INSIGHT

MOONDANCE CANCER INITIATIVE

Digital & AI technologies for cancer care

An expert's guide to digital health

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About us

Moondance Cancer Initiative is a not–for–profit company established to find solutions so that more people in Wales survive cancer. We want to help achieve significant and sustained improvements in cancer survival outcomes over the next ten years. What we do:

- We identify and trial new pathways, practices, and technologies, so that more people in Wales survive cancer
- We work in partnership with the Welsh health community and beyond – connecting great people across different disciplines, sectors, and regions
- Our work is evidence–informed, rigorous, and adventurous: we see value in moving quickly, trying and learning
- We bring funding, research intelligence, and an ethos of collaboration to the table

We're a not–for–profit company (company number 12305964), privileged to be funded by the Moondance Foundation.

About the author

Digital technology in cancer is a fast moving field, with huge potential impact on how we deliver cancer care. Here at Moondance, we decided to commission this informed expert view, to help us identify what really holds promise for cancer services and patients in Wales.

Dr Jonathan Gregory worked in the (English) NHS for 20 years, with the last ten as a consultant cancer surgeon. He held numerous regional and national roles, including lead clinician for two supra–regional cancer MDTs, Clinical Service Lead, Cancer Network Expert Advisory Group member, and a member of two National Cancer Research Institute Clinical Study Groups.

Jonathan now bridges the gap between digital innovation and clinical medicine. He works with the computational oncology team at Imperial College London and provides digital healthcare consultancy services to a variety of public, private and third sector organisations. He is a member of the NHS Clinical Entrepreneur programme, the Faculty of Clinical Informatics and has been an assessor for the NIHR (National Institute for Health Research) artificial intelligence grant awards and the AHSN Network National Innovation Accelerator Fellowships.

What do we mean by digital healthcare?

Digital healthcare can be understood as encompassing mobile health (mHealth), health information technology (HIT), wearable devices, telehealth and telemedicine and personalised medicine.[1] It utilises computing platforms, connectivity, software and sensors in order to improve healthcare. Digital health products can have the intended purpose of:

- Improving access to care
- Empowering patients to self–manage their care
- Reducing inefficiencies
- Improving quality
- Facilitating the delivery of personalised medicine.

Adoption of digital healthcare technologies is in large part driven by the mass adoption of digital communication in recent years, which have created new ways to monitor and report changes in health and to access information.

Categories of digital healthcare

There is no one system of categorisation, and many products now transcend boundaries of use or architecture; however the following categories do allow consideration of products under broadly similar use cases, impacts, risks or regulatory requirements.

Software as a medical device

This is 'software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device'.[2] They can be run on general purpose computing platforms not specialist medical platforms, e.g., a smart phone. This category contains both conventional and AI empowered products and is an area of huge growth.

Mobile medical applications

There are more than 370,000 health–related apps available online.[3] There is no official requirement to register mobile apps either as 'software as a medical device' or with the MHRA as a class 1 medical device. However, standalone software apps that meet the definition of a medical device are required to be CE marked (UK CA in the future) in line with the Medical Devices Regulations 2002. CE marking is a minimum standard when considering digital products (see regulation and governance section below).

Health IT

Health information technology (IT) describes computer hardware, software and associated infrastructure used to record, store and retrieve clinical information, and associated administration and financial information.

This includes **Electronic Patient Records (EPRs)** and **Electronic Healthcare Records (EHRs).** An EPR is a longitudinal data record relating to a patient at a single institution. An EHR by contrast is a longitudinal record of a patient across

multiple providers from birth to death. Electronic prescribing and personalized medical records are further examples of Health IT.

Joined up healthcare IT – that connects multiple systems and enables safe use of AI around the needs of local populations – requires the right infrastructure platform. Historically many platforms were designed to enable delivery of what administrators wanted to know rather than delivering excellent user experiences or great data management. Going forward, these platforms need to be much better, with much more attention paid to user experience for clinical teams and data extraction for data scientists.

Data structures that will allow easy integration with 3rd party products and services, and facilitate healthcare data scientists to provide real-time real-world insights are key. Purchasers need to be aware of the risks of vendor lock in due to data structure or architecture. The difficulties of implementation and integration cannot be ignored. However, delivered well, a good EPR / EHR can support clinical and non-clinical teams to transform the services they provide.

Telehealth

Telehealth is the delivery of healthcare, health education and health information services via remote technologies. Therefore, many aspects of 'digital healthcare' are telehealth products. **Telemedicine** is a subcategory of telehealth and is defined as "The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries'.

Wireless medical devices including fitness trackers become telehealth if the wireless device is performing remote patient monitoring and collects, evaluates and reports patient health data through electronic devices (wearables, smartphones). If a tracker is not evaluating data and only recording it then it is not a medical device.

Explaining AI

Artificial Intelligence (AI) has become synonymous with digital healthcare – and is surrounded by confusion, dis–information, hype and pessimism. AI is in fact only a small part of what constitutes digital medicine. It is a range of theories and mathematical techniques that allow computers to perform tasks. As such, it is a branch of data science.

Key terms in data science

Data science is a multi–disciplinary field combining statistics, mathematics and computer science. When these teams combine with domain experts, they can identify insights and knowledge from data that were not previously appreciated. Data science includes the preparation of data, use of statistical methods and visualisation techniques to gain new understandings. It usually involves large quantities of data and mathematical models being applied to identify patterns and relationships between different data items.

Data mining aims to uncover correlations and possible causal links which are not visible in smaller datasets. It requires large amounts of data and well curated electronic patient records and electronic healthcare records. Via data mining, the adoption of digital healthcare can drive new insights and understanding of health and disease and so indirectly improve patient care.

Data registries aim to capture a minimum dataset on *every* patient who has a particular condition. For example, a cancer registry will aim to collect a uniform minimum dataset on every patient with breast cancer nationally but the data might be limited in depth. A **data repository** on the other hand, is usually a group of patients who do not necessarily represent the whole of a population of patients. For example, it contains patients who have had breast cancer but *not all* patients who have had breast cancer.[4] However, the data collected is usually more uniformly completed and may be of greater depth than a registry. Depending on the methodology used to create the repository there is a risk of bias depending upon how the data was collected e.g. recruited at one hospital.

Artificial intelligence (AI)

AI has several definitions. One of the most helpful is 'the science of making machines do things that would require intelligence if done by people'. [5]

Artificial intelligence as a concept is itself contentious, as it assumes only biological systems possess 'real' intelligence, which puts great weight onto definitions of what it is to be intelligent. It has been proposed that using the phrases 'human intelligence' and 'computer intelligence' may aid discussion of these topics as the methods used to convert inputs to outputs are very different. We need to be very clear that computers are not mimicking human methods of 'thinking' or being 'intelligent'. They are using different methods to convert data inputs into outputs.

One of the problems with a general definition of AI is that there are different types of AI. At the highest level, AI can be described as general or narrow.

- **General AI** refers to an artificially intelligent computer that could perform as well, or better than, humans over many different tasks and is able to

interpret complex phenomena such as emotions. This is the AI of science fiction and is what is often called to mind by people when AI is discussed. There are no computers which display general AI today, and most experts in the field believe it will be many years until such AI will exist in any meaningful way, if ever.

- **Narrow AI** does exist and is used by most people every day. Narrow means that it can perform tasks well in a very narrow well-defined field.
    - Amazon Alexa, Apple Siri and Google Home are examples of everyday narrow AI. They use machine learning to 'understand' human commands, improve their performance based upon previous interactions and then communicate back to the user.
    - Internet search engines utilise machine learning methods to find and rank webpages that match your search criteria and prioritise the results based upon what you have previously looked at and how long you looked at them.
    - Recommender systems, for example Netflix and Amazon, use a combination of data science techniques to group customers according to behaviour and use AI to make predictions of what you might like. Based upon your responses to it's recommendations it 'learns' which things to recommend in the future that will have the greatest chance of being selected.

AI methods

There are many different AI methods, with different complexity and different benefits and problems. I discuss three for illustrative purposes.

Symbolic AI

This is based upon logic and is the foundation of expert systems which use rules to provide advice and guidance. Several healthcare products advertised as AI rely on this method. **Symbolic AI** is good where there are clear rules that humans can give the computer to follow. Many clinical decision support tools rely on symbolic AI: the computer applies human-produced rules to generate outputs. However, symbolic AI does not perform well where patterns in data are unclear or where we cannot provide 'rules' for the AI to follow.

Machine learning

Machine learning is now over 60 years old but has really come to the fore in the last 10–15 years due to improvements in computing capacity, and work to improve AI models. The aim of machine learning is to create algorithms that can automatically learn the relationship between input data and what you want as output data without being 'narrowly' programmed. Traditional programs provide computers with a fixed set of instructions and the computer works through these to generate outputs. With machine learning the computer 'learns' based upon mathematical relationships in the data.

Machine learning AI methods require providing computers with data. The amount of information and rules that the computer is given varies with different methods. Probably the easiest method to understand is called **supervised learning**. The

computer is provided with data that has been curated and checked so as to provide the 'truth' – e.g., provided with 2000 x–rays and told (in the opinion of humans) which show lung cancer and which do not. The computer then identifies any patterns in the data that it can use to explain the 'cancer' 'not cancer' categories.

It is worth remembering the computer is not 'looking' at images like a human, it is looking at numbers that represent pixels in the image and analysing these numbers for patterns. The computer is then provided with new data without the answers and instructed to categorise them into the 'cancer' 'not cancer' groups and this is compared to the 'truth' by humans. Feedback is given to the computer on which it got right and wrong and then the computer works through the data again changing its calculations which it's hoped improves its accuracy. This is not 'learning' in a human sense, rather the computer is adjusting its use of mathematical rules and algorithms to improve its performance against a set of parameters or truths that the human programmers provide.

A robot mouse: the difference between symbolic AI and machine learning

Imagine a robot mouse which has to navigate a maze.

A symbolic AI approach would mean we give the robot mouse all the rules it needs in order to navigate through the maze to the end e.g. turn left, move 10cm, turn right. This means humans have to develop all the rules and if the maze changes or a new situation arises the robot will get stuck and cannot do anything to resolve the problem itself.

The same robot mouse being made with a machine learning AI approach would 'wander' around the maze making its own mistakes and would take much longer than the symbolic AI mouse to navigate around the maze. However, it will eventually work out rules for itself (these are unlikely to be the same as the rules we would have given the symbolic AI mouse but would have the same end result).

If the maze changes there is the possibility that the machine learning mouse could adapt, unlike the symbolic AI mouse.

Based upon illustrative example in Defence Science and Technology Laboratory (dstl) Biscuit Book[6]

Natural Language Processing

Natural Language Processing (NLP) uses data science and AI techniques to interpret spoken or written human language. For example, an AI model which 'listens' to a conversation and creates a summary transcript or an AI which can go through unstructured written records (e.g., medical notes) and extract key words and phrases. Training NLP systems can be difficult depending upon the use case and the deployment environment. They offer powerful ways of automating some processes which take a lot of time and effort.

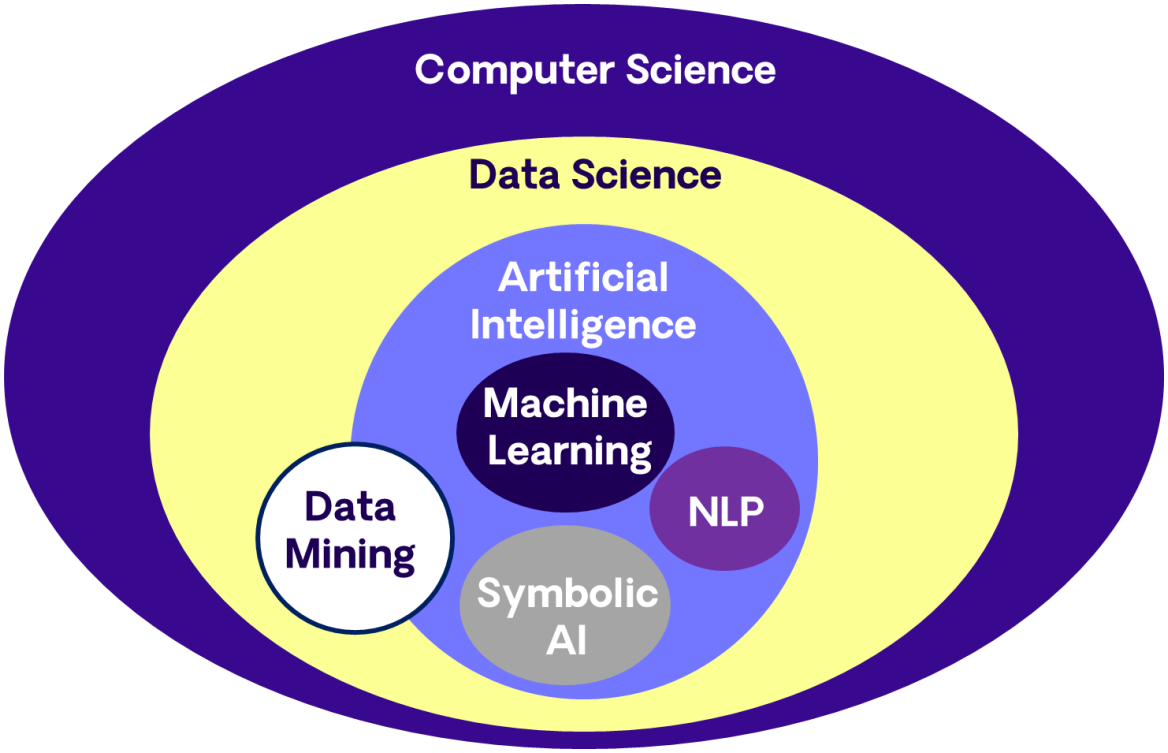

Fig 1. The relationships between different aspects of computer science

Key challenges

Interoperability: rate-limiter of digital transformation

Realising the full benefit of many digital applications (AI and non-AI) demands effective, consistent data collection and for the solution to sit within a system that allows the application to be integrated seamlessly into workflows. **Device interoperability** is the ability for different devices and applications to exchange information safely, securely and seamlessly.

At present, many stand-alone solutions are being developed for individual diseases, but these need to be joined up in order to be scalable, sustainable and safe. For example, you could have a variety of mobile apps helping you and your doctor to manage your diabetes, heart failure and late effects from your bowel cancer treatment, but these apps need to talk to each other and to all the healthcare providers involved in your care. For this reason, many experts feel that the life of standalone disease-specific apps is limited. Either big vendors will provide whole solutions or, more likely, they will offer agnostic frameworks into which disease-specific apps developed by them or others can be integrated.

Interoperability in digital health is still relatively immature compared to sectors where it was an absolute necessity, for example financial services. However, this issue threatens to be the rate-determining step in delivering improvements in health outcomes from digital advances.

EHRs as the key to interoperability

The backbone of healthcare interoperability will be electronic health records that are agnostic to different app and device manufacturers, enabling new apps and devices to be bolted on as they become available. EHRs will need to span primary and secondary care and have an interface to allow patients to have sight of their own records. Surveying the market today, there are issues of vendor lock-in to proprietary systems, and non-integration of third party software – which can prevent the use of disease-specific apps or AI products.

Work ongoing in Wales towards the National Data Resource (NDR) may represent a path towards this broad, interoperable EHR.

EHRs need to be well curated to provide data on the population both locally and nationally. This data will enable the performance of some digital & AI products to be optimised. If AI is developed using data from one place it cannot automatically be assumed that the AI will perform as safely and effectively in a new population. A hypothetical AI trained on data from Manchester, England would probably work just as well in Cardiff, Wales but this would need to be confirmed, and data required to do this 'local tuning'. However, if the AI had been built upon data from a very different population e.g. veterans in the USA, then checking that the AI was safe and effective for use in Wales would be a larger piece of work.

API development

One reason why healthcare is lagging behind financial services digital transformation is the provision of software to link applications. Application Programming Interfaces (APIs) are pieces of software that connect different

software programmes. APIs are translators or links between products that allow the systems to exchange data. In industries with agreed APIs and ready exchange of APIs the ability to integrate applications is well developed and system infrastructure is less of an issue. In healthcare, to date, APIs have not received sufficient focus, with a lack of custom and convention resulting in the problems we see in data exchange in healthcare in the UK. This creates stumbling blocks to even simple digital improvements.

Some initiatives, such as the Digital Health Ecosystem Wales (DHEW) developer portal, are underway to lower the barriers to API development in Welsh healthcare.

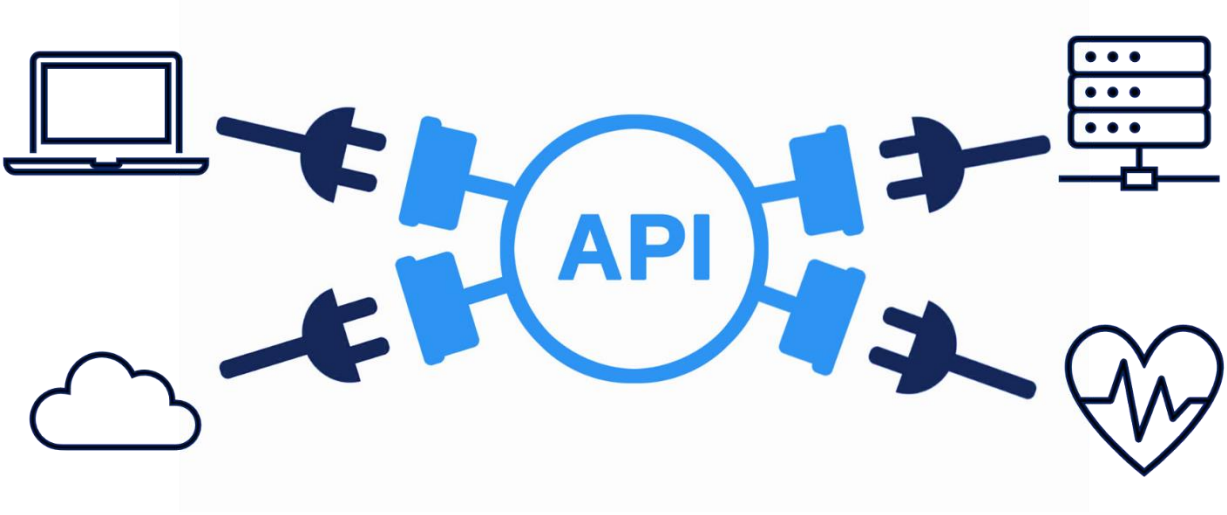

Fig 2. APIs allow the integration and exchange of data between different sources

Market failure and the creation of a missing API

A significant barrier to the adoption of EPRs in paediatrics was the need for growth charts to record a child's growth and development. These graphs are not complex but were difficult to produce in EPRs owing to an absence of APIs to allow different pieces of software to interact.

No company wanted to fund making the API and as none of them provided digital growth charts seamlessly within their EPR, there was no market disadvantage to not providing this important functionality.

Therefore, RCPCH created the API and it is available for EPR companies to use for a small fee. This has removed a barrier to EPR use in paediatrics which in turn removes a barrier to automation of some processes and the use of other digital solutions.

The Royal College of Paediatrics and Child Health (RCPCH)

Difficulties with AI in healthcare

There are many barriers to the safe and effective use of AI in healthcare. Below, I illustrate some of the issues that need to be considered.

Good enough vs human level performance

It is very important when considering AI to reflect on the overall aim. For example, creating an AI tool that can make diagnoses of conditions as well as, or better than, human doctors and do this safely across all patients is very difficult. However, to create an AI that can rapidly, effectively and safely triage test results as normal or abnormal (rather than a specific diagnosis) is usually much more achievable and will still have a big impact on work flow. Anything not 'normal' can be forwarded to a doctor for interpretation but every result that is normal can have an automatic report generated in seconds.

Ground truth

We have to consider what is the 'truth' in any given situation. Often, what we think is objective truth – e.g., a diagnosis of grade 2 breast cancer – is in fact a subjective opinion. Therefore, if we are training an AI on histology slides how do we determine the 'true' diagnosis? Was it grade 2 cancer, or was the pathologist incorrect? A robust and widely–accepted 'ground truth' is paramount when developing AI models.

Generalisable models

The data used to train an AI model has a big impact on the model and how well it will perform in the real world. Say we want to develop an AI model to identify patients with lung cancer on their chest x–ray. We need to know how commonly lung cancer is detected via x–rays in the real world (e.g., 1/100) and the training data needs to be the same. The model will not work well in real life if you train it on a series of x–rays where 1 in 10 cases show lung cancer or 1 in a million cases show lung cancer.

Other data features affect how generalisable an AI model is. For example, differences in the type of population the model was trained on, differences in image capture or quality, differences in extraneous objects (e.g., ECG wires or chest drains). Should the AI model draw upon use these factors in its 'decision–making', then in the real world, any differences may have big effects.

An example of this problem was seen in an AI model that was designed to identify malignant melanoma from non–cancerous moles.[7] The model functioned well on the training and test data. However, when it was used on new data which it had not seen before its performance deteriorated. Upon review, it was established that many of the photos of malignant melanoma used as training data showed skin markings or a ruler next to the lesion (for treatment planning where the clinician had already identified malignancy). The AI used those skin markings as an indicator of melanoma and therefore incorporated this 'data' in its model.

Explainability of AI decisions

As the example above shows, when an AI goes wrong we may find it difficult to understand why. Depending upon the method of machine learning used, explaining the basis for a decision by an AI can be difficult (although there are approaches to help). In healthcare, where we may want to understand why a particular diagnosis or treatment is being recommended by an AI, 'explainability' is very important. Generally, the simpler the machine learning model, the easier it is to ensure its results are explainable. However, for simple machine learning models to work, you need high quality data – and not all healthcare data is high quality, which drives providers to more complex models where 'black box' concerns arise.

People and the digital transformation of healthcare

The role of healthcare staff in the digital transformation of cancer care should not be underestimated. Much of the focus has been on whether doctors will accept AI, but the issue is much wider: what do all healthcare staff think, and what are the views of patients and carers?

Healthcare staff

A report from the Health Foundation has explored the opinions of healthcare staff with regards AI in healthcare.[8] The report shows that healthcare assistants, in particular, are more skeptical of AI than medical and nursing staff. In an in-patient environment, patients will often spend much more time with healthcare assistants than with clinical staff; they will talk to healthcare assistants about their condition, the clinical team and their treatment. We therefore need to be sure that all members of the team that care for patients have a good understanding about digital and AI enabled care.

A recent study found that over 50% of German doctors personally used mobile apps every day at work, and they had a reasonable desire to drive digitalisation.[9] Access to medical knowledge, treatment of orphan diseases and medical research were listed as the main areas they felt would benefit from digitalisation. They viewed patient engagement as one of the least impacted areas.

This differs from my view having now spent a lot of time exploring what digital can offer in healthcare. I believe digital will allow more seamless communication between patients and care teams. For example, using a digital app to collect patient data before appointments will create more time within consultations to discuss the situation and options. In this way, digital technology can help deliver more compassionate care by freeing clinical teams from low value work.

Patients

Patients' ability to utilise digital and AI healthcare technologies will be a key determinant of the pace of adoption of these technologies.

A study in Germany assessed the ability of patients with cancer to search for cancer-related information on the internet whilst the patients were rehabilitating in a healthcare setting after oncology procedures (routine in Germany).[10] The median age of the patients sample was 57 and the demographic spread was reasonable. The study asked participants to perform eight cancer-related search tasks using the internet. All participants experienced some problems in executing all of the tasks; 40% were not completed successfully. Most problems related to search strategies and evaluating the relevance and reliability of web-based information. 95% of participants did not look to control for the source of information or how relevant the information was that was identified. No participants looked to compare information between websites in order to verify the information they had found.

Therefore, it suggests that there is a need to focus on improving the populations information evaluation skills particularly around health and disease information seeking behaviour. If patients are unable to perform a relatively simple digital task such as in this study then will they be able to evaluate more complex digital interventions? It also highlights the importance of clinical teams being able to direct patients to reliable information. Digital tools can assist with this but they will need to be evaluated by the clinical community unless the evaluations skills of patients can be enhanced.

Inequalities of care and access

There is understandable concern that digital healthcare may widen social health inequalities. 2021 data suggests that 30.8 million people in the UK are highly engaged in digital platforms, with 86% of adults using the internet.[11] However, 10 million people in the UK lack basic digital skills and 14.9 million have very low digital engagement. In 2021 1.5 million UK households do not have internet access and 2 million struggle to afford internet access.

We must be aware of this backdrop when considering the adoption of digital solutions in cancer care. Both formal support from healthcare professionals and informal support from friends and family maybe required for some people to utilise digital healthcare products. This 'cost' needs to be accounted for when considering the role of digital.

However, there is no robust evidence that digital health technology worsens social inequality compared to conventional care at a population level. In my opinion, digital healthcare will most likely result in *different* inequalities compared to traditional care models. We should not hold digital healthcare to a higher standard than we do current 'non digital' solutions but we must also aim to prevent digitally–driven inequalities.

Regulation and governance of digital healthcare

Digital healthcare is rapidly evolving. As such the regulatory frameworks for these products are not always in line with the technology, and are themselves evolving rapidly. Relationships between the different regulatory frameworks and guidance are also not well established. An NHSx–hosted multi–agency advice service (MAAS) is planned to ameliorate the issue, but is not up and running yet (it is currently unclear how the ongoing merge between NHSx and NHS digital will affect this).

An outline of the current regulatory environment is provided to aid the reader in understanding what quality assurance is in place for these products and therefore how safely they can be adopted. To my knowledge currently the following bodies have issued guidance, regulations or toolkits concerning digital and / or AI that applies to healthcare: NHSX, NICE, MHRA, ICO, NHS Digital. Beyond the UK, the EU MDR and MDD, and FDA guidelines and regulations are key.

Medical devices (MHRA)

The Medicines in Healthcare Product Regulatory Agency (MHRA) regulates medical devices in the UK (as well as medicines and some blood products).

The MHRA uses the definition of a medical advice from the Medical Devices Regulations 2002: "A medical device is an instrument, apparatus, appliance, software, material or other article whether used alone or in combination together with any accessories including the software intended by his manufacture to be used specifically for diagnosis or therapeutic purposes or both, and necessary for its proper application, which is intended by other manufactures to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or other physiological process.
- Control of conception."[12]

Manufacturers are required to conform to CE marking requirements for any product defined as a medical device. During device development, manufacturers can apply CE markings as part of a clinical investigation before the device has been fully certified. Devices developed in–house are currently outside the medical device requirements, but cannot be used outside the developing organisation. As part of the CE declaration, manufacturers provide an intended use statement. This use statement should be compared to the intended use in an adopting organisation: digital products are much easier to inadvertently 'misuse'.

Medical devices are classified according to risk. Class 1 are devices are not intended for monitoring physiological processes or for diagnostic or therapeutic decision–support. Any devices which monitor physiological processes or supports therapeutic or diagnostic decisions is classed 2a, 2b or 3, depending on

the associated risks. The process for obtaining a CE mark is similar between the difference classes however, the level of evidence required varies:

- Manufactures of Class 1 devices self-certify;
- Devices above class 1 have to meet ISO13485 accreditation or similar and have their conformity checked by a notified body.

Medical devices regulation is changing because of the UK leaving the EU, but also as the position of digital and AI devices within healthcare becomes better understood. UK Conformity Assessment (UKCA) will replace CE marking in the UK. CE marking will be recognised until the 30th June 2023, from which point only UKCA will be recognised.

Under the EU Medical Devices Directive (MDD) AI decision support systems were classified as low risk (class 1). This has been addressed in the new EU Medical Devices Regulation (MDR) and now almost all AI systems are now graded at least medium risk (class 2a). This will result in formal external audit on quality systems and inspection of technical documentation by independent regulatory bodies. Devices currently class 1 through MDD assessment can keep their certification until 2024, by which point they will have had to move over to MDR assessment. However, for digital AI devices, ongoing certification is based on there being no changes to the AI model or significant change to the device.

CE and UKCA are the minimum standard to certify that a device is safe, performs as intended, and the benefits out way the risks. As before, CE certification relates only to the specified use statement made in the conformity assessment; if a device is used differently, a CE or UKCA mark is not a guarantee of safety or performance.

CE and UKCA marks also do not guarantee high performance in a real-world context: one review of smart phone apps to assess the risk of skin cancer demonstrated that the apps did not detect all cases of melanoma or other skin cancers – despite some of the applications having CE marks.[13] On one measure of 'accuracy' the best performing would have missed 4 out of 30 melanomas, and yet still also have generated some false positive results.

AI devices which undertake clinical activity independent of healthcare professionals, such as imaging analysis, also require registration as a service through the Care Quality Commission in addition to having a CE/UKCA mark.

Operational software (NHS Digital)

Operational software is technology that improves operational efficiency and does not have a specific clinical decision-making function. These technologies should be developed in line with ISO82304-1.

In addition, they should have completed clinical risk management assessments (DCB0129). Prior to procurement, an organisation should be able to review the clinical safety management system, clinical safety management plan, the hazard log and the clinical safety case report, which constitute the DCB0129 file. The deploying organisation will be required to be compliant with DCB0160 – Risk management for the deployment of health software.

Where an organisation is looking to develop a product themselves rather than use an off the shelf product, research governance requirements may apply. The MHRA may also require notification if it is a medical device that is being developed.

NHSX Digital Technology Assessment Criteria for Health & Social Care (DTAC)

The DTAC has been developed by NHSX with the aim of pulling together the legislation and good practice that relates to digital health tools and their safety (data protection, technical security, intra–operability, usability and accessibility standards).

It is intended that DTAC will become the expected product standard for adoption by English NHS and social care bodies. Though it does not currently apply in Wales, this may change in the future. DTAC relates to all new digital technology, even if it is only used in a pilot or trial. DTAC is linked to both the DCB0129 and DCB0160 definitions. This means it relates to products being used to provide electronic information for health or social care purposes where the product may include hardware, software or a combination of both.

It is thus intended that DTAC will be used by healthcare organisations to assess products at the point of procurement or during due diligence to make sure that new digital technologies meet minimum baseline standards.

DTAC is relatively recent and as such, is still in the process of being embedded into routine digital procurement. Digital technology which is already in use does not need to be retrospectively assessed but will need assessing if the technology has changed significantly.

NICE evidence standards framework for digital health technologies

NICE has developed this framework to support commissioning decisions around digital health technologies, reducing barriers to use and inconsistencies of approach across commissioning bodies.

The framework describes different levels of functional classification associated with different clinical risks. There are then different evidence levels required in order to satisfy that risks have been considered and appropriate evidence generated. It includes an economic evaluation, which aims to capture the many different ways digital tools afford value, compared to conventional ‘devices’.

Many digital solutions result in costs and benefits which are distributed across organizational boundaries. For example, a technology that improved community palliative care may lead to increased costs in community care, but significant savings in secondary care owing to fewer acute hospital admissions as the technology helped prevent symptom crises; the costs of purchasing such a tool would fall on the community budget, and yet the benefits would be found in secondary care. The framework provides a template for budget impact analysis to try and capture this difference compared to non–digital products.

Practical summary

In summary, it is my understanding that when considering which technologies in the market healthcare organisations should look for the following information:

- The product is CE or CA marked;
- The certification class registered with the MHRA;
- The fit between the statement of conformity and its associated registration class and the intended use of the technology locally;
- For digital and AI technologies brought to market from 2021 onwards, the DTAC documentation for the device;
- Where appropriate, the DCB0129 documentation and any DCB0160 documentation that can be shared from institutions that have already deployed the technology;

I would also suggest using the NICE evidence standards framework for digital health technologies when considering what evidence the vendor should be providing, and the economic implications of using the digital tool.

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- NICE Evidence Standards Framework for digital health technologies 2018 updated 2021 (https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies)
- List of current FDA approved AI / ML enabled medical devices (https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices)

MOONDANCE
CANCER INITIATIVE

Moondance Cancer Initiative helps find solutions so that more people in Wales survive cancer. We actively support people and projects with potential to transform survival outcomes across the country, and we undertake research and insight to inform our work.

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