Impact Assessment (IA)

Title: Health and Care Act (HCA) 2022 Section 95 Open Information Standards and Private Provider enforcement measures

IA number:

RPC reference number: N/A

Lead department or agency: Department of Health and Social Care

Other departments or agencies: NHS England

Date: 25 March 2025

Stage: Final stage

Source of intervention: Domestic

Type of measure: Secondary Legislation

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

RPC opinion: N/A

Summary: intervention and options

Cost of preferred (or more likely) option

(in 2024 prices, millions)

Item	Cost
Total Net Present Social Value	147.5
Business Net Present Value	-17.0
Net cost to business per year	2.0
Business Impact Target Status	Non- 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 care related information in real-time. This lack of interoperability has real-world negative impacts on patient care. Stakeholders agree that an information-standards based approach is the best way to enable interoperability and support the delivery of effective and timely care to patients. However, despite the introduction of legislation for data standards in 2012, adoption is low (around 42%) and not keeping pace with the developing way data is used, processed and stored across the health and

care sector. 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, to ensure systems are fully interoperable. The Health and Care Act 2022 strengthens the existing information standards system under the 2012 powers by requiring both public and private health and social care providers to comply with information standards. This is intended to increase adoption of said standards and so better ensure that data flows through the system in a usable and standardised form. Thereby facilitating system interoperability and supporting appropriate access to information by health and care staff. The intended effects include improved quality of care and patient outcomes, improved standardisation of information to facilitate research and promote innovation, improved decision-making enabled by access to accurate and complete information, and a more dynamic and responsive health and care market.

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

A long list of 6 options were assessed using critical success factors, based on which 3 were short-listed for further analysis. The options considered were:

(1) Do nothing;
(2) Enacting Secondary Legislation under HCA 2022 section 95 on health and social care providers to adhere to common information standards, with financial penalties on private providers;
(3) Delegation of information standards publication to an existing regulatory body;
(4) Issuance of guidance and information, education campaigns;
(5) Use of Directions, under s254 of the HSCA 2012;
(6) Specify requirements in health and social care provider licencing contracts.

This identified the preferred option of Enacting Secondary Legislation under HCA 2022 section 95, an alternative viable option (Option 4) and the “Do nothing” option. The preferred option was selected based on it having the highest strategic fit and potential value for money.

Issuance of guidance and information, education campaigns would have lower implementation costs and provide greater flexibility relative to other options. However, it would not offer sufficient incentives to ensure compliance with standards and could result in lack of uniformity of standards being adopted between providers.

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: Chris Mullins, Chief Economist, DHSC

Date: 05/03/2025

Summary: analysis and evidence – policy option 1

Description

Enacting Secondary Legislation under HCA section 95 on health and adult social care providers to adhere to common information standards, with financial penalties on private providers.

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 Estimate
2024	2024	10	-141.4	-155.8	-147.5

Costs

Estimate	Total transition (constant price) (£million) (2 years)	Average annual (excluding transition) (constant price) (£million)	Total cost (present value) (£million)
Low	**199.5**	**12.4**	**310.4**
High	**269.9**	**16.8**	**420.0**
Best estimate	**234.7**	**14.6**	**365.2**

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

Our analysis indicates that the main cost for 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 £46m for health and care providers (72% of their total incurred costs). Further costs identified: health and care providers on familiarising themselves with the standards; Health and care professionals on training on upgraded systems; and costs incurred by NHSE to monitor and enforce compliance across health and social care providers.

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

There may also be costs incurred for internal IT teams of health and social care providers, where internal IT teams need to update related systems, processes, and databases in line with the standards. 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. 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	18.8	169.1
High	0	29.5	264.2
Best estimate	0	24.2	217.7

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

These measures are part of a wider package of reform and intended to work together with related measures within the Data (Use and Access) Bill. As such, the benefits have been apportioned across the two related IAs – detail of which can be found in table 2. Information standards benefits include cost savings by health and social care providers from no longer needing to standardise/map their data to Shared Care Records, as well as benefits related to interoperability including cost savings from reduced duplicate tests/procedures; reduced bed days and incidence reporting costs from a reduction in medication errors; the saved staff time from better access to data and more efficient processes. Further, there is value to patients from improved patient safety.

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

High compliance with Information standards is a key enabler for interoperability, which has benefits for health and social care providers and patients that include earlier diagnosis, reduced downstream costs, increased patient satisfaction, care pathway optimisation, and better integration across health and social care services. Other societal benefits include research and innovation gains, productivity boosts, reduced taxpayer burden, and environmental benefits from a greener health and social care system.

Key assumptions/sensitivities/risks

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

Realising the benefits of interoperability needs appropriate architecture to be in place. Current

planned activity and investment for the required infrastructure is on track to be in place before standards come into force. There is a risk of increased cost of IT products/services and a risk of private provider non-compliance due to inherent differences in the health and social care provider market.

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.

Business case assessment (Option 1)

Costs (£million)	Benefits (£million)	Net (£million)
1.9	0.0	1.9

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

N/A

Contents

Executive Summary

1. The package of measures in the Health and Care Act (HCA) 2022 was designed to support a digitally enabled health and social care system which harnessed transformative technologies to improve productivity, efficiency, and outcomes for patients across the health and social care system. Delivery of which depends upon timely and effective information sharing and the HCA 2022 sought to remove some of the barriers to this.

2. 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 IT systems across health and adult social care in England to be interoperable, which in turn demand 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.

3. Despite the existing requirement – set out in the Health and Social Care Act (HSCA) 2012 – to have regard to information standards, compliance has remained a challenge, and we have not been able to apply information standards consistently across the health and social care system. The HCA 2022 therefore introduced measures that both make adherence to information standards mandatory and extend their scope to a wider range of organisations – namely Care Quality Commission (CQC)-registered private health and social care providers. The territorial extent of this legislation will be in England only. These measures ensure that all health and social care providers are accountable for meeting basic information standards.

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

What are Information Standards?

5. 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.

6. 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.

7. Currently, the Secretary of State for health and social care or NHS England (NHSE) may prepare and publish information standards, which the Secretary of State, NHSE and publicly funded health and social care organisations in England must have regard to. Changes made by the HCA 2022, once commenced, will make information standards binding and extend them beyond public providers, so that they also apply to CQC registered private health and social care providers.

8. 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 settings and IT suppliers.

Why is a legislative approach needed?

9. The health and social care sector is large and complex, made up of thousands of organisations at national, regional and local levels across primary and secondary health, and social care settings. Data is an essential part of how health and social care services are planned and delivered; however, the use of different systems and different ways of recording and structuring information, prevents them from communicating with each other.

10. Legal powers to set information standards for public health and social care providers were originally set out in Section 250 of the HSCA 2012. However, uptake and adoption of standards is low.

11. 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 5% additional compliance with information standards across ICBs facilitated by the non-legislative, alternative option (issuing guidance). This compares with 14% additional compliance under the preferred, legislative option.[5] Further detail on additional compliance achieved can be found in the 'Assumptions for attributing benefits to HCA legislation' section.

12. A legislative approach is needed to bring about the wholesale, system wide change required.

13. As evidenced in Estonia[1] and Northern Ireland[2], 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.

14. 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. This included a range of alternatives to regulation including issuance of guidance and information, education campaigns, use of Directions (s254 of the HSCA 2012), specifying requirements in health and social care provider licencing contracts 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 the preferred option.

15. 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

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[1] WP8_willis.indd (ox.ac.uk)

[2] eHealth and Care Strategy | Department of Health (health-ni.gov.uk)

(HMT) Green Book guidance.[3] They are: Strategic fit and business needs; Potential value for money; Supplier capacity and capability; Potential affordability; and Potential achievability.

16. The analysis identified a short-list of 3 options, which underwent further assessment. These were: Option 1 - *Do nothing,* Option 2 - *Enacting secondary legislation under HCA section 95 on health and social care providers, and financial penalties,* and Option 4 - *issuance of guidance and information, education campaigns*.

What will this achieve?

17. Mandatory information standards for both private and public health and adult social care providers 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.

18. Enabling information standards to apply to private health and adult social care providers ensures that all relevant parties in the health and social care ecosystem can be held to account.

19. 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

20. Current compliance with standards is set out in Table 3. All economic analysis in this IA is based on apportionment between measures in the Data Use and Access (DUA) Open Data Architecture Information Standards IA and the measures within this IA. It is estimated that these measures 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.

21. The expected outcomes and impacts are detailed in the Theory of Change for the preferred option as outlined in section 1.5. This identifies a wide range of benefits, encompassing both monetisable and non-monetisable. These benefits arise from the enhanced operational efficiency gained through improved data access, which reduces time spent by clinical staff on unnecessary activities and curtails the need to duplicate processes and procedures. Furthermore, the enhancement of patient safety due to better access to patient information contributes to a reduction in medication errors and incidents related to patient safety. These

[3] The Green Book (2022) - GOV.UK

benefits, along with identified costs, form the basis of the economic analysis in this RIA (where sufficiently reliable data was available).

22. 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.

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

24. 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 1.6 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.

25. This Impact Assessment values the total economic costs of the programme to be £88.0 million (present value terms), and the quantified ten-year savings and benefits to be £106.4 million (present value terms). The net present value (NPV) is therefore £18.4 million, and the benefit cost ratio (BCR) is 1.21.

26. Table 1 sets out the costs, and Table 2 the benefits, that have been attributed to this s95 HCA 2022 impact assessment, the DUA impact assessment and overall total. The different rationales for the split of costs and benefits between HCA and DUA is summarised below.

27. **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.

28. **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).

29. **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.

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)

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)

30. There is a cost to private business, with IT suppliers needing to spend time familiarising themselves with the standards and having to incur some internal costs making updates to internal systems. Furthermore, costs will be incurred by private hospitals and private social care businesses familiarising with the standards and making relevant updates to systems as needed. The present value of these costs is £16.7 million over a ten-year period.

31. 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.

32. 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

33. Some of the risks identified are:

- 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, then 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.
- 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 private provider non-compliance due to the inherent differences in the health and social care provider market.

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

Detailed Review

1.1 Problem under consideration and rationale for intervention

Background

35. 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[4] is the best way to achieve this, so getting health and social care providers to adopt the required standards is key.

36. To this end, legal powers to set information standards for public health and social care

providers were originally set out in Section 250 of the HSCA 2012. However, in the twelve years since, uptake and adoption of standards by providers (at 42%[5]) has not met the pace and scale needed for transformation.

37. Recent surveys (see Appendix 4 for further details) conducted by NHSE, however, report both low levels of adoption and use of information standards by health and care providers[6], and low compliance of providers' clinical systems with information and interoperability standards[7].

38. These powers have therefore been strengthened in the HCA 2022 to mandate that all health and adult social care providers comply with information standards, backed up by the power to enforce these standards through financial penalties to private providers. The powers will facilitate the monitoring and enforcement of the adoption and use of the standards and help to ensure the effectiveness of information standards in improving interoperability in the health and care system.[8]

39. 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.

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4 Information Standards and Interoperability Survey, NHS, February 2024

5 Based on health and social care provider compliance with six core information standards, excluding mandatory standards e.g., NHS number. Standards 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

6 Source: Blockers to Standards Adoption - Insights and Recommendations, NHS, Oct 2022

7 Source: Information Standards and Interoperability Survey, NHS, Feb 2024

8 Health and Care Act 2022 Core Measures Impact Assessment (publishing.service.gov.uk)

40. 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.

41. The data provisions in the HCA 2022 are intended to enable improved sharing and more effective use of data across the health and adult social care system, through a standardised approach to the collection, storage and processing of data.[9]

Information standards and interoperability

42. 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.

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

44. Implementing information standards alone will not allow the sharing of, or access to real time patient data across systems; however, the 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.

45. '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.

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

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

48. 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 predicated 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.

49. While common data standards will need to be complemented with the requisite infrastructure, this assessment does not include these additional 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

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

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.[10]

50. 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).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.[11]

51. 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.

52. 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.

53. The benefits considered in this RIA, i.e., as relate 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.

54. Refer to Appendix 4 for further detail on the rationale for regional interoperability underpinned by the ShCR as a basis for this RIA.

Problem under consideration and the issue being addressed

55. 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.

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5 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)

6 Confirmed with NHSE programme leads

56. The UK's Health and Social Care sector is large and complex, with thousands of organisations using different IT systems with different ways of recording and structuring information, which is preventing them from communicating with each other and sharing data that underpins care delivery.

57. Currently health and social care providers cannot easily access or share care related information in real-time. This is partly because current legislation - powers to introduce standards in s.250 of the HSCA 2012 – does not make compliance with information standards mandatory, and does not apply to both public and private health and care providers. This means that health and care providers are not using clinical systems based on common information standards, which would enable interoperability and support the delivery of effective and timely care to patients. Uptake and adoption of standards by providers (at 42%[12]) has not met the pace and scale needed for transformation.

58. The rising demands on the NHS and the wider healthcare system in England require a more efficient and transparent means of recording, transmitting and accessing reliable clinical information to manage and deliver high quality care to patients. The risks that increasing service pressures brings to patients has been highlighted in several reports[13,14].

59. The challenges can be alleviated, in part, by the development and use of IT systems in which data are recorded consistently across all contexts. The implementation of national standards for the clinical structure and content will facilitate shared care, enable interoperability between locations and contexts and yield comparable data to support the management and monitoring of services realising benefits for clinicians and patients.

60. The intention of proposed changes is to mandate standards that would allow a common approach to information processing activities, such as:[16]
    - 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.

61. There are many challenges associated with lack of common information standards across care settings:

    - Inconsistent data recording across the health and social care sector, increasing the risk of poor data quality and impairing the interoperability of data and services that depend upon it.

    - There are many different organisations that collect information in diverse ways using different systems with different standards, making it challenging to share data effectively across health and social care. This lack of interoperability can lead to delays in accessing critical data, potentially compromising patient safety and outcomes.[15] Inaccurate or

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7 Based on health and social care provider compliance with six core information standards, excluding mandatory standards e.g., NHS number. Standards 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

8 Growing pressure on NHS threatens frontline services | The BMJ
9 Workforce burnout and resilience in the NHS and social care (parliament.uk)
10 Interoperability in Healthcare: Benefits and Challenges | Background (cifs.dk)

incomplete patient records can pose risks to patient safety via misdiagnoses and medication errors and adverse events may occur when critical information is missing.

- The NHS and care sectors have multiple, diverse IT systems - including many legacy systems - that hold patient information provided by several different suppliers. These systems often cannot speak to each other, which can result in data being held separately and/or being isolated in parts of the system where it cannot be accessed elsewhere. This causes a technical barrier to direct care, as well as operational planning, research and innovation.

- Where patient information is fragmented and held on distributed systems, in many different formats and structures and where it cannot easily be discovered and accessed when needed[16], duplication of tests and procedures can be commonplace. When healthcare providers cannot access a patient's complete medical history, they may repeat tests or procedures unnecessarily, leading to increased healthcare costs and patient inconvenience.[17]
- To address issues associated with a lack of common information standards, some health providers implement a mapping solution to be able to pull data into a shared system. This solution is costly and inefficient.
- Data sharing can be limited by vendor restrictions and by information blocking by providers, commissioners, and vendors for competitive advantage. As a result, patient data remains fragmented across various healthcare providers and systems. This can result in incomplete or inaccurate patient records, hindering healthcare professionals' ability to make informed decisions.

Common information standards

62. 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. Under HSCA 2012, public providers of health and social care organisations have to give 'due regard' to these standards, the law does not include a legal requirement to follow them.

63. 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.

64. 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.

65. Adherence to common information standards ensure that all relevant parties in the health and social care ecosystem use the same language and the same approach to sharing, storing and interpreting information. Information standards make up the backbone of interoperability - the ability of health systems to exchange medical data regardless of domain or software provider.

Rationale for intervention

66. The measures would allow use of powers provided in the HCA 2022, and so introduce the ability to set mandatory common information standards for public and private health and

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11 NHS England Interoperability strategy, September 2021
12 EHRs: The Challenge of Making Electronic Data Usable and Interoperable - PMC (nih.gov)

care providers, to improve the current compliance rates with information standards, and bring private providers into scope. This will ensure that information flows through the system in a standardised way so that it can be easily accessed and used, helping to ensure the security of that information when it is processed. The application of information standards to private providers also aims to improve the overall experience of patients and quality of care received, especially those who move between publicly and privately funded services. In its totality, the measures are a key enabler for a more integrated and modern health and social care service.[18]

67. Without these changes, compliance rates with information standards will continue to remain at a low level as currently under HSCA 2012 (42%[19]). This is partly due to a lack of incentive for change from health and social care providers and the burden of changing systems and/or suppliers[20] – which will prevent interoperability and its associated benefits from being achieved. In addition, without common information standards being mandated, current issues with the lack of joined up messaging and a lack of alignment of levers and incentives for standards adoption amongst health and social care providers remain.[21] In addition, existing challenges with the fragmentation and sharing of patient information, as well as the associated cost inefficiencies and administrative burden, would remain.

Is there a market failure?

68. 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: One health and social care provider's decision to invest or provide interoperability can be expected to depend on the organisation and the patients it serves' ability to benefit . However, interoperability may have significant knock-on benefits for third parties Examples of this include quicker patient record access for other health and care providers and research and development in the Life Sciences industry.

    - Coordination failure: the full value of interoperability requires high information standards participation from health and social care providers, which needs major coordination. There's less incentive for individual providers 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.

Political and legal context

69. The NHS has been a focal point of political discourse, with various political parties advocating for health and social care reforms. Achieving compliance with common information standards and hence interoperability in IT systems is seen as a crucial step in

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13 Health and Care Bill (Thirteenth sitting) - Hansard - UK Parliament
14 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
15 Acceptance and Resistance of New Digital Technologies in Medicine: Qualitative Study - PMC (nih.gov)
16 NHS England Interoperability strategy, September 2021

achieving the vision of a more efficient and patient-centric healthcare system. The move towards interoperability aligns with the broader consensus that digitalisation can lead to better healthcare coordination, reduced administrative burdens, and ultimately improved patient care.

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

70. 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 healthcare providers, reducing administrative burdens and enhancing patient care coordination. The adoption of international 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 healthcare services while controlling costs.

71. The Hewitt Review, commissioned by the UK government, 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.

72. In the wider policy landscape, the government's commitment to digital transformation and improving healthcare infrastructure has made interoperability a strategic imperative. Regulations promoting interoperability serve as a critical step in realising these policy goals, promoting a modern, efficient, and responsive healthcare system that meets the evolving needs of the UK population.

Markets and stakeholders that will be affected with government intervention

73. 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:** There will be indirect costs incurred by private IT suppliers to familiarise with the standards and make relevant internal updates to their systems in relation to the information standards.

- **Patients:** Patients will benefit through improved access to data for health and social care providers, and the transfer of care will be enabled 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 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**[22]**:** 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 standardise data underpin safe, effective, compassionate, high-quality care. They are an essential part of achieving good outcomes for people who use services allowing:

    1. The capture of information more easily at the point of care,
    2. Support staff to respond more quickly to people's needs,
    3. Sharing of important information quickly, safely and securely between care settings, and
    4. 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 to become compliant once HCA 2022 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 care providers. Currently, these costs have not been monetised because there is a high degree of uncertainty about what proportion of costs will 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.

    - 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

74. Currently only 42% of sampled health and social care providers comply with non-mandatory core information standards.[23] A comparative case of Estonian and British Healthcare Infrastructure shows that in Estonia[24] government regulation has been a very effective

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17 Digital record systems: achieving good outcomes for people using adult social care services - Care Quality Commission (cqc.org.uk)

18 Information Standards and Interoperability Survey, NHS, Feb 2024

19 WP8_willis.indd (ox.ac.uk)

means to addressing issues of achieving compliance with common information standards in health and social care. In Estonia, the government have 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.

75. 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 healthcare 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.

76. This approach facilitates multi-stakeholder engagement, resulting in regulations that reflect the diverse interests of healthcare 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 healthcare sector.

Legal basis for the government to act

77. The Secretary of State for Health and Social Care can make the regulations in exercise of the powers conferred by sections 251(1) and 304(9) and (10) of the Health and Social Care Act 2012.

78. Additionally, the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 govern the legislation around privacy and security of patient data and, along with the Health and Social Care Act 2012, grant the government authority over healthcare practices.

79. These laws, in conjunction with the government's responsibility for public health and safety, provide a legal framework for regulating IT systems to enhance healthcare coordination, reduce errors, and ensure patient safety while upholding data protection standards and healthcare quality.

Interoperability standards adoption by health and social care providers

80. 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 with each of these standards is outlined below:

TABLE 3 – Compliance with Standards[25],[26]

Standard Name	Description	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	83
NHS Data Dictionary Vocabularies	The NHS Data Dictionary contains additional vocabularies that are to be used where appropriate	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	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	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	43
SNOMED CT	SNOMED CT is NHS agreed standard for clinical terminology. It should be used by systems for recording of direct care information.	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.	45
Average		**48**
Average of non-mandatory standards (excluding NHS number)		**42**

81. The analysis reveals that health and social care providers do not fully adhere to the clinical system standards, especially those that are not compulsory.

20 Based on Information Standards and Interoperability Survey, NHS, Feb 2024

21 This is based on the non-mandated standards. The NHS Number is mandatory: https://www.digitalhealth.net/2015/10/nhs-number-use-becomes-law/

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

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

83. 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. For detail, please see Appendix 4. This includes:

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

84. 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.

85. 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.

1.3 Description of options considered

Background

86. This section discusses the approach taken to identify the various policy options, legislative and non-legislative, to achieve the policy objective. The process is outlined in table 4.

87. An options appraisal has been conducted, which provided an opportunity for all relevant stakeholders to make an informed and evidence-based decision. To do this, all relevant advantages and disadvantages for several different policy options were considered.

88. This approach is helpful for several reasons. Firstly, it provides a clear outcome by identifying a preferred option, which is developed in greater detail in this Impact Assessment. The process also allows for key stakeholder engagement and helps identify important priorities and questions regarding the preferred option from their perspective. Lastly, this approach follows best practice outlined by HM Treasury's Green Book and by the Better Regulation Executive.

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

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

90. The long list of options is shown in Table 5. These include both Legislative and non-legislative options, which were evaluated through a review of the previous Impact Assessment. This evaluation was further supported by a series of meetings and workshops with representatives from the NHSE and the DHSC. Each option is designed to ultimately support the achievement of regional interoperability.

TABLE 5 – Outline of Options

Option no.	Option	Description	Legislative
1	Do nothing	Business as usual. Health and social care providers can continue with current approach for processing of information across organisations	No

2	Enacting secondary legislation under HCA section 95 on health and social care providers, and financial penalties.	This option proposes publishing mandatory information standards and extends the application of information standards to include private health and social care providers – this means issuing financial penalties for private providers for non-compliance with information standards.	Yes*
3	Delegation of information standards publication to an existing regulatory body (e.g., CQC, ICE-lead)	Delegation of responsibilities for publishing information standards to existing regulators, guided by non-statutory advisory principles. This is a non-legislative option with existing regulators applying information standards and principles within their remits.	No
4	Issuance of guidance and information, education campaigns	Creation of guidance on best practice for standardised information for health and social care providers to create consistency amongst providers, accompanied by education and training campaigns to establish this best practice.	No
5	Use of Directions, under s254 of the HSCA 2012	The Secretary of State may direct NHSE to establish and operate a system for the collection or analysis of information. For the purposes of complying with a s254 direction, NHSE may require the provision of information (s.259(1)) and may specify the form and manner in which that information is provided (s.259(5)). Directions are used to require private providers of health and social care to share data in a specified format with NHSE to create a central 'Data Lake', negating the need for inter-provider data sharing.	Yes
6	Specify requirements in health and social care provider licencing contracts	All licensing contracts with (public and private) health and social care providers (that are registered with CQC) specify the requirements that support information standards, relating to the processing of information.	No

**This option is the only option which uses new legislation and mandatory compliance, other legislative options rely on the use of existing legislation which does not mandate compliance with information standards.*

1.4 Policy objective

Critical success factors

91. In determining which options to short-list for further evaluation, the long list options were assessed against four 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.
92. 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.

    B. **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?

    C. **Potential affordability:** What are the relative costs of each option compared to the budget available?

    D. **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.

93. These CSFs were based on consultation with NHSE and on Green Book Critical Success Factors[27].

94. Table 6 presents an options scoring matrix, where all options are assessed and scored using a scale of 4 intervals.[28,29] 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.

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22 Green_Book_supplementary_guidance_-_Value_for_Money.pdf (publishing.service.gov.uk)

23 For criteria A, the scale was ‘Not aligned, 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 ‘Significantly over budget, Moderately over budget, Potentially over budget, Within budget’. For Criteria D, the scale was ‘Not achievable, Possibly achievable, Probably achievable, Highly achievable’.

24 Each score in the four-point scale corresponds with a Red-Amber-Yellow-Green colour (RAYG) rating, which is show in Table 6

TABLE 6 – Appraisal Criteria Scoring policy options against critical success factors

Policy Option	CSF A: Strategic and business needs	CSF B: Potential VFM	CSF C: Potential affordability	CSF D: Potential achievability
Option 1 - Do Nothing	Not aligned	No change	Within budget	Highly achievable
Option 2 - Enacting secondary legislation under HCA section 95 on health and social care providers, and financial penalties	Highly aligned	High VFM	Within budget	Probably achievable
Option 3 - Delegation of information standards publication to existing regulatory body (e.g. CQC, ICS-led)	Moderately aligned	Medium VFM	Potentially over budget	Possibly achievable
Option 4 - Issuance of guidance and information, education campaigns	Weakly aligned	Medium VFM	Within budget	Highly achievable
Option 5 - Use of Directions, under s254 of the HSCA 2012	Weakly aligned	Medium VFM	Within budget	Probably achievable
Option 6 - Specify requirements in health and social care provider licencing contracts	Weakly aligned	Low VFM	Potentially over budget	Probably achievable

Options shortlist

95. Based on the scoring assessment, the options were ranked as follows:

TABLE 7 – Option Rankings

Options	Score	Rank	Rationale
Option 2 – Enacting secondary legislation under HCA section 95 on health and social care providers, and financial penalties	14	1	This option is strongly aligned to the UK Government's strategy and objectives for interoperability and provides value for money relative to other options considered. This option is deemed to be affordable and is likely to be achievable for health and social care providers to respond.
Option 4 - Issuance of guidance, information, and	13	2	Despite it being deemed weakly aligned to the Government's strategy and objectives for interoperability, this option appears affordable and highly achievable considering the ability and time

education campaigns			for health and social care providers to respond. This option also demonstrates moderate value for money, as it is assessed to deliver benefits at a relatively lower cost than other non-mandatory options.
Option 5 - Use of Directions, under s254 of the HSCA 2012	12	3	Similar to option 4, this option is deemed weakly aligned to the Government's strategy and objectives for interoperability. It has been assessed as highly affordable and likely to demonstrate moderate value for money relative to other options assessed. However, it is ranked lower because it is comparatively less likely to achieve its objectives of information standards compliance when taking into consideration the ability and time for the health and social care providers to respond, as well as the difficulty and skill set required to implement the option.
Option 3 - Delegation of information standards publication to existing regulatory body (e.g. CQC, ICS-led)	11	4	The option is deemed moderately aligned with the Government's strategy and objectives for interoperability covering all care settings and appears to demonstrate moderate value for money relative to other options. However, there is a risk that this option could be potentially over budget given the need for the delegation to an external regulatory body, which will increase costs. Lastly, the capacity of a regulatory body to take on this additional responsibility is uncertain.
Option 6 - Specify requirements in health and social care provider licencing contracts	10	5 (joint)	This option is weakly aligned with the Government's strategy and objectives for interoperability and appears to demonstrate low value for money relative to other options. This option is likely to be less affordable in comparison to other options and achievability will be challenging since it relies on licencing contract negotiations taking place within the timeframe for renewal of licences.
Option 1 – Do nothing	10	5 (joint)	This option provides no strategic fit, since it does not appear aligned with the Government's strategy and objectives for interoperability. Further, this option does not appear to demonstrate value for money, as no benefits are likely to be accrued. On the other hand, this option is affordable and achievable as it is a continuation of the current state.

96. 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 Secondary Legislation under HCA section 95 on health and social care providers, and financial penalties”
- Option 4: “Issuance of guidance and information, education campaigns”

Analysis of shortlisted options:

97. 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:

- Health and social care providers can continue with their current approach for the processing of information across their organisations which is both “highly achievable” and “affordable”.
  - Previous work towards this goal such as the formation of the NHS Connecting for Health (CFH) agency[30] was criticised for cost escalation and lack of evidence of benefits, as well as widespread delays and disruption, and issues with implementation and procurement.[31] By doing nothing, any potential risks and costs of failure can be avoided. A review of CHF learnings by the Australian Centre for Health Informatics highlighted that the NHS was not sufficiently prepared to take on such a fast-paced, radical and extensive modernisation programme, that it was compromised by workforce shortages in health informatics, and fell into the trap of leading with technology rather than clinical need. Based on these learnings, future NHS programmes and legislation, such as implementing information standards and interoperability, should begin with Regional clinical centres of excellence, where IT skills and efforts can be concentrated. With time, successful technologies, processes and work practices, as well as the personnel trained in them, can then migrate to the rest of the health and social care system.[32]

Opportunities:

- The current arrangements do not provide any opportunities towards common information standards or support interoperability.

Weaknesses:

- Existing challenges with the fragmentation and sharing of patient information, as well as the associated cost inefficiencies, remain.

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25 Making IT work: harnessing the power of health information technology to improve care in England - GOV.UK (www.gov.uk)

26 The National Programme for IT in the NHS – A case history npfit-mpp-2014-case-history.pdf (cam.ac.uk)

27 Lessons from the NHS National Programme for IT Med J August 2007; 186 (1): . || doi: 10.5694/j.1326-5377.2007.tb00774.x

- A lack of interoperability results in patients and their care teams not being able to easily access or share relevant information[33] leading to adverse outcomes and increased costs[34] by reducing the quality of care provided and wasting resources[35].
- Currently, data silos mean that users and their teams are not able to easily access or share data in real time, whilst also creating technical barriers to direct care, operational planning, research, and innovation. These "siloed" systems result in a barrier to new market entrants[36].
- Inefficient data sharing can impose administrative burdens on healthcare professionals who must resort to slow, time-consuming methods to access data.
- Information often must 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.[37]
- 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.[38]

Threats:

- The UK could fall behind its global competitors in terms of interoperability and quality of service in the health and social care sector. This could cause a relative decline in patient safety and quality of care received by UK citizens in England. It would also negatively impact NHS productivity.
- The lack of standardisation amongst private and public health and social care providers could continue, or even worsen, negatively impacting the quality of care received by patients – especially individuals that elect to move between public and private providers.

Option 2: Enacting Secondary Legislation under HCA section 95 on health and social care providers, and financial penalties

Strengths:

- This would support information being in a standard form which is meaningful to recipients when it is accessed or provided. This promotes the frictionless movement of information between providers, contributing to increased interoperability in the

28 DHSC Open Data Architecture Impact Assessment (IA) – 27/05/2022

29 Interoperability in Healthcare | IBM

30 Interoperability of heterogeneous health information systems: a systematic literature review | BMC Medical Informatics and Decision Making | Full Text (biomedcentral.com)

31 TO PUBLISH: Updated Final DPDI (2) Bill Impact Assessment March 2023.docx (parliament.uk)

32 DHSC Open Data Architecture Impact Assessment (IA) – 27/05/2022

33 Interoperability risks and health informatics - ScienceDirect

system. This can also enable a better-connected health system reducing delays and boosting efficiency by removing duplicate data entries.[39]

- This will require all health and social care providers to implement the required information standards at the same pace (moving public providers from the position of having to have 'regard' to information standards to having to comply with them and making private providers having to comply with standards for the first time) giving clarity on the priority and sequencing of implementation and avoiding confusion amongst providers.[40]
- The imposition of financial penalties for non-compliance will strengthen the negotiating position of officials dealing with non-compliant health and social care providers[41] making it more likely that private providers will comply.
- By applying information standards to private providers, the experience of patients who move between publicly and privately funded services will improve because of frictionless movement of information between those providers. This will support timely and appropriate patient care decisions.[42]
- Government regulation establishes prioritisation of public interest, especially in safeguarding patient data. Instituting stringent data security, privacy, and ethical usage standards ensures sensitive medical information is handled responsibly.
- Government regulation provides crucial oversight, consistency, and protection, addressing the intricate challenges of interoperability in the healthcare sector effectively.
- It is aligned with the UK Government's current strategies and objectives. The Government aims to improve sharing of data, such that a patient record is available in all care settings in which they are seen, regardless of which primary system is used to capture the interaction.[43] In addition, the NHS's 'Long Term Plan', established in 2019, is also committed to mandating and rigorously enforcing technology standards.

Opportunities:

Significant enhancement of the quality of care and improvement of patient outcomes thanks to the enabling of seamless access to information.[44]

Opportunity for a more integrated system that can provide a better longer-term focus on improving population health and reducing inequalities[45] through strategic planning.

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34 Interoperability in Healthcare: Benefits and Challenges | Background (cifs.dk)

35 NHS England Interoperability strategy, September 2021

36 Health and Care Act 2022 Core Measures Impact Assessment (publishing.service.gov.uk)

37 Health and Care Bill (Thirteenth sitting) - Hansard - UK Parliament

38 Our plan for patients - GOV.UK (www.gov.uk)

39 01.06.22 CLEAN DHSC Primary Impact Assessment - CLEARED - DSIT edit (1) (2).pdf

40 The Health and Care Act 2022: the challenges and opportunities that lie ahead | The King's Fund (kingsfund.org.uk)

Health researchers will be able to compare and analyse datasets more quickly and easily, and at a greater scale.[46]

Weaknesses:

- The process of enacting legislation can sometimes be slow and complex[47]. There is therefore a risk that additional costs could be incurred if the length of time taken to enact the legislation is longer than expected due to unforeseen circumstances. Furthermore, where guidance on the standards is insufficient, additional time may be required by health and care providers to interpret and act upon the guidance. It could be more expensive in comparison to other legislative or non-legislative options. To issue financial penalties to non-compliant private health and social care providers, a compliance and enforcement regime is required which would involve the costly process for monitoring, issuing, and enforcement of financial penalties.

Threats:

- The digitisation of healthcare is a global trend, and many suppliers are experiencing very high demand for their services beyond the domestic UK economy. This can lead to suppliers facing backlogs for new installations, which may make it difficult for health and care providers to comply with the information standards.

- There is a risk of provider non-compliance due to 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 adult social care market (although commissioned by local authorities) are largely independent, autonomous entities.

- Rules-based regulations may prevent new business models from developing in the health and social care IT supplier market, if they cannot comply with the rules set out in the regulation.[48]

- Smaller health and social care providers, including private providers, may be disproportionately affected by the additional costs of processing data.

Option 4: Issuance of guidance and information, education campaigns

Strengths:

- Easier to implement with an expected lower cost relative to other options due to a lack of significant administrative costs and absence of a compliance and enforcement regime.
- Issuing guidance to the market offers increased flexibility because if amendments are required, they can be faster to implement than for example legislation.

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41 Health Data Research UK publishes 'Recommendations for Data Standards in Health Research' - HDR UK

42 When laws become too complex - GOV.UK (www.gov.uk)

43 Using alternatives to regulation to achieve policy objectives (nao.org.uk)

Opportunities:

- Sufficient implementation of information standards from the guidance and information campaign could facilitate benefits associated with interoperability.

Weaknesses:

- This lacks sufficient incentives to ensure compliance with the standards and success may be difficult to measure if compliance is not monitored or enforced.
- It could result in varied levels of understanding of which requirements to build in amongst providers and a lack of uniformity of standards being adopted between providers – undermining the intended purpose of interoperability.
- The creation of best practice guidance and training campaigns can take significant time to make an impact, from being disseminated through to providers using the information and training materials to change their behaviour.[49] Health and social care providers may choose to implement change at their own pace and issues they want to prioritise.

Threats:

- Potential complete lack of effectiveness or very slow and partial implementation stemming from resistance to change from some healthcare providers who have ingrained preferences for existing processes or hold concerns about the practical application of the standards.

1.5 Summary and preferred option with description of implementation plan

98. The preferred solution is to prepare, publish and mandate standards that apply to public and private health and social care providers, including enforcement on private providers.

99. Work is progressing to develop an open data architecture approach with standards – developed with the industry - that will require products and services to be based on principles of a unified system architecture, open standards and interoperability. This will allow for prescribed information collected or produced by a provider and entered into their information technology system to be made available on demand and in a form specified by the Secretary of State. 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. Technical specifications will be evolving over time as technology changes and improves. This process will begin as part of a pilot, which will focus on the highest priority standards that support interoperability objectives and the delivery of true integrated care.

100. The standards chosen will be tailored to reflect the burden on providers relative to the care setting (for example, a care home is a materially more limited care setting than a major acute hospital) and distinguish between commercially available off-the-shelf (COTS) and in-house developed solutions. The scope and scale of these standards will be clearly defined, particularly in the secondary care market. The Secretary of State will continue to seek adoption of procurement frameworks enabling providers of health and adult social care to be confident that the products and services set out in the framework will meet the standards under the new legislation. The Digitising Social Care Programme and GP IT Futures has

44 Using alternatives to regulation to achieve policy objectives (nao.org.uk)

developed a Dynamic Purchasing System that assures suppliers of digital social care records software and provides a mechanism to meet required interoperability standards.

101. 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 private health and social care provider to bring their product or service into compliance.

    c. If non-compliance persists without an agreement in place or an exemption agreed, the private providers 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. In the US, the Office for Civil Rights (OCR) enforces the Health Insurance Portability and Accountability Act (HIPAA) and has introduced penalties for entities covered under HIPAA in four tiers, which vary from US$100 per violation to US$1.5 million depending on the severity of the violation (e.g., data breaches, denying medical records to patients, failure to carry out risk-assessments).

Theory of Change for preferred option

102. To help consider how the preferred option delivers 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 health and social care providers in adhering to legislation
        - Secretary of state to issue mandatory information standards for processing information (in relation to interoperability) for health and adult social care
        - Cost running the standards, maintenance, enforcement

    Activities – which activities are required to implement the legislation?

    Information standards costs

        - Drafting and refining information standards, legislation, including stakeholder engagement with health and social care providers
        - Negotiation of new IT system contracts for IT suppliers by health and social care providers
        - Familiarisation with new legislation and requirements for health and social care providers

- Provision of training on health information standards for health and social care providers

- Set-up compliance and enforcement regime for private providers

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
- More intelligent procurement by health and social care providers

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

Health and social 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 social care providers

    - Reduced duplicate patient diagnostic lab tests, consultations and procedures

    - 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 medical / 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

Outcomes – what are the further outcomes contributing to success?

Health and social 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 whole system
  - Fewer medical errors and mistake due to incomplete information
  - Increased number of transactions exchanged between health and social care providers
  - NHS staff satisfaction / empowerment
  - Reduced hospital (re-) admissions

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 social care providers

- Interoperability benefits

- Improved clinical outcomes
- Greater innovation in healthcare and wider research and analysis

UK government/tax payers

- Interoperability benefits
  - Reduction in spending on unneccessary 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 work (e.g. due to reduced repetition of diagnostic tests)

Broader economy

- Interoperability benefits
  - Productivity gains from fewer patient sick days

Theory of Change assumptions

103. The TOC assumes that:

- The primary purpose of this regulatory change is to provide health and social care providers with access to (near) real-time longitudinal patient records captured in EPR and other clinical systems in a standardised format.

- The proposed legislation (Health and Care Act 2022: Part 2, 95) comes into effect:

- The passing of legislation under the HCA section 95 results in health and social care providers using specified open data architecture standards.

- 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 whole health and social care system. In addition, the ShCR will be in place by the time legislation comes into effect.

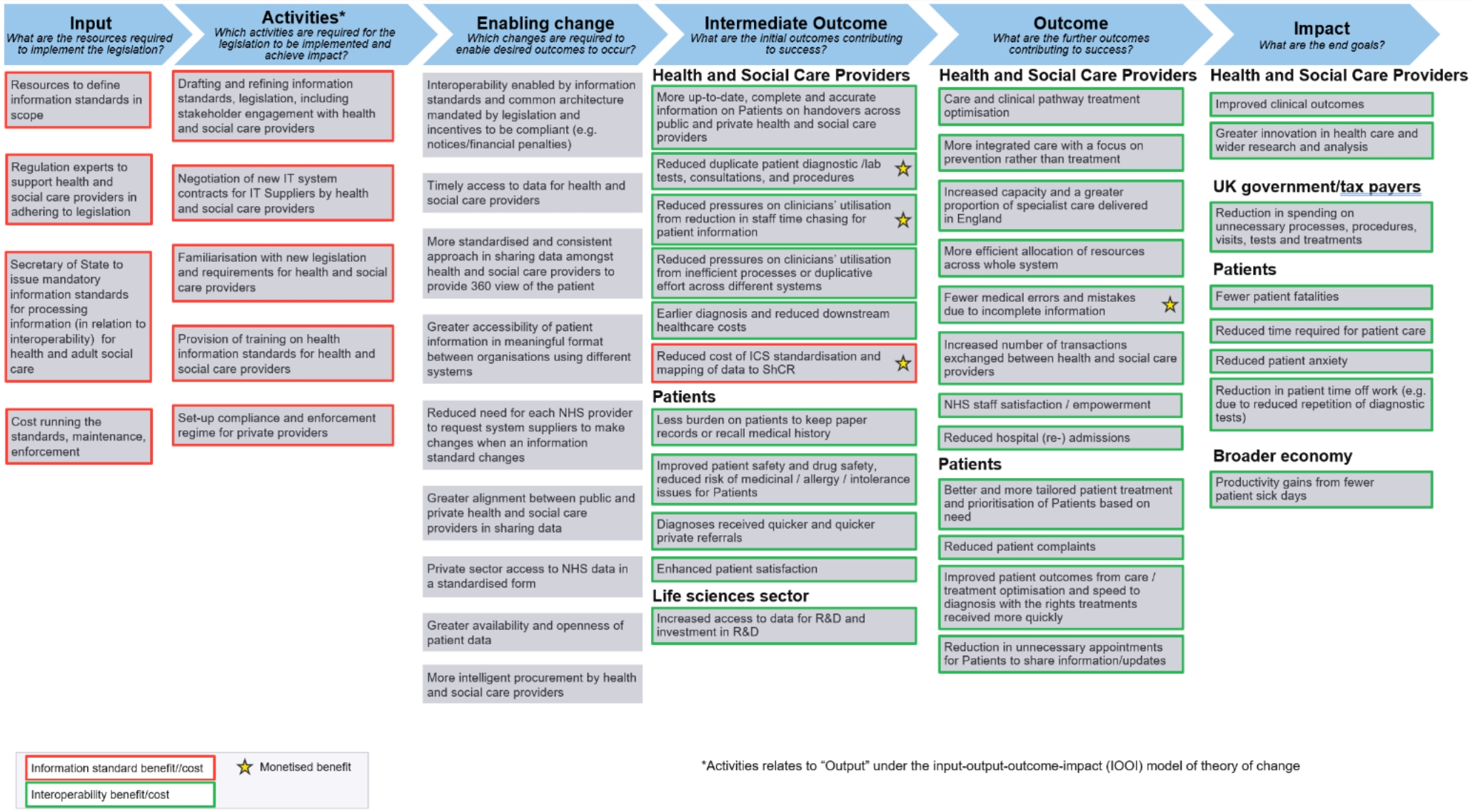
- The benefits and costs will be grouped into those related to common information standards alone and interoperability, as denoted by the green and red outlines in the diagram:

- (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



1.6 Approach to costing

103. 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 HCA 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

104. 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.

105. 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.

106. 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

107. 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.

108. 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

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

Ability to benchmark the costs to implement the standards

110. 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 £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

111. 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 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.

112. The full list of survey questions is at Appendix 4. 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.

113. 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.

114. 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

115. 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:

116. 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.

117. 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

118. 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.

119. 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.

- **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 HCA 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 HCA 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

120. 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.

121. 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.

122. 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.

123. 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.

124. 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

125. As stated in Section 1.8 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.

126. 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.

127. 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

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

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

129. 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

130. 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-Years50. This is in alignment with the Regulatory Policy Committee (RPC) appraisal guidance and the Green Book.51

131. This section begins by looking at the costs and benefits of implementing the legislation to mandate common information standards; 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 is followed by a qualitative analysis of the benefits where quantitative evidence is limited.

132. 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. 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.

133. To ensure interoperability, it is essential to have both the necessary IT infrastructure and the appropriate information standards. This impact assessment focuses specifically on the interoperability that can be achieved through the implementation of information standards, and not the additional infrastructure costs needed to fully deliver interoperability. These infrastructure costs have been accounted for in the budget of the Frontline Digitisation: Connecting Care Records Programme (Phase 1). An internal business case has been submitted to secure the agreed funding required to complete this initiative, with approval expected by August 2024. Consequently, 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

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45 As per Green Book guidance- The Green Book (publishing.service.gov.uk)

51 https://assets.publishing.service.gov.uk/media/5f71e1ace90e0747c084297b/RPC_case_histories_-_appraisal_periods_Sep_20.pdf

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.

134. 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]

- To achieve the benefits of interoperability, there is a critical dependency 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.

135. 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

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

137. 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.

138. These contributory risks include:
    - Procurement risks: the complexity of contract structure and contractor capabilities
    - Project specific risk: the degree of innovation and environmental impacts

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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)

- Client specific risks: inadequacy of the business case and poor project intelligence
- External influences: legislation / regulations and technology

139. 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

140. 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

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

142. In accordance with RPC guidance, all but one of the costs included in this Impact Assessment are **direct costs**. The indirect costs relate to familiarisation costs incurred by IT suppliers to understand the legislation. This is classed as indirect as it is not an unavoidable cost.

143. The primary costs are expected to arise from the need for health and social care providers to update their data, processes, and systems to conform to the information standards. Additional costs will also be incurred to train employees on these new systems and information standards, with some cost incurred across all stakeholders related to familiarisation. Costs will also be incurred by a central body relating to monitoring and enforcing compliance with the HCA legislation in England.

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

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

Cost Type	**Direct or Indirect cost**	**Total cost**
Familiarisation cost (IT supplier)	Indirect	£19,493
Familiarisation cost (health and social care providers)	Direct	£1,224,165
Training cost	Direct	£15,813,025
Information standards system update cost	Direct	£44,059,305
Compliance monitoring and enforcement cost	Direct	£26,870,165
Total	Direct and Indirect	£87,986,152

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

Modelling size groupings

146. 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 5.2. For ease of modelling and because of the data that was collected, these modelling size classifications differ to the size classifications in the Small and micro business assessment (SAMBA).

Option 2 (preferred option) – monetary costs

147. The categories of monetised costs are outlined below. Appendix 1, section 5.1 provides further detail on the method of calculating the costs and the evidence that is used.

a. Familiarisation costs

148. As a result of enacting the legislation, private and public sector stakeholders will incur up-front familiarisation costs to understand the new guidance and its implications. Costs will be incurred by: IT suppliers (indirect); private and public hospitals; and private and public social care providers to understand the new guidance.

149. GPs are not anticipated to bear any costs familiarising themselves with the standards. The reason is that central NHSE budgets shoulder and steer the procurement of systems for GPs[54,55]. As a result, GPs are not expected to be required to spend time familiarising themselves with the standards. Instead, they will only incur costs related to system training, as detailed below.

150. To estimate these costs, 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 HCA in the type of regulation. The incurred familiarisation costs outlined in this review have been used as an estimate for potential costs for this implementation. Based on this review, the time required for each of these stakeholder groups to familiarise themselves with the legislation has been estimated and multiplied by an hourly cost rate to estimate the total cost. IT suppliers are expected to require more time familiarising with the standards as they are likely to require legal support to familiarise with both the guidance and legislation. They will need to spend on average 18 hours[56] familiarising with both the guidance and legislation, with 9 of these hours focussed on legal support and the remaining 9 by IT staff. Whereas health and social care providers will need to spend 3 hours[57] familiarising with the guidance and will not require legal support. Time

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54 This is assumption is based on the plans of the GP IT Futures systems and services programme - GP IT Futures systems and services - NHS England Digital

55 Further confirmed during conversations with NHSE officials.

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

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

for familiarisation will be required for each guidance note issued (for groups of standards released together). There will be 36 hours required in total per IT supplier and 6 hours per health or social care provider.

151. 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%[58] to reflect the full cost of employment by worker (in line with guidance from the Regulatory Policy Committee[59]). 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.

152. Based on the evidence available and approach outlined in Appendix 2, the 10-year present value of familiarisation costs across stakeholders considered is estimated to be £1.2 million and will occur during year one of the roll-out.

b. Training costs

153. We expect there to be changes to how data needs to be processed by health and social care providers to conform with the new standards, alongside upskilling staff to use new systems or new functionalities in upgraded existing systems. This will incur training costs.

154. 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 24% of health and care providers will incur training costs because of HCA 22.

155. To estimate these training costs, we have used published workforce data[60] 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.

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

157. 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. For each of these assumptions, they have been converted to

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58 https://assets.publishing.service.gov.uk/media/5d679af2e5274a1719fdfd3d/RPC_short_guidance_note_-_Implementation_costs_August_2019.pdf

59 https://assets.publishing.service.gov.uk/media/5d679af2e5274a1719fdfd3d/RPC_short_guidance_note_-_Implementation_costs_August_2019.pdf

60 NHS Workforce Statistics – October 2023 (including selected provisional statistics for November 2023) - NHS England Digital

the full cost of employment, based on the Regulatory Policy Committee guidance. The individual assumptions and cost rates used are detailed in Appendix 2.

158. Training on the standards will focus on improving awareness among clinical staff in public and private hospitals, as well as consultants at 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.

159. 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.

160. 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 £15.8 million, calculated by multiplying the number of individuals needing training in each group by the required training hours and the cost per hour for each individual. For more comprehensive information, please refer to Appendix 1.

c. Information standards related systems update

161. 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.

162. 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.

163. For GPs, as with clinical systems procurement[61], the budget for the system updates to comply with the information standards will be funded from central budgets, so many of these system update costs are reflected against NHSE. Laing and Buisson 2013/14 Healthcare Market Review identified that 6% of GPs operate entirely outside of the NHSE; the system update cost for these private GPs is therefore assumed not to be funded from central budgets.

164. For public and private social care providers, £8.2 million has been committed as part of the digitising social care fund[62] to help support providers onto electronic care plans. The costs

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

62 https://transform.england.nhs.uk/key-tools-and-info/adult-social-care-digital-transformation/digitising-social-care-fund/

reflected in this impact assessment are in addition to that and are the costs required to ensure those electronic care plans are compliant with information standards.

165. To estimate the cost of making the relevant updates to systems in relation to the information standards, we obtained data through the NHSE information standards and interoperability survey. The survey indicated that uplifts in cost were likely to be 15% of 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 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.

166. Based on the evidence available and approach outlined in Appendix 1. The 10-year present value for information standards related systems update costs across stakeholders is estimated to be £44.1 million and will occur across years, 2, 3 and 6 in line with the implementation of the standards.

d. Compliance monitoring and enforcement costs

167. NHSE or a similar body would incur costs relating to monitoring and enforcing compliance with the HCA 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 the HCA regulations. The compliance monitoring body would also need to allocate resources for regular assessments and audits to evaluate healthcare organisations' compliance with the legislation. Legal and regulatory experts may be required to provide guidance and oversight. 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 healthcare innovation.

168. For this RIA, we assume that a small regulatory body will suffice to enforce compliance with HCA 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 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.

169. 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.

170. 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.

171. On this basis, we assume that 52 FTEs will be required to implement HCA (Health and care providers). 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 cost of total employment 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%[63] to reflect the total cost of employment. It is them assumed that this cost is incurred annually over the ten-year period.

172. 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 health and social care providers is estimated to be £26.9 million. These costs represent annual recurring expenses that will persist throughout the 10-year period.

e. Penalty costs to businesses

173. This penal regime represents a potential cost to private health providers (including private hospitals, private GPs and private care providers). 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[64] states that when calculating the NPV, business NPV and EANDCB, you 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 HCA legislation

174. Benefits of full compliance and implementation of information standards are apportioned between HCA and DUA. This is based on the additional ICB compliance with information standards that is facilitated by each piece of legislation. This is outlined in table 9.

175. 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 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

63 https://assets.publishing.service.gov.uk/media/5d679af2e5274a1719fdfd3d/RPC_short_guidance_note_-_Implementation_costs_August_2019.pdf

64 Better Regulation Framework Manual (regulatoryreform.com)

- 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%

176. The measures under Option 2 deliver benefits by removing the time burden from local health and social care providers, reducing reliance on the disclosure and transfer of large datasets containing confidential patient information to third parties, and supporting the use of data for purposes beyond direct care while protecting patient privacy.

177. This section demonstrates why patients / citizens / 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.

Option 2 preferred option - Monetary benefits

178. The quantified 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.

179. 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.[65]

65 DHSC: DPDI Primary Impact Assessment

TABLE 10 - Option 2 benefits estimates over a ten-year period - at point of regional interoperability attributed to common information standards and HCA (£m, present value)

Benefit type	Measure	Direct or indirect benefit	Cash or non-cash releasing	Estimated £m benefit
A. Mapping and standardisation costs	Reduction in mapping and standardisation costs across relevant ICSs*	Direct	Cash releasing	6.8
B. Reduced duplicate tests / procedures	Cost savings from reduction in duplicate tests (diagnostic and lab tests)	Indirect	Cash releasing	20.4
C. Time saved accessing information	Value of time saving (patient record access)	Indirect	Non-cash releasing	9.9
D. Reduced medication errors and PSIs	D1. Reduction in cost of excess bed days (transition medication error reduction)	Indirect	Non-cash releasing	5.0
D. Reduced medication errors and PSIs	D2. Quality-Adjusted-Life- Years (QALY) value of prevented fatalities (transition medication error reduction)	Indirect	Non-cash releasing	3.3
D. Reduced medication errors and PSIs	D3. Reduction in cost of excess bed days (non- transition medication error reduction)	Indirect	Non-cash releasing	1.8
D. Reduced medication errors and PSIs	D4. QALY value of prevented fatalities (non- transition medication error reduction)	Indirect	Non-cash releasing	6.1
D. Reduced medication errors and PSIs	D5. Value of time saved reporting medication errors	Indirect	Non-cash releasing	3.6
D. Reduced medication errors and PSIs	D6. Reduction in reporting costs for patient safety incidents (PSIs)	Indirect	Non-cash releasing	49.4
All	All	Direct and Indirect	Cash releasing and non-cash releasing	106.4

180. Based on our calculations, and noting the underlying assumptions, we estimate the preferred option could generate benefits of £106.4 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 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 ICSs (cash-releasing):** Currently, without common information standards in place, there is a cost to relevant ICBs of employing contractors where these information standards are lacking, to standardise and convert data from individual EPRs or IT systems to be mapped to ShCRs. This cost could be eliminated with the implementation of common information standards. This cost is, on average £1.26 million[66] per ICS and is one-off and is 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 the evidence available and the approach outlined, the ten-year present value cost saving from standardisation and mapping costs, attributable to HCA is £6.8 million.

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 healthcare costs.

66 Information Standards and Interoperability Survey, NHS, Feb 2024

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, estimates that an average reduction in duplicate laboratory tests of 8.8%[69] can occur because 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 HCA.

Based on the evidence available and approach outlined, the ten-year present value cost saving from reduced duplicate tests and procedures, attributable to information standards and HCA is estimated to be £20.4 million.

C. **Value of time saving (patient record access):** Working with standardised data and interoperable systems would save staff time due to quicker and more efficient access to patient data. 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 would 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 estimate up for the estimated number of patient accesses across England[73], it is estimated that the ten-year

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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 A preliminary look at duplicate testing associated with lack of electronic health record interoperability for transferred patients - PMC (nih.gov)

70 EUR-Lex - 52022SC0131 - EN - EUR-Lex (europa.eu)

71 2_National_schedule_of_NHS_costs_FY21-22_v3.xlsx (live.com

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 appointments (124.5 million) and A&E attendances in a year (26 million), source: Hospital Outpatient Activity 2022-23 - NHS Digital; https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.england.nhs.uk%2Fstatistics%2Fwp-content%2Fuploads%2Fsites%2F2%2F2023%2F05%2FMarch-2023-AE-by-provider-D6Ni9-revised-110523.xls&wdOrigin=BROWSELINK

present value of staff time saved attributable to regional interoperability and information standards under HCA is £9.9 million, based on the average NHS staff salary per minute of £0.37[74].

D. **D1 and D3. Reduction in excess cost of 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, and by ensuring clinicians and carers have the data they need on patients during transfers, discharges and referrals.[75] Also, enhancing patient safety can mitigate adverse drug reactions by minimising the risk of medication errors and overprescribing. This would 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%[76] 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.

   The impact of reducing these medication errors is twofold: it is estimated to result in 14,275 fewer inpatient care days and save approximately £6.59 million annually[77]. 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.

   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 HCA is £5.0 million. (D1)

   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.[78] 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

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74 https://digital.nhs.uk/data-and-information/publications/statistical/nhs-staff-earnings-estimates/september-2023-provisional-statistics

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

76 Meds_Interoperability_full_report_Elliott_et_al_2023.pdf (manchester.ac.uk)

77 Meds_Interoperability_full_report_Elliott_et_al_2023.pdf (manchester.ac.uk)

78 EUR-Lex - 52022SC0131 - EN - EUR-Lex (europa.eu)

cost saving from prevented excess bed days from non-transition medication errors is estimated to be £5.1 million per year, with an assumed reduction in 80 deaths – this is based on a reduction in number of severe and avoidable non-transition medication errors.[79]

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 HCA is £1.8 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): 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.

A study that considered an electronic reporting system, found that the average time spent reporting a medication error is 4 minutes per error.[80] 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 (this is calculated based on applying a 6% reduction in non-transition medication errors per annum (in line with evidence from Estonia)[81] to the total number of non-transition errors per year (100.7 million)[82], and also adding a 0.7 million reduction in transition errors)[83], the estimated value of time saving is £10.1 million nationally each year. The ten-year present value benefit attributable to HCA is £3.6 million.

In the year to June 2022, there were 2.5 million patient safety incidents in England.[84] 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

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79 Calculated based on number of patient errors by category and proportion of severe and avoidable errors across prescription, monitoring and administration errors. Source: https://qualitysafety.bmj.com/content/30/2/96.long#DC1

80 Prescribing error reporting in primary care: a narrative synthesis systematic review - PMC (nih.gov)

81 (EUR-Lex - 52022SC0131 - EN - EUR-Lex (europa.eu)).

82 https://qualitysafety.bmj.com/content/30/2/96.long#DC1

83 University of Manchester study -(PDF) Estimating the impact of enabling NHS information systems to share patients' medicines information digitally (researchgate.net))

84 https://www.england.nhs.uk/publication/national-patient-safety-incident-reports-up-to-june-2022/

interoperability.[85] In addition, the average cost per incident form is £337.16 – hence there is a potential cost saving of up to £2 million per year from the reduction in patient safety incidents from improved regional interoperability facilitated by HCA. It is estimated that the ten-year present value benefit attributable to regional interoperability and information standards under HCA is £49.4 million.

The value of prevented fatalities from transition and non-transition 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[86], DHSC data on fatalities by age due to adverse drug reactions (ADRs), average life expectancy[87], and using the Green Book 2022 estimates of a QALY (£70,000), which is adjusted for each age group.[88] The benefit is further apportioned based on assumptions outlined below to attribute to information standards and HCA.

Based on this evidence, 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 HCA is £9.5 million, this benefit is discounted at a 1.5% discount rate in-line with Green Book guidance for QALY health effects.[89]

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.

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85 The Impact of Electronic Health Record Interoperability on Safety and Quality of Care in High-Income Countries: Systematic Review - PMC (nih.gov)

86 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?_tp=eyJjb250ZXh0Ijp7ImZpcnN0UGFnZSI6Il9kaXJlY3QiLCJwYWdlIjoiX2RpcmVjdCJ9fQ); 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.

87 National life tables – life expectancy in the UK - Office for National Statistics (ons.gov.uk)

88 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); nice.org.uk/guidance/ng90/documents/economic-report-3

89 The Green Book (publishing.service.gov.uk)

Implementation approach for information standards in scope under legislation

- The roll-out of standards which are in scope for the legislation will be phased in over the next 10 years, prioritising standards considered most important 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.

- 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.

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

    i) 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.

    ii) 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.

    iii) The majority of 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 be accrued in line with the rate of core standards implementation and thus fully achieved by year 4, with recurring benefits occurring each year.

Assumptions for attributing benefits to legislating information standards

- 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 HCA legislation.

    - **Regional interoperability benefits**: According to evidence from NHSE, at least 82%[90] of health and social care provision occurs within a patient's home region (even home ICS). 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

90 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% of care is within a region and will benefit from regional interoperability.

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 immediate objective of this intervention, it is inferred 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 of these standards, such as improved interoperability, can only be harnessed if the underlying systems and technology are adequate 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 ICSs not currently compliant**: Based on information from the Information Standards and Interoperability Survey, 58%[91] 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 ICSs. This sub-set of ICSs will accrue the benefits of implementing information standards, as there will not be additional benefits for ICSs who already comply with information standards.

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

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

Results

186. Based on applying a 3.5% discount factor to the costs and benefits over 10 years (or 1.5% for the QALY benefit)[92], the net present value of Option 2 is £18.4 million, which is equivalent to a benefit-cost ratio of 1.21. Refer to Appendix 1, section 5.3 for annual profile of costs and benefits.

187. It is important to review these results in the context of the broader cost benefit analyses across all the ongoing initiatives in the health and social care ecosystem. Firstly, these provisions from the HCA 2022 will be a key enabler for the Secretary of State's vision for

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

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

health and social care to have national open standards for data and interoperability[93] and, secondly, they help 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.

188. We expect the secondary legislation on health and social care providers will provide significant value for money as despite the costs of changing systems, and costs to NHSE establishing and running processes, there are significant benefits and longer-term efficiencies expected with limited risk. Several benefits have also not been monetised within the NPV, which nevertheless still generate value.

189. Enacting the HCA legislation is expected to unlock benefits in a relatively shorter period (compared to other options such as issuing guidance and education campaigns to health and social care providers) as compliance with standards would be mandatory. This time to comply is illustrated when we consider the adoption of the NHS number across clinical systems, an information standard (ISB 0149) published under the powers in the Health and Social Care Act 2012. A recent NHSE information standards and interoperability survey illustrated that despite the longstanding requirement to have regard to this standard, only c.83% health and social care providers comply in their implemented clinical system.[94] Legislation of standards such as NHS number in the HCA will increase compliance. The survey also highlighted that other core NHS standards, that are currently covered NHS guidance or principles, only showed a c.42% compliance amongst health and social care providers – these included SNOMED CT, ICD-10/11, dm+d, OPCS-4 and NHSE Data Dictionary Vocabularies and HL7 Fast Healthcare Interoperability Resources (FHIR) – UK CORE.

190. Other options, such as issuing guidance and information or education campaigns to health and social care providers, would have a relatively lower value for money as there is low cost of implementation, but reduced benefits relative to legislation.

191. Moreover, secondary legislation of information standards under HCA will be a key enabler of the overarching NHSE policy objectives i.e., that all NHSE clinical systems are interoperable. Secondary legislation of information standards will be an important contributor and enabler to other NHSE initiatives such as the National Record Locator system upgrade; the National Shared Care Record System roll-out and adoption; future legislation of information standards on IT suppliers, and the Federated Data Platform.

192. Further, secondary legislation of information standards will be the underpinning event that unlocks the interdependencies between these different initiatives and the whole system benefits will only be realised through all the investments coming together to work in synergy, where information standards act as the pan-initiative enabler. Other non-legislative options would take a long time to realise objectives, due to these measures (e.g., information campaigns) being non-mandatory and providers incurring costs to change suppliers in the short-term, therefore they may delay implementation until contracts expire and can be renegotiated, or simply act with less urgency on implementing the standards and do this over a longer timeframe.

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93 Department of Health and Social Care. The future of healthcare: our vision for digital, data and technology in health and care. Published 17 October 2018 [Accessed May 2021]

94 ISB 0149 NHS Number - NHS Digital

Representing the social value of the preferred option

193. Where policies have impacts on NHS budgets, it is necessary to consider the impact the policy will have on funding available elsewhere and in turn 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.

194. 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.

195. It is estimated that £15,00095 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.[96]

196. Further to the NPV outlined above, we have calculated the Net Present Social Value (NPSV), which considers the social value of any foregone health benefits through use of NHS budgets and the 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

197. Spending by NHS hospitals, NHS GPs or indeed the NHSE impacts NHS budgets. This spending amounts to £77.7m for the preferred option (in cash terms, over 10-year period, undiscounted). When considering the QALYs displaced from this spending, the social cost of this spending is £362.4m, over a 10-year period.

198. 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 £18.0m (over 10-year period, undiscounted). These costs are not deemed to have an opportunity cost for the NHS and hence remain in cash terms.

199. The total social present value cost is estimated to be £365.2m (over 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

200. 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

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95 *Points to note when preparing impact assessments and submitting to the Senior Review Committee – March 2022*

96 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); nice.org.uk/guidance/ng90/documents/economic-report-3

201. These benefits amount to £31.8m in cash terms (over a 10-year period, undiscounted), and £148.3m in social value (over a 10-year period, undiscounted) based on associated QALYs gained.

202. Other benefits are non-cash releasing and hence do not impact NHS budgets – these benefits remain valued in cash terms, and amount to £94.1m (over a 10-year period, undiscounted).

203. The total social present value benefit is estimated to be £217.7m (over a 10-year period). This includes the social benefit (based on QALYs gained) for cash-releasing benefits, and 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)

204. The NPSV is estimated to be -£147.5m and the BCR is 0.60, when considering the opportunity cost and benefits from impact on NHS budgets. This is summarised below:

Table 11: NPSV and BCR

Item	Cash value (£m)	Social value (£m)
PV Cost	88.0	365.2
PV Benefits	106.4	217.7
NPV / NPSV	18.4	--147.5
BCR	1.21	0.60

205. Although the NPSV is negative and there may be opportunity costs for the NHS in the short term, the proposed intervention is expected to establish a solid foundation for future improvements in healthcare delivery. It will facilitate better coordination among different parts of the health and social care system. This foundational work is anticipated to lead to more effective and efficient use of resources in the long term, which could result in cost savings and improvement in patient safety and outcomes.

Option 4 (alternative option) cost and benefits

206. This section considers the benefits and costs of Option 4 (***Issuance of guidance and information, education campaigns***).

207. Option 4 is non-legislative, and centred on issuing guidance and information on best practice for standardised information; however, it does not mandate health and social care providers to comply.

208. According to the Information Standards and Interoperability Survey, 90% of health and social care providers understand that stated interoperability and standardisation lead to improved care outcomes and efficient operational planning. Therefore, the remaining 10% would benefit from the educational campaign to understand the advantages of standards and interoperability. A conservative assumption is that half[97] of this population (5%) will

97 Conservative assumption that 50% will be swayed by the education campaigns that are targeted at them. This assumption was validated in conservations with NHSE

voluntarily adopt information standards after receiving education and information through the campaigns.

209. Therefore, it is assumed there will be 5% additional compliance with information standards facilitated by Option 4 (this equates to 2 additional ICSs adopting standards under this option). This compares with 14%[98] additional compliance across ICSs under Option 2 (this equates to 6 ICSs, in addition to the 42%[99] of providers who currently already comply with standards) – i.e. Option 4 will support achieving an overall 47% compliance rate with information standards across all ICSs (47% is derived by summing the 5% additional compliance with the 42%[100] who already comply).

210. In addition, adoption of information standards under Option 4 will also be slower than legislation under the preferred option, and timing is expected to be dependent on the expiry of contracts, as health and social care providers are unlikely to incur additional costs to change systems mid-contract under a non-legislative measure. 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.[101] As well as a slower implementation approach than the preferred option, due to Option 4 being non-legislative.

Costs

211. For the alternative option, we estimate that familiarisation, training information standards upgrade, and awareness campaign costs will be incurred for the additional 2 ICSs that adopt information standards under Option 4. This equates to 33%[102] of the undiscounted cost of Option 2 in line with the lower adoption of standards within the ten-year period. In this option, adoption of the information standards will be slower compared with the preferred option and the cost profile has been designed to reflect that slower pace of adoption.

212. We estimate the costs of the alternative option are £23.3 million in undiscounted current prices, and in present value terms are £21.4 million over ten years.

Benefits

213. There will be the same benefits categories under the alternative option compared to (Option 2) legislation under HCA; however, it is expected that the benefits of information standards and interoperability will be achieved at a slower pace. 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 ICSs adopting information standards. Hence due to a lower proportion of ICSs complying with the guidance (2 ICSs complying under Option 4, compared to 6 under

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98 As outlined in Table 7

99 As outlined in Table 7

100 As outlined in Table 7

101 Based on analysis on contracts from https://www.contractfinderpro.com/

102 Proportion of cost is based on ratio of 2 additional ICSs complying under Option 4, compared to 6 under Option 2

Option 2), the total benefits are estimated to be 6.7% of Option 2 benefits – this is calculated scaling benefits down with the reduction in the number of links between ICSs, between Option 2 and Option 4[103]. The information standards benefits (savings in mapping and standardisation costs) are assumed to linearly reduce based on the reduction number of ICSs complying.[104] For the alternative option, benefits are not forecast to occur until year 5, and will slowly ramp up between years 5 and 10.

214. We estimate the alternative option will generate benefits of £9.9 million in undiscounted current prices and in present value terms are £8.0 million over ten years.

Results

215. The net present value of Option 4 is estimated to be -£13.4 million, which is equivalent to a benefit-cost ratio of 0.37.

Comparison of options

216. 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 NPV and BCR of all options

	Option 1 – Do nothing	Option 2 – Preferred option	Option 4 – Alternative option
NPV (£m)	-	18.4	-13.4
BCR	-	1.21	0.37

Non-monetary benefits

217. 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. These benefits are outlined below:

i. **Earlier diagnosis and reduced downstream costs:** Faster diagnoses and care, access to innovative treatments through real-time data availability and evidence-based clinical decision making by medical practitioners. The earlier diagnosis reduces the risk of disease progression and ultimately downstream costs of treatment.

   Interoperability expedites diagnosis and care by enabling faster access to comprehensive patient data and real-time collaboration among healthcare providers. Interoperable systems can integrate clinical decision support tools that provide real-time guidance to healthcare providers at the point of care, resulting in faster and more

103 A link between an ICS relates to the number of connections, i.e. 2 ICSs which are interoperable will have two links (from ICS A to B, and ICS B to A). Based on compliance of 6 additional ICSs under Option 2, there would be 30 links between these ICSs. 2

104 In line with the reduction in costs

accurate decisions and treatment recommendations[105]. Interoperability facilitates the use of telemedicine and remote monitoring technologies[106], allowing patients to connect with healthcare providers virtually and receive timely evaluations and consultations without the need for in-person visits. This enables faster access to care, particularly for patients in remote or underserved areas, and reduces wait times for appointments. In addition, this improves the access to services within the health and social care sector. It aligns with the Secretary of State for Health and Social Care's objectives to deliver "faster, simpler, fairer access to care for patient".[107]

Overall, interoperability optimises the diagnostic process and accelerates care delivery which can potentially reduce downstream costs, as well as benefiting patients by reducing delays and improving outcomes. However, there may also be some potential disbenefits in terms of higher healthcare costs from hospital admissions or treatments from the increased prevalence of or earlier diagnosis, though this could result in better patient outcomes or better choice of treatment.

ii. **Care pathway optimisation:** Interoperability and information standards optimise patient care pathways by facilitating better communication, coordinated care transitions and standardised protocols across healthcare settings. Caregivers will have access to all the authorised information in real-time, regardless of the system they use or its source. This capability facilitates enhanced clinical decision-making by ensuring access to accurate and complete data.[108] Overall, these efforts improve care coordination, enhance patient experiences, and lead to better health outcomes.

iii. **Time saved on inefficient processes and duplicative efforts across systems:** The introduction of open data architecture standards and interoperability would reduce the need for duplicative efforts for staff on data entry across different systems. It also reduces time spent because of inconsistent standards in a region, resulting in time savings for staff – this would enable staff time to be utilised in a more efficient manner.

iv. **Improved integration of health and social care services in England:** Interoperability, coupled with information standards, plays a pivotal role in fostering seamless integration of health and social care services in England. By adhering to standardised information formats and protocols, interoperable systems ensure that health and social care staff have access to comprehensive patient records, medical history, and appointment details across different systems. This standardised approach facilitates efficient coordination of care, reduces the need for time-consuming communication between healthcare providers, and minimises the risk of failed home visits. Moreover, information standards ensure that data is structured and organised uniformly, allowing for more accurate and reliable exchange of information. This streamlined process not only enhances staff productivity and reduces expenses but also promotes patient safety by facilitating timely alerts and risk management strategies. Overall, the combination of interoperability and

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105 Development of an Interoperable and Easily Transferable Clinical Decision Support System Deployment Platform: System Design and Development Study - PubMed (nih.gov)

106 Impact of Electronic Health Record Interoperability on Telehealth Service Outcomes - PMC (nih.gov)

107 NHS England » Over 10,000 NHS pharmacies begin treating people for common conditions

108 Data Protection and Digital Information Bill: updated impact assessment (publishing.service.gov.uk)

information standards optimises the utilisation of health and social care resources and promotes better collaboration across various sectors, ultimately leading to improved outcomes for patients.

218. A regulatory provision can be considered to promote competition if it satisfies the following criteria[109]:

- 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.
- 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.

Based on above criteria, it is not expected that HCA legislation will impact competition amongst health and social care providers, as it is not a core purpose of the measure or impact incentives on health and social care providers.

219. Other non-monetary wider benefits are outlined in section 1.11.

1.7 Direct costs and benefits to business calculations

220. The direct costs to businesses the 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 £17.6 million (undiscounted). Outlined in Table 13 below are these costs per business group over a 10-year period.

221. All direct costs and benefits falling on 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 (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
IT suppliers	0.0
Private hospitals	13.8
Private social care providers	2.6
GPs (operating outside the NHS only)	1.2
Total	17.6

109 The Better Regulation Framework (publishing.service.gov.uk)

222. 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

223. 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

224. 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, i.e. England uses one set of information standards, and the devolved nations use different set of standards, then 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.

Policy risks

225. 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 provider non-compliance due to the inherent differences in the health and social care provider market

226. Whilst the health and social care provider market is largely composed of NHS organisations, the providers in the adult social care market (although commissioned by local authorities) are largely independent, autonomous enterprises. There is already a pronounced level of fragility in the adult social care provider market. The proposed measures, if not implemented with the inherent market differences in view, could be met with non-compliance, due to the costs associated with re-procuring from an accredited list of IT suppliers, placing an additional burden on care providers. To mitigate this risk, we intend to develop the implementation plan with stakeholder input to ensure that the plan is appropriate for the target market.

Implementation risks

227. 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.

228. 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

229. 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.

230. Constant diligence, awareness, and making sure that there is alignment and awareness of security issues will be required to mitigate such risks.[110]

231. Regarding patient consent and privacy, with enhanced interoperability among healthcare platforms, the risk of data circulating online without explicit consent increases.[111]

Analytical assumptions

232. 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 analysis (benefits)

233. To provide an indication of impact of sensitivity of the benefits of Option 2 to key assumptions, the analysis of financial benefits has considered the impact of varying a subset of assumptions on the NPV and BCR outcomes. This sensitivity analysis focuses on variations in the additional compliance of ICSs facilitated by HCA and the proportion of ICSs that do not already comply with information standards. These variables 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 HCA are not yet defined, the actual proportion of current compliance and the potential for additional compliance facilitated by HCA may vary.

234. Further to the cost-benefit analysis presented in section 1.6, the sensitivities have been modelled below:

i. *Additional compliance of ICSs facilitated by HCA*

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110 Data security remains a challenge as interoperability moves closer to reality | Lee Barrett (chiefhealthcareexecutive.com)

111 Healthcare Data Security | Navigating the Interplay between Innovation and Protection (telefonicatech.uk)

We have considered the impact on the overall NPV and BCR from a +/- 25% change in the level of additional compliance of ICSs with information standards facilitated by HCA. 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:

- High case – 17.5% additional compliance of ICSs attributed to HCA
- Base Case – 14% additional compliance of ICSs attributed to HCA
- Low Case – 10% additional compliance of ICSs attributed to HCA

To achieve a net present value (NPV) of zero, thus reaching the break-even point, an incremental compliance rate of at least 10.9% is necessary. This threshold for additional compliance is a conservative estimate, as the legislative framework is structured to promote compliance by implementing deterrents such as fines. Moreover, looking at historical examples, such as the 83%[112] 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 - Net present value (NPV) and Benefit-cost ratio (BCR) for HCA compliance sensitivity

Sensitivity Scenario	NPV HCA attribution (£m)	BCR HCA attribution
Low	-5.9	0.93
Base	18.4	1.21
High	38.3	1.43

ii. *Proportion of ICSs not currently complying with information standards*

We have considered the impact on the overall NPV and BCR from a +/- 15% change in the assumption of proportion of ICSs not already complying with information standards, and therefore varying the incremental benefit from HCA and additional compliance uplift. The base level of current compliance is based on core information standards. Nonetheless, this rate may fluctuate depending on the specific standards targeted by the legislation. A15% sensitivity adjustment was selected as it accounts for the potential variability in compliance levels and is substantial enough to be meaningful.

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

The results of the sensitivity are outlined below. We have also determined that the minimum proportion of ICSs not already complying with information standards would need to be 39% for the NPV to break-even, resulting in a nil NPV. Given that current compliance levels are informed by a survey of providers[113] and align with core information standards expected to be

112 Based on Information Standards and Interoperability Survey, NHS, Feb 2024

113 Based on Information Standards and Interoperability Survey, NHS, Feb 2024

mandated by legislation, there is a reasonable level of confidence that baseline compliance will not fall below 39%.

TABLE 15 - Net present value (NPV) and Benefit-cost ratio (BCR) for ICS current compliance

Sensitivity Scenario	NPV ICS current compliance (£m)	BCR current compliance
Low	3.81	1.05
Base	18.4	1.21
High	32.4	1.33

Sensitivity analysis (costs)

235. To provide an indication of impact of sensitivity of the costs of Option 2 to key assumptions, 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%. 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.

236. The results of the sensitivity are outlined below. It has been calculated that a cost increase of 20.9% 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 20.9% increase is considered minimal.

TABLE 16 - Net present value (NPV) and Benefit-cost ratio (BCR) cost sensitivities

Sensitivity scenario	NPV ICS maturity (£m)	BCR ICS maturity
Low	5.22	1.05
Base	18.4	1.21
High	31.61	1.42

Conclusion on sensitivity analyses

237. Based on this analysis, we conclude that the NPV and BCR of the preferred option 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

238. 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.

239. 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 pinpointed 3,901 small businesses, which include 3,886 private social care providers, 12 private GP practices, and 3 IT suppliers.

240. 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.

241. Table 17 and Table 18 show the cost to small and micro businesses by type of organisation and cost type.

TABLE 17 - Cost to micro businesses (undiscounted)

Organisation	Cost type	Aggregate cost	Implementation cost per organisation	Annual cost per organisation
GPs	Training costs	£69,551	£800	£0
Private social care providers	Familiarisation costs	£165,789	£174	£0
Private social care providers	Information standards related system updates	£88,242	£660	£0

242. Clinician in micro-GP practices will be required to undergo training to use the new systems as updated. This cost, at £800 per organisation (average), 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[114], with the total number of hours varying by headcount at the GP. Only 6%[115] 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.

243. We estimate that micro private social care providers will incur familiarisation costs of £174 per organisation and information standards related systems update costs of £660 per organisation.

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

Organisation	Cost type	Aggregate cost	Implementation cost per organisation	Annual cost per organisation
IT suppliers	Familiarisation costs	£1,562	£521	£0
GPs	Training costs	£8,207	£2,807	£0
Private social care providers	Familiarisation costs	£674,614	£174	£0
Private social care providers	Information standards related systems update	£495,242	£910	£0

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

115 Laing and Buisson 2013/14 Healthcare Market Review

244. We estimate that small IT suppliers will incur indirect costs of familiarisation. These costs will be £521 per IT supplier and will be incurred by suppliers to help understand the guidance.

245. 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[116]. GPs that fit within the small business classification have a larger headcount than those in the micro definition, hence why the cost per organisation, at £2,807, is higher.

246. Small private social care providers will incur an estimated cost of familiarisation of £174 per organisation and 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

247. 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.

248. 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 proposals will make this a consistent duty across public and private providers of health and adult social care services. Exemptions for SMBs has been considered, but ruled out on the basis that exemption of any size business would undermine the policy objective.

249. 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 are paid for centrally from the Department of Health and Social Care budgets with no cost implications

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

for GP surgeries[117]. Similarly, costs for social care providers will be mitigated by the social care fund for digitisation being provided by NHSE, which is providing £8.2 million to support a pilot to support the digitisation of social care[118]. The programme is designed to support ICSs to scale up the solutions that have the biggest impact.

250. 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 providers of any size in the market.

251. More widely, the policy has been designed with consideration of SMBs and we expect that SMBs 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.

1.10 Impact on medium-sized business

252. 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 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
Private social care providers	Familiarisation costs	£193,739	£174	£0
Private social care providers	Information standards related systems update	£441,391	£2,825	£0

253. We estimate that all medium-sized IT suppliers will incur indirect familiarisation costs of £521 per organisation. and will be incurred by suppliers to help understand the guidance.

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

118 Digitising social care fund - Digitising Social Care - NHS Transformation Directorate (england.nhs.uk)

254. We estimate medium sized private social care providers will incur an estimated monetary implementation cost of £2,825, per organisation, to update their systems to make them information standards compliant as new standards are mandated over a ten-year period. As pointed out previously NHSE digitisation support will mitigate the burden on care providers. They will also incur familiarisation costs of £174, per organisation, that relate to 6 hours of an individual's time being spent per provider to familiarise with the guidance.

Exemptions

255. 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).

256. As with SMBs, costs for social care providers will be mitigated by the social care fund for digitisation being provided by NHSE.

Disproportionate burden

257. The burden of familiarisation costs will be mitigated by the issuance of guidance notes. Like SMBs, medium sized businesses will not be required to understand the legislation beyond reviewing circulars to be issued by the NHSE. Circulars of this nature are routinely issued and would normally take an employee a short period of time to read and understand its implications. This is particularly helpful for smaller businesses, reducing their need to buy legal and regulatory expert services to help navigate the familiarisation requirements.

1.11 Wider impacts (consider the impacts of your proposals)

Below is an outline of the wider impacts, which can be achieved through the adoption of information standards and the wider interoperability facilitated through legislation. 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. As described in the theory of change:

i. **Research and innovation benefits:** Adopting common standards for healthcare data is a fundamental requirement to enable and enhance research. Creation of a defined minimum data set that builds on existing work by the Care Quality Commission and Professional Records Standards Body will help to drive a more standardised approach to data collection so that one collection can be shared with multiple stakeholders.[119] A more consistent set of information standards brings substantial benefits for researchers, such as being able to compare and analyse datasets more quickly and easily and at a greater scale. That research, in turn, has the potential to uncover greater insights and enable discoveries that will improve people's lives. Furthermore, they support data discovery and interoperability, allowing data to be compared, aggregated, and synthesized. As a result, they can support data-driven insights and solutions for decision making.

   It is expected that there will be better data available to support the development of new treatments to improve the NHS, making data captured for care available for clinical

119 Data Protection and Digital Information Bill: updated impact assessment (publishing.service.gov.uk)

research, and publish, as open data, aggregate metrics about NHS performance and services. In addition, data can flow between care settings, and between health and social care, both for direct care, and for population health, system management and research. This will enable care in England to be better integrated and prevention focused, rather than on treating disease.[120]

ii. **Improved patient satisfaction and empowerment:** Interoperability provides opportunities to empower citizens and patients with information and tools to support their health, care and wellbeing. This is by bringing people closer to their care records by giving them access to their own information when clinically appropriate to do so. People have transparency in the data that has been captured, and confidence in how their data is used by understanding the safeguards in place.[121]

There is potential for improved patient satisfaction, through the reduction in unnecessary and duplicate tests and appointments (as outlined previously), in addition patients experience less burden in keeping paper records or recalling medical history as their information is readily available and easily accessible to healthcare providers.

In addition, with open data it will be possible to manage waiting lists nationally, allocating patients to alternative settings[122]. This would have the benefit of reducing waiting lists for patents which can speed up patient care and treatment and potentially lead to improved clinical outcomes. As outlined above, improved staff productivity, quicker decision-making from staff, and improved clinical pathways for patients can also result in quicker diagnosis and referrals as well as improved patient outcomes and reduced patient anxiety.

iii. **Wider productivity gains and taxpayer benefits:** As outlined previously, interoperability and information standards in healthcare contributes to better patient outcomes, more efficient care and a reduction in waiting times or unnecessary procedures and appointments. This can lead to reduced time off work through quicker access to care, promoting preventive care, and empowering individuals to manage their health more effectively. This results in less reliance on sickness benefits, fewer absences from work, and a more productive and resilient workforce, ultimately benefiting the economy.

iv. **Broader environmental benefits**: Interoperability can support a greener health and social care system. Data would be held in a cloud-based environment secured by the NHS/DHSC, with access to the data, controlled by an NHS/DHSC/adult social care body – this would reduce the data centre footprint and reduce the need for travel or reliance on buildings and paper storage, as data is accessible across systems anytime or

120 Data Protection and Digital Information Bill: updated impact assessment (publishing.service.gov.uk)

121 Data Protection and Digital Information Bill: updated impact assessment (publishing.service.gov.uk)

122 Data Protection and Digital Information Bill: updated impact assessment (publishing.service.gov.uk)

anywhere.[123] It is not expected that there will be any distributional impacts from the HCA legislation.

1.12. A summary of the potential trade implications of measure[124]

258. 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 healthcare 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.

259. 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 Business and Trade to fully assess any implications for international trade.

1.13. Monitoring and evaluation

260. Effective evaluation practice is needed to demonstrate the impact of this legislation. HM Treasury's latest Green Book states that "monitoring and evaluation of all proposals should be […] an integral part of all proposed interventions".[125]

261. 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.

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

263. It would be reasonable to perform a Post Implementation Review (PIR)[126] within 5 years of implementation. This will include having to carry out two types of proportionate evaluations:

    a) 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.

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123 Data Protection and Digital Information Bill: updated impact assessment (publishing.service.gov.uk)

124 Health and Care Act 2022 Core Measures Impact Assessment (publishing.service.gov.uk)

125 The Green Book (2022) - GOV.UK (www.gov.uk)

126 Producing post-implementation reviews: principles of best practice - GOV.UK (www.gov.uk)

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

264. 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[127], offers a structured approach to understanding 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.

265. 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/post intervention)	When and frequency of evaluation
Interoperability enabled by information standards	Proportion of ICSs complying with information standards set out by the legislation	2027 and assesses annually thereafter
Reduction in spending on unnecessary processes, procedures, visits, tests and treatments	Spending on mapping and standardisation of data per ICS Data on waiting time for appointments, diagnostic tests and procedures Number of diagnostic tests and procedures carried out Patient safety incidence reporting costs	2027 and annually thereafter
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

127 HMT_Magenta_Book.pdf (publishing.service.gov.uk)

266. 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.

267. To ensure accurate attribution of the HCA 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. Then also compare this data with the baseline and counterfactual to assess impact, using statistical methods to isolate the HCA's effect. This analysis could also be supplemented with qualitative insights from stakeholder interviews and case studies.

268. We acknowledge that the effectiveness of this monitoring and evaluation strategy relies on surveying ICSs 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.

TABLE 21 - Current assumptions and proposed monitoring and evaluation approach[128]

Impacts	**Current assumptions**	**Proposed monitoring and evaluation approach**
Interoperability enabled by information standards	Proportion of ICSs complying with information standards set out by the legislation	Currently this is measured based on the Information Standards and Interoperability Survey, NHS, Feb 2024. We would propose this impact measure is monitored based on compliance data from the compliance and monitoring function.
Reduction in spending on unnecessary processes, procedures, visits, tests and treatments	*Standardisation and mapping cost assumptions:* Average spend on mapping and standardising per ICS: £1.26 million Percentage of ICSs 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 ICS.	*Standardisation and mapping cost assumptions*: Since the survey informing this IA sampled health and social care providers, we recommend distributing a survey to each ICS 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 ICSs 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.

	In addition, the survey assessed the proportion of health and social care providers who comply with six existing non-mandated information standards, and an assumption was made that this proportion of ICSs do not incur mapping costs. *Diagnostic tests and procedures assumptions:* Assumptions have been made to estimate the proportion of duplicate lab /imaging tests; and the associated reduction due to interoperability benefits as outlined in Section 1.6.	*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 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 healthcare 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.

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

Appendix 1 – Cost and benefit estimates

1.1 Detailed cost and benefit estimates and annual profiles

1. This appendix provides further detail on assumptions and 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 private and public sector stakeholders will incur up front familiarisation costs to understand the new guidance and its implications. These costs will be incurred by IT suppliers; private and public hospitals; and private and public social care providers (including local authorities).

3. Familiarisation costs have been estimated based on the number of hours required for each of the stakeholder groups to familiarise themselves with the legislation and an hourly cost rate associated with that time. This assumption has been derived from secondary research based on the time required to read similar guidance notes. 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). 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.

4. Under HCA, it is assumed that familiarisation costs will need to be incurred by IT suppliers and health and social care providers.

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:** Across all organisation types, 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%[129] to reflect the full cost of employment by worker. This assumption is in line with guidance from the Regulatory Policy Committee. 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:** For a batch of standards released and guidance issued, IT suppliers will need to spend 18 hours[130] familiarising with both the guidance and legislation, with 9 of these hours focussed on legal support and the remaining 9 by IT staff.[131] Health and social care providers will need to spend 3 hours familiarising with the guidance and will not require legal support.[132] Time spent familiarising is based on evidence from a Post Implementation Review for a similar regulation**.** The familiarisation costs will be incurred with each batch of standards released ahead of implementation, so IT suppliers and health and

social care providers 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) and 6 hours per health and social care provider (3 hours per guidance released) to familiarise with the legislation. A further 10% optimism bias is also added to this cost.

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129 https://assets.publishing.service.gov.uk/media/5d679af2e5274a1719fdfd3d/RPC_short_guidance_note_-_Implementation_costs_August_2019.pdf

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

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

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

TABLE 22 - Familiarisation costs (current prices and undiscounted)[133],[134]

Organisation	Modelling size grouping	Number of organisations	Hours required	Cost rate	Total cost
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
Private hospitals	Large	0	6	£26.30	£0
Private hospitals	Medium	172	6	£26.30	£29,859
Private hospitals	Small	0	6	£26.30	£0
Private hospitals	**All**	172	6	£26.30	£29,859
NHS hospitals	Large	56	6	£26.30	£9,722
NHS hospitals	Medium	107	6	£26.30	£18,575
NHS hospitals	Small	48	6	£26.30	£8,333
NHS hospitals	**All**	211	6	£26.30	£36,630
Private social care providers	Large	132	6	£26.30	£22,915
Private social care providers	Medium	1,116	6	£26.30	£193,739
Private social care providers	Small	4,841	6	£26.30	£840,403
Private social care providers	**All**	6,089	6	£26.30	£1,057,057
Public social care providers	Large	18	6	£26.30	£3,125

Public social care providers	Medium	207	6	£26.30	£35,935
Public social care providers	Small	839	6	£26.30	£145,651
Public social care providers	All	1,064	6	£26.30	£184,712 *(of which local authority direct cost is £15,450)*

133 Including 10% optimism bias

134 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.

b. **Training costs**

7. There may be changes to how data needs to be processed by health and social care providers to conform with the new standards, alongside upskilling staff to use new systems or new functionalities in upgraded existing systems. This will require training.

8. We have considered the inclusion of training costs that would be incurred following the implementation of the legislation. To estimate the scale of these costs, reference has been made to the size of the organisations, with assumptions developed on the number of people required to be trained per organisation.

9. 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. Training costs are expected to be incurred once clinical systems are updated with the standards. Based on this, the cost attributed to each legislation will be in line with our assumption on compliance take-up related to each standard. As such 24% of providers will go live because of the implementation of the HCA. The basis of this assumption is provided in Section 4.6 of the report on benefits. These assumptions are used to determine training costs.

10. Training on the standards will be focussed on improving awareness of the standards. Training will only be required across clinical staff in public and private hospitals and consultants at GPs. A small number of care workers may require training for public and private social care providers, but the number is deemed negligible hence has not been estimated as part of this assessment.

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

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:

- **IT suppliers:** For IT suppliers it is assumed that no training is required beyond the costs of familiarising users with the information standards. No training time is assumed for IT suppliers and, consequently, there is zero cost.

- **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[135] data. It is assumed that all clinical staff will be trained on the standard. As private hospitals are assumed to be similar in size to medium sized public hospitals, average employment is taken from this category, it is assumed 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 is c.7,000 employees needing to be trained per hospital. For hospitals categorised as medium sized, it is c.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

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

2023 published by the ONS. This cost is £15.92 per hour, which is uplifted by 22%[136] 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[137].The minimum cost is £68,975 and the maximum is £104,085, the midpoint of this range is taken, which is £86,530.

TABLE 23 - Training costs (current prices and undiscounted)[138],[139]

Organisation	Modelling size grouping	Hours of Training required per person	Total number of people to train	Cost rate per hour	Total cost
Private hospitals	Large	2.2	0	£19.42	£0
Private hospitals	Medium	2.2	516,000	£19.42	£5,820,753
Private hospitals	Small	2.2	0	£19.42	£0
Private hospitals	**All**	2.2	**516,000**	£19.42	£5,820,753
NHS hospitals	Large	2.2	395,070	£19.42	£4,456,599
NHS hospitals	Medium	2.2	354,317	£19.42	£3,996,884
NHS hospitals	Small	2.2	97,580	£19.42	£1,100,754
NHS hospitals	**All**	2.2	**846,967**	£19.42	£9,554,237
GPs	Large	2.2	9,850	£58.00	£331,832
GPs	Medium	2.2	22,458	£58.00	£756,576
GPs	Small	2.2	6,161	£58.00	£207,555
GPs	**All**	2.2	**38,469**	£58.00	£1,295,963

136 https://assets.publishing.service.gov.uk/media/5d679af2e5274a1719fdfd3d/RPC_short_guidance_note_-_Implementation_costs_August_2019.pdf

137 https://www.healthcareers.nhs.uk/explore-roles/doctors/pay-doctors

138 This is the portion of total cost that relates to the HCA so is 24% of the total training cost.

139 Including 10% optimism bias

c. Information standards related systems update

14. These are costs directly related to implementing the legislation such that clinical systems adopt the requisite standards as set out by the Secretary of State – where the systems do not already comply.

15. We expect there will be 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. The majority of these costs are likely to be passed indirectly to health and social care providers. There will also be costs associated with transitioning existing systems, data and processes to make them compliant with the standards. It is assumed that transition costs will occur because of this.

16. Baseline cost assumptions for clinical systems have been informed by a sample of publicly available contract information, where available, and prorated by the additional 24%[140] compliance under HCA. Where information is not available, cost assumptions have been developed based on the relative size of the organisation. The update costs (as a percentage of the baseline costs) have been informed from survey responses.

17. According to the results of our survey 42% of health and social care providers reportedly already adhere to the standards and therefore these costs are only incurred by the remaining 58% of providers.

18. It is likely that there will also be costs incurred by internal IT teams of health and social 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.

19. For GPs it is acknowledged that budget for the updates to reflect the information standards in systems is likely to be funded from central budgets, therefore these costs are reflected against the NHSE.

20. For public and private social care providers it is acknowledged that £8.2 million has been committed as part of the digitising social care fund[141] to help support providers onto electronic care plans. It is expected that the costs reflected in this impact assessment are in addition to that and are the costs required to ensure those electronic care plans are compliant with information standards.

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

    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)*

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

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140 As per Table 7

141 https://transform.england.nhs.uk/key-tools-and-info/adult-social-care-digital-transformation/digitising-social-care-fund/

- **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:

    - **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 23, 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. These costs are reflected against the NHSE.

    - **Private and public social care providers:** For social care providers, 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 a ten-year period. The system update costs will be incurred with the roll-out of standards under the legislation, and occurring in year two, three and six.

TABLE 24 - Information standards related systems update costs (current prices and undiscounted)[142],[143],[144]

Organisation	Modelling size grouping	Number of organisations	Average baseline Cost	Initial uplift in cost	Total cost
Private hospitals	Large	0	0	15%	0
Private hospitals	Medium	172	£2,000,000	15%	£7,946,400
Private hospitals	Small	0	0	15%	0
Private hospitals	**All**	**172**	-	-	**£7,946,400**
NHS hospitals	Large	56	£10,000,000	15%	£12,936,000
NHS hospitals	Medium	107	£2,000,000	15%	£4,943,400
NHS hospitals	Small	48	£500,000	15%	£554,400
NHS hospitals	**All**	211	-	-	**£18,433,800**
GPs – Cost to NHSE	Large	589	£250,000	15%	£3,401,475
GPs – Cost to NHSE	Medium	2,942	£150,000	15%	£10,194,030
GPs – Cost to NHSE	Small	2,713	£75,000	15%	£4,700,273
GPs – Cost to NHSE	**All**	**6,244**	-	-	**£18,295,778**
Private social care providers	Large	589	Calculated by provider	15%	£524,706
Private social care providers	Medium	2,942	Calculated by provider	15%	£441,391
Private social care providers	Small	2,713	Calculated by provider	15%	£583,484
Private social care providers	**All**	**6,244**	-	-	**£1,549,581**
Public social care	Large	113	Calculated by provider	15%	£40,597

providers					
Public social care providers	Medium	691	Calculated by provider	15%	£82,192
Public social care providers	Small	834	Calculated by provider	15%	£101,374
Public social care providers	**All**	**1,638**	-	-	**£224,162** *(of which local authority direct cost is £16,703)*

142 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 HCA (24%).

143 Including 10% optimism bias

144 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.

d. **Compliance, monitoring and enforcement costs**

23. NHSE or a similar body is likely to incur costs relating to monitoring and enforcing compliance with HCA 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 HCA regulations. The compliance monitoring body would also need to allocate resources for regular assessments and audits to evaluate health and social care provider's compliance with the legislation. Legal and regulatory experts may be required to provide guidance and oversight. 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 healthcare innovation. Our estimation of cost to the compliance monitoring body (which we have assumed to be the NHSE but could be the CQC or another body), assumes that 55 FTEs[145] are required to monitor compliance across health and social care providers each year.

24. The cost of these FTE has been assumed to be the average cost of total employment 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%[146] to reflect the total cost of employment. It is them assumed that this cost is incurred annually over the ten-year period. A further 10% optimism bias is also added to this cost.

TABLE 25 - Compliance monitoring costs (current prices and undiscounted)[147]

Organisation	Cost Assumption	Total Cost
NHSE	Cost of compliance and enforcement	£31,216,477

e. **Penalty costs to businesses**

25. This penal regime represents a potential cost to business. However, it is impossible to accurately quantify the total cost to business of the proposal, as each fine would be determined by the circumstances surrounding, and the severity of, the breach, and the individual circumstances of the businesses. That said, Better Regulation guidance[148] states that when calculating the NPV, business NPV and EANDCB, you should not include any costs (for example fines or penalties) incurred by companies for non-compliance.

1.2 Modelling size groupings assumptions for organisations

26. 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.

i. **IT suppliers**

27. We have used size groupings 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.

145 This is based the FTE of the postal services commission at its period of 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)

146 https://assets.publishing.service.gov.uk/media/5d679af2e5274a1719fdfd3d/RPC_short_guidance_note_-_Implementation_costs_August_2019.pdf

147 Including 10% optimism bias

148 Better Regulation Framework Manual (regulatoryreform.com)

ii. **Hospitals**

28. We have derived size groupings based on the reported adjusted costs of each foundation trust in England. As outlined in Table 23 below, based on the adjusted cost of each hospital we have labelled them as either; small, medium, or large. There are 48 trusts 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 26 - 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**	N/A

iii. GPs

29. We have assigned size groupings for each GP, 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 27 - 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**	N/A

iv. **Social care providers**

30. 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. 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 28 - 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	N/A

Option 2 Preferred option cost position

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

TABLE 29 - Preferred Option cost estimates - These costs are estimated over a ten-year period (current prices, undiscounted)[149]

Organisation	Cost Type	£ Amount	Direct or Indirect cost	Stakeholder type cost is incurred by
IT Suppliers	Familiarisation	£20,832	Indirect	Business
Private Hospitals	Familiarisation	£29,859	Direct	Business
Private Hospitals	Training	£5,820,753	Direct	Business
Private Hospitals	Information standards related systems update	£7,946,400	Direct	Business
Private Hospitals	**All**	£13,797,013	Direct	Business
Public Hospitals	Familiarisation	£36,630	Direct	NHS
Public Hospitals	Training	£9,554,237	Direct	NHS
Public Hospitals	Information standards related systems update	£18,433,800	Direct	NHS
Public Hospitals	**All**	£28,024,666	Direct	NHS
GPs	Training	£1,295,963	Direct	Business
GPs	Information standards related system – *Private GPs only*	£1,097,747	Direct	Business
GPs	**All**	£2,393,710	Direct	Business
Private Social Care Providers	Familiarisation	£1,057,057	Direct	Business
Private Social Care Providers	Information standards related systems update	£1,549,581	Direct	Business
Private Social Care Providers	**All**	£2,606,638	Direct	Business
Public Social Care Providers	Familiarisation	£184,712	Direct	Public Sector
Public Social Care Providers	Information standards related systems update	£224,162	Direct	Public Sector
Public Social Care Providers	**All**	£408,874 *(of which local authority direct cost is £31,153)*	Direct	Public sector

NHSE	Cost of Compliance	£31,216,477	Direct	NHSE
NHSE	Information standards related system = Public GPs update	£17,198,031	Direct	NHSE
NHSE	**All**	£48,414,508	Direct	NHSE
Total	All	**£95,666,241**		All

149 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.

Option 4 (Alternative) costs

32. The different categories of costs are set out in Table 27 for Option 4 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 30 - Option 4 Cost estimates - These costs are estimated over a ten-year period (current prices, undiscounted)[150],[151]

Organisation	Cost type	£ Amount	Direct or Indirect cost	Stakeholder type cost is incurred by
Total	**All**	**£23,284,205**	Direct	All
IT suppliers	Familiarisation	£6,944	Direct	Business
IT suppliers	Training	£0	Direct	Business
IT suppliers	Information standards related systems update	£0	Direct	Business
IT suppliers	Accreditation costs	£0	Direct	Business
IT suppliers	All	£6,944	Direct	Business
Private hospitals	Familiarisation	£9,953	Direct	Business
Private hospitals	Training	£1,940,251	Direct	Business
Private hospitals	Information standards related systems upgrade	£2,648,800	Direct	Business

Private hospitals	All	£4,599,004	Direct	Business
NHS hospitals	Familiarisation	£12,210	Direct	NHS
NHS hospitals	Training	£3,184,746	Direct	NHS
NHS hospitals	Information standards related systems upgrade	£6,144,600	Direct	NHS
NHS hospitals	All	£9,341,555	Direct	NHS
GPs	Familiarisation	£0	Direct	Business
GPs	Training	£431,988	Direct	Business
GPs	Information standards related systems upgrade	£365,916	Direct	Business
GPs	All	£797,903	Direct	Business

Private – Social Care Providers	Familiarisation	£352,352	Direct	Business
Private – Social Care Providers	Training	£0	Direct	Business
Private – Social Care Providers	Information standards related systems upgrade	£516,527	Direct	Business
Private – Social Care Providers	All	£868,879	Direct	Business
Public – Social Care Providers	Familiarisation	£61,571	Direct	Public Sector
Public – Social Care Providers	Training	£0	Direct	Public Sector
Public – Social Care Providers	Information standards related systems upgrade	£74,721	Direct	Public Sector
Public – Social Care Providers	All	£136,291 (of which local authority direct cost is £10,718)	Direct	Public Sector
NHSE	Cost of monitoring compliance and enforcement	£0	Direct	NHS

NHSE	Awareness campaign costs	£5,732,677	Direct	NHS
NHSE	Information standards related systems upgrade	£1,800,951	Direct	NHS
NHSE	All	£7,533,628	Direct	NHS

150 Including 10% optimism bias

151 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.

1.3 Annual cost profiles

33. The annual benefits and costs for Option 2 and 4 are outlined below across a 10-year period, this has been discounted into present value terms.

TABLE 31 - Annual costs of Option 2 – preferred option (£m, present value terms)

Year	**Y1**	**Y2**	**Y3**	**Y4**	**Y5**	**Y6**	**Y7**	**Y8**	**Y9**	**Y10**	**Total**
Costs	**3.8**	**39.6**	**23.5**	**2.8**	**3.3**	**5.3**	**2.5**	**2.5**	**2.4**	**2.3**	**88.0**
Familiarisation Cost	0.7	0.0	0.0	0.0	0.6	0.0	0.0	0.0	0.0	0.0	1.2
Training Cost	0.0	9.7	5.4	0.0	0.0	0.7	0.0	0.0	0.0	0.0	15.8
Information standards system update cost	0.0	26.9	15.2	0.0	0.0	2.0	0.0	0.0	0.0	0.0	44.1
Compliance and enforcement monitoring costs	3.1	3.0	2.9	2.8	2.7	2.6	2.5	2.5	2.4	2.3	26.0

TABLE 32 - Annual benefits of Option 2 – preferred option (£m, present value terms)

Year	**Y1**	**Y2**	**Y3**	**Y4**	**Y5**	**Y6**	**Y7**	**Y8**	**Y9**	**Y10**	**Total**
Benefits	**0.0**	**6.1**	**13.9**	**14.2**	**12.7**	**12.5**	**12.2**	**11.9**	**11.6**	**11.3**	**106.4**
Mapping and standardisation costs reduction	0.0	2.1	3.4	1.3	0.0	0.0	0.0	0.0	0.0	0.0	6.8
Reduced duplicate tests / procedures	0.0	0.9	2.3	2.7	2.6	2.6	2.5	2.4	2.3	2.2	20.4
Time saved accessing information	0.0	0.4	1.1	1.3	1.3	1.2	1.2	1.2	1.1	1.1	9.9
Reduction in cost of excess bed days (transition medication error reduction)	0.0	0.2	0.6	0.7	0.7	0.6	0.6	0.6	0.6	0.5	5.0

QALY gained (transition medication error)	0.0	0.0	0.2	0.3	0.4	0.4	0.5	0.5	0.5	0.5	3.3
Reduction in cost of excess bed days (non-transition medication error)	0.0	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	1.8
QALY gained (non- transition medication error)	0.0	0.1	0.3	0.5	0.7	0.8	0.9	0.9	1.0	1.0	6.1
Value of time saved reporting medication errors	0.0	0.2	0.4	0.5	0.5	0.4	0.4	0.4	0.4	0.4	3.6
Reduction in reporting costs for PSIs	0.0	2.1	5.5	6.6	6.4	6.2	6.0	5.8	5.6	5.4	49.4

TABLE 33 - Annual costs of Option 4 – alternative option (£m, present value terms)

Year	**Y1**	**Y2**	**Y3**	**Y4**	**Y5**	**Y6**	**Y7**	**Y8**	**Y9**	**Y10**	**Total**
Costs	**0.2**	**6.4**	**6.2**	**4.0**	**3.0**	**1.1**	**0.1**	**0.1**	**0.1**	**0.1**	**21.4**
Familiarisation Cost	0.0	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.4
Training Cost	0.0	1.6	1.6	1.0	0.7	0.2	0.0	0.0	0.0	0.0	5.1
Information standards system update cost	0.0	4.5	4.3	2.8	2.0	0.7	0.0	0.0	0.0	0.0	14.3
Awareness campaign costs	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

TABLE 34 - Annual benefits of Option 4 – alternative option (£m, present value terms)

Year	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Total
Benefits	**0.0**	**0.0**	**0.0**	**0.0**	**1.4**	**1.4**	**1.4**	**1.3**	**1.3**	**1.2**	**8.0**
Mapping and standardisation costs	0.0	0.0	0.0	0.0	0.3	0.3	0.3	0.3	0.3	0.2	1.6
Reduced duplicate tests / procedures	0.0	0.0	0.0	0.0	0.2	0.2	0.2	0.2	0.2	0.2	1.3
Time saved accessing information	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.6
Reduction in cost of excess bed days (transition medication errors)	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.0	0.3
QALY gained (transition medication error)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2
Reduction in cost of excess bed days (non-transition medication error)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
QALY gained (non-transition medication error)	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.4
Value of time saved reporting medication errors	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2
Reduction in reporting costs for PSIs	0.0	0.0	0.0	0.0	0.6	0.6	0.5	0.5	0.5	0.5	3.2

Appendix 2 – cost type assumption

1.1 Cost Type Assumption

This appendix provides further detail on costing approach, expanding on Section 1.7.

Cost type
Familiarisation cost
Description
IT suppliers, private and public hospitals, and private and public social care providers will incur up front familiarisation costs to understand the new legislation, any supporting guidance, and its implications.
Rationale for direct/indirect classification
Direct – Familiarisation with new legislation by hospitals and social care providers affects the cost of these organisations and falls on the organisations subject to the regulation. It is therefore considered a direct cost. **Indirect** – Familiarisation with new legislation by IT suppliers to understand how the legislation affects their business. These costs are considered likely to occur, however, will not directly result from the legislation and are therefore considered indirect.
Method for calculating
The product of: • Time taken to read guidance per IT supplier, hospital and social care provider • Average hourly wage rate of employees expected to read the guidance • Non-wage uplift • HCA cost apportionment • Number of IT suppliers, hospitals and social care providers 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 organisation. • 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.

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.	IT suppliers are likely to need to familiarise themselves with new guidance and its implications.
Number of private hospitals required to familiarise with legislation	172	The number of private hospitals in England has been taken from treatment connect.	Private hospitals will be required to familiarise themselves with new guidance and its implications.
Number of public hospitals required to familiarise with legislation	211	The number of public hospitals has been taken from NHSE's system directory.	Public hospitals will be required to familiarise themselves with new guidance and its implications.
Number of private social care providers required to familiarise with legislation	6,089	The number of private social care providers has been taken from the Care Quality Commission (CQC) database.	Private social care providers will be required to familiarise themselves with new guidance and its implications.
Number of public social care providers required to familiarise with legislation	1,064	The number of public social care providers has been taken from the Care Quality Commission (CQC) database.	Public social care providers will be required to familiarise themselves with new guidance and its implications.
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.
Time taken to read guidance per hospital and social care provider	6 hours (Health and social care providers will need to spend 3 hours familiarising with the guidance per standard and will not require legal 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)
HCA cost apportionment	100%	% of additional compliance assumed to be as a result of HCA	We expect familiarisation costs will be incurred by all IT suppliers, public and private hospitals and public and private social care providers, as even those already complying will need to familiarise with the standards to ensure they are compliant.
Total cost	£1,243,658		10-year total cost in discounted prices

Cost type
Training Costs
Description
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.
Rationale for direct/indirect classification
Direct – 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.
Method for 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

- HCA 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.

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 Private Hospitals – 516,000 individuals GPs – 38,469 individuals	For hospitals, data on staff numbers has been based on published NHSE workforce data (CQC The state of health care and adult social care in England 2022/23)	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 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)

HCA cost apportionment	24%	% of additional compliance assumed to be as a result of HCA	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	£15,813,025		10-year total cost in discounted prices

Cost type
Compliance monitoring and enforcement costs
Description
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
Rationale for direct/indirect classification
Direct – 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 for calculating
The product of: • **Number of FTE for compliance body** • **Average hourly wage of compliance body FTE**

- **Non-wage uplift**
- **HCA 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 HCA enforcement: We assume a proportion of the compliance body's resources that will be dedicated to enforcing HCA 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 HCA requirements.**

Variable	Value	Source	Rationale
Number of FTE for compliance body	55 FTE for both HCA and DUA (52 FTE for HCA only following 95% 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 HCA 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 Communication sector	The cost per employee has been assumed to be the average salary for those in the information and communication sector as it is assumed 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.
HCA cost apportionment	95% to HCA	% of total resource assumed to be needed for HCA	This assumption has been based on the split of organisations across IT Suppliers and Health and Care Providers.
Total cost	**£26,870,165**		10-year total cost in discounted prices

Cost type
Information standards related systems update
Description
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.
Rationale for direct/indirect classification
Direct – 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 for 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 HCA** • **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.**

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.
HCA apportionment	24% to HCA	% of additional compliance assumed to be as a result of HCA	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	£44,059,305 for IT Suppliers and Health and Care Providers		10-year total cost in discounted prices

Appendix 3

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

6.1 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)

6.2 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 2022 (Clause 95) (HCA) 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 overarching policy objective as proposed in the HCA 2022 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.

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 a 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 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

Q6. Will your costs increase as a result 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
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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

6.3 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[152] (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%)

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152 For suppliers, this encourages a "wait and see" approach to understand when a published standard is mature and stable enough to invest in.

Appendix 4 – Rationale for regional interoperability

Rationale for regional interoperability underpinned by the ShCR as basis of RIA

34. 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

    - Comprises 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.

35. 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 uses cases[153] that underpin the HCA 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.

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153 NHSE has defined seven priority uses cases that detail data access across the various health and care sectors:

Acute hospital departments and other acute hospitals

Acute hospital discharge to social care

Workforce identity and access management

A&E triage

Referral from primary care to secondary care

Patient demographic and appointment information for capacity planning

Paramedic & Ambulance Triage

36. Based on evidence provided by NHSE, at least 82%[154] 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.

37. 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:

    i. **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.

    ii. **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.

38. 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.

39. 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

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154 This estimate is based on an 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.

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.

40. 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.