

Patient Information Advisory Group

Response

To the Department of Health consultation on:

Records Management: NHS Code of Practice.

The Patient Information Advisory Group (PIAG) is an independent body established to advise the government on issues involving the use of patient information, and to oversee arrangements created under Section 60 of the Health and Social Care Act 2001.

Our response is in two sections, reflecting the structure of the consultation. The first section deals with general issues. This is followed by a table, which documents specific comments on the text of the consultation document.

The first part includes the questions posed by the consultation and the Advisory Group's response. We have omitted the administrative questions including those related to layout of the consultation to focus on the policy questions.

Q. Have you any general comments to make on the retention schedules - Annexes Di and Dii?

- i. At the beginning of Annex D, the maximum period for retention of records is indicated to be 30 years, however this could be highlighted more effectively in the document.
- ii. Additionally, it would have been helpful to have a column for anticipated maximum retention timescales for health records as well. This is because in some instances the 'default' period of 30 years may be excessive and not compliant with the fifth DP principle and Caldicott principle of not retaining data for longer than necessary for the purpose.
- iii. In particular, there needs to be a distinction between when there may be legitimate reason for retaining patient level clinical data for long-term clinical care and audit or research purposes for which data should not be retained in identifiable form without patient consent. This will become increasingly important as electronic health records are implemented.
- iv. I should add that our interest is only in relation to patient information, so annex Dii falls outside of our remit.

Q. Do you anticipate that use of the Code of Practice will incur any additional costs to those currently incurred for managing records? If so, please provide some details for the basis of your estimate.

Almost certainly, because records are likely to need to be reviewed more frequently than at present to determine whether or not they need to be retained or destroyed. Additionally in some areas it is likely that best practice is not currently being followed and this needs to be remedied and require resources to do so.

Q. Please add any other general comments about the Code of Practice here.

- i. A key omission from the document seems to be attention under the sections relating to active record management to the use of the NHS number, i.e. that records must be recorded against NHS number and that temporary numbers are followed up to ensure NHS number is attached to records within a reasonable time frame following creation if not at the point of creation.
- ii. The Code also makes the fundamental assumption that it is legitimate to archive health records for historical purposes. If records are no longer required for the purposes of providing care, then they should not be retained in identifiable form or used for other purposes without patient consent or Section 60 support. Paper records present a major difficulty because they are not easily anonymised and it would be prohibitively laborious. Currently there is no discussion with patients about the range of uses to which their information and record about them may be put, consent cannot then be implied. Even if the information was recorded prior to the DPA, its use now is still subject to the Act.
- iii. Additionally, there were places where the main document seemed to lack detail and referred the reader to one of the annexes or elsewhere. In some places it would have been more useful to have had more detail in the main body of the document (I will try to indicate where on the response sheet)

Specific comments on the text

No.	Document Reference/ Page Number/ Section/ Paragraph	Reviewer's Comment	Priority
1	General context, paragraph 6, page 5	'Information is of greatest value...' It is arguable that information only has value when it is accurate, up to date and accessible. Unreliable data can be misleading and in some instances an absence of data would be preferable.	Minor
2	Monitoring Records Management Performance, paragraphs 10 & 11, page 6	The Litigation Authority risk assessment audit may also be worth mentioning here	Minor
3	Section 3, Paragraph 16	Why only minimum retention periods and not also a specified maximum?	Significant
4	Section 3, Paragraph 18	'Appropriate seniority' should be better defined e.g. at Board level? Additionally, this role should be made known to the public and to the PPIFs	Significant

5	Disclosure and transfer of records, Paragraphs 43 & 44	This section could be expanded to give more detail, specifically on the need to obtain patient consent prior to disclosure to non-NHS bodies such as social care providers or independent sector service providers	Significant
6	Record disclosure, Paragraph 49	'metadata' – will need explanation for some	Minor
7	Annex C	Language in this Annex, because it relates to legal aspects, is not that accessible to the general reader.	Minor
8	Annex C, Administrative Law page C4& Common Law duty of confidentiality page C5	Recognising that this is a summary of relevant legislation, (as indicated on the questionnaire) it would be helpful to indicate where the points of interface between different legislation lie. E.g. the paragraphs pertaining to Administrative law and the Common law duty of confidentiality would both benefit from reference to application for legal support under Section 60 of the Health and Social Care Act 2001. There must also be other examples relating to the points of interface between other pieces of legislation	Significant
9	Health and Social Care Act 2001 page C14 Records Management considerations	Bullet points only relate to the latter 2 points and not 'require or allow patient information to be shared'. Reference has not been made to consideration of when it is appropriate to consider applying for S60 support for activities – suggest insert: 'Consideration to be given to when application for S60 support may be necessary. This does not just apply to research but also to some essential NHS activities such as regional or national audit'.	Minor
10	Annex Di Child Health Records & Children and Young Peoples records	Paediatric illness may be pertinent in adult life so details of diagnosis and treatment may be needed beyond the age of 25.	Significant

11	Genetic Records	An individual's record may be relevant for others in the same family. It is rare for people to refuse consent for their information to be used for the benefit of other family members. It is also not possible to predict whose information may have wider relevance, there is therefore a need to acknowledge the familial nature of genetic information and the potential need to retain data for longer than 30 years.	Significant
12	Maternity Records / Child Health Records / Reproductive Health	Information about children conceived through artificial reproductive techniques may also be relevant into adult life e.g. imprinting may be affected by some techniques and this could cause an increased cancer risk in later life beyond the 25 year retention recommendation. This, like other foetal medicine data may be contained in the record of the mother. This issue needs to be considered in relation the retention of the mothers records where they are pertinent to the health of the child. Again the retention period may not be sufficient for such care purposes.	Significant
13	Annex Di Research Records (patient identifiable) (Di19) Research Databases (Di25) (where these contain patient identifiable information)	The minimum retention period is proposed as 30 years. This seems to be excessive. Clinical trials only require retention for 15 years and for many research projects a pseudonymised dataset is sufficient for analysis. For some longitudinal studies such a long data retention period may be reasonable but these would be exceptional rather than the norm. 30 years may therefore be reasonable as a maximum but not as a minimum. The Advisory Group would like to propose that there is a review of patient identifiable research records every five years to see if they need to be retained or if their identifiability could be reduced. Whilst many research records and databases pre-date DPA and other pertinent legislation, and therefore such stipulations may not be required by law, the CoP should have the intention of improving practice and moving towards compliance.	Critical