



Department
of Health &
Social Care

**Government Response to the House of
Commons Science and Technology
Committee's Third Report of Session
2017-19, 'Genomics and Genome
Editing in the NHS'**

July 2018



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the NHS'**

Presented to Parliament
by the Secretary of State for Health & Social Care
by Command of Her Majesty

July 2018



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Government Response to the House of Commons Science and Technology Committee's Third Report of Session 2017-19, 'Genomics and Genome Editing in the NHS'

This document sets out the Government's response to the House of Commons Science and Technology Committee report on Genomics and Genome Editing in the NHS, chaired by Rt Hon Norman Lamb MP. Detailed responses to each of the recommendations in the Committee's report can be found from page 4 onwards.

Introduction

The Government is an active supporter of innovation in genomics and gene editing and the UK is showing global leadership throughout the life sciences sector. We are committed to supporting the development of genomic technologies in an environment that promotes responsible, equitable and ethical patient care and delivering an Industrial Strategy that stimulates the growth of the life sciences sector for both patient and economic benefit. We would like to thank the Committee for recognising and endorsing the policies and initiatives that have enabled the UK to become world leading in genomics, and for commending the Government for its strong regulatory environment in support of genome editing.

To help realise the UK's ambitious vision for genomic medicine, the Government established the **National Genomics Board**¹ in response to the Chief Medical Officer's (CMO) *Generation Genome* report. The Board is chaired by Lord O'Shaughnessy, Parliamentary Under-Secretary of State for Health and held its inaugural meeting in March 2018. Its goal is to make sure that the UK remains the world's leading centre for genomic medicine and research, and to use this position to deliver quantifiable benefits for NHS patients and the life sciences sector.

The Government announced in the 2015 Autumn Statement investment of over £5 billion in health research and development. This included £250 million for the 100,000 Genomes Project to introduce Whole Genome Sequencing (WGS) in the NHS, ensuring the continued role of Genomics England to deliver the Project and beyond until 2021.

The Prime Minister's speech on the NHS on 18th June announced that the NHS funding will grow on average by 3.4 per cent in real terms each year from 2019/20 to 2023/24. By 2023/24 the NHS England budget will increase by £20.5 billion in real terms compared with today. The Prime Minister highlighted "*the opportunity to lead the world in the use of data and technology to prevent illness, not just treat it; to diagnose conditions before symptoms occur, and to deliver personalised treatment informed not just by general understanding of disease but by your own data including your genetic make-up.*" The Prime Minister also highlighted that we can increasingly use world-leading expertise in genomics to understand the risks to our own individual health. The Government and the NHS will work on a detailed plan to deliver the Prime Minister's five priorities - putting the patient at the heart of how we organise care; a workforce empowered to deliver the NHS of the future; harnessing the power of innovation; a focus on prevention, not just cure; and true parity of care between mental and physical health.

The Government has now asked Genomics England and NHS England to work in partnership to develop a long term plan for genomics which will take into account key recommendations from the *Generation Genome* report, together with important

¹ <https://www.gov.uk/government/groups/national-genomics-board>

research initiatives announced under the Life Sciences Sector Deal. This plan will set out how the UK can harness the power of its genomics datasets to stimulate disease insights and discoveries and turn these into world-leading analytical tools and therapies for the benefit of patients. This will be achieved through a collaborative partnership between the NHS, Genomics England, research funders, industry partners and patients.

Building on the work of the 100,000 Genomes Project and supported by our longstanding NHS, the UK is in a unique position to do this in a way that can quickly benefit patients, drive forward research and development, and which will ensure the highest standards of confidentiality and ethics to maintain public confidence in genomics, in line with the CMO's "genomic dream".

Improved NHS Services

Building on the world leading 100,000 Genomes Project, the UK will enhance its international leadership as one of the first countries in the world to establish a fully integrated **Genomic Medicine Service (GMS)** from October 2018. The GMS will provide comprehensive and equitable access to the latest in genomic testing, including WGS across the whole country.

The new GMS will be supported by a National Genomic Informatics Service (NGIS) and a network of National Genomic Laboratory Hubs (GLHs) that will deliver an integrated system for genomic testing, working to clear common standards and protocols. NHS England, in collaboration with Genomics England, will work to further transform pathways of care and create the multi-disciplinary teams and cross-professional infrastructure that will be critical for the future.

The GMS will also, for the first time, be supported by a comprehensive directory of genomic tests for specified cancers and rare diseases that encompasses the entire testing repertoire from WGS to tests for single genes, molecular markers and other functional genomic tests. The National Genomic Test Directory (the Test Directory) will be updated on an annual basis to keep pace with scientific and technological advances with a systematic review process in place to ensure continued value through the co-ordinated replacement of older tests with new and emerging approaches. The first Test Directory will be published in the coming months and will become operational from October 2018.

Research

The Government's Industrial Strategy named **four Grand Challenges** to put the United Kingdom at the forefront of the industries of the future and in May 2018, the Prime Minister announced the first four missions of our Industrial Strategy – one in each Grand Challenge. As part of the AI and Data Grand Challenge, **the United Kingdom will use data, artificial intelligence and innovation to transform the prevention, early diagnosis and treatment of diseases like cancer, diabetes, heart disease and dementia by 2030**. This mission builds on the recently announced £210m for Data to Early Diagnostics and Precision Medicine as part of the Industrial Strategy Challenge Fund which includes £100m for WGS.

The Prime Minister acknowledged that Britain is ranked first in the world for research into the defining technologies of the next decade and this includes genomics. As knowledge advances, the UK will aim to pioneer and integrate a new generation of genomic technologies into the NHS, linking together several Life Sciences Sector Deal priorities on early diagnosis, data, AI and digital pathology, which can be used

to increasingly predict outcomes and personalise therapies, and help to address the Grand Challenges of the future.

Through the 100,000 Genomes Project the UK has created a unique dataset linking phenotypic (medical) and genomic data which is enabling ground-breaking research and which represents a significant national asset. Researchers and clinicians, from both academia and the NHS, are working together to continually analyse data from the 100,000 Genomes Project to improve the clinical understanding of disease. This will continue into the GMS and the creation of a centralised, national service will further enable the continued accrual of genomic sequences and linked health data to further stimulate and support research.

The life sciences industry is critical to the UK economy and UK health, providing products which the NHS and millions of UK patients rely on every day. Sir John Bell's ambitious **Life Sciences Industrial Strategy** was published in 2017 and provided recommendations on the long term success of the life sciences sector. The report highlighted the pivotal role of genomics, writing: "...the UK has already embarked on two globally leading initiatives, UK Biobank and Genomics England. These projects have positioned the UK as the country that has defined the future of these fields".

The **Life Sciences Sector Deal**, Government's response to the strategy, is a transformative billion-pound agreement between the life sciences sector and Government worth close to £2.5bn of investment in innovative new treatments and medical technologies. The Deal proposes the creation of partnerships that will enable the WGS of an additional 50,000 genomes from cancer patients, to be delivered through NHS England and Genomics England, and sequencing of 500,000 UK Biobank participants.

The Deal also proposes the establishment of a single, unified, secure portal to provide access to our national genomic datasets. This will allow the UK to fully harness the power of its genomics datasets providing, with appropriate consent and permissions for secure access to de-identified data, an unparalleled resource to support research.

Recommendation 1

As the 100,000 Genomes Project approaches the completion of its sequencing target, the Government should formally evaluate it to inform the wider introduction of whole genome sequencing in the NHS (which we explore further below). The 100,000 Genomes Project could be a model for future ‘Health Advanced Research Programme’ projects, as suggested in the Life Sciences Industrial Strategy. If so, HARP projects should have processes and resources put in place from the start to allow their subsequent evaluation, and should explicitly take account of how existing NHS initiatives and resources will be complemented or absorbed.

The Government agrees with the importance of evaluation to inform the introduction of WGS in the NHS. There has been a continuous approach to evaluation throughout the 100,000 Genomes Project’s delivery and as a result we do not believe an additional formal evaluation once the Project has completed is necessary to inform the wider introduction of WGS in the NHS.

The 100,000 Genomes Project is a hugely ambitious programme which, from its inception, was designed to produce new capability for the use of advanced genomic technologies that would begin to transform the NHS. As a result, Genomics England and NHS England recognised the importance in embedding extensive and robust testing, assessment and evaluation throughout its delivery, to ensure the 100,000 Genomes Project will provide the necessary evidence and infrastructure to deliver a transformative service that is fit for purpose.

Examples of such continuous evaluation include:

- A number of pilot sites were established prior to the start of the 100,000 Genomes Project, sequencing over 12,000 genomes via NIHR Biomedical Research Centres and Cancer Research UK sites. An evaluation of the pilot sites was conducted to inform the delivery of the 100,000 Genomes Project at scale across the country.
- A national service evaluation of the consent materials was commissioned at the 10,000 participant mark². This assessment was completed under the auspices of Genomics England’s Ethics Advisory Committee and the 100,000 Genomes Project Participant Panel and gained in-depth feedback from Project participants, patient groups and healthcare professionals. Patient focused materials were re-designed and improved to ensure they continued to meet needs. Work continues to evolve the consent materials to support the implementation of the GMS with significant engagement from patients and other key stakeholders, including the National Data Guardian.
- The Genomics Expert Network for Enterprises (GENE) Consortium³ was established as an initial trial forum for engaging with industry. Following a formal evaluation which looked at issues such as the data embassy, data quality and charges, Genomics England evolved the GENE Consortium into the current Discovery Forum⁴.
- To facilitate ongoing assessment and evaluation of the practical operation of applying WGS within a healthcare setting, NHS England through its contractual mechanisms with the 13 NHS Genomic Medicine Centres (GMCs)

² <https://www.genomicsengland.co.uk/consent-evaluation/>

³ <https://www.genomicsengland.co.uk/working-with-industry/gene-consortium/>

⁴ <https://www.genomicsengland.co.uk/working-with-industry/>

has obtained regular feedback on transformation and implementation through Key Performance Indicator reporting. Additionally, national GMC network events as well as other specific groups made up of representatives from the NHS GMCs have, since 2015, enabled GMC representatives to meet regularly to share best practice, understand and work through practical issues and gain consensus on approach. This has enabled Genomics England and NHS England to share best practice, understand and work through practical issues and gain consensus on approach. This has enabled Genomics England and NHS England to respond quickly and adapt systems where the evidence supports change.

- A study 'Understanding Experiences of Recruiting for and Participating in Genomics Research' is being undertaken at the Department of Health and Social Care funded Policy Innovation Research Unit⁵. The study will include people's experience of taking part in the 100,000 Genomes Project and is due to report later in 2018.
- The 100,000 Genomes Project is subject to regular debate and review in the academic literature. A recent example includes a British Medical Journal paper 'The 100,000 Genomes Project: bringing whole genome sequencing to the NHS'⁶ which discusses current progress of plans to embed genomic medicine into routine care.
- As a Government Major Project, the programme has been under regular review by the Infrastructure and Projects Authority (IPA)⁷ which provides independent assurance of the most complex and strategically significant projects across Government. As part of this, the 100,000 Genomes Project has undergone three significant reviews which considered the Project's delivery, requiring the collation of extensive documentation evidencing the work and progress of the Project and several days of interviews with key stakeholders. At the conclusion of each review the results were shared throughout NHS England, Genomics England and the Department of Health & Social Care to inform continued delivery of the 100,000 Genomes Project.

While we believe that there has been sufficient robust assessment to date to inform the introduction of WGS in the NHS, we recognise that the evidence for its clinical utility will continue to evolve post -implementation of the GMS and as further evidence emerges from the 100,000 Genomes Project. The evaluation and evidence required to support the use of WGS in routine care is explored further in response to recommendations 2 and 3.

As we complete this important transition from the 100,000 Genomes Project to the GMS, the Government will seek the advice of the National Genomics Board on whether it judges additional targeted evaluation to be beneficial to ensuring we deliver the Board's vision for genomic medicine.

The Health Advanced Research Programme (HARP), as described in the Life Sciences Industrial Strategy, is currently in development. HARP proposes that industry, charities, NHS and Government collaborate on ambitious and long-term projects targeted at global healthcare challenges, using technology to transform healthcare in the future and drive UK economic growth.

⁵ <http://www.piru.ac.uk/projects/current-projects/understanding-participation-in-genomics-research.html>

⁶ <https://www.bmj.com/content/361/bmj.k1687.full?ijkey=eOQqGjogjVzNgxz&keytype=ref>

⁷ <https://www.gov.uk/government/organisations/infrastructure-and-projects-authority>

The Life Sciences Sector Deal highlighted that leading health charities are coming together to explore concepts and potential structures to shape the future of the programme. The Government is working with all partners to develop the programme including how projects would be evaluated and how they will operate with existing infrastructure and initiatives. Sir John Bell articulated the importance of the NHS in delivering a programme like HARP in the Strategy, and this will be a key principle as the work on HARP continues.

Recommendation 2 & 3

In advance of the launch of the Genomic Medicine Service, NHS England should undertake and publish a detailed evaluation of the 100,000 Genomes Project, to inform an assessment of the anticipated clinical- and cost-effectiveness of routine whole genome sequencing in the NHS.

We endorse the CMO's recommendation for NHS England to embed implementation research at all stages of redevelopment and laboratory reconfiguration for the Genomics Medicine Service. Where more evidence is needed to approve whole genome sequencing for particular conditions, current diagnostics should be maintained alongside whole genome sequencing, as was done in the 100,000 Genomes Project, unless the genomic diagnostic has proved more accurate for that condition.

The Government agrees with the importance of continuous evaluation to inform the introduction of WGS in the NHS. Through the 100,000 Genomes Project, work has been ongoing to inform the wider introduction of WGS into routine care. NHS England convened expert groups for rare disease and cancer, which included NHS GMC representatives, to consider the optimal testing for a clinical condition, using the evidence from published studies, the evaluation of tests offered by the UK Genetic Testing Network and the evidence from the 100,000 Genomes Project. As a result, 24 subsets of rare disease types and a small number of cancer types have been identified as having a clear benefit for WGS over current standard tests as part of routine clinical care.

As part of the GMS, NHS England will publish the Test Directory to specify the genetic and genomic testing available in the NHS in England. The Test Directory will encompass the entire genetic and genomic testing repertoire, from WGS for the conditions outlined above, to large panel tests and tests for single genes.

The Test Directory will be updated annually, following advice from an expert scientific and clinical committee that will be established to operate in accordance with NHS England's specialised services commissioning processes. The process for updating the Test Directory will consider the co-ordinated replacement of older tests with new and emerging approaches, including considering where evidence still needs to be collected to validate the benefit of moving to WGS, and identifying where alternative genomic diagnostics, such as gene panels or microarrays, will continue to be needed. As the evidence for WGS continues to develop, it is anticipated that over time an increasing number of conditions will be identified as having a clear benefit for performing WGS testing. NHS England intends to publish a methodology for the ongoing evaluation of genomic tests.

To take forward the CMO's recommendation, up to seven GLHs are currently being procured by NHS England to become operational by October 2018. They will facilitate the collection and monitoring of evidence on implementation ranging from

service organisational aspects through to clinical actionability, patient outcomes and the impact on reducing health inequalities.

In parallel to delivering routine testing, the process of ongoing research, evidence-gathering and rigorous evaluation will be enabled by the GLHs as part of the national service, which will be fundamental to the operation and implementation of the Test Directory. The GLHs will co-operate, collaborate and work in a network across the healthcare system in England, with other countries in the UK, with Genomics England, Academic Health Science Networks, the National Institute for Health Research and others to support discovery and developments, with a pipeline that will be ready for implementation, spread and adoption. This will be led by the GLH Scientific Director who will provide the scientific knowledge and expertise. NHS England will also be convening a working group to support this work.

Finally, to support the ongoing development of cancer genomics in the UK, the Department of Health & Social Care and the Office for Life Sciences will continue to work closely with Genomics England and NHS England to develop and implement the cancer genomic programme of the Life Sciences Sector Deal.

Recommendation 4

Given the intention to have the Genomic Medicine Service in operation later this year, the budgets for the required digital infrastructure should be agreed and confirmed now. Decisions on when to provide whole genome sequencing in place of conventional alternative diagnostic tests should take into account the digital infrastructure available to support it, to avoid attempting to roll out a Genomic Medicine Service at a speed that cannot be delivered.

The Government agrees with the importance of having the necessary digital infrastructure in place to support implementation of the Genomic Medicine Service. The 100,000 Genomes Project has already established much of the infrastructure and capability which will be harnessed and modified to support the GMS. The NGIS is the IT system which will underpin the GMS. The NGIS will also enable the research environment created as part of the 100,000 Genomes Project to be further curated and developed.

WGS will be accessed through the GLH national network and the underpinning digital interface will be in place to support this. This is because the GLH national network will be evolved from the existing genetic laboratories and supported by an evolved network of NHS GMCs that were integral to the validation and return of WGS results as part of the 100,000 Genomes Project. The GMS will build on the current digital infrastructure the NHS already has in place to support the return of genomic results. This infrastructure will then be further enhanced by planned delivery of an additional 'results portal' that will be built into the informatics platform.

Under the Partnership Agreement between Genomics England and NHS England, Genomics England takes the lead responsibility for NGIS and the funding for its development comes to Genomics England from the Department of Health & Social Care.

More broadly, the Government is investing over £4 billion over a five year period (2016-21) in digital technology, systems and infrastructure, to provide the health and care system with the digital capability and capacity it needs to provide services more effectively and efficiently. This funding is providing key national infrastructure needed to allow information to flow safely and securely around the health system, as

well as supporting the increased adoption of digital systems by NHS bodies, such as electronic health records by providers.

As outlined in the response to recommendations 2 and 3, the Test Directory will be updated annually following advice from an expert scientific and clinical committee which will consider new evidence which would support the co-ordinated replacement of older tests with new approaches. This will ensure the GMS is rolled out in a systematic and sustainable way.

Recommendation 5

With the Genomic Medicine Service due to be operational later this year, Health Education England should complete detailed workforce planning and modelling as soon as possible. They should also work with the Royal Colleges of Medicine and other stakeholders to embed genomics into relevant curricula and revalidation requirements as a priority. The Government must support them in this work, and ensure the necessary funding is available.

The Government agrees with the need for detailed workforce planning and the importance of embedding of genomics into relevant curricula and revalidation requirements. The 100,000 Genomes Project identified the need for substantial support for the workforce from inception – both for the Project itself and for the anticipated subsequent transformation to deliver a comprehensive GMS. This led to the formation of the £20m Genomics Education Programme within Health Education England (HEE) such that workforce development could occur in parallel to the service and infrastructure developments driven by the 100,000 Genomes Project.

HEE published its draft workforce strategy for the NHS in December 2017, with genomics identified as one of the key areas for development within the NHS. Genomics is also a key element of a major independent review, led by Dr Eric Topol, who was commissioned by the Secretary of State for Health & Social Care to look at the impact of emerging technologies, including genomics, on the roles of future clinicians across the NHS workforce. The review will have a particular focus on how training and education will need to adapt to prepare the future workforce for emerging technologies. This review will produce an interim report in July 2018, after which the review team will engage in a process of stakeholder engagement before publishing a final report and recommendations at the end of 2018.

The Genomics Education Programme will remain a core part of HEE's work in the coming years given the requirements of the healthcare system in this area. HEE's strategic approach includes planning for a workforce review that is aligned to the implementation of the GMS across all professions involved in the service, for example, genomic counsellors and specialist nurses through to genomic oncologists and laboratory scientists. It will seek to understand the mainstream clinical workforce requirements, raising awareness and knowledge of genomic medicine across the NHS workforce. Following the review, workforce planning for genomics will span the entire range of roles that support the patient and sample journey, and HEE will explore opportunities and the possible impact of new professions to support genomic medicine.

In developing its approach, the Genomics Education Programme routinely engages with the Medical Royal Colleges and actively participates in the NHS England and Academy of Medical Royal Colleges (AoMRC) Genomic Champions Group. This Group is co-chaired by Professor Sue Hill (Senior Responsible Owner for the GMS in NHS England and a senior lead for the HEE Genomics Education Programme) and Professor Carrie McEwan (Chair of the AoMRC). One area this group will take

forward is the development of genomic competencies for specialty training as well as investigating the roles and numbers of specialists required going forward. This will include specific work programmes around curricula development and medical revalidation. In addition, the reconfiguration of laboratories to form the network of GLHs requires that each GLH has an Education and Training function to contribute to this work across its geography.

The Government will continue to work with HEE and NHS England, taking into account the conclusions of the Topol review, to understand the evolving workforce requirements for the GMS and how these can be fully embedded into existing work programmes in order to deliver a truly transformative service that delivers for NHS patients.

Recommendation 6

We agree with the CMO's recommendation to establish a national network of multi-disciplinary teams. The Government should set out what funding and support it will provide to enable multi-disciplinary teams to develop from being research-oriented to supporting clinical practice, and factor their costs into the commissioning of the Genomic Medicine Service.

The Government agrees with the aims of this recommendation. Genomic multi-disciplinary teams (MDT) will become increasingly important to support clinical practice. As with current practice, some genomic tests will not require the input of a MDT, while some more complex genomics tests, for example some panel tests and WGS, will.

Through the 100,000 Genomes Project, the NHS GMCs have begun to establish multidisciplinary meetings across their geographies to support the return of results to patients within the clinical care pathway. These teams use the results of WGS within the context of the patient's medical history and other diagnostic testing to help inform their clinical care. To support the implementation of the GMS, it will be necessary to facilitate experts from across different geographical areas to come together to support interpretation and clinical actionability of genomic testing more generally as well as for WGS outcomes. The MDTs will be supported by existing clinical genetics services and cancer care services where appropriate and by the new GLHs. GLHs will be required to create and agree a plan to support MDTs.

NHS England will continue to support this activity as part of the commissioning of the GMS.

Recommendation 7

We recognise the Government's determination to implement the General Data Protection Regulation but it should now significantly increase its efforts to raise public awareness of genomic medicine, and the data-sharing needed to enable it, ahead of the introduction of the planned Genomic Medicine Service. The Government should confirm and publicise the consent framework to be used for the Genomic Medicine Service as soon as possible, to give time for NHS staff and patients to be aware of data sharing implications before routine genomic medicine is rolled out. Following a public consultation, the Government should provide clear information regarding what data will be collected, who will be able to

access that information and for what purposes, and an explanation of the benefits and risks involved in sharing genomic data.

The Government agrees with the aims of this recommendation to improve the public awareness of genomic medicine and the benefits of sharing genomic data. A core objective of the 100,000 Genomes Project is to address aspirations and concerns about genomics in dialogue with participants and the wider public. Genomics England is therefore leading on a range of innovative engagement activities to raise the public awareness of genomic medicine. This includes:

- Initiating the ‘Socialising the Genome’ project – this project revealed that the public’s understanding of principles behind genomics was greater than their understanding of the scientific terms. The 100,000 Genomes Project now concentrates on helping to bridge the gap in language used by healthcare professionals with that understood by the wider public.
- Developing an engagement strategy ‘Earning and maintaining trust’ in consultation with patients and other stakeholders, implementing a wide variety of activities to listen to and better understand public concerns.
- Launching the ‘Genomics Conversation’ – which is still ongoing. The Genomics Conversation has started a dialogue with the general public and relevant stakeholders about ethical and other issues relevant to the 100,000 Genomes Project to better understand potential barriers to embedding genomics into mainstream healthcare today.
- Engaging with the public and a wide range of stakeholder groups to help define the concept of the ‘social contract’ – raised in *Generation Genome* as a foundation to a successful GMS.

NHS England is working with Genomics England on a broader public engagement plan to support the launch of the GMS. This will continue the public dialogue on genomics and will focus on the GMS which becomes operational from October 2018 and beyond. This will be carried out through engaging with service users, the public, clinicians and key stakeholders and will look to address some of the immediate operational challenges, such as consent. NHS England and Genomics England are currently working to finalise these plans to ensure that they engage with all stakeholders appropriately.

Work has been ongoing to develop the consent framework for the GMS with significant engagement from patients and other key stakeholders, including the National Data Guardian. In particular, NHS England and Genomics England convened ‘The Patient Consent in Mainstreaming Genomic Medicine Working Group’ which has been engaging with key stakeholders to develop an agreed NHS consent model. The proposed model will take account of data legislation, the General Data Protection Regulation (GDPR) and national data opt-out and will be shared with a wide group of stakeholders, including patient advocacy groups, charities; healthcare professional organisations; government and NHS organisations; and research bodies. The final consent framework will be published in summer 2018 and will offer patients very clear choices about how their data will be handled and used.

Finally, the National Genomics Board has established an Engagement subgroup. This group will enable discussion and debates on developing issues in genomics across society and inform government, the NHS and scientific and research communities when framing future genomics strategies across healthcare, industry and research. The group will also aim to foster international links to facilitate learning and sharing of good practice.

Recommendation 8

We recommend that the Government seeks to renew the Concordat and Moratorium as soon as possible. The current review should take into account the introduction of whole genome sequencing as part of the NHS Genomic Medicine Service, the likely increase in predictive genetic test results this will cause, and the potential for more conditions to be predictable as genomic medicine progresses. The Government should set up systems to monitor any reluctance among patients to undertake genomic testing due to insurance concerns, assess the experiences of countries that ban insurers' use of predictive genetic test results (addressing in particular the ABI's concerns regarding the potential for adverse selection problems), be ready to consider putting the Concordat and Moratorium on a statutory footing if the current voluntary system begins to limit the uptake of predictive testing.

The Government welcomes this recommendation. Working with the Association of British Insurers (ABI) we are actively reviewing the Concordat and Moratorium on Genetics and Insurance. A draft document was shared with an established group of stakeholders in June 2018 and it is anticipated that the renewed agreement will be published in autumn 2018, well in advance of the existing agreement's expiry in November 2019.

The Government agrees with the conclusion in the *Generation Genome* report that the long-standing Government policy of maintaining a flexible semi-voluntary regulatory structure remains appropriate for this area. CMO's recommendations are being used to inform the review of the current Concordat and Moratorium. As an example, we aim to make the document easier to understand and give greater reassurances for consumers. We aim to retain the fundamental principles of the agreement including the commitment that predictive genetic test results obtained through scientific research should continue to be exempt from disclosure. As was noted by the Committee report, the ABI currently has no plans to bring forward an application for a new test.

The utility of additional findings as part of the GMS has not yet been clinically validated. This means that more research needs to be done to assess whether looking for additional findings as part of routine genomic testing is an effective method for improving patient outcomes in the NHS. As such, additional findings will still be classed as research results until a conclusive assessment has been made.

The Government and ABI are committed to regularly reviewing developments in genomics and insurance. The review is considering, with stakeholders, how increased dialogue and development of the current annual compliance exercise can improve understanding of, and engagement with developments in the field. This could consider the Committee's recommendation to monitor reluctance among patients to undertake genomic testing due to insurance concerns.

Finally, the Government has taken note of the Committee's recommendation that it 'should be ready to consider putting the Concordat and Moratorium on a statutory footing if the current voluntary system begins to limit the uptake of predictive testing'. The Government continues to work with patient interest groups, clinical representatives and the insurance sector to ensure that the agreement in place remains effective and relevant to those concerned and will remain to do so in future, taking any necessary actions should this situation change.

Recommendation 9

The Government must be ambitious in aiming to capture the full commercial value of the genomic and associated datasets it holds, rather than merely aiming to cover its costs. Genomics England should seek to maximise the

commercial value of its datasets and continue to provide industrial and academic access to these data to facilitate the growth of the UK genomics industry and the development of new treatments, while ensuring consent and data safety safeguards. Genomics England should explore technological and commercial mechanisms to enable better integration of genomics data held inside their portal with other NHS data and data owned by private companies. While patient benefit should be the focus of the Genomic Medicine Service, income generated from NHS data can be reinvested in the NHS and further benefit patients in the long-term.

The Government agrees in principle that Genomics England should maximise the full commercial value of the genomic datasets it holds and explore mechanisms to better integrate genomics data with other relevant data. A core aim of Genomics England is to kickstart a thriving UK genomics sector – and as part of this, to realise the economic value to the UK of the 100,000 Genomes Project.

Genomics England is currently exploring the potential opportunities for commercial returns from the knowledge and analytical tools developed in the 100,000 Genomes Project. As this is an emerging marketplace, it is not yet clear how the global market for dataset access will develop – but the UK is in a powerful position to realise rewards as it matures, subject to appropriate, safe, secure and lawful uses of data. Genomics England will consider strategic partnerships with other similar organisations and health systems to enable the wider adoption of the tools and expertise developed in the 100,000 Genomes Project.

Early in the 100,000 Genomes Project, Genomics England established a pre-competitive consortium called the Genomics Expert Network for Enterprises (GENE) Consortium of pharmaceutical and biotech companies which worked with Genomics England to look at how best they could make use of the data that would become available.

The GENE Consortium has now transitioned into the Discovery Forum, which provides a platform for collaboration and engagement between Genomics England, industry partners, academia, the NHS and the wider UK genomics landscape. In doing so, Genomics England aims to align efforts and ensure that ground-breaking genomic discoveries become mainstream genomic treatments as rapidly as possible.

In addition, Genomics England is planning to assist new companies, those that are moving activities into the UK to benefit from our unique landscape, existing companies expanding and strengthening their business and service offerings, and those raising new investment due to their collaboration with Genomics England.

This activity will be supported by the GMS as part of its infrastructure plans to align real world evidence with discovery, research and developments working in partnership and supporting Genomics England.

Recommendation 10

We recommend that the Government specifically require UK Research and Innovation to closely monitor the development of genome editing for potential obstacles to innovation in this area. If it becomes appropriate to review or amend the current regulations in light of technological developments, the Government should use a similar process as the one that accompanied legislative changes to allow mitochondrial donation.

The Government agrees with the Committee's recommendation and has asked UKRI to take this forward. As UKRI brings together research across all areas of research and development, across the research base and in industry it is ideally positioned to

monitor developments and implications of genome editing technologies and to capitalise on strong links across the UK and internationally. The broad spectrum of research supported by UKRI enables it to cover the implications for medical research in addition to biotechnology, agriculture and environmental science and in social science research.

The Government agrees that the UK benefits from a regulatory landscape that allows the application of genome editing technology for a wide range of applications. Regulations related to the contained use of genetically micro-organisms have allowed gene editing to be safely adopted as an established tool for many biological researchers. The UK is also active in the development of therapies involving somatic genome editing. The application of genome editing to human embryos or gametes is currently only permitted for research purposes under licence from the Human Fertilisation and Embryology Authority (HFEA).

Development of the regulatory landscape is supported by an on-going dialogue between research funding organisations and the relevant regulatory bodies. Support for research and development professionals across academia, industry, and the NHS in navigating the regulatory mechanisms is provided by the Regulatory Advice Service for Regenerative Medicine – RASRM.

At present, the Government considers there is no case for a review of current legislation. Any revision of existing legislation would require comprehensive consideration of all the issues spanning the legal, ethical, societal, technological and environmental domains. If legislation should change, the Government agrees that robust pathways regarding: the role of public engagement and public dialogue on acceptability; a robust independent review of emerging evidence; and a strong and trusted regulatory system to oversee the area should be followed, in line with similar processes that accompanied legislative changes to allow mitochondrial donation.

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