Patient Engagement Advisory Committee: Artificial Intelligence and Machine Learning in Medical Devices

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Introductions

20 years in medical device field:
- – Software engineer,
- – Systems engineer,
- – Human Factors engineer,
- – Risk Manager,
- – Regulatory Specialist ("Policy Engineer")

- – New product development,
- – Support for existing and legacy products

- – Participate in multiple AI-related committees, nationally and internationally, including the World Health Organization.

Royal Philips is a leading health technology company focused on improving people's health and enabling better outcomes across the health continuum from healthy living and prevention, to diagnosis, treatment and home care. Philips leverages advanced technology and deep clinical and consumer insights to deliver integrated solutions.

Our purpose

"As a leading health technology company, it is our purpose to improve people's health and well-being through meaningful innovation. We aim to improve 2.5 billion lives per year by 2030."

Potential Impact of AI in Healthcare

"Machines will not replace physicians but physicians using AI will soon replace those not using it."
AI-augmented multidisciplinary teams: hype or hope? (Di Ieva, 2019) The Lancet

Fierce Healthcare coverage of CB Insights Report
AI will be critical in meeting the care needs of a growing, aging population facing projected physician shortages. However, concerted effort is needed to assure this tech advances the quintuple aim.
National Academy of Medicine Report on AI (Matheny et al., 2019)

FIGURE S-1 | Advancing to the Quintuple Aim
SOURCE: Developed by publication editors

Getting to know Patients: Data vs. Knowledge

Merriam Webster defines Knowledge as
  The fact or condition of knowing something with familiarity gained through experience or association.

In healthcare, we have a great deal of data. With the introduction of wearables, we have even more data. It is estimated[1] that there will be 41 billion connected IoT[2] devices generating 79 zetabytes of data (79 trillion gigabytes) by 2025.

This is a very attractive amount of data for developers – there are many different types of analysis that can turn data into evidence.

Unfortunately, data without context, without knowledge of how the data was collected, and under what circumstances, is not very useful and can lead to incorrect conclusions. There is a lot that can be learned from both homogenous and diverse datasets, but we need to understand the context of that data.

[1] https://www.idc.com/getdoc.jsp?containerId=prUS45213219
[2] IoT = Internet of Things

Getting to know Patients, continued..

- To help support our patients, we need to become more familiar with them, their medical conditions, their environment, and their needs and wants to be able to better understand the potentially confounding factors factors that drive some of the trends in the collected data.
- No data set is perfect, and we need patient's help to understand those factors.

Common ML Topic: Bias

- Many conversations about ML eventually start talking about the potential impact of "bias"[1] in the training or test data set.
- An algorithm trained for one subset of the patient population might not be relevant for a different subset. For example, data from a pediatric hospital might not be valuable to a geriatric hospital, and vice versa.
- Similarly, an algorithm trained for the entire patient population might not be relevant for a subset.
- This bias in the data is not intentional, but can be hard to identify.
- It is possible that adaptive systems that continue to learn over time will adapt themselves to a particular hospital's patient population, but this introduces new challenges, including:
  - You may receive different diagnosis / treatment depending on which hospital you go to.
  - What happens when a patient moves from one hospital system to another?
  - Configuration management challenges – software, systems, and biases are different for every hospital

[1] ISO 27000 defines **bias** systematic difference in treatment of certain objects, people, or groups in comparison to others

Common ML Topic: Bias continued..

Suggestion: Encourage the development of a taxonomy of bias types. This would help

       a) in the identification of potential bias during product development,

       b) Provide a consistent naming convention between customer, regulators, and developers

This taxonomy should be publically available and a mechanism be put in place to maintain and update it as the field evolves. This is a potential project for the FDA's Collaborative Community..

Common ML Topic: Trustworthiness

- Many conversations about ML eventually start talking about how "trustworthy" an application is. The system has learned something from it's training data, but there are concerns regarding the "black box" nature of how the algorithm works.
- There are several technical standards currently under development regarding trustworthiness and explainability, however, many of those are not specific to healthcare.
- Industry is very interested in understanding the patient need regarding trust, and what are some of the variables are that impact this trust. Not every patient population will have the same needs, things will vary by the type of disease, the age and education of the patient, past experience, etc. While a lot has already been published about the importance of trust, it would be useful to understand the different shades of gray from the patient's perspective.

Summary

- AI has the potential to improve healthcare in many ways
- One challenge will be turning data into knowledge
- Another challenge will be addressing potential biases
- People won't use what they don't trust

Bottom line: all stakeholders need to be engaged – we especially need representation from a varied population of patients. **We need to use our collective intelligence to help produce better artificial intelligence applications.**