National Voices

April 2017

Report to the Office for Life Sciences

The Life Sciences Strategy and implementing the recommendations of the Accelerated Access Review

On Friday 17 March 2017, National Voices convened a meeting of patient advocacy groups involved in the development of the Accelerated Access Review (AAR), and/or with an interest in its implementation. At that meeting it was agreed that National Voices would coordinate a joint paper to the Office for Life Sciences (OLS) summarising key themes for the implementation of the AAR and the forthcoming Life Sciences Strategy.

This paper has been developed and agreed by the following organisations:

- Action Duchenne
- Breast Cancer Now
- Cancer52
- Cystic Fibrosis Trust
- Diabetes UK
- Digital Health & Care Alliance
- Genetic Alliance UK
- Kidney Research UK
- National Voices
- Parkinson's UK
- Prostate Cancer UK
- Tuberous Sclerosis Association

Overarching matters of access and innovation

Affordability

We understand that the Government plans to take forward some or all of the AAR recommendations in the Life Sciences Strategy, which will feed into the much broader Industrial Strategy.

We welcome indications that Government does intend to establish the recommended Accelerated Access Partnership.

However, the National Institute for Health and Care Excellence (NICE) and NHS England have recently announced a series of changes to Technology Appraisals, including a new 'budget impact test' for new treatments. The new test would mean that rollout of NICE-approved treatments expected to cost more than £20m in any one of their first three years of use could be delayed for up to three years, or in some cases even longer.

This has caused significant concern and runs contrary to the notion of accelerated access. The announcement is converse to the Government's own commitment to access and seems to directly contradict the objective which the Government has given NHS England, in the new Mandate, to accelerate innovation.

We believe these proposals would be a significant disincentive to investment in the Life Sciences sector. This could put at risk the country's status as a centre of excellence for research and development, which would have negative consequences for patients.

We believe that consultation with patients and the voluntary sector on the new test has been inadequate and it appears NICE and NHS England have disregarded the majority views expressed as part of that consultation process. This was a missed opportunity to work with partners on alternative solutions that allow for earlier negotiations and flexible pricing agreements, while avoiding potentially harmful impacts on patients.

The changes implemented on 1 April 2017 focus on short-term costs, not on approving the most innovative and promising new treatments and technologies that would provide significant benefits to patients.

The announcements from NICE and NHS England also raise a range of issues of equality and access, as below:

- The introduction of a £20m budget threshold will include treatments for end-of-life patients. As a result, there is a real risk of patients dying while life-extending treatments are kept just out of reach.
- Similarly, for progressive long term conditions without a cure such as metastatic cancers, multiple sclerosis and dementia, delaying or denying access may leave people's health to deteriorate irreversibly. This would lead to greater costs to the system in the longer term and undermine any perceived saving.
- Common conditions with large patient populations will be disproportionately affected by the threshold. Even if a treatment is cheap, the threshold will be easily breached if it is intended to help a significant number of patients. For example, there are numerous drugs for diabetes that already cost the NHS more than £20m a year due to the number of patients involved (e.g. £77m for Sitagliptin). Such treatments have the potential to *reduce* the overall cost burden.

- We believe the proposed introduction of a £100,000 QALY threshold will not improve access to treatments for patients with rare conditions. It is likely that new treatments will now pass directly into the annual specialised commissioning prioritisation process, which is very slow and lacks transparency.

We call on NICE and NHS England to reconsider urgently these proposals, and to work with health economists, clinicians, specialists and patient advocacy groups to establish alternative solutions with fewer risks.

Repurposing

As well as new treatments receiving 'transformative designation', the Accelerated Access Partnership must also consider repurposing existing treatments. The impact of this could be transformative for patients, whilst reducing the cost of delivering healthcare.

Some treatments already designated as being safe for use could bring benefits to a wider patient population, but it is difficult to collate clinical trial data for licensing drugs for new purposes. Where data does exist, there is no clear pathway for these treatments to become available as they are not considered through the NICE assessment process. These treatments are ideal candidates for transformative designation.

We are calling for the development of a defined pathway for the repurposing of treatments, and for already licensed treatments to be considered for 'transformative' designation' by the Accelerated Access Partnership.

Priorities for the Accelerated Access Partnership

The following are areas we believe to be priorities for implementation.

Patients should be involved in horizon scanning and prioritisation, and this involvement should continue at every stage of the whole innovation pathway

Patients' participation in research is too often dictated by chance - typically by their clinician's knowledge and awareness of relevant clinical trials. The AAR recognises that as medicine becomes more personalised, patients' interest in the development and availability of new innovations means that their involvement, either directly or through charities, is critical.

The Office for Life Sciences should send a signal on the importance of the involvement of patients by endorsing and adopting the 'I Statements for research and innovation'. It should recommend their use as a benchmark for all involved in the research and innovation pathway.

Making a reality of this recommendation will involve a focus on better patient empowerment, information and an increased role in prioritisation. This must be a prime role of the patient representatives on the Accelerated Access Partnership (AAP)and the broader patient engagement it conducts.

In order to generate meaningful patient involvement in the innovation pathway, more can be done to inform patients of clinical trials and opportunities to participate. Although the Clinical Trials Gateway exists, it is not optimised for patient participation. There should be one UK-wide system that puts the patients, and their permission to be contacted by researchers, at the heart of the process.

Improved accountability and transparency around uptake of innovation should be supported by NICE

This is pertinent in the context of recent announcements, as discussed earlier in this paper. The implementation of the budget impact test is counter to the AAR recommendation of increased transparency.

A focus on the digital and medical technologies regulatory pathways, and allied upgrading of digital infrastructure

Information technology, digital and medical technology have the opportunity to facilitate person centred approaches, for example in supported self-management. This has the promise of quick wins for patients and potential cost savings.

Representation of the views and insights of patients on the Accelerated Access Partnership

Gaining true patient input is an issue of concern to all of the organisations supporting this paper.

The Accelerated Access Partnership must understand the different insights that can be respectively brought by: independent Lay Members; individuals with lived experience; and organisations that represent them. All are valuable, but the Partnership must recognise that a solitary patient on a board will not be an adequate or representative level of patient engagement.

Patient representatives on the Accelerated Access Partnership board

The AAR proposed that there be two lay members of the Accelerated Access Partnership board, one with a specific role in represent the 'patient voice'.

It is important to ensure that patient representatives on the Partnership board possess the skills and abilities to operate at that level, to engage positively and to challenge when necessary. Once the responsibilities and accountabilities of the role have been agreed, specific competencies should be developed to meet those role requirements.

The post holder must have access to a diverse set of patient views and be supported and resourced to consult others and gather insight beyond their own experience. That support should include dedicated staff resource, funding to support the gathering of a range of views and input, and remuneration commensurate with the responsibilities of the role. This is vital to ensuring the post is meaningful.

The post should have responsibility for ensuring that the views and perspectives of patients are heard within the Accelerated Access Partnership, and that they are acted upon. To achieve this, the role must be involved in and oversee:

- Liaising with the existing patient advisory bodies and structures of the individual Arm's Length Bodies
- Defining the outcome measures with which to assess transformative products
- Keeping abreast of best practice in patient engagement.
- Promoting the principles in the 'I Statements for research and innovation' across the innovation pathway, and using compliance with these to evaluate products for the 'transformative designation'.
- Agreeing the criteria for transformative designation
- When necessary, commissioning engagement and consultation on specific issues

The role of people with lived experience

The Accelerated Access Partnership should make use of the existing mechanisms for involving patients in service design. For example, the National Institute for Health Research has established processes, and NHS England has a Clinical Reference Group and Programme of Care structure.

The role of charities

The input of charities and community groups representing patients should be formally recognised in the Accelerated Access Partnership, with a defined mechanism for their input to the Partnership board. Charities can play an important role in bringing the wider patient voice, acting as a broker between their beneficiaries and the Accelerated Access Partnership.

Resources should be made available centrally to ensure that organisations are adequately funded to deliver the work needed to ensure decisions on

Transformative Designations are based on the experiences and the needs of those patients who stand to benefit.

Charities have a wealth of expertise in both working with people with lived experiences and representing their views. In establishing the Accelerated Access Partnership, the OLS and other partners should work closely with charities to find workable solutions to ensure patients and the views of people across a range of conditions have their voice represented in a meaningful way.

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