Overview of AI Standardization Activities

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TABLE OF CONTENTS

• ISO/IEC Standards
• Other Standards & Pre-Standards Work
• Terminology Challenges & Success Factors
• World Health Organization
Multiple working groups, developing standards for all industries:

WG1 – Foundational standards (terminology, framework)
WG2 – Big Data (vocabulary, reference architecture)
WG3 – Trustworthiness (incl. risk, robustness, bias)
WG4 – Use cases and applications
WG5 – Computational approaches
JWG1 – Governance implications of AI
AHG1 – Dissemination and outreach

Informally thinking about developing a QMS standard...
BSI-AAMI JOINT INITIATIVE FOR ‘AI HEALTHCARE’ STANDARDS

• UK-U.S. collaboration, with support from MHRA and FDA
• Research, surveys, in-depth discussions
• Stakeholder workshops (autumn 2018):
  – challenges, alignment to regulatory and standards landscape, information gaps, proposed solutions
  – terminology & categorization, alignment to IMDRF principles, next steps and priorities
• Position Paper published February 2019
BSI-AAMI - RECOMMENDATIONS AND NEXT STEPS

• Create an international task force for AI in healthcare
• Map current standards and identify opportunities for new or modified content
• Develop scopes and proposals for new standards covering:
  – Terminologies and categorization
  – Validation processes
• Build a communications and engagement plan
• Current state: working on 2nd whitepaper as well as analysis of IMDRF Essential Principles
OTHER STANDARDS: CONSUMER TECHNOLOGY ASSOCIATION (CTA)

• CTA is the trade association for the consumer technology industry (all consumer industries – not just healthcare)

• Established AI working group, published two whitepapers in 2018 – general introduction & use cases & AI standards committee (R13) & Health Care working group (R13 WG1)

• Plans include terminology and best practices for management and oversight of data, and a paper on trustworthiness. Scope includes consumer health, fitness, and wellness technology.
OTHER STANDARDS: IEEE

• **P7000** “Engineering Methodologies for Ethical Life-Cycle Concerns Working Group”, for all industries; includes Transparency, Privacy, Personal Agents, etc.

• **P2801** Recommended Practice for the Quality Management of Datasets for Medical Artificial Intelligence Recommendation

• **P2802** Standard for the Performance and Safety Evaluation of Artificial Intelligence Based Medical Device: Terminology
• Started in late August 2017 at the Xavier University AI Summit
• Group of experts from medical device and pharmacology industries, academia, government
• Purpose:
  Maximize the advantages of artificial intelligence in advancing patient health by identifying how to provide a reasonable level of **confidence in the performance of continuously learning systems** in a way that minimizes risks to product quality and patient safety
PRE-STANDARDS: XAVIER HEALTH, CONTINUED

• Published 2018 paper on Good Machine Learning Practices – “what’s different about AI?”

• In October 2019 will publish a paper on Trustworthiness

• Next paper will be related to Risk Management
TERMINOLOGY CHALLENGES

• Agreeing to definitions often takes time, even when people are from the same industry.

• Artificial Intelligence practitioners have their own set of terminology that sometimes conflicts with what we think of in medical devices.

• “Validation” for medical devices often refers to meeting user needs; but “validation” in data science is making sure the data is valid (e.g. a negative heart rate is probably not a valid piece of data).

• “Bias” is something that data scientists try to eliminate, but I’ve talked to many caregivers that want algorithms to be biased towards their particular patient demographics.
Many key success factors are things we already know...

We traditionally think of supplier quality as only applying to raw materials, sub-assemblies, etc.

For Machine Learning, the training data is the “raw material” – bad raw material results in poor quality finished product.
SUCCESS FACTOR: GOOD DATA HANDLING PRACTICES

One challenge is that AI seems mysterious and magical, and people think we need a whole new way of thinking about it.

Consider these rules for handling data:

• Keep records / retain information on the origin of the sample
• Sourcing, processing, preservation, testing and handling should be done in a safe manner
• Protect against contamination, viruses

Note: these concepts are already captured in IMDRF GRRP WGN47 FINAL:2018
Continuous Learning Systems (CLS) are a source of uncertainty. Just like people, CLS systems learn over time – how an application performs now might be different than how it performed a year ago – and that makes people uncomfortable.

Or, perhaps we can think of a CLS update as a type of calibration activity...

The point is that we already know many good practices that simply need to be adapted for AI.
ITU/WHO Focus Group AI for Health

- Artificial Intelligence for Health (A4IH) offers substantial improvements for public and clinical health, e.g. early detection, diagnosis and risk identification, treatment decision support, self-management, improved outcomes, ...

- For world-wide adoption, need evaluation standards on effective AI for Health

- Focus Group AI for Health (FG-AI4H) created July 2018; open platform

- FG-AI4H goals: standardized framework for benchmarking and evaluation of AI solutions
Focus Group Operation

Process steps:

A) **Community:** Creating and extending a community around a health topic
B) **Proposals:** Solicitation of AI for health proposals
C) **Evaluation:** Setting up evaluation criteria including data sets and metrics
D) **Report:** Publishing reports about the evaluation and the results
E) **Dissemination:** After successful use of an AI for health solution in practice, repeat FG-Ai4H process steps (A-E)

- All steps (A-E) require strong voluntary participation, while being monitored and documented by ITU or WHO officials.
- Most of the work will be conducted using on-line tools and virtual meetings.
- It is envisioned, that the number of health topic communities will be large 100+
World Health Organization and ITU-T

Structure:
- Expert panel (clinical)
- Establishing benchmarking platform (infrastructure)
- Data & solution quality assessment committee
- Data handling committee
- Regulatory committee (coming soon!)
- Example projects:
  - Outbreak detection
  - Fall predictions
  - Dermatology
  - Neuro cognitive disease
Snakebite: A global health crisis

- **Snakebite** is responsible for over 100,000 human deaths and 400,000 victims of disability globally every year.

- **Snake identification** is key for **adequate clinical management** of patients.

- **Snake identification** is very complex and clinicians are not herpetologists.

Source: G. Alcoba
HerpMapper predicted +50,000 images in 2019
• Charter is to develop a quality assessment approach for candidate AI applications. Includes both data quality and solution(algorithm) quality

• Reviewed 50+ existing standards and guidance documents and created a library of 200+ questions. This was the basis to develop a draft assessment.

• At September 1 - 4 meeting, received feedback from WHO team & am in the process of updating the assessment.

• This is an iterative process – start with an initial set of assessment questions, topic teams will have topic-specific thoughts, individual projects will think of their own criteria, etc (e.g. identify new risks..)

• This is a collective learning environment & information is being captured for future use.
POSSIBLE (NEAR FUTURE) NEXT STEPS

1. Existing Guidance documents + Xavier
   whitepapers = WHO Quality Assessment

2. WHO + CTA + AAMI/BSI = ISO/IEC
   standards for health software

3. Monitor IEEE, ISO SC42, UL for ideas &
   potential conflicts
Xavier
2018 Conference: https://www.xavierhealth.org/ai-summit-presentations
2019 Conference: https://www.xavierhealth.org/ai-summit
Initiative: https://www.xavierhealth.org/xavierai
Whitepapers: https://www.xavierhealth.org/cls-working-team

BSI-AAMI

CTA
ISO AI Committees:
https://www.iso.org/committee/6794475.html

IEEE AI Committees:
https://ethicsstandards.org/p7000/
http://sites.ieee.org/sagroups-7000/
https://sagroups.ieee.org/aimdwg/

WHO ITU-T “AI for Good”
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