

Transparency in Health and Social Care Guidance: Impact Assessment

April 2024



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1. Introduction

This document sets out the findings from our ex-ante assessment of the impact of the transparency in health and social care guidance.

1.1. Context

This impact assessment accompanies the transparency in health and social care guidance. The guidance sets out how organisations in the health and social care sectors can comply with the transparency expectations of UK General Data Protection Regulation (GDPR) and the Data Protection Act (DPA) 2018.

The guidance is primarily aimed at organisations that deliver health and social care services, or process health and social care information (such as for research and planning). The guidance is also aimed at individuals working in health and social care that are involved in preparing and delivering transparency information to the public.

The ICO conducted a public consultation on the draft guidance, with an accompanying draft impact assessment, between 13 November 2023 and 7 January 2024. Overall, 37 responses were received to the consultation. This impact assessment reflects the consultation feedback received, notably in our cost-benefit analysis in Section 2. Further detail on the consultation responses can be found in Annex A.

1.2. Our approach to the impact assessment

We have assessed the potential impacts of the guidance using cost-benefit analysis, which aims to identify the full range of impacts by assessing both the costs and benefits. Our approach follows the principles set out in the ICO's Impact Assessment Framework,¹ which in turn is aligned with HM Treasury's

¹ ICO (2023) *The ICO's Impact Assessment Framework*. Available at: <https://ico.org.uk/media/about-the-ico/documents/4027020/ico-impact-assessment-framework.pdf> (accessed 16 February 2024).

Green Book,² Regulatory Policy Committee guidance,³ and Business Impact Target guidance on best practice for impact assessments.⁴

In identifying the potential impacts of the guidance, it is important to distinguish between:

- Additional impacts that can be attributed to the guidance – these are affected by how the ICO chooses to develop the guidance.
- Impacts that are not attributable to the guidance - these are impacts that simply arise from the existing legislative requirements that controllers are already expected to comply with.

For the purposes of the impact assessment, we are interested in impacts that are attributable to the guidance, rather than those that would have happened in the absence of this regulatory intervention - a concept known as 'additionality'. Additionality can take a number of forms and may include the realisation of impacts at an earlier stage or to a higher scale or standard than would have been the case without intervention.

1.3. Current data protection (DP) landscape – our baseline

To date, the ICO have provided no specific regulatory guidance on transparency expectations for the health and social care sectors. Although these topics are broadly covered in our guidance on the principle of transparency⁵ and the right to be informed⁶, they do not specifically reference the health and social care sectors. This has contributed to a lack of clarity over how the transparency expectations of UK GDPR and the DPA 2018 apply to the health and social care sector.

² HM Treasury (2022) *The Green Book*. Available at: [The Green Book \(2022\) - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/the-green-book-2022) (accessed 9 April 2024).

³ BEIS (2020) *Better Regulation Framework – Interim Guidance*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/916918/better-regulation-guidance.pdf (accessed 16 February 2024).

⁴ BEIS (2019), *Business Impact Target: Appraisal of guidance: assessments for regulator-issued guidance*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/609201/business-impact-target-guidance-appraisal.pdf (accessed 19 January 2024).

⁵ ICO *Transparency guidance*. Available at: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/accountability-and-governance/accountability-framework/transparency/> (Accessed 9th April 2024).

⁶ ICO *Right to be informed guidance*. Available at: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/individual-rights/individual-rights/right-to-be-informed/> (Accessed 9th April 2024).

2. Application of our impact assessment approach

As outlined in our Impact Assessment Framework, impact assessments include the following six elements:

1. problem definition;
2. rationale for intervention;
3. identification of alternatives;
4. description of the regulatory proposal;
5. analysis of benefits and costs; and
6. setting out the proposed monitoring and evaluation needs.

Steps 1 – 4 are covered in Section 2.1, with step 5 addressed in Section 0 and step 6 in Section 3.

2.1. From problem definition to rationale for intervention

The table below provides more detail on the journey from problem identification to the proposed intervention. It covers the market failures and data protection harms we have identified, the groups affected and the options we have considered.

Table 1: Impact assessment, steps 1-4

1: Problem definition	<p>The responsible sharing of patient data has the potential to transform health and social care delivery, and contribute to developments in:</p> <ul style="list-style-type: none">• Advancing medical research in areas such as understanding the cause and prevention of disease.• Improving diagnosis, though linking datasets to offer better and earlier support to patients.• Supporting the planning and delivery of health and social care services. <p>A 2019 report by EY⁷ estimated that data held by the NHS could be worth nearly £10 billion a year, through operational savings, improved patient outcomes and benefits to the wider economy.</p>
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⁷ EY (2019) *Realising the value of health care data: a framework for the future*. Available at: https://assets.ey.com/content/dam/ey-sites/ey-com/en_gl/topics/life-sciences/life-sciences-pdfs/ey-value-of-health-care-data-v20-final.pdf (Accessed 9th April 2024)

	<p>Public attitudes research⁸ demonstrates that patients and service users are supportive of health and care data being used if certain expectations are met, including that it delivers a public benefit. However, if individuals do not understand the intended use of their health and social care information, this can weaken public trust and lead to individuals opting out of sharing their data. The latest NHS figures⁹ show that around 3.37 million patients in England have opted out of sharing their health information beyond the purposes of their own care. This diminishes the potential value of initiatives which depend on the processing of patient data.</p> <p>A lack of public understanding can be the result of poor transparency practices. A National Data Guardian report¹⁰ on the GP data for planning and research programme (GPDPR) found shortcomings in scheme’s transparency and communications programme, which contributed to the delay of the programme. As highlighted by the National Data Guardian¹¹, it is important that organisations are transparent with the public around how their information is processed in order to sustain public trust.</p> <p>For data subjects, a lack of transparency can also result in data protection harms, such as a loss of personal control. These are discussed in more detail in the next section.</p>
<p>2: Rationale for</p>	<p>Rationale for Intervention</p> <p>The ICO is of the view that the existing guidance¹² is high level</p>

⁸ Digital Health (2019) *YouGov survey reveals willingness for patient data to be shared*. Available at: <https://www.digitalhealth.net/2019/06/yougov-survey-reveals-willingness-for-patient-data-to-be-shared/> (Accessed 9th April 2024)

⁹ NHS England (2024) *National Data Opt-Out open data dashboard*. Available at: <https://digital.nhs.uk/dashboards/national-data-opt-out-open-data> (Accessed 27th March 2024)

¹⁰ National Data Guardian (2021) *response to the Department of Health and Social Care’s consultation on its draft data strategy: ‘Data saves lives: reshaping health and social care with data’*. Available at: https://assets.publishing.service.gov.uk/media/61388fc38fa8f503b8df1ec7/NDG_Data_Strategy_Response_v1.0_-_08.09.21.pdf (Accessed 9th April 2024)

¹¹ National Data Guardian (2021) *response to the Department of Health and Social Care’s consultation on its draft data strategy: ‘Data saves lives: reshaping health and social care with data’*. Available at: (Accessed 9th April 2024)

¹² ICO *Transparency guidance* Available at: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/accountability-and-governance/accountability-framework/transparency/> (Accessed 9th April 2024)

intervention

and does not provide sufficient insight into our expectations on standards of transparency for the health and social care sectors. Robust approaches to openness and transparency are vital for building trust and confidence, particularly when personal data is used to support the provision of public services. Without this, the potential benefits of such data sharing can be lost, compromised or significantly delayed. Stakeholder feedback highlights that further clarity on areas such as the exercising of data protection (DP) rights in practice and third-party access to data, is needed to improve regulatory certainty.

Data Protection Harms

A lack of transparency and public understanding over how organisations process their health data can lead to a number of DP harms (as set out in the [ICO's harms taxonomy](#)¹³) and has the potential to undermine public trust. If public information on how an organisation processes personal data is extremely complex, this can deter individuals from accessing and reviewing it, leading to a loss of control of personal data. Where people do not understand the intended use of their health and social care information it may also result in psychological harms such as embarrassment, anxiety or fear. These harms can be exacerbated by the sensitivity and volume of data processed by organisations in the health and social care sectors.

Market Failures

A lack of regulatory certainty around data sharing within the Health and Social Care sectors can result in market failures, including:

- Imperfect information - Where individuals do not fully understand the intended use of their health and social care information, they may be less likely to trust organisations which could lead to them opting out of sharing their data. This diminishes the potential value of initiatives which depend on the processing of patient data. Individuals may also be unaware of the risks of handing their data to

¹³ ICO (2022) *Overview of DP Harms and the ICO's Taxonomy*. Available at: <https://ico.org.uk/media/about-the-ico/documents/4020144/overview-of-data-protection-harms-and-the-ico-taxonomy-v1-202204.pdf> (Accessed 9th April 2024).

	<p>organisations, or that organisations may be processing this information. For individuals, a lack of transparency can also result in data protection harms, such as a loss of personal control.</p> <ul style="list-style-type: none"> • Negative Externalities - In the absence of regulatory certainty, organisations may not consider the invasive or sensitive nature of unnecessarily storing and transferring data and the cost this may impose on individuals. Potential issues with the accuracy and sensitivity of data could also lead to harms (such as discrimination, and the loss of control of personal data) driving the need for intervention.
<p>3: Options appraisal</p>	<p>There are a range of intervention options available to increase regulatory certainty. In this case, it was considered that issuing guidance for the health and social care sectors on ICO expectations around transparency was the most appropriate policy tool.</p> <p>Options considered include:</p> <ol style="list-style-type: none"> 1. Do nothing. 2. Guidance explaining ICO expectations around transparency in the health and social care sector. 3. Other regulatory tools (e.g. engagement, outreach, etc). <p>Option 2, alongside a programme of targeted engagement, was identified as the preferred option.</p>
<p>4: Detail of proposed intervention</p>	<p>Details of intervention</p> <p>The ICO will issue guidance to assist health and social care organisations in understanding our expectations around transparency. This will supplement existing guidance on the principle of transparency¹⁴ and the right to be informed¹⁵.</p> <p>Whilst some of the issues highlighted in the problem statement</p>

¹⁴ ICO *Transparency guidance*. Available at: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/accountability-and-governance/accountability-framework/transparency/> (Accessed 9th April 2024).

¹⁵ ICO *Right to be informed guidance*. Available at: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/individual-rights/individual-rights/right-to-be-informed/> (Accessed 9th April 2024).

are specific to England (such as the application of opt-outs), we are of the view that the guidance can be applied across the UK regions.

The main objectives of the guidance are to:

- Increase awareness of transparency expectations in the health and social care sector.
- Provide regulatory certainty for the health and social care sector.
- Improve public understanding of how personal data is used.

Timeline

The following timeline shows some of the key milestones in the development of the guidance.

Figure 1: Timeline of key milestones linked to the guidance.



Source: ICO

A summary of responses to the public consultation is included at Annex A.

Affected Groups

The main groups we expect to be affected by the guidance include:

- **Health & Social Care Sectors** – This guidance is mainly directed at Health and Social care providers across the UK. While the focus of the guidance will be on the health and social care sector, we expect that it will be applicable more generally too.

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- **Users of health and social care services** - Individuals that engage with health and social care services are also likely to be affected by the guidance.
 - **ICO** - The ICO will be affected, as the regulator of DP legislation and as the producer of the guidance.
 - **Wider Society** - The guidance also has the potential impact on other groups and may have indirect impacts on wider society. This might include:
 - organisations within the supply chain of developers and providers of health and social care services.
 - civil society groups.
 - the wider population.
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Source: ICO

2.2. Cost-Benefit Analysis

The costs and benefits of the guidance have been identified, as far as is possible and proportionate. Table 2 provides an overview of the primary costs and benefits we have considered for our identified affected groups. This should not be viewed as exhaustive or hierarchical.

There is limited quantitative data, and the analysis relies heavily on qualitative information which increases the uncertainty of the assessment. Bearing in mind these caveats, our overall assessment of the intervention suggests that the benefits are likely to outweigh the costs, as detailed below.

Table 2: Summary of potential impacts

Affected groups	Benefits	Costs	Scale of population
Health & Social Care Sectors	<ul style="list-style-type: none"> Improved regulatory certainty over the transparency expectations for organisations in the health and social care sector. Greater confidence and certainty over what is compliant processing of personal data. Potential time and cost savings from more efficient resource planning and service delivery. 	<ul style="list-style-type: none"> Familiarisation costs of reading the updated guidance (£52 per organisation¹⁶). Time costs associated with a potential rise in data subjects exercising their DP rights. Cost of developing and updating transparency materials explaining how data subjects' information is processed. 	<ul style="list-style-type: none"> There are 340,000 businesses registered within 'Human Health and Social Work Activities'¹⁷. These industries account for over 1.6 million full time equivalent employees¹⁸. Assuming up to 65%¹⁹ of organisations engage with the guidance we estimate that 221,000

¹⁶ Further details are provided at Annex B.

¹⁷ Department for Business and Trade (2023) *Business population estimates*. Available at: <https://www.gov.uk/government/statistics/business-population-estimates-2023> (Accessed 9th April 2024).

¹⁸ ONS (2024) *The healthcare workforce across the UK*. Available at: <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthcaresystem/articles/thehealthcareworkforceacrosstheuk/2024> (Accessed 9th April 2024).

¹⁹ The Business Perceptions Survey estimates that, across sectors, the share of businesses that engage with guidance is 65%.

Department for Business and Trade (2022) *Business Perceptions Survey*. Available at: <https://assets.publishing.service.gov.uk/media/64b16e4907d4b80013347338/business-perceptions-survey-2022-research-report.pdf> (Accessed 15th April 2024).

		<ul style="list-style-type: none"> • Cost of facilitating and delivering updated messaging to the public. 	organisations will be affected.
Users of Health and Social Care Services	<ul style="list-style-type: none"> • Reduction in potential DP harms from better understanding over how organisations process sensitive information. • Enhanced understanding of and ability to exercise DP rights. • Improved trust and confidence in data processing by health and social care organisations. 	<ul style="list-style-type: none"> • Potential time costs of engaging with public transparency materials produced by health and social care organisations. • Transparency is a spectrum and, in some cases, may expose individuals to greater privacy risks. 	<ul style="list-style-type: none"> • Due to the nature of the guidance, it is likely to affect the entire population. According to latest estimates, there are around 67 million people in the UK.²⁰
Wider Society	<ul style="list-style-type: none"> • Potential for improved public trust and confidence in the processing of personal data.²¹ • Potential for wider benefits such as improved data for research purposes, as a result of individuals being better informed, and potentially more willing to 		<ul style="list-style-type: none"> • It is difficult to estimate who the guidance would and wouldn't affect indirectly. As such, we estimate the whole population as an upper-end estimate. As stated above, there are

²⁰ ONS (2022) *Population estimates time series data set 2021*. Available at: <https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/datasets/populationestimatestimeseriesdataset> (Accessed 9th April 2024).

²¹ Note that transparency is only one of many factors which influence levels of public trust in health and social care organisations.

consent to their personal data being processed.²²

- Potential for improved health outcomes, and more efficient public services, from individuals being better informed, and potentially more willing to consent to their data being processed.

around 67 million people in the UK.²³

The ICO

- Efficiency savings on advice and support to organisations in health and social care relating to transparency expectations.
- Potential reduction in supervision costs from improved understanding of transparency requirements.
- Potential reduction in supervision costs from improved understanding of compliance.
- Resource cost of issuing guidance to clarify ICO expectations on transparency.

Source: ICO

²² Despite there being a positive link between public trust and willingness to share data, there is a limit to which individuals will consent to data sharing, as a result of increased transparency.

²³ ONS (2022) *Population estimates time series data set 2021*. Available at: <https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/datasets/populationestimatestimeseriesdataset> (Accessed 9th April 2024).

3. Monitoring and evaluation

An appropriate and proportionate review structure will be put in place. This will follow best practice and align with our organisational reporting and measurement against ICO25 objectives.

Annex A: Responses to public consultation on transparency in health and social care guidance

The ICO consulted on our draft guidance on transparency in the health and social care sector and a summary impact assessment for eight weeks between 13 November 2023 and 7 January 2024.

A.1. Background of responses

Overall, 37 responses were received to the consultation. Of these, 23 responses were provided on the questions relating to impact. These 23 responses were received from a mixture of organisations processing health data (9), representative bodies (11), trade union (1), academic (1) and private individual (1); as illustrated below.

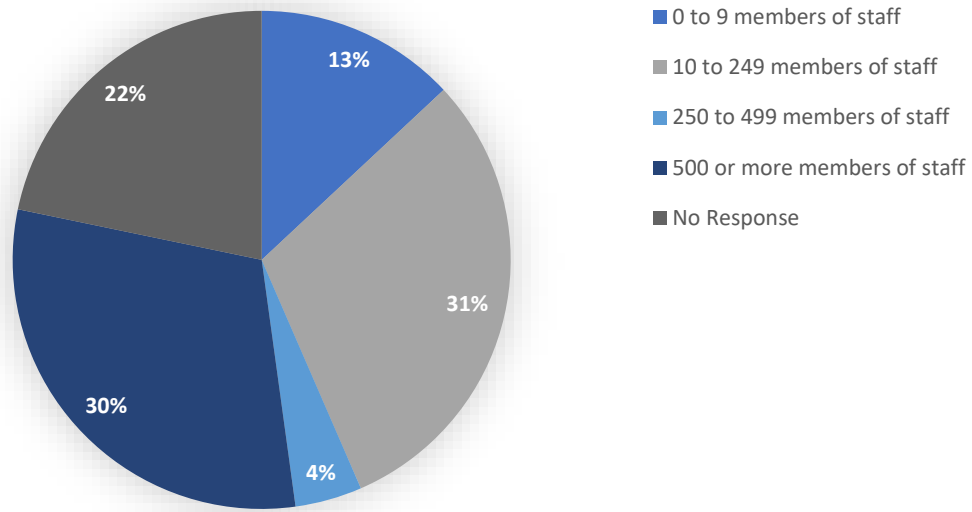
Table 3: Organisation Type

Organisation category	No. of respondents
An organisation or person processing health data	9
A representative of a professional, industry or trade association	4
An organisation representing the interests of patients in health settings (eg GP practice, hospital trust)	3
An organisation representing the interests of patients in social care settings (eg care home)	4
A trade union	1
Other: An academic	1
Other: An individual acting in a private capacity (eg someone providing their views as a member of the public)	1
Total	23

Source: ICO

The size of the organisations varied with 10 responses (43%) from organisations of less than 250 members of staff, while 8 respondents (35%) were from organisations with over 250 members of staff. Five respondents (22%) did not answer.

Figure 2: Organisation size

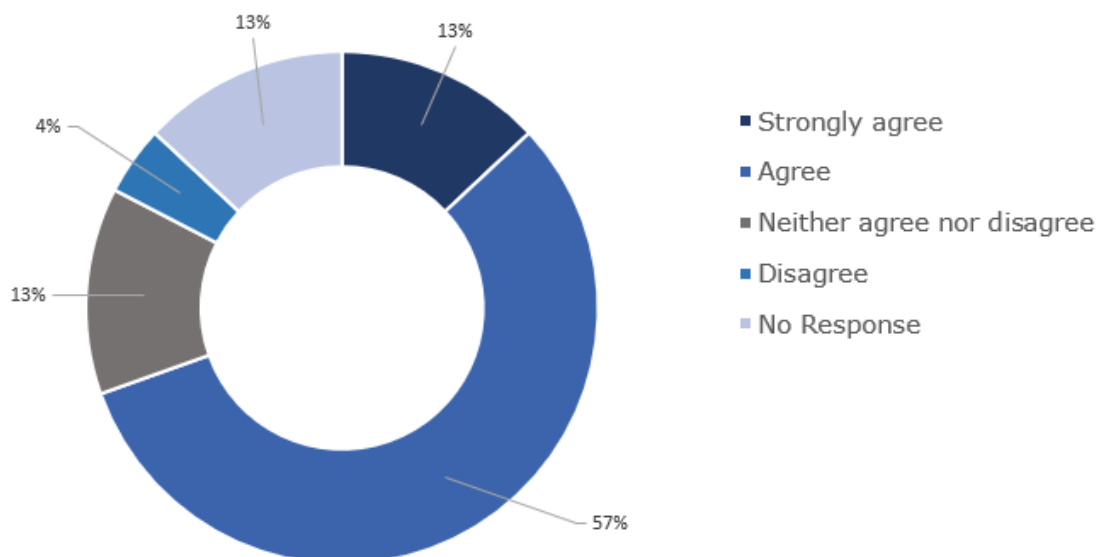


Source: ICO, n=23

A.2. Consultation responses

The chart below shows the extent to which respondents agreed with the scope and coverage of the draft impact assessment presented in the consultation. More than half, 57% (13 respondents), agreed that the impact assessment summary adequately scoped the main affected groups and impacts. Three respondents (13%) did not offer a view.

Figure 3: Extent of agreement with impact assessment's scope and coverage



Source: ICO, n=23

The consultation responses touched on a range of themes and were broadly supportive of our impact approach. Feedback from respondents on impacts included the following response:

'In the costs we should also consider that transparency is a spectrum and that there may be costs in terms of increased privacy risks to the data subjects with published transparency information (for e.g. publishing the names of all practices that contribute data to a database on a website) in the pursuit of excessive transparency'.

When respondents were asked whether the guidance was likely to result in additional impacts:

- Six respondents (26%) thought the guidance presented additional benefits, while seven (30%) thought there would be additional cost.
- A further seven respondents (30%) thought there would be both additional costs and benefits while three respondents (13%) thought there would be neither.
- One respondent (4%) was unsure and five (22%) did not respond.

Most costs and benefits noted by respondents were already accounted for within the summary impact assessment, however some additional types of costs or benefits that respondents felt their organisation might incur, included:

- Increased (bilingual) communication costs (1 respondent).
- Costs of facilitating and delivering transparency and privacy messages to the public (4 respondents).

When asked to provide an estimate of the costs or benefits organisations were likely to incur; the following responses were provided:

- Some areas of improvement to public communications may require additional staff resource (one organisation estimated this could result in an additional £30,000 in staff time).
- Based on some of the interpretations of what constitutes duties around transparency and privacy, up to an additional £500,000 per annum (this was based on one organisation's estimate of the costs of putting in place improved information access tools for the public).
- Transparency does not always improve public trust and that is a risk we have to accept.
- We have to accept some costs in terms of increased opt-outs.

This impact assessment reflects the feedback provided during consultation. We have taken account of the additional costs and benefits highlighted by respondents by updating, where proportionate and appropriate, the summary of potential impacts at Table 2.

Annex B: Familiarisation Costs

This annex sets out the approach taken to estimate familiarisation costs for the guidance, which follows an approach drawn from our previous impact assessments.^{24, 25}

For the purposes of the assessment we assume each organisation will read the guidance in its entirety once. This is not a recommendation on how organisations or individuals should familiarise themselves with guidance, as this will differ on a case-by-case basis.

A.1. Familiarisation costs per organisation

Drawing on impact assessment guidance,²⁶ we have estimated the total time for reading the guidance at 1 hour and 44 minutes. This is based on a word count of around 7,789 words and a Fleisch reading ease score of 36.5.

Table 4: Estimate of the average time taken to read the guidance

Document	Word Count	Fleisch reading ease score	Assumed words per minute	Estimated reading time (hr:mn)
Guidance	7,789	36.5	75	1h44

Source: ICO, BEIS (2019).²⁷

The impact of familiarisation on organisations can be monetised using data on wages from the ONS Annual Survey of Hours and Earnings.²⁸

²⁴ ICO (2021) *Data sharing code of practice – Impact assessment*. Available at: <https://ico.org.uk/media/2619796/ds-code-impact-assessment-202105.pdf> (Accessed 9th April 2024).

²⁵ ICO (2020) *Age appropriate design: a code of practice for online services – Impact assessment*. Available at: https://ico.org.uk/media/2617988/aadc-impact-assessment-v1_3.pdf (Accessed 9th April 2024).

²⁶ BEIS (2019) *Business Impact Target: Appraisal of guidance: assessments for regulator-issued guidance*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/609201/business-impact-target-guidance-appraisal.pdf (Accessed 9th April 2024).

²⁷ BEIS (2019) *Business Impact Target Statutory Guidance*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/776507/Business_Impact_Target_Statutory_Guidance_January_2019.pdf (Accessed 9th April 2024).

²⁸ ONS (2023) *Annual Survey of Hours and Earnings*. Available at: <https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/ashe1997to2015selectedestimates> (Accessed 9th April 2024).

Making the conservative assumption that the relevant occupational group is 'Managers, Directors and Senior Officials', the 2023 median hourly earnings (excluding overtime) for this group is £24.77.

This hourly cost is uprated for non-wage costs using the latest figures from the Regulatory Policy Committee guidance,²⁹ resulting in an uplift of 22% and an hourly cost of £30.22.

We therefore assume the cost of reading the guidance once to be approximately £52.

²⁹ RPC (2019) *RPC guidance note on 'implementation costs'*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/827926/RPC_short_guidance_note_-_Implementation_costs_August_2019.pdf (Accessed 9th April 2024).