# 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- Section 1: Your views on the draft guidance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**Section 1: Your views on the draft guidance**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:

We welcome this guidance for the healthcare sector. Given the close correlation between transparency and public trust, the importance of transparency when using healthcare data cannot be overstated.

The core message of the guidance is clear: being transparent about uses of healthcare data is important. It is helpful that there are sections of the guidance which provide practical advice about how transparency and privacy materials should be developed, and provided to patients and the public, to meet the ICO's expectations (although there are some sections where we believe it is necessary to increase the practical information as detailed in our answers to questions 8 and 9).

There are, however, some fundamental issues relating to the scope of the guidance which impacts on its clarity – as described below. We suggest that these matters are addressed in the introductory sections and the title so that the scope of the guidance is clear from the outset.

**Who is the guidance for?**

The guidance is written 'to help health and social care organisations understand' the ICO's expectations about transparency'. Our understanding, therefore, is that the guidance is primarily aimed at those organisations that provide health and social care services and collect data in order to deliver these services. We have significant concerns about this limited scope for the reasons set out below.

The current scope of the guidance creates an expectation that healthcare providers are solely responsible for meeting transparency requirements. This is highly problematic because it fails to recognise that the processing of data for secondary uses usually occurs outside of health and care providers. There are a wide range of organisations which process data for secondary uses (for example, medical research) and which include government organisations. Therefore, the guidance should not place all of the responsibility on healthcare organisations. Rather, it should apply to the type of data being processed i.e. the guidance should be relevant whenever healthcare data is being processed, regardless of the type of organisation which is carrying out the processing.

For example, if a healthcare provider discloses personal data to a third-party organisation for medical research and the research organisation assumes data controller responsibilities in respect of processing data for this secondary purpose then the responsibility for transparency requirements will fall to the research organisation. The disclosing healthcare provider will still have responsibilities to be transparent about how it uses data and who it has disclosed data to; however, it would not be appropriate to suggest that it is responsible for transparency in relation to the medical research purpose. It is important that the guidance is clear about where responsibility for transparency requirements lies in any given circumstances when healthcare data is being processed.

*Government organisations*

Transparency responsibilities apply to government organisations which process, or seek to process, healthcare data. However, it is often the case that there is a mismatch between the levels of transparency expected by the public and that which is achieved by government organisations. The guidance should emphasise the crucial importance of transparency for government data programmes. This includes patient and public involvement at the early stages of a programme to

allow for scrutiny and questions to be asked rather than simply putting out communications shortly before the programme is due to launch.

The ICO will be aware of the abundance of evidence (for example, care.*data* and GP Data for Planning Research programmes) which shows what happens when governments fail to be transparent and fail to involve and build trust with patients and the public. It is essential that such situations are avoided in the future because of the highly damaging longer-term consequences to people's trust in the confidentiality of healthcare services.

*Direct-to-consumer testing*
There are significant questions relating to transparency and the provision of information for direct-to-consumer testing by private companies. This includes, but is not limited to, genetic testing.

*List of staff at whom the guidance is aimed*
Page 4 of the guidance lists certain groups of staff at whom the guidance is aimed. The list does not include GPs. This is an omission as it will often be GPs who have responsibility for data protection compliance when they are performing their role as data controller for their practice. GPs will have direct involvement in some of the examples of activities (on page 5) where the guidance may be useful – including implementing a new data collection for secondary purposes and setting up a shared care record across a region.

**Secondary uses of healthcare data**
The scope of the guidance includes both direct care and secondary uses of healthcare data; however, it would aid clarity if there was:

- a clearer distinction between direct care and secondary uses; and
- an increased emphasis on the importance of transparency information requirements in relation to secondary uses.

While healthcare providers must be transparent and comply with the privacy notice requirements (in respect of Article 13) to explain how medical records are used to provide direct care, it is highly likely that patients will have far less awareness and understanding about how, why and by whom healthcare data is processed for secondary uses. We see the guidance as an opportunity to help organisations address this issue through the provision of transparency information. We therefore suggest that there should be a greater focus on secondary uses of data within the sections on the provision of transparency information.

**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 agree it is helpful to draw a distinction between transparency information and privacy information.

The guidance is clear that a distinction does exist; however, it could be made clearer and more explicit that:

- the definition of privacy information relates to the specific legal and practical requirements necessary to comply with the right to be informed (with reference to Articles 13/14); and
- that this is separate to the more general and overarching data protection principle of transparency (Article 5) which imposes an obligation to tell people about how their personal data is processed.

References to Articles 13 and 14 (which set out the specific information which UK GDPR requires within privacy information or privacy notices) could help make the difference between privacy information and transparency information clearer.

The guidance would also benefit from being clearer about requirements in relation to how, or the way in which, both types of information are provided. In this context it would be helpful if the following questions could be addressed:

- Does the requirement to provide privacy information to satisfy the right to be informed (Articles 13 and 14) extend to consideration of how this information is provided? Or does the 'how' fall solely under the more general transparency information requirement in Article 5?
- How does the additional Article 12 transparency principle apply in the context of writing privacy notices?

**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):

Yes, and it is important that the ICO makes the legal distinctions clear as covered in our response above.

**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:

Given the fundamental importance of transparency whenever healthcare data is being processed this guidance is an extremely welcome addition to existing guidance which reinforces the expectation that organisations must take their transparency obligations seriously.

Transparency is not a 'nice to have' or add-on. Where organisations fail to demonstrate transparency, they are likely to be viewed by the public as suspicious and untrustworthy. This can have damaging consequences to an individual's own health and potentially to public health, and, also, undermine other uses of data which have enormous benefits for wider society (please see question 7 where we discuss this further).

We believe that this guidance will be very helpful for organisations in understanding what the ICO expects when it is considering how best to develop transparency and privacy information materials.

We note that the ICO guidance comes at a time when the Data Protection and Digital Information Bill (currently in the House of Lords) contains proposals which pull in the opposite direction by reducing transparency requirements. Clause 11 of the Bill disapplies the existing requirement to provide information to data subjects when personal data is processed for a further, separate purpose if it is for scientific research and would require 'disproportionate effort' to provide this information. The BMA will continue to lobby strongly for the removal of this clause because it is a damaging backwards step in terms of transparency obligations.

**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:

Our focus is on health organisations therefore it is difficult for us to comment on what might be the correct balance to strike between health and social care. We agree there is an appropriate focus on health, however, there will be other organisations which are better placed to comment from a social care perspective.

**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:

**Consistency with GMC guidance**

The ICO guidance says that:

***Must*** *refers to legislative requirements (the scope of this guidance is limited to the requirements of DPA 2018 and UK GDPR).*

***Should*** *does not refer to a legislative requirement, but what we expect you to do to comply effectively with the law. You should do this unless there is a good reason not to. If you choose to take a different approach, you must be able to demonstrate that this approach also complies with the law.*

This is a different interpretation, with particular reference to the term 'should', to that in the GMC *Good medical practice* guidance where the terms 'you must' and 'you should' are explained in the following ways.

- *'You must' is used for a legal or ethical duty you're expected to meet (or be able to justify why you didn't).*
- *'You should' is used for duties or principles that either:*
  - *may not apply to you or to the situation you're currently in, or*
  - *you may not be able to comply with because of factors outside your control.*

We understand that the guidance is aimed at the wider healthcare sector, however, any inconsistency between ICO and GMC guidance could cause

confusion for doctors and may interfere with appropriate information sharing. It would therefore be helpful if the ICO's interpretation of 'you should' could more closely reflect that in GMC guidance.

**Importance of the common law duty of confidentiality**

There are certain sections of the guidance which appear to underestimate the importance of the common law duty of confidentiality. For example, in the *How should we reflect choice?* section (pp.12-13) it is implied that the common law duty of confidentiality is relevant only when personal data is being shared for secondary purposes. It should be made clear that the common law is also relevant when sharing for direct care purposes.

We understand that the common law duty of confidentiality does not fall within the ICO's regulatory remit. However, given its importance in the context of sharing healthcare data, we suggest that greater attention should be given to the common law and the importance of consent. This could be achieved by setting out that:

- the duty of confidentiality requires explicit consent where confidential patient information is used for purposes other than an individual's direct care, unless there is an exemption provided by law or an overriding public interest; and
- the legal basis which permits sharing for direct care is implied consent.

References to national guidance from bodies such as the GMC, BMA and NHS England which provide greater explanation about the common law could be usefully provided.

**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:

We agree with the definitions; however, the guidance would benefit from additional information about how openness and honesty can be achieved.

The section on openness refers to the provision of information in 'easily accessible and understandable formats'. This crucial point should include advice about what accessible language looks like, how 'plain English' can be achieved

for an audience with varying levels of literacy and the provision of information for those who do not speak English (or for whom English is not their first language).

The guidance should highlight that openness also extends to being clear with the public about the meaning of the terms used within the transparency information and to avoid the use of ambiguous language. The healthcare sector can often use language, phrases or acronyms which have unclear definitions or may not always be easily recognisable to the public. Without clear and concise explanation as to what these terms mean, transparency will not be achieved.

**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:

We agree a section on harms should be included; however, the guidance as currently written could lead to a misleading understanding of the harms that can occur when organisations are not transparent about how they use healthcare information.

For instance, the example box refers to the bodily and psychological harm if an individual does not see information about a public health campaign because they do not own a mobile phone. This example appears to relate to harms if organisations fail to provide information about available services or to provide advice to people about what they can do to promote their own health. These are separate matters to the issue of organisations being transparent about processing healthcare data.

We suggest this section is reworded so that it is more clearly focused on the harms described below.

There are two fundamental harms to society (and to individuals) which can occur if organisations are not transparent about uses of healthcare data.

*Harm to trust in the confidential nature of healthcare services*

This is the most fundamental of harms – affecting both individuals and wider society - and should be the focus of the harms section. Building on the 'chilling effects' example, the guidance should be explicit that organisations which fail to meet transparency requirements are unlikely to be viewed as

trustworthy custodians of confidential data. If people do not trust the ability of the healthcare system to use and protect their data appropriately this will cause harm to the trust relationship between doctors and their patients. The direct consequence should people feel unable to be frank with their doctor (or not visit the doctor at all) is the potential harm to individual's own health, including public health – and the overall health of wider society in general - should this decision make it difficult, or impossible, for doctors to provide effective treatment or if patients are deterred from consulting healthcare professionals. Avoidance of this harm should be given precedence over the existing examples of harms.

*Harm to public benefit uses of data such as research and service planning*

Should a lack of trust in healthcare organisations result in patients withholding certain information from their doctor, as described above, this will not only have an impact on individual healthcare outcomes, but it may also result in research findings or decisions about service planning being based on biased and/or inaccurate data. This may cause harm to wider society if it will not benefit from ongoing improvements to medicine and decision-making about services. There may also be harm to certain population groups with higher rates of opt-out if they are not represented in datasets on which research findings rely and which are used to make decisions.

Similarly, mistrust in organisations can also lead to an increase in the number of people opting out of secondary uses of data (via the national data opt-out and the 'type one' opt-out in England) with the same negative consequences for society.

**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:

Please note that in this answer we use the term 'patient and public involvement' (PPI) in preference to 'patient engagement' because PPI is the terminology used by the NHS and relevant national research bodies such as the Health Research Authority (HRA)). Our understanding is that the guidance describes PPI i.e. involving the public and patients throughout the process of designing transparency information so that it best meets the needs of those who need to access it, rather than patient engagement.

We welcome that this section highlights the benefits of effective PPI; however, it does not provide enough practical information about how best to achieve it when developing transparency materials. Organisations will need this guidance, particularly if they do not at present have the necessary connections with public and patient groups or networks.

We suggest seeking specialist expert advice from organisations which have experience in PPI so that the guidance can draw on best-practice examples and case studies which include practical advice about how to develop connections with public involvement groups. A good starting point might be the HRA which has detailed online advice about what it expects when researchers undertake PPI and how these expectations can be met. It also has its own public involvement team (public.involvement@hra.nhs.net).

**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:

The points in our response to question 8 also apply here. We believe that this section needs to be expanded to include more practical information and case-study examples to help organisations understand what they need to do when planning the delivery of transparency and privacy information.

The guidance could include real-life examples of best practice which demonstrate how organisations can comply with the principles in this section. For instance, are there examples of other organisations which demonstrate effective communication, including how to determine the target audience and the best methods for reaching this audience?

In the section titled *'How do we provide transparency and privacy information?* the guidance says the provision of transparency information is a '*prime opportunity for you to provide as much information as possible'*. In our view, this is likely to send the wrong message that 'more is better' which will lead to

audience disengagement through information overload or people feeling overwhelmed. We strongly agree with the layered approach as described in the guidance and suggest that this is the message which should be promoted.

We also believe that the guidance should provide more information about organisations' ongoing responsibilities to provide transparency and privacy information. For example, it is not entirely clear what the ICO's expectations are in relation to ongoing communication. The guidance says that people should be notified when significant changes are made to a privacy notice, however, it is not clear whether this means the ICO expects a direct communication to be made in all circumstances when a privacy notice is updated or whether there are other methods which can be used to inform people of changes.

**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:

We agree this section provides a helpful summary; however, we suggest the following amendments could improve clarity and ease of use.

- This section is divided into two parts: the bullet point questions under the heading '*How do we assess if we are being transparent?*' followed by the transparency checklist of 'musts' and 'shoulds'. The bullet point questions are especially helpful but the current format of two sections creates a risk that organisations may be drawn directly to the checklist of 'musts' and 'shoulds', with less attention paid to the bulleted questions. We suggest the two sections could be combined to form a single section to make it easier for organisations to absorb all the duties and tasks - and which would ensure that equal importance is given to the bulleted questions.

- In a number of areas, the checklist relies on the use of the word 'considered' i.e. '*We have considered…'*. It is not clear what the ICO expects consideration to involve and what efforts should be made. Consideration could arguably mean very minimal effort such as one person taking a few minutes to come to a decision unsupported by evidence or research. Determining the best way to communicate with both a general audience or with specific groups requires greater effort, including research and analysis of evidence so that decision-making is informed.

- We suggest rewording which makes the ICO's expectations clearer and which reinforces requirements where they exist. For example, we understand that the ICO would expect organisations to do more than 'consider' what privacy information must be provided within the privacy notice because supplying the specified privacy information is a legal requirement under GDPR.

  Therefore, '*We have considered what privacy information we must provide within our privacy notice*' could be changed to: '*We have included the required information within our privacy notice.'*

  In other areas, the checklist could say: *'We have analysed…' or 'We have researched….'* both of which suggest greater effort than '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.**

**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.**

**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)

**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)

**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 (eg 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):**

British Medical Association

**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.**

**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?**

**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?**