IMDRF /DITTA joint workshop

Artificial Intelligence in Healthcare
Opportunities and Challenges

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Industry Responsibility and Liability

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- Industry Responsibility

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Artificial Intelligence should throughout its entire lifecycle

- Be lawful, complying with all applicable laws and regulations

- Be ethical, ensuring adherence to ethical principles and values

- Be robust and reliable, not to cause unintentional harm

Complying with the law should be understood in the broadest sense as this can relate to technical regulations, product liability, intellectual property, competition policy and others.

There have been multiple papers published from a variety of sources regarding the ethical use of AI

- ❖ International level
  - OECD Principles on AI
  - IEEE - Ethically Aligned Design
  - Asilomar AI Principles

- ❖ Europe
  - EU High Level Expert Group on Artificial Intelligence (HLEG AI) – Ethics Guidelines for Trustworthy AI
  - AI4People – Ethical Framework for a Good AI Society

- ❖ Canada
  - Montreal Declaration for Responsible AI

Items discussed include:
- Users should be made aware they are interacting w/AI
- Should be no discrimination nor exploitation
- Transparency on how information will be used

Note: modern software is very complex and is often a large combination of proprietary code, commercially available code, and open source code. This can complicate the responsibility landscape. Responsibility for data quality can also be complicated.

To achieve this, organizations need to embrace this responsibility early in the development process. One **suggestion is to leverage the concept of "security by design" to implement "ethical by design" processes.**

The organization should also have processes in place for when harm does occur.

WHY CARE ABOUT LIABILITY?

- One of the barriers to AI adoption is concerns regarding liability – who is responsible when something goes wrong?

- Perceived liability concerns further reinforce the need to think about explainability and trust.

- People can have unrealistically high expectations of product performance.

- **Note other industries don't require the level of** explainability that we expect from healthcare – an example is a self-driving vehicle is not required to give a running **narrative justifying it's decisions...**

ACCOUNTABILITY

"AI introduces an increased potential for automation bias, where professional judgement can be influenced by the recommendation of a technology solution. There is an increasing reliance on technology and automation in peoples' lives, which raises questions of whether a person is undertaking their own informed decision-making.

…There needs to be agreement for where liability would lie if an error occurred, and whether the existing frameworks for incident reporting are fit for purpose.

Regulations and standards covering AI technologies need to remain separate from those that address professional practices and healthcare services operations. Medical device regulations protect the public interest in relation to the safety and effectiveness of an AI solution, but are independent from the clinician or hospital utilizing the technology to provide advice or a diagnosis. It is important that clinicians – and service managers in some situations – remain accountable for the decisions they make."

The emergence of artificial intelligence and machine learning algorithms in healthcare: Recommendations to support governance and regulation

Position paper
Prepared by BSI and AAMI

bsi. ✳ MHRA AAMI
Advancing Safety in Health Technology

COCIR Advancing Healthcare JIRA Medtech Canada MITA MEDICAL IMAGING & TECHNOLOGY ALLIANCE A DIVISION OF NEMA THAIMED IMEDA 中国医疗器械行业协会 China Association for Medical Devices Industry abimed Kmdica Korea Medical Devices Industrial Coop. Association ITAC INFORMATION TECHNOLOGY ASSOCIATION OF CANADA

PRIVACY

- Privacy is also of concern – either accidental or malicious disclosure of patient information can lead to liability issues.
- Note this can be an issue during training, validation, or product use.

LIABILITY - OVERTRUST

- Will people stop using critical thinking and will trust the software too much?

- During the 2017 California fires, the LA Times **Reported "The Los Angeles Police Department** asked drivers to avoid navigation apps, which are steering users onto more open routes — in this case, streets in the neighborhoods that are on fire. "
  - http://www.latimes.com/local/california/la-me-southern-california-wildfires-live-firefighters-attempt-to-contain-bel-air-1512605377-htmlstory.html

- Millennials are 2x as likely to fall for phishing and online scams compared to Baby Boomers (Source: **UK's Get Safe Online)**
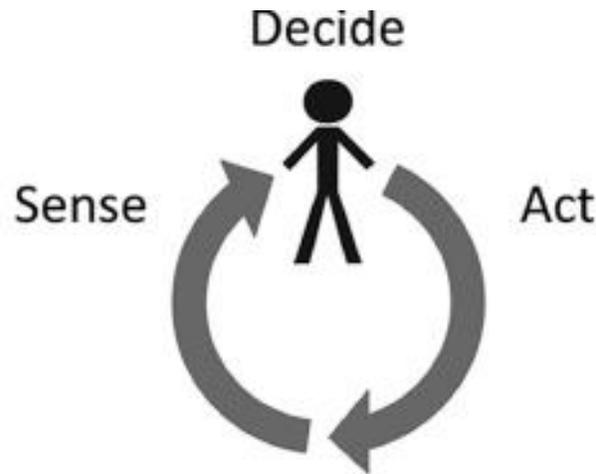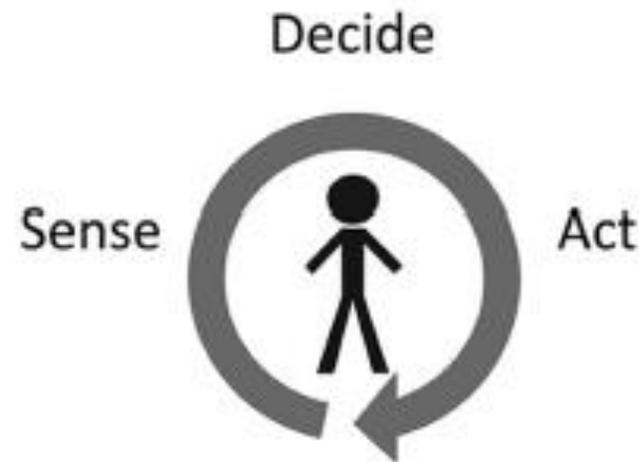
LIABILITY WILL SCALE TO LEVEL OF AUTONOMY..

**First level needs a human to complete the task**

Decide

Sense   Act

The machine performs a task and then waits for the human user to take an action before continuing.

Second level allows for human over-ride

Decide

Sense   Act

The machine can sense, decide, and act on its own. The human user supervises its operation and can intervene, if desired.

Third level does not allow for intervention

Decide

Sense   Act
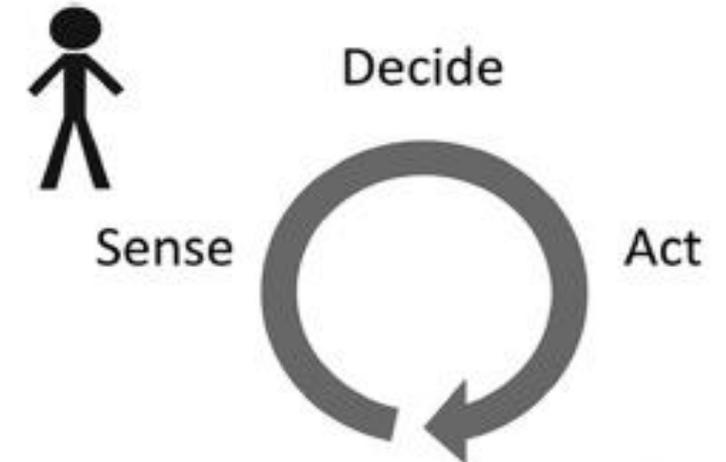
The machine can sense, decide, and act on its own. The human cannot intervene in a timely fashion.

EXAMPLE PROPOSED LAWS

The need to clarify liability laws has been recognized by some stakeholders and there are some draft legislation such as:

- "... **requiring companies ... to conduct impact assessments of highly** sensitive automated decision systems. This requirement would apply both to new and existing systems.

- Require companies to assess their use of automated decision systems, <u>including training data</u>, for impacts on accuracy, fairness, bias, discrimination, privacy, and security.

- Require companies to evaluate how their information systems protect the **privacy and security of consumers' personal information.**

- Require companies to correct any discriminatory issues they discover during **the impact assessments."**

ADDITIONAL QUESTIONS...

- There has been some discussion about joint liability – some use cases have both the clinician and the AI working together to come to a conclusion. If there is patient harm, both parties are liable..
- Clinicians are licensed professionals. What do we need to change about clinician licensing to support informed use of AI?
- It has been suggested the fully autonomous systems should be licensed as well – if they are replacing a clinician, then they should be subject to the same requirements as a clinician.

The more we can understand about a particular event, the better we can identify liability (and improve quality.)
Suggestions include:

- Version control – software executable, data sets, and supportive infrastructure (network, cloud storage, etc)
- Usage logs
- Retention of training data to support incident reconstruction

For high-liability-risk applications, is there a need for **"design for reproducibility" guidelines?**

Thank you!
Спасибо!

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