The Future of Digital Health

Emerging risks, opportunities and how the insurance market is responding



Healthcare digital (r)evolution

The convergence of healthcare and technology is not a new phenomenon; consider the introduction of computers into the healthcare system in the 1960s, the launch of the da Vinci robotic surgical system in 2000 and increasingly sophisticated CT scan systems.

Yet, digital health innovation is a distinguishable technological transformative force that also encapsulates profound cultural shifts and an altogether new way of working within healthcare.1

In short, eHealth/digital health:

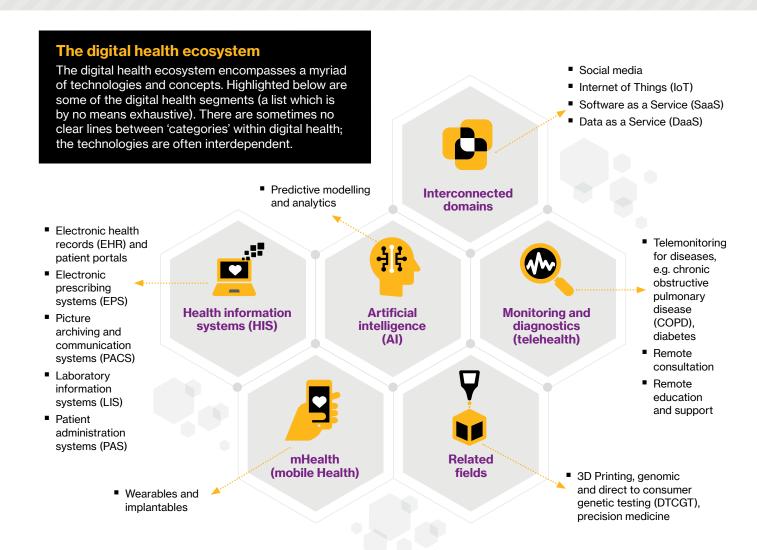
"refer[s] to the organization and delivery of health services and information using the internet and related technologies. In a broader sense, the term characterizes not only a technical development,

but also a new way of working. an attitude, and a commitment for networked, global thinking, to improve healthcare locally, regionally, and worldwide by using information and communication technology".2

As the next frontier of technological advancement in healthcare, there are great expectations about digital health's positive disruptive potential.

There are many variant terms that are used to label this field: digital health, medical informatics, eHealth, telehealthcare, etc. Whilst there has also been much academic debate about what these terms encompass, for the purposes of this discussion we have settled on digital health or eHealth as best incorporating the broader ecosystem.

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Related concepts

- Big data
 - Data governance: access, storage and ownership
 - Data security
 - Secondary data use data reuse/data sales
- Interoperability and health information exchanges
- Usability considerations (ADA compliance, digital divide, heuristics, etc).

Stakeholders in digital health Government Regulators **Payors Providers Pharmacies** and pharma Commercial enterprises Investors Academia and researchers **Charities and** social care orgs Labs **Patients**

Why is it important?

The global digital health market size is estimated to be over \$116 billion (as at 2019) and forecast to be nearly a \$833 billion market by 2027.3 However, interest in digital health technologies is not solely driven by the obvious economic opportunities, there are several forces that are propelling the proliferation of digital health innovations.

Most importantly, digital health tools have robust clinical utility that hold great promise to achieve better quality care, improve access, lower costs and ultimately improve health outcomes through better diagnoses and treatments.

'Big data' is the gas in the engine of most digital health innovations, thus, the sheer availability of data globally is another substantial growth driver.

Consider the global data sphere is projected to grow from 59 zettabytes in 2020 to 175 zettabytes by 2025 a combined annual growth rate (CAGR) of 26%^{4/5}; and because of the digitization of medicine, health data are amassing at an even faster pace – CAGR of 36% through 2025.6

A final driver has been the surge in consumer demand for digital health tools to manage their care. The demand which appeared to plateau in 2018, may have been revitalized by the forces of COVID-19.7

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When considering the current environment. we cannot ignore how COVID-19 has served to thrust digital health onto the world stage.

During this pandemic, multiple healthcare stakeholders have leveraged digital health technologies to facilitate necessary social distancing and enhance employee and patient safety. Thus, an interesting side effect of the pandemic has been to increase global attention towards, investment in and adoption of digital health technology.

COVID-19 has also served to escalate the 'eHealth conversation' within the healthcare property and casualty (P&C) community as insurance carriers, brokers and our clients grapple with real-time liability and insurance implications of the rapid escalation in digital health deployment, adoption and investment.

Challenges faced by the digital health industry

There are substantial challenges that the digital health industry faces that must be considered within any insurance and liability analysis:

- Regulatory and legal frameworks that cannot keep pace within innovation, adoption and use.
- Consumer concerns about security and privacy.
- Ethical questions that inevitably arise in the adoption and use of new technologies, especially regarding the role of commercialism and monetization.
- Interoperability issues and fragmented systems both technical (software, platforms etc.) and 'system structure' (e.g. disparate providers, payors and regulators of healthcare).
- Competing motivations and misalignments payor, provider and patient (what are the priorities and how can they be agreed upon).
- Equity issues that can especially arise from swift digital implementations – e.g. digital literacy issues, digital access issues ('digital divide') and the impact on vulnerable groups (e.g. seniors – the 'grey divide').
- Usability issues for patients and providers alike.

Digital health insurance considerations

In any emerging and rapidly growing field it is important to remain attentive to shifting liability and insurance conditions.

Digital health advancements are catalyzing deployment of novel healthcare delivery and operational models that may in turn produce unforeseen perils and new flows of liability.

Digital health exposures can arise through the provision of technological products and services to patients, providers, payors and a variety of other stakeholders, both within and outside of clinical settings.

There are an extremely wide variety of digital health products and services that are increasingly being utilized in new settings and in new ways.

In such a rapidly evolving field with limited regulatory guidance and little to no legal precedent, how can risk managers and insurance professionals determine what type of insurance coverage they need?



Determining what insurance coverages are necessary requires an analysis of the insured's operations, products and services (including any contractual requirements that underpin their business) within the context of current insurance products available.

Existing relevant insurance solutions are typically siloed within a variety of standalone individual policies that address two core categories of injury: economic injury and bodily injury.

Economic injury:	
Technology errors and omissions (E&O):	Any entity developing, designing, manufacturing, selling or implementing technology products (software, apps, hardware etc.) and services (telecoms, consulting, hosting etc.).
Privacy and security:	Any entity that touches data.

Bodily injury:	
Medical malpractice:	Any entity that provides professional healthcare services.
Products liability:	Any entity manufacturing, distributing or selling a product.

Yet, digital health innovations are likely to result in new or unpredictable risks and potential harms that manifest in varying ways without regard to these traditional lines of delineation between coverages.

As operational models shift and traditional lines between risks continue to blur, insureds will be increasingly unable to distinguish the different types of exposures and potential harms when seeking insurance coverage.

Bodily injury

Economic loss

- Technology E&O
- Products liability
- Clinical trials
- Medical malpractice
- Data security and privacy

To illustrate how the interaction between technology and healthcare can create complex insurance considerations, let's review a typical technology E&O loss scenario:

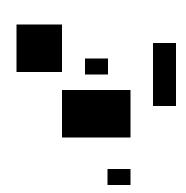
The client, ABC Tech, creates computer programs or applications that are required to perform in certain ways, e.g. analyze sales data and draw conclusions upon which the customer can act. However, if ABC Tech's system doesn't work, the customer may suffer financial loss as a result (lost revenue, increased expenses etc). This is a typical E&O loss scenario and technology E&O coverage can be purchased to cover the customer's financial losses when ABC Tech's product fails to perform.

But what if the services or products that ABC Tech provides are used in a clinical setting where bad outcomes can result in both financial harm to a customer, and bodily injury to a customer's patients? Which insurance policy would provide all the necessary coverage? Considering:

- Standalone tech E&O policies do not typically cover bodily injury.
- Products liability policies do not always cover economic losses.
- Both standardly exclude losses arising from professional healthcare services.

Broadly, if the technology is designed to impact people's health or even their understanding of their health (whether in conjunction with clinical professionals or not) there is the potential for bodily injury exposures in addition to the economic loss traditionally associated with tech exposures.

Similarly, if the patient interaction is facilitated or dependent on an intervening layer of technology, providers should consider whether they have more than just a traditional medical malpractice exposure.





There are a multiplicity of activities, entities and thus corresponding exposures and harms that can arise in digital health contexts:

- Providers using, developing or implementing digital health technologies to facilitate patient interactions (diagnosis, treatment, monitoring and management).
- Digital health platform hosts, developers and designers (software, applications, hardware), especially those that facilitate or provide patient diagnosis treatment, monitoring and management.
- Product manufacturers, distributors, developing digital health technologies (both regulated and unregulated).

These fundamental shifts and new models have no regard for 'traditional' lines between coverage and harms; thus, digital health exposures necessitate evolutions in insurance products and underwriting approaches that address the impact of these technological innovations on risk.

Digital health exposures require coverage for:

- Bodily injury and economic loss
- Regulated and unregulated products
- Products and services often provided in cooperation with or at the direction of medical professionals.

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These potentially intertwined risks demand integrated insurance solutions that creatively knit together multiple iterations of the exposures and the harms that can manifest within these novel and emerging applications of technology within healthcare.

This multi-disciplinary insurance approach is critical to avoid coverage gaps and potential disputes that may arise when seeking redress in two or three (or more?) different insurance towers for complex, interrelated, indistinguishable events.

This intertwining of coverage is not without precedent within the healthcare liability space as most medical malpractice policy forms encapsulate general liability coverages with the specific goal of minimizing potential coverage and tower disputes.

Similarly, technology E&O coverages are often written in conjunction with cyber policies due to the intertwining of coverage triggers and exposures.

However, at present, insureds with digital health exposures must cobble together coverage for their exposures in multiple towers, navigating exclusionary language and coverage terms that are incongruent.

This prevents insureds from developing a seamless and straightforward understanding of what type of loss is covered in which policy. This coverage landscape is predicated on a simplistic conceptualization of coverages and their corresponding losses wherein they each 'stay within their lanes'.

Such a perspective does nothing to address scenarios where technology is facilitating the provision of healthcare services and products outside of traditional 'lanes'. This coverage environment is further complicated by regulatory and legal frameworks that are insufficient to tackle these emerging issues due to lack of precedent (in almost every jurisdiction) and limited or lagging regulatory constructs.



Bermuda market

The Bermuda market currently has limited ability to offer digital health risks and exposures a true multi-disciplinary coverage solution.

Whilst Bermuda has a robust and deeply experienced marketplace in each required discipline (medical malpractice, technology E&O, cyber and products liability) no carrier has developed an integrated digital health coverage alternative that addresses the increasingly blurred lines between these coverages.

Each field has its limitations:

- 1. Medical malpractice and products liability carriers will not provide cover for economic losses.
- 2. Tech E&O and cyber carriers, whilst they often write the two products in tandem, will not provide coverage for bodily injury.
- 3. Only medical malpractice carriers provide coverage for professional healthcare services.

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U.S. market

The U.S. market is perhaps further along the pathway towards offering integrated solutions that attempt to address increasingly intertwined and complex risks.

Carriers that specialize in the life sciences and technology industries have developed forms that endeavor to provide a suite of coverages, including cyber, technology E&O and products liability.

However, many of these solutions exclude professional healthcare services. The healthcare liability market is lagging behind their counterparts in offer multi-disciplinary solutions, with only one U.S.-based carrier offering a solution that provides medical malpractice, technology E&O (and products liability), and cyber coverage in one policy.



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U.K. market

The U.K. has developed two market leading, innovative products which provide cover for digital health risks offering a multi-disciplinary coverage solution. Both solutions cover medical malpractice, tech E&O, cyber, public and products liability for digital health risks and are available to digital health risks located in the U.K., Worldwide and U.S. However, appetite for U.S.-based risks is somewhat more limited and approached on an individual risk basis. Additionally, Worldwide appetites can be constrained due to the complexities of cross border digital healthcare and regulations. These products do have varied approaches to different healthcare segments and seem focused on entities with primarily digital health exposures. We look forward to an expansion of these products into traditional healthcare segments; this will address emerging digital health exposures of healthcare providers seeking to expand their technological offerings.

Aside from these innovative products, integrated solutions in the London market are limited with largely siloed coverage solutions required to address the differing exposures. For example, healthcare liability carriers are seeking to limit their potential exposure for bodily injury arising from data privacy and security events. Thus, clients must increasingly seek this coverage from cyber carriers. However, the cyber market's appetite to provide coverage for bodily injury harms is extremely limited and there are very few cyber insurers who will consider the removal of the bodily injury exclusion (and still may only offer coverage on a sub-limited basis). These gaps are common and are not able to be 'elegantly' addressed when coverage must be cobbled together via siloed products.



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Australasian market

Whilst it is recognized there is a growing need for a dedicated solution in this region, product development is not keeping pace with evolving risks and technology, with only one Lloyd's based hybrid product currently available to digital health companies.

Currently, few insurers have the capability, appetite or necessary licences to underwrite coverage across multiple classes which include cyber, technology liability and healthcare malpractice. As with other territories, cyber insurers are reluctant to remove bodily injury exclusions, creating a fragmented approach to insuring this emerging area.

As market conditions continue to harden in this region, insurer appetite is becoming increasingly conservative. New product development, which is common in softer market conditions, has been largely abandoned as insurers shift their focus from growing market share to portfolio remediation.

Given this move in appetite, insurers have not turned their minds to developing new digital health solutions that fully address the wide range of exposures created by this emerging sector. Additional risk identification work will need to be conducted by the insurance market to understand the complexities and implications of digital health companies' liability and regulatory exposures before they can consider developing innovative blended solutions that meet this need.

In the interim, digital health companies must consider the placement of multiple policies with different insurers to address their risks, creating potential gaps in cover and uncertainty in respect of claims handling.



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Conclusion

The pandemic has propelled digital health onto the global stage, as healthcare providers around the world seek to leverage technology to help combat the crisis.

This, in combination, with worldwide trends towards the digitization of medicine, has resulted in rapid technological adoption and accelerating digital health transformations.

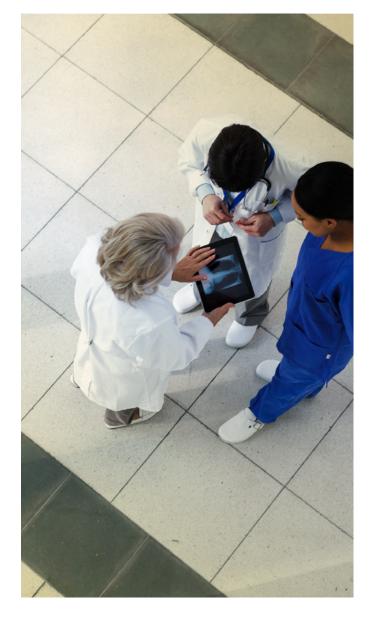
This digital health (r)evolution will profoundly and permanently reshape how healthcare is accessed and provided; a metamorphosis that is likely to produce novel and unexpected risks (and consequent liability).

We have already seen evidence that the convergence of technology and healthcare can produce both economic and bodily harms.

These injuries are often covered within a variety of different insurance products; yet it is increasingly clear that these traditionally siloed approaches to insurance coverage may be inadequate for digital health risks and exposures.

It is imperative that the insurance market consider how to weave together these products to provide integrated solutions that more seamlessly address emerging digital health perils.

In our continuing Digital Health Series, we will explore the insurance and liability considerations within a variety of emerging digital health domains, such as mHealth, artificial intelligence and 3D printing.



Notes

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