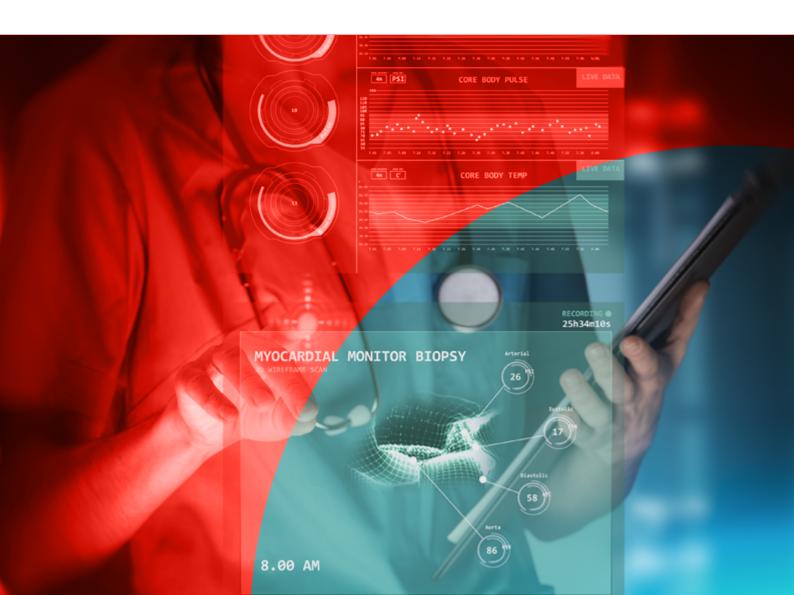


...making excellence a habit."

# Digital maturity in an age of digital excitement

# Digital maturity goes beyond excitement to quality

Professor Harold Thimbleby



It is obvious that digital technologies hold the promise of solving many besetting healthcare problems. Yet if we are too positive, we run the risk of being uncritical and perhaps exploited by unscrupulous marketing, or even marketing equally caught up in the uncritical excitement. How, then, do we rise above this and become more mature? Scoping and understanding digital maturity and its value is the goal of this short paper.

# Introduction to digital maturity

The 'digital agenda' raises a hard problem in healthcare, to balance impact and profit against risks, like cybersecurity, regulatory lag and patient safety. Recent books such as *The Digital Doctor* (Wachter, 2015), *The Patient Will See You Now* (Topol, 2015) and *First Do Less Harm* (Koppel and Gordon, 2012) illustrate the gaps between hope and reality. We need *digital maturity*. Manufacturers need to think better than their competitors; healthcare needs to think better to provide quality care. It is useful to think of digital maturity to be about people and how they understand digital.

For many (Wachter, 2016) 'digital maturity' means digital infrastructure, not competency. Specifically, it means *readiness* (how much do you deploy digital); *capability* (how much do you use digital) and *infrastructure* (how much infrastructure supports this). This definition focuses on tech, not on understanding. On the contrary, once you have digital maturity as understood in this white paper (there is a literature on maturity, see, e.g. the Wikipedia article, 'Capability Maturity Model', https://en.wikipedia.org/wiki/Capability\_Maturity\_Model, 2018), you can more effectively develop, evaluate, buy and use digital. It does not work the other way around.

The scale of healthcare, its levels of *ad hoc* paper-based information and digital legacy begging for modernization, including with apps and portals, raise questions of digital maturity. How do we promote digital maturity in healthcare, which has a traditionally non-digital culture?

In contrast, the rate of change in digital is staggering. Apple's iPhone appeared only in 2007 and introduced us to smartphones, medical apps, personal digital health and more. Now these technologies and the business cultures seem natural and ubiquitous.



#### Implementation bias

Do we want to innovate in a *specific* technology, like canals, or in an *abstract* industry like transport? Canals are obsolete, yet transport is still thriving.

In computer science terms, this question is about *implementation bias*. That is, canals implement transport. Implementation bias means being too concerned with what canals *need* (e.g. water, locks and boats) rather than focusing on what they are *doing* (transporting goods).

Implementation bias creates *The Innovator's Dilemma* (Christensen, 2016) – innovators have to challenge the established value system stuck in legacy implementation.

One example of the power of escaping implementation bias is the highly successful project to teach computer science by *getting rid of computers* (Bell, 2012). It frees learners from the trap of thinking they are learning about computers (like PCs and browsers), freeing them to learn about computation – that is, what computers do *regardless of how they are implemented*. The project improves digital maturity because it teaches digital without teaching implementations (e.g. spreadsheets), let alone the proprietary implementations (e.g. Microsoft Excel). There is a need to know how to use spreadsheets but that is digital literacy, not digital maturity.

Alan Turing worked on the very earliest computers in the 1940s and developed the science of the field. We now talk of a technology as being *Turing Complete* (Weizenbaum, 1976),<sup>1</sup> meaning it can do any computation that can be imagined (see a review, Herken, 1995, or refer to Turing's original paper (Turing, 1933)).

Turing did not anticipate colour displays or 3D printers. Now we can make 'reality' out of anything we can imagine, to say nothing of implants or MRI scanners which can be networked with medical apps, infusion pumps to pacemakers, bronchoscopes to patient records.

The point is digital can do anything we can specify, and therefore in principle frees everything from pre-digital implementation constraints. Digital innovators can free themselves from implementation biases others are locked into.

## Implementation may be distractingly exciting

Any products, but especially digital products, can be designed to create excitement that encourages people to want to own them. This idea has developed as user experience (UX) and persuasion (Fogg, 2003), and it is now routine for product ideas to be tested with users being monitored for hormone levels.

While getting customers excited is necessary, it has a side-effect. Customers, indeed all of us, may be confused between what is exciting and what is worthwhile. For example, I want a new app. I have the feelings of excitement and rightness about this decision. Nevertheless, those hormone-driven feelings are insufficient to justify pushing the app into healthcare. Where is the evidence? If I am not digitally mature, I am likely to say: why do we need evidence when I feel excited?

Existing customers (e.g. people in healthcare) want what they want from within the value system their culture has already established. Any disruptive move challenges that, and will impose change that seems too costly from where they stand. However, from the right perspective, healthcare benefits when an innovation is successfully integrated. The problem is that disrupted companies die or have to reinvent themselves (Kodak, IBM, ICL, etc.), but healthcare is subsidized, which makes it hard to disrupt.

# Healthcare combines diverse implementations

Healthcare as a whole is implemented by:

- already-digital services (like inventory and finance);
- information that is largely on paper but could be digitized;
- traditionally purely physical services (like drugs, operations and beds) that are clearly physical and are fundamentally hard to digitize; and
- medical devices and implants containing embedded sensors and computers.

Note that the business segments that thrive with the different implementation assumptions can get entrenched in their market segments, making them resistant to innovation (Christensen, 2009). Equally, resistance means that *successful* first movers into these segments, those who figure out how to overcome or subvert the resistance to change, have tremendous opportunities.

Yet drugs are experimenting with RFID type technologies to ensure compliance (Proteus Digital Health, <u>https://www.proteus.com</u>), and medical apps are challenging what a medical device is. Digital can deliver what used to require physical visits to the GP. Consider the impact of Crohns.org, patientslikeme.com or 111.nhs.uk, to say nothing of the preparation Google allows us all to make before seeing a doctor. The internet creates decentralization, which allows private business to deliver what patients want.

Patients like Apple products because they are intuitive and easy to use; patients like Google because it provides information. Healthcare is none of this, and therefore digital maturity will disrupt how healthcare works. Social media is changing how patients expect healthcare providers to communicate.

There are opportunities in connecting digital innovation to health and personal data (including big data), location-specific activity, sleep patterns, weight and more. This requires easy to use hardware combined with big data and analytics. In the USA, where most large tech companies are based, employee healthcare is a major cost and a powerful incentive for digital innovation.



What are the liabilities when health-related innovation can cause injury or suicide (Hart, 2018)? For analysis of a multiple fatality, see Cage and McCormick (2004). Having performed rigorous enough testing and post-market surveillance to provide a defence in court would be wise.

Current medical device regulations make complex distinctions (Hoxey, 2017). Thus spreadsheets, which need no approval, can be used for radiotherapy, and apps that are self-assessed for CE marking (Hodges, 2017) are used to email patient names.

Conventional technologies claiming health benefits, like drugs, have to go through appropriate trials before they can be marketed. Increasing patient safety awareness (Hancock, 2018, and more recently Lintern, 2018) will tighten up procurement procedures, then regulation.

Comparisons are often made between healthcare and aviation (aviation has much to admire), but there are few comparisons between their engineering cultures – the cultures that create the systems that people have to work in. In aviation, software is categorized by its possible effects called *Design Assurance Levels* (DALs) (DO-178C, *Software Considerations in Airborne Systems and Equipment Certification*), which, put briefly, are:

- A Catastrophic could cause deaths;
- B Hazardous could cause serious or fatal;
- D Minor could cause inconvenience;
- E No Effect.

Compare this simplicity with digital healthcare regulations, which are very hard to follow (see *Medical device stand-alone software including apps*, <u>https://www.gov.uk/government/publications/medical-devices-software-applications-apps</u>, 2018). Complex compliance encourages products to fit the regulatory classification rather than be innovative. Current digital regulation suffers from implementation bias.

With the increasing number of IT failures in healthcare,<sup>2</sup> especially cybersecurity failures, simplifying regulation and *making it more effective* will become a priority.

## Connectivity and internet of things

The Internet of Things (IoT) means things, like syringes and drug packets, can support computation and communication. We no longer think of computers as such but of things that are able to do anything and are monitored from anywhere. The game changes.

More generally, digital is challenging assumptions, challenging ideas and ways of doing business that have matured over millennia: what we mean, for instance, by signatures, privacy, copyright, money and more.

For example, what is the privacy policy of any medical app? – it has to 'balance' Caldicott-era (The Caldicott Committee, 1999) patient privacy against making money from data arbitrage, against the ways doctors want to use apps like WhatsApp to discuss patients and against what patients want to do themselves online.

DRM (digital rights management) is widespread in entertainment; what opportunities are there for its use in healthcare? Even contracts have become *smart* contracts: they can now be computer programs to do anything. And that's before we worry about challenges to what crime and liability mean. In the 2013 UK Criminal Justice Act (see Mason and Seng, 2017), IT is presumed to work correctly at the material time, which raises – or should raise – clinician resistance, since the law potentially makes healthcare professionals into scapegoats for failed innovation (Thimbleby, 2018).



# Block chain as an example

Consider block chain or bitcoin; both are implementations of money, but they don't implement what coins do, they implement what money needs.

Money has always been used to make money, and new ways to make money attracts investors. This stimulates excitement in entrepreneurs who want funding to develop (and own and license) technologies that promise returns on investment.

In healthcare, the focus is patient benefit, not business or investor benefit. When a company is sold, what happens to the patients relying on its technology, who are relying on on-going bug fixes and upgrades to their heart implants?

Any technology as new as block chain potentially has problems of the sort that the millennia of conventional coinage long since learned to manage: the many ways that people use and abuse coinage is understood and countermeasures have matured. While there are many investors in cryptocurrencies, this does not mean that they are a good investment in healthcare (Green, 2018).

Most block chain investment is implementation biased: crypto is exciting, but excitement is not what's needed in healthcare. For example, a key innovation in cryptocurrencies is relaxing the requirement for a trusted party; but anything in the NHS has the NHS as a trusted party. If you don't trust the NHS, why offer it a technology that imposes high overheads? Why offer it a technology that undermines interoperability (Bates and Samal, 2018)? Of course, these criticisms do not mean that helping healthcare in war zones would not benefit from new techniques.

The lesson is not that block chain should be adopted in healthcare, but, rather, that mature digital thinking itself is the key. Block chain, distributed ledgers and so on are implementations, they should be inspiring more mature ideas about what can be achieved, not driving blind investment.

#### Inspirational systems

High-profile innovators like Amazon, Facebook, eBay and so on inspire trying to tackle healthcare the same way. However, conventional businesses and healthcare have different approaches to safety and error. If an e-commerce operator makes a mistake, they can refund you. In contrast, if a hospital makes a mistake, this may be a disaster, regardless of any 'refund'.

Nobody has thought of a workable way to digitalize health as you can digitize commodities. Health is not fungible (fungible means that things, such as money, shoes or software, are freely interchangeable.). You cannot refund a bug, bad action or decision – you can't return your body to Amazon if the device does not work as hoped.

Although different business models can thrive after digital transformation, we need to be aware that in healthcare the standards and the regulatory frameworks are different – for good reason. This means that the 'low-hanging fruit' of much digital innovation may not translate successfully into healthcare.



#### Al is implementation bias

We can use AI to diagnose eye diseases better than professionally trained humans can (Burgess, 2018). While the excitement is undeniable, other concerns are IPR and balancing an income stream against the traditional view of healthcare as a human right. In turn, most of the mechanisms for creating financial value (e.g. copyright, IPR) mean compromising interoperability, one of the major problems of current digital healthcare (HIMSS, 2018).

Al is merely a way to implement digital systems. Digital maturity means, at least for industry, not thinking of individual digital solutions, but making integrating solutions. These will be disruptive, which by definition means that many healthcare consumers (e.g. clinicians) won't immediately realize they can benefit.

# Universal computing

Turing thought of computer programs being written by humans; Al essentially writes the program by computer, so it is adaptive to a degree that is beyond humans. While Al is amazing, it risks being inscrutable, since nobody is really sure what the 'program' is: it risks having no justification for its insights. In many cases the Al is protected by confidentiality agreements, so there are also legal barriers to finding out how it works.

Al raises questions about liability and regulation. Proprietary rights are an incentive to innovation but healthcare is supposed to be evidence-based, which requires scientific scrutiny.

Current regulation tries to make tight definitions of software, and what sort of software should be regulated, but by its nature digital defies simple classification. For example, *fundamentally* there is no difference between hardware and software, or between data and program.

# Visions of the future

We are bad at assessing our own maturity (Kruger & Dunning, 1999). We don't know what we don't know, so we tend to inflate our self-assessment. Unfortunately, our feelings push us towards being consumers, and hence followers. To be leaders, we need to think beyond implementations to the abstract challenges others are not spotting.

The British visionary Chris Evans, one of the first to experiment using computers to diagnose illness, anticipated back in the early 1970s that computers would become so small and commonplace they'd stick to our shoes like chewing gum and be ignored, but our lives would transform (Evans, 1980).

To date, innovation has forged ahead of regulation (e.g. doctors using social media apps to help patients, but subverting current rules) and it always will until the way regulation is done is itself disrupted. Somehow, and we haven't done this yet, we will have to find a way for innovation and regulation to advance together into a bright digital future. For example, current regulation tries hard to fit software into a conventional physical mould (UDI, unique device identifiers, don't make much sense when software can be continually updated), and that needs changing.

Digital maturity anywhere is good, but when regulations themselves gain digital maturity they will drive improving maturity across the sector.

# Mature reading about digital

M. Thomas, Living in a cyber-enabled world, Gresham Lectures,

https://www.gresham.ac.uk/series/living-in-a-cyber-enabled-world

This is a wide ranging series of high quality videoed public lectures on topics including AI, Blockchain, Internet of Things, Computers and The Future, and more.

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# Published white papers

• The Proposed EU Regulations for Medical and In Vitro Diagnostic Devices: An Overview of the Likely Outcomes and Consequences for the Market, Gert Bos and Erik Vollebregt

• Generating Clinical Evaluation Reports – A Guide to Effectively Analysing Medical Device Safety and Performance, Hassan Achakri, Peter Fennema and Itoro Udofia

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• Technical Documentation and Medical Device Regulation - A Guide for Manufacturers to Ensure Technical Documentation Complies with EU Medical Device Regulation 2017/745, Dr Julianne Bobela, Project Associate; Dr Benjamin Frisch, Senior Associate; Kim Rochat, Senior Partner; and Michael Maier, Senior Partner; all at Medidee Services SA

• Nanotechnology – what does the future look like for the medical devices industry?, Professor Peter J Dobson, the Queen's College, Oxford, with Dr Matthew O'Donnell, BSI

• *Developing and Maintaining a Quality Management System for IVDs,* Melissa Finocchio, Project Portfolio Leader, bioMérieux

## Forthcoming white papers

This paper forms part of a trilogy of shorter white papers on the impact of the digital revolution on the medical devices industry. Other papers in the series are:

*Digital Risk* – covering issues such as patient safety, cyberattacks, complexity, interoperability, international data, blockchain, and how to recognize success.

*Digital Competence* – covering issues such as regulations, post market surveillance, recruitment, human factors, the role of standards, and how the industry can raise standards.

## Other forthcoming white papers on topics of interest to the industry

- Clinical Evaluation Transitioning to the MDR (working title)
- Transitioning UDI from the US FDA Regulation to the EU MDR and IVDR (working title)
- Classification issues for the IVD market (working title)
- Artificial Intelligence (working title)
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