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Is the aim of the health care system to maximise QALYs?

An investigation of ‘what else matters’ in the NHS

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Is the aim of the health care system to maximise QALYs? An investigation of 'what else matters' in the NHS

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Abstract

Background: It is often assumed that the objective of health care is to maximise health using available resources. This is the principle underpinning NICE’s use of cost effectiveness analysis based on incremental cost per QALY gained. Yet research on local NHS decision making shows that cost per QALY is far from the only consideration. Similarly, many key national health policy initiatives appear to be driven primarily not by QALY gain, but by ‘process-of-care’ and other considerations. The apparent disjunction between the goals being pursued by different agencies within the health care system has potentially important implications for efficiency.

Objective: While the criteria used by NICE are well understood, the principles underpinning policy evaluation by the Department of Health (DH) have not previously been subject to any systematic enquiry. Since 2008, the DH has been required to undertake and publish Impact Assessments (IAs) identifying the costs and benefits expected from all new policy implementation. The aim of this study is to identify the benefits considered by the DH as relevant to its decision making, and to highlight implications for decision making across the NHS.

Methods: We analyse all IAs carried out by the DH in 2008 and 2009. The stated benefits of each policy were extracted and a combination of methods used to categorise these. Other DH documents were consulted for information on the means by which these benefits are valued.

Results: 51 IAs were analysed, 8 of which mentioned QALY gains as a benefit. 18 benefits other than QALY gains were identified. Apart from improving health outcomes, commonly referred to types of benefit included: reducing costs, improving quality of care, and enhancing patient experience and empowerment. Many of the policies reviewed were implemented on the basis of benefits unrelated to health outcome. The methods being used to apply a monetary valuation to QALY gains (in IA cost-benefit calculations) are not consistent across IAs or with NICE’s stated threshold range.

Conclusions: The DH, local NHS commissioners of health care and NICE each appear to approach resource allocation decisions in different ways, based upon different considerations and underlying principles. Given that all these decisions affect the allocation of a fixed health care budget, there is a case for establishing a uniform framework for option appraisal and priority setting.

1 Introduction

The appraisal of new health care technologies, as undertaken by the National Institute for Health and Clinical Excellence (NICE) in the UK and by similar agencies in other countries, focuses on the cost effectiveness of those technologies, generally measured in terms of the incremental cost per quality adjusted life year (QALY) gained. While factors other than cost effectiveness are taken into account (NICE, 2008a; NICE, 2008b; Rawlins et al., 2010) and can be observed to exert at least some influence on NICE decisions (Devlin and Parkin, 2004; Devlin et al., 2011), cost effectiveness is the dominant consideration.

The use of cost effectiveness analysis in health technology appraisal reflects an underlying ('non-' or 'extra welfarist') normative position that the principal aim of the NHS is to maximise QALYs (Brouwer et al., 2008; Culyer, 1991; Tsuchiya and Williams, 2001). The threshold range used by NICE to make judgements about cost effectiveness is intended to reflect the NHS budget constraint and the opportunity cost, in QALY terms, of implementing NICE guidance in the NHS.

Yet research on how NHS commissioners of health care allocate their local budgets, and the criteria taken into account when making investment and disinvestment decisions at the local level, shows that cost effectiveness is not the dominant (and often not even a main) consideration. Indeed cost effectiveness evidence seems rarely to be used (Appleby et al., 2009). Where cost effectiveness is taken into account in explicit priority setting frameworks, it is often considered alongside other considerations and criteria (for example, see Mullen, 2004; Devlin and Sussex, 2011). A wide range of factors appear to influence commissioning decisions.

Similarly, at the policy level, a number of key Department of Health (DH) policy initiatives appear not to be driven primarily by the pursuit of QALY gain, but to focus instead on what might be described as 'process-of-care' considerations. For example, NHS waiting times targets were a prominent feature of health policy during the last decade. While some health gain might arise from the quicker treatment of patients, targets can also result in prioritising those who have waited longest over those with the most severe health problems (Dimakou et al., 2009). While some improvement in the timeliness of treatment may have been achieved by greater efficiency, it is clear that targets were achieved mainly through a combination of tough managerial action, practical help to hospitals, political commitment and extra resources. The Government's 2004 Spending Review settlement for the NHS allowed around £2.7 billion for use in reducing waiting times (Department of Health, 2006). Waiting time policies were arguably motivated by considerations of responsiveness, patient satisfaction, and in particular public attitudes towards excessively long waiting times, rather than by the QALYs gained from quicker treatment. The opportunity cost, in terms of QALYs foregone from alternative ways of using those resources to shorten waits, would have been considerable.

Other high-profile examples include the mandatory provision of single sex hospital accommodation by NHS providers. The principal benefits of eliminating mixed sex hospital accommodation are the protection of patients' privacy, respect and dignity. The NHS resources used in meeting these requirements are unlikely to result in QALY gains, and that is not the principal purpose of the policy.

It is clear therefore that substantial amounts of NHS resource are devoted to the achievement of goals other than health improvement. From a QALY maximisation perspective, such initiatives appear hard to justify. It is worth noting that both patients (Burge et al., 2004) and the general public (Dolan et al., 2005) have been shown to be willing to sacrifice at least some aggregate health in order to achieve a range of institutional, distributional, and process-related objectives. This paper, however, focuses on the objectives that are considered relevant by health care decision makers.

Prima facie, there seems to be a disjunction between the views of the DH, NICE and commissioners about what the aims of the NHS are, what (if anything) the health system is intended to maximise, and what importance is attached to the various goals. Where goals are not aligned, this gives rise to obvious concerns about efficiency (defined in broad terms as "the allocation of scarce resources that maximises the achievement of aims" – Knapp, 1984).

NICE's decision making approach is intended to be consistent with NHS collectively agreed objectives and resource constraints, and it has been argued that the Institute has "responsibility for assessing and signalling value on behalf of the whole NHS" (Claxton et al., 2008). Expressed in another way, the NHS (the principal) has delegated to NICE (as its agent) decisions with respect to health care technologies, as a means of addressing the informational asymmetry that exists between the NHS and technology manufacturers. A necessary, but not sufficient, condition for NICE to act as a 'perfect agent' is that it carries out its role in a manner which is congruent with NHS priorities and goals. If it does not, there is a risk that "the objectives of society for the health care system are lost" (Smith et al., 1997). This in turn relies on NICE having a clear understanding of the preferences and priorities of the NHS – that is, the attributes of benefit that are relevant, and the importance attached to these. Whilst NHS core principles and the NHS Constitution set out general frameworks, it is likely that these are too broad to offer any specific guide to health technology assessment or priority setting processes.

The respective roles of DH civil servants and NICE differ. DH civil servants assess the impacts of new policies in order to advise Government ministers, whereas NICE officials assess whether the NHS should commit resources to a health technology. But the policies and technologies they respectively assess depend on the same limited budget of resources. Allocative efficiency within that budget requires that both groups assess according to the same criteria.

The issue of what the NHS is intended to maximise, and how this is reflected in decision making regarding new technologies, has been highlighted by Government plans to introduce value-based pricing (VBP) for new medicines in 2014 (DH, 2010c). Linking the maximum price of medicines to a measure of their 'total value' requires an explicit process for the identification, valuation and aggregation of relevant considerations. While the criteria used by NICE are clearly articulated (NICE, 2008a; NICE, 2008b), the way these criteria are combined via its deliberative processes remains unclear; in contrast, VBP will require an explicit approach to the weights attached to each consideration.

Compared to the considerable attention and close scrutiny paid to the criteria used by NICE in its health technology assessment activity, to date the principles underpinning the DH's approach to policy evaluation have not previously been subject to any systematic enquiry. Since 2008, the DH has been required to undertake and publish Impact Assessments (IAs) identifying the costs and benefits expected from all new policy implementation. The aim of this study is to identify the benefits considered by the DH as relevant to its decision making, and the manner in which they are valued; and to assess the extent to which these are consistent with the considerations taken into account by NICE. We determine empirically the criteria used by the DH in its IAs in 2008 and 2009. Over time, policies change, thus if the exercise were to be repeated in later years it is quite possible that different criteria might be identified and/or particular types of benefit might be cited with different frequencies.

The remainder of the paper is set out as follows: Section 2 provides some background information on IAs and their purpose; Section 3 outlines our approach to extracting and categorising the data from these IAs; Section 4 reports the results of this approach; Section 5 contains a discussion of the implications of our findings in terms of resource allocation, priority setting, and efficiency across the NHS; Section 6 acknowledges some of the limitations of this type of study; and Section 7 draws some conclusions from the analysis.

2 DH Impact Assessments

IAs, which replaced regulatory impact assessments in May 2007, are reported by the DH for all new legislation and policy implementation. An IA is:

> "... a short structured template published with regulatory proposals, new legislation and policy implementation. It concisely describes the issue and identifies costs and benefits that are likely to impact the public, private and/or third sector. An impact assessment must accompany any published new legislation (including European legislation). An IA is an important tool to ensure that the principles of good regulation are followed: proportionality, accountability, consistency, transparency, targeting".
>
> (Department of Health, 2010a)

An IA is viewed as:

> "… a means of developing better policy by careful consideration of the impact of relevant options upon all those affected. A good impact assessment will help a policy maker answer the questions 'What is the purpose of this policy?' and 'Which option will have the most benign impact?' It will also contain a clear analysis of whether the expected net benefits of a policy justifies the likely costs upon taxpayers, compared with a 'do nothing' alternative."
>
> (Department of Health, 2009)

IAs consider multiple policy options, usually including a 'do nothing' option.[1] The DH Technical Guidance on IAs states that the various options subject to cost benefit analysis in an IA should be constructed so as to be mutually exclusive. The objectives and intended effects of the preferred option are set out in the 'Summary interventions and options' section. Each IA also contains an 'Evidence base' section which contains details about the assessment of the policy's costs and benefits.

2.1 Valuing health outcomes in Impact Assessments

HM Treasury's website (HM Treasury, n.d.) advises that where a policy has health impacts, IAs should conform to the guidance provided by a DH guidance document entitled 'Policy Appraisal and Health' (Department of Health, 2004). This document suggests that QALYs should be valued in money terms and provides examples of different ways of valuing health, but it does not specify that any particular methods should be used. Similar advice on valuing health effects is given in the Treasury Investment Appraisal Green Book (HM Treasury, 2003).

However, some of the IAs describe and use a method for valuing QALY gains that is more specific. These refer to DH guidance that, although not published, is regarded as the recommended method, and will be incorporated into future guidance (personal communication). The method and the evidence base behind the figures used are fully described in the IA of the end of life care strategy (Department of Health, 2008a).

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[1] The 'do nothing' option can also be 'status quo', 'maintaining the current situation', 'no changes', 'no action', 'make no change', 'adjudication remains with regulatory bodies', or 'issue no guidance'.

Two different methods for valuing QALYs are used. For example, the IA for vascular checks (Department of Health, 2008b) says: “The first test of cost-effectiveness is to compare the overall cost per QALY of each scenario with the NICE lower cost-effectiveness threshold of £20,000 per QALY.” It then says: “A second test of value for money is to look at the net benefit, which has been calculated using departmental guidelines so that it is derived by subtracting twice the total cost from the [total] benefit.” The first of these is straightforward. It suggests that an incremental cost effectiveness ratio (ICER) should be estimated and compared with the threshold used by NICE. However, the second requires some explanation. It involves a specific calculation of the monetary value of the QALYs in terms of their social value. However, it is not simply a calculation of the value of QALYs gained as a result of the policy: it also includes calculation of their opportunity cost – specifically, the QALYs lost by not spending elsewhere in the NHS, which are then also valued using the social value.

As an example, imagine a policy that produces 100 QALYs and costs £1million. Further imagine that the social value of a QALY is £60,000, so the benefits of the policy are valued at £6million. The opportunity cost of the scheme is the value of the QALYs that could have been obtained by using the £1million some other way. If the current marginal cost of a QALY over all interventions is £25,000, then the next best use of the £1million would have generated 40 QALYs. Those QALYs also have a social value of £60,000, so the opportunity cost is £2.4million. The net benefit is therefore £3.6million (£6million minus £2.4million).

A shortcut method of estimating the opportunity cost is to multiply the costs by the ratio of the social value of a QALY to its marginal cost, which in this example is £60,000/£25,000 = 2.4. The ‘twice the costs’ rule referred to in the IA for vascular checks is simply the result of assuming that the social value of a QALY is £50,000 and its marginal cost £25,000, so that the value of their ratio is 2.

3 Methodology

The main source of data was the DH Publications website (Department of Health, 2010a), from which the IA documents published in 2008 and 2009 were downloaded. We considered only the IAs relating to health care or to both health care and social care; IAs relating only to social care were excluded from the study. The relevant data were extracted in March 2010, so our analysis excludes any IAs that were not available on the DH website at that time. Data extraction was carried out by a single member of the research team (CP), who compiled the relevant information for each IA in a small database using Microsoft Excel.[2] Table 1 summarises the information contained in the database.

Database field	Description
Title	Title of the IA
Date / URL	Publication date and URL of the IA
Decision	The policy option that was chosen as a result of the assessment
Comparator(s)	Rejected policy options against which the chosen option was compared
Net benefit calculations	Cost, benefit, and net benefit[3] of the chosen option
QALYs	Binary flag indicating whether the policy's benefits were valued in terms of QALYs
Number of QALYs	Where applicable, the QALY gains associated with the chosen option
How QALYs valued	Where applicable, information about how the QALY benefits were valued
Other benefits	A list of all of the benefits associated with the chosen option that were not valued in terms of QALYs
How other benefits valued	Information about how these 'other benefits' were valued
Equality impact assessment	Where applicable, information about the corresponding equality impact assessment carried out for this policy
Discount rate	Where applicable, the discount rate applied to the costs and benefits of the chosen option

Table 1: Information contained in the IA database

The 'How QALYs valued', 'Other benefits', and 'How other benefits valued' fields were populated using direct quotations from the relevant IA (paraphrasing was not permitted) in order to minimise researcher bias. The population of the 'Other benefits' field in particular was reliant on the making of subjective judgements about what constitutes a 'benefit' – in cases of doubt, CP was asked to extract as many quotations as possible in order to ensure that all potentially relevant data were captured (decisions about which data to keep/discard were made by the team collectively).

Following data extraction, the next step was to organise the various benefits into categories. In cases where two benefits were identical or very similar to each other (for example, "reduce inequalities" is a stated benefit of the chosen options in both IA 1 and IA 2), duplicates were suppressed by CP in order to produce a list of 'unique' benefits. This list was then randomly ordered, and all references to the source IAs were removed. It was then provided to two other members of the research team (JS and KKS, neither of whom were involved in the data extraction process), who then organised the benefits into categories, independently of each other. These categorisations were then collated, and any benefits about which clear agreement had not been reached were discussed at a meeting attended by all six members of the research team. At this meeting, the final categorisation system (as set out in Table 2) was agreed by the research team.

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[2] This database is available from the authors on request.

[3] Net benefit calculated as total benefit minus total cost. In some instances this was expressed as a range.

4 Results

A total of 51 IAs were identified and downloaded from the DH Publications website (see Appendix for a list). Eight of the 51 IAs (15.6%) evaluated the benefits of the chosen option in terms of QALYs. Most of the IAs also stated that the chosen option was expected to have one or more non-QALY benefits: a total of 138 'other benefits' were identified. Following a suppression of duplicate benefits, a revised list of 93 unique benefits was compiled.

As noted in Section 2, the research team agreed a system for organising each benefit into categories of benefit. This categorisation is shown in Table 2. An improvement in health outcomes (albeit not always measured in terms of QALYs) was found to be the most common type of benefit – this type of benefit appeared in 26 of the 51 IAs. Other common types of benefit included improvements in health service costs and efficiency (19 IAs), improvements in quality (15 IAs), and enhancing the patient and carer experience (11 IAs).

Table 3 shows the costs and monetised benefits of the chosen options in all relevant IAs. It excludes any IAs in which either the costs or benefits were described as being 'unknown', 'non-monetised', or simply 'positive'. In cases where these were described using a range, the median figure was included (for example, in IA 18, the expected cost was '£860,000 to £1.6million', so the corresponding figure in Table 3 is £1.2million). Costs were occasionally described using a phrase such as 'greater than £x' – in such cases, the lower bound figure of £x was included in the absence of sufficient information to justify any other estimate. The majority of IAs had chosen options with both positive costs and positive benefits, and a positive net benefit overall. All but six of the IAs had chosen options with costs of less than £500million and/or benefits of less than £1billion, the exceptions being IAs 1, 7, 31, 33, 39, and 40). Table 3 also includes a column indicating whether the IA evaluated the benefits of the chosen option in terms of QALYs. It is noteworthy that the four IAs associated with the largest monetised benefits all evaluated benefits in terms of QALYs and then applied some social value of a QALY (see Table 4 and Section 5.4 for details) to derive an estimate of the monetised benefits. The IAs that considered QALYs typically did not report any monetised benefits other than those associated with the QALY gains.

Six IAs were associated with negative net benefits (IAs 4, 6, 16, 36, 49, 50 and 51). In most cases this occurred when the chosen policy had positive implementation costs but many or all of its benefits were not monetised. Three IAs were associated with zero costs and zero monetised benefits (IAs 34, 35, 46). This tended to occur when the chosen policy referred to amendments in regulations or when it mainly affected stakeholders outside of the NHS.

Category of benefit	IA that benefit appears in	Examples
Health outcomes	1, 2, 3, 5, 7, 8, 10, 11, 12, 16, 18, 24, 26, 27, 28, 31, 32, 33, 35, 36, 41, 42, 46, 47, 49, 51 Total number of IAs: 26	“reduced morbidity as a result of lower smoking prevalence” “to reduce the risk of infection for MRSA, and ultimately the number of infections”
NHS costs and efficiency	2, 3, 4, 7, 8, 9, 12, 13, 14, 19, 21, 23, 27, 30, 36, 41, 47, 49, 51 Total number of IAs: 19	“more efficient and value for money internal handling of process “preventing companies from raising branded pharmaceuticals prices, which would force the NHS to pay more for the same quantity of medicines”
Quality	4, 6, 9, 11, 13, 17, 19, 21, 22, 24, 25, 32, 34, 35, 41 Total number of IAs: 15	“improvement in quality of patient care, arising from better commissioning underpinned by commercial skills” “to raise the level and consistency of the quality of NHS services”
Patient (and carer) experience and preferences	2, 7, 11, 13, 21, 24, 25, 26, 27, 32, 41 Total number of IAs: 11	“encourage service provision that is both efficient and responsive to patient needs and preferences” “Increase in the quality of healthcare experience for people with learning disabilities and their carers”
Procedural and institutional	4, 7, 13, 17, 20, 22, 26, 29, 42, 50 Total number of IAs: 10	“greater clarity regarding what DH will fund and how” “better information from complaints”
Benefits to external stakeholders	4, 9, 16, 27, 36, 42, 46, 48, 51 Total number of IAs: 9	“greater clarity for contractors, enabling better business planning” “the proposed amendments to the Regulations would benefit sponsors of gene therapy trials not involving novel approaches by simplifying their ethical review”
Patient empowerment	1, 5, 7, 12, 21, 25, 29, 38, 41 Total number of IAs: 9	“to support and improve people's ability to look after themselves” “involving the patient more in decisions about their care could drive wider cultural change to create a more personalised NHS, offering the patient increased control”
Choice and access	2, 11, 12, 26, 27, 41 Total number of IAs: 6	“increased access to services [for people with learning disabilities]”
Equity and fairness	1, 2, 4, 7, 27, 29 Total number of IAs: 6	“reduce inequalities”
Public trust and confidence	17, 23, 35, 36, 44, 45 Total number of IAs: 6	“restoring public and professional confidence in the role of the bodies concerned in ensuring public and patient safety”
Public empowerment	13, 25, 29, 41, 50 Total number of IAs: 5	“allow easy access to quality information, with the intention of encouraging … the public … to demand higher quality services from the NHS”
Safeguards for vulnerable groups	5, 43, 44, 45 Total number of IAs: 4	“improved protection for vulnerable groups by allowing exchange of information between regulators and vetting and barring scheme”
Benefits to staff	6, 17, 20, 26 Total number of IAs: 4	“contribution towards improved staff morale - through recognition of staff achievements in innovation
Markets and structure	4, 26, 27 Total number of IAs: 3	“[the Fund] will benefit Current care providers - PCTs, NHS Trusts, SHAs - as they will be able to commission new health and social care providers and direct resources towards local needs”
Compliance with law	10, 35, 43 Total number of IAs: 3	“bring the legislation for England and Wales into compliance with the European Court of Human rights”
Patient costs and convenience	2, 3 Total number of IAs: 2	“Saving to patients for not having to pay for own travel”
Research and innovation	25, 46 Total number of IAs: 2	“[the amendments] would benefit UK researchers by allowing them to participate in multinational trials of emergency care treatments for children's conditions”
Other	26 Total number of IAs: 1	“[the Fund] will benefit Social Enterprises (SEs) - by stimulating new SEs and encouraging the development of existing SEs”

Table 2: Summary of the non-QALY benefits of 2008-2009 DH policies

IA	Title	Cost (£m)	Monetised benefit (£m)	QALYs used?
1	IA for the Child Health Promotion Programme 2008	153	7,873	Yes
2	IA of extension of the Hospital Travel Costs Scheme	60	73	No
3	IA of moving ahead with Electronic Prescription Service (Release 2) and enabling completely electronic prescriptions in primary care	117	761	No
4	IA of new arrangements under Part IX of the Drug Tariff for the provision of stoma, urology and other appliances	15	0	No
5	IA of regulations to be made under the Public Health (control of Disease) Act 1984, as amended	2	2	No
6	IA of the merger of Postgraduate Medical Education and Training Board (PMETB) and General Medical Council (GMC)	0.18	-3.6	No
7	IA for the Personal Care at Home Bill	1,608	2,083	No
9	IA of the Commercial Operating Model (COM)	29	327	No
10	IA of prohibiting the display of tobacco at point of sale	417	925	No
14	IA of the Medicine (Products for Human Use - Fees) Regulations 2009	2.2	2.9	No
16	IA of the Blood Safety and Quality (Fees Amendment) Regulations 2009	0.02	0	No
18	IA of regulations to require NHS bodies to register with CQC and meet a requirement on HCAI [Healthcare Associated Infections] in 2009	1.2	16	No
24	IA of pharmacy market exit policy	13	13	No
27	IA of proposals to reform ‘market entry’ based on pharmaceutical needs assessments	19	318	Yes
28	IA of mandatory age restriction technology or prohibition for tobacco vending machines	165	643	No
29	IA of the NHS Constitution	195	420	Yes
30	IA of the introduction of a statutory scheme to control the prices of branded NHS medicines	240	240	No
31	IA of screening elective patients for MRSA	219	2,530	No
33	IA: putting prevention first: vascular checks, risk assessment and management	4,506	64,315	Yes
34	IA of fees for the registration of pharmacy premises	0	0	No
35	IA of Directive 2007/47/EC, Council Directive 90/385/EEC, Council Directive 93/42/EEC, Directive 98/8/EC	0	0	No
36	IA of the Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2008	4.0	0	No
38	IA of the reformed CHRE [Council for Healthcare Regulatory Excellence] Council	0.38	0.79	No
39	IA of the end of life care strategy	1,549	6,269	Yes
40	IA of a national screening programme for abdominal aortic aneurysms	420	4,304	Yes
42	IA of the third strategic funding and investment review: consultation with third sector organisations	5.3	6.3	No
46	IA of Amendments to the Medicines for Human Use (Clinical Trials) Regulations 2004	0	0	No
49	IA of the Blood Safety and Quality (Fees Amendment) Regulations 2008	0.05	0	No
50	IA of Local Involvement Networks (LINks) Regulations and Directions	258	77	No
51	IA of the Medicines Products for Human Use - Fees) Regulations 2008	6.9	0.32	No
Total		**10,005**	**91,195**	
Mean		**333**	**3,040**	
Median		**17**	**44**	

Table 3: Costs and monetised benefits for each policy, by IA

Eight of the 51 IAs evaluated policy benefits in terms of QALYs. Table 4 summarises the treatment of QALYs in these IAs.

IA	Title	Evaluation method	Social value of a QALY	QALY opportunity cost	Notes
37	IA of introduction of HPV vaccination	ICER	Not used	Not used	Compares with 'upper' NICE threshold of £30k.
40	IA of a national screening programme for abdominal aortic aneurysms	ICER, NPV	£40,000	Not used	ICER used to compare screening methods, not compared with any specific value
1	IA for the Child Health Promotion Programme 2008	NPV	£40,000	Not used	
21	IA of piloting personal health budgets	NPV	£50,000	Not used	NPV calculations provided but regarded as 'indicative' and not quoted in summary
39	IA of the end of life care strategy	NPV	£50,000	£25,000	
29	IA of the NHS Constitution	NPV	£50 000	£25,000	QALY gains are based on an estimate that £22k spent on 'recently approved new drugs' will generate one QALY.
27	IA of proposals to reform 'market entry' based on pharmaceutical needs assessments	NPV	£50,000	£25,000	Opportunity cost not stated, but implied by use of the 'double costs' rule.
33	IA: putting prevention first: vascular checks, risk assessment and management	ICER, NPV	£50,000	£25,000	Opportunity cost not stated, but implied by use of the 'double costs' rule. ICERs compared with the 'lower' NICE threshold of £20k.

Table 4: Summary of use of QALYs

Note: ICER – incremental cost effectiveness ratio; NPV – net present value

Four of these IAs used the to-be-approved DH method, using the same estimates of the social and opportunity cost value of a QALY. Three IAs calculated an NPV but did not use the QALY opportunity cost method; two of those used a different social value of a QALY. Three IAs calculated ICERs, two of which compared those ICERs with the NICE 'threshold', but one used the 'upper' and the other the 'lower' end of the range normally considered acceptable.

5 Discussion

5.1 Different types of benefits

All of the IAs published in 2008 and 2009 refer to benefits of some type. Taken together, the 51 IAs considered in this study present a long list of individual references to benefits and costs that are expressed in a variety of terms. Sometimes the benefit is referred to only in vague terms, such as "improvement in quality of patient care". From the IA it is then impossible to know precisely what aspects of quality were included. Our analysis has inevitably contained an element of subjectivity, but the mapping of individual benefit types into the 18 categories presented in Table 2 proved to be robust across different members of the research team working independently. But it is nevertheless likely that the categories overlap to some degree. For example, several of our categories might overlap with 'quality'. With that caveat in mind we have nevertheless identified that the DH is pursuing, with taxpayers' money, numerous objectives beyond health gains alone.

It might be thought *a priori* that 'NHS costs and efficiency' might be capable of being fully captured in quantitative, not least financial in respect of costs, terms. But we note that of the 19 IAs referring to 'NHS costs and efficiency', eight do not report any financial costs/savings (IAs 8, 12, 13, 19, 21, 23, 41 and 47) and four of those also make no reference to health gains (IAs 13, 19, 21 and 23). Thus an unquantified, uncosted notion of 'efficiency' is being referred to in at least a few cases, which sounds desirable, but vague. The numerous references to non-specific improvements in 'quality' sound similarly desirable and equally vague.

Some of the other benefits cited are rather clearer and furthermore correspond to statements in the NHS Constitution (Department of Health, 2010b), including:

- patient and carer experience – can be seen as corresponding to NHS Constitution promises about the "quality of care and environment" and "respect, consent and confidentiality";
- patient empowerment and public empowerment – reflect the NHS Constitution's promises to patients and citizens not only of "respect, consent and confidentiality" but also that they are to be enabled to make "informed choice" and to have "involvement in your healthcare and in the NHS";
- choice and access – match the Constitution's "access to health services" pledges;
- equity and fairness – correspond to the Constitution's statement of NHS users' right to non-discrimination in the provision of NHS services on the grounds of "gender, race, religion or belief, sexual orientation, disability (including learning disability or mental illness) or age". The NHS Constitution does not directly refer to equality across socioeconomic classes or income groups but does enshrine the principle of equal access on the basis of need, not ability to pay;
- public trust and confidence, and safeguards for vulnerable groups – are referred to indirectly in the Constitution's section on "quality of care and environment".

Of the other types of benefit referred to in the IAs, some are essentially legalistic or bureaucratic in nature. For example, compliance with the law is not a matter for NHS discretion, so ensuring that its own regulations and practices are so compliant arguably require no further justification, when the laws to be complied with were not the result of Government policy towards the NHS alone or were beyond the Government's jurisdiction – European human rights legislation, for example.

While the NHS does not exist to employ staff and provide them with benefits, few would argue that staff benefits of the kind "improved staff morale" are not worthwhile objectives for the NHS.

The 'markets and structure' benefits presumably derive from an assessment that, for example, promoting the creation of competition markets for provision of some health services will be beneficial in one or more of the other ways we have identified.

5.2 DH perspective vs. NICE perspective

NICE focuses in its technology appraisals, i.e. its economic evaluations of the costs and benefits of medicines and other forms of health care, on "health related benefits" and "costs to the NHS and PSS [Personal Social Services]" (NICE, 2008a). The comparison of these health benefits is then modified by consideration of what NICE terms 'social value judgements'. These include considerations of social equity: "the need to distribute health resources in the fairest way within society as a whole" (NICE, 2008b), but appear not to include some aspects of benefit deemed by the DH to be relevant in its IAs. Some of these benefits, such as those relating to markets and structure, are unlikely to be relevant at the level at which NICE makes decisions. But a review of the publicly available documents outlining the principles its applies when appraising health technologies suggests that NICE also takes no account of: benefits to external stakeholders, patient empowerment, public empowerment, public trust and confidence in the NHS, procedural and institutional benefits, benefits to staff morale, patient costs and convenience, or benefits to researchers. But the DH does. The limited budget of the NHS is at stake in both cases, but two different, though overlapping, sets of criteria are being used by the DH and NICE to guide the allocation of those scarce resources. The debate about which cost-benefit perspective is most 'appropriate' for decision making in a budget-constrained health system remains unresolved (Claxton et al., 2010; Johannesson et al., 2009), but greater consistency within any given health system would be desirable.

5.3 Unquantified benefits

Only eight of the 51 IAs included estimates of impacts in terms of QALYs. A large minority, 21 out of 51 IAs, provided no estimates of impacts expressed in monetary terms but stated that benefits could not be monetised or quantified. Where there are numerous possible criteria and some of them are not readily convertible into financial or QALY terms, consistency across different decisions would be aided, or would at least be more demonstrable to those not making the decisions, if multi-criteria decision analysis (MCDA) techniques were to be employed. At their most basic these simply require an explicit list to be made of the criteria used to assess the impact and an indication of how far the measure being assessed achieved those criteria. Use of such a list would at least help to ensure that full consideration of the same set of criteria was taking place in all decisions affecting the use of NHS resources.

Ensuring consistency across decisions in the trade-offs being made by decision makers between different criteria would, however, require more than simply a listing of those criteria. More sophisticated and formal MCDA techniques could be considered, which present numerical weights for different criteria and numerical scores for the extent to which different measures achieve them, thereby permitting sensitivities to be tested, showing how robust the case for a particular measure is or is not (Devlin and Sussex, 2011; Department for Communities and Local Government, 2009).

5.4 Treatment of QALY gains

Table 4 shows that the treatment of QALY gains in IAs is not entirely consistent in method or in the actual values used. The DH social value/opportunity cost method with values of £50,000 and £25,000 respectively are the most commonly used. Given the enormous resource use consequences of the policies whose impact is being assessed, it is curious that this method has clearly been given as guidance by the DH but has been neither published nor subject to evaluation outside of the DH. Variation in the treatment of QALY gains is apparent not just in the set of IAs analysed in this study but also in IAs published subsequently. For example, whereas we observed figures for the social value of a QALY of £40,000 and £50,000 in our analysis, the 2011 IA of the Strategy for Cancer notes that "it is estimated that the general public value one QALY at £60,000" (Department of Health, 2011). A number of different sources for these various estimates have been cited – see, for example, pp. 30-31 of the IA of the end of life care strategy (Department of Health, 2008a).

6 Limitations of this study

Although steps were taken to minimise bias (for example, by clearly separating the data extraction and categorisation tasks), the content analysis approach used in this study necessarily involves an element of subjective judgement. There is no objective rule, for instance, for deciding what should and should not count as a 'benefit' of a policy. Similarly, the methods used for categorising the benefits were reliant on subjective judgements, although this was mitigated by having two researchers conduct the task independently.

Table 1 presents data on the number of times that a particular type of benefit appears in the 51 IAs. It is not necessarily the case, however, that a benefit that appears many times should be interpreted as being more 'important' than one that appears only a few times. Our methodology did not distinguish between benefits that were the primary objective of a policy and those that were secondary objectives or even unintended (albeit beneficial) side effects.

7 Concluding remarks

The DH and NICE appear to have different views about how to assess the impact of NHS spending. The question of what the NHS is attempting to maximise is in turn closely related to the question of what the relevant budget constraints are. Is decision making concerned with the efficient use of the NHS budget, the public sector, patients, or the whole economy? It is important to note that there is no technically correct answer to this question – it depends in part on the underlying normative framework. In the case of NICE decision making, the focus on publicly funded health and social care costs can mean that appraisal favours technologies that shift costs away from the health care sector onto individuals or other areas of the public sector. However, adopting a wider perspective on costs suggests, taken to the extreme, that "…an 'über-NICE' would be required to compare all possible uses of society's total resources. Decisions made from this broader perspective might maximise society's welfare but would not maximise health gain from the NHS budget" (Devlin et al., 2003).

Regardless of which cost and benefit perspective is deemed appropriate, our analysis suggests that the perspective taken by NICE is very different from the perspective being adopted by the DH in its IAs (and those evident in priority setting frameworks in use in the wider NHS). There are clear implications for efficiency of this misalignment of aims across the health system. If the underlying basis for decision making by NICE is out of keeping with that elsewhere in the NHS, it suggests that welfare could be improved by achieving more of a consensus about what the goal(s) of the NHS are and, if there are multiple goals, what the relative importance of those are. So, bearing in mind Knapp's definition of efficiency, the question remains: what is the aim of the NHS?

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Appendix – list of IAs considered

IA no.	Title of Impact Assessment
1	IA for the Child Health Promotion Programme 2008
2	IA of extension of the Hospital Travel Costs Scheme
3	IA of moving ahead with Electronic Prescription Service (Release 2) and enabling completely electronic prescriptions in primary care
4	IA of new arrangements under Part IX of the Drug Tariff for the provision of stoma, urology and other appliances
5	IA of regulations to be made under the Public Health (control of Disease) Act 1984, as amended
6	IA of the merger of Postgraduate Medical Education and Training Board (PMETB) and General Medical Council (GMC)
7	IA for the Personal Care at Home Bill
8	IA of maintaining access to medicines in the event of a pandemic
9	IA of the Commercial Operating Model (COM)
10	IA of prohibiting the display of tobacco at point of sale
11	IA of Valuing People Now (VPN)
12	IA for implementing personalised care planning for people with long term conditions (including guidance to NHS and social care)
13	IA of the reformed complaints regulations for health and social care - consultation with stakeholders
14	IA of the Medicine (Products for Human Use - Fees) Regulations 2009
15	IA of the Medical Devices (Fees) Regulations 2009
16	IA of the Blood Safety and Quality (Fees Amendment) Regulations 2009
17	IA of creation of the Office of the Health Professions Adjudicator (OHPA)
18	IA of regulations to require NHS bodies to register with CQC and meet a requirement on HCAI [Healthcare Associated Infections] in 2009
19	IA of NHS LIFT guidance for PCTs
20	IA of innovation challenge prizes
21	IA of piloting personal health budgets
22	Final IA: regime for unsustainable NHS providers
23	IA of the introduction of the function to suspend chairs and non-executive directors of health Bodies (SHAs, SpHAs and ALBs)
24	IA of pharmacy market exit policy
25	IA of quality accounts
26	IA of social enterprise measures in Health and Social Care Bill 2007
27	IA of proposals to reform ‘market entry’ based on pharmaceutical needs assessments
28	IA of mandatory age restriction technology or prohibition for tobacco vending machines
29	IA of the NHS Constitution
30	IA of the introduction of a statutory scheme to control the prices of branded NHS medicines
31	IA of screening elective patients for MRSA
32	IA of Commissioning Quality and Innovation payment framework
33	IA: putting prevention first: vascular checks, risk assessment and management
34	IA of fees for the registration of pharmacy premises
35	IA of Directive 2007/47/EC, Council Directive 90/385/EEC, Council Directive 93/42/EEC, Directive 98/8/EC
36	IA of the Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2008
37	IA of introduction of HPV vaccination
38	IA of the reformed CHRE [Council for Healthcare Regulatory Excellence] Council
39	IA of the end of life care strategy
40	IA of a national screening programme for abdominal aortic aneurysms
41	IA of NHS Next Stage Review: proposals for primary and community care
42	IA of the third strategic funding and investment review: consultation with third sector organisations
43	IA of the Mental Capacity Act 2005 deprivation of liberty safeguards to accompany the Code of Practice and regulations
44	IA of Nursing and Midwifery (Amendment) Order 2008
45	IA of Health Care and Associated Professions (Miscellaneous Amendments) Order
46	IA of Amendments to the Medicines for Human Use (Clinical Trials) Regulations 2004
47	IA of the Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008
48	IA of the Medical Devices (Fees Amendments) Regulations 2008
49	IA of the Blood Safety and Quality (Fees Amendment) Regulations 2008
50	IA of Local Involvement Networks (LINks) Regulations and Directions
51	IA of the Medicines Products for Human Use - Fees) Regulations 2008