

Data Sharing Review

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Consultation paper on the use and sharing of personal information in the public and private sector

List of questions for response

We would welcome responses to the following questions set out in this consultation paper. Please follow the question order as set out in the consultation paper, leaving a blank response box for any questions not answered.

Please email your completed form to contact@datasharingreview.gsi.gov.uk

Alternatively you can send a hard copy response to:

Data Sharing Review Secretariat
5.26 Steel House
11 Tothill Street
London
SW1H 9LJ

Thank you.

Section 1: Background

Question 1. Please explain what your interest in information sharing is. If you have an active involvement in personal information sharing, we would be grateful for the following information:

- What kinds of personal information do you collect, hold and share?
- How do you collect, hold and share such personal information?
- For what purposes do you collect, hold and share such personal information?

Comments: The Association of the British Pharmaceutical Industry (ABPI) is the trade association for the research-based pharmaceutical industry in the UK. It has over 75 full members who research and provide medicines for the NHS. It also has around 20 research affiliate members who provide research services on contract to pharmaceutical companies.

The ABPI is a member of the UK Clinical Research Collaboration (UKCRC) Board and as such has lobbied hard for research activity to be part of the remit for Connecting for Health. Indeed, ABPI were actively involved in two of the simulations that the UKCRC/Connecting for Health Advisory Group commissioned in late 2006 and which reported in 2007 to the Minister Lord Hunt. The two simulations were in clinical trial feasibility and active

surveillance of licensed medicines.

In May 2007, the ABPI published its “Guidelines for the Secondary Use of Data for Medical Research Purposes” and a copy is attached to this response. ABPI Guidelines are commended to all member companies and although not binding they are usually followed vigorously by members and often feature in company Standard Operating Procedures (SOPs). ABPI was delighted that Richard Thomas, the Information Commissioner, agreed to provide a foreword to the Guidelines and he stated “Data protection in law provides an effective framework for managing the tension between privacy and access to information. This guidance will help medical researchers to make the best use of personal information whilst respecting the people it is about. Its emphasis on consent and transparency is particularly welcome. Medical researchers’ adoption of best practice in the handling of personal information will engender the trust of the public and encourage their participation. Ultimately, it will help to deliver the obvious benefits that medical research can bring”.

The discovery and development of medicines requires the use of individual’s medical information – for example in the conduct of clinical trials to evaluate the efficacy and safety of an investigation medicine. This information is collected and used according to the International Conference on Harmonisation in Good Clinical Practice Guidelines (ICH GCP) which requires informed, current ethics committee and regulatory authority approval and other measures such as removing information that can directly identify the individual and coding the data to protect patients’ privacy and confidentiality.

Medical information used in research must not be used by researchers to directly identify individuals except where regulation allows. Furthermore, where individuals’ medical information is used for additional or secondary research, additional measures are put in place to protect the privacy and confidentiality of individuals including re-consent or anonymisation of the information

The recent gross and inexcusable breaches of data security held by Government agencies are of concern to UKCRC partners including the ABPI. These concerns must drive researchers to continue to achieve and improve highly ethical standards of information governance.

Section 2: Scope of personal information sharing, including benefits, barriers and risks of data sharing and data protection

Question 2. What in your view are the key benefits of sharing personal information to
a) individuals and b) society? Please provide examples.

Comments: Overall society and future patients benefit via improvements to population health as a result of research on individuals. Medical research is performed primarily for public rather than individual personal benefit but often there is benefit at the personal level too, particularly in trials of medicines. Research study data can be used to alert a clinician as to whether a particular medicine will provide benefit or possible harm to a patient.

Question 3. What in your view are the key risks of sharing personal information to a) individuals and b) society. Please provide examples.

Comments: The ABPI acknowledges that increasing access to personal health data brings new challenges for safeguarding patient privacy. However, modern health services cannot advance for patient benefit without research. Personal health records can be extremely sensitive and inappropriate use or disclosure can cause considerable harm and distress. However, in commercially sponsored clinical trials the sponsor does not have direct access to the identifiable patient data as it is all encrypted before being sent to the data collection point for analysis.

Question 4.

Comments:

Question 5. Please provide examples of where, in your view, the public authorities hold too much data or not enough personal information, and the reasoning behind your response.

Comments: One example where there is currently a lack of information is in monitoring child development after he/she has been exposed to a medicine whilst in utero. By linking the mother with her child's record very valuable data on the effects of various medicines in pregnancy could be obtained. This is of particular importance in mothers with a chronic disease. After all, pharmacovigilance as we know it today was born out of the thalidomide disaster but our data collection systems are still not as good as they might be, nearly, fifty years later.

Question 6.

Comments:

Question 7. Please provide examples of cases where you believe the sharing of personal information between two or more bodies would be beneficial but where it is not currently taking place.

Please explain as fully as possible why information is not being shared, detailing what the barriers to the sharing of personal information are – eg legal, cultural, financial, institutional – and how these barriers can be overcome.

Comments: Significant opportunities exist for increased utilisation and transfer of electronic medical data in the NHS to be used in research. The reticence in some quarters for this to take place is cited as a concern over patient confidentiality. However, in the majority of instances, the researcher has no requirement to have access to personal identifiers and such data can be utilised in a format that renders the individual subject anonymous to the researcher i.e. data can be coded, anonymized or aggregated prior to transfer. Use of NHS records in this secure manner offers benefit to both users and providers of healthcare in the UK. Combining data from primary care and secondary (hospital) care is particularly important for many purposes.

Question 8.

Comments:

Section 3: The legal framework

Question 9. In your view, how well does the DPA work? Please outline the DPA's main strengths and weaknesses and any proposals for changes you would like to see made including suggestions for their implementation.

Comments: By categorising coded clinical trial data, sent to a pharmaceutical company, (where the key code is held securely by the clinical investigator), as not being 'personal' data, the DPA has established a pragmatic framework for the conduct of clinical research in the UK. The approach:

- aligns with the privacy safeguards already required by organisations such as ICH GCP, EMEA and MHRA for clinical trial conduct.
- achieves a balance that protects privacy of a research participant whilst enabling the use and sharing of medical data vital to the discovery, development and monitoring of medicines.

Question 10.

Comments:

Question 11.

Comments:

Question 12.

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Question 13. Are there any other aspects of UK or EU law (such as EU Directive 95/46/EC) that impact positively or negatively on data sharing or data protection? Please provide examples.

Comments: National transposition of the EU Data Directive 95/46/EC has not occurred in a comparable fashion across all Member States. Whilst the UK DPA has taken the pragmatic stance of recognising the existing ICH requirements for clinical trials and not classifying coded clinical trial data received by the research sponsor as personal data, other member states have opted for a far broader definition of 'personal data'. This has become evident in the recent Opinion of the Article 29 Working Party on the definition of personal data and the draft guidelines issued by the Italian Data Protection Agency on Processing Personal Data in Clinical Research.

The emergence of this more conservative approach is unjustified considering the robust mechanisms of the pharmaceutical industry for the management of clinical research, the inherent GCP requirement for informed consent and the use of coded data in clinical trials.

This disparity in the definition of personal data has the potential to negatively impact the conduct of clinical trials should Member States start to impose additional trial administration procedures, eg by requiring supplementary and variable data transfer agreements.

Question 14.

Comments:

Question 15.

Comments:

Section 4: Consent and transparency

Question 16. Is it clear whether and when you need individuals' consent to share information about them? Are you clear about the form that consent should take? Please provide examples.

Please provide details of any initiative you have been involved in that has been based on consent.

Comments: Acceptable further use of primary data for secondary processing without resorting to re-consent would include additional analysis within the scope of the original consent for the further development of a medicine at the same time ensuring that no harm or distress would come to the individual. Testing hypotheses or carrying out studies outside of the original consent would require re-consent or anonymisation or other provisions of the Data Protection Act 1998 or the Health and Social Care Act 2001.

To process the data, the data controller must have legitimate possession of it eg he must already be using the data legitimately in primary research, normally by way of informed consent. For data brought in from an external source eg a university, some evidence of transaction would be required eg a contract.

The consent form should state explicitly a number of factors as follows:

- Personal data will be collected for legitimate, identified purposes
- The personal data collected will be processed by computer eg analysed, aggregated etc
- The patients' information benefits from the protections of a key-code and only the investigator can unlock that code in accordance with the approved protocol
- The personal data will be transferred to countries outside the EEA as indicated where the data will be handled to the same standards as imposed by English law and ICH GCP
- The patient may withdraw from the trial at any time, in which case no further examples or personal data will be collected
- Their right of subject access may be curtailed to the extent that the data remains key-coded

Question 17. What, if any, barriers would a requirement for gaining consent create to the sharing of personal information. Please explain your reasoning.

Comments: In certain circumstances it may not be possible to use the original consent and then a number of options arise:

- Obtain re-consent

- Anonymise the data
- If it is not practicable to locate a patient to re-obtain consent without unreasonable effort and the likelihood of detriment to the patient is negligible, use of previously collected data for research purposes may be justified based on the research exemption (Section 33 of the Data Protection Act 1998). Consideration needs to be given as to whether it is appropriate to contact individuals a long time after a trial has concluded eg in sensitive areas such as cancer as a fertility issue
- For other data cases, it may be appropriate to apply to the Patient Information Advisory Group (PIAG) under Section 60 of the Health and Social Care Act 2001 for dispensation to proceed without consent.

It is prudent to record the justification for choosing use of the above options where consent is not available.

Question 18. Do you have any suggestions on how to make the sharing of information more transparent?

For example, should individuals be given strengthened access rights? And if so, how? Should organisations be expected to do more to explain their use and sharing of personal information to the public? And if so, how?

Comments: One of the reasons for the development of the ABPI Guideline for the Secondary Use of Data for Medical Research Purposes was to make industry's activities in this regard transparent. The guidelines were launched with a press release and conference and are available free on our public website (www.abpi.org.uk). We would strongly recommend all organisations involved in the sharing of information to develop guidelines and publish them. We consulted with the Information Commissioner's Office near to final draft of the guidelines and received very helpful suggestions on improving them which we were happy to institute.

It is also important for organisations to explain why they need to share information, just not how they do it.

Question 19. How can we best ensure that information sharing policy is developed in a way that ensures proper transparency, scrutiny and accountability?

For example:

In your view, how valuable is the Information Commissioner's recently published Framework code of practice for sharing personal information (http://www.ico.gov.uk/upload/documents/library/data_protection/detailed_specialist_guides/pinfo-framework.pdf)?

In your view, how valuable are privacy impact assessments along the lines announced by the Information Commission on 11 December (www.ico.gov.uk)?

Comments: The Information Commissioner's Framework Code of Practice for sharing personal information is an important development in this field and the ABPI welcomes it. As yet we have not compared our Guidelines with it to ensure

compatibility but that will be a task for us in the next few weeks.

Section 5: Technology

Question 20.

Comments:

Question 21.

Comments:

Question 22. How, in your view, could “privacy enhancing techniques” such as the anonymisation or pseudonymisation of personal information help safeguard personal privacy whilst facilitating activities such as performing medical research?

Is sufficient advice about the deployment of such techniques available? Are you confident about using them? What are the barriers to using them?

Comments: Coded clinical trial data is not anonymised since a decode listing exists and it is therefore possible for the patient, under certain circumstances, to be identified by the key-holder. However, the data in commercial research is heavily protected by a secure key code in the control of the investigator, not the sponsor, and access by anyone else is not permitted except where the law allows. Because the key code is not in the possession of, or likely to come into the possession of, anyone who is not the investigator it cannot be used to identify an individual.

Anonymisation of data can be achieved by ensuring any links between the data and the individual has been severed and sufficient identifiers have been removed to protect an individual’s privacy. Removal of some identifiers does not necessarily lead to anonymisation. An acceptable level of anonymisation can be achieved which gives protection to the individual and, at the same time, allows research to be conducted. This acceptable level of anonymisation involves the removal of the obvious identifiers eg name, address, social security number, date of birth, NHS number etc.

It should be noted that removal of all of the identifiers as in the Privacy Rule of the US Health Insurance and Portability Accountability Act 1996 where all 18 identifiers need to be removed to attain de-identification extensively curtailed research and in the process raised the protection of the individual to an excessive and unnecessary level. This situation must not be allowed to arise in the UK. Patients must be protected but medical research for the benefit of society as a whole must be able to continue.

Anonymisation can be greatly assisted by technology, particularly through encryption technology which can provide additional safeguards. The ABPI guidelines provide an algorithm on secondary processing and a number of examples of anonymisation which we would commend to the review panel.

Section 6: International comparisons

Question 23.

Comments:

Question 24.

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Question 25.

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Question 26.

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Section 7: Additional questions

Question 27.

Comments:

Question 28. Please set out any additional suggestions or observations you have that you believe will be of assistance to the review.

Comments: The ABPI is aware of and sensitive to concerns about data privacy. Its intention in promulgating its Guidance is to set an effective standard which safeguards the legal and ethical needs of the community, whilst affording the pharmaceutical industry an appropriate opportunity to deliver medicines which benefit society.

Individually and collectively, pharmaceutical companies adopt a number of measures to ensure that legal requirements are observed and that individuals can rest assured about the treatment of their personal data. These measures vary and include the appointment of specialist data privacy officers, the developments of SOPs to be observed by company staff for the collection and treatment of personal data and the regular training and development of staff involved in this field.

It has been argued by others that access to an individual's health data, under all necessary safeguards, for the purpose of improving the future care for all patients, should be part of the "compact" between the NHS and the patient. We would support this position.