

**Consultation Response: Prof A F Markham, University of Leeds.**

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[Foreword. I am the recently appointed Chair of the “Research Capability Programme” in NHS Connecting for Health. This response is, however, provided in a personal rather than any official, governmental capacity. It reflects my own conviction that there are enormous health benefits to be gained for the public in Britain from more effective sharing of personal information in the public and private sectors. I also believe that using best endeavours it should be possible to provide secure systems of information governance, which command public confidence. These should not make access to information so hard to obtain that delivery of public benefit by responsible parties is rendered excessively difficult, in practice. A major public engagement exercise will be required to persuade ordinary people (on or off the Clapham Omnibus) that they have much more to gain than lose, from collection and analysis of information about them].

**Consultation Questionnaire.**

**General Comment.**

My remarks will be limited to matters relating to the role of “Informatics” in the broad area of healthcare. Although they have not been circulated directly with the consultation paper, I suggest that it would be important to ensure that the views of the following bodies have been received in some form as they are all involved in a variety of ongoing health informatics initiatives:

1. ESRC
2. EPSRC
3. Research Councils UK
4. DIUS
5. The Association of Medical Research Charities
6. (The Association of) Medical Royal Colleges
7. The Academy of Medical Sciences
8. The UK Clinical Research Collaboration.

**Question 1.**

I am interested in “information sharing” because I am aware of the benefits it can provide for patients in the NHS. I have recently been appointed to chair a “Research Capability Programme” in NHS Connecting for Health, established as a result of a UKCRC Working Party’s recommendations. This Programme will attempt to make patient information available, through appropriately regulated channels, to facilitate research for patient benefit in areas such as clinical trial recruitment, public health improvement and health services research.

- Connecting for Health (CfH) in the NHS ‘National Programme for IT’ (NPfIT) collects personal information on patients treated by the NHS.
- Information is collected in a variety of secure databases e.g. the electronic Care Record Service.
- Personal Information (“PI”) is essential for delivery of care to the individual. All healthcare professionals involved in delivering such care have a duty of confidentiality to their patients. PI is also essential for other purposes including Service Improvement and Research. Both of these areas of activity stand to improve the care provided to the individual in time. Therefore, the

individual has some vested interest in their PI being used appropriately for these purposes, and Parliament has recognised this by mentioning medical research in the law. Of course, the individual's vested interest is conditional on having adequate, proportionate safeguards to prevent uses of the information which lead to harm or distress or other damage to individuals' best interests, and on taking measures to record and comply with the specific wishes of individual patients concerning their own PI whenever it is reasonably possible.

**Question 2.**

- a) Benefits to individuals of sharing PI include better personal healthcare: both immediately as a result of more efficient information flows between the patient and the ever increasing range of professionals and support staff involved in care delivery; and in the longer term as a result of more efficient use of limited resources by the NHS to provide optimal clinical outcomes.
- b) Individuals also benefit from living in a healthy population: they benefit when their family members have long productive lives and survive into a healthy old age free of chronic diseases which would make them dependent.
- c) Society as a whole will benefit from the ability to identify and share "best practice" in healthcare (and to identify and eliminate sub-standard practice) by analysing the combined PI of multiple individuals. This should allow improved commissioning of clinical services to the benefit of all branches of society.
- d) Society (and hence individuals) also benefits from a productive economy in which scientists can use reliable information to identify the need for innovations, and test those innovations to be sure they are safe and effective.

**Question 3.**

- a) The key risk to the individual of PI sharing is a harmful or distressing breach of personal confidentiality.
- b) The key risk to society would be loss of public confidence in data sharing, as a result of inappropriate use of PI or because of failure to safeguard the level of confidentiality demanded by any particular individual. Certain individuals may consent to their PI being made more widely available than do others. The systems put in place must be capable of responding to and respecting different individuals' views. It is equally important that the views of those individuals who want their PI to be used as widely as possible to benefit society are respected in the same way as the views of those who take the opposite view and demand the maintenance of absolute confidentiality at all times.

**Question 4.**

- a) Opportunities. "Scope and Methods" that maximise the numbers of individuals who consent to have their PI included in data sharing exercises are likely to maximise the benefits that accrue to society as a result of subsequent analysis. The aspiration to maximise public benefit implies that methods should be found that allow an individual's PI to be reliably anonymised so that it can be included in analysis where it is not straightforward to obtain specific, direct consent.

- b) Risks. Approaches that fail to record and respect what an individual has consented to have done with their PI, will undermine public confidence.

**Question 5.**

- a) I do not have examples where I believe that the public authorities hold too much data, as long as it is secure. I stress that these are my personal views. For example, I do not personally believe that national DNA databases that contain information on innocent people, with their consent, are a threat to civil liberty and I would be happy to have my own DNA data included therein. I realise that not all people share this view and I fully respect their position. They have every right to withhold their consent to inclusion and to expect that this is acted upon.
- b) There are many examples in the healthcare area where, I believe, not enough PI is held. Moreover, insufficient resource has been made available historically to analyse effectively the PI that is already collected, for public benefit. Insufficient effort has been made over time to explain to the public the detrimental effects of this situation, particularly where it has seriously impeded NHS service improvement. One specific example was highlighted in the government's "Cancer Reform Strategy", published in December 2007. The need to further coordinate the work of the National Cancer Registries and to ensure that best practice in the treatment of cancer is identified and implemented nationally, to improve overall clinical outcomes, was recognised by the establishment of a "National Cancer Intelligence Network" charged with delivering this agenda.

**Question 6.**

- a) I have limited my comments to PI held by the public authorities in healthcare. However, clearly PI on individuals treated in the private healthcare sector in the UK will be held in private sector databases. In many situations (e.g. public health research), combining these data with those held on NHS patients will be valid and informative to both the public and private sectors.
- b) There is a degree of concern in some quarters that, for example, the major supermarket chains hold too much PI on their customers' purchasing patterns. The corollary of this is that such databases potentially represent valuable material for research in the public interest (e.g. for the study of patterns of deprivation and the impacts of this on public health).

**Question 7.**

One example where the sharing of PI between two or more bodies would be beneficial is between the NHS NPfIT/CfH and responsible elements of the research community. This is the objective of the Department of Health "Research Capability Programme". Obviously, adequate safeguards to prevent any inappropriate use of PI will first need to be put in place. Informed consent will usually have to be obtained and recorded prior to PI {held in a designated "Research Data Centre(s)"} being potentially made available, for research that has been properly reviewed by a NHS research ethics committee. Much research can and should be conducted on PI that has been "anonymised" so that the identities of the individuals involved cannot be established. Properly done this removes the need for informed consent, The National Programme for IT presents an unprecedented opportunity to anonymise to a consistent standard sensitive personal information which could normally be used only with consent .

There may be circumstances where complete, irrevocable anonymisation of PI is not ideal e.g. because this may then prevent individual participants in research from

benefiting directly as a result of their involvement. An alternative approach is to establish a system of reliable “Research Data Custodians”. These Custodians would undertake “pseudonymisation” of research data sets so that PI could again be provided in an anonymised form to the research community. However, if the case can be made that substantial individual and/or public benefit would accrue if the individuals involved in the research were to have the implications of the research findings explained to them, then the Research Data Custodians would be in a position to make this possible.

Historically, the main barrier to data sharing in this area has been that ‘sharing’ has not been the clear responsibility of any of the various organisations that control either:

- Databases containing PI within the NHS or;
- Access to these resources for research purposes.

There is a growing realisation that both Service Improvement and Research using PI held by the NHS have a similar importance to Care Provision. Therefore concerted efforts are now being made through the “Research Capability Programme” to create the necessary structures to facilitate data sharing. An historical view that anything other than Care Provision is a “Secondary Use” of NHS PI data is breaking down. Service Improvement and Research are increasingly recognised as legitimate “Additional Uses” of NPfIT/CfH data. Similarly, the historical use of the expression “Safe Haven” to describe “Research Data Centres” now seems unhelpful as it could imply (incorrectly) that some NHS data are not held safely. Furthermore, describing “Research Data Custodians” as “Honest Brokers” feels equally inappropriate. There can be no reasonable suggestion that anything in the whole range of NPfIT/CfH activities is not honest.

#### **Question 8.**

I am not aware of any inappropriate data sharing between healthcare bodies. On the contrary, the problem is the lack of sharing.

#### **Questions 9, 10, 11 and 12.**

I repeat that my views on the DPA are those of a private individual, rather than any reflection of the Dept of Health’s position.

A key issue with the DPA and the second principle is interpretation. Regulating the obtaining, holding, use and disclosure of PI is perfectly reasonable and necessary. I believe that the critical part of the second principle lies in the phrase “...shall not be further processed in any manner **incompatible** with that (specified and lawful) purpose or purposes”. The interpretation of the word “incompatible” is critical. In my view, this interpretation may sometimes have erred to much on the side of caution in the case of data from ethically-approved, medical research projects. It seems perverse that data collected at enormous public expense to address a particular clinical question should then be destroyed immediately rather than used to address additional, ethically-justified questions as they arise in the future, where these stand to benefit society and the individual. Surely such additional research involves “processing in a manner that is entirely **COMPATIBLE** with the original purpose” (medical research).

I suspect that the general public (which is usually highly supportive of medical research when the issues to be addressed are properly explained) would be horrified that irreplaceable clinical datasets are knowingly destroyed so as to comply with a particular interpretation of the DPA. There is nothing more profoundly unethical than deliberately persisting in ignorance about the best treatment by failing to undertake ethically-justified medical research. Perhaps the clinical research community has

been insufficiently effective in presenting the case for a regulatory environment that seeks to encourage and facilitate ethical medical research, rather than allowing a particular interpretation of the DPA inadvertently to place barriers in its way. In summary, my sense is that public and private organisations tend to “adhere” to the second principle of the DPA by making a zealous interpretation of what represents “incompatible” further processing, which is not always in either society’s or the individual’s best interests.

**Question 13.**

I am not sufficiently expert to comment adequately on this question. However, EU law has had major impacts on UK healthcare research and may do so again as NHS data sharing increases. It is important that the unique features of the UK NHS are not inadvertently overlooked when shaping European legislation to suit healthcare systems in other member states.

One example in healthcare has been the European Clinical Trials Directive, which placed significant additional requirements on the custodianship of data held on patients participating in clinical trials. Whilst this has generally been seen as a positive change, it has led to a significant increase in the costs of clinical trials, particularly those conducted in the not-for-profit sector. Rather than designing regimes that make it more difficult to do research with existing means, it is far better for the public interest to create support systems that make it possible to do more research with public understanding and without unacceptable breaches of confidence.

**Question 14.**

One example that would facilitate data sharing in the healthcare arena would be the adoption of a unique NHS Number for each individual. This might be analogous to the National Insurance number. The advantage would be that it would be much easier to follow the progress of an individual through complex care pathways and to ensure that all their clinical data are optimally accessible--to the patient’s ultimate benefit (and safety).

**Question 15.**

Not directly applicable.

**Question 16.**

The concept of informed consent is deeply embedded in medical practice. The clinician’s “duty of confidentiality” means that consent is required before sharing identifiable PI about a patient with anyone, except others involved in providing their care (who then share the same duty of confidentiality).

Where PI is permanently anonymised so that it can never be linked back to the individual, then it is accepted that these data can be used for ethically-approved purposes without the direct consent of the individual. Ideally, it is not unreasonable to explain to a patient that such anonymisation and use of their data might take place. The vast majority of patients are eager to assist the medical research process, as long as any potential risks are fully explained to them. It should always be explained in detail to every patient that there is absolutely no requirement for them to participate in research projects, that deciding not to participate will not change their treatment or disadvantage them in any way, that they are fully entitled to withdraw their consent at any time, without providing any reason and without any detriment, and that they cannot expect to benefit directly by participation.

The specific details as to exactly what an individual has consented to, need to be stored with the information to which the consent relates. Historically this has been

achieved by using a signed “Consent Form” (which will usually have been scrutinised by an NHS Research Ethics Committee), a copy of which is included and retained in the patient’s medical records. A similar arrangement will be required as the NHS moves more completely towards comprehensive electronic patient records.

**Question 17.**

This is an important and challenging area, which would benefit from transparent public debate. As and when comprehensive electronic patient records become the norm, opportunities for beneficial sharing of PI will increase. Some examples of issues that might arise in gaining consent for data sharing include:

- A new experimental treatment for a particular condition is developed. A large clinical trial must be conducted to prove its efficacy. If this proves successful, a previously unmet clinical need will be addressed. Would it be ethical to search the NHS patient records for individuals who suffer from this particular disease? Almost inevitably, they will not have given their consent for this in advance.
- If such individuals could be identified (because they had provided some generic form of consent that their PI be accessible, except for specific exceptions) would it be ethical to approach these people directly (or through their General Practitioner) to invite them to consider participation in the clinical trial?
- A patient with a serious medical condition may have died. His/her PI may be valuable for public health research into the aetiology of their disease. No consent has been sought before death. Can this be obtained ethically from next-of-kin? Without pre-existing consent, can it be ethical to link the electronic patient record with the Register of Deaths and scrutinise them together to discover who has died from a particular cause and whether there are any consistent associated factors?

**Question 18.**

All the examples in 17 above (and of course one can imagine many more such scenarios), point towards the need for more transparent sharing of PI. The advantages of providing individuals with strengthened access rights to their own PI are clear, assuming that such strengthened access rights do not make it easier for others to gain such access dishonestly.

In principle, an individual ought to be able to continually update and modify a “Consent Section” attached to their NHS PI. It should be possible to alter automatically the way their data are shared as a consequence. The NHS has a clear responsibility to explain to the public what it is seeking to achieve by its use and sharing of PI. This information might form part of the individual’s personal “Consent Section”. If generic requests for consent to allow PI to be accessed for a particular purpose were posted on web-based “Consent Sections” attached to individually accessible NHS PI, the whole population would be in a position to participate ( or decline to participate) in research activities and to continuously review their decisions whether to do so. In this model, the quality of the work undertaken by the NHS to explain its data sharing objectives will directly influence the public’s willingness to participate and hence the benefits gained by both the NHS and society as a whole. This process lends itself to active performance management.

**Question 19.**

The work of the Information Commissioner is helpful and the NHS NPfIT/CfH programmes will clearly continue to benefit from his advice in the future.

**Question 20.**

Technological advances have clearly had enormous impact on our ability to collect, archive and share NHS PI. They have also provided the means to protect such PI and maintain it securely. Conversely, the astonishing power of modern IT means that huge amounts of data can be lost or stolen frighteningly easily. The media highlights these problems on an almost daily basis. They have become a political issue. The tendency is for public consciousness to be focused on the downsides of potential loss of PI, rather than the huge social advantages to be gained from well managed use of comprehensive electronic systems.

**Question 21.**

I am not sufficiently technically expert to address this question. It will be interesting to discover the views expressed by others through this consultation process.

**Question 22.**

“Privacy Enhancing Techniques” are an important component of the safeguarding of PI. I have discussed the role of data anonymisation in medical research, above. I believe that “Pseudonymisation” of NHS patient data is an important and essential tool. We are at the earliest stages of explaining the rationale for pseudonymisation to the general public. Pseudonymisation means that identifiable PI is modified or “encrypted” by a “Research Data Custodian” so that it can no longer be linked to an individual. It can then be analysed as anonymous data. However, the “Research Data Custodian” does retain the ability to link the encrypted data back to its individual owner. This process means that two worthwhile activities can be undertaken:

- Data for which direct consent has not been obtained can be rendered anonymous so that specific analysis can be undertaken.
- Where the best interests of an individual would best be served by informing them of results emerging from the study of pseudonymised data, this is possible.

The critical factor for the success and acceptability of pseudonymisation approaches will be the public’s trust and confidence in those individuals or organisations designated as “Research Data Custodians”.

**Questions 23, 24, 25 and 26.**

I am not expert in this area. In terms of electronic patient record systems and their governance, the Danish system is apparently well regarded.

Thank you for the opportunity to participate in this important consultation.

Prof A F Markham.

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No specific confidentiality requests.

I would be happy to be contacted for further discussions.