

## Accelerated Access Collaborative Board Meeting

Wednesday 10 November 2021 15:00 – 17:00

**Chair:**

Professor Lord Darzi of Denham OM KBE PC FRS (Director of the Institute of Global Health Innovation, Imperial College London)

**Board attendees:**

Matt Whitty (Chief Executive Officer, Accelerated Access Collaborative and Director of Innovation, Research and Life Sciences, NHS England and NHS Improvement)

Amanda Pritchard (Chief Executive Officer, NHS England and NHS Improvement)

Simon Bolton (Interim Chief Executive, NHS Digital)

Julia Dudley (Deputy Director, NHS Innovation, Office of Life Sciences) *Deputy for Kirsten McLeod*

Peter Ellingworth (Chief Executive, Association of British Health Tech Industries (ABHI))

Professor Gary Ford (Chair, Academic Health Science Networks (AHSNs))

Matthew Gould (Chief Executive, NHSX)

Professor Dame Sue Hill (Chief Scientific Officer, NHS England and NHS Improvement)

Professor Gillian Leng (Chief Executive Officer, National Institute for Health and Care Excellence (NICE))

Hugh McCaughey (National Director of Improvement, NHS England and NHS Improvement)

Dr Ruth McKernan (Chair, Bioindustry Association (BIA))

Steve Oldfield (Director General, Commercial and Life Sciences, Department of Health and Social Care (DHSC))

Ben Osborn (President, Association of the British Pharmaceutical Industry (ABPI))

Catherine Pollard (Director of the Centre for Improving Data Collaboration, NHSX) *Deputy for Matthew Gould*

Dr June Raine (Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA))

Hilary Reynolds (Interim CEO, Association of Medical Research Charities (AMRC))

John Stewart (National Director of Specialised Commissioning, NHS England and NHS Improvement)

Professor Helen Stokes-Lampard (Chair, Academy of Medical Royal Colleges (AoMRC))

Glenn Wells (Director of Strategy & Planning, Medical Research Council, UK Research, and Innovation (UKRI)) *Deputy for Dame Ottoline Leyser*

Doris-Ann Williams (Chief Executive Officer, The British In Vitro Diagnostic Association (BIVDA))

Dr Louise Wood (Director, Science, Research & Evidence, Department of Health and Social Care (DHSC))

Sarah Woolnough (Chief Executive Officer, Asthma UK and the British Lung Foundation; National Voices Representative)

**Other attendees:**

Carla Deakin (Programme Director, National Institute for Health and Care Excellence (NICE))

Sharon De Sa (Project Support Officer, AAC, NHS England and NHS Improvement)  
*Secretariat*

Remi Goldsmith (Manager, AAC, NHS England and NHS Improvement) *Observer*

Harpal Kumar (President, GRAIL Europe) *presenter item 8 only*

Lindsey Hughes (Director of Policy, Research and Engagement, IRLS, NHS England and NHS Improvement)

Pollyanna Jones (Chief of Staff, AAC/IRLS, NHS England and NHS Improvement)

Naomi Miles (AAC Programme Manager, NHS England and NHS Improvement)  
*Secretariat*

Hannah Lom (Senior Policy Advisor, Office for Life Sciences)

Andrew Mabey (Communications Senior Manager, IRLS, NHS England and NHS Improvement)

Steve McAteer (Advisor & Private Secretary to Lord Darzi)

Matthew Newman (Deputy Director, AAC, NHS England and NHS Improvement)

Nick Paget (Senior Policy Advisor; Chair and Chief Executive's Office, NHS England and NHS Improvement)

Sutharsan Satkunarajah (Advisor to Lord Darzi; Imperial College London)

**Apologies:**

Kristen McLeod (Director, Office for Life Sciences)

Dame Ottoline Leyser (Chief Executive Officer, UK Research, and Innovation (UKRI))

Professor Chris Whitty (Chief Medical Officer, Commercial and Life Sciences, Department of Health and Social Care (DHSC))

## Summary of actions

#	Action	Owner	Due Date
1	Board members to email any comments on the papers to note to the AAC team at aac.innovation@nhs.net by 17 November 2021	All	17 November 2021
2	Gillian Leng and Alison Austin to ensure NICE are linked into the work of the IRLS Research Team to embed research in the everyday work of the NHS.	Gillian Leng & Alison Austin	20 December 2021
3	Discussion around novel payment methods for ATMPs to be progressed outside of the AAC Board	ABPI	Next AAC Board - 23 March 2022
4	Julia Dudley to provide an update on how medical research charities who are not explicitly mentioned in the healthcare missions engage with the allocation of the CSR funding.	Julia Dudley	20 December 2021

*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 new board member, Amanda Pritchard, Chief Executive Officer, NHS England and NHS Improvement to the meeting.
- 1.2 Apologies were noted from Dame Ottoline Leyser, Kristen McLeod and Chris Whitty.
- 1.3 There were no conflicts of interest declared
- 1.4 There are three papers (papers 8-10) for the Board to note which will not be presented at this meeting.

#	Action	Lead	Deadline
1	Board members to email any comments on the papers to note to the AAC team at aac.innovation@nhs.net by 17 November 2021	All	17 November 2021

### 2. Review of previous minutes and actions

- 2.1. The previous minutes were accepted by the group as an accurate record of the meeting.
- 2.2. Matt Whitty noted the following two open actions from the previous meeting, both of which are ongoing;
  - *Matt Whitty and June Raine to discuss MHRA's involvement in the Innovation Service further*

- *Peter Ellingworth and Simon Bolton to discuss data sharing and privacy further. ABHI are keen to support on this agenda*

2.3. All other actions have been closed.

### 3. AAC CEO Update

3.1. Matt Whitty provided a verbal update highlighting key progress across IRLS led ACC programmes:

- Matt thanked the **Academic Health Science Networks (AHSNs)** for setting up tours for NHS England and NHS Improvement and AAC Board members and emphasised the important opportunity to showcase the work of the AAC and to better understand the different models of AHSN implementation and their approach to working with NHS systems on the adoption and spread of innovation. All board members will receive invites to attend over the course of next week. The tours started at the beginning of the month with first visit to Health Innovation Network, South London AHSN who showcased an innovative AI solution transforming the dermatology pathway and shifting activity from secondary to primary care. A summary of the outputs from the tour will be shared with the board in due course.
- NICE issued a positive Technology Appraisal for **Inclisiran** in October supported by a population level commercial deal agreed by NHS England and NHS Improvement that will enable greater access to the cholesterol lowering drug for a broader cohort of patients. NICE have endorsed a national lipid pathway, key changes to national policy have been made to reflect this. Matt thanked all the AAC members, including the Department of Health and Social Care (DHSC) for their help around the drug tariff, NICE for the work on the guidance and NHS Digital for help developing an algorithm to identify patients early, noting this was a great example of collaboration. A case study will be presented to the Life Science Council meeting in November.
- The **Patient and Public Involvement strategy** has been accepted and a proposal put forward for a Lay Member to join the Board and support the development of the strategic co-production group.
- The **Innovation Service** has passed its beta GDS assessment on 13 September 2021, allowing it to move to public beta shortly; Matt thanked all the partners for their support.
- On **Demand Signalling and Horizon Scanning**, the Stroke, Learning Disability & Autism, and Mental Health programmes have been completed and the reports will be circulated when published.
- A part of the work to **Embed Research** a series of regional engagement events are underway in collaboration with regional Medical Directors and NIHR CRN to support local health and research leaders, including ICS representatives to prioritise research.
- Matt informed the Board that the **MedTech Funding Mandate** launched in April 2021 and the operational management process for the MTFM 2021/22 policy is in development and will be shared in due course.
- Competition 3 of the **AI Award** closed on 7 September 2021 and received 200 applications. The winners will be announced in February 2022. Matt shared an exciting case study from the first round winner, **Brainomix**, an AI

tool that speeds up the reading of brain scans, taking an hour off the patient pathway in the diagnosis and treatment of stroke. This enables a three-fold increase of patients being able to achieve independence post-stroke. Brainomix is currently being piloted in Reading and Oxford.

- Matt thanked the Board for their on-going support delivering the various AAC programmes and shared the delivery metrics for Q1 of the 21-22 financial year:
    - **£33,7M** in year cost saving to the health system, primarily driven by high intensity statins, PCSK9i and Asthma Biologics.
    - **1,400 fewer days** to be spent in hospital, largely as a result of the use of FeNO devices.
    - a **45K reduction** in unnecessary prescriptions for inhaled corticosteroid medications.
    - Over **1,600 new innovators** and innovations being worked with.
- 3.2. Lord Darzi complimented Matt Whitty for his leadership of the AAC and the work undertaken by his team. Reflecting on the update for the AI Award Lord Darzi gave his endorsement for the use of AI in the stroke care pathway, stressing the patient benefits to be gained from rapid access to imagining outside of specialist centres.
  - 3.3. Gary Ford highlighted the work of the AHSNs in supporting the spread and adoption of Brainomix across both specialist and non specialist centres acknowledging the workforce, as well as patient, benefits of introducing the technology into the stroke pathway.
  - 3.4. Gillian Leng complimented Matt Whitty and team on Inclisiran deal which will be of great benefit to patients. She requested that NICE are sighted on the Embedding Research work and to be included in the discussions around the outputs.
  - 3.5. Matthew Gould acknowledged the great collaboration between the AAC and NHSx on the AI Award. He challenged the group to consider whether sufficient evaluation of the impact of the programme had been undertaken to demonstrate the value to the NHS from investing in AI.
  - 3.6. Matt Whitty welcomed the challenge and acknowledged that Brainomix was the first time we have been able to demonstrate clinical outputs. Reflecting on the significant learning from the early rounds of the AI Award, we are confident that our evaluation process is more sophisticated, and we will see better impact data for round 2.
  - 3.7. Matt reminded the board that this was the first time such a programme has ever been undertaken globally and there is considerable international prestige associated with the AI Award. The award has invested in technologies rather than companies and calculated risks have had to be taken.
  - 3.8. Lord Darzi agreed that the joint working between the AAC and NHSx has led to quick commissioning of these new technologies which is hugely beneficial for patients.

#	Action	Lead	Deadline
2	Gillian Leng and Alison Austin to ensure NICE are linked into the IRLS Embedding Research Programme	Gillian Leng & Alison Austin	20 December 2021

#### 4. Introduction from Amanda Pritchard, NHS England and Improvement Chief Executive

- 4.1. Lord Darzi expressed his pleasure to welcome Amanda Pritchard to join the Board and invited Amanda to share her thoughts on how the AAC can support her to deliver the priorities for the NHS.
- 4.2. Amanda Pritchard thanked the Board for inviting her to join. She acknowledged the beneficial role research and innovation had played in the UK's response to the pandemic and the impact across diagnostics, therapeutics and vaccines. Research into COVID-19 undertaken in the NHS has saved millions of lives and changed clinical practice all over the world, notably the REACT and RECOVERY trials.
- 4.3. She reflected that one of the positives to be taken from the past 18 months has been the raised profile of research and innovation both within the NHS and public perceptions and stressed the opportunity to build on this. The pace with which innovation has been adopted; for example, the vaccine programme sets a new bar for how fast things can move through the life cycle. She highlighted the important role the AAC has in bringing this together.
- 4.4. Amanda touched on future priorities, while we continue response to the pandemic, we also need to address the emerging needs on the NHS:
  - We must reduce health inequalities and address the unacceptable variation in health outcomes for patients from different backgrounds. This includes exploring how we can best use innovation and health technologies to deliver for our whole population.
  - The NHS must continue to deliver on our Net Zero ambition. She was pleased to note that the Greener NHS and IRLS teams are jointly providing funding for medical technologies that then support net zero through the Small Business Research Initiative (SBRI) programme.
  - Support the delivery of the Life Sciences Vision. Equitable access to NICE approved treatments needs to be firmly on our agenda.
  - Finally, supporting access to services and elective recovery. The NHS is facing rising demand which places increasing pressure on service delivery and timely care for our patients. The need for innovation has never been greater.
- 4.5. Amanda set the AAC a bold ambition to continue to work collaboratively to use the collective resources of the AAC to bring innovative solutions to address key patient needs including:
  - Timely and equitable access to NICE approved treatments.
  - Increase patient participation in trials, that participants are more reflective of our diverse population and that we can undertake these even quickly and efficiently.
  - support for medical technologies so that we know we are getting the best ones to patients more quickly.
  - Build on our population health deals such as inclisiran and GRAIL to systematically focus on our patient's highest priority population health needs.
- 4.6. Lord Darzi thanked Amanda for her passion and reiterated that innovation was the only way the NHS will be able to face the challenges ahead. He assured her that every member of the board is committed and delighted to help the NHS address the challenges outlined.
- 4.7. Ruth McKernan invited Amanda Pritchard to meet the UK Bioindustry Association (BIA) to demonstrate innovations being developed by UK-based SMEs.

## 5. Early Stage Support for ATMP's & HITs Programme Update

- 5.1. Lord Darzi invited Matthew Newman, Deputy Director of AAC to present the Early Stage Programme update paper.
- 5.2. Matthew Newman updated the Board on the work of the Early Stage Programme. He touched on the challenges to delivery of the programme, notably the impact of COVID-19.
- 5.3. Despite this, significant progress has been made over the last 18 months. Matthew acknowledged and thanked system partners who led and contributed the programme delivery. The programme has supported Advanced Therapy Medicinal Products (ATMPs) and Histology Independent Treatments (HITs).
- 5.4. Matthew directed the Board to the key achievements outlined in the paper, highlighting a couple of key outputs:
  - NHS Readiness Toolkit developed by the Cell and Gene Therapy Catapult.
  - Changes to the National Genomic Test Directory and implementation of NTRK gene fusion across all seven NHS GLHs following NICE recommendation for the use of Larotrectinib and Entrectinib in May 2020.
  - Development on an end-to-end ATMP Roadmap detailing existing system roles, responsibilities and support, led by the Association of the British Pharmaceutical Industry (ABPI). This is on track for launch in December.
  - Finally, ongoing work of the Commercial Medicines Directorate including publication of the Commercial Framework for New Medicines in February 2021, and the Innovative Medicines Fund (IMF) which is in development. Both aim to enhance existing managed access approaches to innovative treatments, including ATMPs, in an operationally sustainable way.
- 5.5. John Stewart reminded the board that as recently as two years ago there were no systems in place for these new treatments to get through NICE or be adopted. He informed the Board that NICE have approved the majority of ATMPs that it has appraised, notable examples include CAR-T products in oncology. Although there are ongoing challenges and much of the work for CAR-T was undertaken at risk there now is a strong platform to build from.
- 5.6. Ruth McKernan expressed concerns on behalf of the BIA that decision was made not to progress an Outcomes Based Payment (OBP) scheme as part of the Early Stage Programme. She acknowledged that a significant amount of work has been undertaken by partners to support ATMPs, resolving the pricing issue would help a plethora of companies working in this space.
- 5.7. Ben Osborn echoed the positive progress and partnership work; he also reinforced Ruth McKernan's concerns around funding mechanisms. He recommended further exploration of novel pricing methods, in particular staged payment and OBPs. He suggested using Horizon Scanning Mechanism and Innovative Licencing and Access Pathway (ILAP) along with NICE programmes to identify potential candidate products. With the output including published learning from case studies to guide companies
- 5.8. Gillian Leng agreed that new products need to be considered for novel reimbursements schemes and that NICE needs to be involved much earlier.
- 5.9. John Stewart reiterated that the NHS has approved the majority of ATMPs to date without the need for OBP. The Commercial Framework allows companies to

propose complex arrangements such as OBP and NHSE&I is always happy to consider these however due to the administrative burden of transacting and monitoring these arrangements the preference is also for simplicity. Strict government accounting rules have been a barrier to spreading payments across multiple financial years, but the Commercial Medicines Directorate have been working through Horizon Scanning when more innovative approaches are needed.

- 5.10. Sue Hill reflected on learning from the two HITs products and the benefit of early engagement with genomic testing we were able to move away from single targeted gene testing into something that could be incorporated into cancer gene panels. Early involvement was important for driving change and increasing uptake.
- 5.11. Julia Dudley thanked Matthew and remarked that from an OLS perspective there were supportive of plans to redesign the programme and keen to work with the AAC on this. They are also really interested in the lessons learnt, and how we can measure future impact and success.
- 5.12. Further discussion around evidence in other European countries and the approaches taken by Germany and France were mentioned. Ruth McKernan said we need to be careful not to appear anti-innovation, Ben Osborn agreed that there is a lot of work industry can do collectively so there is a more substantial approach. Lord Darzi thanked all the stakeholders and agreed that careful monitoring would ensure we do not lose ground on the international stage in this important area. It was resolved that conversations would continue between AAC Partners outside of the Board to progress this area.

**Action:**

#	Action	Lead	Deadline
3	Discussion around novel payment methods for ATMPs to be progressed outside of the AAC Board	ABPI	Next AAC Board - 23 March 2022

**6. Life Science Vision Update (Verbal)**

- 6.1. Julia Dudley provided a verbal update on the spending review that concluded on 27 October 2021. The settlement provides (DHSC) £5 billion for health-related research and development (R&D) funding over the next three years with investment rising by £2 billion by 2024. This will support:
  - Vital new research funded by the National Institute for Health Research (NIHR) addressing some of the UK’s most significant healthcare challenges.
  - £95 million for the Office for Life Sciences for delivery of the Government’s Life Sciences vision, including launching the Prime Minister’s healthcare missions in cancer, obesity and mental health and to address systemic barriers to the access and uptake of cutting-edge innovations in the NHS.
  - Harnessing the UK’s genomic and health data including Generation Genome, a new pioneering newborn screening programme to detect over 200 rare diseases, and ‘Diverse Data’, to increase representation of minority groups in genomic research.
- 6.2. The department for Business, Energy & Industrial Strategy (BEIS) settlement provides an increase to £38.8 million in 2024/25 to support innovation and help the UK achieve its goal of reaching net zero by 2050 and deliver on the Plan for



Growth. This is a positive outcome and shows a clear commitment from the Government to the sector in recognition of the outstanding contribution during the pandemic.

- 6.3. Internal work continues to ensure suitable governance is in place around the Life Sciences Vision delivery.
- 6.4. Lord Darzi thanked Julia Dudley and her team for their hard work achieving this settlement. He asked Julia how the AAC should respond to the changes to the Life Sciences governance?
- 6.5. Julia advised that the AAC should aligns itself but stays independent of the Life Science Vision.
- 6.6. Lord Darzi provided an update on the Global Biopharma CEO summit, 2nd December 2021 and confirm that Amanda Pritchard, Matt Whitty, and himself would be attending. 25 Chief Executives from pharmaceutical companies along with attendees from UK Government, the NHS and regulators will be attending the summit.
- 6.7. Louise Wood reminded the board that the Research and Development budget included NIHR. The £5bn announced includes funding for the Official Development Assistance (ODA).
- 6.8. Matt Whitty thanked Julia for the update and added that the amount obtained was credible and is good news for the sector.
- 6.9. Sarah Woolnough asked how medical research charities who are not explicitly mentioned in the healthcare missions e.g. respiratory should engage. Julia Dudley advised that the team are still working through the details of the missions and she will take Sarah's query to them for further guidance.
- 6.10. Hilary Reynolds agreed with Sarah Woolnough and said that the Association of Medical Research Charities (AMRC) would also be keen to follow up on how other health challenges would be dealt with through the missions.
- 6.11. Steve Oldfield reflected on the discussion and stated that conversations to ensure the fair allocation of the spending review budget were ongoing and that there are a lot of equally important priorities.

#	Action	Lead	Deadline
4	Julia Dudley to provide an update on how medical research charities who are not explicitly mentioned in the healthcare missions engage with the allocation of the CSR funding.	Julia Dudley	20 December 2021

## 8. Galleri™ Test Trial Launch

- 8.1. Lord Darzi welcomed Sir Harpal Kumar, President, GRAIL Europe to the meeting and invited Harpal to share his experience of launching the Galleri™ test trial in the NHS
- 8.2. Sir Harpal thanked Lord Darzi and the board for the opportunity to present. Sir Harpal delivered a short presentation covering GRAIL's experience launching the Galleri™ test trial and reflected on challenges faced during the process
- 8.3. The two parts to the trial; a randomised trial of 140k asymptomatic patients and 25k symptomatic patients.

- 8.4. The presentation highlighted a number of partnership 'firsts', including the use of DigiTrials-ANRAS data to exclude participants with recent cancer history and the dynamic adjustment of invitations process to ensure representative population.
- 8.5. Some of the challenges experienced included data governances and linkages, Health Research Authority (HRA) processes being unsuited for undertaking trials on non-NHS sites and unanticipated delays due to processes around consent.
- 8.6. Sir Harpal thanked Matt Whitty and the AAC team for their help working through the agreements and getting all negotiating parties to the table. He hopes that the key learnings from this process would be helpful in providing clarity in decision making in the future. This trial will go a long way in contributing to the NHS Long Term Plan ambition to increase early diagnosis of cancer from 50% to 70% to increase cancer survival.
- 8.7. Lord Darzi thanked Sir Harpel for the presentation and asked why GRAIL chose the NHS to pilot the Galleri™ test. Sir Harpal said that while it was not impossible to conduct it in other countries it would be more difficult, and that the NHS set up is ideal to support a trial of this nature. Noting access to national data sets and ability for longitudinal data collection in the NHS which is more difficult to obtain in the US.
- 8.8. Ruth McKernan, ask Sir Harpal what learning he could share for other digital technologies that don't have specific study locations. Sir Harpal noted that almost everything within this study is being done digitally and offered to share learnings with her team.
- 8.9. Gary Ford said it was excellent to see this work, in his experience the approvals process continues to pose challenges in the R&D framework. The model for recruitment was complemented, and it was noted that this is not used by the NHS more widely. Gary suggested the pathway for diagnostics needs to be mapped out.
- 8.10. Sir Harpal said that the evaluation would integrate with current pathways and should the test be proven successful in clinical trial it would be complementary to the current screening programme, it will not replace it. GRAIL have had conversations with the UK National Screening Committee, and he would be happy to link with NICE as well.
- 8.11. Louise Wood agreed that it was very important study for innovative trail design as well as the delivering patient benefits. Louise was keen to learn from this pilot. She said that NHS England and NHS Improvement has commissioned NIHR Policy Research Unit to do an evaluation.
- 8.12. Amanda Pritchard offered her congratulations to all involved in the GRAIL Galleri™ trial and said it is so helpful to reflect on the learning in real time.
- 8.13. Matt Whitty said that GRAIL is a brilliant example of so many AAC partners undertaking one of the NHS's strategic priority on early cancer diagnosis. This will support NHS demand signalling around cancer diagnostics, and lead to horizon scanning for solutions. It showed national level clinical leadership using flexibilities of commercial medicines framework, innovative commercial models and a risk appetite from industry, links to NIHR and NHS Digital and supporting the reduction of health inequalities. Matt noted that this will influence how a disruptive or breakthrough deal pipeline would be built.
- 8.14. Sarah Woolnough said National Voices are supportive, but noted the need to keep communicating with patients and the public to maintain trust.
- 8.15. Catherine Pollard said it was an absolute pleasure working with the GRAIL team and for the AAC or Matt Whitty to provide guidance on how to support companies with less experience with the NHS for other similar projects.

**9. Trusted Research Environments (TRE) development update**

- 9.1. Catherine Pollard provided the Board with an update on the Trusted Research Environments (TRE) development. There is a commitment to using TREs that provide safe and secure data for analysis and research. Unlocking large scale data will ensure this is available for research, AI and will fundamentally protect the public. It will have a robust ethical and governance framework.
- 9.2. Lord Darzi thanked everyone involved in this project.
- 9.3. Hilary Reynolds expressed that AMRC welcomed this paper and offered their continued support to address researchers concerns around TREs. She also stressed the importance of involving and working with researcher including training, ensuring access and interoperability and avoid interruption or disruption.
- 9.4. Helen Stokes-Lampard agreed that this initiative would be welcomed by the academic clinical community.
- 9.5. Sarah Woolnough said National Voices were supportive of the work but reiterated the need to continue to openly communicate to public and patients to maintain trust.
- 9.6. Ben Osborne expressed the full support of ABPI for this work and offered further engagement to help amplify.

**10. AOB**

- 10.1. Ruth McKernan updated the group to let them know that her tenure as Chair of the BIA completes at the end 2021. She expressed her gratitude to be part of the AAC and such excellent work.
- 10.2. Hillary Reynolds also advised it was her final meeting here as CEO of AMRC and extended well wishes to the AAC.

**Next AAC Steering Group meeting is 28 February 2022 at 13:30 – 15:30**

**Next AAC Board meeting is 23 March 2022 at 09:00 – 11:00**