

# Consensus Paper on the Building Blocks for Personalised Healthcare

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## EXECUTIVE SUMMARY

Personalised healthcare is a shift from one-size-fits-all treatment of disease to maintaining high and healthy quality of life over the lifespan by applying the right health interventions for the right person at the right time. An ideal personalised healthcare system involves the collection and analysis of all meaningful health data at scale and the integrated use of tools and services to tailor prevention, diagnosis, treatment and follow-up to each person, while simultaneously cultivating both individual and population health.

Personalised healthcare requires a substantial transformation of the health system, underpinned by radically different ways of providing health and care to populations. Many countries, institutions and international coalitions – such as the European Union or World Health Organisation – have already developed public policies, laws and guidelines to drive this transformation. However, other countries and institutions are at the start of the journey and several others recognise the need to update and refresh plans that were developed several years ago. With this in mind, updated guidance is needed to ensure best practices are incorporated in future plans and initiatives.

Roche launched a multi-stakeholder project to identify the building blocks that underpin personalised healthcare and review how they are addressed in countries' health plans. The building blocks are the underlying units of any health system, which are critical to support personalised healthcare. More than 80 plans from 20 countries were screened and 15 analysed in detail in order to identify the critical building blocks of a holistic and integrated personalised healthcare system plan. These were then validated through a number of expert interviews and of a full-day roundtable with leading experts in precision health and genomics, digital health, public health and health strategy.

The Personalised Healthcare Framework outlines 17 building blocks, themselves composed of 50 elements, that are essential to establish effective and sustainable personalised healthcare:

- **Vision, planning and enablers** – inc. 'strategy and investment', 'patient awareness and empowerment, 'workforce', 'collaboration' and 'system incentives'
- **Health information and IT infrastructure** – inc. 'data legislation, guidance and standards', 'IT infrastructure' and 'data sources and software'
- **Health services** – inc. 'public health and prevention', 'health infrastructure', 'patient-centric care models' and 'integrated care'
- **Health products** – inc. 'legislation, policy and guidance', 'R&D and clinical trial models', 'regulatory frameworks', 'pricing, reimbursement and access pathways' and 'innovative payment models'

The Personalised Healthcare Framework provides a comprehensive and integrated view of the critical building blocks required in any programme of change. It is recommended as a checklist for future planning efforts and personalised healthcare initiatives, and is available on the FutureProofing Healthcare website (<https://futureproofinghealthcare.com/personalised-healthcare>). By showing how different elements are inter-connected, the Framework provides structure and transparency, helping to bring different stakeholders together and demonstrating how their interests and priorities are part of a bigger picture. It also serves as inspiration for national or regional governments establishing or reviewing their own personalised healthcare strategies – it can be used as a checklist to ensure all relevant aspects of personalised healthcare are covered, and to integrate individual aspects that may be addressed in different plans or policies.

By working jointly and learning from existing efforts, we aim to provide a holistic and coherent framework that connects the dots between the various aspects of personalised healthcare, leading to better outcomes for patients and society at large.

Let's build personalised healthcare, together.

## 1. ABOUT PERSONALISED HEALTHCARE

People are living longer and more fulfilling lives, but also age and, as a result, experience chronic disease. Because of the growth of universal healthcare, more individuals – healthy and frail, affluent and vulnerable – now have access to care that falls within the remit of governments, who need to factor in their diverse requirements. In addition, better diagnosis and other technologies provide more insights into pathologies and therefore in the ways to treat them.

With overall healthcare expenditure increasing, many have expressed concerns about the sustainability of current health systems, focusing on causes as diverse as inefficiencies in care settings, affordability of innovative treatments, wastage and end of life care. Paradoxically, spending a larger share of public spending on health does not always improve equity or quality of health services. This highlights the need for a more precise, evidence-based approach to health that is tailored to individuals and improves their outcomes in a way that can be managed by health systems over the long-term.

Transformative advances in genomics, understanding of health behaviours, data science and digital technologies make it possible to generate and analyse clinical, genomic and other forms of health data and to derive meaningful insights from these. These insights can be used by health systems to improve care and optimise the allocation of resources, by researchers and manufacturers to drive more targeted and efficient R&D, by healthcare providers to offer more personalised care, and by patients to become more empowered, compliant and monitor their own health.

From “precision medicine” to “integrated care”, numerous terms have been used to describe this new approach to “personalised healthcare”, defined as “a shift from one-size-fits-all treatment of disease to maintaining high and healthy quality of life over the lifespan by applying the right health interventions for the right person at the right time. An ideal personalised healthcare system involves the collection and analysis of meaningful health data at scale and the integrated use of tools and services to tailor prevention, diagnosis, treatment and follow-up to each person, simultaneously cultivating both individual and population health.”

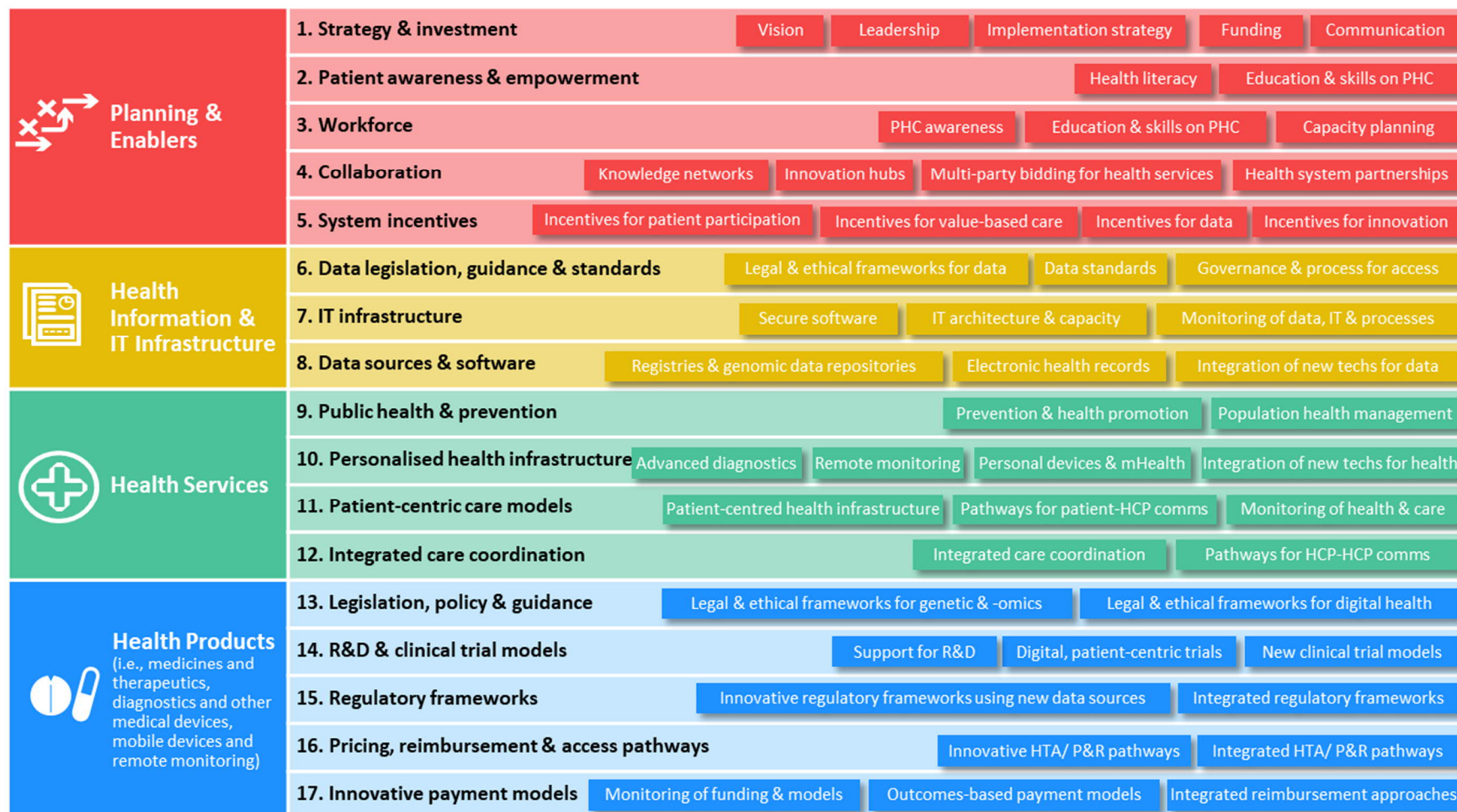
## 2. BUILDING BLOCKS OF PERSONALISED HEALTHCARE

Personalised healthcare is precise in its application but takes a broad range of factors and stakeholders into consideration. Accordingly, for governments and other stakeholders to build the right environment for personalised healthcare requires inter-connected policy building blocks – these differ in scope and maturity, but jointly create an ecosystem in which health can become more personal. The management consultancy Kearney, sponsored by Roche, set out to identify these building blocks (**Figure 1**). More than 80 plans from 20 countries were screened and 15 analysed in detail in order to lay out the building blocks. These were then validated over the course of 12 interviews and of a full-day roundtable with leading experts in precision health and genomics, digital health, public health and health strategy. This framework can form the basis of a national or regional strategy for personalised healthcare.

### Vision, Planning and Enablers

An over-arching strategy and political commitment constitute the essential first step towards realising personalised healthcare. Increased awareness of health-related issues and solutions, of the power of digital and data, and of personalised healthcare in general, will help activate a community of engaged stakeholders. A structured, comprehensive approach to capability development and human resources is essential in any health system, let alone in those undergoing rapid transformation from the personalisation of healthcare – given the expanding number and remit of stakeholders in healthcare, most people involved in health will require new skills. Integration and collaboration are well understood to be the cornerstones of healthcare in general, and of personalised healthcare specifically – yet there is scope to make these broader, more systemic. Well-planned incentives can support a shift towards value-based health.

**Figure 1. Building blocks of personalised healthcare**



## Health Information and IT Infrastructure

Although the importance of data to improve health and care for individual patients has long been understood, the full potential of data is yet to be seen in healthcare. In addition, the exponential growth of data sources has led to inconsistencies in formats, quality and interpretation, limiting the value that is realized. Health systems rely on their IT systems, requiring them to be effective and secure in order to enable the day-to-day operations. However, personalisation of healthcare requires certain aspects to be established, e.g. real-time insights and linkage of health and social information. The number and complexity of data sources has been growing, providing unprecedented opportunities but challenges in the collection and use of data.

## Health Services

The importance of public health has long been understood, but in the past decade its connection to the broader healthcare journey and importance for the sustainability of health systems has become clearer. Several technologies are particularly important for the personalisation of healthcare, and need to be seamlessly embedded into existing health system infrastructure to support better processes and outcomes. There are different ways of putting people at the center of their health and of ensuring that the best outcomes and quality of life are achieved. The large number of stakeholders (e.g. payers, administrators, HCPs, patients) involved in people's health requires the integration of multiple domains and community involvement, but this can be complex and few health systems have done this successfully.

## Health Products and Technologies

Legislations and policies are being developed at the international, national and local levels to frame the development and use of new health products – these should be harmonised and flexible enough to account for the rapidly-changing nature of technology. Research is at the core of all health strategies, but with personalised healthcare it is undertaken by a vast array of private and public stakeholders. Regulatory frameworks have been undergoing numerous changes in recent years, with several testing more adaptive methods to evaluate the safety and efficacy of new technology. Pricing and reimbursement pathways – many of which involve health technology assessment (HTA) – determine access to products on the basis of the value delivered to patients and health systems. With health becoming increasingly consumer-centric and new players becoming involved, new payment models can ensure health system sustainability through payment connected to delivered outcomes.

## 3. MAPPING OF PERSONALISED HEALTHCARE PLANS

Personalised healthcare requires a substantial transformation of the health system, underpinned by radically different ways of thinking about health and providing health and care to populations. Public policies, ranging from laws and guidelines to funding and infrastructure, are therefore needed to drive this transformation. Without these, decades may be needed before the full benefits of personalised healthcare can be realized and people are able to lead healthier, happier lives.

Many governments have begun to lay the groundwork for personalised healthcare through strategies on genomics, digital health and cancer control. Although precision medicine and genomics plans are the most obvious vehicle for some of these recommendations, oncology plans – by focusing on population-based prevention, better diagnostics and targeted therapies – have also helped make substantial headway towards the personalisation of healthcare for cancer patients. Several international institutions are also driving the discussion, indirectly developing a more robust approach to personalised healthcare: notably, the European Data Strategy and World Health Organization's Global Digital Health Strategy provide structure around digital health. Through their ambitious scope yet pragmatic recommendations, these plans could foster similar clarity across other aspects of personalised healthcare.

Many healthcare systems are implementing parts of personalised healthcare, typically via dedicated strategies or action plans. A long-list of 81 plans from 21 countries was therefore screened to provide insight on different countries approaches to enabling personalised healthcare, and to identify the building blocks

that they chose to target. These included 27 digital health plans, 20 health plans, 10 cancer plans, 11 precision medicine plans and 13 other plans.

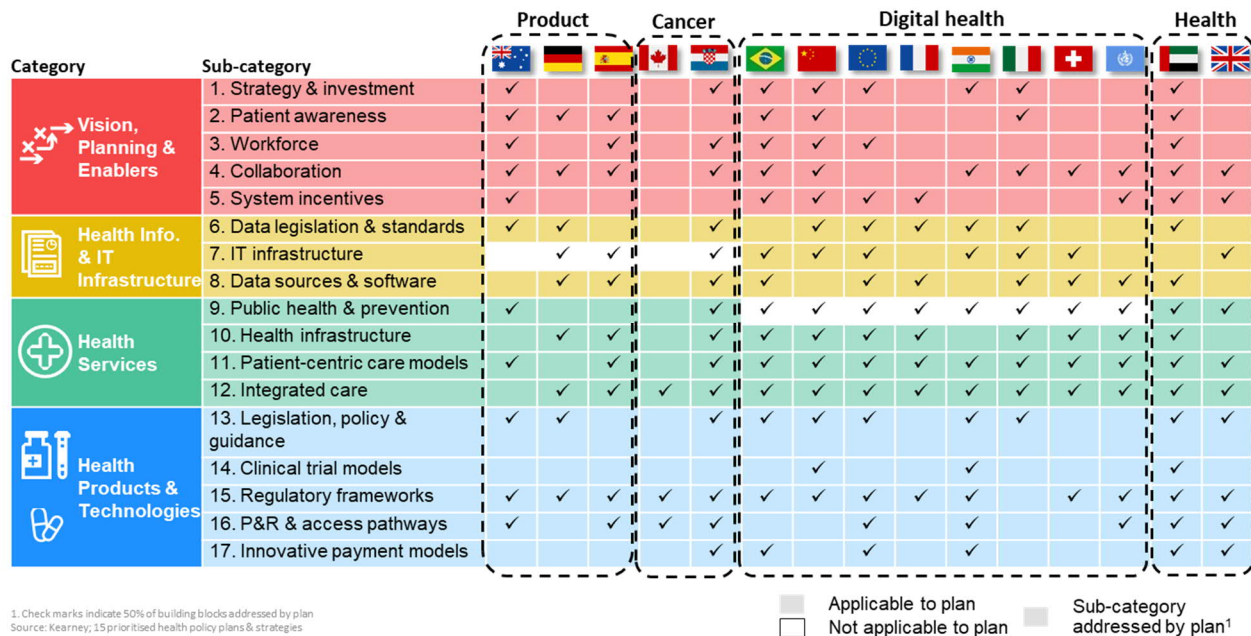
Plans were prioritised on the basis of comprehensiveness, date and actual impact to ensure their relevance, but were expanded to include less detailed plans that would promote diversity (e.g. different types of plans, different health systems or regions). Fifteen plans from across the globe were then reviewed and gaps in expected building blocks for each type of plan were identified (Figure 2).

**Figure 2. Prioritised plans for review**

Plan name	Country / region	Type	Year
National Health Genomics Policy Framework & Implementation Plan	Australia	Precision medicine plan	2017
National eHealth Strategy	Brazil	Digital health plan	2018
Canadian Strategy for Cancer Control	Canada	Cancer plan	2019
Implementation Guide for Facilitating & Standardizing the Development of Big Data Application in Health and Medicine	China	Digital health plan	2016
National Cancer Plan	Croatia	Cancer plan	2018
Communication on Enabling the Digital Transformation of Health & Care	EU	Digital health plan	2018
E-Health 2020 Strategy	France	Digital health plan	2016
Personalised Medicine - Action Plan	Germany	Precision medicine plan	2013
National Digital Health Blueprint	India	Digital health plan	2019
Sicily Digital Health Agenda	Italy	Digital health plan	2018
Dubai Health Strategy 2021	United Arab Emirates	Health plan	2016
National Plan for Advanced Therapies	Spain	Precision medicine plan	2018
eHealth strategy 2018-2022	Switzerland	Digital health plan	2018
NHS Long-term Plan	United Kingdom	Health plan	2019
Action Plan for the Global Strategy on Digital Health 2020-2024	WHO	Digital health plan	2019

By virtue of their focus, different plans were expected to address different building blocks. Overall, health and digital health plans were the most comprehensive but also top-level, tending to cover most of the expected building blocks in minimal detail. Cancer and solution-specific plans (i.e. covering genomics or targeted therapies) were more sporadic in the topics they covered, suggesting that fewer of the broader aspects of personalised healthcare are covered in these strategies (Figure 3).

**Figure 3. Comparison of plans**



When comparing all of these plans side by side, the following findings emerged:

- **Human building blocks** – the objectives of most plans center around people, highlighting the value of collaboration and participation; in practice, however, few plans dig deeper into the necessity of behavioural change, change management, advanced communication efforts, and even more structured capability development efforts that are needed to implement personalised healthcare.
- **Financial building blocks** – although cost and sustainability feature in a number of strategies, especially over-arching ones, the impact of system incentives and the need for financial models is barely touched upon; although many of these topics are no doubt addressed in other types of conversations (e.g. budget planning), they need to be elevated to the policy level to ensure that decision-makers are informed of health systems' gaps and approaches to fill these for personalised healthcare.
- **Health product and technology building blocks** – generally, these tend to be covered (especially in dedicated plans) quite robustly for individual products or technologies; however, few strategies consider the links across all technologies and how these can optimally be connected to inform better health decisioning.
- **Level of detail** – although most of the plans cover most building blocks to some extent, very few (except the solution-specific and digital health plans) go into the details of specific building blocks; the loss of some of these subtleties can translate into policies that are insufficiently robust or flexible, trying to address precise challenges with blanket solutions.
- **Integrated approaches to personalised healthcare** – while many elements are covered across the different types of plans, a truly integrated approach to personalised healthcare is often lacking. Moreover, many plans do not fully consider how the different building blocks can optimally enable personalised healthcare.

#### 4. EXPERT REFLECTIONS ON THE PERSONALISED HEALTHCARE BUILDING BLOCKS

Four success factors are essential for policy plans to measurably foster personalised healthcare:

- **Purpose** – beyond promoting the personalisation of healthcare, plans should focus on enabling overall health. This means emphasizing personalisation as a tool rather than as an objective in and of itself, and establishing it as the next evolution of the healthcare system rather than as a standalone discipline. This should also entail reviewing its intended and unintended consequences to ensure an overall positive impact on people's health and system sustainability, thereby fostering long-term trust and buy-in from a broad range of stakeholders.
- **Local context** – personalised healthcare strategies should reflect the uniqueness and maturity of their country's health system. This means that different building blocks may be necessary across different nations, that the same building block may be implemented differently, and that the legacy health system should inform the application of personalised healthcare – allowing the health system to deliver not only on its old promises (e.g. protection against infectious diseases, management of non-communicable diseases), but also on the new ones (i.e. health promotion and prevention, targeted therapies, remote monitoring, etc.).
- **Implementation** – although many plans lay out the overall direction, few provide implementation strategies with the right level of granularity and many are not devised with those who are expected to run personalised healthcare on a day-to-day basis. It is therefore essential for those with decision-making power to co-create implementation roadmaps with those who will be implementing the strategy, to ensure ideas become reality. Stakeholder engagement planning should be a key component of this.
- **Integration** – while many building blocks are covered in individual policy plans and can, if reviewed jointly, provide a nearly-comprehensive strategy for personalised healthcare, today a truly integrated

approach to personalised healthcare is lacking across most countries. Patients or professionals operating in one field (e.g. oncology) may therefore not have all the tools needed if these are addressed as part of a different strategy (e.g. a digital plan), which reduces the impact of personalised healthcare and prevents people from seeing its full benefits. Without necessarily resorting to the development of a complete standalone personalised healthcare plan, there should be a systematic effort to connect the dots across existing or planned strategies, and provide guidance on using these in a coordinated manner.

## **5. CONCLUSION AND PUTTING THE BUILDING BLOCKS INTO PRACTICE**

The potential for personalised healthcare to improve people's lives while ensuring health system sustainability is high, yet adoption of new technologies and ways of working remains in its early stages even in the most advanced health systems. The scale of change needed is truly transformational in nature, and requires an integrated approach to ensure that patients and society can eventually benefit from its value. This can only be achieved through extensive collaboration between governments, healthcare and non-healthcare professionals, citizens and patient associations, academia, NGOs, industry and others.

The Personalised Healthcare Framework provides a comprehensive and integrated view of the critical building blocks required in any programme of change. It is recommended as a checklist for future planning efforts and personalised healthcare initiatives, and is available on the FutureProofing Healthcare website (<https://futureproofinghealthcare.com/personalised-healthcare>). By showing how different elements are inter-connected, the Framework provides structure and transparency, helping to bring different stakeholders together and demonstrating how their interests and priorities are part of a bigger picture. It also serves as inspiration for national or regional governments establishing or reviewing their own personalised healthcare strategies – it can be used as a checklist to ensure all relevant aspects of personalised healthcare are covered, and to integrate individual aspects that may be addressed in different plans or policies.

Additional materials will be available on the Future Proofing Healthcare website. These include detailed descriptions of the building blocks and examples of countries where they have been applied successfully; and a comparison of how the building blocks are addressed across 15 policy plans. These resources can be used to adopt an aligned terminology and consistent approach to strengthen personalised healthcare across all countries and health systems. They will evolve in response to feedback and application of healthcare's numerous stakeholders, providing a dynamic forum to learn about and develop personalised health.

Only by using an integrated approach and targeting the underlying building blocks of personalised healthcare can the radical change needed for personalised healthcare take place to improve population health and wellbeing.

## **6. ACKNOWLEDGEMENTS**

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**Vision, Planning and Enablers****1. Strategy and investment**

An over-arching strategy and political commitment constitute the essential first step towards realising personalised healthcare.

- A **'vision'** for personalised healthcare requires a strong understanding of what is covered by "personalised healthcare", a clear vision that is co-created with national, regional and local stakeholders, and active communication efforts to disseminate the vision to all relevant stakeholders.
- **'Informed leadership'**, entailing the right knowledge and skills across decision-makers, is needed to foster bottom-up and top-down change.
- It is then important to develop an actionable **'implementation strategy'** and change management, which should be explicit and action-oriented, but flexible enough to reflect the dynamic environment of healthcare and individual health systems' maturity.
- Governments should also allocate long-term, sufficient and sustainable **'funding for personalised healthcare'**, providing investment for areas that deliver proven value (i.e. reimbursing innovating technologies while de-commissioning obsolete ones) or transformative innovation (e.g. genomics).
- A simple, impactful **'communication'** strategy around personalised healthcare helps to make the case for this and emphasize the benefits to patients and society, fostering buy-in and involvement.

**2. Patient awareness and empowerment**

Increased awareness of health-related issues and solutions, of the power of digital and data, and of personalised healthcare in general, will help activate a community of engaged stakeholders.

- **'Health literacy'** and understanding of the personalised healthcare ecosystem are important for people to take ownership of their health, extending beyond patients to include the general population and help all citizens understand their role in health management from prevention to end of life.
- This should be supplemented with **'education and skills'** for patients, e.g. on digital, data and personalised healthcare. It can help ensure that people are comfortable using digital health, sharing their data and providing consent accordingly, or understanding the risks and benefits of different choices in healthcare.

**3. Workforce**

A structured, comprehensive approach to capability development is essential in any health system, and even more so in those undergoing rapid transformation from the personalisation of healthcare – given the expanding number and remit of stakeholders in healthcare, most people with some involvement in health will require new skills.

- It is important to build **'HCPs' and other professionals' awareness'** of the personalised healthcare ecosystem, so that they (including social workers, educators, etc.) gain a more comprehensive view of their role, responsibilities and potential in adopting a holistic, multi-modal view of people's health.
- A more technical programme should target **'education and training for HCPs and other professionals'** on digital, data and personalised healthcare skills, via hands-on, practical capability development for HCPs but also regulators, government stakeholders, social workers, etc.
- This can be conducted as part of **'capacity planning'** and forecasting for a multi-disciplinary workforce to recruit or train as needed.

**4. Collaboration**

Collaboration is well understood to be the cornerstone of healthcare in general, and of personalised healthcare specifically – yet there is scope to make it broader and more systemic.

- **'Knowledge networks'** and best practice sharing mechanisms on technologies and solutions in personalised healthcare are already being set-up and should continue to develop, bringing together patients, HCPs, academia, innovators, etc. across institutions and geographies.
- Active **'innovation hubs'**, incubators and accelerators can offer a hotbed for some of these skills and professionals, provided said centers of excellence are well funded and foster both pilots and scaling efforts.
- Stronger ties between public and private stakeholders should also be fostered through the ability of **'any willing and suitable provider'** – including private enterprises, patient associations and other non-government entities – to bid to provide personalised healthcare services or products (e.g. electronic health records [EHRs]).
- Underpinning these networks, hubs and tenders should be **'health system partnerships'** to establish the full range of healthcare services and products with a clearly-defined purpose, governance and standards. These can help bridge gaps in funding and skills from either side, spurring creativity.

### Strategy and investment

As part of the Australian Genomics Health Futures Mission, significant funding and investment was committed to improve genomic medicine in Australia. This amounted to \$500 mn investment for this 10-year initiative.

In 2016, the French government dedicated €2 billion commitment to eHealth, making it a key axis into its national health strategy.

## 5. System incentives

Appropriately-planned and -implemented incentives can help support a shift towards value-based health.

- System **'incentives for patient'** participation, adoption and compliance should span the entire patient journey, offering declining co-payments or subsidies to foster behaviours that improve people's health.
- Specific **'incentives to support the shift from volume to value-based care'** will uplift the importance of prevention and population health, encourage multi-disciplinary collaboration in the delivery of care, drive efficiencies (e.g. by eliminating waste) and improve outcomes.
- Monetary and non-monetary benefits can be magnified through data, making **'incentives for data'** collection and sharing essential. These can build a stronger evidence base, for example by fostering higher EHR completion by HCPs, use of monitoring devices by patients or general sharing of data.

## Health Information and IT Infrastructure

### 6. Data legislation, guidance and standards

Although the power of data to improve health and care for individual patients has long been understood, the full potential of data is yet to be seen in healthcare. In addition, the exponential growth of data sources has led to inconsistencies in formats, quality and interpretation, limiting the value that is realized.

- Transparent **'legal and ethical data frameworks'** are needed for the effective management of health and genomic data, providing guidance on how it is collected and used and addressing privacy, security requirements, secondary uses of data for general, research and personal use, etc. These frameworks should be robust enough to protect patients, but flexible enough and aligned where possible, to reflect the evolving nature of data technologies.
- Clear **'data standards'** to support collection, linkage, analysis and storage can help ensure that data is interoperable and remains of a high quality – common data models, use of personal health identifiers, open-access standards and certifications are being tested to provide guidelines within which to operate.
- Beyond managing data itself, **'governance and processes for access'** are needed. Transfer and sharing processes for health data should ensure data is secure and used properly, allowing patients to access their own data, share it as needed (including for secondary uses) and enable cross-border

collaboration. There should also be more clarity around how data controllers are allowed to use, share and/or transfer data within their use.

## 7. IT infrastructure

Health systems rely on their IT systems, requiring them to be effective and secure in order to enable the day-to-day operations. However, to enable personalisation of healthcare requires certain specific aspects to be established.

- User-friendly, **'secure software'** is needed to collect, access and share health data, evolving beyond the antiquated technologies that underpin administrative tasks towards dynamic tools that facilitate data collection.
- More broadly, **'health IT architecture and systems'** need to be co-defined and implemented using both private and public input. This should allow for dedicated models of information, a common lexicon to promote interoperability, and sufficient computational capacity to manage complex operations and store large amounts of data.
- Regardless of the IT infrastructure in place, there should be systematic **'monitoring of data, IT and processes'**, to ensure that systems and processes are fit-for-purpose to deliver personalised, data-enabled care.

### IT infrastructure

A unique personal health identifier is issued to all Danish citizens at birth alongside a secure electronic-ID for online EHR access. This links patient details to one of the 15 interoperable EHR systems and alerts patients by email if an HCP views record

In the US, the All of Us Research Program aims to gather data from 1+ million people to accelerate research and improve health.

## 8. Data sources and software

The number and complexity of data sources has been growing, providing unprecedented opportunities but also leading to challenges in the collection and use of data.

- High-quality, connected data sources – including but not limited to **'registries and genomic data repositories'**, claims databases and prescription data, etc. – can offer value to any health system and should continue to be funded and made accessible within and across borders.
- **'EHRs'** are increasingly pooling information from traditional data sources and being supplemented with less traditional ones. These need to be available for patients, healthcare professionals, clinical care and – in a manner that ensures patient privacy and data protection to support research – development. Clear governance for access and integration with non-health data must also be put in place, to ensure data privacy and optimal use.
- The collection and use of data can be measurably improved through the **'integration of new technologies'**, such as machine learning technologies to clean and enrich data, or other techniques to ensure access to data while preserving data privacy. Data analytics has already come a long way in recent years, but machine learning and artificial intelligence (AI) are expected to further enrich this by deriving insights into the development of diagnostics and molecules and the delivery of healthcare.

## Health Services

### 9. Public health

The importance of public health has long been understood, but in the past decade its connection to the broader healthcare journey and importance for the sustainability of health systems has become clearer.

- Public health should be treated as an integral part of healthcare, embedding **'prevention and health promotion'** into people's lives regardless of whether they are affected by disease through early detection and screening, follow-up for disease prevention, etc. Screening campaigns and better, more systematic health communication can build on growing health awareness.

- A data-enabled approach to **'population health management and risk stratification'** (also called "precision public health") allows to identify those most at risk and customise interventions to specific groups. This is particularly essential given growing amounts of information on people's behaviours, risk factors and their impact on health.

## 10. Personalised healthcare infrastructure

A number of technologies are particularly important for the personalisation of healthcare, and need to be seamlessly embedded into existing health system infrastructure in order to support better processes and outcomes.

- Widespread use of best practice **'advanced diagnostics'** will identify underlying risk factors (e.g. genetic profiles) and conditions, helping to foster early detection and prevention and recommend better health interventions and, where needed, treatments. This should include comprehensive genomic profiling and next-generation sequencing, as well as advanced imaging and other diagnostic techniques.
- Personalised healthcare is also about health systems' ability to address their individual patients' needs. Widespread use of **'remote monitoring and telehealth'**, for example through digital consultations and sensors, can help access more remote (e.g. rural) or vulnerable (e.g. elderly) populations, keep care in the community and optimise resource allocation in the health system.
- Beyond health, **'personal and mobile devices'** are essential to support prevention, communication, treatment and recovery. Due to their omni-present use and supplemented with remote monitoring devices and sensors, these technologies can pool vast amounts of health and non-health data (e.g. geolocalisation), for better health insights overall.
- All of this can be further facilitated by the **'integration of new technologies to improve the health journey'**, e.g. using automation to make care more efficient, using augmented reality for alternative treatment options and using AI to optimise quality of care, to triage patients or plan care provision, clinical decision support to provide HCPs with better evidence to treat patients, or augmented reality to manage depression or rehabilitation.

### Personalised health infrastructure & patient-centric care models

In the UK, the NHS provides Babylon Health, a telemedicine service that offers accessible preventative consultations and diagnostics (e.g. RR, pulse) via an app. It also includes integrated point-of-care tests & referrals between app, local GPs and other providers.

In the Netherlands, an integrated diabetes care system connects all relevant care providers. With a single point of entry into the program, it provides a coordinated, multi-disciplinary approach and bundled payment for diabetes since 2007.

## 11. Patient-centric care models

There are different ways of putting people at the center of their health and of ensuring that the best outcomes and quality of life are achieved.

- A **'patient-centred infrastructure'** for health can be enabled by having the right set-up and technologies in place (e.g. clinical decision support), as well as active patient and patient association involvement. It should entail having the right consent frameworks to foster patient ownership of their health, establishing appropriate care centres and specialists where patients need them, and using dynamic labelling to provide patient-relevant product information.
- Systems and tools for continuous **'communication between patients and professionals'** should be in place across and within settings of care, connecting patients and their families to HCPs and the full range of the patient support network.
- **'Monitoring of healthcare provision'**, quality of processes and patient-reported outcomes is particularly essential in the current, rapidly-evolving health setting, requiring the use of both clinical and patient-reported outcomes to track performance and remove low-benefit practices.

## 12. Integrated care coordination

The large number of factors and stakeholders (e.g. payers, administrators, HCPs, patients) involved in people's health requires the integration of multiple domains, but this can be complex and few health systems have done this successfully.

- Stronger **'coordination of prevention, acute care and chronic management pathways'** via the integration of care pathways should build transparency and efficiency in the patient journey. This bridging of settings of care and specialties should retain clear accountabilities and information flows.
- In addition to this, systems and tools for continuous **'communication between HCPs and other professionals'** is critical to ensure that patients' information and outcomes are addressed in a timely, secure and seamless manner by those in both formal and informal care networks.

## Health Products and Technologies

### 13. Legislation, policy and guidance

Legislations and policies are being developed at the international, national and local levels to frame the development and use of new health products – where possible, these should be harmonised and flexible enough to account for the rapidly-changing nature of technology.

- **'Legal and ethical frameworks for genetics, genomics and other -omics'** should be developed to ensure that gene editing and the collection, use, sharing and secure storage of genomic and other -omic information is conducted in a transparent, ethical and fair manner, minimising ill effects on individuals and society.
- With the growing use of mobile health, **'legal and ethical frameworks for digital health'** are also being drafted to address topics such as ownership, accountability (e.g. around clinical decision support or machine learning), or jurisdiction (e.g. if patients undergo consultations with expert sin other countries).

### 14. Clinical trial models

Research is at the core of all health strategies, but with personalised healthcare it is undertaken by a vast array of private and public stakeholders, ranging from academia and life science companies to start-ups and large tech companies.

- In addition to ongoing investment from private entities, government **'support for R&D'** should co-fund continued innovation and, eventually, translation of research findings into clinical practice (as outlined by health system decision-makers).
- Recent years have seen improvements in the quality, breadth and efficiency of research through the use of **'digital, patient-centric trials'** which provide timely, relevant insights into patient preference and outcomes. The use of digital and patient engagement should continue to be explored and improved.
- **'New clinical trial models'** – such as single-arm, basket or adaptive trials – are used to collect clinical data on targeted and personalised treatments and to address challenges in traditional clinical development, such as small target populations and slow recruitment. These models should continue to be used and improved, so that quality results can feed into regulatory frameworks and pricing and reimbursement pathways.

### 15. Regulatory frameworks

Regulatory frameworks have been undergoing numerous changes in recent years, with several – notably in the US and Europe – testing more adaptive methods to evaluate the safety and efficacy of new technology. Although these tend to focus on medicines and, to a lesser extent, on medical devices, there is a growing call to expand such frameworks to digital technologies (e.g. apps, software, etc.).

- **'Adaptive regulatory frameworks using new data sources'** can increasingly be used, using diverse types of information – real-world evidence, digital endpoints, modelled evidence and others – to complement clinical trials and provide an iterative view of health products' safety and efficacy.
- Given the breadth and interconnectedness of new technologies, **'integrated regulatory frameworks'** are needed to evaluate integrated health solutions, i.e. combinations of medicines, diagnostics and digital technologies, tailored to the individual patient.

### 16. Pricing, reimbursement and access pathways

Pricing and reimbursement pathways – many of which involve health technology assessment (HTA) – determine access to products on the basis of the value that they deliver to patients and health systems.

- **'Fit-for-purpose HTA, pricing and reimbursement pathways'** are needed to take into account a complete evidence package that support products' value – including but not limited to patient-reported outcomes and preferences, real-world evidence, surrogate endpoints, etc.
- Beyond this, it is also important to move towards **'integrated HTA, pricing and reimbursement pathways'** to evaluate integrated health solutions and to consider them as part of the joined-up ecosystem to which they belong, rather than as standalone technologies with only medical impact.

### 17. Innovative payment models

With health becoming increasingly consumer-centric and new players becoming involved, new payment models have arisen that provide unprecedented opportunity to ensure health system sustainability through payment connected to delivered outcomes, adaptive to local, regional needs and readiness.

- Regardless of commercial arrangements in place, **'monitoring of funding, payment models'** and procurement practices is key to ensure that sufficient resources are allocated to the right health products and services. Evaluations should be transparent, continuous, and reflect health systems' needs.
- Data-enabled **'outcomes-based payment models'** for health products and services should be considered where relevant, to ensure that risks can be appropriately shared, while evidence is being gathered, and compensation is based on actual value delivered to patients and health systems.
- A broader take on funding for health products and services is also needed, with a move towards **'integrated reimbursement approaches'** that cover populations rather than individuals, as well as value-based bundles rather than standalone health products or services – this will entail adopting a more long-term and value-based mindset that extends beyond current health specialties.

### Regulatory frameworks & funding

The US FDA 21st Century Cures Act in 2016 entailed the creation or revision of regulatory policies to speed patient access to new and breakthrough medical devices. It addressed discovery, innovation, delivery, support and financing of new cures and devices.

Italy has been implementing outcomes-based reimbursement models for innovative drugs, staggering payment based on whether pre-set threshold are met or outcomes achieved. These have been shown to significantly reduce time to market.