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

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Advancing Safety in Health Technology

About

BSI

BSI is a global thought leader in the development of standards of best practice for business and industry. Formed in 1901, BSI was the world's first National Standards Body (NSB) and a founding member of the International Organization for Standardization (ISO). Over a century later, BSI is focused on business improvement across the globe, working with experts in all sectors of the economy to develop codes, guidance and specifications that will accelerate innovation, increase productivity and support growth. Renowned as the originator of many of the world's best-known business standards, BSI's activity spans multiple sectors including aerospace, automotive, built environment, food, healthcare and ICT.

Over 95% of BSI's work is on international and European standards. In its role as the UK National Standards Body, BSI represents UK economic and social interests across the international standards organizations ISO, IEC, CEN, CENELEC and ETSI, providing the infrastructure for over 11,000 experts to work on international, European, national and PAS standards development in their chosen fields.

Medicines & Healthcare products Regulatory Agency (MHRA)

MHRA is an executive agency of the Department of Health and Social Care in the United Kingdom which is responsible for ensuring that medicines and medical devices work and are acceptably safe.

Its responsibilities include operating post-market surveillance for reporting incidents with medical devices; oversight of Notified Bodies that ensure medical device manufacturers comply with regulatory requirements; monitoring compliance with statutory obligations relating to medical devices; and promoting their safe use.

The Association for the Advancement of Medical Instrumentation (AAMI)

AAMI is a non-profit organization founded in 1967. It is a diverse community of approximately 7,000 professionals united by one important mission – the development, management, and use of safe and effective health technology.

AAMI is a primary source of consensus standards, both national (U.S.) and international, for the medical device industry, as well as practical information, support, and guidance for healthcare technology and sterilization professionals.

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Executive summary

Artificial intelligence (AI) and machine learning covers a broad set of technologies that are increasingly being used across the healthcare sector. These solutions can provide earlier diagnoses and targeted treatments for individual patients, whilst driving efficiency and effectiveness in healthcare services.

Governance and regulation of AI solutions in healthcare are recognized as significant challenges. BSI and AAMI are exploring the role for standards in supporting the deployment of novel AI technologies within this highly regulated sector.

This paper summarizes key discussion points from the collaborative activities undertaken by BSI and AAMI, with support from MHRA. It analyses the role that standardization can offer and sets out recommendations for future standardization activities that will assist deployment of AI solutions in healthcare. MHRA and the U.S. Food and Drug Administration (FDA) have a shared interest in seeing the recommendations from this report implemented, and new standards developed in the future.

The following recommendations were agreed through research and workshops. A detailed plan will be established to implement these recommendations throughout 2019.

BSI and AAMI, in partnership with key stakeholders, will:

- create an international task force to provide oversight for the direction of standardization activities related to AI in healthcare;
- undertake a mapping exercise to review the current standards landscape and identify opportunities for new or modified publications;
- develop a scope and proposal for a standard covering terminologies and categorization for AI in healthcare;
- develop a scope and proposal for guidance to cover validation processes for AI in healthcare; and
- create a communications and engagement plan that will continue to build our understanding of the market challenges and educate communities on the benefits of standardization.

AI has the potential to revolutionize patient care in the future. A sustained focus and a proactive approach to standardization will ensure that these technologies are safe, effective and scalable across the entire healthcare system.

1 Introduction

1.1 Background

The use of AI and machine learning algorithms is growing rapidly across healthcare. Emerging solutions can potentially offer earlier diagnoses and select targeted treatments that will improve patient outcomes, whilst benefiting healthcare services by driving efficiency and effectiveness.

AI covers a broad range of technologies, involving complex tasks that would normally require human intervention. Machine learning is a subset of AI, and involves computers processing large amounts of data so that they can learn without being directly supervised.

For the purposes of this paper, we have commonly referred to all these technologies and complex tasks as 'AI'. However, it is recognized that this term covers a broad set of solutions (e.g. deep learning modules, neural networks) and that different approaches may well be needed across each subset, once definitive terminologies for each have been established. Our research focussed on the more complex cases of AI, such as that of continuous learning systems and machine learning algorithms.

The governance and regulation of AI solutions in healthcare have been identified as significant challenges. Studies have been initiated to consider how to address these, and BSI and AAMI have been exploring the role of standards to support the deployment of novel technologies across this highly regulated sector.

These studies have led to the commissioning of this project with MHRA, in partnership with AAMI, along with the participation of experts from the FDA and other stakeholders in the UK and U.S. The paper provides recommendations for standardization activities to support AI in the medical device healthcare sector.

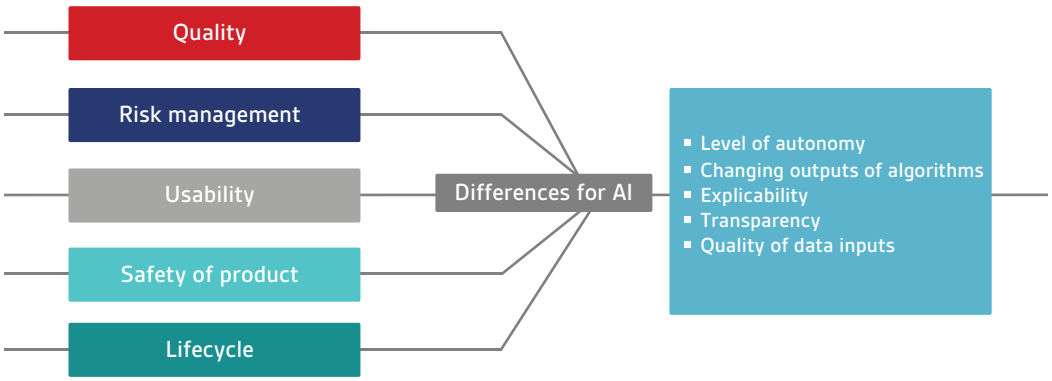
Both the UK and U.S. are acknowledged leaders in innovation for medical technologies and digital healthcare. The regulatory regimes in both countries are considered amongst the most rigorous and responsive to innovation worldwide. In addition, BSI and AAMI support regulators through the development and publication of national and international medical technology standards in their respective countries. These publications are used by industry to demonstrate conformity with regulatory frameworks across different countries and regions. A global approach to standardization of AI in healthcare is imperative to ensure its successful use in the future.

Current medical device regulations include software within their scope, depending on intended use. This can include software that is standalone or incorporated into an existing device. Standards covering the application of traditional *Software As a Medical Device* (SAMD) have been developed over recent years. However, AI solutions introduce a new set of challenges that have not been considered previously. These new challenges include the:

- level of autonomy introduced by AI technologies;
- ability of continuous learning systems to change their output over time in response to new data; and
- ability to explain and understand how an output has been reached.

Currently there are no standards that cover the definition, development, deployment and maintenance of AI in healthcare. Figure 1 outlines a selection of standards relating to traditional SAMD, along with the key differences to AI that were identified during this project.

Figure 1 – Current areas for medical device software standards and differences that AI may introduce



Standardization can help address challenges relating to deployment of any new technology quickly and responsively. Standards can be developed to align with and support existing regulatory frameworks, whilst keeping pace with evolving technologies.

Standardization as a global trading tool and as a means of promoting safety of products and their effectiveness is well established. Standards also represent consensus between all parties – industry, regulators and public interest. They help achieve consistency and harmonization across borders, through independent support of regulatory regimes. The independence of standards bodies, including BSI and AAMI, is a key component to the success of such aspirations and the agreements which underpin them.

1.2 Objectives

The objectives of this project were to create a set of recommendations that will:

- support a joint approach between UK and U.S. regulators, healthcare systems, industry, innovators and standards developers to address the risks and challenges associated with AI in healthcare;
- identify the current standards landscape and potential knowledge gaps, while ensuring alignment with similar initiatives across the wider healthcare system; and
- introduce a phased programme of standardization activities, collaboratively facilitated by both BSI and AAMI.

1.3 Methodology

The project methodology evolved from analysis of prior workshops, surveys and conversations undertaken by BSI, MHRA and other organizations exploring AI in healthcare. Further details and materials referred to (i.e. research, surveys, and workshop summaries) are available upon request.

1. **Standards research**: to provide a brief overview of relevant current formal standards published by national and international standards bodies.
2. **Pre-workshop surveys**: to identify participant knowledge and opinions on the differences and challenges surrounding the deployment of AI in healthcare, the current standards landscape, and knowledge gaps.
3. **Workshops**: two events were held in UK and U.S. respectively with participation from regulators, healthcare professionals, businesses and innovators.
    a) **London event, September 2018**: focussed on identifying the challenges that AI brings to healthcare, and the alignment with the current regulatory and standards landscape. Participants identified where key information gaps existed and discussed potential solutions to address them.

b) **Washington event, October 2018**: built on the outcomes of the London workshop by exploring the information gaps in greater detail (particularly the terminology and categorization of AI), and mapping standards to IMDRF essential principles for safety and performance. This led to a discussion about next steps and priorities for standardization.

4. **In-depth discussions**: in addition to the workshops, a selection of AI businesses, policymakers and professional healthcare practitioners were consulted to shape and verify the recommendations in this paper.

This paper:

- summarizes the key discussion points from the workshops and other activities;
- analyses the role that standardization can offer; and
- sets out recommendations for future activities that will assist with the worldwide deployment of AI in healthcare.

It is recognized that related legislative and governance instruments are also affected by the deployment of AI in healthcare. Examples include regulations covering professional practice and the role of information governance.

At the London workshop, it was acknowledged that other work was already underway in several areas originally highlighted for discussion. As a result, the following topics were considered out of scope for this project and therefore not discussed in further detail:

- research governance and gaining ethical approval for the use of AI;
- rules and best practices relating to data access; and
- regulations relating to professional conduct.

2 Key discussion points

2.1 Workshop outcomes

The two workshops facilitated by BSI and AAMI focused on identifying and exploring the key differences, challenges and knowledge gaps between AI and traditional medical software. They also considered how these specific challenges could potentially be addressed through standardization.

2.2 Terminology and categorization

There was general agreement that AI is used as a term to encompass several different technologies, and therefore the creation of terminologies would help increase transparency of these solutions through common understanding.

It was recognized that any new terminology standards for AI in healthcare should be aligned to current international work under development (e.g. ISO/CD 81001-1, *Health software and health IT systems safety of product, effectiveness and security, Part 1: Foundational principles, concepts and terms*).[1] A common language between traditional health software and AI communities would be beneficial.

A simple, high-level approach to categorization of AI in healthcare could consider groupings based upon different criteria including:

- complexities;
- impacts and benefits; and
- clinical situations.

Whilst closely linked to the associated risks, autonomy should not be the sole dimension for categorization. It was also agreed that categorization of different types of AI should be kept independent from the existing classification of medical devices under regulatory frameworks.

Clear categorization of AI could be a useful tool alongside medical device regulations. There is an example given in a recent healthcare report published in England where simple categorization of AI has been represented by its level of complexity.[2] Ultimately, the AI developer needs to understand and articulate the type of AI that is being developed, the intended use, and the environment in which it will be deployed.

2.3 Validation and versioning

Validation of AI (particularly for continuous learning systems) was a key discussion point in both workshops. This highlighted concerns relating to AI solutions that could potentially provide unsupervised patient care.

Suggested solutions included conditional licensing for newly deployed technologies and clear declarations of each new version of a continuous learning system (i.e. locking down). These could help avoid increased risks presented by technologies providing unsupervised patient care.

It was agreed that the development of use cases to demonstrate AI validation processes would be beneficial.

1 Throughout this paper, we have referred to existing standards using their generic, international reference, e.g. ISO/IEC prefix. However, it is recognized that there are regional and national adoptions of these standards that are applicable in both the UK and the U.S. (e.g. the European EN prefix).

2 Further information is available from: http://www.ahsnnetwork.com/wp-content/uploads/2014/12/AHSN-Network-AI-Report.pdf *(Complexity scale in AI, page 12).*

New guidance to help AI developers to navigate the medical device risk management process could also be useful. It was suggested that this could be written as supplementary 'state of the art' guidance linked to ISO 14971, *Medical devices: Application of risk management to medical devices.*

2.4 Quality of data inputs

AI solutions will only be safe and effective if they are trained on high quality data. Data sets need to include enough variety to satisfy regulators, professionals and patients and avoid inadvertently introducing bias or error into AI outputs.

The same input data used to train separate AI solutions that are working on an identical problem might not provide the same outputs. This does not mean that either solution is wrong; however, acceptable tolerances of outputs, based on the quality of the input data will need to be defined. This problem is compounded in more complex AI systems where two or more algorithms might be working together. A small discrepancy in input data could result in a more significant error in the overall output, and this might be difficult to find and correct.

Further investigation is needed to understand the different failure modes for data. This should be undertaken in conjunction with the activities of other regulators, statutory bodies and data science organizations. Exploring the ways that data is aggregated in clinical trials could also be beneficial in ensuring good management of input data to AI solutions.

2.5 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.

Participants in both workshops agreed that managing the human interface with AI, along with accountability for the AI solution, was critical, especially in the early stages of deployment. 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.

2.6 Lifecycle

The product lifecycle for AI will have synergies with the lifecycle for traditional software. Analysis of current regulatory frameworks covering SAMD should be used to identify gaps for additional guidance to address any specific differences. This is felt to be especially important for continuous learning systems.

Several factors relating to the AI lifecycle were raised during the workshops. These included:

- identifying situations where declaration of each new version of AI might be needed when providing patient care;
- continuous performance monitoring and the overall feedback loop; and
- addressing the different market and social perceptions linked to AI.

The economic aspects of deploying AI solutions need to be considered, for example, the availability of technology and its impact on patient outcomes.

Developers of AI solutions are likely to find it challenging to establish infrastructure around the AI lifecycle. Providing appropriate information at the earliest opportunity will help speed up the innovation journey and provide a better chance of successful deployment of the AI solution.

2.7 Cyber security

Cyber security, whilst initially identified as a challenge, was not discussed in detail during the workshops. It was noted that cyber security is already addressed within existing regulatory frameworks.[3]

It was generally agreed that information security for AI solutions did not pose any known additional or distinct challenges when compared to other types of software.

2.8 The AI landscape in healthcare

The potential of AI in healthcare is being investigated by many other organizations, government departments, research centres and universities. This paper is merely one piece of this landscape. Other key organizations that are critical to the safe and effective deployment of AI in healthcare include:

- regulatory bodies, and policy makers (e.g. for healthcare services, professional practice, data privacy and ethical research);
- professional organizations supporting the healthcare workforce;
- institutions supporting deployment of digital technologies and the application of data in healthcare;
- research and innovation agencies; and
- patient advocate groups and other civil society interests.

To illustrate the importance of work in this area, it is noted that UK government is investing in the:

- development of a Code of Conduct for data-driven healthcare technologies; and
- establishment of five Centres of Excellence covering digital pathology, imaging and AI over the next three years.

Similar initiatives can be found across the UK and internationally, and BSI and AAMI intend to work with and share ideas with other partners around the world.

3 For example, safety and performance requirements for unauthorized access in the EU Medical Device Regulations and the U.S. FDA Regulations on cyber security.

3 Analysis and recommendations

3.1 Enabling innovation, trade and alignment with existing regulatory frameworks

Regulations protect the public interest by ensuring an acceptable and proportionate level of risk for medical technology that is placed on the market.

Innovators need to have a clear understanding of regulatory requirements from an early point in their development journey, to avoid delays and to provide themselves with the best chance of successful deployment in the healthcare system. This can be challenging, particularly where emerging technologies need to align with established regulatory frameworks.

Standards offer a way to address the challenges of deploying AI in healthcare. They provide specifications, good practices and guidelines that help organizations to trade with each other, to improve their productivity, and to support innovation. They also have a role in allowing industry to demonstrate conformity with regulations, for example through EU harmonization, and as FDA recognized consensus standards.

Common global standards developed through international organizations, such as ISO and IEC allow better regulation and innovation, along with increased opportunities to trade across borders. However, for fast-paced emerging technologies such as AI, traditional standards development processes could struggle to keep pace, and alternative ways for delivering knowledge need to be considered.

Both the UK and U.S. are leaders in global medical device and healthcare IT standardization. The emergence of AI in healthcare provides an exciting opportunity to bring together different professional and cultural views to agree on the future standards landscape that will allow these technologies to be utilized at scale across global healthcare systems.

By providing sustained leadership through a UK-U.S. led Task Force, it will be possible to:

- review existing standards and regulatory landscapes, and forge links with organizations undertaking relevant initiatives relating to AI in healthcare;
- provide oversight and prioritization for a phased standardization programme; and
- ensure the rapid development of new knowledge solutions for AI in healthcare that can form the basis of future global standards.

Several opportunities for creating and updating standards and guidance have been identified during this project. For example, terminologies and categorization of AI solutions, along with validation and verification guidance are topics that should be addressed with some urgency (see Recommendations 3 and 4).

The generation, collection, classification and labelling of datasets used to train AI solutions are fundamental to ensuring high quality input data is accessible. This is a further theme for potential future standardization.

Reviewing IEC 62304[4] and its applicability across emerging AI solutions will identify any unique gaps where new guidelines could be introduced.

4 IEC 62304: 2006, *Medical device software - Software life cycle processes*, is the industry standard defining lifecycle requirements for medical device software. The standard requires the use of ISO 14971 for risk management for SAMD. A new edition is in development with an expanded scope that will cover all health software.

The issues of accountability and automation bias are further topics that will require exploration with a broader set of partner organizations.

Recommendation 1: Create an international task force to provide oversight for the direction of standardization activities related to AI in healthcare.

The group will bring together leading experts from industry and healthcare to address market challenges and agree on priority areas and opportunities for standardization on a global scale. It will respond to immediate market needs and to challenges in the longer term by creating a timeline for proposed activities.

3.2 Risk management strategies: addressing current and future landscapes, mitigating risk of AI solutions, and mapping to essential principles for safety and performance

A medical device needs to demonstrate that it meets its intended use without causing any unacceptable risks, such as specification errors (i.e. unforeseen software responses) and implementation errors (i.e. erroneous responses to accurate data inputs).

Current requirements for medical device risk management are set out in a globally recognized standard, ISO 14971[5] which is also referenced in IEC 62304:2006. IEC 80001-1:2010 is another standard that explains how to apply this risk management system for IT networks incorporating medical device software.

These standards, and associated supporting guidance documents, provide the basis for risk management and the lifecycle process for all software that is regulated under medical device legislation. Any new standards and guidelines covering AI solutions cannot be developed in isolation from the existing landscape. By considering AI solutions to be 'state of the art' (i.e. the latest and most sophisticated technology), new standards can be created that to help innovators bring their products to market more quickly and effectively.

Therefore, it will be critical to undertake a detailed mapping exercise, to:

- determine the current standards landscape; and
- identify gaps and areas for new or modified standards and guidance, relating to the risks across all AI solutions.

This mapping exercise should include alignment of any new or revised content to the IMDRF *Essential Principles for Safety and Performance*,[6] particularly those which cover software. Knowledge from other innovative and highly regulated sectors could also be used to draw comparisons and assist with the mapping exercise (e.g. from the automotive and defence industries).

Recommendation 2: Undertake a mapping exercise to review the current standards landscape and identify opportunities for new or modified publications and navigation tools to meet the needs for deployment of AI in healthcare.

The exercise should consider alignment with IMDRF Essential Principles of Safety and Performance and draw comparisons from situations where AI is deployed in non-healthcare environments.

5 ISO 14971:2007, *Medical devices: Application of risk management to medical devices*, is the latest edition of this standard (and is dated 2012 in European adoptions). A new edition is planned to be finalized in 2019.

6 Available from: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf.

3.3 Clarifying definitions and terminology for AI in healthcare

AI covers a broad set of technologies. This leads to difficulties for many people in understanding how AI works, or its suitability for application.

Currently there is no agreed terminology covering AI solutions for healthcare applications. Some attempts have already been made to address this and there is work underway within separate international standardization communities covering health IT software and generic AI.

Developing a high-level categorization system could provide transparency for AI solutions, both for regulated and non-regulated software. Such a system should consider several dimensions (e.g. complexity, impact, and clinical situation). Other non-healthcare sectors have created categorization systems based solely on autonomy.[7] Any categorization system would need to be independent from (and not interfere with) existing regulatory risk-based classification rules and approaches.

There is an opportunity to bring together international expertise from medical devices, healthcare IT and generic AI standardization to deliver an appropriate terminology and categorization solution. Given the rapid evolution of AI technology, a standards-based solution could keep pace with these changes.

However, with standards development already initiated (e.g. ISO/TC 215 and ISO/IEC JTC1/SC 42) this work should be considered as a matter of urgency, to ensure proper alignment and clarity.

Recommendation 3: Create an expert group to develop a scope and proposal for a standard covering terminologies and categorization for AI in healthcare, taking note of the current work programmes in related standardization communities.

3.4 Validation of AI solutions, accessibility of datasets and supervision

Validation of AI solutions is an area where new approaches will be needed to address the challenges that these technologies bring, when compared to traditional software. Two principle reasons for this have been identified.

1. AI developers will need to have access to appropriate datasets to train their solution during the design and development phases. It is important that these datasets contain adequate quantities and variety of information, and that they are appropriate for the intended use of the solution. A pilot study led by MHRA and NHS Digital is currently taking place in the UK.[8] It will create synthetic data-sets that will be used for testing against AI solutions, and could potentially be used by innovators to validate their products in the future.
2. There is a need for effective supervision of continuous learning systems. Active learning presents a challenge because an algorithm can change outputs in response to receiving new data over time. Unintended or erroneous responses to new data inputs could be more difficult to identify under these conditions. Version control (or similar oversight procedures) would need to be put in place to effectively manage these risks.

Alongside the risk management requirements set out in ISO 14971, requirements for quality management systems for medical device regulatory purposes are set out in ISO 13485: 2016.[9] This standard specifies

7 An example is available from: https://www.sensorsmag.com/components/three-sensor-types-drive-autonomous-vehicles.

8 Further information is available from: https://digital.nhs.uk/news-and-events/latest-news/nhs-digital-welcomes-funding-for-joint-project-with-mhra-on-creating-synthetic-devices.

9 ISO 13485: 2016, *Medical devices – Quality management systems – Requirements for regulatory purposes.*

requirements for the procedures and recording of product validation.

Different approaches to validation for AI solutions are likely to be developed, depending on the proportionate levels of risk. These approaches could include analytical and clinical validation methods. How an output is reached by an AI solution must be clearly explained to ensure professional confidence and trust.

Effective communication of validation processes will be needed. Provision of guidance and use cases relating to the management of validation processes for AI solutions, and in relation to their risk levels, would be beneficial.

Recommendation 4: Create an expert group to develop a scope and proposal for guidance to cover validation processes for AI in healthcare (particularly the aspects related to continuous learning).

The guidance should draw upon current research programmes, pilot studies and use cases and align with existing regulatory standards for quality and risk management. Guidance should also be applicable for non-regulated AI solutions.

3.5 Communicating and engaging with wider communities

Communication and engagement are central to ensuring that key stakeholders are kept up to date and informed about new standardization activities relating to the application of AI in healthcare. Such engagement should include:

- showcasing projects and initiatives that are being undertaken;
- dissemination of knowledge (e.g. of use cases being developed); and
- listening to communities of policymakers, healthcare professionals, businesses, and patients about their challenges and requirements.

Communication and engagement can take the form of events, articles, collaborative studies and awareness raising activities to educate the wider community on the benefits and value that AI can bring to the healthcare system. It can also educate on the benefits that standardization can bring to the deployment of AI solutions.

Recommendation 5: Create a communications and engagement plan that will continue to build our understanding of the market challenges and educate communities on the benefits that standardization can bring to the deployment of AI in healthcare.

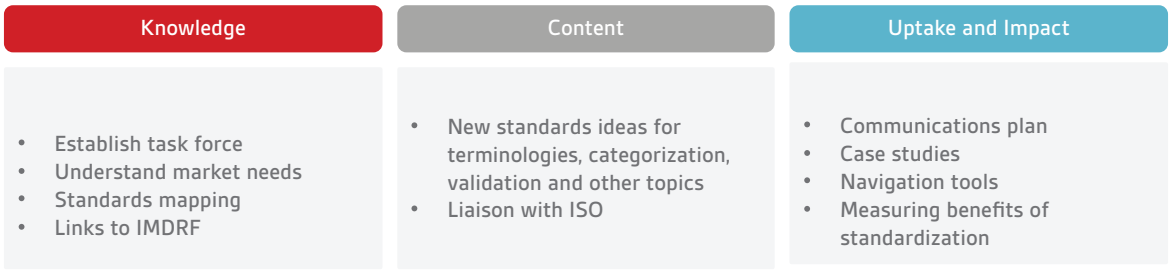
4 Steps for implementing recommendations

Following the publication of this paper, BSI and AAMI intend to present a plan to key stakeholders for implementing these recommendations during 2019 and beyond. This plan, which will be available for comment in early 2019, will include:

- agreeing the constitution, terms of reference, and facilitation model for the international Task Force (see Recommendation 1);
- initiating the standards mapping activities (see Recommendation 2);
- building the business cases for initial standards identified for development (see Recommendations 3 and 4);
- creating an engagement plan and associated activities (see Recommendation 5); and
- identifying the resources and expertise required to execute these recommendations.

In the meantime, BSI and AAMI will continue to engage with key stakeholders and welcome all feedback and suggestions for taking these recommendations forward. The plan will focus on the three primary activities that are set out in Figure 2:

Figure 2 – Implementation activities to support the recommendations



5 Conclusions

It is evident that AI solutions must be demonstrably safe and effective when used in the healthcare system. Any future landscape or regime (of regulation and good practice) must address this issue intelligently and with consistency.

Regulatory frameworks themselves can be difficult for innovators to navigate, so new guidance and use cases are going to be needed to ensure developers are fully informed about their obligations when gaining regulatory approval. This will apply both where approval is required for the deployment of new solutions in the market, and for supervision once in use.

For successful uptake and confidence, healthcare professionals and patients must be able to understand and trust emerging AI solutions. The more transparent the decision-making process is for each individual technology, the more confidence there will be in AI use in the healthcare system.

There will also be significant work required to provide assurance around validating algorithms, both in terms of accessing appropriate datasets for the training of algorithms, and for the purposes of version control once they are actively providing patient care. The parameters of this validation work will need to be clear for the understanding of all participants and stakeholders.

This paper proposes that the creation of new and updated independent standards and information solutions will help meet the key challenges highlighted – of regulatory compliance, safety, transparency, validation and confidence – and help ensure the successful and effective deployment of AI. The proposed standards and guidance can provide the essential, harmonized tools that are required by industry, healthcare professionals and the public to ensure that AI technologies are fit for purpose.

Where there are other areas that require exploration in the future, such as accountability and automation bias, these could also benefit from the development of rigorous and consistent standardization solutions.

Use cases, navigation tools and a comprehensive and internationally-based communication plan will also ensure good uptake of these proposed new knowledge resources.

It is the intention of BSI and AAMI that the timely development of these key resources will have long-term impact on securing confidence in the market, and on ensuring a harmonized and robust framework for the ongoing development and deployment of AI solutions in healthcare.

5.1 Summary of recommendations

Recommendation 1: Create an international task force to provide oversight for AI in healthcare.

Recommendation 2: Undertake mapping to review the current standards landscape and identify opportunities.

Recommendation 3: Develop a proposal for a terminology and categorization standard for AI in healthcare.

Recommendation 4: Develop a proposal for guidance to cover validation processes.

Recommendation 5: Create a communications and engagement plan.

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