Response to GMC consultation on revised confidentiality guidance

February 2016

1. Introduction

1.1 The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and voluntary registration of people working in health and care. We are an independent body, accountable to the UK Parliament. More information about our work and the approach we take is available at www.professionalstandards.org.uk

1.2 As part of our work we:

- Oversee nine health and care professional regulators and report annually to Parliament on their performance
- Conduct research and advise the four UK governments on improvements in regulation
- Promote right-touch regulation and publish papers on regulatory policy and practice.

2. General comments on guidance

2.1 We welcome the chance to comment on the revised GMC guidance on confidentiality. This is an important and complex area and it is positive that the GMC have taken the provision of guidance so seriously. It is important that patients can have confidence that doctors will keep their personal information confidential and only share it for very specific and clear reasons.

2.2 As highlighted by the second Caldicott review[1], information governance is often presented as a barrier to information sharing across different parts of the care and support system. This is a particular problem when information needs to be shared outside the NHS, with other organisations involved in the welfare of a service user, including social care (social workers in particular), schools, the prison service. We would suggest that this may need to be addressed further in the guidance to ensure that the best interests of the patient are always central to decisions around information sharing and that doctors understand the situation where this might occur.

2.3 As several of terms in the glossary are essential to be able to clearly read and understand the document, we would suggest that it would be useful for this to be placed at the front of the document.

[1] Information: To Share Or Not To Share? The Information Governance Review, Fiona Caldicott https://www.gov.uk/government/publications/the-information-governance-review

2.4 It is good to see that the guidance aims to provide detailed guidance on all of the circumstances where there may be a need to consider appropriate sharing of information making it a comprehensive reference document for doctors on this issue. We would suggest that to aid usability it may be useful to include a restatement of the key principles from the guidance at the beginning of the document and may also be worth highlighting explicitly early in the guidance what has changed from the 2009 version to allow professionals to easily identify this.

3. Question 1 - Do you agree that we should structure the guidance around the three purposes: direct care; indirect care; and non-care purposes?

3.1 Yes

3.2 This structure seems logical as this will help to focus the mind of professionals reading it on the different circumstances when they might have to consider disclosing information. It may however be worth referencing that the decision-making process when deciding whether or not to disclose personal information is likely to be broadly the same and therefore the same principles will apply.

4. Question 2 - Is the framework section helpful? (The framework for considering when to disclose personal information (paragraphs 14–35))

4.1 Although useful in referencing the relevant sections, the framework appears in some ways to duplicate the decision making flow-chart at the end of the guidance, therefore it may be worth cross referencing the flow chart here or considering how these parts of the guidance fit together.

5. Question 4 - Do you agree that a doctor should be able to rely on a patient's implied consent to share information about their direct care when all of these conditions are met? (Implied consent to disclose information for direct care purposes (paragraphs 36–45)

(Conditions at paragraph 38 to be met to be able to rely on implied consent: * the person accessing or receiving the information is providing or supporting the patient's direct care, * information is readily available to patients explaining how their information will be used and that they have the right to object, * the patient has not objected, * anyone to whom the patient's personal information is disclosed understands that it is given in confidence, which they must respect.)

5.1 As highlighted in the Caldicott report and other previous work, differences between the regulators in defining 'implied consent' remain. We would therefore suggest that it would be worth including the fuller definition of implied consent in this part of the guidance as well as in the glossary to make it as clear as possible what is being referred to in this instance and to also consider including a more specific example of when this might apply.

5.2 A key issue highlighted previously was the importance of patients understanding how their personal data may be used. We would also suggest therefore, that further prominence is given to the need for professionals to be reasonably sure that the patient has this understanding in addition to this information simply being available, before implied consent is relied upon to disclose personal information.

5.3 In relation to paragraph 40 we would suggest that defining what patients might 'reasonably expect' in terms of how their information it used might be difficult. Instead it might be worth referring to the information that is available to patients about the use of implied consent.

6. Question 5 - Do you agree with the advice about disclosing information for clinical audit? (Clinical audit paragraphs 46–48 - In the revised guidance we say that doctors can rely on implied consent to disclose information for clinical audit if it is to be carried out by members of the team that provided direct care to the patient. If the clinical audit is to be carried out by anyone else then the information should be anonymised or de-identified (which we define in the glossary of the guidance), or the patient should be asked for explicit consent.)

6.1 It may also be useful to be explicit on the point that if any of the outcomes from the clinical audit are to be made public or made available to anyone beyond the team providing the direct care and are likely to include any identifiable information then the explicit consent of the patient should be sought.

7. Question 6 - Do you think that this section strikes the right balance between being sensitive and responsive to those close to a patient, while respecting the patient's right to confidentiality? (Sharing information with, and receiving information from, those close to the patient (paragraphs 49–57)

7.1 It may be useful to more clearly define what a 'compelling reason' for withholding information from those close to a patient might include.

8. Question 7 - Do you agree with the extension of the duty to disclose information about patients who may be at risk of serious harm and who lack capacity to consent? (Disclosing information about patients who may be at risk of serious harm and who lack capacity to consent (paragraphs 73–75)

8.1 Yes

9. Question 8 - Do you think that there may be circumstances in which there is a public interest justification for disclosing information about an adult who has capacity without their consent, even when nobody else is at risk

of serious harm? (Section - Disclosing information to protect patients who have capacity without their consent (paragraphs 76–80)

9.1 Not sure

10. Question 9 - What do you think would be the consequences of us changing our advice in this way? (Section - Disclosing information to protect patients who have capacity without their consent (paragraphs 76–80)

10.1 We would agree with the recommendation to seek legal advice in such circumstances.

11. Questions 11 - Is the guidance on using anonymised and de-identified information helpful?

11.1 Yes

12. Question 12 - Do you agree with this guidance on the process of anonymising or de-identifying information?

12.1 Yes

13. Question 13 - Do you agree with this statement about the very limited scope for justifying disclosure in the public interest of identifiable information for indirect care purposes?

13.1 Yes

14. Question 14 - Do you agree that these are the factors that doctors should take into account when considering whether a disclosure is justified in the public interest?

14.1 Yes

15. Question 16 - Do you agree with this advice on disclosing information to the courts and in connection with litigation? (Section - Disclosures to the courts or in connection with litigation (paragraphs 118–121)

15.1 Yes

16. Question 17 - Is the guidance on disclosing information in the public interest at paragraphs 122–128 helpful? (Disclosures in the public interest (paragraphs 122–128))

16.1 Yes

17. Question 19 - Do you agree with the inclusion of these duties on information governance and compliance with data protection legislation? (Section - Knowledge of information governance and compliance with data protection legislation (paragraphs 134–139)

17.1 Yes

17.2 It may be worth adding that the list of potential material forms that health and care records can take may not be exhaustive (paragraph 133).

18. Question 20 - Do you agree with the guidance on improper access and disclosure? (Improper access and disclosure (paragraphs 140–143)

18.1 Yes

19. Question 21 - Do you agree with the inclusion of these duties for doctors who have responsibilities for managing or recruiting staff? (Section - Records management (paragraphs 144–148)

19.1 Yes

19.2 Alongside the requirement for professionals to ensure that staff they manage undergo training and understand their responsibilities in this area, it may be useful to add a requirement to ensure that staff receive regular refresher training as the guidelines around records management and data handling may change.

20. Question 22 - Do you agree with the guidance on disclosing information after a patient has died?

20.1 Yes

21. Question 24 - Do you have any comments on the glossary?

21.1 Yes

21.2 The glossary is useful but as highlighted earlier we would suggest that the definitions of consent could also be included in the relevant section (direct care uses and disclosure, page 11).

21.3 In addition, the definition of the "healthcare team" refers to professionals - but there are many unregulated practitioners (including those who may be covered by an Accredited Register) who assist in providing direct care and may also need access to information. It would be helpful if this was clarified. In relation to this definition, it would also be useful to clarify what “supporting” as opposed to “providing” direct care means.

21.4 Also in relation to the use of the term "healthcare team" it may be useful to include a separate definition to apply to social care team as this isn’t likely to be seen to apply to any care being provided outside the hospital.

22. Question 25 - Is the legal annex helpful?

22.1 Yes

23. Question 27 - Do you have any comments on the endnotes?

23.1 Yes

23.2 Where other pieces of relevant guidance are referenced, we would suggest that these could be highlighted separately for clarity with links included.

24. Question 28 - Do you think this is helpful? (Flowchart for decision making)

24.1 Yes

24.2 As highlighted previously, it may be worth considering how the flowchart fits with the framework also included from page 7.

25. Question 29 - Overall, how clear is the draft guidance?

25.1 Fairly clear.

25.2 As previously highlighted the guidance is extremely comprehensive in seeking to cover every situation which a doctor might encounter. It is therefore, necessarily a fairly long document and we would suggest that clarity could be improved by having a one page summary of the key principles near the beginning and also a summary of the changes from the previous version.

26. Question 30 - Is there anything missing from the guidance?

26.1 As highlighted previously, we believe that it would be useful for the guidance to address the sharing of information across organisational boundaries and outside of the NHS to ensure that information governance does not become a barrier to effective information sharing between difference bodies involved in care, for example between hospitals and the social care system. Page 46 of the Caldicott review includes a useful list of examples of data transfer issues across organisational boundaries.[2]

27. Question 32 - Are there any issues or situations that you think it might be useful to have a case study on?

27.1 Yes

27.2 As highlighted previously, further case studies on when it might be possible to assume implied consent might be useful due to the complexity of this circumstance. In addition, in relation to the point around information sharing

[2] Information: To Share Or Not To Share? The Information Governance Review, Fiona Caldicott https://www.gov.uk/government/publications/the-information-governance-review

between different organisations, it may be useful to include examples of where this might occur.

28. Question 33 - Do you have any other ideas on how we could show how the guidance might work in practice, such as guidance for patients or interactive flowcharts?

28.1 Yes

28.2 The flow-chart currently included gives a very clear overview of how the decision making process should work so would suggest that this could be the basis for any patient facing communication.

29. Question 34 - Do you think any part of the guidance will affect people with protected characteristics that are covered by equality legislation?

29.1 No

30. Further information

30.1 Please get in touch if you would like to discuss any aspect of this response in further detail. You can contact us at:

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