

Work In Progress – Please do not cite or quote without permission

**‘Letter from America’
An investigation of technology coverage policy in the US,
with particular reference to the use of cost-effectiveness
information**

Stirling Bryan^{1,2}, Alan Garber² and Marthe Gold³

1. Health Economics Facility, University of Birmingham, U.K.
2. Center for Health Policy and Center for Primary Care and Outcomes Research, Stanford University, U.S.
3. City College, City University of New York, U.S.

Corresponding author:

Stirling Bryan, PhD

Professor of Health Economics
University of Birmingham
Health Services Management Centre
Park House, 40 Edgbaston Park Road
Birmingham
B15 2RT, U.K.

Phone: +44 121 414 7706

Email: s.bryan@bham.ac.uk

**Paper presented at the 70th Health Economists’ Study Group meeting, University
of Birmingham, January 2007**

Abstract

Purposes: (1) To understand the principles underlying technology coverage decisions, and the processes employed, in four major US health care organizations; (2) To elicit the views of key professionals in each organization; (3) To make recommendations for strengthening coverage policy in the UK and US.

Problem: The high and rising cost of health care is a near universal problem. A leading contributor to cost growth is the introduction of new health care technologies (drugs, devices and procedures). 'Coverage' refers to whether or not the cost of a technology is reimbursed through the insurance package – it involves setting limits on available services.

Methods: Case study research was conducted in four US organizations: Kaiser-Permanente (not-for-profit health maintenance organisation), Aetna (for-profit health plan), Blue Cross Blue Shield (not-for-profit health plan), and the Veterans Health Administration (federal government agency health care provider). The methodology was qualitative, and data collection involved interviews with key professionals (selected by role/position).

Principal Findings: In many settings in the US, there exists a formal, evidence-based, policy process through which consideration is given to the adoption and use of new technologies. A positive feature, seen in some settings, is of a structured and organization-wide attempt to achieve input and buy-in to the policy formation process. The evidence focus when considering new technologies, in all organizations studied is principally 'effectiveness'. Cost and cost-effectiveness analysis information tends not to be considered.

Conclusions: There is now increasing use of CEA approaches outside the US, most notably in the UK, with evidence of considerable success in its use as an aid to decision making. The picture in the US is very different. The main barriers to use of CEA in the US include a fear amongst health plans of litigation and of public backlash, mistrust of industry and of CEA methods, and a belief amongst some that other approaches can be used more effectively to manage scarcity.

1. Introduction

The high and rising cost of health care is a near universal problem (Pauly, 2003; Aaron, 2004; Garber, 2004; Pauly, 2004) which manifests itself in different ways in different countries, depending on how countries structure their health care financing. In the US, which relies heavily on private insurance, it is seen in rising health insurance premiums, increasing direct payments by insured individuals, cutbacks in public programmes, and growth in the number of uninsured (Garber, 2004; Jost, 2003). In the UK, and other countries with predominantly tax-financed health insurance systems, the pressure of increasing health care costs reveals itself through a growing frustration with constraints on access to some high cost modern health care and restrictions on rapid access to health care generally (Jost, 2005).

The introduction of new health care technologies (i.e. drugs, devices and medical procedures) is a major factor contributing to health expenditure growth in developed countries. The focus for this paper is technology coverage policy; that is, decisions by health care organisations to adopt or recommend for use a new drug, device or therapy. Private health plans and government health insurance programmes both make coverage decisions – a decision not to ‘cover’ a technology indicates that none of its cost will be reimbursed as part of the insurance package (Foote, 2003; Steiner et al, 1996; Pearson et al, 2003; Jost, 2005). In other words, it involves setting limits on the health care services that can be accessed or provided (Daniels and Sabin, 2002).

Formal technology coverage determination processes commonly have five stages (Figure A). First is the identification of or ‘scanning’ for technologies suitable for evaluation, followed by a technology assessment process – that is, an assessment of its safety, efficacy, effectiveness and costs. The process of appraisal and decision making follow, during which the technology assessment evidence is used in arriving at a coverage policy. Such a policy stance can relate to the technology alone (either covered or not covered) or to the use of the technology in defined patient groups where, for example, effectiveness has most convincingly been established. The implementation stage then follows, at which point the challenge of aligning clinical practice with coverage policy is tackled. Finally, policy review and re-evaluation can be an ongoing process in order to ensure that new information relevant to the policy stance is considered and acted upon as it becomes available. The focus of the work reported in the paper is on the technology assessment and appraisal/decision-making stages of the process.

Our research builds upon earlier UK-based work by SB that investigated technology coverage decision-making in the UK (at both national and local levels) and the use of cost-effectiveness information (Bryan et al, 2007; Williams & Bryan, 2007; Williams et al, 2007). The principles and processes underlying coverage decisions in the US are explored here, in addition to consideration of the use made and impact of cost-effectiveness analyses. Views were elicited from stakeholders at four major US health care organisations, with the objective of distilling views and recommendations on how coverage policy in both the US and the UK might be strengthened. The paper outlines the research setting, describes the findings (initially in terms of the technology coverage process in the US compared to the UK and then considers the

specific issue of US health care and cost-effectiveness information), and finally highlights challenges and lessons.

2. Research Setting

The research followed a qualitative case study methodology and examined four US health care organisations: the Department of Veterans Affairs (VA), Aetna, Blue Cross Blue Shield Association (BCBS), and Kaiser-Permanente (K-P). Within the VA the focus was exclusively on the Pharmacy Benefits program. In the other organisations consideration was given to new technologies more broadly, including pharmaceuticals. These four organisations do not provide a representative picture of US health care but cover four key aspects: a federal government agency (VA), a not-for-profit health maintenance organisation (K-P), and traditional insurers from both the for-profit (Aetna) and not-for-profit (BCBS) sectors. The VA is a health care provider to those who received an honourable discharge from the military, and BCBS is the largest health insurer in the US.

The primary source of data was semi-structured interviews, supported by observation and analysis of secondary sources, such as committee documentation. The approach adopted was intended to yield both exploratory and explanatory data, ensuring that the primary research questions were answered whilst allowing new issues to emerge (Pope and Mays, 1995). Interviews were conducted with 16 senior figures from across the four organizations. Interviewees were selected on the basis of their role and seniority, and because they had responsibility for the strategic direction of their organisation in relation to technology coverage.

Interviews were tape-recorded and transcribed. A semi-structured interview schedule (Figure B) was used enabling us to address the research questions whilst allowing the flexibility to pursue other issues or concerns. All interviews were conducted by the same researcher (SB). Data analysis involved code-based identification and analysis of themes. The analysis methods followed those of Bryan et al (2007) and Williams et al (2007), and data from that earlier work was used to draw comparisons between the US and the UK.

The next section of the paper reports research findings on the broad area of technology assessment and appraisal, and this is followed by a section which considers in detail the use of cost-effectiveness analysis (CEA) in US health care.

3. Technology assessment and appraisal

An overview of the main themes relating to technology assessment and appraisal are given in Table 1.

3.1 The policy process

The policy process in all four US settings studied can be characterised as formal and evidence-based. Inevitably there was some variation in approach and level of resource commitment between organisations but the similarities are striking.

Technology assessment teams exist in all four organisations and the main function of such teams is to review and synthesise evidence for presentation to a decision making or advisory committee. For example, BCBS has a Technology Evaluation Center which has responsibility for the assessment work and conducts reviews and analyses and prepares reports on technologies that are then presented to the decision-making body within the Association, the Medical Advisory Panel (MAP). Similarly, at K-P there exist teams of technology assessment analysts at regional levels and their work is prepared for, and presented to, the Inter-Regional New Technologies Committee (INTC). The emphasis on evidence-based decision making is very strong in all four US organisations.

I really think the strength is the evidence-based approach... we basically say, show us the data and there are times when we say, ok there are data there but we don't think the data are yet strong enough...And so really trying to say let's stick with the evidence is the major strength. (BCBS)

we try to be as evidence-based as we can, so we place great emphasis on hard clinical outcomes (VA)

A feature of the technology assessment process seen in some but not all US settings was the use of a structured and organization-wide input into the policy development process. This was most noticeable in the VA and K-P where structures are in place which facilitate effective consultation across relevant stakeholders (e.g. pharmacy leads and physician leads for given clinical areas). This was seen to have advantages in terms of development of sound policy positions on the new technology in question but also to support the organisation in achieving clinical buy-in to the guideline or recommendation.

[the draft monograph] goes to the VISN formulary leaders, who review it and circulate this to people who they think it would be of interest to ... a cardiology drug, they send to various cardiologists. We also broadly disseminate these monographs and so there are technical advisory groups in the VA, such as nephrology, etc. ... and we send a copy to them. (VA)

we spend a lot of time up front getting buy-in and we believe that's important ... We believe that by including them up front and giving them the opportunity, by the time we make the decision and they have some action, there's not going to be as much push-back ... So it works very well. (VA)

In all four settings the process of appraisal and decision-making happens through the vehicle of a formal committee. For example, for non-drug technologies, at Aetna decisions are taken by the Clinical Policy Consul (CPC) and at K-P by the INTC. The broad composition of the committees varied across organisations but in most settings the committee includes some people from outside in order to increase legitimacy. Further, in all four organisations use was made of explicit criteria in reaching committee judgements.

However, there exists variation across organisations in terms of the nature of the decisions taken. At Aetna, the CPC and the pharmaceutical committee make coverage decisions which means that a new technology not approved by such a committee will not generally be available as part of an Aetna health insurance plan. Similarly, if a drug is not supported in the VA by its Medical Advisory Panel (MAP) then it will not be listed on the VA national formulary and will not routinely be available for use by VA physicians and patients. In contrast, some committees,

notably the INTC at K-P and the MAP at BCBSA, are explicit in stating that they do not make coverage decisions. Such committees receive evidence, appraise that evidence and come to a policy position on a particular technology but that position represents guidance and not clinical policy for the organisation more broadly. Policy in BCBS is made by the local state-level plans, and not the federal-level Association, and for K-P, decision making on use of new technologies is ultimately left to the discretion of the individual physician at the bed-side.

The Blue Cross Blue Shield companies ... make independent coverage decisions, the Association does not make coverage decisions for them; we make recommendations to them on policies. Most of the time their policies are consistent with the recommendations in our medical policy reference manual (BCBS)

The INTC does not make coverage decisions. They issue advice and guidance to the eight regions ... Coverage decisions are made at the bedside or on an individual patient level. (KP)

These observations on the US, particularly relating to the formality and evidence-based nature of the technology assessment process, mirror the position at a national level in the UK. Similar observations could be made in relation to the technology appraisals process at NICE. In that setting, technology assessment work is commissioned and the resulting evidence is presented before a decision making body, the technology appraisals committee, which makes a coverage decision that is binding across the NHS. Areas where the policy process employed by NICE is arguably at odds with that observed in the US include the effective organisation-wide input and engagement, and the use of explicit criteria to make decisions.

3.2 The evidence

A striking feature seen in most US settings, and in contrast to the position adopted in the UK by NICE, is the reluctance to make use of unpublished material and the value associated with evidence that has been subject to peer-review through the publication process. This point is, in part, linked to the issue (covered later) of limited input from the pharmaceutical or device industries who, as manufacturers of the technologies in question, represent a potential additional source of information. From the review of documentation, observation of meetings and interviews, it was evident that the focus is largely on making use of data and evidence that had been subject to a peer-review process and is published in high-standing journals.

So I think the strength really is that we're saying data, it needs to be published, its not what was presented at last week's annual meeting of whatever society, but it needs to be published data. (BCBS)

we place our value in published studies and even the published studies will be reviewed by the clinical staff and determine whether the end point in that study was justified by how the study was developed. (VA)

We're really not interested in data on file, the abstracts that they've submitted, because typically there's a reason why it's not published and we just don't want that. (VA)

The position in the UK is that unpublished and commercial-in-confidence data can be, and frequently is, included as part of a manufacturer's submission to NICE. That information is then considered in the process of reaching a coverage decision and

continues to be treated as confidential. It is not made public until authorization is granted from the sponsor.

From an economist's perspective, possibly one of the most intriguing observations of the technology assessment processes seen in all four settings is the almost exclusive focus on issues of effectiveness and the very limited consideration of costs issues. This theme will be explored more fully later in the paper but this quote from an interviewee from a state-level BCBS gives a flavour of the issue.

That's important – cost is not discussed. The physicians involved, the literature, nothing discusses cost. It's only Is it medically necessary, is it safe and is it effective? ... occasionally people will try and get a cost discussion going but we have to shut them down because I don't want anybody saying your medical policy decided this on the basis of cost. (BCBS)

Particularly in the context of the VA, there was an explicit recognition amongst some interviewees that cost issues had to be considered but equally there was a frustration that it was not possible to obtain good information at the time a decision on formulary listing was being made.

We spend a lot of time looking at costs because it's very important that we are good stewards of federal tax money ... and, as you know, most commonly we don't have good CEA data. (VA)

The contrast here with the UK setting is particularly stark – NICE makes explicit use of cost and CEA information and it is recognised as a key information driver of coverage decisions (Raftery, 2001; Devlin and Parkin, 2004; Bryan et al, 2007; Williams et al, 2007). Further, the problem of limited availability of high quality and relevant CEAs has been overcome through two routes: direct commissioning of new analyses by academic teams and making such analyses an expected part of the dossier of information submitted by manufacturers.

4. Cost and cost-effectiveness analysis and US health care

Thus, the data collected as part of this research suggest that cost-effectiveness information and cost considerations more broadly are largely absent from coverage decisions in the US health care organisations studied. This is not the first study to highlight this issue and so initially the literature in this area will be considered before reporting interview data.

4.1 The literature

The evidence used to inform coverage decision-making has previously been explored (Steiner et al, 1996; Garber, 2001) and several recent contributions to the literature highlight the fact that cost-effectiveness information is not routinely considered in coverage decisions, both for public health insurance (e.g. Medicare) and private health plans (Gillick, 2004; Tunis, 2004; Eddy, 2001; Jacobsen and Kanna, 2001). As Tunis (2004) states, specifically in the context of Medicare coverage,

One of the most difficult policy issues confronted in any decision on coverage criteria is the role of cost-effectiveness analysis in deciding what is to be considered reasonable and necessary. (p2197)

Others have expressed similar opinions indicating a reluctance on the part of stakeholders to buy into a cost-effectiveness approach (Ginsberg, 2004; Berenson, 2003). Garber (2004) indicates in the context of Medicare that “The MCAC [Medicare Coverage Advisory Committee] has no mechanism by which it can consider costs or value in making its coverage decisions.” Similarly, in relation to coverage decision making in private health plans, Neumann indicates that “few, if any, providers use cost-effectiveness as a formal policy tool” (Neumann, 2005).

There are, however, some notable exceptions to this rule. In line with our interview data, decision making in the Veterans Health Administration in relation to drug formulary decisions appears to be taking some account of cost information, with formal CEA also being considered where such data can be obtained in a reliable form and in a timely manner (Aspinall et al, 2005). Another example is the US Preventive Services Task Force (USPSTF) which, although not a policy making body, does provide influential guidance to US health care professionals on preventive care. When the USPSTF was first established in 1984, it explicitly excluded cost considerations from its evaluative process but information on costs and cost-effectiveness is increasingly being factored into the USPSTF’s deliberations (Salinsky, 2005).

Despite these pockets of the US health care system where CEA is beginning to play a role, the overwhelming message, even from recent commentators and researchers is that CEA remains largely something to be ignored in US coverage decision making, and at best is seen as a marginal part of the information set (Siegel, 2005; Garber, 2004). And so the rallying call by Power & Eisenberg (1998) for greater use of cost-effectiveness approaches has gone unheeded.

There is no question that financial and medical effects will be considered when making health care decisions at all levels of policy making; the only question is whether they will be considered well. ... CEA can provide a framework for decision-makers at all levels for systematically evaluating the implications of resource allocation.

Power & Eisenberg (1998)

4.2 The interview data

Given the message from the literature of limited use of CEA and the strength of this finding in our interview data, we explored this issue further, probing on the factors driving this observation. This section of the paper focuses on these issues.

First it is important to note that the data contain evidence of some exceptions to the general rule of no use of cost information. The interview quotes below give an indication of this. For example, in discussing decision making concerning formulary decision-making for drugs, one of the K-P interviewees indicated that where there was no clear difference between a new and older drug in terms of efficacy and side effect profile (e.g. where they were in same therapeutic class) then recommending use of the lower cost drug was seen as appropriate. Further, the BCBS Association do occasionally extend the remit of their technology assessments to include cost and CEA as a means of providing information that is seen as potentially supportive and helpful to those working in local plans. This is, however, a rare occurrence. And, as indicated in the literature, VA interviewees indicated a strong recognition of a responsibility to use resources wisely given the fact that federal tax dollars were being used to finance the programme.

CEA tends to be used more in terms of making decisions about selection of drugs within a therapeutic class or for a specific indication (KP)

In a number of situations we have commissioned CE studies ... as a means of providing information to the system. Whether individual plans use those in their decision making or not is uncertain. (BCBS)

We spend a lot of time looking at costs because it's very important that we are good stewards of federal tax money ... and, as you know, most commonly we don't have good CEA data. (VA)

4.2.1 Frustration at lack of use of CEA

The majority of interviewees, from across all four organisations, indicated a sense of frustration in their inability explicitly to consider cost and CEA issues when making decisions on the adoption or coverage of new technologies. There was broadly a consensus amongst interviewees that coverage decisions should be made using information on both effectiveness and cost. However, there was also a sense of pessimism in terms of whether this could be achieved given the magnitude of the constraints and barriers in the way of such a change.

People don't like to put a money value on life and it's dumb. I've had these discussions, ... and every time I get into this issue of cost, people say 'Cost should not be your concern, your concern as a physician ... should be only one thing, what is the best thing for the patient?' ...And I have patients who will say to me 'Ah, the VA is just trying to save money' and I'm unapologetic. I say, what is so bad about that? If money were no issue, if the well springs were open and we had unlimited dollars, I would love not to worry about money. (VA)

However, a small minority of interviewees expressed a very different line which was to recognise the problem of escalating costs but to see solutions in terms of demand management and demand reduction rather than limiting the scope of covered services available through an insurance plan.

The perverse thing in the US is that health care has never really been in the market, because the payer has always paid everything and the doctor and the patient just use it up. If you're going to actually have it be market-based, they have to have skin-in-the-game or it's not market-based. (Aetna)

4.2.2 Fear of media reaction and public backlash

Commercial health plans, by definition, are operating in a competitive market environment and, hence, are primarily seeking to provide a high quality product (both in terms of insurance and health care services) at a price that consumers see as reasonable and are willing to pay. Naturally, therefore, those interviewees working in such a setting reflected on the challenge of explicitly considering cost information given their commercial context. Two related fears or concerns were then expressed. The first was simply that, were a plan to move to coverage on the basis of CEA information, members and other consumers would view that in a very negative light and see it as 'rationing'; the feared consequence being a loss of plan members.

Public resistance to the use of cost-effectiveness analysis in health care is often cited as a major impediment to reform. Authors have claimed that members of the general public crave new technology (Kim et al, 2001), and have a sense of entitlement when

third party payers cover their bills. Americans, it is felt, do not favour explicit limit setting, particularly with regards to their personal benefits. To explain the successful application of CEA methods in other countries, authors refer to a general distrust in America of large organizations and systems which arise from them (Neumann, 2004). However, research into public attitudes in the US towards the use of CEA to control health care costs have been few. However, the work that has been done indicates a willingness on the part of the general public to consider such approaches (Gold et al, in press; Ginsberg, 2004).

The second fear under this header is that the first commercial health plan that made a move to explicit coverage decision making on the basis of CEA would be subject to media scrutiny and that such media exposure is unlikely to be sympathetic to the plan concerned. The price of ending up on the front page of the New York Times would be very high and would be felt in terms of lost market share and lost revenue for the plan.

Personally I would support that. From the organisation perspective, they are so much afraid of being accused of deciding coverage on price that they don't want to do that unless somebody like Medicare does it first. They don't want to take the heat because we would end up in the New York Times (BCBS)

4.2.3 The regulatory environment for private plans and fear of the courts

An issue raised by several interviewees working in private plans was the nature of the regulation of health plans at a state level. Such regulation varies from state to state and so it is difficult to make general statements about such obstacles. The interviews conducted in California provide some insights into the position in that state. For example, the state regulator of managed health care plans (the California Department of Managed Health Care) acts as an arbiter between plans and members when a treatment has been denied by the plan. One interviewee was far from confident that a treatment denial by a plan on the basis of cost-effectiveness would be upheld by the regulator.

I think that in some states there are limits [to what CEA could be used for] ... many states say certain things have to be covered (BCBS)

A similar issue of concern, often cited in the literature as a barrier to use of CEA in the US, is the fear of the courts (Neumann, 2005). The argument is that health care decision makers may exercise caution in explicitly implementing cost-effectiveness analysis in coverage decisions due to legal and regulatory concerns. The use of CEA by private insurers might contravene common contractual obligations to provide all “medically necessary” care. The designation of specific forms of care as “cost-effective” might be perceived as essentially making a medical decision, incurring liability for any adverse outcomes.

The interview data, however, gives us very little on this issue – when given the opportunity to identify barriers to the use of CEA in their own settings, only two interviewees raised this issue and for one it was stated robustly that there was little fear of being sued on this matter.

The hands of providers in the US are tied, especially because of the litigious nature of the US society. (KP)

we fear the media much more than we do the legal because we get sued 4,500 times a year and most of them are civil suits and we fight them and they're all done and don't get in the papers (BCBS)

4.2.4 Concerns with the quality of CE analyses

It is an oft cited concern, and an explanation for the limited use of CEA, that CE methods are too weak, and so the call is for the methods to be strengthened before US decision makers will make use of the technique. The data we collected contain very little reference to this concern with poor methods. There are two possible explanations for this: first, that interviewees were poorly informed about CEA methods and so did not appreciate some of their weaknesses; and second, that they did not see any methods problems as key barriers. In truth, the interview sample gives us some of both – it includes some interviewees who clearly were very well informed about CEA whilst others revealed a more limited understanding of the approach.

The issues raised in relation to cost-effectiveness analyses themselves fall into two broad categories: bias in the analyses given the high prevalence of industry-sponsored work, and lack of direct relevance of the analysis to the patient/client group being served. The latter was particularly an issue in the VA context where the health care system is serving predominantly an older male population.

the problem is that usually when a new drug comes out there is no cost effectiveness stuff, or the only stuff out there is basically garbage from the drug manufacturer (VA)

we don't have good CEA models. The ones that we've looked at are either too rigid, you can't change the parameters, ... or maybe have some basic underlying assumptions which we would not necessarily agree with and that's the foundation for the model ... We don't have the funding to do a CEA for every drug (VA)

5. Conclusions

For the US:

- Bolder health plans?!
 - Why not test the market with policies that have explicit limits/restrictions ('prudent plans')?
 - Would need to overcome multiple fears: media reaction, public backlash, litigation, regulators, not following Medicare
 - Would need strong sales pitch and strong supporters/advocates
- Less duplication of technology assessment activity and more collaboration, including international collaboration
- More widespread consideration of appropriate role/influence of pharmaceutical and device manufacturers (some examples of considerable success)

For the UK:

- Moves towards a more formal, structured and organization-wide input into the policy process from across the NHS
- Review of the value in making use of unpublished, commercial-in-confidence data and materials
- Review of the appropriate role/influence of pharmaceutical and device manufacturers and learning from positions adopted by some US health care organisations

There is now increasing use of CEA approaches outside the US, most notably in the UK, with evidence of considerable success in its use as an aid to decision making. The picture in the US is very different. The main barriers to use of CEA in the US include a fear amongst health plans of litigation and of public backlash, mistrust of industry and of CEA methods, and a belief amongst some that other approaches can be used more effectively to manage scarcity.

Acknowledgements

The work reported here was largely undertaken whilst Stirling Bryan was a Harkness Fellow in Health Care Policy at Stanford University. The work was supported by The Commonwealth Fund. A particular thank-you to all those who agreed to be interviewed and to others at Kaiser-Permanente, the Veterans' Administration, Aetna and Blue Cross Blue Shield who supported me in this work. In addition, thanks to all colleagues at Stanford University, City University of New York and Birmingham University for comments on this work.

References

- Aaron HJ. Should public policy seek to control the growth of health care spending? *Health Affairs* 2004 Web exclusive, March 31, 28-36
- Aspinall SL, Good CB, Glassman PA, Valentino MA. The evolving use of cost-effectiveness analysis in formulary management within the Department of Veterans Affairs. *Medical Care* 2005;43(7 Suppl):20-26
- Berenson RA. Getting serious about excessive Medicare spending: a purchasing model. *Health Affairs* 2003 Web exclusive, December 10, 586-602
- Bryan S, Williams I, McIver S. Seeing the NICE side of cost-effectiveness analysis: A qualitative investigation of the use of CEA in NICE technology appraisals. *Health Economics* (in press)
- Daniels N, Sabin JE. Setting limits fairly. New York: Oxford University Press, 2002
- Devlin N, Parkin D. Does NICE have a cost effectiveness threshold and what other factors influence its decisions? A binary choice analysis. *Health Economics* 2004;13: 437-52
- Eddy DM. The use of evidence and cost-effectiveness by the courts: how can it help improve health care? *Journal of Health Politics, Policy and Law* 2001;26:387-408
- Foote SB. Focus on locus: Evolution of Medicare's local coverage policy. *Health Affairs* 2003;22:137-145
- Garber AM. Cost-effectiveness and evidence evaluation as criteria for coverage policy. *Health Affairs* 2004 Web exclusive, May 19, 284-296
- Garber AM. Evidence-based coverage policy. *Health Affairs* 2001;20:62-82
- Gillick MR. Medicare coverage for technological innovations – time for new criteria? *New England Journal of Medicine* 2004;350:2199-2203
- Ginsberg ME. Cost-effectiveness: will the public buy it or balk? *Health Affairs* 2004 Web exclusive, May 19, 297-299
- Gold MR, Sofaer S, Siegelberg T. Medicare: Time to ask the taxpayers? *Health Affairs* (in press)
- Jacobsen PD, Kanna ML. Cost-effectiveness analysis in the courts: recent trends and future prospects. *Journal of Health Politics, Policy and Law* 2001;25:291-326
- Jost TS. Disentitlement? The threats facing our public health-care programs and a rights-based response. New York: Oxford University Press, 2003
- Jost TS. The Medicare coverage determination process in the United States. In TS Jost *Health Care Coverage Determinations: A International Comparative Study*. Maidenhead: Open University Press, in press
- Kim M, Blendon RJ, Benson JM. How Interested Are Americans in New Medical Technologies? A multi-country comparison. *Health Affairs* 2001;20(5):194-201
- Neumann PJ. Using cost-effectiveness analysis to improve health care. Opportunities and Barriers. Oxford. Oxford University Press. 2005
- Pauly MV. Should we be worried about high real medical spending growth in the United States? *Health Affairs* 2003 Web exclusive, January 8, 15-27
- Pauly MV. What if technology never stops improving? Medicare's future under continuous cost increases? *Washington and Lee Law Review* 2004;60:1233-50
- Pearson SD, Sabin JE, Emanuel EJ. No margin, no mission: health care organizations and the quest for ethical excellence. New York: Oxford University Press, 2003
- Pope C, Mays N. Qualitative Research: reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. *British Medical Journal* 1995; 311:42-45
- Power EJM, Eisenberg JM. Are we ready to use cost-effectiveness in health care decision-making? A health services research challenge for clinicians, patients, health care systems, and public policy. *Medical Care* 1998;36(5 Suppl):10-17
- Raftery J. NICE: faster access to modern treatments? Analysis of guidance on health technologies. *BMJ* 2001;323: 1300-3

Salinsky E. Clinical Preventive Services: When is the juice worth the squeeze? National Health Policy Forum, George Washington University. Issue Brief 806, August 2005 (http://www.nhpf.org/pdfs_ib/IB806_ClinicalPrevServices_08-24-05.pdf)

Siegel J. Cost-Effectiveness Analysis in US Healthcare Decision-Making: Where Is It Going? *Medical Care* 2005;43(7 Suppl):1-4

Steiner CA, Rowe NR, Anderson GF. Coverage decisions for medical technology by managed care: relationship to organizational and physician payment characteristics. *American Journal of Managed Care* 1996;2:1321-1331

Tunis S. Why Medicare has not established criteria for coverage decisions. *New England Journal of Medicine* 2004;350:2196-2198

Williams I, Bryan S, McIver S. Health Technology Coverage Decisions: The NICE approach to use of cost-effectiveness analysis. *Journal of Health Services Research & Policy* (in press)

Williams I, Bryan S. Understanding the Limited Impact of Economic Evaluation in Health Care Resource Allocation: a conceptual framework, *Health Policy* (in press)

Figure A: Technology coverage process

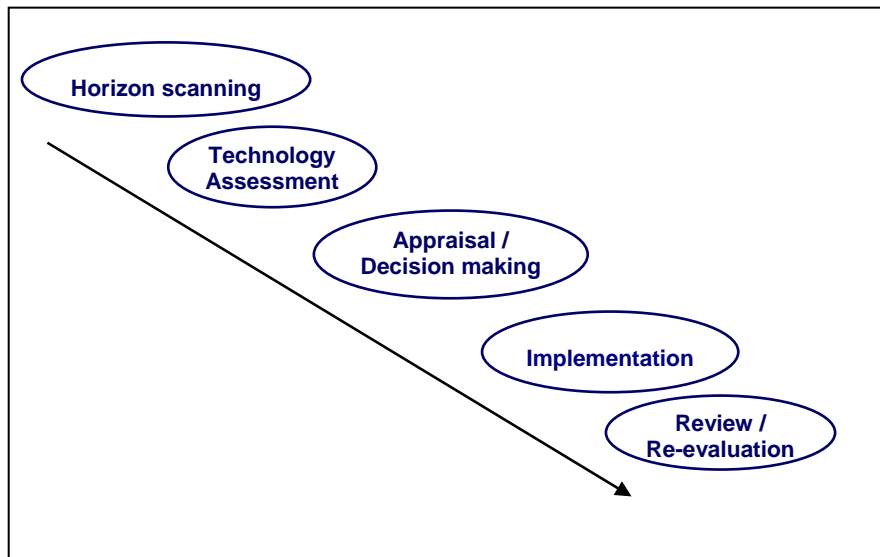


Figure B: Semi-structured Interview Schedule

Interview Schedule	
<i>General introductions</i>	
1.	In broad terms, would you please describe your position and role at <u>Kaiser-Permanente</u> ?
2.	Specifically, what involvement do you have in decision-making concerning the adoption or 'coverage' of health care technologies (drugs, devices, procedures, etc.)?
3.	Can you outline the main processes employed at <u>Kaiser-Permanente</u> in making decisions on adoption / coverage of new technologies? <ul style="list-style-type: none">- What information tends to be drawn upon to inform such decisions?- Who is involved in the process?- How is a decision arrived at?- What criteria are applied?
4.	Once a decision has been made, how are implementation issues addressed? <ul style="list-style-type: none">- Who is involved in the implementation process?- In what ways is technology use by individual clinicians audited / monitored?
5.	In your opinion, do you feel that <u>Kaiser-Permanente</u> 's current technology decision-making process is working well? <ul style="list-style-type: none">- Can you describe some specific success stories?- Are there examples where there have been difficulties or challenges?
6.	From the perspective of someone seeking to learn from the <u>Kaiser-Permanente</u> model (regarding adoption / coverage of new technologies), what is the one key feature you would highlight?
7.	Finally, I would like to ask you some questions specifically about cost-effectiveness analyses. I see a lot of CEAs being undertaken and published in the US, in some high profile places (e.g. NEJM), but very little explicit use of such information. What is your take on this? <ul style="list-style-type: none">- Why is use of CEA so limited in US health care?- What are the main barriers to the more widespread use of CEA?- To what extent are these issues relevant and real at <u>Kaiser-Permanente</u>?
8.	Thank you very much for your time. Is there anything else you would like to add?
<i>End of interview</i>	

Table 1: Overview comparison of technology assessment / appraisal

	Themes observed in the US settings studied	Similar situation in England / NICE?
<i>The policy process</i>	Formal, evidence-based, policy processes	Yes
	Structured and organization-wide input into the policy process	Yes (but strengthening possible)
	Decisions by formal standing committees	Yes
	Use of explicit criteria	Yes (but strengthening possible)
	Decisions made on coverage of technologies	Yes
	Limited input from pharmaceutical and device manufacturers	No
<i>The evidence</i>	Primary focus on 'effectiveness' and not 'costs'	No
	Use of published material predominantly	No