Consultation on the draft Transparency in Health and Social Care guidance

The Information Commissioner's Office (ICO) is producing guidance on transparency in the health and social care sector.

The draft of this guidance is now published for public consultation.

The draft transparency in health and social care guidance has been developed to help health and social care organisations understand our expectations about transparency.

We are also seeking views on a draft summary impact assessment for this guidance. Your responses will help us understand the code's practical impact on organisations and individuals.

This survey is split into four sections. This covers:

- Section 1: Your views on the draft guidance
- Section 2: Your views on our summary impact assessment
- Section 3: About you and your organisation
- Section 4: Any other comments

The consultation will remain open until 7th January 2024. Please submit responses by 5pm on the 7 January 2024. We may not consider responses received after the deadline.

Please send completed form to PolicyProjects@ico.org.uk or print off this document and post to:

Regulatory Policy Projects Team
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Privacy statement

For this consultation we may publish the responses received from organisations or a summary of the responses. We will not publish responses from individuals acting in a private capacity. If we do publish any responses, we will remove email addresses and telephone numbers from these responses but apart from this we will publish them in full.

Please be mindful not to share any information in your response which you would not be happy for us to make publicly available.

Should we receive an FOI request for your response we will always seek to consult with you for your views on the disclosure of this information before any decision is made.

For more information about what we do with personal data please see our privacy notice.

Are you happy to proceed? *

√ I am happy to proceed.

Section 1: Your views on the draft guidance

Answers to the following questions will be helpful in shaping our guidance. Please use the comments boxes to provide further detailed information as far as possible. Some of the questions may not be relevant to you or your organisation, so please skip these as necessary.

1. Do you agree that this guidance clearly sets out what is required of health and care organisations to comply with the data protection transparency principle?

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

Please provide any comments you have (max. 500 characters):

The NHS Health Research Authority (HRA) welcomes the publication of this draft transparency guidance for health and social care organisations, we do however outline some important concerns in this response which require consideration. We believe it would be helpful to work together to finalise the guidance, as it has implications for health and social care research.

The HRA agrees that the draft ICO transparency guidance sets out what is required of health and care organisations to comply with the data protection transparency principle. However, we would stress that clarification is needed as to what parts of the guidance apply to the controller and what to the processor and what to both – i.e. work is needed to clarify who the 'you' is to whom much of the guidance is addressed. In the research context this is especially important given the role of sponsor as controller and research site as processor of data processing for the purpose of the research.

We would ask that you add to your risk assessment the potential harm to the UK economy and the health and wellbeing of the population of guidance that could blur the obligations of different parties in a manner that creates additional barriers to the delivery of health and social care research. We are keen to work with you to further define and mitigate these risks.

Health and social care data in research

We welcome the inclusion of scenarios involving data for research participants and the need for transparency in the draft guidance. Improved transparency within health and social care research has the potential to build public trust in research studies which collect, use and share health data for public good, especially when considering challenges such as health inequalities. The new guidance therefore needs more emphasis on the benefits and opportunities that better data transparency can bring.

HRA's transparency templates

We would ask the ICO to consider signposting to the HRA's transparency guidance and templates. We offer guidance on transparency information to NHS sites, we outline how to be GDPR compliant, and we offer transparency wording for sponsors when designing participant information sheets. It would be beneficial to signpost to this guidance and templates within your new guidance.

HRA's Make it Public campaign

It would be valuable to signpost researchers and funders to the HRA'S Transparency Strategy and Make it Public Campaign within the new guidance. The HRA has a legal duty to promote research transparency and is taking a leading role on behalf of the research system across the UK to champion openness and drive improvements in performance. Speaking with the Chair of the Make it Public Campaign Group they believe there are potential opportunities to work collaboratively to promote this new guidance. Please do get in touch with [redacted] to discuss further [redacted]

2(a). Do you agree that this guidance provides a clear definition of transparency and privacy information?

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

Please provide any comments you have (max. 500 characters):

We would ask for consideration to be given as to whether the terminology chosen in the guidance is appropriate. Using the word privacy for what is legally required, when the word is not used this way in the legislation (the legal obligation is to transparency), could cause confusion.

We would welcome clearer acknowledgement in the guidance that whilst the distinction between transparency and privacy information is based on legal requirements, the public often view both as equally important. There needs to be an appreciation in the guidance that the public might regard the "could" standards as essential to maintain trust in health and social care organisations.

We would also support a clearer, more detailed definition of "transparency information" that guides organisations through all the requirements. There is a need to walk organisations through the total range of material that "should" be provided to comply with the transparency principle, together with additional material that "could" be provided to the public to make transparency material more effective and maintain public trust.

There seems to be inconsistency in the guidance, at times transparency information is used to include privacy information and in other parts of the guidance both terms are used separately.

2(b). Does the distinction between transparency information and privacy information make sense to you?

Yes

No

Unsure

Please provide any comments you have (max. 500 characters):

As outlined in 2(a) above, we would ask for consideration to be given as to whether the terminology chosen is appropriate, using the word privacy for what is legally required when the word is not used this way in the legislation (the legal obligation is to transparency) could cause confusion. Communicating your meaning throughout the guidance is essential.

We also believe the draft guidance would benefit from more clarity on the "must" have requirements, as legal requirements versus the "should/could" requirements to maintain good standards of transparency. Again, we would

emphasise the need to recognise public views on the terminology used within the guidance and to consider the need to align with this.

3. Do you agree that this guidance provides useful additional information to the Health & Social Care sector that is not part of our existing guidance on the principle of transparency and the right to be informed?

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

Please provide any comments you have (max. 500 characters):

The guidance has the potential to be a useful addition to existing ICO guidance, and also complements guidance on the NHS England IG Portal. It would be useful to also reference the latter as it contains complementary, valuable guidance for the sector on, for example, the common law duties of confidentiality, as well as The Caldicott Principles (e.g. Principle 8 on informational duties).

The guidance would benefit signposting from the HRA's transparency guidance and templates outlined in our response to section 2(a). We offer guidance on transparency information to NHS sites, we outline how to be GDPR compliant, and we offer transparency wording for sponsors when designing participant information sheets.

4. Do you agree that this guidance is balanced between the separate areas of health and social care?

Too focused on health

Too focused on social care

About right

Not enough information on either

Unsure / don't know

Please provide any comments you have (max. 500 characters):

There appears to be a good balance between the separate areas of health and social care. The guidance addresses transparency issues in both care settings and the principles outlined seem to be applicable regardless of the specific care

settings, for example the reference to the duty of candour. The guidance does consider different care settings like hospitals, GP practices and care homes.

We would however ask for consistent referencing within the guidance of 'health and social care research' rather than 'health and care research' and would appreciate clarity on the meaning of 'uses' such as 'care and various uses secondary to care'.

Research within the guidance could be more productively set out with reference to the role of the HRA and our guidance. We would highlight that not all data processing for research is for secondary purposes, given that research can also provide care. Using the phrase 'secondary care purposes' could be problematic, if you are trying to convey the purpose is secondary to care, not for the purposes of secondary care.

5. Do you agree that the use of the terms must, should and could in this guidance clearly defines the ICO's expectations in the legislative requirements section and that the terms are applied consistently throughout the guidance?

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

Please provide any comments you have (max. 500 characters):

We would ask the guidance to cite legislative provision when referencing the "must" requirements for health and social care organisations. For example, it would be useful for organisations when mentioning DPIAs to specifically link to the nuanced legal requirement under Article 35 UK GDPR.

6. Do you agree with the definitions we have provided on openness and honesty? Are the examples of how you can demonstrate that you are being open and honest useful and accurate in the context of health and care?

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

Please provide any comments you have (max. 500 characters):

Yes, the definitions and examples for openness and honesty are useful and accurate and are aligned to the goals of transparency. The examples for the concepts provide tangible ways in which organisations can put them into practice, for example – publishing DPIAs, lists of information disclosed to researchers and the reasoning to support this or explaining commercial data access which can be a contentious topic.

7. Do you agree with that the section on harms is useful for organisations when considering the risks of failing to provide sufficient transparency material?

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

Please provide any comments you have (max. 500 characters):

The section on harms provides valuable guidance for organisations to consider the wider impacts of transparency beyond compliance. The harm examples are realistic and aligned to the common categories of harm like psychological, loss of control and chilling effects. It is useful to encourage readers to think about societal and group as well as individual harms.

We would however suggest outlining in the harms section more detail on the need to build public trust and confidence in the use of health and social care data for research. In the guidance, in the section entitled "How do we identify transparency harms?" under the heading Damage to Public Health the text outlines the risks to particular demographic groups if they do not share their data because of a lack of trust. This point could be given more depth with examples from health and social care research, the discussion could also be widened to include aspects of Equality and Inclusion.

We would be happy to work collaboratively to produce guidance which references research usage in the appropriate sections of the guidance. We would appreciate if the guidance also highlighted expectations that the HRA's guidance be followed as the NHS has a legal responsibility to have regard to it and that includes use of our transparency information.

8. Do you agree that the section on patient engagement provides useful information to help organisations develop transparency information that responds to people's needs and priorities?

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

Please provide any comments you have (max. 500 characters):

The HRA is committed to supporting and encouraging researchers to involve patients and the public in their work. We believe involving people with relevant lived experience in the design and development of research can improve its quality and relevance. Good public involvement is worth investing in. It can lead to the development of higher quality research and make it easier to recruit and retain participants.

We welcome recognition in the guidance of the importance of patient and public involvement and engagement, and in particular, the encouragement to involve patient and public groups to develop and evaluate transparency material. We would however recommend considering the promotion of co-production and co-writing of materials. Public involvement at the outset can be hugely valuable, public contributors embedded in the research know the importance of the research, and subsequently make writing the transparency documentation easier whilst building trust. There is an opportunity within the new guidance to showcase public involvement in the development of transparency materials through real life examples set in health and social care research. For example, Research Ethics Committees reviewing studies expect demonstration of public involvement not just in the design of research projects, but also in the participant notification materials where they depart from HRA templates (e.g. for studies involving children as research participants). This is also an expectation shared by the Confidentiality Advisory Group (see comments below under question 12).

We would also emphasise the differing responsibilities of the sponsor for research specific transparency and the research site for more general transparency. Both types of transparency need to be in accordance with HRA guidance.

9. Do you agree that the section on providing transparency information sets out clearly how organisations should approach the delivery of transparency and privacy information?

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

Please provide any comments you have (max. 500 characters):

Yes, the section on 'providing transparency information' does focus on the practicalities of how to provide information in an accessible format covering channels, coordination, and engagement, with emphasis on making information easy to find.

Specifically, the HRA agrees with the ICO's endorsement of a layered approach to information provision, as well as targeting the style of information to the audience that will receive it. Again, we would stress the importance of differing roles for the sponsor for study specific transparency compared to the role of the research site and general transparency. HRA guidance provides support and developed templates. See, for example, Update to data transparency wording - Health Research Authority. Study transparency wording prepared for research participants that do not follow HRA templates will be reviewed by a Research Ethics Committee with HRA approval specialist support to ensure they are appropriate for the study.

10. Do you agree that the transparency checklist provides a useful summary of the guidance and a mechanism to assess an organisation's transparency level?

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

Please provide any comments you have (max. 500 characters):

Yes, the transparency checklist does summarise the key points from the guidance and captures the major themes and compliance steps whilst balancing the legal requirements and recommended practices. It also serves as a self-assessment guide for organisations providing steps that are both required and recommended.

However, it is written at a high level. Therefore, it is essential to add comments about the potential applicability of other legal/regulatory transparency requirements (beyond data protection law) and good practice standards of transparency that may also apply. There are many of these that apply to those engaged in health and social care research.

11. Have you identified any aspects of the guidance that you feel are inaccurate or any areas we have missed or not covered sufficiently?

If so, please provide further details.

The draft guidance is a good starting point, but we would welcome the opportunity to work collaboratively to address our concerns outlined in this response and to offer signposting to support health and social care organisations.

12. We have provided placeholders for case studies and examples in the guidance to further illustrate certain issues relating to: Public trust in use or sharing of health and social care information; Harms associated with transparency and the impacts on patients and service users; Providing easily understandable information to patients and service users on complex forms of data processing; and Organisations working together to develop a 'joined-up' approach to the delivery of transparency information. Do you have any examples of good practice relating to these topics? Would you like to provide these to the ICO to be summarised and included in the guidance?

If so, please provide your name and email address below and we may contact you to discuss further.

The HRA is keen to help in the development of case studies.

Applications to the Confidentiality Advisory Group (CAG) have the potential to form valuable case studies for the new guidance. CAG is an independent body which provides expert advice on the use of confidential patient information. This includes providing advice to us, the Health Research Authority (HRA) for research uses.

The key purpose of CAG is to protect and promote the interests of patients and the public, while at the same time facilitating appropriate use of confidential patient information for purposes beyond direct patient care, where it is not practical/feasible to obtain consent from them. To this end, a key aspect of CAG conditions for setting aside the common law duty of confidentiality (where justified) is the requirement to demonstrate appropriate transparency to those affected patients and the public. This includes demonstrated usage of PPIE. For more, see Guidance for CAG applicants - Health Research Authority (hra.nhs.uk) under 'patient notification'.

The HRA would be willing to help develop case studies which focus on good practice for transparency in research and for patient and participant involvement. The Chair of the Make it Public Campaign, [redacted] is happy to discuss this with you.

In the first instance please contact [redacted] to discuss further.

Section 2: Your views on our summary impact assessment

The following questions are about our impact assessment. Some of the questions may not be relevant to you or your organisation so please skip these as necessary, or as indicated in the descriptions.

We are seeking views on our impact assessment summary table, which was provided as supporting evidence for the consultation. This sets out a high-level overview of the types of impacts that we have considered.

We will consider the proportionality of further assessment of the impacts as we move towards final publication of the guidance.

13. To what extent do you agree that the impact assessment summary table adequately scopes the main affected groups and associated impacts of the guidance?

Strongly agree

Agree

Neither agree nor disagree

Disagree

Strongly disagree

If you answered disagree, strongly disagree or unsure/don't know, please provide further examples of affected groups or impacts we may have missed or require further consideration. (max. 500 characters)

The impact assessment summary table does scope the main affected groups and associated impacts of the proposed transparency guidance. For the ICO, it covers efficiency savings in advice or support and potential supervision cost reductions, noting the resource cost of updating the guidance. For data subjects, the table provides benefits around reduced data protection harms and enhanced understanding of rights. Detail is also provided on health and social care organisations, mentioning improved regulatory certainty and greater confidence in compliance.

The impact assessment does not however adequately address the risk of harm to the UK economy, and to the health and wellbeing of the population, that may arise from the guidance failing to provide greater clarity and instead creating confusion, particularly in relation to the differing responsibilities of controllers and processors (our comments should be read in the specific context of health and social care research and the role of the research site as the processor of the research sponsor for the data processing required by the research protocol). Related risks exist also in creating, not mitigating, confusion in relation to 'general' and 'research project specific' transparency obligations. These related risks are considerable, given the importance of health and social care research to the UK economy and health and wellbeing of the population, and require serious consideration and mitigation. We would welcome formal recognition of

the need for co-production between ICO and HRA of aspects of the guidance relating to health and social care research, as a mitigation to these risks.

We would also emphasise that it is essential that compliance with legal requirements under data protection law are aligned with other compliance standards (e.g., under the common law duty of confidentiality) plus regulatory requirements to promote best practice overall in health and care research. A key aspect is non-duplication and aligned transparency messaging under the different regimes, not least to prevent reader confusion.

Overall, it is likely that the consultation will highlight if any impacts on affected groups are missing.

14. Can you provide us with any further evidence for us to consider in our impact assessment?

Yes

No

If you answered Yes, please could you provide the impact evidence or a link to it in the box below, or contact details where we can reach you to discuss further. (max. 500 characters)

Suggestions below:

- A survey (or extrapolation from existing studies) on public attitudes to health and care data sharing could provide insight into concerns, expectations and benefits or harms, as well as evidence on the public understanding of data rights.
- Data on the volume of ICO queries related to transparency issues could indicate the current scale of the problem of adherence.
    - If possible, quantification of current opt-out rates across UK health and care settings could also help to indicate the scale of the problem caused by lack of transparency or trust.
- Evidence on economic value of health data could help illustrate the scale of potential benefits.
- Projections for future health and care data uses can help illustrate the growing importance of transparency for emerging technologies.

The impact assessment must take account of the risk of harm of misinterpretation/over interpretation and misapplication of principles to inappropriate parties (controller/processor). There is also the risk of misalignment with existing domain specific guidance and expectations. The HRA would welcome the opportunity to develop guidance for the impact assessment in collaboration to make sure research specific guidance is included.

15. Please provide any further comments or suggestions you may have about the impact assessment summary table.

16. Are you acting on behalf of an organisation?

Yes

No

Section 3: About you and your organisation

To further assist our consultation process, it would be useful to know some details about you. Your information will be processed in accordance with our privacy notice.

17. Are you answering as: (tick all that apply)

An organisation or person processing health data

A representative of a professional, industry or trade association

An organisation representing the interests of patients in health settings (e.g. GP practice, hospital trust)
An organisation representing the interests of patients in social care settings (eg care home)

A trade union

An academic

Other (please specify):

18. Please specify the name of your organisation (optional):

Health Research Authority

19. How would you describe your organisation's size?

0 to 9 members of staff

10 to 249 members of staff

250 to 499 members of staff

500 or more members of staff

20. If you work in a health or social care providing organisation, how many patients or care users is your organisation responsible for (approximately)?

21. Who in your organisation needs to read the guidance? Please provide job titles or roles, rather than names.

Head of Policy and Engagement
Head of Data and AI
Head of Co-ordination and Standardisation
Director and Deputy Director of Approvals
Director and Deputy Director of Policy and Engagement
Data Privacy Specialist
Make it Public Campaign Group

22. To what extent (if at all) do data protection issues affect strategic or business decisions within your organisation?

Data protection is a major feature in most of our decision making

Data protection is a major feature but only in specific circumstances

Data protection is a relatively minor feature in decision making

Data protection does not feature in decision making

Unsure / don't know

23. Do you think the guidance set out in this document presents additional:

cost(s) or burden(s) to your organisation

benefit(s) to your organisation

both

neither

unsure / don't know

24. Could you please describe the types of additional costs or benefits your organisation might incur?

The HRA could face initial resource costs to help support the implementation of this new guidance, however anticipated costs could be offset by future resource savings.

Increased compliance to transparency measures and greater public involvement and engagement has the potential to enhance the quality of ethics approval applications for health and social care research. This new guidance could direct individuals to the HRA specific guidance and therefore help streamline the creation and use of transparency information in a way that supports our primary legislative function to co-ordinate and standardise practice in the UK relating to the regulation of health and social care research.

25. Can you provide an estimate of the costs or benefits your organisation is likely to incur and briefly how you have calculated these?

26. Please provide any further comments or suggestions you may have about how the guidance might impact your organisation?

Section 4: Any other comments
This section is for any other comments on our guidance or impact assessment that have not been covered elsewhere. Do you have any other comments you would like to make?

The guidance needs to consider accessibility for different audiences. There are a lot of acronyms in the guidance (a glossary would be helpful), and it can be difficult to understand certain processes or systems being discussed, such as data protection impact assessments. Redirecting readers to other webpages for further description makes navigating the guidance difficult.

The examples in the guidance would benefit from being real life scenarios with much more detail. One of these could include a case study involving the use of AI in a health and care setting to showcase the additional requirements/issues around transparency where AI (and other wholly automated) processing is involved per the ICO's AI guidance. Compare also the transparency section of

the NHSE IG Panel's endorsed guidelines on AI here: Artificial Intelligence - NHS Transformation Directorate (england.nhs.uk).

It would also help to have an introductory section on the role of the ICO to introduce the organisation to the public. The guidance needs some visuals such as infographics or from being more interactive. We want this guidance to be accessible and available to people who are involved in and interested in health and social care research.

In drafting this consultation response, we worked collaboratively with two public contributors with extensive experience of working on the HRA Make it Public Campaign group. Their experience and expertise helped inform this response. The public contributors very much welcomed this draft guidance and the positive impact it potentially offers. However, they wanted to know more about the implementation stages of the guidance. They also emphasised the need for the ICO itself to be transparent in communicating and promoting this consultation and the resulting guidance to the relevant organisations across the sector.

Finally, we would stress again our desire to work with you on the next stages of development for this new guidance. Our role as a regulator of health and social care research can support the aims of this new guidance, working together we can signpost audiences and tailor aspects of the guidance to the needs of health and social care research.