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BOARD PAPER - NHS ENGLAND

Title: Personalised Medicine Strategy.
From: Sir Bruce Keogh, National Medical Director.
Purpose of Paper: • To inform the Board of the development of an NHS England Personalised Medicine Strategy.
The Board is invited to: • To agree the principles that will underpin the approach to Personalised Medicine in the NHS. • To note the work that will be undertaken to develop a Personalised Medicine Strategy for the NHS.

Personalised Medicine Strategy
NHS England Board – 24 September 2015

1.0 INTRODUCTION AND CONTEXT

1.1 Personalised medicine is a move away from a 'one size fits all' approach to the treatment and care of patients with a particular condition, to one which uses emergent approaches in areas such as diagnostic tests, functional genomic technologies, molecular pathway, data analytics and real time monitoring of conditions to better manage patients' health and to target therapies to achieve the best outcomes in the management of a patient's disease or predisposition to disease.

1.2 It requires consolidation of clinical and diagnostic data held about an individual and cross comparison (using data gathered about other individuals) to identify patterns in disease and response to disease, allowing more robust conclusions about diagnosis and treatment to be made. It informs the selection of the most appropriate treatment for individual patients – the right drug at the right time, earlier screening and treatment, smarter monitoring and adjustment of treatments.

1.3 Inherent to any Personalised Medicine Strategy is the recognition that many of the currently available drug treatments are only effective in between 30% - 60% of treated individuals. Adopting a personalised medicine approach will allow the most appropriate intervention for the individual to be used, reducing costs and preventing adverse reactions in those who will not respond to certain treatments. Given the current NHS drugs budget is over £12 billion, using diagnostics to guide treatment interventions is of fundamental importance to NHS England as a commissioning organisation.

1.4 The shift to personalised medicine is already underway - our role as a system leader and commissioning organisation is to consider how this transformation can be accelerated. To date, our main focus has been on the NHS contribution to the 100,000 Genomes Project and on embedding genomic technologies into clinical care pathways, supporting the NHS in becoming one of the most advanced healthcare systems in the world in relation to genomic medicine. To ensure we capitalise on the current NHS transformation and the investment made by both NHS England and the NHS, there is a need to locate this initiative within a broader and more expansive strategy for personalised medicine.

1.5 This paper sets out the concept of Personalised Medicine within the NHS, the underpinning principles and sets out the work that will now be undertaken to develop a Personalised Medicine Strategy.

2.0 A PERSONALISED MEDICINE STRATEGY FOR THE NHS

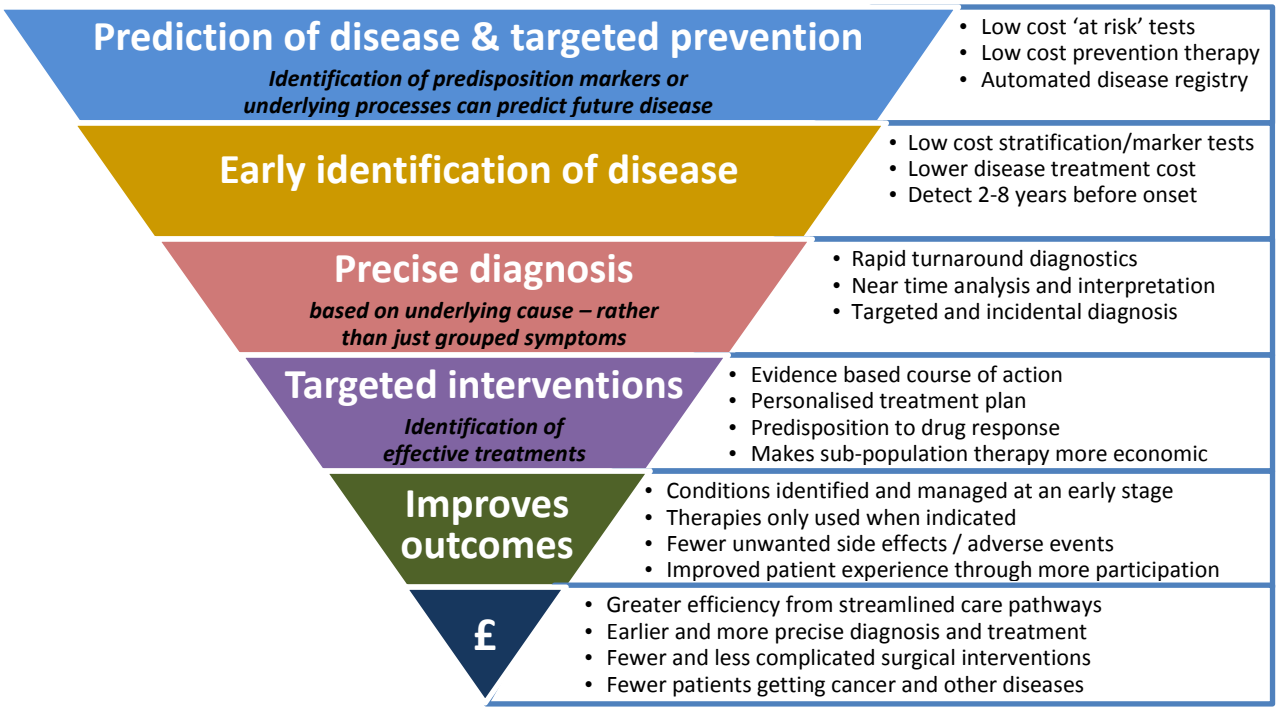
2.1 Personalised medicine has the potential to improve patient outcomes and produce significant benefits for the NHS (summarised in Figure 1 below):

2.2 These aims are consistent with the *Five Year Forward View* and the future challenges for the health system as well as the priorities for the NHS, including:

i. improved prevention based on underlying predisposition;
ii. earlier diagnosis of disease as a result of identifying abnormality earlier;
iii. more precise diagnosis based on cause; and
iv. targeted interventions through the use of companion diagnostics to identify and stratify effective treatments.

2.3 This synergistic approach will lead not only to improved outcomes but also a greater participatory role for patients and the public. These aims are embedded within the high level principles outlined below for a Personalised Medicine strategy for the NHS.

Figure 1: Personalised Medicine – improving outcomes



3.0 EMERGING VISION AND STRATEGY

3.1 The high level vision and strategy is to create a Personalised Medicine service in the NHS embracing four overarching principles (linked to Figure 1):

i. **Prediction** and **prevention** of disease.
ii. More **precise** diagnoses.
iii. Targeted and **personalised** interventions.
iv. More **participatory** role for patients.

3.2 It is proposed that each of these principles is explored further with internal and external stakeholders to create a work programme with four critical and interdependent elements:

i. Building an infrastructure to underpin personalised medicine in the NHS, inclusive of informatics and data systems, commissioning, procurement and financial frameworks.
ii. Developing a clinical change model, incorporating: high impact commissioning challenges; changes to clinical pathways; pharmacogenomics and synergies between companion diagnostics and medicines optimisation; and links to the 100,000 Genomes Project, its findings and NHS transformation outcomes.
iii. Embracing technology and innovation and creating the knowledge base. This will include: the scientific and technological advances in all genomics (incorporating the functional genomics pathway in totality) and in other underpinning diagnostics ; bringing in the knowledge from NHS England Digital Health Services and the NIB ; growing artificial intelligence and machine learning applications; and an NHS England solution to the requirement for an integrated genomic and personalised medicine knowledge base with complex analytical solutions to inform both clinical practice and research and development.
iv. Policy and system alignment including: the *Five Year Forward View*; Department of Health and system partners inclusive of Health Education England, National Institute for Health and Care Excellence (NICE) and the Medicines and Healthcare Products Regulatory Agency (MHRA).

3.3 There will be a programme of engagement with internal and external stakeholders and recognised experts (academia, clinicians, commissioners, industry, voluntary sector, patients and the public) inclusive of those working in the field of information and complex analytical solutions in other sectors. Specifically The Academy of Medical Sciences will work with us on exemplar clinical pathways.

3.4 We are working in partnership with the North West Coast, West Midlands and Imperial AHSNs on a series of activities in October/November from the perspective of commissioning, providers and research/ innovation to unpack the opportunities, challenges and impact of personalised medicine associated with the four elements outlined above. Additionally we have already initiated dialogue with the diagnostics and pharmaceutical industries and with the charities and third sector on the application of molecular diagnostics and personalised medicine in a number of therapeutic areas and health care settings.

3.5 A number of interconnecting initiatives are already shaping and informing the strategy for personalised medicine in the NHS:

i. 100,000 Genomes Project (including its legacy and continued NHS transformation)
ii. Re-procurement of the Regional Genetic Laboratories

3.6 A personalised medicine strategy will require all diagnostic services to be 'state of the art' with the ability to integrate and analyse data in real time and to produce comprehensive individual patient diagnostic profiles. This will require further developments in non- genomic diagnostic services for example in pathology, imaging and pathology. The NHS currently undertakes nearly a billion diagnostic tests per year inclusive of genetic testing. However these services generally exist in isolation – working independently from one another with variable approaches to commissioning and provision. As part of the personalised medicine work programme consideration will be given to improvements in access and efficiency, and the use of artificial intelligence systems such as machine learning.

4.0 100,000 GENOMES PROJECT

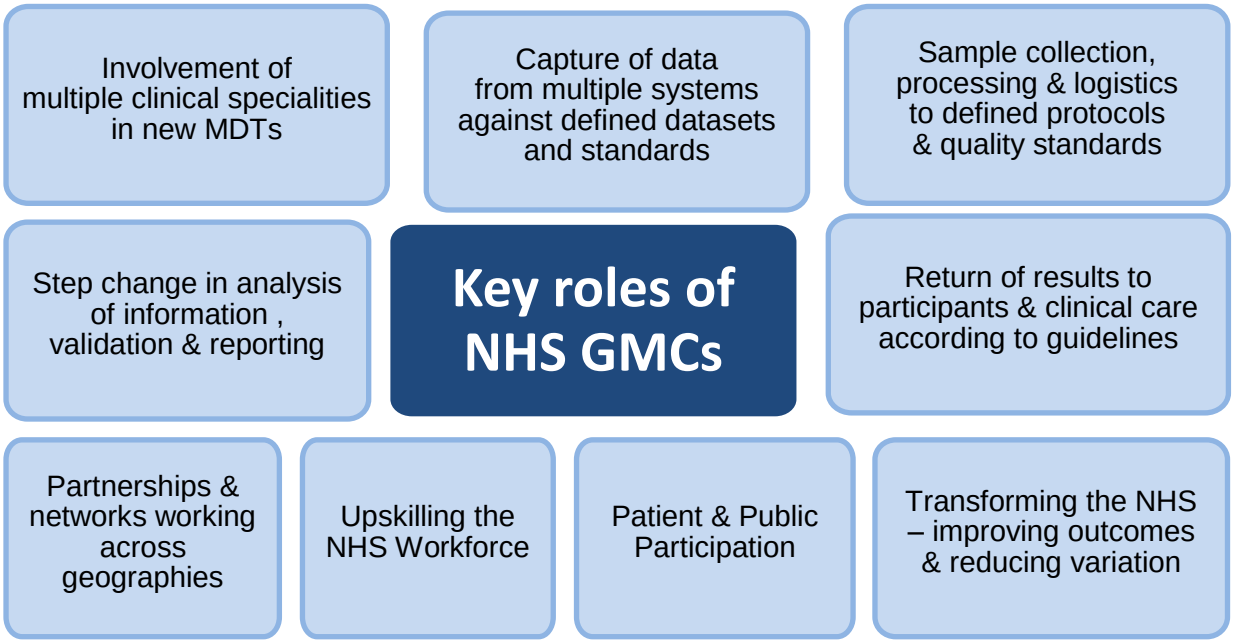
4.1 The NHS is already established as a key delivery partner in the 100,000 Genomes Project, where whole genomes (all the genes in an individual) will be sequenced from eligible patients with rare disease and common cancers. The Project is moving the NHS to a new model of diagnosis and treatment based on an understanding of underlying genetic causes and drivers of disease and a comprehensive phenotypic characterisation of the expression of the disease (rather than deduction from symptoms and individual diagnostic tests). Phenotypic characterisation includes capture of clinical and environmental factors and longitudinal data. This allows treatment response and other clinical events to be documented and related to the observed genetic abnormality – allowing individual disease management plans to be developed and cross comparison between individuals and within an individual over time.

4.2 The eleven wave 1 NHS Genomic Medicine Centres (NHS GMCs) are centred around a Lead Organisation (for contracting purposes) working with Local Delivery Partners in new partnership arrangements, with each NHS GMC covering a population base of between 3 to 5 million. They are all actively consenting and recruiting participants with rare disease, with all samples collected and processed to date having passed the quality control requirements. A wave 2 procurement process is underway to ensure eligible participants in the West of England, Yorkshire and the Humber and, Kent, Surrey and Sussex have access to the Project.

4.3 The Cancer main programme is establishing the optimal processing conditions for whole genome sequencing from tumour tissue. NHS GMCs are participating in a Cancer Implementation Initiation Phase which will involve stringent collection and processing arrangements and will inform protocols for the main programme start in early 2016.

4.4 Since the designation of these eleven Wave 1 NHS GMCs in December 2014, significant NHS transformation across the GMC geographies has been demonstrated and has been a pre requisite to the recruitment of eligible participants as a result of needing to work to the exacting and high quality standards required of the Project. There has been active patient and public engagement and involvement in all NHS GMCs. The key roles of the NHS GMCS are summarised in figure 2 below.

Figure 2: Key roles and transformational elements of NHS Genomic Medicine Centres



4.5 It is vital that we plan now for the legacy and the continued role of the NHS GMCs and their local delivery networks. These NHS GMCs are central to embedding and translating genomic technologies into mainstream medicine and are the forefront of the introduction and delivery of personalised medicine in the NHS.

5.0 GENETIC LABORATORY RE-PROCUREMENT

5.1 Regional Genetic Laboratories are central to all NHS GMCs and have been the focal point for adoption of genomic technologies into healthcare for over 40 years. These laboratories are currently the focus of an NHS England Specialised Commissioning re-procurement exercise, the Invitation to Tender for which is due to be launched shortly. The re-procurement aims to create a new genomic laboratory infrastructure for the NHS in England based on centralised and local genomic laboratory hubs to support rare, inherited and acquired disease as well as the future personalised medicine requirements inclusive of molecular diagnostics in stratified medicine.

5.2 The proposed model is one of hub and spoke provision, creating a national genomic laboratory infrastructure underpinned by both specialised and CCG commissioning. Genomic Centralised Laboratory Hubs are the primary focus of the specialised commissioning re-procurement, who

will work together in a national network and across defined geographies in a similar way to the NHS GMCs. These hubs will be required to establish provider networks of designated Genomics Local Laboratory Hubs and bring together all providers of molecular diagnostics across their geography.

5.3 A national coordinating function will be established focused on the commissioning system and accountable to NHS England. Within an agreed governance and operational framework it will oversee the test repertoire, co-ordinate the provision of new national specialised testing services and monitor the performance of the overall genomics laboratory infrastructure. They will have a critical role in identifying and addressing any inequalities in access to NHS England approved molecular diagnostic testing. The need for more accessible molecular diagnostic provision linked to the currently available targeted therapies has already been recognised in the recently published Cancer Task Force Report and is seen as key to improving outcomes.

5.4 Fully realising the re-procurement ambitions' will require alignment of the whole commissioning system to ensure there is a comprehensive genomic diagnostic testing service in the NHS for all care pathways (where applicable). This will inform the personalised medicine strategy and its work programme.

6.0 GOVERNANCE AND NEXT STEPS

6.1 A Personalised Medicine Strategy Board was established in July 2015, under the chairmanship of Sir Bruce Keogh, with representation from the majority of NHS England Directorates and will provide the governance and oversight for the work to be undertaken. The Chief Scientific Officer will provide a critical clinical and scientific leadership role in the development of the Strategy.

6.2 Next steps will be to produce a strategy for Personalised Medicine in the NHS and a detailed collaborative work programme for the next five years, an investment plan, and the potential for cost savings and efficiency gains. This will be presented to the Board for approval.

7.0 RECOMMENDATIONS

7.1 The Board is asked to:

i. To agree the principles that will underpin the approach to Personalised Medicine in the NHS.

ii. To note the work that will be undertaken to develop a Personalised Medicine Strategy for the NHS.

Author: **Sir Bruce Keogh, National Medical Director**
Date: **September 2015**