An innovative system for health technology evaluation of medical technologies

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Diagnostics Forum, Uppsala

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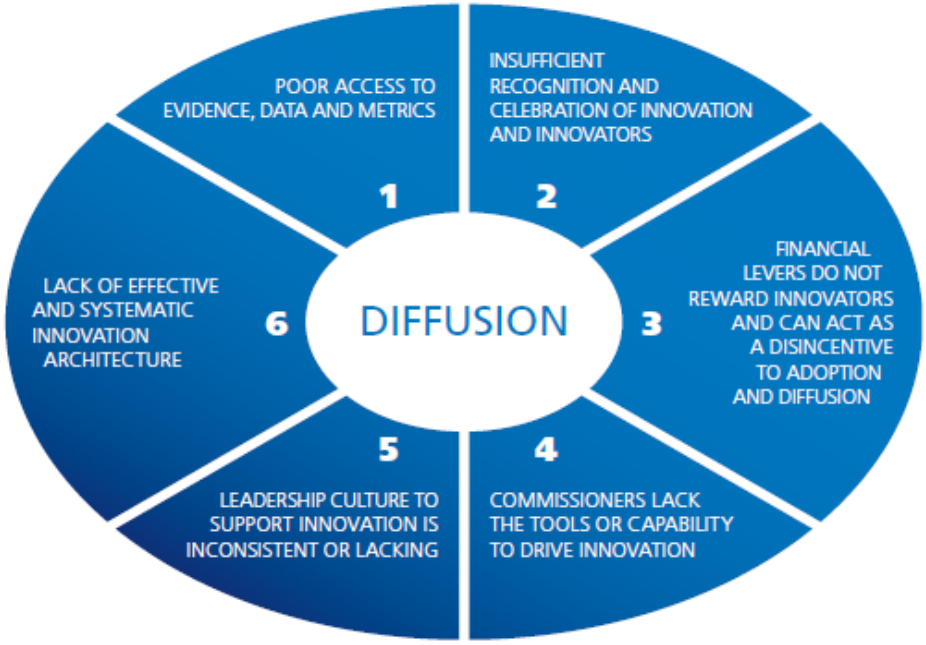
Content

- UK medtech policy and NICE
- Development of the NICE medtech programmes
- Assessing value
- Published guidance

NHS Chief Executive Report on Innovation - December 2011



Barriers to innovation in the NHS



Innovation, health and wealth: promoting uptake of NICE guidance

- Support for adoption of NICE guidance
- Compliance regime and uptake metrics
- End to local duplication of NICE evaluation
- argeted effort to implement two specific guidance products (including one medical device)
- Focus on NICE as single point of entry for innovative medical technologies





ACTION: Through NICE, we will establish an advice service for medical technology companies. This means that businesses and investors will understand the data requirements needed to demonstrate the value of their technology.

December 2011

NHS
National Institute for
Health and Clinical Excellence

Technology Strategy Board

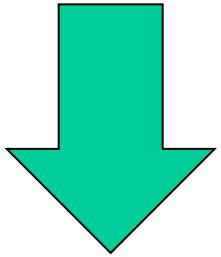
National innovation agency, part of govt department

BIS Department for Business Innovation & Skills

*"to accelerate economic growth by stimulating and supporting **business-led** innovation"*

Major strategic areas, eg comms and IT, health, manufacturing, space, food supply, sustainability

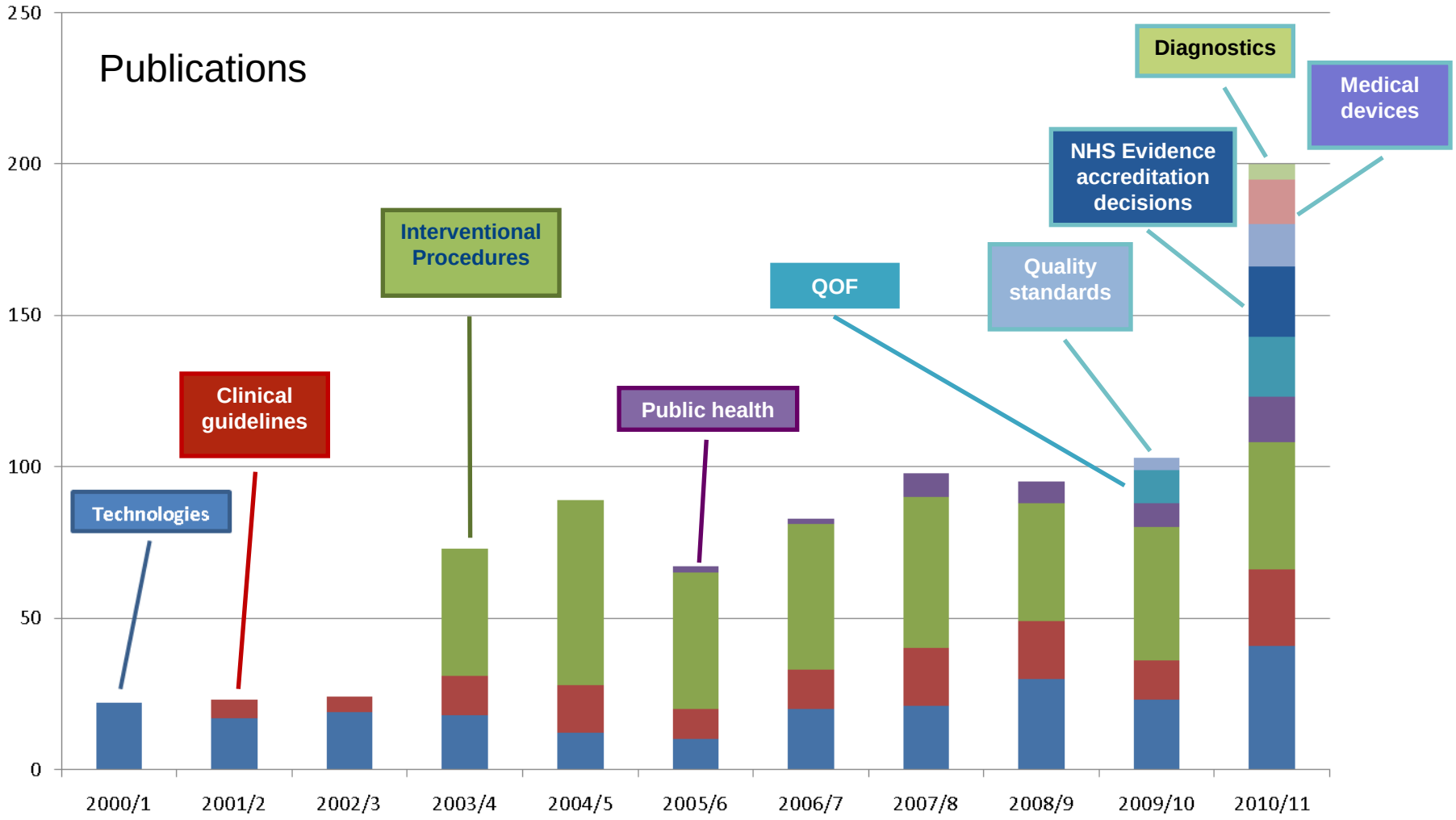
Funds competitions to stimulate economic growth



Stratified Medicine Innovation Platform

NHS National Institute for Health and Clinical Excellence

A short history of NICE



?



Urine-base

"Let ... barley ... eral days. If ... eans a male child. If ... s, it means a female child. If ... do not grow, she will not bear at all."

Testing of this theory in 1963 found that 70 percent of the time, the urine of pregnant women did promote growth, while the urine of non-pregnant women and men did not.

NHS
National Institute for
Health and Clinical Excellence

NICE Medical Technologies Evaluation Programme (MTEP)
Bespoke design features (1)

Characteristic	Programme design and operational features
The relatively sparse evidence base for medical technologies by comparison with, for example, pharmaceuticals	All forms of evidence (published and unpublished and with no design or quality threshold) are considered. Further evidence generation facilitated by NICE for promising technologies with guidance recommendations for further research
Diagnostics is a special case	Custom-designed diagnostics programme
Medical technologies evolve at a rapid pace	Short timelines. 10 weeks from notification to selection, 38 weeks from selection to guidance development
Medical technology products are usually promoted to the NHS with specific claimed benefits when used in place of or addition to standard care	The sponsor's case for adoption drives the initial assessment and, if selected, evaluation of the product to simulate NHS decision-making. Clear and explicit value propositions are required from the sponsor before a decision is taken to evaluate
Medtech products are promoting with different value propositions: - clinical non-inferiority and resource-releasing; - more cost-more benefit	Refer to different guidance programmes with appropriate methods: - cost consequences analysis - cost effectiveness analysis

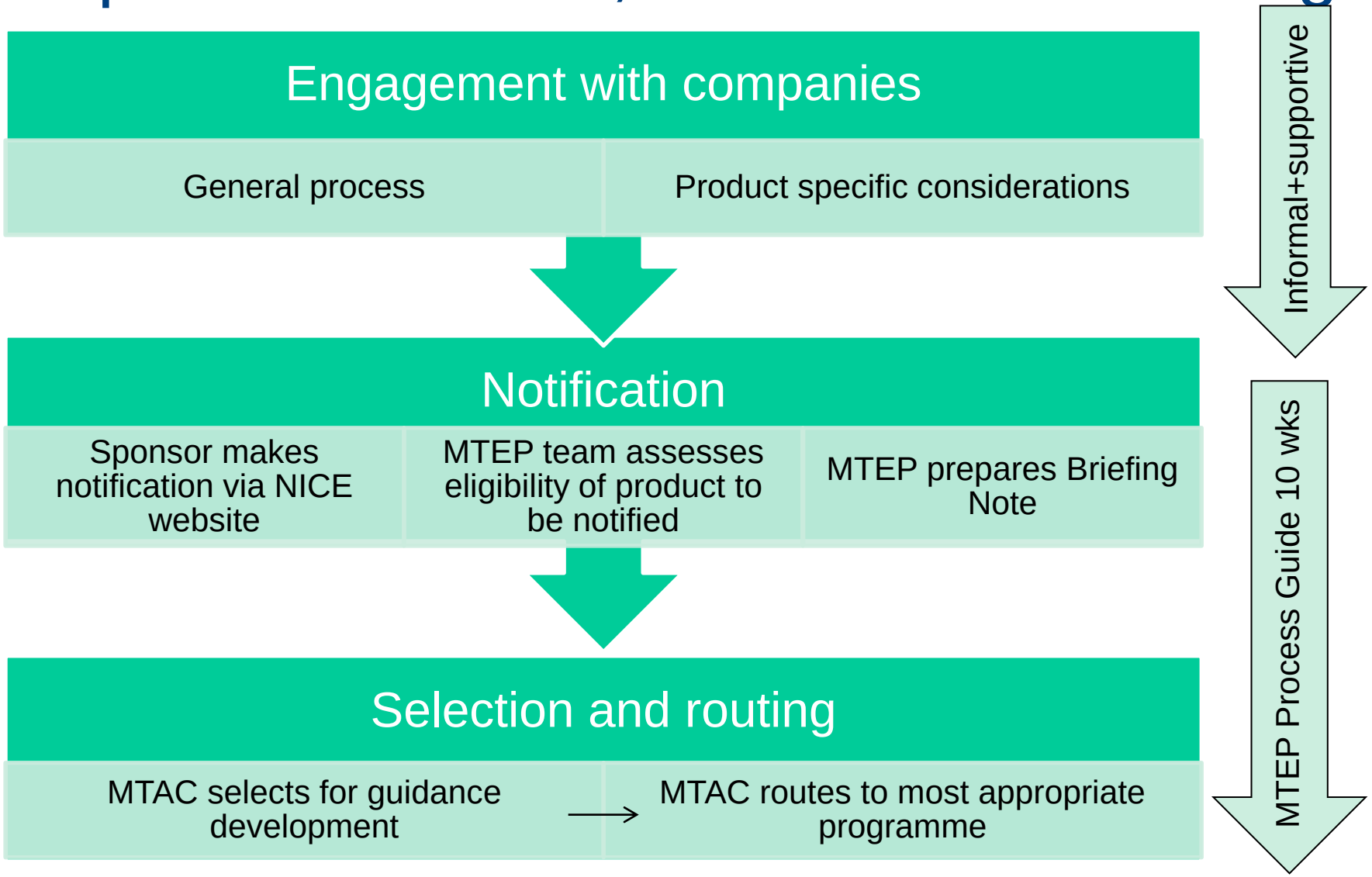
Campbell B, Campbell M. Applied Health Economics and Health Policy 2012; 10 (5): 295-297

Medical Technologies Evaluation Programme (MTEP)
Bespoke design features (2)

Characteristic	Programme design and operational features
The medical technology industry is large and diverse with a high rate of output of innovative products	Innovators (usually a commercial sponsor, i.e. Manufacturer or distributor) notify their products directly to NICE so that as wide a range of products as possible can be considered.
Improving the efficiency of health services is a top policy priority	Medical Technologies Guidance specifically examine products which are plausibly resource releasing and the primary economic methodology used is cost-consequences analysis which gives an estimate of the saving per patient if the case for adoption is supported by the evidence
Innovative products may be slowly and/or unevenly adopted	Products which are novel but not new can be notified and may be evaluated if there is evidence that they have plausible claimed benefits and are not being routinely adopted.
Technical considerations (safety, compatibility, procurement, maintenance, calibration, training, upgrades) can significant influence clinical utility	Access to world-leading technical expertise to commission bespoke studies to answer specific questions which are relevant to the assessment clinical or cost utility

How the programmes work

Step 1. Notification, selection and routing



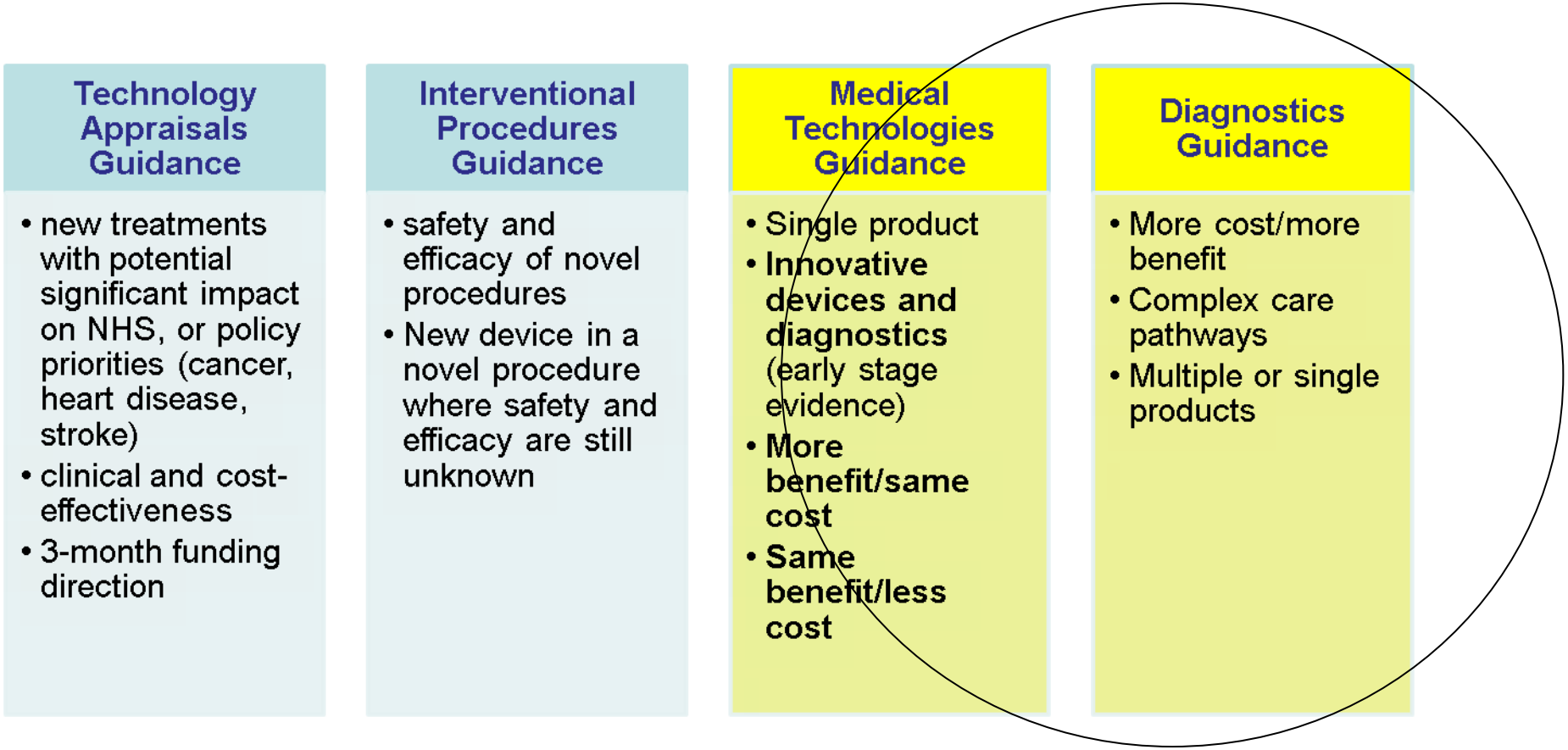
Eligibility and selection criteria

Eligibility	Selection
Timing	Patient ben
New or novel	Systen
Suitable for evaluation	Di
	Cost erations
	Sustainability

Plausible promise

Ineligible or not-selected topics are returned to the sponsor with a summary of the Committee's considerations

Step 2. If selected, evaluation by a guidance programme at NICE



Scenario	NICE Programme
CDx and drug co-developed, drug marketing authorisation requires the use of CDx	TA
CDx and drug co-developed, drug marketing authorisation does not require the use of CDx	TA or DAP
CDx and drug independently developed, CDx applied in drug clinical development, drug marketing authorisation requires the use of a CDx	TA but there may be Dx alternatives
CDx and drug independently developed, CDx applied in drug clinical development, drug marketing authorisation does not require the use of CDx	TA but could be large evaluation if high no of Dx
CDx developed independently and offers the potential to improve targeting of existing drug(s)	DAP but may use extant Rx models

Routing selected (diagnostic) topics: what's the value proposition ?

Clinical performance	Better	At least equivalent
Cost	Higher	Less overall
Patient benefits (inc preference)	Evidenced and used to adjust value	Evidenced and anecdotal – but not used to adjust value
Appropriate evaluation method	**Cost effectiveness**	**Cost consequences**
Type of evaluation	Multiple products (where appropriate). Systematic review and evidence synthesis by external academic group	Single product based on sponsor's claims and submission
Example	Depth of anaesthesia monitoring (DG6)	Confirmation of amniotic fluid leak (MTG, in progress)

Medical technologies guidance - cost modelling – cost consequences analysis

Cost model - examples

- Acquisition costs
- Running costs eg disposables or concomitant treatment
- Staffing costs
- System savings (eg change in setting)
- Reduced costs of improved health outcomes
- Improved ease of use or patient acceptability

New Diagnostics Guidance (DAP)

Single or multiple tests or technologies

Cost-effectiveness methodology (QALY)

In-vitro, monitoring or imaging devices

All diagnostic purposes – initial diagnosis, staging, chemotherapy management etc

Typical diagnostic evidence base (accuracy)

Complex methodology - pathway modelling

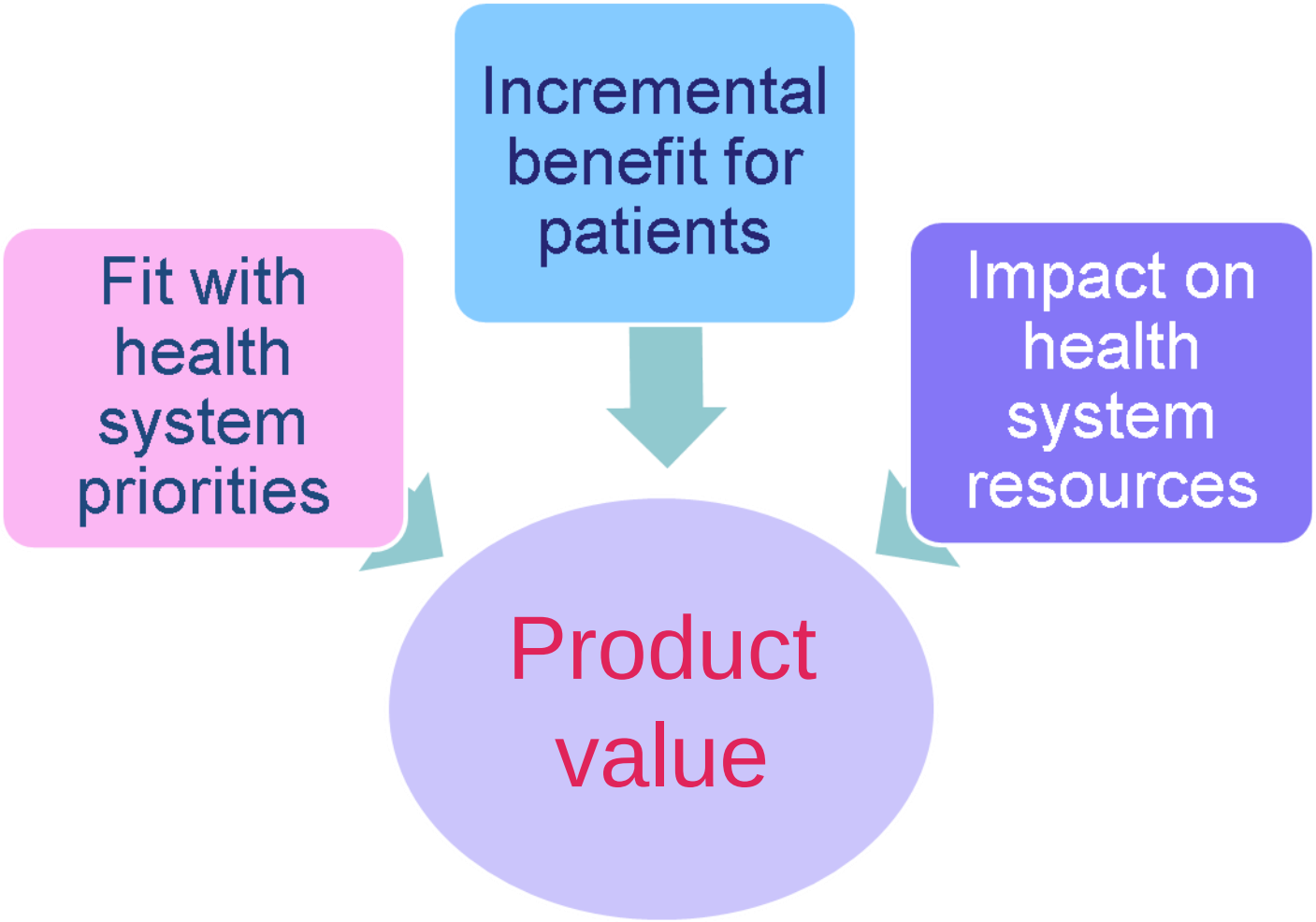
Specialist Committee Members for model inputs

Companion diagnostics

Length of process = 63 weeks

Assessing value

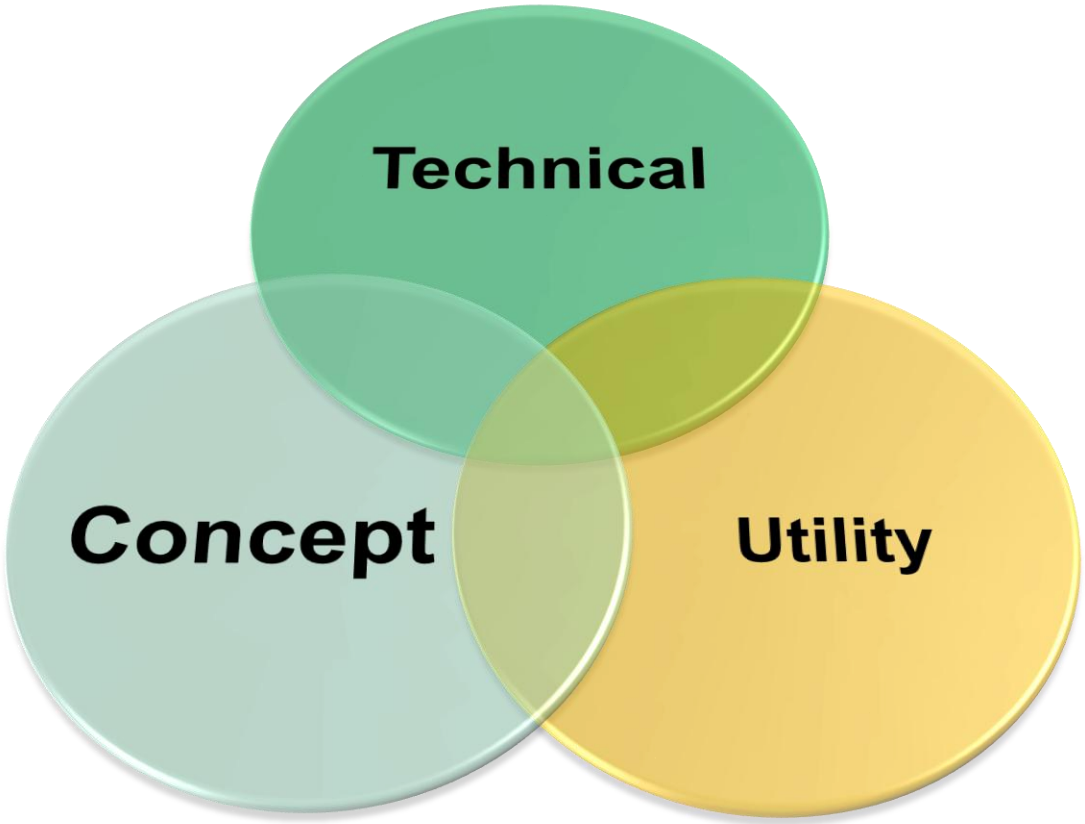
What do decision makers need to know about new technologies?



What evidence does NICE use?



Evidence for medical technologies

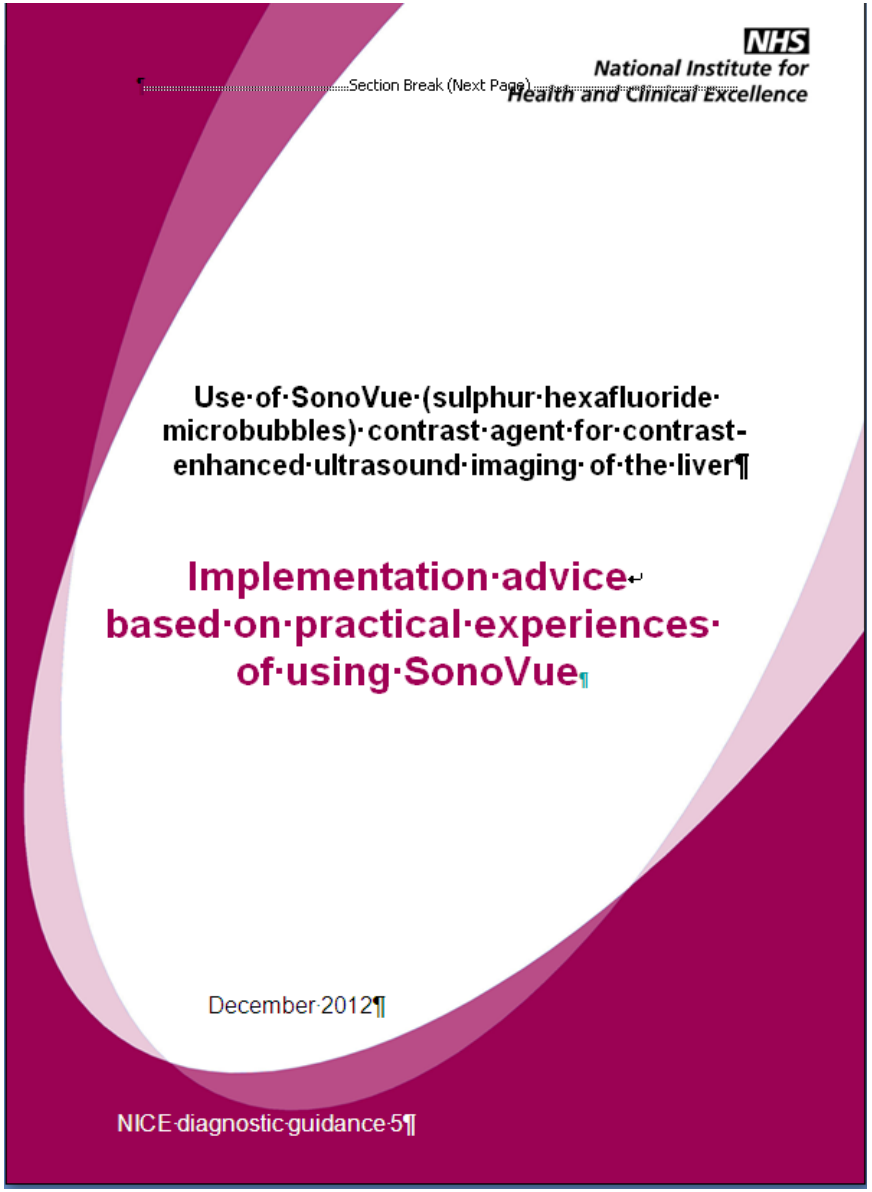


Selected published and in-development guidance

Number (date)	Title	Summary of recommendation(s)
DG4 (August 2012)	Adjunctive colposcopy technologies for examination of the uterine cervix - DySIS and the Niris Imaging System	DySIS is a clinically and cost-effective option, compared with standard colposcopy, for examining the uterine cervix in women referred for colposcopy, and should be considered in procurement plans for colposcopy equipment.
DG5 (August 2012)	SonoVue (sulphur hexafluoride microbubbles) - contrast agent for contrast-enhanced ultrasound imaging of the liver	Contrast-enhanced ultrasound with SonoVue is recommended for characterising incidentally detected focal liver lesions in adults in whom an unenhanced ultrasound scan is inconclusive.
DG6 (November 2012)	Depth of anaesthesia monitors (E-Entropy, BIS and Narcotrend)	The use of electroencephalography (EEG)-based depth of anaesthesia monitors is recommended as an option during any type of general anaesthesia in patients considered at higher risk of adverse outcomes. The Bispectral Index (BIS) depth of anaesthesia monitor is therefore recommended as an option in these patients.
DG7	SeHCAT (Tauroselcholic [75Selenium] acid) for the investigation of bile acid malabsorption (BAM) and measurement of bile acid pool loss	SeHCAT (tauroselcholic [75selenium] acid) is a potentially clinically important test for diagnosing bile acid malabsorption, which may be currently underdiagnosed. Further research recommended.

DG5. SonoVue for CEUS of the liver

- Novel product
- Patient and system benefits
- Guidance plus tailored implementation support
- Limited and inconsistent adoption in NHS



DG6. Depth of anaesthesia monitoring

- Important unmet need
- No previous guidelines
- Combination of evidence scrutiny and NICE advisory body decision-making



Topic	Patient benefits	System benefits	Annual cost saving (£ per patient unless stated)
MTG 7 Inditherm patient warming mattress for prevention of inadvertent perioperative hypothermia	Fewer peri-operative complications (compared with no warming)	Less energy consumption Easier to use Warms only the patient	11,000 per theatre
MTG 8 Veri Q for assessing graft flow during CABG	Reduction in peri-operative morbidity/mortality	Reduction in graft occlusion and subsequent graft revision	115
MTG9 PleurX peritoneal drainage system	Early and frequent treatment of symptoms, compared with in-patient treatment	Avoidance of in-patient treatment	679

Nursing Times.net

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NICE approves catheter drainage system for cancer

1 April, 2012

A device that can help reduce the severe abdominal fluid retention experienced by some cancer patients has been approved by the National Institute for Health and Clinical Excellence.

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Cancer patients should have access to device to treat fluid retention at home, says NICE

BMJ 2012; 344 doi: 10.1136/bmj.e2272 (Published 22 March 2012)
Cite this as: *BMJ* 2012;344:e2272

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Zosia Kmietowicz

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Patients with cancer who have recurrent malignant ascites should have the option of treating themselves at home, says new guidance from the National Institute for Health and Clinical Excellence.

The institute's Medical Technology Advisory Committee says that the PleurX peritoneal catheter drainage system should be used for patients who need vacuum assisted drainage for recurrent malignant ascites and whose treatment for cancer is unlikely to resolve the problem. The guidance applies to England.

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The Lancet, Volume 379, Issue 9822, Page 1171, 31 March 2012
doi:10.1016/S0140-6736(12)60490-5 Cite or Link Using DOI

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End-of-life care: the neglected core business of medicine

High priority should be given to development of devices that improve the quality of life in those with terminal illness. For example, drainage of ascites at home is now possible with a peritoneal catheter system, which enables management of ascites at home rather than needing paracentesis in hospital, which often necessitates admission for one or two days. The UK National Institute for Health and Clinical Excellence has now approved home use of such a peritoneal catheter system. Widespread adoption of such devices could enable many more patients to receive palliative care at home, protected from the unnecessary burden and inconvenience of a hospital admission.

NICE Medical Technologies Guidance 12 and 13

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Ultrasound Treatment To Heal Bone Fractures Approved By NHS

PA | Posted: 09/01/2013 07:02 GMT | Updated: 09/01/2013 16:51 GMT | PRESS ASSOCIATION

A device which uses ultrasound waves to help heal bone fractures has been given the go-ahead for use on the NHS.

The Exogen ultrasound bone healing system can be used to help treat bone fractures that have failed to heal after nine months, the National Institute for Health and Clinical Excellence (Nice) said.

The device emits low intensity waves through the skin to the fracture. These pulses are said to jump-start the body's natural healing process.



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Simple test to prevent a stroke

A SIMPLE test at the doctor's could save thousands of lives a year by detecting a killer irregular heartbeat.

By: Jo Willey
Published: Wed, January 16, 2013



The new £75 device spots racing pulse

A new blood pressure device which can also spot a dangerous heart condition has been approved for use in England from today.

The disorder can cause a racing heartbeat which could lead to tiny blood clots triggering a stroke.

An estimated 12,500 people die from strokes related to the condition, atrial fibrillation, a year and at least a million people suffer from it. But that is thought to be the tip of the iceberg because of delayed detection and diagnosis. Although an irregular heartbeat can cause dizziness, shortness of breath and palpitations, many people have no symptoms and are unaware they are in danger.

Last night one expert said 4,500 strokes could be prevented a year if patients with the condition had appropriate treatment while another described approval for the £75 device as "good news".

Any device that aids in earlier detection of AF should be welcomed
Maureen Talbot, senior cardiac nurse at the British

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