PHG Foundation response to the Article 29 Data Protection Working Party Document on electronic health records

The PHG Foundation is a successor body to the Public Health Genetics Unit and the Cambridge Genetics Knowledge Park and works to maximise health benefit through the responsible and evidence based application of modern biology, particularly genomics and molecular sciences.

Introduction

1. The PHG Foundation welcomes the opportunity to comment on the Article 29 Data Protection Working Document. Members of the Foundation have expertise in data protection issues within the UK, and have contributed to the Academy of Medical Sciences report, '*Personal data for public good: using health information in medical research*'[1] which examined the use of personal data in medical research in the UK setting.

2. The PHG Foundation takes the view the current legislation already provides for checks and balances – allowing sensitive health data to be processed on the basis that its use is shown to be necessary and proportionate with respect to privacy and public interest benefits. The significance of the introduction of electronic patient records is that it has the potential to revolutionise practice by allowing sensitive health data to be **readily** and **generally** accessible which may necessitate more stringent safeguards to be taken to demonstrate necessity and proportionality. The recommendations within the Working document for practical safeguards provide a useful resource and we note that the English centralised electronic patient record scheme, Connecting for Health has the functionality to adopt many of these safeguards such as limiting systems access by role and legitimate relations and providing the data subject with the opportunity of sealing and locking personal information.

Specific Comments

The legal basis for lawful processing

3. The Working Document provides an analysis of the bases upon which personal health data can be lawfully processed within an electronic system. We have concerns that the legal analysis offered in paragraphs 4, 5 and 6 of the Working Document is likely to be interpreted by lawyers, health professionals and health IT specialists as meaning that **only** processing under Article 8(4) is a valid basis for EHR's. It would cause serious difficulties in the UK if Article 8(3) of the Directive was not recognised as a valid basis for processing EHR's. Therefore we strongly recommend that the document be re-worded so that it is much clearer that *any* of the grounds identified in paragraph 3 is sufficient for lawful processing provided certain conditions are met.

[1] Academy of Medical Sciences (AMS), Personal data for public good: using health information in medical research (2006) at http://www.acmedsci.ac.uk/images/publication/Personal.pdf

Consent must be given freely

4. It is well established that coercion negates a valid consent, and whilst we agree with the sentiment of paragraph 4(a)(aa), the PHG Foundation is concerned that as currently worded its effect might make it difficult for patients to act autonomously and dissuade health care professionals from being transparent about treatment choices. This is because the current wording seems to prescribe that when choosing between alternatives offering differences in the quality of treatment, consent to Alternative B is not free if it entails a worse quality of treatment than Alternative A. It would mean that individuals cannot freely choose this course of action Yet in the UK and elsewhere, a patient can freely consent to referral to one provider rather than another even when it offers 'lower quality treatment'– this is a legally valid choice[2]. We suggest that the document be amended to make this distinction and to clarify that consent is not free if a *sanction or penalty* is threatened or imposed for refusing to give consent[3].

Consent must be specific

5. We would not like to see the prescription in paragraph 4(a)(bb) against 'general agreement' curtail existing health practice or lawful research. For example, genome-wide association studies in chronic diseases increasingly identify gene associations which are shared across several clinical boundaries for the purpose of diagnosis and research. This is done on the basis of the patient's general consent[4]. National legislation also provides specifically for generic consent, such as that specified under the UK Human Tissue Act (2004) for generic consent to research for all scheduled purposes[5]. Further, the prescription against 'general agreement' encourages a simplistic view which opposes specific and general consent. We suggest that the Working Document acknowledges a spectrum between specific and non-specific consent and requires that consent to general propositions should be "specific" to some degree. This is important for three reasons: first, consent cannot be absolutely specific. This would be impossible. Second, it is normal to consent to general propositions that involve individuals putting trust in another person or institution (in healthcare, education,

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[2] Indeed the premise of the 'Choose and Book' facility within the UK electronic patient record scheme is that it offers the patient a choice of health care providers. Although this may be a subjective choice to be made by the patient with their primary care provider the choice may well be justified, by the patient at least on the basis that treatment is offered from a local hospital or within a quicker timescale. The medical treatment may be of 'lower quality' but it may be an entirely rational and legitimate choice for the patient and health provider to make that selection. Another example within the UK is that of the National Institute for Clinical Excellence which dictates the basis upon which drugs are available for prescription within the NHS. NICE stipulates that certain drugs may not be prescribed on economic grounds within an NHS setting despite the fact that they have the potential to offer better quality treatment. If this Working Party opinion was adopted without clarification or amendment it could imply that a patient could not consent to treatment using the cheaper drug on the basis that this consent was not freely given.

[3] For example, by repetition of the words 'under threat of' before 'lower quality treatment in a medical situation'.

[4] The Wellcome Trust Case Control Consortium Management Committee Data and Analysis Committee et al 'Genome-wide association study of 14,000 cases of seven common diseases and 3,000 shared controls' Nature 447, 661- 678 (7 June 2007).

[5] The supporting codes of practice to the UK Human Tissue Act (2004) at http://www.opsi.gov.uk/acts/acts2004/20040030.htm and http://www.hta.gov.uk/_db/_documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_1_-_Consent.pdf provides that consent should be generic wherever possible.

marriage, banking, consumer purchases and most other social relationships). Third, we consider that this clarification would limit the tendency for arguments about specificity to be reduced to an administrative checklist and encourage more open communication.

Definition of Electronic Health Records

6. We believe that the definition of 'electronic health record' within the document may inadvertently cover geographically limited, locally held records which happen to be held electronically rather than electronic health records **systems**, which are characterised by ease of information retrieval and universal access subject to authorisation[6]. We suggest the definition of 'electronic health record' be amended accordingly.

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13 June 2007
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[6] 'Once compiled, the HER data would be available in electronic form to all authorized health care professionals and other authorized institutions wherever and whenever this information is needed'. Article 29 Working Document pages 4 and 5.