Seeking excellence in health outcomes: a personal commentary on the history and practice of NICE in the UK

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Disclaimer

- I thank the organisers for the honour of speaking to you today
- If I deserve it at all I guess it is because I have been closely involved with NICE before and since its creation and therefore perhaps have some insights into its strengths and weaknesses
- However, since I have been so involved in its development I am an enthusiastic supporter and the presentation I am about to give you needs to be seen as coming from such an enthusiast
- This is a personal view and should not be taken as necessarily representing the views of the NICE Board

NICE: Prehistory

- During the early to mid 1990's the responsibility for deciding which technologies and services should be paid for by the National Health Service (NHS) was placed on Directors of Public Health in District Health Authorities, typically serving a population of about 300,000 – 500,000 people
- These Directors had no or few staff to assist with any assessments/judgements they needed to make
- In two Regions the Directors decided to work together to share analyses that they undertook and to agree common commissioning policies
- In one of those Regions, Trent, I was asked to Chair the group that made the commissioning decisions
- This Group came to be known as the Working Group on Acute Purchasing

Evolution of the Working Group on Acute Purchasing

- The PH Directors in Trent decided to contract with ScHARR at Sheffield University to provide an analytical service to the group
- A similar process was happening in South West Region where Southampton University was commissioned, led by Andrew Stevens
- The two Universities started to use techniques and concepts from the HTA literature to develop standard methods of assessment and both groups presented results in terms of cost/QALY gained by any new technology; they also adopted a guidance threshold of £20,000 per QALY
- The two universities also tried to harmonise their methods and to avoid duplicating reviews, accepting one another's reports
- About 40 reviews per year were produced and their influence, both in the Regions that had commissioned them and elsewhere, attracted the attention of the Health Ministry which imposed committees, comprised of members of its choosing, to approve reports before they were issued.
- The reports were thus endorsed by these "Development Evaluation Committees" (DECs) and became even more influential
- DECs considered drugs, devices and procedures

Postcode Prescribing

- In 1997 a new government came in to office and it was concerned with press complaints that expensive drugs, for example for treating cancer, and procedures, such as surgery for morbid obesity, were available in some parts of the country but not others
- This reflected the fact that purchasing was a local responsibility
- In 1998 it was decided to create an agency to provide **National** advice on purchasing with the express purpose of removing geographical variations in services; the DECs were to be wound up
- **Note that the purpose was not to control NHS spending**, that was handled via parliamentary vote, but to develop definitive views on what was the best way to provide services
- The advice was to be provided by a new institute to be called the National Institute for Clinical Excellence, which gave us the initials NICE; this came into being in April, 1999

NICE duties

- NICE was to undertake, initially, two roles:
  - The first was to provide advice on which technologies, particularly drugs, to adopt – the HTA role;
  - The second was to standardise and provide authority for clinical guidelines

NICE HTA Methods

- A committee of ten people was created, including the Chairman and CEO designates; the appointed technical lead for the HTA programme; Andrew Stevens and myself from the DECs; three other health economists and two eminent physicians
- The purpose of this committee was to determine the methods by which NICE would work
- Many of the processes and methods adopted were taken from the established practices of the DECs
- Important decisions related to
  - retention of a cost per QALY approach from the DECs with a guide threshold of £20,000 per QALY;
  - rejection of the adoption of a formal scoping phase, as was the case in the DECs;
  - the review and synthesis of evidence, including modelling, to be undertaken by university groups – these were initially Sheffield and Southampton to which were added York, Aberdeen and Liverpool

Guidelines

- Initially NICE worked with the bodies, mainly medical professional groups such as the Royal Colleges, that were already producing guidelines and accredited them
- With time, NICE funded the production of Guidelines by these professional bodies but required that proper methods of review and synthesis of evidence were followed in their preparation
- NICE also required that, where relevant, cost effectiveness should be considered as part of the Guideline production
- Health Economists were appointed to the Royal College groups, for example

Early Years of HTA

- In its early years NICE had just one HTA committee, but over time, as the volume of work increased, this was expanded to four
- Most of the topics considered related to pharmaceuticals, but not all
- The absence of a scoping phase quickly caused problems and one was adopted, initially informally, then after three years, formally
- Initially, responsibility for selection of topics for NICE to consider rested with one of the junior health ministers but this delayed decisions for so long that after three years a Topic Selection Committee was created to refer to HTA.
- Note that NICE has never considered **all** new drugs but now considers most of them

DECISION MAKERS AND MEETINGS

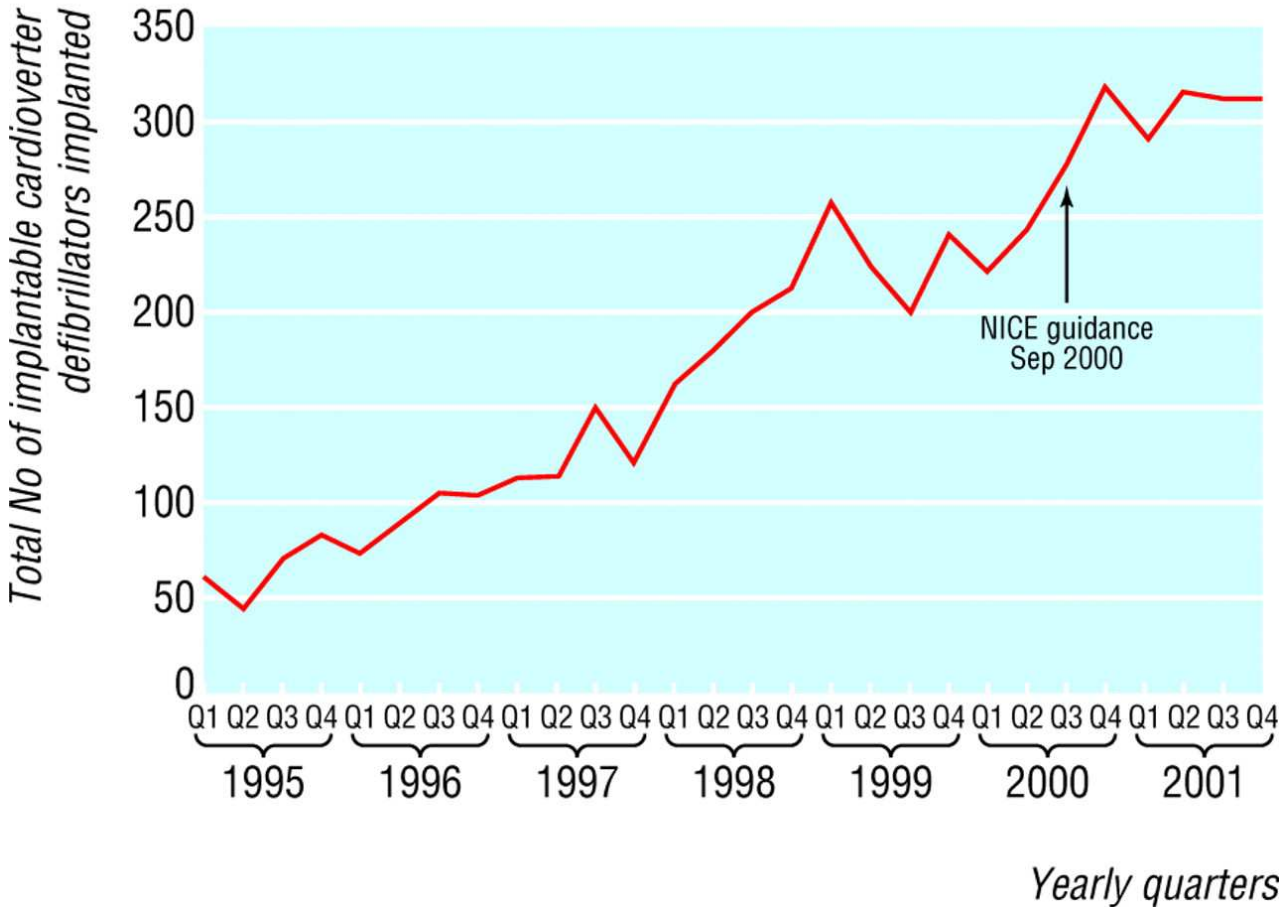
Country	Expert Committee	Voting (N)	Chair (n)	Clinician	Payer	Ministry officials	Industry	Health insurer	Academic	Patient	Ethicist	Statistician	Lay member	Health economist	Other
France	CT	20	1	✓	✓#	✓#	✓#	✓							
Germany	G-BA	13	1*	✓	✓	#	#			✓					✓
Italy	AIFA	17	-	✓	✓	✓			✓						
Poland	AHTAPol	12	-	✓	✓	✓									
Sweden	TLV	7	1	✓		✓				✓				✓	
Spain	AETS	?	?			✓									
Netherlands	WAR	24	1	✓		✓#		#		✓	✓			✓	
England	AC	30	1*	✓#	✓		✓#		✓	✓		✓	✓	✓#	

*= Impartial chair; #= Non-voting members; ✓= Voting members; CT= Transparency committee; G-BA= Joint federal committee; AIFA = Italian Medicines Agency scientific and technical committee; AHTAPol= Agency for Health Technology Assessment in Poland; TLV = Sweden's Dental and Pharmaceutical Benefits Agency; AETS= The Health Technology Assessment Agency expert committee; WAR= Scientific Advisory Board; AC= Appraisal Committee; NB: Other stakeholders may be involved regularly or ad hoc both as committee members and commentators; In a number of countries, the process of evaluation for reimbursement and discussions on pricing are conducted by different committees

Early review of Impact

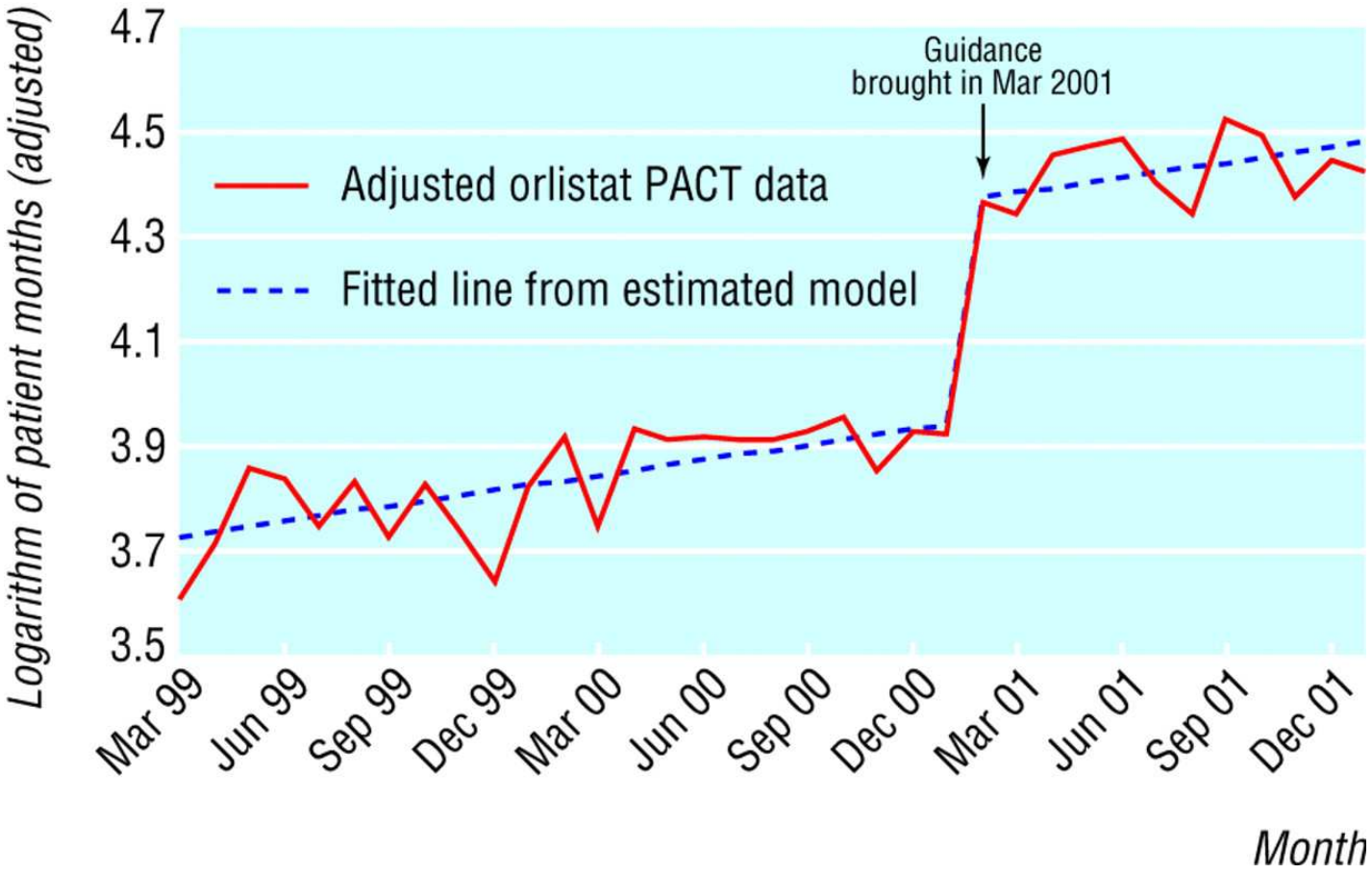
- After five years of operation of NICE more press stories about postcode prescribing began to surface and a review was commissioned to be led by Trevor Sheldon at the University of York into the effects of NICE
- It was found that not all local payers were implementing recommendations and the effect of NICE decisions on the uptake of technologies was variable

Cardioverter defibrillators implanted



Sheldon T A *et al.* (2004) What's the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients' notes, and interviews. *BMJ* 329:999

Use of orlistat in the community



Sheldon T A *et al.* (2004) What's the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients' notes, and interviews. *BMJ* 329:999

Mandatory Guidance

- As a consequence of the Sheldon et al research, NICE TA guidance was made **mandatory** on local payers (but not guidelines or other, subsequent forms of guidance such as PH)
- This decision was recently reiterated when NICE was made a statutory body under primary legislation

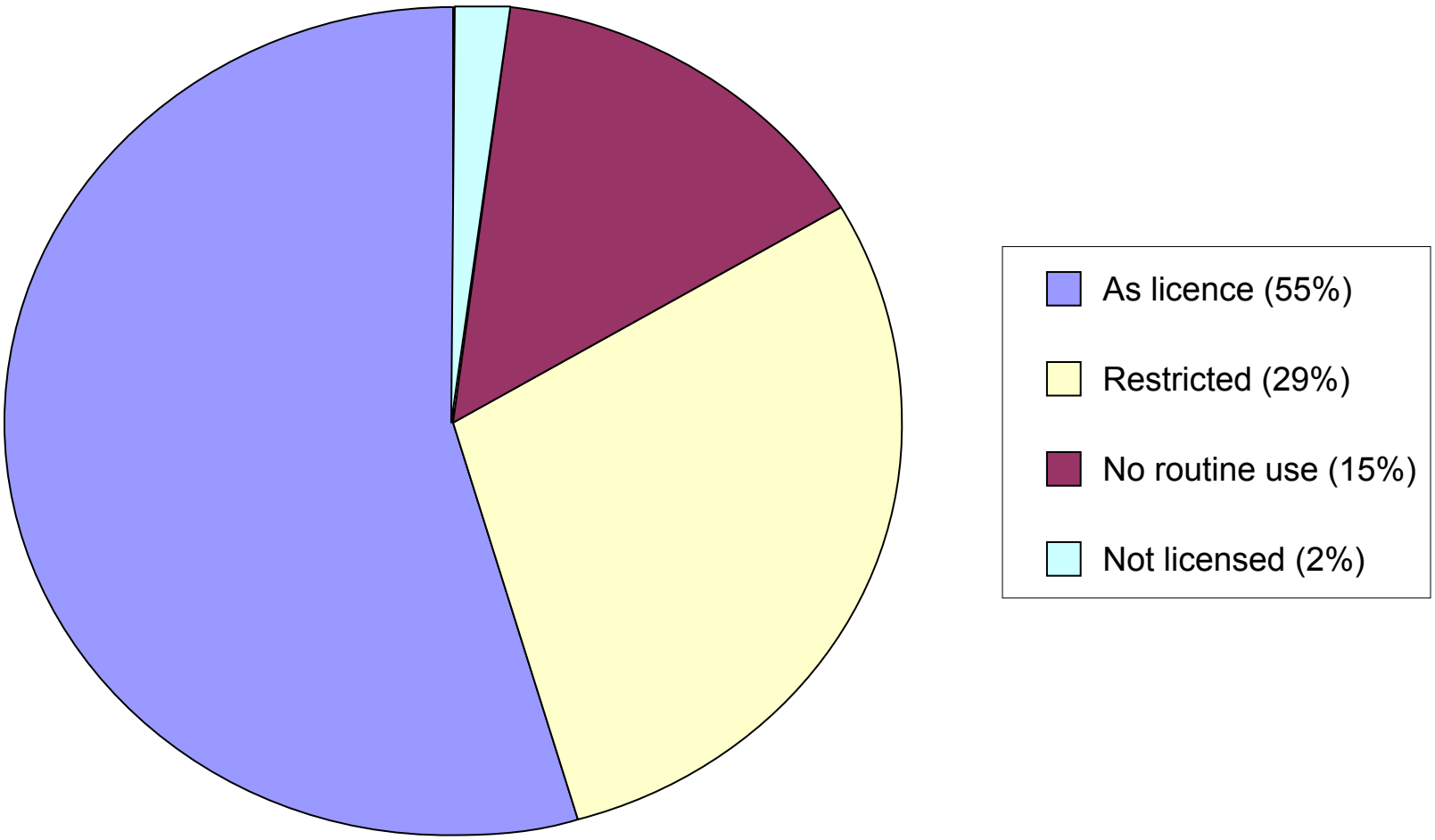
Developments over time in HTA(1)

- NICE HTA **processes** have developed over time:
  - In particular, for appraisals that involve only a single new technology, an STA, the prime source of evidence is a dossier submitted by a manufacturer, which is then reviewed and critiqued on behalf of the Appraisal Committee by a university based Evidence Review Group
  - Also manufacturers are able to get advice from NICE early in their development of a technology on the evidence they will need to provide to be successful at NICE
- NICE HTA **methods** have developed over time and the approach taken to improving how evaluations are done and supported have been approached systematically
  - Creation of the Decision Support Unit (DSU)
  - Production of technical support documentation in the form of Working Papers
  - Three yearly updates to the Technical Guidance for Submission and the Submission Template
  - Link to National Institute for Health Research to ensure nationally funded research supports decision making – research may be empirical or methodological
  - Big strides in methods of using evidence

Developments over time in HTA(2)

- Processes have become much more inclusive
  - Identification of **stakeholders** (manufacturers of the technology and of its comparators; expert physicians; affected physicians; other expert or affected clinical groups, such as therapist or nurses; patients; local health service managers) for every evaluation
  - **Their inclusion** in scoping, providing commentary on evidence and providing commentary on decisions
  - Methods are subject to widespread review, including the **use of citizen councils** which supplement academic investigations of population preferences
  - Expert, patient and lay input into committees themselves

NICE recommendations: cancer drugs



Developments over time in scope of NICE

- It was realised that by addressing only the technologies that came from the Health Care Industries NICE was only looking at a small part of what actually affected the health outcomes of the population. The Institute has, therefore become responsible for evaluating a **wide range of health care interventions**
- This has led to a range of new programmes:
  - MTAC – topics from a variety of sources
  - Public Health Interventions
  - Interventional Procedures – surgery, interventional radiology – may be no sponsor
  - Diagnostics
  - Ultra Rare Diseases
- All backed up by a programme of assessment of **implementation** and the barriers to implementation

Involvement

- The new evaluation programmes have brought completely new participants into the evaluation processes, such as bench scientists into the diagnostics advisory group and a variety of people in Public Health from Housing, Transport, Social Security, Criminology etc.
- The new committees do not necessarily have the same processes as the original HTA Committees, for example the Highly Specialised Technologies Committee takes direct evidence from informed clinicians and patients; the Diagnostics Advisory Committee includes topic experts as voting members of the Committee for each topic

How are these people who make input paid?

- The result of this activity is that literally thousands of people at some time make input into NICE committees and yet more are involved as reviewers and commentators
- This has promoted a clinical and general population that is relatively HTA literate
- The permanent staff of NICE are, of course, paid as are Committee chairs, but most other people give their time for free
- This produces a robust independence on the part of Committee members, who have at times proved themselves to be very resistant to pressure from politicians to come up with a different decision

Conclusions on NICE

- Become a widely respected and followed advisory body on a variety of forms of intervention in health
- Has produced in clinical staff an awareness of and familiarity with HTA and Health Economic Methods which is probably second to none worldwide
- Has similarly produced a relatively HTA literate general population, at least at a basic level
- Has linked decision making to a research programme to inform it
- Has contributed greatly to the development of methods and measures in HTA by which both trial and real world evidence can be used to make better decisions
- Has extended the thinking well beyond drugs alone

Threats to NICE

- Care has been taken to make NICE a supporter of the NHS, not an organisation that makes life difficult for local budget holders
- In part this was ensured by the linking of the approval of new technologies with their funding through the Horizon Scanning process and Treasury processes of funding an ever expanding health budget
- Both growth in health budgets and the budget of NICE itself were cut back in 2011, while NICE was actually given more responsibilities
- With current policies of no growth in health expenditure it becomes very important that the cost effectiveness threshold is respected as reflecting the Opportunity Cost of what is displaced by a new technology
- A new Minister of Health tried to introduce what he called Value Based Pricing to the responsibilities of NICE, responding to pressure from industry, which argued that NICE processes did not capture the value of new technologies
- It took some time for the industry to realise they should have been careful what they wished for and for the Prime minister to move the Health Minister on

- The discussion of VBP has caused an attack on QALYs and with a new health minister responsible for NICE who is an enthusiastic supporter of the Life Sciences industries there is danger that what was a coherent approach to policy recommendations will be lost. He is pressurising NICE to say yes more often.
- We need to make sure that does not happen and that mechanisms are agreed to allow costly but cost effective technologies to be adopted by the NHS, in particular by putting into place appropriate arrangements to cope with big budget impacts of decisions, in particular allowing interim priorities to be set while use of the new technology is phased in.
- Otherwise there is a risk that there could be a diminution of the influence of NICE and chaos in the decision making and implementation processes

Thank you for your kind attention

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