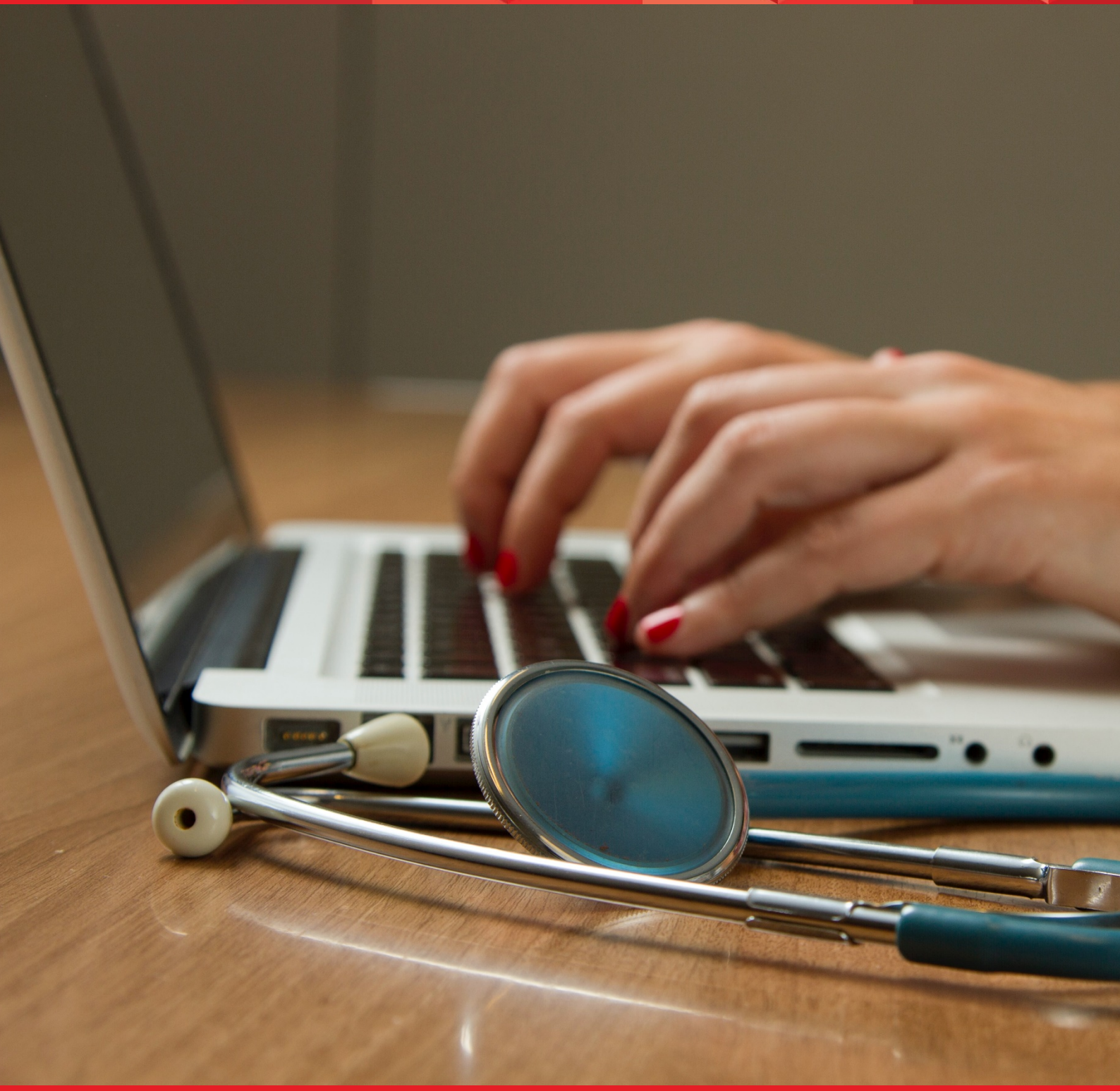
THE LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE

The Role of Virtual Health Care and the Pharmaceutical Sector in Improving Population Health

Bregtje Kamphuis, Jennifer Gill, Michelle Vogelzang, Madeleine Haig and Panos Kanavos | June 2021



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Abbreviations

ACA	Affordable Care Act
AI/ML	Artificial Intelligence and Machine Learning
AIDS	Acquired immune deficiency syndrome
AF	Atrial fibrillation
AHSN	Academic Health Science Networks (UK)
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (DE)
CCG	Clinical Commissioning Group
CDE	Certified diabetes educators
CDRH	Center for Devices and Radiological Health
CMS	Center for Medicaid and Medicare Services
DE	Germany
DHCoE	Digital Health Center of Excellence
DiGA	BfArM's App Directory
DRG	Diagnosis Related Group
DPP	NHS Diabetes Prevention Programme (UK)
DTAC	Digital Technology Assessment Criteria (UK)
DVG	Digitale-Versorgung-Gesetz (Germany's Digital Supply Act, DE)
DVPMG	Digital Healthcare and Nursing Care Modernization Act (DE)
ECG	Electrocardiogram
EMR	Electronic Medical Records
FDA	Food and Drug Administration
FTC	Federal Trade Commission
GDPR	General Data Protection Regulation
GMLP	Good Machine Learning Practices
GK	Gesundes Kinzigtal
GKV	Social Health Insurance (DE)
HHS	US Department of Health and Human Services
HIN	Health Innovation Network (UK)
HIPPA	Health Insurance Portability and Accountability Act of 1996
HITECH	Health Information Technology for Economic and Clinic Health Act
ICS	Integrated care systems
MHRA	Medicines and Healthcare Products Regulatory Agency (UK)
MIB	Medtech innovation briefing
NICE	The National Institute for Health and Care Excellence (UK)
NHS	National Health Service (UK)
NPS	Net Promoter Survey
ONC	Office of the National Coordinator for Health Information Technology
PH	Population health
PHM	Population health management
PHV	Private Health Insurance (DE)
SaMD	Software as a Medical Device
STP	Sustainable Transformation Partnerships
UK	United Kingdom
US/USA	United States of America
VA	Veterans Administration (USA)

Executive Summary

Objectives and methods

The objective of this report is threefold: first, to understand the role and value of the pharmaceutical sector within the use of virtual/digital health care (VHC) to improve population health; second, to create awareness and identify some of the key policy issues to address in order to ensure a diverse and competitive market in VHC which benefits patients and health systems; and third, to highlight opportunities for partnership with key stakeholders, including policy-makers, purchasers, VHC players, key experts, health care professionals and patients.

This report draws on both primary and secondary research to explore how VHC can improve population health management within the thematic scope of diabetes and cardiovascular disease across the three health system archetypes: a tax-based system (United Kingdom), a social insurance-based system (Germany), and a predominantly privately funded system with multiple insurers and significant public funding (the United States). Primary data collection was informed by interviews with key experts and material from a policy roundtable, organised by LSE, which focused on key challenges of Population Health Management from a health system perspective, the potential value-added of virtual health to population health management as well as the potential role of the pharmaceutical industry. The roundtable also included a co-creation session on shaping a short- and long-term policy agenda to address challenges and opportunities in using virtual health care to address population health.

Population health

Whilst there is no single accepted definition of population health (PH), the concept covered here includes the health outcomes of a group of individuals, including the distribution of such outcomes within the group, as well as a methodology for identifying those at risk of ill health (both physical and mental) and the application of the appropriate interventions for prevention or care and rehabilitation. It balances the intensive management of those in the greatest need of health care with preventative and personal health management for those at lower risk levels. In order to function effectively, six components of PH are key: data aggregation, patient satisfaction, care coordination, patient engagement, performance reporting, and good administration. Population health management (PHM) works towards improving PH by data-driven planning and delivery of proactive care to achieve maximum impact via segmentation, stratification and impact modelling to identify local 'at risk' cohorts. The resulting targeted interventions prevent ill-health, improve care and support for people with ongoing health conditions and reduce unwarranted variations in outcomes.

PH for healthcare systems and gaps

A move from a reactive to proactive illness prevention is the future of healthcare systems as life expectancy increases and chronic conditions become more frequent. Pre-existing weaknesses and gaps in many healthcare systems, including shortages of clinical supplies and personnel, underinvestment in the public health infrastructure, and a lack of coordination and agility amongst policy makers, political authorities and healthcare systems may reduce the impact PH could have.

To be effective, PH requires robust holistic and longitudinal patient data to allow clinicians to address acute and chronic conditions at the same time as expanding their focus to identify all individuals in their patient population with potential conditions. This allows healthy patients to remain healthy alongside the monitoring of at-risk patients. Virtual healthcare (VHC) has a space in helping care providers efficiently and

cost-effectively aggregate and analyse patient data, facilitate care coordination and enable patient communication, self-management, and education to maximise the potential of PH. In the 21st century the health care landscape is primed for the expanded adoption of virtual healthcare and several factors have increased interest including physician shortages, patient/consumer demand, the evolution of the policy landscape to meet patient/consumer demand, and advancing technology. The Covid-19 crisis further accelerated the expansion of virtual healthcare.

VHC interventions: gaps and learnings

Six virtual healthcare case studies set across three study countries (Germany, the United States of America (USA) and the United Kingdom (UK), focusing on England) were reviewed in this report to analyse key policies and practices. Evidence on the case studies showcase positive outcomes across clinical and health measures, patient experience, and cost-saving evidence, suggesting the potential for VHC solutions to contribute to improved population health and cost containment. It is important to note that this is speculative, as existing evidence is limited and often conducted or funded by the technology developer, and there is a wider lack of evidence for many of these interventions across impacts on health outcomes, provider experiences, and impact on costs. Lastly, while the field is saturated with stakeholders, much of the activity in the area is siloed with little evidence of cross-stakeholder collaboration and the possible misalignment of incentives and value-drivers across each stakeholder segment.

Barriers and bottlenecks to VHC and population health management

Although there are clear advantages to both expanding VHC and a health system shift towards population health management, this report identified several barriers and bottlenecks that can be summarised as (a) health system challenges, (b) culture and mindset barriers, (c) regulatory bottlenecks, (d) technical challenges, and (e) stakeholder and trust barriers.

Health system challenges such as general health system set up and existing administrative boundaries can impact the effectiveness of large-scale, digital-based population health. Furthermore, multiple insurers and limited operability between existing systems can result in health system fragmentation barriers. Experts also highlighted the need to change providers' and purchasers' culture and mindsets towards patient self-management, digital innovation, and the value of prevention. In particular, the three systems studied in this report are traditionally seen as reactive, rather than proactive towards the management of disease as they lack an embedded focus on prevention and instead focus on treatment. Covid-19 has supported an increasing openness to virtual health care which is helping shift health systems culture; however, a digital divide still remains. Another cultural barrier is that current health providers are primarily patient-focused organisations, largely leaving population well-being and public health in the domain of other organisations. A shift to the population-level therefore requires system-wide changes in priorities and mindsets around a previously episodic patient relationship.

Regulatory challenges centre around approval pathways for new products as traditional market entry and take up pathways were designed for pharmaceuticals and medical devices. This report found a need to update review processes to include pathways for digital health and prevention products. Further regulatory challenges extend to uncertainty around proving therapeutic benefit with digital devices as well as uncertainty in reimbursement strategies. Technical challenges such as poor investment in technology and infrastructure, insufficient funding, and limited high-level capability and skill threaten the expansion of virtual health. Issues around general health system digital readiness may need to be addressed before any virtual care delivery can be expanded. Digital maturity, including standards for interoperability, data

sharing, and analytical ability to use generated data for decision-making, can signal system readiness to engage of digitally-enabled population health management.

The final barrier to population health management and VHC centres around stakeholders and trust. There are several reasons why there may be distrust between health purchasers, care providers, and industry. To move forward with any intervention there needs to be enhanced cooperation between the pharmaceutical industry, regulators, and healthcare systems. Currently pharmaceutical companies work more closely with regulators than local decision-makers who are essential stakeholders in population health interventions. Thus, industry seeking to enter the population health space will needs to communicate aligned intentions and goals with health systems in order to build trust and establish new forms of engagement.

Aligning stakeholder incentives

Stakeholders including policymakers, manufacturers, purchasers, healthcare providers, and patients are understandably driven by different motivations and values. However, pharmaceutical companies considering a VHC solution should identify how incentives can be aligned to drive take up. The key value drivers for these various stakeholder groups operate within the gaps and challenges associated with virtual healthcare. Country settings and willingness to encourage uptake of VHC also play a role: existing infrastructures may be weak, incompatible, or outdated, and silos or pathways between relevant institutions may be embedded in a deep, historical manner which produces an environment which does not lend itself to fast and easy uptake of novel solutions. Most notably, incentives and value drivers across relevant stakeholder groups vary to a large degree. Notice must be taken to ensure these are not misaligned to a degree where a significant barrier to the necessary collaboration or joint production of efficient and effective solutions is developed.

Opportunities and the potential role of the pharmaceutical industry

As we move further into the 21st century the healthcare landscape is primed for the expanded adoption of virtual healthcare, particularly within the remit of PHM. There is a possible role for the pharmaceutical sector in population-level managed care and virtual health care tools. There is an increasing role for tech companies in health care and health care delivery and opportunities for partnerships beyond health providers and patients will likely increase in the short-term. Broadly, this report found that opportunities for pharmaceutical companies to engage in population health management through digital health include: first, leveraging existing expertise in key therapy areas including rare diseases; second, supporting links between patients and care; third, working with early-stage companies; fourth, supporting collective goals of stakeholders; fifth, gathering data and facilitating real world evidence generation; and, sixth, focusing on emerging markets.

Involvement of the pharmaceutical industry may be well placed at the boundary between care services, facilitating transitions between self-management and primary care as well as between primary and secondary care, or alternatively in offering their knowledge of key diagnoses, products and patient outcomes to support patients at all stages of a disease lifecycle, by improving health literacy and health education. The sector may be well placed to host forums which bring together stakeholders such as patients, patient groups and carers, health care professionals, and regulatory agencies, to identify gaps and challenges, facilitate digital health technologies, and to establish trusted and accepted platforms for providing given types of preventive and therapeutic care. Pharmaceutical sector involvement may also be welcomed in areas supporting rare diseases or indications, particularly those where they have existing

expertise, and in the development of enhanced services for groups subject to stigma and allied forms of rejection.

Short and long-term policy agenda to address challenges and opportunities

When planning to productively engage with key stakeholders, industry should prioritise open and transparent discussions with the public, engaging the public in discussions to establish what is achievable and realistic behavioural change, understanding the allocation and distribution of health care in PHM; and building the case for population health by defining the philosophy behind it and leveraging opportunities created by the pandemic to highlight the potential for PHM.

Experts were adamant that any successful VHC solution to support PHM would be designed from the patient perspective and place patients at the centre. Additionally, early engagement should begin to address any behavioural and technical barriers to the uptake of VHC, such as focusing on interoperability, ensuring there is a systematic measurement framework for the quality of patient experience in VHC, or building clinician confidence in digital platforms. Another action to further mitigate these concerns could be establishing data-sharing agreements, positioning data as a public good, or linking data collection to a medical device. However, even if this were achieved many health care providers and funders are still likely to feel that VHC platforms should not be unilaterally controlled by third parties that have commercial interests in particular products.

Lastly, experts emphasised the importance of trust and transparency. Governments and citizens may be hesitant to take actions that are seen to expand the sector's reach and influence in health by facilitating access to and control over more population data. Furthermore, providers and funders may not wish for VHC platforms to be fundamentally controlled by third parties that have commercial interests in particular products. Successful industry-supported initiatives then need to increase trust by demonstrating a robust understanding of the social and economic determinants of health alongside the bio-medical causes of disease. This includes showing insight into and respect for the value of human relationships in health and social care processes and the role of professionalism in maintaining and improving care quality.

1. Introduction

Healthcare systems across the world are confronting similar challenges that threaten the sustainability of healthcare financing. Systems need to identify inefficient spending and focus on methods to optimize the delivery of high-quality care at reasonable cost. Aging populations have a profound impact on future healthcare costs (Dieleman et al., 2017) and this is often accompanied by a decline in the working-age population. Consequently, systems with pooled resources may be supporting a population with a large older cohort who are more susceptible to needing healthcare while proportionally less is contributed to health system's finances. This phenomenon coexists with other issues to address, such as wasteful spending on care delivery, health inequalities, and fragmentation in care delivery. These disruptive characteristics all contribute to the likelihood of health systems delivering ineffective and inefficient care.

To address these issues, countries need to focus on strategic shifts within health systems, notably, by understanding the needs of patients and the population at large. To achieve closer synergy between supply and demand, countries need to review resource allocation and pursue new models of provision, such as virtual healthcare and population health management. Health systems should also be held accountable for patient and population outcomes through a shift from cost-based payment systems to outcomes-based, and, therefore, value-based healthcare, where healthcare providers are paid based on patient outcomes as opposed to the amount of healthcare services provided (NEJM Catalyst, 2017). Value-based healthcare ensures lower costs and better outcomes for patients, improved patient satisfaction for patients and providers, and better cost control for payers (NEJM Catalyst, 2017).

Population health is increasingly relevant for today's health and care systems and can help address some of these ongoing challenges. It recognises the wider determinants of health – individual behaviour, accounting for 40 to 50% of a person's (or population's) relative health, physical and social environment, accounting for 20%, genetics (10-20%) and medical care (10-20%) (Harris & Skinner, 2019). While population health is not a new concept, attempts to implement the principles around it have been fragmented, with health policy still largely focused on clinical treatment. Population health brings together an understanding of population needs through big data, patient engagement, and health and care delivery based on three principles: prioritizing outcomes over volume of care, prevention (both secondary & primary) over treatment and patient-centred care over episodic care.

Additionally, medical care accounts for 10% to 20% of patient outcomes, but 88% of spend. Interventions impacting other determinants of outcomes (e.g., behavioural and social determinants of health) are critical to improve the spend-outcome relationship. Chronic disease management is complex and requires holistic, patient-centric and – frequently - daily interventions. However, despite the development of new innovative treatments, patients with chronic diseases often struggle with disease self-management and the experience of care can feel complex and disjointed with long periods of self-management between short consultations with healthcare professionals.

Digital technologies have been proven to improve health outcomes for various chronic disease areas, including cardiovascular disease and diabetes (Murray et al., 2016), but there are a limited number of examples of successful incorporation of such interventions into population health management (Soobiah et al., 2020). Following the expansion of virtual health care during the Covid-19 crisis, it is predicted that

digital health will see significant growth in the next few years with up to $250 billion of current US healthcare spend having the potential to be made virtual. Whilst impressive, this shift is not a foregone conclusion and will require new ways of working for all stakeholders, as well as new partnerships with industry (Bestsennyy et al., 2020). Looking ahead, healthcare players, such as the pharmaceutical industry may wish to consider investment now that will support such a shift and improve their future position.

1.1. Objectives

The objective of this report is threefold: first, to understand the role and value of the pharmaceutical sector within the use of virtual/digital health care (VHC) to improve population health; second, to create awareness and identify some of the key policy issues to address in order to ensure a diverse and competitive market in VHC which benefits patients and health systems; and third, to highlight opportunities for partnership with key stakeholders, including policymakers, purchasers, VHC players, key experts, health care professionals and patients.

The report is structured as follows: Section 2 describes the methodology; Section 3 provides an overview of the concepts and definitions of population health, population health management, and virtual healthcare; Section 4 outlines key policies and practices for population health and VHC in three health system archetypes (Germany, the UK and the USA); Section 5 presents six case studies from these health systems that incorporate virtual health care or population health; Section 6 presents findings from roundtable discussions and discusses the use of digital technology for population health, with a particular focus on the role that the pharmaceutical sector and other stakeholders can play in the use of digital technologies; and Section 7 provides overarching conclusions.

2. Methodology

This report draws on both primary and secondary research to explore how VHC can improve population health management within the thematic scope of diabetes and cardiovascular disease across the three health system archetypes: a tax-based system (United Kingdom), a social insurance-based system (Germany), and a predominantly privately funded system with multiple insurers and significant public funding (the United States).

Primary data collection

An essential component of this research is the primary data collection which was conducted to enhance the report with further insights and input on the role of the pharmaceutical sector in improving population health through virtual healthcare. Experts and stakeholders were selected through the network of the Medical Technology Research Group at the LSE and included representatives from the broader stakeholder community (patients, health care system representatives and academics).

Three interviews were conducted with expert professionals. One interviewee was a patient engagement expert specialised in growing digital health ecosystems and supporting market development, and the other interviewees were experts in strategic health decision making. These interviews covered issues related to virtual healthcare and population health management with the aim of triangulating the information found through desk research and obtain expert insight into the practical implementation of these solutions and the role of the pharmaceutical industry.

Additionally, eight experts and stakeholders participated in a policy roundtable discussion with members of the Medical Technology Research Group and client representatives. The roundtable stimulated discussion on an early draft of this report and focused on key challenges of Population Health Management from a health system perspective, the potential value-added of virtual health to population health management as well as the potential role of the pharmaceutical industry. The roundtable also included a co-creation session on shaping a short- and long-term policy agenda to address challenges and opportunities in using virtual health care to address population health.

Literature review

We reviewed peer review and grey literature across the three study countries to provide an understanding of the current state of digital technologies and/or population health efforts across the following areas: key characteristics of health systems, particularly related to funding and coverage; population health-related policies, if any; digital strategy and policies, if any; regulation, evaluation, and pricing and reimbursement of digital technologies.

Case studies and analytical framework

Forty-eight case studies of digital technologies in the three study countries were identified, from which six were selected for review based on the following criteria: the application or receipt of reimbursement or approval decisions, the primary country in which the digital technology is in use, the primary users and/or stakeholders, and the type of intervention.

An analytical framework was created to scrutinise the contribution that each of these case studies can make to population health and identify any remaining gaps. Specific endpoints for the evaluation of the case

studies are presented in Table 1 below. A literature review was conducted to gather data for each of these endpoints across each of the six case studies, including sources from peer-reviewed and grey literature.

Table 1: Evaluation framework for case studies

Thematic area	Endpoints
Design and set-up	1. Type of intervention 2. Intended user(s)/Target population 3. Ownership / stakeholders (e.g. public/private participation or ownership) 4. Regulatory approval 5. Interoperability
Costs and funding	6. Funding 7. Cost and payers 8. Reimbursement status and cost-sharing arrangements 9. Cost-containment/efficiency savings/cost optimisation
Clinical and health outcomes	10. Intermediate clinical outcomes and likely health improvement(s) (control of blood pressure, LDL-C, HbA1C, BMI) 11. Changes in the use of hospital and other health care (e.g. changes in admissions, length of stay, specialist care over time) 12. Evidence on the use of process indicators (e.g. check-ups, diagnostic/lab tests, eye tests)
Experience	13. Changes in patient experience 14. Changes in provider experience
Security, data, ethics	15. Integration & interoperability 16. Security standards 17. Privacy & confidentiality 18. Ethical conflicts

Source: The authors.

The cost and funding thematic area covers (a) the necessary funding in terms of set-up, any grants received to deploy the intervention and any financial incentives (positive or negative) to providers; (b) the cost of the intervention, e.g. the cost per patient per annum; (c) the proportion of the cost that is reimbursed by health insurance and the concomitant cost-sharing by users; (d) evidence on assessment of the intervention in terms of macroeconomic efficiency (cost containment) and the extent to which it delivers efficiency savings to the health care system.

The clinical and health outcomes thematic area incorporates (a) performance evidence on intermediate clinical outcomes and likely health improvements (e.g. on indicators such as HbA1C, LDL-C, blood pressure); (b) changes in the use of health and related services (e.g. changes in hospital admissions, length of stay, specialist care over time, nursing home admissions); and (c) evidence on the use of process indicators (e.g. check-ups, lab tests).

The experience thematic area covers (a) changes in patient experience (e.g. quality of life, patient satisfaction, change of insurance scheme); and (b) changes in provider experience (e.g. perceived quality, greater patient centeredness).

The security, technology, data, and ethics thematic area captures several dimensions relating to: (a) the integration of the initiative into existing systems and its interoperability with the broader structure and other operating systems; (b) the security standards and measures in place to prevent hacking; (c) privacy and confidentiality; (d) regulatory issues relating to privacy and confidentiality; and (e) ethical conflicts.

3. Overview of Population Health, Population Health Management & Virtual Health Care

To analyse the role that the pharmaceutical industry can play in virtual health care within the population health setting it is vital that we first define virtual health care, population health, and population health management. This section then focuses on components of a successful population health management programme and the impact of Covid-19 on the uptake of virtual health care so that country reforms, opportunities and barriers can be placed in context of wider objectives and health system change.

3.1. Defining Virtual Health Care, Population Health, and Population Health Management

For this report, we will use the terminology virtual health care (VHC) to denote the use of digital technologies in health care. We recognise there are several definitions and terminologies surrounding digital technology in health, including 'e-health', 'telehealth', and 'telemedicine'; however, there is no universal definition that is agreed upon. In their definition of virtual health care, McKinsey segments VHC intro three core categories: telehealth, digital therapeutics, and care navigation, as shown in Appendix 1.

Definition: Virtual Health Care (VHC)

VHC describes digital technology interventions that encompass all aspects of care including, but not limited to: physician-patient relations, data monitoring and transmission, digital therapeutics, and service navigation and delivery. VHC refers to a "healthcare delivery approach across the whole consumer well-being lifecycle, including before and after any care episodes" (Deloitte, 2019b). Broadly, digital technologies for health can be divided by their use spatially (in-person or across distance) and temporally (real-time or not in real-time).

Definition: Population Health (PH)

'Population Health' was first used in 2003 to describe the health outcomes of a group of individuals, including the distribution of such outcomes within the group. This definition evolved to include a methodology for identifying those at risk of both physical and mental ill-health and applying the appropriate interventions for prevention or care and rehabilitation. Overall, population health aims to improve the health of an entire population by improving physical and mental health outcomes, ensuring the wellbeing of people within defined populations whilst at the same time addressing wider determinants of health to reduce health inequalities (Buck et al., 2018).

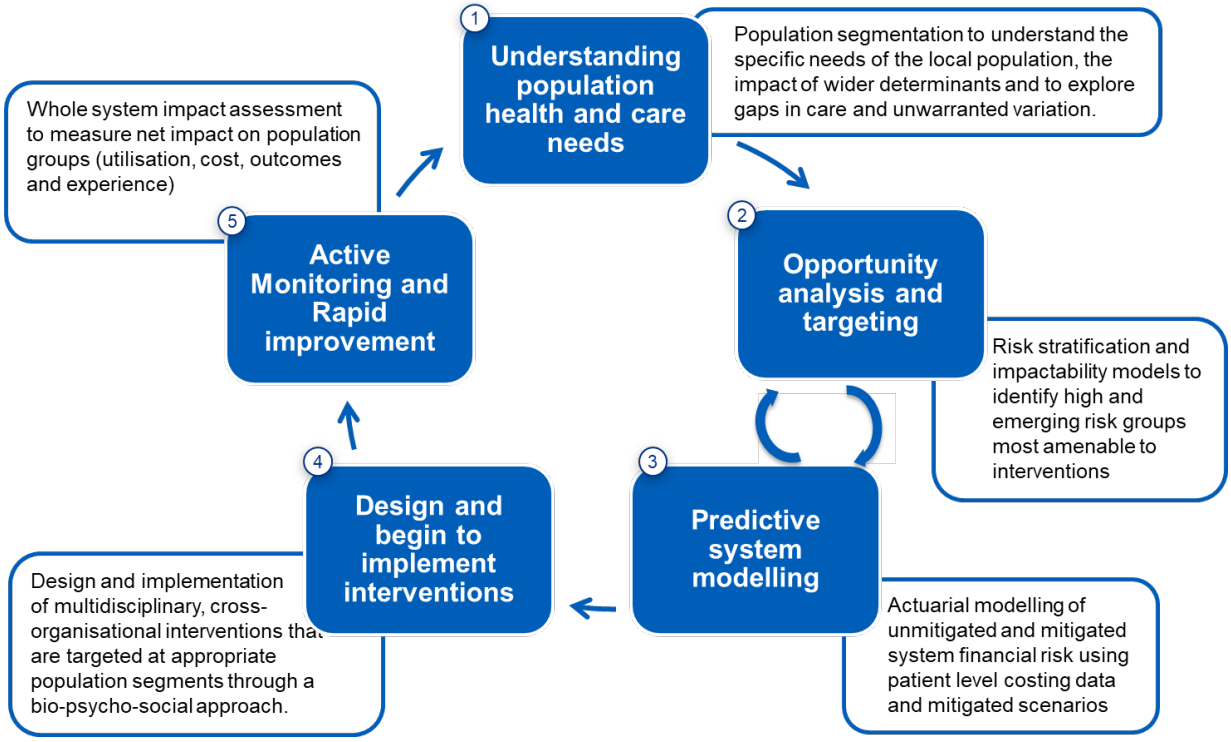
Like virtual health care, there is no single accepted definition of population health with several, overlapping terms used to describe similar concepts. The King's Fund sees population health as a broad, overarching notion, aimed at improving the health of an entire population and encompassing the concept of public health (Buck et al., 2018). Population health balances the intensive management of those in the greatest need of health care with preventative and personal health management for those at lower risk levels (Deloitte, 2019a).

Population health management (PHM) can be seen as an ongoing cycle of intelligence-led care design (Figure 1). It is one of many tools for the utilisation of data to help guide planning and delivery of care with maximum impact on PH (Buck et al., 2018). Improvements in data analytics, machine learning and digital technologies can make PHM a reality via effective risk identification and patient population stratification as well as improving the speed and accuracy of diagnosis and designing personalised treatment plans (Deloitte, 2019a).

Definition: Population Health Management

Works towards improving PH by data-driven planning and delivery of proactive care to achieve maximum impact. It involves segmentation, stratification and impact modelling to identify local 'at risk' cohorts and the subsequent design of targeted interventions to prevent ill-health, improve care and support for people with ongoing health conditions and reduce unwarranted variations in outcomes (NHS England et al., 2018).

Figure 1: Population Health Management: The ongoing cycle of intelligence-led care design



Source: Adapted from NHS Digital.

3.2. Building Blocks of Population health and Population health management

Population Health is a cornerstone of the 'Quintuple aim of healthcare' which focuses on improving the health of the population, enhancing the experience of care, reducing the overall costs of care, reducing health and care inequalities, and ensuring staff and carer wellbeing. This updates the 2002 US Institute of Health Improvement derived concept of the 'triple aim'; a framework for delivering economic, efficient and

effective care (NHS England et al., 2018). The addition of the focus on staff and carer wellbeing recognises the increasing demands on staff and increased risk of staff burnout. For PH to function effectively, six components are key, notably data aggregation, patient satisfaction, care coordination, patient engagement, performance reporting and good administration.

Whilst PHM is an iterative process, which can take many years to show impact and lacks a specific, single globally accepted 'rule-book', there are several distinct building blocks and critical success factors enabling a health and care system to effectively adopt a PHM approach:

1. ***Infrastructure***:

    i. Integrated data architecture including primary, secondary and social care – and data on clinical, economic and social determinants of health.

    ii. System-wide information governance arrangements.

    iii. Digitised health & care providers and common health and care record.

2. ***Insights***: Identify patients in need of, and most likely to respond to, prevention and clinical intervention. By leveraging big data and analytics/AI to uncover insights on treatment and stratify purchasers' high-risk patients (in clinical, behavioural and economic terms), so as to identify those most likely to show clinical improvement, as well as reduce purchasers' costs:

    iv. Advanced analytical tools and multi-disciplinary analytical teams.

    v. Actionable insights supporting providers' focus on population health.

3. ***Interventions***: Interventions to address single or multiple parts of the patient journey to support one of the four disease management pillars: behavioural change, coaching and self-management, nutrition counselling and peer support. These include:

    vi. Design and delivery of new care models and anticipatory care interventions which support an integrated approach to physical, mental and social care for target patient groups.

    vii. Building and utilising strong partnerships with the voluntary and community sector, with a specific focus on reducing health inequalities.

    viii. Workforce and incentives development based on population health analysis.

4. ***Impacts***: The ability to track risk and predict outcomes will enable provision of optimal and value-based solutions as well as risk-sharing among stakeholders:

    ix. Population engagement and patient activation with enhanced patient self-sufficiency in care management.

Alongside these building blocks are a set of key drivers for PHM required to bring together big data, patient engagement and healthcare delivery. The primary driver is behavioural change, both from the point of view of healthcare providers and patients with a focus shift towards prevention and patient activation measures delivered in a tailored manner using an array of analytics, technology and communication tools. Secondly, the proactive identification and monitoring of high-risk patients alongside equitable access to evidence-based medicine, both in terms of prevention and treatment, and the improvement of function and wellbeing for all individuals. Thirdly, the realignment of funding flows and incentives to encourage staff to work differently across care settings, underpinned by an appropriate outcomes framework. And finally, the

regular monitoring of interventions as well as frequent reflection and review by all stakeholders to increase impact and outcomes.

3.3. Effect of Covid-19 on Virtual Health Care

The Covid-19 crisis has accelerated the pre-existing interest in virtual health and a recent survey found 75% of respondents believed that the pandemic will speed up the provision of virtual health by at least two years (Choueiri et al., 2020). Covid-19 exposed pre-existing weaknesses and gaps, for example, shortages of clinical supplies, underinvestment in public health infrastructure and a lack of coordination and agility amongst policymakers, political authorities and healthcare systems (Clawson et al., 2020). It triggered a revolution in the way in which health systems deliver outpatient care, with the launch of new care pathways at unprecedented pace or 'Covid speed'. In the US, consumer use of virtual health increased from 11% in 2019 to 46% in 2020 (Bestsennyy et al., 2020). Similarly, a US healthcare provider, Providence St. Joseph Health, rolled out automated care and remote-monitoring tools for Covid-19 patients in only four days (Horner et al., 2020). In the UK, primary care doctors transitioned from having 90% of consultations in person to providing 85% remotely in the space of a few weeks (Horner et al., 2020). The fight against Covid-19 is also pushing health systems towards a more population-based, integrated, and value-based approach to managing disease. Systems, like the US Kaiser Permanente and Intermountain Healthcare, that had already adopted integrated care approaches with investment in digital technologies have been able to better weather the pandemic by rapidly shifting towards an increasing reliance on virtual health care (Clawson et al., 2020).

4. Health systems in a new era: transformation to meet health system objectives

This section examines three health system archetypes: a tax-based system (United Kingdom), a social insurance-based system (Germany), and a predominantly privately funded system with multiple insurers and significant public funding (the United States). The relative "readiness" of each health system is reviewed in the context of key policy drivers (Table 2) and focuses on the key policy drivers of regulation and reimbursement for virtual health care and population health. This policy overview provides essential context for the six Case Studies presented in Section 5 and informed roundtable discussions with experts.

More information on these health system funding structures and stakeholders is available in Appendix 2.

Table 2: Indicative "readiness" for health systems to engage on PHM and VHC

	Population Health Management	Virtual Health Care	Important Future Developments
Germany	Medium	High	Digital Healthcare and Nursing Care Modernization Act (DVPMG) (mid-2021) expected to revise regulations on prescribed VHC applications and expand digital care.
United Kingdom	High	Medium	The National Institute for Health and Care Excellence (NICE) has established an Office for Digital Health and will release an updated Digital Health Evidence Standards Framework in mid-2022.
United States	Medium	High	Anticipated demand from patient groups for permanently expanding VHC coverage with coverage already extended in some states.

4.1. Germany

The German Federal Ministry of Health places a high priority on the digitisation of healthcare services. Germany's strategy for healthcare digitisation has involved recent widespread reforms that have promoted the inclusion of digital innovations in patient management and standard care. Major components of the country's digital health strategy include the creation and expansion of its telematics infrastructure to support the collection and sharing of health data, shifts in rules around prescribing, the reimbursement of digital health applications, and the introduction of evidence-based assessments of digital health applications.

Germany's movement towards population health management models has been less rapid despite a successful and well-documented proof-of-concept with Gesundes Kinzigtal (GK). In Germany, there is a strong separation of primary and specialist care as well as out-patient and hospital care (*State of Health in the EU: Germany Country Health Profile 2017*, 2017). Although integrated care systems and population-based care approaches are not well established, there is significant support at the national and subnational level for population health reforms.

4.1.1. Policies for digital technologies

The first major health policy that influenced the adoption of e-health innovations was the 2004 "Law to modernize the Statutory Health Insurance" (*GKV Modernisierungsgesetz*). This law introduced the concept of an electronic health card (*elektronische Gesundheitskarte*) to the German health system which lay the groundwork for future digitisation (Rehmann, 2016). Since then, multiple acts and laws have been enacted to enhance the use of digital medicine. Most recently, in late 2019, the Digital Supply Act (*Digitale-Versorgungs-Gesetz (DGV))*, viewed by many as the country's most revolutionary law, was adopted by the Bundestag. It promoted the use of 'virtual' health across the healthcare system, established a framework for how health data can be used in clinical research, and required the reimbursement of prescribed digital health applications (DiGA) for all those on social health insurance (Gerke et al., 2020). To qualify for reimbursement, digital health apps must meet certain criteria, be classified as lower-risk medical devices, and be listed in the BfArM register *(Bundesinstitut für Arzneimittel und Medizinprodukte* – Germany's regulatory body) (Gerke et al., 2020).

Looking to the future, the Digital Healthcare and Nursing Care Modernization Act (DVPMG) is expected to be enforced from mid-2021. DVPMG focuses on supporting digital interventions for those in long-term care and also revises regulations on prescribed digital health applications (Hiller, 2021).

4.1.2. Approval and reimbursement policies around digital health

Virtual health products that classify as other types of medical devices, regardless of whether they are used by in-patients or out-patients, are subject to standard European regulatory review processes before they can be provided through the health system. Virtual health is encouraged through certain reimbursement structures. For example, doctors are incentivised to provide e-prescriptions through higher reimbursement than traditional prescribing (Carmen Paun, 2019) while patient video consultations and approved medical applications are now covered under national insurance (Med Tech Reimbursement Consulting, 2019). Alternatively, some virtual health services may be covered through selective contracts, usually with integrated care systems (Walzer et al., 2015).

To be reimbursed digital health applications must be listed in the BfArM DiGA directory via an application through BfArM's new DiGA review process to prove safety, functionality, quality, data security, data protection and therapeutic benefit (BfArM, n.d.; Gerke et al., 2020). BfArM commits to a fast-track review process, ensuring all applications are decided within three months. If therapeutic benefit is not yet proven, applications can be listed in the register for a preliminary 12 months, allowing the collection of more data. This may be extended for a further 12 months if necessary (Gerke et al., 2020). Currently, approved apps are not subject to maximum price restrictions although this has been considered among regulators (Hiller, 2021). When DVPMG comes into effect in mid-2021, reimbursement of digital health applications and care applications will likely be extended to apps that use the services of doctors, pharmacists, and midwives.

4.1.3. Value drivers and stakeholder involvement for population health

The German health care system is regularly critiqued for being less cost-efficient than nearby neighbours. Opportunities for cost-saving through population health management are therefore important to insurers and policymakers. Gesundes Kinzigtal, one of the interventions we review in the next section, is a successful

German model for population health management and was centred around achieving the Triple Aim of "1) better population health; 2) improved experience of care; and 3) reduced per capita costs" (Groene et al., 2016). Key stakeholders in German population health models include physicians, sickness funds and health insurers, elected management companies, community organisations, and employers (Groene et al., 2016). Other important stakeholders at the national level include the Federal Ministry of Health which is responsible for new laws including the legal framework for Germany's e-health infrastructure (Rehmann, 2016), health insurers, and Gematik, the body responsible for implementing and expanding telematics infrastructure (Rehmann, 2016).

4.2. United Kingdom

Over the last decade, the UK has strongly prioritised both digitisation and patient-centred integrated care. After a major failed attempt at top-down digitisation of NHS England through the National Programme for IT, the NHS has adopted a cautious approach to digitisation with recent emphasis on digitisation of secondary care and data sharing (Justinia, 2017; Wachter, 2016). Since the Covid-19 pandemic, the UK, like other countries, has rapidly scaled up the use of technology and digital ways of working at all levels of health care provision. The pandemic has further highlighted the importance of joined-up care and population health management, which is delivered in England through integrated care systems and Sustainable Transformation Partnerships.

4.2.1. Policies for population health management and digital technologies

NHS England's 2014 5 year Forward Plan focused on improving prevention efforts and health services for the population by altering traditional boundaries between primary care, secondary care, and community services (NHS England, 2014). By 2017 population health-focused Sustainable Transformation Partnerships (STPs) had been introduced (NHS, 2017) to bring together NHS providers, commissioners, local authorities, and other partners and funders to plan services based on the long-term needs of their local populations (STPs explained, Kings Fund). Evolving from these STPs, integrated care systems (ICS) are a move towards improved population health management, allowing for closer collaboration between stakeholders and greater autonomy and responsibility for resources (Charles, 2020). The 2019 NHS England Long-term Plan aims to have all parts of England served by an ICS by 2021 (Charles, 2020).

Over the last decade, digital policies have focused on establishing and revising standards and frameworks to guide the design, procurement, and introduction of digital systems in health and social care. In 2013, NHS Digital was established to provide organisation and leadership in England around information and data (*About NHS Digital*, n.d.). By 2019 NHSX was responsible for driving England's system transformation and digital policy (*Digital Transformation*, n.d.). Over the last 5 years, these central bodies have set standards and guidance around security, information governance, interoperability, IT procurement, and evidence standards for digital health applications to help improve interoperability and accessibility between systems, which is essential for population-based health approaches. The 2019 NHS Long Term Plan laid plans for digitally-enabled care to "go mainstream" throughout the NHS. Other progress in digitisation has been made with e-referrals, e-prescriptions, online triaging, virtual consultations, and online appointment booking being expanded across England (*NHS Long Term Plan*, 2019) although some geographic divides still exist (Asthana et al., 2019). The NHS Long-Term plan also highlighted the need to digitally-enable

patients and carers to access their care records and make use of technology to self-manage their chronic conditions, such as CVD (*NHS Long Term Plan*, 2019).

4.2.2. Approval and reimbursement policies around digital health

There are no laws that specifically regulate virtual health in the UK; however, there are laws regulating privacy and health care providers and services, which are subject to standard legislation and codes of conduct, have an obligation to ensure patient safety. Privacy and data collection is regulated per GDPR and virtual health products that are considered medical devices are regulated by product safety regulations and are subject to a Medicines and Healthcare Products Regulatory Agency (MHRA) review process.

As virtual health may pose additional risks to patients, regulators have issued guidance for NHS providers and commissioners focused on interoperability, data standards, security, clinical risk management, technical stability, accessibility, procurement, economic impact standards, evidence for effectiveness, and an identification framework for determining if an app is considered a medical device.

Two main frameworks exist in England to help inform NHS commissioners considering buying digital health products:

- The NICE Evidence Standards Framework for digital health technologies, developed by the new Office for Digital Health, helps NHS commissioners identify what good evidence of therapeutic benefit and economic impact looks like for digital products (NICE, n.d.). NICE is particularly focused on devices with high clinical, operational, or financial risk and after a successful pilot of the evidence framework, the organisation updated their guidance in early 2021 with additional revisions that cover AI expected in 2022 (Boysen, 2021).
- Digital Technology Assessment Criteria (DTAC), launched in February 2021. The DTAC focuses on commissioned digital technologies, especially those that are patient-facing, and provides a minimum baseline of standards for digital technologies to meet. The DTAC is intended to complement the NICE Evidence Framework.

Lastly, restrictions on the use of certain tools might come from healthcare managers directly. For example, following the rise in remote working during the Covid-19 pandemic, some NHS trusts banned communication platforms Zoom and WhatsApp, citing security concerns (Murphy, 2020).

In terms of reimbursement, digital products that are commissioned by the NHS (usually by Trusts and Foundations) are generally available to patients as part of standard care. These technologies might include communications platforms, patient record systems, remote monitoring devices, and anything used in the provision of secondary care. As local commissioners make their own purchasing decisions, it is difficult to map the range and extent of digital health tools in use. Additionally, while many technologies are procured from external suppliers, there are several examples of the NHS designing and building their own products. In England, technology that is less likely to be reimbursed includes low-risk medical devices and applications, especially anything that is unlikely to be connected to or share data with NHS systems.

4.2.3. Value drivers at stakeholder level for the adoption of population health

Three "widening gaps" were identified in the Five Year forward view (2014). Addressing these gaps is the basis of establishing STPs and integrated care systems in England. These gaps are 1) the health and well-being gap (in particular failures in prevention and increasing health inequalities), the care and quality gap (which focuses on harnessing technology and meeting patient's changing needs), and the funding and efficiency gap (NHS England, 2014).

4.3. United States

The United States' health system has changed significantly in the fifteen years since the introduction of the Affordable Care Act (ACA) in 2010, which led to significant electronic medical record (EMR) reform, patient protections, and increased coverage. The passage of the 21st Century Cures Act (2016) called for increased transparency, interoperability, and improved certification around digital health technology. In recent years, the Food and Drug Administration (FDA) has pursued initiatives outlined in the Cures Act with a focus on software and artificial intelligence in medical devices. In response to the Covid-19 pandemic, the United States has made significant changes in digital health policies, particularly in virtual healthcare, to scale up capabilities to meet demand additionally, US policies are shifting to a patient-centred focus with a push towards value-based care.

4.3.1. Policies for digital technologies

The FDA is the primary entity responsible for digital health technology regulation. Other important policymakers include the Department of Health and Human Services (HHS) and the Federal Trade Commission (FTC). The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinic Health Act (HITECH) govern the privacy and security of protected personal health information (Gilroy et al., 2020) alongside individual state laws specifying additional requirements. The 21st Century Cures Act aims to accelerate medical product development and bring innovations to patients faster and more efficiently and also includes efforts to establish improved health record interoperability and prevent data blocking (*21st Century Cures Act*, 2020).

The FDA Digital Health Innovation Action Plan outlines key goals including: issuing guidance to provide clarity on the FDA's regulation of digital health products, increasing the number and expertise of digital health staff at the FDA, and developing the Digital Health Software Precertification Pilot Program (Pre-Cert) (which assesses the developer primarily and the product secondarily) (*About the Digital Health Center of Excellence*, 2020; *Guidances with Digital Health Content* , 2020). In September 2020, in response to the Cures Act, the FDA launched its Digital Health Center of Excellence (DHCoE) within the Center for Devices and Radiological Health (CDRH). The DHCoE is responsible for aligning and coordinating digital health work across the FDA and carrying out the Digital Health Innovation Action Plan.

The Digital Health Innovation Action Plan clarifies medical device classification and oversight by the risk the device presents (*Digital Health Innovation Action Plan*, 2017) whereby the FDA only regulates those devices "whose functionality could pose a risk to a patient's safety if the device (including software) were to not function as intended" (*Policy for Device Software Functions and Mobile Medical Applications*, 2019).

The FDA also classifies some software as a medical device (SaMD). Clinical decision support software guidance published in 2019 categorizes the level of impact the software could have on patient outcomes, safety, and privacy while explaining the regulations based on these categorizations (Abernethy, n.d.).

4.3.2. Approval and reimbursement policies around digital health

ACA provisions that aim to make reimbursement dependant on outcomes have incentivized digital health products. The regulatory pathway and required level of clinical evidence depends on the novelty of the digital health product and how great a risk it poses to the patient if it does not work as intended (Makin, 2019). Therapies that are similar to existing therapies only have to prove "substantial equivalence" rather than new clinical evidence.

The reimbursement of health apps occurs through multiple channels and has not always been straightforward. However, in response to the Covid-19 pandemic, the federal government has eased funding policies regarding digital health and virtual health in particular. There is wider virtual health coverage, more lenient prescribing and cross-state care, and the Office for Civil Rights is allowing medical providers to use more informal communication services such as FaceTime or Skype to interact with their patients. These policies are temporarily in place because of the public health emergency, and it is unclear what their long-term effect will be. Similarly, all federally-funded programmes and most private insurers have expanded coverage to include all remote services and federal grants are in effect to aid providers who are incurring costs of new virtual health technology (Gilroy et al., 2020).

5. Virtual Health Care interventions for population health

There are a wide range of virtual health interventions which can be utilized for the improvement of population health with variations spanning across issues like the type of intervention, the condition(s) it seeks to improve, the health outcome improvements it seeks, and the primary users and stakeholders it engages with. Six case studies which use digital technology for population health were selected for review, undergoing an assessment along the parameters outlined in Table 1. The data collected for each of these case studies provide an overview of key benefits, barriers, or contexts which these interventions encounter, as well as the country setting, both of which are essential to understanding the current environment for virtual health care and future developments in the field. Table 3 outlines the case studies.

Table 3: Case studies of digital VHC technologies for population health

	Country	Condition	Population Health
Gesundes Kinzigtal	Germany	General	Integrated care management
Kaiser Permanente	USA	General	Integrated care management
KardiaMobile	UK	CVD	Management
Livongo	USA	Diabetes	Prevention; management
MySugr	Germany; UK	Diabetes	Management
Nujjer	UK	Diabetes	Prevention; management

5.1. Design and set-up

5.1.1. Type and users of intervention

Table 4 outlines the types of interventions and the users of each intervention across the six case studies.

Table 4: Types and users of six VHC interventions

	Intervention				User of intervention		
	App	Device	Platform	Description	Patient	Insurer	Health system
Gesundes Kinzigtal			✓	Organized care across all health services; population-based integrated care approach with systemwide electronic health records	✓	✓	✓
Kaiser Permanente			✓	Insurer with extensive electronic health record system and in-house research department to visualize data	✓	✓	✓
KardiaMobile	✓	✓		Mobile app with personalized electrocardiogram monitor	✓		✓
Livongo			✓	Chronic condition management programs incl. a meter and test strips	✓		
MySugr	✓	(✓)		Mobile app with optional blood glucose monitor	✓		
Nujjer	✓	✓		Personalized diabetes prevention with activity sensitive wristband and smartphone application	✓		

CASE STUDIES

Gesundes Kinzigtal

Gesundes Kinzigtal is responsible for the health care service budget for nearly half of 69,000 inhabitants of the Kinzigtal region in Germany covered by one of two participating sickness funds: Allgemeine Ortskrankenkasse (AOK) Baden-Württemberg and Landwirtschaftliche Krankenkasse (LKK). GK was initiated in 2006 when the two sickness funds, the local physician network (Ärztenetz MQNK) and a management company with a background in health sciences (OptiMedis AG) entered into a cost-saving agreement to manage the health services for their 30,000 policy holders with the objective of fostering patient self-management and enhancing shared decision-making about individual treatment plans and goal setting between physicians and citizens/patients (Lupiañez-Villanueva & Theben, 2014). It now operates an integrated care system for the region, encouraging cooperation between, patients, healthcare professionals, and insurers.

Kaiser Permanente

Kaiser Permanente is the largest non-profit, integrated health care delivery system in the United States (McCarthy et al., 2009) and renowned for tight integration of its clinical services (McKinsey, 2009). Whilst telehealth has been available to members in various forms at Kaiser Permanente since the late 1990s (including electronic medical records (EMR), KP HealthConnect, which enables coordinated care across clinical professionals, and a wide range of options for accessing care, in September 2020 they released their Virtual Plus Care Plan, centred on delivering healthcare through telehealth (Boerger, 2020). The goal of Virtual Plus is to give consumers the ability to more conveniently access care via phone, video, chat or email.

Livongo

Livongo was founded in 2014 as a small start-up focused on chronic disease management. A deal with Teladoc in 2020 expanded the reach of Livongo's pioneering Applied Health Signals platform (Hale, 2020). Initially focused on a 'cloud-based' diabetes management, it has since diversified to cover diabetes prevention, high blood pressure and behavioural health, developing a 'cuff-to-cloud' blood pressure device and wireless-enabled scales in the process. Their platform collects patient reported glucose data which their service analyses. Patients also have access to certified diabetes educators to work towards bringing any elevated readings down as quickly as possible. It can also give members feedback during the day and enables them to receive updates to their device 'on the go'. As part of the package it also offers free and unlimited home delivered test strips and lancets (Idrus, 2017). Livongo initially focused on diabetes monitoring and prevention but is now expanding its programs to address cardiovascular disease and other chronic conditions (Forrester, 2020).

KardiaMobile

KardiaMobile is a credit card sized, single-lead ECG device that transmits an ultrasonic signal to the microphone of a compatible smartphone or tablet. The accompanying Kardia app on a compatible mobile device (such as a smartphone or tablet) shows the ECG trace, a measure of heart rate, and classification of the rhythm, as well as providing an instant interpretation and PDF of the ECG (Lang et al., 2020; NICE, 2020). KardiaMobile integrates the patient user with the healthcare system, as the app analyses the ECG recording and shares it with a healthcare professional for interpretation (NICE, 2020). Accuracy studies have shown that sensitivity ranged between 77.0% and 96.6% and specificity ranged between 76.0% and 99.1% in the detection of cardiac arrhythmia (NICE, 2020).

MySugr

MySugr was launched in Austria in 2012 to support users in the self-management of their diabetes (Fredrick Debong et al., 2019) via 'gamefication', and was recently acquired by Roche (Spencer, 2017) (Neumann et al., 2019). The MySugr app monitors daily health data to allow for better informed therapy decision-making and therapy compliance incentives through motivational triggers, the provision of feedback on an individual's current therapy status, and rewards (MySugr, 2019). It allows users to log meals, medications and blood sugar levels (all stored in the cloud for future monitoring) as well as calculate HbA1c levels (Spencer, 2017). Other information, for example on physical activity, can be imported automatically from other apps adding additional context to the clinical data. Immediate access to certified diabetes educators (CDEs) is considered a key feature of the MySugr app, as these CDEs identify and monitor at-risk patients and provide individualized coaching and advice (Fredrick Debong et al., 2019).

Nujjer

Nujjer is a combination of a wristband and smartphone application which aims to change behaviour towards weight loss and type 2 diabetes prevention. The highly sensitive wristband automatically monitors users' activities, sleep patterns and eating frequency (monitoring triggered by the wearer), and a smartphone application, which provides access to educational sessions targeting diet, physical activity and mental resilience. These educational sessions (22 over the 12 month programme (Murray et al., 2019)) have been developed by world-leading psychiatrists and the messaging spans both mental and physical aspects of diabetes prevention. The app also provides users with feedback on their personal data. In the UK a collaboration between King's Health Partners and Buddi Nujjer was selected to take part in a national pilot to test digital technologies for the prevention of type 2 diabetes and obesity (health Partners, 2017).

MySugr, Nujjer, and KardiaMobile all seek to improve care through the combination of a mobile app with an accompanying device aimed at patient users, though there is variation in the content and style of each of these apps. Examples include the collection and monitoring of regularly collected health data, education modules with behavioural components, in-app reminders or messages, and access to expert individuals or healthcare professionals. Livongo, a platform to support individuals with chronic conditions, also relies on the aggregation of real-world patient health data to provide the user with actionable, personalized insights, and drives behavioural change through nudges, together with support from healthcare professionals, sharing data between family, friends, and clinicians, and the timely provision of necessary medical items, such as test strips (Livongo, 2019; Sanofi, 2020).

Kaiser Permanente and Gesundes Kinzigtal are examples of interventions which integrate several users at once. Virtual health options have been available to members in various forms at Kaiser Permanente since the late 1990s, including EMRs and KP HealthConnect, which enables coordinated care across clinical professionals and a wide range of options for accessing care, including phone, email, doctor-to doctor consults, and two-way video (Kaiser Permanente, 2020a). Gesundes Kinzigtal, a population-based integrated care approach in Germany, organizes care across all health service sectors and indications for people of all ages and care needs in the district. As part of this provision, GK supports physicians in improving their case management and providing additional services, such as education programmes, for patients.

5.1.2. Ownership / stakeholders

Often, these interventions are owned and operated by a private organization, as is the case for Nujjer, owned by the British private technology company Buddi, and KardiaMobile, owned by AliveCor (AliveCor, 2019; Buddi, 2021). Kaiser Permanente is owned by the Kaiser Foundation Health Plan, Inc. a non-profit health care organization. Gesundes Kinzigtal itself is a joint venture between two partners: the Hamburg-based health management company OptiMedis AG (which owns one-third of the shares) and the Medizinisches Qualitätsnetz—Ärzteinitiative Kinzigtal (which owns two-thirds of the shares) (Busse & Stahl, 2014). Gesundes Kinzigtal brings together a complete network of health stakeholders to collaborate on the improvement of the health outcomes of those in the initiative (Lupiañez-Villanueva & Theben, 2014).

There are examples of acquisitions, collaborations or partnerships with other stakeholders, or large-scale purchasing for some of these products. For example, Livongo originally started as a small start-up, but was acquired by the private American-based multinational company Teladoc Health Inc. in 2020, and MySugr was developed in 2012 and acquired by the pharmaceutical multinational Roche in 2017 (Roche, 2017; Teladoc Health, 2020). MySugr and Roche collaborated prior to the acquisition, notably through a small equity investment through Roche's venture fund (Roche, 2017, 2021). MySugr retains its independence despite Roche being the exclusive shareholder since 2017 (Roche, 2021). Another example of collaboration is seen as Nujjer is one of five digital interventions promoted through the NHS Diabetes Prevention Programme (NHS DPP) 'Healthier You', launched in 2016 to support people who are at high risk of developing type 2 diabetes (Nujjer, 2021).

5.1.3. Regulatory approval

Table 5: Regulation and/or approval of six VHC interventions

	Country	Regulatory approval	CE mark
Gesundes Kinzigtal	DE	In use since January 2006	-
Kaiser Permanente	USA		-
KardiaMobile	UK	NICE review in Medtech Innovation Briefing	Class IIa medical device
Livongo	USA	FDA approval	-
MySugr	UK / DE	Applied to DIGA; reimbursed (DE) Recommended in the NHS app library	Class I medical device
Nujjer	UK	Recommended in the NHS app library	-

The study countries do not conduct an in-depth regulatory approval for apps. Both Germany and the UK offer a database of apps recommended by the system: MySugr was included in the first phase of applications for inclusion in DiGA, while the NHS has included Nujjer in the NHS app library (Consulting, 2020; NHS App Library, 2018; Nujjer, 2021). The UK NHS is undertaking an evaluation of Nujjer as part of an assessment of digital technologies for type 2 diabetes for the NHS Healthier You: Digital Diabetes Prevention Programme (NHS England, n.d.). A randomised controlled trial on Nujjer has been conducted in South London on 200 patients at risk of developing type 2 diabetes (Nujjer, n.d.). The NHS has also identified Nujjer as one of 13 apps that are 'safe and secure' for the management of diabetes (Fleming et al., 2020). KardiaMobile was the subject of a Medtech innovation briefing (MIB) by NICE, which provides advice on a wide range of technologies, notably medical devices and equipment, to NHS and social care commissioners and staff for the assessment of use of new medical devices (NICE, 2015). Livongo was approved for marketing in 2020 (Perez-Torres, 2020).

In the European Union, medical devices need to comply with the EU Medical Device Directives and are catalogued in four classes of medical devices - Class I, IIa, IIb, and III – which denote increasing risk for patients (Class III is the highest). The mySugr app and mySugr Logbook are CE-marked as a class I medical device in the European Union, the mySugr Bolus Calculator module has class IIb approval and the KardiaMobile heart monitor and app were CE-marked as a Class IIa medical device (MySugr, 2018b; NICE, 2020). Livongo is classified as a Class II device in the US (Perez-Torres, 2020). No information was found on Nujjer.

5.1.4. Integration/ Interoperability

Ideally, developers should ensure apps operate consistently to the same standard across mobile platforms, and data recorded should be easily transmitted from smartphones to other platforms (Fleming et al., 2020). MySugr, KardiaMobile, and Nujjer are all available on Google Play and the App Store and compatible with smartphones. Some apps may require the ownership of relevant devices, such as the ECG device for KardiaMobile and the wristband for Nujjer.

5.2. Costs and funding

5.2.1. Funding

It is common for VHC innovations to be funded through public grants or private venture funding in order to fund set up or implementation costs. For example, MySugr's development has been funded by Roche Venture Fund, XlHealth, iSeeds Ventures and XL Group (Crunchbase, 2021), and Nujjer was developed and funded by Buddi with a grant from Innovate UK, the UK government's innovation agency (Health Partners, 2017). Livongo has partnerships with Amazon, Apple, Samsung, Fitbit, Target and pharmaceutical companies and revenue comes from these client companies which pay Livongo in the region of $65 to 75 a month for each employee monitored (Saporito, 2019).

5.2.2. Costs and payers

Table 6: Costs and payers of six VHC interventions

	Funder	**Cost**
Gesundes Kinzigtal	Insurance and GK, government funding	Covered through two sickness funds responsible for the health care service budget for nearly half of the Kinzigtal inhabitants
Kaiser Permanente	Private insurances Medi-Cal and Kaiser-Permanente Insurance	-
KardiaMobile	NHS; patient	Free app KardiaMobile device: £99 to 149 KardiaCare Membership: £99 / year
Livongo	Private insurers; employers	$75 per member / month
MySugr	Patient (out-of-pocket) (UK) Insurers; patients (Germany)	Free app MySugr Pro: £2.99 per month or £20.99 per year MySugr bundle: €999 / year MySugr coach: €357 / year
Nujjer	Patient (out-of-pocket)	Free app Nujjer programme: £99 fixed and £9.99 / month
Key:		
-	No information / evidence	

The case studies which are app or app/device-based – KardiaMobile, Nujjer and MySugr – are generally borne as an out-of-pocket cost by the patient/user. All three of these interventions offer a free app accompanied by additional payments for further features which can include an upgraded version of the app (e.g. MySugr Pro), a device (e.g. KardiaMobile requires a one-off purchase of an electrocardiogram (ECG) device) or memberships or bundles with additional benefits. Examples of the latter include KardiaCare Membership, which provides users with monthly heart health reports, 3-monthly ECG reviews by a cardiologist, cloud storage, and device replacements, among other features. Similarly, the MySugr coach includes access to a diabetes coach and the Pro app and the MySugr bundle, which adds unlimited test strips and a glucometer to the features of the MySugr Coach option (MySugr, n.d.-a; NICE, 2020).

Platform or integrated care is usually insurance based: Livongo can be covered by a user's employer, insurance, or other coverage at a monthly cost of $75 per member. All providers in Gesundes Kinzigtal

are paid by the insurer with total expenditure for all insured inhabitants compared to risk-adjusted standardized costs with the insurer and GK sharing any savings.

5.2.3. Reimbursement and cost-sharing arrangements

Table 7: Reimbursement of six VHC interventions

	Country	Reimbursement
Gesundes Kinzigtal	DE	n/a
Kaiser Permanente	USA	n/a
KardiaMobile	UK	Reviewed by NICE, cost-sharing arrangement
Livongo	USA	Reimbursed by insurers / employers
MySugr	UK / DE	Reimbursed (DE) Recommended in NHS App Library (UK)
Nujjer	UK	Recommended in NHS App Library (UK)

MySugr has partnerships with five German health insurers in Germany and the MySugr bundle is reimbursed in health systems in the EU and US (Fredrick Debong et al., 2019; MySugr, 2018b). Both Nujjer and MySugr are recommended in the NHS App Library and paid for out of pocket in the UK. Livongo is reimbursable through insurers and employers in the US.

No cost-sharing arrangements were identified apart from for KardiaMobile. KardiaMobile is available for patients to purchase out of pocket but some regions of the NHS are currently covering the cost of the ECG device. NHS England has set aside £500,000 to purchase KardiaMobile ECG devices and the Health Innovation Network (HIN) in South London distributed 400 mobile ECG devices, three-quarters of which were KardiaMobile (Alivecor) (Lang et al., 2020).

5.2.4. Cost-containment/efficiency savings/cost optimization

Table 8: Cost saving evidence for six VHC interventions

	Cost savings
Gesundes Kinzigtal	Observed in third-party studies
Kaiser Permanente	Unclear, though suggested resource allocation and performance is better than other systems
KardiaMobile	Potential suggested by UK regulatory body
Livongo	Observed in third-party study
MySugr	No information, but potential suggested by company
Nujjer	No information, but current assessment conducted by the NHS

Source: The authors.

The potential for cost savings is detailed across the case studies, though with limitations in generalizing these costs to the whole system. See Appendix 3 for an overview of the cost-saving evidence discussed. Largely, cost savings are suggested to exist and can potentially be quite high. The UK regulatory body,

NICE, concluded that KardiaMobile may impact resource use as it could reduce the number of referrals for ECGs and result in increased detection of atrial fibrillation (AF), though there was insufficient evidence to determine if this would occur in practice (Network, 2020; NICE, 2020). Other sources estimate that health savings for costs related to diagnosis of AF could be around £2 billion (PharmaTimes, 2018), with an average cost of £46,039 avoided in the five years after someone suffers from a stroke if the devices are shown to increase the rate of AF detection (Network, 2020). These estimations depend, of course, on the volume and penetration of KardiaMobile. Livongo reports that annual gross medical savings per member are $1,908 (Livongo, 2020a). Livongo has been associated with a 22% decrease in medical spending, translating to savings of $88 per member per month, and compared to non-members, members experiences a 10% reduction in diabetes-related medical spending and a 25% reduction in spending on office-based services (Whaley et al., 2019).

Integrated care efforts are also reported to be associated with cost savings. Predicted health gains for Gesundes Kinzigtal may result in a substantial comparative reduction of health care costs in the region compared with the German standard (Hildebrandt et al., 2010), slow the rise in health care costs for the population GK serves (The King's Fund, 2021), and lead to a net annual saving of 3% for the two insurance companies (Lupiañez-Villanueva & Theben, 2014). A 2002 comparison of Kaiser Permanente and the NHS found that KP achieved better performance at roughly the same cost as the NHS (Feachem et al., 2002).

No studies on Nujjer or MySugr were found in the UK and Germany, respectively. However, Nujjer aims to encourage prevention of type 2 diabetes, which accounts for around 9% of the annual NHS budget at around at 8.8 billion a year with an estimated five million people in England are at high risk of developing type 2 diabetes, suggesting the potential for budgetary impact exists if found to have an impact on behavior (NHS, n.d.; NHS England, n.d., 2017). No savings data for MySugr was found in Germany, but in the US, the company suggests a monthly cost saving of between 58 to 100 USD per member for employers paying for the MySugr app (MySugr, n.d.-b).

5.3. Clinical and health outcomes

5.3.1. Intermediate clinical outcomes and likely health improvement(s)

Table 9: Reported clinical outcomes for six VHC interventions

	Reported outcome	Change in outcome
Gesundes Kinzigtal	Mortality	Decrease
Kaiser Permanente	-	-
KardiaMobile	Detection of cardiac arrhythmia	Increase
Livongo	Likelihood of having a day with hypoglycemia	Decrease
	Hyperglycemia	Decrease
MySugr	Glucose control	Improved
	Blood glucose levels	Significant improvements
	HbA1c	Reduced levels
Nujjer	-	-
Key:		
-	No evidence	

There are not many long-term, high quality studies on the impact of app interventions (Fleming et al., 2020). Findings from early studies suggest that simply logging data with the MySugr app may have positively impacted the quality of blood glucose control. The MySugr Bundle (with features such as CDE-led coaching, bolus advisor, and other features) has been shown to prompt positive changes in glucose control (Fredrick Debong et al., 2019; Mayer et al., 2019). This impact may be even greater in individuals with less well-controlled diabetes(Fredrick Debong et al., 2019). Overall, the literature reports positive findings for MySugr: significant improvements were observed in mean blood glucose and monitoring (Mayer et al., 2019) and a reduction in HbA1c levels has been observed (Rose et al., 2013). MySugr, among other diabetes management apps, was found to be positively associated with self-care behaviour, suggesting that apps are able to support lifestyle changes and glucose monitoring in these populations (Kebede & Pischke, 2019). However, research into diabetes apps suggested there is 'no consensus regarding what diabetes management means', and suggests that the ability of these apps to support diabetes management varies (Jimenez et al., 2019).

Use of KardiaMobile resulted in a five-fold increase in the number of patients for whom an ECG was captured (Reed et al., 2019). UK NICE reports that KardiaMobile resulted in more cardiac arrhythmias detected over standard care, also reporting quicker time to diagnosis and lower cost of diagnosis (NICE, 2020). An evaluation of KardiaMobile found that of the 5,586 possible cases of AF that were detected between January 2018 and March 2019,this could potentially have avoided 187 strokes (Network, 2020). Reports on KardiaMobile state patients had avoided unnecessary 12-lead assessments (Wessex Academic Health Science Network, 2020).

Livongo reportedly assisted members with an average 18.4% decrease in the likelihood of having a day with hypoglycemia and an average 16.4% decrease in hyperglycemia (BG >180 mg/dL) (Downing et al., 2017), though these findings have been disputed, notably, because the authors were all employees of or consultants for Livongo (Lewis, 2020).

Gesundes Kinzigtal measures a number of outcomes through its own qualitative and quantitative evaluation modules (Lupiañez-Villanueva & Theben, 2014). GK saw a decrease in mortality 2.5 years after enrollment (Busse & Stahl, 2014).

Results are awaited from a study for a two-arm, parallel, single-blind RCT for people at high risk of type 2 diabetes comparing Nujjer's app and wristband to a control group using only the wristband and receiving the same lifestyle advice (Ismail et al., 2018).

5.3.2. Changes in the use of hospital and other health care

Livongo states there is a reduction in hospital admissions accompanying its services in Pennsylvania and New Jersey (Sheldon et al., 2020). A pilot at a Chicago hospital found that diabetics following the Livongo programme lowered their glucose levels, had a 17% reduction in diabetes-related medical costs, an 11% drop in all medical claims and 21% fewer emergency room visits (Saporito, 2019).

Within the region covered by Gesundes Kinzigtal, an increase in admissions was observed with a decrease in the length of stay (Busse & Stahl, 2014). One of the main drivers of observed savings for Gesundes

Kinzigtal compared to a comparator group is related to emergency hospital admissions: between 2005 and 2010, emergency hospital admissions for patients in Kinzigtal increased by 10.2% compared to a 33.1% increase in the comparator group (Lupiañez-Villanueva & Theben, 2014; The King's Fund, 2021). An evaluation of GK found that there was a reduction in the over-, under- and misuse of healthcare and an increase in healthcare quality (Lupiañez-Villanueva & Theben, 2014).

5.3.3. Evidence on the use of process indicators

Evidence on the use of process indicators is scarce. KardiaMobile allows HCPs to analyse ECG recordings taken on the KardiaMobile device. MySugr and Livongo allow users to take blood glucose readings, though these are not necessarily provided to HCPs as progress updates. Kaiser Permanente and Gesundes Kinzigtal use process indicators as part of their roles as insurers/providers. Nujjer does not utilize process indicators.

5.4. Experience

5.4.1. Changes in patient experience

Table 10: Patient experience measures across six VHC interventions

	App rating	General satisfaction scores	NPS score	Client retention
Gesundes Kinzigtal	n/a	✓◇	-	✓
Kaiser Permanente	n/a	-	33	✓
KardiaMobile	4 stars*	✓	-	-
Livongo	n/a	~◇	64	~
MySugr	4.6 stars*	- (Germany) ✓ (USA)	70	✓
Nujjer	-		-	-
Key:				
*	Average rating in App Store and Google Play			
✓	Good			
~	Questioned			
✓◇ / ~◇	Assessed based on proxy indicators			
-	No evidence			

Generally, user satisfaction seems to be high among these interventions. Gesundes Kinzigtal tends to receive high patient satisfaction scores with over 90% of members willing to recommend the service to friends or relatives and satisfaction scores remain stable (Pimperl et al., 2017; Siegel et al., 2016; Siegel & Wilhelm, 2017). Studies have found that MySugr encourages positive trend data on mean blood glucose and glycemic variability, leading to the suggestion that the provision of educator-led coaching and unlimited access to blood glucose test strips has a positive impact on both user satisfaction and the sustainability of behavioural changes (Fredrick Debong et al., 2019). No data was found for MySugr in Germany, but studies in the US suggested customer satisfaction with MySugr is positive: results from a

satisfaction survey showed 86% of respondents who had communicated with a MySugr diabetes educator via smartphone were satisfied with the coaching service. Similarly, a study of the use of the AliveCor device in a paediatric population reported that user satisfaction was high, and '98% of the survey responses indicated that it was easy to obtain tracings, 93% found it easy to transmit the tracings, 98% showed added comfort in managing arrhythmia by having the device, and 93% showed interest in continued use of the device after the study period ended' (Nguyen et al., 2015). The NICE MIB reports KardiaMobile patients appreciated the technological innovation and the quick and easy testing experience (NICE, 2020).

Net Promoter Survey (NPS) scores are commonly used for apps as a user feedback method, though the use as a measure of satisfaction have been disputed. On a scale of 0 to 100, reported NPS rates were 70 for MySugr, 64 for Livongo, and 33 for Kaiser Permanente, though the latter is noted to be higher than the industry average of 14 (F Debong, 2016; Kaiser Permanente, 2019; Tullman & Burke, 2020).

Other proxy measures of satisfaction include retention rates: reports for Gesundes Kinzigtal suggest almost all patients would join the scheme again and significantly fewer of those enrolled left their sickness fund to join another compared to people who were not enrolled in GK (Busse & Stahl, 2014; Saporito, 2019). Livongo had a 90% retention rate in 2018 and 94% client retention rate in 2019, though other reports state Livongo reportedly struggles with member enrollment and engagement: in 2018 only 34% of total recruitable individuals signed up after 12 months (Durant, 2020; Livongo, 2020a; Tullman & Burke, 2020). Retention among active MySugr users is 95% for the first month, 90% for the second month and 85% for the third (MySugr, 2018c). Similarly, Kaiser Permanente reports client retention rates of 88% after one year, 78% after three years, and 71% after five years in southern California (Kaiser Permanente Southern California, 2021).

A large-scale evaluation of digital diabetes prevention programmes, including Nujjer, in the UK plans to collect data on effectiveness, satisfaction and patient activation, among others endpoints (Murray et al., 2019). Results have not yet been reported.

Overall, this section highlights a number of measures to capture the patient experience across the 6 technologies reviewed in this report. There may be additional measures for other technologies or apps. The diversity and disparity of measures to account for the patient experience highlights, among others, the absence of a systematic measurement framework for the quality of patient experience in VHC, which is an area that could potentially attract attention in the future.

5.4.2. Changes in provider experience

Ideally, the use or provision of VHC interventions would see a change in provider experience. This can include increases or decreases in perceived quality, patient centeredness, or improved cooperation. Little evidence is available on this from the six case studies. MySugr was ranked highest out of nine key diabetes apps amongst physicians who reviewed and rated them in terms of effectiveness, functionality, design, user friendliness and credibility (Doctorpedia, 2020). Gesundes Kinzigtal has reportedly led to improved cooperation among physicians, and 80% of providers would reportedly re-join GK (Busse & Stahl, 2014). A study on the role of Kaiser's nursing organization on the quality of care reported nurses working in

Kaiser hospitals were significantly less likely to report being dissatisfied or intending to leave their job[1] (McHugh et al., 2016).

5.4.3. Summary

The case studies above demonstrate how different health system types may embrace virtual health care solutions. These reviews showcase positive population outcomes across clinical and health measures, patient experience, and cost-saving evidence, suggesting the potential for VHC solutions to contribute to improved population health and cost containment exists. However, it is important to note that existing evidence is limited and often conducted or funded by the developers of technology and so the full impact of the six case studies, and other examples of VHC, is speculative to a degree.

[a1] *This study compared Kaiser hospitals to Magnet (hospitals known for having excellent nurse work environments) and non-Magnet hospitals. This statement is compares Kaiser nursing staff to non-Magnet hospitals.*

6. Discussion and policy implications

On a basic level, a successful PHM programme requires clinicians and, more generally, health care systems, to address both existing acute and chronic conditions, as well as expand their focus beyond the care and treatment of those patients with known problems to identify all the individuals in their patient population with potential conditions. The latter has historically been difficult due to a lack of robust holistic and longitudinal patient data. Such a proactive approach is needed to enable healthy patients to remain healthy and to continually monitor the status of those at-risk patients. Technology can help care providers efficiently and cost-effectively aggregate and analyse patient data, facilitate care coordination, and enable patient communication and education to maximise the potential of PHM. In fact, technology underpins all the critical success factors for PHM by improving the efficiency and effectiveness of performance monitoring and financial planning, the application of financial incentives, the re-design and management of clinical workflows, and the implementation of services at scale (Deloitte, 2019a).

Virtual health encompasses several modalities of digital and telecommunication technologies that may be used to deliver healthcare, help enhance access, improve value, personalise care and establish competitive advantage by operationalizing technology solutions. Specifically, experts interviewed for this report identified that utilisation of virtual health can reduce gaps in care by allowing patients to access physicians remotely without having to rely on scheduled, routine visits, helping patients to seek care when most needed and reducing the number of 'high cost' visits or emergency hospital admissions. It also has the capacity to bridge the gap between specialists by coordinating patient needs with multiple specialists and enhancing integrated care and allowing those in remote areas to effectively access healthcare (Raegen, 2016). Some now view it as a care delivery transformer (Deloitte, 2017).

To benefit from a positive contribution of VHC to achieving population health requires a degree of preparedness of health systems at local, regional, and macro level and a willingness of the system to engage with stakeholders and novel digital technologies. The three country overviews and six case studies were shared with a cohort of experts. This section thus incorporates findings from secondary research as well as key insights from experts interviewed and roundtable discussions to (a) identify key barriers and bottlenecks to expanding VHC and PHM; (b) explore the value drivers and motivations of essential stakeholders at the health system level; (c) provide examples of opportunities as highlighted by experts for the potential role of industry in VHC for PHM; and (d) offer a suggested way forward in the form of an agenda for policy engagement.

6.1. Barriers and bottlenecks to VHC and population health management

Although there are clear advantages to both expanding VHC and a health system shift towards population health management, roundtable discussions and interviews with experts identified several barriers and bottlenecks that prevent the introduction and scale up of VHC for population health. These challenges are grouped into (a) health system challenges, (b) culture and mindset barriers, (c) regulatory bottlenecks, (d) technical challenges, and (e) stakeholder and trust barriers.

6.1.1. Health system challenges

General health system set up. General health system set up, such as administrative boundaries and fragmentation, can impact the effectiveness of digital-based population health. For example, in England, STPs now cover large geographic areas and require the coordination of different stakeholders that have not previously relied on each other and may not have linked financial incentives such as similar budget constraints. On a more local scale, Local Authorities (who provide social care) and CCGs (who focus on health care) do not always share the same geographic area. This limits how these two important stakeholders can jointly commission or plan services (Wenzel & Robertson, 2019).

Health system fragmentation. Health system fragmentation is also likely to be a bottleneck for the delivery of virtual healthcare in systems where multiple insurers operate, e.g. in the US. For example, a lack of mandatory system interoperability (only introduced in the public system) can lead to lack of consistency across the electronic medical record system when patients change insurers. Fragmentation between primary and secondary care may also be slowing the adoption of VHC solutions due to a lack of coordination between primary and secondary care professionals (Infosys, 2019). Experts also raised the concern that new VHC solutions may lead to further fragmentation within systems, leaving patients with multiple platforms for different conditions that do not interface with each other. On the other hand, roundtable discussions pointed out that VHC solutions for population health need to strike a balance between serving larger areas that would benefit from standardised systems and processes and catering to local nuances and needs.

Elements of paternalism. Lastly, in publicly funded health systems like the NHS in the UK, experts noted that that there is a sense of paternalism that could reduce the effectiveness of VHC. In paternalistic systems, taxpayers (patients) may feel less responsible for their own health. This could pose a challenge to population health programmes that rely on creating informed and empowered patients to facilitate self-care and reduced reliance on advanced clinical interventions. If this is to change, significant investment is needed in changing culture and cultivating a different mindset.

6.1.2. Culture and mindset barriers

Roundtable discussions highlighted that in addition to health system structures, providers' and purchasers' culture and mindset towards patient self-management, digital innovation, and the value of prevention could be a barrier to PHM.

Reactive vs. proactive management of disease. Experts identified that the three systems studied in this report are traditionally seen as reactive, rather than proactive towards the management of disease as they lack an embedded focus on the prevention of chronic diseases such as CVD and diabetes. As prevention has not historically been prioritised equally with treatment, there needs to be a shift in thinking, organisation, resource use, reporting, and monitoring in health and care delivery. This can be a challenge for some organisations who have been driven by organisational and patient outcome targets that do not strongly focus on prevention efforts (NHS England, 2014).

Cultural shift requirements. Additionally, several cultural shifts in how care is planned and provided are necessary for a system to embrace virtually supported PHM. Firstly, providers and patients need to be open to operating digitally. As our country case studies have highlighted and our experts have confirmed, the

Covid-19 crisis has facilitated an openness to VHC, and digital tools are now more widely accepted. However, roundtable participants pointed out that a 'digital divide' remains in many countries and that this could limit the extent of virtual population-based care.

Patient centredness vs. population well-being. Experts also raised the challenge that current health providers are primarily patient-focused organisations, largely leaving population well-being and public health in the domain of other organisations. In the case of the UK NHS, the adoption of integrated care services and focus on population health is a paradigm shift. This shift in focus to the population-level requires system-wide changes in priorities, work cultures, and mindsets around a previously episodic patient relationship.

Engagement with other stakeholders. A final cultural shift that could signal that a health system is ready to engage in virtually enabled population health management is that the health system is willing and ready to engage with other stakeholders, including the pharmaceutical sector. Currently, the pharmaceutical sector often engages with regulators and, depending on the country context, can have little engagement with local care planners and providers.

6.1.3. Regulatory bottlenecks

Whilst effective regulation is important for patient and provider confidence, it can also frustrate suppliers if it does not move fast enough. Outdated regulatory procedures not equipped to respond to rapid technological advancement may unwittingly hold back potential advancements in clinical treatment, artificial intelligence, and digital health to improve health outcomes and reduce disparities.

Updating review procedures. Traditional market entry and take up pathways were designed for pharmaceuticals and medical devices. Encouragingly, we saw in all three study countries that review procedures for digitally enabled devices are slowly being updated; however, current regulatory and value-assessment systems usually focus on products that address existing health conditions rather than prevention.

Reducing uncertainty around regulatory pathways and reimbursement strategies. Uncertainty around the regulatory pathways for digital device approvals remains, particularly regarding proving therapeutic benefit. Thus, it is essential that further progress is made to establish clearer pathways for regulatory approvals for digital prevention products if prevention is to be prioritised under population health management (EIT Health Think Tank, 2020). Similarly, many countries lack a clear and practical reimbursement strategy for digital tools, including those provided at population level or focusing on prevention. If a health system has these in place then this is a strong signal that the system is ready to engage on virtual care for PHM.

Transparency and user input. There is also a need for improved transparency and user input into regulators and insurers value-judgement decisions, especially for innovative interventions like virtual health tools. Variation in both regulatory and reimbursement rules within countries, for example between states in the USA, can confuse patients who are not able to understand which services are reimbursable. In the USA, particularly, there may also be variations in insurance coverage for VHC services offered by private payers which can affect patient uptake (Infosys, 2019).

Cooperation among key stakeholders. Roundtable discussions also raised the question of how to facilitate a shift into a new environment with enhanced cooperation between the pharmaceutical industry, regulators, and healthcare systems. As highlighted previously, currently pharmaceutical companies work more closely with regulators than local decision-makers who are essential stakeholders in population health interventions. Industry seeking to enter the population health space will need to establish new forms of engagement and any engagement must be productive and distinct to current regulatory processes. Experts felt that emphasising "drug agnostic" models would be attractive for stakeholder engagement.

6.1.4. Technical challenges

Technical challenges, funding levels and investment. Roundtable discussions pointed out that technical barriers such as a lack of knowledge and access to high level capability, data security and privacy issues, basic technical issues (i.e. low bandwidth) due to insufficient funding, and poor investment in modern equipment for health systems can also affect the adoption of VHC. On several occasions, experts highlighted the positive shift following COVID-19 that has spurred the adoption and willingness to use digital tools. Since 2020, both patient/end user and health systems have increasingly utilised VHC where previously there was more of a general reluctance to embrace modern technology and a lack of patient and provider trust in VHC offerings.

Requirements for standards and processes. There are also issues around general health system readiness that may need to be addressed before any digital-based care delivery can be expanded. Expert discussions pointed out that health systems need standards and processes in place to fully realise virtual care for populations. Digital maturity, including standards for interoperability, data sharing, and analytical ability to use generated data for decision-making, can signal system readiness.

6.1.5. Stakeholder and trust barriers

There may be distrust between health purchasers, care providers, and industry. One expert flagged that there is a danger that naive commentators with conventional business backgrounds could make assumptions about using VHC services to promote population health that are not in line with the reasons why primary care doctors, public health practitioners, or specialised physicians and surgeons might favour an extended use of VHC. Whilst the creation of systems providing new and more convenient routes to accessing medicinal products might be well intended and desirable from a managerial and public cost-minimising perspective, such strategies may be seen as threatening the flexibility and choice-linked interests of many clinicians and health service users. They might also be regarded as failing to understand the wider objectives of public health interventions in publicly funded health care systems which seek to optimise overall public/population health, as distinct from maximising individual health care opportunities.

In thinking about some of the barriers specific to the pharmaceutical industry's role in VHC for PHM, some experts identified that the industry will need to address the challenge that it usually has no direct contact with patients and there is widespread scepticism around its motives for establishing a virtual or population-based solution. Thus, industry needs to communicate aligned intentions and goals with health systems in order to build trust.

6.2. Aligning stakeholder incentives: Value drivers for VHC uptake

When it comes to the potential for VHC to contribute to population health management, stakeholders including policymakers, manufacturers, purchasers, healthcare providers, and patients are understandably driven by different motivations and values. However, pharmaceutical companies considering a VHC solution should identify how incentives can be aligned to drive take up.

Table 11: Stakeholder value drivers for the uptake of VHC for population health management

Stakeholder	Primary Value Driver(s)	Secondary Value Drivers
Regulators	Safety; Effectiveness	Privacy; Security; Interoperability; Other minimum requirements
Policymakers	Quality of care; Financial stability	Health inequality reduction
Purchasers	Cost-effectiveness; Improved member experience; Effectiveness; Budget impact	Big data; Long-run cost management (macro-economic efficiency)
Healthcare Providers	Care quality; Patient relationships; Reimbursement	Targeted health care delivery; Chronic disease prevention; Self-management
Patients/ Carers	User experience; Health gain	Credibility; Health benefits; Convenience

Regulators. To understand regulator values, we need look no further than virtual health product assessment criteria from the FDA, BfArM, or NICE/NHSX. These review processes set the minimum expected parameters of these digital tools and establish the importance of privacy, security, interoperability, and clinical benefit. However, underlying these minimum standards, regulators are motivated to support the introduction of innovative products that are safe and effective (FDA, n.d.).

Policymakers. In some contexts, policymakers extend beyond regulators and include those responsible for setting health strategies in organisations or geographic areas. These stakeholders rely on the oversight provided by regulators and are motivated by a desire to provide quality care, ensure financial sustainability, and, in some environments, to meet people's health needs and reduce health inequalities (NHS England, 2014).

Purchasers. Health systems are primarily motivated by cost-effectiveness, budget impact and patient experience and see potential in population-based virtual care to improve on these (Friesdorf & Deetjen, 2019). Data on patient populations are also highly valued by purchasers and commissioners of care as it has the potential to provide insights to funders, allowing them to take a data-driven approach to premiums, resource allocation, and co-payments. Effective population-based interventions to prevent chronic disease and support self-management are also valued by insurers who anticipate such interventions to help manage costs in the long-run (Imison et al., 2016).

Providers. When producing and marketing a VHC product, suppliers often need to consider two customer types: providers, who often act as gatekeepers for products, and patients or carers, who may interact with and use the product.

Healthcare providers generally place trust in regulatory bodies to ensure that products available meet safety and effectiveness requirements. Where these are certain, providers are concerned about ensuring patients' privacy and respect, building trust with patients, and delivering the same or improved standard

of care as face-to-face service (Imison et al., 2016). On this latter point, experts interviewed emphasised the importance that physicians do not feel that virtual consultation loses the ability to observe the whole patient as this could have an impact on diagnosis. On the other hand, increasingly, providers have also realised the potential for virtual healthcare to support self-management and save time.

Patients. For patients, user experience was identified as one of the main success factors for patient-facing platforms, followed closely by credibility/trust and perceived health benefit (Roland Berger, 2020). Fortunately, manufacturers can leverage formal regulatory review processes for virtual healthcare products to signal credibility and health benefits. The rise in virtual consultations during the pandemic led to positive reports from both patients and providers in many countries who found VHC convenient, time-saving, and with the ability to streamline workflows (Car et al., 2020).

The key value drivers for these various stakeholder groups operate within the gaps and challenges associated with virtual healthcare. These include issues such as those related to regulatory environments, including the lack of consistent evidence on the assessment of impact of digital tools, outcomes, and cost for specific interventions - particularly those not widely covered by regulatory regimes, such as apps. The diversity of measures to account for the patient experience highlights the absence of a systematic measurement framework for the quality of the patient experience in VHC.

Country settings and willingness to encourage uptake of VHC also play a role: existing infrastructures may be weak, incompatible, or outdated, and silos or pathways between relevant institutions may be embedded in a deep, historical manner which produces an environment which does not lend itself to fast and easy uptake of novel solutions. Most notably, incentives and value drivers across relevant stakeholder groups vary to a large degree. Notice must be taken to ensure these are not misaligned to a degree where a significant barrier to the necessary collaboration or joint production of efficient and effective solutions is developed.

6.3. Opportunities and the potential role of the pharmaceutical industry

As we move further into the 21st century the healthcare landscape is primed for the expanded adoption of virtual healthcare, particularly within the remit of PHM. By 2025, global spend on digital health is predicted to reach €1 trillion and digital products and services will grow to a market share of 12% (Choueiri et al., 2020), leaving little doubt that virtual health and digital platforms will transform healthcare in the coming years. Several key factors have increased interest in the implementation of virtual health technologies by healthcare bodies, for example, physician shortages, patient/consumer demand and the evolution of the policy landscape to meet patient/consumer demand, advancing technology, and Covid-19.

There is a possible role for the pharmaceutical sector in population-level managed care and virtual health care tools. In the US in particular, roundtable participants mentioned the increasing role of tech companies for health care and health care delivery and that opportunities for partnerships beyond health providers and patients will increase in the short-term.

Leverage existing expertise. One of the key value offerings from the pharmaceutical sector identified by experts is their expertise and information on population groups. Through the sector's work on producing and bringing new products to market, pharmaceutical companies have developed broad knowledge and detailed data on populations and health conditions. This data, as well as companies' intimate understanding

of conditions, available products, uptake, and patient outcomes position the sector to support data-driven population health management initiatives or even value-based pricing and the identification of gaps in care or care provision which could benefit from digital solutions. Pharmaceutical sector involvement may also be welcomed in areas supporting rare diseases, particularly those where they have existing expertise. In a similar vein, experts suggested that knowledge of a disease, relevant treatments, and knowledge of patients and their behaviour and needs are often held by separate stakeholders and the industry could play a role in bridging and sharing this information through technology applications.

Support links between patients and care services. Roundtable participants also identified that virtual health solutions could support patient engagement and facilitate self-management of health and care. The pharmaceutical industry may be best placed at the boundary between care services, facilitating transitions between self-management and primary care or between primary and secondary care. Another opportunity for the sector in population health management is to use their knowledge of products and patient outcomes to support patients at all stages of a disease lifecycle by improving health literacy or health education. This could be offered through virtual service-orientated models or other virtual tools such as developing an app alongside new medicines with information on how to use new medicines, information to support adherence, or information about trial results. Alternatively, experts identified that there might be opportunities for the pharmaceutical sector to support population-level primary and secondary care through vaccinations, 'maintenance therapy' supply, behavioural interventions, or by leveraging its expertise in rare diseases. Furthermore, a holistic solution from the pharmaceutical industry could further current population-level initiatives by serving populations that are underserved due to stigma, other allied forms of rejection, or by specifically targeting health inequalities or serving less developed health systems. Lastly, experts flagged the potential for IT to act as a gatekeeper to care. The industry can explore the development of a tool that supports the entrance of patients into the health system.

Work with early-stage companies. Many of the interventions developed at a patient-user level (e.g. apps or devices) are developed as a start-up. Several roundtable experts supported the idea that there is a significant potential for the pharmaceutical industry to look to partner with and/or fund initiatives at this level, such as seen in the collaboration between Roche and MySugr: originally supported by a Roche venture fund grant, Roche later acquired MySugr and allows it to continue to operate independently.

Support collective goals that promote collaboration and promote trust. Experts emphasised considering focusing on conditions that foster stakeholder collaboration and build transparency and trust between partners. The sector may be well placed to host forums which bring together necessary stakeholders in a given area, such as patients and patient groups, health care professionals, and regulatory agencies, to identify gaps and challenges and facilitate digital health technologies. Additionally, beyond sponsoring one-off VHC initiatives, companies may wish to explore opportunities with professional, voluntary and public sector partners in order to establish trusted and accepted platforms for providing given types of preventive and therapeutic care.

Gather data and facilitate real world evidence generation. Additionally, roundtable discussions noted that while data generated from population-based interventions has the potential to be incredibly valuable to health systems, not all systems are equipped to use this data in a meaningful way or allow data, especially data on adherence or impact, to flow back to the system. That may mean that even if data-

focused interventions are implemented and efficient, there could be only a small effect on population health if systems are not designed and updated to be able to accommodate the learnings from these efforts. The industry can work with other stakeholders to design interventions and tools which can generate data for real world impact. This may require collaboration to recognise system and population needs and to coordinate evidence-based decision-making for resource allocation and planning.

Focus on emerging markets may present significant opportunities for growth. In this report, we have discussed VHC in developed markets. Once a health care system is set up nationally, it may be difficult to implement significant change within the boundaries of that system. Emerging markets with limited IT infrastructure have an opportunity to build well-integrated systems from the ground up while learning from the barriers and bottlenecks of more established systems. For example, in developing IT infrastructure, newly established health care systems have the luxury of knowing how widely used smartphones and apps are. This presents an opportunity to partner with the private sector and introduce policies surrounding app creation that will ensure data interoperability. Emerging country health care systems should consider implementing the most cutting edge and scalable health IT infrastructure to prevent future data sharing issues.

Overall. In summary, roundtable discussions identified several opportunities for industry to offer digital solutions to support population health management. Above all, the role of the pharmaceutical industry will be dependent on the contexts being addressed. Action in this field should be combined with sensitivity to local and national health sector variations and with an understanding of the challenges associated with collaborative approaches to digital health integration. A possible challenge for some pharmaceutical companies is their ability to demonstrate knowledge beyond biomedical interventions, such as an understanding of the social and economic determinants of health. Demonstrating this knowledge would help build trust among providers and patients and avoid possible unintended consequences of new virtual interventions. Incorporating digital tools into population-level care may alter the way services are delivered and managed. In particular, the patient-provider relationship will shift. Healthcare providers are likely to be more interested in interventions designed to support the relationship between providers and patients or those that maintain the professionalised role of clinicians. If pharmaceutical companies were to provide virtual services, they need to engage early to align the incentives of multiple stakeholders and work to ensure that tools that standardise or control care pathways do not remove patient flexibility or choice.

6.4. Short and long-term policy agenda to address challenges and opportunities

As part of this report, roundtable discussion groups proposed a roadmap for the industry to begin to productively engage with essential stakeholders. Essential stakeholders to involve included the public (both patients and their carers), health care systems, employers, and industry.

Collectively, experts agreed that the following agenda items should be prioritised:

- Open and transparent discussions with the public through some event or activity that drives support for the case for industry involvement in VHC and PHM;
- Engage the public in discussions to establish what is achievable and realistic behavioural change;
- Discussions to understand the allocation and distribution of health care in PHM; and

- Building the case for population health by defining the philosophy behind it and leveraging opportunities created by the pandemic to highlight the potential for PHM.

Placing patients at the centre. When planning a successful venture for developing a VHC solution to support PHM, experts were adamant that design should be driven from a patient perspective, rather than an industry perspective. Patients and carers should be involved in designing these interventions and that digital solutions should focus on prevention and self-management in order to maximise value, especially in resource constrained settings.

Experts also identified the importance of solutions presenting the right business model for health systems to help establish a mandate for change. Solutions that reduce fragmentation across systems are highly valuable and may support a value-for-money or value-for-outcomes business case.

Addressing behavioural barriers. Additionally, roundtable discussions also suggested that early engagement should begin to address any behavioural barriers to the uptake of VHC. Pressure from the demand-side and campaigns to raise awareness of the benefits of VHC could incentivize users and providers to accelerate VHC adoption. Clinician training, to allow the workforce to become more familiar with VHC and its benefits as well as increasing interoperability and standardisation plus enhanced data security and regulations could help overcome any technical barriers.

Building trust and respecting transparency. According to experts, building trust between industry and other stakeholders was one of the single most important actions the sector could take. When designing a way forward for industry, while there may be tangible economies of scale for the pharmaceutical sector to engage with data creation, collection, and analysis through digital technology, particularly where evidence may not exist, issues related to data confidentiality and security remain a salient issue. In other words, while data is essential to providing VHC services, it can also be commodified and used in ways which users are not aware of. Experts emphasised the importance of trust and transparency and noted that governments and citizens may be hesitant to take actions that are seen to expand the sector's reach and influence in health by facilitating access to and control over more population data, and providers and funders may not wish for VHC platforms to be fundamentally controlled by third parties that have commercial interests in particular products. Successful industry-supported initiatives in the area of VHC and population health improvement could work towards increasing trust by demonstrating a robust understanding of the social and economic determinants of health alongside the bio-medical causes of disease. This includes showing insight into and respect for the value of human relationships in health and social care processes and the role of professionalism in maintaining and improving care quality.

Data-sharing agreements. Another action to further mitigate these concerns could be establishing data-sharing agreements, positioning data as a public good, or linking data collection to a medical device. However, even if this were achieved many health care providers and funders are still likely to feel that VHC platforms should not be unilaterally controlled by third parties that have commercial interests in particular products. This is always likely to be the case, albeit problems could be mitigated if companies can convincingly display a commitment to generating health improvement for communities that takes primacy over their need to provide financial returns for shareholders.

7. Concluding remarks

In conclusion, there is consensus among the literature and experts consulted for this report that virtual health care has a clear role in the efficient and expanded provision of population health. The three country studies indicate an openness from decision-makers across different funding models for both virtual health solutions and population-based programmes. Furthermore, the six VHC interventions discussed in this report indicate that while solutions vary widely in their design, successful interventions are all patient-centred and deliver perceived value to the health system it operates in. Many of these interventions also involved pharmaceutical companies, which suggests there is potential for industry to take a strong lead in these areas.

Based on the findings of this report, the pharmaceutical sector has a potential role to play at the boundary between service types but faces several barriers, most notably around health system structures (including reimbursement and infrastructure) as well as potential challenges with stakeholder buy-in and cooperation. However, evidence suggested that the industry could establish strategic partnerships with patients, providers, payors, and regulators by leveraging existing relationships, aligning incentives, taking value and outcomes seriously, and by ensuring that any designed VHC solutions complement or are easily integrated into existing systems.

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Appendix 1: Segments of VHC

Category	Subcategory	Definition
Telehealth	Synchronous (telemedicine)	Live, two-way audiovisual interaction between patients and providers (eg, video conference visits)
		Live, two-way interaction between providers and providers (eg, video conference review of pharmacy prescriptions)
	Asynchronous (store and forward)	Provider-to-provider transmission of recorded health history (eg, sending a lab test, X-ray, MRI, to a specialist to request a clinical opinion)
		Provider-to-patient transmission of patient information (eg, a provider emailing/ texting a patient to check on them in post-visit follow-up, a patient sharing photos of a skin rash for review and diagnosis)
	Remote patient monitoring	Collection of electronic personal health/medical data which is transmitted for review by a remote provider
Digital thera-peutics	Replacement therapies	Evidenced-based therapeutic interventions which leverage software to prevent, manage, or treat a medical condition, in lieu of conventional treatments (eg, pharmaceuticals)
	Treatment optimization	Optimizes medication, extending the value of pharmaceutical treatments (eg, improving medication adherence, monitoring side effects of medication)
Care navigation	Patient self-directed care	Patients accessing their own information (eg, website with secure, 24-hour access to personal health information)
	E-triage	Tools that provide support in searching for and scheduling appropriate care based on symptoms/conditions as well as price and quality of providers

Source: (Fowkes et al., 2020).

Appendix 2: Additional country-based information

Germany

Type	Multi-payer healthcare system with mandatory insurance (Gerke et al., 2020)
Coverage	Universal health coverage with~ 90% of population on Social Health Insurance (GKV) and 10% of population on Private Health Insurance (PHV) (Gerke et al., 2020)
Competition	Competitive market and citizens have choice of insurance and care providers
Decentralised	Federalised system where federal state implements national health policies with decentralised governance.

Funding and Resources

Traditional Funders

Since a 2009 reform, a central health fund (*Gesundheitsfond*) collects and distributes finances for the approximately 90% of citizens that are under statutory health insurance. Sources of funds include members' contributions, employer contributions, and the federal government (Busse & Blümel, 2014). Health insurers receive funding based on the risk structure compensation of their insured members with additional allowances for other expenses, including administrative and discretionary spending. Health insurers may also collect additional contributions from their members. Future national funding allocation changes are planned in order to promote prevention and early-detection (of Health, n.d.).

As an alternative to statutory health insurance, residents can enrol in private health insurance. Private health insurers collect revenue from members based on their risk profile and how long they have been privately insured (*State of Health in the EU: Germany Country Health Profile 2017*, 2017). Privately insured citizens make up approximately 10% of the population (*State of Health in the EU: Germany Country Health Profile 2017*, 2017). As a result of mandatory insurance coverage, private out-of-pocket spending is considered low compared to other countries, accounting for approximately 12% of total health expenditure (*State of Health in the EU: Germany Country Health Profile 2017*, 2017).

Non-Traditional Funders

In addition to standard funding allocations, hospitals can apply for "Innovation Funds" from the Federal Government or health insurers. These funds are designed to support the introduction of innovations in medical care and support integrated care systems (Berghöfer et al., 2020; Pinto et al., 2016).

United Kingdom

Type	Tax-payer financed health system (>80% of funding from public sources)
Coverage	Universal access to health care that is mostly free at the point of delivery
Competition	Limited competition between providers in public system
Decentralised	Health care financing and service organisation is devolved within UK and decision-making fairly decentralised

Funding and resources

Traditional funders

UK residents pay taxes which entitles them to receive free-at-the-point-of-service health care from the NHS. NHS services cover all aspects of prevention, management, treatment, and rehabilitation as set forward by NICE. NICE is a national public body that reviews evidence for new interventions and provides guidance on health care improvements, thus all devices used to support, manage, or treat illness need to be approved for use through NICE.

Private insurers are an alternative type of traditional funder. Private health care is widely available in the UK but remains a relatively small market. Major private healthcare providers leverage shorter waiting times and innovative technologies not available through NICE to attract their customer base.

Non-traditional funders

Occasionally, the national government sets funds aside for initiatives within the NHS that is funding beyond what is normally allocated. For example, in 2016, the UK Treasury provided £4.2 billion for NHS digitisation (Wachter, 2016). Additionally, national allocations of ring-fenced funding has been provided to help establish STPs and Primary Care Networks (Baird & Beech, 2020).

Financial flows and funding environments

Currently, funding for standard care and services is allocated to CCGs by NHS England and NHS Improvement based on a formula that considers geographic distribution, local health needs and health equity, and the type of services commissioned by the CCG ("Allocations," n.d.). However, per the Long-term Plan (*NHS Long Term Plan*, 2019), the NHS intends to reform its payment system from a majority activity-based reimbursement scheme to something that is population-based.

Funding allocations for population-based programmes such as STPs and ICS is separate and less certain. Some research suggests that STP funding is distributed through ring-fenced funds to CCGs. This funding may be capitation based with additional "boosts" from the Department of Health; however, given the relatively new and evolving nature of these partnerships, it is unclear what this means for recurrent funding (*The Sustainability and Transformation Fund and Financial Control Totals for 2016/17: Your Questions Answered*, 2016).

Stakeholder involvement

Stakeholders in population health

There is no single stakeholder involved in population health. STPs/ ICS are possibly the largest unit that work at the population health unit, although they are formed through the collaboration of stakeholders from health, social care, and community organisations. Stakeholders in STPs that are likely the most influential include Primary Care Networks, CCGs and Local Health Authorities.

Stakeholders in digital health

NHS CCGs and Trusts are the largest purchasers of digital health platforms across England and are gatekeepers to the introduction of many virtual health products. The NHS has also established the

Accelerated Access Collaborative and 15 Academic Health Science Networks (AHSN) who are tasked with identifying and supporting the introduction of digital technology to the NHS (*The AHSN Network*, n.d.). These AHSNs have identified several priority areas for digital health interventions, including atrial fibrillation (*Atrial Fibrillation*, n.d.).

United States

Type	Mixed system with public and private, for-profit and non-profit insurers and providers.
Coverage	8.5% of the population is uninsured as of 2018 (Tikkanen et al., 2020).
Federalist	The federal and state governments share responsibility and power, collaborating through the ACA. The federal government sets minimum eligibility requirements for programmes that states must meet. States have the power to set up and monitor their own insurance exchanges, determine state-wide minimum benefits requirements, and monitor premiums. Insurers set their own cost-sharing structures within federal and state regulations. (Rice et al., 2020).

Funding and resources

There is no nationally defined benefits package. The federal government funds Medicaid and Medicare (CMS) which provide coverage for low-income individuals and people over 65, respectively. The federal government also funds the Veterans Health Administration (VA). Private insurance, by which the majority are covered, is primarily provided by employers (Tikkanen et al., 2020). If a person is not provided coverage through any of the above means, they can purchase insurance through marketplaces created under the Affordable Care Act (ACA) (Tikkanen et al., 2020).

Stakeholders and public health

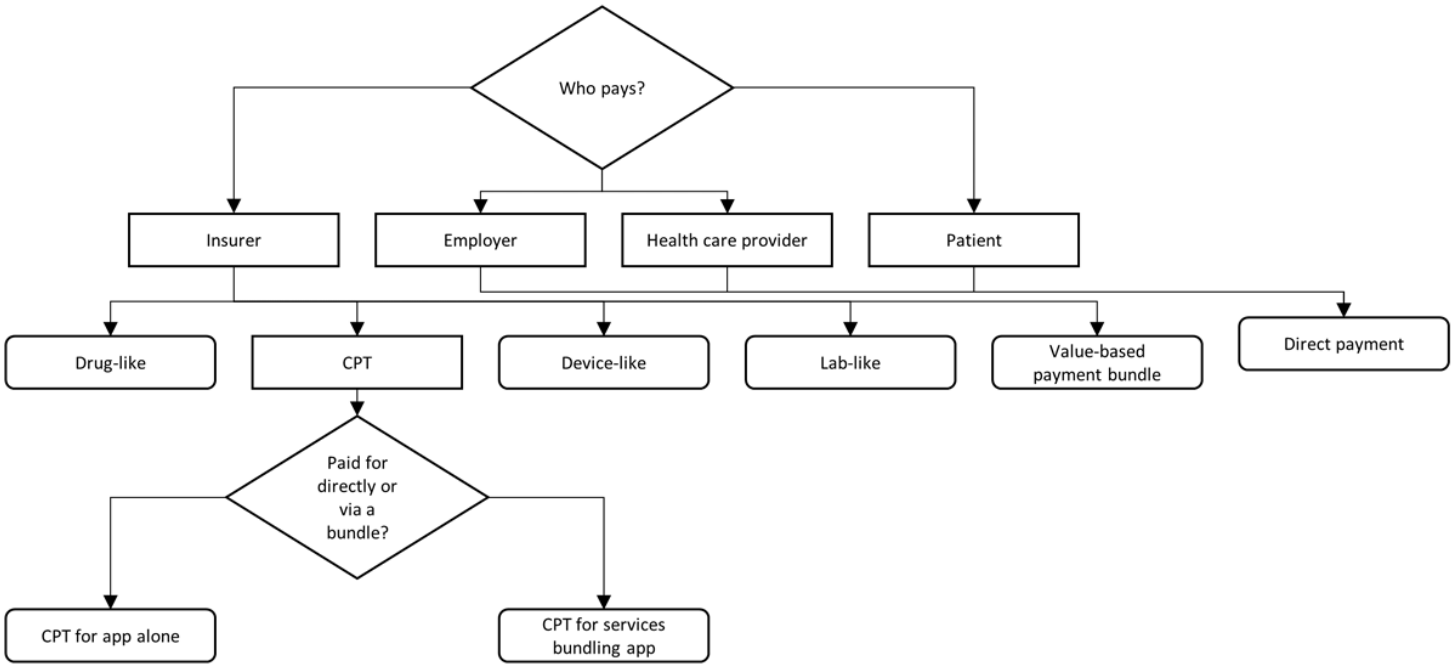
In each of the new policies created in the last fifteen years, the FDA describes the need to put patients first and work towards a model of value-based healthcare. The 21st Century Cures Act is particularly patient focused and is the first mental health reform bill in over fifty years (Lengyel-Gomez, 2018). With regard to the law, the FDA states, "The law builds on FDA's ongoing work to incorporate the perspectives of patients into the development of drugs, biological products, and devices in FDA's decision-making process. Cures enhances our ability to modernize clinical trial designs, including the use of real-world evidence, and clinical outcome assessments, which will speed the development and review of novel medical products, including medical countermeasures" (*21st Century Cures Act*, 2020). Their aim is to bring medical innovations to patients who need them faster and more efficiently in order to improve the health of the American population (*21st Century Cures Act*, 2020).

The FDA Digital Health Innovation Action Plan describes putting patients at the forefront of their vision and explains the necessity of digital innovation in addressing public health issues. They state, for example, "Medical software can help address public health crises, such as the opioid epidemic devastating many American communities, by providing immediate information on nearby treatment options and emergency help" (*Digital Health Innovation Action Plan*, 2017). The action plan explicitly recognizes the need for trust between the American public and the medical devices they use and explains that they must adapt their process for the American people to see the full benefit of digital technology (*Digital Health Innovation Action Plan*, 2017). By focusing on "high-risk" medical devices only, the market is opened for health apps designed to encourage healthy lifestyles, which will help get more innovative "low-risk" technology in the public's hands (Lengyel-Gomez, 2018).

Reimbursement pathways around digital health

The reimbursement of health apps occurs through multiple channels, which are shown on Figure 2.

Figure 2: Channels involved in the reimbursement of health apps



CPT: Current Procedural Terminology
Source: (Powell et al., 2019).

Appendix 3: Cost-saving evidence from PH case studies

Gesundes Kinzigtal: A reported net annual saving of 3% for the two insurance companies (Lupiañez-Villanueva & Theben, 2014). The contract between Gesundes Kinzigtal GmbH and the two health insurers aims for shared savings through the provision of financial incentives for managers and health care providers encouraging efficiency gains. Corresponding efforts have been taken to ensure that financial incentives for managers and providers to encourage savings will not result in the under-provision of services or risk selection (Hildebrandt et al., 2010). In the first three years after the Gesundes Kinzigtal started utilizing integrated care, the contribution margin (the difference between the amount received from the health fund pool and its spending) improved by €151 (US$203) per person compared to the unenrolled population (Busse & Stahl, 2014). A study from 2014, suggested GK has achieved savings compared to usual care, particularly due to lower pharmaceutical, hospital and rehabilitation or home care costs (Lupiañez-Villanueva & Theben, 2014; Struckmann et al., n.d.).

Kaiser Permanente*:* A 2002 comparison of Kaiser Permanente and the NHS found that KP achieved better performance at roughly the same cost as the NHS (Feachem et al., 2002). This was found to be due to KP having better 'integration throughout the system, efficient management of hospital use, benefits of competition, and greater investment in information technology' (Feachem et al., 2002).

KardiaMobile*:* The UK regulatory body, NICE, concluded that KardiaMobile may impact resource use as it could reduce the number of referrals for ECGs and result in increased detection of atrial fibrillation (AF) (NICE, 2020). However, although there is potential for the ECG devices to be cost effective, it was concluded there was insufficient evidence to determine if this would occur in practice (Network, 2020). Other sources have estimated that the health savings for the NHS could be around £2 billion when purely considering costs related to diagnosis of AF (PharmaTimes, 2018). Furthermore, they could avoid an average cost of £46,039 in the five years after someone suffers from a stroke if the devices are shown to increase the rate of AF detection (Network, 2020). These estimations depend, of course, on the volume and penetration of KardiaMobile.

Livongo*:* A reported 22% decrease in medical spending (translating to savings of $88 per member per month at year 1 (Whaley et al., 2019). Compared to non-members, members experiences a 10% reduction in diabetes-related medical spending and a 25% reduction in spending on office-based services. (Whaley et al., 2019). Livongo reports that annual gross medical savings per member are $1,908 (Livongo, 2020a).

MySugr*:* No savings data for MySugr was found in Germany, but in the US the company suggests a monthly cost saving of between 58 to 100 USD per member for employers paying for the MySugr app (MySugr, n.d.-b). No external studies for the potential savings of MySugr were found.

Nujjer*:* No studies on the potential savings of Nujjer were found. The NHS reports that type 2 diabetes accounts for around 9% of the annual NHS budget at around at 8.8 billion a year, and an estimated five million people in England are at high risk of developing type 2 diabetes (NHS, n.d.; NHS England, n.d., 2017).