

Consultation on the draft Transparency in Health and Social Care guidance – HDR UK Response.

Health Data Research UK¹ is working to unite the UK's health data to enable discoveries that improve people's lives. Our vision is for large-scale data and advanced analytics to benefit every patient interaction, clinical trial, and biomedical discovery, and to enhance public health.

We are an independent, registered charity with five years of core funding from nine of the UK's leading medical research funders, including UK Research and Innovation, the Department of Health and Social Care in England and equivalents in Northern Ireland, Wales and Scotland, and leading medical research charities. HDR UK is a virtual institute, with staff and partners in all four nations of the UK and an office in central London.

The UK is in a unique position to realise the potential of health data, thanks to the NHS and its cradle-to-grave records for a population of over 65 million people. Safe and secure use of this data could improve treatments, deliver better health care and save lives. It could help tackle some of the biggest health challenges worldwide, including cancer, diabetes, and cardiovascular disease. However, access to this data for researchers is often a lengthy, fragmented process, meaning the potential for improving healthcare is far from being realised in full.

HDR UK is committed to accelerating trustworthy access to health data. By working in partnership with the NHS, industry and universities, we aim to facilitate research to better understand diseases and discover new ways to prevent, treat and cure them. Patients and the public are involved throughout, shaping the Institute's work and ensuring that access to data for research is enabled by safe and secure systems and generates public benefit.

HDR UK welcomes the ICO's draft transparency guidance, as one of our key values is advocating for transparency across all aspects of the health data research ecosystem. Building and maintaining public trust in use of data for research is a HDR UK priority, and trust cannot be earned without transparency.

Our response to the draft guidance draws from our experiences and includes input from our Public Advisory Board, a group of members of the public which who help guide our work and ensure that it is driven by delivering benefits to patients and the public. We have also consulted and incorporated feedback from some members of the UK Health Data Research Alliance ("Alliance")² – an independent alliance of over 90 leading health and research organisations. HDR UK convenes the Alliance to establish best practice for the trustworthy and ethical use of UK health data for research at scale.

¹ <https://www.hdruk.ac.uk/about-us/what-we-do/>

² <https://prezi.com/i/view/Kuf20mZFKRvHPvj0LTaP/>

The Alliance and PAB in partnership have developed and published Transparency Standards³⁴ to guide best practice for transparency within data access processes. To encourage adoption of the Transparency Standards, a funding⁵ call was run in September 2023 offering awards of up to £15,000 to support individual data custodians with adoption of the Transparency Standards. We received over 24 applications and awarded funding to 19 projects⁶ covering a range of approaches to improve accessibility and transparency.

We would be happy to have a discussion about the issues raised in our response.

³ <https://zenodo.org/records/8262453>

⁴ [Pan-UK Data Governance Steering Group makes progress in improving transparency in processes for accessing health data for research | UKHDRA \(ukhealthdata.org\)](#)

⁵ [Funding Opportunity to improve transparency in health data access processes for research. | UKHDRA \(ukhealthdata.org\)](#)

⁶ [New funding awarded to improve transparency of health data access processes for researchers and the public | UKHDRA \(ukhealthdata.org\)](#)



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? *

x 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
- x Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

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

We are pleased to see the guidance acknowledges that good practice for transparency goes beyond legal requirements. Transparency plays a critical role

in building public trust and confidence in the safe and secure collection and use of data.

It would be helpful to include more detailed, specific, "real world" examples, as the examples given in the draft guidance are very high level and simple. It would also be helpful to link to additional existing resources relevant to transparency (see Q12).

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

- Strongly agree
x Agree
 Neither agree nor disagree
 Disagree
 Strongly disagree

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

We would welcome an explicit acknowledgement in the section "How does this guidance approach transparency?" that whilst the distinction between transparency and privacy information is based on legal requirements, members of the public often see them as being equally important and may expect the "could" standards to be met by any responsible organisation.

We found the definition of "Transparency information" somewhat unclear and would suggest the following changes:

This describes the total range of material you **should** provide to comply with the transparency principle, together with additional information that you **could** provide to people to make your transparency material more effective.

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

- X Yes
 No
 Unsure

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

Members of our public advisory board (PAB), who help guide work at Health Data Research UK (HDR UK) and ensure that it is driven by delivering benefits to patients and the public, felt that the guidance positioned transparency information as being less important than privacy information. As noted above,

clarification that transparency information and privacy information are often viewed by the public as being equally important would be welcome.

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
- X Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

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

As noted above, more detailed case studies and examples would assist in understanding and implementation of the guidance. More examples related to social care would be helpful.

We note that front line health and social care staff are not included under "who this guidance is for", however we would suggest that staff working in the NHS and social care settings who interact with the public should have an understanding of and training in the principles of transparency and the right to be informed. We note that the ICO Accountability Framework supports this, saying "*Your organisation can demonstrate that any member of front-line staff is able to explain the necessary privacy information to data subjects and provide guidance.*"

We also note that the guidance uses "you" rather than being framed as applying to organisations / data controllers which is a different approach to other ICO guidance. It would be helpful to make clear under "who is this guidance for" that transparency is ultimately an organisational responsibility.

We would welcome creation of an "easy read" plain language version of the guidance suitable for a lay audience, to support better public understanding of transparency and the right to be informed and to educate those working in health and social care who are less familiar with the topic.

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
X Not enough information on either
 Unsure / don't know

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

In our view it would be helpful to include more specific worked examples relevant to social care, noting that there are a large number of smaller organisations in social care (e.g. care homes) and these organisations may not have significant legal or information governance resources available. We would also suggest adding a specific statement in the section "who is this guidance for" clarifying that it applies to care homes and other providers of social care services.

For both health and social care, more detailed, specific, "real world" examples are needed as the examples given in the draft guidance are very high level and simple.

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
X Agree
 Neither agree nor disagree
 Disagree
 Strongly disagree

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

Members of our PAB expressed concern that "should" and "could" requirements feel "optional" in the guidance which risks creating a misconception that minimum requirements are acceptable and/or only the "must" requirements are needed. We would therefore suggest that an explicit statement is added under the heading "What is a legal requirement in this guidance and what is good practice?" clarifying that for the "should" and "could" requirements there may be different ways to comply with the law, but the transparency requirements are not optional and best practice is strongly encouraged.

It would also be helpful to delineate between "must", "should" and "could" more clearly e.g. with a table with "must" "should" "could" headings in each section and an overall summary table at the end.

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):

As noted above, more specific and detailed case studies would aid understanding of the guidance. "Open" and "Honest" are subjective terms and hard to quantify.

In the section "Data Opt-Outs" under "How should we reflect choice?" we would suggest adding a link to more information about the opt-out and clarifying that in some cases the opt-out "must" be applied to comply with the common law duty (even if not mandated by data protection laws):

<https://digital.nhs.uk/services/national-data-opt-out>

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 example given is helpful in explaining the risks of not reaching all sections of the public via appropriate channels. We would welcome the addition of a further example highlighting the risks of not properly engaging the public so that the public understand and trust how their data is going to be used. The GDPR programme (currently paused) could be referenced as a 'real life' example of this in practice; the impact on public trust of the project during the summer of 2021 can clearly be seen in the publicly available opt-outs dashboard. A loss of public trust, at least in part due to a lack of effective public engagement, resulted in a large number of opt-outs over a period of a few months:

<https://digital.nhs.uk/dashboards/national-data-opt-out-open-data>.

We would also strongly encourage the ICO to make clear in the guidance that being transparent about the benefits of using data to public health, as well as the risks, can promote trust e.g.: <https://cprd.com/examples-how-research->

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
- X Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

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

The section on patient engagement is useful in prompting organisations to think of different and more innovative ways of communicating transparency information, particularly through focusing on the patients’ needs/priorities. We have the following suggestions for improving and clarifying the content of this section:

- The reference to a “bus stop” advertisement as a “method of public communications which let people know about how you use their information” is potentially unhelpful and we would suggest removing it. It would be very difficult to convey this type of information in a “one glance” advert.
- The guidance gives the example of a letter as a direct communication method, we would suggest amending this to say, “e.g. a letter, email or text message”. Email and text message are also key direct communication methods and can be very effective.
- We would suggest including case studies authored by members of the public who have experienced successful and unsuccessful patient engagement to bring the public voice into the guidance. There are many patient engagement initiatives that have taken place and HDR UK would be pleased to discuss further with the ICO how members of the public could contribute to case studies. By way of example, public contributors who shape and influence the work of HDR UK have contributed to videos and blogs about their experiences here: <https://www.hdruk.ac.uk/about-us/involving-and-engaging-patients-and-the-public/get-involved/hdr-uk-stories/>

Links to the following best practice guidance on patient engagement could also be added to the guidance:

- PEDRI- Best Practice Standards
- UK Standard for Public Involvement- Learning for Involvement

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):

See response to Qu 8 above. Additional case studies authored with members of the public would be a very helpful addition to this section of the guidance.

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):

There is no "could" section in the checklist, we would suggest this is added, as the "could" standards set out in the guidance should always be considered.

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.

It is not clear whether public and patient opinions on the guidance are being actively sought by the ICO and we would welcome clarification of this. If specific engagement with the public on the guidance has not yet been carried out, we would suggest an extension to the consultation end date and a focus on direct public engagement before the guidance is finalised.

In addition, awareness of the guidance in the health data research sector appears to be low and with the deadline for responses coming just after the Christmas break this may hinder broad feedback to the consultation. We would therefore suggest that an extension of the 7 January deadline should be considered in any event.

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?

We would be happy to discuss the following examples with the ICO for inclusion in the guidance:

Transparency Standards co-created by the Pan-UK Data Governance Steering Group (a sub-working Group of the UK Health Data Research Alliance) and members of the public. These standards set out good practice for being transparent with the public about how researchers can apply to access and use data and how data is used:

- The Standards are published here:
<https://zenodo.org/records/8262453>
- More information on the standards is published here:
<https://ukhealthdata.org/news/pan-uk-data-governance-steering-group-makes-progress-in-improving-transparency-in-the-use-of-health-data-for-research/>

Data Use Register Standard published by the UK Health Data Research Alliance, which sets out recommendations for a data use register standard to be adopted by organisations responsible for the safe sharing of data used for research and innovation. A data use register is a public record of how data is being used for research, by who and for what purpose and is a critical element of transparency:

- https://zenodo.org/records/5902743#.YfAI__7P2Uk

Building trust in data access through public involvement in governance: Survey findings and recommendations from HDR UK's Public Advisory Board are published here:

- <https://www.hdruk.ac.uk/wp-content/uploads/2021/07/280621-PAB-Data-Access-procedures-paper-Building-trust-in-data-access-through-public-involvement-in-governance.pdf>

If so, please provide your name and email address below and we may contact you 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)

N/A

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)

Please see response to Qu. 12 above.

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

In the "cost-benefit analysis" section under "Wider Society" the following sentence is potentially misleading:

"Potential for wider benefits such as improved data for research purposes as a result of individuals being better informed, and potentially more willing to consent to their personal data being processed."

As the guidance rightly notes, consent under UK GDPR is rarely the appropriate lawful basis in the context of health and care information. In our view it would be more accurate to say:

"Potential for wider benefits such as improved data for research purposes as a result of individuals being better informed, and less likely to opt out of their personal data being processed."

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 (eg GP practice, hospital trust)

- An organisation representing the interests of patients in social care settings (eg care home)
- A trade union
- An academic
- X Other (please specify):

HDR UK is the national institute for health data science, a charity working to unite the UK's health data to enable discoveries that improve people's lives.

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

Health Data Research UK

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

- 0 to 9 members of staff
- X 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)?

N/A

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

Head of Legal, Trust & Ethics

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

- X 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?

N/A

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

N/A

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

N/A

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?

N/A