THE WINSTON CHURCHILL MEMORIAL TRUST OF AUSTRALIA

Report by
ANGELA RYAN 2017 Churchill Fellow

To investigate methods to reduce patient harm through national digital health safety governance

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Date
“Success is not final, failure is not fatal: it is the courage to continue that counts”.
Winston Churchill

“In complex systems things happen every day that have never happened before”
Professor Jeffrey Braithwaite, October 17, 2018, ‘Refashioning the Quality Agenda Over the Next Decade’
Health Quality Transformation 2018, Toronto, Canada
DEDICATION
I dedicate this report to my parents Colleen and Vincent for their unwavering belief in me, now and always.

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Contents

THE WINSTON CHURCHILL MEMORIAL TRUST OF AUSTRALIA........................................................................ 1
EXECUTIVE SUMMARY ........................................................................................................................ 5
OVERALL FINDINGS AND PRINCIPLES ............................................................................................. 8
RECOMMENDATIONS............................................................................................................................ 13
BACKGROUND ....................................................................................................................................... 15
INTRODUCTION AND CONTEXT ........................................................................................................... 16
COUNTRY PROFILE: AUSTRALIA ............................................................................................................. 20
DISCUSSION .......................................................................................................................................... 22
COUNTRY HIGHLIGHTS: ENGLAND ....................................................................................................... 26
COUNTRY HIGHLIGHTS: CANADA .......................................................................................................... 29
COUNTRY HIGHLIGHTS: UNITED STATES ............................................................................................ 34
GLOSSARY OF TERMS AND DEFINITIONS ............................................................................................ 47
APPENDIX A ............................................................................................................................................ 51
ITINERARY ................................................................................................................................................ 52
REFERENCES .......................................................................................................................................... 59
Executive Summary

Digital health technologies play a mission critical role in the care delivery lifecycle; in our hospitals, and across our health services. Australia’s ‘National Digital Health Strategy: Safe, seamless and secure: evolving health and care to meet the needs of modern Australia’ notes that “Digital information is the bedrock of high quality healthcare. The benefits for patients are significant and compelling: hospital admissions avoided, fewer adverse drug events, reduced duplication of tests, better coordination of care for people with chronic and complex conditions, and better-informed treatment decisions. Digital health can help save and improve lives.”

Many components of digital health have significantly improved the quality of health care and reduced medical and other errors and there is no question that continuing to use paper records can place patients at unnecessary risk for harm and substantially constrain our ability to reform health care.

In Australia the Commonwealth, and all states and territories, have prioritised digital health as key to improving service delivery and health outcomes, as have many healthcare providers. Entrepreneurs and developers across the country are investing in new tools and ways to use data as well as innovative ways to provide health services. This work in partnership, and coalescence of effort, is contributing to the evidence base to support the role of digital technologies in modern clinical practice in Australia.

These technologies do provide safer care for patients – in fact, such systems are central to improving the safety and quality of health services, but evidence shows that poorly designed and operated systems can harm patients and even lead to death. The scale of the problem has grown as digital health has become more ubiquitous; and while researchers now have a much better understanding of the types of issues occurring, there remains limited data on the frequency of occurrence and severity, and it is not yet possible to quantify the rate of digital health safety events with any precision using existing reporting infrastructure. Hundreds of patients can be impacted when IT in a hospital fails. Research has shown that better coordination of digital health safety governance can improve patient safety and prevent patient harm.

In 2018, I travelled to England, Canada and the United States of America (USA) to interview clinicians, researchers, policy makers and industry stakeholders with expertise in digital health and patient safety, to understand lessons learned associated with the design, development, deployment and surveillance of digital tools and technologies. I conducted interviews utilising a pre-prepared set of questions informed by my knowledge of the sector and a set of outcomes I intended to realise through this process. These are attached at Appendix A. I also attended meetings and conference sessions relative to this topic. The set of outcomes was informed by an article authored by Professor Enrico Coiera and colleagues which prescribed underlying principles for national digital health safety governance. These are outlined in Box 1 below. Utilising these principles, I intended to ascertain if they reflected current best practice in the environments I was examining, and, based on these findings, how they could be implemented in practice in Australia.

I will note here that Professor Enrico Coiera (article author and Director, Centre for Health Informatics, Director NHMRC Centre for Research Excellence in Digital Health at the Australian Institute of Health Innovation) is my Churchill Fellowship project sponsor, with support from Associate Professor Farah Magrabi (Associate Professor & Leader - Patient Safety Informatics, Centre for Health Informatics, Australian Institute of Health Innovation). Mr Tim Kelsey (CEO, Australian Digital Health Agency) is my professional sponsor.
While in 2019 there remains no framework in Australia as prescribed by Coiera and colleagues governing digital health ‘end-to-end’, there are a number of national organisations that articulate standards and guidelines for the safe use of digital health. These are the Australian Commission for Safety and Quality in Health Care13 (the Commission) and the Australian Digital Health Agency (the Agency). The Agency’s rule is explicit in regard to ensuring “clinical safety in the delivery of the national digital health work program14” and I will elaborate on this in the ‘Introduction and Context’. Similarly, the Commission’s work plan is explicit in regard to its focus on digital health programs, and again, this will be elaborated in the ‘Introduction and Context’. The Therapeutic Goods Administration (TGA) does not regulate electronic medical records (EMRs) or electronic health records (EHRs), although is contemplating regulation for Software as a Medical Device (SaMD), which does not explicitly include the above15.

There are not yet standards or governance processes that specifically deal with Artificial Intelligence (AI), although this was contemplated in a recent submission to the Medical Research Future Fund (MRFF) by the ‘Australian Alliance for Artificial Intelligence in Healthcare’ (AAAiH), led by Professor Coiera. One of the key components of the AAAiH Research Plan submitted by the Alliance, is the establishment of the ‘Safety, Quality and Ethics Program’ which highlights that “Digital technologies must not only be safe in the hands of users, they must adhere to robust ethical principles. Developing the appropriate frameworks for safety and ethical governance and regulation of healthcare AI is the focus of this program, and our Stage One activities will ensure our full proposal will lead to Australia leading internationally in this area16”. Further to this, the Australian Coalition party who was recently returned to government at the May 2019 election has provided unanimous support toward the development of a “...comprehensive strategy to prepare for the adoption of AI in healthcare17”, according to the Royal Australian and New Zealand College of Radiologists website, which lists election commitments18. This is timely given the recent technological advances in the field of AI – particularly in radiology, and the likelihood of rapid dissemination of this technology and implications for patient safety19.

This is not to say that patient safety relative to digital health is not a priority for Australia; rather that the governance is dispersed and managed at the state or territory level through government, or locally at the primary care or health district level. These organisations have worked to establish rigorous digital health safety governance within and across their organisations. However, without better coordination and integration of efforts and learnings from a whole-of-system perspective, there can be no collective learning of past errors or sustainable improvements in patient safety outcomes, from ‘bits to bedside’.

Australia is in a unique position. Most of Australia’s hospitals and health services have deployed, or are in the process of deploying, digital tools and technologies to support the delivery of health care. For the first time in our nation’s history we have federal, state and territory policy alignment supporting the expansion of digital health for all Australians. We can use this timing now to enshrine the future safety for all of us; not just for health and care providers, not just for industry and government, but for all of us as consumers. We can play a greater role in actively reducing patient harm.

In concert with the National Digital Health Strategy we have the opportunity to save many more lives, save money, and underpin the critical need for health system modernisation. We can leverage global learnings to augment the already sophisticated quality and safety environment to step up and out to develop a world-first nationally coordinated approach that is focused on digital health and patient safety. My report outlines why this is needed and how we as a nation can develop and support this timely approach.
## Box 1: Principles for national e-health clinical safety governance

1. **E-health clinical safety governance must be national but independent of government or industry, to avoid conflicting interests that may lead to resisting change for commercial, professional or political reasons. It must be expert-based rather than organisationally representative.**

2. **Safety is an emergent property of a whole system. Certification of individual components does not guarantee that the whole system is safe.**

3. **E-health clinical safety governance should integrate with mainstream patient-safety processes. Harms arise from sequences of events involving both technical and non-technical elements.**

4. **Governance must assure all components are safe, both alone and in combination with pre-existing elements. Standards and regulatory processes such as accreditation should underpin this, with full legislative backing.**

5. **The safety of the whole system must be monitored in routine use to detect potential risks and actual harm events, as well as clusters. Open disclosure should be paramount.**

6. **Governance must build defences against harm, including safety processes, system redundancies and training, to minimise unsafe use or the creation of unsafe settings.**

7. **Any governance body must have a capability to investigate, analyse and act upon significant risks in the system.**
Overall Findings and Principles

These findings are informed by the clinicians, researchers, policy makers and industry stakeholders I interviewed during the course of my Churchill Fellowship. They are intended to be high-level to set the context for further discussion in the body of the report. The reader will also determine that the findings and principles are interrelated and coalesce.

It is evident that Coiera et al’s principles are still relevant, and many of those I interviewed internationally – particularly clinicians, felt that better coordination of digital health safety governance was needed, from bits-to-bedside’, to ensure patient safety. This was in the context of increasing use, not just in hospitals, but across health services.

For noting, my itinerary was such that more than sixty per cent of my time was spent in the US, and this is evidenced in my findings and recommendations. That being said, I have incorporated the learnings of all of the countries I travelled to, to derive my recommendations for Australia.

1. Safety is everybody’s business

The development and promotion of a safety culture in every organisation is critical. It should not need to be highlighted but patient and consumer safety should be at the centre of every health care organisation’s vision, not just for the community it serves but for its people as well. The development, and active and ongoing promotion of a safety culture allows organisations to consider risks through this lens and ensure that the patient and consumer is firmly at the centre of key decisions that are taken. It also ensures that whatever digital health solutions are proposed, that the risks for patients and consumers can be actively minimised. There were numerous examples provided by interviewees that highlighted that the “active and ongoing” nature of a safety culture is as important as the development itself.

This culture must include the collection and analysis of data which is presented back to the organisation to highlight risks and actual issues, which in turn promulgates a learning healthcare system. This requires organisational leadership, where senior leaders model the safety culture and “walk the talk”. For instance, the Canadian Patient Safety Institute has developed a Framework for Establishing a Patient Safety Culture, which among other components contains a ‘bundle’ for CEOs and Senior Leaders, which is based on a set of evidence-based practices that must all be applied in order to deliver good care.

Safety is a system, not a program, project or department.

2. Safety should be a shared responsibility

Safer implementation and use of health IT is a complex, dynamic process that requires a shared responsibility across all of the actors engaged across the health system. This was highlighted by an Institute of Medicine report on digital health and patient safety in 2012, which posited that building digital health for safer use is a shared responsibility between key stakeholders which must involve health care organisations, clinicians, consumers, IT departments, public and private agencies and vendors.

This is not a new concept, but in many countries, it has not gained traction due to the competing priorities of each of these stakeholders. The risk in what effectively becomes ‘safety in siloes’ is a lack of accountability, with liability shifted downstream to users. Accountability and responsibility that is shared among each of these stakeholders can reduce the impact to users, and importantly
create an environment where risks and issues are collectively addressed and solutions collectively derived, as opposed to attributing these risks and issues to each other.

Earlier this year, the internationally renowned patient safety and human factors expert and advocate Rollin J (Terry) Fairbanks tweeted “It was 1973 when #aviation implemented safe, protected reporting. 1973. Look at them now”⁴⁰. Aviation remains the best example when considering the concept of shared responsibility relative to safety – despite recent safety failures associated with the Boeing 737 Max 8 aircraft. ⁴¹ This is not to say that the health care system should be compared with aviation – the environments, drivers and complexities are completely different. It is what we can learn from it. What it demonstrates is what can be achieved when different interests are brought together for a common goal. Pilots, aircraft manufacturers and government regulators have worked together and established safety standards, reporting, investigation and dissemination of findings. ⁴² This has included the recognition of human factors as a causal effect in concert with the product design, the procedures, the training and the environment, the end result of which is a building of trust between the stakeholders and a system that in most cases can be relied upon. ⁴³

3. **We need to learn, and keep learning or “Those who do not remember the past are condemned to repeat it.”**

The development and active promotion of a learning healthcare system (LHS) is paramount. An LHS occurs when “science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience.” ⁴⁴ This is achieved through the development of a framework that supports data, research and evidence and its application and reuse across the sector to drive improvements in digital health safety. It requires collaboration and cooperation among all health care stakeholders to ensure a shared commitment to transparency, and there are initiatives already underway in Canada – through the Canadian Institutes for Health Research, the USA, through the Agency for Healthcare Research & Quality and the UK, through the Learning Healthcare Project. ⁴⁵ While many organisations in Australia contribute to the principles of a learning healthcare system, it’s still largely a theoretical construct and there are fundamental building blocks that need to be put in place to enable it. ⁴⁶ It is also not yet the explicit mandate of any national body.

4. **Take digital health safety governance ‘mainstream’**

Digital health is increasingly becoming mainstream in the delivery of health care. It can no longer be isolated as an ‘add-on’ or simply a ‘tool’; recognising this, attributes its import as fundamental in how health care is delivered. Most modern health care systems are built on digital health technologies, that is, it is becoming the norm. This is especially the case in the USA, where 2017 statistics demonstrated that nearly all reported hospitals (96%) possessed a “certified EHR technology”, of which 84% had adopted at least a ‘Basic EMR’ system; this represents a “9-fold increase” since 2008, following a $36 billion investment by government as part of the American Recovery and Reinvestment Act of 2009 (ARRA). ⁴⁷ While the scale of this EMR adoption is isolated to the USA, there is also rapid growth in the UK and Canada. In Australia, the My Health Record system, the nation’s EHR, has recently registered more than 22 million people – equivalent to 90.1 per cent of the population, following the conclusion of the National My Health Record Expansion Program.

Health is a complex-adaptive system comprising technology, processes and importantly people – governance should not stand alone, especially where errors are concerned. Digital health safety processes should be integrated with mainstream patient safety processes.
5. Use existing instruments more efficiently

Regulation, funding, and policy levers must be used efficiently in concert. There is no one solution to eradicate digital health-related harm (e-iatrogenesis); in fact, it is entirely reasonable to argue that e-iatrogenesis will not be eradicated fully, as with other patient harms associated with health care. That said, there are a range of instruments already in place to support effective safety governance in digital health, and they could be used more efficiently *in concert*, as a mechanism to close the gap from ‘bits to bedside’. In Australia, like the countries I visited, the diaspora of regulation, certification, and accreditation relative to digital health contributes to the inefficiency of the system *as a whole* to respond to e-iatrogenesis concerns and events. This is exacerbated through the dissipation of policies and funding models across jurisdictions, and the inability for these instruments to be applied consistently. While they can work efficiently inside jurisdictions, there would be greater efficiencies realised through national alignment.

6. Adopt digital health patient safety measures now

Digital health patient safety measures should be agreed nationally and implemented. This was a topic of frequent discussion and is further highlighted in the literature. Earlier studies have suggested that quantification of digital health-related patient safety events is challenged by the small number of reports within very large databases not specific to digital health\(^4\). The National Quality Forum in the USA has identified and prioritised a set of measures\(^4\). The UK recently concluded a consultation to develop a National Patient Safety Strategy for the NHS, which was published in July 2019 and includes the identification of digital health-specific patient safety measures\(^4\). The Australian Commission on Safety and Quality in Health Care has led important work in this area in concert with researchers, although Australia has yet to see an agreed national dataset and an associated implementation pathway.

Further, data fragmentation across hospitals, primary care, and health services is a major inhibitor to the adequate detection, reporting, and remediation of e-iatrogenesis concerns and events. Currently, codified data collection occurs in most of these systems, but the lack of universal identifiers or a mechanism to link them means that the datasets exist largely in isolation. This fragmentation persists beyond hospitals, primary care, and health services, where incident reporting data, which is collected in every jurisdiction, is not aggregated and shared nationally. Health researchers, who play an important role in the production and expansion of the evidence-base, often find themselves having to compile datasets from scratch, or painstakingly glue together a multiplicity of datasets, due to the paucity of large-scale linked datasets, combined with the administrative, legal, and regulatory constraints and restrictions that exist across hospital and health service boundaries. We are, in effect “flying partially or completely blind”\(^4\).

7. Openness and transparency is good for everyone

As with the enablement of a safety culture, the enablement of a culture of transparency shouldn’t need to be emphasised as a mechanism to better support digital health safety. Yet, here we are. If we don’t know what is wrong, how can we fix it? In my discussions with interviewees, I heard that researchers and clinicians are advocating for the relaxation of contractual clauses that prevent health care organisations from sharing specific information contained in EMRs and EHRs – such as screenshots, to aid usability improvements\(^4\). Medical device companies have long been required to share useability and safety issues, but the agreements in place between many organisations and their vendors still perpetuate these “gag clauses”, and this is a very real issue in the USA. This is despite legislation already being in place to effectively prevent the prohibition of this information.
It should also include the support and promulgation of an organisational culture that promotes incident reporting and avoids blame, accompanied by a feedback mechanism that promotes improvement. We must work together to enable and support all health care stakeholders to be transparent. In so doing we acknowledge that the health care system is complex and adaptive, and that errors rarely occur in isolation, or that one individual is responsible. We know what ‘open disclosure’ has done for patients and their families, and for clinicians and administrators, following adverse incidents\textsuperscript{47}. The same principles apply.

8. Support the health care workforce

The commitment to a digitally-capable health workforce should be a high priority for all of us. Much has been written on this topic with landmark reports and strategies highlighting the criticality – think Wachter\textsuperscript{48}, Australia’s National Digital Health Strategy\textsuperscript{49} and more recently Topol\textsuperscript{50}.

A workforce that is appropriately schooled in the nuances of the digital environment enters the workplace with a degree of digital literacy, understanding the component pieces: legal and regulatory requirements, data governance, data quality, etc., and the nexus with patient safety. The UK has committed substantial funding through the National Health Service (NHS) to support the digital health workforce and I heard first-hand how this is being achieved. Similarly, the ONC injected $118M into educating the health workforce in the USA, with aspects of the Program continuing beyond the end of the period of grant funding. Nevertheless, all countries face shortages in suitably qualified digital health professionals – this was evident almost everywhere I went.

9. Are we there yet? Health as a complex-adaptive system

"In complex systems things happen every day that have never happened before" Professor Jeffrey Braithwaite, October 17, 2018, ‘Refashioning the Quality Agenda Over the Next Decade’ Health Quality Transformation 2018, Toronto, Canada\textsuperscript{51}.

The health care system is unpredictable, non-linear and dynamic, comprising networks of component parts (e.g. patients, families, carers, hospitals, health services and residential aged care facilities, alongside governments and the private sector). This is in contrast to mechanical systems that interact in a linear way to produce predictable outputs\textsuperscript{52}. There is no system more complex, nor with the equivalent range and breadth. "Patient presentation is uncertain, and many clinical processes need to be individualised to each patient. Healthcare has numerous stakeholders, with different roles and interests, and uneven regulations that tightly control some matters and barely touch others\textsuperscript{53}. Despite the widespread variation in the delivery of health care across international jurisdictions, as compared with Australia, this is true of all health systems and was acutely evident in conversations with interviewees. While health care professionals are cognisant of the challenges that a complex adaptive system poses on the safety of its patients, there needs to be greater recognition of this beyond the boundaries of our hospitals, primary care and health services. “If it was easy, everyone would be doing it\textsuperscript{54}.”
Principles for national e-health clinical safety governance

- E-health clinical safety governance must be national but independent of government or industry, to avoid conflicting interests that may lead to resisting change for commercial, professional or political reasons. It must be expert-based rather than organisationally representative.
- Safety is an emergent property of a whole system. Certification of individual components does not guarantee that the whole system is safe.
- E-health clinical safety governance should integrate with mainstream patient-safety processes. Harms arise from sequences of events involving both technical and non-technical elements.
- Governance must assure all components are safe, both alone and in combination with pre-existing elements. Standards and regulatory processes such as accreditation should underpin this, with full legislative backing.
- The safety of the whole system must be monitored in routine use to detect potential risks and actual harm events, as well as clusters. Open disclosure should be paramount.
- Governance must build defences against harm, including safety processes, system redundancies and training, to minimise unsafe use or the creation of unsafe settings.
- Any governance body must have a capability to investigate, analyse and act upon significant risks in the system.
Recommendations

In making these recommendations I draw on the opportunities presented through the overall findings and principles articulated above, which dovetail with the principles as originally defined by Coiera and colleagues. I also draw on the premise of the ‘Health Information Technology (HIT) Safety Center’ (the Centre) model developed in the USA. I do this in part as it is the only fully elaborated model supported by an extensive evidence base, the structure of which is informed by learnings beyond the USA borders56.

The Centre was originally recommended by the Institute of Medicine (IOM) Report Health IT and Patient Safety: Building Safer Systems for Better Care57 in 2012, with a subsequent commitment by the Obama administration to establish the roadmap to develop the Centre, and it was further endorsed through the USA Food and Drug Administration Safety and Innovation Act (FDASIA) of 201558.

While the Centre has not been implemented as it was originally envisioned, many of its proposed members are active in the ‘Partnership for Health IT Safety’, a multi-stakeholder collaborative of more than fifty organisations that come together to analyse safety events and hazards, identify, and share solutions and safe practices, and inform policymakers and the broader healthcare community about priorities for health IT safety59.

1. Australia should assemble a taskforce of experts from across the health sector, to include clinicians, consumers, government, researchers, policy makers and industry to develop the vision, mission, outcomes and roadmap for better coordinated digital health patient safety in Australia. The taskforce’s expressed purpose is to ensure digital health is safer for patients and will build upon the significant progress already made in Australia, and internationally.

2. The taskforce’s objectives should include:
   a. Assembly: provide an opportunity for experts across the digital health spectrum to work together in a trusted environment, unconstrained by the competing interests of individual stakeholders.
   b. Cooperation: provide an opportunity for experts to share existing knowledge, evidence and resources and collectively contribute to actions and outcomes; and
   c. Collaboration: provide an opportunity for experts to work together to detect, report, remediate and disseminate information and solutions.

3. The work of the taskforce should not replace existing patient safety activities, such as those that exist within the States & Territories, or within hospitals and health services; rather, focus on how digital health safety governance could be better coordinated across the nation.

4. The taskforce should examine the depth and breadth of policy, funding and regulatory levers that apply to all hospitals, primary care and health services, to identify gaps and determine solutions. This would include an environmental scan on what currently exists to better inform the solutions.

5. The taskforce should examine the requirements for national reporting of digital health-related patient safety events, to include an agreed set of metrics, along with the supporting infrastructure required to build it.
6. The taskforce should be ‘housed’ within an existing national organisation, such as the Commission or the Agency, to expedite the establishment of its operations. Importantly however, it should function independently of the host organisation, and at arm’s length of government or industry to avoid conflicting interests.

7. The taskforce could integrate with the Australian Alliance for Artificial Intelligence in Healthcare\textsuperscript{60} (AAAiH), led by Professor Coiera, given that one of the key components of the AAAiH is the establishment of the ‘Safety, Quality and Ethics Program’, which will contemplate the development of appropriate frameworks for safety and ethical governance and regulation of healthcare AI.
Background

I am a Registered Nurse and Fellow of the Australasian College of Health Informatics (ACHI), and currently serve as the College’s President. I work for the Australian Digital Health Agency (the Agency) as the Chief Clinical Information Officer (CCIO) & General Manager, Workforce & Education, and have more than 30 years’ experience in hospitals and public-sector organisations. I have worked within local, state and federal jurisdictions to further policy, implementation and research regarding digital health.

Australia has a long and distinguished history of innovation: we are ranked 19 out of 128 countries in the 2016 Global Innovation index, have produced 15 Nobel Prize winners, and rank 8 out of 140 economies for the quality of our science and research institutions\(^{61}\).


We’re also making great strides in the digital health space. More than 90% of our General Practitioners use electronic records to manage our care\(^{62}\) and our hospitals and health services are equally invested\(^{63}\). As of February 2019, more than 22 million Australians – equivalent to 90.1 per cent of the population\(^{64}\) have a My Health Record, following the conclusion of the National My Health Record Expansion Program. In concert with this proliferation, an opportunity exists to develop a framework that could articulate ‘end-to-end’ digital health safety governance; it was this ‘opportunity’ to explore what could be, that became the catalyst for my Churchill Fellowship pursuit.

For the purposes of this report, digital health includes a broad range of products, including electronic health records (EHRs), electronic medical records (EMRs) patient engagement tools (e.g. personal health records and apps), clinical decision support tools and data storage; excluded is software for medical devices (e.g. software in an implantable cardioverter-defibrillator) and medical devices.
Introduction and Context

“Health IT is not one specific product that, once implemented, can automatically result in highly safe and effective health care. It encompasses a technical system of computers, software, and devices that operate in the context of a larger sociotechnical system—a collection of hardware and software working in concert within an organization that includes people, processes, and workflow. It is widely believed that, when designed and used appropriately, health IT can help create an ecosystem of safer care while also producing a variety of benefits such as reductions in administrative costs, improved clinical performance, and better communication between patients and caregivers. In this view, it can be a positive, transformative force for delivering health care65”.

In 2012, Coiera and colleagues stated somewhat prophetically that “(o)ver the next 10 years, more information and communication technology (ICT) will be deployed in the health system than in its entire previous history66”. No doubt the authors were reflecting on the scale of the investment in the USA through the ‘Health Information Technology for Economic and Clinical Health’ (HITECH) Act but were also offering the likely reality. In Q3 2018, StartUp Health’s ‘Insights Global Digital Health Funding Report’ reported that “…Q3 closed with a total of $4.5B in digital health funding, pushing the market well into double digit billions – $11.1B YTD”, and that “...this quarter was the largest Q3 and overall quarter since we began tracking funding in 201067”. See the below ‘Funding Snapshot’:

While most of us won’t experience serious harm as patients, many of us will experience an adverse event – and in most cases, won’t even be aware of it. Sadly though, there are those that do experience significant harm and even death and while those numbers are small, digital health tools and technologies exist to improve the status quo, not worsen it.

There is this: A Sydney father-of-two who went into hospital for a routine knee reconstruction died after being given high doses of opioids meant for another patient, when his anaesthetist inadvertently prescribed the opioids into his electronic record. “The doctor had to override 22 electronic alerts to enter the high-risk drugs into the [deceased’s chart] but did not notice his mistake68”. This: In NSW, a hospital’s IT system has been blamed after doctors failed to administer prophylactic anticoagulation to a burns patient who later died of pulmonary emboli. A

https://www.slideshare.net/StartUpHealth/startup-health-insights-global-digital-health-funding-report-q3-2018

Across the world, there has been exponential growth in the digital health sector, the premise of this investment being improved health outcomes for patients, in addition to improvements in the safety and quality of care. The evidence is still growing^, but there are many good examples of where digital health has demonstrated these outcomes^^. What is needed is a reimagining of the governance in place, with a focus on collective and collaborative national leadership to prevent further harm.

^ https://jamanetwork.com/journals/jama/article-abstract/2724003
^^ https://academic.oup.com/jamia/article/22/4/784/745784
The coroner has heard that the display of the Electronic Medical Management software was too wide for a computer’s monitor display\textsuperscript{49}. This: a 58-year-old patient with Hodgkin’s Lymphoma was found dead in his hotel bed four days after a scan at a Melbourne hospital showed signs of “potentially fatal lung toxicity linked to the [deceased’s] treatment but the results were faxed to the wrong number\textsuperscript{70}”. And this: “A baby was born with brain damage in a Queensland hospital after critical patient data was entered into different sections of the mother’s electronic medical record, meaning obstetricians were ‘unlikely’ to have seen a key test result\textsuperscript{71}.”

Importantly what these cases highlight is the ‘complex adaptive’ nature of health care. As described earlier, the health care system is unpredictable, non-linear and dynamic, comprising networks of component parts (e.g. patients, families, carers, hospitals, health services and residential aged care facilities, alongside governments and the private sector). In the first case, the Counsel assisting the inquest noted that “…there were 15 missed opportunities for medical practitioners to spot the fatal error and save [the deceased’s] life\textsuperscript{72}”. This is true of the other cases, and many more, where the lack of ‘bits to bedside’ governance is not in place. We should be working to better coordinate this governance to reduce patient risk and harm.

While there is not yet a nationally-agreed governance framework that governs digital health in Australia from ‘bits-to-bedside’, there are a number of national organisations that articulate standards and guidelines for the safe use of digital health. These are the Australian Commission for Safety and Quality in Health Care (the Commission) and the Australian Digital Health Agency (the Agency). The Agency’s rule is explicit in regard to ensuring “clinical safety in the delivery of the national digital health work program\textsuperscript{73}” and similarly, the Commission’s work plan is explicit in regard to its focus on digital health programs\textsuperscript{74}.

The Therapeutic Goods Administration (TGA), which is responsible for the regulation of therapeutic goods including prescription medicines and medical devices, does not regulate electronic medical records (EMRs) or electronic health records (EHRs), but is contemplating regulation for Software as a Medical Device (SaMD), which does not explicitly include EMRs or EHRs\textsuperscript{75}. SaMD refers to software that is intended to run on general purpose computing platforms and is also a medical device. Platforms could include computers, tablets, phones, web browsers, e.g. Image processing for diagnosis or pathology, software that collects information and makes a clinical decision or referral, and apps that calculate drug dose\textsuperscript{76}. It is proposed that new rules to appropriately classify SaMD products are done so according to the potential harm they could cause; this is modelled on the European classification system.

The Commission defines clinical governance as “the set of relationships and responsibilities established by a health service organisation to deliver safe and high-quality health care. It ensures that the community and health service organisations can be confident that systems are in place to deliver safe and high-quality health care, and continuously improve services\textsuperscript{77}.”

In Australia, clinical governance is monitored through the National Safety and Quality Health Service (NSQHS) Standards, which were developed by the Commission in concert with the Australian Government, state and territory partners, consumers and the private sector. The Commission was established in 2006 by the Australian, state and territory governments to “lead and coordinate national improvements in safety and quality in health care\textsuperscript{78}”. Strategic priorities are focused on:

- patient safety;
- partnering with patients, consumers and communities;
- quality cost and value; and
- supporting health professionals to provide safe and high-quality care.
“The primary aim of the NSQHS Standards is to protect the public from harm and improve the quality of health care. They describe the level of care that should be provided by health service organisations and the systems that are needed to deliver such care.”

In 2017, the Commission released the ‘National Model Clinical Governance Framework 2017’, to be used in concert with the NSQHS Standards. While there is no explicit reference to digital health (or recognised synonyms such as ‘eHealth’ or ‘Health IT’), the Framework does reference ‘Healthcare Records’, which is the first-time electronic health records and their use in practice have been contemplated in the standards. These include the requirement to enable optimised access to the ‘My Health Record’ system – Australia’s national electronic health record system, along with articulated processes, the use of national identifiers and terminologies, and data quality. This is an important step, with subsequent editions likely to articulate digital health in more detail.

The Agency appointed the Commission to undertake a clinical safety program for the My Health Record system and national digital health infrastructure and the Commission publishes the ‘Clinical Safety Reviews’ on its website. Other Commission digital health programs of focus are the:

- My Health Record in Emergency Departments Project;
- Certification framework for digital mental health services;
- Electronic medication management (EMM) systems in hospitals – A Guide to Safe Implementation (3rd edition);
- Electronic discharge summary (EDS) systems;
- National guidelines for on-screen display of medicines information; and
- Safety Issues at Transitions of Care: Consultation report on pain points relating to clinical systems.

In 2018, as part of its combined 2017/20 workplan, the Commission appointed the University of Sydney to develop a literature review to analyse evidence on the types of digital health interventions which have been shown to improve health care, with a focus on the safety and quality impact of five digital health interventions. The Review notes that it is “...intended to assist governments and healthcare organisations to identify elements of digitisation in health care that best improve the safety and quality of patient care. It will also help healthcare organisations to monitor their digital progress against best-practice targets, and to increase the value they derive from their digital activities.” This follows a 2017 Commission literature review and environmental scan on approaches to the review and investigation of health IT-related patient safety incidents. The review noted that “numerous methodologies exist and that no single method was appropriate to detect, investigate and classify all HIT incidents” however “(s)uccessful HIT safety systems need to have in place a multidisciplinary team with appropriate skill sets from a clinical, health informatics and system safety perspectives and use a tailored approach to investigate HIT patient safety incidents.”

The Agency published its ‘Clinical Governance Framework’ (the Framework) in February 2018. While the Agency does not provide clinical care to the Australian community nor is it a regulator of digital health, it does have a legislated responsibility to ensure the safety and quality development of the products, services and infrastructure it manages. The Public Governance Performance and Accountability Rule (PGPA Rule) under which the Agency was established, specifically acknowledges that a core function of the Agency is to “(d)evelop, implement and operate comprehensive and effective clinical governance, using a whole of system approach, to ensure clinical safety in the delivery of the national digital health work program.” The Agency has adopted a Framework for the organisation which focuses on the end-user experience, effectively manages risk, promotes a shared responsibility for safe and high-quality care, and enables continuous
improvement. A key element supporting continuous improvement outlined within the Framework are the requirements around quality performance and evaluation, including external assurance.

Sharing the right health information at the right time is critical to high quality, sustainable health and care. Australia’s National Digital Health Strategy – *Safe, seamless and secure: evolving health and care to meet the needs of modern Australia* – highlights the importance of connected health services and calls for the definition of standards to support interoperability that will support clinicians, patients and citizens make the best health and care decisions. This in turn, will lead to substantial improvements in patient safety. Later this calendar year the Agency will publish the Interoperability Roadmap, the culmination of a lengthy consultation with industry, consumers, clinicians, governments and jurisdictions, to define a shared vision and a set of agreed standards to improve workflow, accessibility and outcomes within the healthcare sector. This will be a further opportunity to enshrine digital health patient safety within a set of nationally agreed standards.

The countries I travelled to were selected for the purpose of learning more about the challenges inherent in establishing better coordinated digital health safety governance. What I learned was that all demonstrated varying degrees of maturity relative to a national approach. It was often the expressed desire of many of the individuals I spoke with, however all highlighted a number of barriers present which have prevented this outcome from being realised in practice. Within these countries, there are some excellent examples of digital health safety governance in place, although none exist at the national level. The best template for a nationally-coordinated approach comes from the USA, and I drew on its vision, mission and outcomes in defining my recommendations. As noted previously, while this approach has not been implemented as it was originally envisioned, many of its proposed members are active in the ‘Partnership for Health IT Safety’, a multi-stakeholder collaborative of more than fifty organisations that come together to analyse safety events and hazards, identify, and share solutions and safe practices, and inform policymakers and the broader healthcare community about priorities for health IT safety.

The opportunity for Australia is to bring this ‘Partnership’ – or taskforce, into existence.
The Australian Healthcare System (Brief)

Three levels of government are collectively responsible for providing universal health care: federal; state and territory; and local. The federal government mainly provides funding and indirect support to the states and health professions, subsidising primary care providers through the Medicare Benefits Scheme (MBS) and the Pharmaceutical Benefits Scheme (PBS) and providing funds for state services. It has only a limited role in direct service delivery.

States have the majority of responsibility for public hospitals, ambulance services, public dental care, community health services, and mental health care. They contribute their own funding in addition to that provided by federal government. Local governments play a role in the delivery of community health and preventative health programs, such as immunisation and the regulation of food standards.

https://international.commonwealthfund.org/countries/australia/

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**Organization of the Health System in Australia**

[Diagram showing the organization of the health system in Australia]

All health systems are complex, and digital health tools and technologies can unpack the ‘wicked’ nature of the problems that drive this complexity. Australia’s health system remains complex, particularly in the context of ‘connected care’, and the 2016 Capital Markets Cooperative Research Centre (CMCRC) Report: ‘Flying Blind’ – Australian Consumers and Digital Health Australian Health Data Series (Volume 1) outlines what these fragmentations arise from:

- Private and public health services;
- Different levels of (non-integrated) primary, secondary, in-hospital, ancillary and allied healthcare;
- Multiple sources of funding and payment from public and private sources and consumers themselves;
- Multiple legislative and contractual frameworks across the jurisdictions and funding/payer environments;
- Numerous policy, administrative and compliance bodies and agencies operating at state, territory and Commonwealth government levels; and
- Multiple reporting regimes and data collection requirements.

The complexity is expertly demonstrated in the below Figure, highlighting the barriers to data sharing.

Figure 1: The Australian healthcare environment

One of the tenets of the 2016 business case to support the transition to the national ‘opt-out’ model for Australia’s national EHR, the ‘My Health Record’ system, was this fragmentation of data and lack of connectedness. This policy change has since occurred, and now more than ninety percent of Australia’s population has a My Health Record. The evidence-base to support the benefits case for My Health record is expanding, and in the absence of greater connectedness within our health system represents the best mechanism to provide patients and consumers access to a summary of their health information, anywhere, anytime.
Discussion

Prior to the commencement of my trip, I had the honour and privilege of interviewing Australia’s 27th Prime Minister, Julia Gillard. I did so to learn more about how best to implement large scale policy reform, Ms Gillard having been responsible for many of Australia’s important policy reforms in recent years (and who also had – and still has, the highest rate of passing legislation of any Australian Prime Minister – even Hawke\(^{94}\)). Among other things she highlighted the criticality of being able to have “...the right message, for the right audience, at the right time...”, to ensure the best chance of success.

She went further: “In my experience, for any big reform there has to be a backstory of analysis and gathering of evidence, and consulting, and working out what the best change is. Then once you have the right idea and are clear on what the reform is going to be, you need to shepherd your policy proposal through various decision-making levels. In government there’s a series of things you’ve got to do to get the policy proposal through, including cabinet committees and cabinet ultimately, so that it’s the policy of the government. But at that point, the processes that you did of consultation in design, I think come back around and meet you again. You’ve got pre-existing relationships with people, you know whether what you’re proposing meets their agenda or is slightly different to their agenda. When you’re at that stage, another important foundation stone for a big reform is to take the time to explain to people what it is that you’re doing. Often that doesn’t get done very well, but it is vital because everybody’s at risk of getting misconceptions in their head, especially in the modern age where the media cycle is so fast. You can’t rely on the media to do a deep and accurate explanation of the reform. You have to do that yourself.”

This important advice not only emboldened me in my travel preparation but has guided my thinking in how my findings and recommendations could be implemented.
Notwithstanding the differences in health systems in England, Canada and the USA, digital health is a national priority for each of these countries. Like Australia, all have embarked on significant investments in digital health to drive improvements in patient outcomes and the safety and quality of care, accompanied by national strategies and significant reforms.

Following the introduction of the American Recovery and Reinvestment Act (ARRA) of 2009 and the subsequent implementation of the HITECH Act, there has been exponential growth in the adoption of digital health in the healthcare sector. As of 2017, 94 percent of non-federal acute care hospitals and 86 percent of office-based physicians adopted certified health IT95, along with massive adoption of wearable health devices, a huge injection of capital into digital health start-ups, formal Food & Drug Administration (FDA) guidance and support for digital health applications, and the entrance of tech giants like Apple, Amazon, and Facebook96. To support this rise in digital health the Office of the National Coordinator for Health IT (ONC HIT) amassed a task force of nationally recognised experts in digital health to devise a Health IT Safety Center roadmap. This Center “...was broadly envisioned as a public-private entity... committed to a learning health system.... to promote the objectives of using health IT to make care safer and of continuously improving the safety of health IT97”. Despite its ambitions, the Center as it was imagined is yet to be implemented, however serves as a template for other countries looking to implement national digital health safety governance.

The landmark report, ‘Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England – Report of the National Advisory Group on Health Information Technology in England’ was handed down to advise the Department of Health and NHS England on its efforts to digitise the secondary care system98. The set of recommendations reads as a cautionary tale for any country looking to invest in digital health. Coming off the back of the largest investment in digital health in the UK’s history – the National Program for IT (NPfIT), the recommendations take a ‘learning’ approach to how digitisation can move forward. The UK has also seen unprecedented investment in digital health capability for its national health service (the NHS), and facilitated through one of its ‘Arms-Length bodies’, NHS Digital.

NHS Digital is the national information and technology partner for the health and care system99, supporting the development and maintenance of the NHS Spine and other services. The NHS Spine supports the IT infrastructure for health and social care in England and joins together more than 23,000 healthcare IT systems in 20,500 organisations100. In January 2019, it was reported as having reached one billion transactions in a month for the first time with the platform handling at peak 3,500 messages a second101. National services offered through the Spine include the Summary Care Record, the Electronic Prescription Service and the e-Referral Service. The ‘Summary Care Record’, a summary of the GP record information intended for use in emergency or out-of-hours care and introduced in 2008, is largely restricted to clinician-to-clinician sharing of information.

At the time of writing, a new organisation has been created: NHSx102 brings together teams from the Department of Health and Social Care, NHS England and NHS Improvement, with responsibility for technology, digital and data policy housed under the one roof. NHS Digital will continue to exist and work in close concert with NHSx.

The NHS Outcomes Framework (NHS OF) is a set of indicators developed by the Department of Health and Social Care to monitor the health outcomes of adults and children in England. The framework provides an overview of how the NHS is performing. This report provides information about the indicators updated in this release103.

Importantly, the UK is one of the only countries to publish a set of standards supporting health and care organisations, and health IT software manufacturers, to assure the safety of their systems and
software; specifically, the ‘Clinical Risk Management in the Deployment and Use of Health IT Systems (DCB0160)’ standard, and the ‘Clinical Risk Management in the Manufacture of Health IT Systems’ standard (DCB0129). These standards provide a set of requirements that support the effective application of clinical risk management by those health organisations responsible for the development and maintenance of Health IT Systems, and those organisations responsible for the deployment, use, maintenance or decommissioning of Health IT Systems within the health and care environment. NHS England has been offering education and training to clinicians across the UK in safety and risk in health IT since 2005, with patient safety embedded into their risk management and conformance testing processes. Clinicians are accredited through this process by NHS Digital, which then enables them to certify systems as ready for use, prior to go-live.

One other significant reform for the United Kingdom is the introduction of the European Union’s General Data Protection Regulation (GDPR), heralded as “…the most important change in data privacy in twenty years”, according to the GDPR.org website. Changes apply in the following areas: increased territorial scope, penalties and consent, in addition to ‘Article 20’: data portability provisions, which stipulate that a person shall be able to transfer their personal data from one electronic processing system to another, without being prevented from doing so by the data controller. The legislation came into effect on 25th May 2018 and has implications globally given that the GDPR applies to businesses that collect and use personal information from citizens of the EU, regardless of where the business itself is located. This approach to privacy gives the GDPR a global reach.

Canada’s acceleration of digital health systems and solutions is driven in part through the activities of ‘Canada Health Infoway’, a not-for-profit organisation which is federally funded, and governed by the 14 federal, provincial and territorial Deputy Ministers of Health, who are its members. Infoway’s focus has been to invest in foundational elements, including infrastructure, to enable the spread and adoption of digital health systems, and promote the vision of an interoperable and connected health system across Canada. These investments have reaped benefits, with use of EMR systems by primary care physicians growing in 2017 to 85%. Similarly, investments in hospital information systems, pharmacy systems, and other provincial and regional infrastructure have contributed to the growth in the digitisation of the Canadian health care system. Like the UK, patient safety in digital health has benefited from the development of a set of ‘eSafety’ Guidelines, originally developed by COACH (now Digital Health Canada) in 2013. These guidelines were informed by the aforementioned work of the UK, in addition to the 2012 IOM Report, and are supported by a maturity model, which defines a pragmatic approach to embedding digital health safety.

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**Figure 2: Digital Health Canada eSafety Maturity Model**

Level 5: A formal eSMP, policy and processes are in place and documented, and well integrated into enterprise risk management and patient safety policies.

Level 4: A formal eSMP, policy and processes are in place and documented, and may be integrated into enterprise risk management and patient safety policies.

Level 3: A formal eSMP is in place and documented.

Level 2: High-level eSMP in place but lacks management support to enable adoption.

Level 1 | Early recognition of the importance of eSafety, but no formal eSafety Management Program (eSMP) in place.

Level 0: Little to no recognition of the need for addressing eSafety.
Like the USA and the UK, digital health safety governance is not coordinated nationally, with a recent report noting that “...one of the largest challenges is creating and sustaining processes and their buy-in across the broad range of autonomous but interdependent organizations — regional health authorities, hospitals, clinics, private practitioners, community health clinics, pharmacies, and laboratories.” In acknowledging this, the report highlights the importance of “engaging innovative partnerships to leverage connected health information”, where those individuals and organisations with the skills and expertise in digital health are brought together for the collective benefit of all Canadians.

The following sections provide highlights from each country I visited, showcasing aspects of the extraordinary work they are doing. My itinerary was such that more than sixty per cent of my time was spent in the USA, and this has influenced my findings and recommendations. That being said, I have incorporated the learnings of all of the countries I travelled to, to derive an exemplar model for Australia.
Country Highlights: England

The English Healthcare System (Brief)

Responsibility for health legislation and general policy in England rests with Parliament, the Secretary of State for Health, and the Department of Health. Under the Health Act (2006), the Secretary of State has a legal duty to promote a comprehensive health service that provides care free of charge, apart from services with charges already in place. Rights for those eligible for National Health Service (NHS) care are summarized in the NHS Constitution; they include the right to access to care without discrimination and within certain time limits for some categories, such as emergency and planned hospital care. The Department of Health provides stewardship for the overall health system, but day-to-day responsibility for running the NHS rests with a separate public body, NHS England.

NHS England manages the NHS budget, oversees 209 local Clinical Commissioning Groups (CCGs), and ensures that the objectives set out in an annual mandate by the Secretary of State for Health are met, including both efficiency and health goals. Budgets for public health are held by local government authorities, which are required to host “health and well-being boards” to improve coordination of local services and reduce health disparities. [https://international.commonwealthfund.org/countries/england/](https://international.commonwealthfund.org/countries/england/)

Organization of the Health System in England

Leeds

I commenced my Churchill journey in Leeds, England. I chose this as my first destination given NHS Digital is headquartered here. I met with some of the leadership team, including Mr Rob Shaw, Ms Debbie Chin, Professor Martin Severs and Dr Manpreet Pujara.

Mr Shaw, Deputy CEO of NHS Digital, referred to Health Education England’s (HEE) establishment of the ‘Commission on Education and Training for Patient Safety’, whose explicit remit is patient safety education and training across the NHS. HEE works with system partners and providers to embed the recommendations in practice and offers a suite of online tools using real life examples of risk hazard assessment. “Any clinician can register for the online training – there are 8 modules which equate to six hours of CPD.” This is the first program of its kind, at this scale. The NHS has also developed an assessment framework for patient-facing mobile apps, complete with pre-qualification and digital assessment questions to ensure app providers products are evidence-based, particularly in the areas of clinical safety, security and usability. There are currently 71 apps on the site. This has been developed by NHS Digital, in close concert with the National Institute for Health and Care Excellence (NICE) and NHS England, who have recently published the ‘Evidence Standards Framework for Digital Health Technologies’.

I met with the former Chief Nurse of NHS Digital Anne Cooper, who talked about her “big hairy audacious goal” which was to help “Every nurse [become] an e-nurse” by 2020. Ms Cooper worked with the Royal College of Nursing to spearhead this initiative and the first output from this work is a joint publication between Health Education England and the Royal College of Nursing: Improving Digital Literacy. Ms Cooper also introduced me to Dr Victoria Betton, founder and Director of mHabitat, “an NHS-hosted team specialising in co-design, digital skills & inclusion, policy & strategy, evaluation” We met at ‘Co>Space North’ which “connects, collaborates and co-creates both online and on-site at the co-working space in Leeds.” https://wearemhabitat.com
Manchester
I spent a day at Salford Royal NHS Foundation Trust, which is a ‘Global Digital Exemplar’ (GDE), one of 16 Trusts chosen by NHS Digital to participate in an ‘NHS Driving Digital Maturity’ program, aiming to ensure that the “…NHS is paper free at the point of care”.

I met with Mr Chris Chapman, Digital Ecosystems Lead at the Digital Experience Centre, where the Centre is engaged in more than 50 separate digital projects. Pennine Acute Hospitals NHS Trust is partnering with Salford Royal to become Manchester’s first GDE ‘Fast Follower’ organisation. Among other innovations, Mr Chapman also talked about the 3D printing program which used 3D printing technology to correct the spine of a 64-year-old patient with the chronic condition Ankylosing Spondylitis (AS), during a 15-hour operation – it was the first of its kind in the country, using 3D printing technology (it took five hours alone to safely anaesthetise and position the patient).

https://www.salfordgde.nhs.uk/news-and-events/helping-helen/

Notably @SalfordRoyalNHS has been rated ‘Outstanding’ twice in a row by @CareQualityComm

London
I met with Dr Natasha Phillips, Chief Nursing Informatics Officer, University College Hospital & Visiting Research Fellow National Nursing Research Unit, Kings College London. UCLH leads a Safety Surveillance Program. Safety Officers are trained by NHSD, who come on site to train safety officers over 2 days. Prior to go-live the safety case needs to be brought before the Trust Board and then onto NHS Digital for approval.

Cambridge
I met with Ms Helen Balsdon, Associate Director of Nursing (Informatics, Improvement & Transformation & End of Life Care), at Addenbrooke Hospital, Cambridge University Hospitals NHS Foundation Trust. Ms Balsdon talked about the digital transformation that has occurred in Cambridge University Hospital NHS Trust, that saw Epic® replace the 200 systems in place prior – which was not without incident. She also spoke about the emphasis on reducing the burden of documentation, particularly for Nurses – a theme which continues to transcend international boundaries.
Country Highlights: Canada

The Canadian Healthcare System (Brief)

Provinces and territories in Canada have primary responsibility for organizing and delivering health services and supervising providers. Many have established regional health authorities that plan and deliver publicly funded services locally. Generally, those authorities are responsible for the funding and delivery of hospital, community, and long-term care, as well as mental and public health services. The federal government co-finances provincial and territorial programs, which must adhere to the Canada Health Act (1985), which in turn sets standards for “medically necessary” hospital, diagnostic, and physician services. The act states that to be eligible to receive full federal cash contributions for health care, each provincial health care insurance plan needs to be: publicly administered, comprehensive in coverage, universal, portable across provinces, and accessible (for example, without user fees).

The federal government also regulates the safety and efficacy of medical devices, pharmaceuticals, and natural health products; funds health research; administers a range of services for certain populations, including First Nations, Inuit, members of the Canadian Armed Forces, some veterans, resettled refugees and some refugee claimants, and inmates in federal penitentiaries; and administers several public health functions. https://international.commonwealthfund.org/countries/canada/

Organization of the Health System in Canada

Canadian Constitution

Provincial and territorial governments

Regional health authorities

Ministers and Ministries or Departments of Health

Federal government

Minister of Health

Canada Health Act (1984)

Health Canada

Public Health Agency of Canada

Canadian Institutes for Health Research

Canadian Agency for Drugs and Technologies in Health (1994)

Canadian Institute for Health Information (1994)

Canada Health Infoway (2001)

Canadian Blood Services (1996)


Note: Solid lines represent direct relationships of accountability while dotted lines indicate more indirect or arm’s-length relationships.

Much like Australia, the organisation of Canada’s health care system is largely determined by the Canadian Constitution, in which roles and responsibilities are divided between the federal, and provincial and territorial governments. The provincial and territorial governments have most of the responsibility for delivering health and other social services. The federal government is also responsible for some delivery of services for certain groups of people. Publicly funded health care is financed with general revenue raised through federal, provincial and territorial taxation, such as personal and corporate taxes, sales taxes, payroll levies and other revenue. Provinces may also charge a health premium on their residents to help pay for publicly funded health care services, but non-payment of a premium must not limit access to medically necessary health services. There is more to health than the health care system.

Since its inception in 2001, Canada Health Infoway (CHI) has functioned as an independent, federally-funded, not-for-profit organisation and has worked as a strategic investor with Canadian provinces to accelerate the development of EHRs and EMRs across Canada. With the goal of attaining a 50% EHR adoption rate among Canadians by 2010, CHI had invested $1.58 billion in 283 individual projects as of March 2009. In the 2017/18 Infoway Annual Report, it was noted that a total of $2.45 billion had been received by CHI since its inception with the reinvestment resulting in $26 billion in benefits (cost savings and efficiencies) to Canadians and their health system since 2007. Highlights from the 2017-2018 Annual Report are below:

### Highlights from 2017-2018

**$26 billion**

in benefits (cost savings and efficiencies) have accrued to Canadians and our health care system since 2007 as a result of investments in connected health information, telehealth and telehomecare, drug information systems, diagnostic imaging, and physician and ambulatory clinic electronic medical records (EMRs).

- An estimated $1 billion in health system value
- 18 million hours in time savings for patients
- 5.9 million hours in time savings for providers
- $189 million in economic productivity gains

Every $1 invested in telehealthcare programs generates more than $4 in health system value in the first year alone.

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I met with Infoway staff on arrival in Toronto. Mr Fraser Ratchford, ACCESS e-Services Group Director at Canada Health Infoway, talked about Infoway’s vision to deliver digital health technologies across Canada. “ACCESS Health is a program to enable more Canadians access to their personal health information and e-services through digital health. Foundational to this program is the ACCESS Gateway – a national platform to allow information to move among various channels of the citizen’s choice within a trusted framework. Provinces will be able to connect to this infrastructure and use the services of the Gateway to expose their data to citizens and clinicians. Vendors will also be able to connect once using common APIs and not have different integrations for each province, health region or customer”. This program was launched in April 2018. With respect to
citizen access to their own health information, some provinces have implemented their own patient portals. Uptake has been variable and scaling the solution has proven challenging.

‘ACCESS Atlantic’ Atlantic provinces (Nova Scotia, New Brunswick, Prince Edward Island, Newfoundland and Labrador). At the time of our meeting ACCESS Atlantic was just being launched, but at the time of writing, four priorities have been established. The initiative is implementing technology infrastructure across the region to improve access to digital health services and transform the way health care is delivered. This will help patients and their families through access to:

- PrescribeIT™, Canada’s national electronic prescribing service
- e-Mental health and addiction services
- Citizen access to personal health information
- Identity, access and consent management

Although the initiative is concentrating in the Atlantic, it is intended that solutions and learnings from this initiative will spread across the country.

I met with Dr Jennifer Zelmer, the Canadian Foundation for Healthcare Improvement’s (CFHI) President and CEO who spoke of the opportunities the Foundation presents to work with industry partners to accelerate innovations in health care. The CFHI identifies proven healthcare innovations and accelerates their spread across Canada by helping organizations adapt, implement and measure solutions that improve the patient experience and healthcare outcomes. Like Infoway, the CFHI is a Pan Canadian Healthcare Organisation (PCHO). PCHOs are federally funded, self-governed and non-profit organisations originally established to respond to health policy issues. PCHOs underwent a review in 2018 which recommended better coordination across PCHOs and closer alignment with federal health policy objectives to meet national goals.

Canada Health Infoway is working with Health Canada, the provinces and territories, and industry stakeholders to develop, operate and maintain the national e-prescribing service known as PrescribeIT™. PrescribeIT™ will serve all Canadians, pharmacies and prescribers and provide safer and more effective medication management by enabling prescribers to transmit a prescription electronically between a prescriber’s electronic medical record (EMR) and the pharmacy management system (PMS) of a patient’s pharmacy of choice.

Infoway has a dedicated benefits evaluation team and evidence-based practice framework, which has been established to demonstrate the link between investments, clinician or citizen use, and demonstrated outcomes; and acknowledge key lessons learned and critical factors for benefits realization relevant to multiple stakeholders. Mr Chad Leaver spoke of the need to “…bring good evidence to bear throughout the lifecycle”.

Dr Rashaad Bhyat, Clinician Lead, Infoway, and practicing Family Physician, spoke of his work with physician organisations, and the increasing focus on direct engagement, which has evolved and matured over time. He also noted that while interoperability is still a challenge for Canada, the ‘Access Atlantic’ Program should result in improved integration in one region of the country.
I spoke with Mr David Meurer, Provincial Director, eQuality and eSafety, Patient Safety, Quality Healthcare Improvement, Alberta Health Services (AHS), who highlighted that “...patient safety is a core value at AHS, and that systematic provision must be made for maximising health information technology safety and quality, while minimising and mitigating new risks”. Mr Meurer also referred to the eSafety Guidelines originally developed by COACH (now Digital Health Canada) in 2013. Governance is a central theme in these guidelines, which lay out a framework for organisations to adopt coherent, robust and consistent eSafety and eQuality practices, and also audit, manage, report and work toward continuous quality improvement. These guidelines strengthen the overall organisation of patient safety within Alberta Health Services and have been adopted through existing governance committees. The ‘Accountability Principle’ within the Guidelines requires the establishment of a “governance framework that ensures a coordinated response to eSafety and eQuality issues. This governance structure illustrates that these issues span a number of portfolios across the organisation and therefore the responsibility must be shared, with final accountability residing with the Executive, which is the home of all patient-related safety and quality issues.

eSafety is just another Patient Safety & Quality Improvement measure that can be managed through existing structures, however it requires a structured approach to effectively integrate into existing practice/programs.”

This is an excellent example of digital health patient safety in practice. The framework has been drawn from experiences in the National Health Service (NHS) UK, the Office of the National Coordinator for Health IT (ONC HIT) USA, the Institute of Medicine (IOM) USA, and Australia.

I also had the opportunity to speak with Dr Rob Hayward, CMIO for Alberta Health Services, who spoke of the development of the ‘Connect Care’ Program, and how patient safety is a central tenet. He noted the importance of embedding eSafety within existing committees, and that eSafety should not be “orphaned off” outside of existing governance.

^Connect Care is a province-level electronic health record, supporting the collection, use and sharing of information, supporting the delivery of health services to persons and populations in multiple settings across the continuum of care. The scope is highlighted below:

For more information: https://www.albertahealthservices.ca/info/cis.aspx

Photo credit: https://www.albertahealthservices.ca
I visited the Women’s College Hospital in Toronto and spoke with researchers in The Women’s College Hospital Institute for Health System Solutions and Virtual Care (WIHV), where work is underway on a new Centre for Digital Health Evaluation. Experimental in nature, WIHV’s focus is on evaluating and testing new models of care, with a view to spread and scale across the health system.

The team at WIHV have introduced the simple heuristic “[Tool+Team+Routine]” to shift perspective from the ‘implementation’ of new digital tools toward one focused on ‘service design’. The concepts introduced have provided a “starting point for shifting thinking away from conventional approaches to implementing technologies and moving toward a more comprehensive approach to service design. Viewing technology adoption as an iterative process, involving complex interactions between a tool, a team, and newly established routines, stands to help teams envision new services arising from the adoption of technologies beyond the added work of new forms of data entry and communication.”

https://www.nature.com/articles/s41746-018-0059-8
Country Highlights: United States

The US Healthcare System (Brief)

The Affordable Care Act (ACA), enacted in 2010, established “shared responsibility” between the government, employers, and individuals for ensuring that all Americans have access to affordable and good-quality health insurance. However, health coverage remains fragmented, with numerous private and public sources, as well as wide gaps in insured rates across the U.S. population. The Centers for Medicare and Medicaid Services (CMS) administers Medicare, a federal program for adults 65 years and older and some people with disabilities and works in partnership with state governments to administer both Medicaid and the Children’s Health Insurance Program (CHIP), a conglomeration of federal–state programs for certain low-income populations.

Private insurance is regulated mostly at the state level. In 2014, state and federally administered health insurance marketplaces were established to provide additional access to private insurance coverage, with income-based premium subsidies for low- and middle-income people. In addition, states were given the option of participating in a federally subsidized expansion of Medicaid eligibility.

In 2015, about 67.2 percent of U.S. residents received health coverage through private voluntary health insurance (VHI): 55.7 percent received employer-provided insurance, and 14.6 percent acquired coverage directly. Public programs covered roughly 37.1 percent of residents: Medicare covered 16.3 percent, Medicaid 19.6 percent, direct-purchase 16.3 percent, and military coverage 4.7 percent.1

In the first quarter of 2016, 27.3 million individuals were uninsured, representing 8.6 percent of the population, down from 9.1 percent in 2015.2 The implementation of the ACA’s major coverage expansions in January 2014 has increased the share of the population with insurance. These reforms include: the requirement that most Americans procure health insurance; the opening of the health insurance marketplaces, or exchanges, which offer premium subsidies to lower- and middle-income individuals; and the expansion of Medicaid in many states, which increased coverage for low-income adults. Between 2014 and the start of 2016, the overall rate of health insurance coverage increased for most racial and ethnic groups. Hispanics had the largest increase (6.6 percentage points), followed by Asian Americans (4.8 points), non-Hispanic blacks (3.1 points), and non-Hispanic whites (2.4 points).3 It is projected that the ACA will reduce the number of uninsured by 24 million by 2018.4 However, with the likely repeal of the health law by the new Congress and administration, it is unknown how progress in reducing the uninsured population will be affected.

Public programs provide coverage to various, often overlapping, populations. In 2015, more than 10 million Americans were both entitled to Medicare and eligible for Medicaid services (the so-called ‘dual eligibles’). CHIP, which in some states is an extension of Medicaid and in others a separate program, covered more than 8.1 million children in low-income families in 2015.

Undocumented immigrants are generally ineligible for public coverage, and nearly two-thirds are uninsured. Hospitals that accept Medicare funds (which are the vast majority) must provide care to stabilize any patient with an emergency medical condition, and several states allow undocumented immigrants to qualify for emergency Medicaid coverage beyond “stabilization” care. Some state and local governments provide additional coverage, such as coverage for undocumented children or pregnant women.

https://international.commonwealthfund.org/countries/united_states/
My journey in the USA started in Philadelphia PA, where I was lucky enough to time my visit to the ECRI Institute with the ‘Partnership for Health IT Patient Safety’ meeting. The Partnership provides a “trusted, non-punitive forum for all stakeholders to collect and analyse safety events and hazards, identify, and share promising solutions and safe practices, and inform policymakers and the broader healthcare community about priorities for health IT safety”. As a multi-stakeholder collaborative the Partnership boasts more than 50 member organisations, including The ECRI Institute, the American Medical Informatics Association (AMIA), the Association for the Advancement of Medical Instrumentation (AAMI), The Joint Commission, The Healthcare Improvement Foundation, the Healthcare Information & Management Systems Society (HiMSS), The Institute for Healthcare Improvement, Cerner, Allscripts and the American Association of Physician Leadership, among many others. It is sponsored through funding from the Gordon & Betty Moore Foundation and the Expert Advisory Panel includes seminal digital health thought leaders such as Dr David W. Bates, Ms Jeanie Scott, Dr Patricia P. Sengstack, Dr Christoph Lehmann, Dr Peter J Pronovost, Dr Hardeep Singh and Dr Dean Sittig, many of whom were present at the meeting.

The agenda included discussions with ‘Health IT Safety Practices’ workgroup chairs and panel members on ‘Measures and CDS for Safer Opioid Prescribing’ and ‘Safer Health IT Practices for Drug Allergy Interactions’ and use of data for safety.

ECRI Institute convened the partnership in 2014. Learn more about the national health IT safety collaborative by visiting www.hitsafety.org
I was struck by the volume of work being undertaken and the number of important safe practice recommendations and toolkits that had already been developed. Many of these recommendations and toolkits are readily transferable across jurisdictions – well beyond USA borders and should serve as mandatory reading before any digital health undertaking, particularly given the process of development, along with the expertise engaged in it.

Following the Partnership meeting I had the pleasure of sitting down with ECRI staff to understand more about how patient safety is organised in the USA. I met with Ms Amelia Vagnozzi, Ms Amy Goldberg-Alberts, Mr Asa Adadey, Mr Bill Marella, Dr Lorraine Possanza, Ms Patti Giuffrida and Mr Rob Giannini. ‘The Patient Safety Quality Improvement Act’ of 2005 established Patient Safety Organisations (PSOs). PSOs provide organisations a private and protected space to share learnings.

Organisations choose to participate in PSOs and they do this for shared learnings from aggregated data, for solutions to issues that they and others face, and for the protections offered under the Patient Safety Act. The AHRQ regulates and sets standards for PSOs, of which there are approximately 80 in the USA. Some are national; but most are regional or state. In the absence of the funded and established HIT Safety Center, ‘The Partnership’ serves as its de facto entity.

ECRI Institute was founded by Joel J. Nobel MD in 1968, who also designed the first “MAX Crash Cart” which sits in the entrance of the Institute.

Lorraine noted that Philadelphia is the home of the first US hospital and the region – combining NY, PA and MA, a “…great corridor of health services innovation”.

The Health IT Safe Practices: **Toolkit for the Safe Use of Health IT for Patient Identification** toolkit includes information about the ‘Retract & Reorder’ Measure.

This was the first Health IT Safety Measure Endorsed by the National Quality Forum.

https://www.ecri.org/hit/safe-practices

**Workgroups convened by the Partnership conduct in-depth study and issue safe practice recommendations and toolkits, including:**

- Health IT Safe Practices for Closing the Loop: Mitigating Delayed, Missed, and Incorrect Diagnoses;
- Safer Opioid Prescribing;
- Safer Health IT Practices for Drug Allergy Interactions;
- Safe Practice Recommendations for Developing, Implementing, and Integrating a Health IT Safety Program;
- Health IT Safe Practices: Toolkit for the Safe Use of Health IT for Patient Identification; and
- Copy and Paste

The Partnership publicly disseminates these materials and encourages their use and distribution.

[This measure assesses the number of times an order was entered on the wrong patient, then retracted and reordered on another patient within a 10-minute period.]
Houston

From Philadelphia I travelled to Houston, where I met with Dr Hardeep Singh and his team from the Center for Innovations in Quality, Effectiveness and Safety (IQuESt). IQuESt is a partnership between the Veterans Affairs Health Services Research & Development Service and Baylor College of Medicine (BCM). It is the largest centre for health services research in the Southwest and houses nearly 200 faculty, postdoctoral fellows, trainees and research staff. On the IQuESt website it states that “On an average day in IQuESt you could encounter a team consisting of a primary care doctor, a computer scientist, an industrial/organizational psychologist, a psychiatrist or other medical subspecialist, a social worker, a biostatistician, and a communications scientist—all teeming up with the goal of studying how to deliver health care with the highest quality and efficiency. Our overall goal is to make a positive impact on health delivery and quality122”. This was certainly my experience over the 4 days I was resident at the Center. The staff were generous with their time and taught me about the scope and scale of research being conducted, including health care quality and safety, medical errors, patient safety and EMRs, physician decision-making, population health, and patient-facing research – e.g. patient-reported adverse events.

Dr Singh is a giant among peers in his advocacy for patient safety, alongside Dr Dean Sittig and Dr David Bates. They have written extensively about the digital health safety conundrum and offer compelling evidence for how to move forward.

While in Houston I also visited TMCx. Located in the TMC Innovation Institute, the program provides startup companies with shared workspaces, a curriculum tailored to the needs of health care entrepreneurs and access to >200 advisors from industry front lines. Companies have access to the world’s largest medical center, working with staff to build relationships. I met with Mr Johann Lipman, Product Development Manager for an Australian start-up, ‘De Motu Cordis’, whose vision is to “…significantly improve patient outcomes through enabling rapid and effective therapeutic drug delivery in emergency care.” https://demotucordis.co/

I met with many other clinicians, researchers and academics, including Dr Bob Murphy, who spoke to leadership being instrumental in promoting a positive safety culture, along with the active use of data to “…drive the human narrative”.

Mr Lipman spoke of the opportunities presented through the accelerator program, including access to the US marketplace.
I had the opportunity to meet with Austrade’s Ms Emma Aitken who is certainly living Austrade’s mission to drive "international trade promotion and investment attraction." Ms Aitken spoke of the recent bilateral announcement by Australia’s Health Minister the Hon. Greg Hunt MP regrading a ‘Medical research collaboration between Australian and United States researchers’ at The Texas Medical Centre (TMC) to collaborate “…on transforming and saving lives through medical breakthroughs and clinical trials^”. Ms Aitken has also been instrumental in driving Australia’s tech component in the March 2019 ‘SXSW’ in Austin, Texas, supporting Australia’s national digital health accelerator ANDHealth, and a delegation of nine Australian companies, including Patienteer.


San Francisco

The American Medical Informatics Association’s (AMIA) Annual Symposium was held in San Francisco November 3 – 7 2018. The theme was 'Data, Technology & Innovation for Better Health'. I met with Dr Dean Sittig, Dr Adam Wright and Dr Allison McCoy, following their panel on ‘Making Electronic Health Records Safer: Practical Strategies for Evaluation and Improvement’, which covered the assessment, measurement, monitoring and mitigation of EHR-related safety risks. The panel was also shared by Associate Professor Farah Magrabi, one of Australia’s internationally-recognised researchers in patient safety and digital health. I also heard from Dr Jason Adelman, Associate Professor Julia Adler-Milstein, Professor Vimla Patel, Dr Christine Dymek, Dr Patricia Flatley Brennan, Dr Chris Longhurst, Dr Jon White, Dr Teresa Zayas Caban and Dr Patricia Dykes, some of whom I met following. AMIA’s schedule is gruelling and the quality and standard of the papers is very high. There was also a large university footprint in the Exhibitors hall, presenting a vast array of health and biomedical informatics degrees. While there are obvious differences between the way higher education is set up in the USA, there is much Australia could learn here.

Dr Brennan highlighted the National Institutes of Health’s (NIH) Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative, which provides access to NIH data through commercial cloud computing services, partnering with Amazon Web Services and Google to facilitate access for NIH researchers and more than 2500 academic institutions across the USA to accelerate discoveries in biomedical research. I also heard about ‘Green Button’ an initiative being run out of Stanford, which allows clinicians to search millions of electronic records for lookalike cases, allowing the generation of a composite summary of the outcomes of ‘like’ cases (e.g. same race, same height, same age, same symptoms, lookalike lab-test results) to understand what drug or treatment might best suit.

I heard too about the increasing use of EMR audit log data being used for research, specifically clinical work flow patterns and patient safety. According to the authors, major EHR vendors are investing in making audit log data (and derivative measures) accessible and easier to work with. The research presented was clear on the value of EHR log data for answering various clinical informatics and clinical research questions, along with its potential. Associate Professor Adler-Milstein hosts a ‘National Research Network’ Webinar series each month which presents on research in this space. The webinar is open to anyone to join.
Dr Patricia Dykes talked to me about the ‘Patient-Centered Fall Prevention Toolkit’, which was the output of a mixed-methods study she and colleagues conducted to identify primary causes of hospital patient falls and the interventions that are most feasible and effective in preventing them. Fall TIPS is working with facilities across the US: Brigham and Women’s Hospital, in concert with Montefiore Medical Center and New York-Presbyterian have formed a Fall TIPS Collaborative to spread the Fall TIPS Toolkit to ensure that all patients have access to evidence-based fall prevention care. More than 140 hospitals nationwide are now reducing their patient fall rates and improving outcomes with Fall TIPS: www.FallTIPS.org

#AMIA2018 San Francisco over and out. So many people doing smart research in #DigitalTransformation and #PatientSafety, especially these folk: @SusanHFenton @FarahMagrabi @DeanSittig @ONC_HealthIT and Patricia C. Dykes @AMIAINformatics @AuDigitalHealth @ChurchillTrust
Washington D.C.

I visited with staff from the Office of the National Coordinator for Health Information Technology (ONC HIT) as part of my time in Washington D.C. I met with Dr Teresa Zayas Caban’s research team who have been working closely on the Sync for Science (S4S) and Sync for Genes projects, part of the ‘All of Us’ Research Program, a Precision Medicine initiative launched in 2015. These projects use the Fast Healthcare Interoperability Resources (FHIR®) specification as the basis for data exchange. I met with Dr Andy Gettinger, the Chief Clinical Officer (CCO) for the ONC, who talked of some of the challenges inherit in evolving digital health and the need to realise the “digital dividends”. Dr Gettinger rightly noted that we “shouldn’t need to argue the benefits or return on investment of digitisation…no one argues that we need electricity or water…”. I also met with Don Rucker, the National Coordinator for Health IT (ONC), Ms Lisa Lewis, Dr Jon White and Dr Teresa Zayas Caban and we discussed the 21st Century Cures Act, which was passed unanimously in 2016 under the Obama Administration. Congress provided the Department of Health and Human Services (HHS) with the authority to “enhance innovation, scientific discovery, and expand the access and use of health information. The Cures Act includes key provisions (in Title IV) related to:

- the development and use of upgraded health IT capabilities;
- transparent expectations for data sharing, including through open application programming interfaces (APIs); and
- improvement of the health IT end user experience, including by reducing administrative burden. 123

A particular focus is open APIs and ongoing efforts to deter information blocking. At the time of writing this report, the ONC had announced the proposed rule addressing the above provisions and it is currently out for comment. There have been further significant announcements since my return to Australia which include the CMSs proposal to provide Medicare beneficiaries access to their claims data through open APIs and the Department of Veteran Affairs (VA) pairing with Apple to make health records available via iPhones to more than 9 million patients later this year.

We had a good discussion about safety as a system and that digital health should not be isolated, at the same time acknowledging that there are unique issues relative to digital health. Dr Rucker felt that automation could play a role here in “… designing out safety hazards…” Dr Rucker also felt that a high level of interoperability would improve digital health safety and further minimise risk. The notion of safety culture arose again, as it has done in each of my interviews – it would seem this is a view not only held widely, but a practice that must be fundamental to business operations.
From ONC HQ I travelled to MedStar Health to meet with Dr Raj Ratwani and Professor Rollin J Terry Fairbanks at the National Center for Human Factors in Healthcare, the first Centre of its kind in the USA. Both Ratwani and Fairbanks have been vocal in highlighting usability issues with EHRs and have called for greater action to combat patient safety and associated harms. Ratwani spoke of the barriers created through ‘hold harmless’ clauses with EHR vendors, which tend to shift responsibility back onto provider organisations, in addition to ‘gag clauses’ which prevent sharing of screen shots and other material that could identify a vendor. Dr Ratwani referred to the website ‘The Doctors Company’ which highlights the increasing volume of legal claims related to EHRs, but it is still not possible to understand proportionality. Dr Ratwani spoke also of “…shared responsibility – the next step is to define what this looks like for each party…”. Dr Fairbanks highlighted Dr Robert Wachter’s Report ‘Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England’\(^\text{124}\), as a landmark study and necessary reading for anyone working in this space.

I spoke with Ms Susannah Fox, one of the Obama administration’s Chief Technology Officers. When I asked Ms Fox about her perspectives on the best mechanisms to successfully implement large scale health policy reform she noted how important it was to “…create a movement that is so obviously for the good of the country and its people that we all seek to serve it, and it can then sustain across administrations”, and the importance of finding ways to work across party lines from the outset. This is possibly true of digital health policy in the USA since President George W. Bush created the ONC in 2004, in that there has been an overall shared vision regarding improved patient safety and health outcomes through the use of digital health to modernise healthcare, although the forces effecting change have been motivated differently.

I was lucky enough to time my visit in Washington D.C. with ONC’s ‘2018 Annual Meeting’. The themes focused on transitioning to a ‘value-based health system’ and how digital health could support this; patient access to and control over their own data; interoperability; and reducing provider burden. A value-based health system shifts the payment emphasis from ‘fee-for-service’, to patient outcomes, and there was considerable discussion about how this could be effected. Since my return to Australia, the Centers for Medicare and Medicaid Services (CMS) has announced a new value-based payment model for primary care in 2020, dubbed ‘CMS Primary Cares Initiative’\(^\text{125}\).

This initiative dovetails with ONC’s ‘draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs\(^\text{126}\)’, which was published just prior to the ONC meeting commencing (it has since closed for comment). The strategy was a commitment made through the 21st Century Cures Act, which identified the importance of easing administrative and regulatory burdens associated with the use of EHRs and digital health. The agenda included fireside chats with both sides of Congress – USA Senators Tammy Baldwin (D-WI) and Lamar Alexander (R-TN), reemphasising for me the bipartisan support for digital health. Both Senators sit on the USA Senate Committee on ‘Health, Education, Labor and Pensions’ (HELP), where, as at the end of November 2018 the Committee had already had 5 hearings on reducing healthcare costs in as many months – hence the theme on the value-based health system.
I had side meetings with Dr Christine Dymek (AHRQ), Mr Ben Moscovitch (Pew Charitable Trusts), Mr Jeffrey Smith and Mr Scott Weinberg (AMIA) and Mr Steve Posnack (ONC), all of whom are dedicated digital health professionals looking to improve the safety of digital health through research, policy and technology. I also travelled to the National Library of Medicine (the NLM is the world’s largest biomedical library and the producer of digital information services used by scientists, health professionals and members of the public worldwide) to meet with its Director, Dr Patricia Flatley Brennan, one of ten female Directors at the NIH and the first nurse to serve as its director. We talked a lot about data: Dr Brennan talked about terminology and what it tells us about what we care about: the overrepresentation of pathophysiological terms vs. societal. She said we should be “... planting the seed that there is a philosophical commitment before the coding begins”. We also discussed the ‘Learning Health System’ and the opportunities to be realised through learnings actively being embedded to support improvements in patient safety – especially in real time.

While in Washington, Ms Jeanie Scott advised me about the efforts in the USA regarding the development of American National Standards Institute (ANSI) standards for digital health safety and forwarded me the new provisional standard ‘HIT1000-1, Safety and Effectiveness of Health IT Software and Systems—Part 1: Fundamental Concepts, Principles, and Requirements’. Part of a series of standards (AAMI HIT1000 series) which provide a framework for managing the safety and effectiveness of digital health software and systems, to effect better outcomes for patient, this provisional standard identifies the fundamental components necessary to core concepts and principles needed to maintain safe and effective digital health software and systems. It also identifies roles and defines responsibilities, activities, and best practices that are necessary for managing that safety and effectiveness127. Ms Scott advised that this standard “… defines the
concept of shared responsibility, that is the role of both vendor and user and varies throughout the lifecycle for health IT systems”.

In my travels in the USA I was often reminded of Dr Sittig and Dr Singh’s ‘Socio-technical Model for Studying Health Information Technology in Complex Adaptive Healthcare Systems’.

It was first published in 2010, and nine years on, remains just as relevant. It should be fundamental curricula for every higher education course and/or degree in health care.

Another frequent feature of discussions in the US was The Institute of Medicine’s (IOM) 1999 Report ‘To Err Is Human’ which transformed the patient safety landscape. Never had there been such an explicit focus on patient harm and it was galvanising. According to Dr David Bates and Dr Hardeep Singh, who published ‘Two Decades Since To Err Is Human: An Assessment of Progress and Emerging Priorities in Patient Safety’ while I was visiting, the report made several major points: Errors are common; costly; errors can be the result of systems-related problems; errors are preventable; and safety can be improved128.

Following the release of the IOM Report, there were sweeping changes which saw a substantial rise in research focused on patient safety, with the charge led by grant funding from the Agency for Healthcare Research and Quality (AHRQ), in addition to hospital programs focused on measurement, accreditation, and regulation. Significantly, there was a more than 250 percent increase in the number of studies addressing safety gaps, many of which were conducted where there had traditionally been a paucity of research129. Despite this, errors persist and there are a multitude of contributing factors that have already been described within my report.

Dr Bates and Dr Singh went on to state that “Policy levers should ... create mechanisms for shared responsibility for safety between health systems, care providers, industry, and relevant public and private agencies. One such mechanism would be a national safety center that leverages public-private partnership. The creation of a national center that would focus on health IT-related safety and enable key knowledge sharing has already been proposed. Such a center could help modify barriers to knowledge sharing contained in EHR software license agreements, nondisclosure provisions, and intellectual property protections. Loosening these provisions would enable better sharing of data related to patient safety130”.

Angela Ryan: angryan@gmail.com | +61 413 494294
Onwards to Boston, and home to Dr David Bates – an internationally renowned pioneer in the use of digital health to improve patient safety, Dr Bates, like Dr Dean Sittig and Dr Hardeep Singh, has been engaged at all levels of the digital health policy debate in the USA, and according to Google Scholar is the most cited researcher in the fields of patient safety and biomedical informatics. Dr Bates spoke of the history of digital health policy in the USA and offered his thoughts on learnings. He noted that the Leapfrog Group’s ‘Leapfrog Hospital Survey’ should be part of any national digital health safety governance framework Australia may implement. Leapfrog has collected and publicly reported safety and quality information about inpatient care for nearly 20 years, and now represents almost 70 percent of U.S.A hospital beds. Dr Bates also noted the import of the SAFER (Safety Assurance Factors for EHR Resilience) Guides, developed by Dr Sittig, Dr Singh and Professor Joan Ash, as part of the governance framework. Dr Bates’ advice to me in building this framework was to “… take a pragmatic approach and don’t shoot too high... quite a lot can be achieved with not a lot of resources...”.

Dr Bates introduced me to some of his clinical colleagues, including Dr Ishani Ganguli, Dr Lipika Samal and Dr Karen Sherritt, all Primary Care Physicians and Dr Jeff Schnipper, a Hospitalist, who spoke of their efforts to make improvements in their EHRs in the face of an increasing cognitive load and its associated burden. It was clear to me how invested they are in doing this, being big believers in the transformative nature of digital health and its impact on their patients.

I met with Dr Adam Wright, Dr Hojjat Salmasian and again with Dr Patricia Dykes, whose collective research efforts are focused on making EHRs safer and more usable. Some of the focus areas:
- clinical decision support;
- medication safety, CPOE;
- wrong patient, wrong entry (retract and reorder);
- neonates and identity management; and
- Falls prevention.

My final interviews in the US were with the ONC’s Dr Andy Gettinger, the Chief Clinical Officer for ONC and Ms Elise Sweeney Anthony, Executive Director of Policy, ONC. We had good discussions regarding the development and implementation of digital health policy in the US since HITECH, and the challenges that persist regarding patient safety. We also talked about Title 4 of the Cures Act which is where ONC largely exists, and what the upcoming proposed rule (comment open until June 2019) would mean for the next stage of digital health progress.

With the benefit of hindsight all can see that there were gaps in the legislation as originally prescribed; the question now is how the changes being introduced can address some of these shortcomings.
After arriving back in Australia at the end of December I followed up on a few colleagues I’d been unable to connect with in person.

<table>
<thead>
<tr>
<th>Robert Wah MD</th>
<th>Emphasised the importance of having the clinical perspective part of the process from very beginning, right at the early stages of design and development. Dr Wah, then President of the AMA, was instrumental in the AMA’s founding partnership of Health2047 in 2016, which brings together entrepreneurs, physicians and companies to develop new tools and products for physicians and their patients. More here: <a href="https://health2047.com">https://health2047.com</a></th>
</tr>
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</table>
| • Global Chief Medical Officer, DXC  
• Co-Chair, Health Information Technology Advisory Committee (HITAC) at HHS  
• Former President, American Medical Association (AMA)  
• First Deputy National Coordinator for Health IT |  |

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<tr>
<th>Kate Goodrich MD MHS</th>
<th>Ms Goodrich has been instrumental in administering the Center’s large suite of Programs, including meaningful use. Ms Goodrich acknowledged that there were limitations in the way the Program was implemented and has shifted gear to initiatives that are reducing clinician administrative burden. She described one such initiative, ‘Patients Over Paperwork’, which was launched by CMS to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience, and ultimately improve the time providers spend with their patients. <a href="https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html">https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html</a></th>
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| • Health IT Advisory Committee, Federal Representative  
• Director of the Center for Clinical Standards and Quality (CCSQ) and  
• CMS Chief Medical Officer (CMO), Centers for Medicare and Medicaid Services (CMS) |  |

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<tr>
<th>Amy Billett MD</th>
<th>Dr Billett referred to the case of Betsy Lehman, a Boston Globe health reporter who died in 1994 after receiving a massive overdose of chemotherapy, which galvanised health leaders in Boston to reduce medical errors and improve patient safety. Some of Dr Billett’s early work was in the design and development of a paediatric oncology information system, and this focus continues today.</th>
</tr>
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</table>
| • Director of Safety and Quality, Division of Pediatric Hematology/Oncology at Dana-Farber Boston Children’s Cancer and Blood Disorders Center  
• Institute Physician  
• Associate Professor of Pediatrics, Harvard Medical School |  |

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<th>Matthew Holt BA MS</th>
<th>Mr Holt described the current state of digital health as a 3-layered problem: 1) there is monumental EHR adoption, but systems haven’t been designed in a contemporary way; 2) the tension between patients/citizens having the right access to data but also having it protected (“nothing about me without me”); and 3) providers – “we’ll know more about them than ever!”.</th>
</tr>
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</table>
| • President, SMACK.Health  
• Co-Chair, Catalyst Health 2.0  
• Founder/Author, The Health Care Blog  
• Venture Partner, Nina Capital |  |

| Jason Adelman MD MS BA | Dr Adelman described the opportunities access to electronic data presents, where “…you can look for rules violations and errors and use them to assess the safety of the system”. In one hospital, the research uncovered thousands of wrong patient error measures: near-misses which were all self-caught. “It allows us to continually inform |
• Executive Director, Patient Safety Research, Columbia University Irving Medical Center/New York-Presbyterian
• Co-Director, Patient Safety Research Fellowship in Hospital Medicine, Columbia University Irving Medical Center/New York-Presbyterian
• Assistant Professor of Medicine
• Assistant Professor of Biomedical Informatics

other measures. “Dr Adelman is a key collaborator with the Partnership for Health IT Safety and works with the ECRI Institute to ensure the information is shared.
Glossary of Terms and Definitions

<table>
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<th>Term</th>
<th>Definition</th>
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<tr>
<td><strong>Artificial Intelligence (AI)</strong></td>
<td>A collection of interrelated technologies used to solve problems autonomously and perform tasks to achieve defined objectives without explicit guidance from a human being. This definition of AI is expansive insofar as it encompasses neural networks and deep learning, as well as less sophisticated, but still important, applications with significant impacts on people, such as automated decision systems. There are other definitions of AI, including those that distinguish between ‘strong’ (general) and ‘weak’ (narrow) AI.</td>
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> **^** Ibid.  

| **Clinical decision support (CDS)** | Clinical decision support provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. CDS encompasses a variety of tools to enhance decision-making in the clinical workflow. These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools. |

> [https://www.healthit.gov/topic/safety/clinical-decision-support](https://www.healthit.gov/topic/safety/clinical-decision-support) |

| **Digital health** | See “Health information technology (HIT)”  
For the purposes of this report, digital health includes a broad range of products, including electronic health records (EHRs), electronic medical records (EMRs) patient engagement tools (e.g. personal health records and apps), clinical decision support tools and data storage; excluded is software for medical devices (e.g., software in an implantable cardioverter-defibrillator) and medical devices. |

| **Digital health and patient safety** | The application of leading practices to protect patients from harm in the development, implementation and use of digital health solutions. It is widely believed that health IT, when designed, implemented, and used appropriately, can be a positive enabler to transform the way care is delivered. Designed and applied inappropriately, health IT can add an additional layer of complexity to the already complex delivery of health care, which can lead to unintended adverse consequences, for example dosing errors, failure to detect fatal illnesses, and delayed treatment due to poor human-computer interactions or loss of data. |

> [https://www.nap.edu/read/13269/chapter/2](https://www.nap.edu/read/13269/chapter/2) |

| **e-iatrogenesis** | Patient harm caused at least in part by the application of health information technology. An e-iatrogenic event can be associated with just about any aspect of a comprehensive HIT system and it may involve errors of commission or omission. These unintended adverse events may fall into technical, human-machine interface or |
organisational domains. Some e-iatrogenic events will represent the electronic version of “traditional” errors, such as a patient receiving the wrong drug dosage due to a human click-error. But other HIT precipitated or enabled errors may have no exact analog in the non-electronic context. For example, a clinical decision support system (CDSS) embedded within an electronic health record might contribute to a clinician’s incorrect diagnosis or treatment plan; this could represent either a “type-one” or “two” error (e.g. making a diagnosis that was not present or missing one that was).

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2244888/

### Electronic Health Record (EHR)

A repository of personal health information in a computer-processable form. Its primary purpose is the support of continuing, efficient and quality healthcare.  
Definition adapted from [ISO 20514].

Australian Digital Health Agency Glossary

### Electronic Medical Record (EMR)

This term is sometimes used to distinguish detailed state-based patient records from EHRs in general, which in contrast are said to be summary-style records that cross the boundaries of state and federal health systems.

Australian Digital Health Agency Glossary

### Error

Error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. According to noted expert James Reason, errors depend on two kinds of failures: either the correct action does not proceed as intended (an error of execution) or the original intended action is not correct (an error of planning). Errors can happen in all stages in the process of care, from diagnosis, to treatment, to preventive care.

Not all errors result in harm. Errors that do result in injury are sometimes called preventable adverse events. An adverse event is an injury resulting from a medical intervention, or in other words, it is not due to the underlying condition of the patient. While all adverse events result from medical management, not all are preventable (i.e., not all are attributable to errors). For example, if a patient has surgery and dies from pneumonia he or she got postoperatively, it is an adverse event. If analysis of the case reveals that the patient got pneumonia because of poor hand washing or instrument cleaning techniques by staff, the adverse event was preventable (attributable to an error of execution). But the analysis may conclude that no error occurred, and the patient would be presumed to have had a difficult surgery and recovery (not a preventable adverse event).

https://www.ncbi.nlm.nih.gov/books/NBK225179/

### Healthcare sociotechnical ecosystem

People, process (workflow), technology (including health IT software and systems), organisation, and external environment organised to deliver services for healthcare or wellbeing.

Note 1: The interaction and interdependence of the elements of the healthcare sociotechnical ecosystem are significant as safety is an emergent property of the sociotechnical ecosystem.

| **Health information technology (HIT)** | The application of information processing involving both computer hardware and software that is intended to store, retrieve, share, and use data, information, and knowledge for the purposes of affecting human health and health care. HIT will be referred within this report as **digital health**. |
| **Health IT software (HIT software)** | Software that is intended to capture, store, retrieve, analyse, share, and use data, information, and knowledge for the purposes of affecting human health and health care.  
**Note 1:** Health IT software consists of many components including programs, executable code, libraries, value sets, algorithms, and documentation, and is usually designed to be configurable by system integrators and health care delivery organisations to support specific business processes and use cases.  
**Note 2:** Health IT software may be incorporated into a health IT system or may be an independent part of the technology element of the healthcare sociotechnical ecosystem if it is not integrated with other components. |
| **Human factors engineering usability engineering** | Process of applying knowledge about human behaviour, abilities, limitations, and other characteristics to the design and implementation of health IT systems and software.  
[Adapted from IEC 62366-1:2015] |
| **Iatrogenesis** | Any injury or illness that occurs as a result of medical [clinical] care.  
[Taber’s Cyclopedic Medical Dictionary, 2013].  
[https://www.sciencedirect.com/topics/medicine-and-dentistry/iatrogenesis] |
| **Patient safety** | The reduction of the risk of unnecessary harm associated with health care to an acceptable minimum.  
[Source: World Health Organization, 2011]  
**Note:** Patient safety, however, requires systems and software that are designed and operated in ways that reliably promote that general safety. |
| **Quality** | Degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.  
[Source IOM, 2012] |
| **Safety** | Reduction of risk of unnecessary harm to an acceptable minimum.  
[Source: World Health Organization, 2011]  
2018 Association for the Advancement of Medical Instrumentation ■ AAMI HIT1000-1 (PS):2018 |
| **Sociotechnical system** | Construct identifying the interactions between people, processes, technology, organisations, and environment that influence complex systems.  
[Source: IOM, 2012] |
| **Software as a Medical Device (SaMD)** | The term SaMD refers to software that functions on a general computing platform, such as a laptop computer, smartphone or tablet, and that has an intended purpose consistent with the |
definition of a medical device. Software is regulated by the TGA under the existing medical device framework; however, advances in technology, including the emergence of ‘apps’, are not adequately covered in the current scheme. Many health and lifestyle apps are not SaMD and are therefore not subject to regulation by the TGA.

<table>
<thead>
<tr>
<th>Usability</th>
<th>Extent to which a product or system can be used by intended users to achieve their goals with effectiveness, efficiency, and satisfaction in the intended contexts of use.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Note: All aspects of usability, including effectiveness, efficiency, and user satisfaction, can potentially affect safety.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use environment</th>
<th>Actual conditions and setting in which users interact with the health IT software and system.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[Adapted from ANSI/AAMI/IEC 62366-1:2015] 2018 Association for the Advancement of Medical Instrumentation ■ AAMI HIT1000-1 (PS):2018</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>User</th>
<th>Person interacting with (i.e. operating or handling) the health IT software or system.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Note: Such individuals serve in a variety of roles, including administrative staff, clinical staff, regulatory staff, technical staff, or as patients.</td>
</tr>
<tr>
<td></td>
<td>2018 Association for the Advancement of Medical Instrumentation ■ AAMI HIT1000-1 (PS):2018</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>User interface</th>
<th>Means by which the user and the health IT software and system interact.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[Adapted from ANSI/AAMI/IEC 62366-1:2015] 2018 Association for the Advancement of Medical Instrumentation ■ AAMI HIT1000-1 (PS):2018</td>
</tr>
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## Appendix A

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Could you provide a brief overview of your role and expertise, noting any relevance to digital health/health IT policy reform over the years?</td>
</tr>
<tr>
<td>2</td>
<td>What do you see are the ongoing barriers to digital health/health IT safety reform?</td>
</tr>
<tr>
<td>3</td>
<td>From your perspective, what are the best mechanisms to successfully implement small and large-scale health policy reform?</td>
</tr>
<tr>
<td>4</td>
<td>What are your perspectives on successfully embedding digital health safety governance as part of routine safety and executive governance?</td>
</tr>
<tr>
<td>5</td>
<td>What are your perspectives on how to ensure appropriate stakeholder representation and oversight at all levels of governance?</td>
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<td>No</td>
<td>Date</td>
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<td>19/10/2018</td>
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**Canada**

**United States**

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<th>Time</th>
<th>Name</th>
<th>Position</th>
<th>Location</th>
<th>Notes</th>
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<tbody>
<tr>
<td>17</td>
<td>23/10/2018</td>
<td>18:00 – 21:00</td>
<td>HIT Partnership Pre-meeting dinner</td>
<td></td>
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<td>In person</td>
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<tr>
<td>18</td>
<td>24/10/2018</td>
<td>08:00 – 16:30</td>
<td>HIT Partnership Meeting</td>
<td>See <a href="https://www.ecri.org/solutions/hit-partnership">https://www.ecri.org/solutions/hit-partnership</a></td>
<td></td>
<td>In person</td>
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<tr>
<td>19</td>
<td>25/10/2018</td>
<td>08:30 – 10:30</td>
<td>1. Bill Marella MBA MMI Lorraine Possanza DPM JD MBE Amy Goldberg – Albers MBA</td>
<td>Executive Director, Operations and Analytics, Patient Safety, Risk and Quality, ECRI Institute Senior Patient Safety, Risk, and Quality Analyst, Health Information Technology Safety Liaison, ECRI Institute</td>
<td>ECR Institute Headquarters, 5200 Butler Pike, Plymouth Meeting PA</td>
<td>In person</td>
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<tr>
<td></td>
<td>Date</td>
<td>Time</td>
<td>Event Description</td>
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<tr>
<td>20</td>
<td>25/10/2018</td>
<td>10:30 – 11:00</td>
<td>Kerry Riek, Cybersecurity, Applied Solutions Group BSN BS (Chemical Engineering)</td>
<td>Kerry Riek, Cybersecurity, Applied Solutions Group BSN BS (Chemical Engineering)</td>
<td>Senior Associate, Applied Solutions Group at ECRI Institute</td>
<td>Kerry Riek, Cybersecurity, Applied Solutions Group BSN BS (Chemical Engineering)</td>
</tr>
<tr>
<td>21</td>
<td>12:30 – 13:30</td>
<td></td>
<td>Tour of Engineering Lab</td>
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<tr>
<td>22</td>
<td>29/10/2018</td>
<td>12:00 – 13:00</td>
<td>Hardeep Singh MD MPH</td>
<td>Chief, Health Policy, Quality and Informatics Program, Center for Innovations in Quality, Effectiveness and Safety; Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine</td>
<td>'One Size DCISn't Fit All’ Noon seminar Delivered to Center staff</td>
<td>Hardeep Singh MD MPH</td>
</tr>
<tr>
<td>23</td>
<td>29/10/2018</td>
<td>12:00 – 13:00</td>
<td>Alastair M Thompson FRCSed BCM</td>
<td>'One Size DCISn't Fit All’ Noon seminar Delivered to Center staff</td>
<td>‘One Size DCISn’t Fit All’ Noon seminar Delivered to Center staff</td>
<td>Alastair M Thompson FRCSed BCM</td>
</tr>
<tr>
<td>24</td>
<td>29/10/2018</td>
<td>13:00 – 13:30</td>
<td>Daniel Murphy, MD, MBA</td>
<td>Physician &amp; Patient Safety Researcher, Baylor College of Medicine; Medical Director, General Internal Medicine</td>
<td>‘One Size DCISn’t Fit All’ Noon seminar Delivered to Center staff</td>
<td>Daniel Murphy, MD, MBA</td>
</tr>
</tbody>
</table>
| 25 | 29/10/2018    | 13:30 – 14:00 | 1. Traber Giardina, PhD  
2. Umber Shahid                                | 1. Assistant Professor, Baylor College of Medicine  
2. Graduate Assistant, University of Texas School of Public Health | ‘One Size DCISn’t Fit All’ Noon seminar Delivered to Center staff | 1. Traber Giardina, PhD  
2. Umber Shahid                                | 2002 Holcombe Blvd. 152 Houston | In person |
<p>| 26 | 29/10/2018    | 14:00 – 14:30 | Debra Choi, PhD, MPH                                                                | Post-Doctoral Fellow, VA Health Services Research Center for Innovations in Quality, Effectiveness, and Safety | ‘One Size DCISn’t Fit All’ Noon seminar Delivered to Center staff | Debra Choi, PhD, MPH | 2002 Holcombe Blvd. 152 Houston | In person |
| 27 | 29/10/2018    | 16:00 – 18:00 | Glaser Society Proceedings at the University of Texas School of Biomedical Informatics | Welcoming Remarks from Dr John P. Glaser, Presentation of the 2018 John P. Glaser Health Informatics Innovator Award to H. Stephen Lieber, Principal, Avisos Partners, LLC and Former President and CEO of HIMSS: 2018 John P. Glaser Health Informatics Innovator Award Recipient’s Lecture: “Paper to Digital: How Federal Policy Transformed Health IT in America” H. Stephen Lieber | ‘One Size DCISn’t Fit All’ Noon seminar Delivered to Center staff | Glaser Society Proceedings at the University of Texas School of Biomedical Informatics | UT Health Institute of Molecular Medicine Building Beth Robertson Auditorium | In person |
| 28 | 30/10/2018    | 11:00 – 12:00 | Safer Dx Meeting                                                                    | Center staff                                                             | ‘One Size DCISn’t Fit All’ Noon seminar Delivered to Center staff | Safer Dx Meeting | 2002 Holcombe Blvd. 152 Houston | In person |</p>
<table>
<thead>
<tr>
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<th>Date</th>
<th>Time</th>
<th>Event Details</th>
<th>Location</th>
</tr>
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<tbody>
<tr>
<td>29</td>
<td>30/10/2018</td>
<td>12:00 – 13:00</td>
<td>Special Seminar: ‘Driving healthcare improvements through digital innovation and digital health safety governance – an Australian perspective’ delivered by me</td>
<td>2002 Holcombe Blvd. 152 Houston In person</td>
</tr>
</tbody>
</table>
| 30 | 30/10/2018 | 13:00 – 13:30 | 1. Jessica Baldwin, BA  
2. Arushi Khanna, MPH  
3. Sahar Memon MPH  
4. Tyler Satterly M. ENG.  
1. Research Coordinator, VA Health Services Research Center for Innovations in Quality, Effectiveness, and Safety, Michael E. DeBakey Veterans Affairs Medical Center & Baylor College of Medicine  
2. Research Coordinator, VA Health Services Research Center for Innovations in Quality, Effectiveness, and Safety, Michael E. DeBakey Veterans Affairs Medical Center & Baylor College of Medicine  
3. Research Coordinator, VA Health Services Research Center for Innovations in Quality, Effectiveness, and Safety, Michael E. DeBakey Veterans Affairs Medical Center & Baylor College of Medicine  
4. Human Factors Engineer, Research Coordinator, VA Health Services Research Center for Innovations in Quality, Effectiveness, and Safety, Michael E. DeBakey Veterans Affairs Medical Center & Baylor College of Medicine |
| 31 | 30/10/2018 | 13:30 – 14:00 | 1. Ashley Meyer, PhD  
2. Li Wei, MS  
1. Cognitive Psychologist, Assistant Professor of Medicine, Baylor College of Medicine  
2. Programmer, VA Health Services Research Center for Innovations In Quality, Effectiveness, and Safety, Michael E. DeBakey Veterans Affairs Medical Center & Baylor College of Medicine |
| 32 | 31/10/2018 | 09:15 – 10:00 | Susan Fenton PhD, MBA, BS, RHIA, FAHIMA  
Associate Professor and Associate Dean for Academic Affairs, University of Texas Health Science Center, School of Biomedical Informatics |
| 33 | 31/10/2018 | 10:00 – 12:00 | 1. Samantha Reeves MHA  
2. Melissa Feldman  
3. David Kolacy B  
1. Innovation Program Manager, TMC Innovation Institute  
2. Program Analyst, TMC Innovation Institute  
3. Digital Health and Medical Device Innovation Strategy, TMC Innovation Institute |
| 34 | 31/10/2018 | 12:00 – 13:00 | Johann Lipman BME  
Product Development Manager, De Motu Cordis, TMC Innovation Institute |
| 35 | 01/11/2018 | 08:00 – 10:00 | Emma Aitken MA BA  
Investment Director, Houston, Australian Consulate-General Australian Trade and Investment Commission (Austrade) |
| 36 | 01/11/2018 | Staff Meeting | Center staff |
| 37 | 01/11/2018 | Robert E. Murphy MD | Associate Dean, Associate Professor, Applied Informatics, University of Texas Health Science Center, School of Biomedical Informatics |

Angela Ryan: angryan@gmail.com | +61 413 494294
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<th>No.</th>
<th>Date</th>
<th>Time</th>
<th>Name and Title</th>
<th>Description</th>
</tr>
</thead>
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<tr>
<td>38</td>
<td>05/11/2018</td>
<td>08:00 – 18:00</td>
<td>American Medical Informatics Association (AMIA) 2018 Annual Symposium</td>
<td>AMIA Conference San Francisco Hilton In person</td>
</tr>
</tbody>
</table>
| 39  | 05/11/2018 | 10:30 – 12:00 | 1. Dean F. Sittig PhD FACMI  
2. Adam Wright PhD MS  
3. Allison McCoy PhD MS | Professor, University of Texas Health Science Center, School of Biomedical Informatics; AMIA Board of Directors; UT Memorial Hermann Center for Healthcare Quality & Safety; Executive Director, Clinical Informatics Research Collaborative  
Associate Professor of Medicine, Harvard Medical School; Senior Scientist, Division of General Medicine at Brigham and Women's Hospital, Boston  
Assistant Professor, Vanderbilt University Medical Center, Tennessee | San Francisco In person                         |
| 40  | 05/11/2018 |                | Farah Magrabi PhD BE  
Associate Professor, Centre for Health Informatics, Australian Institute of Health Innovation | AMIA Conference San Francisco Hilton In person    |
| 41  | 05/11/2018 | 17:00 – 18:00 | N. Lance Downing MD  
Clinical Assistant Professor, Medicine – Biomedical Informatics Research; Medical Informatics Director, Stanford Health Care; Program Director, Partnership in AI-assisted Care (PAC, Clinical Effectiveness Research Center) | AMIA Conference San Francisco Hilton In person    |
| 42  | 06/11/2018 | 08:00 – 18:00 | AMIA 2018 Annual Symposium                                                                                                                     | AMIA Conference San Francisco Hilton In person    |
| 43  | 06/11/2018 | 13:30 – 14:00 | Patricia Dykes PhD, RN, FAAN, FACMI                                                                                                              | AMIA Conference San Francisco Hilton In person    |
| 44  | 06/11/2018 | 14:00 – 14:45 | Teresa Zayas Caban PhD MS  
Chief Scientist, Office of the National Coordinator for Health Information Technology (ONC HIT), US Department of Health and Human Services | AMIA Conference San Francisco Hilton In person    |
| 45  | 07/11/2018 | 08:00 – 13:30 | AMIA 2018 Annual Symposium                                                                                                                     | AMIA Conference San Francisco Hilton In person    |
| 46  | 07/11/2018 | 14:00 – 15:00 | Martin Seneviratne MD  
Masters Student in Biomedical Informatics, Stanford University  
John Monash Scholar (Australia) | San Francisco In person                         |
| 47  | 27/11/2018 |                | 1. Teresa Zayas Caban PhD MS  
2. Stephanie Garcia MPH BA  
3. David Chaney  
4. Janet Adeola | Chief Scientist, ONC HIT  
Public Health Analyst, ONC HIT at US Department of Health and Human Services  
CHECK  
Pathways Intern, Chief Scientist Division, ONC HIT | In person                                     |
| 48  | 27/11/2018 |                | 1. Teresa Zayas Caban PhD MS  
2. Don Rucker MS MBA MD  
3. Jon White MD BA | Chief Scientist, ONC HIT  
National Coordinator, ONC HIT  
Deputy National Coordinator, ONC HIT  
Chief Clinical Officer, ONC HIT | In person                                     |
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<th>Name</th>
<th>Title / Role</th>
<th>Location</th>
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<tr>
<td>49</td>
<td>27/11/2018</td>
<td></td>
<td>Raj Ratwani PhD MA BS</td>
<td>Center Director, National Center for Human Factors in Healthcare</td>
<td>In person</td>
</tr>
<tr>
<td>50</td>
<td>27/11/2018</td>
<td></td>
<td>Terry Fairbanks MD MS BA</td>
<td>Vice President, Quality &amp; Safety, MedStar Health; Founding Director, National Center for Human Factors in Healthcare; MedStar Institute for Innovation, Professor, Emergency Medicine, Georgetown University; Attending Emergency Physician, MedStar Washington Hospital Center</td>
<td>In person</td>
</tr>
<tr>
<td>51</td>
<td>28/11/2018</td>
<td>14:30 – 15:00</td>
<td>Susannah Fox BA</td>
<td>Former Chief Technology Officer, Health &amp; Human Services (HHS) (Obama Administration), Board member, Healthcare consultant</td>
<td>Teleconference</td>
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<tr>
<td>52</td>
<td>29/11/2018</td>
<td>All-day</td>
<td>ONC 2018 Annual Meeting</td>
<td>Project Director, Health Information Technology, The Pew Charitable Trusts</td>
<td>Washington Hilton Washington DC In-person</td>
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<td>54</td>
<td>29/11/2018</td>
<td></td>
<td>Jeffrey Smith MPP, Scott Weinberg MPA</td>
<td>Vice President, Public Policy, AMIA, Public Policy Specialist, AMIA</td>
<td>Washington Hilton Washington DC In-person</td>
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<td>29/11/2018</td>
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<td>Dr Patricia Flatley Brennan RN, PhD</td>
<td>Director, National Library of Medicine, National Institutes of Health, US Department of Health and Human Services</td>
<td>National Library of Medicine, National Institutes of Health Bethesda, MD 20894 In-person</td>
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<td>56</td>
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<td>ONC 2018 Annual Meeting</td>
<td>Executive Director, Office of Technology, ONC HIT</td>
<td>Washington Hilton Washington DC In-person</td>
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<td>Steve Posnack MHS, MS, BS</td>
<td>Executive Director, Office of Technology, ONC HIT</td>
<td>Washington Hilton Washington DC In-person</td>
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<td>30/11/2018</td>
<td></td>
<td>Christine Dymek Ed. D</td>
<td>Director, Division of Health Information Technology, Agency for Healthcare Research and Quality’s (AHRQ) Center for Evidence and Practice Improvement.</td>
<td>Washington Hilton Washington DC In-person</td>
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<td>03/12/2018</td>
<td>15:00 – 16:00</td>
<td>Janet M Marchibroda</td>
<td>Fellow, Bipartisan Policy Center</td>
<td>In-person</td>
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<td>61</td>
<td>10/12/2018</td>
<td>09:00 – 10:00</td>
<td>Dr David Bates MD MSC FACMI</td>
<td>Physician, Brigham and Women’s Hospital, Professor of Medicine, Harvard Medical School</td>
<td>In-person</td>
</tr>
<tr>
<td>Date</td>
<td>Time</td>
<td>Participants</td>
<td>Details</td>
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| 10/12/2018| 10:00 – 11:00  | 1. Ishani Ganguli, MD, MPH, Lipika Salmal MD MPH, Jeff Schnipper MD, MPH, BA | 1. Clinician Investigator, Brigham and Women’s Hospital Division of General Internal Medicine and Primary Care
2. Associate Physician, Brigham and Women’s Hospital Assistant Professor of Medicine, Harvard Medical School
3. Associate Physician, Brigham and Women’s Hospital Assistant Professor of Medicine, Harvard Medical School | In-person |
| 10/12/2018| 11:00 – 12:00  | Karen M. Sherritt, MD                                                        | Assistant Professor of Medicine, Part time, Harvard Medical School; Primary Care Physician, The Phyllis Jen Center for Primary Care, Brigham and Women’s Hospital | In-person |
| 11/12/2018| 09:00 – 10:00  | Hojjat Salmasian MD PhD MPH                                                  | Program Director, Data Science and Evaluation at Brigham and Women’s Hospital | In person |
| 11/12/2018| 11:30 – 12:00  | Adam Wright PhD BS                                                           | Associate Professor of Medicine at Harvard Medical School and a Senior Scientist in the Division of General Medicine at Brigham and Women’s Hospital | In person |
| 11/12/2018| 11:30 – 12:00  | Amy L. Billett, MD 'Clinical Informatician’s Guide to Patient Safety' Seminar: Francis A. Countway, Library of Medicine, Harvard University | Director of Safety and Quality, Division of Pediatric Hematology/Oncology; Institute Physician; Associate Professor of Pediatrics, Harvard Medical School Dana-Farber/Boston Children’s Cancer and Blood Disorders Center, Boston Children’s Hospital | In-person |
| 11/12/2018| 11:30 – 12:00  | Karen M. Sherritt, MD                                                        | As above                                   | Follow-up Teleconference |
| 11/12/2018| 11:30 – 12:00  | Patricia Dykes, RN, PhD, MA                                                  | As above                                   | Follow-up meeting In-person |
| 13/12/2018| 16:00 – 16:30  | Andrew Gettinger MD                                                         | Chief Clinical Officer, ONC HIT            | Follow-up Teleconference |
| 13/12/2018| 16:30 – 17:00  | Elise Sweeney Anthony JD                                                     | Executive Director, Office of Policy, ONC HIT | Teleconference |
| 04/01/2019 | 08:00 – 08:30  | Robert Wah MD                                                                | DXC’s Global Chief Medical Officer; Former President, American Medical Association (AMA); First Deputy National Coordinator for Health IT [https://www.healthit.gov/hitac/member/wah](https://www.healthit.gov/hitac/member/wah) | Teleconference |
| 08/01/2019 | 08:30 – 09:00  | Kate Goodrich MD                                                             | Director, Center for Clinical Standards & Quality, Chief Medical Officer, Center for Medicare & Medicaid Services (CMS); Associate Professor of Medicine George Washington University Medical Center | Teleconference |
| 12/01/2019 | 08:00 – 08:30  | Amy L. Billett, MD                                                           | As above                                   | Teleconference |
| 17/01/2019 | 08:00 – 08:30  | Matthew Holt MS BA                                                           | President at SMACK.Health; Co-Chair, Health 2.0, Co-Chair, Catalyst @ Health 2.0, Founder, The Health Care Blog | Teleconference |
| 19/01/2019 | 08:00 – 08:30  | Jason Adelman MD MS BA                                                       | Chief Patient Safety Officer, Associate Chief Quality Officer, Executive Director of Patient Safety Research; Executive Director, Patient Safety Research; Co-Director of the Patient Safety Research Fellowship in Hospital Medicine; Assistant Professor of Medicine; Assistant Professor of Biomedical Informatics | Teleconference |
References

2 Ibid
3 https://www.ncbi.nlm.nih.gov/books/NBK189648/
6 http://hshafa.ajums.ac.ir/centrallib/Documents/Article%20203_20150419_133924.pdf
7 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3240763/
8 https://academic.oup.com/jamia/article/24/2/246/2723147
16 Australian Alliance for Artificial Intelligence in Healthcare, 2019, Submission to the Medical Research Future Fund, Stage One Research Plan
18 Ibid
19 Ibid
23 https://www.ncbi.nlm.nih.gov/books/NBK189648/
24 Dean F. Sittig, Elisabeth Belmont, Hardeep Singh, Improving the safety of health information technology requires shared responsibility: It is time we all step up, Healthcare 6 (2018) 7–12
25 Dean F. Sittig, Elisabeth Belmont, Hardeep Singh, Improving the safety of health information technology requires shared responsibility: It is time we all step up, Healthcare 6 (2018) 7–12
26 https://twitter.com/TerryFairbanks/status/1091991395705999361
28 Dean F. Sittig, Elisabeth Belmont, Hardeep Singh, Improving the safety of health information technology requires shared responsibility: It is time we all step up, Healthcare 6 (2018) 7–12
30 Dean F. Sittig, Elisabeth Belmont, Hardeep Singh, Improving the safety of health information technology requires shared responsibility: It is time we all step up, Healthcare 6 (2018) 7–12
31 https://en.wikiquote.org/wiki/George_Santayana
32 http://www.learninghealthcareproject.org/section/background/learning-healthcare-system
33 https://www.ncbi.nlm.nih.gov/books/NBK189648/
34 https://www.longwoods.com/content/24724/healthcarepapers/embedding-research-in-the-learning-health-system
36 http://www.learninghealthcareproject.org/about.php
42 https://academic.oup.com/jamia/article/22/2/472/695545?searchresult=1
46 Ratwani et al, 2018, Improving Electronic Health Record Usability and Safety Requires Transparency, JAMA Network
47 https://www.ecu.edu.au/__data/assets/pdf_file/0005/685274/86_Allan_OD_Literature_Review.pdf
48 Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England
51 Professor Jeffrey Braithwaite, October 17, 2018, ‘Refashioning the Quality Agenda Over the Next Decade’ Health Quality Transformation 2018, Toronto, Canada
52 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3511782/
53 https://www.bmj.com/content/361/bmj.k2014

Angela Ryan: angryan@gmail.com | +61 413 494294
Eyal Zimlichman,1 Ronen Rozenblum,1 Claudia A Salzberg,1 Yeona Jang,2 Melissa Tamblyn,3 Robyn Tamblyn,4,5 David W Bates1


https://www.ecrc.org/hit/assembling-stakeholders

https://www.ecrc.org/hit/assembling-stakeholders/

https://www.houston.hsrresearch.va.gov/about.asp


https://webstore.ansi.org/standards/aami/saamihit1000ps2018


https://webstore.ansi.org/standards/aami/saamihit1000ps2018


https://www.houston.hsrresearch.va.gov/about.asp

https://www.ansi.org/standards/aami/aamihit1000ps2018
