# Consultation response: the Topol review

## **physical controls foundation** making science work for health

### Submitted to

Health Education England

## Submitted by

Hilary Burton hilary.burton@phgfoundation.org

Sobia Raza sobia.raza@phgfoundation.org

Alison Hall alison.hall@phgfoundation.org

## September 2018

## Preparing the healthcare workforce to deliver the digital future

## Which technology does your submission relate to?

Our evidence relates to all three broad technology themes being considered by the Topol Review:

- Genomics
- Digital medicine
- Artificial intelligence and machine learning

For each area our submission considers the following questions:

What will health professionals need to know, be able to do (competence) and what (new) approaches may be required?

Do we have the current set of professional who address these, - are there problems of capacity, or a possible new 'breed' of health professionals needed?

## Which areas of patient care does your submission relate to?

- Genomics: relevant to primary, community and secondary care
- Digital medicine: relevant to primary, community and secondary care
- Artificial intelligence: relevant to primary, community and secondary care

## Is this about: work you've done/a projected scenario?

Our evidence submission is informed by our extensive body of work around the implementation of genomic technologies and the mainstreaming of genomics into clinical practice, as well as our research into the opportunities and implications of other innovative and emerging technologies to deliver better and more personalised healthcare.



We are setting out a vision that will encompass the role and impact of emerging and promising biomedical and digital technologies in the personalistion of healthcare Specific programmes of work at the Foundation that are of particular relevance to the Topol Review include:

#### Genomics in mainstream medicine

We have, over more than ten years been closely involved with policy development over the implantation of genomics within mainstream medicine, including detailed consideration of genomics in ophthalmology and cardiology. <sup>1, 2</sup> For the last 6 years (until 2017 when the group was suspended) we have also led the Genomics in Mainstream Medicine working group which was a sub-committee of the Royal Colleges Joint Committee on Genomic Medicine. This group included clinical specialists taking a leadership role in genomics from 17 mainstream specialties. In 2017 we also held a workshop particularly focused on the integration of whole genome sequencing in mainstream medicine. <sup>3</sup>

#### My healthy future

Examining how healthcare may change in the next 20 years or so - the next generation of healthcare. We are setting out a vision that will encompass the role and impact of emerging and promising biomedical and digital technologies in the personalisation of healthcare as well as the changing role of individuals in their health and care.<sup>4</sup>

#### The personalised medicine technology landscape

A recently published evidence synthesis for NHS England on the developments in science and new technologies that could play a role the greater personalisation of medicine. The report includes an analysis of the impact of the digital revolution and also examines several near-term (1-3 years) opportunities that could underpin the delivery of personalised medicine and how they could be integrated most effectively. <sup>5</sup>

#### **Regulating algorithms**

considering how legislation such as the GDPR and IVDR affect the application of algorithms in healthcare. It is also evaluating how innovators and developer can protect the algorithms they develop through proprietary and non-proprietary means. The regulatory landscape will have important implications for healthcare professionals with regards to issues such as liability, and how algorithmic tools, particularly AI based tools are used to guide decision making.<sup>6</sup>

It is important that the health system of the future has the capability and capacity to provide high quality advice and management to patients based on an evolving understanding of the contribution of genetic variation to disease

### **Genomic Medicine**

Genomics is relevant in every area of clinical medicine and provides enhanced capabilities for assessment of risk, prediction and prevention, diagnosis and treatment of disease. Currently the main applications of genomics are within rare disease (including heritable subsets of common disease such as inherited breast cancer due to BRCA1/2 mutations, or familial hypercholesterolaemia), cancer and infectious disease (consideration of the genomics of pathogens).

As mentioned in the Topol interim report, pharmacogenomics is also becoming important. The contribution of genetic variation to common complex diseases such as cardiovascular disease, breast cancer or dementia is now becoming much clearer from the emerging science – for example we now know the contribution of more than 100 breast cancer variants to breast cancer risk. However, there is less evidence about the ability to modify risk or the effectiveness of stratified approaches to preventive interventions in the various risk groups.

It is important that the health system of the future has the capability and capacity to provide high quality advice and management to patients based on an evolving understanding of the contribution of genetic variation to disease, the ways in which genomic biomarkers can assist in the precise characterisation of disease and, for pharmacogenomics, the likely response of the individual to treatments in order to provide precision management programmes.

Many of the new requirements have been well rehearsed in the Topol interim report. However we would like to make the following extra points related to the complexity and scale of what will be required:

- Genomics is important in the great majority of clinical specialty areas. <u>Our</u> <u>Genomics in Mainstream Medicine resources</u> provide information on the relevance in 15 different specialties and covering current and upcoming applications in inherited disease, cancer, common complex disease and pharmacogenomics.<sup>7</sup>
- Mainstream clinical specialties that we have included are: cardiology, ophthalmology, paediatrics, respiratory medicine, oncology, neurology, nephrology, gastroenterology, dermatology, rheumatology, audiovestibular and endocrinology.
- Medical specialists, whether in primary, secondary or tertiary care have to take consultant level responsibilities for their patients; a general 'level of increased awareness' is not enough.
- Consultant level decisions will be required as doctors: identify which
  patients will benefit from genomic testing; refer appropriately for testing;
  provide the necessary supporting clinical phenotypic information;
  interact as necessary with the laboratory and other members of the
  multidisciplinary genomic medicine team regarding interpretation
  of variants; communicate results to patients and help them to make
  informed decisions about options for managements. None of these
  activities is straightforward (see our report on Genomics in Mainstream
  Clinical Pathways <sup>3</sup>) and in the UK there is a large deficit in the number of
  consultants able to operate effectively and safely in genomic medicine.

If genomics is to expand... into the mainstream... it is hard to see that any of these doctors can avoid the need to be proficient in providing genomic testing

- The scale of consultant development required is considerable. According to the GMC there are 94,000 doctors on the specialist register and as an example in some of the most relevant specialities there are 25,000 in medicine, 2,763 in general cardiology, 6,976 in paediatrics, 2,948 in ophthalmology, 1,142 in dermatology, 6,109 in psychiatry, 1,504 neurology, 1,188 renal, 2,156 respiratory, 4,986 O&G. If genomics is to expand beyond the specialist service into the mainstream, and particularly if wider genome testing is undertaken at an earlier stage in the diagnostic pathway (thus by-passing much of the harmful 'diagnostic odyssey') it is hard to see that any of these doctors can avoid the need to be proficient in providing genomic testing.
- In addition there are 70,246 doctors on the GP register and 60,683 doctors in training.
- It is also necessary to have a number of specialists in each specialty and in each region operating as sub-specialists in inherited disease. Our detailed reviews of the current status of sub-specialist services in ophthalmology and cardiology showed that such services are currently grossly inequitable in the UK with many regions having no service at all.<sup>1,2</sup> In most regions outside London the specialist inherited service is mainly staffed by clinical geneticists with a specialist interest in the clinical area (cardiology etc.) rather than vice versa (i.e. mainstream specialists with an interest in genomics). We identified at the time that there needed to be an expansion of sub-specialist consultants. Our 2011 analysis of inherited cardiac services led us to estimate that each year in the UK there was an average shortfall of at least 7,000 new patients who were not seen by consultants with sub-specialist expertise. Although this has not been documented we believe that this situation is replicated across all the specialties and will require the development of formal sub-specialist training programmes – to our knowledge none of this has happened.

We have focused here on the medical profession because of their leading role and responsibility for diagnostics and patient care. However, a wide range of other health professionals will need to develop knowledge and skills in genomics in order to support the patient journey (e.g. to help to communicate risk, or provide information on how the data is used and safeguarded), to use their interactions with patients and the public to promote positive attitudes about the importance of genomics for population health and well-being and to be part of the debate about how to implement this in a way that maximises benefit and minimises harm. Professionals such as nurses will also develop specialist roles with respect to inherited disease – as noted in the Topol Interim Report with the example of diabetes – and this needs to be developed at sufficient scale to provide equitable high quality services across the country. It will be important to consider work force requirements in the context of how care pathways may need to adapt to maximise the utility of these devices

### **Digital medicine**

Including the use of smartphones or computers for telemedicine or remote care, apps, wearables, virtual reality, bio-nanotechnology and point-of-care diagnostic tests.

The Topol Review report defines digital medicine as digital technologies and products that directly impact diagnosis, prevention, monitoring and treatment of a disease, condition or syndrome. We have reviewed many of these technologies within our recent report, the personalised medicine technology landscape.<sup>5</sup> With respect to the healthcare workforce two general considerations are that:

- The pace, scale, and extent to which these technologies will impact the delivery of healthcare within the NHS, and consequently impact the roles and functions of healthcare professionals, is linked to the pace of progress in establishing the critical underpinning digital infrastructure across the health system to support the integration of these technologies.
- How digital medicine will change roles and functions of staff will to an extent depend on decisions around how these technologies are deployed within the health system. It will be important to consider workforce requirements in the context of how care pathways may need to adapt to maximise the utility of these devices, and the clinical contexts within which these technologies are deployed and most likely to have a positive impact on patient outcomes.

What will health professionals need to know, be able to do (competence) and what (new) approaches may be required?

- In alignment with the observations of the interim Topol Review, expected trends in digital medicine over the next two decades may include:
- Greater dependence on a wide range of data generated from within the health system and beyond, including the commercial sector and citizen generated data
- Greater direct physician interaction with patient and citizen generated health data
- Health professionals may use digital technologies to assist communication and decision making with patients (e.g. communicating complex risk information or helping individuals to understand the impact of health choices
- More remote patient-physician consultations and remote delivery of care
- Adaptations of professional interactions with patients including integration of pathways in which patients access healthcare via digital based interactions with the healthcare system
- A broader repertoire of clinical tests that take place outside of a laboratory setting and near or at-the-point of-patient care
- Interventions which increasingly focus on disease prevention, health and well-being

Deliberate and advance planning to develop these skills will be essential for a health system which is seeking to advance personalised healthcare These changes will raise the following demands on knowledge, skills, and attitudes:

#### **Basic digital literacy**

Across all patient-facing clinical specialisms there will be a need for baseline competency in interacting with digital tools and good practice in data security. Whether it is to hold virtual consultations or to operate near-patient testing devices, basic digital literacy skills will be essential. However healthprofessionals should be supported by a digital strategy which places an emphasis on simple, user-friendly and intuitive interfaces and systems that implement data security by design. Complex and clunky digital tools, may hinder and burden rather than help health professionals augment care delivery. Given the number and range of digital health technologies that may arise over the next two decades, it will be especially important that they are easy for healthcare professionals to use and to incorporate into practice.

#### Health coaching

The interim review notes that healthcare professionals will have to be trained to analyse and interpret patient generated data (including data from wearables acquired over several weeks or months). This, along with an increase in interventions focused on disease prevention and wellbeing will command time and place greater emphasis on skills in communicating with patients, explaining risk, and advising on improving health. With the increasing availability of data from consumer-facing health/fitness devices and the variability in the quality and accuracy of data they generate, healthcare professionals will need support to determine which data/tools to incorporate into decision making. In our recent report we highlight that the health system will need to assess whether and how to engage with the growing consumer-driven digital health movement.<sup>5</sup> This will be vital if there is an expectation for healthcare professionals to use this data in informing the care of their patients.

#### Large-scale data analytics

Our report describes how the widespread diffusion of mobile technology, mHealth and wearables will provide a rich source of health-related data that could in principle catalyse the development of personalised health approaches through improved knowledge and novel insights. <sup>5</sup> Achieving this in practice will require a cadre of human skills in data science, ranging from bioinformaticians, 'omics analysts, data curators, and Al expertise. <sup>5</sup> The interim Topol review also notes that 'new roles and career pathways will emerge for clinical bioinformaticians and healthcare data specialists with an interest in developing machine learning algorithms to analyse NHS datasets'. Deliberate and advance planning to develop these skills will be essential for a health system which is seeking to advance personalised healthcare. Having a clear vision of how a tool will be used and its likely effectiveness will involve working in a multidisciplinary manner

#### Adaptation of professional approaches to enhance person centred care

Overall health professionals will need to embrace working with digital systems and tools as the norm. They will also need to adapt to accommodating the different levels of digital literacy across the population. The opportunities of digital medicine should be used to underpin person-centred healthcare by providing new tools to support: a holistic understanding of the individual; well-informed decision making that respects and integrates data generated by the patient (citizen generated data); and different ways of accessing care. It will be important that machines are not used to substitute for personal relationships – and thought should be given how to enhance attributes such as compassion and dignity within the new interactions. It will also be important to keep in mind the various dimensions of a 'whole person' rather than reducing them to a dataset.

## Artificial intelligence and machine learning

What will health professionals need to know, be able to do (competence) and what (new) approaches may be required?

#### Al development

The use of AI in healthcare is not currently widespread, and much work is needed to collate and improve the datasets upon which AI development relies. Clinical knowledge will be essential to this process. One example is the process of 'labelling' data that will be used to train machine learning algorithms; a radiologist may help 'label' x-ray data to assign which images contain a tumour and which do not.

For those healthcare professionals intimately involved in the use of patient data for – and the development of – AI techniques, understanding the impact of relevant EU regulations on data processing and device regulation, and knowledge of the code of conduct for data-driven health and care technology and data ethics framework will be imperative.<sup>8,9</sup> Having a clear vision of how a tool will be used and its likely effectiveness will involve working in a multidisciplinary manner. Health professionals will also need a broad understanding of the need for transparency, the basis on which data is used and the requirement to entrench principles of data minimisation and data security in AI development processes.

#### **Digital competence**

Taking the example of histopathology, the future deployment of AI driven analysis in this field is first contingent on the implementation of digital pathology systems. Rather than analysing glass slides directly under a light microscope, the pathology slides are scanned and then analysed using a computer. As the transition to digital pathology alters the traditional histopathology workflow, laboratory staff and pathologists in digital image analysis may need training including the ability to navigate digital images on a computer rather than a microscope. <sup>5</sup> Healthcare professionals will need to be willing to engage in the development, testing, and evaluation of Al algorithms in healthcare – some of which may need to occur in collaboration with the Al sector Beyond histopathology, the development of AI analytics in other disciplines will also rely on the digitisation of health data, again placing a demand on baseline levels of digital competency.

#### Patient-clinician communication

If AI can be used in a way that reduces the administrative burden on healthcare professionals (e.g. data entry and automation of repetitive/routine managerial tasks), then this could in theory allow healthcare professionals more time for interacting with patients. AI may indeed place greater demand on patient-facing roles, for example to ensure that patients are informed appropriately about how their data will be used, to discuss the outputs of AI driven analytics with patients, or to respond to AI-based alerts that are integrated into patients' digital devices and wearables, or even within their electronics health records.

#### Working with AI

As AI applications transition from a research phase into clinical care, there is a need to understand how greater reliance on AI might translate into new standards for healthcare professionals using AI tools in clinical care.<sup>6</sup> Applications which are closest to implementation include uses in imaging and pathology for cancer screening, diagnosis, treatment and management. Current regulation (such as the General Data Protection Regulation) provides safeguards for situations in which automated processing produces a significant or legal effect for an individual. These safeguards include seeking specific consent from the person concerned, or having human input into the decision making process. Ultimately, it seems likely that best practice guidelines will be created that incorporate the principles that are iterated in generic guidance (such as the initial code of conduct for data-driven health and care technology <sup>8</sup>) into meaningful standards for professionals on a sector specific basis. Looking further ahead, current systems for addressing clinical negligence will also need to be addressed to explore whether algorithms and their developers should or could be responsible for negligent outcomes where patients are harmed.

#### Adaptation of professional approaches

Clinical and scientific knowledge is essential to the development of successful Al in healthcare. Healthcare professionals will need to be willing to engage in the development, testing, and evaluation of Al algorithms in healthcare – some of which may need to occur in collaboration with the Al sector. All healthcare professionals will need to be prepared for working in an increasingly Al integrated healthcare workspace. In their everyday work, they will need to maintain best practice in data capture and curation to support the creation of high quality health datasets on which Al algorithms can be trained. We echo and strongly support the views in the interim review around the necessity of high quality, secure, and safeguarded information infrastructure Do we have the current set of professional who can address these knowledge, skills, and competencies for digital medicine and for artificial intelligence and machine learning? Are there problems of capacity, or a possible new 'breed' of health professionals needed?

#### **Developing Al**

Scientific (biomedical) and clinical expertise to support the development of machine learning algorithms for healthcare exists. Healthcare professionals to understand their discipline (whether it is pathology, radiology, cardiology, ophthalmology etc.) better than computer scientists and programmers. They also possess first-hand experience into the challenges and bottlenecks in their field that Al could potentially help to address. Engaging healthcare professionals and obtaining their input is key to the effective development and deployment of Al in the healthcare setting. In a recent 'state of the nation' survey on accelerating Al in health and care, 92% of respondents felt that engagement of healthcare professionals was very or extremely important to realising the potential of Al for health and care.<sup>10</sup> A compelling example of clinician informed AI development is the collaboration between Moorfields Eye Hospital and DeepMind Health to design technology that can identify eye disease and make referral recommendations.<sup>11</sup>

Another challenge is one of capacity, and providing healthcare professionals with the protected time and space to help co-develop AI tools for their discipline along with machine learning practitioners. In addition, the opportunity to learn principles of machine learning and its related technical and ethical issues (e.g. of AI bias and transparency) would further enhance their aptitude to help create robust and viable AI technologies.

## Large-scale data analytics

We echo and strongly support the views in the interim review around the necessity of high quality, secure, and safeguarded information infrastructure.<sup>5</sup> The review notes that 'one of the NHS's greatest assets is its comprehensive datasets'. With the appropriate data integration, infrastructure and policies, NHS datasets including the data amassing from genomics, biomedical and digital technologies can be harnessed, mined and analysed to inform improvements, generate new knowledge, and facilitate the greater personalisation of care. <sup>5</sup> As noted earlier (page 5) this will require a cadre of skills in data science. It is important to acknowledge that this is not 'one' category of professional but a range of professionals who may contribute at different levels. This might be to analyse data; or to create tools and systems for data capture and management; or help develop machine learning algorithms; or to inform user-driven design of tools; and other roles too. Some of these 'data' professionals may also need to possess domain knowledge of specific clinical/ scientific areas, and indeed some professionals may stem from these domains. The health system will require a strategy on how to access or acquire and foster these skills sets. It will also be important to consider how to attract and retain staff, whose skills are also highly in demand in other sectors and industries.

#### **Basic digital literacy**

These skills and competencies exist, but levels of basic digital literacy across the workforce are variable. HEE's work around digital literacy and other efforts are necessary to increase and achieve more consistent levels of literacy across the workforce.

#### Patient communication/health coaching

These skills already exist and are an integral part of undergraduate and postgraduate medical education. However the nature of patient-clinician conversations and interactions will evolve, as more of these take place in a virtual environment, and as healthcare professionals interact with more sources of patient data, and increasingly focus on interventions for disease prevention and health/wellbeing.

- 1. Moore T, Burton H. Genetic ophthalmology in focus. <u>A needs assessment and review</u> of specialist services for genetic eye disorders. PHG Foundation. 2008.
- 2. Burton H, Stewart A, and Alberg C. <u>Heart to heart inherited cardiovascular conditions</u> services. PHG Foundation. 2009.
- 3. Burton H, Hall A, Kroese M, *et al*. <u>Genomics in mainstream clinical pathways</u>. PHG Foundation. 2017.
- 4. <u>My healthy future</u>. PHG Foundation. 2017.
- 5. Raza S, Blackburn L, Moorthie S, *et al*. <u>The personalised medicine technology</u> <u>landscape</u>. PHG Foundation. 2018.
- 6. <u>Regulating algorithms</u>. PHG Foundation. 2018.
- 7. <u>Genomics in Mainstream Medicine Working Group</u>. PHG Foundation. 2017.
- 8. <u>Guidance: Initial code of conduct for data-driven health and care technology</u>. Department of Health & Social Care. 2018.
- 9. Guidance: Data Ethics Framework. Department of Health & Social Care. 2018.
- 10. Accelerating Artificial Intelligence in health and care: results from a state of the nation survey. The ASHN network. 2018.
- 11. De Fauw J, Ledsam JR, Romera-Paredes B, *et al*. <u>Clinically applicable deep learning for</u> <u>diagnosis and referral in retinal disease</u>. Nature Medicine. 2018.

## **@PHGFoundation**

## www.phgfoundation.org

PHG Foundation is a health policy think tank with a special focus on how genomics and other emerging health technologies can provide more effective, personalised healthcare