Insights from the NICE 2019 Annual Conference on Transforming Care

9 May 2019

Introduction

On 9 May, the National Institute for Care and Health Excellence (NICE) held its annual meeting, *'NICE 2019: Transforming Care'*, celebrating 20 years of its commitment to healthcare. The meeting brought together stakeholders across the life sciences, health technology, and digital sectors to discuss NICE's role in the delivery of high quality, fully-integrated, patient-centered guidance.

Evidera had several representatives in attendance to garner insight into NICE's perspective on improving access to innovative treatments and what it means for our clients.

The content in this document represents the thoughts and observations of Evidera and not necessarily the views of NICE.

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NICE 2019

9 May | Manchester

Over the last 20 years, the role and scope of NICE has grown significantly. Today, NICE is one of the international leaders in health technology assessment (HTA) standards and processes, and an increasing number of companies across the life sciences industry are engaging with the organisation for technical and strategic support. During the day-long meeting, NICE updated stakeholders across the industry on the following key themes.

EARLY
ENGAGEMENT

Evolution and expansion of early engagement through scientific advice

PROCESSES &
GUIDELINES

NICE processes and guidelines development

NEW
TECHNOLOGIES

Challenges and opportunities from new technologies

Expansion of early engagement through NICE Scientific Advice

A common theme throughout the meeting was the benefit of early involvement of NICE in the drug development process to allow better alignment of evidence needs for both regulatory approval and market access.

NICE Scientific Advice (NSA)

NSA aims to provide detailed guidance to companies on prospective clinical and economic evidence generation plans, enabling companies to develop an evidence base that clearly demonstrates the value of their product. Recently, NSA has provided advice relating to patient preference studies. Key insights from independent clinical and academic experts are involved in the process, as well as NHS decision-makers and patient advocates. NSA is also often used as a point of reference for other agencies. For example in the US, ICER indicated they are looking to provide scientific advice in a similar format to NICE.

Preliminary Independent Model Advice (PRIMA)

NSA is also now providing PRIMA – a new health economics model advice service. While the NSA currently provides companies with advice on the design and structure of economic models at the conceptual stage of the development process, PRIMA offers an advanced level of service via an external peer review of models. The PRIMA team systematically inspects the model and provides a detailed report of model enhancement recommendations for consideration.

NICE collaborations across Europe and North America

Additionally, NSA has established or is working on collaborations with several bodies, such as:

NSA Concurrent European Service
Provides a solution in the event that NICE cannot be part of the Parallel EMA EUnetHTA consultation process after the UK leaves the European Union

More details can be found here

Parallel Consultation with the European Medicines Agency (EMA) and European Network for Health Technology Assessment (EUnetHTA)

Canadian Agency for Drugs and Technologies in Health (CADTH)

Read more about CADTH's recent parallel scientific advice programmes here

Blue Cross/Blue Shield (BCBS) to identify a company for the first scientific advice discussions started with a US payer

Commercial engagement within NHS is also moving towards earlier discussions with companies

NHS is evolving as well, and in April 2019, NHS England and NHS Improvement came together to act as a single organisation. Additionally, its commercial medicines division has become increasingly savvy over the last few years, working alongside NICE and moving towards earlier commercial discussions with companies. However, their advancement is not free from challenges – the ones below were mentioned during the meeting.

Commercial Medicines Division

Oversees all commercial discussions with companies in relation to individual technologies, including:

- Drugs that trigger the £20m budget impact test (BIT)
- Commercial arrangements associated with the Cancer Drug Fund (CDF)
- Commercial arrangements relating to NICE's Highly Specialised Technology (HST) appraisal programme
- Commercial arrangements relating to NHS England's clinical policy process overseen by its Clinical Priorities Advisory Group (CPAG)

REGENERATIVE MEDICINES MAY POSE CHALLENGES

- **The large gap between regulatory and payer data requirements.** Technologies may receive regulatory approval based on small populations treated in single arm trials, which can lead to considerable uncertainty for payer decision-making.
- **Identifying and evaluating regenerative medicines.** With seven gene therapies expected to go through the appraisal process in the next few years and significantly higher numbers to follow, identification of the most impactful therapies through horizon scanning will be critical. The challenge of evaluating and designing optimised pricing and reimbursement approaches for regenerative medicines was highlighted during the discussion as well.
- **Implementation and service delivery for regenerative medicines.** Identifying potential implementation challenges and the associated implications on service delivery will be critical as more regenerative medicines come into the market.

Commercial framework to increase collaboration between companies, NICE, and NHS England and ensure alignment on objectives

The commercial medicines division is also engaging in earlier discussions with NICE, ultimately bringing the companies, NICE, and NHS England closer together to allow for more transparent and integrated pricing and market access processes. This increased interaction will help to enable:

- A strengthened market access process
- Enhanced horizon screening
- Increased confidence that commercially-sensitive information is respected
- Proactive interaction to ensure alignment of mutually beneficial objectives
- Alignment with the NICE process

HOWEVER, SOME CHALLENGES STILL REMAIN

Clinical evidence base

Demonstrate value to payers as well as regulators

Early engagement

Engage early with NSA and the NICE Office for Market Access (OMA), and commercial functions within NHS

Value proposition

Value proposition should be clear and transparent with price based on clinical value

Salami slicing

Price should start off at a reasonable level, rather than the highest and 'salami slicing' until an agreement is made

Evolving processes within the NSA

While many companies have worked with OMA, some are not as familiar with NSA and when it would be appropriate to engage with that team. During the meeting, the NSA team discussed its efforts to move forward several key objectives to support new technologies:

- Accelerating the HTA and commercial negotiation processes for faster patient access and less intensive resource use for NICE
- Greater importance placed on the technical engagement step in the HTA process with earlier involvement of committee members to reduce uncertainties in the evidence base and prevent the need for multiple committee meetings
- Accommodating the needs of small companies to make the process easier to understand and navigate

Advancing processes within NICE

Single Technology Appraisal (STA)

A 'one size fits all' approach

(Delays can occur after 1st committee meeting)

Fast Track Appraisals (FTA)

Faster patient access, less resource intensive process for low risk appraisals

Technical Engagement Step

Faster patient access, less resource intensive process for many appraisals

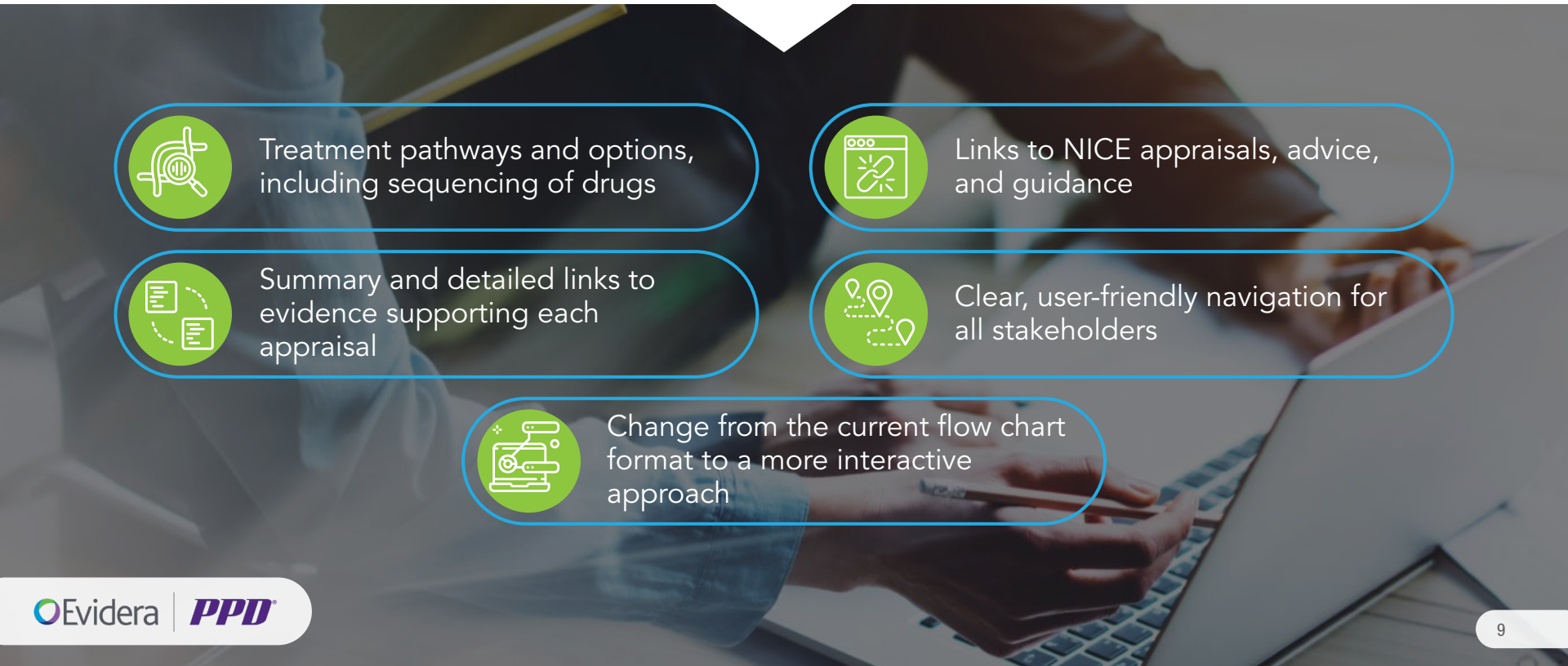
Methods and Processes Review

Where change is clearly needed, supported by the evidence, and agreed to by all key partners

Increased interactive content coming to NICE Pathways and Guidelines webpage

NICE will be enhancing their Pathways and Guidelines on their website with interactive content to improve access to relevant information and the overall user experience for all stakeholders, including companies, healthcare providers, and patients.

This is an ambitious endeavor and a longer-term project, but the goal is to include the following.



- Treatment pathways and options, including sequencing of drugs
- Links to NICE appraisals, advice, and guidance
- Summary and detailed links to evidence supporting each appraisal
- Clear, user-friendly navigation for all stakeholders
- Change from the current flow chart format to a more interactive approach

Encountering challenges and opportunities from new technologies

There was a particular emphasis on new technologies at the conference, including how NICE can lead the evaluation of genomic tools and treatments, along with the fight against antimicrobial resistance.

Genomics and targeted/gene therapies

- There is an increasing role for genomics in medicine due to rapid technological advances; however, testing is still not available to everyone or all indications under the NHS
- More research is needed to understand genomic mutations and meaningfully interpret test results
- Treatment for a condition attributable to a genetic alteration must be available to maximise the benefit from genetic testing and reduce the potential psychological impact from testing
- Other challenges include:
  - Ethics regarding data sharing and confidentiality
  - Data management
  - Understanding the impact on clinical pathways and resourcing within the NHS
  - Pricing and funding concerns given the high cost of some treatments

Antimicrobial resistance

- NICE recognised the need to redefine value for new antibiotics to align clinical and R&D goals
- Value is broader than mortality; it also includes reducing transmission, prophylaxis for procedures, and diversity in antimicrobials
- NICE is working with NHS England, Department of Health, and Public Health England to design and pilot a new payment model to stimulate the development of new antibiotics which would:
  - forecast value at launch and inform payments in installments
  - compare efficacy of two antibiotics (currently all trials are based on a non-inferiority design)
- Assessing value is a major global challenge – NICE hopes to pioneer a successful approach that can be adapted or followed by other countries

In summary, NICE continues to evolve and expand as a global leader in HTA appraisal

The 20th anniversary gave attendees an opportunity to look back at the evolution of NICE and get a glimpse of its initiatives for the future. NICE's expanding remit, global influence on other HTA agencies, and presentations at the conference suggest that their trend of helping move the industry forward looks likely to continue.

It was clear that NICE recognises evolving population needs and advancements in new health technologies requires timely yet robust processes. Furthermore, it was stressed that engagement in clinical development programme discussions earlier in the process is critical for developing a sound value story and supporting evidence.

Clients are likely to benefit from NICE's early engagement and scientific advice services, while at the same time demonstrating the transparency of their work. Patients can be reassured that NICE will continue to be a patient-centered organisation focused on incorporating patient perspectives in making decisions on the availability of new technologies.

For more information or to discuss your evidence strategy, contact info@evidera.com

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