- We will focus on regulatory updates in the area of medical devices
- Specifically, CDS and AI tools

The Food and Drug Administration (**FDA**)	Safety Effectiveness	Adoption Accessibility	The Office of the National Coordinator for Health Information Technology (**ONC**)
Centers for Medicare & Medicaid Services (**CMS**) & The Federal Trade Commission (**FTC**)	Meaningful use No deception	Privacy Security	The Health Insurance Portability and Accountability Act (**HIPAA**) of 1996 enforced by the Office for Civil Rights (**OCR**)

Example – CDS Guidance and Regulation

- Federal Food, Drug and Cosmetics Act (**FFDCA**) of 1938; its multiple amendments

- The **21ˢᵗ Century Cures Act** of 2016.

- On September 28, 2022, FDA clarified the scope of clinical decision support (**CDS**) software that it considers subject to medical device regulation

HIMSS EHR Association Letter to FDA

- highly intertwined nature of CDS with EHR technology

- "*The FDA's guidance does not appropriately reflect the reality that decision alerts are frequently created and configured by provider organizations and that for many health IT solutions, the developer asserts little or no control over CDS configuration*"

- "*It is unclear who ultimately has an obligation to enforce compliance when a provider is using the solution to deliver CDS they have developed themselves or purchased and implemented directly from a third party.*"

CDS Coalition Petition to FDA

- FDA's guidance exceeds Congress's statutory definitions of what is considered CDS and threatens to undermine lawmakers' goals

- FDA's own record in connection with CDS software shows that there is no public health problem to be solved.

- FDA is harming, not helping, public health by dissuading innovators from evolving CDS software for the betterment of the public and imposing arbitrary rules on technology development that do not serve their intended purpose.

https://www.healthcareitnews.com/news/cds-coalition-requests-fda-rescind-final-decision-support-guidance

Conclusions

• Need for harmonization of legislation
• Much of this software is used to reduce medical errors, provide the best evidence based CDS tools to ensure patients get the best ideas/care from overworked, overwhelmed and burned-out providers who are contemplating leaving the profession based on COVID excess, irrational demands, etc.
• Trade off analysis: The FDA should be weighing the value of reducing potential automation bias against the amplification of clinician burnout by reducing the development/use of clinical innovation tools such as CDS.

Australia

Clinical safety governance: rules and processes to maximise <u>whole of system</u> safety

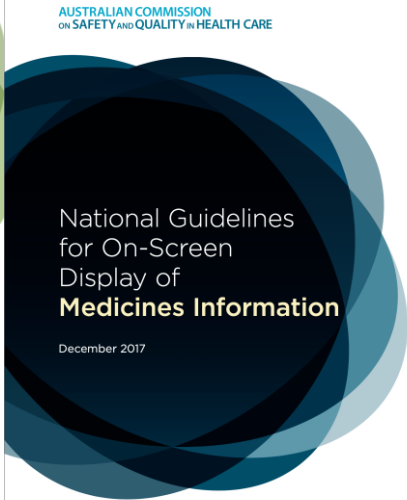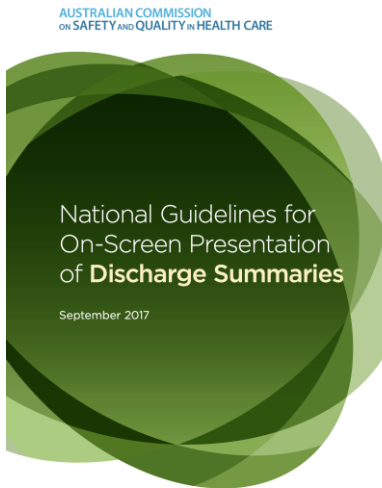**Focus:** design & build, implementation or use

1. **Information system standardisation**
   - guidance
   - technical standard
   - regulation mandated standard
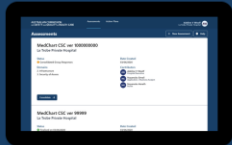
2. **Oversight**
   - certification
   - regulation
   - incident monitoring

Guidelines

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

National Guidelines for On-Screen Presentation of **Discharge Summaries**

September 2017

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

National Guidelines for On-Screen Display of **Medicines Information**

December 2017

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Electronic Medication Management Systems

A guide to safe implementation

3rd edition

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

EMMSAT
Electronic Medication Management
Self Assessment Tool

A free, flexible, multi-contributor standardised assessment tool that supports Health Service Organisations (HSOs) identify and target EMM systems issues for improvement.

Login →   More Info   Register

Standards: Digital Mental Health

National Safety and Quality Digital Mental Health Standards

Clinical and Technical Governance Standard

Model of Care Standard

Partnering with Consumers Standard

National AI priorities in Healthcare	Rank	Percentage (%)
Safety, quality and ethics	1	17.8
Privacy and security	2	15.3
Governance and leadership	3	13.7
Research and development	4	11.7
Workforce	5	11.6
Consumers	6	11.2
Adoption	7	10.5
Industry	8	8.2

MACQUARIE University

AUSTRALIAN INSTITUTE OF HEALTH INNOVATION

AAAiH — Australian Alliance for Artificial Intelligence in Healthcare

A ROADMAP FOR ARTIFICIAL INTELLIGENCE IN HEALTHCARE FOR AUSTRALIA

Regulation of software as a medical device

Australian Government
Department of Health
Therapeutic Goods Administration

Regulatory changes for software based medical devices

Version 1.2, August 2021

TGA Health Safety Regulation

Artificial Intelligence Chat, Text, and Language

Artificial intelligence text-based products like ChatGPT, GPT-4, Bard, and other large language models (LLMs) have recently received media attention.

When LLMs have a medical purpose and are supplied to Australians, they may be subject to medical device regulations for software and need approval by the TGA. It is important to note that regulatory requirements are technology-agnostic for software-based medical devices and apply regardless of whether the product incorporates components like AI, chatbots, cloud, mobile apps or other technologies. In these cases, where a developer adapts, builds on or incorporates a LLM into their product or service offering to a user or patient in Australia - the developer is deemed the manufacturer and has obligations under section 41BD of the *Therapeutic Good Act 1989*.

June 2023

Current initiatives

Australian Government
Department of Industry,
Science and Resources

**Safe and responsible
AI in Australia**

Discussion paper

June 2023

| consult.industry.gov.au/supporting-responsible-ai

Australia's AI Ethics Principles

A voluntary framework

The principles are voluntary. We intend them to be aspirational and complement – not substitute – existing AI regulations and practices.

By applying the principles and committing to ethical AI practices, you can:

- build public trust in your product or organisation
- drive consumer loyalty in your AI-enabled services
- positively inf
- ensure all Au

**Mandatory Ethical Principles for
the use of AI**

On this page

Community benefit

Fairness

Privacy and security

Transparency

Accountability

NSW GOVERNMENT

Digital.N

CSIRO National Artificial Intelligence Centre

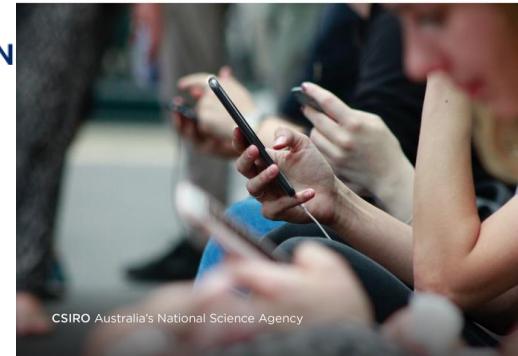GRADIENT INSTITUTE

Implementing Australia's
AI Ethics Principles:

A selection of Responsible AI
practices and resources

June 2023

CSIRO Australia's National Science Agency

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Japan

Regulations and Strategies

- Pharmaceuticals and Medical Devices Agency (PMDA), Japan

- Pharmaceuticals and Medical Devices (PMD) Act
    - 2019 Amendment
    - May 2023

- DASH for SaMD (DX(Digital Transformation) Action Strategies in Healthcare for SaMD, 2020)

- IDATEN - Improvement Design within Approval for Timely Evaluation and Notice (2020)

Risk-based classification system for medical devices

Risk class	Definition	Registration category	Review body
General medical device Class I	The risk to patients in the event of malfunction is regarded as almost **negligible**.	Notification	**Self Declaration**
Controlled medical device Class II	The risk to patients in the event of malfunction is regarded as **relatively low**.	Certification or Approval	**PMDA or Registered Certification Body**
Specially controlled medical device Class III	The risk to patients in the event of malfunction is regarded as **relatively high**.	Certification or Approval	PMDA or Registered Certification Body
Specially controlled medical device Class IV	The device is highly invasive with **potentially fatal risk** to patients.	Approval	PMDA

Programmable medical devices

DASH for SaMD, 2020

a package strategy that promotes the early practical use of cutting-edge programmable medical devices

Unable to grasp emerging seeds (ideas)

Substantial time required for case publication

Early identification of seeds

Development strategy with practical application in mind

Case publication/ Guidelines

Individual consultations and guidance

Rapid approval review

Early approval of cutting-edge medical devices

Uncertain applicability of the PMD Act / Unclear review process and performance trial

Absence of a central platform for consulting services / Fragile review and consultation system

DX(Digital Transformation) Action Strategies in Healthcare for SaMD(Software as a Medical Device).
https://www.mhlw.go.jp/content/11124500/000761867.pdf

IDATEN - Improvement Design within Approval for Timely Evaluation and Notice (2020 onwards)

- A system to enable the approval of improvement plans for medical devices based on their anticipated future enhancements and unique characteristics.
  - Applicable to programmable medical devices
- Since 2018, more than 24 AI Medical Devices have emerged in Japan (as of Nov 2022), these include COVID-19 pneumonia image analysis (2021; Fujifilm - CT), nodoca (2022; Aillis - Endoscope)

Original

Initial Approval Application
- Application -> Examination Approval ->
- Fee incurred

Product improvement

Partial Change Approval Application
- Application -> Examination Approval ->
- Fee incurred

Further Product improvement

Partial Change Approval Application
- Application -> Examination Approval ->
- Fee incurred

IDATEN program

Initial Approval Application
- Application -> Examination Approval ->
- Fee incurred

Product improvement

IDATEN Application/ Notification
Confirmation of improvement plan

Minor Change Notification
- No examination*
- Fee incurred

*If the change is as per the advance improvement plan

Messages

- DASH allows private consultation to promote the early practical use of cutting-edge SaMD

- Timely evaluation and notification of improvements are possible under IDATEN

- A concept of two-step approval is newly introduced to ensure safety and efficacy from pre-marketing to post-marketing. (May, 2023)

- In Japan, AI is utilized as a supporting tool and is not intended for treatment or diagnosis unless it has obtained approval as a medical device.
  - Physicians (human) remain the subject of judgment

European Union

Stephanie Medlock

- Assistant professor in Decision Support systems

- Developer, implementer, evaluation researcher

- Involved in implementation of 2 systems under the new EU MDR

When did it change?

- Announced 2018, implemented 2020

What changed?

- Most importantly for our field: software is now *explicitly* identified as a medical device; many applications now belong to a higher risk class

What was the goal of the changes?

- To provide more oversight and regulation around the proliferation of software devices making health-related claims

What does it mean for researchers?

If the trial is *testing the medical device functions*, then the trial must be registered as a medical device trial

Two options:

- Article 62: Trial is a part of the CE mark process (including early pilots)
- Article 82: Trial is *not* part of the CE mark process

... but there appears to be different interpretation of this between countries!

In practice, most researchers seem to be intimidated by the process and try to avoid projects which involve a clinical trial.

What does it mean for implementers?

If the software is a medical device, it *cannot be distributed* unless the users are participating in a clinical trial *or* it has a CE mark.

This introduces a major hurdle between bench and bedside.

Other issues

- Misconceptions and misunderstandings

    "Open source software is not compatible with the MDR" (it *is* compatible, and open hardware medical devices have been around a long time)

    "You don't have to get a CE mark if it's integrated with the EHR" (you *do*, if it adds functionality that wasn't approved by a previous CE mark)

- Different interpretations in different EU countries

    NL: "Clinical investigation carried out for conformity purposes fall under MDR article 62. All other clinical investigations fall under MDR article 82."

    IT: "All clinical trials should be registered under article 62.

Tips (for EU researchers)

- Don't be intimidated!

- Understand the requirements for a clinical trial and file the paperwork on time.

- If you want users to keep using the software after the trial, make sure the partners, sufficient time, and funding to get a CE mark are included in the project plan.

- May be easier to get a CE mark *only for the medical device functionality*, not for the whole software package.

United Kingdom

- Topics

  - Regulatory messiness

  - Diverse political attitudes to regulation

  - Differing conceptualization of "computable knowledge", "device" and "medical purpose"

- UK regulatory messiness

  - Brexit has left many unfortunate gaps and loose ends…
    - Northern Ireland is still in EU single market so follows EU device regulation.
    - Great Britain (England, Scotland, Wales) has its own regulation.

  - Health is a devolved policy, so each UK nation has a different focus and its own set of agencies. There is no single NHS in the UK.

- UK regulatory messiness
  - Multiple agencies collaboratively provide "AI and Digital Regulations Service"
    - Medicines and Healthcare products Regulatory Agency (MHRA, UK for some things, GB for others)
    - National Institute for Health and Care Excellence (NICE, England and mostly Wales)
    - Health Research Authority (HRA, mostly England, partly UK)
    - Care Quality Commission (CQC, England).

  - Status of English NHS clinical safety standards for health IT systems (DCB 0160, 0129) is unclear given more recent legislation.

- Diverse political attitudes to regulation
  - Right-wing parties are anti-regulation and pro-innovation.
  - Left-wing parties are pro-regulation and pro-innovation.
  - Crudely, current English government is right-wing, Wales and Scotland are left-wing and Northern Ireland is in limbo.
  - Innovate UK does provide funding across all 4 nations.

- Differing conceptualization of "computable knowledge", "device" and "medical purpose"
  - Concept of computable knowledge as distinct from data or software is gaining traction but does not fit regulatory worldview embodied in law.
  - MHRA recognizes "device" (physical thing or executable software) and "medical purpose" (broadly, diagnostic or therapeutic).
  - "Computable" knowledge may or may not be executable (think risk calculator versus referral e-form) and may or may not have a "medical" purpose (think prescribing decision support versus directory of services used in triage)
  - Yet, the generation and implementation of knowledge *of all types* is at the heart of Learning Health Systems – the essence of continuous innovation and improvement.

Discussion

- What are your thoughts?

- What is the right balance between regulations and innovations?