

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
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11 Tothill Street
London
SW1H 9LJ

Thank you.

Section 1: Background

Question 1.

The BioIndustry Association (BIA) welcomes the opportunity to respond to the Ministry of Justice's data sharing review consultation.

The BIA is the trade association for innovative enterprises in the UK bioscience sector, representing over 300 members, the majority of which are involved in realising the human health benefits that bioscience promises. The BIA seeks to represent the interests of these innovative companies to all stakeholders to present positive evidence based suggestions for policy change that assists the development and uptake of innovation for the benefit of the UK patient population.

In this response the BIA is highlighting the use of patient record information for the future benefit of public health in the context of clinical research.

The BIA and its members are mindful of public concerns regarding access to personal data in particular personal health records. BIA echoes the need for the protection of patient data

confidentiality and recognises the need to ensure all concerns are properly and openly discussed. However, it is crucial that the potential benefits of appropriate access to patient records for the purposes of clinical research are considered together with these concerns.

The BIA is committed to the responsible use of bioscience. The UK bioscience sector adheres to strict regulatory and legislative frameworks and we encourage public discussion of the ethical, legal and social implications of bioscience research. Our Bioethics Statement¹ demonstrates our commitment to ensuring that bioscience is used for human good and we review these principles as the technology advances.

In this response our focus is therefore on the issues raised in sharing personal information for the purposes of clinical, public health and health services research.

BIA members are actively engaged in the research and development of new medicines and clinical trials of late stage products which should ultimately benefit the UK patient population. Central to the success of this activity is appropriate access to patient records for the purposes of clinical research.

The BIA is a partner organisation of the UK Clinical Research Collaboration (UKCRC²) whose main aim is to re-engineer the environment in which clinical research is conducted in the UK, to benefit the public and patients by improving national health and increasing national wealth. Our focus is therefore on the issues raised in sharing personal information for the purposes of clinical, public health and health services research.

The BIA supports the view that there is a unique opportunity to access data from a national health service, providing healthcare to a population of more than 50 million patients. Much of the personal data that is of interest for research purposes, such as safety monitoring and clinical trial research, is also of interest to those conducting public health studies, NHS clinical treatment and NHS management activity. Whilst ensuring patient confidentiality is critical, there is a significant amount of vital research that cannot be conducted without access to identifiable information about patients.

A clear example is the potential and development of personalised medicines which will mean that the information about an individual can be more detailed and potentially life changing than ever before. The public's concerns and the ethical implications of these advances need to be considered and addressed

¹ http://www.bioindustry.org/cgi-bin/contents_view.pl

² www.ukcrc.org

Indeed within the industry, mechanisms to promote patient confidentiality during pharmaceutical research are well-established. For example, only coded data is supplied to the researcher who has no direct access to the patient or identifying details such as name, address etc.

Additionally, the ABPI has recently developed comprehensive guidelines for the secondary use of data for medical research purposes, providing guidance to its members³. There is also a body of opinion suggesting that electronic data will allow greater security than paper-based systems.

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

Question 2.

The BIA recognises the sensitivities surrounding the process of consent, confidentiality of data, commercial involvement and end use of data. On all of these issues, the BIA believes it is essential to ensure that the public is confident that its records will be handled in a responsible, respectful and ethical manner.

The BIA is fully supportive of the Connecting for Health⁴ (CfH) project. CfH is the National Programme for IT which will bring modern computer systems into the NHS to improve patient care and services. Over the next decade, it will connect over 30,000 GPs in England to almost 300 hospitals and give patients access to their personal health and care information, transforming the way the NHS works

It could lead to more effective new treatments for serious adult diseases such as cancer and heart disease, and could help scientists and medical practitioners to predict and prevent diseases. CfH is vital to continued medical advance and the BIA wants to ensure that these exciting prospects are not unduly impeded by ethical concerns that we feel have been responsibly and comprehensively addressed by an existing system GP Research Database (GPRD)⁵.

³ http://www.abpi.org.uk/publications/pdfs/phase1_guidelines.pdf

⁴ C <http://www.connectingforhealth.nhs.uk/>

⁵ <http://www.gprd.com/home/>

The GPRD is the largest computerised database of anonymised longitudinal medical records from primary care. Currently data are being collected on over 3.4 million active patients (approx. 13 million total) from around 450 primary care practices throughout the UK. It is the largest and most comprehensive source of data of its kind and is used worldwide for research by the pharmaceutical industry, clinical research organisations, regulators, government departments and leading academic institutions. The GPRD Division provides data and services to support medical and public health research through secure, global access via the internet or via datasets on CD-ROM. This makes GPRD the GOLD Standard of research databases.

Not to realise the real research potential of a unique resource would be a lost opportunity for public health. CfH should benefit all involved with UK healthcare were its research potential to be fully realised

- Patients would benefit from an overall increased quality in healthcare. Providers would benefit from improved and cost-efficient patient care
- Regulators would benefit from improved safety and greater efficiency
- The NHS would benefit from reduced costs
- Bioscience & Pharmaceutical companies conducting R&D would benefit from improved economics of clinical trials, increased drug safety and reduced development time

The CfH vision will not be delivered unless patients are willing to allow their data to be used and those they have confidence in the systems in place to handle this data confidentially.

The BIA is committed to proactively communicating the benefits of Connecting for Health and the GPRD while openly engaging in debate on any concerns people may have in regard to the project.

In more general terms, data are collected for many types of research study, such as clinical trials, safety monitoring and epidemiology. In the case of epidemiological research where researchers require information about groups of patients for their studies rather than individual patients, they still need data to be linkable and comprehensive at the individual patient level in order to answer clinical problems. This data is most often in pseudonymised form. For maximum value, and to allow quality and completeness to be validated, some identifiers need to be available to researchers.

The benefits for public health are in establishing connections between data sources such as

those holding primary care patient records and disease registry records to enable trends and associations which may have a huge potential impact on patient outcomes to be explored. Examples of such studies include the health of miners⁶ or the social distribution of cancer⁷. Importantly, society benefits in improvements to population health resulting from research which does not require the exposure of members of the public to risks of experimental or long-term treatments to determine outcomes which may already be available from linkage of currently collected data.

Question 3.

The BIA acknowledges that increasing access to personal health data brings new challenges and responsibilities for safeguarding patient privacy. The risks mainly arise from inappropriate sharing or loss of data where there is a lack of well trained staff or effective systems of data security.

However modern health services cannot advance or be delivered for the benefit of patients without clinical, public health and health services research. Personal information held as e-health records can be extremely sensitive and inappropriate use or disclosure has the potential to cause harm or distress. The research community is overwhelmingly aware that experience of inappropriate disclosure might induce patients to withhold information from a health professional or even avoid treatment altogether.

The research community is keen that systems to regulate access to personal data strike a balance between the need to protect patient privacy and the potential for great benefit for individual and public health in using this data for effective research. However it should be noted that the great majority of the research uses of personal data are of low risk focussing on patient or population groups rather than individuals.

Question 4.

The bioscience and pharmaceutical industries firmly believe patient confidentiality should remain protected. Mechanisms to promote patient confidentiality during pharmaceutical research are well-established. For example, only coded data is supplied to the researcher who has no direct access to the patient or identifying details such as name, address etc. It is

⁶ Fox AJ, Goldblatt P & Klein LJ (1981) A study of mortality of Cornish tin miners. British Journal of Industrial Medicine 38, 378 – 80

⁷ Kilne LJ (1988) The longitudinal study and the social distribution of cancer. British Medical Journal 297, 1070

therefore essential that confidentiality is maintained in any future electronic system.

Additionally, the ABPI has recently developed comprehensive guidelines for the secondary use of data for medical research purposes, providing guidance to its members⁸. There is also a body of opinion suggesting that electronic data will allow greater security than paper-based systems.

The UKCRC R&D Advisory Group to Connecting for Health was established in 2006 under sponsorship from the Department for Health and NHS Connecting for Health in England to consider the feasibility of using electronic personal data from the NHS Care Records Service to conduct high quality research for patient benefit. The report⁹ of the group was published online in summer 2007 and made a number of recommendations including some on data access, availability, data quality and mandating use of the NHS number. There was a close working relationship with the Care Record Development Boards (CRDB) working group on secondary uses of patient data¹⁰. Both reports discuss the need for robust information governance that is also responsive to the needs of research. The reports also propose the development of an enhanced infrastructure that can link and integrate patient information, in a secure format to provide a comprehensive service for research with ultimately direct benefits for patients.

These two reports recommend development of 'honest brokers' as a way of engendering trust amongst patients, clinical professionals and the research community. The role of the honest broker is a dual one, ensuring patient confidentiality and security as well as scientific integrity of the data delivered to the research community.

In addition, the CRDB report recommended the development and use of information guardians to facilitate access to identifying data for research where this is essential. Information Guardians are designated physical or electronic areas which provide appropriate levels of security for the use of the most sensitive and confidential information. Examples of this model are found in Canada where research data centres¹¹ are used as a means of providing researchers with access to confidential micro data in a controlled environment.

⁸ www.abpi.org.uk

⁹ UKCRC R&D Advisory Group to Connecting for Health: Report of the research simulations. June 2007 <http://www.ukcrc.org/publications/reports.aspx>

¹⁰ Report of Care Record Development Board (CRDB) Working Group on Secondary Uses of Patient Information. August 2007 <http://www.connectingforhealth.nhs.uk/crdb/workstreams/secusesreport.pdf>

¹¹ Statistics Canada. The Research Data Centre www.statcan.ca/english/rdc/index.htm

The reports demonstrated that development of an enhanced infrastructure presents huge opportunities for research in the UK. It will enhance our research communities' ability to link together information about the same individual in order to assess patterns of disease outcome or causation from which general inferences can be drawn. The greatest risk likely to occur is where secure procedures for data-handling are not in place, understood or monitored. Data in which personal identifiers are minimal and encrypted or held separately from the main clinical database reduce significantly the risk of disclosure. The focussing of data handling and linkage into centres where procedures are well established will go a long way towards reducing this risk.

Question 5.

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.

BIA and ABPI members' interests related to the electronic patient record are to increase patient safety through the active monitoring of safety and efficacy of new and existing medicines and to provide additional health benefits from research. These aims cannot be achieved without access to the detailed electronic patient record. This will not be provided by CfH in the proposed centrally-held Summary Care Record.

It is our understanding from CfH that the proposed central Summary Care Record will be only a small subset of the complete patient record held on the current GP systems and will not contain specific data to be of much use to improve safety and to enhance clinical research.

The Summary Care Record will be an abstract from the existing detailed primary care record, together with abstracts from hospital care patient records which will be provided through the National Care Records Service (NCRS). Over 95% of the UK population already

has an electronic record through their GP's system.

We are unaware of any significant changes being proposed to local patient record systems. Initiatives such as GP Systems of Choice (GPSoC) may be moving to a more standardised and accessible record. Such moves could potentially offer greater patient safety, pharmacovigilance and research quality.

Question 8.

Comments:

Section 3: The legal framework

Question 9.

The BIA supports the UKCRC position that researchers consider that the main weaknesses of the data protection act as the law governing data sharing is the confusing and overly complex language. The resulting variation in interpretation of the Act by data controllers appears to contrast unfavourably with the approach taken by the Information Commissioner's office to similar questions. UKCRC partners are concerned that the law fails to consider the relative harms that can be caused by different types of information processing. The sharing of personal data for medical research appears to be viewed as being equally intrusive as when sharing them with other bodies such as the police, insurance companies or social security agencies.

UKCRC partner concerns about data sharing stem directly from the fact that, currently, it is illegal for researchers to access identifiable patient data without consent because they are not part of the direct care team. This introduces two important issues for research:

- The need to obtain consent to access medical records in order to identify eligible research participants to invite them to participate in a research study
- Confusion about whether general consent or opt-out consent qualifies as valid consent for information processing under the Data Protection Act 1998

The use of personal data from patient health records in research was the subject of a study

by the Academy of Medical Sciences in 2006. The study culminated in the publication of a report¹², Personal Data for Public Good: Using Health Information in Medical Research. Publication of this report was followed in June 2006 by a symposiumⁱⁱ involving senior members of the legal profession and academics.

In their report the Academy of Medical Sciences discuss the definition of fair processing as defined in the Data Protection Act and its difficulties for research using personal data.

Research is often a secondary use of the personal data that has been collected. As a result it is not always possible to predict the research purposes for which data might be used in the future. Research using personal data often involves very large numbers of individuals' data who cannot be readily contacted with fair processing information.

Question 10.

Comments:

Question 11.

Comments:

Question 12.

Comments:

Question 13.

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

¹² Personal data for public good: using health information in medical research. Academy of Medical Sciences January 2006 <http://www.acmedsci.ac.uk/p48prid5.html>

procedures, eg by requiring supplementary and variable data transfer agreements.

Question 14.

Comments:

Question 15.

Comments:

Section 4: Consent and transparency

Question 16.

BIA supports the views of ABPI regarding patient consent via continued opt out as the preferred arrangement. As with current international research practice today in the use of existing databases, future systems should support use of patient level data via an 'opt out' patient consent protocol. Patient identification at GP level to enhance pharmacovigilance will be vital, a topic that has previously been identified for action by the Health Select Committee¹³. The recommendations from the Cooksey Report¹⁴ and those of Best Research for Best Health¹⁵ will not be delivered without access to patient level data being fully optimised in terms of data quality and speed of access.

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

¹³ <http://www.publications.parliament.uk/pa/cm200607/cmselect/cmhealth/422/422we05.htm>

¹⁴ http://www.hm-treasury.gov.uk/independent_reviews/cooksey_review/cookseyreview_index.cfm

¹⁵ http://www.dh.gov.uk/en/Researchanddevelopment/ResearchAndDevelopmentStrategy/DH_4127109

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.

Available evidence suggests that the current level of public awareness in relation to the use of medical records in research is low. The BIA would encourage increased public engagement around the value of research using health care records and the circumstances and procedures by which such records may be accessed for research purposes. The BIA would like to see the issue of personal autonomy versus public good from data sharing become a feature in any dialogue with the public.

As a first step, this was investigated in two recent reports by UKCRC partners: the Ipsos Mori/MRC Consultation on public attitudes toward the secondary use of personal health information for medical research (June 2007) and the Wellcome Trust Public attitudes to research governance (June 2007). Both of these reports investigated whether patients are content to have people other than those providing direct care (in this case researchers) accessing their medical records. The findings revealed that there is often public support for the goals and societal benefits of research. Individuals affected by different conditions are more likely to be responding to the condition under study than the over-arching issue of data-sharing.

To give an example, 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.

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 the ABPI website (www.abpi.org.uk). The BIA would strongly recommend all organisations involved in the sharing of information to develop guidelines and publish them. ABPI consulted with the Information Commissioner's Office near to final draft of the guidelines and received very helpful suggestions on improving them which they 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.

Comments:

Section 5: Technology

Question 20.

Comments:

Question 21.

Comments:

Question 22.

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.

Comments:

Question 25.

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Question 26.

Comments:

Section 7: Additional questions

Question 27.

Comments:

Question 28.

The BIA is aware of and sensitive to concerns about data privacy.

Individually and collectively, bioscience and 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.