

Are you happy to proceed?
I am happy to proceed.
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?
Agree
<p>Please provide any comments you have:</p> <p>The guidance provides helpful high-level principles however there is room for differing interpretations in terms of what counts as proportionate. This is quite critical for the health and social care sector organisations that need to implement the guidance because of the costs of developing and updating transparency materials and feasibility of wider dissemination. For example, consider the case of a data custodian that makes pseudonymised electronic healthcare data available for public health research. This data custodian implements the transparency and privacy guidance in the following way: including a data protection notice on its website that outlines what data is held, the legal bases for processing, how long is the data held, what GDPR data subject rights patients have, how they can opt-out, any relevant approvals for the use of the data (for e.g., HRA REC and CAG approvals), the purposes for which the data are used and summaries of approved protocols submitted as part of data access requirements. In addition, print and electronic posters are shared with all GP practices contributing data to the database so that they can be displayed in the practice premises and where available, on the practice website. These posters state that the practice contributes pseudonymised patient data to this particular database and includes a web link for more information including on opting out. Is this considered proportionate? If yes, it would be helpful for the guidance to include this and other examples showing how the guidance could be operationalised in a proportionate way. Otherwise, some data protection officers have taken a very hard stance on transparency requirements including asks like setting up technology systems so that patients can tell exactly which studies their data have been included in, or having to list every contributing GP practice name on the data custodian's website (which can in itself slightly increase the risk to privacy by letting malicious actors know which practices contribute data to the database), or requiring contributing GP practices to send text messages to all their patients every six months to let them know they are contributing data to a specific database and how they can opt out, lest they miss the posters in the practice premises or on the practice website. The costs associated with these types of asks are immense and not proportionate from a typical public sector data custodian perspective that operates on a cost-recovery model. It would therefore be very helpful to include such examples to better explain what is proportionate in the ICO's view.</p>
2(a). Do you agree that this guidance provides a clear definition of transparency and privacy information?
Agree
<p>Please provide any comments you have:</p> <p>Yes, conceptually the definitions are very clear but as stated above, the operationalisation is subject to differing interpretations. It would be helpful to state who decides on what is a sensible operationalisation stance? Should this be left to the health and social care sector organisation? What if there is a difference in opinion on operationalisation within the organisation? Who should take this decision on what is proportionate? Who will moderate this?</p>
2(b). Does the distinction between transparency information and privacy information make sense to you?
Yes
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?
Agree
4. Do you agree that this guidance is balanced between the separate areas of health and social care?

About right

Please provide any comments you have:

The transparency checklist is helpful especially the separation of the 'musts' and 'shoulds'. More case studies on how the guidance could be operationalised would be helpful.

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

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?

Agree

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?

Agree

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?

Agree

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?

Agree

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?

Agree

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.

More fully worked out case studies or exemplars of operationalisation would help.

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.

████████████████████

<p>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?</p>
<p>Agree</p> <hr/> <p>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. 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.</p>
<p>14. Can you provide us with any further evidence for us to consider in our impact assessment?</p>
<p>No</p>
<p>16. Are you acting on behalf of an organisation?</p>
<p>Yes</p>
<p>17. Are you answering as: (tick all that apply)</p>
<p>An organisation or person processing health data</p>
<p>18. Please specify the name of your organisation (optional):</p>
<p>Clinical Practice Research Datalink</p>
<p>19. How would you describe your organisation's size?</p>
<p>10 to 249 members of staff</p>
<p>20. If you work in a health or social care providing organisation, how many patients or care users is your organisation responsible for (approximately)?</p>
<p>N/A</p>
<p>21. Who in your organisation needs to read the guidance? Please provide job titles or roles, rather than names.</p>
<p>Research Data Governance, Information Governance and Communications teams</p>
<p>22. To what extent (if at all) do data protection issues affect strategic or business decisions within your organisation?</p>
<p>Data protection is a major feature in most of our decision making</p>
<p>23. Do you think the guidance set out in this document presents additional:</p>
<p>both</p>
<p>24. Could you please describe the types of additional costs or benefits your organisation might incur?</p>

It is currently difficult to say as we already do a lot in terms of transparency and privacy. I personally find the guidance helpful in its emphasis on proportionate execution with a clear distinction between the 'musts' and 'shoulds', so it depends on whether this guidance will be used by some of the committees that we report to, to argue for even more transparency and privacy without considering the resource burden.

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

This is challenging as it depends on interpretation. One person may for instance, feel that their organisation is compliant with the guidance though there are some areas of improvement that may require some staff resource (perhaps an additional £30K in staff time). However, someone else may interpret this guidance differently and based on some of the interpretations of what constitutes our duties around transparency and privacy, that I have heard from other quarters previously, the costs could easily be an additional £500K per annum. Transparency is in principle a good thing but we do have to accept some costs in terms of increased opt-outs simply because a transparency update usually acts as a trigger for more opt-outs especially if there is a media story that had undermined public trust around the time of the update. Transparency does not always improve public trust and that is a risk we have to accept.

Do you have any other comments you would like to make?

The CPRD senior management team is happy for CPRD to be included as a case study for the guidance.

