ACCELERATED ACCESS COLLABORATIVE





OUR YEAR IN FOCUS 2019/20 Getting the best new treatments to patients **faster than ever**

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EQUALITY AND HEALTH INEQUALITIES STATEMENT

Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement's values. Throughout the development of the policies and processes cited in this document, we have:

• given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it

• given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and to ensure that services are provided in an integrated way where this might reduce health inequalities.



FOREWORD

A future vision for the Accelerated Access Collaborative

The true power of the AAC is collaboration. I want to personally thank all of those from across the NHS, regulators, government, industry and patient representative groups, who have come together under the AAC to tackle barriers to adoption and spread. I would also like to thank Dr Sam Roberts for her excellent contribution as the first AAC Chief Executive and to Matt Whitty for picking up the baton over the past six months. Their tireless efforts mean the AAC now has strong foundations on which to build.

But we cannot rest. We are at an inflection point in global healthcare with new technologies and treatments offering untold potential to improve the lives of patients across the UK. We need to seize on this momentum to bolster the AAC, learn from successes to date, and tackle systemic barriers to embed innovation within the NHS.

The AAC has my full support and I am confident that it will deliver on its important and ambitious mission.

We already have exciting plans in place. The MedTech Funding Mandate will launch in April, to help drive the uptake of selected cost-saving devices, diagnostics and digital products, followed by the 'Innovation Service', to make it easier for innovators to design, develop and deploy their innovations within the NHS. And our plans don't stop there, with AAC partners also delivering a host of key initiatives. The MHRA is launching its new Innovative Licensing and Access Pathway in January, NICE is undertaking a thorough review of its methods and processes, NHS England and NHS Improvement are developing proposals to extend the successful cancer drugs fund to an innovative medicines fund and NIHR are continuing to support new and innovative clinical trial designs. Together, this will help ensure the UK keeps pace with the development of cutting-edge innovations.

However, we can and must go further. By harnessing the collective power of our innovators, alongside our world-leading regulators, our clinical trials specialists, and our unique NHS, we can make the UK one of the most pro-innovation healthcare systems in the world, where all patients can access the best new treatments and technologies helping them to live longer and happier lives.

That is the future of the AAC, that is what patients need and that is what we will deliver.



Bether

The Right Honourable Lord Bethell Parliamentary Under-Secretary of State for Innovation

ABOUT THE AAC

Our ambition is to help the NHS become stronger in supporting clinicians and patients to access new innovations at pace and scale. We are doing this by making the NHS a great place to innovate.

One year ago, the remit of the accelerated access collaborative (AAC) expanded and as a boosted AAC we became the umbrella organisation for UK health innovation. The new AAC acts as the front door for innovative support, and sets the strategy for the entire health innovation ecosystem.

We have provided over 700,000 patients with access to proven innovations. In turn, we have delivered estimated patient benefits of more than 12,000 fewer hospital admissions and 125,000 fewer days spent in hospital – and achieved significant cost savings for the NHS that exceed £50 million.

We have supported a wide variety of innovations and helped thousands of innovators, including our own NHS staff. Further proof of our impact lies in over £450 million of investment and the creation or safeguarding of more than 1,500 jobs.

These are some incredible achievements, benefiting thousands of patients and supporting clinicians across the country, and I would like to take this opportunity to thank the whole AAC team. In particular, my thanks go to Dr Sam Roberts, who recently stood down as chief executive, for her enthusiasm, drive and vision.

Although there is much work still to do, we are buoyed by our successes and have a growing appetite to realise the enormous potential for heightened impact. Together, our steadfast commitment will continue to ensure that the best new innovations reach patients faster than ever.

Lord Ara Darzi, Chair, Accelerated Access Collaborative

"Our goal is simple, speeding up access to the best technologies and products – leading to better care for patients."

Lord Ara Darzi



Lord Ara Darzi, Chair Accelerated Access Collaborative

WHO BENEFITS?

• PATIENTS

Patients increasingly have access to new technologies and treatments, **faster than ever.** Understanding the needs of patients and communicating them clearly to industry is critical in helping to develop solutions.

INDUSTRY INNOVATORS

The AAC is driving deeper collaboration between industry, government and the NHS, bringing them closer together to shape the best new health innovations through the regulatory system and get these to patients **faster than ever**. This is supporting strong industry–NHS partnerships, as evident, for example, through our COVID-19 response and Artificial Intelligence in Health and Care Award programme.

• CLINICIANS

Clinicians are benefiting from **faster than ever** access to new technologies and interventions that will help them deliver excellent patient care. Communicating the needs of clinicians to industry and innovators is helping to address the most pressing healthcare problems.

• INVESTORS

The AAC is helping to increase the confidence of investors, **faster than ever**, by becoming the guardian of a more joinedup oversight of UK health innovation. This approach includes an effective regulatory environment and more opportunities for flexible and mutually beneficial funding arrangements. This is supporting investors to make more informed decisions about which technologies will benefit NHS patients the most, and their investment in the treatments and diagnostics of the future.

ABOUT THE AAC

WHO WE WORK WITH



ABOUT THE AAC

OUR PROGRAMMES

In 2019/20, our first operational year, the AAC commissioned and supported a range of programmes to help each step in the AAC innovation pipeline to provide a structure for our work.

• Artificial Intelligence in Health and Care Award (AI Award):

run by the AAC, NHSX and National Institute for Health Research (NIHR), the AI Award is making £140 million available over three years to accelerate the testing and evaluation of the most promising AI technologies which meet the strategic aims set out in the NHS Long Term Plan.

- Academic Health Science Centres: eight new Academic Health Science Centres (AHSCs) were announced in April 2020 to support the translation of scientific advances into treatment for patients.
- Clinical Entrepreneur training programme:

a range of entrepreneurial support and development for clinical and non-clinical staff.

• AAC early stage innovations:

categories of new, potentially highly effective, products which need support through the regulatory and approvals process.

• Small Business Research Initiative for Healthcare:

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competitions that invite companies to address unmet health needs by applying for funding and support to develop and share innovations that meet these challenges.

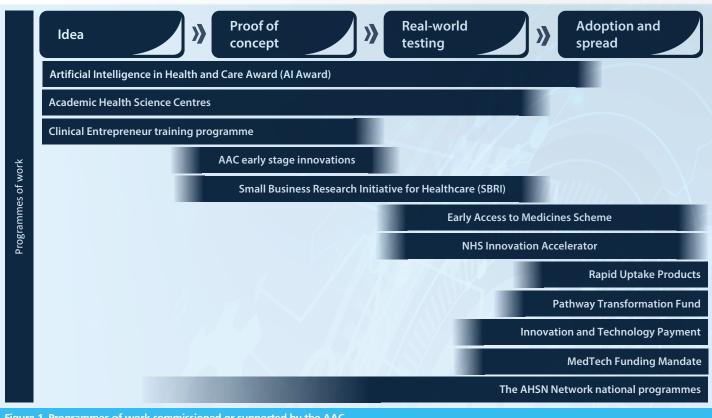


Figure 1. Programmes of work commissioned or supported by the AAC

- Early Access to Medicines Scheme: helps to give people with life-threatening or seriously debilitating conditions early access to new medicines.
- NHS Innovation Accelerator: supports innovators to accelerate the uptake of high-impact innovations for the benefit of patients, the population and NHS staff.
- Rapid Uptake Products programme: tailored support for selected innovations that have been given approval by the National Institute for Health and Care Excellence (NICE).
- Pathway Transformation Fund: funding to help NHS organisations integrate the rapid uptake of products into everyday practice.
- Innovation and Technology Payment programme:

removes some of the financial and procurement barriers associated with introducing new technologies.

- MedTech Funding Mandate: a ministerial and NHS Long Term Plan commitment to accelerate the uptake of selected NICE-approved, cost-saving health tech and diagnostic products into the NHS.
- Academic Health Science Networks: support the delivery of the AAC's national programmes locally and the adoption and spread of innovation across seven identified improvement areas as commissioned by NHS England and NHS Improvement for 2018–2020.

OUR YEAR IN FOCUS

In our first year, the AAC has seen some of the greatest challenges the NHS has faced in its 72-year history, yet we have delivered some incredible achievements, benefiting thousands of patients and supporting clinicians across the country. We have made this progress in the knowledge that there will always be more to do, and we are steadfast in our drive and commitment to get the best new treatments to patients faster than ever.

In 2019/20, our programmes have:

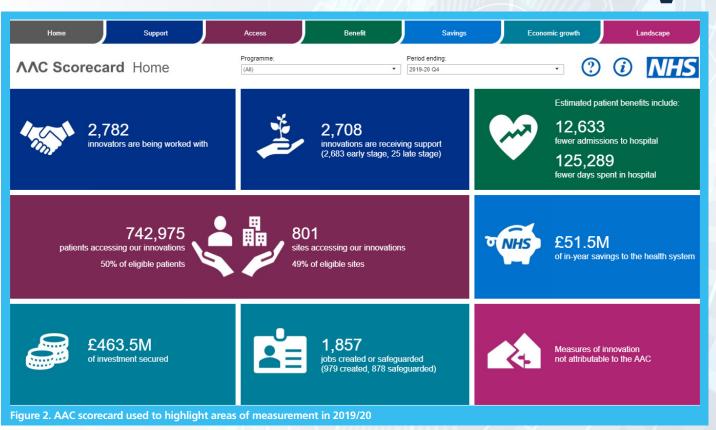
- provided more than **700,000 patients** with access to proven health and care innovations
- helped over 2,500 innovators, including
 477 health professionals as part of the Clinical Entrepreneur training programme
- supported over 2,500 innovations
- delivered patient benefits, that we estimate include 125,000 fewer days spent in hospital
- saved the NHS more than £50 million.

At the same time, we have made a significant contribution to wider economic growth in the UK, with our programmes attracting **over £450 million of investment** and **creating or safeguarding over 1,500 jobs.**

In 2019/20, we worked with the NIHR to jointly designate eight new AHSCs, which were announced in April 2020. These partnerships across academia and NHS organisations deliver an increase in the translation of early scientific research into benefits for patients, further accelerating innovation in the NHS.

This review shares our story and examples of how our work supports a wide range of different types of innovation, across medicines, diagnostics, devices, digital products, pathway changes and workforce models.

You will hear from innovators, patients and clinicians, as well as some of our team, and read about the continuing progress and our ambitious plans that continue to bring new and innovative medicines and treatments to patients faster than ever.



Matt Whitty

Chief Executive AAC



"NICE is a committed AAC partner. NICE's role at the intersection of technology development and patient access underpins our wide-ranging understanding of, and working connections with, AAC partner organisations and stakeholders. Our working insight into the challenges system partners are facing enables us to fully play our part in identifying and evaluating the solutions needed to support accelerated access. We are proud of the achievements made in the AAC to date and look forward to many more as our understanding and collaboration continues."

Professor Gillian Leng, Chief Executive, NICE

EVIDENCE-BASED PRINCIPLES UNDERPINNING INNOVATION AND ADOPTION

During 2019/20, the AAC also collaborated with the <u>Care Quality Commission (CQC)</u> to co-produce a paper which highlights six evidence-based principles that underpin innovation and adoption.

The principles are based on reviews of the innovation literature and engagement with over 60 health and social care organisations. The paper gives providers a starting point for how to innovate well and uses case studies to demonstrate that providers don't have to be the biggest or best resourced to innovate and have a real impact on people who use services.

The paper will be published imminently. We are also discussing ideas for joint working with the CQC and the National Quality Board.



COVID-19

We could not publish our achievements for this year without highlighting the impact of the COVID-19 pandemic on our programmes and how we and our partners have pivoted a lot of our work to respond to the needs of patients and the NHS. For this reason, we have extended the timeline of this annual review.

It has never been more important for us to bring together industry, government, regulators, patients and the NHS, to remove barriers and accelerate the introduction of ground-breaking new treatments and diagnostics that can transform care and patient outcomes. We are also working with our colleagues in NHS England and NHS Improvement's **Beneficial Changes Network**, led by the Improvement Directorate, which has gathered evidence on innovation and collaboration across the NHS in response to the pandemic. We are now bringing together the expertise of our AHSN partners and the NIHR Applied Research Collaboratives (ARCs) to systematically review and support the evaluation and implementation of the innovations with the greatest impact.

"Pharmaceutical companies and the NHS continue to work closely together to deliver non Covid-19 healthcare services, and the industry has set out recommendations to support NHS recovery. This means evaluating and embedding new approaches to diagnosis and care delivery, alongside accelerating implementation of the NHS long term plan and its goals."

Haseeb Ahmad, President, ABPI Global Head of Value and Access and Commercial Development and Country President UK of Novartis Pharmaceuticals

OUR YEAR IN FOCUS

EARLY STAGE SUPPORT

In June 2019, the AAC Board agreed an ambitious programme of work to support Advanced Therapy Medicinal Products (ATMPs) and Histology Independent Therapies (HITs) as part of the Early Stage support activities.

ATMPs and HITs were chosen as categories of product for support from the AAC as each individual product is likely to face systemic barriers to implementation in the NHS that could be addressed more effectively as a category. The barriers for ATMPs thematically fall under value assessment, regulation and service implementation. For HITs, the barriers include genomic testing capacity and service implementation. The work programme was designed to develop solutions to key system barriers to enable timely adoption of cost-effective therapies.

"In many ways the AAC's work programmes for early stage products might ultimately prove to be the most important for the pharmaceutical industry, and for patients, because they will allow the NHS to ensure all of the barriers are removed, so they can hit the ground running in adopting new types of innovation as soon as those products become available."

Paul Catchpole, Value and Access Policy Director, ABPI The response to COVID-19 has had an impact on activity this year. There have been delays to a number of workstreams but progress has been made in others.

For workstream 3, the Association of the British Pharmaceutical Industry (ABPI) has continued to drive progress in work to develop an explanatory roadmap, so companies know who, when and how to engage with the system and therefore can more confidently navigate the route to NHS adoption of ATMPs. For workstream 8, the NICE Methods Review is now out to consultation, and for workstream 11, there has been significant development of genomics infrastructure, with the first two HITs to become available to patients via the Cancer Drugs Fund.

Following the impact of the response to COVID-19, activity across all workstreams recommenced in autumn 2020 and is a priority for the AAC.

The work programme consists of 12 workstreams (see Table 1), which are being co-ordinated by the AAC and led by partners across the system, including NICE, ABPI, the Medicines and Healthcare products Regulatory Agency (MHRA), and the Cell and Gene Therapy Catapult.

	WORKSTREAM	AIM OF THE WORKSTREAM
1	Patient and public involvement (ATMPs and HITs)	Systematic and successful meaningful involvement of people with lived experience in the project and information for patients.
2	Horizon scanning (ATMPs and HITs)	The information supplied from enhanced horizon scanning enables the system to prepare adequately for the early stage product categories.
3	System roles and responsibilities (ATMPs)	Companies can more easily and confidently navigate the route to NHS adoption of ATMPs.
4	Standardisation of system requirements (ATMPs and HITs)	The supply chain, logistics and delivery for ATMPs are more scalable and Trusts can more easily adopt new ATMPs.
5	Data infrastructure (ATMPs and HITs)	The NHS can collect robust long-term use data for ATMPs where needed, using viable robust mechanisms for real-world data collection to help reduce clinical uncertainty and increase patient access to clinically and cost-effective treatments.
6	NICE Methods Review (ATMPs and HITs)	Ensure that ATMPs and HITs are value assessed comprehensively and appropriately as part of the NICE Methods Review.
7	Exploration of reimbursement approaches (ATMPs)	Ensure ATMPs that are recommended by NICE have an appropriate payment mechanism in place, where needed, to support their commissioning.
8	NHS pathway preparedness (ATMPs)	Aim to ensure that the NHS is ready for the implementation of new products in line with publication of NICE guidance, and products are adopted as part of business as usual for the NHS specialised commissioning.
9	Marketing authorisation (ATMPs and HITs)	Increased evidence generation and support for companies across the whole of the medicines regulatory pathway.
10	NHS communications (ATMPs and HITs)	Co-ordinated and impactful communications about the workstreams produced and disseminated.
11	Histology independent (HI) pathway preparedness (HITs)	Genomic Laboratory Hubs are performing HI diagnostic genomic testing with no inequity in patient access in broad line with product availability.
12	Updating cancer guidance and pathways (HITs)	Process in place for timely update of relevant cancer guidelines and pathways after positive NICE appraisal of HI products.

 Table 1. The 12 workstreams co-ordinated by the AAC as part of a work programme to support

 ATMPs and HITs as part of the early stage support activities

EARLY ACCESS TO MEDICINES SCHEME

Another way we support pre-NICE approved products is the well-established Early Access to Medicines Schemes (EAMS). EAMS helps to give people with life-threatening or seriously debilitating conditions early access to new medicines that do not yet have a marketing authorisation but where there is a clear unmet medical need.

By promoting early engagement between companies and key AAC partners, including MHRA, NICE and NHS England and NHS Improvement, EAMS helps to create a smoother route to market for new treatments. AAC partners including ABPI, MHRA, NICE, Scottish Medicines Consortium (SMC) and NHS Specialised Commissioning.

The main aims are themed around increasing knowledge of EAMS across healthcare practitioners and the public, reducing the administrative burden for Trusts, and extending the duration of the scheme, so new patients can access EAMS treatments in the gap that currently exists between market authorisation and health technology assessment. "To keep pace and maintain our position as a leader in the global market, particularly as the UK leaves the EU in January 2021, there has been real value working with AAC partners to evolve the scheme, so that patients in need continue to access innovative treatments."

Malcolm Qualie, Pharmacy Lead, Specialised Commissioning, NHS England and NHS Improvement

"The collaborative approach of the AAC and partners is allowing us to work together on improvements to EAMS procedures, making it easier for NHS Trusts and patients to access innovative treatments."

Daniel O'Connor, Expert Medical Assessor at MHRA

EAMS is a key part of our commitment to accelerate patient access to innovative, life-changing treatments, and supports the UK's position as a global leader in life sciences.

Since its 2014 launch, over 1,400 people with a broad range of conditions have benefited from early access to new treatments through EAMS.

During 2019, the Office for Life Sciences jointly co-ordinated and developed a series of recommendations, supported by



OUR PRIORITIES

To deliver our ambition, we identified six priorities which we are committed to delivering together with our partners, patients and the public.



>> INNOVATION SERVICE

Creating a 'front door' to the innovation ecosystem, with information, support and signposting to partners all available in one place.



>> WORLD-LEADING TESTING INFRASTRUCTURE

Creating an infrastructure that has vital opportunities for innovators to develop and improve their products and establishing high-quality evidence for adoption and spread.



>> DEMAND SIGNALLING

Helping innovators to understand the kinds of innovation the NHS really needs in order to meet its challenges.



>> ADOPTION & SPREAD

Helping the NHS become stronger in its adoption of innovations and in its support for the spread of the best new solutions, getting them into the hands of clinicians and patients much more quickly.



>> HORIZON SCANNING

Making it easier for NHS teams to have clear sight of the best new innovations, so that health systems are prepared and ready to support them.



>>> FUNDING STRATEGY

Creating more practical funding for innovation support, which aligns with the government's health innovation funding and the work of charities, research organisations and investors.



Innovation Service

CREATING A 'FRONT DOOR' TO THE INNOVATION ECOSYSTEM, WITH INFORMATION, SUPPORT AND SIGNPOSTING TO PARTNERS ALL AVAILABLE IN ONE PLACE.

The UK-wide Innovation Service will be the go-to place for innovators to navigate the path to market and receive co-ordinated support from organisational partners in accelerating innovations that meet the needs of patients and the NHS.

The Innovation Service is a single 'front door' for innovator support and addresses the following problems identified in the <u>Accelerated Access</u> <u>Review (2016)</u>:

- Innovators do not know what they need to know
- Innovators spend too much time 'knocking on doors'
- Support organisations currently work in silos.

In summer 2019, an innovator workshop explored whether a digital solution could address these known challenges and corresponding opportunities. Since then, over 40 interviews with innovators have been undertaken to test prototypes of the Innovation Service, along with more than 20 interviews, workshops and activities with organisations such as NICE, NIHR, AHSNs and NHS Supply Chain, who we will now refer to as 'accessors'. Extensive engagement with more than 100 stakeholders has catalysed important conversations, such as the role of MHRA and NHS Supply Chain in innovation, and also expanded the Innovation Service to the devolved nations.

The Innovation Service is being built collaboratively, working across the innovation landscape to meet the needs of all AAC stakeholders and beyond, so it will have credibility and momentum in the wider ecosystem.



The current prototype has already demonstrated added value to innovators by showing them new and useful information. The current focus is on designing how the interfaces between innovators and accessors, the collaborative processes among accessors, and the end-to-end journey, will work.

Throughout 2020, we have worked to create and test prototypes that use existing infrastructure to deliver immediate value while paving the way for future expansion.

To ensure the 'single front door' will be open to everyone and actively promotes equality, diversity and inclusion, we have so far engaged over 40 innovators with diverse professional and demographic backgrounds and abilities, including NHS staff and innovators with lived experience. We are also working closely with people from more than 20 accessors to co-design improved collaborative processes.

"The Innovation Service is another valuable step forward to support the life sciences sector and BIVDA looks forward to this pulling together all the elements needed for innovations to be widely adopted at pace within the NHS."

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Doris-Ann Williams, Chief Executive, British In Vitro Diagnostics Association (BIVDA)

Our latest prototype features:

- information on priority areas regulations, funding, demand signalling
- a facility for innovators to create and update a shared innovation record – like an electronic patient record – that is visible to organisations providing support, so they understand what stage of development the innovation is at and can see what progress is being made
- dashboards for innovators and accessors to manage interactions/workflow in one place
- collaborative processes for organisations that support/assess innovations to give joined-up advice.

The Innovation Service will link to other critical AAC infrastructure, such as the NIHR Innovation Observatory (NIHR IO) horizon-scanning tool, as well as assets of our partners, such as the AHSN Network Pipeline and Portfolio Management approach pioneered by Health Innovation Manchester. To join up support for innovators even further, we have initiated discussions to bring in devolved nations, local support organisations and MHRA, as well as programmes under development, including the NHSX Digital Technology Assessment Criteria (DTAC) and the Multi-Agency Advice Service for artificial intelligence (AI) regulations.

HOW WE ARE JOINING UP THE SYSTEM FOR INNOVATORS

The goal of the Innovation Service is to provide innovators with joined-up advice and support, and one of the most urgent areas of need is for digital technologies. Following feedback from innovators, over the summer NHSX has revised the existing Digital Assessment Questionnaire to create a set of minimum standards that form the new DTAC.

NHSX proposed that the DTAC should form part of the Innovation Service journey for digital innovators, because this would:

- help digital innovations to be 'compliant by design' as innovators fulfil criteria as they progress their innovation record
- provide streamlined support for innovators all in one place, including 'hybrid' innovations (that is, ones that combine digital with another technology)
- steer digital innovators to undertake DTAC while getting support, with the 'carrot' of access to digital procurement frameworks at the end of their journey.

This is one example of many that show how the AAC is ensuring a genuinely joined-up experience for innovators by integrating critical policies and programmes. Our user research supports this approach, as innovators articulate themselves: "If only there was a single door where industry could knock and say, 'This is what we have'."

Content on the DTAC will be among the first elements to go live on the Innovation Service, along with mapping of the wider 'innovation journey'.

>> FUTURE PLANS FOR THE INNOVATION SERVICE

We continue to engage with stakeholders, including the devolved nations, to ensure that we meet the needs of the wider ecosystem, as well as pursuing alignment with relevant programmes, such as the AI Multi-Agency Advice Service.

In the long term, the Innovation Service will be a platform for communicating NHS needs (demand signalling), as well as providing a source of data for horizon scanning and facilitating delivery of the AAC's targeted support programmes. An operational version of the Innovation Service is scheduled to go live in summer 2021.



HEI PING INNOVATORS UNDERSTAND THE KINDS OF INNOVATION THE NHS REALLY **NEEDS IN ORDER TO MEET ITS CHALLENGES.**

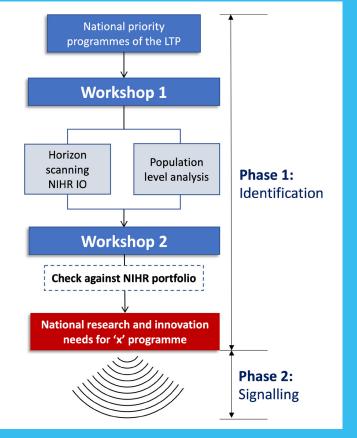


Figure 3. Demand signalling process, identification and signalling phases

The NHS needs to clearly articulate where innovation and research are most needed to meet the challenges outlined in the NHS Long Term Plan (LTP; 2019). The AAC is addressing this by introducing a programme of work that will enable us to give clear signals to innovators and research funders on where efforts should be focused.

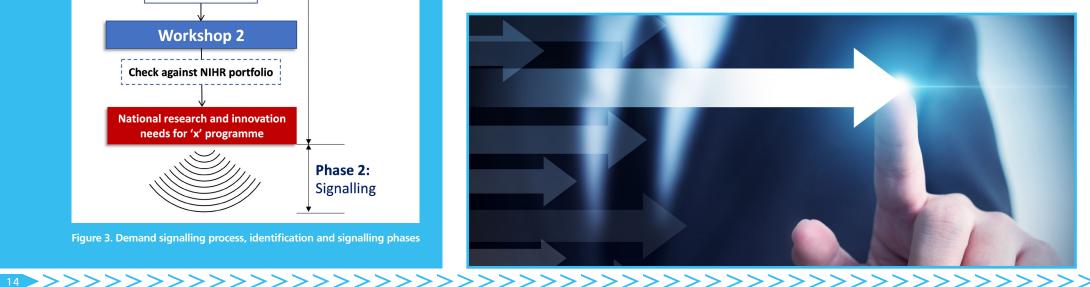
During the summer of 2019, we designed a programme using an evidence-based approach* for building consensus. This included engagement with stakeholders via two workshops to identify priority areas for research and innovation for LTP programmes.

*A Delphi methodology was used. See: https://www.healthknowledge.org.uk/public-health-textbook/researchmethods/1c-health-care-evaluation-health-care-assessment/use-delphi-methods.

We initially focused on three key areas: stroke, mental health, and learning disability and autism. In 2019, the relevant National Clinical Director for each area hosted an initial workshop involving around 40 delegates from across the health and care system for their programme. Delegates included policy leads, clinical leads, allied health professionals, analysts, leading academics, representatives from royal colleges and charities, people with lived experience and carers. These workshops identified and prioritised five to six broad areas where research or innovation is needed.

Reviews of the current innovation and research pipelines and further analysis took place in March

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>> Demand Signalling

2020 to identify any relevant research or innovations relating to the broad areas identified for each workstream that are already in the pipeline. This was intended to ensure that the second workshops focused on areas where there is currently little or no research under way or innovation in the pipeline.

A second series of workshops was planned for spring 2020, but this was paused due to the COVID-19 pandemic. The timing of restarting the programme is currently being agreed with National Clinical Directors and policy leads.

The new workshops will be run virtually, with the aim of developing robust, tangible innovation needs and research questions in each area, and prioritising them. The outputs will be shared with innovators through the Innovation Service and they will be 'signalled' to research funders and researchers through relevant forums and networks.

Once this work is complete, we will review the programme and make any necessary revisions to improve relevant processes and agree which LTP priority areas are to be included in the second round of the demand signalling programme.

"We have valued our collaboration on the patient engagement strategy across all the AAC workstreams. As part of the demand signalling workstream, we were able to highlight our members' work on unmet need, the results of which will feed into future innovation and research – ensuring that it helps patients the most. COVID-19 has highlighted the importance of helping patients to self-care and directing future research and development to supporting patients and their families."

Hilary Newiss Chair, National Voices

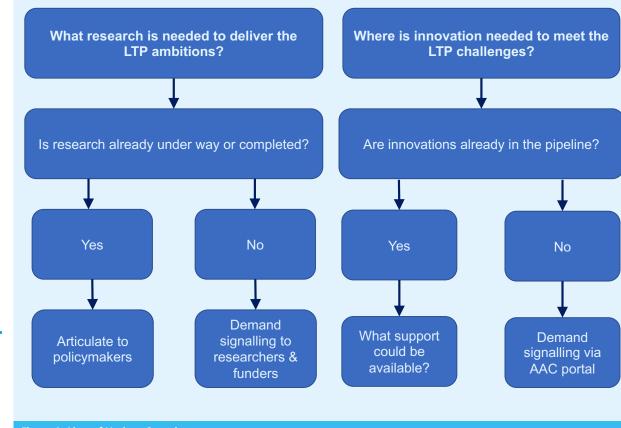


Figure 4. Aims of Horizon Scanning

Horizon Scanning

MAKING IT EASIER FOR NHS TEAMS TO HAVE CLEAR SIGHT OF THE BEST NEW **INNOVATIONS, SO THAT HEALTH** SYSTEMS ARE PREPARED AND READY TO SUPPORT THEM.

Horizon scanning supports and enables much of the AAC's work and is a vital tool in understanding the future healthcare environment, both for medicines and medical technologies.

We have brought together our partners to develop a robust core horizon-scanning function, supported by a Horizon Scanning Steering Group (HSSG), whose membership includes NHS England and NHS Improvement, NICE, MHRA, Public Health England (PHE), the Office for Life Sciences (OLS), the Government Office for Science (GO-Science), UK Research and Innovation (UKRI), ABPI, the Association of British HealthTech Industries (ABHI), the AHSN Network and the NIHR IO.

"Choosing the right game-changing innovations which deliver the maximum health gain to the UK population, whilst supporting the NHS to deliver more efficient and more effective care is absolutely critical in ensuring AAC resources are put to the best possible use. An integrated, transparent and inclusive horizonscanning system is pivotal to enabling this."

Paul Catchpole, Value and Access Policy Director, ABPI

"During the first wave of the pandemic, the support of the AAC for the RAPID C-19 work has been important to ensure that clinical results for potential treatments could be translated into practice quickly. The collaborative approach between regulators, the AAC and the NHS created a welcome synergy between oversight and implementation capability. It's an approach we should seek to replicate for the introduction of all evidence-based innovation across the NHS."

Colette Goldrick, Executive Director, Strategy and Partnerships, ABPI



In 2019/20, our work has been fundamental to:

- the foundation of a £250 million AI lab with an AI scan – the results underpinned the focus of the Artificial Intelligence in Health and Care Award programme
- the £10 million Cancer Innovation Fund a scan of new cancer diagnostics in the pipeline informed the decision-making around the use of the Cancer Innovation Fund
- the independent review on cancer screening - scanning was undertaken to review cancer screening
- the AAC's early stage product programme for HI cancer treatments and ATMPs.

Horizon scanning of new and emerging COVID-19 therapies has delivered three medicines into the COVID-19 treatment pathway and is actively monitoring another 22 priority medicines for early signs of promise.

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>>> Horizon Scanning

RESEARCH TO ACCESS PATHWAY FOR INVESTIGATIONAL DRUGS IN COVID-19 (RAPID-C19)

The COVID-19 pandemic created a critical need for co-ordination of stakeholder efforts and cross-system intelligence, which enabled the AAC to demonstrate its ability to rapidly step up to the challenge and mark out its role in facilitating stakeholder collaborations, underpinned by horizonscanning intelligence.

To support the COVID-19 response, AAC member organisations quickly came together to redeploy their horizon-scanning function resources and expertise, including the NIHR IO scanning and the AAC secretariat function (analytical and programme management) at NICE. From here, a multi-agency approach was quickly and collectively established, working across NICE, NHS England and NHS Improvement, the MHRA and the NIHR to create the Research to Access Pathway for Investigational Drugs in COVID-19 (RAPID-C19) initiative.

This created a powerful collaboration, enabling safe and timely patient access to medicines that showed evidence of benefit in treating symptomatic COVID-19 patients or for disease prevention. It is now also supported by the Therapeutics Taskforce at the Department of Health and Social Care (DHSC) and the health technology agencies in the devolved nations. The RAPID-C19 process supported rapid access to the NHS for three COVID-19 treatments that, because of this process, were available on the NHS within hours of the study (including the RECOVERY trial):

- remdesivir for patients hospitalised with COVID-19
- dexamethasone for patients with severe or critical COVID-19
- hydrocortisone for patients with severe or critical COVID-19.

To enable fast access to those treatments that have a positive readout, the RAPID-C19 process provides:

- clear, succinct topic briefing documents shared across all system partners and the Therapeutics Taskforce
- action plans to co-ordinate the activities required in the market access pathway with relevant organisations
- structured confidential interactions with companies to progress topics through to the next stage
- evidence summaries to support NHS England to draft commissioning policies prepared by NICE
- commissioning policies developed by NHS England
- Central Alerting System (CAS) alerts to provide healthcare professionals with urgent and important safety guidance

 published online and prepared and supported by NHS England and NHS Improvement and MHRA
- a prescribing brief which is issued alongside the CAS alert to help front-line staff to understand that the evidence/ direction in the CAS alert is produced by NICE.

Collectively, this provides national decision-makers with the intelligence required to facilitate timely regulation and market access of effective treatments, and supports ongoing exploration and scheduling of therapeutics for consideration in this space. RAPID-C19 provides a living example of the key overarching aim of the AAC in showing that the accelerated innovation pathway can be considerably shortened when system partners rapidly and actively collaborate and adapt or reimagine traditional methods of access.



>>FUTURE PLANS FOR HORIZON SCANNING

During the pandemic, other horizon-scanning activity has been paused. Over the coming months, while continuing our support for the COVID-19 response, we will restart this activity.

Building on our first year, we are now learning lessons to help us to develop standard methodology, operational procedures and taxonomy for our future scans. We are also working with the NIHR to develop a central horizonscanning platform that will be shared across the AAC partners to help the NHS to speed up patient access to the newest and best technologies and products – leading to better care and healthier populations.



>> World-Leading Testing Infrastructure

CREATING AN INFRASTRUCTURE THAT HAS VITAL OPPORTUNITIES FOR INNOVATORS TO **DEVELOP AND IMPROVE THEIR PRODUCTS, AND ESTABLISHING HIGH-QUALITY EVIDENCE FOR ADOPTION AND SPREAD.**

Building a healthy pipeline of innovations that meet the needs of the NHS is vital work for the AAC.

In 2019/20, we worked with over 550 innovators through our established testing programmes: Clinical Entrepreneurs, the Small Business Research Initiative (SBRI) and NHS Innovation Accelerator (NIA). Together, these innovators have developed or tested over 500 innovations, secured over **£200 million** of investment (public and private) and created or safeguarded over 900 jobs. We continue to build our testing infrastructure and this year have added the Artificial Intelligence in Health and Care Award to our portfolio as an early stage programme.

ARTIFICIAL INTELLIGENCE IN HEALTH AND CARE AWARD

The Artificial Intelligence in Health and Care Award (AI Award) accelerates the testing and evaluation of the most promising AI technologies which meet the strategic aims set out in the NHS Long Term Plan (2019).

Launched in early 2020 and run by the AAC in partnership with NHSX and the NIHR, the AI Award makes £140 million available over three years.

The importance of the AI Award, in the context of COVID-19, has never been more stark, as we seek to fasttrack pioneering AI to deliver technologies that have the biggest impact, reduce pressure on the NHS and make a difference in the broader coronavirus response. More than 500 applications were received in the first round from AI developers in the UK and overseas, and a total

of 42 awards were made across the four phases, with £54 million awarded in total. Products selected for Phase 4 have been operationally tested in clinical settings, and the AI Award allows for robust evaluation across multiple sites to help build the evidence for national rollout, including supporting the development of relevant guidance from NICE and Public Health England.

continues >>

"The AI Award is an important and welcomed function to support the implementation of the chosen technologies into routine pathways and a clear signal that the UK aims to consolidate its position as a global leader in Health AI."

Peter Ellingworth, Chief Executive, ABHI



>> World-Leading Testing Infrastructure

		For Phase 2 onwards, bids will be assessed by a single decision-making panel			
Feasibility	Development & clinical evaluation	Real-world testing	Initial health system adoption	National scale-up	
Phase I AI Award NIHR	Phase 2 Al Award NIHR	Phase 3 AI Award NHSX/AAC	Phase 4 AI Award NHSX/AAC	Phase 5 Not fundable	
To show product and clinical feasibility of the proposed concept, product or service	To develop prototypes and generate early clinical safety/efficacy data towards CE/UKCA marking	First real-world testing in health and social care settings to develop evidence of efficacy and preliminary proof of effectiveness, including evidence for routes to implementation to enable more rapid adoption	To facilitate initial systems adoption of the AI technologies with market authorisation into the NHS, evaluating the AI technology within clinical or operational pathways to determine efficacy or accuracy, and clinical and economic impact	To address barriers to adoption into routine care for NICE-approved products with proven health system benefits, in order to facilitate rapid uptake nationally	
6–12 months Up to £150k	12–36 months Funding uncapped but typically range £500k–£1.5m	12–36 months Funding uncapped but typically range £500k–£1.5m	12-36 months Funding uncapped but typically range £1m–£7m	Not eligible for research and development funding under this programme	

Figure 5. Phases in the Artificial Intelligence in Health and Care Award

The AI Award supports a pipeline of products, from early stage interventions and services ready for wider testing through to helping already established products achieve large-scale commissioning and deployment. The AAC particularly focuses on providing bespoke support to those innovations seeking to build the evidence base to support national roll-out within two to three years.

Of the 42 winners announced, the AAC is providing bespoke support to 10 Phase 4 winners who broadly address either screening, diagnosis, decision support or improving system efficiency.

ACCELERATED ACCESS

COLLABORATIVE

In total, 63 identified sites will act as research collaborators for the innovations.

The 10 technologies chosen are:

- <u>Aidence</u>: The Veye Chest platform improves the treatment of lung cancer by enabling faster, more accurate decision-making.
- Brainomix Ltd: The e-Stroke suite is a set of tools that improves stroke care, by providing quick, easy access to test results.

- <u>Deloitte</u>: Referral and Intelligent Triage Analytics (RITA) automates the triage of GP referrals, helping patients get the right treatment faster.
- <u>Healthy.io (UK) Ltd</u>: Smartphone albuminuria self-testing uses a home test kit and app to turn a smartphone camera into a medical device, enabling home testing, increasing uptake and reducing workload in primary care.
- <u>ICNH Ltd</u>: DrDoctor uses data to predict those less likely to attend appointments and customises communication using these demographics accordingly.
- <u>iRhythm Technologies Ltd</u>: Zio Service monitors and detects problems with the heart rhythm as patients go about their daily lives.
- <u>Kheiron Medical Technologies</u>: Mia Mammography Intelligent Assessment is deep learning software that improves breast screening services.
- Mirada Medical Ltd: DLCExpert automates the timeconsuming and skill-intensive task of outlining (or contouring) healthy organs on medical images for radiotherapy planning and avoiding irradiation during treatment.
- <u>Optos plc</u>: OptosAl provides a rapid retinal imaging service which allows patients with potentially sightthreatening disease to be referred more quickly.
- <u>Ultromics Ltd</u>: The EchoGo Pro app empowers physicians to make fast, accurate decisions when diagnosing cardiovascular disease.

continues >>

NHS INNOVATION ACCELERATOR

Set up in 2015, the NHS Innovation Accelerator (NIA) is an NHS England and NHS Improvement initiative delivered in partnership with England's 15 Academic Health Service Networks (AHSNs), hosted at UCLPartners. It supports faster uptake of highimpact, evidence-based innovations that improve NHS services and patient care.

In 2019/20, the NIA supported 32 innovators (called Fellows) representing 34 innovations that were implemented across 510 new NHS sites. An independent economic evaluation of NIA innovations is currently projecting annual cost savings upwards of £60 million to the health and social care system. A final report is expected before the end of 2020.

A priority of the NIA is to capture real-world insight into the spread of innovation in the NHS to help national bodies understand the opportunities and challenges facing innovators. These learnings are shared through a quarterly INSIGHTS newsletter, learning events and annual research. The latest <u>INSIGHTS newsletter</u> was published in March 2020, in partnership with the Nuffield Trust.

The 2021 call for applicants closed in October 2020, having received 136 applications. This year, the NIA focused on increasing the diversity and breadth of applications. The call was promoted among a broader reach of networks and the language and imagery used was amended in order to appeal to a more diverse audience. Additionally, the NIA has

The AHSN Network England

worked with Innovate UK's Knowledge Transfer Network to provide independent advice and support to applicants less accustomed to completing application forms of this nature.

CLINICAL ENTREPRENEUR PROGRAMME

Focused on developing the commercial skills, knowledge and experience of healthcare staff, to nurture a culture of developing and seeking out the very best and most effective new products and technologies in the NHS, the Clinical Entrepreneur programme is helping to make the NHS a great place to innovate.

The NHS Clinical Entrepreneur programme offers a range of support to both clinical and non-clinical healthcare professionals, including direct education, mentoring, networking, and access to exclusive opportunities, expertise and resources. The NHS Clinical Entrepreneur programme was established to allow participants the opportunity to create solutions to the challenges they have faced, without having to leave the NHS. This helps the NHS to retain its best entrepreneurs to help deliver world-class care for generations to come.

Over 150 health and care professionals were appointed to the Clinical Entrepreneur programme in 2019/20, joining over 350 existing entrepreneurs who have already been supported by the programme.

Entrepreneurs supporting our workforce

Most clinical entrepreneurs recruited since 2016 have remained in their clinical and NHS roles and have been deployed to support the COVID-19 response. In addition to their day jobs, many took the skills, experience and innovations they had developed on the Clinical Entrepreneur programme to go the extra mile to support their colleagues and patients during the COVID-19 pandemic.

CASE STUDY

The Doctor's Kitchen

Rupy Aujla is an NHS GP working in emergency medicine and completing a master's degree in nutritional medicine.

He is the founder of <u>The Doctor's Kitchen</u>, which currently has 250,000 users across various social media platforms and strives to inspire and educate everybody about the beauty of food and the medicinal effects of eating well. Rupy creates healthy recipes using carefully selected ingredients, explaining the clinical research behind them across his media platforms. He is a *Sunday Times* bestselling author of *The Doctor's Kitchen* and *Eat to Beat Illness*. He is also the founding director of <u>Culinary Medicine</u>, a non-profit organisation which aims to teach doctors and medical students the foundations of nutrition.



Rupy commented:

"The Clinical Entrepreneur programme has been an excellent source of information and guidance. The mentorship, meet-ups with other like-minded people in healthcare and the support have been amazing. I'd highly recommend it to anyone interested in bringing their solution to life."

continues >>

CASE STUDY

🔪 Apian

Clinical entrepreneurs Chris Law and Hammad Jeilani founded Apian while training as student doctors. Hear their story and more about their work here.



"Apian is leading the way in drone logistics, with plans for a National Air Grid, connecting the NHS through 'Droneways' in the sky for the delivery of vital NHS supplies.

In addition to securing over £1.5 million of UKRI/UKSA-ESA* funding for trial flights between NHS hospitals in Essex, the programme has helped founders, Chris Law and Hammad Jeilani, turn their vision into reality.

Recent media coverage has attracted over 109 million views worldwide, with multiple international expressions of interest in partnering with the NHS as this technology develops."

Professor Tony Young, NHS National Clinical Lead for Innovation

*UK Research and Innovation/UK Space Agency-European Space Agency

continues >>

>> World-Leading Testing Infrastructure



Founders of Inovus Medical - Dr Elliot Street and Jordan Van Flute

SMALL BUSINESS RESEARCH INITIATIVE FOR HEALTHCARE

The Small Business Research Initiative for Healthcare (SBRI) is part of the government's wider SBRI programme but is directly funded by NHS England and NHS Improvement, delivered by LGC Group, and supported by the AHSN Network.

It takes its place in the AAC portfolio as a cutting-edge programme supporting the early development of innovations which meet known NHS challenges.

This demand-led approach enables industry to respond directly to healthcare challenges and feeds the innovation pipeline with products that have an existing demand from the NHS, allowing faster adoption and spread of these products, benefiting patients more quickly.

The programme helps the NHS to access new innovations through research and development that solve identified healthcare challenges and unmet need, as well as supporting the UK economy by enabling companies to attract investment and deliver technologies that are ready for global markets. The diversity of solutions introduced to date has been vast, including a 3D-printed bionic limb, a chemical detection technology to be used to diagnose lung cancer, an augmented reality portable laparoscopic simulator that provides easily accessible, minimally invasive surgery simulation, and a digital chronic obstructive pulmonary disease self-management programme.



In 2019/20, SBRI Healthcare supported 57 innovators, and this support included awarding 10 projects a share of £1 million Phase 1* funding to develop solutions across two challenges – one for cardiovascular disease, and the other for integrated and social care. Five further projects were also awarded a total of £4.2 million Phase 2** funding through two further competitions – the first in dentistry, oral health and oral cancers, and the second in improving outcomes in musculoskeletal disorders.

Hundreds of proposals can be received from across the innovation landscape for each competition, and the programme follows a robust selection process to select the most promising solutions. The SBRI Healthcare team draws upon its extensive network of clinical, commercial and technical experts to assess each proposal across a range of criteria, including potential impact on patients, value for money for the NHS, commercial sustainability of the product, and the feasibility of each project.

continues >>

 ^{*} Phase 1 SBRI funding focuses on exploring the feasibility of proposals.
 ** Phase 2 SBRI funding concentrates on continued research, development and testing.



HELPING THE NHS BECOME STRONGER IN ITS ADOPTION OF INNOVATIONS AND IN ITS SUPPORT FOR THE SPREAD OF THE **BEST NEW SOLUTIONS, GETTING THEM** INTO THE HANDS OF CLINICIANS AND PATIENTS MUCH MORE QUICKLY.

Strengthening the way the NHS supports clinicians and patients to access and use the best new treatments and diagnostics, at pace and scale, is vital in making the NHS a genuinely great place to innovate.

The AAC funds a number of programmes that drive the adoption and spread of proven innovations. In 2019/20. more than 700.000 patients had access to proven innovations through AAC programmes, ranging from preventing cerebral palsy in preterm babies (PReCePT) by giving mothers in preterm labour a £1 magnesium sulphate injection, to a gel called SpaceOAR[™] that reduces the risk of rectal injury during prostate radiation therapy.



ACADEMIC HEALTH SCIENCE NETWORKS

England's 15 Academic Health Science Networks (AHSNs) are key AAC partners, operating as the 'innovation arm' of the NHS and enabling people to live longer, healthier lives by helping to get the best innovations to patients and clinicians faster than ever. They work locally and as a nationally connected network (the AHSN Network) acting as a bridge across all parts of the health system with a role in innovation and transformation.

AHSNs play a critical role in connecting commercial and clinical innovators to health and care organisations, providing advice and support at every stage of the innovation pathway, and matching proven technologies to NHS challenges.

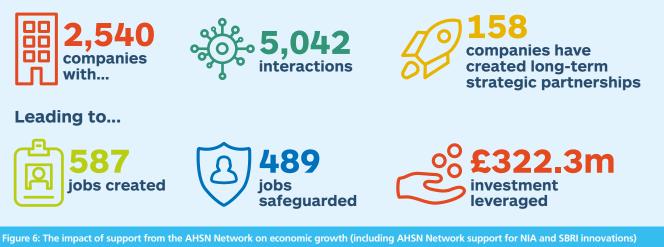
The AHSNs:

- support thousands of innovations and technologies that improve people's lives and patient outcomes
- extend a series of national innovation programmes agreed with NHS England and **NHS** Improvement
- lead the adoption of high-value technologies and medicines identified by the AAC
- co-ordinate or support a series of NHS initiatives, including the NIA and SBRI.

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The AHSN Network

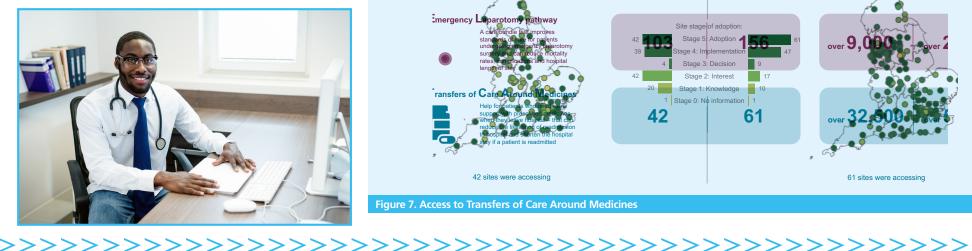
During 2019/20, the AHSN Network has provided support to...



>>> Adoption & Spread

Highlights from AHSN national innovation programmes in 2019/20 include:

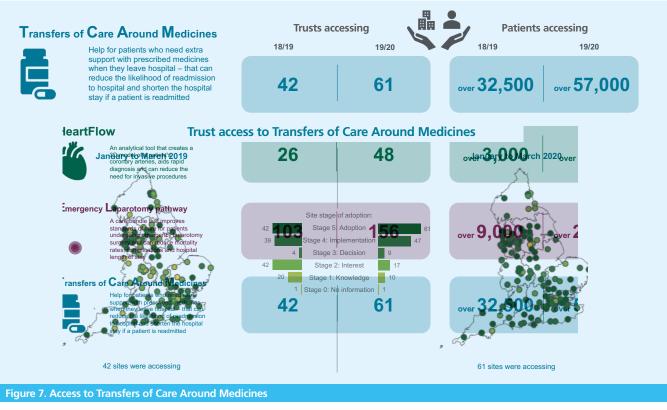
- Almost 2,000 GP practices have adopted a pharmacist-led digital tool (PINCER) which helps patients get the maximum benefit from their medicine while reducing the risk associated with certain types of medicines and clinically important errors in general practice prescribing. PINCER is estimated to have avoided over 24,000 medication prescribing errors.
- More than 57,000 referrals for medication advice were made by local community pharmacists under the Transfers of Care Around Medicines (TCAM) programme. Such referrals can reduce the likelihood of readmission to hospital and shorten the hospital stay if a patient is readmitted.
- Over 73,000 more patients were diagnosed with atrial fibrillation, which is estimated to have helped to prevent more than 2,000 strokes.



"The abilities of AHSNs to collaborate as a national network whilst understanding the needs of their local systems, means the AAC is able to drive rapid adoption of innovation in ways not achieved before. One example is the outstanding impacts of the AHSNs' Atrial Fibrillation programme, with an extra 290,000 patients now receiving anticoagulation medication to prevent stroke since 2015, saving 2,900 lives"

Professor Gary Ford,

AHSN Network Vice-Chair and Chief Executive, Oxford AHSN



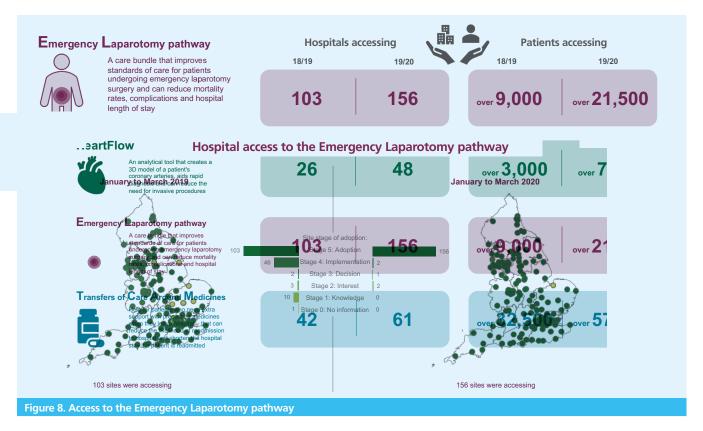
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ACCELERATED ACCESS COLLABORATIVE

>> Adoption & Spread

- More than 8,000 people with chronic joint pain participated in musculoskeletal courses, which can improve mobility and reduce pain (ESCAPE-pain).
- More than 21,500 patients underwent emergency laparotomy surgery in hospitals implementing the Emergency Laparotomy pathway, which can reduce hospital length of stay and mortality rates.
- Almost 3,000 mothers in preterm labour received a £1 magnesium sulphate injection (84 per cent of those eligible), which is estimated to have prevented 81 babies being born with cerebral palsy. (PReCePT)





"The AAC fulfils a unique role in the health ecosystem, drawing together partners across the life sciences sector to stimulate growth for UK PLC. As a key partner the AHSN Network is excited by the opportunity to do even more over the challenging year ahead, helping the AAC explore the global economic potential to position our life sciences sector on the world stage."

Dr Nicola Hutchinson, Chief Executive, NENC AHSN and AHSN Network lead for Economic Growth

>>> Adoption & Spread

The impact of COVID-19

As the pandemic unfolded, AHSNs pivoted their activity to support the NHS response:

- They supported the rapid roll-out of digital primary care, helping NHS England and NHS Improvement, NHSX and NHS Digital to achieve 99 per cent uptake of video and online consultation in GP surgeries' technologies in only two months, taking a leading role in embedding online consultations in primary care practices in England.
- They deployed staff to support front-line clinical care, the DHSC-led Medicines and Testing Supply programmes and other national COVID-19 programmes (more than **150 AHSN staff and 75 per cent of the AAC team** were redeployed to COVID-19 activity during spring/summer 2020).
- They identified and shared a list of more than 200 'ready to go' relevant products with potential for spread – providing expertise and support on the deployment of these products.
- They supported NHSX in the identification and deployment of other digital technologies, mobilising the workforce to support the <u>NHSX's TechForce19</u> challenge to innovators for digital solutions.
- They supported validation of COVID-19 tests, including identification of sites for pilot areas, implementation support, testing roll-out mechanisms and the production of implementation guides for additional sites.

Together, the AAC and AHSN Network will build on the rapid adoption of innovation seen during the pandemic, learning lessons to identify the particular strategies and drivers that made this possible.

The **AHSN**Network

In the coming year, as well as continuing their support for established AAC programmes, the AHSNs will focus on:

1. Driving the spread of three new national programmes:

- Preventing cardiovascular disease (CVD), with lipid management and familial hypercholesterolaemia: CVD affects around seven million people in the UK and is a significant cause of disability and death. Lipid management is the detection and treatment of raised lipids/cholesterol to reduce CVD risk. Targeted interventions in primary care for people with high cholesterol, including treating patients with the inherited disorder familial hypercholesterolaemia, is supported, with further regional activity focusing on atrial fibrillation and high blood pressure.
- Improving diagnosis of attention deficit hyperactivity disorder (ADHD): ADHD is a treatable disorder yet, if left untreated, it can have a significant impact on personal development, academic outcomes and family interaction.
 Work will focus on supporting mental health trusts and community paediatric services to improve the assessment process for ADHD using computer-based tests.
- Faster support for young people aged 16 to 25 with eating disorders: Eating disorders are serious mental health problems with high levels of mortality. Evidence suggests that treatment outcomes are best if the condition is identified

and treated at the earliest opportunity, within the first three years of illness. Work will support mental health teams across England to speed up diagnosis and treatment of eating disorders in young people.

2. Scoping a new programme around workforce innovation:

The AHSNs will be working on supporting system partners in delivering innovation and transformation for the NHS workforce.

3. Rolling out a new patient safety commission from October 2020, in collaboration with NHS Improvement:

The commission will align with the COVID-19 response and recovery, focusing on maternal/ neonatal care, deterioration, medicine safety, support for care homes, and mental health.

"The AAC is an essential platform for cross-sector partners to address inequalities and ensure innovation serves all our populations. As well as the communities we serve, we will continue to champion the case for diversity within our healthcare workforce, and develop diversity within our NHS innovation pipeline by supporting innovators from BAME communities."

Richard Stubbs, AHSN Network lead for inclusion and Chief Executive, Yorkshire and Humber AHSN

INNOVATION AND TECHNOLOGY PAYMENT AND RAPID UPTAKE PRODUCTS PROGRAMMES

These programmes support the adoption of proven cost-saving innovations. The Innovation and Technology Payment (ITP) programme builds on the Innovation and Technology Tariff (ITT) and was developed in recognition of the need for different funding mechanisms for these innovations, with NHS England and NHS Improvement covering the cost of innovations, and the AHSN Network driving adoption through local networks. Our learnings and insights from this proven method of offering a confirmed funding mechanism has informed the development of the MedTech Funding Mandate (see page 31).

Our Rapid Uptake Products (RUP) programme scales up the adoption of NICE-endorsed medicines, products and technologies that offer significant patient and system benefits but are currently under-adopted. It offers bespoke packages of support for the individual products, to address the specific barriers they face in areas such as funding, policy, system infrastructure, variation and clinical best practice dissemination. Funding to support access to RUPs comes from the <u>Pathway Transformation Fund</u>.

In 2019/20, almost 500,000 patients at more than 200 sites had access to products supported through these programmes.

"The learnings from the first wave show us it is possible to set out a clear case for change, garner clinical leadership and unlock barriers. This progress is key to unlocking the potential for the next wave of RUPs."

continues >>

Su Jones, NHS Engagement Policy Partner, ABPI

PRODUCT	DESCRIPTION	PROG	RAMME
		RUP	ITP/IT1
Cladribine	A tablet, taken in two treatment courses, one year apart and used to treat adults with rapidly relapsing multiple sclerosis. It can help manage symptoms and reduce the risk of further problems, lessening relapses and slowing the progression of disability.	>	
Endocuff™	A disposable sleeve that fits over the end of colonoscopes. Designed to improve visualisation of the bowel and increase flexibility and stability during a colonoscopy.		>
Episcissors-60	Episcissors-60 reduce the incidence of obstetric anal sphincter injuries during birth that can have a devastating impact on the quality of life for new mothers by preventing inaccurate visual estimations of the cutting angle in standard episiotomies.		>
GammaCore	A non-invasive vagus nerve stimulator used as a highly effective treatment for migraine and cluster headaches, reducing pain and improving the quality of life for patients.		>
HeartFlow	A non-invasive analytic tool that uses data from coronary computerised tomography (CT) angiography to create a 3D model of the coronary arteries to help clinicians rapidly diagnose patients with suspected coronary artery disease.		
High-sensitivity troponin (HsT)	A test that helps diagnose heart attack and other heart-related conditions more rapidly and accurately, helping to save lives and improve patient outcomes.	>	>
Non-injectable arterial connector (NIC)	A medical device that prevents medication being incorrectly given into the arterial line. It also prevents arterial line infections and accidental blood spillages during sampling and protects patients and staff.		>
PCSK9 inhibitors	PCSK9 inhibitors increase the options available to treat high cholesterol levels and reduce the risk of cardiovascular disease (CVD), including heart attack or stroke, in patients with the genetic disease familial hypercholesterolaemia, or those who have had a previous CVD event. PCSK9 inhibitors can be used together with statins, or independently for those who are unable to take statins.	>	
PIGF (placental growth actor A diagnostic test used in pregnancies where there is clinical suspicion of preterr pre-eclampsia. It helps to accurately rule out pre-eclampsia, assess the risk for associated complications, and reduce life-threatening complications.		>	>
PLUS sutures	Absorbable sutures containing an antiseptic coating of triclosan to prevent bacterial colonisation and reducing the risk of surgical site infection.		>
Pneux™	A system designed to prevent pneumonia associated with long-term ventilation.		>
SecurAcath	A device to secure catheters without requiring sutures or adhesives, which reduces complications that can arise when peripherally inserted central catheters are moved or dislodged at the insertion site.		>
SpaceOAR™ (Absorbable spacer)	Improves patient safety by decreasing the risk of rectal injury during prostate radiation therapy with a hydrogel spacer that pushes the rectum away from the prostate.		>
UroLift®	A minimally invasive procedure for treating lower urinary tract symptoms of benign prostatic hyperplasia, a common and chronic condition where the enlarged prostate can make it difficult for a man to pass urine.	>	>

Table 2. Products selected for support by RUP and ITP/ITT in 2019/20

>>> Adoption & Spread

CASE STUDIES: PROGRAMMES MAKING A DIFFERENCE

The following case studies on PIGF and HeartFlow demonstrate the difference that support from these programmes has made.

CASE STUDY

Placental growth factor (PIGF) based testing

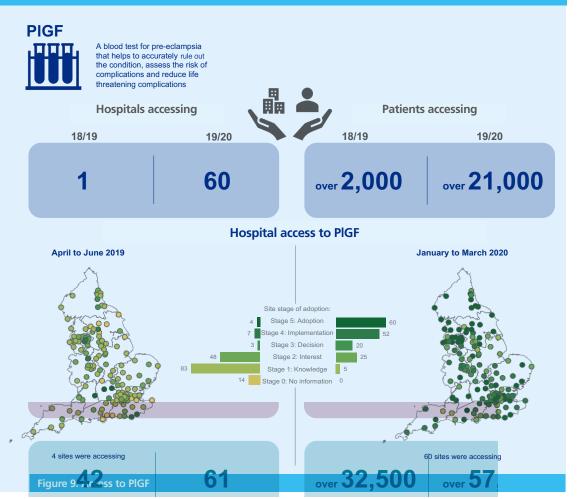
Pre-eclampsia affects approximately 3 per cent of all pregnancies. Prior to PIGF, there was no definitive test to rule out pre-eclampsia. If allowed to progress, the disease can result in maternal organ failure and foetal growth restriction and, in some cases, foetal or maternal death.

Clinical teams therefore have a high degree of suspicion for preeclampsia and a low threshold to admit pregnant women with a suspected diagnosis. In practical terms, this means that many women are unnecessarily admitted to hospital as a precautionary monitoring measure. PIGF testing helps to overcome this with:

- improved patient safety through rapid, accurate results
- reduced unnecessary admissions
- improved patient experience by reducing anxiety and the need to be in hospital
- improved maternity ward capacity due to monitoring fewer women.

At Royal Albert Edward Infirmary, Wigan they used the PIGF point-ofcare test, which takes less than 30 minutes compared to their previous experience of four to six hours incurred when they needed to transport test samples to central laboratories. This rapid result turnaround facilitated earlier rule out of pre-eclampsia in high and intermediate risk groups, enabling immediate clinical decision-making and better patient outcomes.

Pennine Acute Hospitals NHS Trust used the PIGF test and a home blood-pressure monitoring service during COVID-19 to assess women remotely, which noticeably helped to reduce the number of hospital admissions during this period.



>>> Adoption & Spread

CASE STUDY



Newcastle upon Tyne Hospitals NHS Foundation Trust reduced the rate of diagnostic-only invasive testing, with 86.7 per cent of patients seeing adequate blood supply and circulation restored following invasive angiography after HeartFlow analysis, compared with 50 per cent after cardiac CT alone.

Royal United Hospitals Bath NHS Foundation Trust has also devised a protocol based on HeartFlow that speeds up the diagnosis and treatment pathway, with the mean time of next investigation or definitive treatment down from 41 to 24 days. continues >>

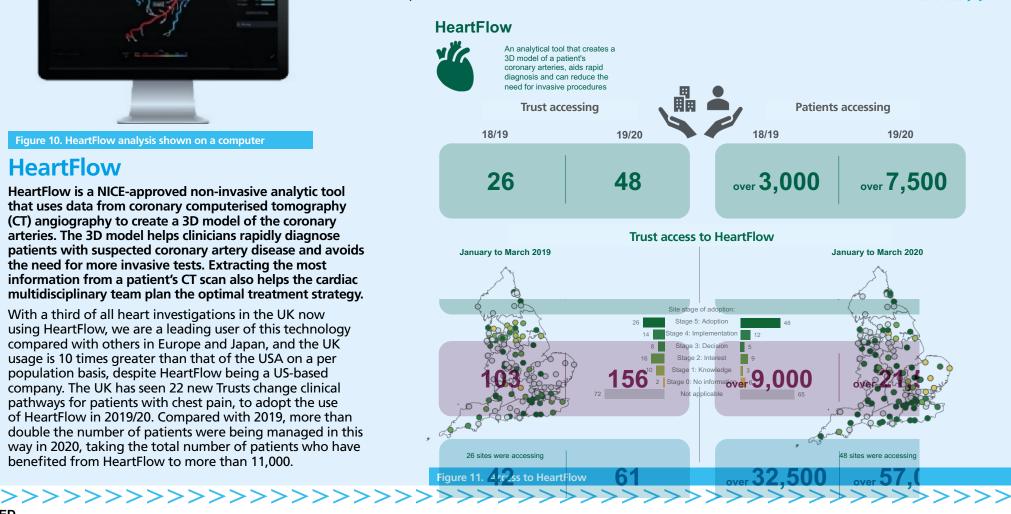


Figure 10. HeartFlow analysis shown on a computer

HeartFlow

HeartFlow is a NICE-approved non-invasive analytic tool that uses data from coronary computerised tomography (CT) angiography to create a 3D model of the coronary arteries. The 3D model helps clinicians rapidly diagnose patients with suspected coronary artery disease and avoids the need for more invasive tests. Extracting the most information from a patient's CT scan also helps the cardiac multidisciplinary team plan the optimal treatment strategy.

With a third of all heart investigations in the UK now using HeartFlow, we are a leading user of this technology compared with others in Europe and Japan, and the UK usage is 10 times greater than that of the USA on a per population basis, despite HeartFlow being a US-based company. The UK has seen 22 new Trusts change clinical pathways for patients with chest pain, to adopt the use of HeartFlow in 2019/20. Compared with 2019, more than double the number of patients were being managed in this way in 2020, taking the total number of patients who have benefited from HeartFlow to more than 11,000.

FLASH GLUCOSE MONITORING

Although not directly led by our adoption and spread work programme, we're very proud to share how we have enabled the transformation of flash glucose monitoring through our work with the NHS England and NHS Improvement Diabetes Prevention Programme and Abbott Laboratories.

The intention to provide flash glucose monitors to all qualifying patients was announced in November 2018 and this commitment was further endorsed in the *NHS Long Term Plan* (2019).

FreeStyle Libre, the first flash glucose monitoring system on the market, is supplied by Abbott Laboratories and comprises a wearable sensor the size of a f2 coin that is worn for up to 14 days at a time on the back of the upper arm. The sensor relays blood glucose levels to a smartphone or e-reader, thus eliminating the need for painful finger-prick blood testing, enabling patients to better manage their diabetes. The electronic sharing of data with the patient's routine care provider also allows clinicians to monitor people's diabetes remotely.

Figure 12. Heat map showing primary and secondary care prescribing of a CCGs population of people living with type 1 diabetes in England

With just 8 per cent of the estimated quarter of a million people in England with type 1 diabetes using FreeStyle Libre in March 2019, work involving key stakeholders, including Diabetes UK and NHS Clinical Commissioners, was undertaken to develop new national funding arrangements and clinical criteria. The aim was to ensure that flash glucose monitoring systems were prescribed to groups where clinical outcomes were expected to be the greatest, including people with type 1 diabetes unable to routinely self-monitor their blood glucose levels due to disability, or people with any form of diabetes on haemodialysis and on insulin treatment, as well as those requiring intensive monitoring and other clinically vulnerable groups.

New national funding arrangements now mean that Clinical Commissioning Groups (CCGs) are reimbursed on the basis of prescribing data. Importantly, supporting, educating and encouraging primary care practitioners to be confident about initiating flash glucose monitoring has resulted in a marked increase in flash glucose monitoring across the country. As of July 2020, national uptake is 31.5 per cent of all people with type 1 diabetes.

> The recommendation of flash glucose monitoring for some people with type 2 diabetes also helps to reduce health inequalities among South Asian, Chinese, Black African and African-Caribbean people, who have a higher risk of developing type 2 diabetes at an earlier age and at a lower BMI level. Additionally, the team is striving to ensure that the prescription of sensors is unaffected by either health or socio-economic inequalities, by working with local diabetes teams and CCGs to understand variance, and by providing extra support.

CASE STUDY

FreeStyle Libre diabetes management

Phil, a busy TV producer, has lived with type 1 diabetes for 44 years.

Due to occasional night-time hypoglycaemia (low blood glucose levels) and an unpredictable work routine, Phil's consultant recommended the **FreeStyle Libre** system. This glucose monitoring system has transformed the way Phil manages his diabetes.

Increased monitoring – more convenient and less timeconsuming (and less painful) than finger pricking – and greatly reduced stress levels in work and social situations, have led to better diabetes management, and Phil's glucose levels are the best they've ever been. He can now plan his day without the anxiety of wondering when he'll be able to check his glucose levels. Instead, he scans his sensor with the app on his phone.

Phil's diabetes management is now more joined-up too, as he can share his readings remotely with his healthcare team to optimise treatment decisions. With information from the device, Phil knows when to react, so his glucose levels stay more stable, which is crucial for his long-term health and helps avoid complications.

"FreeStyle Libre has given me more freedom and confidence and helped me to manage my condition far more effectively. It's been life-changing."

* The population of people with type 1 diabetes in England is 242,925, showing that an additional 51,014 patients have benefited from this innovative treatment in 15 months (April 2019 to July 2020). This takes the total number of people who have benefited from FreeStyle Libre to 77,007 since it became available.



CREATING MORE PRACTICAL FUNDING FOR INNOVATION SUPPORT, WHICH ALIGNS WITH THE GOVERNMENT'S HEALTH INNOVATION FUNDING AND THE WORK OF CHARITIES, RESEARCH ORGANISATIONS AND INVESTORS.

A vital element of the AAC funding strategy is the MedTech Funding Mandate policy. The policy is an *NHS Long Term Plan* commitment to get selected NICE-approved cost-saving devices, diagnostics and digital products to patients more quickly.



We consulted on a policy proposal stating that products meeting specific criteria would be included in annual guidance published by NHS England and NHS Improvement. It also proposed that making these available as treatment and diagnostic options would become an NHS contractual requirement for providers and commissioners.

The consultation received strong support. We asked stakeholders what criteria products should meet to be supported by the MedTech Funding Mandate policy and, after analysis of feedback, set the inclusion criteria.

The policy was due to be launched in April 2020; however, due to COVID-19, two other documents that support the mandate – the 2020/21 NHS Standard Contract and the 2020/21 National Tariff Payment System – were suspended and therefore the launch of the MedTech Funding Mandate was not possible. The products that were due to be supported by the MedTech Funding Mandate continue to be funded by the Innovation and Technology Payment (until March 2021). Meanwhile, work continues to strengthen the policy to ensure its success on launch in 2021. The AAC plans to publish details on the MedTech Funding Mandate this winter to support commissioners and providers to plan for the launch of the mandate in April 2021.



One of the most significant barriers is allocation of funds: there isn't a direct funding mechanism for reimbursing diagnostic tests. This is why the AAC initiative to support the MedTech Funding Mandate is so important for our sector.

Richard Hames, Executive board member, BIVDA and General Manager, Werfen

FUTURE PLANS

In 2019/20 the AAC has made significant progress in achieving its ambitions, despite the impact of the COVID-19 pandemic on programme delivery.

Our established programmes have gone from strength to strength and we have built solid foundations for the new priority programmes, such as demand signalling and horizon scanning. As we look forward to the year ahead, there are some milestones identified in this report that we should highlight:

- The MedTech Funding Mandate will be launched in April 2021 to accelerate patient access to clinically proven NICE-approved medical devices.
- The Innovation Service will go live next summer, making it easier for innovators to navigate the health innovation system and, ultimately, enabling innovations to get to patients faster.
- The Artificial Intelligence in Health and Care Award will grant funding to Phase 2 applicants in May 2021, supporting the acceleration of testing and evaluation of the most promising AI technologies for the NHS. The next competition opens in summer 2021.
- In our Rapid Uptake Products programme, we will be delivering four workstreams to accelerate the adoption and spread of proven innovations. The workstreams cover 10 products across asthma diagnosis and management, cancer prevention and lipids management.

We are also preparing for the UK's exit from the EU at the end of 2020. During the coming months, we will continue to work with all our partners, and especially MHRA, to overcome the uncertainties and embrace the opportunities that withdrawal from the EU may bring.

We look forward to next year's results of the NIHR and AHSN evaluations of the innovations identified by the Beneficial Changes Network. We will be focusing on those innovations shown to have had the highest impact to influence our priorities moving forward, as well as learning the lessons of how rapid adoption was achieved.

A key area of focus for the coming year is to ensure that research in the NHS is supported. COVID-19 has reconfirmed the importance of research for the NHS. During the first stage of the pandemic, many clinical trials paused as the focus shifted to Urgent Public Health COVID-19 studies. While that priority remains, more non-COVID-19 studies have been recruiting participants, and we want to build resilience so that this trend continues. We have already started working with partners across government, industry and the NHS to develop an action plan to achieve this ambition. Finally, we will continue to work closely with NHS England and NHS Improvement's commercial medicines directorate to enable us to support the introduction of more new treatments into the NHS.

Driving research and innovation remains hugely important. A key lesson from the response to COVID-19 is that the NHS can undertake worldleading research and rapidly adopt innovation even under the most challenging circumstances. The AAC and its partners will build on our strong first year and continue to get the best treatments to patients faster.



>> CONTACT US

There are many ways to get involved and to be supported by the AAC and its partners.

To find out more, have a look at: www.england.nhs.uk/aac/ where you can find details of how to contact the AAC or one of our members.

Questions can be directed to the AAC secretariat at aac.innovation@nhs.net

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