper.

Section 2: What the current methods guide says

The current methods guide refers several times to the cost effectiveness threshold. In chapter 6, (p33), it states:

"The Appraisal Committee does not use a fixed ICER threshold above which a technology would automatically be defined as not cost effective or below which it would. Given the fixed budget of the NHS, the appropriate threshold is that of the opportunity cost of programmes displaced by new, more costly technologies. However, estimating this threshold would require complete information about the costs and QALYs from all competing healthcare programmes and the Committee does not have this information. Furthermore, the threshold will change over time as the budget for healthcare changes. Although the use of a threshold is inappropriate, comparisons of the most plausible ICER of a particular technology compared with other programmes that are currently funded are possible and are a legitimate reference for the Committee."**Error! Bookmark not defined.**

This statement acknowledges the importance of the considering the opportunity cost of implementing new treatments given a fixed threshold – whilst conversely suggesting that, since the data required to estimate the threshold quantitatively are not available, it is inappropriate to use a threshold. Our interpretation of this apparently contradictory statement is that it is use of a *particular* threshold that is to be avoided, hence NICE's emphasis on a range.

The Guide then goes on to consider a range of possible other factors to take into account, in cases of technologies with ICERs at the lower and upper boundary of the range:

"Below a most plausible ICER of £20,000/QALY, judgements about the acceptability of a technology as an effective use of NHS resources are based primarily on the cost-effectiveness estimate. Above a most plausible ICER of £20,000/QALY, judgements about the acceptability of the technology as an effective use of NHS resources are more likely to make more explicit reference to factors including:

- the degree of uncertainty surrounding the calculation of ICERs
- the innovative nature of the technology
- the particular features of the condition and population receiving the technology
- where appropriate, the wider societal costs and benefits." (p33)

This approach echoes ideas advanced by Akehurst in 2002 and seems to imply that NICE's 'effective threshold' is actually £20,000 per QALY. When cost effectiveness ratios for a treatment exceed this the Appraisal Committee considers (a) whether the characteristics of the condition or population receiving the treatment would lead them to value the health gain produced by the intervention more highly than the estimate made in the analysis; (b) whether innovative characteristics of the intervention are such as to require explicit consideration of the Secretary of State's instruction to give due weight to innovativeness, despite the excess opportunity cost from a purely efficiency perspective; and (c) whether other benefits to society, outside of those considered by the cost effectiveness analysis, are such that it is 'socially desirable' for the treatment to be made available.

The proposed role of uncertainty in decision making is unclear. The text may mean that when the ICER exceeds the lower bound of the threshold range, the committee will seek greater levels of certainty to support a positive recommendation. However, the text is also consistent with Akehurst's proposal that when there is great uncertainty about an ICER in excess of the threshold value, it is appropriate to the estimate as not significantly different from the threshold value.

Use of additional criteria such as these is not inconsistent with the operation of an explicit, single threshold value, nor is it inconsistent with much of the literature on social preferences over health care resource allocation. However, as we discuss below, there are substantive issues concerning the ways in which such additional considerations should be operationalised.

Section 3: Setting the cost effectiveness threshold

There is significant argument about how the cost effectiveness threshold should be determined. Three broad approaches have been proposed: (i) it should be inferred from previous decisions; (ii) it should be set so as to determine the optimal health care budget and (iii) it should be set so as to exhaust an exogenously determined budget.

Inferring the threshold from previous decisions

Rawlins and Culyer, and Devlin and Parkin made two attempts to infer NICE's cost effectiveness threshold from reviews of previous decisions. The former was an essentially qualitative analysis whilst the latter treated NICE decisions as discrete choice experiments.

Rawlins and Culyer identified an increasing likelihood of rejection as the ICER increased beyond £15,000; with few interventions being approved with an ICER > £30,000. Devlin and Parkin in contrast estimated the threshold to be 'somewhat higher than the £20,000 - £30,000 which NICE has publicly identified.' (p450)

There are several problems with basing the current threshold on previous decisions. First, it is not necessarily desirable for current decisions to use the same decision rule as for previous ones; consistency of decision rule (the cost effectiveness threshold) can conflict with consistency of objective (maximising expected health gain). We discuss in more detail why the threshold might change over time in Section 4. Second, this approach requires that that previous decisions either took no account of any 'other' considerations or that any such consideration was judged not sufficient to have an impact on the decision, otherwise the linking of particular ICERs to a particular threshold value will have (largely unknowable) biases.

Settting the threshold to determine the optimal health care budget.

Some have suggested that that the appropriate process is to identify the marginal value that society attaches to health. NICE itself has promoted two research projects to examine what value people in the United Kingdom attach to an additional QALY. If the cost effectiveness threshold were set by such an empirically revealed monetary value the implication is that interventions having an ICER below that value should be approved. The health care budget would then be whatever sum was required to implement the purchases. Setting the threshold would thus effectively determine the NHS's budget. The budget would be demonstrably consistent with the value that 'society' attached to health and the state would be committed to increase the budget so long as the ICERs for new interventions fell below the threshold.

Three approaches have been suggested for quantifying the marginal value of health: discovering the willingness to pay for health gain of a representative sample of society; using the value of life/health employed in other areas of public sector resource allocation;**Error! Bookmark not defined.** and setting it equal to Gross Domestic Product per capita.

If there were a direct link between society's willingness to pay for health gain and the budget of the health care system, setting the threshold with reference to it would seem appropriate. However, in the UK, as in many other countries, the budget of the health care system is determined in large part by parliament and is done (doubtless imperfectly) by broad assessments of the marginal value of extensions of a wide variety of public programmes and of the value of purchasing power left in the pockets of consumers. The budget allocated to health care by parliament therefore already contains an implicit value of marginal health gain - relative to alternative uses of public funds It is difficult to see how experimental methods for revealing the social value of a QALY could capture these opportunity costs more effectively (or more legitimately) than Parliament. To substitute the 'direct democracy' of public opinion for a parliamentary process plainly also raises constitutional issues well beyond the scope of this paper.

The health care system is not the only area of public policy concerned with promoting health. For example, transport investment decisions typically take account of the expected impact on injury and death rates when appraising road building schemes. It is therefore intuitively appealing that the value of health ought to be consistent across public sector activities. Loomes has suggested that the ICER threshold should be set at a level consistent with the value attached to a life in other parts of the public sector. Whilst health and life are the primary (although not sole) objectives of the National Health Service, they are not the primary objectives of other public sector activities. The budgets allocated to these different activities by parliament imply a relative valuation of these objectives as well as the impact on health and length of life. It would be a major task to isolate the 'health component' in these other activities. Currently, only transport uses an explicit value and, as one of us has previously observed, 'NICE simply does not have (and nor is it mandated to acquire) the kind of information about outputs in non-health sectors that it would need to form necessary judgements about the marginal costs and benefits of health spending versus spending in other areas of public services'. (p11) Thus, although it may be intuitively appealing, it is not feasible for the threshold to be set (by NICE) by reference to other public sector activities.

Williams suggested that a 'common sense' value for the threshold would be per capita Gross Domestic Product. At the time of lecture this was somewhat lower than the bottom of the threshold range used by NICE. The appeal of this proposal is that if every member of society were to be given a 'fair share' of nation's wealth, they would receive the per capita GDP. The maximum they could therefore spend on health gain in any one year would be the per Capita GDP. Three significant problems present themselves. First the approach implies that the society might be willing to devote all its wealth to health care, which is manifestly not the case. Second the same thought experiment will yield the same 'maximum' for *any* good or service in GDP and so provides no basis whatever for choosing between any of them. Third, the *average* cost effectiveness of health care can be at or below per capita GDP with the cost effectiveness of *marginal* programmes being markedly higher thanks to

diminishing marginal returns. NICE has to establish whether a new intervention is more cost effective than the marginal interventions that would have to be displaced in order to pay for it from a constant budget. Use of an arbitrary average risks rejecting interventions that were more cost effective than ones already provided.

Setting the threshold to exhaust a budget optimally

From the beginning, NICE's use of cost effectiveness analysis has been perceived as a means of promoting the efficient use of available NHS resources. The cost effectiveness threshold ought thus to be the cost per QALY of the least efficient funded treatment (i.e. the intervention with the highest cost per QALY). For a new intervention to add to health it must be more efficient per unit of resource than the least efficient currently funded interventions and ought to displace it in whole or part so that the marginal productivity of each intervention in terms of health was everywhere equalized. Here too, however is another evident informational challenge. If identifying the marginal interventions for disinvestment is too difficult the threshold requires an alternative justification. Here we need to tread with care. On the one hand there is an issue of principle – what the threshold ought to represent - a value judgement; – and, on the other, an empirical question - the value it should take in any specific context.

Figures 2a and b, reproduced from Culyer et al, illustrate the situation in which some interventions not provided by the NHS are more efficient than some interventions that are. If the function of NICE is to substitute more efficient interventions for less efficient ones, it can do this through specifying a 'working' cost effectiveness threshold, reflecting the Institute's estimate of the ICER of the least cost effective activity undertaken by the NHS. This working estimate is drawn from (a) the incomplete evidence base on the cost effectiveness of interventions that the NHS does provide; and (b) stakeholders' personal and professional knowledge of the likely value of

funded interventions for which formal evaluations are not available. Over time this 'working' ICER can be adjusted in a casuistical fashion reflecting developments in the published evidence base and evidence on the efficiency of disinvestments made to fund the recommended interventions, changes in the health care budget and in judgments about the efficiency of health care production.

Although the 'threshold-searcher' model describes how resource allocation processes can utilise ICERs for health care resource allocation decisions at the margin, the authors did not address the frequently cited criticisms of Birch and Gafni, who have repeatedly argued that decision makers cannot maximize health gain from limited resources by using ICERs in isolation from information on budget impact. To do so, they say, is a recipe for 'continued expansion of expenditure. Their argument is that the opportunity cost of a positive decision is determined by the total budgetary impact, not the incremental cost effectiveness ratio. It is possible for the total budget for an existing health intervention to be less than that for the new intervention even though the new intervention has a lower ICER. If the new intervention is mandated on the basis of the ICER alone, then extra funds would need to be found.

<u>The cost effectiveness threshold and the budget impact</u>

The threshold searcher model can be used to explore the relationship between budget impact and the cost effectiveness threshold. The threshold is the inverse of the marginal health gain per unit of expenditure of the least efficient intervention in current use. In Figure 2, the substitution of a more for a less efficient intervention causes the marginal health gain of the least efficient intervention to rise. As a result, the threshold for future decisions decreases. The next candidate intervention will need to be even more efficient in order to justify its inclusion as a funded intervention. This is the case even if the budget impact of the substitution is neutral, i.e. when the budget impact of the new intervention is identical to the budget impact of the displaced

intervention. Thus, the cost effectiveness threshold is, as a matter of logic, endogenous once one allows for dynamic interactions even though, in an overall sense, it is constrained by the budget determined by Parliament.

To the extent that the total cost of the new intervention is greater than that of the procedure it replaces, a positive recommendation requires more disinvestment until the budgetary impact of successive substitutions is neutral and the budget constraint holds. This means that the cost effectiveness threshold for an intervention with a large budgetary impact should be lower than that for an intervention with a small impact. In this way, allocation processes based on a cost effectiveness threshold can fully capture the opportunity cost of both positive and negative investment recommendations.

The rate of change of productivity also matters. Thus, when productivity is rising through the use of relatively efficient technologies, the substitution of generics for branded products, and so on, the health production function is displaced upwards. As the budget increases, the cost effectiveness threshold should also increase, i.e. less efficient interventions should be incorporated into the portfolio of treatments provided by the NHS provided that the productivity of existing health care activities grows at a slower rate than the budget. In times of rapid expansion of the NHS budget, such as have been seen over the past seven years, the countervailing effects of the implementation of new treatments and increases in the budget may have made the adoption of a cost effectiveness range a (fortuitously) appropriate approach. Conversely, when budgetary growth is less than the net budget impact of investment and disinvestment decisions, the cost effectiveness threshold should fall to reflect the increased efficiency of the marginal intervention. These relative rates of growth of the budget and productivity of health care also have implications, which do not concern us here, for discounting.

Summary

The budget of the National Health Service is set by Parliament. NICE is charged 'to appraise the clinical benefits and costs of such health care interventions as may be notified by the secretary of state or the National Assembly for Wales….and to reach a judgement as to whether, on balance, this intervention can be recommended as a cost effective use of NHS and PSS resources.' It is clear that NICE is not mandated to determine the budget of the NHS and, since setting a threshold independently of the budget is logically equivalent to determining the budget, NICE cannot be mandated to do that either. The appropriate approach to NICE's cost effectiveness threshold is therefore to see it as an equilibrating variable that promotes the efficient (health maximising) use of a fixed budget.

Section 4: Implications of setting the ICER threshold to exhaust a fixed budget optimally

The ICER Threshold and Innovation

Figure 3 shows the total health gain to the NHS population under three scenarios. Consider an intervention costing £20,000 per patient. At this price the ICER is below the cost effectiveness threshold and the net health benefit of the intervention is one QALY per person. At a price of £40,000, the ICER is exactly equal to the threshold and at this point the net benefit from the new intervention is zero: the loss of health from displaced technologies being the same as the gain.

However, if the new treatment is more effective than existing treatments, then setting price at a level that produces an ICER equal to the cost effectiveness threshold implies that the full value of the innovation (greater efficacy) is captured by the manufacturer. As the manufacturers are typically profit maximisers they will seek to price as close to this point as possible. Strictly, what is happening is that the cost-effectiveness information is information not previously available to manufacturers about the maximum willingness to pay

of the demanders and makes the task of perfect price discrimination, or the use of an ‘all-or-nothing’ demand curve more readily achievable by producers.

While it is appropriate for manufacturers to appropriate a share of the value of innovations it would be unwise to create a system under which they extract it all. The public sector subsidises research and development in a number of ways, through publicly funded research, tax incentives and research infrastructure investment. Therefore, even if society were unconcerned about who benefits from innovation (NHS patients or the pharmaceutical industry) it would not be efficient to allow full appropriation of the value of innovation by the manufacturer. However, society is most certainly concerned about this distribution and it is reasonable that at least some of the benefits of innovation should accrue to NHS patients. In pharmaceuticals, as in other industries where innovation is protected, society currently permits monopoly rents during patent protection but does not allow full appropriation by, for example, facilitating perfect price discrimination.

Such concerns as this are somewhat tangential to those of the Institute. Of direct relevance for NICE, however, is the use of innovation as an argument for recommending interventions having ICERs above the threshold. When the ICER is close to, or at the threshold value, the full value of the innovation is already being paid to the manufacturer. To recommend an intervention when the ICER is above the threshold is to pay more for the innovation than it is worth (in terms of the population’s health). Promoting population health is consistent only with recommending treatments with ICERs that are below the threshold. It seems inappropriate for NICE to seek to honour its obligations to promote innovation through such a subsidy and at possible cost to NHS patients. NICE’s contribution to innovation is more likely to be realised effectively through clarity and consistency in the criteria that it uses to make its recommendations. The ultimate benefit is to bring the desire of the NHS to use interventions that are no more costly than they need be into the research plans of manufacturers so that the market is not disrupted by unforeseen changes in requirements and innovation is of the sort that maximises and properly rewards industry’s contribution to the nation’s health.

The ICER Threshold and Equity arguments

The threshold represents the opportunity cost of the implementation i.e. the health gain forgone by other patients. While the threshold is critical to the determination of the most efficient i.e. health maximising use of NHS resources, the Appraisal Committee also considers whether there is any ground in equity for weighting the health gains and losses of different people differentially or for recommending technologies with relatively high ICERs on grounds of their beneficial impact on equity.**Error! Bookmark not defined.**

While efficiency, in the sense of health maximisation, is a major concern of NICE's Appraisal Committee, it is not the only one, nor, indeed, is it possible to identify efficiency without making assumptions about the relative value of additional QALYs to different people. Interpersonal comparisons are therefore inherent in the process of establishing efficiency. An important further consideration relates to the wider opportunity cost of Appraisal Committee decisions. When the threshold is being used to allocate a fixed budget, there is not just one category of patient interest (those patients who would receive the new treatment or some alternative) but two: in addition there are the patients who bear the opportunity cost of its provision, i.e. those whose service availability is reduced by virtue of the expenditure on the new treatment.

We have already observed that NICE does not know, and probably cannot know, which patients bear the opportunity cost of its appraisal guidance. If NICE recommends an intervention on equity grounds, it necessarily has to make assumptions about the characteristics of those patients who bear the opportunity cost. Specifically, in making a positive recommendation, it must assume that the health gain forgone of those who bear the opportunity cost is valued less than that of those who receive the benefit.

Procedural justice would seem to require that the character of the claims of the anonymous bearers of the opportunity cost be properly considered in

NICE appraisals. In particular, when claims are made by advocacy and other groups about the special nature, need, etc. of the people they represent, NICE appraisal must do their best to assess the extent to which these claims carry greater weight than the claims that could be made by those bearing the opportunity cost. Given the typical pattern of NHS expenditure, the typical bearer of the opportunity cost is, for example, likely to be elderly and in the last year of life. It does not therefore appear intuitively plausible to suppose that the weight to be attached to beneficiaries' health gains must necessarily be higher than that attached to the anonymous losers. Plainly this is an area in which information is poor and broad generalisations will for some while have to substitute for more specific identification of the characteristics of 'typical' displaced health gain. The matter is ripe for research.

Monitoring and recommending disinvestment

The current methods guide avoids defining an explicit threshold on the grounds that the correct figure cannot be known. However, both the previously suggested casuistry (building up of specific cases) and the threshold searching model imply that it may be reasonable for NICE to utilise explicit thresholds which might converge over time on a 'best estinate'. A crucial part of this search process would be the identification of activities for disinvestment or, when there is budgetary growth, to identify other planned investments that ought to be abandoned in order to fund NICE recommendations.

There has been little research either on selecting or implementing disinvestments in the NHS. NICE has commissioned research from Brunel and City Universities which has yet to be reported. Should it turn out that actual disinvestments have tended to be more cost effective than the NICE recommended interventions, there would be prima facie evidence for supposing either that the current threshold is too high or that NHS trusts and commissioners were making poor decisions at their levels. Discovering which the case was would plainly be an important piece of work. However, it will not be easy to discover. Local commissioners' choices will be determined by

several factors including their total budgets, cost structures, the case mixes of the populations they serve and even the ease of implementation. As these factors vary across PCTs, the threshold is also likely to vary by PCT, so whether NICE appraisal guidance has a positive or negative impact on the efficiency of local health care will also vary by PCT.

Martin and colleagues examined the actual changes in programme budgets and health across Primary Care Trusts (PCTs) and estimated the average budget elasticity of health, that is, the proportionate changes in health resulting from marginal changes to programme budgets. They provide empirical estimates of the cost effectiveness threshold expressed as life years gained. They report a range from £7,397 for respiratory problems to £26,453 for diabetes. The threshold estimates for cancer and circulation problems were £13, 931 and £8,426 respectively. These figures need to be interpreted with some care as they take no account of the many interventions that impact upon quality of life rather than survival. This said, the results are consistent with a central estimate across all programme budgets around the lower limit of the current range.

The variation in thresholds between programme budgets has implications for NICE. It implies that the opportunity cost of a NICE recommendation also varies depending upon where it falls, so it may be efficient or inefficient dependent on local circumstance. The risk of NICE Guidance being inefficient will depend *inter alia* on (i) the degree to which national resource allocation captures geographical variation in health needs; (ii) the degree to which local resource allocation processes reflect variations in health needs between patient groups; and (iii) whether the technology appraisal programme is focussed on those areas with the greatest potential for increasing the efficiency of NHS activity. Local commissioners will almost certainly need guidance on how best to identify and then manage disinvestments and postponement of planned investments following NICE recommendations. It seems obvious that the criteria they use ought not to conflict with those used by NICE (though doubtless supplemented by further criteria).

Culyer et al. suggested that NICE should actively make both disinvestment and investment recommendations. The Institute has started to explore this possibility. External organisations have also started to recommend that the NHS, via NICE or other routes, should disinvest from activities not having a robust evidence base.[13] Most recently the House of Commons Select Committee recommended that NICE should appraise potential candidates for disinvestment; commenting that it was unacceptable that the Institute had ignored the Committee's earlier recommendation to this effect. Unfortunately, the catalogue of procedures for which the evidence base is poor or absent is very long and, where there is advantage to be had from disinvestment, it is unlikely to be the case that the scale of disinvestment required entails the entire elimination of a procedure. So the task of specifying disinvestment guidance is by no means an easy one.

The use of a cost effectiveness threshold is, at its core, about matching investment and disinvestment to increase the total health produce by the health service. To date, NICE has focussed its efforts on investment. Knowing what in fact is disinvested from can provide some insight into whether, on average, NICE Appraisal Guidance is improving the efficiency of the NHS. In the future, a programme of disinvestment guidance, to balance the investment guidance might give the public and the NHS greater confidence that the net benefit of the NICE Appraisal Programme was positive.

Section 5: The changing threshold ICER

The Chair of NICE recently observed that the current threshold range has been utilised for seven years and noted that the Methods Review Process would need to consider whether the range should change or remain the same.

[13] Association of Directors of Public Health. http://www.adph.org.uk/jan07.pdf (accessed 22nd August 2007).

Empirical estimate of the threshold

The House of Commons Health Committee thought that the choice of threshold was 'of serious concern'. The grounds for this concern were that "it is not based on empirical research and is not directly related to the NHS budget. It seems to be higher than the threshold used by PCTs for treatments not assessed by NICE." (p68)

The Institute's response to the Health Committee's comments identified 17 technology appraisals that had produced costs savings and stressed that most of the recommendations from the clinical guidelines programme – if implemented – would save the NHS money. It went on to highlight the range of knowledge promotion activities it is pursuing to promote efficiency in clinical practice and commissioning. Whilst these are important and valuable activities, it would seem appropriate, given the mandatory nature of Guidance from the Technology Appraisal Programme, that the value of the threshold gives the NHS and the people it serves, confidence that the opportunity cost of the programme is less than the value of the health gain it produces.

Budget impact and the threshold ICER

A disadvantage of using a moving/converging threshold, or one that was subject to periodic adjustment, is that it would evidently introduce an additional uncertainty and provide a less secure environment for industrial innovation. Whether this additional source of uncertainty would be significant, given all the other major uncertainties facing industry, such as the high failure rates in phase 3 drug development, is unclear. Current pricing arrangements allow companies to amortize the cost of these failures through the price of future successes, so the system may even encourage unnecessarily high risk investments. Changes in the threshold could be used to signal to the pharmaceutical industry and others, the changes in the efficiency in the NHS that the Institute was established to promote, and allow the industry to incorporate these changes into its investment appraisal processes. This in turn would reduce the risk of treatments coming to market which did not

deliver sufficient additional health gain to justify the price consistent with an acceptable return on investment. What would also help would be the wide promulgation of the principles upon which changes in the threshold would be made, thus enabling future changes to be anticipated.

Should the threshold ICER change?

The empirical evidence of Martin et al. indicated that even the lower end of the current cost effectiveness range may be too high and likely to lead to less efficient treatments being implemented at the cost of more efficient ones. The Select Committee report observes that the current threshold is higher than the ICER used by PCTs in their commissioning processes. Thus, there is a prima facie case for considering reducing the threshold. However, it maybe premature to substantially change the threshold on the basis of the current narrow range of studies.

The efficiency of NICE Guidance may be promoted without changing the threshold. The current methods guide indicates that £20,000 is the threshold at which other criteria than the ICER come into play. A substantial proportion of the treatments approved by NICE have been in this range. Modifying the utilisation of these 'other factors' in line with the arguments we have set out, would have the effect of strengthening the lower bound of the current range as the effective threshold and thus promote the efficiency of future NICE Guidance.

Section 6: Summary

The incremental cost effectiveness threshold, as used by NICE, is a means for promoting the optimum allocation of a fixed budget. It is not necessarily an expression of society's willingness to pay for health. Using the threshold searcher model described by Culyer et al to explore the implications of this, we conclude that:

(a) it is feasible and probably desirable to operate an explicit single threshold rather than the current range;

(b) the threshold should be seen as a threshold at which 'other' criteria are taken into account beyond the ICER itself

(b) interventions with a large budgetary impact may need to be subject to a lower threshold as they are likely to displace more than the marginal activities;

(c) reimbursement at the threshold transfers the full value of an innovation to the manufacturer. Positive decisions above the threshold on the grounds of innovation reduce population health;

(d) the value of the threshold should be reconsidered regularly to ensure that it captures the impact of changes in efficiency and budget over time;

(e) the use of equity weights to sustain a positive recommendation when the ICER is above the threshold requires knowledge of the equity characteristics of those patients who bear the opportunity cost. Given the barriers to obtaining this knowledge, and knowledge about the characteristics of typical beneficiaries of NHS care, caution is warranted before accepting claims from special pleaders.

(f) uncertainty in the evidence base should not be used to justify a positive recommendation when the ICER is above the threshold;

(f) the development of a programme of disinvestment guidance would enable the Institute and the NHS to be more confident that the net health benefit of the Technology Appraisal Programme was positive.

Figure 1: Relationship between cost effectiveness and probability of rejection (Rawlins and Culyer)

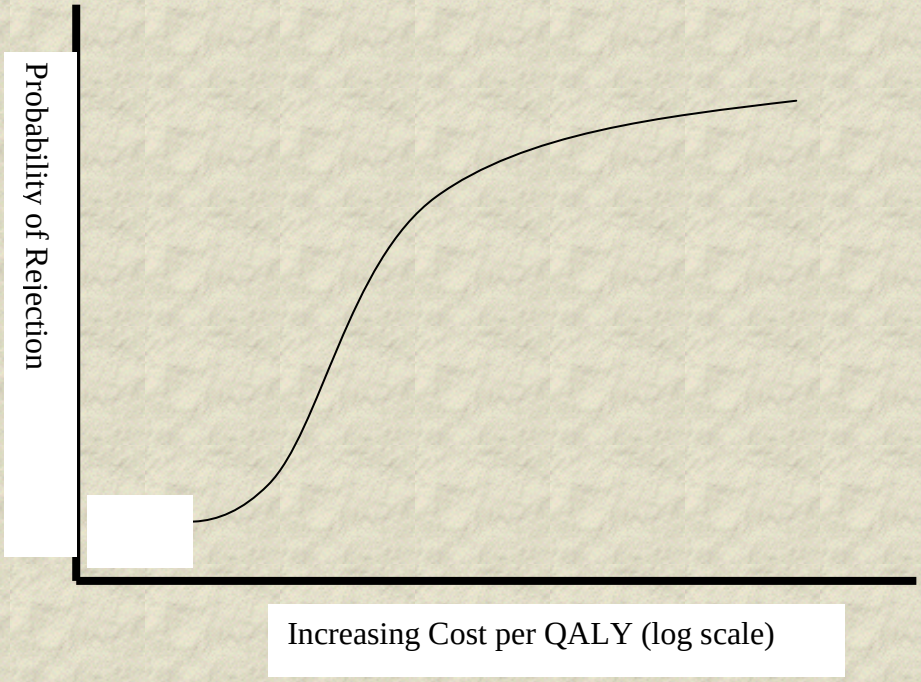


Figure 2: NICE as a Threshold Searcher

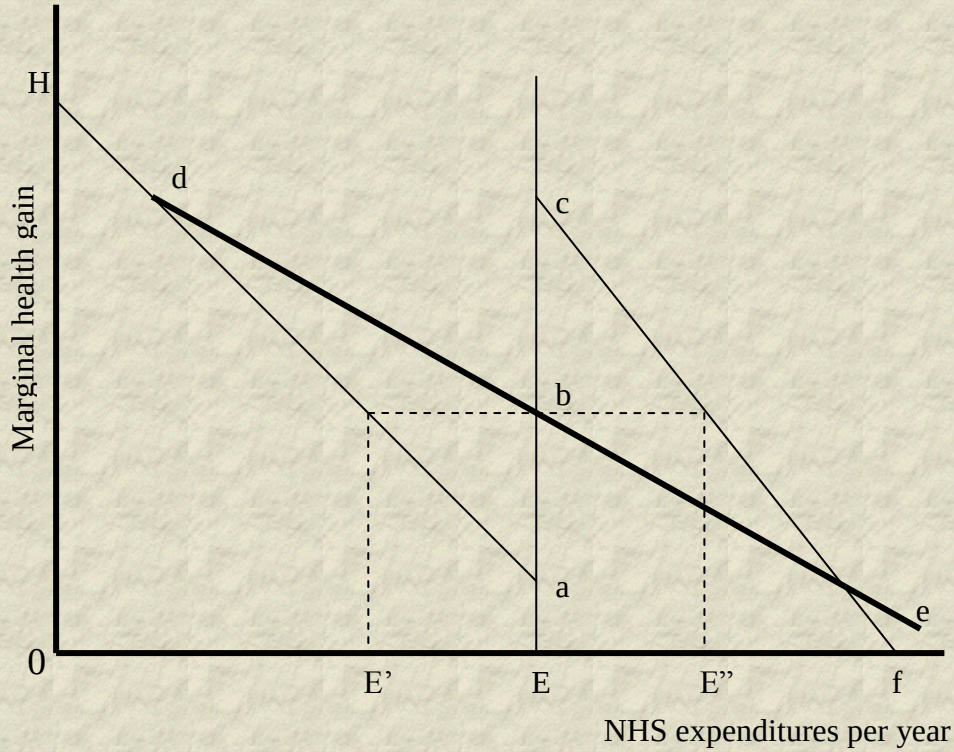
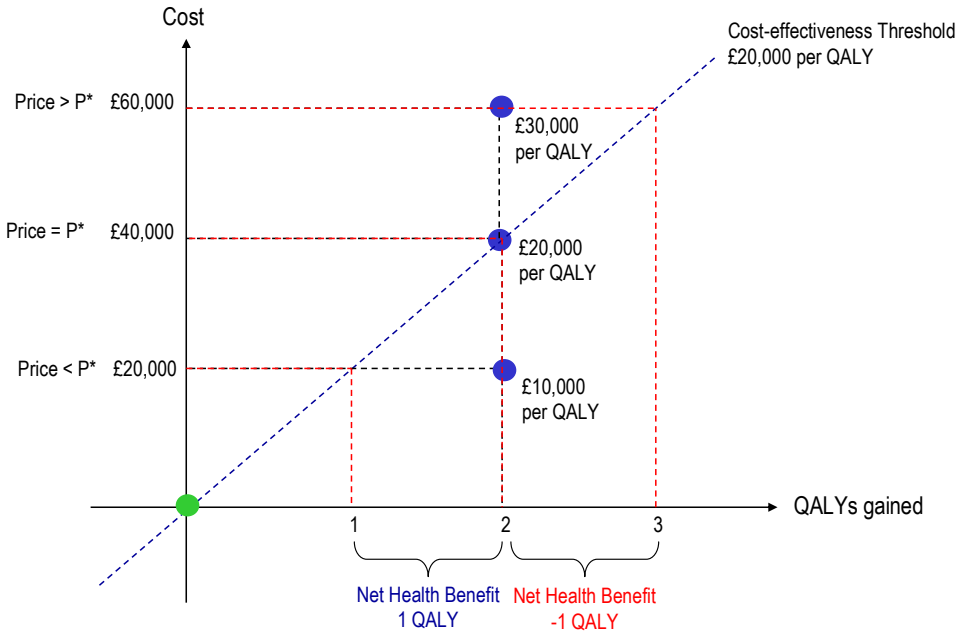


Figure 3: Threshold and Health Gain



Searching for a threshold, not setting one: the role of the National Institute for Health and Clinical Excellence

Anthony Culyer, Christopher McCabe, Andrew Briggs, Karl Claxton, Martin Buxton, Ron Akehurst, Mark Sculpher, John Brazier

Introduction

The quality-adjusted life-year (QALY) is the outcome measure of choice in England and Wales for the National Institute for Health and Clinical Excellence (NICE).1 There has been much speculation about whether NICE has a 'threshold' figure for the cost of an additional QALY above which a technology will not be recommended for use in the National Health Service (NHS), and there has been some suggestion that NICE is dissembling in its denials that such a threshold exists.2 Retrospective analysis of appraisal determinations in its first year of operation suggested that positive recommendations were in general associated with a cost per QALY of £30,000 or less; higher cost per QALY figures would receive approval only if there were special factors accepted as relevant and not covered by the formal modelling.3

Attempts to infer what any such threshold might be, based on published appraisal decisions, have identified a general concentration of estimates in the region of £20,000–£30,000 in one study2 and a suggestion that the threshold might be considerably higher than £30,000 in another.3 In April 2004, NICE confirmed that interventions with a cost per QALY below £20,000 were likely to be recommended, while the acceptability of therapies between £20,000 and £30,000 per QALY is more likely to depend upon other factors, such as the innovative nature of the therapy.1 Prior to this, the only published specific threshold came from the Department of Health4 in which a threshold of £36,000 was set, specific to a risk sharing agreement with the pharmaceutical industry over the provision of disease-modifying drugs for people living with multiple sclerosis. There are good reasons why it is improper for NICE to apply a specific threshold. NICE's proper function is as a 'threshold-searcher', seeking to identify the optimal threshold that lies somewhere between the least cost-effective technology currently provided and the most cost-effective technology not yet available routinely in the NHS. It is not constitutionally proper for NICE to determine the threshold.

NICE's function in relation to appraisals is to appraise the clinical benefits and the costs of such health care interventions as may be notified by the Secretary of State or the National Assembly for Wales and to reach a judgement on whether on balance this intervention can be recommended as a cost-effective use of NHS and PSS resources.5

The logical implications of NICE's mandate can be made clear in the following way. Consider a rank ordering of all the technologies available to the NHS

and the most efficient ways of spending NHS funding, as shown in Figure 1. Those that have the largest possible impact on health per pound spent are plotted on the left with each addition to health gain falling as people with the best chances of being helped have already been
helped. The downward slope continues until the point E is reached, at which the available NHS budget has been used up. The height of the line at this point (Ea) shows the marginal health gain (mhg) from additional expenditure, given the current budget. Its inverse shows the marginal cost-effectiveness of NHS expenditure, or the threshold incremental cost-effectiveness ratio. The total health gain produced by this expenditure is the entire area under the curve. It is the greatest gain in health achievable, given the range of technologies available and the current NHS budget. It requires that this budget is effectively spent by the NHS so that none of the technologies with an mhg less than Ea is used. If the objective is indeed to maximize the impact of health services on health, then we can approach the defining characteristic of this objective in either one of two ways. We can either speak of a budget that is to be efficiently spent, which entails using all the technologies embodied in the figure up to 0E, which implies the threshold mhg of Ea; or we can speak of a threshold QALY gain per unit of expenditure – Ea, which entails
using all technologies whose mhg is higher than Ea, which will (just) require a budget of 0E. The two are equivalent: we may either spend the budget to maximize health (which implies the threshold), or purchase all technologies up to the threshold (which implies the budget). Both produce the same outcome.

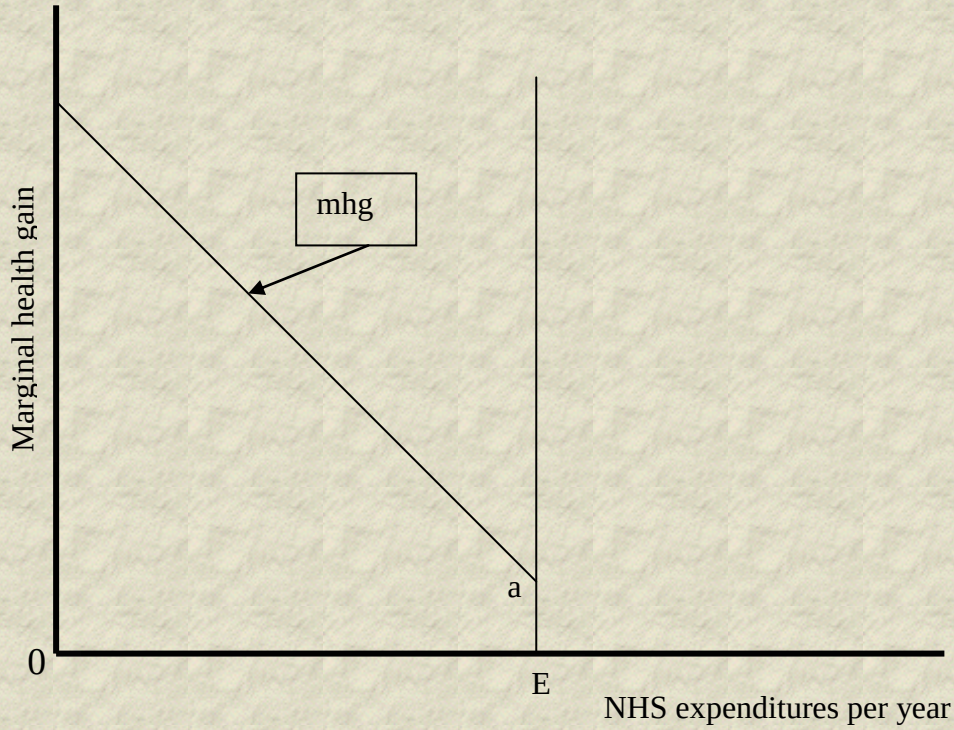


Figure 1 Marginal health gain

Determining the budget is Parliament's business. NICE is neither mandated nor qualified to make judgments about the relative value of public money spent on health care versus education, defence, environment, etc. and, of course, private consumption. But, since determining the threshold is logically equivalent to determining the budget (given the available technologies embodied in the curve), NICE cannot be qualified to pronounce on that either. Therefore, information about how much an individual or society values improvements in health (i.e. their willingness to pay for a QALY) is not at all relevant to the NICE remit. These values could only be used as the appropriate threshold by NICE if it were also given responsibility to set the NHS budget. NICE as a threshold-searcher The information demands of optimizing NHS expenditure are manifestly huge. NICE has incomplete and uncertain information on the mhg function in Figure 1 and, therefore, does not know the value of the
threshold. The threshold is neither taken by NICE (from government) nor made by NICE. NICE is neither a threshold-taker nor a threshold-maker. NICE is, in effect, a threshold-searcher, where the threshold is logically implied by the combination of the technologies that are available and the budget, but is not readily visible.

Figure 1 assumes the NHS is able to allocate its budget on programmes in order of their health gain per pound spent. Figure 2 explores the more realistic analytical problem for NICE when the current budget is not allocated in this efficient manner. In Figure 2, the range of technologies in 0E embodies those in the NHS. Let us assume that all are positive and that the least productive one has, as before, an mhg of Ea. However, we now assume that there are many technologies that are not currently provided within the NHS. These technologies are ranked in a separate
downward-sloping function to the right of E labelled cf. A composite mhg curve is the horizontal sum of the two lines, Hde, which combines all available technologies: those in use as well as those that could be used but are not, and again orders them by contribution to health gain. It is immediately apparent that NICE confronts three potentially interesting mhgs, the size of none of which it can be sure of. Ea is the actual mhg implied by current use in the NHS. It is what the current 'threshold' would appear to be if a comprehensive assessment were to be made of the ways in which NHS resources are used. Ec is the health gain to be achieved from adopting the best technology not currently in use. Eb is the threshold above which technologies ought to be adopted and below which they ought not. The incorporation of any technology not in current
use with an mhg above Eb would represent an increase in health gain as long as it displaces a technology with a lower mgh (in the range E0E). The optimal solution is plainly to cease using all those technologies in the range E0E on Ha and substitute for them all those in the range
EE00 (¼E0E) on cf.

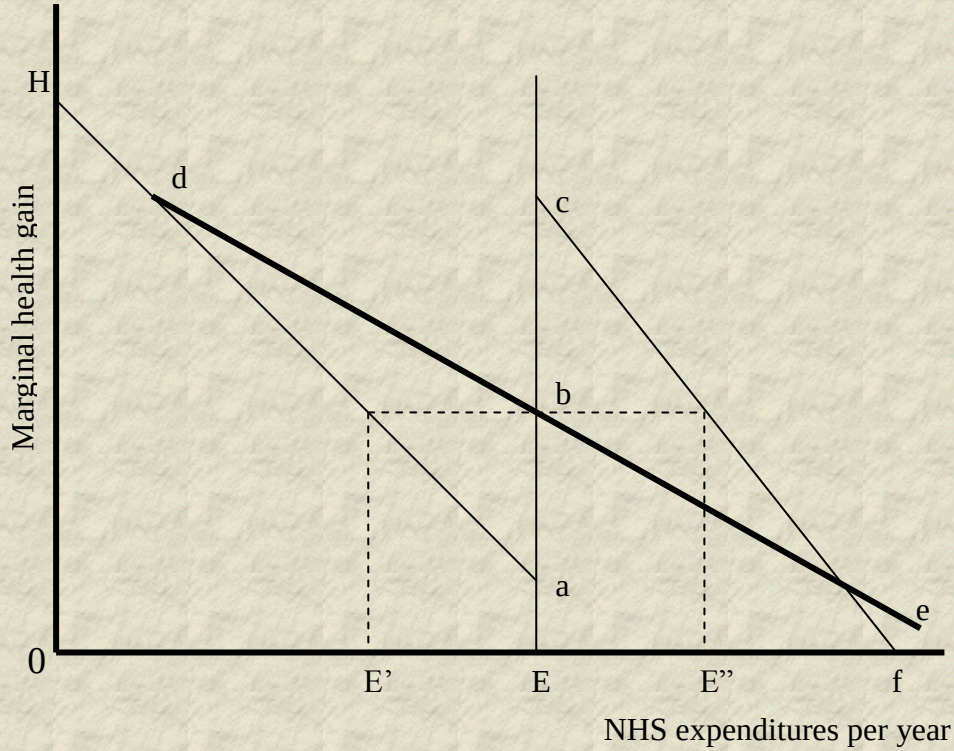


Figure 2 Three thresholds for NICE

The search strategy for NICE is to work within the zone of substitution, defined by E0E00, identifying technologies in current use that are the least productive uses of current NHS resources, and identifying better value technologies that are not currently provided.
NICE's search strategies It is not feasible for NICE to examine the cost-effectiveness of all interventions to reveal the location of Hde. Instead, NICE adopts a number of strategies consistent with the behaviour to be expected of a threshold-searcher. In collaboration with the Department of Health, it engages in horizon scanning to explore technologies that probably lie in the zone of substitution. NICE also relies upon a broad consultative process with all stakeholders, including the general public, to identify technologies for both investment and disinvestment. The proposals obtained through the consultation process inform which therapies to put forward for review.6 Within the review process, the appraisal committee's judgments on the cost effectiveness of a new technology must include judgments on the implications for health care programmes for other patient groups, how the cost effectiveness of the technology being appraised relates to other interventions/technologies currently being applied in the NHS.

If this system were to work well, we would expect to see a mixture of investment and disinvestment opportunities being reviewed by NICE. However, in practice almost all NICE appraisals have only considered

opportunities for investment,7 leaving consideration of disinvestment opportunities to local purchasers. While some of the latter have established formal processes for considering local disinvestment and investment decisions,8,9 there is substantial variation in both the quality and the degree of transparency in such processes.10 In view of this, a common evaluative framework producing information on the cost-effectiveness of a larger range of technologies might help to make a bridge between local purchasing and NICE. For example, NICE could work with local purchasers to identify programmes and technologies for which there exists a prima facie case for disinvestment. It could then appraise these over time together with emerging technologies, in the expectation of providing a more balanced set of investment and disinvestment opportunities.

Conclusions

It is not NICE's constitutional role to determine the value of an additional QALY since the setting of the NHS budget is properly a matter for parliament. NICE, nonetheless, needs a criterion on which to judge the cost-effectiveness of technologies that pass through its appraisal process and it is the search for the threshold implied by the prevailing NHS budget that is the appropriate task for NICE. This will require NICE to grasp the disinvestment nettle and include within its current appraisal process technologies that should no longer be provided as well as candidate technologies to replace them.

Acknowledgements

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Equity in economic evaluations of workplace health and safety

Anthony J. Culyer and Emile Tompa

A basic tenet of economics is that resources are scarce, so it is in the interest of individuals and societies to put them to their best uses. This is the notion underlying allocative efficiency—to get the most for the least. Economic evaluation is a tool to assist with achieving it. Invariably, it requires placing values on both the resources consumed and the consequences their use has produced in order to compare inputs and outputs within and across alternatives. Also inherent in the process is the need to compare and, where appropriate aggregate, costs and consequences across individuals and groups.

Allocative efficiency is a central objective in economic evaluation, but equity is equally important. Equity is commonly considered to be of two main kinds: distributive equity/justice, which refers to the fairness of the allocation of benefits and burdens, and procedural equity/justice, which refers to the fairness and acceptability of decision making processes (see Box 1 for definitions).

Box 1: Key efficiency and equity constructs

Allocative efficiency: refers to a situation in which resources are allocated to production processes and the outputs of these processes to consumers so as to maximize the net benefit to society.

Distributive equity/justice: concerns what is just or fair with respect to the allocation of benefits and burdens (consequences and costs) between individuals or groups of individuals. The focus is on outcomes.

Procedural equity/justice: concerns the fairness and transparency by which decisions are made. The focus is on process.

Within the broad equity constructs of distributive and procedural justice there are many rival notions. All have it in common that they embody values, so none can be assessed solely on scientific terms. They are also based upon an idea of distancing the balancing of conflicting interests in a way that is detached from personally or institutionally selfish interests. They are intended to inform behaviour or decisions that help answers questions such as: ‘how ought management choose between alternatives?’, ‘should monetary costs and consequences accruing to workers be valued the same as monetary costs and consequences to employers?’, ‘what is a fair distribution?’, ‘what is the fairest way to prioritize occupational health and safety (OHS) options (within a workplace, a region, or a jurisdiction)?’. Equity concepts, both distributive and procedural, involve more than one person; they are about

relationships and comparisons of people (both individuals and groups). In short, they are about making interpersonal comparisons.

Equity (or its absence) is a characteristic of a society. It is usually treated at the macro (country, societal) or meso (system) level but in some cases is it treated at the micro level, where, perhaps, no more than two people are involved, as for example in physician-patient relationships. In the health economics literature, textbooks such as McGuire *et al.* (1992), Mooney (1992), Dolan and Olsen (2002), Folland *et al.* (2004), and Donaldson *et al.* (2005) focus on macro and meso equity issues associated with health care system design and evaluation. Few discuss the central topic of this chapter: the microeconomics of economic evaluation using CEA, CUA and CBA methods. We discuss macro and meso level equity, but try also to provide some initial guidance on how best to address equity issues, of whatever kind, in the context of economic evaluations of OHS interventions.

Since equity is a topic in several disciplines, we recommend a few references as a starting point to scoping out a vast literature. For a review of equity from a general philosophical perspective see Plant (1991). For a review of equity from a general economics perspective see Hausman and McPherson (2006), and for a more specific health-oriented philosophical perspective see Daniels (1985). Williams and Cookson (2000) provide a good review of the equity literature focusing on the macro and meso health economic perspective. Wagstaff and van Doorslaer (2000) also provide a review of the health economics perspective but with a focus on finance and delivery.

Equity and Equality

There is an important characteristic that concepts of equity have in common-- they all have to do with equality or inequality. Thus it becomes important to ask the question: equality or inequality of what? Equity does not equate to equality, however. Sometimes one deals with ‘just inequalities’ and the question is then ‘what is the criterion for deciding which inequalities are fair or unfair?’ Equity thus means treating likes alike and unalikes appropriately differently. It requires that relevantly similar cases be treated in similar ways, and relevantly different cases be treated in appropriately different ways. This brings to the fore two important concepts: horizontal equity and vertical equity. Horizontal equity is the equal treatment of people who are equal in a relevant respect. Vertical equity is the unequal treatment of people who are unequal in a relevant respect (see Box 2 for details). It also requires us to be clear about what factors count as relevant respects.

In the context of OHS interventions and the associated costs incurred and consequences produced, equal or unequal treatment for the purpose of fairness or equity amounts to assigning priorities to costs and consequences accordingly. As has been seen in previous chapters, many research studies arbitrarily restrict the categories of cost or consequence considered, for example by ignoring costs or consequences that fall on workers’ families, or by attributing an implicitly high weight to positive productivity effects on the bottom line or by minimizing the negative consequences of OHS interventions for companies and their owners. There are probably some implicit social values underlying these biases but, quite apart from the unattractiveness of using analytical methods that mask rather than expose important equity issues, what might the relevant criteria be for inclusion or exclusion or differential weighting?

What criteria correspond to these relevant respects? Drawing on the health care literature, we describe several commonly adopted equity criteria.

Box 2: Horizontal and vertical equity

Horizontal and vertical equity are constructs of fairness often called upon in health care and tax policy. These are two principal areas of social systems where similar treatment of equals and dissimilar treatment of unequals is at the forefront of notions of fairness or justice. In health care, the concern is often the fair distribution of health care services, of the burden (usually on individuals) of financing them or of health itself. In finance policy, it is the fair distribution of tax burdens or, in a labour force context, the fairness of the premiums on employers that often funds the system.

Horizontal equity: the equal treatment of people who are equal in a relevant respect. In health care, the relevant criterion for equality of treatment may be equality of needs, abilities to benefit, or some other aspect that makes individuals equal in their deservedness or entitlement to health care services. In tax policy, the relevant criterion is often equality of incomes.

Vertical equity: is the unequal treatment of people who are unequal in a relevant respect. In health care, individuals may be considered unequal in their deservedness due to differences in need or some other relevant respect. In tax policy, individuals are often treated unequally when their incomes differ (as in progressive taxation).

One very common criterion is need. In terms of horizontal and vertical equity it requires the equal treatment of people with equal needs, and more favourable treatment of people with greater needs. A fundamental challenge with this criterion is that it is far from clear how to define need. It can be defined by ill health, which would suggest that people who are equally ill ought to be treated the same (i.e., receive the same priority in attending to or treating their injury or disease), and those that are sickest ought to receive higher priority. Need might also be defined by risk exposure, in which case people equally at risk of injury, disease or death ought to be treated the same, and those with greater risk should be given priority.

A key disadvantage of the need criterion is that it appears to assume that all the conditions in question are equally treatable by health care or preventive measures, and that all conditions or hazardous situations are equally costly to remedy. But this is clearly not always the case. It does not make much sense to provide equal priority for health care services to individuals with equal need if their ability to benefit differs substantially, or if the costs of healthcare provision are vastly different. In the context of OHS interventions, it can hardly be appropriate to require a workplace to provide health care services or preventive measures regardless of effectiveness or cost simply because of equality of need define by risk exposure or rates of sickness absenteeism. In short, the proportionality requirement implied by the criterion of need (and the share of resources the criterion suggests that each workplace receive) seems arbitrary and therefore inequitable.

A second common criterion is deservedness (desert). This criterion requires that people having equal deservedness be treated the same, and people with greater deservedness be given higher priority. Aspects of deservedness that proponents of this view often have in mind are lifestyle choices such as macho workplace behaviours, smoking, drug abuse, poor diet, dangerous sports, careless and promiscuous sex that increase exposures to deleterious health risks and the probability of experiencing injury, disease or death. Lifestyle choices that adversely affect health are grounds for giving individuals that make such choices a low priority. In contrast, individuals with greater deservedness should be given higher priority. Greater deservedness may be based on characteristics such as clean living, higher productivity, more dependent children, or more public service work.

There are two critical concerns with the criterion of deservedness. First, it is difficult to distinguish empirically between lifestyle choices and other factors that bear on health. Second, it assumes that lifestyle differences are avoidable rather than socially conditioned, thus making the people in question culpable for the impact of these differences on their health. In this respect the criterion becomes close to victim-blaming. For example, is it fair to blame (or to discriminate against) a drug addicted youth for their poor health if that youth had parents with similar addictions and was raised in a deprived and marginalized household? In the workplace setting, is it fair to blame a worker for compromising their health following a workplace accident in which the person did not wear the appropriate safety equipment? It might have been that the safety equipment was not provided by management, or emphasis was given to expediency rather than safety, or that it was widely perceived that the general culture of the organization gave safety a very low priority. Even the apparently quantifiable criterion of deservedness based on social contribution is difficult to measure without arbitrariness. Are claimed contributions to be taken at face value? Can one meaningfully separate the productive contributions made in team work? Might not even partial measures of deservingness exacerbate rather than diminish inequity?

A third criterion concerns the resources employed to address equity issues. This criterion is usually presented as a strictly horizontal equity argument. It suggests that, since all people are to be regarded as fundamentally equal, each individual ought to have an equal amount of resources available to address health concerns, and that the per capita distribution ought to be everywhere the same. While the criterion is usually thought of in the context of assigning health care budgets to regional health care providers or commissioning agencies, it is also implicit in claims that certain workplaces, or occupational groups, or industries have an unfair share of OHS resources.

A primary disadvantage of this criterion is that, like the criterion of need, it ignores the productivity of the resources expended to address health concerns. It is difficult to justify an equal expenditure of resources in cases where the capacity to benefit differs. For example, it would seem inappropriate to invest an equal amount of resources in prevention in all workplaces, when in some cases it may be very effective (and low cost) and in others quite ineffective (and high cost). The same issue arises with resources expended for the treatment of health care conditions arising from workplace exposures. What is equitable about expending the same amount regardless of the injured or ill worker’s capacity to benefit from it?

This leads to a fourth equity criterion: capacity to benefit. This requires that people with an equal capacity to benefit be given equal treatment, and those with greater capacity be given priority. Applied to the workplace, it suggests that people with an equal capacity to benefit health wise from a workplace intervention ought to be treated the same, and those with higher capacities to benefit ought to be given priority and/or have more resources expended on them.

While the capacity to benefit criterion addresses the concern about the productivity of resources invested in health care and prevention, it so happens that individuals with a relatively greater capacity to benefit generally have better health to begin with (e.g., individuals with higher education and higher income). Hence, the application of this criterion in health care and the workplace context would exacerbate existing health and income/wealth inequalities. This equity criterion is a good example of how there can be fundamental conflicts between different equity criteria.

A fifth criterion on which to base equality is health itself. The objective of this criterion is to achieve the greatest possible equality of health by giving priority to those with relatively poor health. This approach was formalized in Rawl's maximin principle (Rawls 1971), which we discuss in the next section. The equality of health criterion could be implemented by prioritizing interventions based on the level of health of individuals in different work settings (e.g., by giving higher priority and/or investing more resources on those who are the furthest away from the average health level of the population), or based on the level of health risk exposure in a workplace.

A key disadvantage of the equality of health criterion is that it suggests expending enormous amounts of resources for very sick individuals, or those most at risk. But such interventions may not be very health enhancing and they might well be undertaken at the expense of interventions that would generate much greater health gains for others. This concern is similar to that presented in the equality of need criterion.

A sixth equity criterion is equity of access. In health care it is often framed as equality of access for equal needs. It would entail providing equal access for equal needs, and priority access for greater needs. This criterion is perhaps the most frequently encountered type of equity criterion invoked in health care, but could also be applied to OHS interventions. For example, one could allow for equality of access to health and safety training programs or equality of access for worksites to resources for investment in prevention interventions. Greater need might be defined by productivity or income, and hence priority or faster access to health care and return-to-work services might be given to injured workers on the grounds of their economic productivity or to minimize compensation benefits.

Box 3: Summary of equity criteria

Equity Criteria	Horizontal equity interpretation	Vertical equity interpretation	Disadvantages
Proportionality of need (process)	treat people with equal needs the same	give priority to people with greater needs	• capacity to benefit may differ for similar needs • cost may differ to address similar needs
Proportionality of deservedness (process)	treat people with equal deservedness the same	give priority to people with greater deservedness	• difficult to distinguish between choices and other factors • assumes lifestyle differences are choices • difficult to measure social contributions
Proportionality of expenditures (process)	provide an equal amount of resources for each person	---	• capacity to benefit may differ across individuals • local price variations result in different resources per person
Proportionality of capacity to benefit (outcomes)	treat people with equal capacity to benefit the same	give priority to people with greater capacity to benefit	• can exacerbate existing inequalities since capacity is generally higher for healthier, higher income individuals
Proportionality of health endowment (outcomes)	treat people with equal health the same	give priority to those with relatively poor health	• maximin principle suggests expending enormous amount of resources on the worst off • small gains at high cost may be at the expense of large gains at low cost
Proportionality of access (process)	provide equal access for people with equal needs	give priority access for people with greater needs	• substantial resources may be expended if access is exercised • capacity to benefit may differ for similar needs • health inequalities may persist • large gains at low costs may remain untapped

A disadvantage of this criterion is that it might result in high costs if many workers exercise their right to access, yet health gains associated with access may vary substantially. Related to this concern is that health inequalities may persist, and there may remain many untapped gains that could be had at a low cost.

Box 3 presents a synopsis of the six equality criteria. The six are not an exhaustive list of possible criteria, but are illustrative of the many and conflicting ways in which equality may be defined. Each has disadvantages and no one is best for all decision contexts. Ultimately, a process in which stakeholders and decision makers participate in the assessment of equity implications of an evaluation might result in the most appropriate choice of equality principle to adopt for a particular situation.

Efficiency versus equity

There is a fairly robust tradition in both the economics and the philosophical literatures that casts efficiency and equity in competing roles. While it is undoubtedly true that conflicts can arise, it is helpful to bear in mind two considerations:

- the tension between rival equity criteria is greater and often harder to resolve than the tension between equity and efficiency;
- the tension between equity and efficiency arises largely because efficiency requires the aggregation of individual consequences, and if this aggregation is undertaken without thought being given to its distributive equity implications, it is highly likely that the efficient alternative will appear inequitable (Culyer 2006).

The tension between rival equity criteria may be hard to resolve, but it can at least be elucidated by identifying and clarifying the criteria under consideration. In the context of a specific evaluation, if there is a concern about the relevant criteria to be considered, then offering stakeholders and decision makers a list of possibilities as presented in Box 3 may be a useful point of departure.

The apparent tension between efficiency and distributive equity can be illustrated by an example from health technology assessment. A typical evaluation would consider the health consequences of alternative treatment options measured in Quality-Adjusted Life-Years (QALYs). The objective may be specified as selecting the technology with the highest incremental cost-utility ratio from a set of possible options. Total health consequences would be measured as the net present value of a discounted stream of future QALYs and added across the individuals who are predicted to benefit. Simple addition within and across individuals assumes that the social value of an additional QALY is the same regardless of who receives it, and how many any one individual receives. Essentially, all QALYs are given equal weight.

Should it turn out that QALYs are thought to be of different value depending on who receives them and/or how many are received by any one individual then the efficient alternative might be in conflict with the relevant equity criterion. The conflict disappears if appropriate weights are attached to QALYs instead of assuming equal value. Weights might be based on generic characteristics of recipients such as age, gender, and number of QALYs received (we discuss equity weights in greater detail later in the chapter). Alternatively, the efficiency analysis based on the assumption of equal value of QALYs could be explicitly presented as provisional, with the ultimate decision to be taken after a decision-making body gives due consideration to the equity implications of alternatives in addition to the provisional efficiency analysis. The key point is that both efficiency and equity must be considered in tandem, with neither trumping the other.

Perhaps the principal lesson from this brief review of equity criteria is to emphasise the importance of being clear about the underlying equity principles being invoked when assessing the distributive equity of alternatives. As is apparent in the above descriptions there are multiple concepts of equity, some of which are compatible and others which are not. Many discussions of equity are typically fraught with generalized slogans and particular interest groups will tend to select those that most favour their own interests. In order to enhance the clarity of analyses of the equity

implications within the context of economic evaluations, we suggest considering, consulting and reporting the answers to the following questions:

- What are the appropriate relevant respects (criteria) to be borne in mind in the situation at hand?
- Are the equity criteria under consideration appropriately distanced from the particular interests likely to be affected by the intervention?
- Are the equity criteria addressing horizontal or vertical equity?
- Are the equity criteria addressing process such as access or exposure (procedural justice) or outcome/consequences such as better health (distributive justice)?

Equity constructs

In what follows, we review several well-know equity constructs found in the literature. Some have been considered in the economics literature, and specifically in health economics, whereas others come from other disciplines. Some approaches provide guidance on how to embody equity in a decision-making algorithm, as through the use of weights to adjust health or utility values based on the characteristics of recipients. Others provide guidance on how equity concerns can be incorporated alongside evidence into the decision-making process itself in order to afford an opportunity for decision makers to delve more deeply by considering the individuals that are likely to gain or lose from an intervention and the nature of their gains or losses. Decision makers may also consider how best to manage the introduction of a worthwhile intervention that has both gains and uncompensated losses in light of equity concerns. Our emphasis is on providing appropriate information to decision makers rather than deciding precisely how equity is to be embodied in the analysis.

The fair innings approach

Williams' (1997) fair innings approach was developed in the context of the UK's National Health Service (NHS) to address issues of distributive equity, specifically as they related to vertical equity. The approach assumes that one of the objectives of the NHS is to reduce inequalities in people's lifetime experience of health. Age matters in two respects. First, it affects people's capacity to benefit and therefore places older people at a general disadvantage if another objective is to maximise the (unweighted) benefits of health care. Second, older people are more likely to have had fair innings in terms of experiencing many years of healthy life, and this places them at a lower priority based on the notion of minimising differences in lifetime health. Williams argued that it would be equitable to provide small benefits to young people even if in so doing the elderly were denied large benefits, provided that the young recipients had a low probability of achieving a fair innings. The approach does not necessitate young people having absolute priority for benefits compared to older people. Rather, it simply means that their health benefits are given greater weight. Applied to economic evaluative methods, the fair innings approach suggests that generic characteristic be used to weight benefits (and possibly costs) differently. Age would be the principal characteristic to consider, though other characteristics might also be used in the developing weights. In all cases, the following three factors should be considered:

- Is the ethical argument for weighting benefits differently based on a recipient's characteristics acceptable in the context of the given evaluation?

- Is there an acceptable method for identifying or developing appropriate weights?
- Are the issues involved best addressed by weighting benefits or through a deliberative approach that would allow for additional evidence to be considered in the decision-making process?

The World Health Organization developed a weighting system based on age for use with a health outcome measure known as Disability Adjusted Life Years (DALYs) to measure the global burden of disease (Murry and Lopez 1996). DALYs measure the health gap due to injury, disease and premature mortality based on a gold standard of a full and healthy life of 80 years for men and 82.5 years for women. Weights were developed for DALYs based on the notion that years of healthy life in early adulthood are worth the most to society. DALYs during the early years of life from birth are given lesser weight but increase substantially in the years to early adulthood and decline gradually thereafter into old age.

Justice as fairness

Rawls (1971) developed a theory of equity that has been particularly influential for health economists, even though he explicitly excluded health and health care in his analysis of justice as fairness. Rawls proposed a hypothetical situation for assessing equity issues in which individuals making decisions are shrouded by a 'veil of ignorance' such that they have no knowledge about their own personal circumstances or position in society. Such a veil provides a distance between self interest and considerations of equity. Rawls conjectured that such an approach would result in an agreement on two basic principles of fairness:

- Basic liberties (such as the rights to vote, freedom of speech, and the right to own property) ought to be both equally distributed and as complete as is consistent with equality; and
- Primary goods (such as basic liberties, income and wealth, position of responsibility, and respect) should be distributed such that only inequalities that were to the benefit of the least advantaged people would be permitted. This criterion is known as the maximin principle.

Primary goods include attributes essentially determined by the interactions in human societies, but not 'natural goods' such as health. Primary goods are a means to an end, a means to attaining welfare. Rawls excluded health from the list of primary goods because health is an end in itself, because it is determined largely by nature, and because he felt that the application of the maximin principle to health could lead to large amounts of health care resources being devoted to the health of people who would gain little from it, possibly at the expense of driving others into poverty.

Equity and capabilities

Sen (1980, 1993) argued that non-utility characteristics often provide better grounds for assessing the equity implications of alternative social states than utility and welfare. According to Sen, a particularly important class of non-utility information is people's basic capabilities. These capabilities are ones that enable people to engage in activities that are important to them, such as working, using leisure time, community involvement, and living a healthy life. Equity concerns should thus focus on the distribution of basic capabilities. The approach suggests that equity is about moving society towards a more equal distribution of capabilities. Sen suggested that many

basic capabilities can be measured as levels of functioning. This is certainly true for health.

The basic capabilities approach is extra-welfarist in that it goes beyond the evaluation of human welfare and its distribution in terms of individual utilities. The approach does not provide an algorithm. Its value lies in the framework it provides for thinking about equity issues. It leaves a good deal to the discretion of analysts, such as determining what counts as basic capabilities in health and in a workplace context, how they are to be measured and weighted. One approach for the economic analyst might be to create a process for reasoned agreement with stakeholders, bearing in mind the specific decision context.

The rule of rescue

The rule of rescue approach to equity consists of an injunction to rescue identifiable individuals in immediate peril, regardless of cost. The plausibility of the rule is well-expressed in the following quote (Jonsen 1996, quoted by Cookson *et al.* 2007):

'*Our moral response to the imminence of death demands that we rescue the doomed. We throw a rope to the drowning, rush into burning buildings to snatch the entrapped, dispatch teams to search for the snowbound. This rescue morality spills over into medical care, where our ropes are artificial hearts, our rush is the mobile critical care unit, our teams are the transplant services.'*

The appeal of the rule lies in the heroics expressed in the rescue process. The downside is that though an intervention may rescue people facing imminent death, it may give them only a small increment in extra life. Furthermore, the cost of funding the rescue technology may divert resources away from other activities that provide substantially greater benefits to others. Essentially, the rule of rescue focuses on the benefit to one group (whose identities are usually known) and ignores the cost to others (who are probably anonymous potential beneficiaries of forgone opportunities). There is an implicit interpersonal comparison which values the benefits of one group over those of another. Concern for identifiable individuals in immediate peril unambiguously implies less concern for unidentifiable individuals in future peril. Such discrimination, when it is seen for what it is, seems intuitively unpalatable. Though it is based on a natural human expression of good will, it entails gross inconsistency in the way it treats the value of resources (Cookson *et al.* 2007). The approach is not the same as having a concern for the severity of a current health condition or risk exposure in a working environment. Rather, it would suggest providing increases in safety of a value that need not be compared with its cost in order to favour identified individuals at the expense of the unidentified.

Libertarianism

Some procedural approaches operate at a very broad level. Libertarianism in its classical forms (e.g., Locke 1967) or its contemporary version (e.g., Alchian 1965; Nozick 1974) accords a minimal role to the state, based on the premise that there is little justification for any regulation beyond that required to operate a system of exchangeable private property rights. There is no scope for agencies to promote or regulate efficiency, equity or health and safety. No individual's right, small or large, should ever be sacrificed for any other end, including the rights of other. This approach is tantamount to denying the legitimacy of any concept of equity, unless

outcomes are automatically defined as equitable if they are a product of an equitable process which, according to libertarianism, would exist in a market uncluttered by regulation. The pure form of libertarianism plainly implies that allocative decision-making tools such as economic evaluation are not liberal. However, provided that the stakeholders in any given practical situation in which an economic evaluation is being planned can agree that the existing rights and entitlements of stakeholders are satisfactory, it is possible that a case can be made for a consultative process that would determine the methods to be used to choose the optimal set of health and safety interventions and how evidence, and what kind of evidence, would be incorporated into the process.

Accountability for reasonableness

A much less extreme approach than libertarianism is that of 'accountability for reasonableness' (Daniels and Sabin 1998; Daniels 2000). This approach incorporates the fact that there is often reasonable disagreement about relevant equity criteria. The approach provides some principles of a legitimate and fair process for making decisions without needing to specify any specific outcome. Key elements of a fair process include transparency about the grounds for decisions, appeals to rationales that all can accept as relevant to decision making, and procedures for revising decisions in light of challenges to them. Together these principles insure accountability for reasonableness. Box 4 provides an example of an application of this approach.

Box 4 Application of accountability for reasonableness

Accountability for reasonableness has been adopted by the National Institute for Health and Clinical Excellence (NICE) in the UK. NICE describes accountability for reasonableness as follows (NICE 2007 p. 13):

> For decision-makers to be accountable for their reasonableness, the processes they use to make their decisions must have four characteristics: publicity, relevance, challenge and revision, and regulation.
>
> **Publicity:** Both the decisions made about limits on the allocation of resources, and the grounds for reaching them, must be made public.
>
> **Relevance:** The grounds for reaching decisions must be ones that fair-minded people would agree are relevant in the particular context.
>
> **Challenge and revision:** There must be opportunities for challenging decisions that are unreasonable, that are reached through improper procedures, or that exceed the proper powers of the decision-makers. There must be mechanisms for resolving disputes and transparent systems available for revising decisions when more evidence becomes available.
>
> **Regulation:** There should be either voluntary or public regulation of the decision-making process to ensure that it possesses all three of the above characteristics.

Deliberative processes

A deliberative process is characterised by a careful, deliberate consideration and discussion of the advantages and disadvantages of various options in an effort to assist people with making a decision (Hajer and Wagenaar 2003). A deliberative process is used to elicit and combine various types of evidence. A deliberative process integrates scientific analysis and social context, with stakeholder or lay public views elicited through consultation and participation. However, a deliberative process is different from a consultative process in that it requires participation rather than simply consultation (see Box 5 for an example of a consultative process that was not a deliberative process). Employing a deliberative process increases the likelihood of achieving a sound and acceptable decision (Daniels 2000). If properly executed it will be more comprehensive in the relevant issues embraced, more consistent in the way they are embraced and more engaging of the people affected by the outcome than a closed-door or ad hoc process (Culyer and Lomas 2006).

Box 5: Example of a consultative process

The Oregon priority-setting exercise for health care interventions initiated in 1989 is a well known example of a consultative process. The exercise entailed 47 community meetings, 12 public hearings and 54 panel meetings with health care providers. The information from these meetings was provided to the Oregon Health Services Commission to inform the prioritisation of health care procedures (Garland 1992). Thus many individuals and groups were consulted but relatively few participated in the discussions where the data and evidence collected was synthesized and integrated to develop the final prioritisation.

The following conditions are hypothesized to be those under which a deliberative process is most likely to be warranted:

- evidence from more than one expert discipline is involved;
- evidence from more than one profession is involved;
- stakeholders have conflicting interests;
- there are technical disputes to resolve;
- evidence may be scientifically controversial;
- evidence gathered in one context is to be applied in another;
- costs and consequences extend beyond the conventional boundaries of business planning;
- there is substantial uncertainty about key values and risks that needs to be assessed and weighed;
- there are social and personal values not taken into consideration in the scientific analyses;
- there are issues of equity involved;
- there are issues of implementability and operational feasibility; and
- a wide public and professional ownership is desired.

As is apparent, equity is one of the items on the list, and it is often one of the most important and intractable factors under consideration. A deliberative process is particularly useful when equity is a central concern in a decision because of the uncertainty surrounding the appropriate equity criterion to adopt, the general absence of quantitative data to inform equity issues, and the uncertainty about how to trade off

equity against other considerations such as efficiency, implementability and manageability.

Equity and incidence

A matter that may have considerable implications for judgements about equity is the divergence between the initial and final incidence of costs and benefits. The most common application of the theory of incidence in economics is in the field of taxation, where the initial incidence of a tax change is compared with its final incidence or burden after all market adjustments in response to the change have been completed. As an example, consider the kind of effects that might follow the adoption of a costly new intervention to enhance worker safety. The initial incidence of costs will reside with the firm as new equipment is acquired, old equipment modified, new training schemes deployed and new management structures created. However, in the medium to long term the combination of a safer working environment and shifts of the skill mix and other substitutions may cause wages to decrease since, all else being equal, a safer environment will generally result in a lower wage (higher wages normally compensating to some extent for higher risks). The effects on the production side may affect overall marginal costs and generate a change in the price of the products produced, which in turn may generate a change in the amount demanded in any time period. It is possible that what was initially a cost to the firm turns out to be no burden at all, with the costs falling on consumers, or workers or both via higher prices and lower wages. However, the working environment will still be safer than before the intervention, which is of benefit to workers. Moreover, if greater safety has positive productivity effects, it may translate into an increase in wages and profits.

The implications for assessing the equity aspects of OHS interventions should be apparent: if it is possible for the initial incidence of the costs or benefits of any change to be shifted to others, then any assessment of the equity of the change that fails to account for this would be flawed. How significant such effects are is an empirical matter. Whether it is worth modeling these shifts to estimate their magnitude will be a judgment that should be based on factors such as:

- How far reaching the intervention is in terms of the number of workers and firms affected. The greater the scope of the intervention, the more likely it is that incidence will be shifted in ways that might affect judgments of equity.
- The size of the firm level intervention in terms of cost, health and productivity effects. A modest intervention will generate smaller shifts.
- The competitiveness of the labour and product markets in question. Less competitive labour and product markets will have smaller elasticities, and hence lesser responses.
- The speed of implementation of the intervention. The costs of slow or gradual implementation tend to be lower than fast implementation and shifting of burdens will take place over a longer period of time.
- The effectiveness of the intervention. A less effective intervention will generate less scope for shifting.

Recommendations

- Identify the relevant stakeholder groups who may gain or lose from an intervention and provide an analysis of the gains and losses by group.
- Ensure, so far as possible, that the idea of equity is distanced from the self-interest of any participating stakeholder group.
- Determine whether the equity issues are horizontal, vertical or a mixture of both.
- Clarify the relevant respect(s) or criteria in terms of which individuals and groups are to be differentiated.
- Decide whether the process of decision making or of subsequent roll-out of the intervention is itself a part of the equitable solution.
- Consider whether equity is better treated in an algorithmic fashion (e.g., by weighting various elements of a calculated cost-effectiveness ratio) or by consultation/deliberation of some sort.
- Consider differential weights for costs and consequences accruing to different individuals and groups. Be clear about their calibration and justification.
- Explore the possibility of determining equity weights through sampling relevant sections of the population.
- Consider whether, should a consultative route be followed, it be merely consultative or also deliberative.
- Be on guard for special pleading masquerading as the rule of rescue.
- Consider, where appropriate, adjusting for the difference between the initial and the final incidence of costs and consequences.

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What is a little more health and safety worth?

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The innocent-sounding question posed in the title of this chapter is our way into these issues. It is meant to lead us into an exploration of the issues that arise in evaluating the effectiveness and cost-effectiveness of workplace interventions to promote health

and safety (note that some researchers may consider that cost-effectiveness already includes effectiveness, but it is a distinction commonly made and familiar to many people-- see Box 1 for some basic definitions).

Box 1: Some basic definitions

Efficacy, Effectiveness and Cost-effectiveness

Efficacy: the positive impact on health and other outcomes of an intervention when it is performed under ideal conditions, such as in a randomized controlled trial when full adherence is ensured.

Effectiveness: the positive impact on health and other outcomes of an intervention when it is performed under usual operating conditions.

Cost-Effectiveness: the effect on health and other outcomes of an intervention subject to a limit on the available resources for its implementation or, equivalently, the resource cost necessary to achieve a given effect on health and other outcomes, usually relative to some alternative such as the status quo or a rival intervention.

Cost-Effectiveness Analysis: the systematic consideration of the effect on health and other outcomes of an intervention relative to the resources used for its implementation, usually evaluated through a comparison with some alternative, such as the status quo or a rival intervention.

Ends and means

Our thesis question may appear odd to those in the world of workplace health and safety who are not economists. After all, better health seems a reasonable objective for individuals and governments to aim at. It is an *end*. But safety at work is a means— one of many means— to the end of better health. More precisely, the means are the methods by which risks to health in the workplace are managed; so the means are the instruments, policies, workplace interventions and the like that are adopted in workplaces and which reduce the probabilities of events occurring that are harmful to health. These means are at best intermediate outcomes that lie on the road to the more ultimate outcome, better health. Hence, the worthiness of any risk reduction is presumably to be measured in terms of its impact on health. Considering the value of both health and safety is to invite the danger of double counting (see Box 2 on forms of double counting). It is health that is to be valued. The value of safety depends primarily on the value of the incremental health it enables.

But means and ends can become intertwined. Less risk, independent of any health or other consequences, may be preferred since people are generally risk-averse. Just feeling more secure is a benefit. It is not a health benefit in the conventional sense of what health is, but it does affect a person's welfare.

Box 2: Forms of double counting

Double counting is a hazard in any method of appraising options. There are three common forms.

Simple errors: due to incorrect arithmetic.

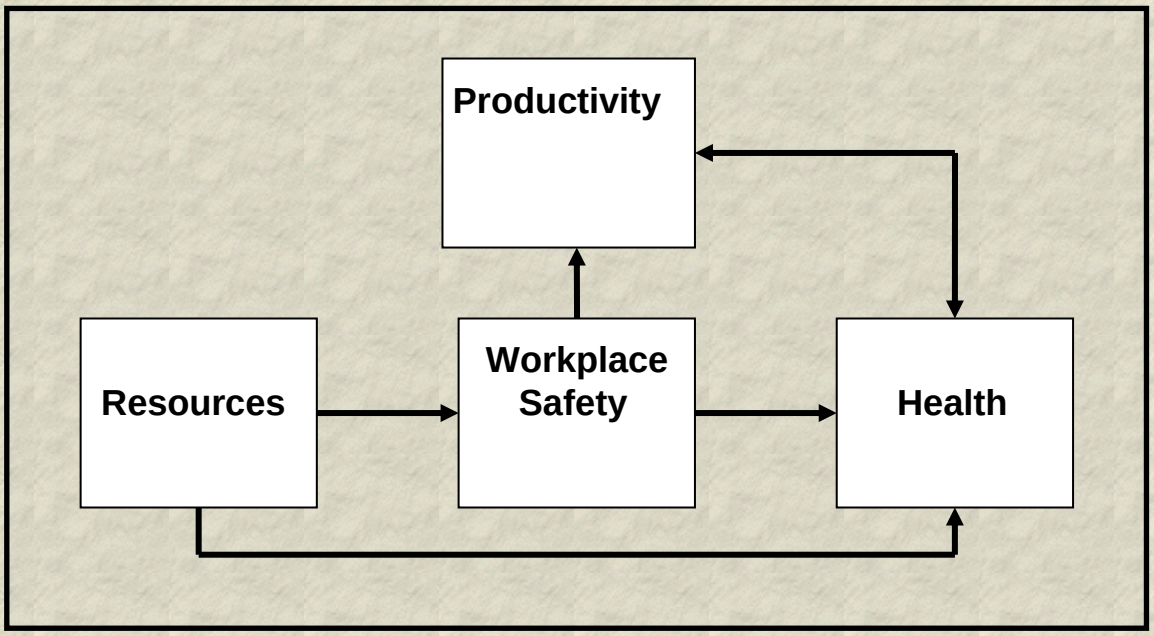
Suspicious circumstances: due to fraudulent accounting practices.

Subtler forms: due to poor administrative records or poor accounting of resource costs. Example 1: logging a medical procedure in two places even though it was performed only once, due to the patient being transferred from one hospital to another at some stage while the procedure was being undertaken. Example 2: computing and adding the cost of a surgeon's time for an operation when that cost is already included in the total fee. Example 3: adding increased earnings effects to the consequences even though they have already been included in a patient-based measure of the increase in the quality of life.

One might focus on consequences other than health. For example, an employer may implement engineering controls in order to eliminate a safety hazard and increase productivity without considering the direct value of health benefits. This suggests another perspective, one that does not view health as the ultimate objective but, rather, increased productivity. From such a perspective the means remain the reductions in risk, but the end is increased output, something to which it is relatively easy to attach a monetary value. Of course, in many cases health and safety interventions enhance both health and productivity.

Notwithstanding the fact that safety is in many cases a means, we have identified three ends associated with resource investment in health and safety that are of value to society: improved health, the inherent value of greater security, and enhanced productivity. Resource use may be directly linked to improved health, as is the case with health care services. In some cases productivity effects (note that we use the terms 'consequence,' 'benefit' and 'effect' interchangeably) may arise through the impact of resources on health, as when effective disability management enables a safe return to work sooner than would otherwise have been the case, or when sickness absences are reduced through safer working conditions. In other cases, productivity may be affected directly through workplace safety enhancements. There may also be a link from productivity increases to health increases. These various pathways are depicted in Figure 1 below.

Figure 1: The relationship between productivity and health



Two types of complexity are involved in the foregoing. The first is a complexity arising out of the need to determine what consequences ought to be considered. Three beneficial consequences have been mentioned and depicted in the diagram, but what other possible candidates are there and how are they to be measured and compared? Furthermore, consequences to whom? Is it only those to workers, or ought we also to consider workers' families and dependents, owners of firms, insurance agencies, and consumers of the outputs produced by the workplaces in question? And when we use the word 'ought,' what are the ethical criteria to which we are appealing? These are lofty questions which we try to address in what follows in this chapter. The second complexity concerns the pathways of causation and interaction between means and ends, and how some ends can even, as we have seen, in turn become means.

These complexities are familiar challenges to economists. The first set involves a discussion of human welfare, its measurement, its distribution, and its aggregation. The second involves the production function, or in other words, the analysis of the ways in which inputs are transformed into outputs and how feedback effects are taken into account.

Cost-effectiveness analysis (CEA) is something of a hybrid of the two kinds of complexity. It usually considers both benefits and opportunity costs as being dependent on people's preferences and it tends to be action-oriented by focusing on the use of technologies to change workplace practices, or on the technologies of health care. The notion of technology can be very broad: a drug, a guard on a machine, non-slip surfaces, an OHS management system, a modification to a health insurance system such as the introduction of a no-fault system, or the introduction of experience-rated employers' premiums. In effect, the technologies that are evaluated in cost-effectiveness analysis are 'ways of doing things'.

The philosophical framing of economic evaluation

The approach economists generally adopt is known as ‘consequentialism’ in philosophical writing. Consequentialism is a class of ethical theories sharing the view that the morality of actions or arrangements is to be judged by their consequences. Consequentialism is often contrasted with deontological moral theories which hold that the morality of actions and arrangements is to be judged in terms of duties and rights. Essentially, consequentialism is the notion that the outcome ought to justify the means. The most famous approach within this class is called ‘act utilitarianism’ (see Box 3).

Box 3: Utility theories

What is utility in economics

Utility in economics is an abstract way of ordering a person’s preferences by assigning numbers to the consumption of goods and services or to characteristics of goods and services. It can be measured either as an ordinal (like temperature) or a cardinal (like distance) construct.

Ethical theories based on utilitarianism

The three most common theories based on utilitarianism are**:**

Act utilitarianism: the right thing to do is any actions that generate, on balance, the most utility.

Preference utilitarianism: the right thing to do is whatever best matches the preferences (utilities) of the people who are deemed to count in society.

Rule utilitarianism: the right thing to do is to follow the rule that is most likely to generate the most utility, if it were generally to be followed.

Consequentialism may not be a useful approach in some decision contexts. For example, considering only costs and consequences is certainly not the only way of evaluating the pros and cons of alternatives for a disciplinary case. One may want to take account of the motives of a person who might be subject to disciplinary action. There are other objections to consequentialism. The most common one comes in the form of a dogmatic statement, ‘the end can never justify the means.’ But if an end cannot justify a means, then what can? It may be that a particular end does not justify a particular means, and it may also be that some means are so awful that they cannot be justified by any end. But, if there is a justification for adopting any particular means of advancing safety at work, we adopt the working hypothesis that it lies in its consequences for workers’ health, for their families’ welfare, for productivity, for the need for compensation and, indeed, for the well-being of any and all those affected by it.

The question of perspective

There is a value judgment in the foregoing. We have asserted that the justification ought to be in terms of the well-being of any and all who are affected by it. This is to

adopt a particular perspective, commonly termed the ‘societal perspective’. In the world of affairs this is not always, and perhaps rarely, the way in which decisions are reached. In some workplaces, the decisions will be taken by managers who see their prime responsibility as being to serve the interests of owners, so that interventions having benefits that accrue exclusively to workers will not gain acceptance. Workers, on the other hand, may perceive only the benefits that accrue to them, fight to achieve them, and ignore the disadvantages that fall on the owners. Plainly, the distribution of costs and consequences affects behaviour, attitudes, and the chances of success in advocacy. In practical politics these things matter. But they also matter when a deeper ethical question is addressed: ‘what policies, controls, regulations, interventions, inspections, penalties and rewards and the like ought to be introduced?’ Or put another way: ‘what is the value of a little more safety in the workplace, and of value to whom?’

Another notable feature of the question in the title of this chapter is that it needs to be asked at all. One might have expected that the question of the worthwhileness of health and safety would have been resolved long ago, or at least that the methods by which an answer is to be reached, and the principles underlying those methods, would have been long-since settled.

The answer may lie partly in the inherent difficulty of conceptualizing and measuring the effects of workplace health and safety interventions. Conducting experiments that control for confounders in hugely complex work situations is virtually impossible. Another part of the answer lies, we conjecture, in the way that the academic disciplines that are closely engaged in the OHS field have been applied. It seems that many analysts amongst the practitioners of the various clinical, statistical, public health and social scientific fields engaged with workplace health and safety issues view more health and better safety as always preferred, regardless of what they may cost. It is really only a question of figuring out what works. There has been, we detect, a tendency to see things through the lenses of the workers. Moreover, scientists have often not set out to refute hypotheses about the effectiveness of the means they adopt or recommend, but rather have focused on proving them, thus reversing the standard scientific and statistical approach to hypothesis testing (We are not intending to imply support for naïve falsificationism here). In opposition are views that may be more characteristic of employers, for whom the lens of worker welfare may seem less relevant, unless there were some indirect effects on profitability, and for whom the bottom line and managerial convenience may be the dominant considerations. Neither set of attitudes is to be despised, but a truly analytical approach to addressing the question of the social value of greater workplace safety and better worker health must find some way of escaping sectional bias.

Scylla, Charybdis and a safe passage

There are three commonly used approaches to evaluating health and safety procedures. Navigating around the first two, we feel much like Odysseus sailing around Scylla and Charybdis, the rocky reef and whirlpool in the straits of Messina. In what follows we outline each of the three approaches, explain the disadvantages of the first two, and describe our reasons for preferring the third. The three go by the following names: the perfect market approach, the human capital approach and the decision-maker approach.

The perfect market approach

The perfect market approach is premised on the notion that markets function reasonably efficiently, thus rendering formal evaluation of the effectiveness of health and safety procedures unnecessary. The general objective and ultimate criterion for deciding 'worthwhileness' embodied in this approach is the standard economic maximand: the sum of the expected utilities of all affected persons. This leads one to the Panglossian conclusion that the world is best left as it is (Doctor Pangloss was Candide's mentor, for whom the world today was the best of all possible worlds). Workers and employers are best left free to negotiate mutually agreeable terms of employment which cover wages, salaries, other benefits and workplace safety. Both sides can shop around costlessly, according to their preferences and, in particular, their attitudes towards risk, in order to find a suitable matching of person to job and job environment. Those who are risk-averse will seek safe environments or require compensation for working in riskier workplaces, and trade off the positive and negative aspects of the various offers of labour or employment available. All other things being equal, safer environments will tend to be associated with higher priced products and lower real wages than less safe environments, as there will be no necessity for employers with safer environments to offer compensating wage differentials. In equilibrium, all pros and cons will have been duly weighed within the overall resource constraints of the economy and safety and health will have been optimized, along with everything else.

In such a vision of the world, neither the interventionist policies we commonly observe, nor the normative economic calculations that can underpin them, are necessary. Nor even are voluntary collective actions by firms such as the Voluntary Protection Programs in the USA (Rees 1988). A risk that is voluntarily adopted after whatever compensation is agreeable to the consenting parties is a socially acceptable risk. It is the best that can be done in a world in which risk of injury and disease is generally to be avoided but is in practice costly to avoid.

In general, the theory of compensating wage differentials predicts that jobs requiring a higher level of education will, other things equal, pay more than those requiring a lower education in order to compensate employees for their investment in additional education. Jobs associated with higher risk of injury or disease will, other things equal, pay risk-averse workers more than they could earn in other safer jobs for which they are qualified, thus compensating them for the greater likelihood that their working life may be shortened, as well as any financial and psychic costs they might suffer due to injury or disease.

Compensating wage differentials must be offered by employers who save on health and safety costs by offering less desirable work environments. Such differentials enable unpleasant but necessary jobs to be done. Employers who improve the health and safety of work environments do not have to offer compensating wage differentials, but they incur the costs of the improved work environments. Whether environmental changes at work dominate over wage adjustments will depend partly on the relative costs to the employer of changing work environments and the anticipated responses of potential workers to these changes and any changes in pecuniary offers.

The extent to which markets generate the desired results depends on the efficiency of the matching process between workers and jobs in the economy. John Stuart Mill, the great utilitarian, observed at the turn of the 20th century that there were imperfections in the market which often resulted in the least pleasant jobs also paying the lowest wages under circumstances which could only implausibly be interpreted as offering a net compensating advantage of any kind (Mill 1965). He also noted that significant unemployment would constrain workers' ability to negotiate higher wages or to reject job offers. Mill further argued that people from marginalized groups, such as immigrants or poor and ill-educated people could be ghettoized into the least desired employment strata within the labour market, leading to an over-supply of such people in competition for the least desirable jobs.

The compensating wage differential model assumes free and complete information on the part of workers and employers. However, if workers are unable to assess the risk of injury or disease accurately, they may not negotiate a sufficiently high wage. While there is some evidence to suggest that workers are fairly good at assessing risk of death, they are less able to assess the risk of chronic disease, or acute events, such as injury arising from slips and trips on shop floors (Dorman 1996). Supervisory and workgroup relationships may lead workers systematically to over- or under-estimate the significance of the various job attributes. While workers might over time acquire a good perception of the bundle of job characteristics, the threat of moving to another position if wage compensation or other adjustments in the package were not implemented may be weakened and this weakness can be reinforced if health, pension, seniority and other benefits are at risk of being lost. Hence, the high costs of changing jobs can impede the effective working of the market mechanism. High rates of staff turnover are also costly to employers, since they may lose workers in whose skills they have invested. They will also incur hiring costs and may incur short-term losses in productivity.

Externalities are another source of market imperfection (see Box 4 for a definition) Many aspects of working conditions are external to the decision makers in that they affect third parties either financially, physically or psychically. For example, Leigh *et al.* (1996) estimated that workers' compensation insurance premiums paid by employers represents only 11 percent of the costs of occupational injury and disease in the United States, the remainder of the costs fall to workers and taxpayers. The total economic burden is estimated at around three percent of Gross Domestic Product, but only 10 percent of this burden is borne directly by employers. When external costs are added to internal costs, it amounts to what economists call 'social cost.' Yet, it does not follow that the activity which generates external costs ought to

be eliminated, nor does it follow that externalities should be eliminated should there be ways of reducing them.

Box 4: Externalities

‘Externality’ is an economics term for the effects on others of a person’s or group’s decisions. These effects can be both positive and negative. Economists classify costs as internal (i.e., those that fall on the decision maker, such as wages and salaries) and external (i.e., those that fall on others, such as the smoke of a factory that pollutes the air in a community and burdens it with increased cleaning costs, disease, etc.). The sum of internal and external costs is called social cost. Similarly, benefits may be internal, such as the revenue from sales, or external, such as the blossoms of a farmer’s orchard that is made available to the bees in a nearby farmer’s honey farm.

There are three basic types of externality:

Pecuniary externalities: affect the value of other resources, as when an innovation makes unskilled labour redundant or increases the value of skilled labour.

Physical externalities: affect the physical characteristics of other people or their property, as in the case of disease communicated via workplaces, or herd immunity is acquired through vaccination.

Utility or psychic externalities: affect the sensibilities of others, as when the knowledge of poor working conditions of some people makes one feel wretched, or the knowledge of good employment practices makes one glad.

The optimal social adjustment will be one that induces the firm to act as though it recognized the external cost so as to reduce the activity rate to that at which the marginal social benefit equals the marginal social cost. In the case of reducing the externality by other methods, the principle is again that the optimal investment is that at which the social cost of reducing the risk of harmful events is set equal to the best estimate of the social benefit from it, i.e., the benefit to workers plus that accruing to the externally affected parties.

The important logical implication of this is that, because there is a cost to reducing harm, it will generally be the case that there is an optimal degree of reduced harm which falls short of complete elimination. Economic analysis treats the benefits from hazard reduction in the same way as it treats other benefits. The art therefore lies in judging the point at which reducing a hazard costs more than the reduction is considered to be worth. This leads us to the critical issue of perspective. One needs to consider whose costs and benefits matter. In turn this leads us to the issue of distributive justice or equity, a topic we return to later.

The absence of full employment, imperfect information, lack of perfect labour mobility across jobs, and the existence of externalities suggests that the market, left to its own devices, will *not* yield an optimal level of compensation for risk and therefore workers will face a higher than optimal level of risk. This discrepancy provides the

basic case for government intervention through workplace health and safety regulation, imposition of minimum OHS standards, education and public information programs, and evaluative research including the use of analytical methods of assessing risks to health, the social significance of such risks to employers, workers, their families and the wider community, the availability of technologies through which such risks might be reduced, the costs of implementing such technologies and the distribution of those costs across employers, employees and the wider community.

There is also the issue of equity, which is related to the fairness of the initial distribution of wealth and power and the advantages and disadvantages that result to various players in the labour market. Many social inequities are multiple. Health is systematically correlated with wealth, as it is to income. In general, the least well-off financially are also the least healthy and least educated. They are also often the least empowered and organized. Regulatory and other interventions have often been applied on these grounds alone, regardless of the foregoing efficiency considerations outlined in this section. So even if the market actually was perfect, its outcome may well not be regarded as equitable. Those most at risk would in general be the poorest paid, the least skilled and least educated. The pay-off to investment in safety as seen by managers would rise in proportion to the productivity of the employees most affected, so safety investments that benefited the rich would dominate over those that benefited the poor. Such an outcome would violate the most basic principles of horizontal and vertical equity: that people who are alike in relevant respects ought to be treated alike and those who are not alike in relevant respects ought to be treated unequally in relation to their relevant differences. That is, unless one is prepared to argue that productivity differentials are morally relevant aspects that justify such discrimination.

Dismissing the perfect market line of thought will tend to also require dismissing benefit estimation techniques based on market behaviour. This is particularly the case in cost-benefit studies that use estimates of, for example, willingness to pay for reductions in risk of injury or death (e.g., Gegax *et al.* 1991; Moore and Viscusi 1988) or that use observed wage differentials across employments judged to be similar in most respects, except for the risks to which they expose workers, in order to estimate the cost of safety (e.g., Rosen 1986; Knieser and Leeth 1991). These are vulnerable to the same criticisms on the grounds of both efficiency and equity. The occasions when they are sufficiently immune to such objections always need careful assessment. In general, we think that the usual presumption has to be that the distortions are large and significant. So it is the use of market-based, benefit estimation techniques, rather than their rejection, that needs explicit justification on a case by case basis.

That was our Scylla. If it can be skillfully sailed around, the would-be evaluator is likely to be confronted by our Charybdis: the human capital approach.

The human capital approach

The human capital approach dates back to the earliest attempts at applied economics with William Petty (1691) and William Farr (1853). Petty discounted estimated wages to infinity to compute a capital value, while Farr discounted the difference between future income and an estimated cost of future maintenance, adjusted for the probability of death (for details on discounting see Chapter 12). That, essentially, is the approach adopted today by those using the human capital approach such as Health

Canada (1998). It is, to put things rather sharply, tantamount to treating humans as though they were carthorses. They are good only for what they produce, after deducting what they cost in fodder and watering (for details on this criticism, see Pritchard and Sculpher 2000). The approach neglects any benefit to individuals that is not work-related, as for example, the direct benefit of being free from pain, or not depressed, or not severely stressed, or able to move about. It neglects the value to individuals of leisure time, and it also fails to consider any external valuations of people's time, such as valuations by their families and friends.

The method is particularly vulnerable to equity objections. If one person's human capital is worth twice that of another, then it will be worth expending twice as much to avoid losing a certain fraction of it. So those who have expectation of monetarily productive life will have further benefits heaped upon them in the shape of safer workplaces and better rehabilitation.

Of further detriment to the approach is that it is not grounded in any modern welfare economics theory. The conventional neoclassical position is that the appropriate valuation of a reduction in the probability of loss of life is a person's willingness to pay for such a reduction. Although subject to the same objections on the grounds of equity as the perfect market method, it is less susceptible to the efficiency objections provided that the willingness to pay can be obtained under appropriately controlled experimental conditions, and provided that external effects are taken into account (Jones-Lee 1989; Jones-Lee *et al.* 1985). The obvious alternative to willingness to pay to avoid a harm is willingness to be compensated for accepting it, but this too is not captured by the human capital approach.

Matters become more complicated if the maximand is more comprehensive. For example, estimates of the benefits over a working lifetime of a workplace safety intervention will underestimate the total productive value of a life by assigning a zero worth to childhood and retirement. If averted productivity losses are simply added to other types of estimates, such as averted losses of health and the averted costs of health care, there is the risk of serious double counting. Depending on the construction of a health outcome measure, the value of work and its contribution to one's standard of living over time will already be embodied in the measure. If already included, the only productivity component that ought to be added is the friction cost associated with replacing a worker such as delays in replacement, cost of recruitment and training, etc. (Koopmanschap *et al.* 1995; Koopmanschap and Rutten 1996; see also Chapter 11).

Does the difference matter? The difference in question is that between treating people as carthorses on the one hand and as sentient flesh-and-blood people (not mere consumers either) on the other. The issue arises from the fact that humans are both factors of production and also sentient beings. In some cases public policy emphasizes the productive role of people, and in others their human characteristics. The tension in public policy arises from the fact that the best estimate of benefit that the human capital approach can hope to achieve is a precise measure of the market productivity of workers. The best to be hoped for from an alternative based on an evaluation of the consequences for the quality of a person's life, is a set of relevant and believable measures of characteristics of people and their working environments— features that are not directly marketed at all. Those characteristics are essentially health and safety.

Health services are marketed, and so are goods and services that contribute to safety, but health and safety as such are not. They are like the environmental characteristics of societies that are not marketed even though they have impact on the prices of assets such as houses (e.g., pollution, noisiness, and beautiful views). They may not even be marketable, and so cannot be included in the measures of national accounts.

We do not go so far as to say that the human capital approach ought never to be used. However, it should always be accompanied by explicit acknowledgment of its shortcomings, and used only if the client for the analysis insists upon it after having considered the alternatives.

The decision-maker approach – the safe passage?

Having successfully negotiated a passage around both Scylla and Charybdis, we now turn to our suggested way forward. It may have become clear by now that underlying the discussion so far is a centrally recurring issue that relates to objectives, i.e., what are we trying to accomplish, and on whose authority? Addressing this question occupies the rest of this chapter.

Implicit in the perfect market approach is the maximand of the total sum of expected utilities. Implicit in the human capital approach is the maximand of national income, Gross Domestic Product or Gross National Product. Implicit in many ergonomic studies is the maximand of worker safety. In others, the criteria are narrowly commercial and the implicit maximand is profit. Implicit in many health care evaluations is the maximand of health. A related set of issues concerns matters of equity. How is fairness or social justice defined, on whose authority, and how ought they to be embodied in economic evaluations? Addressing each of these issues requires the exercise of judgment and, in particular, that critically important subset of judgments generally known as social value judgments. We turn to these now.

Making the unavoidable value judgments explicitly

There are at least three broad approaches that a reasonable person might adopt in addressing the value judgments embedded in methods of evaluating workplace interventions. The first is to adopt an ethical convention commonly employed in a particular discipline, conventions such as ‘workplace safety’ or ‘utility maximization’. Two advantages to such a choice are that it has probably been thoroughly worked over and understood and that one can communicate with fellow disciplinarians on the basis of an immediately shared understanding of concepts, theories and their applications. However, this approach has little intrinsic ethical merit, and some downsides are that the convention’s weaknesses may have been glossed over or largely ignored. Thus, maximizing workplace safety carries the baggage that it suggests every reduction in workplace hazards as worth undertaking. Utility maximization carries the baggage that it is only individual welfares of a particular kind that matter. Moreover, though communication with fellow disciplinarians may be facilitated, communication with fellow transdisciplinarians may be difficult.

The second approach is to seek to discover what society thinks are the appropriate value judgments to make. In pursuing this line, one might trawl public utterances by those with public responsibility, such as departmental ministers, to discover whether labour market, health, or employment policy is about maximizing, utility, national income, health or something else. This is not an easy task, but if accomplished will

give an analysis the moral authority that the previous approach lacked, as well as a direct communications bridge of understanding. The main reasons why this is not an easy task is that public utterances of the required sort are few in number, nearly always ambiguous, at an unsuitably high level of generality, and often contradictory. Moreover, there are major empirical problems of construct validity and measurement which remain. There is a further problem: the list of possible maximands rises as one trawls ministries. This gives rise to three questions. First, is it sensible somehow to combine the plurality of objectives in an overall social welfare function? Second, how are the trade-offs between them to be made? Third, what ought the analyst do about any omitted plausible aims and objectives that no one claims for their own?

The third approach is to create a professional scientific consensus, a kind of reference case (Gold *et al.* 1996), that permits all potential perspectives, objectives and trade-offs to be taken into account, and that for any particular study design enables the scope of the analysis, including its perspective, to be selected according to the values and intentions of the stakeholders on whose behalf the study is done. The consensus group we have in mind is the multidisciplinary and multi-professional group of researchers who investigate the merits of OHS interventions.

This third approach might involve guessing at what the public utterances would be if they were made less ambiguously and without contradiction, and adopting them as one's ethical basis. Alternatively, it might involve seeking a consensus from the ranks of fellow scientists, or seeking a consensus from amongst those deemed to be stakeholders. It might be eclectic, seeking to approach evaluative questions in a flexible way, depending on who were the main clients for the research, or in multiple ways by evaluating workplace interventions from more than one perspective, thus exposing important possible differences in the values of different stakeholders.

We think it is worth trying to build a professional scientific consensus based on a reasoned attempt to distil what government, workers, workers' families, employers, workers' compensation boards, health and safety regulators, other third party payers, indeed any stakeholder is seeking to achieve. It can be changed as the distilling becomes more refined, or as the things distilled themselves change with the changing political scene. It would be desirable to adopt practical tools derived from it that are used elsewhere in the same jurisdiction. This may be the best way forward on the grounds that, done well, the professional approach may come to be seen as 'the approach': the one most persuasive on ethical grounds and, with time, the one most acceptable through familiarity and clear understanding.

A pragmatist objects

In the health and safety literature there is a robust tradition of pragmatism, so one may readily anticipate a pragmatic objection. It runs along the following lines: theoretical discussion of means and ends, efficiency and equity, science and ethics, social welfare and the like are rather beside the point. The real point is that decisions on health and safety are taken on the basis of their impact on the bottom line. Do they enhance productivity and, if so, do they do so sufficiently to warrant their undoubted cost to employers? That is all there is to it. The only question for the analyst is to measure the bottom line effect. There can be little doubt that this has been the focus of much of the evaluative literature on workplace health and safety interventions in the past. More recently, researchers have begun to pay attention to the measurement of health

effects— but still largely for instrumental reasons, that is, that they generate beneficial productivity and hence bottom line consequences. The hope, of course, is that business managers will be more likely to listen to health and safety staff, who are all too often at the margins of operational decision-making, and become allies in the diffusion of interventions for safety throughout the business.

This is a powerful argument. Even though it makes fairly heroic assumptions about what it is that motivates management, it is an argument that scientists ignore at their peril. The pragmatist is, however, only half right. The bottom line does indeed matter and the impact of interventions on it needs to be evaluated. But the employers' bottom line is not the only such line and it would seem wise to consider the balance of advantage over disadvantage from all relevant points of view. Moreover, in order to know whether the intervention is one worth supporting in the first place, a broader evaluative framework is implied that takes everyone's interests into account, including the distributional and redistributional consequences.

Two critical levels of analysis

We propose that there are two critical levels at which evaluative research must operate. One level addresses the question 'ought this intervention to be adopted?' The second level addresses the question 'what is the best way of encouraging the intervention in question to be adopted?'

The first question seeks to discover what ought to be done. The natural perspective from which to consider this question entails a social value judgment which we suggest be as uncontroversial as possible. Therefore, we propose that the perspective from which this question is addressed be explicit and universal. Our suggestion is for the perspective also to be the societal one: that is, inclusive of the health and safety consequences for all possible stakeholders. The advantages of this approach are several. First, it becomes clear which benefits and costs, and to whom, are to be included, so that any bias arising out of a less than comprehensive inventory is exposed and minimized. Second, its starting point is one in which any cost or benefit can, in principle, be included in the analysis, making the informational content as complete as possible. Third, for practical purposes it enumerates an agenda of costs and benefits that can be further considered by the decision-making clients for inclusion or exclusion according to their, rather than the analyst's, values. Fourth, it enables a comprehensive view of distributional and redistributional effects to be taken into account, so that they can be traced, assessed and their acceptability addressed. Distributional effects are usually important factors in determining the social desirability of interventions. This inclusive and universal perspective was also that proposed by the Washington Panel (Gold *et al.* 1996).

The second question addresses issues of whose interest it is, or is not, for the intervention to be adopted, what instruments might be needed in order to persuade those whose interests it does not match voluntarily to adopt it, or what instruments of regulation and control might be used that force them involuntarily to adopt it. In most cases the benefits and costs of greater health and safety will not be distributed equally across all stakeholder groups. This asymmetry should not to be ignored by analysts, and empirical research that seeks to assess the significance of such costs and benefits, whether quantitatively or qualitatively, seems to be the best way to work out what type of encouragement (e.g., a subsidy or some form of cost sharing) might be

effective in gaining consent in circumstances where the workplace decision-makers are not convinced of the dominance of advantage over disadvantage from their own perspective. It seems also to be wise for researchers to establish the likely size and location of any political resistance that would arise to regulatory solutions. Here the emphasis is not on the inherent fairness or unfairness of the consequences of an intervention but on its acceptability to all affected parties, in order to focus on the policy implementation issues of persuasion, compensation and enforcement.

A specific proposal and some of its implications

We seek to define a value-laden end which can serve as the basis for evaluating OHS interventions, one that is relatively immune to the criticisms of the perfect market approach, one that does not treat people as carthorses but is infused with a clear humanity, one that will enable comparisons to be made across similar activities within the jurisdiction, such as health care and road safety, so as to avoid significantly different investment criteria being used, one that preferably uses or adapts instruments that are widely available and whose characteristics are well-understood, one that will enable matters of fairness and distributive equity to be addressed explicitly and analytically, and one that addresses the informational needs both of workplace parties and of the wider community.

To this end, we propose three broad framework principles for evaluative analyses. The first ethical proposition is:

(1) The prime objective of health and safety interventions is to enhance the expected health-related welfare of individuals in the workplace. It is not to enhance expected utility or national income.

Supplementary objectives might include health-related welfare effects on others, such as family members and care givers, effects described earlier as externalities. The perspective from which such evaluations ought to take place is thus narrower than the societal one advocated by many economists (e.g., Gold *et al.* 1996) but it is different from and broader than the narrow focus on the business bottom line. It will be necessary to determine the scope of cost effects that one routinely ought to take account of, as in a reference case (Gold *et al.* 1996). This step also involves making social value judgments. There is a strong case to be made for flexibility in the choice of perspective, since studies may reasonably take different views on the grounds that responsibility for managing resources varies from one situation to another. Common to all evaluations is a focus on those working in the workplaces and likely to participate in, benefit from or incur costs as a result of the interventions. Where the emphasis should lie in any particular study will be a matter for prior determination by researchers working with research commissioners. The second ethical proposition is:

(2) The perspective of particular evaluative studies will be determined in conjunction with relevant stakeholders and supplemented where necessary by analyses that incorporate significant external effects.

The purpose here is to enable a clear focus on both the pragmatist's concern, such as the bottom line, and the wider interests of other stakeholders. To take an extreme example, a costly workplace intervention whose benefit falls entirely on workers and

their families in the form of health and which has no productivity impact, may be amply justified in social terms, but may not be in any individual employer's interest to implement.

The third ethical proposition concerns equity:

(3) Economic evaluations should, in addition to considering efficiency, identify potential equity issues of significance in conjunction with stakeholders and always present results in a way that reveals how the incidence of costs and benefits falls both immediately and after any predictable market adjustments have been made.

The distribution of costs and benefits is important not only so that matters of equity can be addressed, but also in order to facilitate thinking about how an intervention might best be implemented. Identifying the incidence of costs and benefits is more difficult than may appear at first to non-economists in that changing costs of production will usually generate consequential changes in the type and amount of resources that businesses will employ, with further consequences for prices and wages (see Box 5 for definitions). Thus, a cost that may initially appear to be borne by employers might, as time goes by, come to be passed on to consumers in the form of higher prices and/or to workers in the form of lower wages. Such effects will have implications not only for the assessment of the desirability of an intervention but also for that of its implementation. For example, there seems little point in compensating employers for cost-increasing measures if the negative consequences for employers have been passed on to the consumers in the form of higher prices of their products.

Box 5: The meaning of incidence in economics

Incidence in epidemiology: the number of *new* cases of a health condition occurring in a population during a period of time (compared with ***prevalence***, which is the number of cases of a health condition in a given population at a specific date).

Incidence in economics: the entities that bear the cost of an intervention or receive its benefit (compare ***initial incidence***, which is the apparent or legal impact, with ***final incidence***, which is the impact after all consequential adjustments have occurred).

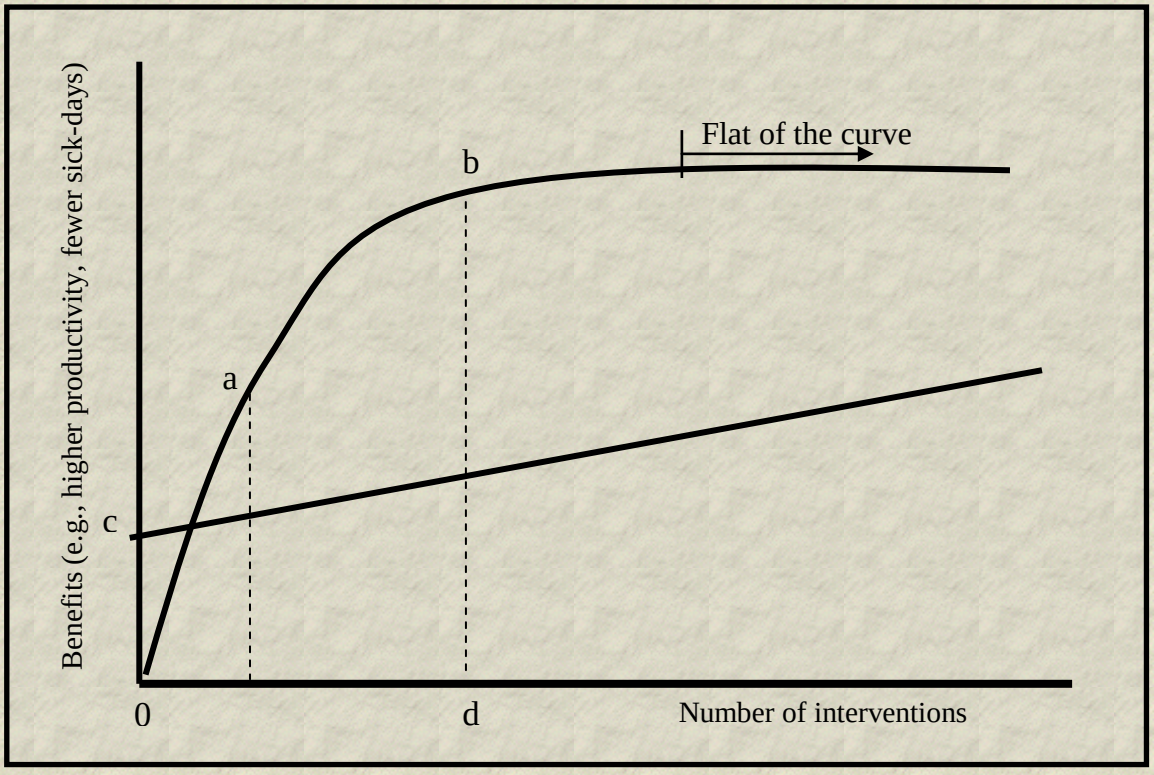
There can be a considerable difference between the two kinds of economic incidence, initial incidence and final incidence. For example, employers might be taxed, whether for OHS or other purpose, but the tax may be effectively shifted to employees and/or consumers. The extent to which this happens depends on the motivation of the firm and the characteristics of demand and supply.

What is a little more health and safety worth?

A little more health and safety is not of infinite value. If it were, economic evaluation of workplace interventions to enhance health and safety would be unnecessary. The need for evaluation arises because the benefits are not infinite, because they are uncertain, because they come with a price tag and because each of these has an impact that is different from one stakeholder group to another.

Taking a broad view across an economy, it seems highly likely that the relationship between the size of benefit and the number of interventions will be non-linear. A stylized example is portrayed in Figure 2. In this example we assume that interventions are ranked from left to right in descending order of their additional contribution to the benefit. Thus on the far left, machine guards are fitted to those machines most likely to cause serious injury. As one moves rightward, there lie guards applied to machines that are less likely to cause a hazardous event and/or have events that are less damaging. On the far right are guards applied to machines that pose virtually no threat to health and safety at all. The cumulative benefit always rises as the number of interventions increases, though it does so at a diminishing rate. At any one time an economy may be located at particular points on this curve such as *a* or *b*, where *b* represents an economy that has invested more in health and safety than the economy at *a*. A more realistic picture might be that different sectors of an economy are at different points. So, if we suppose that the manufacturing and the transport sectors each face the same functional relationship shown in the figure, one sector may be at point *a* and the other at point *b*.

Figure 2: Conceptualization of the relation between interventions and consequences



Even if we had sufficient information to form a judgment about the shape and height of the curve in Figure 2, this would be insufficient to determine where on the curve one ought to locate. The flat of the curve is an unlikely segment to choose but there is plainly much scope for choice in the region to its left. The missing information is the costs of the interventions, which we may assume not to fall as interventions increase. Making the simplifying assumption that these are constant at the level *c*, the optimal location is determined at point *d*. Additional interventions beyond that point cost more than the amount of benefit they bring. At points to the left of *d* additional interventions add more benefit than they cost. Any such judgment depends critically on consideration of all the costs and benefits that are deemed relevant.

Despite its high degree of simplification, Figure 2 represents the essential character of the solution to the question ‘what is a little more health and safety worth?’ The answer depends on a balancing of cost and benefits, disadvantage and advantage with a presumption that those projects whose benefits exceed costs ought to be adopted and those for which that is not true ought not.

The rest of the book will develop this fundamental model and extend it in various ways, for example, by including distributional consequences in the evaluation, taking account of risk and uncertainty, the duration of costs and benefits, and exploring in greater detail the characteristics that make for high quality research studies of workplace interventions.

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Lessons from Health Technology Assessment

Anthony J. Culyer and Mark Sculpher

Introduction

Economic evaluation is widely used to assist decision making in health care. The forms most commonly met are cost-effectiveness analysis (CEA) and cost-utility analysis (CUA). These methods are well-suited to one of the objectives common to many health care systems in developed countries, which is to maximise health subject to a budget constraint. One of the reasons why many societies do not rely completely on private markets for health care and health insurance is that markets are imperfect and do not always generate efficient outcomes. Another reason is that societies may have strong views on distribution of health and health care, issues that are not easily addressed through private markets alone.

The more common market imperfections in health care include the presence of professional and industrial monopolies, asymmetries of information between providers and consumers, imperfect agency relationships between health professionals and patients (and third party payers and health professionals), supplier-induced demand, externalities, incomplete markets for health care and health insurance, adverse selection, moral hazard, and the fact that individuals with limited ability to pay often have the greatest need for care (for a more complete review of the implications of these factors, see Culyer 1991). While the markets for many goods and services are characterized by the presence of some of these features, few are so thoroughly imbued with all of them. The workplace health and safety field has many of these same characteristics as health care (see the discussion in Chapter 2 for details) and, in addition, is markedly affected by the ways in which the labour market operates, which is beset by further market failures.

In light of the weaknesses of much of the economic evaluation work that has been conducted to date in workplace health and safety (see Chapter 3 for details), there is good reason to consider the lessons that can be learned from health technology assessment, where methodologies and the use of economic evaluation in policy decision making are much more advanced. Hence, in this chapter we draw on the experiences in health technology assessment to inform the use of economic evaluation in occupational health and safety (OHS), and touch on some of the problems that arise in connection with the application of these methods in health and safety interventions,

especially those that differentiate their application in this field from applications in health care. We also provide a checklist to help researchers to design better studies, and to help researchers and research consumers alike to assess the quality of studies better than has usually been the case. Finally, we discuss the arguments for developing a reference case.

Economic evaluation in the policy context

Policy context in health care

As has just been noted, economic evaluation has been used widely in the health care sector as a key element in funding and formulary decisions, clinical guideline development and other health policy planning. However, establishing the cost-effectiveness (or its absence) of various interventions in the health care setting is a costly undertaking and in general is prohibitively expensive for individual hospitals, small health regions or even provinces like those found in Canada. For this reason, high-level arms-length bodies have emerged such as the National Institute for Health and Clinical Excellence (NICE) in England and Wales, the Pharmaceutical Benefits Advisory Committee in Australia and the Common Drug Review process in Canada, which provide evidence on the economic merits of health technologies and which are intended to inform national decision making. These organizations review existing evidence related to the costs and consequences of health care interventions and employ standard evaluation techniques in order to make recommendations to regulators, drug plans, health regions or governments (regional and national). Likewise, in a workplace health and safety context, there may be interventions of relevance to many industries, firms, and workers, but it will often be too costly for individual firms to evaluate them and the benefits of doing so will flow well beyond the confines of any individual organization. This suggests that health and safety evaluation studies have some of the characteristics of a public good and that those which are undertaken will often be of use to a number of organizations, particularly if such studies were to present results in a way that facilitated both a comparison with other evaluations and an assessment of generalizability of the results.

A dual purpose in the evaluation of workplace interventions

In health care, economic analyses typically take a single perspective (such as that of the payer or health care system as a whole), whereas in other contexts there is value in studies considering costs and consequences from a range of different perspectives such as those of employers, workers, workers' families, injured workers' care-givers, insurers, and public authorities. This is likely to be the case in evaluating workplace interventions.

Considering multiple perspectives highlights two possible information roles for economic evaluation. First, it serves to identify those interventions that are worth undertaking from whichever perspective is selected. This purpose is, therefore, that of helping decision makers to form a view as to whether, on balance, an intervention ought to be adopted. Second, evaluations can help to identify the reasons why some apparently worthwhile interventions are not adopted by highlighting the way in which the gains and losses from implementation are distributed across different groups. For example, a workplace intervention whose benefits accrue mainly to workers but whose costs fall mainly upon employers is less likely to be implemented, even if overall benefits exceed overall costs, than one in which the benefits and costs are both

realized entirely by employers. Not all evaluations of interventions will meet the criteria of a full-scale social welfare maximization exercise, since the informational requirements of such an analysis are substantial. But they can still provide information to workers and employers that can be used in the bargaining process, thereby reducing asymmetries of information, and they can increase the information available to higher-level decision makers seeking to form an overall judgment of the worthwhileness of inventions of various kinds.

We shall assume that both information roles are equally as important. The first helps to establish the social worthwhileness of interventions (and their appropriate scale), and the second helps to identify the steps that might need to be taken in order to ensure implementation, either voluntarily, through regulation, or through subsidy. In addition, the second role can help identify specific distributional matters that ought to form part of the assessment of social worthwhileness seen through the lens of equity or social justice.

The methods of economic evaluation

The National Institute for Health and Clinical Excellence (NICE) in the UK, more than any other health care agency, has made the use of economic evaluation a key decision tool for public policy regarding the introduction and manner of use of health care technologies. Given the parallels between the challenges faced in the health care sector and those in OHS, there is clearly value in examining the ways in which agencies such as NICE have employed standardized economic evaluation techniques to inform the resource planning process across diverse groups (patients, care providers, insurers). We draw on their experience in the rest of this chapter.

Different types of analysis

There are broadly four kinds of economic evaluation, each of which can be found in the literature of health economics: cost-benefit analysis (CBA) (sometimes called benefit-cost analysis), CEA (sometimes called cost-efficiency analysis), CUA, and cost-minimization analysis (CMA). In addition, cost-consequence analysis (CCA) compares disaggregated costs and consequences of options without attempting to add or combine them in any way, leaving these tasks to the decision maker (see Box 1 for summary descriptions and Chapter 9 for details). Although cost-consequence analysis has generally been thought to fall short of a full economic evaluation in health care, it is often a useful precursor to a full-fledged analysis and it is a helpful framework for dealing with multiple perspectives. For the purpose of our discussion here, it suffices to say that the primary difference between the various types of economic analyses is the metric used for the key consequences (the terms ‘benefit,’ ‘outcome,’ and ‘effect’ are also used regularly in place of ‘consequence’).

Box 1: Types of economic evaluations

cost-benefit analysis (benefit-cost analysis): compares the costs and the money-valued benefits of various alternative courses of action.

cost-effectiveness analysis (cost-efficiency analysis): compares the opportunity costs of various alternative courses of action in terms of a common unit of outcome. Used when benefits are difficult to value monetarily, when it is socially unacceptable to do so, and when those that are measurable are not commensurable, as when the objectives of the system are in terms of health itself.

cost-utility analysis: a close relative of cost-effectiveness analysis (and sometimes referred to as such) but which measures benefit in standardized units such as Quality-Adjusted Life-Years (QALYs). It takes its name from the use of utility type measures of outcome.

cost-minimization analysis: a simplified form of cost-effectiveness analysis, in which cost is the dominant determining factor in a choice between alternatives, as the outcome or the value of the outcome is for practical purposes the same for each alternative.

cost-consequence analysis: compares disaggregated costs and consequences of options without attempting to add or combine them in any way.

Although there are important differences between the different types of economic evaluation (see Sculpher *et al.* 2005), they have shared features. Each requires the calculation of present values of cost and benefit using a social discount rate. Each requires the systematic comparison of all the relevant effects of proposed alternative interventions with a view to determining: (1) which intervention, scales of intervention, or combination of interventions, produces the best outcome (either minimum cost or maximum difference between benefits and costs) or (2) the magnitude of the benefit that can result from interventions having similar costs. Depending on the perspective of the analysis, costs falling on different affected parties (e.g., health system, patients) will be included. Each customarily uses sensitivity analysis for assessing the robustness of the conclusions in the face of variations in the assumptions and uncertainty in the evidence used. Other common characteristics are explicitness in the objectives, assumptions and methods, and consistency in the principles guiding the choice among alternatives.

Opportunity cost

Each type of economic evaluation relies on the concept of opportunity cost. Opportunity cost is the value of a resource in its most highly valued alternative use. In a world of perfect markets in which all goods are traded, opportunity costs are revealed by the market prices of resources, since these prices represent the lowest sum of money required to bid the resources away from their most highly valued possible alternative uses. Where the stringent conditions required for perfect markets are not met, opportunity costs and market prices can diverge and true opportunity costs (shadow prices) may need to be imputed. The opportunity cost of a resource already owned by an organization is not usually revealed through a market price. The best

alternative may be an alternative use within the organization but it is not revealed by competitive bidding between managers but through planning processes, with the opportunity cost being elicited through discussion and judgment, without the cost necessarily being cast in terms of money.

One example of the importance of opportunity costs arises in health technology assessment when a budget-constrained health care system is considering funding a new technology which will impose additional costs. To balance the budget an existing technology/program will have to be removed. The aim of economic evaluation methods is to assess whether the benefits of the new technology outweigh the opportunity costs.

Opportunity costs should not be confused with transfer payments. When trades take place in a monetized economy, payments reflect the compensation required for resource owners to part with something of value. Transfer payments, on the other hand, are not made in exchange for resources and so do not measure the value of any such resources. They are merely a transfer of purchasing power from one individual or group to another. Box 2 identifies alternative concepts of costs and prices. Chapter 10 elaborates on these constructs. In general, opportunity cost cannot be defined independently of the decision-making context, since it involves identifying the expected consequences of alternative courses of action, and so cannot simply be read off conventional financial accounts.

Box 2: Alternative concepts of costs and prices

opportunity cost*:* the value of a resource in its most highly valued alternative use.

market price*:* the price of a resource in the market. This price may reflect the marginal value of resources embodied in the good or service if the market operates well.

shadow price*:* the price a consumer is willing to pay for one more unit of a good or service. This is a reflection of the opportunity cost, but may differ from the market price if there are constraints in price and/or restrictions in supply. It is the equilibrium price in a perfect market.

transfer payment*:* a transfer of purchasing power from one individual or group to another that is not a compensation for parting with the ownership of something (like a consumable item or labour). Usually made for the purpose of social equity or, as is the case with subsidies, to provide incentives for people to behave in particular ways.

Analytic perspective

'Analytic perspective' refers to the nature of the analyst's role and task in the context of an economic evaluation. One common perspective is often termed the 'social decision-making perspective'. Under the social decision-making perspective, the analyst addresses questions of concern to, and the values of, the decision maker or the organization in which (s)he operates. In one form of this, the analyst plays the role of consultant, having the social decision maker as client. In another, the organisation has

its objectives and constraints explicitly defined, for example by a higher policy making body, and these can guide the analyst. Another analytic perspective is termed the societal perspective. This usually entails the analyst defining a more or less broad concept of social welfare and making explicit the social value judgments involved in so doing. With this approach there is the risk that the analyst adopts criteria that are seen as irrelevant by real world decision makers. Other perspectives are more particular, for example those of the owners of businesses, or (not the same thing) the managers of businesses, or unionized workers, or all workers, or workers' families, or third party payers (such as workers' compensation boards). The things that count as benefits and costs, and that get caught up in externalities, can vary significantly depending on which viewpoint is adopted. A major guiding principle of all economic evaluations is consequently that the analytic perspective must be stated explicitly so that readers can assess for themselves the consequences by way of inclusion or exclusion of the various possible effects for the decisions informed by the analysis.

Value judgments

All forms of economic evaluation require value judgments. The choice of perspective itself commits the analyst to particular value judgments. In addition, the analyst needs to make other critical choices, all of which involve value judgments, some of which may be more specific and precise than the ones directly or indirectly implied by the values embodied in the chosen perspective. For example, a perspective emphasizing health may specifically entail selecting the QALY as an outcome; a perspective emphasizing social cost may specifically select costs falling on the public sector; and a general requirement for equity may need specific decisions relating to the weighting of consequences based on whether a dollar is gained/lost by stockholders or workers. A decision to treat monetary consequences with equal weights regardless of who is experiencing the loss or gain is not a means of escaping the value issue. On the contrary, it is to make a very specific value judgment, which is that it is appropriate to value each dollar of consequence equally.

Evaluation of interventions – the health technology assessment experience

In the health care field the word 'technology' is used quite broadly to refer to 'a means of accomplishing something.' It includes the use of health care technologies such as scanners, prescription drugs, bed rest, and watchful waiting. Although less frequently encountered there, it applies also to the evaluation of technologies of governance and managerial arrangement. Counterparts in OHS might be the use of machine guards or ergonomically designed workstations and the use of OHS management systems.

Health technology assessment (HTA) has had an increasingly prominent position in health care policy internationally. Although much HTA research has been funded and published since the late 1960s, it was not until the mid-1990s that it gained a formal foothold in policy making. In the last decade, many health care systems in developed countries have decided to inform decisions about the adoption of new health interventions by use of economic evaluation of the clinical and epidemiological evidence. While these requirements have been applied principally to pharmaceuticals, the range of technologies requiring such evidence before adoption has tended to be broadened over time (for example, public health interventions were added to NICE's

range of responsibilities in 2005). A formal requirement for economic analysis to support reimbursement or coverage began in the public systems of Ontario, Canada (Ministry of Health 1994) and Australia (Commonwealth Department of Health 1992), but have since spread widely (Hjelmgren *et al.* 2001). Australia, Belgium, Canada, England and Wales, Israel and Scotland have all published guidelines for economic evaluations as inputs into decisions about coverage and reimbursement (Tarn and Smith 2005).

The methodology of economic evaluation has developed rapidly over the last 40 years. The research methods used for health care system decision making today are much more sophisticated than those employed in the past. Early economic evaluations commonly assumed (often only implicitly) that the objective of health care was to maximise gross domestic product. This may be illustrated by an analysis of the economic consequences of preventing the birth of babies with Down's Syndrome through screening (Hagard and Carter 1976). In this study the benefits of screening were seen in terms of avoiding the costs of caring for and educating a child with Down's Syndrome, implicitly assuming that there was no intrinsic or even human capital benefit to a life (Culyer 1987). As noted in Chapter 2, the naive human capital approach to valuing the benefits of health care fails to recognise that individuals value health for reasons other than the productive potential it generates and they value lives for reasons other than the gross domestic product each life may manufacture (net, of course, of human maintenance costs) (Mishan 1971; Blades *et al.* 1987).

For much of the subsequent period it became increasingly clear that there were serious tensions between the principles of standard welfare economics (essentially the societal perspective described above) and a more flexible and decision-oriented perspective on evaluative research towards which many health economists were leaning. Though standard welfare economics gives clear guidance on what is meant by efficiency, how costs and benefits should be measured, what perspective should be taken, and whether the adoption of a new health technology improves social welfare, it has strong normative underpinnings which require leaps of faith to accept (Sculpher *et al.* 2005).

Essentially, welfare economics has a number of significant and controversial implications for evaluation in health care. The first is that heath care programs should be evaluated in the same way as other programs. The concern here is that standard welfare economics relies on a particular construct of efficiency known as a 'potential Pareto improvement' measured by a compensation test like 'can the gainers compensate the losers – either in theory or practice – and still retain a net gain?' The criteria are meant to ensure that there are no utility losses after suitable compensation, only utility gains, since the principles of welfare economics do not allow one to make a direct comparison of the value of utility losses to one individual with the value of gains to another (see Box 3 for more detailed definitions). An outcome where there are some utility gainers and no net utility losers is considered to mark an unambiguous gain in social welfare.

The standard welfare economics approach is not well-suited to addressing matters such as whether an intervention improves life expectancy or health, which is the standard clinician's or health policy decision maker's question. It focuses on the much more obscure matter (from clinician's or policy maker's viewpoint) of whether the

intervention improves utility. The clinician's or health policy decision maker's approach is, however, the basis of outcome metrics known as health-related quality of life (HRQL) measures and many health economists essentially adopt an approach that is based on the idea that health services exist primarily to create health rather than utility.

Box 3: Pareto constructs

Pareto criterion of efficiency: An allocation is considered efficient if there is no way to reallocate resources (with compensation to losers) such that one or more individuals is made better off without making someone else worse off in terms of their net utility. This is a very restrictive concept of efficiency, since it limits the types of reallocation that can be made.

Potential Pareto improvement: This is measured by a compensation test like 'could the gainers in principle compensate the losers and still retain a net gain?' It is a less stringent criterion than the Pareto criterion of efficiency, since it allows net utility losses and gains.

A second controversial aspect of welfare economics is an implicit view that the current distribution of income is, if not optimal, then at least acceptable (Pauly 1995) and that the distributive impact of a decision based on economic evaluation is, or ought to be, negligible. Other controversies include the conditions of rationality and consistency that are required for individuals to maximise their utility, which have been shown to be violated in most choice situations (Machina 1987), and the problem of second best (e.g., Ng 1983), whereby first best solutions in a second best world (i.e., a situation where only some of the conditions of the ideal solution are met) may actually represent a reduction in social welfare as defined by the potential Pareto criterion.

There is an alternative to the standard welfare economics approach to economic evaluation in health care. In the United Kingdom and elsewhere, an approach described as 'extra welfarist' (Culyer 1991) has provided the methodological foundations of economic evaluation in health care (see Box 4 for details). It is a version of the social decision-making perspective and uses cost-utility analysis rather than CBA. It is based on an exogenously defined objective (such as population health maximization) and an exogenously determined budget constraint for health care. The efficiency problem is thereby transformed into another constrained maximization problem (i.e., how to maximize the amount of incremental health produced by a given budget). This pragmatic approach is well-suited to partial analyses that assume that there are few significant repercussions of health care decisions beyond the health sector itself. Correspondingly, it is not well-suited to the analysis of inter-sectoral choices, where the outcome measures will typically be different and pose major issues of relative valuation, and where opportunity costs may become difficult to identify.

Box 4: Welfarism and extra-welfarism

Welfarism in economics: the welfare economics approach is based on individual utilities and preferences, expressed through market or shadow prices, as the basis for the evaluation of efficiency.

Extra-welfarism: the extra-welfarist approach in health care views health as the maximand rather than utility or social welfare. The concept of 'health' may or may not be based on the preferences of the target population.

One of the implications of using the extra-welfarist approach in health care is that it facilitates a multi-disciplinary outlook to the research, requiring the identification and synthesising of relevant clinical and other evidence; mathematical models to characterise the natural history of a given disease and the effects of interventions; the definition of measurement and valuation of health gain; and quantification and valuation of the resource implications. Hence, major contributions to this research are made by various disciplines including clinical science, cognitive psychology, decision science, epidemiology, medical statistics, and operations research, in addition to economics.

Differences in the sources and treatment of bias

A major difference between the information available for an economic appraisal in health care compared to that available for workplace intervention evaluation is the character and treatment of bias. In evaluating the effectiveness of medical technologies (in particular drugs), randomisation is often used in clinical trials to control for potential confounding factors, whereas this is rarely possible in workplace intervention evaluation. Both the location and the size of workplace evaluations rarely permit randomization. Thus, it becomes necessary to anticipate confounders as best as may be possible—for example by measuring them explicitly in observational studies for subsequent multivariate analysis or, minimally, by exercising well-informed judgment. The careful use of sensitivity analysis often enables the identification of omitted variables or poorly measured ones, as well as giving an indication of the extent to which the changes in outcome attributed to the intervention are robust.

A second source of bias relates to the decisions made by the analyst about the costs and consequences that are to be measured, how one is traded off against another, and how to add them up across different individuals (see Chapter 2 for a more detailed discussion of these issues). These matters may be of less concern in health care because costs and consequences are less often distributed across such varied categories of stakeholders. In general, there is no right answer to these questions. The answers are likely to be controversial and raise major questions of policy, politics, ethics and public acceptability. This is not an argument for helplessness, for the identification of such issues is an important part of the decision making process and any measurement of relevant dimensions will usually be helpful. The conclusion therefore is that analysts ought to be open and explicit about the value content of their analyses, to face up directly to the challenges that rival values might pose, and whenever useful, to subject value judgments to the same kind of sensitivity analysis that is recommended for design attributes. The merit of this approach is in identifying value judgments that do or do not, as the case may be, affect the major results of the

analysis, and providing decision makers with such evidence about values that may have a bearing on their decisions.

A brief description of current key methodological guidance

As economic evaluation has become more widely undertaken and formally used in health care decision making, much energy has gone into developing methodological guidelines for researchers. In general, these can be divided into two categories: guidelines developed as a scientific statement of good practice in the field, and guidelines issued by particular decision-making agencies to define the approach to economic evaluation deemed to be appropriate in their jurisdiction.

With regard to scientific statements of good practice, two particularly authoritative documents are worth noting. The first is a widely known textbook, *Methods for the Evaluation of Health Care Programmes*, now in its third edition (Drummond *et al.* 2005). A consistently important element of this book since its first edition has been its inclusion of a methods checklist for critiquing economic evaluation studies. An adaptation of this is reproduced in Table 1. Essentially, the checklist focuses on the need for clear description of a study and the use of those methods that are considered to be good practice in economic evaluation. The list emphasises key aspects of a sound evaluation such as explicitly stating the perspective used in the analysis, using incremental analysis, discounting future costs and consequences, and giving adequate attention to uncertainty in the estimates and to the implications of omitted relevant variables. The need for such a list became clear from reviews of earlier evaluations, most of which were deficient in many more than just one or two respects.

<insert Table 1, found at end of document, about here>

The second document was developed by a multi-disciplinary panel convened by the US Public Health Service and published in 1996 (Gold *et al.* 1996). It too provides a description of methods issues and recommendations for good practice. This text is more prescriptive in its recommendations than Drummond *et al.* (2005). It also introduced the idea of a reference case, a concept to which we return later. Key aspects of the US Panel's recommendations were:

- *A societal perspective should be taken.* In part, this relates to resource costs, and requires that costs falling both on a health care budget and outside it should be included in analyses. Importantly, it requires inclusion of costs such as travel costs borne by patients and time costs borne by relatives caring for patients. The US Panel took an innovative view on the treatment of the productivity effects of health interventions. They concluded that, in part, these would already be captured by the valuation of health (they recommended use of the QALY as the outcome measure), while residual productivity effects (such as those falling on the wider community through, for example, reduced taxation) ought to be explicitly included. The choice of a societal perspective also implies the inclusion of all health and non-health effects (both positive and negative) to intended recipients and others. Evaluative studies of workplace interventions have typically left the issue of perspective implicit. Some appear largely to view evaluation through a worker's lens and other through an employer's lens. Virtually none has systematically taken a more comprehensive view.

- *Health effects should be expressed in terms of QALYs*. This is a measure of health which incorporates the effects of interventions on both mortality (through changes in survival duration) and morbidity (through effects on health-related quality of life). The U.S. Panel thus embraced CUA/CEA as the appropriate analytic paradigm. In the workplace intervention evaluation literature there is no convention regarding the measurement (or even the relevance) of health effects, other than through its impact on productivity.
- *Effectiveness estimates from best-designed and least-biased sources should be used.* Reflecting the typical limitations and heterogeneity of the clinical evidence base available for economic evaluation, this recommendation leans towards using best available evidence. The point can also apply to sources of non-clinical evidence such as resource costs. Other guidelines have emphasised the importance of incorporating all evidence given the hazards of selecting best evidence (National Institute for Clinical Excellence 2004). As noted earlier, effectiveness evidence is more likely to be biased in various ways when based on data observed in workplaces. Assessment of bias or the quality and generalizability of evidence is rarely addressed in any systematic way in workplace intervention evaluations.
- *Comparison should be made with existing practice and (if necessary) viable low-cost alternatives.* Comparator technologies (minimally the status quo) are always necessary. However, decisions about the range of options to compare within an economic evaluation are central to the appropriate specification of an economic evaluation to guide decision-making. Leaving out a relevant option can result in highly misleading results. Comparators are rarely used in workplace evaluations and, where they are, they are rarely described explicitly.
- *One-way and multi-way sensitivity analysis (for important parameters) should be undertaken.* It is recognised that all analyses will be characterised by uncertainty about key elements of evidence. Sensitivity analysis is, as has been seen, a means of exploring the extent to which the conclusions of a study are robust to the changes in the value of key inputs. In analysing workplace interventions, problems of incompatible values and political differences are likely to loom more prominently than in the case of the clinical literature, so sensitivity analysis ought also to be used to test the dependence of the conclusions on controversial value judgments. Sensitivity analysis is virtually unknown in the evaluative literature of workplace interventions.

There are now many methods guidelines issued by decision making agencies. These have recently been surveyed by the International Society for Pharmacoeconomics and Outcomes Research (Tarn and Smith 2005). They display considerable variation, both in terms of how prescriptive they are and in their specific recommendations. Table 2 illustrates the variation using the example of recommendations for the selection of options for comparison.

Table 2: Variation in recommendations for comparator technologies reproduced from Sculpher and Drummond (2006) based on data from Tarn and Smith (2005).

Recommended comparator technology	No. of guidelines
Most commonly used alternative	8
Existing technology, most effective or minimum practice	2
Existing or most effective technology	1
A justified alternative technology	1
Both existing technology and no treatment	2
Most common technology, least costly, no treatment	1
Most common technology, most effective, least costly, and no treatment	2
Most common technology, least costly, and most effective	1
Most likely technology to be displaced	1
Most efficient technology, most effective, and do nothing	2
All relevant comparators	2
Most effective technology and no treatment	1
Not clear or unspecific	3

The National Institute for Health and Clinical Excellence (NICE) in the UK issued methods guidelines for analyses being undertaken as inputs to its Technology Appraisal Programme (National Institute for Clinical Excellence 2004). The guidelines set out the requirements for economic evaluation based on the characteristics of the decisions that the organization is charged to make and the specific constraints under which it operates. NICE's recommendations are prescriptive and go beyond those of the US Panel in a number of respects. Notable recommendations are:

- The use of systematic reviews to identify all appropriate evidence on effectiveness for economic evaluation.
- The use of a validated generic measure of health-related quality of life as a basis for formulating the morbidity component of QALYs.
- Restrictions on the types of costs and consequences to a set deemed relevant by policy makers in the Department of Health (the perspective taken is essentially that of public sector managers).
- The use of probabilistic sensitivity analysis which, simultaneously, assesses the implications of uncertainty in all parameters within an evaluation and allows this to be presented in terms of the probability that a particular option is the most cost-effective, conditional on how much the health care system is willing to pay for a QALY (Claxton *et al.* 2005).

Case for a reference case

A key feature of both the US Panel's statement of good practice in economic evaluation and NICE's 2004 methodological guidance is the definition of a reference case. The purpose of a reference case is to provide consistency in methods used in all evaluations regardless of the disease areas or technologies being evaluated.

The need for consistency is a response to two important features of economic evaluation in health care. The first is the lack of consensus about some areas of methodology. These include the choice of study type (e.g., CUA vs. CBA), the source of preference and value data (e.g., patients versus the general public), the approach to

describing health states for valuation, and the inclusion of future costs that appear to be unrelated to the intervention of interest but are incurred because life expectancy is extended by the intervention. By taking a position on each of these, a reference case can be seen as either defining an authoritative view about the most appropriate method, or as simply selecting one approach in order to avoid unhelpful variability between analyses. The second feature of consistency between studies relates to pragmatic uncertainty. This relates to the need for decision makers to specify their preferred methods, in particular as they embody political or value content in the policy context in which the analysis is to be used. For example, they may wish to be explicit about what they consider to be the appropriate cost perspective and the types of equity issue to be considered.

Stipulating a reference case does not preclude analysts undertaking other types of analysis (e.g., different approaches to health valuation). However, such alternative approaches would need to be undertaken in addition to the reference case and should be justified on the basis of potential shortcomings of the reference case in a specific context.

Would a reference case be helpful to guide researchers undertaking economic evaluations in the context of OHS interventions? It is clear that there is even greater lack of consensus about appropriate evaluation methods for workplace interventions than in health care (see Chapter 3). As a result, the vast majority of studies do not meet the minimal quality requirements in the checklist and it is virtually impossible to make comparisons between the effectiveness, let alone the cost-effectiveness, of alternative interventions reported in different studies. There is, however, an important difference between work-related interventions and health care: there is no single decision maker (such as a reimbursement agency in health care) for whom the analysis is undertaken, and who might be perceived as having an authoritative set of objectives and constraints that ought to be reflected in the methods chosen for the economic analysis. Rather, policy changes relating to workplace health and safety are more likely to be based on interactions between key stakeholders. These include employers (who are likely to incur much of the cost of interventions and only a portion of benefit in terms of productivity changes), as well as labour representatives, workers' compensation and insurance boards, government and regulators. Therefore, any reference case in this area would need to reflect the multiple perspectives that may be had in any particular decision context. It would be appropriate for the reference case to stipulate a societal perspective on costs, health effects and other effects which would indicate what should be done considering the net cost and effects on everyone. However, it would also be necessary for the reference case to require that analyses include estimates of the distribution of costs and effects between stakeholders, which would provide both the various parties affected with a basis for policy negotiations and political decision makers with a basis for making an overall assessment.

Conclusions

The way in which the labour market determines decisions about health and safety is fraught with imperfections. This suggests that a reliance on market mechanisms alone is unlikely to deliver the optimal degree of prevention, protection or compensation. The labour market is also the classic setting for political conflict between labour and

employers. It can generate profound inequalities in society which many may regard as inherently and deeply unjust. For such reasons, if economic analysis is to be used to replace or substitute for the market mechanism it needs to offer a methodology that does not replicate these imperfections, nor one that introduces new and no less unsatisfactory biases. One way may be to simulate the operation of a perfect market (this is, in essence, the objective of economic evaluations done according to the customary rules of neoclassical welfare economics) and the other is to postulate specific objectives and constraints that are appropriate to the sector and problem at hand (this is, in essence, one manifestation of the social decision-making perspective).

We do not advocate either in preference to the other here. However, what we do suggest is that analysts ought to be as explicit as possible about the key structural elements of their analyses, their sources of evidence and the values embodied in their interpretations of findings. We have provided a checklist based upon one commonly used in health technology assessment. It serves to assist those wishing to undertake well-designed workplace intervention studies with economic components, and those wishing to compare or evaluate existing studies.

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Table 1. A checklist for assessing economic evaluations based on Drummond *et al.* (2005).

1. Was a well-defined question posed in answerable form?

1.1 Did the study examine both costs and effects of the intervention?

1.2 Did the study involve a comparison of alternatives?

1.3 Was a perspective for the analysis stated and was the study placed in any particular decision-making context?

2. Was an adequately comprehensive description of the competing alternatives given? (i.e., can you tell who did what to whom, where, and how often for each option?)

2.1 Were all relevant alternatives included?

2.2 Was a *do-nothing* alternative considered? If not, were there good reasons why it was inappropriate?

3. Was the effectiveness or ineffectiveness of the intervention established?

3.1 Was this done through a randomised, controlled trial? If so, did the trial protocol reflect what would happen in regular practice? If not, how were confounding factors controlled?

3.2 Were effectiveness data collected and summarised through a systematic review of studies? If so, were the search strategy and rules for inclusion or exclusion outlined?

3.3 Were observational data or assumptions used to establish effectiveness? If so, what were the potential biases in the results?

3.4 If the study was an efficacy study, was any attempt made to assess its generalisability?

4. Were all the important and relevant costs and consequences for each alternative identified?

4.1 Was the range wide enough for the research question at hand?

4.2 Did the range include material useful to all relevant perspectives?

4.3 Were all relevant costs (labour, capital, as well as operating costs) included?

4.4 Were all relevant consequences (for all parties potentially affected, whether or not engaged in the workplace) included?

5. Were costs and consequences measured accurately in appropriate physical units (e.g., hours of nursing time, number of physician visits, work days gained or lost, life-years gained or lost, effects on workers' families)?

5.1 Were the sources of resource utilisation described and justified?

5.2 Were any possibly significant costs or consequences omitted from consideration or, if identified, not measured well? What weight did they carry in the subsequent analysis?

5.3 Were there any special circumstances (e.g., joint use of resources) that made measurement difficult? Were these issues handled appropriately rather than being simply ignored?

6. Were costs and consequences valued credibly?

6.1 Were the sources of all values clearly identified? (Possible sources include market values, worker or employer preferences and views through surveys, policy makers' views and health professionals' judgments.)

6.2 Where market values were absent (e.g., value of family care-givers' time) or did not reflect actual values (such as clinic space donated at a reduced rate), were adjustments made to approximate market values?

6.3 Was the valuation of consequences appropriate for the question posed (i.e., was the appropriate type of analysis (CEA, CUA, CBA) selected)?

7. Were costs and consequences adjusted for differential timing?

7.1 Were costs and consequences occurring in the future discounted to their present values?

7.2 Was any justification given for the discount rate(s) used?

8. Was an incremental analysis of costs and consequences of alternatives performed?

8.1 Were the additional (incremental) costs generated by one alternative over another compared with the additional effects, benefits, or utilities generated?

9. Was allowance made for uncertainty in the estimation of costs and consequences?

9.1 If workplace level data on costs or consequences were available, were appropriate statistical analyses performed?

9.2 If a sensitivity analysis was employed, was justification provided for the ranges or distributions of values (for key study parameters), and the form of sensitivity analysis used?

9.3 Were the authors' conclusions sensitive to the uncertainty in the results, as quantified by the statistical and/or sensitivity analysis?

10. Did the presentation and discussion of study results include all issues of concern to users?

10.1 Were the conclusions of the analysis based on some overall index or ratio of costs to consequences (e.g., cost-effectiveness ratio)? If so, was the index interpreted

	intelligently or in a mechanistic fashion? If not, was any guidance offered as to how decision makers might seek to make an overall judgment of effectiveness or cost-effectiveness?
10.2	Were the results compared with those of others who have investigated the same or similar question? If so, were allowances made for potential differences in study methodology?
10.3	Did the study discuss the generalisability of the results to other settings, workplaces or industrial sectors?
10.4	Did the study allude to, or take account of, other important factors in the choice or decision under consideration (e.g., distribution of costs and consequences, political constraints, or relevant ethical issues)?
10.5	Did the study discuss issues of implementation, such as the feasibility of adopting the preferred program given existing financial or other constraints, and whether any freed resources could be redeployed to other worthwhile programs?
10.6	Did the study involve key stakeholders at relevant phases, such as the choice of intervention and comparators, selection of research question, selection of workplaces, choice of value judgments (such as the weights to be attached to dissimilar consequences), the concept of equity to be used, and the ease of implementation in the short, medium and long term?

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Journal of Health Economics

The *Journal of Health Economics* welcomes articles on the economics of health and medical care written for a readership of health economists. Karl Claxton, Andy Street, Luigi Siciliani and I are the editors with responsibility for all non-US articles. The address to which submissions should be sent is on the Elsevier website: http://ees.elsevier.com/jhe/.

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or to the Journal secretary, Michelle Hickman on journal-health-econ@york.ac.uk

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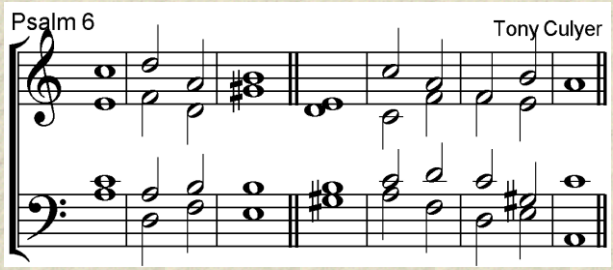
Anglican chants

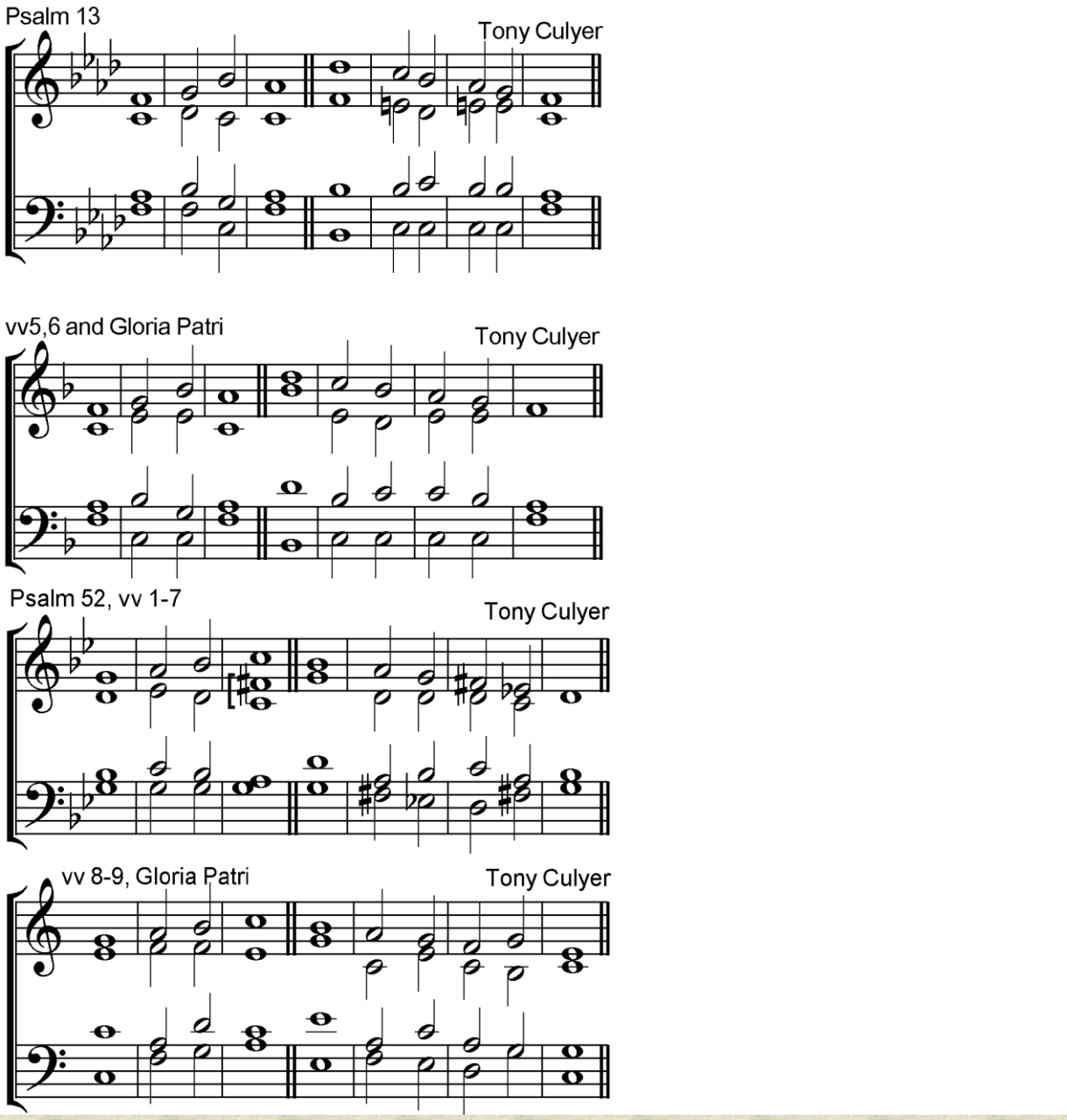
ANGLICAN CHANTS FOR PSALMS

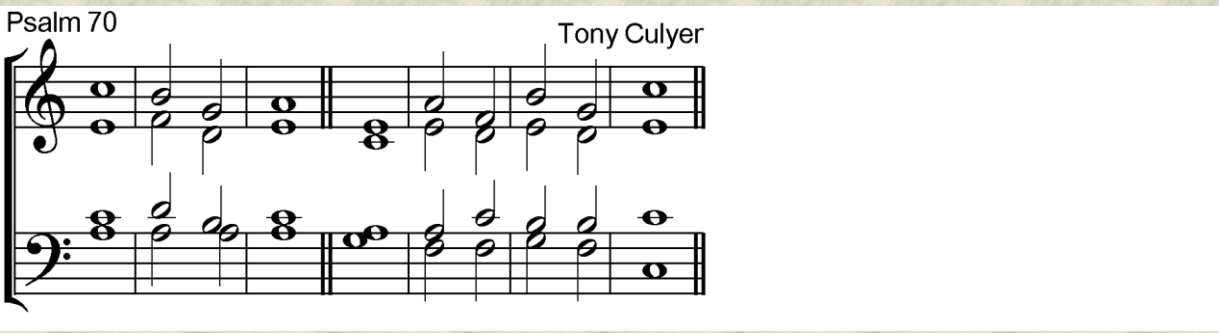
These chants have each been written with a specific psalm in mind. I have tried to capture the 'feel', especially of the opening verses. Of course some psalms have many moods and these cannot always be accommodated simply by varying the way the psalm is sung (harmony or unison, lower or upper voices, full or semi-chorus, cantoris or decani, with or without cantor, solo with hummed accompaniment, with or without antiphons, etc.). The only recourse then is to another chant and then possibly yet another. I have provided for this in the most obvious places. Moods that are commonly not embraced by the music include pain, anguish and despair. I have tried to remedy this. In one case by including tritones.

I have tried to match the structures of the chants to those of the psalms: synonymous, antithetical, constructive, climactic, and also to the groupings of the verses.

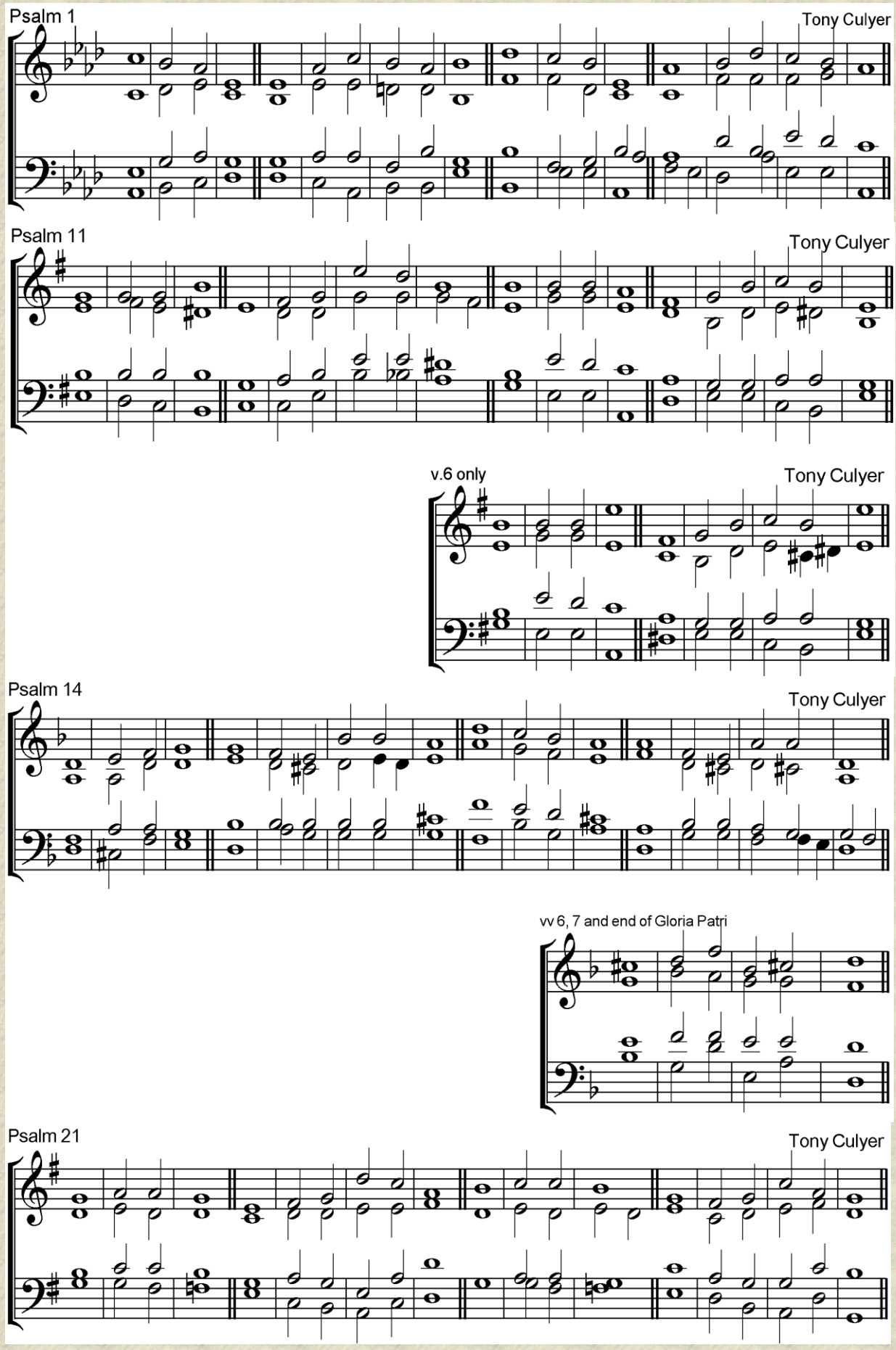
Single chants

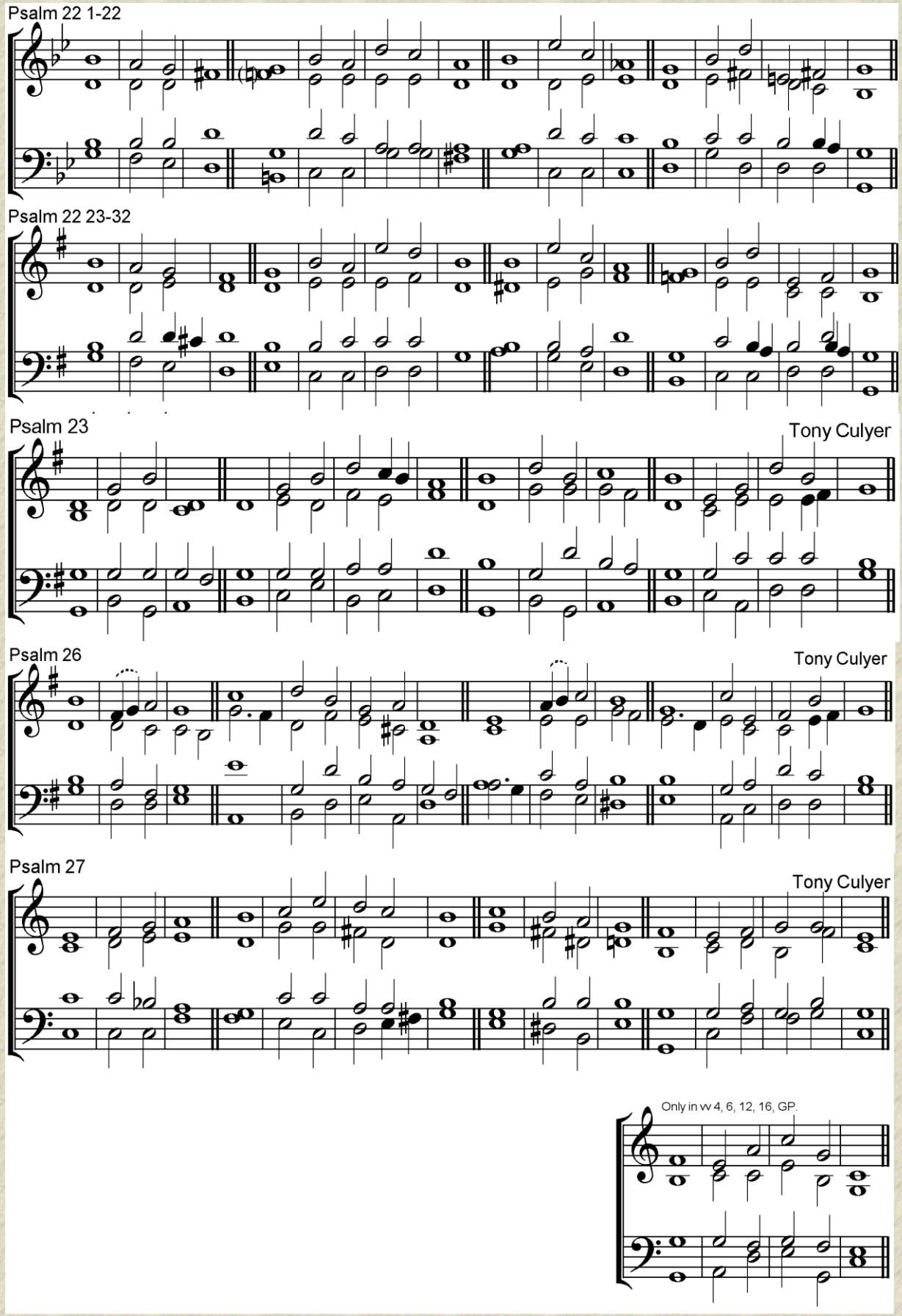


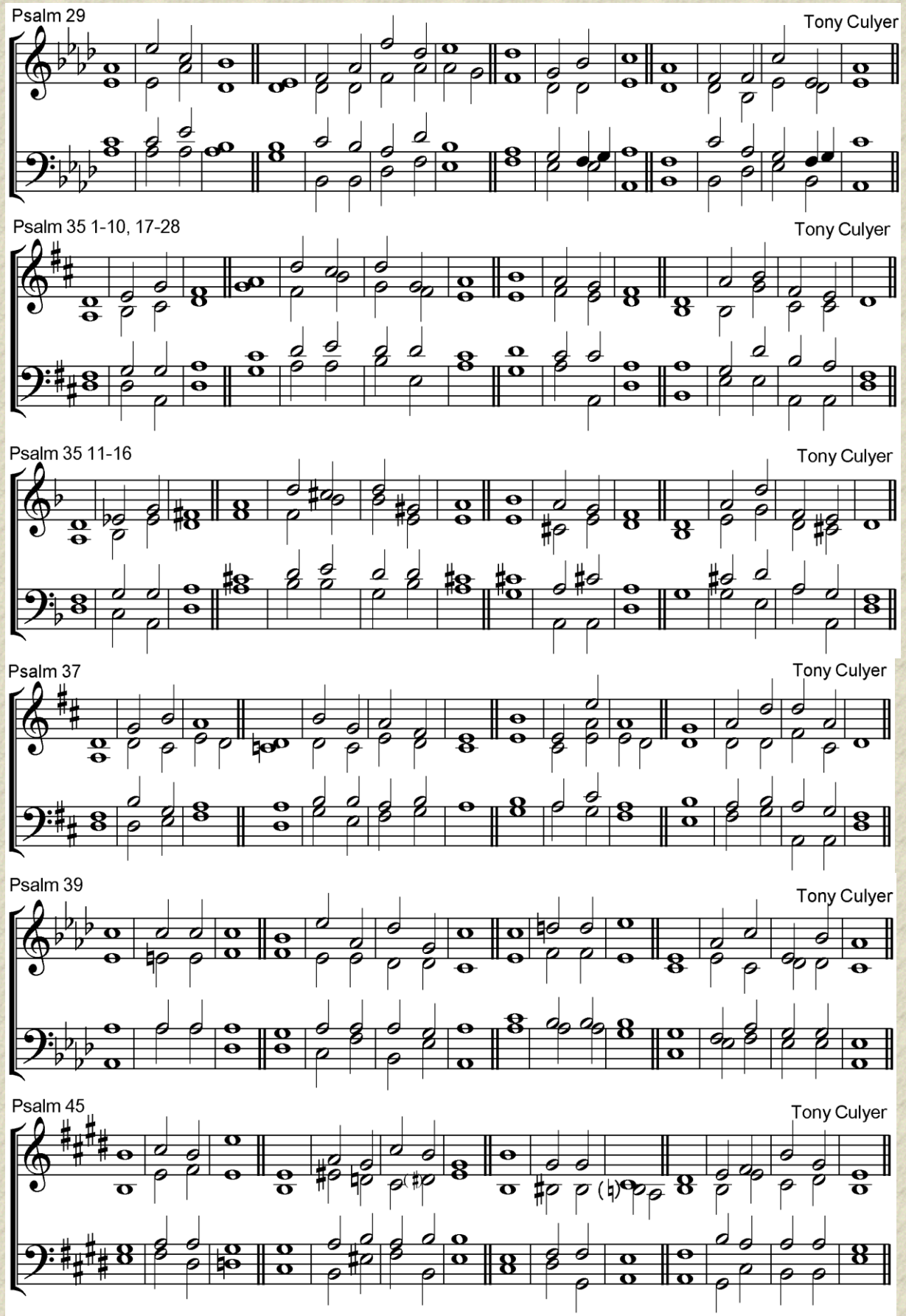


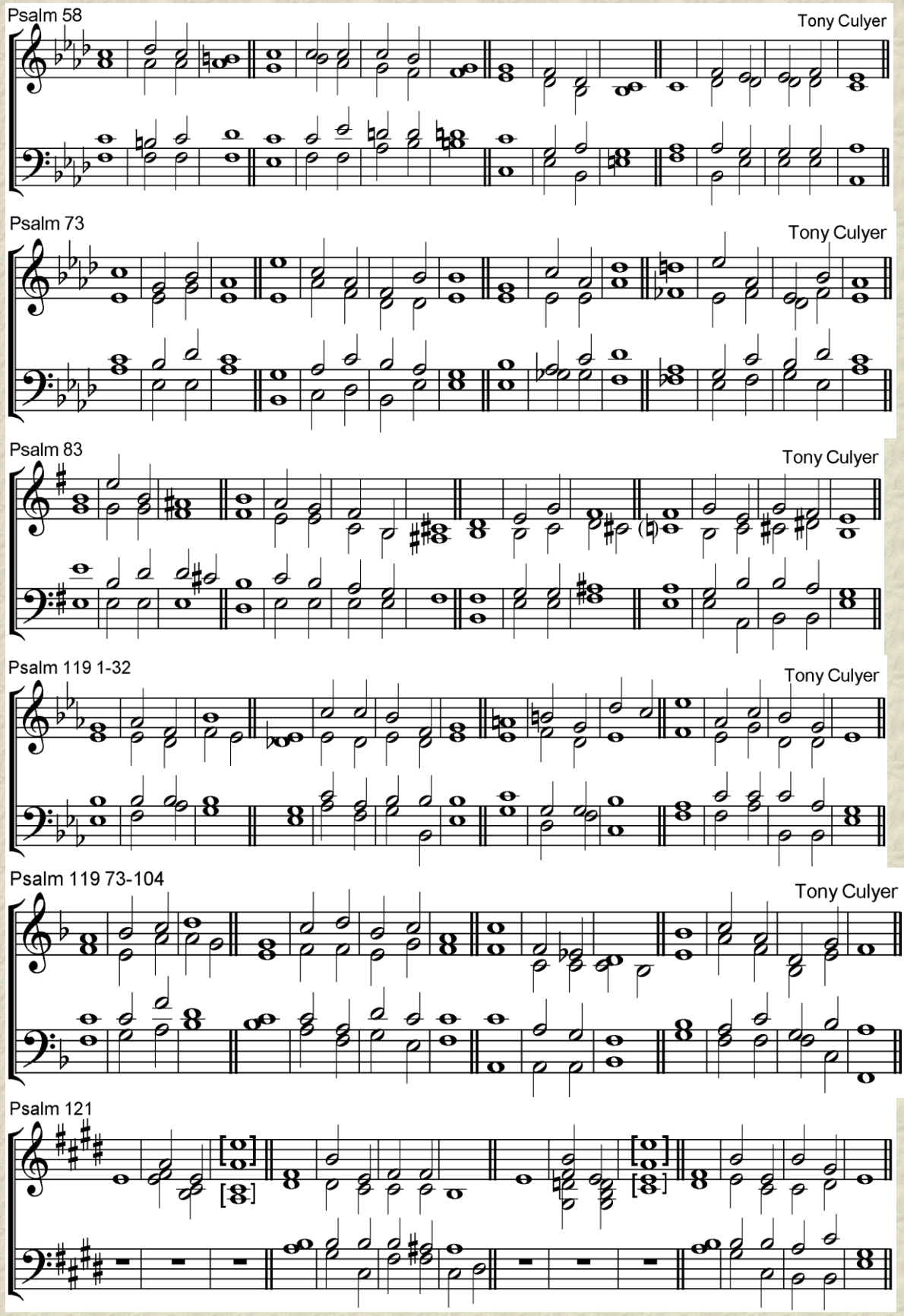


Double chants


Psalm 1
Tony Culyer
Psalm 11
Tony Culyer
v.6 only
Tony Culyer
Psalm 14
Tony Culyer
vv 6, 7 and end of Gloria Patri
Psalm 21
Tony Culyer


Psalm 22 1-22
Psalm 22 23-32
Psalm 23
Tony Culyer
Psalm 26
Tony Culyer
Psalm 27
Tony Culyer
Only in vv 4, 6, 12, 16, GP.


Psalm 29
Tony Culyer
Psalm 35 1-10, 17-28
Tony Culyer
Psalm 35 11-16
Tony Culyer
Psalm 37
Tony Culyer
Psalm 39
Tony Culyer
Psalm 45
Tony Culyer


Psalm 58
Tony Culyer
Psalm 73
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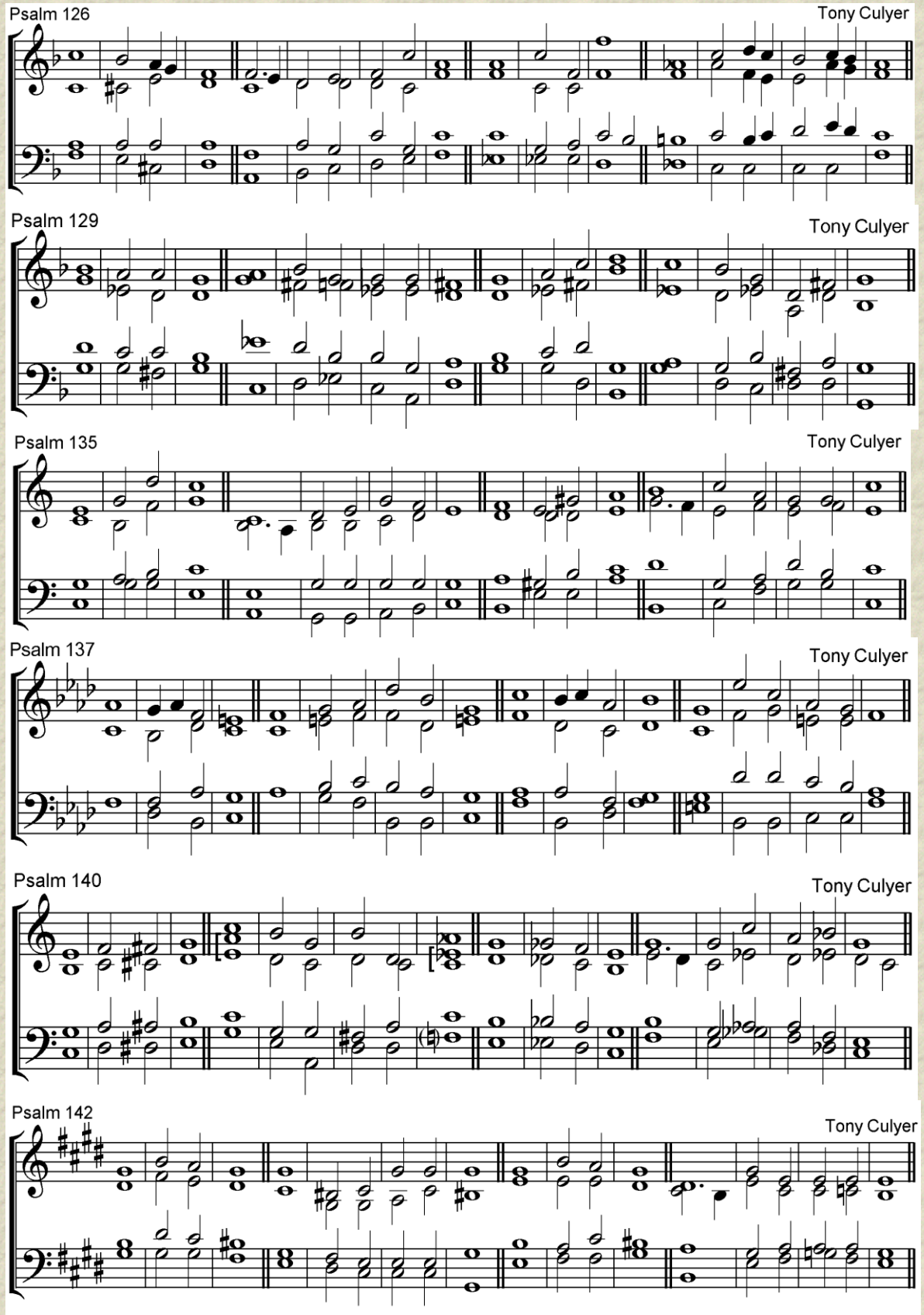
Psalm 83
Tony Culyer
Psalm 119 1-32
Tony Culyer
Psalm 119 73-104
Tony Culyer
Psalm 121


Psalm 126
Tony Culyer
Psalm 129
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Psalm 135
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Psalm 137
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Psalm 140
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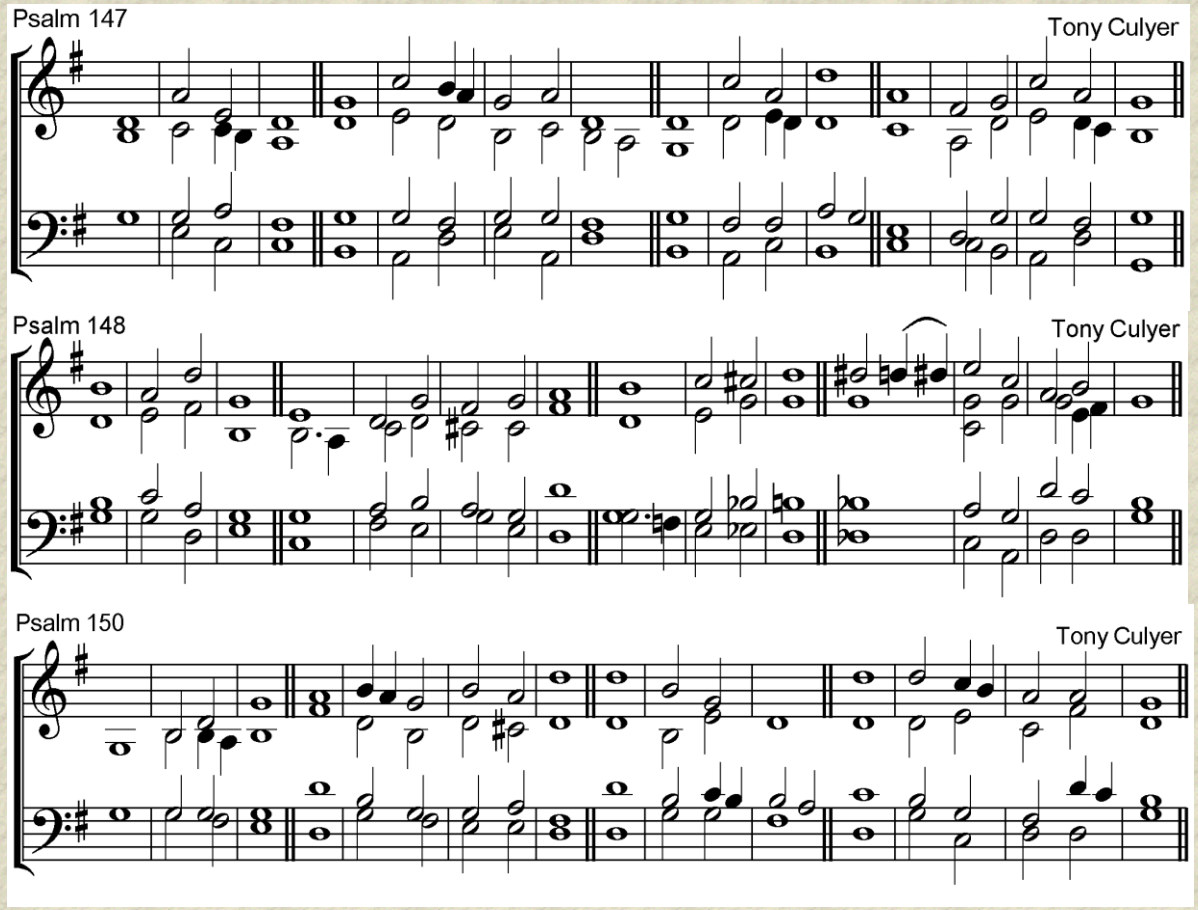
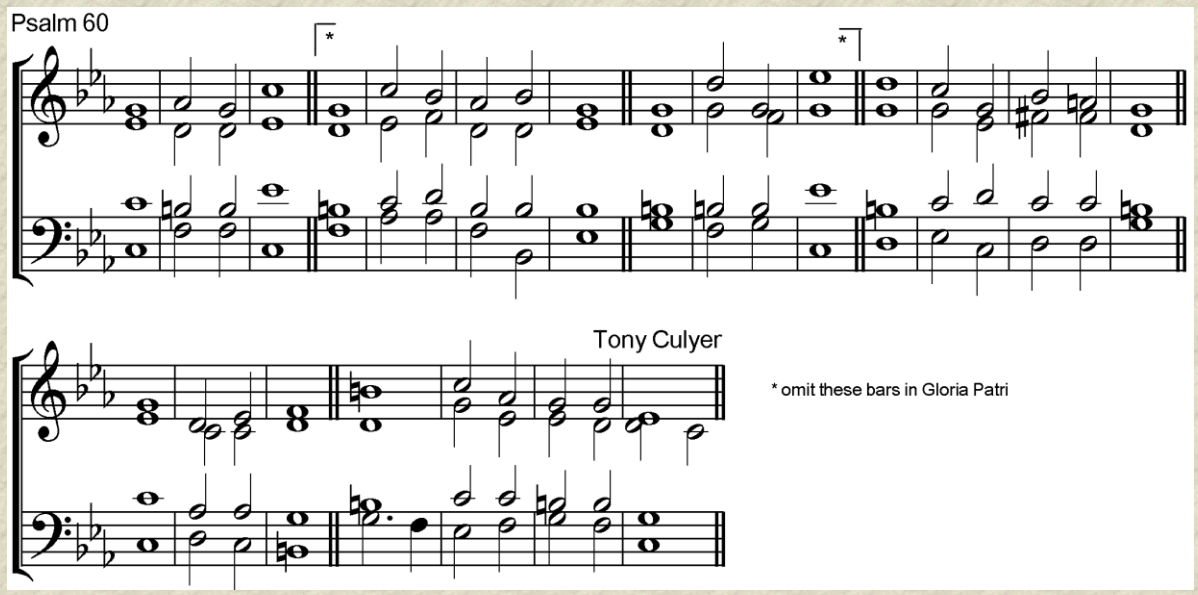
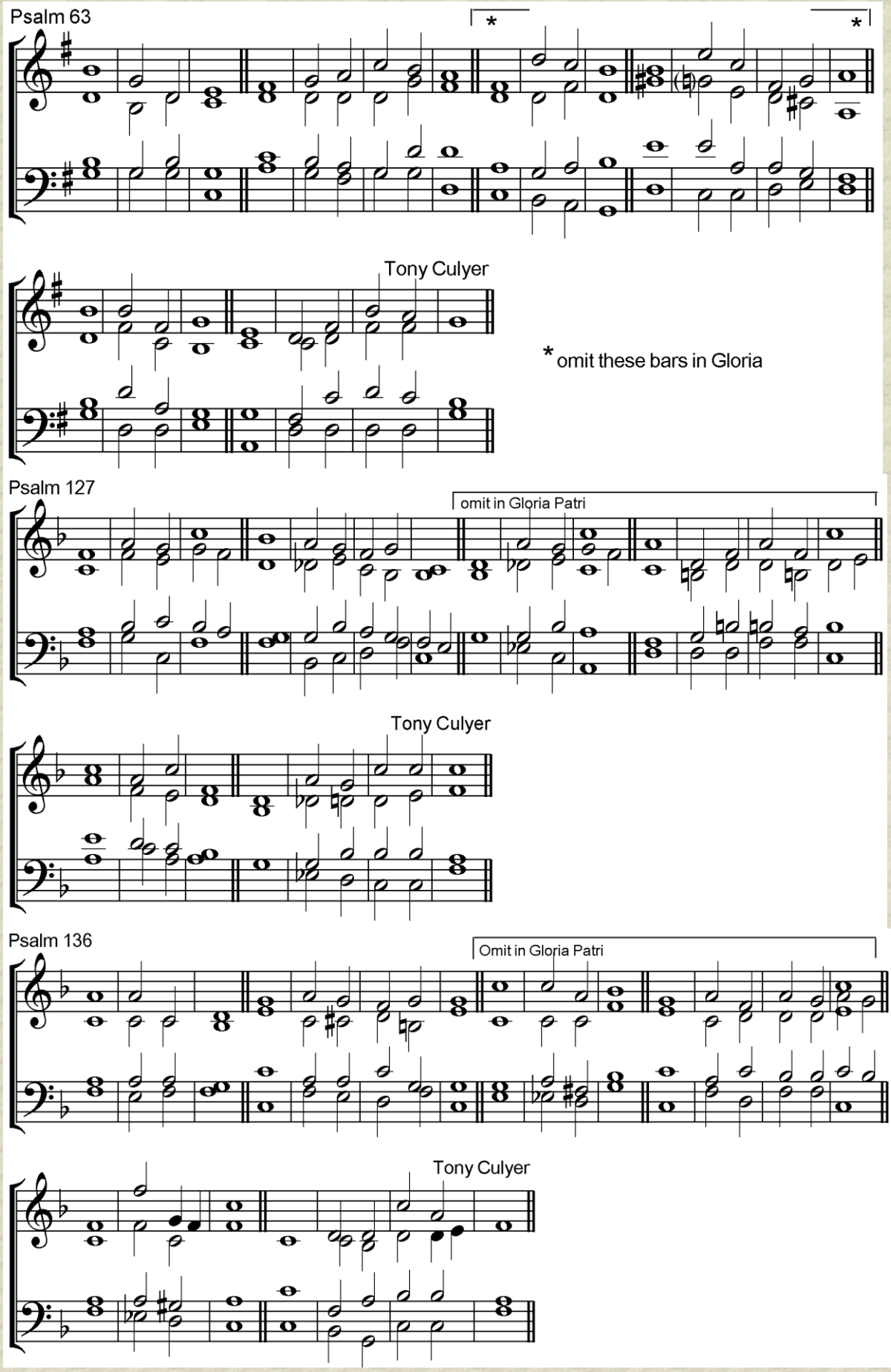
Psalm 142
Tony Culyer

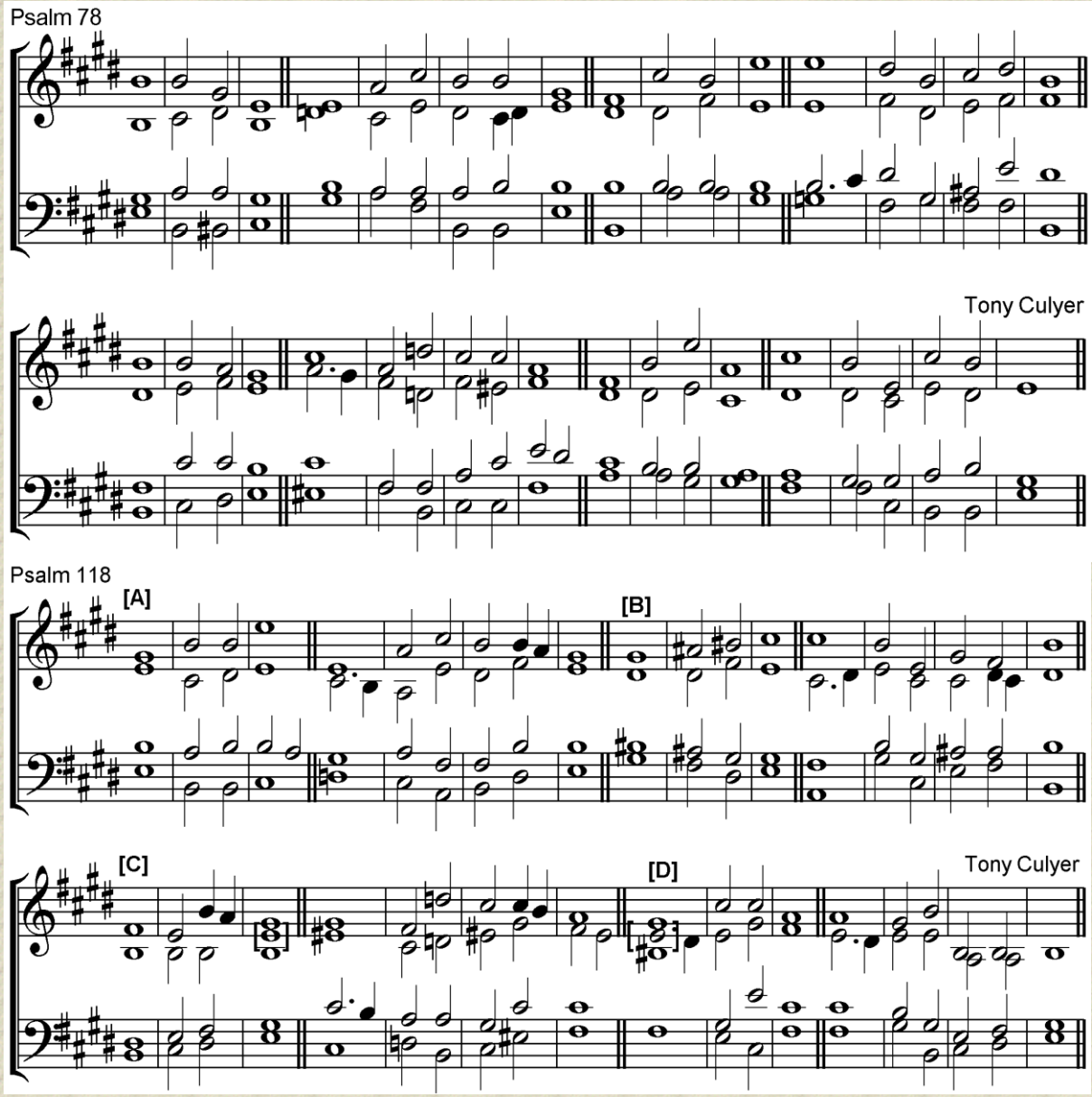


Triple chants




Psalm 63
*
*
Tony Culyer
* omit these bars in Gloria
Psalm 127
omit in Gloria Patri
Tony Culyer
Psalm 136
Omit in Gloria Patri
Tony Culyer

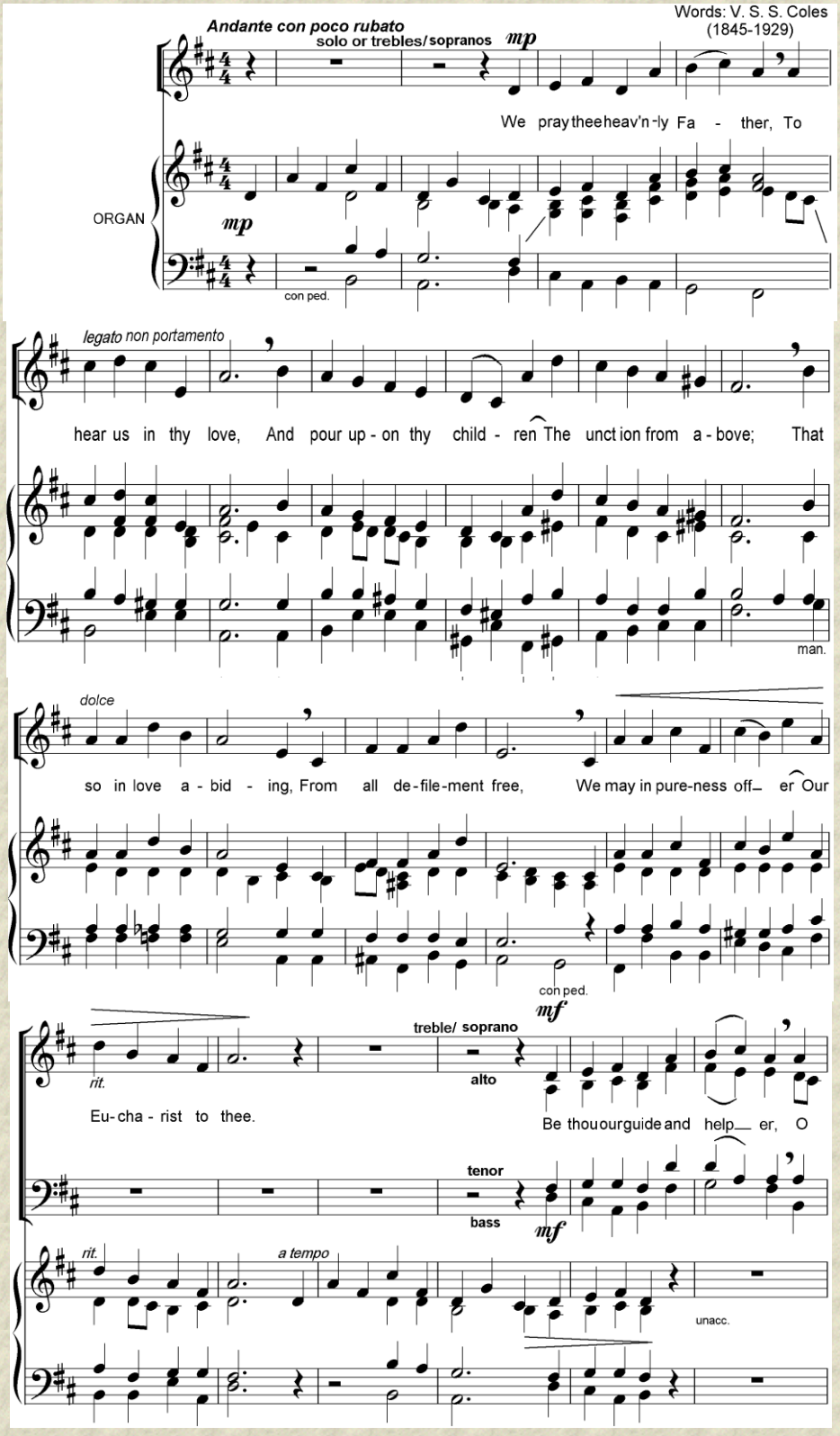
Quadruple chants

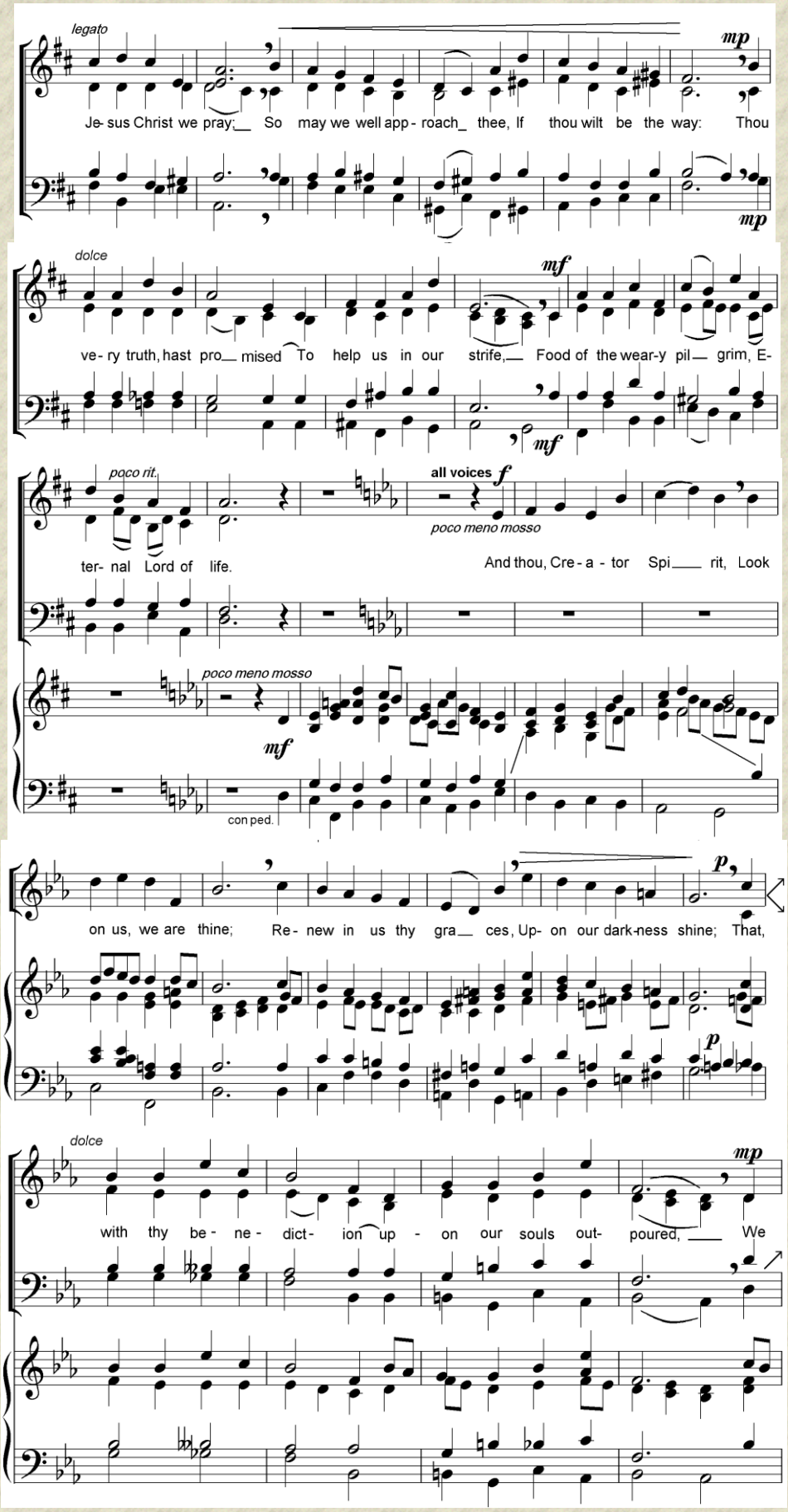


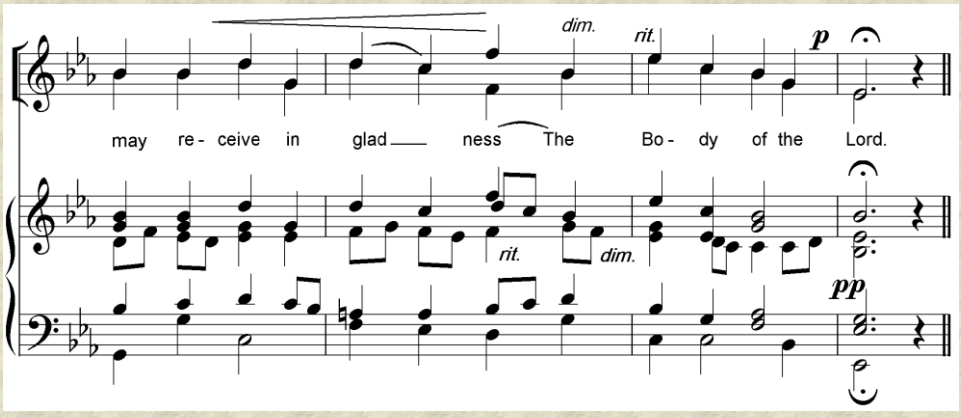
Other pieces

We pray thee, heavenly Father
(homage to John Bacchus Dykes)

Music:Tony Culyer


Words: V. S. S. Coles
(1845-1929)
Andante con poco rubato
solo or trebles/sopranos
mp
We pray thee heav'n-ly Fa - ther, To
ORGAN
mp
con ped.
legato non portamento
hear us in thy love, And pour up - on thy child - ren The unct ion from a - bove; That
man.
dolce
so in love a - bid - ing, From all de-file-ment free, We may in pure-ness off- er Our
con ped.
mf
treble/ soprano
rit.
alto
Eu-cha - rist to thee.
Be thou our guide and help- er, O
tenor
bass
mf
rit.
a tempo
unacc.


legato
mp
Je- sus Christ we pray; So may we well app- roach thee, If thou wilt be the way: Thou
mp
dolce
mf
ve- ry truth, hast pro mised To help us in our strife, Food of the wear-y pil grim, E-
mf
paco rit.
all voices f
poco meno mosso
ter- nal Lord of life.
And thou, Cre- a - tor Spi rit, Look
poco meno mosso
mf
con ped.
p
on us, we are thine; Re- new in us thy gra ces, Up- on our dark-ness shine; That,
p
dolce
mp
with thy be- ne- dict- ion up - on our souls out- poured, We

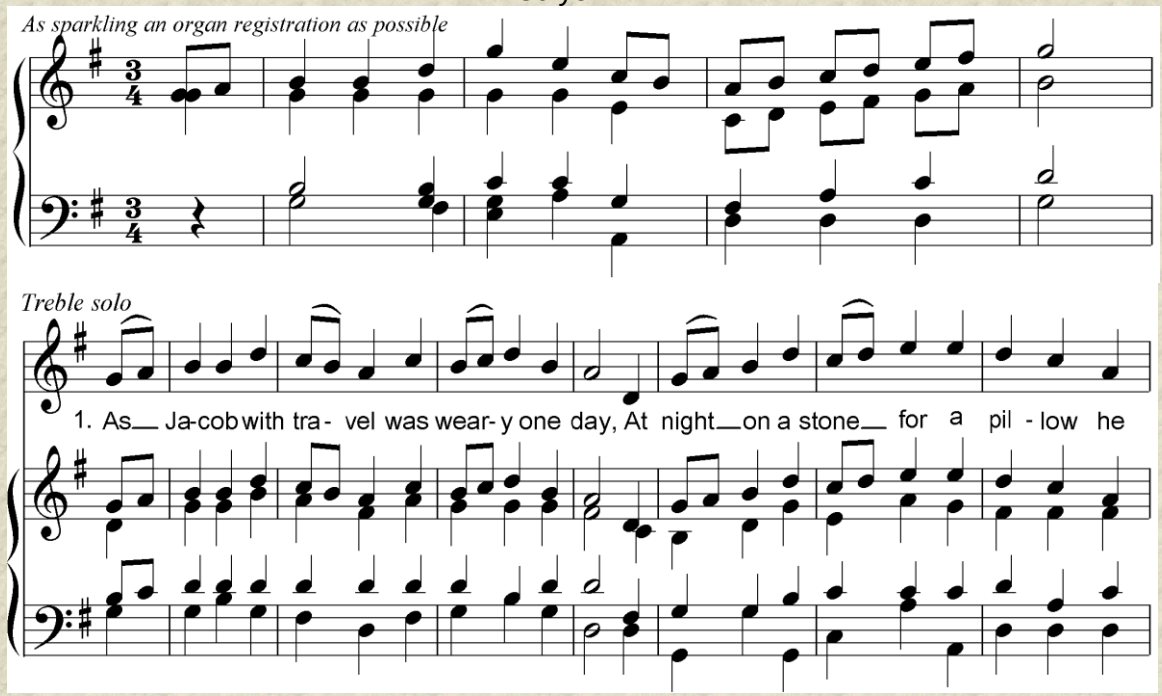


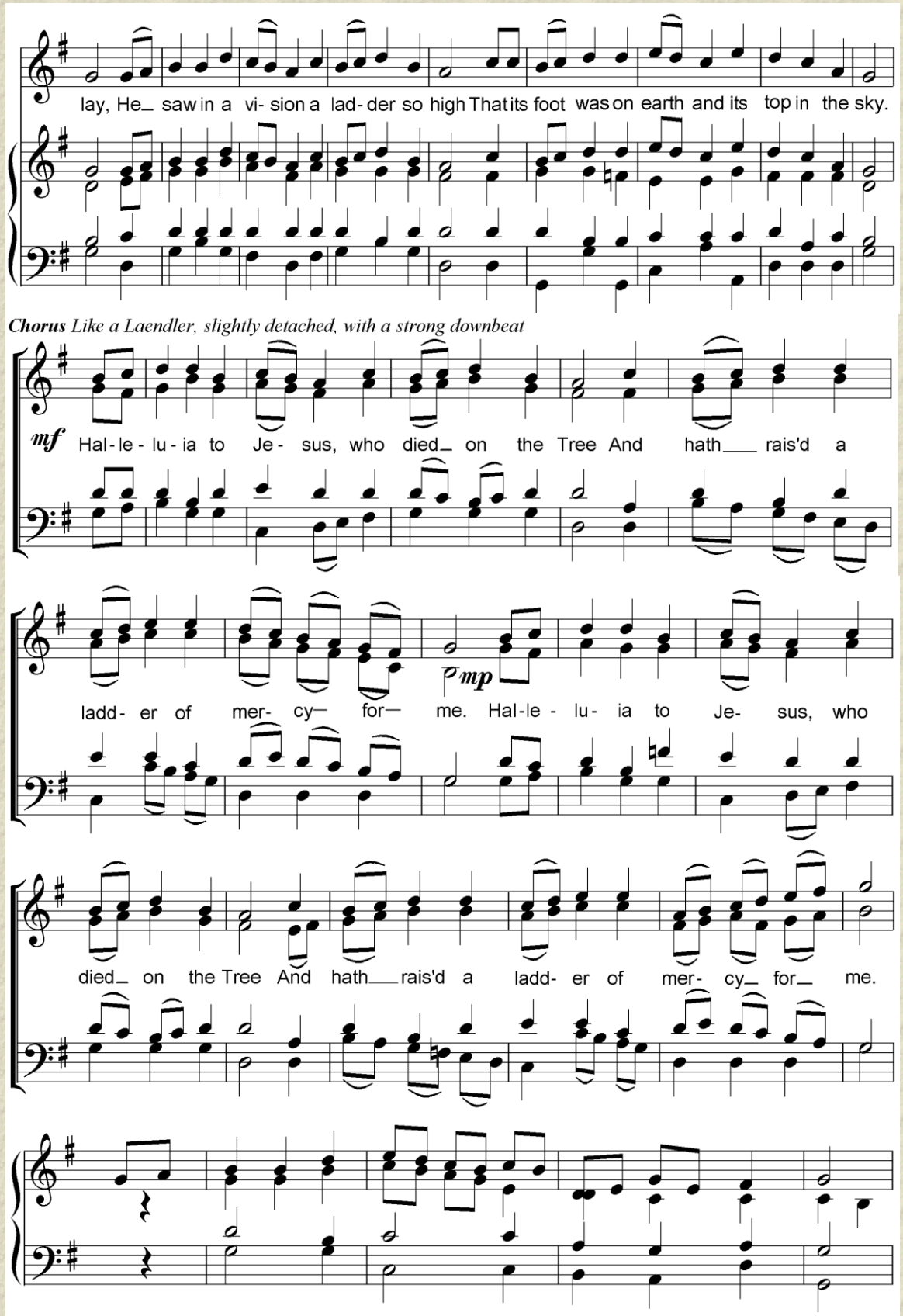
JACOB'S LADDER

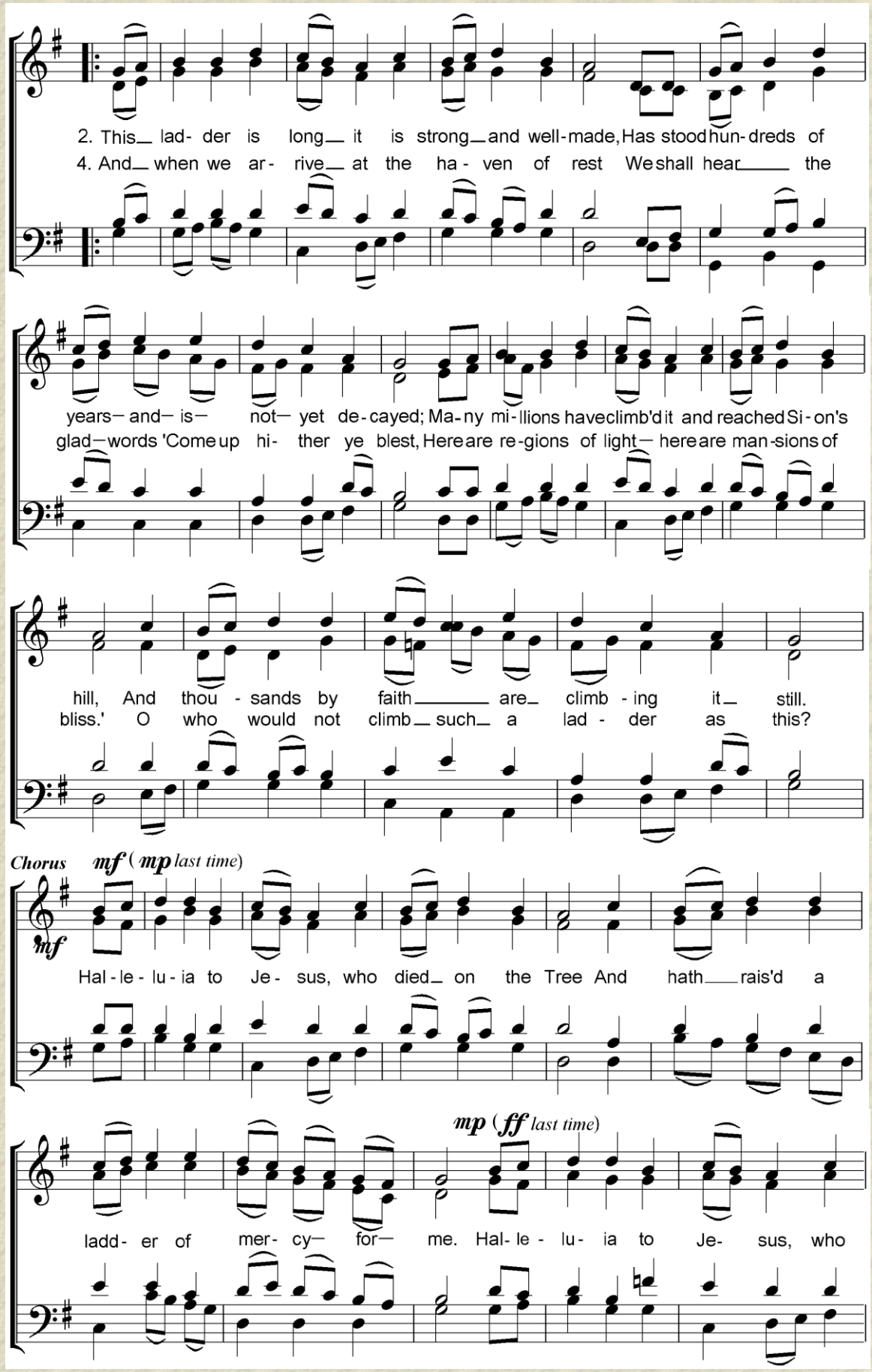
An Eastertide Carol

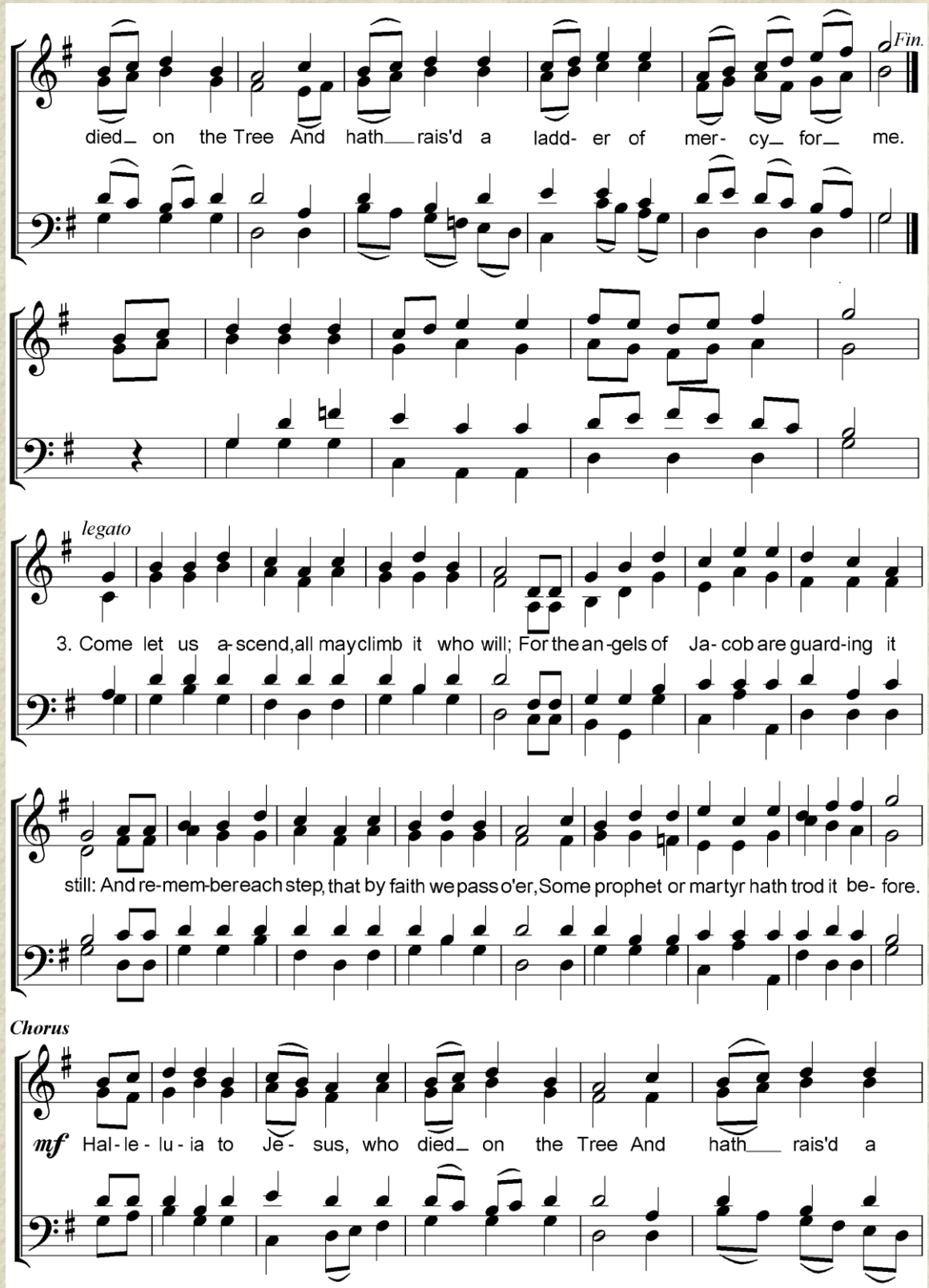
Words 18th Century English Folk

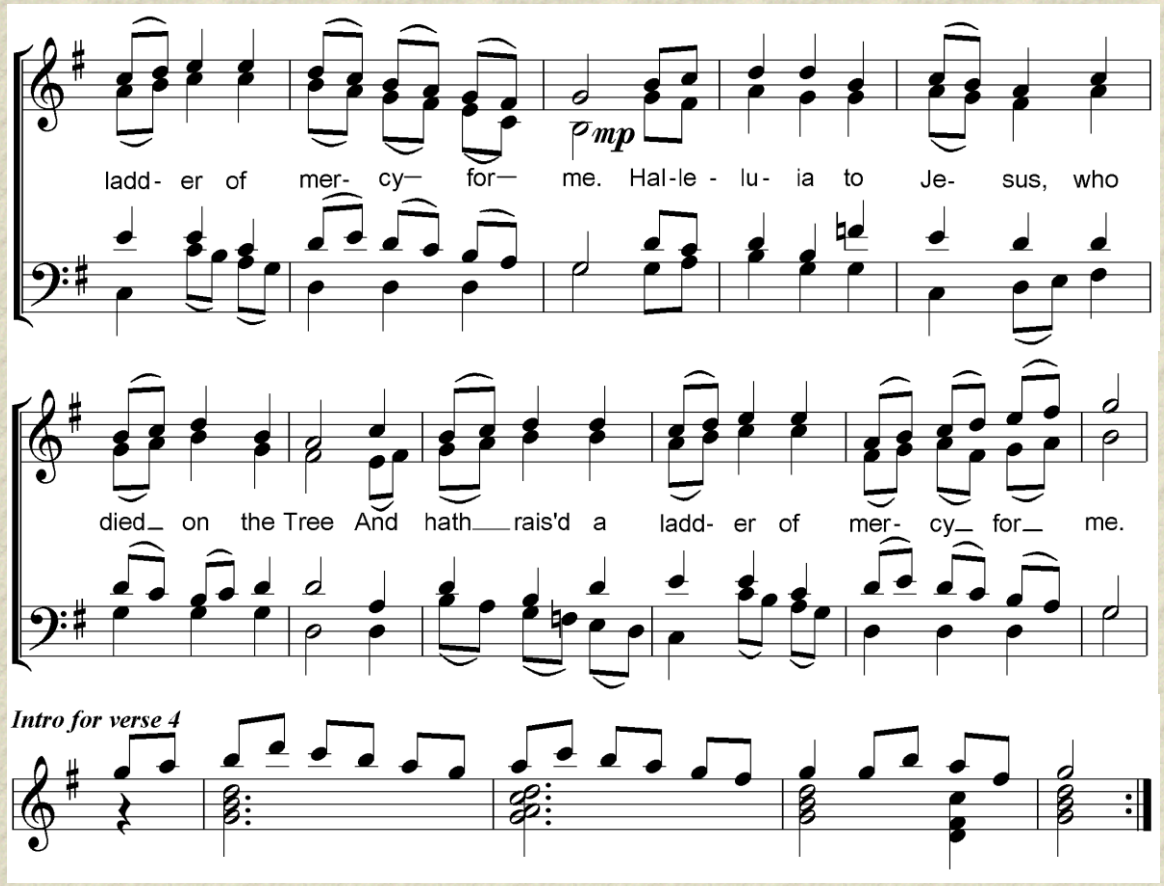
Music: Tony Culyer




lay, He_ saw in a vi- sion a lad- der so high That its foot was on earth and its top in the sky.
Chorus Like a Laendler, slightly detached, with a strong downbeat
mf
Hal- le- lu- ia to Je- sus, who died_ on the Tree And hath___ rais'd a
mp
ladd- er of mer- cy— for— me. Hal- le- lu- ia to Je- sus, who
died_ on the Tree And hath___ rais'd a ladd- er of mer- cy_ for_ me.

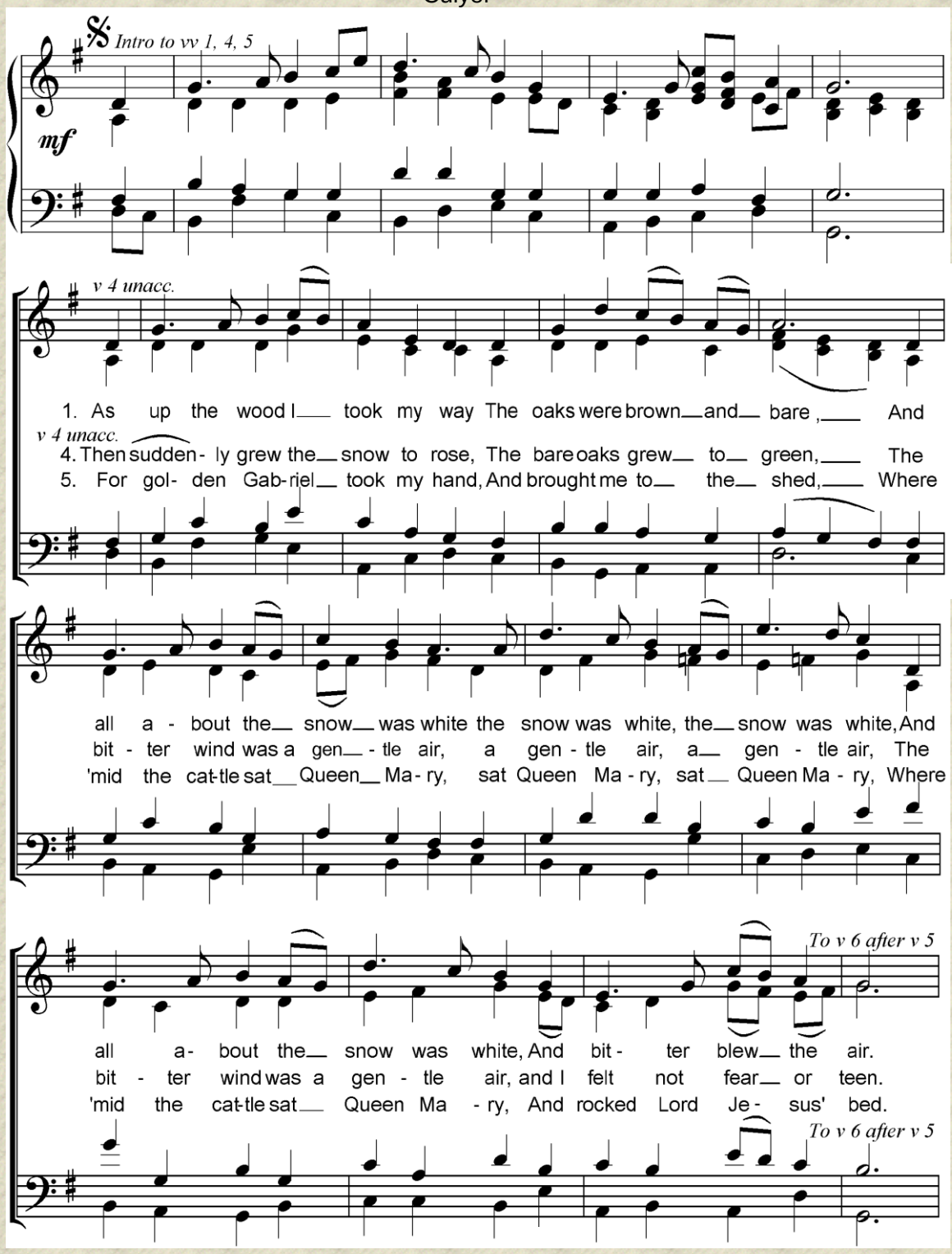

2. This lad- der is long it is strong and well-made, Has stood hun- dreds of
4. And when we ar- rive at the ha- ven of rest We shall hear the
years and is not yet de- cayed; Ma- ny mi- llions have climb'd it and reached Si- on's
glad words 'Come up hi- ther ye blest, Here are re- gions of light here are man- sions of
hill, And thou - sands by faith are climb - ing it still.
bliss.' O who would not climb such a lad - der as this?
Chorus
mf (mp last time)
mf
Hal - le - lu - ia to Je - sus, who died on the Tree And hath rais'd a
mp (ff last time)
ladd- er of mer- cy for me. Hal- le - lu- ia to Je- sus, who

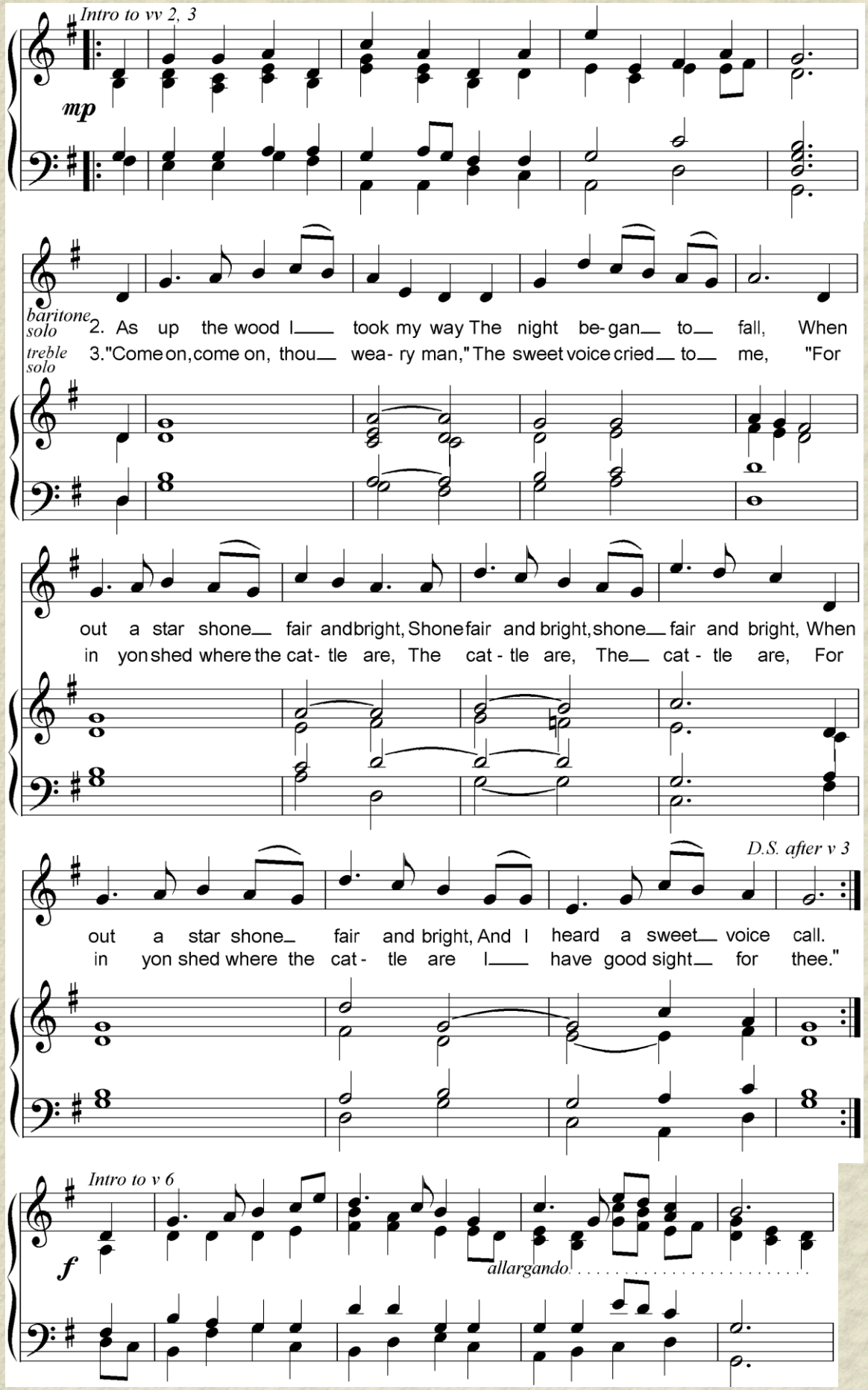

Fin.
died_ on the Tree And hath___ rais'd a ladd- er of mer- cy_ for_ me.
legato
3. Come let us a- scend, all may climb it who will; For the an- gels of Ja- cob are guard- ing it
still: And re- mem- ber each step, that by faith we pass o'er, Some prophet or martyr hath trod it be- fore.
Chorus
mf Hal- le- lu- ia to Je- sus, who died_ on the Tree And hath___ rais'd a

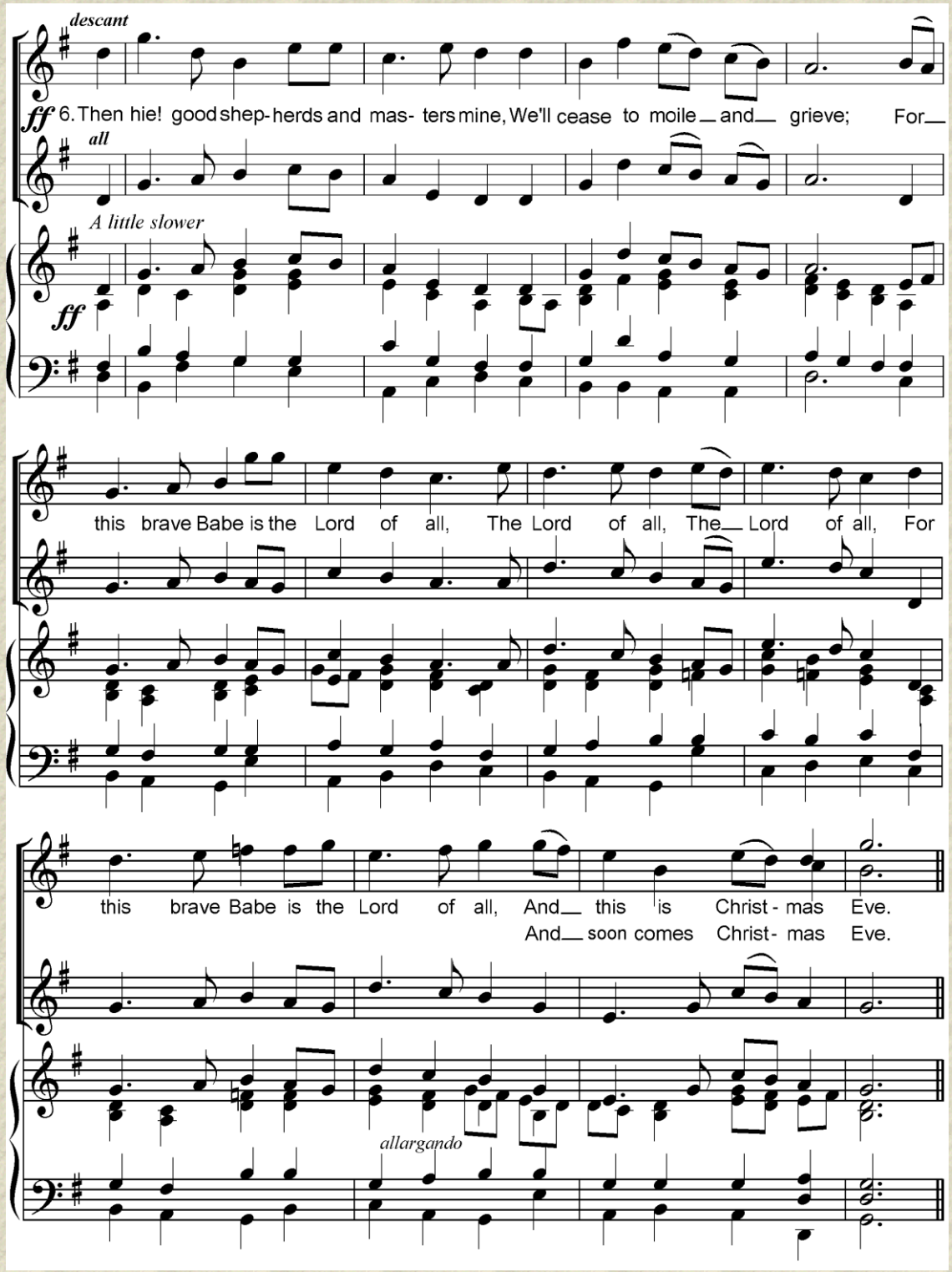

mp
ladd- er of mer- cy— for— me. Hal-le - lu- ia to Je- sus, who
died— on the Tree And hath— rais'd a ladd- er of mer- cy— for— me.
Intro for verse 4

As up the wood I took my way

Words: Selwyn Image (1849-1930) Music: Tony Culyer




Intro to vv 2, 3
mp
baritone solo
2. As up the wood I took my way The night be- gan to fall, When
treble solo
3."Come on, come on, thou wea- ry man," The sweet voice cried to me, "For
out a star shone fair and bright, Shone fair and bright, shone fair and bright, When
in yon shed where the cat- tle are, The cat - tle are, The cat - tle are, For
D.S. after v 3
out a star shone fair and bright, And I heard a sweet voice call.
in yon shed where the cat - tle are I have good sight for thee."
Intro to v 6
f
allargando


descant
ff
6. Then hie! good shep- herds and mas- ters mine, We'll cease to moile and grieve; For
all
A little slower
ff
this brave Babe is the Lord of all, The Lord of all, The Lord of all, For
this brave Babe is the Lord of all, And this is Christ - mas Eve.
And soon comes Christ - mas Eve.
allargando

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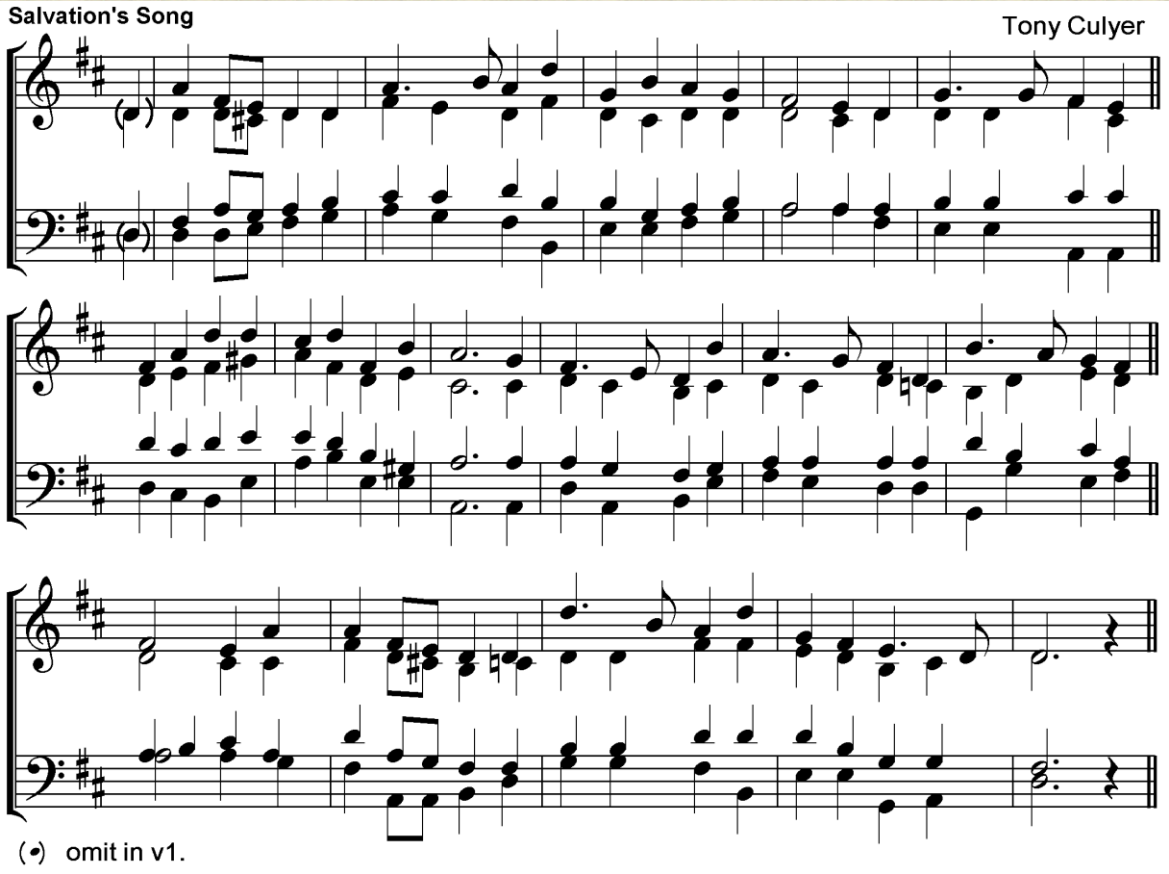
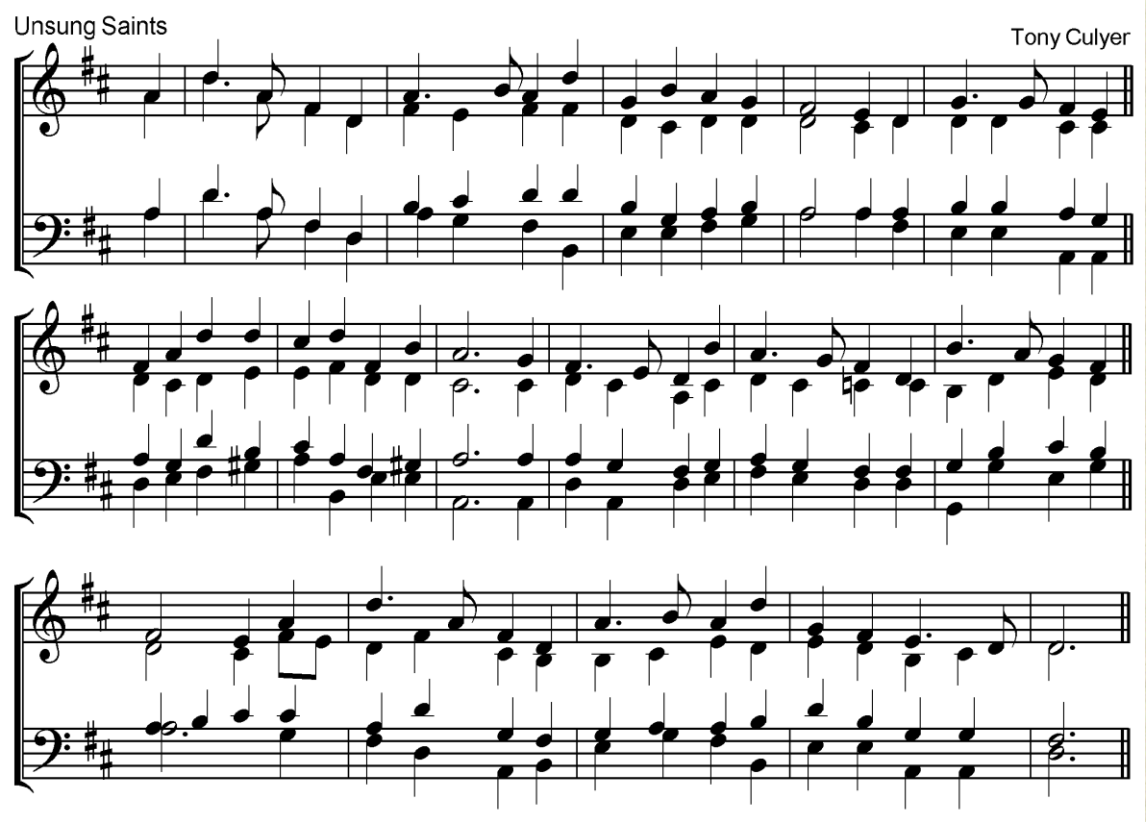
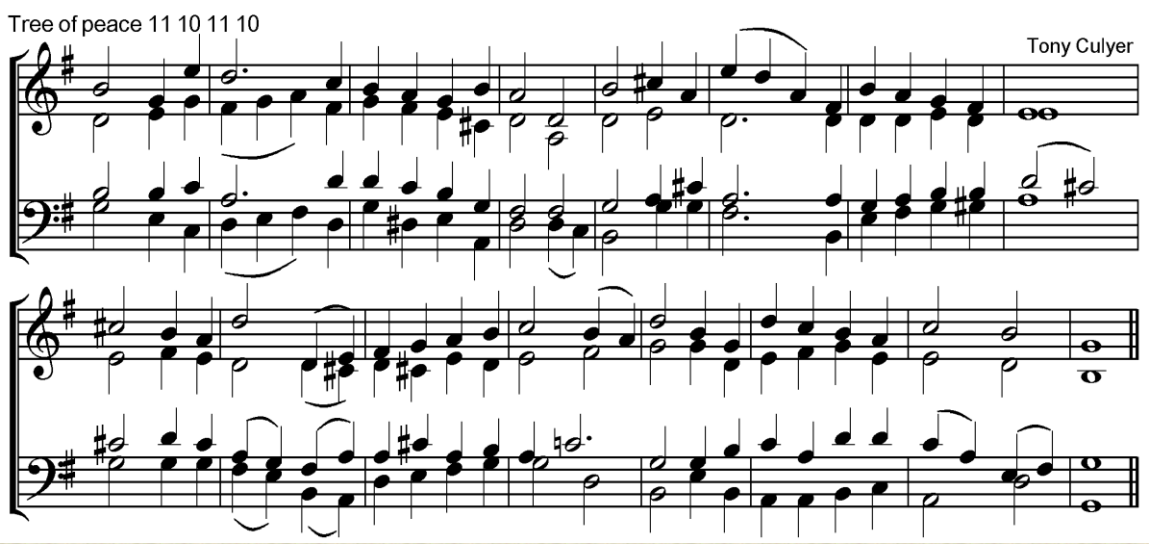
Hymn Tunes



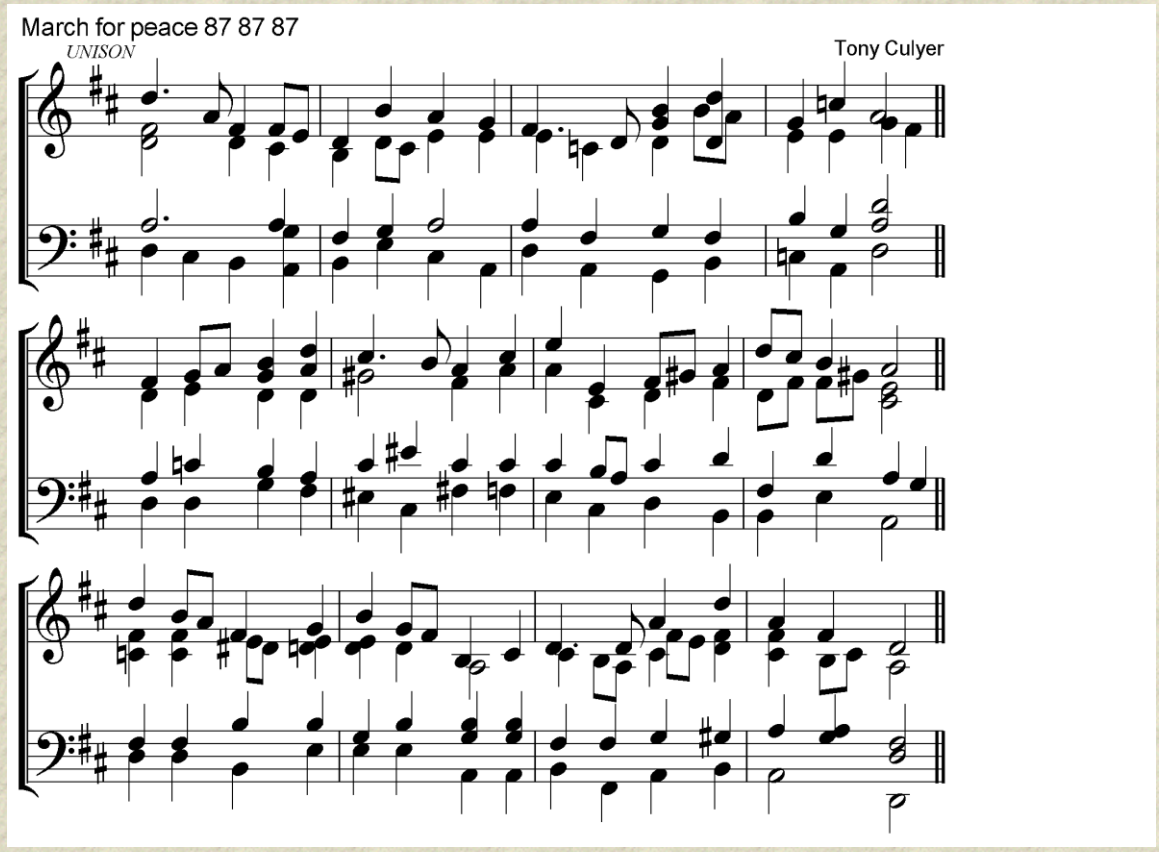
To 'How shall we sing salvation's song' by Timothy Dudley-Smith.



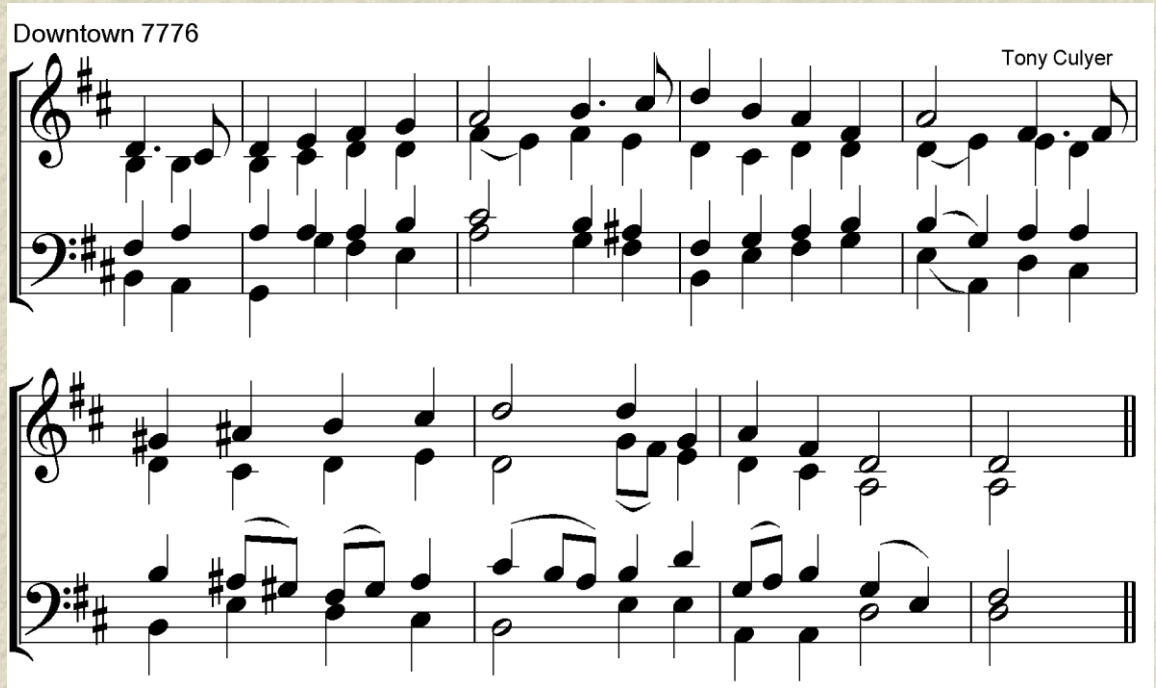
To: We sing for all the unsung saints, by CARL P. DAW Jr



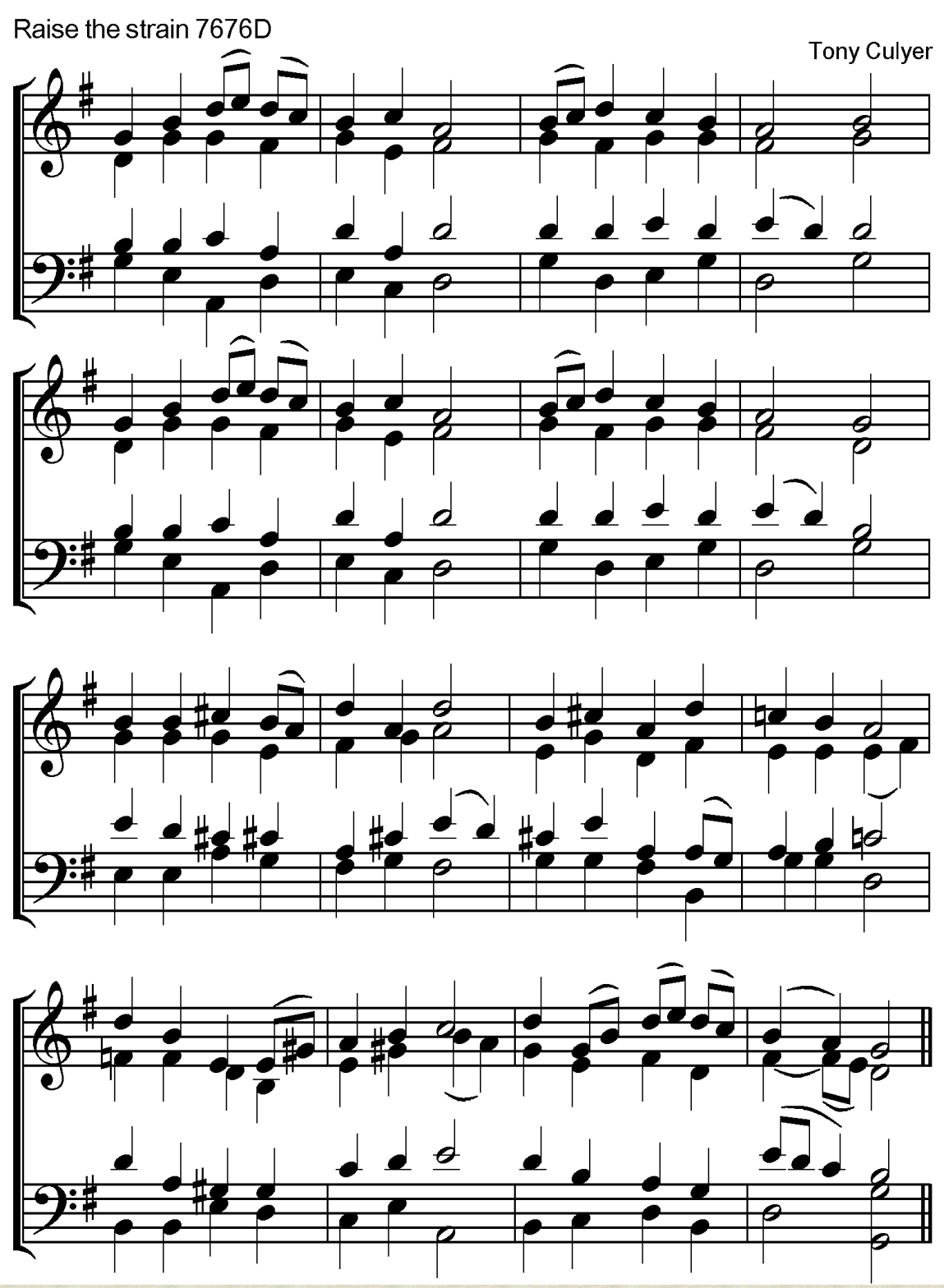
To: O Christian, love you sister and your brother! By John Greenleaf Whittier (1807-1892) (alt.)



To: GOD of freedom, God of justice, by Shirley Erena Murray (b. 1931)



To: Bless the Lord, created things, by Judy Davies



To: Come, ye faithful, raise the strain of triumphant gladness! By St John of Damascus (d. c. 754); (trans. J M Neale 1818-1866)

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Royal School of Church Music

The website of the RSCM is http://www.rscm.com/. As a trustee, member of Council and chair of the Voluntary Forum for Chairs, I am happy to receive representations from members and pass them on the appropriate people. I can be got at by e-mail (tonyandsiegi@btinternet.com). On matters Canadian, the website is http://www.rscm.com/international/canada.php and again I am happy as a director on the RSCM (Canada) Board to receive and pass on representations. My home telephone numbers are (UK) 01759 307177 and (Canada) 416 369 9973.

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