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Validation framework for the use of artificial intelligence (AI) within healthcare – Specification

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Contents

Summary of pages
This document comprises a front cover, an inside front cover, pages I to II, pages 1 to 28, an inside back cover and a back cover.

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Foreword

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The provisions of this standard are presented in roman (i.e., upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is "shall".

Commentary, explanation, and general informative material is presented in smaller italic type and does not constitute a normative element.

Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. "organization" rather than "organisation").

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0 Introduction

0.1 Purpose

Artificial intelligence (AI) has been adopted to automate tasks in many contexts.

AI products developed for a healthcare setting require rigorous evaluation so that they:

a) have demonstrable benefits;

b) reach sufficient standards of safety and performance;

c) successfully and safely integrate into the proposed environment;

d) are developed and used ethically; and

e) produce equitable outcomes.

A body of guidance and academic literature has emerged which attempts to address a range of key technical, organizational and ethical factors pertaining to the use of AI products in healthcare.

However, AI product suppliers might either lack the capacity or the full range of expertise necessary to translate separate pieces of existing guidance into their production practice.

Similarly, healthcare organizations looking to procure AI products might not be sufficiently resourced to carry out their own assessments of AI products.

This British Standard is based on a review of existing guidance literature and good practice, which translates the assessment of complex functionality into an auditable framework for AI products in healthcare.

This British Standard can serve as a guide for the safe and ethical development, implementation, and monitoring of AI products. Further, AI products can be assessed for conformity to this British Standard.

0.2 Relevance to users

In practice, this British Standard could be used by several different parties involved in healthcare:

a) *AI system suppliers*: during the development of a given AI system, suppliers can choose to conform to the requirements in this British Standard, documenting responses and evidence against each clause for evaluation by external auditors;

b) *external auditors*: auditors can assess supplier responses and evidence against each clause, to determine whether the healthcare AI system conforms to this British Standard;

c) *healthcare providers*: healthcare providers could mandate conformity to this British Standard as part of their purchasing requirements;

d) *clinicians and healthcare staff*: clinicians and staff at the procuring organization can have confidence that healthcare AI products conforming to this British Standard are safe and effective;

e) *patients and the public*: patients and the public can gain assurance that AI products used in the delivery of care have met the standards of quality and social equity required to achieve conformity to this British Standard; and

f) *other stakeholders*: stakeholders such as pharmaceutical companies, healthcare insurers, innovation and market access consultancies and consumer technology companies.

NOTE See Figure 1 for the implementation pipeline for this British Standard.

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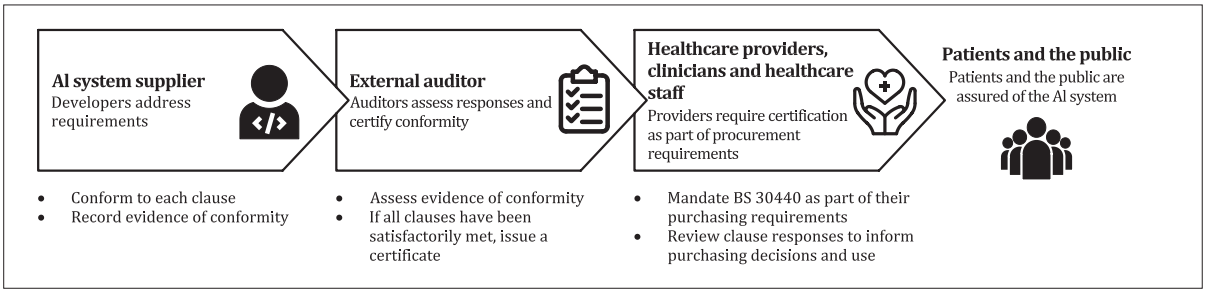
Figure 1 — *Implementation pipeline for BS 30440*



0.3 AI in the regulatory landscape

Regulation and governance for healthcare AI products is undergoing significant development to keep pace with the speed of technological change.

This British Standard is intended to complement these efforts by offering a framework for assessment of AI products in a healthcare context.

It serves as a starting point for products to meet a minimum standard across a range of criteria identified as important in guidance and academic literature.

AI products that fall outside of the scope for current and future regulation can still be subjected to a process of assessment and certification for quality.

This British Standard aligns in part to other standards for assessment for healthcare AI products, including NHS standards *DCB0129* [1] and *DCB0160* [2].

This British Standard can be applied to a broader range of products than those which are in scope for regulation as medical devices, and its requirements address a broader range of assessment domains than other assessment processes.

0.4 Contents

The requirements in this British Standard take into account the needs of a range of relevant stakeholders who might either directly use or be affected by the use of this British Standard in practice.

The clauses of this British Standard (Clause **4** to Clause **8**) have been divided into five phases, following the development lifecycle for a healthcare AI system. Each phase includes a collection of thematic criteria, addressing key requirements for a healthcare AI system within that phase of development. The phases and thematic criteria are:

a) Clause **4** – inception: requirements relevant to the initial phase of development during which a healthcare need is identified, and an AI system is conceived:

- healthcare need: the supplier shows that the product addresses a healthcare need;

b) Clause **5** – development: requirements relevant to the phase during which the AI system is built:

1) **5.1** – stakeholder involvement: the supplier demonstrates that stakeholders were involved in the development of the product;

2) **5.2** – training data: the supplier demonstrates that the training data was obtained and handled ethically, providing summary statistics of its characteristics;

3) **5.3** – model development: the supplier documents the process of creating an AI model, demonstrating that the input and output variables are valid for the healthcare need; and

4) **5.4** – human factors and ergonomics;

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c) Clause 6 – validation: requirements relevant to the phase during which the AI system is subjected to a series of assessments on clinical, economic, and ethical performance prior to deployment:

1) **6.1** – healthcare effectiveness: the supplier demonstrates that the product is effective at addressing the relevant healthcare need;

2) **6.2** – external validity: the supplier demonstrates that the product has reproducible performance in different contexts; and

3) **6.3** – equity and bias: the supplier demonstrates that its product does not create unfair outcomes for different groups of users and persons affected by the system;

d) Clause 7 – deployment: requirements relevant to the phase during which the AI system is deployed into the intended healthcare setting:

1) **7.1** – resourcing: the supplier states the resourcing requirements (including infrastructure and training) for adopting their product into a healthcare system;

2) **7.2** – cost and healthcare system resource impact;

3) **7.3** – assessing security vulnerabilities: the supplier shows they conform to good practice in cyber security;

4) **7.4** – user safety: the supplier demonstrates the steps taken to mitigate risks of danger to users from the product; and

5) **7.5** – explainability: the supplier provides clear information about the AI system and its behaviour to users and those affected by its use; and

e) Clause 8 – monitoring: requirements relevant to the ongoing monitoring of the AI system from deployment to decommissioning:

1) **8.1** – routine monitoring: the supplier documents a system to report safety concerns once the product is deployed, and provides a plan for how the performance of the product is to be monitored after deployment;

2) **8.2** – product modification process: the supplier documents the systematic version control process for the product; and

3) **8.3** – decommission: the supplier documents processes for decommissioning the product.

1 Scope

This British Standard specifies requirements for evaluating the development of safe, effective and ethical healthcare AI products, including:

a) healthcare benefits;

b) standards of performance;

c) successful and safe integration into the healthcare working environment;

d) ethical needs; and

e) socially equitable outcomes from system use.

This British Standard is applicable to products, models, systems or technologies whose function uses elements of AI, including machine learning (ML), and whose key function is to enable or

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provide treatment or diagnoses, or enable the management of health conditions, for the purposes of healthcare, including:

1) both regulated medical devices (such as software as a medical device) and those healthcare AI products that are not within remit for such regulation;
2) AI products that are clinician facing (such as imaging software) or service user facing (such as smartphone chatbots using AI); and
3) AI products that are used in the home (such as monitoring products) or in community, primary, secondary or tertiary care settings.

This British Standard is relevant to healthcare AI product suppliers, procuring healthcare provider organizations, clinicians and healthcare staff, product auditors, users, patients and others affected by healthcare AI products.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes provisions, or limits the application, of this document[1)]. For dated references, only the edition cited applies. For undated references, the latest edition of the reference document (including any amendments) applies.

BS ISO/IEC 22989, *Information technology – Artificial intelligence – Artificial intelligence concepts and terminology*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in BS ISO/IEC 22989 and the following apply.

3.1 adverse event

event causing, or almost causing, an injury, or a wrong or delayed diagnosis and treatment

3.2 AI system

set of methods or automated entities that together build, optimize and apply a model (**3.14**) so that the system can, for a given set of predefined tasks, compute predictions, recommendations or decisions

NOTE 1 Products are designed to operate with varying levels of automation.

*NOTE 2 Predictions (**3.17**) can refer to various kinds of data analysis or production (including translating text, creating synthetic images, or diagnosing a previous power failure). It does not imply anteriority.*

3.3 bias

systematic difference in treatment of certain objects, people or groups in comparison to others

*NOTE Treatment is any kind of action, including perception, observation, representation, prediction (**3.17**), or decision.*

3.4 explainability

property of an AI system (**3.2**) that expresses factors influencing the AI system results in such a way that humans understand

1) Documents that are referred to solely in an informative manner are listed in the Bibliography.

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