



# Health Technology Assessments:

The European experience and patient access

**Karen Facey**

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# Health Technology Assessments

## About the Speaker



Karen Facey became Chief Executive of the Health Technology Board for Scotland in 2000, responsible for the provision of authoritative advice on the clinical and cost effectiveness of health interventions to the NHS in Scotland. Since 2003 she has been consulting on all matters related to evidence-based assessment of interventions, working in UK, Canada, Australia and Finland. She was a consultant to the WHO Europe Health Evidence Network.

Karen Facey chairs the NHS Scotland Resource Allocation Committee, designed to improve the formula for allocating resources to the 14 NHS boards in Scotland. She is also a member of the Committee on Safety of Devices, which advises the UK regulatory authority. She is a Director of HTA International, and chairs the Patient and Citizen Involvement Interest Group

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### Karen Facey:

Thank you very much, Stephen, and CNE, for inviting me to speak today. What I am going to talk about today is health technology assessment (HTA), focusing particularly on Europe. I have many hats, but today I am speaking from a very personal view as an observer of health technology assessment around the world. I will start by presenting the key drivers in health services quite briefly and then about the challenges of investing in innovation. I will explain the breadth of health technology assessment, because this can be easily misunderstood from media reports. Then I will present a hot topic of the moment: NICE and the Alzheimer's medicines. And finally, I want to talk about the future direction of HTA in Europe. I will break for questions after I have talked about the whole breadth of HTA, and then after addressing NICE and Alzheimer's, and finally after HTA in Europe. I will break it up into three parts.

Let me speak to you first as the non-executive director of my local health board, in Scotland. What I see is that we have lots of conflicting factors all of which have to be considered in allocating healthcare resources.

First, most healthcare systems have been organized in legislative terms to have statutory financial accountability. That means that, for the last twenty years, most healthcare systems have literally just had to just balance the books. And that is all that has been written in legislation. In the last five or six years, countries have recognized that, actually, there is a lot more to healthcare than just balancing the books. We actually need to improve the quality of care. We need to involve patients in decision-making. And we need to think about health and treatment. Many countries have revised their key legislation around healthcare in the last five or six years, to include those kinds of issues. So, that has been an important step forward. Many healthcare systems are based on ensuring access to care, according to need, in some cases, or in some cases, particularly in the United States, according to the ability to pay. I know that, in a sense, it might seem a quite different paradigm, but we can look at them together.

The other things, I think, that have been happening in the last five or ten years, is that we have recognized inflating costs. In the United Kingdom, we have been incredibly lucky. We have been getting ten percent increases in the National Health Service's budget. And that has been unparalleled.

Alongside that, we have inflating costs. We have complex medicines available for new diseases. We have new processes to provide better diagnoses and more holistic treatment programs. Also, the population is living longer, and we need to treat people as they go into older years of life.

Finally, and perhaps most importantly, I think the key thing which has changed, is patient and public expectation. We are in quite a different world than we were, even ten to fifteen years ago. We have shared decision-making with patients, or we should have. And the patient, on top of it, has very high expectations of the NHS. And if health is in the political arena, which it is in the United Kingdom, but not in all other European countries, then that can affect the political scene, as well. The public certainly talk to their politicians about issues around health and it is a key part of the political agenda.

So, in the United Kingdom, what has happened is that local health authorities have been left to cope with these changes, on their own. We have lots of targets. In the United Kingdom, we are a very target-driven organisation, so we have targets for how long it is necessary to keep patients in hospital, how long it takes to see a physician, in terms of waiting lists. And I know that waiting lists are an issue across a number of countries in Europe. But actually, no matter what country you are in, we are all struggling with the same issue. And that is trying to obtain the best value from the resources we have, whether that is staffing or financial, to get the most health gain. And that is, I think, the common thing across all countries.

And one of the key things in thinking about best value is how should we invest in innovation? And in healthcare I think we can think about whole works of innovation, which are coming our way, from medicine and vaccines, through medical devices – lots of interesting new equipment coming for scanning,

particularly used for cancer, and other injuries, for example. Surgical techniques... more and more surgical techniques are refining and improving.

NHS redesign – that is actually a huge innovation – different staff doing different things: extended nurse practitioners, ambulatory care centres, the way we provide care. That is innovation, in itself. And also, importantly, as we recognize the issues of long-term illness, we recognize that we need to intervene earlier. And so, public health interventions are increasingly being put on the healthcare agenda.

Scotland is a small country of five million people. We have similar issues to other larger countries, but also some issues that are different. Shetland is a twelve-hour boat ride from Aberdeen, which is the nearest major hospital. And that means that providing health care for the islands is challenging. Each island health board serves about twenty thousand people on a variety of small islands. One island of fifty people requires its own primary care practitioner. And that is the kind of problem that they are dealing with in Scotland, lots of issues of remoteness. And I know that that is similar to, for example, issues in the Scandinavian countries.

I work in Forth Valley. Forth Valley is very average, in the middle of Scotland. We have a population of about two 283,000. And these figures are different from your hand-outs, because these figures are hot off the press. We had a board meeting yesterday, and we agreed on budgets for 2007 and 2008. The current population is growing. It is two hundred and eighty three thousand. As I said, our budget is increasing dramatically. We now have a budget of four hundred and four million. We have two major hospitals, with eight hundred beds. And we are spending about fifteen percent on primary care prescribing. So, we intend to spend seventeen point five million pounds this year. And the point five is interesting, because that represents money which is put aside for new drugs approved with health technology assessment, by the Scottish Medicines Consortium. And not only is it drugs that we are investing in, we have approved capital expenses for things like a new MRI scanner. A specific investment to improve our waiting times for diagnostic services.

So, that is kind of a brief overview of what it feels like to be in the service, managing a large budget, but with lots of things coming onto that budget. We had a discussion yesterday, at a board meeting, that we cannot afford to do everything that we want to do. We need to start disinvesting. And that is what planning is now looking at. Planning is looking at what can we disinvest in if we want to invest in something else.

So, when considering whether to invest in innovation of what I would call the broad range of 'health technologies' I listed out for you, let's look at medicines and devices. We could say that we could invest in anything that is authorized, that is, anything that has been approved by the EMEA or the national regulatory authority. For the regulators will have reviewed the product, in terms of quality, safety, and efficacy (that is testing that the product *works*). . So, we could say that we could invest in all of those regulatory approved products.

The question for health boards, like my own is: *is the product providing best value; is it value for money?* And actually, we need to know more than: *does it work?* With new drugs, we need a fairly wide-ranging policy analysis to help us to consider that technology in a broad framework. And, to my mind, that is what health technology assessment is. It is not always sold this way, but this is what it should be.

I am taking, here, a definition from a European collaborative group (ECHTA) that published their results in 2002. And they define health technology assessment as a multi-disciplinary activity that systematically examines:

- the technical performance - particularly for devices
- the safety, clinical efficacy, and effectiveness – and for those of you who read the relative effectiveness work from the European Commission, you will know that efficacy is evaluated in a controlled situation, normally compared to a placebo. Effectiveness is about: *does it work in the real world clinical testing, when you have got patients who, perhaps, have other conditions, who perhaps are on other treatments, who are not treated within the strict confines of a clinical trial? And often, does it work relative to another comparator?*
- cost, and cost effectiveness, is important but not the only issue. I think that, sometimes, people see HTA as being synonymous with cost effectiveness. Actually, it is much broader, because it should consider issues like
- the organizational implications,
- social consequences,
- legal and ethical considerations of how you apply a health technology.

The importance of legal and ethical considerations will vary depending on the technology. But as we see the growth of developments relating to genetics, for example, I think that those areas are going to become much more important, in decision-making.

Another way of looking at HTA is to break it down into four components. Firstly, consider the technology, in terms of effectiveness. *Is it going to work in a real life setting?* This is going to be different when you compare it in different ways, for example, in Scotland compared to in Finland. So a national assessment of effectiveness is essential.

Secondly, consider costs and cost effectiveness – and I will talk a bit more about that – but also consider how budget impact influence decision-making. If a drug is high cost, but is actually only going to treat one or two patients per year, there are mechanisms to handle that. If it is going to be fairly high cost for a large number of patients, then value will clearly need to be demonstrated very well.

Thirdly there are organizational issues around staffing, equipment, and patient access. Fourthly there are patient issues, related to psychological, social, and ethical issues. And again, I will talk about this aspect in a bit more detail later.

Every country does health technology assessment in a different way. Not all countries call it “health technology assessment”, but most countries have some kind

of policy analysis that feeds into decision-making, in which they consider whether to introduce a new technology, either on their reimbursement list, or in their healthcare system. And so, the form of assessment or policy analysis varies, depending on the setup of the national system and the culture. Some countries only look at effectiveness. They do not look at cost at all. This is quite common in the USA. The USA does very little cost effectiveness evaluation. Other countries focus on cost effectiveness. For example in England and Wales, the National Institute for Health and Clinical Excellence (NICE) focuses on cost effectiveness. The key thing is that health technology assessment is designed to take evidence from a variety of sources, and combine it to inform policy, in a national context.

I am going to spend time talking about cost effectiveness, because it seems to be the issue that hits the media – that, in effect, patients are denied access because drugs have been termed to be not cost effective. So, we can define economic evaluation, or cost effectiveness, as the comparative analysis of alternative courses of action, in terms of both their costs, and their consequences. And that sounds as quite a straightforward definition, but for any of you who have been involved in an economic evaluation of a product, it is an incredibly complex analysis. You need to create a model that describes what happens to patients during their disease process over a long period of time. This involves assessing the long-term benefit of the new technology. You would really be looking for benefits in terms of slowing disease progression, or in terms of improving length of life. Quite often, though, you do not have those long-term benefits. You struggle to find data over more than, perhaps, two years, or so, in a clinical trial and often rely on outcomes such as quality of life over a shorter period. You balance these benefits against side effects and against costs of treatment. And what you do is you take that model, for those on treatment, and try and model what will happen to those who have not had treatment, Then you balance out the costs and consequences for that comparison of having treatment versus no treatment. And what you hope is that you have a good-sized benefit for a cost that is affordable. And within England and Wales, there is discussion that around twenty to thirty thousand pounds per quality adjusted life-year gain is sort of acceptable.

And the issue is, as I said, that these models are incredibly complex. You take data from a variety of sources. And there is lots of uncertainty. And this is where, in a sense, policy analysis gets difficult because when there is uncertainty, people have different values and judgments about those uncertainties, and that can lead to different decisions and different perspectives.

Another area I would like to talk about is the patient, because actually, patients should be involved in the health technology assessment, but in fact, they rarely are. ECHTA emphasized that the impact, use or non-use of a technology, in terms of psychological, social, and ethical benefits, or harm, is an important part of HTA, and that, actually, patients influence how effective a product is. So, if a patient does not take a medication according to the label, if they forget doses, if they don't take them at the right time, if they do not take them without food, that is actually going to impact on their effectiveness. And, indeed, some patients find devices, in particular,

very difficult to use. For instance, things like asthma inhalers, there is a huge issue about that. Also, consider how well patients cope with complex medications, when they are taking several medications, again. And this debate takes the fore with AIDS patients. AIDS patients are very articulate in outlining their needs for treatment. But they have also highlighted a number of other areas about living with the disease that are important to patients. There are psychological issues around being labelled. There are anxieties. There are social issues, equity, and there are ethical issues.

As I said, I think that a lot of these issues will gain a higher profile in the future. But a number of people have said, but *how do we get to the heart of those matters?*

Well, actually, you can work with patients to get strong evidence about a lot of these issues by using standard qualitative research techniques. But, very few of us in the healthcare field rely on what people call social science research. And one of my key areas of interest is that we should be looking more at this kind of research to elicit patients' needs and preferences. Furthermore, patients can be used throughout the technology development and assessment process to help us, firstly, to design innovation, which is really needed by the patient, and then really put the true value of that innovation into perspective. The Danish HTA Agency, DACEHTA, has advocated this for years. And they have two whole chapters in their HTA handbook about how to undertake good research with patients, which can be input into the decision making process.

I think, quite traditionally, health technology assessment has been considered the same as evidence-based medicine. I would say it is quite different. In my mind, evidence-based medicine is based generally on scientific publications. For example, the Cochrane collaboration searches only for published papers, and focuses on the highest level of trial, the so-called randomised control trial. HTA does take that scientific information, and it's an important cornerstone for work. But some agencies will also take manufacturers' submissions to allow the input of unpublished data. Not all agencies will. And I think that that is an issue, because they do not get the most up-to-date, or often full picture, of all available information.

But, actually, to make a clear decision, you need other evidence. You need input from health professionals, who understand how the service is provided to patients, at the moment, and what the impact of this new technology might be. You also need to understand the needs and preferences of patients and carers. And I think that then, what we need to recognize is, we have a variety of different forms of evidence, and we need to pull those together. There is uncertainty in the way we pull that together. And, in a sense, this is where value judgments come in. Value judgements actually come in, in a way, to collect all individual pieces of evidence. Then there are big value judgments made when we combine different forms of evidence to say, yes, we think this new technology is of value and that we should invest in it for all patients in our healthcare system.

And so what HTA tries to do is to be clear about – be systematic about – the way in which it collects the evidence; to be clear about the value judgments, so we can

provide guidance, generally to national healthcare systems. HTA guidance around Europe varies. Some agencies are actually very restrictive and say “this is cost-effective, that is not cost-effective, this should be reimbursed, that should not”. Others are much more: “Well, here is the evidence; we will let you judge”. And that is more the case in the Scandinavian countries. And what can happen to guidance coming from HTA varies dramatically across Europe. In some cases if there is guidance that a new medicine or a new technology is cost-effective, then it must be implemented, locally, within a certain time scale. Now, particularly thinking of NICE, in England and Wales, NICE’s recommendations are supposed to be implemented, locally, within three months. Experience shows us that that actually is not the case. In some cases, a recommendation is given to local health units, and this happens in Scotland. We have areas where they make a decision locally about whether a new technology would have been approved by HTA, and then it can be made available locally.

But some recommendations actually take years to implement, for example when a national screening programme is approved, e.g. for foetuses with abnormalities, or for cancers of, for example, the breast or colorectum. So you cannot always have immediate implementation.

In some cases, negative decisions can be overturned by lobbying and political influence. And this is certainly the case with Multiple Sclerosis. There are a number of countries where HTA organizations have said treatments are not cost-effective, but countries have said it will still be made available within the health system.

Scotland is an interesting case. My home town, as it were – because in Scotland, if you do not have a health technology assessment for a medicine, which has been undertaken by our Scottish Medicine Consortium, there is no routine use of that drug, at all, in Scotland. So you can only get your product, considered by hospitals or GPs, if it has an HTA.

Before I go on to specific examples, are there any questions about that? I will just go on to the example, then:

I changed my talk quite quickly on Monday night, because as I was driving home, I heard the news on the radio, which said that the court has upheld an appeal and that NICE will be taken to judicial review about one of its recommendations. So, I just thought that it might be helpful to just look at this particular topic. And the topic in question is NICE’s Technology Appraisal Guidance, which was issued in November, last year, on medicines for Alzheimer’s disease. This is interesting because it was a review of what they had done previously, as they automatically review their work every three years. Previously, they had recommended it for use in mild and moderately severe Alzheimer’s disease patients. But, this new guidance was restricting that purely to patients with moderate Alzheimer’s disease.

Let’s look at the background is: *what does the regulatory authorization for the product say?* These products were authorized, probably about seven, ten years ago within

Europe in terms of quality, safety and efficacy. There are three what I'm going to call cholinesterase inhibitors, and they are authorized for mild to moderately severe Alzheimer's disease. And there is another product that is called Memantine which is only authorized for moderately severe to severe Alzheimer's disease.

In terms of clinical and cost-effectiveness, what NICE are now saying is that these three cholinesterase inhibitors can only be given to patients with moderate severity only and that their use must be reviewed every six months. Memantine is not recommended for general use, unless in clinical trials. So, what you see is a honing down from the indication, and obviously this has implications for patients.

I took the following 3 slides [slides can be found at the end of this document] from the BBC report. This report shows the reaction of two pharmaceutical companies and patient organisations to NICE's decision that NHS patients with newly diagnosed, mild Alzheimer's disease should not be prescribed the drug. The companies claimed the process, leading to this guidance, was unfair. They claimed that NICE's conclusions on the Alzheimer's treatments cannot be supported legally, or are irrational. And so they plan to apply for judicial review of the way NICE had reached its conclusion. The companies were also asking for a fully transparent working form of the cost effectiveness model. Other European countries are more open about the way they make their decisions, in terms of providing their economic model with all data (nothing commercial in confidence). So this it is interesting that this issue has been focused on, because this many push NICE to be more open about what they publish. I believe the full economic model should always be published, but often it is manufacturer confidentiality clauses that restrict this.

NICE's November decision was reached after extensive consultation with stakeholders and the public and internal appeals with stakeholders. Stakeholders included not only the manufacturers, but physicians and patient organisations. The patient organisations also support the judicial review, pointing out that patients in the early stages of Alzheimer's disease were now going to be denied access, and that actually the cost of the drug was only two pounds fifty per day.

So how did NICE judge the evidence? They felt that the benefits in terms of cognition were relatively small and long-term effectiveness was inconclusive.

What NICE recognise in their appraisal document, is that they recognize that the evidence has matured since their last review of it. But, it still demonstrates a small but consistent gain in cognitive and global scale for mild to moderate disease. The question is, I think, *what benefit would that have really had in the patients' lives in the longer term? Is that really a tangible benefit for patients that we want to invest in?* Long-term effectiveness outcomes, such as quality of life, delayed time to nursing home placement was limited, and largely inconclusive. And these are the things, actually, that will drive cost-effectiveness. If you could show benefits, in terms of delaying time to nursing home placement, and long-term effectiveness, that would make a benefit.

Full details of NICE's appraisal are published in their Technology Appraisal Guidance issued in November 2006 and I will paraphrase it with my own opinions here.

NICE recognize that lots of people have undertaken cost-effectiveness models, and obtained lots of different results. Each of the manufacturers have undertaken their own models. NICE have a model from a university, which they commissioned. And they were all coming up with different results. Manufacturers were probably using optimistic assumptions, and obviously, NICE were looking for something that was in middle ground. But, after further modelling, they finally said that it was outside the range of cost-effectiveness that might be usually considered appropriate. And I will come back to that.

Interestingly, although NICE already had all of these economic models, they created another model in-house to try and overcome some of the problems observed in the other models. This model clearly involved lots of input from professional groups and from patients. It appears that NICE judged the testimonies carefully to create new inputs to the model. The appraisal guidance clearly shows how they considered the different arguments and their resulting action. Here is a list of some of the arguments they took on board in their new economic model. One argument was that not enough benefit was being allocated to the treatment group. Utility is a form of benefit, on a scale of 0 to 1. So they increased the utility gains for patients (0.06) and added a utility gain for carers (0.01), noting much discussion about benefit for carers, but that this is very difficult to quantify. Benefit in terms of behavioural symptoms was noted and NICE seems to have incorporated that, but it is not entirely clear to me how. They looked at different costs for full-time care of people with Alzheimer's disease. There was a proposal to use new costs from a study in London, but this was rejected. And in the end, they took average published costs, I guess, from England.

A number of other things were not accepted. There was a lot of discussion about carers. However, as we do not take account of the savings produced by carers for the NHS, and the model is based on an NHS perspective, this could not be included for in the economic model. They looked at different sources of mortality estimates and admitted that the ones in the model were not ideal, but they could not find any better alternatives.

So, they, in the end, came up with a final model, which had taken into account some of the issues raised by professionals, patients, and manufacturers. In this model, they found that when they did a sub-group analysis based on moderate Alzheimer's disease, this resulted in a cost-effectiveness estimate, in the range of twenty three thousand to thirty five thousand pounds. And if you remember, I said, the English threshold was about twenty to thirty thousand pounds. So that is why they recommended the products for that group of patients. For the less severe patients, with mild Alzheimer's disease, the cost-effectiveness estimates were £56,000 to £72,000. And this was way above the usual threshold. And that is why this decision was made to exclude them from the recommendation.

So, as I indicated, on Monday the high court had granted permission for judicial review to proceed. This will be very interesting because it is the first time that NICE will have undergone this process. I think that it will raise issues of transparency, although I must say, NICE are actually more transparent than many other agencies, in terms of how they judge the evidence. In the past, the courts have tended to side with health authorities over decisions about access to new treatments, but this has recently been different with the case of Herceptin. So, this will be very important, I think, for the whole issue of what I would call health technology assessment, and how we present evidence.

I am going on far too long, so I apologize about that. And so, I am going to quickly, therefore, skip to something, which will be of interest to you. To say that health technology assessment works right across Europe, and indeed, the world. And there is an international network of HTA members. It has been running for fifteen years, or so. It has over forty members from many countries. And what I have done, here, is just to highlight for you the breadth of health technology assessment. In yellow, you can see the countries in Europe that are involved in health technology assessment. We have Austria, Finland, Denmark, France, Germany, Hungary, Latvia, interestingly, Netherlands, Norway, Poland, Spain, Sweden, Switzerland, and the United Kingdom. Some European countries are not mentioned in this list, but they do have an HTA presence. For example Italy, has lots of small units, working within hospitals, but not on a national level.

Of most interest to you, perhaps, as I have indicated, is that the European Commission has always been interested in health technology assessment, and there is a feeling that they would like to organize it on a European-wide level, perhaps a bit like the EMEA, to have one central evaluation of health technology assessment.

Member States have always resisted this, obviously on the principle of subsidiarity, because they all manage their own healthcare systems, nationally. And actually, health technology assessment has to be dealt with in the national context, because it depends on how you deliver healthcare, locally. However, in 2004, following the ECHTA report in 2002, they highlighted HTA as a political priority, as part of the mobility work that was going on at the time. The Commission funded a project, called EUnetHTA, which started last January. EUnetHTA involves twenty-seven European countries, twenty four Member States, thirty five partners, which include international partners, out of Europe, and will be reporting at the end of next year, in 2008. Their objective is to connect national HTA's with health ministries to enable effective exchange of information, and support policy decisions by European Union Member States, doing this through effective and efficient health technology assessment procedures within European countries. They are not trying to create an EMEA-like procedure, but more of a network, or a collaboration of HTA agencies. This network will share information, with a key goal to create core information on clinical effectiveness for a technology that can be shared with individual Member States who can then create their own HTA. The network would outline the issues that each individual country would need to consider in terms of the social, economic, and ethical issues. EUnetHTA also wants to look at how they can support

transferability of HTA projects, monitor emerging health technologies that would be of high impact, and support countries without HTA.

So, I think that this is an interesting area, because what they are looking to do is to create a permanent framework of European Union collaboration on HTA. And that could have its pros and cons, I guess, for different stakeholders.

And I am going to end there. And I apologize again for going on so long. Just to say that, in my mind, health technology assessment is not just about cost-effectiveness. It is about balancing cost to benefit, within a value framework. And value depends on ethical and social issues. But, we need to be transparent about how we are determining that value. We do not do that well, or consistently, across Europe at the moment, but we are trying to improve that.

So, I am happy to take any questions.

*(Applause.)*

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## Q and A

Stephen Pollard:

Thank you very much for that, Karen. One element that was missing, and I am curious to know how you think it fits in, is innovation

A – Karen Facey:

In a sense, I started with innovation, by saying that HTAs should consider what innovation they need to evaluate. And I think the big discussion within cost-effectiveness and economic evaluation in particular, is should you make a compensation for the fact that companies have spent ten years getting to this point, and they are, perhaps, first market with a new and innovative product. HTA agencies actually just dodged that, and say that is a pricing issue, and it varies among countries. For example, in the United Kingdom, the price of a product is generally higher than in many other European countries, because we do allow for the fact that industry benefits the United Kingdom economy, whereas in Australia, for example, prices are generally much lower.

Q –QUESTION INAUDIBLE

Can HTA equip patients to have truly informed decision making discussions with their clinicians, when they need to make choices about treatment options?

A - Karen Facey:

I think that it is an area that health technology assessment has not taken on well enough, yet, in terms of equipping patients with the evidence that they need for the consultation. Some HTA Agencies produce what we call consumer information. I work with surgeons in Australia, and they provide plain English guides about surgical techniques, which is quite a challenge to do. But actually, what you want, is exactly what you are saying which helps a patient to answer *what are the risks and benefits of each, individual option, so that I can view them in my own situation?* And we know that particularly with cancer, that people will make different choices, depending on where they are in their own, lives and what they want to achieve. One of the best tools we can use to facilitate patient decision making is what I would call a patient decision aid. A group in Canada, run by Annette O'Connor, has produced some wonderful patient decision aids, which present issues around risk and benefit in a manner understandable to the patient. But really, HTA has not ventured into that field yet, and I feel that there is a gap there. Unfortunately I think what patients do is go to a website, where they may be influenced by evidence that is biased or of poor quality. If we could help them to judge that information that would be good. For example, we did an HTA of ultrasound scanning in pregnancy, and there, we actually did not make an overall judgment, because the judgment on whether you have particular scans or particular tests depends on what makes is important to you. Is it most important to identify a foetal abnormality in an unborn baby, or is it most important to preserve the life of that foetus, because some of those tests may lead to miscarriage. We found that we could not give an overall view of that. Actually what you need to do, is equip the clinician to be able to have that conversation with the mother to allow informed choice. Actually, few people are fully informed to have those discussions, at the moment. Having said that, there are some things, which have been done well. For prostate cancer screening there are good decision aids used in the United Kingdom. But, in general, it is not done well enough. So, I think that it is an area that we need to work on.

Q - QUESTION INAUDIBLE

Will there be a EuroNICE?

A – Karen Facey:

I hope that there will be a European network of HTA, but I doubt that it will look like NICE, because NICE works very much on the national level, so they are making the decisions. The European network, I think, will stop at a level below that. It will provide, for example, I think, a basic systematic review that will be given to individual Member States with a framework, that suggests how ethical and social issues can be considered nationally. But, the individual Member State will make the final decision.

QUESTION – We’ve had lots of European initiatives relating to HTA in the last 10 years, from EUR-ASSESS and ECHTA and now to EUnetHTA. The previous initiatives have not produced anything concrete or changed the way HTA is performed across Europe. Do you really think EUnetHTA is going to be different?

A – Karen Facey:

I think that EUnetHTA is very aware that they have to produce something tangible and permanent, in terms of collaboration, at the end of this project. There is not going to be another three years to get this sorted out, they must come up with concrete proposals at the end of the project. And so, they are much more driven to goals. They are, for example, creating a core HTA for two different forms of technology, to see if this can be shared among Member States and used in national decision making. They are creating a tool kit to adapt HTAs from other countries. So with these tools they will go a lot further than any of the other European reports have gone in terms of effective collaboration that will help overcome duplication of effort. I could not speak for the Commission, but the European Commission clearly is concerned about issues related to health technology assessment. So, this network is determined to make something permanent, and useable, and offer the opportunity for the creation of a central source of advice on HTA in Europe, which will be unlike any other previous Commission HTA project.

*– End of transcript. Slides follow. –*

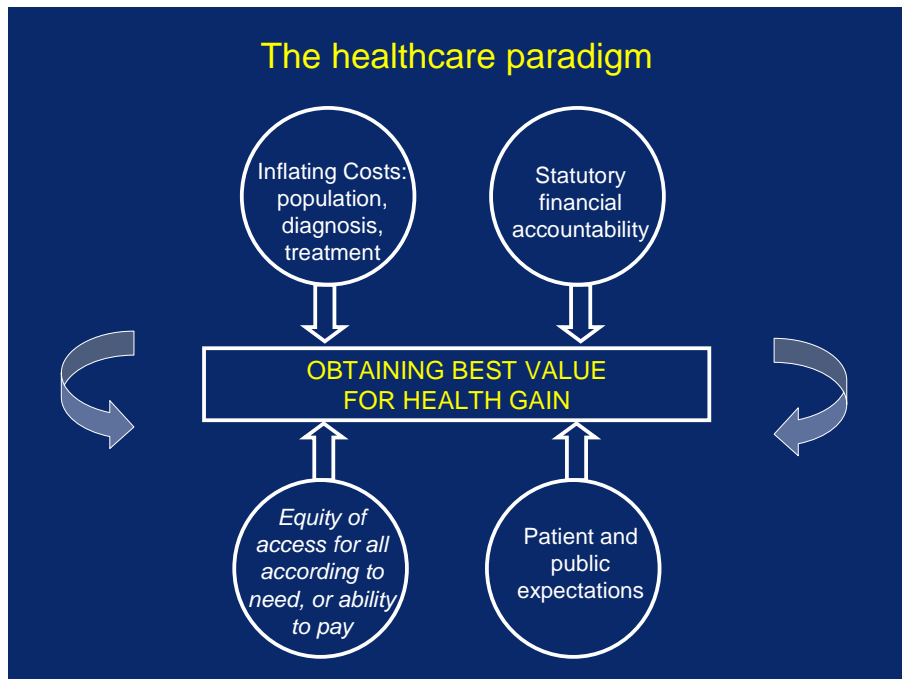
# Health Technology Assessment In Europe

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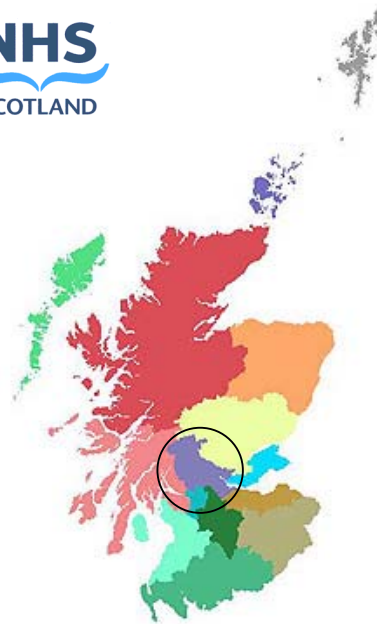
## Health Technology Assessment (HTA) In Europe

- Key drivers in health services
- Investing in innovation
- The breadth of HTA
- NICE and the Alzheimer's medicines
- The future direction of HTA in Europe



### Forth Valley: 2007-08

- Population ~ 283,000
- Budget= £404 million
- 2 hospitals with 800 beds
- ~15% spent on prescribing in primary care (£70.5mi)
- Recent investment in new MRI scanner (capital and revenue) to reduce waiting times



## Investing in innovation??

Consider new health technologies:

- medicines,
- vaccines,
- devices,
- surgical techniques,
- health service redesign,
- public health intervention, etc....

## Firstly consider 'authorised' products

- Medicines and vaccines: EMEA – quality, safety, efficacy
- Devices: National competent authorities – quality, performance
- (No authorisation for health service organisation, public health interventions, etc....)
- **Need policy analysis to help encourage wise investment of alternative choices**

## Health Technology Assessment (HTA)

Health Technology Assessment is a multidisciplinary activity that systematically examines the

- technical performance,
- safety, clinical efficacy and effectiveness,
- cost and cost-effectiveness,
- organisational implications,
- social consequences,
- legal and ethical considerations

of the application of a health technology.

(ECHTA, 2002)

## Health Technology Assessment

- Technology (clinical effectiveness)
- Cost (cost effectiveness, budget impact)
- Organisation (staffing, equipment, patient access)
- Patient (psychological, social, ethical)

Evidence based with focus that varies depending on HTA Agency remit and resources

All seek to inform policy decisions, by focussing on national context

## Cost effectiveness

- Economic evaluation (cost effectiveness) defined as  
*'the comparative analysis of alternative courses of action in terms of both their **costs** & **consequences**'*  
(Drummond & McGuire, 2001)
- Economic model estimates what happens to patients on treatment in terms of
  - benefits in slowing disease progression, QoL, etc
  - side effects *Lots of uncertainties!!*
  - costsover a long timeframe  
vs what happens to those on comparator

## ECHTA and the patient (IJTAHC, 2002)

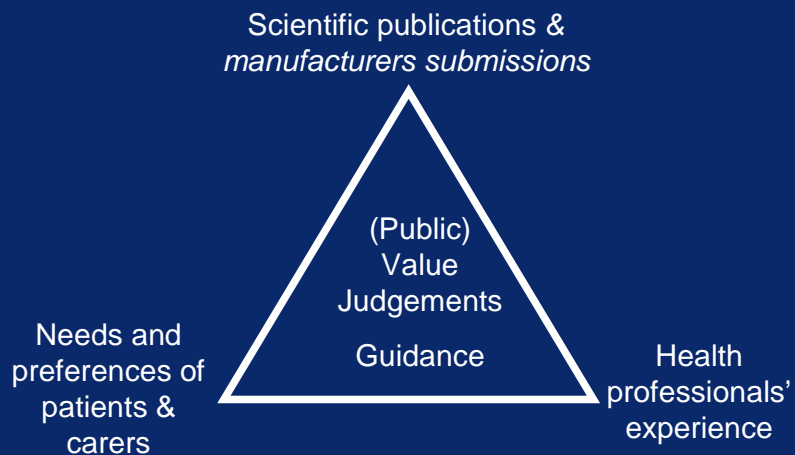
Assessment of the impact, or the use or non-use, of a technology in terms of psychological, social and ethical benefits or harm is an important part of HTA.

- Psychological (subjective) effects
  - feeling labelled, fear, anxiety, satisfaction
- Social effects
  - changes in equity or access to care
- Ethical effects (affecting values)
  - discrimination, human rights, consent, moral issues

## Studies to evaluate Patient Issues (DACEHTA)

- Health status
- Field research (Patient stories)
- Interviews
- Focus groups
- Questionnaires/surveys
- Delphi
- Futures workshop

## HTA: Evidence based decision-making



## What happens after HTA?

- HTA guidance: summary of evidence or recommendations
- Could lead to
  - Addition of technology to reimbursement list
  - 'Must' be implemented locally within a certain timescale
  - Given to health units for further consideration
  - Require other infrastructures to support implementation (eg national screening programme)
  - Overturned by lobbying/political influence
- In Scotland if there is no 'HTA' for medicine from the Scottish Medicines Consortium there is no 'routine use'

## NICE Technology Appraisal Guidance 111: Medicines for Alzheimer's Disease (Nov. 2006)

### Quality/Safety/Efficacy

- Donepezil, galantamine, rivastigmine (acetylcholinesterase inhibitors) authorised for mild to moderately severe AD
- Memantine authorised for moderately severe to severe AD

### Clinical/Cost Effectiveness

- Acetylcholinesterase inhibitors recommended as options for people with AD of moderate severity only, with review every 6 months
- Memantine only recommended as part of well designed clinical studies

## Drugs watchdog faces legal review

BBC: 17/11/2006

'A decision by the government's drugs watchdog to restrict the use by the NHS of Alzheimer's medication is to be challenged in court.

Two drug companies plan to apply for a judicial review of the way the NICE reached its conclusion.

NICE ruled NHS patients with newly diagnosed, mild Alzheimer's disease should not be prescribed the drugs. Eisai and Pfizer claim the process leading to this guidance was unfair. They claim many of NICE's conclusions on the Alzheimer's treatments - which include donepezil, rivastigmine and galantamine - cannot be supported legally or are "irrational".'

## Drugs watchdog faces legal review

BBC: 17/11/2006 – The Company View

Eisai and Pfizer, who produce donepezil (Aricept) are also asking the institute to disclose a "fully transparent working version of the calculations used in the cost effectiveness model for independent evaluation and comment".

They would like NICE to develop a new guidance using "both a more accurate cost effectiveness model and data".

Dr Paul Hooper, managing director of Eisai Limited, said: "We are deeply concerned about the way that NICE's decision on treatment recommendations for early Alzheimer's disease was reached. A judicial review is now the only option remaining to us to ensure that NICE reconsiders how it arrived at such flawed conclusions."

## Drugs watchdog faces legal review

BBC: 17/11/2006 – The Patient Organisation View

Campaigners have repeatedly argued patients in the early stages of Alzheimer's should also have access to the £2.50-per-day drugs.

Neil Hunt, chief executive of the Alzheimer's Society, said: "It's great news that NICE will be challenged in court. NICE holds the fate of thousands of people's lives in its hands and it is only right that it is brought to account."

Last month, NICE rejected their appeal saying studies showed the drugs "did not make enough of a difference".

## NICE's consideration of the evidence

- Evidence has matured and continues to demonstrate small but consistent gains in cognitive and global scales for mild to moderate AD
- Evidence on long-term effectiveness on outcomes, such as QoL and delayed time to nursing home placement was limited and largely inconclusive

## NICE's consideration of the evidence

- Substantial differences in cost effectiveness estimates between manufacturer and academic models, with several optimistic assumptions from the manufacturer
- Outside the range of cost effectiveness that might usually be considered appropriate for the NHS

## NICE's consideration of the evidence

After testimony from clinical and patient experts economic model revised by NICE to include

- Higher levels of utility gains for patients (0.06)
- Utility gain for carers (0.01)
- Benefit on behavioural symptoms
- Average published costs of full-time care

## NICE's consideration of the evidence

NICE revised model

- (No carers costs – as it's an NHS perspective)
- (Revised costs from London study not used)
- (Mortality estimate not reduced)
- (Responder definition could not differentiate treatment vs placebo effect)

## NICE: The 'final'? results

- Sub-group analyses by manufacturers and Medical Research Council on severity of cognitive impairment is clinically plausible
- For moderate AD this results in estimates of cost-effectiveness of £23,000-£35,000
- For mild-moderate AD this results in estimates of cost-effectiveness of £56,000-£72,000

## Monday 26 March 2007: The Court's Initial View

The High Court has granted permission for the judicial review to proceed.

This will be the first time a NICE decision has been contested at this level.

## HTAi: Health Technology Assessment International

[www.htai.org](http://www.htai.org)

- ISTAHC 20 years
- New society created 4 years ago, broad membership.

## INAHTA: International Network of Agencies for HTA

[www.inahta.org](http://www.inahta.org)

- Global network established in 1993
- Now links over 40 not for profit, mainly publicly funded HTA Agencies from 23 countries

## INAHTA Members

Argentina	IECS
Australia	AHTA, ASERNIP-S, MSAC
Austria	LBI@HTA
Belgium	KCE
Brazil	DECIT-CGATZ
Canada	AETMIS, CADTH, iHE/AHFMR, MAS
Denmark	DACEHTA, DSI
Finland	FinOHTA
France	CEDIT, HAS
Germany	DAHTA@DIMDI
Hungary	HunHTA

Israel	ICTAHC
Latvia	VSMTVA
Mexico	CENETEC, IMSS
Netherlands	CVZ, GR, ZonMW
New Zealand	NZHTA
Norway	NOKC
Poland	AHTAPol
Spain	AETS, AETSA, AVALIA-T, OSTEBA, UETS
Sweden	CMT, SBU
Switzerland	MTU-SFOPH
United Kingdom	CRD, IAHS, NCCHTA, NHSQIS, NHSC
United States	AHRQ, VATAP

## EunetHTA: European Network for HTA

[www.eunetha.net](http://www.eunetha.net)

- 2004: EC and Council of Ministers targeted HTA as a 'political priority'
- EC 3-year funded project, started January 2006
- 27 European countries
- 35 Partners
- Final report December 2008

## EunetHTA: European Network for HTA

[www.eunetha.net](http://www.eunetha.net)

### Objective

- to connect national HTA Agencies, research institutions and health ministries to enable effective exchange of information and support to policy decision by EU Member States

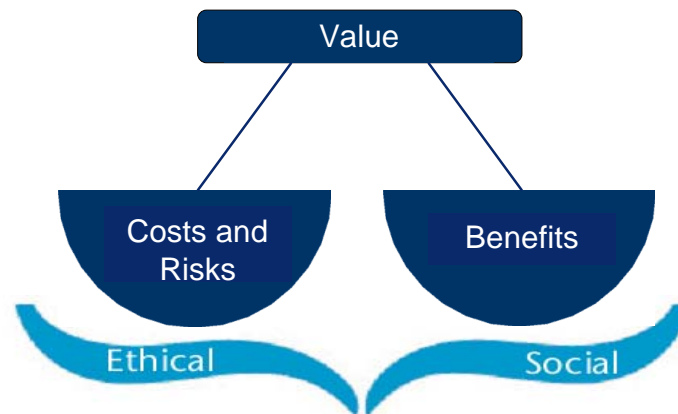
### Aim

- to achieve rapid uptake and use of effective health technologies, expected to contribute to major improvements in patient outcomes and promote wise investment of resources

## EunetHTA

- Establishing 'core' information about effectiveness and safety that can be shared (thus avoiding duplication)
- Outlining cultural, economic, social and ethical issues to be considered in national contexts
- Supporting and assessing transferability of national HTA reports to other contexts
- Monitoring emerging health technologies
- Supporting countries without HTA
- **Creating a permanent framework for EU collaboration on HTA???**

## Health Technology Assessment



– End of transcript. Slides follow. –