The potential offered by AI for making quicker and more accurate diagnoses for patients is starting to excite health professionals around the world. However, for regulators, there are many questions to be answered before they are ready to trust AI to make life or death decisions.

In early February BSI, in partnership with US standards organization The Association for the Advancement of Medical Instrumentation (AAMI), published a report that highlights some of the key issues to be considered in relation to deployment of AI in healthcare. The UK and the US are recognized as leaders in innovation in medical technologies and our regulatory regimes are considered some of the most rigorous in the world.

The report, 'The emergence of AI and machine learning algorithms in healthcare: recommendations to support governance and regulation', was commissioned by the Medicines & Healthcare products Regulatory Agency (MHRA).

Rob Turpin, Healthcare Market Development Manager, one of the authors of the report, is coordinating BSI’s activity in this area. "We are starting to build evidence so we can develop standards that benefit healthcare providers and patients. "We need to be able to demonstrate the benefits of AI in healthcare to patients and clinicians in order to build trust and reassure people that a product is safe and effective while being clear about the risks. 

“It’s not just about whether AI is a good piece of technology, it’s about whether clinicians and patients can trust it and that it’s transparent so people can understand how it works and reaches the decisions that it does. This is where standards come in.”

For standards makers the challenge has always been to provide reassurance that a medical device will work as it is meant to. While regulating traditional software is relatively well established, the nature of AI and algorithms brings new challenges.

For example, AI can learn from data over time, changing a diagnosis over a period of weeks or months as it adapts to new information. How do you keep track of outcomes from an algorithm that is constantly learning and adapting?

Many people reading this, inside and outside of the medical profession, will already be uncomfortable with the prospect of AI making decisions that have always been made by a clinician. The interface between the human and machine decision-making is one which will be given careful consideration.

Said Rob, “Work needs to be done on terminology and categorization of AI into different groups so both clinicians and patients have an understanding of how AI actually works. In order to build trust, there needs to be an understanding of how AI is doing this.”
THE HUMAN TOUCH

BSI’s Consumer & Public Interest Network, which protects consumers in standards development, now has artificial intelligence firmly in its sights.

In the brave new world of the Fourth Industrial Revolution, artificial intelligence (AI) is the next development on the horizon which presents huge opportunities for improving our lives, but also potential threats to how we live our lives.

As we read the latest headlines about how the digital world is undermining our privacy and autonomy, we can be forgiven for wondering who is speaking up for the interests of consumers.

Well, BSI for one. Consumer Policy Manager Sadie Homer coordinates the input of consumer and public interest stakeholders into standards development, including BSI’s Consumer and Public Interest Network (CPIN).

“Consumers are often under-represented and our specific job is to make sure that the consumer is protected in all outcomes,” said Sadie. “Standards play an important role in the consumer protection toolkit by creating good practice for organizations that provide goods and services. BSI standards are developed by all key stakeholders and it’s important they have a consumer voice to ensure they are robust and credible.”

CPIN is a group of trained, independent volunteers who represent UK consumers in the development of British Standards. It works closely with representatives from other UK consumer organizations and is supported by BSI, with additional funding from BEIS (see above right).

“AI is developing so quickly that all the implications of its use in our daily lives are still not fully understood”

CPIN volunteers work from a set of principles to help them assess what a standard for a consumer product or service needs to address. These principles are; access, safety, information, choice, redress and sustainability.

CPIN is currently applying these principles to the issue of artificial intelligence, the workings of which are outside of the knowledge of the average citizen.

“AI is developing so quickly that all the implications of its use in our daily lives are still not fully understood,” said Sadie. “Whenever AI is a feature in a product or service we want to make sure there is transparency, accountability, and that consumers are able to make an informed choice, have equal access to its benefits and are protected from unintended or malicious harm.

“For example, emotions of consumers during interactions can be tracked and recognized by AI. It may be in our interests, but it equally could be manipulating us in ways we’re not aware of. It’s about protecting the autonomy of individuals.”

However, despite possible doomsday scenarios, Sadie is optimistic that consumer interests can be protected through the use of good practice standards in AI.

“Consumers are more likely to have confidence in businesses that work to British Standards and so are more likely to use their products and services. It’s a win-win situation for business and consumer - it builds consumer trust and increases trade.”

Join CPIN and make your voice heard

If you or your organization would like to join our consumer network, please email consumer@bsigroup.com

You can learn more about CPIN and its work at www.bsigroup.com/consumers

Sadie Homer is one of 50 CPIN volunteers who represent the voice of the consumer on BSI’s standards committees.

A retired systems engineer, David has a longstanding interest in AI and the human factor in systems. “I wanted to be engaged in something worthwhile after I retired. I'd worked with BSI during my career and also my wife worked for BSI so I was aware of the valuable work that it does to protect the consumer.”

AI, says David is becoming ubiquitous and raises practical and ethical considerations for which giving consumers a voice