

THE ROYAL COLLEGE OF RADIOLOGISTS

Response to: National Data Guardian for Health and Care's Review of Data Security, Consent and Opt-Outs Public Consultation

September 16

- 1) Please tell us which group you belong to**
 - The Royal College of Radiologists (RCR)

- 2) If you are a member of an organisation or profession, please tell us if you are responding in a personal or private capacity**
 - RCR organisational response

- 3) If the Department of Health or other organisations were to create further opportunities to engage on data security and the consent/opt-out model, would you be interested in attending? If so where would you find it helpful an event to be held?**
 - The RCR would be interested in attending events, ideally held in London or Birmingham.

- 4) The Review proposes ten data security standards relating to Leadership, People, Processes and Technology. Please provide your views about these standards.**
 - The RCR mostly welcomes these standards, however, "appropriate purposes" should more explicit.
 - The RCR also understands that in order to implement these there will need to be adequate training given to all staff groups.
 - Specific comments are given in question 6

- 5) If applicable, how far does your organisation already meet the requirements of the ten standards? Please provide examples which might be shared as best practise**

N/A

- 6) By reference to each of the proposed standards, please identify any specific or general barriers to implementation of the proposed standards?**
 - Standards 1-2 will require staff training.
 - Standard 3 will be problematic in terms of staff time, as the NHS already struggles with the amount of statutory training time required.
 - Standard 4 The RCR believes that there may be a risk to patient safety in the case of medical emergencies if access to personal data is withdrawn/not given to the doctors who urgently need access to it for emergency treatment
 - Standard 8 may indirectly disadvantage patients, as having immediate access to the internet allows medical staff to consult the literature and consider differential diagnoses, which may otherwise be missed.

7) Please describe any particular challenges that organisations which provide social care or other services face in implementing the ten standards

- The RCR is aware that due to poor continuity between NHS IT systems and difficulties in anonymising data, fax and other paper based modes of communication are often used which can be considered less secure

8) Is there an appropriate focus on data security, including at senior levels, within your organisation? Please provide comments to support your answer and/or suggest areas for improvement

- No comment

9) What support from the Department of Health, the Health & Social Care Information Centre, or NHS England would you find helpful in implementing the ten standards?

- The RCR recommends online training materials, which include proof of completion, implementing the standards
- Practical and financial support for improved IT systems

10) Do you agree with the approaches to objective assurance that we have outlined in paragraphs 2.8 and 2.9 of this document?

- The RCR supports these approaches

11) Do you have any comments or points of clarification about any of the eight elements of the model described above? If so please provide details in the space below, making it clear which of the elements you are referring to.

- Statement 2; The RCR believes that there is a balance to be struck between the risks of data sharing and the benefits, especially in the context of cancer treatment where most patients expect data to be used and interpreted.
- Statement 2; The risks associated with such a decision by the patient must be carefully explained to the patient, and written consent obtained from them. Such risks include possible suboptimal care for the patient in an emergency situation where urgent access to their data is needed by doctors who would not normally be expected to be caring for the patient.
- Statement 3; The RCR would like to emphasise the importance of as near complete as possible national data. This is of particular importance in the monitoring of cancer outcomes. It is essential that high quality data should be collected in order to assess the impact of the implementation of new technologies and treatments.
- Statement 5; The vast majority of electronic systems used in healthcare today, have no means of recording the fact that a patient has refused to allow his/her data to be passed on to others involved in their care. These systems also have no means of acting upon this information and blocking having the data passed on.
- Statement 6; It may be more beneficial to allow patients to opt-out of certain aspects rather than completely opt-out and then give explicit consent for certain things.
- Statement 8; Although there is reference to some exceptional circumstances where the opt out will not apply there is no reference to the potential harm to medical care caused by lack of data access.
- Statement 8.12; What does this mean in practise? Please give at least one example.

12) Do you support the recommendation that the Government should introduce stronger sanctions, including criminal penalties in the case of deliberate re-identification, to protect an individual's anonymised data?

- Stronger sanctions should be introduced, provided the staff duties and training are made absolutely clear. Staff should not be blamed when problems are the consequences of poor systems.

13) If you are working within health or social care, what support might you or your organisation require to implement this model, if applicable?

- For this to be implemented it will be necessary to produce clear guidelines, implement training and provide adequate software.

14) If you are a patient or service user, where would you look for advice before making a choice?

- This is a problem area in the field of cancer treatment, where patients are already required to take on board much information about their illness, proposed treatment and then to give informed consent for treatment and sometimes clinical trials. To introduce another process for explaining the issue of data storage would constitute another burden at a difficult time.

15) What are your views about what needs to be done to move from the current opt-out system to a new consent/opt-out model?

- We believe the issue of consent will pose problems for many patients with cancer. The ongoing distinction between Patient Identifiable Data and anonymised data in any case remains problematic. Recent work has shown that 'anonymised' data can be re-identified fairly easily, and current definitions of 'anonymised' are insufficiently defined. In addition, we suspect that most patients would expect that if they opt-out, that would cover anonymised versions of their data as well.
- Statement 6; It may be more beneficial to allow patients to opt-out of certain aspects rather than completely opt-out and then give explicit consent for certain things.

16) Do you think any of the proposals set out in this consultation document could have equality impacts for affected persons who share a protected characteristic, as described above?

- No comment

17) Do you have any views on the proposals in relation to the Secretary of State for Health's duty in relation to reducing health inequalities? If so, please tell us about them.

- We have concerns about the impact on equality. One of the key tools in reducing inequality is epidemiology, and studying the epidemiology of care without access to linkable data is difficult.

The Royal College of Radiologists

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