Impact Assessment (IA)

Title: Data (Use and Access) Bill : Open Data Architecture Information Standards

IA number: DHSCIA9646

RPC reference number: RPC-DSIT-5358(1)

Lead department or agency: Department of Health and Social Care

Other departments or agencies: NHS England

Date: 23 October 2024

Stage: Final stage

Source of intervention: Domestic

Type of measure: Primary Legislation

Contact for enquiries: dhsc.publicenquiries@dhsc.gov.uk

RPC opinion: Fit for purpose: green rated

Summary: intervention and options

Cost of preferred (or more likely) option

(in 2024 prices, millions)

Item	Cost
Total Net Present Social Value	137.6
Business Net Present Value	-61.2
Net cost to business per year	7.1
Business Impact Target Status	Qualifying provision

What is the problem under consideration? Why is government action or intervention necessary?

Currently health and social care providers cannot easily access or share relevant care-related information using the systems in use in the NHS. Inconsistencies in interoperability have negative impacts on patient care. There is little existing incentive for IT suppliers to address variation and provide products that adhere to common standards. IT suppliers also need clarity about what are ‘musts’ for the products and services they provide, and individual health and care providers are not well equipped to negotiate changes to their systems. Strengthening the arrangements for ensuring

information standards are met across the NHS will improve interoperability, the effectiveness with which systems manage and share data, and outcomes for patients.

What are the policy objectives of the action or intervention and the intended effects?

The policy objective is to improve compliance with information standards in the health and social care sector, across providers of care and IT systems, to ensure systems are fully interoperable, so data can flow through the system in a usable and standardised form – thereby supporting appropriate access to information when and where it is needed. The measures provided in the DUA bill build on those set out in the IA for s95 HCA 2022, which make information standards mandatory and extend their application to include private health and care providers. The DUA measures extend the scope of information standards further to apply to IT suppliers of products and services used in the health and care system to our interoperability vision to be delivered further, faster. This aims to ensure both provision of care, and provision of the IT supporting that care, are bound by the same standards and have a joint responsibility for meeting them. Intended effects include improved patient outcomes, better procurement and commissioning by health and care providers, and a more dynamic and responsive health and social care IT market.

What policy options have been considered, including any alternatives to regulation?

A long list of 7 options were assessed using critical success factors, based on which 3 were short-listed for further analysis.

These were: Do nothing; Policy option 1 - Enacting legislation on IT suppliers (preferred option); and Policy option 2 - Issue guidance to health and social care providers to prohibit new contracts that do not comply with specified information standards after a specific date (public and private) (alternative viable option).

Using guidance (option 2) would have low implementation costs and provide greater flexibility for IT suppliers, however, it would create increased administrative burden on individual health and care providers and may be contingent on the availability of IT products that meet specified standards. However, legislative change (option 1) would ensure that IT products or services are designed to meet centrally coordinated, information standards, and this option has the highest strategic fit and potential value for money.

Is this measure likely to impact international trade and investment?

Yes

Are any of these organisations in scope?

Micro: Yes

Small: Yes

Medium: Yes

Large: Yes

What is the CO_2 equivalent change in greenhouse gas emissions?
(million tonnes $C0_2$ equivalent)

Traded: Not applicable

Non-traded: Not applicable

Will the policy by reviewed?

No.

If applicable, set review date: N/A

I have read the Impact Assessment, and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible: DHSC Chief Economist

Date: 20/09/2024

Summary: analysis and evidence – policy option 1

Enacting legislation on IT suppliers

Description
Enacting legislation to direct IT suppliers in the health and social care sector to adopt an open data architecture approach using information standards to enable interoperability.

Full economic assessment

Price base per year	PV base year	Time period	Net benefit (present value (PV)) (£million) Low	Net benefit present value (PV)) (£million) High	Net benefit present value (PV)) (£million) Best
2024	2024	10	23.4	248.2	137.6

Costs

Estimate	Total transition (constant price) (£million) (2 years)	Average annual (excluding transition) (constant price) (£million)	Total cost (present value) (£million)
Low	178.0	0.4	172.4
High	240.9	0.6	233.3
Best estimate	209.4	0.5	202.9

Description and scale of key monetised costs by 'main affected groups'

All costs and benefits are incremental, as additional compliance with information standards achieved through the DUA measures depend on the impact of the s95 HCA measures. Our analysis indicates that the main cost for IT suppliers and health and social care providers (including Local Authorities who provide care) is likely to relate to information standards related system updates, at an estimated undiscounted cost of £9.5m for IT suppliers (75% of their total incurred costs) and £147.1m for health and care providers (73% of their total incurred costs). Further costs identified: IT suppliers on familiarising themselves with the standards; Health and care professionals on training on upgraded systems; and IT suppliers on fees to certify compliance with the standards. Survey data suggests a large portion of costs may be passed by IT suppliers on to providers. Monitoring and enforcement costs (including public censure) would be incurred by a designated authority.

Other key non-monetised costs by 'main affected groups'

There may also be costs incurred for internal IT teams in health and social care providers because of the legislation. These costs would be incurred where internal IT teams need to update other related systems, processes and databases in line with the standards, although IT systems by their nature are subject to regular updates and upgrades, to which users must respond, and we do not anticipate this would exceed Business as Usual requirements). Beyond that, no further significant non-monetised costs have been identified in this Impact Assessment.

Benefits

Estimate	Total transition (constant price) (£million)	Average annual (excluding transition) (constant price) (£million)	Total benefit (present value) (£million)
Low	0	30.3	256.7
High	0	49.8	420.7
Best estimate	0	40.3	340.5

Description and scale of key monetised benefits by 'main affected groups'

As noted, these measures build on those in the IA for s95 HCA 2022 – enabling the benefits identified to be achieved faster. As these benefits have been apportioned across these two related IAs – detail of which can be found in Table 2 – the benefits allocated to the DUA measures are dependent on the impact of the s95 HCA measures. Overall, the benefits of these measures identified result from information standards enabling interoperability, including: cost savings to health and social care providers; staff time saved from better access to data and more efficient processes; and value to patients from improved patient safety.

Other key non-monetised benefits by 'main affected groups'

In addition to the non-monetised benefits detailed in the impact assessment for s95 HCA 2022, benefits impacting the IT supplier market include enhanced reputations, through compliance with nationally set standards, improved competitiveness and potentially improved access to global opportunities as a result.

Key assumptions/sensitivities/risks

Discount rate: 3.5% (1.5% used for QALYs)

Many of the benefits and costs attributed to the DUA measures are dependent on measures in the s95 HCA 2022 having limited impact. If impact from s95 HCA 2022 exceeds estimates, the incremental impact from the DUA measures presented in this IA would be reduced.

Despite best endeavours to collect and draw upon strong evidence, cost and benefit assumptions remain assumptions based on the limited evidence available in places. To mitigate this uncertainty, we have applied optimism bias, carried out sensitivity analysis and planned monitoring and evaluation.

Information standards are a key enabler to achieving interoperability. Current planned activity and investment for the required infrastructure are on track to be in place before standards come into force; this infrastructure will complement information standards to achieve interoperability.

There is a risk that IT suppliers leave the market and that increased cost of IT products/services will be borne by taxpayers, although this is thought to be unlikely given the significance of health and social care as a marketplace for information systems, and one in which IT providers are keen to participate.

Business case assessment (Option 1)

Costs (£million)	Benefits (£million)	Net (£million)
7.1	0.0	7.1

Score for Business Impact Target (qualifying provisions only) £million:

35.6

Contents

Executive Summary

1. The NHS does not lack data. However, the NHS suffers from data being held in multiple sources. Effective information sharing is reliant on the ability of these IT systems across health and adult social care in England to be interoperable, which in turn demands standardisation to allow for information to be shared easily, in real time, between organisations. Interoperability will enable enhanced quality of care and safety for patients and better informed clinical and care decision-making, empowered by access to precise and comprehensive information.

2. The requirement for public health and care organisations to have regard to information standards was originally set out in the Health and Social Care Act (HSCA 2012). However, in the twelve years since, adoption of standards by both health and social care providers (at 42%), and IT suppliers of health and social care (at 56%) has not met the pace and scale needed for transformation.[1]

3. The Health and Care Act (HCA) 2022 made several changes to the powers in the HSCA 2012 to strengthen information standards for the health and social care system, including extending their scope to include private health and care providers and making compliance with standards mandatory.

4. The Information Standards measures set out in the Data (Use and Access) (DUA) Bill are intended to build on this and so enable the vision of improved integration and effective use of data to be delivered further, faster - by making those involved in supplying IT systems used for processing health or and social care information accountable for meeting certain standards.

5. The measures extend the scope of information standards to make it clear that information standards include standards relating to information technology (IT) or IT services used, or intended to be used, in connection with the processing of information. They also expand the scope of the application of information standards so that they can apply to providers of IT products and services used in connection with the provision in, or in relation to, England of health and social care.

6. Additionally, they expand the types of enforcement action available with respect to IT providers (to include compliance notices and public censure, in addition to monitoring compliance and financial penalties), and introduce a power to establish and operate an accreditation scheme for IT products and services intended for use in the health and social care sector in England.

7. The territorial extent of this legislation is limited to England.

8. These measures are intended to relieve burden on health and social care providers by supporting the more effective commissioning of IT products or services that meet their needs and the needs of the people they serve, in the knowledge that they meet the required standards, providing a legal mandate previously lacking. It will not diminish the importance of contractual obligations on IT providers,

9. Introducing mandatory information standards for IT suppliers is intended to encourage greater innovation in the health and social care IT supplier market by levelling the playing field. It will better enable access to and learning from smaller suppliers, local innovation and

1 Information Standards and Interoperability Survey, NHS, February 2024

international exemplars. In doing so, it ensures that standards are realistic, do not favour larger or more established suppliers, and do not overburden small suppliers.[2]

10. The impact assessment for s95 HCA 2022 has additional background information.

What are information standards?

11. Information standards in the health and social care sector are standards that relate to the processing of information, prepared and published under section 250 of the Health and Social Care Act (HSCA) 2012, as amended by the Health and Care Act (HCA) 2022.

12. Information standards are needed to enable interoperability, defining a common series of criteria which interoperable IT systems must meet. Currently, in the absence of binding legislated standards, health and care system providers and suppliers are not accountable for meeting the standards and we are unable to monitor and enforce compliance accordingly.

13. In the context of the goal of information interoperability, information standards have two key features:
    - **Information structure:** this ensures that patient information is described in a structured way, as far as possible, so that patient records are comprised of structured data - the form and meaning of which can be read and transmitted unambiguously between healthcare systems. In practice, this means the content of each data field has a defined form, selected from lists set out in the standards, or it is input-validated (information only accepted if input in the prescribed way).

    - **Standards selection:** setting standards at the centre ensures that, with sometimes multiple standards available in each information area, the same standards are adopted so information can be exchanged directly between systems without needing intermediate mapping. Additionally, adopting international standards, which is our intention where possible, rather than developing NHSE-specific standards, will give the best possible alignment across all care setting and IT suppliers.

Why is a legislative approach needed?

14. There are no existing powers that compel IT suppliers for the health and care system to provide products that enable interoperability. Furthermore, IT suppliers have said they need clarity about what are 'musts' for the products and services they provide, and individual health and care providers are not well equipped to negotiate changes to their systems.[3]

15. Currently only 42% of sampled health and social care providers, and 56% of IT suppliers to the health and social care system, comply with core information standards (excluding NHS number).[4] It is estimated that there will be 13% additional compliance with information standards across ICBs facilitated by the non-legislative, alternative option (issuing guidance). This compares with 44% additional compliance under the preferred, legislative option.[5] Further detail on additional compliance achieved can be found in the 'Assumptions for attributing benefits to DUA legislation' section (Paragraph 186).

---

2 Data saves lives: reshaping health and social care with data - GOV.UK (www.gov.uk)
3 Information Standards and Interoperability Survey, NHS, February 2024
4 Information Standards and Interoperability Survey, NHS, February 2024
5 Information Standards and Interoperability Survey, NHS, February 2024

16. Furthermore, as evidenced in Estonia[6] and Northern Ireland[7], government regulation has been shown to be the most effective means to address the issue of achieving compliance with common information standards in health and social care. Government regulation can unlock further compliance and benefits in several ways, such as through established standardised guidelines, clear rules and the provision of enforcement mechanisms to ensure compliance.

17. An options appraisal was undertaken, which considered both legislative and non-legislative options to make an informed and evidence-based decision to achieve the policy objective. These include a range of alternatives to regulation including self-certification by suppliers, and an analysis of the "Do nothing" option. The options were evaluated against a set of defined criteria based on input from stakeholders, leading to the selection of a preferred option.

18. The criteria, known as Critical Success Factors, were selected to provide a consistent and objective framework to analyse each option. These are based on His Majesty's Treasury (HMT) Green Book guidance.[8] They are: Strategic fit and business needs; Potential value for money; Supplier capacity and capability; Potential affordability; and Potential achievability.

19. The analysis identified a short-list of 3 options, which underwent further assessment. These were: "Do nothing", Policy option 1 - *Enacting legislation on IT suppliers* (preferred option), and Policy option 2 - *Issue guidance to health and social care providers to outlaw new contracts that do not comply with specified information standards after a specific date (public and private*) (alternative viable option).

20. A non-legislative approach, using guidance for health and social care providers to advise they contract only with providers who actively comply with specified standards (option 2) and maintain that performance, would have low implementation costs and provide greater flexibility for IT suppliers. However, it would create increased administrative burden on individual health and care providers, may be contingent on the availability of IT products that meet specified standards, and it would be more difficult to achieve the central coordination needed for system-wide change.

21. However, extending the scope of information standards to include IT suppliers (option 1) would ensure that the IT products or services used in the health and social care system are designed to meet centrally coordinated information standards, and this option has the highest strategic fit and potential value for money.

What will this achieve?

22. Mandatory information standards for IT suppliers will help to ensure that when information is accessed or provided it is in a standard form, both readable by and consistently meaningful to the user or recipient.

23. The British Medical Association (BMA) surveyed over 1,300 doctors across primary and secondary care in 2022, making a case for urgent investment in information technology in the NHS. One of the 5 areas of improvement identified was interoperability supported by

---

6 WP8_willis.indd (ox.ac.uk)
7 eHealth and Care Strategy | Department of Health (health-ni.gov.uk)
8 The Green Book (2022) - GOV.UK (www.gov.uk)

clear standards. Responses from doctors cited interoperability between primary and secondary care systems as a priority, noting that the significant backlogs in the system require improved information between primary and secondary care systems. Critically, the ability for local solutions for patient populations to be developed was dependent on common standards rather than seeking more centralised technology solutions such as a single system.[9]

24. Enabling information standards to apply to providers of IT products and services to the health and social care sector – in addition to public and private health and care providers - ensures that they can be directly held to account. Also, it supports the system and its suppliers to work in closer collaboration when providing systems and solutions.

25. Information standards make up the backbone of interoperability - the ability of health systems to exchange medical data regardless of domain or software provider – and so adopting common information standards can offer several benefits. These include: greater productivity, improved patient experience; supporting innovation and faster implementation of new technologies; improved data quality and patient care; and more intelligent procurement.

Economic analysis

26. Current compliance with standards is set out in Table 3. All economic analysis in this IA is based on apportionment between measures in the s95 HCA 2022 impact assessment and the measures within this IA. As such, many of the costs and benefits of DUA are incremental and dependent on the impact of the HCA measures. It is estimated that the s95 HCA 2022 will enable an additional 14% of ICBs to comply with standards. The premise is that these suppliers are currently using compliant systems with functionalities disabled. This cohort accounts for 24% of currently non-compliant ICBs, and hence 24% of the compliance costs and total information standards benefits (under full compliance) are attributed to HCA. It is estimated when DUA legislation is in place, alongside HCA, DUA will facilitate faster and easier compliance for the remaining non-compliant providers (76%). Therefore, it is assumed 76% of the compliance costs and total information standards benefits are attributed to DUA. It is recognised that a greater adoption than expected under the HCA will increase the net benefit of the HCA and reduce the net benefit of the DUA and vice versa.

27. The expected outcomes and impacts are detailed in the Theory of Change for the preferred option as outlined in section 1.4. This identifies a wide range of benefits, encompassing both monetisable and non-monetisable. These benefits result from the enhanced operational efficiency gained through improved data access, which reduces time spent by clinical staff on unnecessary activities and reduces duplication of processes and procedures. Furthermore, improved patient safety due to better access to patient information contributes to a reduction in medication errors and incidents related to patient safety. There are also further benefits to IT suppliers, from IT systems being more harmonised with international standards and greater clarity through legislation on standards requirements. These benefits, along with identified costs, form the basis of the economic analysis in this Regulatory Impact Assessment (RIA), where reliable data was available.

---

9 Local areas must review what works for them and the focus must be on ensuring interoperability between software and a common data space rather than opting for common systems that improve data sharing but remove functionality or usability bma-infrastructure-2-report-getting-it-right-dec-2022.pdf

28. Where sufficient robust data is available, we have estimated the monetary impact of the various reforms, both direct and indirect. Where this evidence is not yet available, we have provided an in-depth explanation of the potential costs and benefits and ensured that any evidence gaps will be referenced in our monitoring and evaluation plan which can be found at the end of this IA.

29. Our approach to costing common information standards under the DUA is based on four key considerations:
    1. The extent of current knowledge on the scope and specificity of the information standards;
    2. The ability to benchmark the costs to implement information standards;
    3. The interaction of the information standards proposed under the DUA and the related preceding legislation, namely the Health and Care Act 2022; and
    4. The diverse nature of Health and Social Care Providers in England.

30. In brief, as future information standards remain an unknown, the costing has had to be based largely on a set of informed assumptions, rather than defined NHSE implementation proposals. Of these, the most important is that information standards will reflect the current/emerging international technology and data-use landscape, as has characterised information standards and tech investment in the NHS to date, so will not pose unreasonable operational challenges to potential providers. Section 1.5 explains the basis of each of these factors and their implications for costing, together with the rationale for why the approach taken is still considered sufficiently robust for the purposes of this IA.

31. This Impact Assessment estimates the total economic costs of the programme to be £202.9 million (present value terms). The quantified ten-year savings and benefits are estimated to be £340.5 million (present value terms). The net present value (NPV) is therefore £137.6 million, and the benefit cost ratio (BCR) is 1.68. (For the alternative viable option, the NPV is -£28.5 million, and the BCR 0.47.)

32. Table 1 sets out the costs, and Table 2 the benefits, that have been attributed to the s95 HCA 2022 impact assessment, this DUA impact assessment and overall total. The different rationales for the split of costs and benefits between HCA and DUA is summarised below.
    (a) **Familiarisation costs:** Separate costs for familiarisation are estimated to occur per piece of legislation; however, Health and Care providers are not expected to be directly required to familiarise themselves with the DUA. DUA familiarisation costs are therefore only expected to occur for IT suppliers.
    (b) **Training costs, Information standards system update costs and all benefits– Take up of compliance*:*** Across HCA and DUA, there are separate assumptions on the portion of compliance achieved by each bill. Based on results from the NHSE information standards and interoperability survey, 42% of health and social care providers comply with standards. It is assumed that HCA measures will enable 14% of providers to comply (24% of non-compliant providers), whereas DUA will facilitate compliance of the remaining 44% of providers (76% of non-compliant providers).
    (c) **Compliance monitoring and enforcement costs*:*** The size of a compliance body who will oversee compliance for Health and Care providers, and IT supplier (beyond accreditation) has been estimated as an early indicator of what compliance costs may be. We assume a proportion of the compliance body's resources that will be dedicated to enforcing DUA legislation, taking into account the relative size of IT suppliers within the broader landscape of Health and Care providers and the anticipated complexity of the DUA requirements. Based on this, it has been assumed 95% staff will be focussed on Health and Care Providers and 5% of staff on IT Suppliers. At this stage, these are considered to be the best evidence available for estimating the appropriate split.

(d) **Conformance testing and accreditation costs:** These costs are only expected to occur as a result of DUA to certify that IT Suppliers are complying with the standards laid out in DUA. This cost is therefore only estimated in DUA.

Table 1: Split of costs between HCA and DUA - These costs are estimated over a ten-year period (£, present value)

Cost type	HCA amount	HCA %	DUA amount	DUA %	Total amount	Rationale
Familiarisation cost	£1,243,658	98%	£19,493	2%	£1,263,151	(a)
Training cost	£15,813,025	24%	£50,074,579	76%	£65,887,604	(b)
Information standards system update cost	£44,059,305	24%	£148,576,724	76%	£192,636,029	(b)
Compliance monitoring and enforcement cost	£26,870,165	95%	£1,550,202	5%	£28,420,367	(c)
Accreditation cost	£0	0%	£2,631,263	100%	£2,631,263	(d)

Table 2: Split of benefits between HCA and DUA - These benefits are estimated over a ten-year period (£, present value)

Benefit type	HCA Amount	HCA %	DUA Amount	DUA %	Total	Rationale
Reduction in mapping and standardisation costs across relevant ICBs	£6,763,301	24%	£21,642,563	76%	£28,405,864	(b)
Cost savings from reduction in duplicate tests (diagnostic and lab tests)	£20,443,315	24%	£65,418,607	76%	£85,861,922	(b)
Value of time saving (patient record access)	£9,934,936	24%	£31,791,794	76%	£41,726,730	(b)
Reduction in cost of excess bed days (transition medication error reduction)	£5,037,632	24%	£16,120,424	76%	£21,158,056	(b)
Quality-Adjusted-Life-Years (QALY) value of prevented fatalities (transition medication error reduction)	£3,336,139	24%	£10,675,645	76%	£14,011,784	(b)
Reduction in cost of excess bed days (non-transition medication error reduction)	£1,803,770	24%	£5,772,064	76%	£7,575,834	(b)

QALY value of prevented fatalities (non-transition medication error reduction)	£6,138,496	24%	£19,643,187	76%	£25,781,683	(b)
Value of time saved reporting medication errors	£3,567,630	24%	£11,416,417	76%	£14,984,047	(b)
Reduction in reporting costs for patient safety incidents (PSIs)	£49,376,559	24%	£158,004,988	76%	£207,381,547	(b)

33. It is anticipated that wider adoption of information standards would enhance the effectiveness of various other initiatives through better uses of data, leading to increased efficiency in operations, reduced waiting times, faster diagnosis, and swifter discharges - and ultimately resulting in better patient care.

34. Based on this, mandating information standards will be a key enabler of the overarching NHSE policy objectives for all NHSE clinical systems to be interoperable and support other NHSE initiatives by providing a legislative framework that can be used to support roll-out and adoption.

Risks

35. Some of the risks identified are:
    - All costs and benefits attributed to these measures are dependent on measures in the s95 HCA 2022 IA having limited impact, such that full benefits are only realised with the addition of the measures within the DUA bill. If the impact of s95 HCA 2022 exceeds estimates, additional impact from these measures under the DUA would be commensurately reduced.
    - Healthcare is a devolved matter. This has the potential to impact the benefits if there is no medium for achieving similar outcomes in other nations of the UK, i.e. England uses one set of information standards, and the devolved nations use different set of standards. As a result, clinical information sharing will be limited to within England, and information sharing with NHS Wales, Scotland, Northern Ireland will be challenging and time consuming. This will require investment in staff time to ‘translate’ clinical records to the standards used by the devolved nation.
    - If mandated standards are not designed properly, and do not address clinical and care provider requirements, there is a risk that these standards could inadvertently lead to an increased administrative workload for healthcare professionals or reduced clinical engagements with their systems. Such an increase in workload could negate the anticipated time-saving benefits that the standards are supposed to deliver. Moreover, if the standards are seen as excessively complex, they may be viewed unfavourably by vendors in the supplier market, potentially leading to reduced involvement from suppliers and a decrease in market competition.
    - The risk of IT suppliers leaving the market due to an increased burden to deliver a product or service that is for England only.

- The risk of increased cost of IT products/services because the increased cost of compliance outweighs the downward pressure on prices resulting from increased competition.
- The risk of provider non-compliance due to the inherent differences in the health and social care provider market.

36. Mitigation strategies have been identified to address some of these risks, this is outlined in section 1.8.

Detailed Review

1.0 Problem under consideration and rationale for intervention

Background

37. Stakeholders generally agree that ensuring usable data can flow between different IT systems in different organisations will yield important benefits for health and social care delivery and that a standards-based approach is the best way to achieve this.[10],[11] To this end, the Health and Social Care Act (HSCA) 2012 was passed - setting out a requirement for public health and social care providers to have regard to information standards (Section 250).

38. However, in the twelve years since, adoption of standards by both providers (at 42%), and IT suppliers for the health and social care sector (at 56%) has not met the pace and scale needed for transformation[12].

39. The HCA 2022 strengthened these powers to mandate that all health and social care providers (both public and private) comply with information standards, backed up by the power to enforce these standards through financial penalties to private providers.

40. Furthermore, significant work is ongoing in NHSE, working with stakeholders to develop the operational procedures and necessary standards, and make clear which standards are 'musts' for the sector and how we plan to enforce them.

41. Moreover, in social care, we have published a standards and capabilities roadmap for digital social care record solutions to ensure that assured digital social care records suppliers have clarity about what their products need.

42. However, health and care providers ability to meet mandatory standards is partly a function of their IT supplier's conformity to the standards. We have therefore included further changes to Section 250 of the Health and Social Care Act 2012 in the Data (Use and Access) (DUA) Bill.

43. This includes a power to apply standards to suppliers of IT systems and services equivalent to those applied to health and social care providers, as well as the power to enforce these

---

10 PwC Blockers survey, NHSE
11Kings Fund, Interoperability is more than technology, Sep 2022
12 Based on health and social care provider compliance with six core information standards, excluding mandatory standards e.g., NHS number. Standards include NHS Data Dictionary Vocabularies; OPCS-4; dm+d; ICD-10/1; SNOMED CT; and HL7 FHIR UK CORE. Source: Information Standards and Interoperability Survey, NHS, Feb 2024

standards - through compliance notices and financial penalties - and the power to establish and operate an accreditation scheme.

44. These changes, together with those made in the HCA 2022, are intended to facilitate transformation of the health and care system such that data is in a standard form, both readable by, and consistently meaningful to, any reader anywhere in the system.

Information standards and interoperability

45. NHSE has defined interoperability as follows:

Interoperability, in the context of health and social care, is the capability for people involved in the provision and receipt of care to interact and complete a task across software and organisational boundaries; and use equipment, systems, or products from different vendors, which operate together in a coordinated fashion, with minimal to no human intervention.

46. This seamless exchange of information across health and social care settings is key to the delivery of the future vision of care in England.

47. Implementing information standards alone will not allow the sharing of, or access to real time patient data across systems; however, information standards will be an enabler for such interoperability. To realise the benefits of interoperability, NHSE will also need fit-for-purpose architecture that allows the real time transfer of information between providers across public and private health and social care ecosystems. This interoperability architecture will have a cost associated with its implementation, testing, roll out and training, as well as ongoing support.

48. 'Interoperability' might look different in different contexts, and there is continual potential for further development and progression. It is not a concrete, fixed state, which can be simply achieved.

49. To assess costs and benefits in an interoperability context, analysis in this IA has been undertaken within the framing of a regional level of interoperability.

50. Regional interoperability, supported by the National Record Locator (NRL), was agreed by NHSE and DHSC as the minimum required to facilitate effective information exchange, as it covers the Integrated Care Boards (ICBs) within each region.

51. Existing NHSE programmes – namely, Shared Care Records (ShCR), also known as Connected Care Record (ConCR) – are in place to establish the clinical architecture and systems necessary to achieve regional interoperability. The evaluations in this impact assessment are based on the assumption that this architecture will be operational. The justifications for selecting regional and ShCR as the bases for the minimum level of interoperability are discussed in more detail in Appendix 4.

52. This assessment does not include infrastructure costs required to achieve interoperability. These costs have been budgeted as part of a different programme, under which the NHSE have committed that, by March 2025, all clinical teams in an Integrated Care Board (ICB)

will have appropriate access to a complete view of a person's health and social care record to which they can contribute.[13]

53. A business case has been submitted internally to draw down on agreed funding to complete this work with an anticipated approval date of August 2024 under the Frontline Digitisation: Connecting Care Records (ConCR) Programme (Phase 1). All ICBs currently possesses a ShCR, however the extent to which standards are adopted varies across ICBs. It is anticipated with a strong degree of confidence that conformity with the International Patient Summary (IPS) standards will be achieved by March 2025, and it is believed there will be no delays in meeting this target.[14]

54. At present, there is limited data sharing between ShCR and LA systems at a local level. As of August 2024, 69.5% of LA's are connected to their local ShCR and the ConCR programme continues to provide funding to ensure all ShCR are connected to LAs.

55. In addition, Digital Shared Care Record implementation (for social care) has focussed on care providers to date, and discussion across DHSC and NHSE is ongoing on system interoperability and standards, and the programme will be supporting further work on interoperability with LA's and other ASC sector organisations as part of a Spending Review, which is due to be submitted to Treasury with anticipation of confirmation in the Autumn.

56. The benefits considered in this RIA, i.e., as it relates to mandating information standards, are therefore limited to:

- Benefits associated with the implementation of common information standards alone; for example, following implementation of the standards, a clinical episode would be described in common/standard clinical terms by different providers across the health and social care ecosystem.

- Benefits regarding interoperability to the extent that implementation of common information standards is the missing element needed to realise said benefit in the context of infrastructure and systems already in place.

Problem under consideration and the issue being addressed

57. There is need for efficient and transparent means of recording, transmitting and accessing reliable clinical information to manage and deliver high quality care across the health and care system. This can be achieved through development and use of standardised and interoperable IT systems.

58. Current legislation (HSCA 2012 as amended by the HCA 2022) places an administrative burden on providers to seek and acquire IT products and services that meet specified standards, which they may lack the personnel, or expertise, to understand. As it stands,

---

13 NHSE have committed by March 2025, that all clinical teams in an Integrated Care Board (ICB) will have appropriate access to a complete view of a person's health and social care record that they can contribute to. All 42 ICBs have been funded to meet a minimum requirement (Minimum Viable Solution (MVS) 1.0 - as of March 2021) focused on sharing historical records between NHS trusts and general practice. A business case has been submitted internally to draw down on agreed funding to complete this work with an anticipated approval date of August 2024 under the Frontline Digitisation: Connecting Care Records Programme (Phase 1)

14 Confirmed with NHSE programme leads.

compliance relies on the availability of IT products meeting specified standards, without easy access to readily available accredited products in the market.

59. A survey of health and care providers and IT suppliers, conducted by PwC, to probe what was blocking the adoption of standards, found that the most cited reason by care providers of not implementing an information standard is that the supplier does not offer the feature. At the same time, the most cited reason by IT suppliers was that customers had not requested the feature. Health and Care providers responses indicated that they felt they were not sufficiently equipped to manage IT suppliers in driving increased interoperability. The survey found that the key enabler to address these blockers would be statutory requirements on suppliers to adopt and implement interoperability standards.[15] (Further detail in Appendix 3, section 1.3)

60. Without further action, the current issues relating to data-sharing and lack of interoperability will continue to be a burden because, at present, IT suppliers to the health and care system are not held accountable for ensuring the products they supply meet prescribed standards. There are no powers to compel IT suppliers to adopt such common standards.

61. In contrast, under DUA, IT suppliers would have the same information standards applied to them. The objective is that this should compel IT suppliers to adjust their offerings to meet these standards, thus sharing the burden of statutory compliance between providers and suppliers. Consequently, it would become easier for health and social care providers to find suitable IT systems, streamlining procurement processes and reducing the need to change suppliers - accelerating the rate of compliance with information standards and facilitating quicker attainment of interoperability.

62. Additionally, under current circumstances, some providers experience vendor lock-in, characterised by extreme difficulty in transitioning from one IT supplier to another and resulting in a barrier to new market entrants. In other words, even if alternative IT suppliers offer better quality products or services, a health and care provider can face significant challenges in switching due to its reliance on their current IT supplier. This results in an inability to cease using a product or service, regardless of its quality or suitability for the needs of the NHS. This has led to a limited choice of IT suppliers and information technology systems and a lack of power from individual providers, or central government, to set specific standards for these IT suppliers to meet.

63. The intention of proposed changes in the DUA bill is to mandate standards that would allow a common approach to information processing activities, such as:[16]

15 PwC Blockers Survey, NHSE
16 Information standards for health and adult social care in England – GOV.UK (www.gov.uk)

- How health and care providers describe which roles should have which level of access to certain types of information.
- The minimum information content that systems should be able to record for provision of care.
- The format and structure of that information, and technical interfaces through which that information should be made available.
- Standards in connection with cyber security.

Immediate objective for interoperability

64. The immediate objectives for interoperability are set out in s95 HCA 2022 impact assessment section 1.1.

Common information standards

65. Information standards in relation to the health and adult social care sector are standards relating to the processing of information, prepared and published under section 250 of the Health and Social Care Act (HSCA) 2012 as amended by the Health and Care Act (HCA) 2022, and as proposed to be amended by the Data (Use and Access) (DUA) Bill. The HCA 2022 changes the definition of 'an information standard' to a standard in relation to the processing of information (as opposed to a document containing such standards) and sets out that an information standard must specify to whom it applies.

66. Additionally, changes made by the HCA 2022 will make information standards binding and will extend them so that they may also apply to Care Quality Commission (CQC)-regulated private health and adult social care providers.

67. Changes proposed in the DUA Bill make organisations providing IT products and services to health and social care organisations accountable for meeting these standards and gives the Secretary of State for Health and Social Care powers to issue notices to suppliers who are suspected of non-compliance.

68. Information standards make up the backbone of interoperability - the ability of systems used by the health and care system to exchange data regardless of domain or software provider.

Rationale for intervention

69. Health and social care IT vendor markets for primary, community and mental health are fragmented with similar levels of market concentration in each of the relevant segments. Intervention to set regulations and promote competition is required to incentivise suppliers to follow standards, improve service, reduce costs, and innovate.

Is there a market failure?

70. Despite the value that interoperability could bring, the market has failed to reach an optimal level of interoperability on its own. Government must intervene to overcome the following key market failures:
    - Economic externalities: An IT supplier's decision to invest or provide interoperability can be expected to depend on its ability to monetise benefits through charging its own customers. However, interoperability may have significant knock-on benefits for third parties that the first party cannot monetise. Examples of

this include quicker patient record access for health and care providers, fewer patient safety incidents or increased competition in the market.

- Coordination failure: the full value of interoperability requires high information standards participation from IT suppliers, which needs major coordination. In a free market, there's little incentive for individual suppliers to change or play a role in coordination, making it challenging to achieve. Government intervention can ensure high participation and move towards realising the full benefits of interoperability.

- Imperfect competition: depending on their competitive position in the market, IT suppliers may face disincentives to being interoperable. Greater openness can enhance the appeal of other IT supplier's services with which it interoperates, both through exposure and removing barriers to switching suppliers – ultimately leading to a loss of customers. Government intervention can reduce market power of incumbents or gatekeepers, enabling greater competition from smaller firms and potential entrants.

Political and legal context

71. The NHS has been a focal point of political discourse, with various political parties advocating for health and social care reforms. Interoperability in IT systems is seen as a crucial step in achieving the vision of a more efficient and patient-centric health and social care system. The move towards interoperability aligns with the broader consensus that digitalisation can lead to better health and social care coordination, reduced administrative burdens, and ultimately improved patient care.

How the intervention fits with government objectives and the UK policy landscape

72. The UK government's healthcare policy framework is notably exemplified in the NHS Long Term Plan, which envisions a patient-centred, technology-driven healthcare system that addresses the challenges of an ageing population, chronic diseases, and healthcare accessibility. Interoperable IT systems are integral to this vision, as they facilitate the seamless exchange of patient information among health and social care providers, reducing administrative burdens and enhancing patient care coordination. The adoption of common information standards is an important enabler to achieving interoperability. This interoperability enhances the efficiency and effectiveness of the NHS, ultimately contributing to the government's goal of improving health and social care services while controlling costs.

73. The Hewitt Review recognised the need for digital innovation in healthcare to optimise the use of data and technology. The review emphasised the importance of interoperable IT systems in streamlining healthcare operations, driving clinical innovation, and improving patient experiences. It recommended actions to overcome barriers to data sharing and interconnectivity, providing a foundational framework for the regulatory measures aimed at interoperability.

74. Regulations promoting interoperability serve as a critical step in promoting a modern, efficient, and responsive health and social care system that meets the evolving needs of the UK population.

Markets and stakeholders that will be affected with government intervention

75. The stakeholders that will be impacted by the government intervening via legislation include:

- **IT suppliers of products and services for the health and care system:** Suppliers of IT products and services will need to be compliant with regulatory requirements and specified standards. This will require them to adapt their existing products or develop new ones to meet regulatory requirements, otherwise they may also be subject to enforcement measures and penalties.
- **Patients:** Patients will benefit through health and care providers having improved access to data. The transfer of care will be improved by real time sharing of their data across public and private health and care sectors. There will be less burden on patients to keep paper records or recall medical history. Access to standardised data will speed up patient care through care pathway optimisation and earlier diagnoses of diseases leading to improved outcomes because of earlier treatment interventions. Standards and data access can also improve patient and drug safety and reduce the risk of medication errors and patient incidents. Satisfaction and patient experience will also improve with better chronic disease management, preventive care, monitoring and self-management.
- **Public healthcare providers (hospitals, GPs, clinics)**: They will need to invest in, and implement compliant IT systems, train staff, and adapt their workflows to ensure seamless data sharing. Healthcare providers will also benefit from greater time saved from inefficient processes and duplicative efforts across systems. They will also benefit from cost savings from reduced mapping/standardisation costs, reduced cost of duplicate tests / procedures and a reduced prevalence of medication errors and associated reporting and treatment costs.
- **Private health and care providers:** Private hospitals, private social care providers and private GPs will need to make IT system related updates based on the information standards, train staff and adapt their workflows to ensure seamless data sharing.
- **Adult social care providers[17]:** They will benefit from improved integration across health and social care services in England through the combination of interoperability and information standards. This optimises the utilisation of social care resources and promotes better collaboration across various sectors, ultimately leading to improved outcomes for patients, and improved efficiency. Good quality records with standardised data underpin safe, effective, compassionate, high-quality care. This allows the communication of the right information, clearly, to the right people, when they need it. They are an essential part of achieving good outcomes for people who use services allowing:
    - The capture of information more easily at the point of care,
    - Support staff to respond more quickly to people's needs,
    - Sharing of important information quickly, safely and securely between care settings, and
    - Minimising risks to people's safety.

- **Local authorities:** As local authorities (LA's) are partners in ICBs and responsible for commissioning and providing social care, mandating information standards on IT suppliers of products and services used in health and social care will impact them in 3 ways:
    - As providers of social care. In instances where LAs provide care themselves, we expect those who are not already compliant under s95 HCA 2022 to become compliant once DUA is in place and therefore face direct costs related to information systems update costs. This is monetised within this IA.
    - As commissioners of care. LAs commissioning care may face increased costs passed on from IT suppliers via care providers. Currently, these costs have not been monetised because there is a high degree of uncertainty about what

17 Digital Record Systems: achieving good outcomes for people using adult social care services – Care Quality Commission (cqc.org.uk)

proportion of costs will be passed from IT suppliers to care providers and the proportion of these costs that will then be passed on to LAs as commissioners of care. As we begin implementation, we will monitor the impact on LAs as commissioners of care to improve our evidence base and work closely with OGD's such as DfE and MHCLG to ensure cross-government considerations are taken into account.

  - As users and purchasers of IT Systems that are subject to the powers provided in this bill. There is a risk that IT suppliers will pass on costs of mandatory information standards to LAs as users and purchasers of IT Systems that are subject to the powers provided in this bill. Currently, these costs have not been monetised as the work on standards for LA Adult Social Care systems is in its infancy, and therefore specific costs and benefits are uncertain. As this work develops, we will improve our understanding and evidence and work closely with OGD's such as DfE and MHCLG to ensure cross-government considerations are taken into account.

- The direct costs incurred by local authorities as well as total costs for Public Social Care Providers are outlined in Appendix 1.

Why the government is best placed to resolve the issue?

76. Currently only 42% of sampled health and social care providers and 56% of IT suppliers to health and social care comply with core information standards (this excludes NHS number)[18]. A comparative case of Estonian and British Healthcare Infrastructure shows that in Estonia[19] government regulation has been a very effective means to addressing issues of achieving compliance with common information standards in health and social care. The government has developed a technical framework for sharing information and makes it possible for government services to communicate digitally with each other. In addition to this technical capacity, there are certain policies and laws specifying that healthcare providers must send certain information to the national health information system. This presents avenues for advancement in England. Taking Estonia as an example, every citizen can digitally access both government and select private-sector services. Moreover, these services are interconnected allowing for seamless exchange of data to accomplish complex tasks. For example, when someone applies for a driver's license, their health record is verified automatically through the online system, eliminating the need for any physical paperwork to fulfil this administrative procedure. Key features which facilitate the system in Estonia include a nationwide data-exchange platform, universal health coverage for all citizens, and standardised national data.

77. Government regulation can unlock further compliance and benefits in several ways:
    - First, it allows for the establishment of standardised guidelines and clear rules that ensure a consistent approach to data exchange among health and social care providers and technology vendors. This standardisation is crucial for seamless communication among different systems.
    - Secondly, government regulation prioritises public interest, particularly the protection of patient data. It enforces stringent data security, privacy, and ethical usage standards, thereby guaranteeing the responsible handling of sensitive medical information.
    - Thirdly, government intervention provides accountability and enforcement mechanisms. Regulatory bodies can investigate and penalise entities that do not comply with interoperability standards, fostering adherence and ensuring that stakeholders take these standards seriously.

---

18 Information Standards and Interoperability Survey, NHS, Feb 2024
19 WP8_willis.indd (ox.ac.uk)

78. This approach facilitates multi-stakeholder engagement, resulting in regulations that reflect the diverse interests of health and social care providers, technology vendors, and patient advocates. Overall, government regulation offers the necessary oversight, consistency, and protection essential for addressing the complex challenges of IT system interoperability in the health and social care sector.

Legal basis for the government to act

79. The legal basis for the UK government to introduce regulations for information standards relating to interoperability lies in the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, which govern the privacy and security of patient data, along with the Health and Social Care Act 2012, granting the government authority over health and social care practices. These laws, in conjunction with the government's responsibility for public health and safety, provide a legal framework for regulating IT systems to enhance health and social care coordination, reduce errors, and ensure patient safety while upholding data protection standards and health and social care quality.

Interoperability standards adoption by market

80. About 55%[20] of the NHSE priority/preferred IT suppliers to the health and care sector in England are international providers and the World Health Organisation emphasises that global growth in the IT systems market stems from a rising demand for centralisation of health and social care administration and standardisation of processes.[21] The 20 core IT suppliers providing systems to the NHS state that they are already orientating their strategic and planning direction towards supporting interoperability standards.

81. Most of these core NHS suppliers (80%) support interoperability standards such as HL7 FHIR (most common). However, when a broader set of suppliers were specifically asked about HL7 FHIR UK core standards, only c.67% stated they were compliant with HL7 UK core standards[22]. Further to HL7, 69% stated their systems comply with SNOMED CT, 50% with ICD 10/11, 61% with the NHS dictionary of medicines and devices (aka dm+d), 33% with the NHS classification of interventions and procedures (OPCS-4), 53% with NHS dictionary terms and 86% with NHS number.[23]

82. Seven core information standards are fundamental for the health and social care system, with many currently published under existing HSCA 2012 powers. The current compliance rates for the health and social care providers and IT suppliers with each of these standards is outlined in Table 3.

20 EY analysis of IT clinical system suppliers provided by NHSE
21 Electronic Health Records (EHR) Market Estimates & Trend Analysis from 2021 to 2028, Grand View Research
22 Information Standards and Interoperability Survey, NHS, Feb 2024
23 Based on Information Standards and Interoperability Survey, NHS, Feb 2024

Table 3: Compliance with standards[24]

Standard name	Description	IT supplier compliance	Health and social care provider compliance
NHS Number	The NHS number is the NHS standard for identifying a specific recipient of care. The NHS number should be used to identify information regarding an individual receiving care when it is exchanged between systems	86%	83%
NHS Data Dictionary Vocabularies	The NHS Data Dictionary contains additional vocabularies that are to be used where appropriate	53%	38%
OPCS-4	OPCS-4 is the NHS current classification system for procedures. It should be used by systems for statistical purposes and calculation of reimbursements	33%	38%
dm+d	The Dictionary of Medicines and Devices is a dictionary of descriptions and codes representing medicines and devices in use across the NHS. It should be used by systems for recording or exchanging information about medicines and devices	61%	29%
ICD-10/11	ICD-10 is the NHS current classification system for diagnostic health information. It is used for statistical purposes and calculation of reimbursements. NHS are currently migrating to ICD-11	50%	43%
SNOMED CT	SNOMED CT is NHS agreed standard for clinical terminology. It should be used by systems for recording of direct care information.	69%	57%
HL7 FHIR UK CORE	HL7 Fast Healthcare Interoperability resources is the NHS standard for passing care data between systems. The UK CORE contains a list of specific profiles for use in England and the rest of the UK.	67%	45%
Average	The average of all the standards within this table.	60%	48%
Average	The average of the standards within this table excluding NHS number[25]	56%	42%

24 Based on Information Standards and Interoperability Survey, NHS, Feb 2024
25 This is based on the non-mandated standards. The NHS number is mandatory: NHS Number use becomes law | Digital Health

83. These insights demonstrate that clinical systems that IT suppliers provide to the England's health and social care providers are not fully compliant, although there appears to be a proportion of systems that are compliant with NHS information standards.

1.1 Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

84. DHSC and NHSE have worked alongside analysts from across Government to establish the rationale, options, costs and benefits and detail of the impact of options.

85. The analysis in this impact assessment has been informed by information obtained through review of existing literature and previous impact assessments, as well as engagement with stakeholders across the health and care system – including IT suppliers. For detail, please see Appendix 2. This includes:

- responses to a public consultation on Information Standards in the health and care system
- discussions with cross-government experts NHS England officials, and external consultants
- the NHSE information standards and interoperability survey, completed by IT suppliers and health and social care providers

86. Where evidence is available, we have included it in the analysis; however, despite best endeavours to collect and draw upon strong evidence, cost and benefit assumptions remain uncertain and based on limited evidence availability in places, reflecting especially the fact that the information standards have not yet been defined. To explore some of the uncertainties surrounding the data, sensitivity analysis has been employed across impacts to consider variability in data and assumptions. We begin by assessing the available evidence to develop theories of change for each option, and to establish the evidence available to support the quantitative and qualitative analysis.

87. Where evidence exists that has allowed us to attempt to quantify impacts, this has come from a variety of sources and assumptions referenced in this impact assessment. Where quantitative evidence is not available, qualitative analysis of impacts has been undertaken.

1.2 Description of options considered

Background

88. This section discusses the approach taken to identify the various policy options, legislative and non-legislative, to achieve compliance with common information standards across IT products and services in the health and care system. The process is outlined in table 4.

89. An options appraisal has been conducted, which provided an opportunity for all relevant stakeholders to make an informed and evidence-based decision, considering all relevant advantages and disadvantages for several different options.

90. This approach is helpful for several reasons: first, it provides a clear outcome by identifying a preferred option, which is developed in greater detail in this Impact Assessment; secondly, the process allows for stakeholder engagement and helps identify important priorities and questions regarding the preferred option from their perspective; thirdly, this

approach offers confirmation that the defined guidance from the Green Book and Better Regulation Executive has been followed.

Table 4: Process for appraising options

Step Number	Step Name	Description of step
1	Identify a long list of options (legislative and non-legislative).	Identifying options is, in most cases, an iterative process. The aim is to consider as many realistic options as possible. Approaches that were used include: literature review, benchmarking and discussions.
2	Define critical success factors (CSFs) and associated weights, if applicable.	Defining and agreeing CSFs for the options appraisal provides a consistent and objective framework to analyse each option. Three themes are adopted – strategic fit, feasibility and impact.
3	Assess the long list using CSFs.	This step involves assessing each option against the CSFs to determine whether they should progress to the short-list in the IA for further assessment or be discounted at an early stage.
4	Shortlist at least 3 viable options including a 'Do nothing' option.	Objectively score each option against each criterion using a collaborative process with relevant stakeholders to build consensus.
5	Carry out qualitative and quantitative appraisal.	Qualitative and quantitative appraisal will be carried out on the short-listed options and involve a SWOT and Cost-Benefit analysis.

Description of options considered

91. The option identification process resulted in the development of an evidence-based long list of seven options, which was subject to an options prioritisation exercise. Several policy options have been considered covering a spectrum of market-driven to government-driven solutions, both legislative and non-legislative.

92. The long list of options is shown in Table 5 and includes both legislative and non-legislative options. a review of literature. These were evaluated through literature review as well a series of meetings and workshops with representatives from the NHSE and DHSC.

93. The options in the long-list were chosen as each is designed ultimately to support achieving regional interoperability – either through information standards or architectural solutions. Options 2-5 can be identified as information standards options, whilst Options 6-7 are architectural options.

94. There have been previous failed attempts to deliver a solution that would improve efficiency of data sharing across the health and care system, some of which were similar to those set out in the long-list of options. This includes high profile attempts to introduced single IT systems (e.g. The National Programme for IT). This history has contributed to our options analysis.

Table 5: Outline of options

Option	Description	Type of Solution	Legislative
Option 1 - Do Nothing	Business as usual. IT products and services that may not adhere to open information standards will remain on the market. The onus on finding the right product stays with health and social care providers.	Not applicable	No
Option 2 - Enacting legislation on IT suppliers	Legislation to direct IT suppliers to adopt an open data architecture approach using Information Standard Notices.	Information Standards	Yes
Option 3 - Issue guidance to health and social care providers to outlaw new contracts that do not comply with information standards	Guidance to health and social care providers, to advise that all contracts between health and social care providers and IT suppliers after a set date have to build in new open data architecture standards as a requirement for IT suppliers.	Information Standards	No
Option 4 - Creation of a self-regulation scheme (industry led self-regulation)	Industry-level regulation amongst IT suppliers (of systems used in health and social care) without intervention from an external body. This would be led by a relevant trade association, which would set and enforce rules and standards; 'self-policing' would be the primary mechanism to ensure compliance and provide remediation.	Information Standards	No
Option 5 - Self-certification (individual supplier-led approach)	Individual IT suppliers would be responsible for maintaining required standards, demonstrated through measures such as conformance testing and self-accreditation.	Information Standards	No
Option 6 - Centrally procure a single IT system across health and social care	Health and social care providers adopt a centralised approach to IT systems and procure with a single IT supplier nationally. This reduces the number of systems used within health and social care, hence need for easier integration.	System Architecture	No
Option 7 - Single IT solution is built in-house across health and social care.	A single IT solution is built in-house across health and social care providers, and hence replaces the need for procurement of an IT solution.	System Architecture	No

1.3 Policy objective

Critical success factors

95. In determining which options to short-list for further evaluation, the long list options were assessed against five critical success factors (CSFs). The CSFs are the attributes that any

successful proposal must have if it is to achieve successful delivery of its objectives. The set of CSFs used to assess each option are summarised below:

A. **Strategic fit and business needs:** To what extent does the option fit with government strategies and objectives for interoperability and digital records. Considering time and achievability of objectives, structural complexity of the NHS and timing differences for implementation across NHS entities. **Potential value for money (VFM):** What is the relative scale of benefits reached by the option in terms of coverage of interoperability achieved across institutions and data categories, considering the scale of costs and risk? **Supplier capacity and capability:** Can IT suppliers deliver the required service under the option? Is the option attractive to the IT suppliers?
B. **Potential affordability:** What are the relative costs of each option compared to the budget available?
C. **Potential achievability:** How well the option is likely to be delivered given the ability and time for IT suppliers, health and care providers and NHSE =to respond and the skills set and difficulty to implement the option.

96. These CSFs were based on consultation with NHSE and based on the Green Book Critical Success Factors[26].

97. Table 6 presents an options scoring matrix, where all options are assessed and scored using a scale of 4 intervals[27],[28]. To arrive at the final score, equal weighting was applied to all criteria. Weights indicate the relative strength-of-preference of the criteria compared to each other and during the assessment all the criteria were deemed to be equally important. The option assessment process was undertaken through independently led workshops by a panel of NHSE and DHSC staff. considering the presentation and strength of evidence from research and the inclusion of input from NHSE and external information standards and interoperability subject matter experts and stakeholders. Individual scores were discussed to reach a consensus. Scores generally reflect how well each option performs relative to each other.

Table 6: Appraisal criteria scoring policy options against critical success factors

Policy Option	CSF A: Strategic fit and business needs	CSF B: Potential VFM	CSF C: Supplier capacity and capability	CSF D: Potential affordability	CSF E: Potential achievability
Option 1 – Do nothing	Not aligned	No Change	High capacity / capability	Within budget	Highly achievable

26 Green_Book_supplementary_guidance_-_Value_for_Money.pdf (publishing.service.gov.uk)
27 For criteria A, the scale was 'Not aligned, weakly aligned, Moderately aligned, Strongly aligned'. For Criteria B, the scale was 'No VFM, Limited VFM, Moderate VFM, Significant VFM". For Criteria C the scale was 'No capacity/capability, Limited capacity/capability, Moderate capacity/capability, Significant capacity/capability'. For Criteria D, the scale was 'Significantly over budget, Moderately over budget, Potentially over budget, Within budget'. For Criteria E, the scale was 'Not achievable, Possibly achievable, Probably achievable, Highly achievable'.
28 Each score in the four-point scale corresponds with a Red-Amber-Yellow-Green colour (RAYG) rating, which is show in Table

Option 2 - Enacting legislation on IT suppliers	Highly aligned	High VFM	High capacity / capability	Within budget	Highly achievable
Option 3 - Issue guidance to health and social care providers to outlaw new contracts that do not comply with information standards	Weakly aligned	Medium VFM	High capacity / capability	Within budget	Highly achievable
Option 4 - Creation of a self-regulation scheme (industry led self-regulation)	Weakly aligned	Medium VFM	Low capacity / capability	Within budget	Highly achievable
Option 5 - Self-certification (individual supplier-led approach)	Weakly aligned	Low VFM	Medium capacity / capability	Within budget	Highly achievable
Option 6 - Centrally procure a single IT system across health and social care	Moderately aligned	Medium VFM	Low capacity / capability	Significantly over budget	Possibly achievable
Option 7 - Single IT solution is built in-house across health and social care	Moderately aligned	Low VFM	No capacity / capability	Significantly over budget	Possibly achievable

Options shortlist

98. Based on the scoring assessment, the options were ranked from 1 to 7 – as set out in table 7 below:

Table 7: Option rankings

Rank	Score	Option	Rationale
1	20	Option 2 - Enacting legislation on IT suppliers	This option is strongly aligned with the UK Government's strategy and objectives, whilst likely providing significant potential value for money. Existing IT suppliers are also highly likely to have the relevant capacity and capability to implement the standards within set budget.

2	17	Option 3 - Issue guidance to health and social care providers to outlaw new contracts that do not comply with information standards	This option is likely to provide moderate value for money considering the scale of costs and risks. Furthermore, IT suppliers are likely to have significant capacity and capability to enact this option. This option also demonstrates high potential affordability and achievability.
3	15	Option 4 - Creation of a self-regulation scheme (industry led self-regulation)	This option is likely to be highly achievable and cost of implementation is also likely to fall significantly within set budget. However, it is weakly aligned with the UK government's strategy and objectives for Digital Records – as this intervention is voluntary with minimal incentives for IT suppliers to join the scheme, hence it is limited in its ability to achieve interoperability objectives. Capacity and capability of IT suppliers to implement this option is likely to be limited, given a central agreement would be needed on which standards are to be met.
3	15	Option 5 - Self-certification (individual supplier-led approach)	This option is likely to be highly achievable and significantly within set budget. However, it is weakly aligned with the UK government's strategy and objectives for Digital Records, as this intervention is voluntary with minimal incentives for IT suppliers to join the scheme, hence it is limited in its ability to achieve interoperability objectives. Option 5 is likely to demonstrate limited value for money since some suppliers are unlikely to participate without sufficient incentives like penalties.
5	14	Option 1 – Do nothing	Doing nothing does not provide strategic fit or meet business needs, nor does it provide any VFM. However, doing nothing would not have additional outlay since associated central costs are limited. Achievability of this option is high as it requires no particular skills to implement by from health and social care providers.

6	11	Option 6 - Centrally procure a single IT system across health and social care	This option involves greater risk, as risk is heightened by having a single supplier for such a complex and important system. This option is only likely to exhibit moderate potential value for money, whilst expensive enough to go significantly over any specified budget. It is also likely to be complex and difficult to achieve its implementation objectives.
7	9	Option 7 – Single IT solution is built in-house across health and social care	This option is moderately aligned with the UK government's strategy and objectives for Digital Records. However, the level of complexity means capacity or capability to deliver this will be constrained. The costs are therefore likely to be significantly over specified budget.

99. Based on the above rankings, the shortlisted options that will be taken forward for further evaluation include the 'Do nothing' option, and the two top ranked options:
    - Option 1: "Do nothing"
    - Option 2: "Enacting legislation on IT suppliers"
    - Option 3: "Issue guidance to health and social care providers to outlaw new contracts that do not comply with specified information standards after a specific date (public and private)"

Analysis of shortlisted options

100. To get a better understanding of the three shortlisted options, a Strengths, Weaknesses, Opportunities, Threats (SWOT) analysis was conducted. This provided a structured framework for understanding the pros and cons of each option, helping to inform future decision making.

Option 1: Baseline (Do nothing)

Strengths:

- There will be some incremental improvements in the adoption of information standards and progress towards interoperability based on the existing measures of s95 HCA 2022, without DUA being in place.
- No additional costs are incurred, and any potential failures in attempting to achieve interoperability are avoided and reliance on additional architecture within the IT system to achieve interoperability. Therefore, by doing nothing, any potential risks and costs of failure can be avoided.

Opportunities:

- The current arrangements provide limited opportunities towards common information standards or advancements towards supporting interoperability through HCA 2022; however, this is at a slower pace than without DUA and measures taken by IT suppliers.

Weaknesses:

- These current issues relating to data-sharing and lack of interoperability continue to be a burden and have negative consequences because interoperability is achieved at a much slower pace under Option 1 and through the existing HCA 2022 legislation. These continued issues are outlined below:
    - Without taking action to achieve improved interoperability at a faster pace, existing challenges with the fragmentation and sharing of patient information, as well as the associated cost inefficiencies remain.
    - Currently, data silos exist that results in users and their teams not being able easily to access or share data in real time, whilst also creating technical barriers to direct care, operational planning, research and innovation. These "siloed" systems also result in a barrier to new market entrants.[29]
    - The fragmentation of patient data can make it difficult for clinicians to access up to date medical history, and can lead to redundant testing, misdiagnoses, and adverse medical outcomes.
    - Inefficient data sharing can impose administrative burdens on health and social care professionals. This is because they must resort to slow, time-consuming methods to access data, sometimes resulting in delays.
    - Information often has to be manually shared and entered into multiple systems, giving rise to duplicate records, increased likelihood of error or missing information, repeated testing and delay in diagnosis and treatment, as well as creating a data burden on front line clinicians.[30]
- Ensuring compliance with data protection regulation, such as GDPR, becomes more complex when patient data must be shared across disconnected systems. Hence, the risks relating to patient privacy and security should be taken into consideration[31].

Threats:

- Market failure currently exists in the form of low competition in the IT supplier market, imperfect information and negative externalities. These market failures are likely to continue to give rise to negative consequences such as lack of innovation within the industry.

Option 2: Enacting legislation on IT suppliers

Strengths:

- Government regulation facilitates the creation of standardised guidelines and cohesive rules, fostering a uniformity in data exchange among health and social care providers and technology vendors. This is beneficial as it ensures there is clarity for the supplier market concerning what they will need to provide for in their products and services – applying to both existing and new suppliers. This uniformity can facilitate seamless communication between disparate systems.
- By enacting legislation that mandates IT suppliers to adopt shared open data architecture principles, the likelihood of achieving interoperability goals faster increases, compared to other options. This approach relieves the administrative burden on health and social care providers, who would otherwise face difficulties searching for suitable IT systems. It also mitigates vendor lock-in issues commonly faced by suppliers. Legislation

---

29 Updated Final DPDI (2) Bill Impact Assessment March 2023.docx (parliament.uk)
30 [INTERNAL - NOT PUBLISHED] - DHSC Open Data Architecture Impact Assessment (IA) - 27/05/2022
31 Interoperability risks and health informatics - ScienceDirect

ensures all suppliers implement the required information standards simultaneously, or face financial penalties, which is more effective than relying on softer, market-based regulatory reforms.
- Government regulation establishes a prioritisation of public interest, especially in safeguarding patient data. By instituting stringent data security, privacy, and ethical usage standards, government regulation ensures sensitive medical information is handled responsibly, promoting compliance and seriousness towards interoperability standards.
- Government regulation provides crucial oversight, consistency, and protection, addressing the intricate challenges of interoperability in the health and social care sector effectively.

Opportunities:

- Implementing interoperability via the legislation on IT suppliers could significantly enhance the quality of care, improve patient outcomes, and enable seamless access to information.[32] This could not only pave the way for comprehensive research, effective strategic planning, and innovation at a population-wide level, but could also optimise clinical outcomes.[33]
- It has the potential to enhance procurement and commissioning strategies within health and social care providers, fostering a dynamic and adaptive health and social care IT market.[34] Applying new legislation-based information standards to IT suppliers enables providers to choose from a diverse set of supplier products and systems, fostering competition and encouraging suppliers to innovate and improve their offerings to meet the standards. This not only enhances the quality and variety of products available to health and social care providers but also drives advancements in technology and service delivery within the health and social care sector.[35]

Weaknesses:

- The process of enacting legislation can be slow and complex.[36] In the context of the health and social care sector this can be a weakness. If the legislative process takes too long, market failures that exist in the IT supplier market may be left uncorrected for longer than necessary.
- Once legislation becomes law it can be challenging to change or amend. This is because, under rules-based regulatory approaches, any changes require the department to go back to the original legislation.[37] Therefore, there is a risk that under significant future market changes, legislation may need to be updated, which could be a lengthy and difficult process.

Threats:

- There may be some resistance from suppliers who currently dominate the market, which could establish a risk of some IT suppliers leaving the market[38]. This is due to an increased burden to deliver a product or service that is compliant in England and may be different from the information standards required in the rest of the UK, European

---

32 01.06.2022 DHSC Primary Impact Assessment [INTERNAL – NOT PUBLISHED], DHSC

33 Updated Final DPDI (2) Bill Impact Assessment March 2023.docx (parliament.uk)
34 Updated Final DPDI (2) Bill Impact Assessment March 2023.docx (parliament.uk)
35 Information standards for health and adult social care in England - GOV.UK (www.gov.uk)
36 When laws become too complex - GOV.UK (www.gov.uk)
37 Using alternatives to regulation to achieve policy objectives (nao.org.uk)
38 Updated Final DPDI (2) Bill Impact Assessment March 2023.docx (parliament.uk)

countries or broader international markets such as the USA. To mitigate this risk, however, the DUA legislation intends to consider international best practice concerning interoperability and to engage with the health and social care IT supplier market to ensure both inform the contents of the IT standards under DUA.[39]

- Given that the digitisation of health and social care is a global trend, many suppliers are experiencing high demand for their services beyond the domestic UK economy. This then can lead to suppliers facing backlogs for new installations.
- There is also a risk of increased cost of IT products/services, or IT supplier 'passing on' development costs to health and social care buyers (where these costs are associated with clinical system updates to include the legislated information standards), as despite an increase in competition from all suppliers being compliant and meeting standards, prices of IT products/services may increase because the increased cost of compliance to IT suppliers outweighs the downward pressure on prices resulting from the increased competition. To mitigate this, under DUA the intention is to develop the information standards and implement these measures in consultation with varying supplier types, to ensure these do not create a negative burden for suppliers to comply with.[40]
- There is a risk of provider non-compliance due to the inherent differences in the health and social care provider market. Whilst the health and social care provider market is largely composed of NHS organisations, the providers in the social care market (although commissioned by local authorities) are largely independent, autonomous enterprises.
- Rules-based regulations may also prevent new business models from entering the health and social care IT supplier market, if they cannot comply with the rules set out in the regulation.[41]

Option 3: Issue guidance to health and social care providers to outlaw new contracts that do not comply with specified information standards after a specific date (public and private)

Strengths:

- The associated implementation costs for the NHSE are likely to be low compared to other architectural or single IT solution options. In addition, negotiating and building in contract requirements may be quicker to action between health and social care providers and IT suppliers, compared to implementing legislation or building an architectural solution.
- IT suppliers are likely to have significant capacity and capability to deliver the required service under the option, due to having the required skillset, time and ability to respond.[42] Many IT suppliers are already capable of providing services that are interoperable and abide by open data architecture standards. Building this as a requirement into contracts is likely to increase compliance even further.
- Since these requirements would only come into effect once contracts expire, IT suppliers would have more flexibility and time to be aware of amendments mandated prior to having to implement the changes (compared to enacting legislation). Overall, this is beneficial as the level of disruption to health and social care providers and IT suppliers caused by this option would be minimal.
- This option provides more time for IT suppliers to effectively plan and adapt their capabilities and procedures, such that they conform to the new open data architecture

39 Updated Final DPDI (2) Bill Impact Assessment March 2023.docx (parliament.uk)
40 Updated Final DPDI (2) Bill Impact Assessment March 2023.docx (parliament.uk)
41 Using alternatives to regulation to achieve policy objectives (nao.org.uk)
42 Based on NHSE and DHSC Insight

standards. This is because IT suppliers can wait for their existing contracts to expire and be renegotiated before they must adopt the new open data architecture standards.

Weaknesses:

- It may create an increased administrative burden on health and social care providers, to search for and procure IT products and services that meet standards that they may not have personnel to understand. It is also contingent on the availability of IT products and services that meet the specified standards, which the option cannot ensure.[43]
- Given this option is non-legislative, some health and social care providers may choose to not comply with the guidance and not build the requirements into new contracts at all.

Threats:

- Risk of IT suppliers leaving the UK market (similar to the risk under the option to enact legislation). As suppliers are experiencing high demand for their services, leading to significant backlogs for new installations[44]. A supplier may choose to leave the market as opposed to complying with contract requirements, as there is demand elsewhere.
- In addition, as this option is non-legislative and requires action from health and social care providers and IT suppliers to renegotiate contracts based on guidance issued, this could result in varied levels of understanding of which requirements to build in amongst suppliers and a lack of uniformity of standards being adopted between suppliers and a lack of system-wide consistency – which could lead to the standards not achieving their intended purpose of interoperability, this is compared to centrally mandated standards which achieves greater consistency.
- Furthermore, since contracts with suppliers are of varying lengths with health and social care providers, there is a threat that the cost burden of complying with standards is primarily passed onto health and social care providers who are amongst the first to enter new contracts with IT suppliers (who comply with the guidance).

1.4 Summary and preferred option with description of implementation plan

101. The preferred solution is to prepare, publish and mandate standards that apply to the products and services provided by IT suppliers (Option 2).

102. As outlined in the impact assessment for s95 HCA 2022, work is progressing in the design and development of an open data architecture approach with information standards that will require products and services to be based on principles of a unified system architecture, open standards and interoperability. It is expected that the standards will be published as part of a staged process, with the aim of driving interoperability across the next 10 years and beginning with a pilot which will focus on the highest priority standards.
103. Public health and care providers have had to have due regard to information standards since introduction of the HSCA 2012 powers, and private health and care providers were brought into scope by changes made in the HCA 2022. The changes to information standards made in the DUA bill will additionally make information standards mandatory for IT suppliers. Alongside this, DHSC will examine existing contracts between IT suppliers and health and care providers to identify any impact from changes in the law and will seek to ensure that the standard contract terms for future contracts require suppliers to comply with standards mandated under the legislation even after the contract has been agreed.

---

43 Updated Final DPDI (2) Bill Impact Assessment March 2023.docx (parliament.uk)
44 01.06.2022 CLEAN DHSC Primary Impact Assessment – DSIT [INTERNAL – NOT PUBLISHED], DHSC

104. DHSC will continue to seek adoption of procurement frameworks that enable health and care providers to be confident that the products and services set out in the framework will meet the required standards. This would be similar to the model established by the Digitising Social Care Programme and GP IT Futures, which has developed a Dynamic Purchasing System that assures suppliers of digital social care records software and provides a mechanism to ensure they meet required interoperability standards.

105. Approach to enforcement is outlined below:

    a. The Secretary of State for Health and Social Care would be designated as responsible for enforcing the standards, and an appropriate body will be identified to manage and administer enforcement of the regulations including regular compliance checking.

    b. Non-compliance to the standards would result in a formal written warning and an agreed timeframe for the IT supplier to the health and social care system to bring their product or service into compliance.

    c. If non-compliance persists without an agreement in place or an exemption agreed, the IT suppliers may be subject to a financial penalty. Each fine would be determined by the severity of the breach and the individual circumstances of the businesses.

    d. Imposing public censures will assist in raising awareness of regulatory information standards and principles and will aim to change the behaviour of the IT suppliers, health and care providers, deterring similar suppliers and providers from engaging in non-compliant products and services.

Theory of change for preferred option

106. To help consider how the preferred option delivers a positive impact and derives benefits more broadly, a Theory of Change (TOC) has been developed that outlines how and why the activities will lead to the outcomes and impacts. The TOC is described below and shown diagrammatically in Figure 1.

Input – what are the resources required to implement the legislation?

- Information standards costs
    - Resources to define information standards in scope
    - Regulation experts to support IT suppliers in adhering to legislation
    - Enforcement costs associated with non-compliance
    - Implementation guidance for IT suppliers
    - Reconfiguration costs for IT suppliers who seek to modify their products and services

Activities – which activities are required for the legislation to be implemented and achieve impact?

- Information standards costs
    - Drafting and refining information standards, legislation, including stakeholder engagement with health and care providers
    - Familiarisation with new legislation and requirements for IT suppliers
    - Procurement by HCPs of new interoperable systems which meet information standards
    - Provision of training for IT suppliers on information standards
    - Set-up compliance and enforcement regime for IT suppliers
    - Accreditations processes for IT systems to ensure they meet standards

- Updating of records in retained systems and IT suppliers transitioning to new systems

Enabling change – which changes are required to enable desired outcomes to occur?

- Interoperability enabled by information standards and common architecture mandated by legislation and incentives to be compliant (e.g. notices/financial penalties)
- Timely access to data for health and care providers
- More standardised and consistent approach in sharing data amongst health and care providers to provide 360 view of the patient
- Greater accessibility of patient information in meaningful format between organisations using different systems
- Reduced need for each NHS provider to request system suppliers to make changes when an information standard changes
- Greater alignment between public and private health and care providers in sharing data
- Private sector access to NHS data in a standardised form
- Greater availability and openness of patient data
- Greater IT supplier compliance and proportion of interoperable solutions in the market. Reduced vendor lock-in and burden on HCPs to negotiate contracts and identify systems which meet standards

Intermediate outcomes – what are the initial outcomes contributing to success?

Health and care providers

- Information standards benefits
  - Reduced cost of ICS standardisation and mapping of data to ShCR*
- Interoperability benefits
  - More up-to-date, complete and accurate information on patients on handovers across public and private health and care providers
  - Reduced duplicate patient diagnostic/lab tests and procedures*
  - Reduced hospital (re-)admissions
  - Reduced pressures on clinicians' utilisation from reduction in staff time chasing for patient information*
  - Reduced pressures on clinicians' utilisation from inefficient processes or duplicative effort across different systems
  - Earlier diagnosis and reduced downstream healthcare costs

Patients

- Interoperability benefits
  - Less burden on patients to keep paper records or recall medical history
  - Improved patient safety and drug safety, reduced risk of medicinal/allergy/intolerance issues for patients
  - Diagnoses received quicker and quicker private referrals
  - Enhanced patient satisfaction

Life sciences sector

- Interoperability benefits
  - Increased access to data for R&D and investment in R&D

IT suppliers

- Information standards benefits

- IT systems harmonised with international standards
- Greater clarity on standards requirements and investment in systems

Outcomes – what are the further outcomes contributing to success?

Health and care providers

- Interoperability benefits
  - Care and clinical pathway treatment optimisation
  - More integrated care with a focus on prevention rather than treatment
  - Increased capacity and a greater proportion of specialist care delivered in England
  - More efficient allocation of resources across the whole system
  - Fewer medical errors and mistakes due to incomplete information*
  - Increased number of transaction exchanged between health and care providers
  - NHS staff satisfaction/empowerment

Patients

- Interoperability benefits
  - Better and more tailored patient treatment and prioritisation of patients based on need
  - Reduced patient complaints
  - Improved patient outcomes from care/treatment optimisation and speed to diagnosis with the right treatments received more quickly
  - Reduction in unnecessary appointments for patients to share information/updates

Impact – what are the end goals?

Health and care providers

- Interoperability benefits
  - Improved clinical outcomes
  - Greater innovation in health, care and wider research and analysis

UK government/taxpayers

- Interoperability benefits
  - Reduction in spending on unnecessary processes, procedures, visits, tests and treatments

Patients

- Interoperability benefits
  - Fewer patient fatalities
  - Reduced time required for patient care
  - Reduced patient anxiety
  - Reduction in patient time off (e.g. due to reduced repetition of diagnostic tests)

Broader economy

- Interoperability benefits
  - Productivity gains from fewer patient sick days

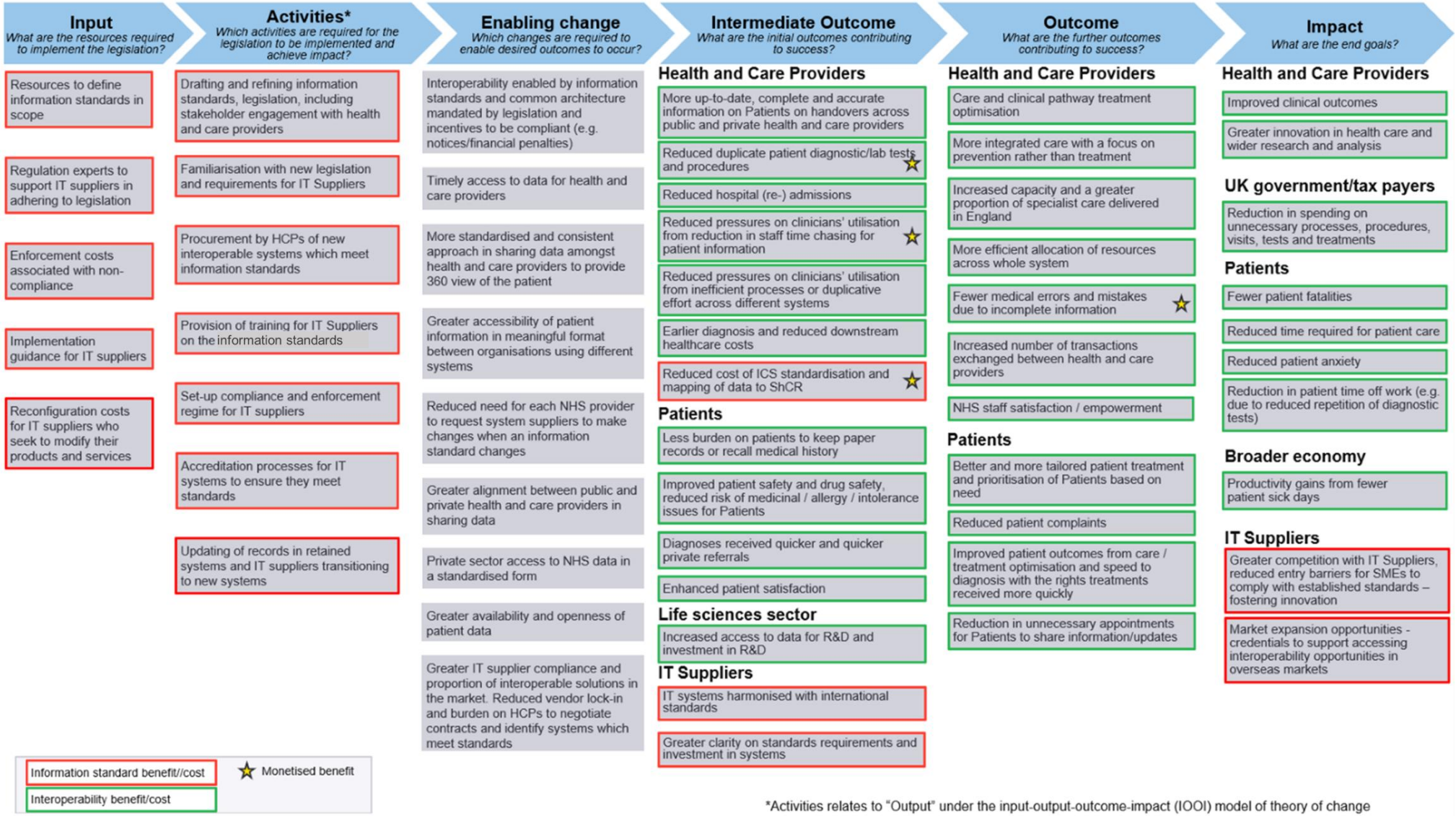
IT suppliers

- Information standards benefits
  - Greater competition with IT suppliers, reduced entry barriers for SMEs to comply with established standards, fostering innovation
  - Market expansion opportunities, credentials to support accessing interoperability opportunities in overseas markets

Theory of change assumptions

107. The TOC assumes that:
    - The primary purpose of this regulatory change is to provide health and social care providers with access to procure IT systems that are information standards compliant.
    - The proposed legislation below comes into effect:
        - Data (Use and Access) Bill: interoperability.
    - Enacting the legislation under the DUA Bill (interoperability) results in IT suppliers using specified open data architecture standards.
    - Stakeholders will be receptive to and actively support the proposed changes.
    - The necessary physical, financial, human and time resources will be available and accessible throughout the process.
    - Adoption of interoperable IT systems by health and social care providers will progress at a reasonable pace across the health and social care system. In addition, the ShCR will be in place by the time legislation comes into effect.
    - The benefits and costs will be grouped into those related to common information standards alone and interoperability, as denoted by the green and red outlines in the diagram:
        - (Red outline) Costs and benefits associated with the implementation of common information standards alone without regard to interoperability.
        - (Green outline) Costs and benefits regarding interoperability which occurs due to the implementation of common information standards which realises the intended full benefit from interoperability infrastructure and systems already in place or expected to be in place.
        - Benefits with a ‘Star’ have been monetised within Section 1.6

Figure 1: Theory of Change



1.5 Approach to costing

108. Future information standards have not yet been defined. The costing has therefore had to be based largely on a set of informed assumptions. Our approach to costing common information standards under the DUA is based on four key considerations, each of which is explored further below:

    i. The extent of current knowledge on the scope and specificity of the information standards;
    ii. The ability to benchmark the costs to implement information standards;
    iii. The interaction of the information standards proposed under the DUA and the related preceding legislation, namely the Health and Care Act 2022; and
    iv. The diverse nature of Health and Social Care Providers in England.

Scope and specificity of the standards

109. There are a wide range of possible information standards that could be implemented in England, as well as unknown future standards reflecting changes in policy and technology.

110. The DUA is primary legislation with the purpose of giving the Secretary of State the ability to prepare and publish mandatory information standards to which IT suppliers for the health and care system must comply, without specifying the actual information standards, with regulations specifying the approach to setting standards – these will be critical to ensuring standards are reasonable, deliverable etc.

111. NHSE is currently developing its plans for which information standards will be implemented, when. We have a strong idea about a set of 'core' information standards which would be priorities for mandating, but these plans are not yet sufficiently mature to be shared with and costed explicitly by IT Suppliers and Health and Social Care Providers. They will, of course, reflect current expectations of IT provision to the NHS, so providers would not be suddenly required to deliver something significantly divergent from their current contractual obligations.

112. At the time of this RIA, therefore, it is unclear precisely which information standards will be mandated, when and who will be subject to said mandatory information standards; for example, how the information standards will apply to Acute Care will likely be different to those applied to Social Care, where there are major differences care pathways and the provision of care, as well as different requirements for IT systems e.g. capturing clinical diagnosis, procedures and treatment pathways versus documenting the delivery of contracted care

Implications for costing approach

113. Costing in this IA is based primarily on assumptions about the scope and timing of the information standards roll-out, of which the most important are:

    - NHSE will adopt international standards to the greatest extent possible, e.g., SNOMED CT, ICD 10-/11, HL7 FHIR and the International Patient Summary, rather than develop England-specific standards; reasons for this include:
        - Material adoption already by IT Suppliers of international standards in their systems, which means that Health and Social Care Providers in England will have more effective and cost efficient access to compliant IT systems if

international standards are adopted – this is evidenced by the NHSE information standards and interoperability survey which showed that the majority of IT suppliers are >50% compliant with the SNOMED, ICD10/11 and HL7 FHIR UK CORE information standards (See Table 3), yet provider compliance with the same standards is much lower, and that for NHS-specific information standards such as for OPCS and NHS dictionaries IT supplier compliance is lower.
    - Likewise, this approach of adopting international information standards (where possible) minimises the risk of IT Suppliers exiting the UK market when international standards are mandated;
- A phased approach to adopting information standards to reduce costs on suppliers; and
- NHSE is currently producing a roadmap detailing the identification, implementation and operating model.
- An appropriate and proportionate process for selecting standards to be applied, with DHSC and NHSE governance, as codified in the proposed Health and Care Act regulations.
- As stated above in relation to defining the specific information standards, NHSE is also developing the timelines for the implementation of said information standards. These plans are not yet sufficiently mature to be shared with and costed explicitly by IT Suppliers and Health and Social Care Providers. We have assumed that the roll-out of information standards which are in scope for the legislation will be carefully phased in over the next 10 years, prioritising standards considered most important for implementation, with minimal shocks to the provider market. This will consider the complexity of standards, duration to implement and the standards which contribute the most towards interoperability objectives.
- Data from Thames Valley & Surrey (TVS) Connected Care Programme found that 18% of patient care was provided outside of the TVS region (and hence 82% provided within the region). Since regional interoperability is considered as the immediate objective of this intervention, it is inferred that regional interoperability achieves 82% of total national interoperability benefits. As such, sharing across regions will only provide incremental benefits when patient information is needed out of Region, e.g. for A&E use or in the case of certain high speciality care/tertiary care episodes.

114. The rationale for these assumptions is that they align to, are consistent with several other related NHSE initiatives and commitments and, taken together, should realise synergistic incremental benefits, especially:
    - The National Record Locator system upgrade
    - The National Shared Care Record System (Connected Care Records; ConCR) roll-out
    - The Federated Data Platform adoption, and
    - Future legislation of information standards on IT suppliers

115. At this stage, these are considered to be the best assumptions available.

Ability to benchmark the costs to implement the standards

116. There are several factors that make it challenging to benchmark accurately the costs of the information standards to IT Suppliers and Health and Social Care Providers in England:

    - Health and Care systems should share a common language (standards, semantics and structure) thus avoiding translational interoperability friction. The importance of

interoperability is well acknowledged not only within the NHS but includes social enterprise, community and voluntary and local authority.

- Recent work commissioned for NHSE[45] highlights that many countries are pursuing patient record interoperability, for which information standards are a pre-requisite for interoperability. There is no single country the size of England that has national interoperability (although several countries are striving for this ambition) across all its major systems, but exemplars from countries with smaller populations offered possibilities for health systems the size of the currently cast Integrated Care Boards (ICBs).
- Some countries, like Norway, Estonia, Netherlands, Slovenia, Israel, Spain (Catalonia) and the UAE - and even devolved nations and/or regions within the UK like Scotland, Northern Ireland and London - have progressed rapidly to centrally-mandated national systems with extensive interoperability, benefitting from small populations and having very limited legacy technology to have to adapt. Even if the relevant cost data could be freely accessed, however, it is not considered useful for benchmarking, because it is not representative of the health and social care IT landscape in England.
- Other countries, like the integrated delivery network in the USA, are more advanced in their adoption of international standards; however, the US context for information standards is primarily about configuring systems for patient billing so, again, the cost data is not considered representative of the health and social care IT landscape in England.
- The UK has many unique factors when it comes to assessing the costs of implementing information standards, including:
    - The highly decentralised approach to procurement which, in the absence to date of binding information standards, has contributed to IT systems being customised for each Provider. Where Health and Social Care Providers have bought patient record systems from the same IT Supplier, they are not necessarily adopting the international information standards that are available to them; for example, in the survey, NHS Healthcare providers stated that 'focus on implementing a fit for purpose EPR' is the biggest barrier preventing them from implementing a fully interoperable clinical system. The age and decentralised set-up of the NHS also means that there is very substantial legacy IT estate that varies materially from Provider to Provider, which is another reason why Provider adoption of information standards lags the IT Supplier provision of common information standards. The survey shows that c.81% of IT suppliers provide modest levels of customisation to their clinical services – leading to higher costs of implementing information standards. This also means that the costs to adopt common information standards may differ materially from Provider to Provider. Accordingly, gathering detailed costs from IT Suppliers – especially when the nature of what is being costed cannot be accurately specified – is unrealistic as a way to gather the costs of implementing common information standards (sample sizes would be unreasonably small, even if IT Suppliers and Health and Social Care Providers collaborated to provide such costs).
    - Specifically considering social care providers, adoption of commonly recognised systems, let alone information standards, is in its infancy. Approximately 30% of social care providers are partially digitised, with a further 30% still using entirely paper-based systems. The NHS is providing funding of

45 Open Health and Care Data Architecture, NHSE, June 2022

£8.2 million to support the digitisation of social care[46]. On the one hand, this may be seen to provide an opportunity to standardise rapidly around a unified approach. Conversely, the cost of achieving this can only be assumptive in the absence of any specific proposals regarding how the standards will be implemented and, for this sector specifically – which has a very large number of SME and micro-businesses - how NHS England will support these providers. There are also no established mass-market IT suppliers in this sector.

- As such, in the context where it is not currently known with any specificity by IT Suppliers and Health and Social Care Providers which standards will be mandated (or when), the ability to estimate key cost categories by using benchmarks, for example, the IT configuration costs associated with moving to common standards adoption, will be very limited.

Implications for costing approach

117. At this stage, while there are some benchmarks that are considered useful, e.g., national wage data, the costing for this IA has to be supplemented with alternative means of data gathering. Accordingly, for this RIA, NHSE has commissioned an IT clinical system suppliers market analysis[47] and a NHSE information standards and interoperability survey[48] to gather cost data, covering:

- 20 clinical IT system suppliers, representing >95% of the UK health and social care market. These 20 'preferred' IT suppliers are on the Government Framework and their Clinical Systems contracts have been made available publicly on contract finder[49]. New IT suppliers are likely to enter the social care provider ecosystem as the provider requirement for electronic care records and digital care planning systems increases – these suppliers will not be captured in the current IT supplier landscape review.

- Based on a landscape review of publicly available contracts, the top 5 clinical IT system suppliers (by market share) constitute 66% of the total contracts, while the next 5 suppliers constitute 25% of the total contracts/

- 35% of the clinical IT system suppliers have more than 10 contracts each, while the average number of contracts for bottom 12 suppliers is 2.

- Size groupings were used to inform assumptions of cost across IT suppliers. Across the 20 IT suppliers in the sector, we have placed them into a size grouping based on reported headcount. There are 12 large IT suppliers, 5 medium supplier and 3 small suppliers in this classification.

- IT systems used in the social care setting are far less mature than those used in the healthcare setting. Care management systems are widely used to support planning, delivering and monitoring care services, including case management, scheduling and financial management. At this time, in the absence of clearly defined information standards, it is unclear how the legislated information standards will impact these IT systems, if at all. The legislated information standards are more likely to impact IT

46 Digitising social care fund - Digitising Social Care - NHS Transformation Directorate (england.nhs.uk)
47 IT clinical system suppliers market analysis, NHSE, January 2024
48 Information Standards and Interoperability Survey, NHSE, Feb 2024
49 www.contractfinderpro.com

systems such as electronic care records and digital care planning systems, when they become widely used across the social care sector. Communicating information standards with the relevant IT supplier will avoid requirements to upgrade systems that are currently being deployed to social care providers. These digitalisation initiatives are part of a broader effort to ensure that technology enhances the independence and well-being of those receiving care, while also reducing avoidable hospital admissions; however, there are currently no standardised design principles for IT systems in the social care setting.

118. The full list of survey questions is at Appendix 3. The survey has explicitly sought IT Supplier and Health and Social Care Provider responses to the impact on current contract spend of adopting common information standards (noting that it was not possible at the time of the survey to be more specific than identifying a selection of possible international standards).

    - IT Suppliers were asked to quantify the impact as a percentage of current contract cost and whether or not they would absorb any such impact or pass it on to their respective Health and Social Care Provider. By combining such percentage information with available NHSE data on Provider numbers and sizes, this has given the basis for one of the biggest areas of cost. Other survey responses have similarly been used to inform the cost estimates. It is recognised that a survey-based approach using banded ranges is not as accurate as an explicitly costed response (e.g., as an IT Supplier might make for a contract change notice), but this approach was nevertheless considered to be the most appropriate way, given the limitations, to estimate core cost categories like IT upgrade costs at this stage.

119. It is recognised that the costing is an estimate and may need to be updated when there is a clear plan setting out which standards will be mandated, when, for which health and social care providers.

120. At this stage, this is considered to be the best costing evidence available. The analysis carried out in this Impact Assessment is as detailed and robust as the evidence supports. Where numerical evidence is not yet available, we have provided a qualitative assessment of the costs and benefits of the preferred option. Inevitably, for the reasons explained, the assumptions carry some level of uncertainty. We have therefore ensured that we have carried out sufficient sensitivity analysis and testing to make sure that we accounted for these potential risks.

The interaction of the standards proposed under the DUA and the related preceding legislation, namely section 95 of the HCA 2022

121. The costs and benefits of implementing common information standards sit across two pieces of legislation – the DUA and the preceding s95 of the HCA 2022. Ascribing cost and benefit to each piece of legislation is challenging because:

    - The two pieces of legislation differ primarily in the markets to which standards will be applied, whereas the standards adopted are expected to be the same. In principle, the s95 HCA 2022 could secure 100% adoption of common information standards, in which case the DUA measures would not be needed; equally, depending especially on the appetite or otherwise for sanctioning public sector health and care providers for not adopting common information standards, the HCA 2022 could have no effect and all of the uplift burden could fall on the DUA. While the two pieces of legislation together should achieve full common information standards adoption, it is necessary

to use a set of informed assumptions to estimate the impact of each piece of legislation on its own.

- Between them, the two pieces of legislation should not incur more than 100% of the total cost or benefit associated with full adoption of the standards.

Implications for costing approach

122. Instead of costing each piece of legislation independently, it is considered more appropriate to estimate the total cost of adopting mandated information standards and then apportion the costs, where applicable, between each piece of legislation (and a similar approach taken to benefits). An apportionment approach also helps to avoid double counting of costs that could arise if assessed independently for each piece of legislation.

123. The recommended apportionment methodology and assumptions are based on the NHSE information standards and interoperability survey responses from IT Suppliers and Health and Social Care providers. For each cost type, the assumption used to split costs between HCA and DUA is provided below:
    - **Familiarisation costs**: Separate costs for familiarisation are estimated to occur per piece of legislation, however, Health and Care providers are not expected to be directly required to familiarise with DUA. Familiarisation costs are therefore only expected to occur for IT suppliers under DUA.
    - **Training costs**: For training costs, total costs across Health and Care Providers have been estimated based on total training required to achieve 100% compliance. Across HCA and DUA, there are separate assumptions on the portion of compliance achieved by each bill. Based on results from the NHSE information standards and interoperability survey, it is assumed that currently 42% of health and social care providers comply with standards. It is assumed that HCA measures will enable 14% of providers to comply (24% of non-compliant providers), whereas DUA will facilitate compliance of the remaining 44% of providers (76% of non-compliant providers)
    - **Information standards related system update costs**: The total cost associated with updating systems in relation to the standard has been estimated based on achieving 100% compliance with the standards. As above, to apportion these costs across HCA and DUA, assumptions on the additional compliance relating from each measure have been used to apportion costs.
    - **Conformance testing and accreditation costs**: These costs are only expected to occur as a result of DUA to ensure that IT Suppliers are complying with the standards laid out in DUA. This cost is therefore only estimated in DUA.
    - **Compliance monitoring and enforcement costs**: in the absence of a detailed organisation design, the size of a compliance body has been estimated as an early indicator only of what compliance costs may be. We assume a proportion of the compliance body's resources that will be dedicated to enforcing DUA legislation, taking into account the relative size of IT suppliers within the broader landscape of Health and Care Providers and the anticipated complexity of the DUA requirements. Based on this it has been assumed 95% staff will be focused on Health and Care Providers and 5% of staff on IT Suppliers. At this stage, these are considered to be the best evidence available for estimating the appropriate split.

The diverse nature of Health and Social Care Providers in England

124. The large number and diverse nature of the Health and Social Care Providers in England means that they have to be grouped and scaled based on representative samples e.g.

acute care, ambulance, care homes, children, community, integrated care, mental health, specialist, social care, women's settings.

125. Each GP organisation, primary care network (PCN), NHS Trust, Integrated care system or board (ICS or ICB) or social care provider has its own procurement process and requirements from IT systems. New procurements are often protracted. For existing contracts, there is likely to be a series of re-negotiations to cover legislated information standards. There are no national standards, meaning scaling, update to meet legislated information standards, and connecting across IT systems is likely to be problematic, and increase cost.

126. The current NHS systems landscape is a hybrid set of solutions which are clinically led and locally chosen, supported by a range of national services.

127. There is no 'one-size fits all clinical IT system and health, and care providers will customise clinical systems based on their requirements e.g. clinical pathways, patient workflows, local authority contractual requirements, etc. To estimate the cost of the relevant updates to the diverse range of customised IT systems would require a system-by-system bottom-up approach working with individual IT system suppliers as well as with the specific providers to understand the bespoke cost of system upgrades including system requirements, development, data transformation, system testing, release requirements and training.

128. To estimate, for example, the cost of the relevant updates to systems in relation to the information standards, we obtained data from IT suppliers through the NHSE information standards and interoperability survey. The survey indicated that uplifts in cost were likely to be (on average) 15% of the existing contract value. Baseline contractual values were identified for the majority of the public health and social care providers using publicly available contract information. Where information was not available, we developed cost assumptions using secondary research, interview data and accounting for the relative size of the organisation – with separate assumptions used per the size of the organisation considered. The recognition that system costs tend to correlate with an organization's size has led to the creation of distinct assumptions for each size category, with the specific details of these assumptions presented in Appendix 2.

Implications for costing approach

129. As stated in Section 1.6 of the RIA, our cost estimates have been derived using specific assumptions per stakeholder group, based on modelling size groupings within that group. For each group we have identified the number of stakeholders that are either large, medium, or small and have developed stakeholder specific assumptions based on these size definitions. Outlined in the appendix of the IA are the basis for modelling size groupings that have been used in our cost estimates. These modelling size classifications differ to the size classifications used in the SaMBA.

130. At this stage, these are considered to be the best evidence available for estimating the appropriate split. The analysis presented in this impact assessment is proportionate and detailed. Where costs and benefits have been able to be monetised, this has been carried out using certified and robust data sources. Where assumptions have had to be made due to a lack of available evidence, we have highlighted these and carried out sensitivity analysis to test them where possible.

131. Based on these overarching approaches, cost types (and benefit types) have been standardised across IT Suppliers and Health and Social Care Providers as follows:

    - Familiarisation costs

- Training costs
- Information standards IT upgrade costs
- Compliance Monitoring & Enforcement costs
- Conformance Testing & Accreditation costs

We have set out at Appendix 2a detailed breakdown of the estimating assumptions and supporting evidence for each of these cost categories.

1.6 Monetised and non-monetised costs and benefits of each option (including administrative burden)

132. A proportionate approach has been taken to estimate costs and benefits. Best endeavours have been made to carry out primary research and draw on existing evidence to inform the analysis; however, strong relevant evidence has been limited and so cost and benefit assumptions remain uncertain in places. Where this is the case, we have consulted with NHSE experts to develop assumptions and applied appropriate sensitivities to adjust for uncertainty. It should be recognised that the overall benefit of improved compliance with information standards is an improved interoperability in the NHS and an improved efficiency in the use of key systems, which would remove duplication and save time, freeing up resources for other elements of care.

133. The preferred option and an alternative viable option have been analysed and estimations of the potential costs and benefits are assessed over a period of 10 years discounted using a rate of 3.5%, or 1.5% for health benefits in terms of Quality-Adjusted-Life-Years.[50]This is in alignment with the Regulatory Policy Committee (RPC) appraisal guidance and the Green Book.[51]

134. This section begins by looking at the costs and benefits of implementing the legislation to mandate common information standards (preferred option); this includes the savings in data mapping costs for health and social care providers and the costs and benefits associated with adoption of common information standards. This will be followed by a qualitative analysis of the benefits where quantitative evidence is limited. All economic analysis in this IA is based on apportionment between measures in the s95 HCA 2022 impact assessment and the measures within this IA. As such, many of the costs and benefits of DUA are incremental and depend on the impact of the HCA measures. It is estimated that the s95 HCA 2022 will enable an additional 14% of ICBs to comply with standards. The premise is that these suppliers are currently using compliant systems with functionalities disabled. This cohort accounts for 24% of currently non-compliant ICBs and hence 24% of the compliance costs and total information standards benefits (under full compliance) are attributed to HCA. It is estimated that when DUA legislation is in place, alongside HCA, DUA will facilitate faster and easier compliance for the remaining non-compliant providers (76%). Therefore, it is assumed 76% of the compliance costs and total information standards benefits are attributed to DUA.

135. As outlined previously, the benefits evaluated in this assessment are confined to:

- Benefits derived solely from the adoption of common information standards, independent of broader interoperability considerations. For example, following implementation of the standards, a clinical episode would be described in

50 As per Green Book Guidance – The Green Book (publishing.gov.uk)
51 RPC Case Histories Sept 2020

common/standard clinical terms by different providers across the health and social care ecosystem.

- Benefits related to interoperability that arise specifically because the implementation of common information standards provides the critical component necessary to unlock the full potential of interoperability infrastructure and systems that are either already operational or anticipated to be in place.

136. Benefits identified are dependent on the Shared Care Records (ShCR) being in place during March 2025. These ShCR will need to have all the fields and information in it to meaningfully support interoperability. Hence the benefits in this IA are contingent on:
    - This infrastructure being put in place, i.e., clinicians can directly access the ShCR.
    - The ShCR content containing a meaningful representation of populated fields (beyond the NHS number) from the required standards, for example, the International Patient Summary (IPS).
    - The ShCR being used.

137. Current planned activity and investment for the required infrastructure is on track to be in place before standards come into force during 2025 and this infrastructure will complement information standards to achieve interoperability.[52]

138. The measures outlined in this IA will apply equally to both foreign and domestic products/suppliers, with no expectation of a disproportionate impact on either.

Optimism bias

139. To mitigate for a scenario where the assumptions around timing, complexity or achievability of the cost or benefits of each option are understated or overstated, an adjustment for optimism bias was made. Including this adjustment for optimism bias is designed to complement good practice in terms of calculating project specific risk.

140. To account for optimism bias, an uplift of 10% has been applied to all cost estimates. This is calculated based on Green Book guidance on optimism bias for 'Equipment/Development' projects.[53] The optimism bias used for costs was arrived at by reducing the upper bound (54%) based on the extent to which the contributory risk factors for similar types of projects have been managed and hence this reduces the optimism bias to 10%, which has been applied to costs.

141. These contributory risks include:
    - Procurement risks: the complexity of contract structure and contractor capabilities
    - Project specific risk: the degree of innovation and environmental impacts
    - Client specific risks: inadequacy of the business case and poor project intelligence
    - External influences: legislation / regulations and technology

---

52 NHSE have committed by March 2025, that all clinical teams in an Integrated Care Board (ICB) will have appropriate access to a complete view of a person's health and social care record that they can contribute to. All 42 ICBs have been funded to meet a minimum requirement (Minimum Viable Solution (MVS) 1.0 - as of March 2021) focused on sharing historical records between NHS Trusts and general practice. A business case has been submitted internally to draw down on agreed funding to complete this work with an anticipated approval date of August 2024 under the Frontline Digitisation: Connecting Care Records Programme (Phase 1)

53 Microsoft Word – GreenBook_optimism_bias.doc (publishing.service.gov.uk)

142. For benefits, the upper-bound optimism bias of 54% has been applied to reduce certain benefits where there was less evidence or lower confidence in the approach and assumptions made. These adjustments reduce the NPV and Benefit Cost Ratios (BCRs) for each option.

Option 1 "Do nothing" Costs and Benefits

143. Under the "Do nothing" scenario (Option 1), there are no incremental costs or benefits. Any advancements towards common information standards or interoperability are facilitated by other interventions already committed to, or progressing outside of the scope of this IA.

Option 2 (Preferred Option) Costs

144. We provide an overview of the estimated costs faced by UK businesses (including IT suppliers, private hospital, private social care providers and private GPs) and public health and care organisations (NHS hospitals, public social care providers, local authorities, NHSE and NHS GPs) resulting from the intervention.

145. Our analysis indicates that the main cost for IT suppliers and health and social care providers (including Local Authorities who provide care) is likely to relate to upgrading clinical IT systems. We have identified additional costs including: IT suppliers on familiarising themselves with the standards; Health and care professionals on training on upgraded systems; and IT suppliers on fees to certify they are meeting the standards. Survey data suggests a large portion of costs may be passed by IT suppliers on to providers. Monitoring and enforcement costs (including public censure) would be incurred by a designated authority.

146. We have considered which costs are direct and which are indirect. All costs within this IA considered in Table 7 are direct costs. These direct costs include IT supplier costs such as familiarisation, information standards system update costs and accreditation costs. Also included as direct costs are those incurred by health and social care providers because of these providers implementing standards due to DUA. These providers costs are deemed as direct cost because they relate to costs for a subset of providers who would have otherwise not implemented standards without DUA mandating IT suppliers to provide the compliant systems. These costs are not captured as direct costs in the s95 HCA 2022 IA, but are captured as direct costs in this DUA IA. Further rationale for the classification of each cost type can be found in Appendix 2.

147. There is no clear definition of direct and indirect effects or any such distinction in the HM Treasury Green Book. According to RPC guidance, "the distinction is not always intuitive and in some rare instances can result in an outcome that could seem perverse."

148. In line with RPC guidance, all significant business and other impacts, whether direct or indirect, have been covered in this impact assessment and have been included in the net present value. The focus on direct impacts reflects the government's objective of constraining the impositions placed by regulation on business, irrespective who eventually bears the burden. Therefore, it is only for Equivalent Annual Net Direct Cost to Businesses (EANDCB) purposes that we are specifically concerned with direct impacts.

149. The different categories of costs are set out in Table 8.

Table 8: Option 2 Cost estimates - These direct costs are estimated over a ten-year period (£, present value)

Cost Type (direct costs)	Total cost

Familiarisation cost	£19,493
Training cost	£50,074,579
Information standards system update cost	£148,576,724
Compliance monitoring and enforcement cost	£1,550,202
Accreditation cost	£2,631,263
All	£202,852,262

150. The evidence and calculations used to determine these estimates are set out below and in further detail in Appendix 1.

Modelling size groupings

151. The stakeholder groups: IT suppliers, health and social care providers are of varying sizes. Some costs borne will be dependent on the size of the organisations and how many providers they supply (IT suppliers) and how many clinicians they employ (health and social care providers). In our cost estimates, we have placed stakeholder groups into modelling size classifications of either small, medium, or large. For each stakeholder group, a summary of the size classification groupings is provided in Appendix 1, section 1.2. For ease of modelling and because of assumptions data collected, these modelling size classifications differ to the standard size classifications used in the Small and micro business assessment (SaMBA).

Option 2 (preferred option) - monetary costs

152. The categories of monetised costs are outlined below, with further detail on the calculation methodologies in Appendix 1, section 1.1. Despite best endeavours to collect and draw upon strong evidence, cost and benefit assumptions remain uncertain and based on limited evidence availability in places. The variables, sources and rationale used to build up each cost are further detailed in Appendix 2.

a. Familiarisation costs

153. As a result of enacting the legislation, IT suppliers will incur up front familiarisation costs to read and understand the new legislation and accompanying guidance provided to support it. Health and care providers incur costs of familiarisation under s95 HCA 2022 and therefore will not incur them under DUA. This is reflected in both RIAs to prevent double counting.

154. To estimate the familiarisation costs faced by IT suppliers, we have used evidence from a Post Implementation Review for an analogous measure, the Network and Information System (NIS) regulations. The objective of NIS, which supported the 2016-2021 National Cyber Security Strategy, was to establish a common level of security for network and information systems NIS was deemed a suitable comparator to DUA in the type of regulation and requirement of private business to familiarise with it. Using evidence from the NIS Post Implementation Review, we estimate the time required to familiarise with the legislation as 36 hours in total per IT supplier, comprising of IT and legal support. This has been multiplied by an hourly cost rate to estimate the total cost.

155. The cost per hour of this time will on average be £21.56. This is based on the median hourly earnings for the Information and Communication sector from the Annual Survey of Hours and Earnings (ASHE) 2023 published by the Office for National Statistics (ONS). This cost is uplifted by 22% to reflect the full cost of employment by worker (in line with guidance from the Regulatory Policy Committee). This sector is used as familiarisation will

be required by staff who are familiar with the current systems, to help understand what changes are required.

156. Based on the evidence available and approach outlined in Appendix 1 and Appendix 2, the 10-year present value of familiarisation costs across IT suppliers is estimated to be £0.02 million and will occur during year one of the roll out.

b. Training costs

157. We expect there to be changes to how data needs to be processed by health providers to conform with the new mandatory standards for IT suppliers, alongside upskilling staff to use new systems or new functionalities in upgraded existing systems. This will incur training costs.

158. Training costs will be incurred once clinical systems are updated with the standards. Based on this, the cost attributed to each legislation will be dependent on our assumption of compliance take-up (details of compliance assumptions are included in the economic analysis section of the executive summary). As such 76% of health and care providers will incur training costs because of DUA.

159. To estimate these training costs, we have used published workforce data[54] on the number of staff that will need to be trained in each stakeholder group and primary research on the training time required per individual.

160. As part of our primary research (the NHSE information standards and interoperability survey) health providers indicated that 2.2 hours of training will be required on average per individual on the mandated information standards. This training time will be borne in line with the roll-out of standards under legislation and occur in years two, three and six.

161. This provides us with the total time required for training across each stakeholder group, which we have then multiplied by average annual hourly costs to obtain the full training cost. The cost rate per hour of training is based on average hourly salary costs in related sectors for each organisation. The average hourly cost assumptions have been converted to the full cost of employment, based on the Regulatory Policy Committee guidance. The individual assumptions and cost rates used are detailed in Appendix 2.

162. Training on the standards will focus on improving awareness among clinical staff in public and private hospitals, as well as consultants and GPs. A small number of care workers may require training for public and private social care providers, particularly those involved in developing service user care plans alongside healthcare providers and social workers. However, the number of care workers needing training is expected to be negligible because most carers are focused on delivering pre-defined tasks assigned in service users' care plans. As a result, we have not monetised these costs as it was deemed disproportionate to do so.

163. It is acknowledged that training time may be repurposed from existing earmarked time; however, it is prudent to reflect the value of that time in this assessment.

---

54 NHS Workforce Statistics - October 2023 (Including selected provisional statistics for November 2023) - NHS England Digital

164. Based on the evidence available and approach outlined in Appendix 1 and Appendix 2, the 10-year present value for training costs across stakeholders considered is estimated to be £50.1 million, calculated by multiplying the number of individuals needing training in each group by the required training hours and the full cost of employment for each individual. For more comprehensive information, please refer to Appendix 1.

c. Information standards related systems update

165. We expect there to be costs directly related to ensuring clinical systems adopt the mandatory standards as set out by the Secretary of State – where the systems do not already comply.

166. We expect there to be reconfiguration costs for IT suppliers who seek to modify their products and services to meet the required standards to supply products and services to health and social care providers. These costs will be incurred for those suppliers that currently do not provide products or services that comply with the standards. Based on data from the NHSE information standards and interoperability survey, it is estimated these costs will be incurred by 44% of IT suppliers[55].

167. We expect there will be additional costs associated with transitioning providers existing systems and processes to make them compliant with the standards. It is assumed that transition costs will occur because of this. These costs are likely to be passed on to health and social care providers. No costs for cleansing or renormalisation of historical data are considered. Also, as health and social care providers will need to procure compliant IT products and services, we anticipate that there may be administrative costs associated with revisiting existing contract arrangements and/or switching suppliers should any of their procured products or services be non-compliant. These impacts are likely to vary between provider sizes and types.

168. For GPs, as with clinical systems procurement[56], the budget for the system updates to comply with the information standards will be funded from central budgets, so these costs are reflected against NHSE. Laing and Buisson 2013/14 Healthcare Market Review identified that 6% of GPs operate entirely outside of the NHSE, therefore the systems update cost for these private GPs are not assumed to be funded from central budgets.

169. For public and private social care providers £8.2 million has been committed as part of the digitising social care fund[57], to help support providers onto digitising care plans. The costs reflected in this impact assessment are additional and are required to ensure those digitised care plans are compliant with information standards.

170. To estimate the cost of the relevant updates to systems in relation to the information standards, we obtained data from IT suppliers through the NHSE information standards and interoperability survey. The survey indicated that uplifts in cost were likely to be 15% of the existing contract value. Baseline contractual values were identified for the majority of the public health and social care providers using publicly available contract information. Where information was not available, we developed cost assumptions using secondary research,

55 Information Standards and Interoperability Survey, NHS, Feb 2024
56 NHS England » Securing Excellence in Primary Care (GP) Digital Services: The Primary Care (GP) Digital Services Operating Model 2021-2023
57 Digitising social care fund - Digitising Social Care - NHS Transformation Directorate (england.nhs.uk)

interview data and accounting for the relative size of the organisation – with separate assumptions used per the size of the organisation considered. The recognition that system costs tend to correlate with an organization's size has led to the creation of distinct assumptions for each size category, with the specific details of these assumptions presented in Appendix 2.

171. Based on the evidence available and approach outlined in Appendix 1 and Appendix 2 the 10-year present value for information standards related systems update costs across stakeholders considered is estimated to be £148.6 million and will occur across years 2, 3 and 6 in line with the implementation of the standards.

d. Conformance testing and accreditation costs

172. Establishing an accreditation scheme requires additional regulations. The full impacts cannot be accurately appraised at this stage because of significant uncertainty regarding the timing of any use of the powers and the content of any regulations. We will improve our assessment of the impact on both providers and suppliers and how we can mitigate this as part of the development of such regulations. Regulations will also be designed to minimise these costs to small and micro business as far as possible.

173. Below we provide our current assumptions regarding the accreditation scheme and associated costs.

174. To implement the information standards for IT systems in the health and social care sector, IT suppliers' products will need to be assessed to prove their conformance with required standards. Different standards will require different assessment approaches, and this flexibility will be built into our process design. There will be three options for conformance testing and accreditation:

- **Self-assessment** – as part of the standards publication, a clear set of tests and supporting tools to assess conformance will be provided to suppliers who will then be able to self-assess conformance. Suppliers may be required to provide the detailed results of their tests to buyers as part of procurement, compliance checks, or as part of accreditation.
- **Central assurance** – as part of the process for onboarding and remaining on procurement frameworks, NHSE may conduct testing either using its own staff or a subcontractor. This model is already used to some extent with Primary Care and Social Care record systems which are tightly and actively managed via enduring contractual arrangements that sit alongside procurement framework. This may also be performed as part of compliance process (e.g., if care providers report non-conformance).
- **Certificates of Conformance** – a formal scheme for assessing conformance will be developed in conjunction with the United Kingdom Assessment Services (UKAS) that oversees conformance testing of industry standards in the UK. Third party Conformance Assessment Bodies (CAB) would register with and be assessed by UKAS as fit for conformance testing and providing certificates of conformance to suppliers. Suppliers would be required to show a valid certificate of conformance issued by a CAB.

175. Self-assessment has the lower cost footprint, while central assurance imposes some costs on suppliers and significant costs on NHSE. The third option sees the bulk of the costs for conformance testing falling on suppliers and is by far the most rigorous but must be proportionate to the benefit conformance gives. It is worth noting that some of these costs may be offset if standards are harmonised and certifications are required by other

jurisdictions. As a matter of principle NHSE will require the least burdensome and costly approach that is proportionate to the risk an individual supplier's non-compliance poses.

176. NHSE will offer a voluntary scheme where suppliers may seek accreditation from NHSE to reduce the friction and administrative overheads in procurement by individual care providers where this is not already centralised. This would be particularly valuable where supplier self-certification of conformance is used. While public accreditation by NHSE would be voluntary, there is a risk that suppliers opting to demonstrate conformance directly to buyers may find that buyers – particularly those lacking in digital maturity – may prefer to restrict themselves to those that are members of the accreditation scheme. There is currently no indication or expectation that membership of the voluntary accreditation scheme could be become a de-facto requirement for suppliers to win contracts.

177. For each IT supplier it is estimated that accreditation costs will be required because of the implementation of the DUA legislation. To estimate these costs, we have used the cost for other national standard certifications as a reasonable benchmark to estimate the likely costs associated with accreditation. This cost has been based on average costs associated with ISO 27001 certification.[58] In addition to these costs, we have also included an estimate for internal costs incurred by IT suppliers to demonstrate compliance and gain accreditation. This estimate is based on the time required each year, which is assumed to be two months of one FTE per IT supplier. Refer to Appendix 1 for further detail on assumptions and calculation.

178. Based on the evidence available and approach outlined in Appendix 1 and Appendix 2, our estimate at this stage for the 10-year present value for accreditation costs is £2.6 million.

e. Compliance, monitoring and enforcement costs

179. The potential costs that NHSE or an equivalent organisation may face in relation to overseeing and enforcing compliance with DUA legislation in England extend beyond the initial accreditation process. The accreditation process is typically a point-in-time evaluation, which ensures that IT suppliers meet the required standards at the time of assessment. However, continuous monitoring is necessary to ensure that these suppliers and health and care providers maintain compliance with standards across both HCA and DUA legislation.

180. NHSE or a similar body would incur costs relating to monitoring and enforcing compliance with DUA legislation in England. These costs would include the development and implementation of monitoring mechanisms, staff training on data protection laws, and the establishment of audit processes to ensure adherence to DUA regulations. The compliance monitoring body would also need to allocate resources for regular assessments and audits to evaluate IT suppliers' compliance with the legislation. Legal and regulatory experts may be required to provide guidance and oversight. This cost also includes the costs required to run the public censure process. Overall, these costs would be essential for maintaining the integrity and security of patient data, safeguarding privacy, and upholding legal compliance within the evolving landscape of digital health and social care innovation.

181. For this RIA, we assume that a small regulatory body will suffice to enforce compliance with DUA regulations. We anticipate that an intelligence-led approach to monitoring will enable a compact yet efficient team. To estimate the necessary full-time equivalent (FTE) staff, we

58 www.itgovernance.co.uk/iso27001-certification-costs

have used the FTE count from the Postal Service Commission (Postcomm), a small regulatory body, now integrated into Ofcom, as a reference for the regulator's potential size.

In selecting this benchmark, we assessed the size of all UK regulators to find one similar to our proposed regime. Among the smallest regulators, such as the Gambling Commission (350+ FTE), Pensions Regulator (900 FTE), and Information Commissioner's Office (1,000 FTE), we deemed the Postal Services Regulator as the most fitting comparison.

Postcomm's shift towards compliance monitoring and upholding the universal service obligation, with minimal direct intervention, mirrors our expected regulatory approach, which is less extensive than other economic regulators. Additionally, its small size corresponds with our projected requirements. However, it should be noted that the specific operating model for this new regulator remains to be developed.

182. On this basis, we assume that 3 FTEs will be required to implement. For this calculation, the body is assumed to be NHSE, but the costs are equivalent irrespective of the body, which could be the CQC or another body, as the cost of these FTE has been assumed to be the average wage for workers in the information and communication sector, which is £44,733 for 2023 according to the Annual Survey of Hours and Earnings (ASHE) 2023. This wage has been uplifted by 22%[59] to reflect the total cost of employment. It is them assumed that this cost is incurred annually over the ten-year period.

183. Based on the evidence available and approach outlined in Appendix 1 and Appendix 2, the 10-year present value for compliance monitoring and enforcement costs for IT suppliers is estimated to be £1.6 million. These costs represent annual recurring expenses that will persist throughout the 10-year period.

f. Penalty costs to businesses

184. This penal regime represents a potential cost to IT suppliers. Given each fine would be determined by the severity of the breach and the individual circumstances of the businesses, it would not be proportionate to accurately quantify this cost. Furthermore, Better Regulation guidance[60] states that when calculating the NPV, business NPV and EANDCB, we should not include any costs (for example fines or penalties) incurred by companies for non-compliance.

Option 2 (preferred option) benefits

Assumptions for attributing benefits to DUA legislation

185. Benefits of full compliance and implementation of information standards are pro-rated for the additional compliance achieved due to DUA legislation. This is based on the additional ICB compliance with information standards that is facilitated by the DUA. This is outlined in table 9.

186. As outlined previously, survey evidence shows that on average 42% of ICBs are compliant with current non-mandated core standards[61] (and therefore 58% are non-compliant). This is

59 RPC short guidance note Implementation costs August 2019
60 Better Regulation Framework Manual (regulatoryreform.com)
61 Based on health and social care provider compliance with six core information standards, excluding mandatory standards e.g., NHS number. Standards. This includes: NHS Data Dictionary Vocabularies; OPCS-4; dm+d; ICD-10/1; SNOMED CT; and HL7 FHIR UK CORE. Source: Information Standards and Interoperability Survey, NHS, Feb 2024

compared to 56% of IT suppliers being compliant – this aligns with supplier and provider interviews conducted, which found that generally there is a greater rate of IT supplier compliance with standards – and a proportion of health and social care providers that do use compliant systems, but with the standards functionalities disabled (and hence do not comply with standards). The difference between rates of supplier and provider compliance infers that 14% of providers do not comply with standards but use compliant systems with disabled functionalities (this is part of the 58% of providers who do not comply with standards).[62]

- **Attribution of benefits to s95 HCA 2022:** It is estimated that HCA measures will enable 14% of ICBs to comply with standards. The premise is that these suppliers are currently using compliant systems with functionalities disabled. This cohort accounts for 24% of currently non-compliant ICBs, and hence 24% of total information standards benefits (under full compliance) are attributed to s95 HCA 2022. Under just HCA 2022 legislation there is limited incentive for IT suppliers to adapt their IT systems to comply with information standards, hence under just HCA 2022 legislation, the 14% of health and care providers who can easily become compliant with limited IT supplier action, will comply and all others will be restricted by IT supplier inaction and difficulty to change systems or suppliers due to current contracts - hence 100% total compliance will not be achieved, and there will be 56% compliance overall.
- **Attribution of benefits to DUA:** It is estimated when DUA legislation is in place, alongside s95 HCA 2022, DUA will facilitate faster and easier compliance for the remaining non-compliant providers (76%). They may otherwise need to change systems or suppliers and face a greater burden to comply without the introduction of DUA and mandatory IT supplier compliance.[63] Therefore the incremental benefit from DUA is assumed to be 76% of the total benefits from information standards legislation.

Table 9: Compliance with standards and attribution to legislation

Option 2 (preferred option)	**Level of health and social care compliance with standards**	**Proportion of additional compliance attributed to legislation**
Current compliance	42%	Not applicable
Additional compliance due to s95 HCA 2022	14%	24%
Additional compliance due to DUA	44%	76%
Total compliance post s95 HCA 2022 and DUA legislation	100%	100%

187. As set out in the s95 HCA 2022 impact assessment, the measures under Option 2 deliver benefits through cost savings to health and social care providers; staff time saved from better access to data and more efficient processes; and value to patients from improved patient safety.
188. This section demonstrates why patients, citizens and staff having the right data, delivers positive care outcomes across the entire health and social care ecosystem. Below we have summarised the quantitative and qualitative benefits as set out in the Theory of Change.

62 All assumptions based on Information Standards and Interoperability Survey, NHS, Feb 2024
63 All assumptions based on Information Standards and Interoperability Survey, NHS, Feb 2024

Option 2 (preferred option) - monetary benefits

189. The expected monetary benefits over a ten-year period are summarised in Table 10 - the complexity of the analysis and limited evidence means we cannot be certain that these benefits will be realised in full. Therefore, the upper-bound optimism bias of 54% has been applied to reduce benefits where there was less evidence or lower confidence in the approach and assumptions made.

190. The annual benefits will be gradually realised as mandatory information standards are introduced in phases. This phased approach will be informed by an analysis of clinical and non-clinical use cases and is designed to address interoperability challenges according to their priority level.[64]

64 Updated Final DPDI (2) Bill Impact Assessment March 2023.docx (parliament.uk)

Table 10: Option 2 Benefits estimates over a ten-year period – at point of regional interoperability attributed to common information standards and DUA (£m, present value)

Benefit type	Measure	Direct or indirect benefit	Cash or non-cash releasing	Estimated £m benefit
A. Mapping and standardisation costs (this benefit is one-off once standards are implemented and non-recurring)	Reduction in mapping and standardisation costs across relevant ICBs	Direct	Cash releasing	21.6
B. Reduced duplicate tests / procedures	Cost savings from reduction in duplicate tests (diagnostic and lab tests)	Indirect	Cash releasing	65.3
C. Time saved accessing information	Value of time saving (patient record access)	Indirect	Non-cash releasing	31.8
D. Reduced medication errors and PSIs	D1. Reduction in cost of excess bed days (transition medication error reduction)	Indirect	Non-cash releasing	16.1
D. Reduced medication errors and PSIs	D2. (Non-Cash Releasing) Quality-Adjusted-Life-Years (QALY) value of prevented fatalities (transition medication error reduction)	Indirect	Non-cash releasing	10.7
D. Reduced medication errors and PSIs	D3. (Non-Cash Releasing) Reduction in cost of excess bed days (non-transition medication error reduction)	Indirect	Non-cash releasing	5.8
D. Reduced medication errors and PSIs	D4. (Non-Cash Releasing) QALY value of prevented fatalities (non-transition medication error reduction)	Indirect	Non-cash releasing	19.6
D. Reduced medication errors and PSIs	D5. (Non-Cash Releasing) Value of time saved reporting medication errors	Indirect	Non-cash releasing	11.4
D. Reduced medication errors and PSIs	D6. (Non-Cash Releasing) Reduction in reporting costs for patient safety incidents (PSIs)	Indirect	Non-cash releasing	158.0

All	All	Direct and indirect	Cash releasing and non-cash releasing	340.5[65]

191. Based on our calculations, and noting the underlying assumptions, we estimate the preferred option could generate benefits of up to £340.5 million in a ten-year period in present value terms. These benefits would arise from the operational efficiency from data access, which reduces time spent by clinical staff on unnecessary activities and the reduction in duplicate processes and procedures. In addition, other benefits are expected through improved patient safety from patient information and hence reduced medication errors and patient safety incidents. The rest of this section sets out our approach and evidence used to quantify these benefits. Benefits are classified between direct and indirect and cash releasing and non-cash releasing as follows:

- **Direct benefits:** benefits that are attributable to Common information standards benefits

- **Indirect benefits:** broader interoperability benefits are achieved because of the adoption of common information standards, which facilitates interoperability alongside the required interoperable architecture and infrastructure.

- **NHS cash releasing benefits:** these provide immediate cashable savings to a provider. There is no impact on the overall NHS budget. Examples may be:
  - Reduction in medical equipment purchases
  - Decommissioning of services

- **NHS non-cash releasing benefits:** these provide saving to the NHS but are not cashable to the provider. Examples may be:
  - Time saved by NHS staff within a service that continues
  - De-duplication within existing ongoing activities

Our analysis has identified, as per Table 10 above, one direct cashable benefit, one indirect cashable benefit, with all the other benefits being indirect and non-cashable.

A. Reduction in mapping and standardisation costs across relevant ICBs (cash-releasing): Currently without common information standards in place, there is a cost to relevant ICBs of employing contractors where these lacking these information standards are lacking, to standardise and convert data from individual EPRs or IT systems to be mapped to ShCRs. We expect This cost could be eliminated with the implementation of common information standards. This cost is, on average, £1.26 million[66] per ICB and is one-off and cash-releasing. This has been calculated based on survey responses from health and care providers on spend per annum on mapping and standardising data from clinical systems to ShCR.

Based on this evidence available and approach outlined, the ten-year present value cost saving from standardisation and mapping costs, attributable to DUA is £21.6 million

65 Numbers do not sum due to rounding
66 Average spend is based on Information Standards and Interoperability Survey, NHS, Feb 2024

B. Cost savings from reduction in duplicate tests (diagnostic and lab tests): Improved access to comprehensive patient data, and more up-to date and accurate patient records is expected to minimise unnecessary duplicate tests, procedures and medication prescriptions, leading to a reduction in health and social care costs.

Studies show that up to 30%[67] of medical tests, and 20-30% of blood tests[68] are duplicated. Interoperable systems with integrated decision support could assist in minimising unnecessary tests due to lack of, or poor patient data. A cost-benefit analysis of electronic medical records in primary care suggests an average reduction in duplicate laboratory tests of 8.8%[69] can occur as a result of the implementation of decision support within the electronic health record, whilst ensuring interoperability at national level could contribute to reduced duplicated medical imaging of 10%[70].

This is calculated based on the total cost of diagnostic (£1.4 billion) and lab tests (£0.9 billion)[71]. It is also based on calculating the proportion of duplicate tests (30% for diagnostic tests, 20% for lab tests, as outlined above) and calculating the cost saving based on a reduction in these duplicate tests (10% reduction in duplicate diagnostic tests and 8.8% reduction in duplicate lab tests, as outlined above). The cost was further converted into present value terms, and apportioned for current compliance with standards, regional interoperability benefits and adjustment for attribution to DUA, as outlined in paragraph 186.

Based on this evidence available and approach outlined, the ten-year present value cost saving expected from the reduction in laboratory and diagnostic imaging tests, attributable to information standards adoption and DUA is estimated to be £65.4 million.

C. Value of time saving (patient record access): Working with standardised data and interoperable systems could save staff time due to quicker and more efficient access to patient data. We expect this would remove the need for manually retrieving physical notes or accessing multiple records as well as reduce the time spent on information gathering or reviewing data. It may result in time saving for health and social care workers, which could be refocused on more value-add activities to the benefit of patients. It was estimated that the joining up of direct care within the OneLondon programme had a time saving per system access of at least 0.5 minutes, with potential for up to a 20-minute time saving on more complex cases[72]. Scaling this time saving for the estimated number of patient accesses across England[73].

Based on this evidence available and approach outlined, it is estimated that the ten-year present value of staff time saved attributable to regional interoperability and information

---

67 A new EPR can help stop unnecessary medical tests – EPR (airedale-trust.nhs.uk)
68 Electronic Patient Record (EPR) benefits realisation case study (ouh.nhs.uk)
69 Electronic Patient Record (EPR) benefits realisation case study (ouh.nhs.uk)
70 A preliminary look at duplicate testing associated with lack of electronic health record interoperability for transferred patients - PubMed (nih.gov)
71 National schedule of NHS costs_FY21-22_v3.xlsx (live.com), NHS
72 Economic Analysis of Digital Health Infrastructure: The Case of OneLondon's Impact on Time Efficiency and Safety in Healthcare Services
73 Based on number of outpatient and A&E attendances in a year

standards under DUA is £31.8 million[74], based on the average NHS staff salary per minute of £0.37[75].

D1 and D3. Reduction in cost of excess bed days, from reduction in transition and non-transition medication errors: Improved patient safety is expected from a reduction in errors resulting from re-entering information across systems and care settings. It also ensures clinicians and carers have the data they need on patients during transfers, discharges and referrals. Also, enhancing patient safety can mitigate adverse drug reactions by minimising the risk of medication errors and overprescribing. This could reduce the resources that the NHS dedicates to medication errors, and thus lead to a reduction in the number of excess bed days.

A study by the University of Manchester highlighted the potential benefits of implementing the DAPB4013 information standard for Medicine and Allergy/Intolerance Data Transfer. The adoption of this standard could lead to a 40% reduction in medication errors during patient transitions, such as when care is transferred between settings or healthcare professionals. The standardisation of data transfer ensures that accurate medication information is consistently communicated, minimising the risk of errors that can occur due to misinterpretation or missing information.

E-prescribing, enabled by interoperability, was shown to result in up to a 6% reduction in medication errors in Estonia and a 15% reduction in prescription errors in Sweden.

The impact of reducing these medication errors is two-fold: it is estimated to result in 14,275 fewer inpatient care days and save approximately £6.59 million annually. These savings stem from avoiding the additional treatments and extended hospital stays that often follow medication errors. Beyond the economic benefits, the most significant outcome is the potential to prevent 20 deaths per year caused by such errors. This underscores the critical role that standardised information transfer plays in enhancing patient safety and healthcare efficiency.

The benefits of interoperability go beyond just transition errors. Health and social care providers and patients could also benefit from the reduction in other prescription, administration and monitoring errors. The cost saving from prevented excess bed days from non-transition medication errors is estimated to be £5.1 million each year, with an assumed reduction in 80 deaths. This is based on a reduction in number of severe and avoidable non-transition medication errors.

Based on the evidence available and approach outlined, the estimated ten-year present value cost saving from reduction in excess bed days from reductions in transition medication errors, attributable to DUA is £16.1 million (D1).

Based on the evidence available and approach outlined, the estimated ten-year present value cost saving from reduction in excess bed days from reductions in non-transition medication errors, attributable to DUA is £5.8 million (D3).

D2, D4, D5 and D6. QALY value of prevented fatalities from medication errors, value of time saved reporting errors, and reduction in reporting costs for patient safety incidents (PSIs): The value of prevented fatalities from transition and non-transition

74 Based on the average NHS staff salary per minute of £0.37, based on https://digital.nhs.uk/data-and-information/publications/statistical/nhs-staff-earnings-estimates/september-2023/introduction
75 https://digital.nhs.uk/data-and-information/publications/statistical/nhs-staff-earnings-estimates/september-2023/introduction

medication errors has also been quantified in terms of the additional Quality-Adjusted-Life-Years (QALYs) gained. This is calculated based on the number of estimated deaths prevented from a reduction in medication errors[76], DHSC data on fatalities by age due to adverse drug reactions (ADRs), average life expectancy[77], and using the Green Book 2022 estimates of a QALY (£70,000) which is adjusted for each age group. The benefit is further apportioned based on assumptions outlined below to attribute to information standards and DUA.

As described above, information standards and interoperability are expected to reduce the prevalence of avoidable medication errors. In addition, access to real-time patient data can support providers making better informed decisions. Standards can reduce the risk of miscommunication or misunderstandings which can compromise patient safety and hence prevent patient safety incidents. This reduction in medication errors and patient safety incidents can reduce the time spent reporting and investigating such errors for staff, as well as the consequences for patient health and fatalities.

Based on the evidence available, the ten-year present value of QALYs gained due to the reduction in transition and non-transition medication errors attributable to regional interoperability and information standards under DUA is estimated to be £30.3 million (D2 and D4), this benefit is discounted at a 1.5% discount rate in-line with Green Book guidance for QALY health effects.[78]

Studies show that the average time spent reporting a medication error is 4 minutes per error[79]. This creates the opportunity for significant time savings from the reduction of medication errors. Based on the value of staff time per minute and a 6.8 million reduction in the number of medication errors[80] (this is calculated based on applying a 6% reduction in non-transition medication errors per annum (in line with evidence from Estonia) to the total number of non-transition errors per year (100.7 million) , and also adding a 0.7 million reduction in transition errors)[81], the estimated value of time saving is £10.1 million nationally each year.

---

76 Based on 20 deaths prevented due to a reduction in transition medication errors, based on the University of Manchester study (https://www.researchgate.net/publication/371609011_Estimating_the_impact_of_enabling_NHS_information_systems_to_share_patients'_medicines_information_digitally); and estimated 80 deaths prevented from non-transition medication errors, calculating based on the proportion of severe adverse drug reactions, associated deaths for transition medication errors – and the reduction in non-transition errors.
77 National life tables – life expectancy in the UK Statistical - Office for National Statistics (ons.gov.uk)
78 The Green Book (publishing.service.gov.uk)
79 Prescribing error reporting in primary care: a narrative synthesis systematic review - PMC (nih.gov)
80 Calculated based on a 6% reduction in non-transition medication errors per annum in line with evidence from Estonia (EUR-Lex - 52022SC0131 - EN - EUR-Lex (europa.eu)). This is applied to the total number of non-transition errors per year (100.7 million, as per https://qualitysafety.bmj.com/content/30/2/96.long#DC1. In addition, a 0.7 million reduction in transition errors is included (based on a University of Manchester study - (PDF) Estimating the impact of enabling NHS information systems to share patients' medicines information digitally (researchgate.net))
81 (PDF) Estimating the impact of enabling NHS information systems to share patients' medicines information digitally (researchgate.net)

Based on the evidence available and approach outlined, the ten-year present value benefit attributable to DUA is estimated to be £11.4 million (D5).

In the year to June 2022, there were 2.5 million patient safety incidents in England[82]. It was reported in a study by Adam et al that 7.9% of patient safety incidents were related to problems with Electronic Health Record interoperability[83]. In addition, the average cost per incident form is £337.16 – hence there is a potential cost saving of up to £6.76 million per year from the reduction in patient safety incidents from improved regional interoperability facilitated by DUA.

Based on this evidence, the ten-year present value benefit attributable to regional interoperability and information standards under DUA is estimated to be £158.0 million (D6).

As mentioned previously, the complexity of the analysis and limited evidence means we cannot be certain that these benefits will be realised in full. Therefore, the upper-bound optimism bias of 54% has been applied to reduce benefits where there was less evidence or lower confidence in the approach and assumptions made.

Implementation approach for information standards in scope under legislation

189. The roll-out of standards which are in scope for the legislation will be carried out in a phased approach over the next 10 years, based on priority standards for implementation. This will consider the complexity of standards, duration to implement and the standards which contribute the most towards interoperability objectives. The exact standards to be rolled out and roadmap for implementation will be determined during the pilot, which will focus on the highest priority standards.

190. Preference will be given to international and open standards and the operational process will include robust governance mechanisms – set out in regulations under the HCA 2022 – to ensure necessary considerations are taken into account when preparing and publishing information standards. These considerations could include impact on provision of services and capacity of the health and adult social care system to implement a new standard.

192. The modelling of costs and benefits for the preferred option takes the following approach:

- Year 1-3 will focus on implementation of the core information standards, to unlock interoperability benefits. This will result in 60% of overall standards implementation costs being incurred in year 2, and 35% in year 3.
- Non-core standards will be implemented in later years and 5% of overall standards implementation costs will be incurred in year 6 to implement these non-core standards.
- Most benefits are indirect and depend on interoperability being achieved (as previously); however, as the core standards are assumed to be implemented fully by the start of year 4, the benefits are assumed to accrue in line with the

82 https://www.england.nhs.uk/publication/national-patient-safety-incident-reports-up-to-june-2022/
83 The Impact of Electronic Health Record Interoperability on Safety and Quality of Care in High-Income Countries: Systematic Review - PubMed (nih.gov)

rate of core standards implementation thus fully achieved by year 4, with recurring benefits occurring each year.

Assumptions for attributing benefits to legislating information standards

193. For the interoperability benefits outlined above, several assumptions have been made to adjust the benefits to account for the incremental benefit from legislating information standards under legislation.

- **Regional interoperability benefits**: According to evidence from NHSE, at least 82%[84] of health and social care provision occurs within a patient's home region (even home ICB). This estimate is based on an analysis that was undertaken of patient flow in 2018 and 2019 for Acute outpatient and inpatient care and A&E attendances, for patients registered at a GP surgery in the Thames Valley and Surrey (TVS) area. The analysis looked at 'care in-area' i.e., within the patient's TVS home area, and patient flow fell into two categories: (1) Care out of area but still within TVS; and (2) care provided outside of TVS. The study demonstrated that c.18% of all episodes of care we classified as 'care provided outside of TVS' and consequently these patients where not deemed to benefit from the TVS shared care records programme. Since regional interoperability is considered as the target future state of this intervention, it is assumed that regional interoperability achieves 82% of total national interoperability benefits. This is based on the estimated proportion of patient care taking place within a region with the remaining 18% occurring outside the region.

- **Infrastructure is in place to unlock benefits of information standards:** To realise the benefits of common information standards it is essential that health and social care providers have the necessary 'fit for purpose' infrastructure in place. The benefits outlined are dependent on having appropriate underlying systems and technology to support them. This infrastructure is set to be delivered by the Shared Care Record rollout (via the Connecting Care Records programme). All ICBs are on track to implement Shared Care Records by March 2025, in time to accrue interoperability benefits from the introduction of these information standards. This expectation assumes that current budgets are approved, and that progress continues as planned.

- **Proportion of ICBs not currently compliant**: Based on information from the NHSE information standards and interoperability survey, 58%[85] of health and social care providers are not currently compliant with information standards, and it has been assumed that this level of compliance also applies to ICBs. This sub-set of ICBs will accrue the benefits of implementing information standards, as there will not be additional benefits for ICBs who already comply with information standards.

194. To adjust total estimated interoperability benefits based on the assumptions above, the equation below has been applied:

---

84 This is based on data provided by NHSE from the Thames Valley & Surrey (TVS) Connected Care Programme, which found that 18% of patient care was provided outside of the TVS region (and hence 82% provided within the region). Based on this, we assume this split of care within and outside of a region is applicable for the rest of England, and hence 82% if care is within a region and will benefit from regional interoperability.

85 Information Standards and Interoperability Survey, NHS, Feb 2024 – compliance wih core non-mandatory standards

Benefit from legislating information standards (DUA) = *Total national benefit under DUA x proportion benefit from regional interoperability (82%) x Proportion of ICBs with required infrastructure in place (100%) x Proportion of ICBs not currently compliant with common information standards (58%)*

Results

197. Based on applying a 3.5% discount factor to the costs and benefits over 10 years (or 1.5% for the QALY benefit)[86], the net present value of Option 2 is estimated to be £137.6 million, which is equivalent to a benefit-cost ratio of 1.68. Refer to Appendix 1, section 1.3 for annual profile of costs and benefits.

198. In accordance with the Green Book Review 2020, it is important to review these results in the context of the broader cost benefit analyses across all the ongoing initiatives across the health and social care ecosystem. Firstly, these provisions from the DUA Bill will be a key enabler for the Secretary of State's vision for health and social care to have national open standards for data and interoperability and, secondly, they help enable the NHS Long Term Plan to support integration and create an environment for innovation to thrive through creation of well-designed APIs, transparent and open-source development, and published open standards.

199. We expect enacting the DUA legislation will unlock benefits in a relatively shorter period (compared to other options such as issuing guidance to health and social care providers to outlaw new contracts after a specific date) as legislation is not dependent on renewal of existing contracts with IT suppliers. Additionally, we expect the measures in the DUA bill will deliver benefits faster and further than the HCA 2022 legislation alone. This time to comply is illustrated when we consider the adoption of core NHS information standards across clinical systems. A recent NHSE information standards and interoperability survey illustrated that, despite the longstanding requirement to have regard to these standards, only showed an average.42% compliance (excluding NHS number) amongst health and social care providers, and 56% amongst IT suppliers. (The standards surveyed included SNOMED CT, ICD-10/11, dm+d, OPCS-4 and NHSE Data Dictionary Vocabularies and HL7 Fast Healthcare Interoperability Resources (FHIR) – UK CORE.)

200. Enacting-legislation will result in minimal disruption to health and social care provider 'business as usual' activities as there is no need to re-negotiate contracts and potentially change clinical systems to compliant systems, hence saving time and cost, whilst realising the associated benefits. Other options, such as issuing guidance to health and social care providers to outlaw new contracts after a specific date, would have a relatively lower value for money as there is low cost of implementation, but reduced benefits relative to legislation.

Representing the social value of the preferred option

201. Where policies have impacts on NHS budgets, it is necessary to consider the impact the policy will have on funding available elsewhere and the consequent potential health impacts that might occur across the NHS or the wider health system. These health impacts represent the opportunity costs of allocating funds, as they reflect the social value of the foregone health benefits that the money could have otherwise provided.

---

86 Based on Green Book guidance - The Green Book (publishing.service.gov.uk)

202. In addition, where policies have the benefit of releasing cash for NHS budgets, this has the impact of creating opportunities for spending elsewhere which can improve health outcomes for society.

203. It is estimated that £15,000 of spending or cash-released from NHS budgets is equivalent to one displaced Quality-Adjusted life year (QALY), whilst the value of a QALY to society is £70,000.[87]

204. Further to the NPV estimated above, we have estimated the Net Present Social Value (NPSV), which considers both the social value of any foregone health benefits through use of NHS budgets, as well as potential health gains through cash released. The social value and costs of these health benefits are estimated and reported in QALY terms, from cash terms, to reflect the social value impact of the policy.

Social costs

205. Spending by NHS hospitals, NHS GPs or the NHSE impacts NHS budgets. This spending amounts to £141.0m for the preferred option (in cash terms, over 10-year period, discounted). When considering the QALYs displaced from this spending, the social cost is £678.1m, over a 10-year period.

206. Other costs associated with the preferred option do not impact NHS budgets (i.e., spending by IT suppliers, private hospitals, private GPs, private social care providers and public social care providers including local authorities). These costs amount to £61.9m (over 10-year period, discounted). These costs are not deemed to have an opportunity cost for the NHS and hence remain in cash terms.

207. The total social present value cost is estimated to be £740.0m (over a 10-year period, discounted). This includes the social cost (based on QALYs displaced) of NHS spending, and other costs in cash terms for other non-NHS spending. The social costs (based on QALYs) are discounted using a discount factor of 1.5%, whilst the other costs are discounted using a rate of 3.5%.

Social benefits

208. Of the benefits of Option 2, previously outlined in Table 10, the following benefits are 'cash-releasing' and have a positive impact on NHS budgets:
    - Cost savings for mapping and standardisation
    - Cost savings from reduced duplicate tests / procedures

209. These benefits are estimated to be £87.0m in cash terms (over a 10-year period, discounted), and £443.2m in social value based on associated QALYs gained.

210. Other benefits are non-cash releasing therefore do not impact NHS budgets – these benefits remain valued in cash terms, and are estimated at £253.4m (discounted).

211. The total social present value benefit is estimated to be £699m (over a 10-year period). This includes the social benefit (based on QALYs gained) for cash-releasing benefits, and

---

87 The Green Book (publishing.service.gov.uk) - QALY value of £70,000 is adjusted for age group using EQ-5D scores - DSU Age based utility - Final for website.pdf (sheffield.ac.uk); economic-report-3 (nice.org.uk)

the cash value of all other benefits. The benefits based on QALYs gained are discounted using a discount factor of 1.5%, whilst the other non-cash releasing benefits are discounted using a rate of 3.5%.

Net Present Social Value (NPSV)

212. The NPSV is estimated to be -£40.9m and the BCR 0.94, when the opportunity cost and benefits from impact on NHS budgets are considered. This is summarised in table 11 below:

Table 11: NPSV and BCR

Item	Cash value (£m)	Social value (£m)
PV Cost	202.9	740.0
PV Benefit	340.5	699.0
NPV / NPSV	137.6	-40.9
BCR	1.68	0.94

Option 3 (alternative option) costs and benefits

213. This section considers the benefits and costs of Option 3 (***Issue guidance to health and social care providers to outlaw new contracts that do not comply with specified information standards after a specific date - public and private***).

214. Option 3 is non-legislative, and centred on issuing guidance on new contracts to incorporate information standards but does not mandate IT suppliers or health and social care providers to comply. It is assumed there will be 13%[88] additional compliance with information standards facilitated by Option 3 (this equates to 5 additional ICBs adopting standards under this option). This compares with 44% additional compliance across ICBs under DUA Option 2 (this equates to 18 ICBs, in addition to the 14% additional ICBs complying under s95 HCA 2022 legislation, and the 42% who already comply[89]) – i.e., Option 3 will support achieving an overall 69% compliance rate with information standards across all ICBs. This estimation is based on current compliance with the SNOMED standard by IT suppliers[90], this is deemed to be a reasonable expected compliance level without IT supplier legislation, given that SNOMED is currently a non-mandatory standard which is deemed to be a clinically valuable standard and benchmark.

215. In addition, adoption of information standards under Option 3 will be slower than via legislation under the preferred option, and timing will be dependent on the expiry of contracts. Based on contract expiry dates for a sample of EPR contracts that we have identified, 80% of contracts are due to expire within the next four years.[91] As well as a slower implementation approach than the preferred option, due to Option 3 being non-legislative.

Costs

88 Information Standards and Interoperability Survey, NHS, Feb 2024
89 As per Table 9
90 Information Standards and Interoperability Survey, NHS, Feb 2024
91 Based on analysis on contracts from https://www.contractfinderpro.com/

216. For the alternative option, we have estimated that familiarisation, training, information standards upgrade will be incurred for the additional 5 ICBs that adopt information standards under Option 3. This equates to 28%[92] of the undiscounted cost of Option 2, in line with the lower adoption of standards within the ten-year period. In this option, as adoption of the information standards is dependent on the expiry of contracts, the cost profile has also been designed to reflect the slower pace of adoption.

217. We estimate the costs of the alternative option are £58.2 million in undiscounted current prices, and in present value terms are £53.7 million over ten years.

Benefits

218. There will be the same categories of benefits under the alternative option compared to (Option 2) legislation under DUA. However, it is expected that the benefits of information standards and interoperability will be achieved at a slower pace (also based on the timing of contracts expiring). In addition, the full regional interoperability benefits are achieved when there is critical mass (or full compliance with information standards) and reduces exponentially with the reduction in number of ICBs adopting information standards. Hence due to a lower proportion of ICBs complying with the guidance (5 ICBs complying under Option 3, compared to 18 under Option 2), the total benefits are estimated to be 6.5%[93] of Option 2 benefits - this is calculated scaling benefits down with the reduction in the number of links between ICBs, between Option 2 and Option 3. The information standards benefits (savings in mapping and standardisation costs) are assumed to linearly reduce based on the reduction number of ICBs complying.[94] For the alternative option, benefits are not forecast to occur until year 5, in line with contracts expiring, with the profile of these benefits spread evenly over years 5 to year 10.

219. We estimate the alternative option will generate benefits of £31.2 million in undiscounted current prices and in present value terms are £25.2 million over ten years.

Results

220. The net present value of Option 3 is -£28.5 million, which is equivalent to a benefit-cost ratio of 0.47.

Comparison of options

221. Outlined in Table 12 below for comparison are the net present values and the benefit cost ratios associated with each option.

Table 12: Comparison of 10-year NPV and BCR of all options

Option	NPV (£m)	BCR
Option 1 – Do nothing	-	-
Option 2 – Preferred option	137.6	1.68
Option 3 – Alternative option	-28.5	0.47

92 Proportion of cost is based on ratio of 5 addition as complying under Option 3, compared to 18 under Option 2

93 Calculated based on the exponential reduction in number of ICBs connected with each other between Option 3 and Option 2

94 In line with the reduction in costs

Non-monetary benefits

222. Several other benefits and impacts arise as shown in the Theory of Change for the preferred option and have not been quantified due to lack of sufficient data and evidence to inform a robust assessment. These benefits are therefore not included in the BCR, but nevertheless still generate social and economic value.

223. Several of these benefits are detailed in the s95 HCA 2022 impact assessment– but will be achieved at a faster and wider scale under DUA. These benefits are:

- Earlier diagnosis and reduced downstream costs
- Care pathway optimisation
- Time saved on inefficient processes and duplicative efforts across systems
- Improved integration of health and social care services in England

224. In addition, we anticipate the following non-monetary benefits arise from the DUA measures:
    - **Improving competition and market expansion in the IT supplier market:** Improved competition in the IT supplier market is a benefit stemming from the implementation and the enforcement of information standards. Mandating information standards ensures that all IT suppliers must adhere, which creates a level playing field in the market. IT suppliers are incentivised to innovate and differentiate their offerings to stand out in the market - this competition drives continuous improvement and encourages suppliers to develop more advanced, efficient, and user-friendly solutions.
    - **Lower barriers to entry for new entrants into the IT supplier market to meet regulatory requirements:** This occurs because all suppliers must comply with the same standards. In addition, health and social care providers would benefit from easier procurement and avoid vendor lock-in[95], this would support innovation by enabling providers to choose from a diverse set of supplier products and systems. This is in the knowledge that they will not lose access to information and that the technology will work with technologies in other parts of the health and social care system. The increased choice creates competition and enables each provider to choose the IT solution that best meets their needs. Furthermore, there are opportunities for market expansion - information standards would be designed to confirm with international norms; therefore, compliance opens up opportunities for IT suppliers to enter new markets, driving further competition and innovation on a global scale.

225. A regulatory provision can be considered to promote competition if it satisfies the following criteria[96]:

- The measure is expected to increase, either directly or indirectly, the number or range of sustainable suppliers; to strengthen the ability of suppliers to compete; or to increase suppliers' incentives to compete vigorously.

- The net impact of the measure is expected to be an increase in [effective] competition and the overall result is to improve competition.

---

95 Vendor lock-in is characterised by extreme difficulty in moving from one provider to another, resulting in inability to cease using a product or service regardless of quality: Information standards for health and adult social care in England - GOV.UK (www.gov.uk)
96 The Better Regulation Framework (publishing.service.gov.uk)

- Promoting competition is a core purpose of the measure.
- It is reasonable to expect a net social benefit from the measure (i.e., benefits to outweigh costs), even where all the impacts may not be monetised.

  As outlined above, the preferred option is expected to strengthen the ability of suppliers to compete, create a level-playing field, reduce instances of vendor lock-in and hence increase effective competition. The overall impact is also a positive net present social value as outlined in the Summary: Intervention and Options section. Whilst the primary objective of the legislation is to improve outcomes in health and care delivery, creating a level playing field in this way will inevitably promote competition.

1.7 Direct costs and benefits to business calculations

226. The direct costs to businesses are the accreditation, familiarisation, training and information standards related system upgrade costs related to IT suppliers, private social care providers, private hospitals and GPs. These costs are estimated to be £64.8 million (undiscounted). Outlined in Table 13 below are these costs per business group over a 10-year period.

227. All direct costs and benefits falling upon businesses operating in the UK (regardless of nationality of ownership) have been included. These businesses have been identified from the NHSE frameworks (IT suppliers), NHS system directories and the CQC directory (private health and care providers). We expect some pass through of these costs to health and care providers, although this will be an indirect impact and is not captured in the EANDCB.

Table 13: Cost to business £m (ten-year period undiscounted)

Organisation	**Total cost (£m)**
IT suppliers	12.6
Private Hospitals	43.6
Private Social Care Providers	4.9
GP's (operating outside the NHS only)	3.7
All	64.8

228. In this assessment, the monetised benefits are for the health and care system as a whole and have not been attributed to specific organisation groups. In addition, non-monetary interoperability benefits, such as improved integration across the care system, will extend to private health and social care providers. While competition and opportunities for expansion in the IT supplier market will affect supplier businesses.

1.8 Risks and assumptions

229. In this section we provide a breakdown of the risks identified and the sensitivity analysis carried out. We also provide an overview of the risks related to the legislative intervention.

Risks

Devolved administration handling

230. Healthcare is a devolved matter, with each UK nation funding and organising its health and social care services separately. This has the potential to impact the benefits if there is no medium for achieving similar outcomes in other nations of the UK. That is, England uses one set of information standards, and the devolved nations use different set of standards. The implication is clinical information sharing will be limited to within England, and information sharing with NHS Wales, Scotland, Northern Ireland will be challenging, time consuming and require investment in staff time to 'translate' clinical records to the standards used by the devolved nation NHSs.

Implementation risks

231. There is a risk that if the mandated standards are not designed properly, or address clinical and care provider requirements, they could lead to an increased administrative workload for healthcare professionals or reduced clinical engagements with their usage. This additional burden could negate the anticipated time-saving benefits that the standards aim to provide.

232. Furthermore, there is a concern that if the standards are seen as overly complex, especially any that are NHS specific (bespoke) standards as opposed to internationally recognised ones, they may be viewed unfavourably by vendors in the supplier market. Such a perception could lead to a decrease in the number of suppliers willing to engage, potentially driving up the costs for health and care providers due to reduced competition.

Data security risks

233. With interoperability and increased data sharing between systems, there may be an increased risk of access to unauthorised information if proper security measures are not in place. Additionally, different systems may have different varied levels of security, and this would need to be managed to ensure consistency of security protocols and reducing risk of security vulnerabilities.

234. Constant diligence, awareness, and making sure that there is alignment and awareness of security issues will be required to mitigate such risks.[97]

235. Regarding patient consent and privacy, with enhanced interoperability among healthcare platforms, the risk of data circulating online without explicit consent increases.[98]

Policy risks

236. Through clinical and non-clinical use case analysis, it is anticipated that the introduction of information standards compliance will be staggered and aligned to resolving interoperability challenges in line with the highest priority patient and citizen pathways. This will limit (and signposts) the impact of changes required to be made by suppliers.

The risk of IT suppliers leaving the market

237. Digitisation of health and social care is a global trend, and many suppliers are facing high demand for their services, leading to backlogs for new implementations. While many of the biggest suppliers are global, there are no global standards around interoperability. This means that suppliers can prioritise investing in standard configurations for other, larger markets, such as the US and not in bespoke products to meet the proposed health and social care IT standards. Our proposals therefore risk IT suppliers leaving the market due to an increased burden to deliver a product or service that are for England only. To mitigate

97 Data security remains a challenge as interoperability moves closer to reality | Lee Barrett (chiefhealthcareexecutive.com)
98 Healthcare Data Security | Navigating the Interplay between Innovation and Protection (telefonicatech.uk)

this, we intend to consider international best practice concerning interoperability and engage with the health and social care IT supplier market to ensure both inform the contents of IT standards. That said, according to the NHSE information standards and interoperability survey, most IT suppliers say they are already meeting these standards, hence for those suppliers the risk of exiting the market is considered low.

The risk of increased cost of IT products/services

238. There is a risk that, despite an increase in competition, prices increase because the increased cost of compliance outweighs the downward pressure on prices resulting from the increased competition. To mitigate this, we intend to develop the standards themselves and implementation of the measures in consultation with different types of suppliers.

239. There may be a small risk to LAs when commissioning care, if IT suppliers pass on any potential increased costs incurred in meeting mandated information standards back to providers of care, who in turn pass them on to LAs who have commissioned care. We will consider these carefully when implementing the provisions in the bill. We do not anticipate such a risk to social workers developing care plans.

Analytical assumptions

Costs and benefit assumptions

240. It is important to note that, many of the benefits and costs attributed to the DUA measures are dependent on measures in the s95 HCA 2022 having limited impact. If the net benefit impact from s95 HCA 2022 exceeds estimates, the incremental net benefit impact from the DUA measures presented in this IA would be commensurately reduced.

241. Despite best endeavours to collect and draw upon strong evidence, cost and benefit assumptions remain uncertain and based on limited evidence availability in places. To mitigate this uncertainty, we have applied optimism bias, carried out sensitivity analysis and planned monitoring and evaluation.

Sensitivity analyses

Sensitivity analysis (Benefits)

242. Sensitivity analysis was undertaken, to consider the impact of varying a subset of key assumptions on the NPV and BCR for Option 2. This sensitivity analysis focuses on variations in the additional compliance of ICBs facilitated by DUA and the proportion of ICBs that do not already comply with information standards. These assumptions were chosen for the sensitivity analysis because changes in them will significantly impact the benefit values, affecting all categories of benefits uniformly. Additionally, since the standards in scope for legislation under DUA are not yet defined, the actual proportion of current compliance and the potential for additional compliance facilitated by DUA may vary.

243. Further to the cost-benefit analysis presented in section 1.6, the sensitivities have been modelled below:
    i. Additional compliance of ICBs facilitated by DUA – impact on NPV and BCR shown in table 14.

       We have considered the impact on the overall NPV and BCR from a 25% reduction in the level of additional compliance of ICBs with information standards facilitated by DUA. The 25% sensitivity adjustment was chosen as it considers the risk of variability in compliance levels, whilst also being a significant enough of a change to substantially impact values:

There is no upper scenario due to the base case assuming 100% compliance across DUA and s95 HCA 2022:

- Base Case – 44% additional compliance of ICBs attributed to DUA
- Low Case – 33% additional compliance of ICBs attributed to DUA

To achieve a net present value (NPV) of zero, thus reaching the break-even point, an incremental compliance rate of at least 11.5% is necessary. As outlined above, this threshold for additional compliance also depends on limited net benefit impact resulting from measures in s95 HCA 2022. If net benefit impact from s95 HCA 2022 exceeds estimates, additional net benefit impact from these measures would be commensurately reduced. Nonetheless, the legislative framework is structured to promote additional compliance by implementing additional deterrents for IT suppliers (such as public censure and fines). Moreover, looking at historical examples, such as the 83%[99] compliance rate achieved by providers with the NHS number standard, it is plausible to anticipate that a comparable level of adherence could be achieved with the new regulations.

Table 14: NPV and BCR DUA compliance sensitivity

Sensitivity scenario	NPV DUA attribution (£m)	BCR DUA attribution
Low	111.7	1.55
Base	137.6	1.68

ii. Proportion of ICBs not currently complying with information standards - impact on NPV and BCR shown in table 15.

We have considered the impact on the overall NPV and BCR from a +/- 15% change in the assumption of proportion of ICBs not already complying with information standards, and therefore varying the incremental benefit from DUA and additional compliance uplift. The base level of current compliance is premised on core information standards. Nonetheless, this rate may fluctuate depending on the specific standards targeted by the legislation. A 15% sensitivity adjustment was selected as it accounts for the potential variability in compliance levels and is substantial enough to be meaningful.

- High Case – 73% ICBs not complying with information standards
- Base Case – 58% ICBs not complying with information standards
- Low Case – 43% ICBs not complying with information standards

The results of the sensitivity are outlined below. We have also determined that the minimum proportion of ICBs not already complying with information standards would need to be 13.6% for the NPV to break even, resulting in a nil NPV. Given that current compliance levels are informed by a survey of providers[100] and align with core information standards expected to be mandated by legislation, there is a reasonable level of confidence that baseline compliance will not fall below 13.6%.

Table 15: NPV and BCR for ICB current compliance

99 Based on Information Standards and Interoperability Survey, NHS, Feb 2024
100 Based on Information Standards and Interoperability Survey, NHS, Feb 2024

Sensitivity scenario	NPV ICB current compliance (£m)	BCR ICB current compliance
Low	90.5	1.54
Base	137.6	1.68
High	182.7	1.77

Sensitivity analysis (costs)

245. Sensitivity analysis was undertaken, to consider the impact of varying a subset of assumptions on the NPV and BCR for Option 2 – results shown in table 16. The analysis of financial benefits has considered the impact of varying a subset of assumptions on the NPV and BCR outcomes. For the low scenario, we have assumed that costs will rise by 15% and, for the high scenario, we have assumed costs are reduced by 15%. A 15% sensitivity adjustment was selected as it considers the risk of variability in costs and is driven by variation in current compliance levels (as above), this level of sensitivity is also significant enough to have a meaningful impact.

246. The results of the sensitivity are outlined below. It has been calculated that a cost increase of 67.8% would be the threshold to reach a break-even NPV, resulting in a zero NPV. To mitigate the risk of underestimating costs, we have incorporated an optimism bias into our cost estimates, providing an additional layer of protection against potential overruns. Additionally, considering that UK inflation peaked at 11.1% in the last 30 years, the likelihood of costs exceeding a 67.8% increase is considered minimal.

Table 16: NPV and BCR cost sensitivities

Sensitivity scenario	NPV ICB maturity (£m)	BCR ICB maturity
Low	107.2	1.46
Base	137.6	1.68
High	168.1	1.97

Conclusion of sensitivity analyses

247. Based on this analysis, we conclude that the NPV and BCR of Option 2, is not overly sensitive to the assumptions that have been varied. The overall outcome is relatively unchanged, the outcome is still a positive NPV and a BCR of greater than 1. However, as previously outlined, it should be noted that this intervention is one of several fundamental pillars to unlock interoperability benefits, whereby there will be larger combined benefits across these various interventions, as well as frontline digitisation plans.

1.9 Impact on small and micro businesses

248. Small businesses are defined in the better regulation framework guidance as those that employ between 10 and 49 full-time equivalent (FTE) employees. Micro businesses are businesses that employ between one and nine employees.

249. The size of businesses has been used to estimate headcount per organisation type (method for each provided in Appendix 1 and 2), which has been used to determine the number of businesses in scope of the regulation within each size category. Our analysis has identified 1,317 micro businesses, comprising 362 private GP practices and 955

private social care providers. Additionally, we have identified 3,901 small businesses, which include 3,886 private social care providers, 12 private GP practices, and 3 IT suppliers.

250. We acknowledge that compliance costs for SMBs represent a higher proportion of their total capacity and resources than larger businesses. In this section we have estimated the impact on SMBs. Consistent with the rest of the economic analysis, only micro and small businesses that aren't already compliant with information standards, originally or through s95 HCA 2022, are impacted. This is a subset of the in scope SMBs above.

Table 17 and Table 18 show the cost to SMBs by type of organisation and cost type.

Table 17: Cost to micro businesses (undiscounted)

Organisation	Cost type	Aggregate cost	Implementation cost per organisation[101]	Annual cost per organisation[102]
GPs	Training costs	£220,246	£800	£0
Private social care providers	Information standards related systems update	£279,433	£660	£0

251. Clinicians in micro-GP practices will be required to undergo training to use the new systems as updated. This cost, at £800 per organisation, represents an allocation of clinicians' time. It is not unusual for clinicians to periodically undergo training. Training time per GP is estimated at 2.2 hours[103], with the total number of hours varying by headcount at the GP. Only 6%[104] of GPs are considered as operating completely outside of the NHS and therefore considered as private businesses, it is only these GPs included in this analysis.

252. Micro private social care providers will incur a monetary cost of £660 per organisation to update systems to make them information standards compliant as new standards are mandated over a ten-year period. Whilst we have taken the conservative approach to include these costs; it should be noted that NHSE is providing funding of £8.2 million to support a pilot on the digitisation of social care[105]. The programme will then support ICBs to scale up the solutions that have the biggest impact. It is unclear what the scale of this support will be, but this should alleviate or significantly mitigate the burden on social care providers.

Table 18: Total cost to small businesses over ten-years (undiscounted)

101 Including 10% optimism bias
102 Including 10% optimism bias
103 Based on Information Standards and Interoperability Survey, NHS, Feb 2024. 10% optimism bias is also included on top of the cost of these hours
104 Laing and Buisson 2013/14 Healthcare Market Review
105 Digitising social care fund - Digitising Social Care - NHS Transformation Directorate (england.nhs.uk)

Organisation	Cost type	Aggregate cost	Implementation cost per organisation[106]	Annual cost per organisation[107]
IT Suppliers	Familiarisation costs	£1,562	£521	£0
IT Suppliers	Information standards related systems update	£108,900	£82,500	£0
IT Suppliers	Accreditation costs	£453,194	£11,000	£14,006
GPs	Training costs	£25,987	£2,807	£0
Private social care providers	Information standards related systems update	£1,568,266	£910	£0

253. We estimate that all small IT suppliers will incur familiarisation costs of £521 per organisation and accreditation costs made up of £11,000 upfront implementation costs and £14,006 annual costs over 10 years. We expect information standards related systems update costs will be incurred only by suppliers that are currently not compliant, as new standards are implemented. We estimate the information standards related systems update cost per organisation to be £82,500 over 10 years. It should be noted that only 15% of IT suppliers in this market are considered small businesses.

254. Similar to GPs classified as micro businesses, we anticipate that GPs classified as small businesses will incur training expenses. These expenses represent an allocation of clinicians' time, which is expected to be sourced from existing resources for the purposes of completing the necessary training, thereby not incurring any additional financial burden**.** The estimated training time per GP is 2.2 hours[108]. GPs that fit within the small business classification typically have a larger headcount than those that meet the micro business criteria, which explains why the cost per organisation, at £2,807, is higher. As with small businesses, only 6% of GPs are considered as private businesses.

255. Small private care providers will incur an estimated monetised implementation cost of £910 per organisation to update their systems to make them information standards compliant as standards are mandated over a ten-year period. As pointed out previously, NHSE digitisation support will mitigate the burden on care providers.

Exemptions and mitigations

256. The better regulation framework guidance states (paragraph 2.3.3): "*The default option is to exempt small and micro-businesses from the requirements of new regulatory measures*." If an SMB exemption is not applied, and there are disproportionate impacts on SMBs, mitigation options must be considered.

256. Achieving system wide interoperability will require all the constituent parts of the health and care system and the IT suppliers to adopt common data standards. The proposed legislation will make this a consistent duty across providers of both care and IT services supporting care. Exemptions for SMBs has been considered, but ruled out on the basis

106 Including 10% optimism bias
107 Including 10% optimism bias
108 Based on Information Standards and Interoperability Survey, NHS, Feb 2024. 10% optimism bias is also included on top of the cost of these hours

that exemption of any size business would undermine the policy objective.

257. As per our analysis, GPs and social care providers make up 99.9% of the entities that fall into the SMB category. This is all but 3 of the 5,219 businesses. Whilst the regulation does not include any exemptions, it should be noted that systems update costs being paid for centrally from the Department of Health and Social Care budgets with no cost implications for GP surgeries[109]. Similarly, costs for social care providers will be mitigated by the social care fund for digitisation being provided by NHSE.

258. We recognise the costs of this legislation on small IT suppliers and have therefore considered the following mitigations to lessen the impact.

259. The burden of familiarisation costs for IT suppliers will be mitigated by the issuance of guidance notes, with no need for small and micro businesses to understand the legislation beyond reviewing circulars to be issued by the NHSE. These circulars will provide tailored information and advice which will be adequate to support compliance with the legislation. This is particularly helpful for smaller businesses, reducing their need to buy legal and regulatory expert services to help navigate the familiarisation requirements.

260. Information standards related system update costs will be incurred only by those small IT suppliers who are not already compliant. To mitigate this cost, the standards are designed to be rolled out in phases. This will support smaller suppliers by allowing them to phase their transition and therefore the associated costs over an extended period of time.

261. Currently, there is uncertainty regarding the timing of using the accreditation powers and the content of the required secondary regulations. We will further assess the impact of accreditation on small and micro-IT suppliers and how we can mitigate this as part of the development of these regulations.

262. The standards introduced would not be designed so as to place any additional burden on a company depending on its size: by their nature, information standards, such as L7 FHIR UK CORE or SNOMED CT, set requirements for technical build, processing, how data is handled etc., and such requirements should be fully deliverable by IT providers of any size in the market.

263. More widely, the policy has been designed with consideration of SMBs and we expect that SMB IT suppliers can benefit from mandatory information standards through:
    - Increased competition - by enhancing the appeal of alternative IT suppliers' services with which larger companies interoperate and removing barriers to switching suppliers.
    - Customer confidence - allowing SMBs to show customers that their products and services meet recognised standards.
    - Market access – by adopting international standards as a preferred policy approach we will open up SMBs to access a worldwide market.

1.10 Impact on medium-sized business

264. Alongside the small and micro business assessment (SaMBA), we have included in this Impact Assessment an assessment of the case for how medium-sized businesses (in the

109 NHS England » Securing Excellence in Primary Care (GP) Digital Services: The Primary Care (GP) Digital Services Operating Model 2019-21

range 50 to 499 employees) might be affected and mitigation of the impacts on these businesses. This is shown in table 19.

Table 19: Total cost to medium businesses over ten-years (undiscounted)

Organisation	Cost type	Aggregate cost	Implementation cost per organisation	Annual cost per organisation
IT Suppliers	Familiarisation costs	£2,604	£521	£0
IT Suppliers	Information standards related systems update	£726,000	£330,000	£0
IT Suppliers	Accreditation costs	£755,323	£11,000	£14,006
Private social care providers	Information standards related systems update	£1,397,738	£2,825	£0

265. We estimate that all medium-sized IT suppliers will incur familiarisation costs of £521 per organisation and accreditation costs made up of £11,000 upfront implementation costs and £14,006 annual costs over 10 years. We expect information standards related systems update costs will be incurred only by suppliers that are currently not compliant, as new standards are implemented. We estimate the information standards related system update cost per organisation to be £330,000 over 10 years. Medium sized private care providers will incur an estimated implementation cost of £2,825 to update their systems to make them information standards compliant, based on existing standards as pointed out previously NHSE digitisation support will mitigate the burden on care providers.

Exemptions and mitigations

266. As above, achieving system wide interoperability will require all the constituent parts of the health and care system and the IT suppliers to adopt common data standards. Exemptions for medium sized business have been considered and ruled out, as exemption of any size business would undermine the policy objective (interoperability).

267. As is the case for SMBs, the costs for medium sized social care providers will be mitigated by the social care fund for digitisation being provided by NHSE.

268. The burden of the legislation on medium-sized IT suppliers will also be lessened by the mitigations set out in the SMB section above, including issuance of guidance notes, phased standards rollout and consideration of impact and appropriate mitigations in the development of accreditation regulations. Wider impacts (consider the impacts of your proposals).

269. The wider impacts which can be achieved through the adoption of information standards and the wider interoperability facilitated through legislation are described in detail in the s95 HCA 2022 impact assessment. These are considered wider benefits, as legislation is

an enabler of these impacts, and these impacts have broader societal benefits and are likely to occur over a longer timeframe compared to other benefits.

270. These impacts are summarised below:

- **Research and innovation benefits:** Adopting common standards for health and social care data is a fundamental requirement to enable and enhance research.
- **Improved patient satisfaction and empowerment:** Interoperability provides opportunities to empower citizens and patients with information and tools to support their health, care and wellbeing.
- **Wider productivity gains and taxpayer benefits:** Better patient outcomes and more efficient care – because of information standards and interoperability - can lead to less reliance on sickness benefits, fewer absences from work, and a more productive and resilient workforce, ultimately benefiting the economy.
- **Broader environmental benefits**: Interoperability can support a greener health and social care system as Data would be held in a cloud-based environment thereby reducing the data centre footprint and reliance on buildings and paper storage.[110]

271. It is not expected that there will be any distributional impacts from the DUA legislation.

272. A Public Sector Equality Duty assessment was carried to consider at a high level the potential impacts on equalities that may arise because of the provisions of the DUA Bill, including the impact of open data architecture provisions, which was considered in Section 6 of the assessment[111].

1.11 A summary of the potential trade implications of this measure

Boosting trade and market expansion

274. Clinical systems vendor markets for primary, community and mental health are highly fragmented with similar levels of market concentration in each of the relevant segments, with the General Practice EPR market being a duopoly. A mixture of interventions to set regulations and promote competition for the market are required to incentivise suppliers to follow standards, improve service, reduce costs, and innovate.

275. Legislation on information standards can enable products and services to be built on principles of a unified system architecture, open data standards and interoperability – with reference to international best practice. This can support information access and aid system providers and suppliers, whilst giving clarity to new market entrants on information standards requirements in the industry.

276. Furthermore, there is also opportunities for market expansion - information standards would be designed to confirm with international best practice, therefore compliance with information standards opens opportunities for IT suppliers to also expand to new markets, driving competition and innovation on a global scale.

---

110 Data Protection and Digital Information Bill: updated impact assessment (publishing.service.gov.uk)
111 Public Sector Equality Duty assessment for Data Protection and Digital Information (No.2) Bill - GOV.UK (www.gov.uk)

International trade[112]

277. The UK has always protected its right to choose how we deliver NHS health and social care services in trade agreements, and we will continue to do so. The procurement of the UK's public services, including NHS health and social care services, are protected in the trade agreements to which the UK is a party. The protections are based on a set of agreed principles including maintenance of the UK's right to regulate public services. The UK will continue to ensure that the same rigorous protections are included in future trade agreements.

278. The provider selection regime (PSR) is being developed to provide the NHS and local authorities with the tools to deliver better value for patients, taxpayers, and the population. As such, this may cause some divergence between UK rules set out under the PSR and rules under the EU system. Depending on the structure of the new regime, this has the potential to impact international trade and investment, but it is currently not possible to estimate how much given the use of the power is not finalised. In line with Better Regulation Guidance, DHSC are engaging with partners across Government including the Department for International Trade to fully assess any implications for international trade.

1.12. Monitoring and evaluation

279. Effective evaluation practice is needed to demonstrate the impact of this legislation.

280. HM Treasury's latest Green Book states that "monitoring and evaluation of all proposals should be […] an integral part of all proposed interventions".[113]

281. The proposed legislation is designed to play an important role in the delivery of common information standards as an enabler to interoperability and its mission of delivering better care outcomes.

282. Key metrics that will be tracked and measured going forward will be able to gauge the success of the proposed measures have been identified.

283. It is reasonable to perform a Post Implementation Review (PIR)[114] within 5 years of the implementation of the bill. This will include having to carry out two types of proportionate evaluations:

    - Process evaluation: to assess ongoing activities to understand their implementation and identify opportunities for improvement in future reforms. This will include a review of how useful the standards are, which will focus on identifying areas for refinement.

    - Impact evaluation: to assess the scale of effects caused by the planned changes, compared to initial ambition of the measure.

284. As this is a legislative change that applies to various stakeholders from the point of implementation, we will be basing our assessment around a theory-based evaluation. Therefore, the basis of both the impact and process evaluation comes from the Theory of Change presented earlier in the assessment. This theory-based approach for evaluation as suggested by the Magenta Book[115], offers a structured approach to understanding

112 Health and Care Act 2022 Core Measures Impact Assessment (publishing.service.gov.uk)
113 The Green Book (publishing.service.gov.uk)
114 Producing post-implementation reviews: principles of best practice - GOV.UK (www.gov.uk)
115 HMT_Magenta_Book.pdf (publishing.service.gov.uk)

interventions by focusing on their underlying theories of change. It helps identify causal pathways, make predictions, and manage the complexity of impacts and outcomes. This approach is proposed for evaluation due to the complexity of the health system and the various interactions of difference programmes and regulations working towards interoperability.

285. The Theory of Change outlined the expected long-term outcomes and impacts of the preferred option. Table 20 details the proposed methodologies and resources required to measure the success of the proposed legislation.

Table 20: Impacts and outcomes of legislating information standards and how these will be monitored and evaluated

Impacts	How this will be monitored and evaluated (pre and post intervention)	When and frequency of evaluation
Interoperability enabled by information standards	Proportion of ICBs complying with information standards set out by the legislation.	2027 and annually thereafter
Greater competition with IT suppliers, reduced entry barriers for SMEs to comply with established standards – fostering innovation	To assess this impact, we would evaluate data points before and after the intervention as outlined below: • Number of health and social care providers changing contracts with IT suppliers (reduced vendor lock-in)[116] • Data on the cost and number of times new IT equipment is procured • Number of IT suppliers in the market and number contracted with health and social care providers • Number of IT supplier SMEs in the market and contracted with health and social care providers	To be agreed, on a needs basis
Market expansion opportunities – credentials to support accessing interoperability opportunities in overseas markets	• Number of local IT suppliers with international contracts since implementation.	To be agreed, on a needs basis
Reduction in spending on unnecessary processes, procedures, visits, tests and treatments	• Spending on mapping and standardisation of data per ICB • Data on waiting time for appointments, diagnostic tests and procedures • Number of diagnostic tests and procedures carried out	2027 and annually thereafter

116 Information standards for health and adult social care in England - GOV.UK (www.gov.uk)

	• Patient safety incidence reporting costs	
Fewer medical errors and mistakes due to incomplete information	• Number of medication errors (monitoring, administration, prescription, transition) • Percentage of avoidable medication errors • Number of patient safety incidents	2027 and annually thereafter
Reduced time required for patient care	• Average appointment length (minutes) • Average time from patient hospitalisation to discharge • Average patient waiting time • Average time spent on administrative tasks by clinical professionals	2027 and annually thereafter
Reduced patient anxiety	• Patient experience / satisfaction survey results • Number of patient complaints	2027 and annually thereafter
NHS staff satisfaction / empowerment	• Staff experience / feedback surveys • Staff turnover • Staff absenteeism	To be agreed, on a needs basis

286. Many of the impacts and outcomes will rely on new data sources required to address current evidence gaps and assumptions made. This Impact Assessment highlights the modelling assumptions made due to insufficient existing evidence. It is essential to establish a strategy for recording these assumptions going forward. Table 21 outlines these assumptions and proposes methods for monitoring and evaluation them moving forward.

287. To ensure accurate attribution of the DUA legislation to each impact measure, it would be necessary to gather and analyse historical data to establish a baseline, define a counterfactual using control groups or statistical models, and continuously collect post-implementation data. Following which data is compared with the baseline and counterfactual to assess impact, using statistical methods to isolate the DUA's effect. This analysis could also be supplemented with qualitative insights from stakeholder interviews and case studies.

Table 21: Current assumptions and proposed monitoring and evaluation approach

Impacts	Current assumptions	Proposed monitoring and evaluation approach
Interoperability enabled by information standards	Proportion of ICBs complying with information standards set out by the legislation	Currently this is measured based on the information standards and interoperability survey, NHSE, Feb 2024. We would propose this impact measure is monitored based on compliance data from the compliance and monitoring function.

Greater competition with IT suppliers, reduced entry barriers for SMEs to comply with established standards – fostering innovation	N/A – data currently not collected as part of IA and no assumptions made	The impact measures could be determined based on enquiries and surveys of the relevant procurement and contract teams across different health and social care providers.
Market expansion opportunities - credentials to support accessing interoperability opportunities in overseas markets	N/A – data currently not collected as part of IA and no assumptions made	The data on number of IT suppliers with international contracts since implementation could be collected through surveys of IT suppliers in the market.
Reduction in spending on unnecessary processes, procedures, visits, tests and treatments	Standardisation and mapping cost assumptions: • Average spend on mapping and standardising per ICB: £1.26 million • Percentage of ICBs already complying with non-mandated core information standards (and therefore have no mapping costs): 42% As part of the benefits quantification in this IA, survey evidence from a sample of health care providers was used to estimate the average spend on mapping costs. However, an assumption has been made that this cost is also the cost per ICB. In addition, the survey assessed the proportion of health and social care providers who comply with six existing non-mandated information standards)[117] and an assumption was made that this proportion of ICBs do not incur mapping costs. Diagnostic tests and procedures assumptions: • Assumptions have been made to estimate the proportion of duplicate lab	Standardisation and mapping cost assumptions: Since the survey informing this IA sampled health and social care providers, we recommend distributing a survey to each ICB to capture total expenditure on mapping and standardisation pre and post information standards implementation. This approach would provide a more precise assessment of cost reduction without assuming compliance for ICBs already adhering to information standards. Furthermore, this approach ensures that the survey aligns with the standards in scope under the legislation, which may differ from the standards covered in the survey. Diagnostic tests and procedures assumptions: Further data could be collected to validate these assumptions, for example continuously collecting data on duplicate testing incidents during the implementation period. This may involve reviewing electronic health records, laboratory information systems, or other relevant sources to identify instances of duplicate testing. Another approach could involve modifying diagnostic test request forms to include factors such as "missing patient test results" as

117 Standards included: NHS Data Dictionary Vocabularies; OPCS-4; dm+d; ICD-10/1; SNOMED CT; and HL7 FHIR UK CORE

	/imaging tests; and the associated reduction due to interoperability benefits as outlined in Section 1.6.	reasons for requesting diagnostic tests or procedures. Furthermore, a reduction in waiting lists for diagnostic tests could serve as an indicator of decreased unnecessary or duplicate tests and an associated increase in capacity for individuals on waiting lists.
Fewer medical errors and mistakes due to incomplete information	Assumptions have been made regarding the reduction in non-transition medication errors and patient safety incidents due to interoperability benefits as outlined in Section 1.6.	Pre- and post-implementation data on total medication errors across relevant categories (transition, prescribing, administration, monitoring) and patient safety incidents could be monitored for any overall change in total errors/incidents. Additionally, it is important to attribute pre- and post-implementation errors to interoperability or information standards-related issues (e,g, a lack of patient data on allergies).This may involve monitoring error reports, conducting audits, or analysing incident reports related to medication errors and patient safety incidents. to identify any changes in the frequency or nature of medication errors/safety incidents related to interoperability issues.
Reduced time required for patient care	N/A – data currently not collected as part of IA and no assumptions made	One measure is to track the average time spent on administrative tasks versus direct patient care activities by clinical professionals. This can involve time-motion studies, electronic health record audits, and feedback from health and social care providers. Additionally, any changes in patient, waiting times, and overall efficiency of patient care time (from admission to discharge) could be monitored to evaluate how interoperability affects the allocation of time and resources towards delivering patient care.
Reduced patient anxiety	N/A – data currently not collected as part of IA and no assumptions made	Patient feedback surveys could be issued and complaints monitored, focusing on factors such as ease of access to medical records, communication between health and social care providers, and clarity of treatment plans. Additionally, there should be tracking of reductions in anxiety-inducing factors such as repeated information requests or delays in care coordination – to

		measure how interoperability-specific improvements contribute to alleviating patient anxiety. Moreover, it is important to introduce a measure that examines the degree to which patients must navigate their own care or input their information multiple times across different healthcare platforms, which can serve as an indicator of the extent to which the data standards promote user-friendliness and efficiency.
NHS staff satisfaction / empowerment	N/A – data currently not collected as part of IA and no assumptions made	To monitor NHS staff satisfaction and empowerment post-interoperability, staff surveys could be conducted to understand perceptions of efficiency improvements, access to patient information, and overall job satisfaction. Additionally,workforce data could be analysed to assess any changes in staff turnover rates or absenteeism.

288. We acknowledge that the effectiveness of this monitoring and evaluation strategy relies on surveying ICBs or employing a similar method. This approach ensures thorough evaluation, maintains analytical rigour, and preserves independence. It aims to address any evidence gaps and obtain essential information and data by leveraging existing evaluation resources for evaluation, or commission new primary research.

Appendix 1 – Cost and benefit estimates

1.1 Detailed cost and benefit estimates and annual profiles

1. This appendix provides further detail on the estimation of costs and benefits, expanding on Section 1.6. More detail on the variables, sources and rationale used to build up the costs is included in Appendix 2.

Monetised costs

a. Familiarisation costs

2. As a result of the proposed legislation, IT suppliers will incur up front familiarisation costs to read and understand the new legislation and accompanying guidance provided to support it. These costs will be incurred by IT suppliers under DUA, and are outlined in table 22.

3. Familiarisation costs have been estimated based on the number of hours required for IT suppliers to familiarise themselves with the legislation and an hourly cost rate associated with that time. To estimate the time taken for IT suppliers to familiarise with DUA, we have used secondary evidence from a Post Implementation Review for an analogous measure, the NIS regulations[118]. The objective of NIS, which supported the 2016-2021 National Cyber Security Strategy, was to establish a common level of security for network and information systems. NIS was identified as a suitable comparator to DUA in the type of regulation and requirement of private business to familiarise with it. These costs do not relate to additional costs suppliers and providers may incur considering the impact of the standards and how they will deal with it (these costs are reflected in the information standards related update costs). Familiarisation will be needed with each batch of standards released ahead of implementation, so IT suppliers can familiarise themselves with guidance. Therefore, we expect familiarisation costs will occur in year one and year five, ahead of the implementation of the core and non-core standards being released, as outlined in Paragraph 192.

4. Under DUA, it is assumed that familiarisation costs will only be incurred by IT suppliers.

5. To calculate familiarisation costs, the equation below has been used to estimate costs per organisation, on a size grouping basis:

Familiarisation Cost = *Number of Organisations per Size Group x (Hours of Familiarisation required per Size Group x Cost Rate)*

6. The following assumptions have been used to develop these cost estimates:

    - **Cost rate:** We have used an hourly cost rate of £21.56 for familiarising with the guidance. This is based on the median hourly earnings for the Information and Communication sector from the Annual Survey of Hours and Earnings (ASHE) 2023 published by the Office for National Statistics (ONS). This cost is uplifted by 22%[119] to reflect the full cost of employment by worker. This assumption is in line with guidance

118 Post-Implementation Review of the Network and Information Systems Regluations 2018 (publishing.service.gov.uk)
119 https://assets.publishing.service.gov.uk/media/5d679af2e5274a1719fdfd3d/RPC_short_guidance_note_-_Implementation_costs__August_2019.pdf

from the Regulatory Policy Committee)[120]. This sector is used as it is assumed that familiarisation will be required by staff who are familiar with the current systems, to help understand what changes are required.

- **Time taken to read guidance**: Using evidence from the NIS Post Implementation Review, an analogous measure, we have estimated for a batch of standards released and guidance issued, IT suppliers will need to spend 18 hours familiarising with both the guidance and legislation, with 9 of these hours focussed on legal support and the remaining 9 by IT staff.[121] The familiarisation costs will be incurred with each batch of standards released ahead of implementation, so IT suppliers can familiarise themselves with guidance. This will occur in year one and year five, ahead of the implementation of the core and non-core standards being released. There will be 36 hours required in total per IT supplier (18 hours per guidance released) to familiarise with the legislation. A further 10% optimism bias is also added to this cost.

7. Further detail on the variables, sources and rationale used to build up this cost are available in Appendix 2

Table 22: Familiarisation costs (current prices and undiscounted)

Organisation	Modelling size grouping	Number of organisations	Hours required	Cost rate	Total cost [122]
IT suppliers	Large	12	36	£26.30	£12,499
IT suppliers	Medium	5	36	£26.30	£5,208
IT suppliers	Small	3	36	£26.30	£3,125
IT suppliers	All	20	36	£26.30	£20,832

b. Training costs

8. There may be changes to how data needs to be processed by health providers to conform with the new mandatory standards for IT suppliers, alongside upskilling staff to use new systems or new functionalities in upgraded existing systems. This will require training. Costs outlined in table 23.

9. We have considered the inclusion of training costs that would be incurred following the implementation of the bill. To estimate these training costs, we have used published workforce data on the number of staff that will need to be trained in each stakeholder group and primary research on the training time required per individual.

10. As part of our primary research (the NHSE information standards and interoperability survey) health providers indicated that 2.2. hours of training will be required on average per individual on the mandated information standards. We expect this training time will be borne in line with the roll-out of standards under legislation, and occurring in year two, three and six – as per Paragraph 192.

---

120 https://assets.publishing.service.gov.uk/media/5d679af2e5274a1719fdfd3d/RPC_short_guidance_note_-_Implementation_costs__August_2019.pdf

121 Post-Implementation Review of the Network and Information Systems Regluations 2018 (publishing.service.gov.uk)

122 Including 10% optimism bias

11. Training costs are expected to be incurred once clinical systems are updated with the standards. Based on this, the cost attributed to each piece of legislation depends on our assumption of compliance take-up (details of compliance assumptions are included in the economic analysis section of the executive summary). As such 76% of health providers incur training costs because of DUA. The basis of this assumption is provided in Section 1.5 of the report. These assumptions are used to determine training costs.

12. To calculate training costs, the equation below has been used to estimate costs per organisation, on a size grouping basis:

Training Cost = *Cost Rate x (Number of Organisations per size group x Number of Staff per Size Group x Hours of training required per person)*

13. The following assumptions have been used to develop this cost estimate:
    - **Hours of training required:** Based on the results of the NHSE information standards and interoperability survey, it is assumed that per individual, 2.2 hours of training will be required on the mandated information standards. A further 10% optimism bias is also added to this cost.
    - **Total number of clinicians to be trained:** To identify the total number of clinicians to be trained, a summary of each provider type is provided below:
        - **Private hospitals:** Data on staff numbers has been collected from NHS workforce data[123]. It is assumed that all clinical staff will be trained on the standard. Given the relative strength of available data on NHS hospitals we have assumed private hospitals are similar in size to medium sized public hospitals, and that 3,000 employees need to be trained in each of the 172 private hospitals.
        - **NHS hospitals:** Data on staff numbers has been collected from NHS workforce data. Using this data, we have estimated the number of clinical staff that will require training on the standard. These estimates have been collated per hospital and are summarised below as the total number of people that require training per hospital size grouping. For large hospitals, this works out at about 7,000 employees needing to be trained per hospital. For hospitals categorised as medium sized, it is approximately 3,000 employees per hospital and for small hospitals it is 2,000 employees per hospital.
        - **GPs:** For GPs within each size grouping, it is assumed that on average the number of GPs requiring training per GP surgery, is 18 for large GPs, 15 for medium GPs, and 2 for small GPs.
    - **Cost rate per hour:** The cost rate per hour of training is based on average hourly salary costs in related sectors for each organisation. For each of these assumptions, they have been converted to the full cost of employment, based on the Regulatory Policy Committee guidance. A summary of each organisation type is provided below:
        - **Private and NHS hospitals:** This assumption is based on median hourly earnings for the Human Health and Social Work activities sector from the ASHE 2023 published by the ONS. This cost is £15.92 per hour, which is uplifted by 22%[124] to £19.42, to reflect the total cost of employment.
        - **GPs:** This assumption is based on average costs for salaried GPs that are published by the NHS[125].The minimum cost is £68,975 and the maximum is

123 NHS Workforce Statistics - October 2023 (Including selected provisional statistics for November 2023) - NHS England Digital
124 https://assets.publishing.service.gov.uk/media/5d679af2e5274a1719fdfd3d/RPC_short_guidance_note_-_Implementation_costs__August_2019.pdf
125 https://www.healthcareers.nhs.uk/explore-roles/doctors/pay-doctors

£104,085, therefore we have taken the midpoint of this range is taken, which is £86,530.

Further detail on the variables, sources and rationale used to build up this cost are available in Appendix 2

Table 23: Training costs (current prices and undiscounted)

Organisation	Modelling size grouping	Hours of training required	Total number of people to train	Cost rate per hour	Total cost [126], [127]
Private hospitals	Large	2.2	0	£19.42	£0
Private hospitals	Medium	2.2	516,000	£19.42	£18,432,386
Private hospitals	Small	2.2	0	£19.42	£0
Private hospitals	All	2.2	516,000	£19.42	£18,432,386
NHS hospitals	Large	2.2	395,070	£19.42	£14,112,563
NHS hospitals	Medium	2.2	354,317	£19.42	£12,656,798
NHS hospitals	Small	2.2	97,580	£19.42	£3,485,721
NHS hospitals	All	2.2	846,967	£19.42	£30,255,083
GPs	Large	2.2	9,850	£58.00	£1,050,801
GPs	Medium	2.2	22,458	£58.00	£2,395,825
GPs	Small	2.2	6,161	£58.00	£657,257
GPs	All	2.2	38,469	£58.00	£4,103,883

c. Information standards related systems update

14. We expect there to be costs directly related to ensuring clinical systems adopt the mandatory standards as set out by the Secretary of State - where the systems do not already comply. These costs are outlined in table 24.

15. We expect there will be direct reconfiguration costs for IT suppliers who seek to modify their products and services to meet the new standards to supply products and services to health and social care providers. These costs will be incurred by those suppliers that currently do not provide products or services that comply with the standards. Based on data from the NHSE information standards and interoperability survey, it is estimated these costs will be incurred by 44% of IT suppliers (details of compliance assumptions are included in the economic analysis section of the executive summary).

126 This is the portion of total cost that relates to DUA so is 76% of the total training cost
127 Including 10% optimism bias

16. We expect there will be additional costs associated with transitioning providers' existing systems and processes to make them compliant with the standards. It is assumed that transition costs will occur because of this. These costs are likely to be passed on to health and social care providers. No costs for cleansing or renormalisation of historical data are considered.

17. As the powers will require health and social care providers to procure compliant IT products and services, we anticipate that there may be administrative costs associated with revisiting existing contract arrangements and/or switching suppliers should any of their procured products or services be non-compliant. These impacts are likely to vary between provider sizes and types.

18. For GPs, as with clinical systems procurement[128], the budget for the system updates to comply with the information standards will be funded from central budgets, so these costs are reflected against NHSE. Laing and Buisson 2013/14 Healthcare Market Review identified that 6% of GPs operate entirely outside of the NHSE, therefore the systems update cost for these private GPs are not assumed to be funded from central budgets.

19. For public and private social care providers £8.2 million has been committed as part of the digitising social care fund[129] to help support providers onto digitising care plans. The costs reflected in this impact assessment are additional and are required to ensure those digitised care plans are compliant with information standards.

20. To estimate the cost of the relevant updates to systems in relation to the information standards, we obtained data from IT suppliers through the NHSE information standards and interoperability survey. The survey indicated that uplifts in cost were likely to be 15% of the existing contract value. Baseline contractual values were identified for the majority of the public health and social care providers using publicly available contract information. Where information was not available, we developed cost assumption using secondary research, interview data and accounting for the relative size of the organisation – with separate assumptions used per the size of the organisation considered. The recognition that system costs tend to correlate with an organization's size has led to the creation of distinct assumptions for each size category.

21. The cost of updating systems in relation to the updated standards, will occur because of the s95 HCA 2022 and DUA. It is assumed that 24% of systems will require updating because of the HCA 2022 measures, and 76% will be updated because of DUA. This apportionment is used to allocate costs between the HCA 2022 and DUA.

22. It is likely that there will also be costs incurred by internal IT teams of Health and Care Providers to maintain and update related internal systems in line with the standards. The costs to maintain and update for further changes in legislation post implementation would be expected to be marginal to existing work of existing IT teams. Given this is not deemed proportionate to estimate these costs below.

23. To estimate the cost of updating existing systems for mandated information standards, the equation below has been used to estimate costs per stakeholder group:

---

128 NHS England » Securing Excellence in Primary Care (GP) Digital Services: The Primary Care (GP) Digital Services Operating Model 2019-21
129 Digitising social care fund - Digitising Social Care - NHS Transformation Directorate (england.nhs.uk)

Information standards related system update costs = *Number of organisations per size group * (Average contract cost per size group * Assumed uplift in cost per size group)*

24. The following assumptions have been used to develop this cost estimate:

- **Average baseline cost:** Average baseline costs have been collected based on publicly available contract information. The approach taken for each organisation type is summarised below:
    - **IT suppliers:** For 44% of IT suppliers, it is assumed that their systems already have the capacity to adhere to updated information standards and therefore internal update costs will be minimal. For the remaining percentage, we have calculated uplift costs based on a single contract value, with £10,000,000 being used for large suppliers, £2,000,000 for medium and £500,000 for small.
    - **Private hospitals:** For private hospitals, it is assumed that contract costs are equivalent to the costs estimated for medium-sized public hospitals. The baseline costs assumption for private hospitals is £2,000,000 per annum.
    - **NHS hospitals:** Average contract costs have been derived from publicly available information. These costs have been collated based on sizes of NHS hospitals. As shown in Table 22, these sizes are large, medium, and small. Based on the sample of publicly available information, for large hospitals average baseline costs are assumed to be £10,000,000 per annum, for medium hospitals it is £2,000,000 per annum and for small hospitals it is £500,000 per annum.
    - **GPs:** Existing average contract costs have been derived by considering average contract costs available for GPs. We have identified a range of EPR contracts costs from c£140,000 to c£230,000. We have used this range as a basis for our modelled costs and have assumed that for small GPs annual contracts costs are £75,000, for medium GPs £150,000 and for large GPs £250,000.
    - **Private and public social care providers:** For social care providers (including local authorities), costs have been estimated on a provider-by-provider basis based on the number of beds the provider looks after. It is estimated contract costs are equivalent to £160 per service user. This assumption is based on indicative costs of £4,000 per provider that deals with less than 25 service users, reported by the West Midlands Care Association (WMCA).
    - **Assumed uplift in cost:** The assumed uplift in cost has been informed by survey responses. Across all organisation types in the health and social care sector, between 50% and 80% of respondents indicated that expected investments to make clinical systems information standards compliant would be less than 15% of the contract cost. As such, an assumption of a 15% uplift in baseline costs has been made. A further 10% optimism bias is also added to this cost.
- **Number of years:** It is assumed that the percentage uplift in contract costs is incurred as standards are implemented over the ten-year period. The system update costs will be incurred with the implementation of standards under legislation, and occurring in year two, three and six – as per Paragraph 192.

- Further detail on the variables, sources and rationale used to build up this cost are available in Appendix 2.

Table 24: Information standards related systems update costs (current prices and undiscounted)

Organisation	Modelling Size grouping	Number of organisations	Average baseline cost	Initial uplift in cost	Total cost [130, 131]
IT suppliers	Large	12	£10,000,000	15%	£8,712,000
IT suppliers	Medium	5	£2,000,000	15%	£726,000
IT suppliers	Small	3	£500,000	15%	£108,900
IT suppliers	All	20	-	-	£9,546,900
Private hospitals	Large	0	0	15%	0
Private hospitals	Medium	172	£2,000,000	15%	£25,163,600
Private hospitals	Small	0	0	15%	0
Private hospitals	Total	All	-	-	£25,163,600
NHS hospitals	Large	56	£10,000,000	15%	£40,964,000
NHS hospitals	Medium	107	£2,000,000	15%	£15,654,100
NHS hospitals	Small	48	£500,000	15%	£1,755,600
NHS hospitals	All	211	-	-	£58,373,700
GPs (94% funded by NHSE and 6% funded by private GPs)	Large	589	£250,000	15%	£10,771,338
GPs (94% funded by NHSE and 6% funded by private GPs)	Medium	2,942	£150,000	15%	£32,281,095
GPs (94% funded by NHSE and 6% funded by private GPs)	Small	2,713	£75,000	15%	£14,884,196
GPs (94% funded by NHSE and 6% funded by private GPs)	All	6,244	-	-	£57,936,629
Private social care providers	Large	132	Calculated by provider	15%	£1,661,570
Private social care providers	Medium	1,116	Calculated by provider	15%	£1,397,738

130 This total cost represents 60% of total IT suppliers and 52% of health and social care providers in line with current compliance and is then the portion of cost that relates to the DUA (76%)
131 Including 10% optimism bias

Private social care providers	Small	6,089	Calculated by provider	15%	£1,847,699
Private social care providers	All	13,057	-	-	£4,907,007
Public social care providers	Large	18	Calculated by provider	15%	£128,557
Public social care providers	Medium	207	Calculated by provider	15%	£260,274
Public social care providers	Small	839	Calculated by provider	15%	£321,017
Public social care providers	All	1,064	-	-	£709,848 (of which £52,893 is a direct cost to local authorities) [132]

d. Accreditation costs

25. To implement the information standards for IT systems in the health and social care sector, IT suppliers are likely to have to incur costs. These costs would likely include obtaining compliance certification from regulated Conformance Assessment Bodies (who would be regulated by the UK Accreditation Service) that certify that the software adheres to specified standards. This approach is similar to that adopted in other IT products contexts (notably ISO 27001 for information security management). NHSE would look to identify and harmonise to international standards such that certifications were similar or the same as those required in other jurisdictions to reduce costs.

26. For each IT supplier we have assumed costs associated with this accreditation and estimated total costs incurred because of the implementation of DUA legislation. These estimates are summarised in Table 25. The cost of running the accreditation service is assumed to be cost-neutral, with the accreditation fees fully recovering the cost of the accreditation body.

27. The following assumptions have been used to develop this cost estimate:

- **Cost per organisation:** We have identified similar costs of accreditation for comparable information standards, which indicate an up-front cost per organisation of £15,000 is a reasonable assumption to make. This same basis has also been used to identify annual costs, which are assumed to be £5,000 per organisation. This assumption has been developed using estimates of costs associated with an ISO 27001 certificate, which range from £6,000 to £33,000[133] based on the size and complexity of the organisation. We have assumed that cost of certification is uniform across IT suppliers. This may however disproportionately burden small and medium businesses. A further 10% optimism bias is also added to this cost.
- **Internal annual cost:** It is assumed that IT suppliers will incur internal costs annually to make sure they are complying with accreditation standards. We have assumed that two months of one employee's time a year may be required to demonstrate this compliance

132 This relates to the cost incurred by Local Authorities who are also providers of care. The remaining costs of Public Social Care Providers will also ultimately be passed onto Local Authorities.

133 Typical ISO 27001 certification costs (itgovernance.co.uk)

and have used the full cost of employment based on average wages in the information and communication sector. A further 10% optimism bias is also added to this cost.

28. Further detail on the variables, sources and rationale used to build up this cost are available in Appendix 2

Table 25: Accreditation costs (current prices and undiscounted)

Organisation	Modelling size grouping	Number of organisations	Total cost [134]
IT Suppliers	Large	12	£1,812,775
IT Suppliers	Medium	5	£755,323
IT Suppliers	Small and micro	3	£453,194
IT Suppliers	Total	20	£3,021,291

e. Compliance monitoring and enforcement costs

29. NHSE or a similar body is likely to incur costs relating to monitoring and enforcing compliance with DUA legislation in England. These costs would include the development and implementation of monitoring mechanisms, staff training on data protection laws, and the establishment of audit processes to ensure adherence to DUA regulations. The compliance monitoring body would also need to allocate resources for regular assessments and audits to evaluate IT suppliers' compliance with the legislation. Legal and regulatory experts may be required to provide guidance and oversight. This cost also includes the costs required to run the public censure process. Overall, these costs would be essential for maintaining the integrity and security of patient data, safeguarding privacy, and upholding legal compliance within the evolving landscape of digital health and social care innovation.

30. Our estimation of cost to the body of monitoring compliance, assumes that 55 FTEs will be required to implement both bills.[135] Further detail on the variables, sources and rationale used to build up this cost are available in Appendix 2. This figure has been split 5% to 95% split in the level of monitoring and compliance activity between DUA (IT Suppliers) and s95 HCA 2022 (Health and care providers). This has been reflected in the split of dedicated FTEs across both stakeholder groups within the overall monitoring and compliance function. 3 Full Time Equivalents (FTE) are therefore required to monitor compliance across IT suppliers on the government framework that supply health and care organisations. The cost of these FTE has been assumed to be the average wage for workers in the information and communication sector, which is £44,733 for 2023 according to the Annual Survey of Hours and Earnings (ASHE) 2023[136], uplifted by 22% to reflect the total cost of employment. It is

134 Including 10% optimism bias
135 This figure is based on the number of employees in the former postal services commission at the time of its closing: Postal Services Commission annual report and accounts 2011-12: (for the year ended 31 March 2012) HC 160, Session 2012-2013 (publishing.service.gov.uk). We have used this as it was the smallest sized regulator and we assume regulation will be intelligence led which will require a small team.
136 https://assets.publishing.service.gov.uk/media/5d679af2e5274a1719fdfd3d/RPC_short_guidance_note_-_Implementation_costs__August_2019.pdf

assumed that this cost is incurred annually over the ten-year period. A further 10% optimism bias is also added to this cost. Compliance monitoring and enforcement costs outlined in table 26.

Table 26: Compliance monitoring and enforcement costs (current prices and undiscounted)

Organisation	Cost Assumption	Total Cost [137]
NHSE	Cost of compliance and enforcement	£1,800,951

1.2 Modelling size groupings assumptions for organisations

31. As stated in Section 1.6, our cost estimates have been derived using specific assumptions per stakeholder group, based on modelling size groupings within that group. For each group we have identified the number of stakeholders that are either large, medium, or small and have developed stakeholder specific assumptions based on these size definitions. Outlined in the tables below are the methods used to derive these size groupings. These modelling size classifications differ to the size classifications used in the SaMBA.

IT Suppliers

32. We have used size groupings to inform assumptions of cost across IT suppliers. Across the 20 IT suppliers[138] in the sector, we have placed them into a size grouping based on reported headcount, this data has been sourced from a combination of Companies Financial Statements and information published on the Companies websites. These size groupings are based on the UK Companies Act 2006 definition of SME's[139]. Based on this, there are 12 large IT suppliers, 5 medium supplier and 3 small suppliers in this classification (table 27).

Table 27: Size assumptions used for IT Suppliers

Reported headcount for IT Supplier	Number of IT Suppliers	Modelling Size Grouping
Headcount of less than 50	3	Small
Headcount of between 50 and 250	5	Medium
Headcount of greater than 500	12	Large
Total	20	Not applicable

Hospitals

33. We have derived size groupings based on the reported adjusted costs of each foundation trust in England. As outlined in the Table 28 below, based on the adjusted cost of each hospital we have labelled them as either; small, medium, or large. There are 48 trusts

137 Including 10% optimism bias
138 NHSE provided 20 clinical IT system suppliers representing the 'preferred' IT suppliers on the Government Framework and that their Clinical Systems contacts are available on contract finder
139 Small and medium-sized enterprises action plan 2020 to 2022 (publishing.service.gov.uk)

defined as small, 107 as medium and 56 as large. For the 172 private hospitals, we have assumed that their size is equivalent to the medium size grouping.

Table 28: Size assumptions used for NHS hospitals

Foundation Trust size – by adjusted cost	Number of Trusts	Modelling size grouping
Between £0 and £99,999,999	20	Small
Between £100,000,000 and £199,999,999	28	Small
Between £200,000,000 and £299,999,999	45	Medium
Between £300,000,000 and £399,999,999	40	Medium
Between £400,000,000 and £499,999,999	22	Medium
Greater than £500,000,000	56	Large
Total	211	Not applicable

GPs

34. We have assigned size groupings for each GP, outlined in table 29, based on the reported headcount at the practice. Where headcount is less than 5, the GP is classified as being small, where it is between 6 and 14 it is medium and where it is 15 or greater it is large.

Table 29: Size assumptions used for GPs

GP size – by headcount	Number of GPs	Modelling size grouping
Less than 3	989	Small
Between 3 and 5	1,724	Small
Between 6 and 8	1,340	Medium
Between 9 and 14	1,602	Medium
Between 15 and 19	386	Large
20 or over	203	Large
Total	6,244	Not applicable

Social care providers

35. Size groupings have been made based on the number of beds per provider site, which is taken to be the equivalent of the number of service users looked after by the provider. This is outlined in table 30. Where a provider has between 1 and 19 beds it is classified as small, where it has between 20 and 49 beds it is classified as medium and greater than 50 beds is defined as large.

Table 30: Size assumptions used for social care providers

Provider size – by headcount	Number of private providers	Number of public providers	Modelling size grouping
Over 200 beds	132	18	Large
Between 40 and 200 beds	1,116	207	Medium
Between 8 and 40 beds	3,886	698	Small
Less than 8 beds	955	141	Micro
Total	6,089	1,064	Not applicable

Option 2 preferred option cost position

36. Outlined in table 31 below is the summarised cost position for the preferred option, with direct and indirect costs identified.

Table 31: Preferred Option cost estimates – these costs are estimated over a ten-year period (current prices, undiscounted)

Organisation	Cost Type	Cost amount	Direct or Indirect cost	Stakeholder type cost is incurred by
All	All	£214,272,109	Direct and Indirect	All
IT Suppliers	Familiarisation	£20,832,13	Direct	Business
IT Suppliers	Information standards system update	£9,546,900	Direct	Business
IT Suppliers	Accreditation	£3,021,291	Direct	Business
IT Suppliers	All	£12,589,023	Direct	Business
Private Hospitals	Training	£18,432,386	Direct	Business
Private Hospitals	Information standards system update	£25,163,600	Direct	Business
Private Hospitals	All	£43,595,986	Direct	Business
Public Hospitals	Training	£30,255,083	Direct	NHS
Public Hospitals	Information standards system update	£58,373,700	Direct	NHS
Public Hospitals	All	£88,628,783	Direct	NHS
GPs (private only)	Training	£4,103,883	Direct	Business
GPs (private only)	Information standards system update	£3,476,198	Direct	Business
GPs (private only)	All	£7,580,081	Direct	Business
Private Social Care Providers	Information standards system update	£4,907,007	Direct	Business
Private Social Care Providers	All	£4,907,007	Direct	Business
Public Social Care Providers	Information standards system update	£709,848	Direct	Public Sector
Public Social Care Providers	All	£709,848 (of which £52,893 is	Direct	Public Sector

		a cost to local authorities)[140]		
NHSE	Cost of compliance	£1,800,951	Direct	NHS
NHSE	Information standards system update	£54,460,431	Direct	NHS
NHSE	All	£56,261,382	Direct	NHS

Option 3 (Alternative) costs

37. The different categories of costs are set out in Table 32 for Option 3 and are classified by the stakeholder bearing the burden of the costs, this is estimated over a ten-year period. Values are presented in undiscounted terms over a ten-year period.

Table 32: Option 3 cost estimates – these costs are estimated over a ten-year period (current prices, undiscounted)

Organisation	**Cost Type**	**Cost amount**[141].	**Direct or Indirect cost**	**Stakeholder type cost is incurred by**
All	All	£58,180,519	Direct and Indirect	All
IT Suppliers	Familiarisation	£5,787	Direct	Business
IT Suppliers	Information standards system update	£2,651,917	Direct	Business
IT Suppliers	All	£2,657,703	Direct	Business
Private Hospitals	Training	£5,120,107	Direct	Business
Private Hospitals	Information standards system update	£6,989,889	Direct	Business
Private Hospitals	All	£12,109,996	Direct	Business
Public Hospitals	Training	£8,404,190	Direct	NHS
Public Hospitals	Information standards system update	£16,214,917	Direct	NHS
Public Hospitals	All	£24,619,106	Direct	NHS
GPs (private only)	Training	£1,139,968	Direct	Business
GPs (private only)	Information standards system update	£965,610	Direct	Business
GPs (private only)	All	£2,105,578	Direct	Business

140 This relates to the cost incurred by Local Authorities who are also providers of care. The remaining costs of Public Social Care Providers will also ultimately be passed onto Local Authorities

141 Including 10% optimism bias

Private Social Care Providers	Information standards system update	£1,363,058	Direct	Business
Private Social Care Providers	All	£1,363,058	Direct	Business
Public Social Care Providers	Information standards system update	£197,180	Direct	Public Sector
Public Social Care Providers	All	£197,180 (of which £14,692 is a cost to local authorities)[142]	Direct	Public Sector
NHSE	Information standards system update	£15,127,898	Direct	NHS
NHSE	All	£15,127,898	Direct	NHS

1.3 Annual cost and benefit profiles

38. The annual benefits and costs for Option 2 and 3 are outlined in tables 33 to table 36 below across a 10-year period, this has been discounted into present value terms.

Table 33: Annual costs of Option 2 – preferred option (£m, present value terms)

Cost Type	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Cost over 10 years
All cost types	0.7	121.9	68.9	0.4	0.4	9.2	0.4	0.4	0.3	0.3	202.9
Familiarisation cost	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Training cost	0.0	30.6	17.2	0.0	0.0	2.2	0.0	0.0	0.0	0.0	50.1
Information standards system update cost	0.0	90.8	51.2	0.0	0.0	6.6	0.0	0.0	0.0	0.0	148.6
Compliance monitoring and enforcement cost	0.18	0.17	0.17	0.16	0.16	0.15	0.15	0.14	0.14	0.1	1.6
Accreditation cost	0.5	0.3	0.3	0.3	0.2	0.2	0.2	0.2	0.2	0.2	2.6

Table 34: Annual benefits of Option 2 – preferred option (£m, present value terms)

142 This relates to the cost incurred by Local Authorities who are also providers of care. The remaining costs of Public Social Care Providers will also ultimately be passed onto Local Authorities

Benefit Type	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Benefit over 10 years
All benefit types	0.0	19.5	44.4	45.5	40.6	40.0	39.0	38.1	37.2	36.3	340.5
Mapping and standardisation cost reduction	0.0	6.7	10.8	4.2	0.0	0.0	0.0	0.0	0.0	0.0	21.6
Reduced duplicate tests / procedures	0.0	2.8	7.2	8.7	8.5	8.2	7.9	7.6	7.4	7.1	65.4
Time saved accessing information	0.0	1.4	3.5	4.3	4.1	4.0	3.8	3.7	3.6	3.5	31.8
Reduction in cost of excess bed days (transition medication error reduction)	0.0	0.7	1.8	2.2	2.1	2.0	1.9	1.9	1.8	1.8	16.1
QALY gained (transition medication error)	0.0	0.1	0.6	1.0	1.2	1.4	1.5	1.6	1.7	1.7	10.7
Reduction in cost of excess bed days (non-transition medication error)	0.0	0.2	0.6	0.8	0.7	0.7	0.7	0.7	0.6	0.6	5.8
QALY gained (non-transition medication error)	0.0	0.3	1.1	1.8	2.2	2.6	2.7	2.9	3.0	3.2	19.6
Value of time saved reporting medication errors	0.0	0.5	1.3	1.5	1.5	1.4	1.4	1.3	1.3	1.2	11.4
Reduction in reporting costs for PSIs	0.0	6.8	17.5	21.1	20.4	19.7	19.1	18.4	17.8	17.2	158.0

Table 35: Annual costs of Option 3 – alternative option (£m, present value terms)

Cost Type	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Cost over 10 years
All cost types	0.0	16.9	16.3	10.5	7.6	2.4	0.0	0.0	0.0	0.0	53.7
Familiarisation cost	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Training cost	0.0	4.3	4.1	2.6	1.9	0.6	0.0	0.0	0.0	0.0	13.5
Information standards system update cost	0.0	12.6	12.2	7.8	5.7	1.8	0.0	0.0	0.0	0.0	40.2

Table 36: Annual benefits of Option 3 – alternative option (£m, present value terms)

Benefit Type	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Benefit over 10 years
All benefit types	0.0	0.0	0.0	0.0	4.6	4.4	4.3	4.1	4.0	3.9	25.2
Mapping and standardisation cost reduction	0.0	0.0	0.0	0.0	0.9	0.9	0.9	0.8	0.8	0.8	5.1
Reduced duplicate tests / procedures	0.0	0.0	0.0	0.0	0.7	0.7	0.7	0.7	0.6	0.6	4.1
Time saved accessing information	0.0	0.0	0.0	0.0	0.4	0.4	0.3	0.3	0.3	0.3	2.0
Reduction in cost of excess bed days (transition medication error reduction)	0.0	0.0	0.0	0.0	0.2	0.2	0.2	0.2	0.2	0.2	1.0
QALY gained (transition medication error)	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.7
Reduction in cost of excess bed	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.4

days (non-transition medication error)											
QALY gained (non-transition medication error)	0.0	0.0	0.0	0.0	0.2	0.2	0.2	0.2	0.2	0.2	1.3
Value of time saved reporting medication errors	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.7
Reduction in reporting costs for PSIs	0.0	0.0	0.0	0.0	1.8	1.7	1.7	1.6	1.6	1.5	9.9

Appendix 2 – cost type assumption

1.1 Cost type assumption

This appendix provides further detail on costing approach, expanding on Section 1.6.

Cost Type – Familiarisation Cost

IT suppliers will incur up front familiarisation costs to understand the new legislation, any supporting guidance, and its implications.

Familiarisation with new legislation by IT suppliers affects the cost of business activity and falls on those businesses subject to the regulation. It is therefore considered a direct cost.

Method of calculating

The product of:

- Time taken to read guidance per IT supplier
- Average hourly wage rate of employees expected to read the guidance
- Non-wage uplift
- DUA cost apportionment
- Number of IT suppliers required to familiarise with legislation

Rationale for method:

- In the absence of established benchmarks to guide the anticipated costs of familiarisation, our approach to estimating these costs has concentrated on assessing the probable time needed to become acquainted with the standards. From this, we have derived an estimated cost for each IT supplier.
- The purpose of this estimate is to give an indication of the possible magnitude of these costs, based on reasonable assumptions.
- The assumptions used are based on the best available information at this time and may be subject to revision and more detailed design as implementation is undertaken.

Table of variables for calculating familiarisation cost

Variable	Value	Source	Rationale
Number of IT suppliers required to familiarise with legislation	20	NHSE provided 20 clinical IT system suppliers representing the 'preferred' IT suppliers on the Government Framework and that their Clinical Systems contracts are available on contract finder.	Only IT suppliers will need to familiarise with this legislation because Health and Care Providers will have familiarised themselves with the standards under the s95 HCA 2022 measures, so it is not assumed that further costs will be incurred by them.
Time taken to read guidance per IT supplier	36 hours (18 hours for each batch of standards comprising of 9 hours of legal support and 9 hours of IT support)	Post-implementation review of the Network and Information Systems Regulations 2018 (May 2020)	In the absence of precise estimates of reading time associated with the standards, this source was used as an estimate of the time required to read the legislation. This source was used as it represents a published benchmark on the time taken to familiarise with a complex piece of legislation, that has been validated post implementation. It is noted that the implementation review cited this as a conservative estimate and that costs may vary across organisations.
Hourly wage rate of employees expected to read the guidance	£21.56	ASHE median hourly earnings for Information and Communication sector	Estimate of cost per hour of reading the document is based upon the median hourly earnings for the Information and Communication sector. This is intended to reflect the average salary of employees working the IT sector.
Non-wage uplift	22%	RPC implementation cost guidance	We have uplifted the hourly wage to account for the full cost of employment (e.g. National Insurance contributions)
DUA cost apportionment	100%	% of additional compliance assumed to be as a result of DUA	We expect familiarisation costs will be incurred by all IT suppliers, as even those with systems already in place will need to familiarise with the standards to ensure they are compliant.
Total cost to IT suppliers	£19,493		10-year total cost in discounted prices

Cost Type – Training Cost

To conform with new mandatory information standards, there will be changes to how data is processed by health providers. Staff processing and using this data will therefore require upskilling to use the new systems or new functionalities in upgraded systems. There is therefore a cost associated with training staff.

To ensure compliance with the standards, health provider clinical staff will require training on the new systems and new standards and so training costs are deemed as a generally immediate and unavoidable cost to ensure compliance. It is therefore considered a direct cost.

Method of calculating

The product of:

- Hours of training required per individual
- Number of individuals requiring training per organisation type
- Average hourly wage of individual being trained
- Non-wage uplift
- DUA cost apportionment

Rationale for method:

- In the absence of detailed design principles outlining what standards will be covered, this estimate has been based on engagement with providers through the information standards and interoperability survey.
- Based on information from the NHSE information standards and interoperability survey, we have an estimate of the number of hours of training required on average per individual on the mandated information standards.
- To calculate the total time required for training, we have made assumptions on the number of employees requiring training per organisation.
- Individual average wage costs have been used to help value the training time required. It is acknowledged that training time may be repurposed from existing earmarked time; however, it is prudent to reflect the value of that time in this assessment.
- A small number of care workers may require training for public and private social care providers, particularly those involved in developing service user care plans, alongside healthcare providers and social workers. However, the number of care workers needing training is expected to be negligible because most carers are focused on delivering pre-defined tasks assigned in service users' care plans. As a result, we have not monetised these costs as it was deemed disproportionate to do so.
- It is recognised that training will occur both as a result of HCA 2022 and DUA measures, with some organisations undertaking training following HCA 2022. Assumptions around compliance have therefore been used to apportion these costs between the HCA 2022 and DUA measures.

Table of variables for calculating training cost

Variable	Value	Source	Rationale
Hours of training required per individual	2.2 hours	NHSE information standards and interoperability survey	As part of our primary research (the NHSE information standards and interoperability survey) health providers indicated that 2.2. hours of training will be required on average per individual on the mandated information standards. In the absence of further information on the roll-out of the standards, this is the best estimate of training time required.
Number of individuals requiring training per organisation type	Public Hospitals – 846,967 individuals	For hospitals, data on staff numbers has been based on published NHSE	For public hospitals, we have extracted the number of clinical staff per hospital from NHS workforce data. This data is used to develop an assumption of the number of

	Private Hospitals – 516,000 individuals GPs – 38,469 individuals	workforce data (CQC The state of health care and adult social care in England 2022/23)	employees requiring training. For Private Hospitals, this figure has been estimated, assuming that private hospitals employ a similar number of employees to medium public hospitals. This was based on the assumption that even the largest private hospitals (Cleveland Clinic is the second largest with 184 beds) are broadly comparable with average bed numbers in the England – 185 beds per hospital. In the absence of detailed data, this represented a reasonable assumption. For GPs, an estimate of the number of GPs per size grouping has been used. This estimate was used in the absence of detailed data listing headcount per GP site. This approach incorporated regional data on the number of practices falling into specific size categories: fewer than 3 GPs, 3 to 6 GPs, 6 to 9 GPs, 9 to 15 GPs, 15 to 20 GPs, and more than 20 GPs. For the purpose of creating a conservative headcount assumption, we selected the lower end of the range for each category. This method has been used to help develop an assumption of the number of individuals requiring training across different size groupings to inform insight on the impact across small and medium businesses.
Average hourly wage rate of individual being trained	Public Hospitals - £15.92 Private Hospitals - £15.92 GPs - £47.54	Public and Private Hospitals - ASHE median hourly earnings for Human Health and Social Work activities Based on average salary for General Practitioners for 2023 published by the NHSE	The estimate of the cost per hour of training has been developed based on the average earnings in the sector for Human Health and Social Work activities for employees in Hospitals. It is noted that there is likely to be variance in the cost per employee, but this measure is intended to capture the average cost. For GPs, data on the average salaries for GPs has been obtained to help determine the hourly cost of training. This figure has been used to determine the hourly cost based upon a 52-week year and 35 hour working week.

Non-wage uplift	22%	RPC implementation cost guidance	We have uplifted the hourly wage to account for the full cost of employment (e.g. National Insurance contributions)
DUA cost apportionment	76%	% of additional compliance assumed to be as a result of DUA	Currently 42% of health and social care providers comply with standards. It is assumed that HCA measures will enable 14% of providers to comply (24% of non-compliant providers), whereas DUA will facilitate compliance of the remaining 44% of providers (76% of non-compliant providers).
Total cost	£50,074,579		10-year total cost in discounted prices

Cost Type – Conformance testing and accreditation costs

IT suppliers' products will need to be assessed to prove their conformance with required information standards. A regime will therefore be required to provide assurance that IT suppliers are conforming with the standards. Establishing an accreditation scheme requires additional regulations, and the full details are not fully developed at this stage. For this RIA, we have costed a scenario where a certification scheme is used and based this on benchmarks for other national standards.

This regime is likely to occur directly to those businesses subject to the regulation to ensure compliance and is therefore considered a direct cost.

Method of calculating

The product of:

- Upfront and annual certification cost per organisation
- Number of IT suppliers

Plus, the product of:

- Internal time spent
- Average hourly wage of Data Protection Officer
- Non-wage uplift
- Number of IT suppliers

Rationale for method:

- As the regime for ensuring conformance is yet to be determined, this IA has estimated expected costs to IT suppliers should the regime require obtaining compliance certification from regulated Conformance Assessment Bodies (who would be regulated by the UK Accreditation Service) that certify that the software adheres to specified standards.
- We will assess potential burden and/or impact on both the accreditation body, providers and suppliers, and how we can mitigate this, as part of development of the regulations.
- This approach is similar to that adopted in other IT products contexts (notably ISO 27001 for information security management). NHSE would look to identify and harmonise to international standards such that certifications were similar or the same as those required in other jurisdictions to reduce costs.
- To calculate potential costs, we have therefore examined publicly available benchmarks for the ISO 27001 certificate. This certificate relates to an international standard to manage information security, while this is not a perfect comparison to proposals under DUA, it provides us with an available benchmark to consider costs with.

Table of variables for calculating conformance testing and accreditation cost

Variable	Value	Source	Rationale
Up-front certification cost per organisation	£15,000	Typical ISO 27001 Certification Costs	The ambition of the accreditation scheme is to rely on automated testing (i.e. provision of test harnesses and stub APIs centrally, or test packs) that suppliers can connect to or deploy themselves rather than in depth witness testing methods and instead focus on setting process standards for suppliers around testing and release as a way to assure they are meeting technical standards around product features. ISO 27001 is a similar such process standard designed to ensure robust risk/quality management that is used widely and so used as a model for these process assessments. It has therefore been used as a benchmark to consider typical certification costs. These are reported as being between £6,000 and £33,000 per annum. An assumption has been made that initial start-up costs may be £15,000 per organisation to obtain the certification, with an annual fee thereafter of £5,000. These figures were initially based on the range provided for ISO 27001 certification costs and then developed and validated by DHSC, EY and NHSE to provide an agreed assumption.
Annual certification cost per organisation	£5000	Typical ISO 27001 Certification Costs	ISO 27001 is a similar such process standard designed to ensure robust risk/quality management that is used widely and so used as a model for these process assessments. It has therefore been used as a benchmark to consider typical certification costs.
Number of IT Suppliers	20 IT suppliers	NHSE provided 20 clinical IT system suppliers representing the 'preferred' IT suppliers on the Government Framework and that their Clinical Systems contracts are available on contract finder.	Under DUA, only IT Suppliers will require accreditation or certification to demonstrate conformance with the standard.

Amount of internal time spent	2 Months of 1 Data Protection Officer FTE	Assumption developed by EY, NHSE and DHSC	It is assumed that meeting accreditation requirements each year will not require a full-time role to be established in each IT Supplier. Instead, it is assumed that a portion of an existing role will be utilised. In the absence of detail around what standards will be adopted and what accreditation is required, a conservative estimate of 2 months of an FTE time has been used to calculate the amount of internal time required.
Average hourly wage of Data Protection Officer	£21.56	ASHE median hourly earnings for Information and Communication sector	It is assumed that time will be required from a role similar to a Data Protection Officer to ensure conformance. The average salary for this has been taken from average hourly cost for in the information and communication sector, as a relevant proxy for a Data Protection Officer salary.
Non-wage uplift	22%	RPC	Account for full cost of employment as per RPC guidance.
DUA cost apportionment	100%	% of additional compliance assumed to be as a result of DUA	We expect accreditation or certification costs will be incurred by all IT suppliers to demonstrate conformance with the standard.
Total cost	£2,631,263		10-year total cost in discounted prices

Cost Type – Compliance monitoring and enforcement costs

The potential costs that NHSE or an equivalent organisation may face in relation to overseeing and enforcing compliance with DUA legislation in England extend beyond the initial accreditation process. The accreditation process is typically a point-in-time evaluation, which ensures that IT suppliers meet the required standards at the time of assessment. However, continuous monitoring is necessary to ensure that these suppliers and health and care providers maintain compliance with standards across both HCA and DUA legislation.

As a consequence, this IA considers the costs to NHSE or a similar body is likely to incur relating to monitoring and enforcing compliance with DUA legislation in England. These costs would include the development and implementation of monitoring mechanisms, staff training on data protection laws, and the establishment of audit processes to ensure adherence to DUA regulations. The compliance monitoring body would also need to allocate resources for regular assessments and audits to evaluate IT suppliers' compliance with the legislation

To regulate compliance with the legislation, a compliance monitoring body will need to be established. This is a direct impact of the legislation and the market it is regulating.

Method of calculating

The product of:

- Number of FTE for compliance body
- Average hourly wage of compliance body FTE

- Non-wage uplift
- DUA apportionment (for resource focussed on enforcing DUA)

Rationale for method:

- The method for calculating compliance monitoring and enforcement costs is based on a pragmatic approach to estimating the potential size and expenses of a compliance body within this sector. It involves three key components:
    - Estimating the size of the compliance body: We use the number of Full-Time Equivalents (FTE) from the smallest-sized regulator as a proxy, under the assumption that an intelligence-led regulatory approach would require a similarly small, efficient team.
    - Calculating average salary costs: We determine the average salary per FTE using the median hourly earnings from the ASHE for the Information and Communication sector, which is relevant due to the similar skill set needed for monitoring IT suppliers' compliance.
    - Assessing the focus on DUA enforcement: We assume a proportion of the compliance body's resources that will be dedicated to enforcing DUA legislation, taking into account the relative size of IT suppliers within the broader landscape of Health and Care Providers and the anticipated complexity of the DUA requirements.

Table of variables for calculating compliance monitoring and enforcement cost

Variable	Value	Source	Rationale
Number of FTE for compliance body	55 FTE for both HCA and DUA (3 FTE for DUA only following 5% apportionment)	This figure is based on the number of employees in the former postal services commission at its time of closing.	For the purposes of this RIA, it is assumed that the establishment of a small-sized regulatory body will be sufficient to ensure compliance with DUA regulations. This supposition is grounded in the expectation that an intelligence-led strategy for monitoring adherence will require only a streamlined and effective team. To approximate the potential full-time equivalent (FTE) staffing needed for this team, we have referenced the FTE composition of another small regulatory body, the Postal Service Commission, as a benchmark for potential team size. This particular body was chosen because it offers the most current data on the FTE makeup of a small regulatory body. While acknowledging that there may be variations in the size of this regulatory team, it is important to note that even significant increases in FTE count would have a marginal effect on the overall NPV given that compliance costs constitute less than 1% of the total costs.
Average hourly wage of compliance body FTE	£44,733	ASHE median hourly earnings for Information and	The cost per employee has been assumed to be the average salary for those in the information and communication sector as it is assumed

		Communication sector	that a similar skillset will be required to monitor compliance across IT suppliers.
Non-wage uplift	22%	RPC	Account for full cost of employment as per RPC guidance.
DUA cost apportionment	5% to DUA	% of total resource assumed to be needed for DUA	This assumption has been based on the split of organisations across IT Suppliers and Health and Care Providers. Despite IT suppliers constituting a small fraction of the total, a 5% resource allocation to the DUA bill is presumed, considering the potential complexity of the requirements.
Total cost	£1,550,202		10-year total cost in discounted prices

Cost Type – Information standards related systems update

We expect there to be reconfiguration costs for IT suppliers who seek to modify their products and services to meet the required standards to supply products and services to health and social care providers. These costs will be incurred for those suppliers that currently do not provide products or services that comply with the standards.

We also expect there will be additional costs associated with transitioning providers existing systems and processes to make them compliant with the standards. It is assumed that transition costs will occur because of this. These costs are likely to be passed on to health and social care providers.

Reconfiguration costs occur directly to IT suppliers subject to the regulation to ensure compliance and is therefore considered a direct cost.

The passing of transition costs by IT suppliers to health and social care providers is considered a direct cost to health and social care providers. The impact on health and care providers is necessary for the IT supplier market being regulated to be compliant (a ‘partial equilibrium effect’).

Method of calculating

The product of:

- Assumed uplift in cost of existing contracts based on NHSE information standards and interoperability survey
- Assumption on baseline contract value across providers/suppliers based on size group
- Number of organisations per size grouping
- Assumption on uptake in compliance resulting from DUA
- Portion of IT Suppliers that will need to update systems.

Rationale for method:

- To estimate the costs associated with system updates, we based our calculations on survey responses regarding expected uplift costs. Since a significant number of respondents anticipated that these costs would not exceed 15%, we have adopted this figure as an estimate for the cost increase.
- We then derived average baseline contract costs from a limited sample of known contract values. Although there may be variations in actual costs, this data provides the most reliable indication of typical contract values. Due to the absence of centralised cost data for EPR

providers, as confirmed by discussions with NHSE, our figures represent the best information currently accessible.

- Regarding IT suppliers, we expect there to be some reconfiguration costs. We applied the 15% uplift to the average contract values to estimate the potential internal costs that IT suppliers might bear.

Table of variables for calculating information standards related systems update cost

Variable	Value	Source	Rationale
NHS Hospitals – Average Baseline Cost	Large: £10,000,000 per annum Medium: £2,000,0000 Small: £500,000 per annum	Average contract costs have been estimated based on publicly available contract values.	Based on the sample of contract costs across NHS Hospitals, we have assumed average contract costs for large, medium and small hospitals based on the information available to us.
Private Hospitals – Average Baseline Cost	£2,000,000 per annum	Average contract costs have been estimated based on publicly available contract values.	For private hospitals, it is assumed that contract costs are equivalent to the costs estimated for medium-sized public hospitals. This was based on the assumption that even the largest private hospitals (Cleveland Clinic is the second largest with 184 beds) are broadly comparable with average bed numbers in the England – 185 beds per hospital. In the absence of detailed data, this represented a prudent assumption.
GPs - Average Baseline Cost	Large: £250,000 Medium: £150,000 Small: £75,000	Average contract costs have been estimated based on publicly available contract values.	Existing average contract costs have been derived by considering average contract costs available for GPs. We have identified a range of EPR contracts costs from c£140,000 to c£230,000. We have used this range as a basis for our modelled costs and have assumed costs per size grouping based on this sample.
Social Care Providers - Average Baseline Cost	Contract costs based on £160 per service user and determined by average number of service users per provider.	West Midlands Care Association	For social care providers (including local authorities), costs have been estimated on a provider-by-provider basis based on the number of beds the provider looks after. It is estimated contract costs are equivalent to £160 per service user. This assumption is based on indicative costs of £4,000 per provider that deals with less than 25 service users, reported by the West Midlands Care Association (WMCA).

Assumed uplift on cost	15% of the contract cost	NHSE information standards and interoperability survey	The assumed uplift in cost has been informed by survey responses. Across all organisation types in the health and social care sector, between 50% and 80% of respondents indicated that expected investments to make clinical systems information standards compliant would be less than 15% of the contract cost. As such, an assumption of a 15% uplift in baseline costs has been made.
Portion of IT Suppliers incurring cost	56% of IT Suppliers	NHSE information standards and interoperability survey	Based on the results of the NHSE information standards and interoperability survey, 44% of IT suppliers, already have the capacity to adhere to updated information standards and therefore internal update costs will be minimal.
DUA apportionment	76%	% of additional compliance assumed to be as a result of DUA	42% of health and social care providers comply with standards. It is assumed that HCA measures will enable 14% of providers to comply (24% of non-compliant providers). DUA will facilitate compliance of the remaining 44% of providers (76% of non-compliant providers).
Total cost	£148,576,724 for IT Suppliers and Health and Care Providers		10-year total cost in discounted prices

Appendix 3 – Landscape, survey and questionnaire

This appendix outlines details of the consultation undertaken, and survey questions asked, that informed to this IA.

1.1 Public consultation – Information Standards for Health and Adult Social Care in England

This consultation sought views and provided opportunity for stakeholders to feedback on proposals for the procedure to be set out in regulations in connection with preparing and publishing information standards for health and adult social care in England.

This included proposals for who should be involved in the process going forward, how that should take place, and what would be important considerations when developing information standards.

The responses were used to inform process design, to ensure it is reasonable and appropriately considers possible impacts on stakeholders in the system.

Summary of responses

The consultation was launched on 15 February 2024 and ran for 6 weeks, until 28 March 2024. It was shared widely with stakeholders – including public and private health and care providers, IT suppliers, industry bodies, and subject experts.

There were 132 responses to the consultation. Of these, 56 (42.4%) responded on behalf of an organisation, 55 (41.7%) as an individual sharing their professional views, and 21 (15.9%) as an individual sharing their personal views.

The majority of respondents were satisfied with the consultation process (75%).

Key takeaways included:

- There was strong support for consideration of impact on provision of services (87.9%) and capacity of the health and adult care system to implement a new standard (86.4%), but respondents were least supportive of consideration of impact on existing contracts (71.2%).
- There was high level agreement for requirement to review information standards at a specified minimum interval (77.3%).
- Generally, respondents highlighted the importance of implementation allowing sufficient notice for providers and supplier to prepare for changes.
- Respondents also emphasised the importance of continued engagement when developing standards – particular mention was given to IT suppliers, health and care providers, local authorities, and the public who use health and care services.

Consultation questions

Preparing and publishing mandatory information standards

1) Do you think that, before preparing an information standard, the Secretary of State or NHS England should be required to obtain advice? (For example, from an advisory board or other persons)

2) Which of the following areas should be represented on such a board or included as other persons from whom advice is sought? (Select all that apply)
    - Publicly funded health and care providers
    - Privately funded health and care providers
    - Health and care providers that are funded in part publicly and in part privately
    - IT suppliers
    - Patient and public representatives
    - Representatives of NHS England
    - Other (please specify)

3) In addition to seeking advice, which of the following do you think the Secretary of State or NHS England should consider before preparing an information standard? (Select all that apply)
    - Capacity of the health or adult social care system to implement a new standard
    - The need for alignment with open or international standards
    - Impact on the provision of health or adult social care services
    - Cost of implementation
    - Impact on existing contracts

- Other (please specify)

4) In your opinion, which of the following should be included in an information standard when published? (Select all that apply)
    - Name of the information standard
    - Date on which it was published
    - The fact that it must be complied with
    - The consequences of failure to comply
    - The fact that the Secretary of State may require a person to provide the Secretary of State with documents, records or other information for the purposes of monitoring the person's compliance with information standards
    - Information on any guidance about implementation of the standard
    - A list of changes to the information standard - for example, revisions over time
    - The person who prepared the information standard and their contact details
    - Any related information standards
    - Information on the interval at which the information standard is to be reviewed
    - Such other information as the decision maker considers appropriate
    - Other (please specify)

The regulations may require an information standard to be reviewed periodically. It is proposed that there could be a requirement for information standards to be reviewed at such intervals as the Secretary of State considers appropriate.

5) What do you think would be an appropriate minimum interval for reviewing an information standard?
    - No fixed interval - case by case decision
    - Reviewed every 18 months
    - Reviewed every 3 years
    - Reviewed every 5 years
    - Other (please specify)

6) Should the regulations specify that minimum interval?

7) If you think that any other procedures should be followed in connection with the preparation and publication of information standards, please list them.

Revising information standards

Once issued, it may be necessary to revise an information standard.

Revisions could follow the same procedures as for preparing and publishing a new standard, a 'light touch' version of that procedure or different procedures. Alternatively, no procedure could be required.

8) In your opinion, which procedure should revisions to an information standard follow?
    - Revisions should go through the full procedure
    - Revisions should go through a 'light touch' procedure
    - Only some revisions should go through the full procedure - for example, those that the decision maker considers significant and that are not made in discharge of a legal obligation
    - Only some revisions should go through a 'light touch' procedure - for example, those that the decision maker considers significant and that are not made in discharge of a legal obligation

- Revisions should not go through any procedure
- Revisions should go through other procedures (please specify)

9) In your opinion, which steps should a ‘light touch’ procedure for revisions to an information standard include? (Select all that apply)
    - Obtain advice, such as from an advisory board or other persons
    - Consider capacity of the health or adult social care system to implement changes
    - Consider alignment with open or international standards
    - Consider impact on the provision of health or adult social care services
    - Consider cost of implementation
    - Consider impact on existing contracts
    - Don’t know
    - Other (please specify)

Revoking information standards

Once issued, it may be necessary to revoke (withdraw) an information standard.
Revoking (withdrawing) could follow the same procedure for preparing and publishing a new information standard, a ‘light touch’ version of that procedure or different procedures. Alternatively, no procedure could be required.

10) In your opinion, which procedure should revoking (withdrawing) an information standard follow?
    - Revocations should go through the full procedure, except those made in discharge of a legal obligation
    - Revocations should go through a ‘light touch’ procedure, except those made in discharge of a legal obligation
    - There is no need for revocations of information standards to go through any procedure
    - Revocations, except those made in discharge of a legal obligation, should go through other procedures (please specify)

11) In your opinion, which steps should a ‘light touch’ procedure for revocations of an information standard include? (Select all that apply)
    - Obtain advice, from an advisory board or other persons
    - Consider capacity of the health or adult social care system to implement changes
    - Consider alignment with open or international standards
    - Consider impact on the provision of health or adult social care services
    - Consider cost of implementation
    - Consider impact on existing contracts
    - Don’t know
    - Other (please specify)

Adopting information standards

It may be necessary to adopt an information standard prepared or published by another person.
Adopted information standards could follow the same procedure for preparing and publishing a new information standard, a ‘light touch’ version of that procedure, or different procedures. Alternatively, no procedure could be required.

12) In your opinion, what procedure should adopting information standards follow?
    - Adopted information standards should go through the full procedure
    - Adopted information standards should go through a ‘light touch’ procedure

- There is no need for adopted information standards to go through any procedure
- Adopted information standards should go through other procedures (please specify)

13) In your opinion, which steps should a 'light touch' procedure for adopted information standards include? (Select all that apply)
    - Obtain advice from an advisory board or other persons
    - Consider capacity of the health or adult social care system to implement changes
    - Consider alignment with open or international standards
    - Consider impact on the provision of health or adult social care services
    - Consider cost of implementation
    - Consider impact on existing contracts
    - Don't know
    - Other (please specify)

General

14) Do you have any other feedback you'd like to share? (Maximum 150 words)

1.2 Information Standards and Interoperability Survey, NHS, Feb 2024

* this survey was conducted under the previous government and, as such, refers to previous governments legislation.

Survey respondents: IT suppliers, Health and Social Care providers

Description: Currently health and social care service users and their care teams cannot easily access or share, in real time, all the health and/or social care information that is relevant to their care. One of the causes of this challenge is the lack of adoption of common standards in IT systems which creates complexity and effort when organisations want to integrate or share data across systems.

The Health and Social Care Act (HCA) 2022 (section 95) allows for the publication of mandatory information standards relating to the processing of information and extends the provisions to private providers of health and adult social care. It requires organisations to 'comply' with standards, rather than, as previously, simply to have regard to them. This is to help ensure that information flows through the system in a standardised way so that it is easily accessible, in a meaningful format, to recipients and users, as well as helping to ensure the security of that information when processed.

The NHS Transformation Directorate has also introduced changes to Information Standards within Data Protection and Digital Information (DPDI) Bill (Part 4 of the Bill). These proposed changes will extend the provisions and enforcement to include providers of IT products and services to the health and adult social care sector in England. This measure will extend the obligations that currently sit with public and private Care providers under Health and Social Care Act 2022 to also include IT Providers.

The overarching policy objective as proposed in the HCA 2022 and DPDI Bill is to ensure health and care systems are interoperable, to facilitate the appropriate access to information needed by health and care staff, thus aiding their ability to improve the quality of care they provide and improve outcomes for people accessing the health and care system. The secondary objectives are to facilitate population wide research and analysis, operational planning and promote innovation within the health and care IT supplier market. The intended effects are improved clinical outcomes for patients, improved clinical/care decision making enabled by access to accurate and complete information, better procurement and commissioning by health and care providers, and a more

dynamic and responsive health and care IT market.

Survey Questions

Background Questions

Q1. Are you a:

a. Healthcare provider
b. Social care provider
c. IT supplier providing clinical services

Questions for IT suppliers

Q1. Which of the following options do you believe is most likely to achieve adherence to Government published common information standards? [can we rank the answers?]

a. Primary legislation to mandate IT Suppliers to comply with the standards
b. Health and Care providers only being able to sign new contracts that comply with the standards
c. A self-regulatory enforceable industry-led scheme
d. Self-certification by suppliers
e. Centrally procured single IT systems across health and care providers
f. NHSE-led in-house single-IT system across health and care providers

Q2. What clinical services do you supply to NHS providers? Please tick the clinical services you provide

a. Electronic medical record (EMR)
b. Electronic patient record (EPR)
c. Laboratory information management system (LIMS)
d. Radiology information management system (RIS)
e. Other

Q3. Which health and care sectors do you provide clinical services to? Do you supply to NHS providers? Please tick the health and care sectors to whom you provide clinical services:

a. GP Surgeries
b. Acute trusts
c. Mental health trusts
d. Ambulance services
e. Community health trusts
f. Care providers
g. Private providers
h. Dental services and Optometry
i. Other

Q4. Are the clinical systems you provide ‘Software as a Service’?

a. Yes
b. No

Q5. When you provide clinical systems to the NHS care providers, how much customisation is required?

a. None

b. Modest
c. Significant

Q6. Do you provide NHS customers with regular software releases?

a. Yes
b. No

Q7. Do your NHS customers have options not to accept/implement a release?

a. Yes
b. No

Q8. Do your NHS customers have to pay for each release?

a. Yes
b. No

Q9. When providing clinical systems to an NHS provider at what level are you delivering the systems?

a. Individual hospital or GP practice
b. Clusters of hospital e.g., Foundation Trusts or GP practices
c. ICBs or PCNs
d. Clusters of ICBs

Q9.1 If b, c, or d then are your requested to provide fully interoperable systems that comply with current UK information standards? Yes/No

Q10. What do you see as the barriers to NHS providers implement full interoperable EPR or clinical systems? Please rank

a. Focus on implementing EPR or clinical systems
b. Cost or budget
c. Interoperability is not a priority

Q11. Which of the following interoperability and information standards does your UK implemented EPR/clinical system comply with? Tick all that are applicable

a. HL7 FHIR UK CORE
b. SNOMED CT
c. ICD-10/11
d. dm+d
e. OPCS-4
f. NHS Data Dictionary Vocabularies
g. NHS Number

Q12. How much investment would you need to develop additional product capabilities to comply with the new information standard legislation? (Note information standard legislation would include HL7 FHIR UK CORE, SNOMED CT, ICD-10/11, dm+d, OPCS-4, NHS Data Dictionary Vocabularies, and NHS Number)

a. None
b. Less than 5% of contract cost
c. Between 5-15% of contract cost
d. Between 15-25% of contract cost

e. Between 25-50% of contract cost
f. Greater than 50% of contract cost

Q13. How much user training would you need to provide to health and care providers on the use of the updated clinical systems (per system user)?

a. None
b. Less than 1 hours
c. Between 1-2 hours
d. Between 2-4 hours
e. Greater than 4 hours

Q14.To the extent you incur investment costs, what impact do you expect on the contract cost with your NHS provider customers?

a. None
b. Less than 5% of contract cost
c. Between 5-15% of contract cost
d. Between 15-25% of contract cost
e. Between 25-50% of contract cost
f. Greater than 50% of contract cost

Q15. Specifically focusing on your HL7 UK CORE standards within your clinical system - are all 71 specific profiles definitions (HL7 UK FHIR Reference Server) available in your UK EPR system i.e., UK components?

a. Yes
b. No

Q16. How often would you like to work with NHSE to develop priority use cases and associated new information standards?

a. Quarterly
b. 6-monthly
c. Annually

Q17. How much notice would you require from notification of the introduction of new standards to full implementation and compliance?

a. Less than 6 months
b. Between 6 & 12 months
c. 12 months or over

Q18. How would you prefer to evidence your clinical systems compliance with the latest standards?

a. External (third party) accreditation
b. Assessed by the NHS provider organisation
c. Self-assessed

Questions for healthcare providers

Q1. Are you an NHS, public or private healthcare provider?

a. NHS or Public

b. Private

Q2. Which region do you work in?

a. North West
b. North East
c. East Midlands
d. West Midlands
e. South East
f. South West
g. London

Questions for public healthcare providers

Q1. Which of the following best describes your interoperability objectives. Is it to freely share:

a. information/documents
b. standardised data
c. mine data to improved clinical pathways or cost effectiveness.

Q2. Does interoperability and standardisation of the patient data held within your clinical systems (here defined as electronic medical record (EMR), electronic patient record (EPR), laboratory information management system (LIMS), radiology information management system (RIS), etc.) lead to:

a. improved care outcomes? Yes/No
b. cost efficiencies? Yes/No
c. more effective operational planning? Yes/No

Q3. To what extent should your clinical services be interoperable (defined as EMR, EPR, LIMS, RIS etc.)?

a. Fully interoperable
b. Materially interoperable
c. Partially interoperable
d. Not interoperable

Q4. Which of the following interoperability and information standards does your implemented EPR/clinical system comply with, tick all relevant:

a. HL7 FHIR UK CORE
b. SNOMED CT
c. ICD-10/11
d. dm+d
e. OPCS-4
f. NHS Data Dictionary Vocabularies
g. NHS Number
h. I am not suitably informed to answer this question

Q5. How many of your clinical systems do not use the NHS Number as the primary means of personal identification?

a. All
b. Most (more than 10)
c. Some (less than 10)
d. None

e. I am not suitably informed to answer this question

Q6. What is preventing you from implementing a full interoperable system where healthcare professionals can see data across clinical systems and access patient data from other providers in your network, please select all that apply [can we rank the answers? Please answer at least your top priority, and rate as #1]:

a. Our focus is implementing a fit for purpose EPR
b. Cost or budget constraints
c. Technology does not support implementation
d. Pre-existing contractual agreements
e. I am not suitably informed to answer this question

Q7. Assuming that your EPR system is HL7 UK CORE compliant – how many of the 71 specific profiles definitions (HL7 UK FHIR Reference Server), i.e., UK components, are available in your EPR system?

a. <5 profiles
b. 5-10 profiles
c. 11-25 profiles
d. > 25 profiles
e. I am not suitably informed to answer this question

Q8. Do you currently have a Shared Care Record system in your ICB?

a. 1./ Yes
b. 2./ No

Q8.1. If yes, i.e., you have a Shared Care Record system, is it

a. ‘read only’
b. ‘read and write’

Q8.2. If yes, how much do you spend per annum. on mapping and standardising data from your clinical systems to your Shared Care Record system?

a. <£1M
b. £1-5M
c. >£5M
d. I am not suitably informed to answer this question

Q8.3. If yes, how much have you spent (to date) developing, implementing and supporting a portal for healthcare professionals to view patient records

a. <£1M
b. £1-5M
c. >£5M
d. I am not suitably informed to answer this question

Q9. How many clinical fields are captured and available for healthcare professionals to view in your Shared Care Record system?

a. <3 fields
b. 3-8 fields
c. >8 fields
d. I am not suitably informed to answer this question

Q10. Is your Shared Care Record system interoperable with other ICB's Shared Care Record systems? Yes/No

a. If yes, with how many other ICBs?
    i. 1
    ii. 2-5
    iii. >5
    iv. I am not suitably informed to answer this question

Q11.1. When a social care service user is admitted to hospital, would it be valuable to be able to view the service user's care plan? Yes/No

Q11.2. How do you currently view a service users care plan?

a. Electronic
b. Paper
c. Not at all
d. I am not suitably informed to answer this question

Q12. Co-design of services is critical to the success of the health and care sector. How often would you like to work with NHSE to develop priority use cases and associated new information standards?

a. Quarterly
b. 6-monthly
c. Annually

Q13. How much notice would you require from notification of the introduction of new standards to full implementation and compliance?

a. Less than 6 months
b. Between 6 & 12 months
c. 12 months or over
d. No specific interval, dependent on the standard

Q14. Who do you think should be accountable for the adherence to new standards being published?

a. Local compliance officer
b. Local CIO
c. Regional ICB board
d. NHS England
e. Other

Q15. How would you prefer IT suppliers to evidence their compliance with the latest standards?

a. External (third party) accreditation
b. Assessed by your organisation
c. Self-assessed

Q16. Would you find it valuable to be provided with a directory of compliant IT suppliers and systems?

a. Yes
b. No

Questions for social care providers

Q1. Are you a public, local authority or private social care provider?

a. Public or local authority
b. Private social care provider

Q2. When a patient is discharged from hospital, would it be valuable to be able to view information related to the specific hospital episode and would this inform the updated service user's care plan?

a. Yes
b. No

Q3. Do hospitals generally request your service user's care plan if they are admitted to hospital?

a. Yes
b. No

Q4. Do you currently use electronic care records? Yes/No

a. If no, what is preventing you from implementing electronic care records?
    i. cost
    ii. size of our business
    iii. not core to care delivery
    iv. If yes, is your electronic system
    v. developed in house and customised for our organisation,
    vi. an 'off the shelf' offering from an IT service supplier
    vii. a customised 'off the shelf' offering

Q5. If you have an electronic record system, which of the following interoperability and information standards it does not complies with, tick all relevant

a. HL7 FHIR UK CORE
b. SNOMED CT
c. ICD-10/11
d. dm+d
e. OPCS-4
f. NHS Data Dictionary Vocabularies
g. NHS Number
h. I am not suitably informed to answer this question

Q6. Will your costs increase because of the information standards legislation (Data Protection and Digital Information Bill)?

a. Yes
b. No

Q6.1. If yes, how much do you expect to spend on upgrading your systems to address the legislative requirements for information standards?

a. <£0.5M
b. £0.5-1M
c. £1-3M
d. >£3M

e. I am not suitably informed to answer this question

Q7. What elements of your cost will change? Tick all that apply

a. Training
b. Digitalisation of existing records
c. Systems requirements e.g., technology and licences

Q8. Does your electronic care record system need to be mobile enabled (e.g., on carer's mobile devices)?

a. Yes
b. No

Q9. Co-design of services is critical to the success of the health and care. How often would you like to work with NHSE to develop priority use cases and associated new information standards?

a. Quarterly
b. 6-monthly
c. Annually

Q10. How much notice would you require from notification of the introduction of new standards to full implementation and compliance?

a. Less than 6 months
b. Between 6 & 12 months
c. 12 months or over

Q11. Who do you think should be accountable for the adherence to new standards being published?

a. Local compliance officer
b. Local CIO
c. Regional ICB board
d. NHS England
e. Other

Q12. How would you prefer IT suppliers to evidence their compliance with the latest standards?

a. External (third party) accreditation
b. Assessed by your organisation
c. Self-assessed

Q13. Would you find it valuable to be provided with a directory of compliant IT suppliers and systems?

a. Yes
b. No

1.3 PwC Blockers survey

The survey was conducted as part of a discovery into what was acting as a blocker to the adoption of standards. We surveyed care providers, other NHSE bodies, and suppliers.

The key findings were that:

- Adoption of key standards such as SNOMED and DM+D were not widely adopted.
- Suppliers' delivery of mature level 3 (structured and coded) interoperability solutions was low, with only 49% of suppliers having the ambition of offering solutions of level 3 maturity to their customers on their roadmap. Only 17% of care providers were satisfied with their suppliers' efforts to improve interoperability and adopt standards.

The survey probed the perceived causes for this: The most cited reason by care providers for not implementing an information standard is that the supplier does not offer the feature. However, for suppliers the most common reason was that customers had not requested the feature. Contributory factors were that internal decision-making processes in trusts do not put sufficient priority on interoperability, with only 36% of suppliers and providers agreeing that the value of interoperability is well understood by making final investment decisions.

Fundamentally, the view of providers was that they were not sufficiently equipped to manage suppliers in driving increased interoperability:

- Only 15% of care providers agree they had the contractual levers to get suppliers to prioritise implementation of standards and interoperability features.
- 76% of care providers indicated they didn't have the support they needed from NHSE in negotiating contractual terms.
- Only 22% of providers agree that they understand the costs that suppliers charge for interoperability features.

The five biggest blockers with total agreement between suppliers and providers:

- Lack of clear prioritisation of which standards/features to focus on (80%)
- Lack of financial incentives (78%)
- Procurement and contracting processes (74%)
- Lack of sight/visibility on the operational impact and benefits of adoption (73%)
- Speed of getting standards created and updated[143] (72%)

Suppliers and providers differed on key enablers to address these blockers, but the ones most unified were:

- Statutory requirements on suppliers to adopt and implement interoperability standards (47%)
- A set of consistent specifications across all national services and clear transition path (37%)
- A clear and published national interoperability roadmap of APIS that once published has a clear commitment to deliver (34%)

Appendix 4 – Rationale for regional interoperability

Rationale for regional interoperability underpinned by the ShCR as basis of RIA

143 For suppliers, this encourages a "wait and see" approach to understand when a published standard is mature and stable enough to invest in

1. There are seven NHSE regions that support local systems to provide more joined-up and sustainable care for patients, each responsible for the quality, financial and operational performance of all NHS organisations in their region. These NHSE regions:

    - Support the 42 Integrated Care Systems (ICSs), with each ICS covering populations of around 500,000 to 3 million people.

    - Comprise 4-11 ICSs, each of which covers a partnership between organisations that meet health and social care needs across an area and play a critical role in aligning action between partners to achieve their shared purpose: to improve outcomes and tackle inequalities, to enhance productivity and make best use of resources and to strengthen local communities.

2. We considered NHSE regional interoperability as the immediate objective to allow NHSE to achieve its policy goals to facilitate the appropriate access to information needed by health and social care staff. This is with a view to aiding their ability to improve the quality of care they provide and improve outcomes for people accessing the health and social care system. This future state aligns with the seven NHSE use cases[144] that underpin the HCA 2022 and DUA policies. These seven NHSE use cases include: the transfer of care across care settings; the discharge of citizens from acute hospitals to social care; A&E triage; referral from primary to secondary care; and capacity planning including workforce management. These use cases will be enabled through the implementation of UK information standards, in conjunction with a future state architecture which will enable information interoperability.

3. Based on evidence provided by NHSE, at least 82%[145] of health and social care provision occurs within a patient's home region (especially home ICS), and, as such, the ability to share patient data within a region is pivotal. Sharing across regions will only provide incremental benefits when patient information is needed out of region e.g. for A&E use or in the case of certain high speciality care/tertiary care episodes. Identifying patient records outside of the region with use the existing NHSE National Record Locator (NRL). This 82% coverage of care within a patient's, or citizen's home ICS or region, underpins the NHSE immediate objective of delivering regional interoperability to realise its policy objectives goals to facilitate the appropriate access to information needed by health and social care staff.

---

144 NHSE has defined seven priority uses cases that detail data access across the various health and care sectors:

1. Acute hospital departments and other acute hospitals
2. Acute hospital discharge to social care
3. Workforce identity and access management
4. A&E triage
5. Referral from primary care to secondary care
6. Patient demographic and appointment information for capacity planning
7. Paramedic & Ambulance Triage

145 This estimate is based on analysis that was undertaken of patient flow in both 2018 and 2019 calendar-years for Acute outpatient & inpatient care and A&E attendances, for patients registered at a GP surgery in the Thames Valley & Surrey (TVS) area. The analysis looked at 'care in-area' i.e., within the patient's TVS home area, and patient flow fell into two categories 1. Care out of area but still within TVS and 2. Care provided outside of TVS. The study demonstrated that c.18% of all episodes of care we classified as 'care-provided outside of TVS' and consequently these patients where not deemed to benefit from the TVS shared care records programme

4. For the purposes of defining information content, the regions are required to implement a standardised NHSE shared care record (ShCR) system, which addresses two architectural requirements:

    - **To ensure that all ShCR systems are interoperable, scalable and can be connected across ICSs:** The ShCR joins up information based on the individual rather than one organisation. Local ShCR systems and the ability to share these records across the regions via a fit-for-purpose Health Information Exchange (HIE). Patient records will be 'read only' via healthcare professional portal securely linking to the ShCR, or alternatively the NHSE App for patients / citizens to view their own medical record. 'Write' will be at point of entry, although some more advanced ShCR systems offer read and write capabilities.

    - **To ensure that ShCR content aligns with the needs of clinicians across the health and social care settings, e.g., data fields aligning with (at least) the International Patient Summary (IPS):** IPS represents the minimum patient details to be shared to unlock benefits of information standards and interoperability. The IPS is a minimal and non-exhaustive set of basic clinical data of a patient, specialty-agnostic, condition-independent, but is readily usable by all clinicians for the unscheduled (cross-ICS/intra-regional) patient care. A patient summary is a standardised set of basic clinical data that includes the most important health and social care related facts required to ensure safe and secure healthcare.

5. Regional interoperability requires that all ICSs have 'fit for purpose' clinical systems that, at a minimum, include laboratory informatic systems (LIS), radiology information systems (RIS) and picture archiving communications system (PACS) that connect to an electronic patient record system (EPRs) or electronic medical record (EMR) system. These EPRs, in turn, connect to a ShCR system which is a safe and secure way of bringing all a patient's separate records from different health and social care organisations together digitally.

6. This regional interoperability with a regional pan ICS ShCR system will allow NHSE to address proposed policy objectives that all NHSE clinical systems are interoperable, thereby facilitating the appropriate access to information needed by health and social care staff, thus aiding their ability to improve the quality of care they provide and improve outcomes for people accessing the health and social care system. This immediate objective for interoperability will support secondary objectives i.e., to facilitate population wide research and analysis, operational planning. This will lead to improved clinical outcomes for patients, improved clinical/care decision making enabled by access to accurate and complete information, better procurement and commissioning by health and social care providers and a more dynamic and responsive health and social care IT market.

7. To unlock the full benefits of regional interoperability, we have assumed that the operating model accounts for the critical behavioural aspects which means health and social care professionals make full use of their ability to access records, including:
    i. Clinicians use this data to inform their decision making.
    ii. Relevant clinical data, rather than necessarily all clinical data, is shared - clinicians do not want everything to be shared.
    iii. The data is easily accessible on a timely basis.