

Response to the All Party Parliamentary Group on Access to Medicines and Medical Devices consultation on the NICE Methods Review

**April 2019** 

### Overview

We welcome the opportunity to respond to this consultation on **the NICE Methods Review** – one of the Academy's objectives is help secure a future where independent, high-quality medical-science advice informs the decisions that affect society such as the uptake and adoption of new medical innovation.

The Academy of Medical Sciences promotes advances in medical science, and campaigns to ensure that these are translated into healthcare benefits for society. Our elected Fellowship includes experts drawn from a broad range of research areas.

The Academy fully supports the role of NICE in providing guidance for the promotion of good health and the prevention and treatment of ill health and we recognise NICE as a world leader in effective and innovative health technology assessment (HTA). We appreciate that this is a challenging role, and that it is almost inevitable that some of the decisions taken by NICE will be controversial. However, we wish to highlight a number of areas that should be addressed by a comprehensive review of NICE methodology. Firstly, translation, uptake and adoption of medical innovation remains slow in the NHS due to challenges along the innovation pathway and the demands of sustainability and affordability in the NHS. Secondly, to maintain the UK's excellence in HTA it is essential that the balance between the cost and benefit of new treatments, especially those that provide transformative health outcomes, be scrutinised carefully.

# Accelerating access for pioneering products

The Academy recognises the essential role of NICE as the UK's regulatory HTA body and how this influences the uptake and adoption of innovation into the NHS, particularly in a time of rapid medical developments. Supporting uptake and adoption of innovation is a key priority for the Academy, and we have explored this topic in detail through our FORUM programme of events, which links industry, academia, healthcare, and charity and regulatory sectors. 1,2,3

During these events, experts have highlighted the importance of the robust evaluation of innovation pathways. Access to innovative treatments in the NHS is often slow and the route to market for innovative products developed by the UK's life science's sector is not straightforward. The Academy therefore welcomes the implementation of the Accelerated Access Pathway (AAP), which will enable a fast-track route to supporting the uptake and adoption of pioneering products that will help change the lives of patients. The Academy has been actively engaged in the development of the AAP, both through our Fellows contributing their expertise to the Accelerated Access Review External Advisory Group as well as hosting a

<sup>&</sup>lt;sup>1</sup> The Academy of Medical Sciences (2017). *Accelerating access to medical innovation: a research agenda for innovation science*. <a href="https://acmedsci.ac.uk/file-download/80863587">https://acmedsci.ac.uk/file-download/80863587</a>

<sup>&</sup>lt;sup>2</sup> The Academy of Medical Sciences (2015). *Input to the governments 'Accelerated Access Review'*. https://acmedsci.ac.uk/file-download/37881-56000397d292d.pdf

<sup>&</sup>lt;sup>3</sup> The Academy of Medical Sciences (2016). *Accelerated Access Review interim report*. <a href="https://acmedsci.ac.uk/filedownload/37602-56b4bbdba9b0d.pdf">https://acmedsci.ac.uk/filedownload/37602-56b4bbdba9b0d.pdf</a>

https://acmedsci.ac.uk/more/news/government-response-to-the-accelerated-access-review

FORUM workshop on accelerating access to medical innovation.<sup>5</sup> We believe it is important to build upon the AAP initiative to ensure that innovative medicines and technologies are accessible to patients throughout the country. The scheme should be regularly reviewed to identify any opportunities for the pathway to be expanded to include additional categories of products.

# Building a system which recognises value

At a number of events held by the Academy experts have voiced the importance of involving a breadth of stakeholders in discussions around the value assigned to medical interventions, including measures of value beyond direct health outcomes. <sup>6,7,8</sup> The Academy maintains that a broader definition of 'value' is required to reflect the true value of innovations beyond their direct health benefits. <sup>9</sup> It has been highlighted that the impact and economic gains of transformative innovations can extend beyond their direct health outcomes, for example to include the value of preventing an incident of ill health, and wider societal and cultural benefits such as enhancing the ability of patients to contribute to the economy and reducing their reliance on carer support and public services. <sup>10,11</sup> In addition, the NHS must be better able to recognise the long-term value of emerging technologies and employ them accordingly; a culture of short-term cost-saving measures in the NHS will inhibit the adoption of innovation which could deliver long-term benefits and efficiencies to the system.

The review of NICE methods should therefore consider how NICE appraisals assess the wide variety of potential benefits of new innovations. It has been proposed that new models for pricing and reimbursement be considered to reflect this value and offer a more pragmatic, affordable solution for the healthcare system by more closely aligning price with value and thereby driving uptake and adoption in the NHS. <sup>12</sup>

## Supporting the use of emerging technologies in healthcare

There are many emerging innovative areas of science and technology which will challenge existing paradigms of healthcare delivery. These include advances in genomics, genome-editing, advanced therapies, companion diagnostics and data-driven technologies such as artificial intelligence (AI). <sup>13,14,15,16</sup> For example, algorithms are becoming increasingly

<sup>&</sup>lt;sup>5</sup> The Academy of Medical Sciences (2017). *Accelerating access to medical innovation: a research agenda for innovation science*. <a href="https://acmedsci.ac.uk/file-download/80863587">https://acmedsci.ac.uk/file-download/80863587</a>

<sup>&</sup>lt;sup>6</sup> The Academy of Medical Sciences (2017). *Accelerating access to medical innovation: a research agenda for innovation science*. <a href="https://acmedsci.ac.uk/file-download/80863587">https://acmedsci.ac.uk/file-download/80863587</a>

<sup>&</sup>lt;sup>7</sup> The Academy of Medical Sciences (2015). *Input to the governments 'accelerated access review'*. https://acmedsci.ac.uk/file-download/37881-56000397d292d.pdf

<sup>&</sup>lt;sup>8</sup> The Academy of Medical Sciences (2016). *Accelerated Access Review interim report*. <a href="https://acmedsci.ac.uk/filedownload/37602-56b4bbdba9b0d.pdf">https://acmedsci.ac.uk/filedownload/37602-56b4bbdba9b0d.pdf</a>

<sup>&</sup>lt;sup>9</sup> The Academy of Medical Sciences (2017). Response to the House of Lords Science and Technology Committee call for evidence into the Life Sciences Industrial Strategy <a href="https://acmedsci.ac.uk/file-download/25500651">https://acmedsci.ac.uk/file-download/25500651</a>

<sup>&</sup>lt;sup>10</sup> The Academy of Medical Sciences (2017). Accelerating access to medical innovation: a research agenda for innovation science. <a href="https://acmedsci.ac.uk/file-download/80863587">https://acmedsci.ac.uk/file-download/80863587</a>

<sup>&</sup>lt;sup>11</sup> The Academy of *Medical* Sciences (2016). *Health economics for stratified medicine*. <a href="https://acmedsci.ac.uk/file-download/61141574">https://acmedsci.ac.uk/file-download/61141574</a>

<sup>&</sup>lt;sup>12</sup> Academy of Medical Sciences (2017). *Response to consultation on the Industrial Strategy Green Paper* https://acmedsci.ac.uk/file-download/85348127

<sup>&</sup>lt;sup>13</sup> The Academy of Medical Sciences (2016). Response to the Nuffield Council on Bioethics Genome Editing Call for evidence. <a href="https://acmedsci.ac.uk/file-download/38579-56bc88dc0dea4.pdf">https://acmedsci.ac.uk/file-download/38579-56bc88dc0dea4.pdf</a>

<sup>&</sup>lt;sup>14</sup> The Academy of Medical Sciences (2016). *Response to the House of Commons Science and Technology Committee inquiry into regenerative medicine*. <a href="https://acmedsci.ac.uk/file-download/41544-579600d1a3795.pdf">https://acmedsci.ac.uk/file-download/41544-579600d1a3795.pdf</a>

<sup>&</sup>lt;sup>15</sup> The Academy of Medical Sciences (2017). Response to the House of Commons Science and Technology Committee inquiry into genomics and genome-editing. <a href="https://acmedsci.ac.uk/file-download/83063056">https://acmedsci.ac.uk/file-download/83063056</a>

<sup>&</sup>lt;sup>16</sup> https://acmedsci.ac.uk/policy/policy-projects/use-of-patient-data-in-healthcare-and-research

commonplace in healthcare, guiding clinicians through the diagnosis and decision-making process. As new or improved tools are developed they are reviewed and reflected in NICE guidelines. <sup>17</sup> When, as expected, these algorithms become more complex, NICE will need to retain the methods and expertise to effectively evaluate them. This expertise will need to be similarly developed and maintained for other emerging technologies.

The Academy believes that NICE and the NHS should take an active role in outlining the unmet need that AI and other emerging technologies could fulfil to guide the research and development of clinical tools such as decision aids. <sup>18</sup> The effectiveness of different forms of decision aids, including the use of machine learning and artificial intelligence, and their relative utility, should therefore be subject to research evaluation. <sup>19</sup>

# Patient and public involvement

In order to improve patient health and commission treatments of clinical value, it is critical to understand the needs and priorities of patients. <sup>20</sup> By taking into account user's perspectives and ensuring that HTA is informed by the preferences and needs of patients, the quality, relevance and effectiveness of HTA can be enhanced. <sup>21</sup> Patient, carer and public involvement (PPI) can also be mutually beneficial. PPI can benefit patients by facilitating communication between patients and healthcare providers, improving their comprehension of medical information and the understanding of their disease. We recognise that NICE is increasingly seeking to involve patients and the public in its HTA processes <sup>22</sup> and we are supportive of this approach. Any review into NICE methods should consider maintaining and potentially expanding the role of patient and public involvement in NICE decision making.

## Conclusion

The Academy of Medical Sciences fully supports the role of NICE. However we recognise that reviewing the methods used by NICE may help to address some of the barriers to translating medical innovations into the healthcare setting. In reviewing NICE methodology, it will be important to consider how NICE balances the benefits and costs of emerging technologies, while continuing to place patients at the centre of the decision making process.

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<sup>&</sup>lt;sup>17</sup> The Academy of Medical Sciences (2017). Response to the House of Commons Science and Technology Committee inquiry into algorithms and decision-making. <a href="https://acmedsci.ac.uk/file-download/79291192">https://acmedsci.ac.uk/file-download/79291192</a>

<sup>&</sup>lt;sup>18</sup> The Academy of Medical Sciences (2017). Enhancing the use of scientific evidence to judge the potential benefits and harms of medicines. <a href="https://acmedsci.ac.uk/file-download/44970096">https://acmedsci.ac.uk/file-download/44970096</a>

<sup>19</sup> Ibid.

<sup>&</sup>lt;sup>20</sup> Ibid. <sup>21</sup> Ibid.

<sup>&</sup>lt;sup>22</sup> <u>http://www.nice.org.uk/get-involved/citizens-council</u>