# NICE Annual Conference 2017

## Conference Report

18–19 May 2017

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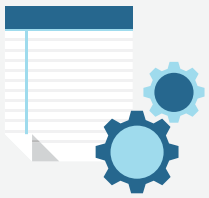
## Introduction

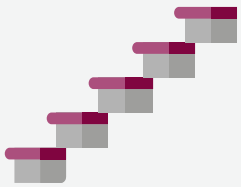
The NICE Annual Conference returned to Liverpool this year and once again attracted delegates and speakers from each of the various sectors of healthcare, including the pharmaceutical and medical devices industries, third-sector organisations and the NHS, as well as representatives from NICE itself. This year's conference was held against the backdrop of continued financial pressure on the NHS but the conference programme did also provide reasons to be positive, with several examples and discussions as to how innovation can help to improve patient care. In keeping with the role of NICE in driving change within the NHS through the publication of evidence-based guidelines and the evaluation of new technologies, the key themes of the NICE Annual Conference 2017 were Innovation. Access. Transformation.

The upcoming General Election undoubtedly cast a shadow over the conference, with many speakers restricted by purdah rules as to what they could say publicly. The conference was not, however, without lively debate on the future of health and social care in the UK, with the final plenary session specifically looking ahead to 2020 and the opportunities and challenges that the sector will face between then and now. Also making an appearance was Sir Hugh Taylor, who discussed the findings from the Accelerated Access Review and stressed the importance of future innovation for a sustainable NHS, a vibrant life sciences industry and a successful UK Plc. Change at NICE itself also featured prominently at the conference, with representatives from NICE and NHS England providing a session that summarised and contextualised the recent changes to NICE's technology appraisal processes.

This report features the four key areas of discussion at the NICE conference that were of most relevance to the pharmaceutical and medical devices industries.



Changes to the NICE Technology Appraisal Process



Five Steps for Putting Together a Value Proposition

Engaging with NICE (for Patients and Industry)

Implementation of NICE Guidance

## Changes to the NICE Technology Appraisal Process

April 2017 saw a considerable update to NICE's technology appraisal process, and the NICE conference provided a platform for representatives from NICE and NHS England to present a summary of the recent changes; namely, the introduction of the Fast Track Appraisal (FTA) and the Budget Impact test, and changes to the Highly Specialised Technology (HST) appraisal process.

### Fast Track Appraisal

In introducing the FTA process, Jennifer Prescott from NICE highlighted the need to balance the risks and challenges posed by the available evidence with the size and complexity of the appraisal process, and stated that the intention behind the FTA process is to provide an *equally robust* but *less resource intensive* appraisal option. For those technologies with either an incremental cost-effectiveness ratio (ICER) of below £10,000 per quality-adjusted life year (QALY) gained or sufficient evidence to warrant a cost-comparison

analysis, the new FTA process will reduce the time taken for NICE to publish final guidance (from 43 weeks to 32 weeks from the invitation to participate) and also the period of time within which NHS England must make funding available (from 90 days to 30 days).

Critical to the FTA process will be the scrutiny of the manufacturer's submission in Weeks 8–11. During this time a decision will be made as to whether or not the technology qualifies for the Fast Track, and for those that do, the Evidence Review Group (ERG) and NICE will jointly produce a technical briefing document ahead of the first and only Appraisal Committee meeting (Week 21), instead of a separate ERG report and pre-meeting briefing document.

**10**

topics have already been identified as potential FTAs

**2**

evidence submissions have been received for Fast Track consideration

### Budget Impact Test

Helen Jones from NHS England introduced her session by discussing the difficulty sometimes faced by the NHS when having to provide statutory funding for NICE-recommended technologies that have a high budget impact. It is in this context that a budget impact test has been introduced, whereby any technology with a net budget impact of >£20 million in any of the first three years of funding will trigger a commercial discussion between the manufacturer and NHS England. The majority of technologies recommended by NICE are not expected to fail the budget impact test, with only 20% of recently recommended technologies exceeding the budget impact threshold.

It was emphasised that the £20 million threshold does not represent the maximum funding cut-off point for new technologies (i.e. importantly, commercial arrangements do not necessarily have to reduce the budget impact to below £20 million). The threshold was instead framed as the point at which it becomes difficult for NHS England to provide funding for the other services to which the NHS has already committed in a given year.

Manufacturers were encouraged to seek an early dialogue with NHS England and it was noted that NHS England would be open to suggestions of innovative commercial agreements. Various scenarios were outlined during the session; for example, in the event that a commercial agreement cannot be reached, NHS England would go back to NICE with the aim of negotiating a longer time period for introducing the technology concerned. The emphasis on flexibility of arrangements during the session suggests it is likely that there will be much to learn on a case-by-case basis for both manufacturers and NHS England; indeed, it was noted that the HST programme may provide key learnings on approaches to negotiation and implementation of novel commercial access arrangements.

Finally, manufacturers should be aware that the detailed processes for assessment of budget impact are still not yet finalised, and should keep an eye on any developments in this area.

### Highly Specialised Technology Appraisal Process

Updates to the processes and methods of the HST programme for assessing technologies for very rare conditions represent the third major development at NICE, and Sheela Upadhyaya provided a guide to these changes for conference delegates. Each of these technologies provides its own unique set of challenges, not least due to the sparsity of clinical evidence to support their use. Since 2013, NICE have published guidance on only four HSTs and most of these were introduced as part of a managed access scheme to collect real-world evidence to confirm the extent of clinical benefit. The aim of the proposed changes to the appraisal process was to create a decision framework that was systematic, transparent and repeatable, and that focussed on the therapeutic benefit to patients in terms of QALYs gained.

The consultation on the proposed changes led to a number of the proposals being scrapped, including the need for HSTs to be subjected to the Budget Impact test and also the possibility for HSTs not recommended by NICE to be subsequently assessed

by the NHS Clinical Priorities Advisory Group. Nevertheless, the new HST appraisal process features a number of eye-catching changes, including the introduction of a £100,000 per QALY gained threshold and QALY weighting system, as well as formal recommendations to explore a lower discount rate for truly transformative technologies. However, the HST topic selection criteria will remain unchanged, with around three topics being appraised each year, and the involvement of patients and rare disease experts in the appraisal process will continue to be an important part of the appraisal process.

### The ABPI Response

Paul Catchpole from the Association of the British Pharmaceutical Industry (ABPI) provided a clear response to each of the changes and in doing so identified both areas of concern and optimism for the pharmaceutical industry (see below).

## Summary of ABPI response to the changes to the NICE appraisal processes

**Fast Track Appraisal process**

- A welcome route to achieving patient access
- Increased co-ordination between HTA and regulatory 'fast track' programmes encouraged
- £10,000 per QALY gained threshold a "reasonable starting point"

**Budget Impact test**

- Does not acknowledge the existence of the Pharmaceutical Price Regulation Scheme (PPRS) to handle affordability
- Risks delayed access due to need to negotiate commercial arrangements
- Earlier engagement in commercial discussions is welcome, but an increased focus on outcomes-based commercial arrangements is required

**Highly Specialised Technology appraisals**

- Practical challenges to cost-effectiveness analysis exist for rare diseases, as recognised in the Montgomery Report in Scotland
- Ongoing data collection will be important
- There is lack of clarity over routing into different appraisal programmes for technologies for rare conditions; consolidation is required

## Five Steps for Putting Together a Value Proposition

Sir Andrew Dillon kicked-off the "Access" stream at the conference with a presentation of the five key ingredients of a great value proposition:

1. Ensuring the value proposition is aligned to the ambitions and capacities of the health system, which for companies means recognising the constraints faced by the system and taking opportunities for early engagement on adoption pathways

2. Acknowledging that NICE and NHS England apply a transparent and flexible evaluation framework in order to establish key decision determinants and appropriately capture the complexity and uncertainty of their decisions; manufacturers therefore need to be prepared to adhere to the same principles of transparency and flexibility

3. Building-in the opportunity for commercial discussions at the earliest stage, which helps to manage complex reimbursement proposals and is particularly important for high net budget impact products

4. Considering managed access arrangements, which are appealing as they provide risk-sharing opportunities

5. Building the business case for adoption alongside the clinical case, for instance considering:
   - How the new technology will change clinical practice
   - Whether your product provides "bankable" (i.e. short-term and realisable) resource advantages
   - What needs to be done in order to implement the new therapy, and how can the manufacturer support this

The value proposition ultimately needs to reassure NICE that the risk of adoption is an acceptable one, and in this context Carole Longson hinted at future development in NICE's methods for formally measuring the risk associated with adoption of a new technology. It was noted that NICE have been looking for the last 18 months at developing greater guidance on methods for assessment of uncertainty, perhaps suggesting we can expect formal NICE guidance in the near future on techniques such as expected value of perfect information (EVPI) analysis.

## Engaging with NICE (for Patients and Industry)

### Patients

The need to engage patients throughout the development, evaluation and implementation of new technologies and models of care was a major theme of the conference. For example, the development of new care models with a focus on patient experience was explored in the Transformation stream of the conference programme and patient-centricity was highlighted by each panellist as a key goal of developing innovative approaches to better care in one of the plenary sessions. Throughout the various sessions, the emphasis was placed on quality, safety and compassion in the delivery of care.

Presentations from representatives of the European Medicines Agency and NICE Scientific Advice highlighted the importance of engaging with patients during the clinical development of new technologies in order to ensure that the most relevant outcomes for patients with the condition are included in trial protocols. In addition, the role of patient experts in the NICE technology appraisal process was discussed. The contributions made by these patient experts was described as additional 'evidence' for Committees to consider and their involvement was seen to be critical to help frame the questions asked of new technologies. However, it was also recognised that there is no 'optimal' patient who can represent the views and experiences of the entire patient population and that the views of carers should also not be neglected. Actions speak louder than words when it comes to patient involvement, and it was therefore interesting to hear Dr Leeza Osipenko, Associate Director at NICE Scientific Advice, state that they are aiming to increase the number of patient experts at NICE Scientific Advice meetings to two patients, rather than the current single representative of the patient voice.

### Industry

Representatives from the Office for Market Access and NICE Scientific Advice joined the Chair of NICE Committee C, Professor Andrew Stevens, in describing the ways in which industry can engage with NICE, both within and outside the guidance development process.

The NICE Office for Market Access was described by Associate Director, Carla Deakin, as providing a 'safe harbour' environment for manufacturers to engage with various stakeholders. Manufacturers were encouraged to ask questions and share their plans at an early stage in order to gain insight from different stakeholders and benefit from having everyone in the same room at the same time. The role of NICE Scientific Advice in providing more direct guidance to manufacturers, including on modelling approaches, was also outlined. Delegates were encouraged to explore the seminars run by NICE to gain an insight and understanding of HTA processes, and also to look out for new NICE Scientific Advice services on the horizon, such as the Medtech Early Technology Assessment Tool (META) assessment tool kit, through which NICE can provide advice for medical devices in the early stages of development.

Echoing the points raised in the 'Five Steps for Putting Together a Value Proposition,' Professor Stevens provided a Committee Chair's perspective on what makes a good evidence submission and what factors are playing into a Committee's decision. With regards to the former, the key elements for a good submission were, perhaps unsurprisingly, the product itself, the price, and also clarity and transparency in the way that evidence is presented. In terms of factors being considered by Committees in their decision-making, Professor Stevens noted that subgroups, degree of innovation, inequality and disease severity all play on the mind of a Committee, and made the point that a Committee will generally be opposed to providing a "yes" recommendation where they feel that this will result in exclusion of access for a small minority of patients.

## Implementation of NICE Guidance

One notable shift in emphasis at this NICE conference compared to previous years was the increased focus on adoption and implementation of technologies post NICE guidance, with a higher level of critical consideration of the extent to which positive NICE recommendations actually translate to availability of a technology throughout the NHS. A number of questions from delegates probed NICE on their processes for monitoring implementation and ensuring adoption of their guidance. Indeed, NICE acknowledged a need for them to do more to critically and systematically appraise the impact and disruption of approved therapies on care pathways (both positive and negative) in order to help ensure clinical and cost-effectiveness potential is realised.

NICE took the opportunity to describe their two teams dedicated to enhancing implementation of their guidance:

- **Adoption Team:** this team looks at technologies that have been recommended by a technology appraisal or the medical technologies or diagnostics programmes (technologies assessed via HST and cancer therapies are not considered), identifies those technologies that might face significant barriers to adoption and develops resources that provide practical solutions to support adoption
- **Impact Team:** this team is dedicated to measuring the uptake and impact of NICE guidance

Although audience members did highlight individual experiences of having difficulty accessing NICE-approved pharmaceuticals, NICE recommendations for pharmaceuticals do result in a funding mandate, which is not the case for medical devices. Detailed discussion on implementation of guidance at the conference therefore focused in particular on medical devices. For technologies going through NICE's Medical Technologies Evaluation Programme (MTEP) and Diagnostics Assessment Programme (DAP), NICE's Adoption and Impact teams engage with front-line users of the recommended technology to understand challenges to implementation. Key learnings from this activity are published as "Insights" on the Tools and Resources sheet of the relevant guidance on the NICE website, and aim to provide real-life examples to help organisations understand and implement challenges to adoption. Ensuring successful adoption of medical devices that can bring value to the NHS appears likely to be an increased focus going forwards; however, with funding still non-mandatory for technologies going through MTEP, the decision to implement NICE recommendations will continue to be taken at the local level for the time being at least.

## Costello Medical Consulting

Costello Medical provides scientific support to the healthcare industry in the analysis, interpretation and communication of clinical and health economic data. Due to growing demand across an increasing range of service offerings and geographies, Costello Medical has grown organically since foundation in 2008 to a team of over 90 based in Cambridge and Singapore.

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## Further Assistance

If you would like any further information on the themes or research presented above, please do not hesitate to contact Matt Griffiths at: matt.griffiths@costellomedical.com.