AESTIMO INSIGHTS

A cloud or a perfect storm? Assessing current status and future needs in healthtech and healthcare IT infrastructures.

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On the 25th of May 2018 the European General Data Protection regulation (GDPR) became a legal necessity. This necessary regulation has global ramifications due to the nature of personal data storage and handling with high relevance in health care; only 5 non-EU countries (Argentina, Uruguay, New Zealand, Japan and Israel (CNIL 2019)) are compliant with the regulation related to personal data handling. In the context of Cloud and IT deployment in healthcare it is also questionable whether Cloud deployed health IT systems are operating correctly or providing benefit. Within the healthcare sector, the structures of which are now moving to or have already moved to Cloud based architecture, the increasing privacy and regulatory constraints highlights the fragility of these systems when related to the total healthcare ecosystem. Generic IT infrastructure and data management system deployments, while seeming trendy and exciting solutions, maybe generating more long-term problems than expected.

In light of the recent recurrent data-abuse events that demonstrate the ease with which personal data can be misused and the stressed budget environment in healthcare, the accelerated digitization of almost every component of patient management may not be ideal. Without fully integrated and interfaced systems, including the stream of emerging healthtech solutions aimed at patients and healthcare practitioners alike, matched with a suitable support system of how to manage the data and what to do when it goes wrong, incorrect implementation may exacerbate mission critical failings that could lead to the whole system buckling, and not achieving the goal of reducing costs and providing better and preventative care.

The underlying and defining problem, is something common to many other healthcare innovations and their development; fundamentally all the stakeholders are not aligned in the design and decision making throughout the whole ecosystem meaning that solutions are generated in a fragmented mode, which do not integrate or interface with each other, the existing infrastructure or customer needs and capacities. This makes justification of the total cost and economic benefit of their development and implementation questionable and as such the possible benefits of the constantly evolving modern IT infrastructure maybe lost. Fundamentally a 'new shiny toy' is not going to help. Here we discuss the underlying fault lines in the system and solutions to lay a better foundation for cutting edge IT usage in healthcare.

i. Healthcare costs: now and into the future

The most recent figures for annual healthcare expenditure per capita in countries with government/compulsory and voluntary financing systems makes for sobering reading (*OECD: health at a glance 2017*). Figures obtained from 2016 range from USD 1K total to USD 10K total, with the average hovering around USD 4.5K. With the global population stretching about 7 billion, with the OECD countries around 20% of the population, that means total costs of USD 6.3 Tn. This does not account for the additional significant healthcare costs in non-OECD countries in which non-communicable diseases are rapidly increasing in frequency.

The costs are also rising: in the US since 2017 and speculated until 2026, the per capita figures are estimated to have increased from nearly USD 11K to over USD 16K (*Health system tracker 2017*), while over shorter time frames (up to 2020), all countries are expected to have significant increases averaging around 5% increases (*Deloitte 2017 global health care sector outlook*); a value higher than inflation. Health care inflation is determined by how much a given reimbursement agency is willing to pay for a product or service; if there is significantly more demand, then the cost increases.

The drivers for cost increases are now well known: for the total world demographic in 2016 the disease burden by age group was 458 millions of <5 years of age, 127 million for 5-14 years of age, 807 million for 15-49 years of age, 617 million for 50-69 years of age and 379 million for 70+ years of age; within these totals 1.47 billion of the disease instances were non-communicable, an increase in frequency of 50% from 1990. Similarly, within the same date range, the 50 – 70+ age demographic increased from 660 million to 996 million instances, while the <5 to 14 year olds decreased from 1.15 billion to 585 million instances (*Our world in data 2018*).

At a greater level of detail, the older you become the more frequent non-communicable diseases manifest themselves, starting as single manageable morbidities which within a decade become significant numbers of simultaneous chronic comorbidities. This overwhelms the healthcare system on all levels: available experts, support staff, social care, and, of course pharmaceutical interventions, the latter of which is already becoming economically unsustainable.

The average 50-year-old routinely takes one prescription drug frequently, by the age of 65 this reaches five prescription drugs and two over the counter drugs (typically analgesics), plus dietary supplements, which alters metabolism and therefore drug PKDM (*koziolek, 2019; Briguglio 2018; Kim 2018; Genser 2008*); this polypharmacy is the largest problem in primary healthcare as it is difficult to manage. In the aged, due to compliance and communication issues, it is the most difficult to actually change. By 2020, it has been estimated that 50% of the world's healthcare costs will be due to cardiovascular disease, cancer and respiratory disorders, and for each of these diseases, multiple additional tissues are also affected. Polypharmacy is one of the largest growing issues precipitating Drug Induced Liver Injury (DILI) for which there is no medical solution (*NEC NHS 2019*).

Not all the reasons for these figures are simply down to ageing; within population health it is widely known that healthcare costs are driven by policy making, social factors, physical environment, available health services, biology and genetics, and individual behaviour (*Healthy People.gov Determinants of health 2018; 2003 Factors influencing health*). It is worth

delving a little deeper into these determinants, as they have precipitated the present IT, healthtech and mHealth (mobile health) products that try to provide solutions.

All of the following can have impacts on any person's health status at any given time, and typically all impact each other:

i) job opportunities
ii) employment status
iii) salary
iv) access to all types of food
v) exposure to detrimental environments, including proximity to all forms of waste
vi) access to modern technology, comfort with using modern technology
vii) education level
viii) transportation options
ix) living environment (city vs countryside, industrial vs non industrial environments, low traffic vs high traffic volumes)
x) diet (nutritional deficit and over nutrition)
xi) level of activity
xii) unhealthy consumption
xiii) level of sanitation.

Similarly, a person's own natural biology and genetic status obviously greatly impacts health response and prescription as well. The implication is that healthcare is not and cannot be solved exclusively through medical intervention; the reimbursement bodies simply cannot afford to pay for this and therefore are trying to resolve the issues by social restructuring (smart cities, smart lifestyles), early diagnosis, preventative measurement and better health data management, all of which require cutting edge IT products and their deployment.

ii. Healthcare systems and infrastructure

Human health data is rather unique, it encompasses a combination of personal identifiers (location, age, date of birth, government identifications in various formats, social security/national insurance numbers, amongst many others) with highly sensitive health related information which, in addition to the obvious health management related issues, can also have significant impact on the life and cost of life of the individual (*HIQA 2017*).

Explicitly, your health status and even genetic background will influence all forms of insurance, types of jobs you can have, how you are able to move around e.g. permitted to drive a car, what you consume, your lifestyle choices, your socioeconomic possibilities, your social status, and how much you will cost to society in the long term. In the wrong hands, therefore, it can be used for nefarious purposes (*Jalali 2018*).

Before advancing into modern solutions to the growing need, it is necessary to take a balance of exactly what status modern healthcare is in with regard to its data management; after years of following the adage '*if it is not broken, do not fix it'* most healthcare structures are woefully underprepared for any modern solution or regulation, and this includes basic infrastructure such as family doctors personal computers and IT training for health care professionals.

Contrary to hopes and expectations, medical information collection and storage is totally fragmented, everywhere (even in the US and Europe). Information gathered in a primary care setting (local doctor, GP) is not integrated informatically in any way with the IT systems in secondary care (specialised centres), tertiary care (hospitals) or post care (nursing homes) structures. No nurse, doctor or specialist in

any of the settings above has total access to all the medical history and data of a patient. Data is stored in various formats, on various operating systems with varying degrees of modernity in many different applications.

Additionally, in the context of the implementation of human clinical trials for the validation of new medical interventions and diagnostics, the multi-centric nature of such trials in later stages of development, can and often does mean that this data is collected from centres all over the planet, often from countries which have no recognised IT or personal health information management standards. Clear examples of this are in the rare diseases field, in which patients are typically scattered and isolated globally, and clinical trials are highly fragmented with regard to physical location of implementation. Many geographically distinct clinical centres often have only 1 patient being treated.

This means there is no harmonisation in data collection and in all likelihood there ever will be. The reason is more simple than imaginable; in addition to language differences and associated abbreviation differences, from an early age we are also taught to input numbers differently. The decimal point in France and Italy is a comma, in the USA and United Kingdom it's a point, in Portuguese cultures, multiple decimal points; in some cases the comma is above the number sometimes below (see http://www.statisticalconsultants.co.nz/blog/how-the-world-separates-its-decimals.html for the global differences), which all seems very trivial until you start to input, store or open data. Anyone who is familiar with any Number Processing Software (NPS) will be able to easily sympathise with the problem, without moving into highly complex medical questionnaires. Opening a NPS file from a different country without the same format generates programme errors while the actual integers also change; to correct this requires either a total homogenisation of early educational training globally, a retraining of medical and IT staff to recognise this or that the software recognises the difference and correct. Unfortunately, the problem is significantly more severe than one piece of software and its cultural differences.

Many healthcare infrastructures simply have not been updated which means out of date operating systems and incompatible software, incorrect interfacing, no interoperability, poor encryption or data breach, many software applications to be used in healthcare are not compliant with modern security regulations (*Digitalguardian 2018, Skyhigh 2015; solutions review 2019; information age 2018; propser suite 2017*), IT glitches result in patient death (*Guardian 2018*), historical data is revealed to have not been inputted correctly, with the recent example from Texas of using the wrong cause-of-death codes in which women who had died were indicated as being pregnant when they were not, thereby inflating maternal death statistics (*CNN 2018*), while there are over 350 different types of Electronic Medical records software (*Captera 2018*), some of which cannot be used in the Cloud, and many of which cannot be used on portable devices.

In addition to this, is the growing list of mobile-based mHealth and healthtech auto-diagnosis or remote healthcare monitoring and management systems that enable patients to better manage their lives and engage in preventable medicine. This seems ideal in the context of the growing global burdens of healthcare, but unfortunately many of the systems have not been clinically proven to be informative or beneficial, and as discussed below, when integrated with Cloud deployment may not actually reduce costs.

These applications are also turning primary healthcare into a day-to-day problem; patients are showing up at the clinics telling the medical staff the disease they have rather than relying on trained specialists to diagnose them. Many aged members of the population do not have, do not want to have, or do not know how to use modern devices or their associated applications. Given how highly trained medical staff are, and the limited amount of time that they have to spend with any given patient, diagnoses go astray. These time and personnel constraints mean that the accredited training of the medical staff, so that they actually understand in depth how to obtain and manage data from remote devices does not actually occur due to both time and budget constraints.

This results in almost everyone being dependent on the Graphical User Interface to enable any level of understanding, without considering:

- How secure the device is that is storing the data (many medical staff use personal computer devices without appropriate security patches for their work, which they then use at home for VOIP communication),
- The volume of data that is obtained (a significant portion of which is based on the user manually inputting the data on their device)
- The quality of encryption that occurs to the data prior to wireless transit
- The quality and integrity of the location of where the data is stored.
- Has the solution actually been proven to provide benefit

Finally, there is the issue of automatic updates, or more specifically automatic updates in only one of the software applications or systems within an IT ecosystem that is already struggling to maintain interoperability.

This results in an interface misalignment meaning that nothing else works and system security has either been compromised, or the whole system has shut down because the security software has recognised a problem. For fragile patients, who have been told to use mHealth to liaise with their healthcare practitioners, this will cause patient panic, stress, upset and chaos, yet mHealth products are routinely rolled out that never really seem to address this issue.

Obviously neither of these is acceptable in a 365/24/7 healthcare system, and the medical staff, do not know how to fix it, while the IT managers find out at 7.30 in the morning when they get paged into the office.

iii. Cloud transition: are we sure there are real savings?

The decision, therefore, to transition the IT healthcare management ecosystem to the Cloud with associated digital solutions, in this context seems a little premature. The driving force seems to be an understandable economic consideration; Cloud and digital solutions have been widely touted as a low cost alternative to modern IT which moves costs from a capital expenditure to an operational expenditure model (or combination of both in Hybrid systems). Many providers have Cloud calculators as the marketing tool to convince would be consumers of the cost advantage of the transition, however there are several non-health focused studies which raise doubts on these calculations, while a rudimentary consideration of how a healthcare system functions would

definitely suggest the savings may not be as great as previously thought.

The number of add-ons by Cloud providers can also rapidly increase the price of even the most simple IT based endeavour, even with auto-scaling and auto-management i.e. their IT system manages the structure needs. The risk here is that a complete transition to Cloud would enable hegemony of IT systems, thereby meaning that prices can be increased simply because the competition is non-existent. *Vis-à-vis* the energy market, this means the Cloud becomes the only solution, prices are increased because they can be, and because innovation has been stifled, over a short period of time, to even develop a cheaper or better alternative will create significant adaptation costs.

*Deckle*r, in 2016 made a detailed analysis on total costs of ownership, and it became clear that while cloud was cheaper than on-premise models, there was an economy of scale, which was mainly linked to server costs. When there was a low economy of scale, cloud based systems ended up being around 20% more expensive than on premise, however, when scaled up to include many servers and a larger cloud usage, the commonly accepted 20-30% cost reduction of using cloud was observed.

In 2017, he revisited this calculation, as Microsoft had created there own total cost of ownership calculator, and in an apples-for-apples comparison, cloud based systems were 57% cheaper. This is quite a significant decrease in total cost in 12 months, so he delved deeper into Microsoft's calculations, which revealed significant areas that need to be considered. It seemed that Microsoft was underestimating labour costs as well as cloud usage.

It would seem that there are a lot of 'baseline' assumptions in cost calculations, which may not correspond to real world usage, and the calculators permit these baseline calculations to be altered to provide the clients own real world costs. But as Deckler stated "this exercise has once again confirmed that cloud and on-premises cost calculations are not trivial'.

In addition, *Miller* made several observations in 2015 regarding the price of risk, specially regarding mission-critical data centres. While the accepted list of total cost of ownership comparators were made, the use of cloud systems results in increased 'data breach and security risks and potential for data loss and business disruption'. He quoted the large cyber attack on Target's data centres, resulting in 56 million credit and debit card numbers exposed, resulting in a $10 million lawsuit settlement and several C-grade company officers being fired. In healthcare the liabilities related to IT mismanagement are going to be significantly greater. Yet the liability of the actual cloud provider, who is responsible for the infrastructure is zero, meaning that it is the entity that is taking all the risk.

Despite apparent benefits, and the evolution of packages and security systems that exist, there still exist many reasons why an entity maybe reluctant to move their IT infrastructure to an entirely off-site or even hybrid cloud based systems. As reported by *Helpnetsecurity (2017)* "A new Fugue survey, fielded to over 300 IT operations professionals, executives, and developers, found that most respondents believe that the cloud is not living up to expectations because of compliance and security concerns, unexpected downstream costs, and the glut of cloud management tools available in the market."

The over-reaching issue is data sensitivity: which can be broadly divided into privacy, security, technology reliability and confidentiality related issues, which highlights a major shortcoming in applying this to Healthcare. To effectively manage these four critical points for data that is generated *en masse* constantly is going to require a level of quality control and data management that can only be achieved by maintaining the IT workforce and associated infrastructure, or keep the critical info in on-site IT systems: fundamentally the cost advantage starts to erode. In the context of Europe, the GDPR indicates the need for data compliance officers and additional safeguards, which further reduces benefits.

Finally, to complete the costs, healthcare practitioners need routine accredited training: the regulatory control of all forms of Health means that the medical practitioners, and quite possibly the patients themselves, will need to be trained, and because the systems update, continue to be trained and certified in using the combination of applications and Cloud structures.

iv. Data mismanagement

Historically, in health we do not leverage our data completely: negative data is typically not communicated, specially during development of novel therapeutics and interventions, which has now resulted in returns on investment in R&D being at a paltry 1.8% (one fifth of the cost of capital related to R&D in the pharmaceutical sector). Additionally as indicated above, data input is not homogenous in quality or integrity; the reason it is pertinent to state this so explicitly is because it is tempting to look at AI based approaches as a solution. Irrespective of the hype, they are not solutions, despite the claims by Mckinsey that AI and big data processing systems could save USD 100Bn per year (Mckinsey 2017). However it also begs the question, how much would the savings have been if the same companies had invested in optimised data management and implementing searchable databases across their historical knowledge siloes?

There are several reasons for this perspective; the first is data integrity and completeness, both of which can have significant impact on conclusions. If data is missing it is very difficult to obtain statistically relevant conclusions, on which almost all health expenditure decisions are founded. Despite homogenised forms within clinical trials and even patient monitoring, if the patient does not provide the correct data or

refuses to provide the information then meaningful outcomes are difficult to obtain. Similarly within AI, which uses algorithms to perform statistical analysis of data, it has been reported that in a survey of 400 algorithms presented in papers only 6% shared the code, which means reproducibility has been close to impossible to obtain (*Hutson M 2018..missing data*).

Additionally, it has been demonstrated to be difficult to understand how a particular AI has reached its conclusions, while some algorithms work and others do not, but no one understands why; these represent significant risks in applying their use to health decisions. AI algorithms optimise as function of the volume of data they see, however health data is restricted and stored in siloes, meaning that accessing the data becomes problematic, and the security risk high.

The restriction of access to this data is also going to increase, not decrease, which means that AI based modern IT solutions are not going to solve any healthcare issues in the near future. Despite some publicity, the reality is that for these new IT approaches to demonstrate any benefit, the conclusions they generate need to

have statistical relevance, which means that it is using statistical models that are already being used. The implication is that if and when these approaches do become validated, the data that will be validated and conclusions drawn from, will be the same data that the same conclusions can be drawn from now, without their use.

The volume of data that will be generated is also going to increase; several strategic solutions presented by large firms seem to imply real world evidence (RWE) and advanced analytics as key facilitators. The problem is the costs of implementation of these approaches seem rather high, and too high for overstrained healthcare infrastructures to be able to assign extensive budgets when priorities lie elsewhere. Advanced RWE management as a function of the discipline of population health will augment health management, however if this is co-joined with a counter-dependency on AI, then the logic of Bayesian statistics which serves as the foundation for AI, infers that general outcomes are statistically sufficient to reflect all needs, but innovation, and specifically healthcare innovation, simply does not work that way.

It is also questionable if these approaches will actually solve a healthcare problem at any point in the health ecosystem. Given that we will never understand the total biological complexity of any given individual versus another individual due to the number of diverse factors that can influence that individual's health, RWE and AI seem to be polar opposites. One cannot generalise and individualise a patient simultaneously, meaning that dependence on these approaches will become statistical guesswork in a best case scenario, and potentially open up healthcare structures for ethical malpractice if a patient number of 'n = 1' is used to prescribe an intervention and that same intervention causes damage.

What is Artificial Intelligence (AI)

AI is fundamentally Bayesian statistics or inference

Bayesian statistics is dependent on the establishment of both 'parameters' and 'models'. These parameters and models are defined by the practitioner, not by the computer, therefore AI, *per se*, does not exist. The computer does not define the rules.

Bayesian statistics is based on probabilities expressed as a 'degree of belief' in an event which is both based upon and changes as a constant function of new data being collected.

Bayesian statistics works well for cancer management, because, cancer intervention approval occurs if the intervention gives the patient 12 more weeks of life. Since the late 1960's, starting with bone marrow transplantation and moving onto other oncological treatments, there is a global collection of hundreds of thousands of data points corresponds to 12 more weeks of a life for a patient.

This means that a computer can analyse these data points, along with all the associated patient biometric data and group the patients into groups: type and stage of cancer, age, standard biometrics, associated conditions and so on, and then infer, that for a certain 'group' of patients, a specific medical approach seems to be the best solution.

No other pathology has had this level of data on patients, but there are numerous global efforts being implemented in multiple pathologies to correct for this.

For a medical practitioner to apply the conclusions drawn from a computer system alone will mean that they would be willing to forgo all their own medical training, continued learning and decision making and put all liability responsibility in the hands of a computer and its associated software. If this was relevant then medical training would not be necessary and we would simply have a technician input data and let the computer tell the patient what they need at a terminal similar to a bank machine. Practitioners may accept this if the risk and liability is transferred to their

employer, who in turn tries to transfer it elsewhere. As has been seen in the reimbursement strategy for CAR-T, where reimbursement is very complicated (*cell and gene 2018*), in the context of IT, this would mean all liabilities eventually transfer to Cloud and other IT healthcare solution providers; who have already demonstrated that they refuse to accept any liabilities with regard to security and data management.

v. What are the solutions

Typical to many innovations, to a large extent we are running before we can walk. Within sensitive sectors, such as healthcare a significantly more structured and knowledge based strategy is required, prior to trying to stamp a squared shaped innovation into a round shaped healthcare hole.

This is a common problem in R&D and healthcare development at present: budget constraints and constant growing needs are precipitating knee jerk and ill thought out solutions. Solutions that fail at the final hurdle, because the underlying foundation for the decision made was not as robust as originally thought.

The list of things that should be done in healthcare are long and obvious: the list of things that can be done with regard to evolving present infrastructures and staff understanding and IT is significantly shorter, and this is where we should start. It is very easy to suggest science fiction strategies from the benefit of an office, with a wish list of ‘it would be nice’, but as indicated in this article there are several pivotal issues which are going to block any significant benefit for modern IT in healthcare.

What should not be forgotten is that healthcare is personal, it is not a factory; this is witnessed in primary health. Aged or fragile patients do not feel comfortable with online or electronic reservations; they like to talk to a receptionist, while patients are moved out of hospital beds because limited statistical data indicates they ‘might be ok’ to leave and there is a higher cost patient waiting. Only for the discharged patient to be taken back into hospital three days later because they have an infection and there is not sufficient budget for home healthcare.

These are the realities of modern health, and worse is countries in which healthcare infrastructure is less developed. Expecting fragile people, which is a common trait when they are ill to depend on IT solutions is a stretch. Applications and generic IT infrastructure are not going to resolve this problem or reduce costs for 1.47 billion people with non-communicable diseases and a fragmented health record.

When integrating IT and health, given the non-interventive nature of its application, all new innovations can and probably should be treated as research projects until sufficient evidence has been generated that actually supports their application. This is used for all other modern medical innovations, why it is not used in IT for health is confusing. We should also solve the major problems that

exist, do not create solutions that ignore the major problems to create nano-progress solutions that create more problems and kick the real problem further down the road.

vi. The necessity for health technology assessment (HTA) in mHealth

The landscape for healthtech and mhealth is rapidly evolving and regulators, like the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK and the Food and Drug Administration (FDA) in the USA, have published guidance on their assessment of devices and apps (MHRA, FDA).

However, beyond regulatory approval someone will have to pay for these developments, e.g. insurers, National Health System (NHS) payers, etc.

Whilst, in the past, it was enough for companies to gain regulatory approval before being able to market their product, nowadays payers are increasingly requiring companies to demonstrate the health and economic benefits of their products to them beyond the requirements of regulators. For example, Public Health England has published guidance for health app assessments stating that a company must provide evidence that their app (Public Health England):

- Improves outcomes for patients and users
- Provides value for money
- Meets users' needs
- Is stable and simple to use, and that people actually use it.

It further states that companies will need to demonstrate a high level of clinical effectiveness for the app to be considered for 'NICE evaluated' status.

Since then NICE, together with NHS England, Public Health England, Medcity and Digital Health London, had published an evidence standards framework for digital health technologies (NICE 2019). This document comprises detailed required evidence standards for effectiveness and economic impact developers have to address when they want payers to commission their digital health products.

For pharmaceuticals such assessments have been a longstanding and constantly evolving requirement, not so for healthtech and mhealth.

Increasingly HTA organisations like the National Institute for Health and Care Excellence (NICE) in England are assessing the health and economic benefits of devices and digital technologies. NICE also provides HTA scientific advice for healthtech developers and evidence guide for app developers and digital health evidence case studies (NICE Scientific Advice).

HTAs require additional meaningful and robust evidence on the clinical effectiveness, the relative safety / adverse events beyond the requirements of regulators. HTAs also require resource use and cost information as well assessments of the cost-effectiveness of the new technology. All of these against the relevant standard of care.

With more costly health care technologies (pharmaceuticals, diagnostics, healthtech and mhealth) coming to market and the rapidly evolving landscape especially for the latter two we already observe payers to scrutinise companies value propositions more and more. We anticipate this trend to further accelerate and to globalise. Many companies already engage with official HTA procedures, such as NICE, for healthtech and mhealth products to find support to overcome payers' objections.

Therefore, companies have to develop their evidence base not only for regulatory purposes but also for HTA and payer requirements. If they don't do it

reimbursement and uptake will be delayed or prohibited thus having a significant negative impact on sales and return of investment.

Support is available to companies to address these requirements bot on National and sub-national levels. One such example is the NICE Scientific Advice programme which for devices and digital technologies offers:

- Scientific advice: a detailed clinical and economic advice on company's evidence generation plans (clinical and economic) are sufficient.
- Medtech Early Technical Assessment (META) Tool (NICE META): an online tool which helps companies, in collaboration with a NICE certified facilitator. Identify potential gaps in their evidence base and the steps a company can take to bring their product successfully to market.
- Medtech advice driven by the META Tool process, the NICE Scientific Advice team can provide companies with scientific advice on how to address any gaps identified in their evidence base.
- Bespoke seminars and masterclasses: providing valuable insights on the latest developments.

Additional support is available to companies through specialist consultants with experience in clinical trials and HTAs.

We recommend companies to engage both with the official procedures, such as the NICE support outlines above, as well as with specialist consultants.

vii. What next?

Potential solutions should include:

Use of AI structured solutions to screen data banks and homogenous data input formats as much as possible prior to any further steps.

Generation of IT solutions that seamlessly and rapidly solve integration and interfacing issues between all software types, so that at least 90% of existing approaches can interact with each other, or force software developers to include code that enables there software to integrate with all other software, as opposed to just working on as many different operating systems as possible.

Creating software solutions that enable integration of individual patient data from all healthcare sources, and transfer ownership of that data to the patient, exclusively and in its entirety.

Investing in more data analysis approaches that address the patient as an 'n of 1' first, with a total data collection and integration across all sources of healthcare infrastructure, which also integrates in population health drivers, and then looks at mapping across all other patients so that precision medicine can be achieved.

Finally, as painful as it seems, the harsh reality in healthcare is that reimbursement for unproven approaches is going to continue to transition towards a fee-for-service approach due to the absence of effective patient data management. This applies as much to mobile applications, IT infrastructures and solutions as it does to more interventive approaches such as CAR-T.

None of these help the patient and fundamentally does not really change healthcare costs; if the patient does not respond to therapy they will still need extensive and expensive support. Therefore, healthcare, at least in the short term, and specifically with regard to people needs to stop being looked at as a marketplace. To continue to do so will not

generate solutions, it will not decrease costs, and will not increase returns on investment.

A more altruistic approach incorporating all stakeholders in which global patient data (negative and positive) and precise health status drivers (historical and ongoing) are pooled and analysed by all and for all diseases is necessary: an area where Cloud, AI and RWE can have a profound impact on future decisions. The patient data should also include, as much as possible, all known drugs and supplements consumed and being consumed.

The data, obviously anonymised, can then be made available under controlled conditions so that innovators can generate real and applicable solutions that can be assessed and tailored for individuals or groups. The generation of these solutions will have lower development costs by default, meaning that the price of the prevention or intervention will be affordable, proven and beneficial.

Healthtech, mHealth, and IT innovations can really facilitate healthcare and solve significant global social problems, however it requires a fundamental paradigm shift in perspectives of what is a patient, what is patient data, what overstrained medical practitioners can actually do and how cutting edge IT will realistically help them.
As well as a restriction on the constant stream of untested and incorrectly validated 'shiny new toy' products that resolve nothing.

Clinical testing and mHealth products

The number of smartphones worldwide is predicted to reach 5.8 billion by 2020

The ubiquitous use of smartphones in consumer's lives with on-demand apps and data analytics has filtered through to healthcare.

There are over 318,000 mHealth apps available, with more than 200 new ones added each day

There are four broad categories of mHealth apps: (1) information apps, which provide the public with general health information; (2) diagnostic apps, which are used to input patient information and help guide the physician to a diagnosis; (3) control apps, which allow remote monitoring and control of medical devices such as insulin pumps; and (4) adapter apps, which essentially transform a smartphone into a mobile medical device

In order for digital health to flourish, it needs to be implemented in hospitals to demonstrate evidence-based health outcomes.

Xcertia, a non profit entity is trying to establish some core guidelines on assessment based on four core principles: operability, privacy, security and content.

More investment is needed in expanding the evidence base necessary to show the accuracy, effectiveness, safety and security of mHealth apps

The global mHealth app market is expected to reach up to US$102.35 billion by 2023

Healthcare consumers continue to show strong use of digital technology, with numbers rising each year: 75% of consumers surveyed said technology is important to managing their health.

Present regulations relate to the transformation of a mobile platform into a regulated medical device (Mobile Medical Applications), and only about 100 apps fall in to this category

From 2008 to 2018 6 systematic reviews including 23 RCTs evaluating 22 available apps that mostly addressed diabetes, mental health and obesity were performed.

Most trials were pilots with small sample size and of short duration. Risk of bias of the included reviews and trials was high. Eleven of the 23 trials showed a meaningful effect on health or surrogate outcomes attributable to apps.

For a basic mHealth app that looked at weight and cardiac status in the elderly, the patients had to be trained how to use the app

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