The Digital Transition of Healthcare; Stay Left, Shift Left!
A new paradigm, policy and platform for Healthcare Transformation

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Abstract

The across-the-board adoption of Digital Health as a paradigm, platform and a policy will be fundamentally important to the achievement of United Nations Sustainable Development Goal #3; Ensure Healthy Lives and promote wellbeing for all at all ages. This paper is a synthesis of the input, dialog and output for the first UNGA 78 Digital Health Symposium held virtually in September 2021. It will serve as a platform for future digital health symposia to drive alignment, acceleration, and amplification of collective efforts to transform our global health system.

Introduction – Why?

All around the world healthcare systems are facing increasing pressures and demands. Well developed countries are facing challenges related to ageing population and epidemics such as Diabetes or Obesity while developing countries struggle to leverage diagnostics and access to affordable medicines. All health systems have struggled to cope with the Covid-19 pandemic but there has been a benefit from building on innovative vaccine technologies and in that many health systems turned to digital solutions to cope with this challenge. Despite the progress many countries have runaway health budgets with rates of growth which are unsustainable. Arguably Digital is the best Medicine for our sick healthcare system. Leading physicians such as Eric Topol and Robert Wachter have written about the creative destruction of medicine and digital doctors respectively but how do we make the digital transition of healthcare as quickly and sustainably as possible. Michael Porter and Elizabeth Teisberg have long advocated for redefining healthcare using value-based competition. In this context a new paradigm is emerging, Open Innovation 2.0 which helps enable structural transformation of an Industry through digital technologies and trust-based co-opetition.

In the past the arrival of a single disruptive technology such as railways or the internal combustion engine drove dramatic societal change and benefit. Today we are at a unique point in history where we have multiple digital disruptive technologies all showing up at the same time. Technologies such as Cloud Computing, Mobile and Social Networks, Artificial Intelligence, Blockchain and the Internet of Things create opportunities to radically transform healthcare. According to the OECD Healthcare is a decade behind other industries in digitalizing but the time is now to harness these digital technologies to help lengthen life expectancy, reduce morbidity, and provide more effective and cost-efficient care. Covid-19 has been a big bang disruptor forcing the healthcare industry to adopt digital solutions – necessity is the mother of invention and innovation. Digital technology can be a democratizing force for achieving health equality and equity with digital solutions enabling remote diagnostics, consultations, behavior modification, health inclusion and more effective medicines for all.

The opportunity: The Digital Dividend

Digital Technologies create the opportunity for the dominating paradigm of healthcare to change. Today's healthcare systems are reactive and focused on trying to restore health to ill people. The opportunity exists to shift resources, focus and use gamification to keep healthy people well or help treat people with chronic conditions mainly in their homes or in the community. With digital technologies it is becoming possible to offer citizens equivalent or better care in their homes than in a hospital or clinic and at lower infection risk and price. Acute hospital services consume much of healthcare systems budget but basing the healthcare system on secondary care is inefficient – there is a higher return both financially and in terms of patient outcomes by applying a community-based, proactive healthcare approach, for example supporting earlier diagnosis and personalized diagnosis through the collection of molecular and other information by digital devices. Additionally, citizens and patients can be offered monetary and non-monetary rewards for engaging in behaviors which better support their health.

What? - Stay Left, Shift Left

To align initiatives and accelerate progress we propose that countries adopt a **Stay Left, Shift Left** (SL2) paradigm, policy and platform for adopting digital health solutions. Ireland's digital innovation strategy is called Stay Left, Shift Left (SL2) and extends the concept of "Shift Left" which was first introduced by Intel Corporation's Doug Busch and Andy Grove. It is an approach to using digital and technology solutions to make people's health better. SL2 helps implement the Irish Government's health policy *Slaintecare.* The approach could be more generally applicable globally as a model for orchestrating a cohesive, coherent digital transformation of all health systems.

Stay Left: is about keeping healthy people well or, if someone has a chronic condition or needs rehab, they can be optimally managed at home.

Shift Left: is about moving patients as quickly as possible from an acute to community to a home setting wherever possible (Figure 1).
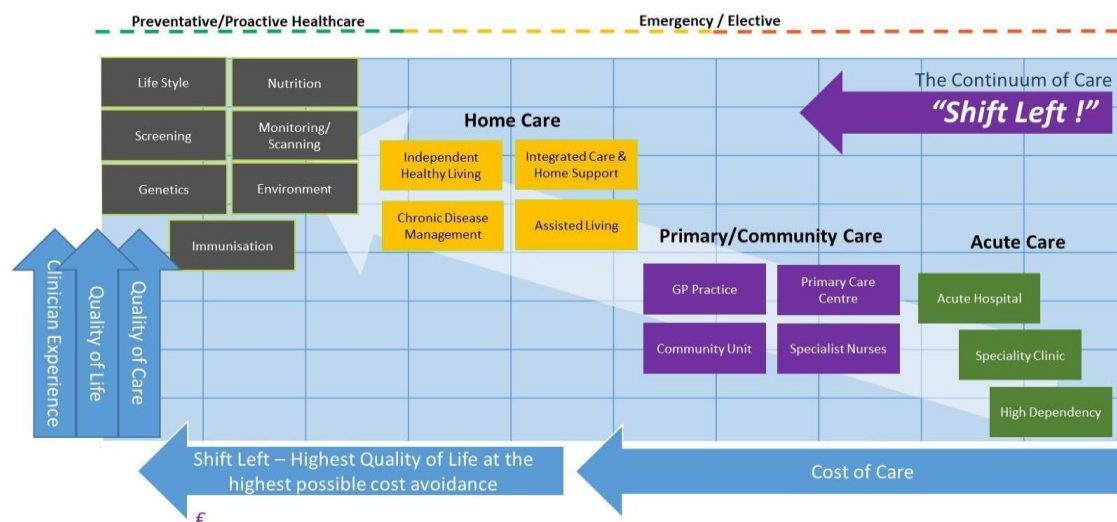

Figure 1 Stay Left, Shift Left

Each time we seek a disruptive technology outcome we look for four linked outcomes, the so-called quadruple aim: improvement in patient quality of care, quality of life, clinician/patient experience and reduction in cost of care/improvement in value. To achieve such multi-faceted results requires a new approach, by establishing health data ecosystems that are connected, thereby creating the next generation of healthcare systems. To secure this we need better data policy and a more thoughtful investment in data infrastructure and trusted data environments to support more sustainable healthcare systems using user centric business models, in contrast to change being viewed as one-time capital costs.

Care is delivered and results are achieved at the level of individuals and families. High value care, and the shift-left, stay left agenda are about improving care and outcomes at the level of delivery and value creation. Thus, policy must translate into outcomes which positively impact individual citizens, patients, clinicians and administrators alike.

Leap Frog Strategy

With the confluence of different digital technologies there is the possibility for both developing and developed countries to agree and execute a Leapfrog strategy (Figure 2). Countries should focus on deploying home and community-based solutions and shared care records that are mobile and cloud based, as part of their efforts to establish data-enabled healthcare. Advances in the Medical Internet of Things mean that low cost, but effective remote monitoring and consultation tools can be deployed. Health system wide efficiency and effectiveness can be significantly improved as well as individual outcomes being significantly better. Collaboration and interoperability at the nexus of acute-primary-home care will contribute to the emergence of health data ecosystems.
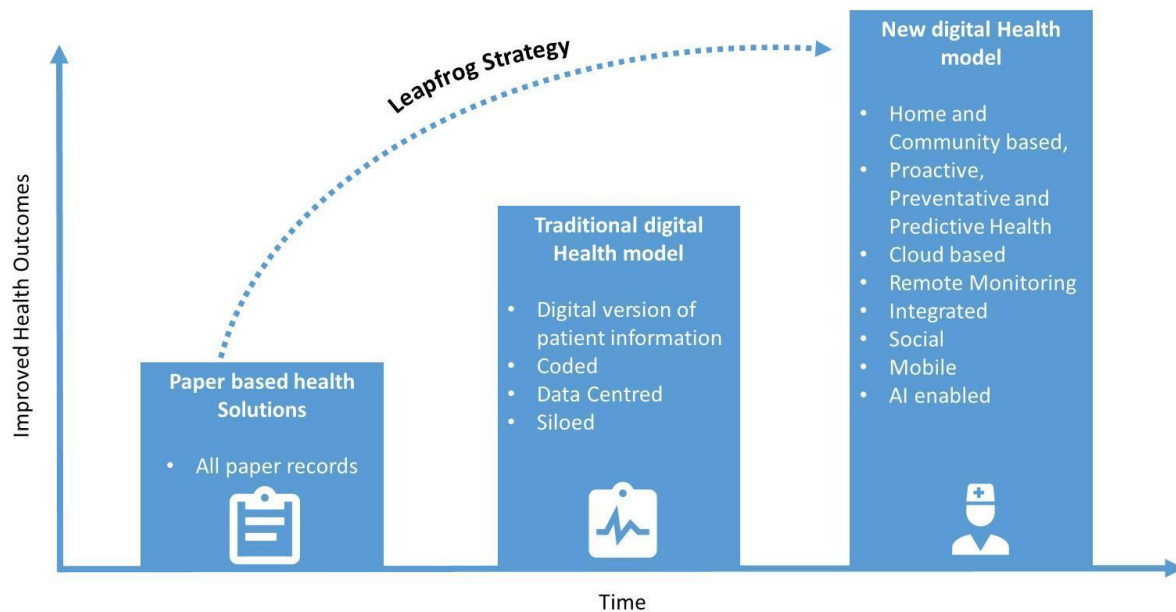
Figure 2 Leapfrog Strategy

We propose that countries move their healthcare systems from paper and presence-based systems to digital, virtual and cloud based systems whereby healthcare takes place primarily in the home and community. In this new model the focus shifts to proactive, preventative, personalized and predictive health. Data is more joined up, linked and used to better specify and target interventions. The use of closed loop digital systems, enabling the provision of proactive and precision real-time can anticipate and solve problems before they become real issues and illnesses. Digiceuticals and digital therapeutics will become commonplace with physicians supported by real-time AI systems suggesting and actioning new or modified titrations of medicine. Digital Therapeutics are an emerging class of intervention whereby software programs help prevent, manage or treat a disease. A Digiceutical is the combination of a pha Already Germany has moved to put in place a registry and approval progress for so called DIGAs (German acronym for certified 'digital health applications').[1]

Best practice – DiGA Fast Track in Germany

Before January 2020, digital health applications had no way to enter the highly regulated German healthcare system, as they did not fit into the existing paradigm. At the end of 2019, the German parliament passed the Digital Health Care Act (Digitale-Versorgung-Gesetz, or DVG) to established a regime by which to qualify and evaluate digital health applications (DiGA) in order to register them in a central directory (DiGA Verzeichnis). Once an application is approved by BfArM, the German equivalent of the FDA, a DiGA can be prescribed by any German doctor to

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[1] https://hbr.org/2020/12/want-to-see-the-future-of-digital-health-tools-look-to-germany

any German statutorily insured citizen (>85% of the population), and the statutory health insurance covers the costs – just as they do for medication.

The application process is labelled 'Fast Track' as the BfArM has only three months to decide whether an application qualifies as a DiGA or not. Each DiGA has to fulfil four main criteria, as shown below (Figure 3).
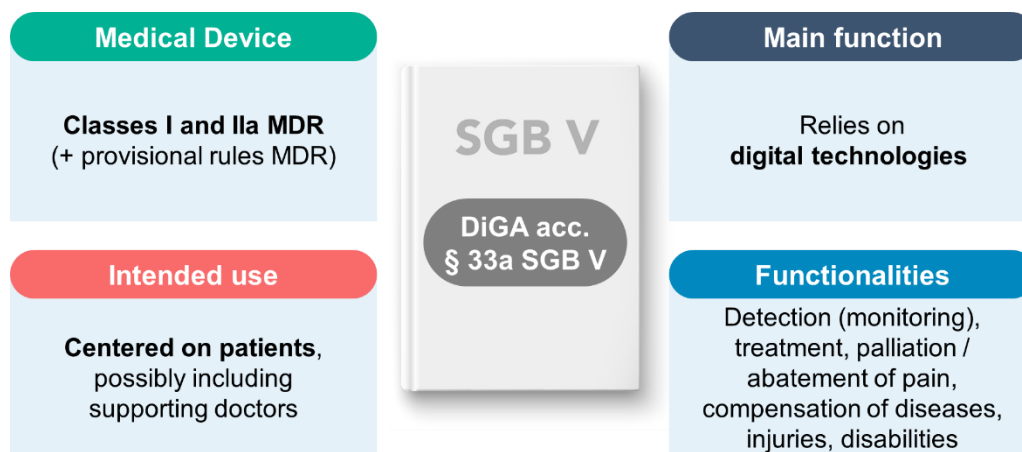

Figure 3 Main criteria to qualify for a DiGA, source: health innovation hub

The first criteria (Medical Device) specifically ensures that only professional, pre-certified applications can apply to be listed in the registry. This limits the risk for patients. The process is constantly evaluated, frequently adjusted based on learnings, and will continue to evolve. Once all stakeholders have enough experience with the new digital category, it will be determined whether and how to establish a process for higher-risk DiGA.

The DiGA Fast Track process has embraced innovation, such as enabling temporary listing for DiGA that do not yet have full clinical evidence, but a clear research path and convincing pilot data. These DiGA have the first 12 months to gather all evidence, following which BfArM decides if the listing will be permanent, depending on the clinical data. Some 75% of all DiGA are presently temporarily listed, meaning the German healthcare system would have missed the vast majority of the digital diagnostics and -therapeutics opportunities in the absence of the temporary option. All requirements have been 'translated' for tech companies in the BfArM DiGA guide.

The Fast Track process was officially launched in August 2020 and 12 months later, 20 DiGA were in the registry. There has been a strong focus on mental health, and all DiGA have or are currently conducting randomized controlled trials (RCTs), the gold standard for evidence. Only 22% of applications were successful, due to the high level of evidence required. More than 20 countries have reached out to the Federal Ministry of Health and their health innovation hub to gain deeper understanding of the process, the lessons so far and to draw on this experience to enable a faster adoption of innovations in their healthcare systems.

Digital Health Capability Maturity Framework

Many countries lack a roadmap for digital health progression. Together with Maynooth University in Ireland, the HSE and other stakeholders we have set a collective goal of building a Digital Health Capability Maturity Framework (Figure 4) which will allow countries to assess their current level of digital health maturity and determine next actions to improve outcomes. Having a simple common model will streamline how all actors in the digital health ecosystem can innovate and work together to provide best outcomes for all.

Maturity Levels	Digital Health Macro Capabilities			
	Digital Health Budget	Digital Health Capability	Digital Health Value	Digital Health Business Model
5. Optimizing	Sustainable Economic Model	World Class	Optimized Value	Value Centre
4. Advanced	Funding Amplification	Regional Leader	Managed Yield and Portfolio	Investment Centre
3. Intermediate	Managed Spending	Average	Value Measurement	Service Centre
2. Basic	Low Spending	Mediocre	Establish Benchmark	Cost Centre
1. Initial	Min. Budget	← Beginning →		

Figure 4   Digital Health Capability Maturity Framework

The capability maturity framework consists of four macro capabilities and maturity paths: how much and how we spend our digital health budget; how we develop and orchestrate collective digital health capability; how we measure and manage digital health value; and the business model we deploy and use for digital health. We expect that in the future all health will become digital health but for now it is useful to discuss and measure digital health maturity. Inherent in this model is the health and digital literacy of citizens and patients which are of critical importance in achieving impact.

Determinants of Health

Most healthcare spending is focused on Healthcare Delivery but paradoxically healthcare outcomes are estimated to be 10% determined by direct Healthcare delivery. As well as genetics the influence of individual behavior, social and economic factors and the physical environment play a considerable role in determining the health and wellbeing of individuals. Although a crudely matched estimate, mapping accessible data points against these social determinants leads to a conclusion that globally we are basing patient management decisions

on approximately 16% of available data (Figure 5). Today, we treat patients based on probabilities from populations' data (that may or may not reflect some of their characteristics) as opposed to the data that is unique to that patient, which would provide more effective and efficient diagnosis-treatment-monitoring and screening. The emergence of digital technologies such as the internet of things and by using AI capabilities, we can blend citizen generated data with formal health and care data and data from other credible sources to understand the lived experience of individuals. This can significantly influence and alter behaviors, allow us to make better informed decisions and create personalized and precision interventions to benefit individuals. By giving citizens the digital tools to be able to hold and curate their own data we can support people to make better informed health and wellbeing choices, allow them to access services on their own terms and so enable a shift in policy, budget and emphasis towards proactive/preventative healthcare. By creating enabling cloud based ICT architectures we can develop safe, secure and assured consent driven data sharing environments that puts control in the hands of citizens, allows them to become the point of integration for their own data and enables them to have full access to the care they need. By transforming data assets into financial assets, we can provide tangible benefits to users (Universal Health Income) and improve their mental, physical and financial health. This is how we can evolve lower cost sustainable health and care services, with more care being delivered by the person themselves with the support of family, circles of care and their community rather than being dependent on formal health and care services.

Determinants of Health	Impact %
Behavioural Patterns	40
Genetic Disposition	30
Social Circumstances	15
Medical Care	10
Environmental Exposures	5

Figure 4 Determinants of Health McGinnis, JM et al

A HSE Digital Living Lab in Ireland is proposed which will monitor participants on a weekly basis and predict using AI the potential onset of a chronic disease, thereby allowing early proactive intervention.

From Doctor knows best to Patient Self-Management/co-production

In the past the prevailing paradigm was that the doctor knew best, and that the citizen/patient was a passive participant in the healthcare process. Doctors made the decisions and patients all-too-often blindly followed this advice. With the dramatic explosion in information available to patients and internet of things devices, patients can sometimes know more about their condition or have accumulated better health data than their clinicians. There is a strong correlation between health and digital health literacy and better outcomes. We are also moving to a network centric healthcare model whereby teams of clinicians working with a patient and his/her family/carers can create better results and care for patients through better shared knowledge and collective intelligence.

Trusted Data Environments for Digital Transformation of Health Systems

Digital transformation and data driven innovation of health systems will have major impacts on sustainability of health systems in both developed and developing countries. The new paradigm has the potential to improve innovation, support smarter, more evidence-based decision-making in the clinic and home care, and enable health systems to focus more on effectively and sustainably meeting the needs of patients, healthcare providers and the populations they serve. This transformation critically relies on building a health systems data ecosystem that captures and harnesses the potential of the 84% of data that is not included in current patient management or clinical decision making. For this reason, a trusted environment for health data has to be established; one in which patients and patient groups have the confidence to share data. Articulated governance frameworks are required to address key topics such as privacy, confidentiality, transparency (who gets access, to what data, under what circumstances), and how data is to be shared. Without a common understanding of privacy, security and ethical aspects in various data access and sharing approaches it will not be possible to establish the trust of patients in digital technologies. Without appropriate controls, visibility of the value to be generated in the ecosystem, transparency on the objectives and intended use of the data, stakeholders will remain reluctant to share data due to privacy and general concerns.

This environment requires multiple elements such as i) a common legal basis (e.g., the European General Data Protection Regulation and the proposed European Health Data Space), ii) patient engagement, iii) innovative privacy preserving technologies, iv) governance models, v) data sovereignty, and vi) fair benefit sharing from using patient data. In order to ensure that data is maintained in a trusted environment throughout the path from research to innovation and implementation in health care, solutions enabling data analysis locally in a trusted environment instead of sending data to users (bringing the user to the data instead of sending them to users)

will become increasingly important for international collaboration. In protecting the rights of the individual and establishing trust we can ensure that data is liberated so as to yield a societal benefit.

Value Based Healthcare

Porter and Teisberg (2006) famously wrote that financial success of health system participants does not equal best outcomes for patients. A new paradigm based on value for patients is needed, one where the focus moves from outputs to outcomes and from transactions to relationships. Value based healthcare (VBH) is fundamentally about a new business model where health service providers are paid based on patient outcomes rather than being paid on transaction volume or fee for service. VBH drives more accountability incentivizing providers to actually improve patients' health rather than maximizing volume and fees. Overall, such a healthcare system redesign has benefits for some but not all participants in the ecosystem, particularly with patients likely achieving better health for lower cost, better cost control for payers and lower risks, and a healthier society for lower cost. We should witness an improvement in overall health system performance as delivery entities sharpen their focus   and are incentivized to deliver better outcomes rather than maximize transactions.

In the context of VBH Braithwaite et al call out what they label a healthcare performance paradox (the 60:30:10 paradox) and argue that improvements in healthcare have flatlined for three decades. They document that 60% of care on average is value adding and in line with level 1 evidence and clinical guidelines; 30% has little impact or is outright waste while 10% of care harm to patients. A new approach is needed to drive improvement and fidelity, an approach which is non-linear and radical rather than one which is linear and incremental and one that leverages network effects. The Stay Left, Shift Left approach is the antidote to this system-level homeostatic rigidity.

How? Open Innovation 2.0

To achieve digital transformation, we need to drive digital transformation cohesively and globally through collaboration amongst all ecosystem players. We propose that to help guide the digital transition needed in healthcare we use a new work and innovation paradigm: Open Innovation 2.0. Open Innovation 2.0 (OI2) is a new innovation paradigm whereby all the actors in an ecosystem including citizens and patients align around a shared vision and work towards enabling and realizing this. This paradigm encompasses user-oriented innovation models to take full advantage of the cross-fertilization of ideas, leading to experimentation and prototyping in real world settings. OI2 is based on principles such as integrated collaboration, co-created shared value, cultivated innovation ecosystems identity and fina unleashed exponential technologies, new business models like coopetition (collaborative competition and extraordinarily rapid adoption. Central to OI2 is the use of digital living labs which allow rapid iteration and adoption

of digital solutions in real world environments. A managed innovation pipeline consisting of four phases is used to iterate and test solutions to eventual broad adoption and benefit.

Leveraging the Quadruple Helix for the Health and Wellness Ecosystem

The pursuit of health and wellness is a basic right, and a shared fundamental responsibility. This responsibility extends beyond payers, providers (governments and private) distributors and benefit managers to enterprises and the society at large. Social determinants of health such as economic inequities, identity and financial exclusion, government policies, lifestyle choices and global events like pandemics are dimensions that are now of major significance in defining the holistic Health and Wellness (H&W) of an individual. And we observe that longevity and the need for equitable and affordable care is driving a shift from:

- Reactive treatment to proactive value-based wellness management
- A siloed medical care system to an ecosystem of players who now own a stake, such as payors, care givers, pharma companies, government agencies, regulators, lifestyle management guides, retailers (nutrition, beauty, furniture), travel industry (wellness tourism, safe travel experiences) and technology providers.

Furthermore, the opportunity exists to expand beyond a patient-centric to a patient-driven approach through securitizing data assets and transforming patients from passive health service users to active health and wealth producers.

The underpinnings of digital technologies are critical in enabling these H&W participants and their ecosystem ambitions. And current technologies such as AI/ML, Cloud, IoMT, AR/VR, 5G offer much promise for healthcare transformation.

 "Ecosystems" as a network of connected stakeholders interacting in ways that create, enhance and capture value for all participants. We believe that the network effect of a collaborative ecosystem can offer better health & wellness outcomes for all. And technology can enable this low touch integrated ecosystem. The pandemic has taught us the value of this digital transformation of health and wellness services. To make this transformation possible in the realm of health uniformly, some caveats are to remember:

- There is an opportunity to re-invent care, rather than just digitizing existing processes.
- Personalizing care and treatment need research, modelling, data based insights
- There is a need to creating a digital backbone of health data that is interoperable.
- Data governance becomes important, and ambiguities around regulations must be resolved.
- Confidence of patients and other ecosystem participants must be boosted.

- We need also to recognize the economic benefits of healthier citizen and reinvest a portion of returns in further improving health

From Health Insurance to Health Assurance

As part of the VBH paradigm we also need to move to an era of Health Assurance, away from an era of Health Insurance. With the possibility of the quantified self. Healthcare insurers have the opportunity to reinvent their business models and services by proactively providing health assurance services to their customers, lowering overall costs and providing better individual and societal health.

This is happening at a time of expanding longevity. A child born today in the developed world can expect to live 95 years. Health Assurance is all about living a Healthy life from cradle to old age.

Health Assurance is based on proactive personalized intervention. This takes the form of real time health metrics, examining large population health patterns, connecting Genomics to lifestyle and deploying Artificial Intelligence.

Additionally old indemnity and catastrophic insurances can be transformed into parametric and algorithmic plans that provide patients fast and flexible payments and help keep insurances solvent during hard-to-predict events.

The costs of Data processing, communication and storage have collapsed, opening up huge opportunities to accelerate this move to Health Assurance.

Conclusion

Better health is what everyone wants and every citizen and government desires. Health is relatively unique in that there is little downside to meaningful cohesive collaboration on global health improvement. The UN Sustainable Development goals provide an overarching framework for sustainable development and SDG3 particularly frames the target for health improvements efforts and targets. The concurrent arrival of multiple disruptive digital technologies at the same time affords the opportunity to both re-think and re-design a new kind of healthcare paradigm and system where individuals are better empowered to own their own health, where big data provides the opportunity to create new insights and therapies, the use of digital therapeutics provides better tools to help both individuals and systems change behavior and allows a new focus on health preservation rather just health restoration. Small shifts in budget from reactive, restorative care to proactive, prevention efforts can have radical impacts on outcomes and longer-term costs.

We also note about the power of digital to enable tracking meaningful outcomes. Not only can this accelerate learning and improvement, but it enables alignment of health care with its true purpose of improving health – for each and for all.

We propose a simple new paradigm and metaphor 'Stay Left, Shift Left' to help guide, orchestrate and focus digitally enabled healthcare improvement efforts to allow combinatorial and multiplicative solutions and benefits. We hope that the broad adoption of this paradigm can simply, unite, amplify and accelerate digital health benefits for all – accessible, affordable, additive, authentic and agnostic. The Stay Left, Shift Left paradigms represents the collective impact of multiple sub-paradigm shifts which include from Reactive to Proactive Health, from Health Restoration to Health Preservation, Health Insurance to Health Assurance, from Citizen Health Ignorance to Citizen Health Literacy, from Doctor knows best to collective responsibility and so on.

As a global leadership group, we hope to continue to develop theories, design patterns, processes, practices and solutions which provide and promote good health for all.

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