



Digital – making the most of technology

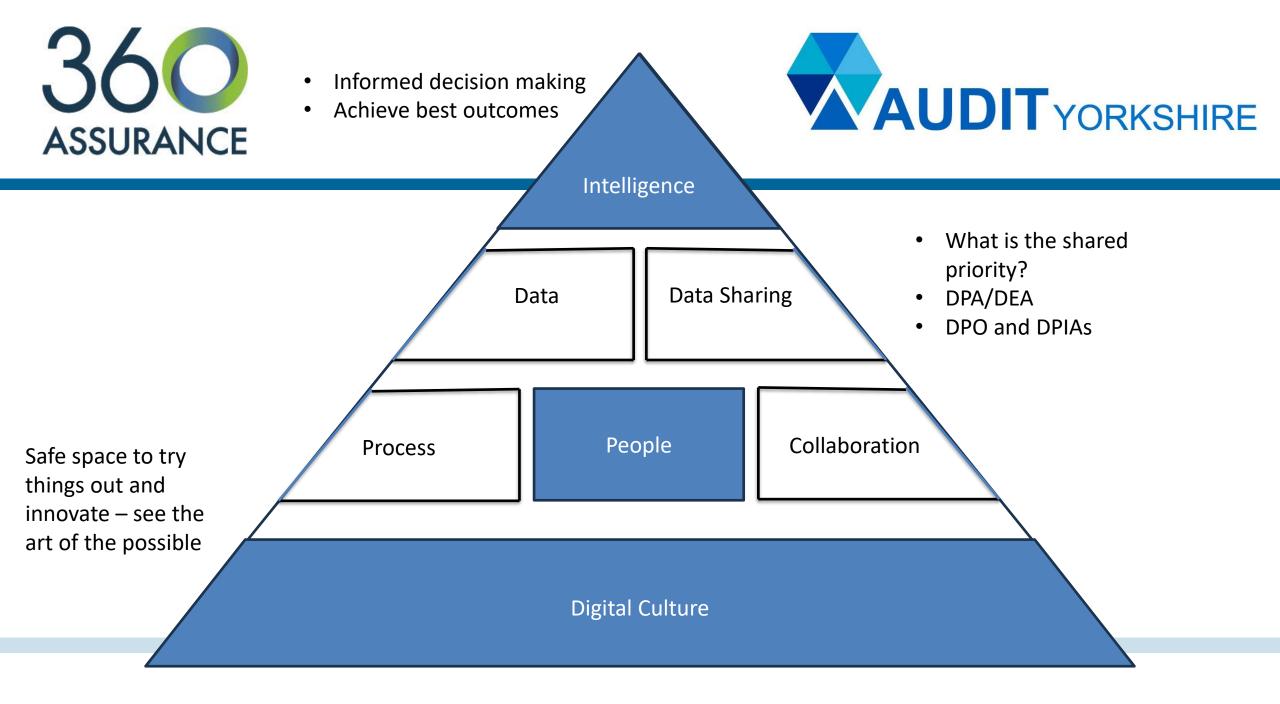
Welcome





Setting the Scene

Elaine Dower, Deputy Director, 360 Assurance







- Collect data in electronic form
- Replicate manual process eg speech-to-text transcripts
- Present/visualise data to make it more accessible/understandable eg Power BI
- Analysis basic through to complex
- Automate processes power automate to run the same reports every week/ month
- Continuous analysis identifying anomalies/outliers in real time while there is still time to intercept
- AI (classical) Boolean operators and logical conditions/rules to make predictions
- Machine learning (subset of AI) supervised/unsupervised
- Generative Al
- Large Language Model (LLM) AI
- Agentic Al/ Al Agent





Questions to consider when considering new technology

- What's the objective(s)/priority(ies) you're trying to achieve or problem you're trying to solve and therefore what genuinely is the question you're trying to answer?
- Co-design
- Fraud controls access, segregation, inbuilt access/activity audit trails
- Cyber security deep fake recognition
- Data ownership especially with third party technology providers
- Is the platform on which the digital technology is running innovating and keeping pace?
- How will it interact with our legacy systems/ICT?
- What's the skill gap for our staff to be able to use effectively and how will it be bridged?





Cyber Security – the pitfalls of increased technology and AI, within a fraud context

Richard Gentile, Principal Consultant – Digital Trust Cyber Security, PA Consulting Group





Unfortunately, Richard's slides are not currently available.

www.360assurance.co.uk @360Assurance www.audityorkshire.nhs.uk @AuditYorkshire





The Regulation of Digital Technology and Al in Healthcare

Dr Stewart Duffy, Solicitor & Legal Director Weightmans/Cyxcel



The Regulation of Digital Technology and AI in Healthcare

Dr Stewart Duffy, Solicitor & Legal Director



EU definition from EU AI Act

 'AI system' means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments;



- Predictive AI
- Generative Al
- Range of methodologies of machine learning



We don't regulate Al



 $\ensuremath{\mathbb{C}}$ CyXcel 2024. A business division and trading style of Weightmans LLP



Regulation of AI and Digital Technology

- We regulate **products**
- We regulate **people**
- We regulate **risks**
- We recognise rights and impose obligations to ensure rights are respected



We regulate products

🕼 GOV.UK

Home > Product Safety Alerts, Reports and Recalls

Product Safety Report: Teddy Bear with Striped Jumper (2408-0030)

Product Safety Report for Teddy Bear with Striped Jumper presenting a serious risk of choking.

From: Office for Product Safety and Standards Published 31 October 2024

Alert type: Product safety report Risk level: Serious Product category: Toys Measure type: Destruction of the product and Import rejected at border Recall/alert date: 31 October 2024



What is a Medical Device?

Definition EU

- (1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability

- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,



🖆 GOV.UK

Home > Health and social care > Technology in health and social care > Software and artificial intelligence (AI) as a medical device

Medicines & Healthcare products Regulatory Agency

Guidance

Software and artificial intelligence (AI) as a medical device

Updated 13 June 2024

Contents

Overview

Innovative devices: Software Group Classify your software as a

general medical device or an IVD

Overview

Software (including AI) plays an essential part in health and social care. In the UK, many of these products are regulated as medical devices (or as in vitro diagnostic medical devices (IVDs). This guidance provides access to important Software Group outputs that might be of assistance.



Imposes evidential requirements to demonstrate that the device is fit for its intended purpose;

- Imposes obligations in relation to post-marketing surveillance
- Notifiable incidents

🖾 GOV.UK

<u>Home</u> > <u>Health and social care</u> > <u>Medicines, medical devices</u> > <u>Vigilance, safety alerts and guidance</u> > <u>Medical devices: examples of reportable incidents</u>

Medicines & Healthcare products Regulatory Agency



The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024: examples of incidents to report under the vigilance system

Published 15 January 2025

1. A urinary catheter was used even through the lubricious coating had dried. This may have been due to inadequacies in the labelling.

Rationale: there is potential for serious injury should the device be used with ineffective lubricious coating. The report should include consideration of whether there is a need to improve the information provided with the device to promote its proper and safe use.

2. The administration set used with an infusion pump becomes occluded and no therapy is delivered. After some time, the infusion pump alarms to alert the user to the problem.

V Menu



We Regulate People



Professional standards

In effect: 30 January 2024

General

Medical

Council

Delegation and referral





Delegating safely and appropriately

 66 You must be confident that any person you delegate to has the necessary knowledge, skills and training to carry out the task you're delegating. You must give them clear instructions and encourage them to ask questions and seek support or supervision if they need it.



Employment – Contractual Obligations

Schedule 2 Associated duties and responsibilities

- A consultant has continuing clinical and professional responsibility for patients admitted under his or her care or, (for consultants in public health medicine) for a local population. It is also the duty of a consultant to:
 - keep patients (and/or their carers if appropriate) informed about their condition
 - involve patients (and/or their carers if appropriate) in decision making about their treatment
 - maintain professional standards and obligations as set out from time to time by the General Medical Council (GMC) and comply in particular with the GMC's guidance on 'Good Medical Practice' as amended or substituted from time to time.
 - maintain professional standards and obligations as set out from time to time by the General Dental Council (GDC) (Dental consultants only).



Regulation 5: Fit and proper persons: directors

Guidance for providers and CQC inspectors

January 2018



An example of mismanagement:

 "Failing to implement quality, safety and/or process improvements in a timely way, where there are recommendations or where the need is obvious."



We regulate risks

STATUTORY INSTRUMENTS

2017 No. 1322

HEALTH AND SAFETY

The Ionising Radiation (Medical Exposure) Regulations 2017



IRMER

Regulation 12(9)

- "This regulation requires the employer to ensure that a clinical evaluation of the outcome of each exposure, other than exposures to carers and comforters, is recorded, as set out in the employer's procedures. It is recommended that such an evaluation should be accurate and timely, such that it contributes appropriately to the care of the exposed person. In practice clinical evaluation might include the resulting diagnostic findings or therapeutic implications, as appropriate or, in the case of therapy exposures, a clear record that the exposures delivered are consistent with those prescribed, or where these have deviated, the basis for this."
- "evaluation" means interpretation of the outcome and implications of, and of the information resulting from, an exposure;

٠



Regulation of Risks within the NHS

- CQC
- Network Information Systems Regulations
- Clinical Risk Standards (under statutory framework) DCB0129, DCB0160 and DTAC
- NHS Duties re Climate Change and Modern Slavery – NHS Act 2006 as amended



CQC Regulations

- Regulation 12 Safe Care and Treatment
- Regulation 15 Premises and Equipment
- "All premises and equipment used by the service provider must be –

Suitable for the purpose for which they are being used.



We recognise rights and impose obligations to ensure rights are respected

- Rights to life, bodily integrity, autonomy e.g under ECHR
- Protected by traditional common law torts – clinical negligence including informed consent, product liability
- Human Rights Act 1998

• Rights in relation to Data Protection



UK GDPR – Article 22

 The data subject shall have the right not to be subject to a decision based <u>solely</u> on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her.



'Profiling'

 'means any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements;



Examples



FT Magazine Health (+ Add to myFT

Algorithms are deciding who gets organ transplants. Are their decisions fair?

Sarah Meredith was in urgent need of a liver when she found out an algorithm would be making the life-or-death decision

Correspondence

Implausible algorithm output in UK liver transplantation allocation scheme: importance of transparency

Algorithm-based allocation of resource-limited health-care interventions is growing; however, concerns over transparency and bias have restricted its use.¹ Transparent algorithms can be readily explained, allowing patients and clinicians to clearly understand the basis for decision making.² In 2018, the Transplant Benefit Score (TBS) was introduced to allocate deceased donor livers to patients with chronic liver disease and primary liver cancer (hepatocellular carcinoma) on a national basis. Patients might also undergo transplantation for acute liver failure, although these patients are allocated organs via a different process. The TBS algorithm uses seven donor and 21 recipient parameters to predict the difference in survival without transplantation (need) to that after transplantation (utility) for each potential recipient (TBS=utilityneed).3 Balancing the risk to benefit ratio between patients with chronic

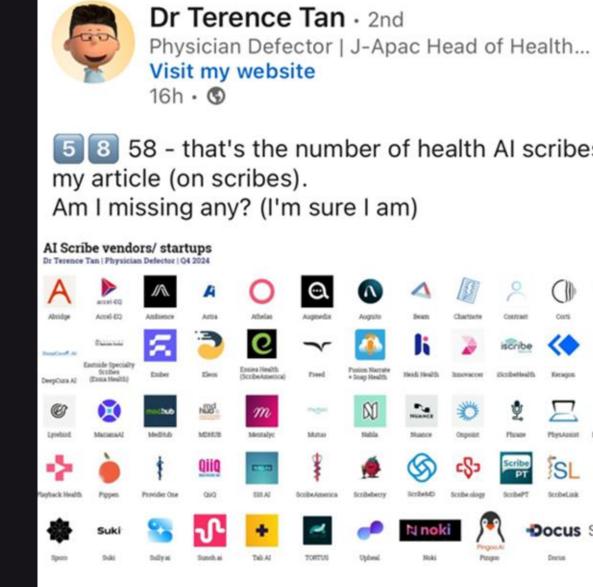
liver disease and patients with cancer, which typically arises on a background of chronic liver disease, is challenging.4 National reports show that for the first 3 years of the TBS scheme (excluding the period when TBS offering was suspended due to COVID-19), patients with cancer were rarely allocated livers by the TBS model and that waiting list removals for death or deterioration were considerably increased compared with patients with chronic liver disease alone (relative risk=1.58, 95% CI 1.22-2.06; appendix p 1).5 We aimed to understand TBS-derived allocation decisions with deterministic simulation methods.



Published Online March 1, 2023 https://doi.org/10.1016/ \$0140-6736(23)00114-9

See Online for appendix







8 - that's the number of health AI scribes I found for

...more

M

Deeptoribe

Knowledge

1

Physiciae Asiat

Settin

EMBO AL

Sneptor

AutoMand

PuzzlaAl

Contrast

iscribe

iScribeHealth

Ŷ

Ploate

PT

ScolePT

Ketager

PhysAdmint

S

ScribeLink

Docus Seapme





The NEW ENGLAND JOURNAL of MEDICINE

SPECIALTIES V TOPICS V MULTIMEDIA V CURRENT ISSUE V LEARNING/CME V AUTHOR CENTER PUBLICATIONS V Q

This content is available to subscribers. Subscribe now. Already have an account? Sign in.

PERSPECTIVE

f 🗙 in 🖾

Large Language Models and the Degradation of the Medical Record

Authors: Liam G. McCoy, M.D. O, Arjun K. Manrai, Ph.D. O, and Adam Rodman, M.D., M.P.H. Author Info & Affiliations Published October 26, 2024 | N Engl J Med 2024;391:1561-1564 | DOI: 10.1056/NEJMp2405999 | VOL. 391 NO. 17

Copyright @ 2024

E 🗊 🤊



Hallucinations...

You see, I and my parents all go to the same medical group for primary care. So the AI read through, noted that relationship, and cross indexed their medical history with mine and helpfully filled in all the blanks on my medical history.

You know, the blanks that exist because I am adopted and it was a closed adoption so I have no information on the DNA providers' medical histories.

AI just falsified my medical records because if adoptee then do not cross index with non biological family members is apparently too difficult to code.

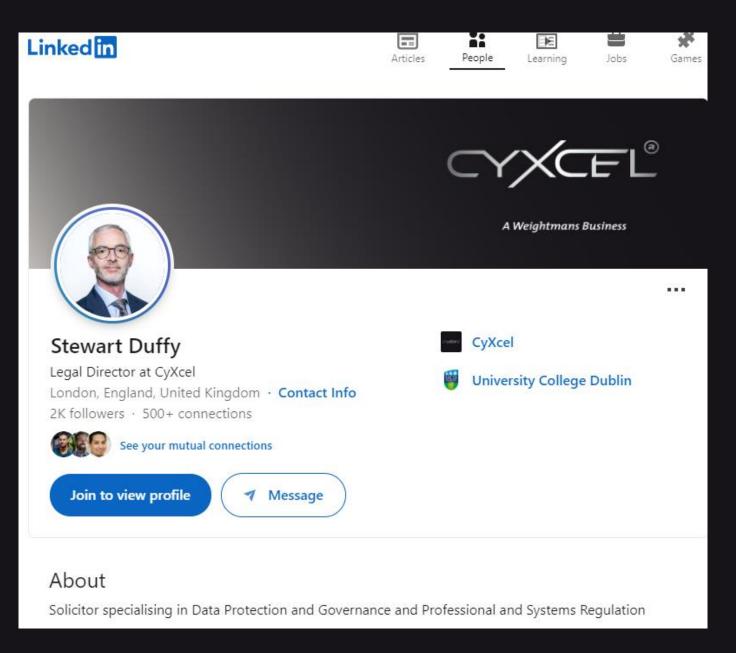
So, no, I do not think AI is just spiffy when it comes to medical records.



Regulation of AI and Digital Technology

- Is the use of AI in Healthcare Regulated?
- Is a technology neutral approach to regulating products and risk the right approach?
- Is AI a special case which should be treated preferentially to other technologies?







Incident response

Solutions 🗸 About Us 🗸 Sectors Global Legal Service Partnerships Knowledge Hub Contact

Cybersecurity. Law. Technology. Geopolitics.

CyXcel is a next-gen professional advisory business — created to manage crises, solve challenges, and seize opportunities for everyone in the digital world.

About Us







Everything, Everywhere, All at Once

Paul Rice, Chief Digital Information Officer, Bradford Teaching Hospitals NHS FT and Airedale NHS FT





Everything everywhere all at once...

Paul Rice, PhD, MSc, BA, MPLA, PGDip, FBCS

CDIO

Bradford Teaching Hospitals NHS Foundation Trust Airedale NHS Foundation Trust

What is digital transformation?

Applying the culture, processes, business models and technologies of the Internet era to respond to Peoples raised expectations

Tom Loosemore, Public Digital

Digital transformation is the integration of digital technology into all areas of a business, fundamentally changing how you operate and deliver value to customers. It's also a cultural change that requires organizations to continually challenge the status quo, experiment, and get comfortable with failure. The Enterprisers Project

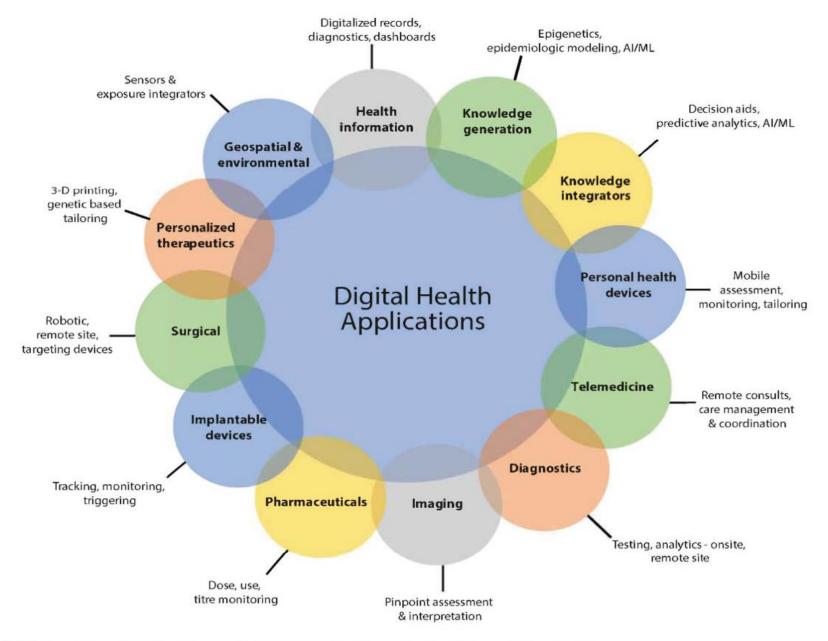


FIGURE 1 | Evolving Applications of Digital Technology in Health and Health Care

SOURCE: National Academy of Medicine. 2019. Digital Health Action Collaborative, NAM Leadership Consortium: Collaboration for a Value & Science-Driven Health System.

THE CHANGING NEEDS OF CARE TEAMS OF THE FUTURE

Collaboration

Work with all stakeholders across the care continuum focusing solely on the patient. Drive collaborations to improve clinical outcomes

Population Health Approach

Work with stakeholders and communities to deliver care & use resources to improve the physical, mental and social wellbeing of the whole population

Sustainable Systems

Use sustainable tools to provide quality care while balancing the economic, environmental, social constraints & demands

Compliance and Consent

Educate patients on consent management. Work with stakeholders to ensure adherence to patient confidentiality and privacy laws.

Shared Decision Making

Have patients at the center to support shareddecision making. & enable them to use available care, systems & tools



Patient Advocacy

Help patients navigate complex healthcare systems. Foster partnerships and engage patients to promote person-centred & personalised care

Patient Empowerment

Empower and enable them to use technology. Educate them to use appropriate remote monitoring for better disease management

Technology Adoption

Harness technology, and adopt new technology to improve care delivery. Guide patients to use digital tools for better disease management

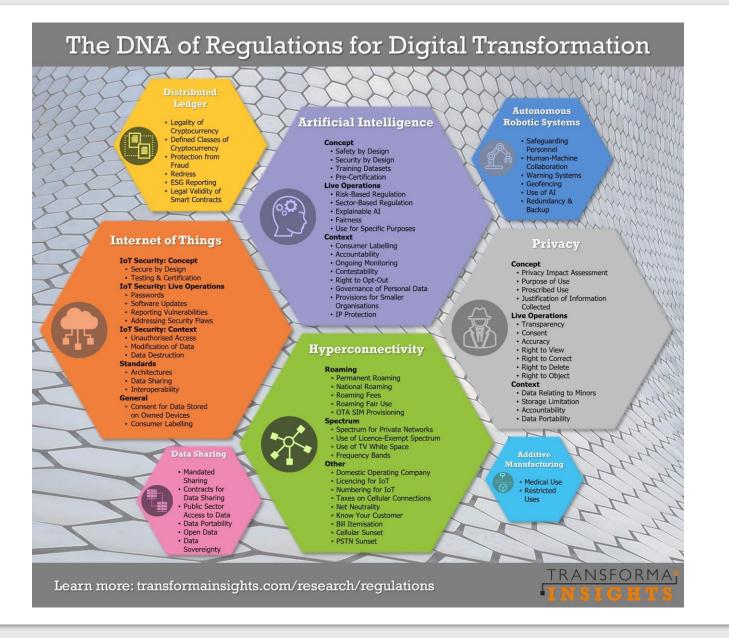
Interoperability

Adopt data-driven technologies to reduce medical errors, and improve clinical decisions. Focus on integrations allowing use of patient data to drive preventive care

Emerging technologies

Explore new emerging technologies that are shaping the future of healthcare. Adopt systems that add value to the existing system, reduce burden and promote personlised care.





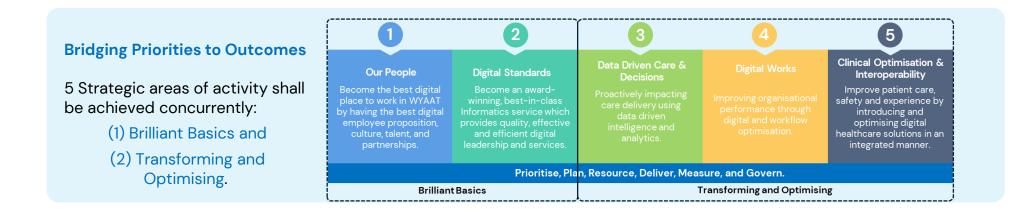


Digital and Data Transformation Strategy

2025-2030

Becoming a clinically driven, digitally outstanding Trust

Delivery – How we will be a clinically driven, digitally outstanding Trust





Strategic Objective 5 – Clinical Optimisation – Bringing it together

5 Clinical Optimisation & Interoperability Improve patient care, safety and experience by introducing and optimising digital healthcare solutions in an integrated manner

A fresh approach to clinical optimisation and change

Clinical Optimisation means making the most of what a Clinical System can do to support clinical outcomes. Optimisation can take many forms; it can be by way of an 'Everyday Approach' in the form of small fixes that make it easier to use (for example, a new field or form). Conversely, optimisation can mean undertaking significant change to implement, change or replace a new digital system or workflow.

Whatever the scale of optimisation and change, we will apply a refreshed end-to-end methodology which will ensure well-designed, coproduced and clinically driven change – and one which incorporates all our strategic objectives, with the patient at its heart. This will be enhanced with a comprehensive engagement plan towards the priority and sequencing of optimisation.

Transforming and Optimising Our

Our approach to delivering a variety of optimisation programmes, with EPR as a priority will be as follows:





Bradford Teaching Hospitals NHS Foundation Trust

Thanks for Listening

Questions?

Contact: Paul.Rice@bthft.nhs.uk





NHS Federated Data Platform Overview

Jon Cort, Chief Information Officer, Chesterfield Royal Hospital NHS FT





Unfortunately, Jon's slides are not currently available.

www.360assurance.co.uk @360Assurance www.audityorkshire.nhs.uk @AuditYorkshire





Al: From Everyday Convenience to Healthcare Innovation

Clarence Mpofu, Managing Director, Barts Assurance (part of Barts Health NHS Trust)



'From Everyday Convenience to Healthcare Innovation—Enhancing Lives with Intelligence, Efficiency, and Precision'.

What is AI?

Presenter:

Clarence Mpofu, BSc, FCCA. MBA (Managing Director-Barts Assurance)

27th March 2025

What is AI?

Artificial Intelligence (AI) is the simulation of human intelligence in machines designed to think and learn like humans.

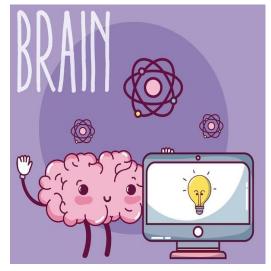
Key Aspects of AI:

• Learning: Al systems can learn from data (open and closed data).

NB: Open data consists of digital records that are available for everyone to see, access and use without any restriction.

Closed data, on the other hand, consists of digital records restricted to one or more users. For commercial applications, it's far more common than open data.

- Reasoning: AI makes decisions based on logic.
- **Problem Solving**: Al solves complex problems.



Artificial intelligence can:

speed up operations improve operational quality improve decision-making and save money

Types of AI

• Narrow AI (Weak AI):

Designed for a specific task (e.g., voice assistants like Siri, image recognition).

• General AI (Strong AI):

A hypothetical AI that would perform any intellectual task a human can do (still under development).

• Super intelligent AI:

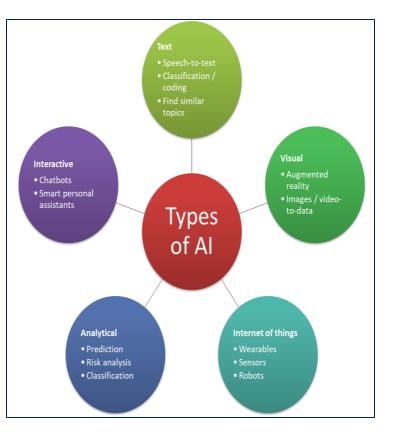
Al that surpasses human intelligence (theoretical at this point).

Examples of Al

- Voice Assistants (e.g., Siri, Alexa, Google Assistant):
 - Recognise and respond to voice commands.
- Recommendation Systems (e.g., Netflix, Amazon):
 - Use past behaviour to predict what you might like to watch or purchase.
- Autonomous Vehicles:
 - Cars that use AI to drive themselves by analysing surroundings.
- Facial Recognition:
 - Used in security systems to recognise individuals based on their facial features.
- Chatbots:
 - Al systems used for customer service, answering common queries.







How AI is Used in Daily Life?

o Smartphones:

Al powers features like predictive text, facial recognition, and navigation.

• Online Shopping:

Al recommends products based on browsing history.

• Streaming Services:

Al suggests movies or shows based on past preferences.

• Social Media:

Al curates your feed, analyses trends, and offers personalised content.

Interesting fact:

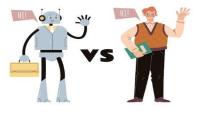
New AI cameras have been trialled that could help detect drivers under the influence of drugs or drink. Developed by Acusensus, the cameras identify unusual driving patterns and then send alerts to police officers who can carry out further investigations. The trial took place in Devon and Cornwall in December 2024



Humans vs Al

The things that make us uniquely human is our *capacity for creativity, empathy and emotional intelligence*. This sets human intellect apart from AI.

Unlike AI, which follows set rules and algorithms, *humans possess the innate ability to think critically, adapt to new situations and express complex emotions*



Al systems are already much better than people at logically and arithmetically correct gathering (selecting) and processing (weighing, prioritising, analysing, combining) large amounts of data. *They do this quickly, accurately and reliably.*

How AI is Used in the NHS?

• Diagnostics:

Al helps analyse medical images (e.g., X-rays, MRIs) for early signs of diseases like cancer.

• Predictive Analytics:

Al is used to predict patient outcomes, such as the likelihood of readmission or the risk of developing certain conditions.

• Personalised Treatment:

Al systems can recommend personalized treatment plans based on a patient's medical history and genetics.

• Virtual Health Assistants:

Chatbots or AI assistants help patients with appointment scheduling, medication reminders, and general health inquiries.

• Robotic Surgery:

Al-driven robots assist surgeons in performing more precise and minimally invasive surgeries.

• Managing Health Records:

Al can streamline electronic health record management, making it easier for healthcare professionals to access critical patient information.

Benefits of AI in the NHS

• Improved Accuracy:

Al systems can identify patterns that may be missed by 'human' doctors.

• Efficiency:

Al can process large amounts of data quickly, saving time in diagnosis and treatment.

• Cost Reduction:

Al can help streamline processes and reduce costs.

• Better Patient Outcomes:

Al can provide more personalised care and faster interventions.

Practical Examples-Barts Health NHS Trust

Al used to spot missing appointments

An artificial intelligence tool trained to read clinical letters has prevented a number of patients from missing out on key appointments.

A team at <u>St Bartholomew's Hospital</u> used machine learning to analyse thousands of outpatient letters within the <u>congenital heart disease service</u> and to understand if the correct action had been taken by either the patient or the clinical team.

This could range from booking a follow-up appointment, a referral to another specialist or a request for a scan.

The machine was taught to identify key phrases within patient letters and check them against electronic health records.

Over six months the system read 1,500 letters and identified 16 so-called 'high risk' cases where action was needed to prevent delays in care or even serious harm.

The technology was also deployed within uro-oncology.

It is the first time AI has been used in this way at Barts Health.

Practical Examples-Barts Health NHS Trust

Using AI to ease A&E pressures

A new initiative using artificial intelligence (AI) and personalised clinical coaching is set to improve care for thousands of patients with long-term conditions across North East London.

Launched in December 2025, by NHS North East London in partnership with Health Navigator, UCLPartners, and Barts Health NHS Trust, this three-year programme will proactively identify patients at risk of unplanned hospital visits and provide them with targeted support.

The programme uses advanced AI technology to screen patients and pinpoint those who could benefit from early intervention. Trained clinical coaches will then provide personalised advice and self-management techniques over the phone to help patients avoid unnecessary hospital visits.

Forecasting models suggest it will significantly alleviate pressure on the NHS, with an anticipated annual reduction of: 13,000 A&E attendances. 26,673 unplanned bed days over three years.

The programme's success builds on a pilot in Staffordshire, which demonstrated reductions in emergency hospital visits, GP referrals to secondary care, and overall bed days.

Practical Examples-Barts Health NHS Trust

An artificial intelligence tool that can detect heart disease in record time is helping to see more patients on the waiting lists.

The first-of-its-kind programme analyses MRI scans of the heart in just 20 seconds whilst the patient is in the scanner.

This compares to around 13 minutes when done manually by a human. The technology can also detect changes to the heart's structure with 40 per cent greater accuracy and extracts more information than a person is able to.

Each year around 120,000 cardiac MRI scans are performed in the UK. Around 7,500 of these take place at our <u>Barts Heart Centre</u>, located at St Bartholomew's Hospital.

It is estimated that using artificial intelligence will save around 3,000 clinician days every year nationwide, helping us to see more patients on our <u>waiting lists</u>, which have increased as a result of the pandemic.

At the start of the programme the technology was being used on over 140 patients a week across St Bartholomew's, UCL and Royal Free hospitals.

Barts Heart Centre cardiologist Dr Rhodri Davies said: "The beauty of the technology is that it replaces the need for a doctor to spend countless hours analysing the scans by hand. "We are continually pushing the technology to ensure it's the best it can be, so that it can work for any patient with any heart disease."

Dr Sonya Babu-Narayan from the <u>British Heart Foundation</u>, which funded research into the technology, said: "Innovations like this help fast-track diagnoses and ease workload so that in future we can give more patients the best possible care much sooner."

Challenges and Considerations of Al

• **Data Privacy**: Ensuring patient data is securely handled.

Ethical

- Bias: AI systems must be trained on diverse, unbiased datasets to avoid discriminatory outcomes.
- Job Displacement: Automation <u>might</u> impact certain job roles, though it may also create new opportunities.
- **Regulation**: Proper frameworks and standards must be developed /are being developed to ensure safe AI use.

No UK AI regulation. However the UK government has announced plans to introduce legislation in 2025 to address AI risks, making voluntary agreements with AI developers legally binding.

Other laws affecting Al

There are several domestic laws that will affect the development or use of AI, including but not limited to:

- Data protection laws
- Intellectual property laws
- Human rights laws (particularly, anti-discrimination laws such as the Equality Act 2010 and the Human Rights Act 1998)
- Consumer and competition laws
- The proposed Digital Information and Smart Data Bill

Future of AI in the NHS

• Al-driven Drug Discovery:

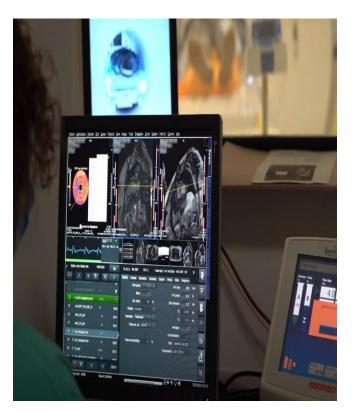
Al can help identify new treatments faster by analysing medical research data.

• Al-powered Virtual Care:

Al could enhance telemedicine by providing more personalised remote consultations.

• Continuous Monitoring:

Wearable devices powered by AI can track patient health in real time and alert healthcare providers to potential issues.



SUMMARY

• Al is revolutionising many industries, including healthcare.

- Its application in daily life and the NHS shows promise in improving efficiency, accuracy, and patient care.
- While there are challenges, the future of AI in healthcare is exciting and holds immense potential for better care and innovation.

Live Demonstration

Comparison of a Trust's Procurement Policy with the new Procurement Act using ChatGPT

(https://www.legislation.gov.uk/uksi/2025/163/contents/made)

NB: On 24 February 2025, the Procurement Act 2023 came into force, driving greater efficiency, transparency, and fairness in public sector procurement. The Act introduces stronger rules on the exclusion of suppliers where they pose particular risks to public procurement







Data Security and Protection Toolkit (DSPT)

John Hodson, Senior Information Assurance, NHSE

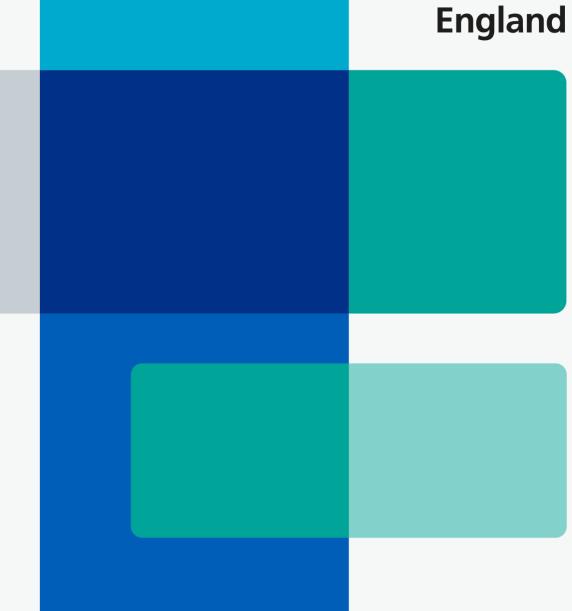


Data Security and Protection Toolkit

DSPT Update

March 2025

John Hodson



Changes to the Data Security and Protection Toolkit

What has happened

Significant change to DSPT in 24-25 with NCSC Cyber Assessment Framework (**CAF**) replaces National Data Guardian 10 data security standards as underlying **DSPT** framework for large NHS Organisations (Trusts, CSUs, ALBs and ICBs) still covering both **cyber** and **information governance.**

New Framework, questions, guidance and language.

Responding at a higher (**outcome**) level than previously.

Scope is 'Essential service' which for NHS

Organisations is everything.

Why

Key element of **Cyber security strategy for health** and social care: 2023 to 2030 supporting organisations are better able to manage their cyber risk. Aim is:

Good decision-making over compliance.

Ownership of information risks at the local organisation level where those risks can most effectively be managed.

Support a culture of evaluation and improvement and **understanding the effectiveness** of practices.

What this means

A **health and care overlay** to CAF has been developed and implemented into the DSPT.

Organisations asked to confirm their achievement level of **Not achieved/Partially Achieved/Achieved** against 47 Outcomes. Additional questions covering key data collection and policies (Audit, MFA and RTACA).

A profile sets out the **expected achievement levels** which, if met, leads to a **Standards Met** DSPT status.

The expected achievement levels for some outcomes is Not achieved for 24-25.

Data Security and Protection Toolkit

Lessons from engagement

Engagement programme on pre-launch and on-going

Webinars popular, now run monthly and moved to **YouTube** to make them more accessible.

Organisations worried about the **bar being raised**, and **scope creep**, guides re-written to highlight this clearly.

Engagement continuing throughout the year and beyond and summary audit guide published early.

Expectations (no statements/evidence required) for Interim assessment recognises the work involved.

Challenges remaining

Concern about **raising expectations** in future years. **Profile to be published up to 2030** to support planning.

Profile to 2030 linked to Cyber Improvement programme resourcing and will not be achieved across every outcome by 2030.

Explaining how being **Not Achieved** for an **outcome is expected in 2024-25** and beyond.

Recognised that there may be a **reduction** in the number of organisations achieving Standards met.

What we need your help with

Developing reporting to senior management and boards from within the DSPT.

Support to produce a dashboard/report which demonstrates the progress being made in a sensitive way.

Looking for **volunteers** to support us in **developing** and **testing** this.

Continuing to **engage and provide feedback** on the DSPT. Would appreciate coming back to a future session to listen and update.

Interim Assessment

Interim Assessment

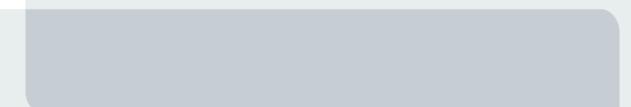
Interim deadline

All NHS Organisations submitted a snapshot at December 2024.

Summary

No one reported that that are meeting all expected levels or haven't started yet

Most met	Least met	Typical organisation
B1.a Policy, development E1.a Privacy and transparency E2.a Managing data subject rights	A3.a Asset management B3.a Understanding Data E4.a Managing Records	Trusts - not meeting 12 outcomes ICBs - not meeting 8 outcomes



Audit



Changes to the Audit process

Several things will be different this year, including the timing and duration of assessments, the introduction of an outcome-based testing methodology, the skills and requirements of both the independent assessors and the relevant departments of the assessed organisation, and the approach to nationally directed technologies and processes, such as Multi Factor Authentication (MFA).

	Assessment duration and planning	We anticipate that assessments this year will need to be conducted between January and June 2025. We expect there will be a minimum of two weeks of fieldwork for the review. Additional time should be planned before and after the field work for pre-review planning and report write up (see Appendix B for an indicative timeline). With the DSPT aligning with CAF, greater reliance on evidence and input from the cyber security and information governance teams should be factored into planning to ensure the CAF-aligned DSPT assessment is completed before the mandatory deadline of 30 th June 2025. Further information on assessment planning will be available in the independent assessment guide and future communication from NHSE.
(Arranging assessments	NHSE encourages organisations to choose assessors from the <u>NCSC Cyber Resilience Audit Scheme</u> or equivalent. Due to the change in focus and nature of the assessment, it is encouraged that independent assessments are conducted by qualified and skilled assessors who are experienced in and can competently assess against the CAF. (See Appendix A for an indicative RACI for the independent assessments).
.	Approach to testing	The CAF-aligned DSPT is less prescriptive in what an organisation presents as evidence for each outcome than the previous DSPT. Indicators of good practice (IGP) give examples of procedures and processes which organisations can refer to when deciding whether they have met the expected achievement levels. There may be some instances where organisations judge that they have met a contributing outcome in a way which does not correspond to, or align with, the suggested IGP's. Assessors will need to work closely with organisations to understand how they can evidence success against the outcomes and expected achievement levels. For a number of outcomes, sample testing will be required by assessors to verify the achievement of one or more IGPs. Where sample testing is required, the organisation will need to provide a list of the entire population, along with evidence that the population is complete and accurate. The assessor will select a sample, the size of which will be a representative proportion of the entire population. Assessors will also now be required to follow up on management actions post-assessment to check that they are aligned to the original assessment findings and to confirm their implementation status. The results of this work should be reported to NHSE.
1	Outcomes-based approach, with certain national directive policy requirement	The CAF-aligned DSPT framework primarily adopts an outcome-based approach, emphasising the achievement of best practices without dictating specific methods for their implementation. This flexibility empowers organisations to tailor their practices to their unique circumstances while ensuring adherence to the desired outcomes. However, the framework also has a limited number of national directive policy requirements, deemed essential for achieving the desired outcomes, for example the MFA policy. More information can be found in the NHSE DSPT Independent Assessment Framework, to be published in November 2024.

Audit Mandatory Outcomes 24/25

Outcome	Expected achievement level
A2.a Risk management process	Partially achieved
A4.a Supply chain	Partially achieved
B2.a - Identity verification, authentication and authorisation	Partially achieved
B4.d - Vulnerability management	Partially achieved
C1.a Monitoring coverage	Partially achieved
D1.a - Response plan	Partially achieved
E2.b – Consent	Achieved
E3.a Using and sharing information sharing for direct care	Achieved

Plus 4 outcomes chosen with the org...

Detailed guides: web Audit guides - NHS England Digital; PDF https://www.dsptoolkit.nhs.uk/Help/Independent-Assessment-Guides

For each outcome a suggested approach to testing for Partially Achieved and Achieved

Suggested Documentation for Partially Achieved* and Achieved

*Where Partially achieved is available



As documented in the introduction to this framework, independent assessors are expected to use their professional judgement when assessing organisations against the Cyber Assessment Framework (CAF).

The approach and documentation list described below provides guidance on how to conduct testing and should be adapted as appropriate in order to assess whether the NHS providers outcomes are effectively achieved.

Suggested approach to testing – Partially achieved

- 1. **Policies , procedures and processes -** Obtain the policies, processes and procedures relevant to security governance, risk management, technical security and regulatory compliance, and assess whether:
- a) The organisation has undergone a process (such as reviewing its suite of policies, processes and procedures against the outcomes of the CAF-aligned DSPT) to ensure all necessary areas are covered to reasonably mitigate known security and information risk. The organisation should be able to justify how it has reached its conclusion; (PA#1)
- b) The contents are appropriate for the type of organisation, and include key elements such as roles and responsibilities, laws and regulations to follow and the risk appetite of the organisation; (PA#1)
- c) The organisation has aligned its policies, processes and procedures to national policies (such as the National Data Opt Out) and legal frameworks (such as the National data opt out). The organisation should be able to demonstrate how it has identified relevant national policies and legal frameworks and appropriately incorporated them. (PA#3, A#7)
- Update following major incidents and data breaches Discuss with management the process for identifying changes required to policies, procedures and processes following major cyber security incidents and data breaches, and the process for getting those changes approved and implemented. Obtain evidence from the last major cyber security incidents and/or data breach and assess whether the process was followed. (PA#2, A#4)

Additional approach to testing - Achieved

- Policies, procedures and processes Obtain the overarching security governance and risk management approach, technical security practice and specific regulatory compliance documentation. In addition to the controls assessed in step 1 of "partially achieved" assess whether:
- a) The organisation has identified a set of key information governance principles (for example accountability, transparency) and cyber security principles (such as least privilege, application security), and has undergone a process to ensure its policies, processes and procedures reflect the best practical ways of fulfilling these principles. The organisation should be able to justify how it has reached its conclusion; (A#1)
- b) Policies, processes and procedures are mapped to relevant essential functions and technologies. The organisation has a scheduled or efficiently reactive review process when new technologies are implemented to identify and remediate areas



Suggested documentation - Partially Achieved

- policies, processes and procedures relevant to security governance, risk management, technical security and regulatory compliance.
- evidence of policies, processes and procedures being updated following major cyber security incidents and data breaches.

Additional documentation - Achieved

- Evidence of key information governance and cyber security principles being considered.
- Evidence of mapping policies, processes and procedures to essential functions and technologies.
- Evidence of assessing applicability of policies, processes and procedures to staff groups.
- · Evidence of key performance indicators (KPI) reporting to executive management.
- Evidence of regular review of documentation.
- Evidence of review of documentation following any changes to the essential functions, or changes to the threats faced by those functions.
- Evidence of design and implementation of failsafe measures.

Case study: Scoring – Organisation's risk scoring

When rating there 1. Co as IG in yo ris

2.

3.

of outcomes that have not met the minimum achievement levels to the table below and assign an overall rating to the organisation.

Vhen scoring the risk ating of the organisation,	Outcome	Description	IGP #	Organisation assessment	KPMG assessment	Comment	Overall assessment
here is three steps to take:		A2.a Your organisation has effective internal processes for managing risks to the security and governance of information, systems and networks related to the operation of your essential	PA#1	Not Achieved	Agree but Insufficient	We obtained and inspected documentation, and noted that this IGP is Not Achieved.	
. Complete the assessment of every			PA#2	Achieved	Agree	We obtained and inspected documentation, and noted that this IGP is Achieved.	
IGP for each outcome in scope. This will give			PA#3	Partially Achieved	Agree	We obtained and inspected documentation, and noted that this IGP is Partially Achieved.	
you the outcome level risk rating	A2 a Systems and networks		PA#4	Not Achieved	Agree but Insufficient	We obtained and inspected documentation, and noted that this IGP is Not Achieved.	Overstated
2. Assess the outcome result against the		function(s) and communicating associated activities. This includes	PA#5	Partially Achieved	Understated	We obtained and inspected documentation, and noted that this IGP is Achieved.	
minimum requirement level for each	impact assessments (DPIAs).		Partially Achieved	Understated	We obtained and inspected documentation, and noted that this IGP is Achieved.		
outcome.		PA#7	Achieved	Overstated	We obtained and inspected documentation, and noted that this IGP is Partially Achieved.		
outcome. B. Compare the number			PA#7	Achieved	Overstated		

2

Objective	Outcome	Minimum achievement level	Outcome result	Minimum achievement level met?	Overall Risk Assessment
•	A2.a	Partially Achieved	Not Achieved	Achievement not met	
Α	A4.a	Partially Achieved	Not Achieved	Achievement not met	
В	B2.a	Partially Achieved	Achieved	Achievement exceeded	
	B4.d	Partially Achieved	Partially Achieved	Achievement met	
С	C1.a	Partially Achieved	Partially Achieved	Achievement met	High
D	D1.a	Partially Achieved	Partially Achieved	Achievement met	
E	E2.b	Achieved	Achieved	Achievement met	
	E3.a	Achieved	Achieved	Achievement met	

Overall risk rating across all tested outcomes	Explanation
Very high	More than 4 outcomes are rated as not meeting minimum achievement levels required and/or the organisation cannot comply with mandatory policy requirements.
High	Between 2 and 4 outcomes are rated as not meeting minimum achievements levels required.
Moderate	No more than 1 outcome is rated as not meeting minimum achievement levels required.
Low	All minimum achievement levels have been met.
Very low	All minimum achievement levels have been met and achievement levels have been exceeded for at least 1 outcome.

3

A few things that can help



Expectations Statements

https://www.dsptoolkit.nhs.uk/News/154

Produced following user feedback to set out what being Approaching Standards means for organisations and a recognition of the volume of change this year.

Data Security and Protection Toolkit 2024-25 for large NHS Organisations

Update for NHS Trusts, CSUs, ALBs and ICBs

← Back to list of news

In September 2024 the DSPT changed to adopt the National Cyber Security Centre's Cyber Assessment Framework (CAF) as its basis for cyber security and IG assurance. This led to NHS Trusts, CSUs, ALBs and ICBs seeing a different interface, which sets out CAF-aligned requirements in terms of objectives, principles and outcomes. The scope of the 24-25 DSPT includes additional cyber and information governance requirements compared to the 23-24 DSPT.

The new CAF-aligned DSPT is split into 47 contributing outcomes, each of which are supported by indicators of good practice, grouped into levels of achievement – 'Not Achieved', 'Partially Achieved' or 'Achieved'.

To achieve Standards Met, NHS organisations will have to meet the expected achievement level set by NHS England for each outcome. This is called a profile and is available in the DSPT or at: https://www.dsptoolkit.nhs.uk/News/DSPT-Changes-in-24-25.

It is recognised that the move to a CAF-aligned DSPT is a significant change and will be a considerable challenge for many NHS organisations. This represents an increase in the data security requirements for organisations. The main areas of uplift are in the requirements to protect your organisation from cyber risk. There is understanding that this may take some time to meet all the requirements. Due to the significant change in how the DSPT is answered, organisations that rely on DSPT 'Standards Met' for contractual or data exchange

Specimen Supporting Statements

Produced following user feedback Two launched this week

The templates are examples only. Organisations are free to use an approach that suits their environment

Available in the Overview section of the help menu

Speak to your auditor about what they need

	Specimen·Supporting·Statement·for·B1.a·Policy,·process·and·procedure·development
	¶ OUTCOME:ACHIEVEMENT:LEVEL¶
	¶ "
	This organisation believes it can justify an achievement level of Partially Achieved for DSPT outcome B1.a Policy, process and procedure development.
	୩ SIGNED·OFF·BY:·Sally·Smith·-·outcome·owner¶ ୩
	॥ CONFIRMED·BY:·Check·and·challenge·session·at·the·May·2025·Information·Governance· Committee·(minutes·uploaded·as·2024-05-28·IGC·minutes)·¶ •
	זו REPORTED TO: Risk and Audit Committee (minutes uploaded as 2024-06-18 RAC minutes), the Board with delegated responsibility for Cyber Security and Information Governance.¶
	¶ INDICATORS:·PA#1·and·PA#3¶
ach	¶ We·conducted·a·review·of·our·policies·and·procedures·(uploaded·as·IG·and·Cyber·Policy· and·Procedure·review·24-25·October·2024.pdf), to·assess·how·comprehensively·they· documented·our·approach·towards·criteria·outlined·in·PA#1.·The·analysis·was·conducted·by· the·IG·Manager·and·Cyber·Security·Manager.·The·sources·we·mapped·our·policies·and· procedures·against·were:¶ ·¶
9	 a)→The·24-25·DSPT·indicators·of·good·practice·(see·IG·and·Cyber·Policy·and·Procedure·review·24-25·October·2024.pdf)¶ b)→The·relevant·risks·on·our·risk·register·(see·IG·and·Cyber·Policy·and·Procedure·review·24-25·October·2024.pdf)·¶
	c)→NHS·England·IG·guidance·(seé·IG·and·Cyber·Policy·and·Procedure·review·24-25· October·2024.pdf)·¶
	d)→NHS·England·Cyber·Security·guidance·website·(see·IG·and·Cyber·Policy·and· Procedure·review·24-25·October·2024.pdf)··¶
	\P
	Points a) and c) provided assurance of PA#3, as well as discussions that took place with IG

colleagues at the local SIGN meeting to support peer review (Minutes uploaded as SIGN

On going help and support

Exeter Helpdesk

https://www.dsptoolkit.nhs.uk/Hom e/Contact

ssd.nationalservicedesk@nhs.net

Tel: 0300 303 5035

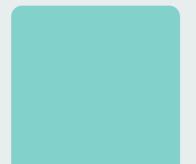
Scheduled Webinars

3rd Tuesday of the month

https://www.dsptoolkit.nhs.uk/ <u>News/webinars</u> Includes Immersive Sims

Cyber Associates Network	IG Networks	Regional Security Leads
Peer Support Lots of different perspectives Webinar recordings	GMIGG Y&H IGN Mix of IG and Cyber	Advice and Support Improvement plans

Questions and Feedback







Thank you for coming

We hope to see you again soon