AAC (01)

Accelerated Access Collaborative Board Meeting: Public Minutes

Wednesday 23 October 2019 11:00 – 13:00	
Attendees:	
Chair Professor Lord Darzi of Denham OM KBE PC FRS - Chair (Director of the Institute of Global Health Innovation, Imperial College London) **Board members** Simon Stevens (Chief Executive Officer, NHS England & Improvement) Sir Andrew Dillon (Chief Executive Officer, NICE) Dr Louise Wood (Director: Science, Research & Evidence, Department of Health and Social Care) Dr June Raine (Interim Chief Executive, MHRA) Piers Ricketts (Chair, AHSN network) Haseeb Ahmad (President, Association of the British Pharmaceutical Industry) Hilary Newiss (Chair, National Voices) Aisling Burnand MBE (Chief Executive Officer, Association of Medical Research Charities (AMRC)) Hugh McCaughey (National Director of Improvement, NHS England & Improvement) John Stewart (National Director of Specialised Commissioning, NHS England & Improvement)	**Other attendees** Professor Peter Clark (National Clinical Lead for the Cancer Drug Fund, NHS England & Improvement) Meindert Boysen (Director, Centre for Health Technology Evaluation, NICE) Gareth Arthur (Director of Strategy and Policy, Specialised Commissioning, NHS England & Improvement) Claire Foreman (Head of Acute Programmes, Specialised Commissioning, NHS England & Improvement) Dr Alison Austin (Head of Patient and Public Involvement, NHS England & Improvement) Roxanne Smith (Deputy Director, Office for Life Sciences, Department of Health and Social Care) Gillian Leng (Deputy CEO and Centre Director of Health and Social Care, NICE) Dr Siu Ping Lam (Director of Licensing Division, MHRA) Professor Carol Longson (supporting NHS England and NHS Improvement) Private secretary to Lord Darzi AAC team (NHS England & Improvement, Office for Life Sciences and Secretariat)

Dr Sam Roberts (Chief Executive Officer, Accelerated Access Collaborative and Director of Innovation and Life Sciences, NHS England & Improvement) Matthew Gould (Chief Executive, NHSX) Mark McIntyre (Board Member, ABHI & Senior Director of Health Economics and Government Affairs EMEA), deputising for Neil Mesher (Board Member, Association of British Healthcare Industries) Richard Hames (Executive Board Member, BIVDA & General Manager, Werfen)	
Apologies:	
Neil Mesher (Board Member, Association of British Healthcare Industries)	

Note: These minutes are a summary record of the main points discussed at the meeting and the decisions made. They are not intended to provide a verbatim record of the Board's discussion.

1 Welcome and introductions

1.1 Lord Darzi welcomed board members to the meeting and noted that Carole Longson was attending as an observer supporting the AAC team at NHS England & Improvement and not acting in her role working for the ABPI.

1.2 The board noted the declarations of interests tabled. In relation to the ATMP paper, Hilary Newiss noted that she is a board member of the Cell and Gene Therapy Catapult.

2 Review of minutes from the previous meeting

2.1 The board questioned if progress had been made on discussions with devolved nations. Following discussions with Northern Ireland and Wales the AAC team will spend a day in these devolved nations to develop an agreement on promising areas for joint work. An initial meeting has been requested in Scotland.

Action: Sam Roberts

2.2 The board approved the content of the minutes. Sam Roberts provided an update on the status of the actions and all were completed or ongoing. It was agreed that the actions should be updated with timelines for completion.

Action: AAC Secretariat

3 Programme overview

3.1 Sam Roberts informed board members that the AAC's work programme is progressing well following the transfer of functions from OLS to NHS England & Improvement. Key to this has been agreeing actions in all areas for the first 6 months.

3.2 The 3 main risks are:

- Communications – More needs to be done on this. An AAC website will be launched later this year and communications staff have now been recruited.
- Recruitment – This will continue to be a challenge.
- The nature of the partnership – The AAC team would like to ensure we make the full use of the expertise within all partners across our workstreams and would welcome further discussions on how this can best be achieved.

3.3 June Raine noted that there is more that the MHRA could offer in particular and would welcome the opportunity to explore this further with AAC team.

Action: June Raine

3.4 The board discussed the plans for innovation surgeries and agreed that it will be essential to ensure that this is coordinated and the support offer is clear, to avoid confusing companies and duplicating work. It was suggested that it would be useful to map out the partners including their skills and roles, as well as how they connect together to provide clarity.

Action: Anna Dijkstra

3.5 The board were informed that the commercial framework was out for limited engagement and it is yet to be published for full formal consultation. Formal consultation is anticipated to open at the end of October. Consultation on the MedTech Funding Mandate will open in November.

4 Patient and Public Involvement in the AAC

4.1 The board noted the importance of understanding patients' needs. It considered the workstreams to be ambitious but not unachievable, and it recognised that it will take time to embed new approaches.

4.2 Board members stressed the importance of ensuring patient and public involvement had a positive impact and National Voices would share examples of methods used to measure impact.

Action: Hilary Newiss

4.3 The board were pleased with the systematic approach to patient and public involvement. Andrew Dillon noted that NICE have decades of experience and encouraged the AAC to work with the NICE Public Involvement Programme (PIP) team to learn from success and failures in this area. It was also suggested that a short concise annual review is produced outlining the value of the AAC's programme on patient and public involvement.

Action: Alison Austin

4.4 It was noted that it will be important to take into account the level of risk that patients are prepared to accept in relation to new products with a lot of uncertainty, and this is

something the MHRA have recently consulted on. It was agreed that the MHRA would share insights with the board.

Action: June Raine

5 Advanced Therapy Medicinal Products

5.1 Sam Roberts encouraged the board to consider the following questions for each paper:

- Have the key issues been identified?
- Is the proposed effort of the AAC proportionate?
- What are partner organisations doing, or what can they do, that isn't reflected in each paper?

5.2 Board members agreed that all papers should include a section on what success will look like. It also noted that it would like to see more consistency between all of the individual papers.

Action: Sam Roberts

5.3 The board requested that the main risks for the AAC as a whole and each workstream are highlighted.

Action: AAC Secretariat

5.4 Sam Roberts informed the board that the AAC will take an action plan with agreed timelines to the next steering group meeting in December.

5.5 Claire Foreman summarised the paper on Advanced Therapy Medicinal Products (ATMPs). The board were informed the Specialised Commissioning team at NHS England & Improvement worked with a range of stakeholders to develop the paper. The paper sets out the following 5 key issues raised by partners and stakeholders:

- Patient involvement and communication
- Regulatory procedures, approval times and the pace of innovation
- Data and dealing with uncertainty
- Cost effectiveness assessment, affordability and reimbursement options
- Service and infrastructure requirements

5.6 It was explained that the proposed workstreams to address the key issues are not mutually exclusive and some will overlap/interface.

5.7 The board agreed that patient and public involvement and managing patient's expectations in this area is crucial.

5.8 The ABPI requested that information presented in appendix 2 is redacted for publication of the board papers as it may indicate anticipated licensing windows.

Action: AAC Secretariat

5.9 The board requested that timelines and expected outputs be presented at the next board meeting.

Action: Sam Roberts

5.10 The board advised the AAC to engage with NIHR biomedical research centres to understand the pipeline of products, as there are ATMPs coming through their systems.

Action: Lindsey Hughes

5.11 The board approved of the focus on speed of regulatory approval and highlighted the Food and Drug Administration (FDA) have made decisions based on real world data. MHRA will attend a strategy meeting in November and will feedback to the board at the next meeting on what can be done at a national level.

Action: June Raine

5.12 Andrew Dillon noted that the NICE methods review already has multiple workstreams attached to it and it is important for NHS England to link up with these to avoid duplication of effort. It was noted that there is only so much the NICE methods review can fix, it is therefore important to be adventurous and inventive in the commercial framework to help reach long term solutions.

5.13 The board were informed that NICE is launching a fundamental change in the presentation and development of guidance. A key part of this is how NICE manages and accesses data, along with a new way of presenting data via new digital approaches.

6 Tumour Agnostic Therapies / Histopathology-Independent therapies

6.1 Peter Clarke, Gareth Arthur and Meindert Boysen summarised the paper. Gareth explained the name has changed from tumour agnostic to histopathology-independent to fit in with regulatory conventions.

6.2 It was highlighted there is huge opportunity in this area through the new genomic medicines service and the 100,000 genomes project. The key questions are how these therapies will impact existing clinical pathways, how can they be looked at in a fair and equitable way, how to get diagnostic capacity in place (within pathology labs and genomic labs), and how to carry out the value assessment in a fair way learning from factoring in all the costs relevant to the NHS. NHS England & Improvement are currently working with NICE to put measures in place for the two products currently being appraised by NICE and welcome input from other partners.

6.3 NICE will make it as simple as possible for committees to appraise these products, but we will need to consider more than the single technology appraisals alone. We will also need to consider how these technologies impact NICE pathways and clinical guidelines

6.4 Peter Clark outlined the Cancer Drugs Fund as an opportunity to collect data to address uncertainties. Although implementation in oncology services is usually quick (3 months), implementation of these therapies may take a little longer due to requirements for genomic testing.

6.5 The board agreed genomic testing is critical and in Q2 2020 panel testing will start. It is necessary to work out how to roll out panel testing fairly and equitably. There are plans outlined in the Long Term Plan to roll out panel testing across cancers.

6.6 The board requested that an update on the timelines for the roll-out and staging be presented at the next board meeting.

Action: Gareth Arthur

6.7 Board members recognised a longer-term opportunity for a joint endeavour between NICE and MHRA colleagues to ensure alignment in regulatory and HTA data flows, especially for evidence collection post-marketing authorisation approval

Action: Andrew Dillon and June Raine

6.8 It was noted that for CAR-T the US already had databases up and running before patient access, and the UK is behind in this regard. The board recognised the importance of ongoing evidence collection and agreed that this is a key area for the AAC.

6.9 Sam Roberts summarised the following areas will be brought to the next board meeting:

- Spending review categories
- Potential RUPs for selection and the methodology used
- Horizon scanning and Innovator portal/single front door

7 Close