Cancer Research UK Submission to Information: to share or not to share? Information Governance Review

Executive Summary

In 2010-11, Cancer Research UK spent over £24 million funding research in which the use of patient data played an important role.[1]

The use of patient data is especially important for cancer research as epidemiological studies are crucial to our understanding of cancer. We estimate that 42% of cancers are preventable[2] and it is the use of patient data which has allowed us to identify many of the causal factors, such as tobacco, smoking, alcohol and ultraviolet exposure.

Equally, population data used in epidemiological research and clinical audits allow us to evaluate the effectiveness of healthcare services and ultimately benefit patient outcomes.

We recognise that patient data are often highly sensitive and that strong safeguards must be put in place to ensure that patient confidentiality is maintained during the research process. However, we also find that many patients actively want to be involved in research. For example, in the Department of Health 2012 National Cancer Patient Experience Survey, 95% of patients who discussed research with their doctor were glad they did so and over half of those who did not discuss it wished they had.[3]

Cancer Research UK believes that the regulation and governance of the use of patient data should be proportionate both to the potential risks to the privacy of the individual and to the potential benefits to the wider public derived from the research.

Our detailed response to the consultation questions are listed below, however, in summary:

- Cancer Research UK believes that when using patient data in research the rights of individuals must be balanced against the public good - safeguarding privacy and patient rights while also allowing researchers to access data efficiently for use in ethically approved research.
- The significant steps which have been taken to streamline the regulation and governance environment around patient data, especially the establishment of the Health Research Authority, are very welcome. However, significant confusion and duplication of effort still surround the process of accessing patient data for research and further progress must be made to improve the process.

[1] By patient data we mean both individual patient records and also the wider data sets which these individual records contribute to.

[2] The Fraction of Cancer Attributable to Lifestyle and Environmental Factors in the UK in 2010, Dr D Max Parkin; with Lucy Boyd, Professor Sarah C Darby, David Mesher, Professor Peter Sasieni and Dr Lesley C Walker; with a Foreword by Professor Sir Richard Peto , British Journal of Cancer, Volume 105, Issue S2 (Si-S81), 6th December 2011.

[3] Cancer Patient Experience Survey 2011/12 - National Report, Department of Health, p.58.

- The draft European Data Protection Regulation is welcome as it allows the use of patient data in research, while still providing legal protection for patients. However, further clarification is needed, in particular surrounding the status of key coded data.
- The development of 'safe havens' is a positive step as it facilitates access to patient data. However, there remains a need to ensure that 'safe havens' give good national coverage and include data on hard-to-reach groups, such as deprived communities.
- The Government commitment to keeping patients informed of possible clinical trials is a positive step, as is the consultation on an opt-out system governing the use of individual data in research. To support this, both healthcare professionals and members of the public must be fully engaged in and informed about the use of patient data in research and encouraged to see the vital role which research plays in the work of the NHS.
- Cancer Research UK believes that it should be possible to share a wide range of data relevant to public health across different organisations.
- Cancer Research UK believes that patient privacy and confidentiality should be maintained as far as is reasonably possible when assessing local population needs for commissioning purposes.

Research

1. **Terminology and Definitions**

The variation between terms used for different types of data can become problematic when it leads to ambiguity about what issues are under discussion.

The definitions which Cancer Research UK uses are as follows:

> **Identifiable:** Data which include personal identifiers such as names, addresses, dates of birth and NHS numbers. A researcher may need identifiable data if they wish to contact patients to invite them to participate in a clinical trial. However, researchers may also need to use identifiable data in epidemiological studies, for example if they are researching geographic variance in disease incidence.
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> **Key-coded:** Data which cannot be directly used to identify an individual, but which can be re-linked to identifiable data if the person using it has access to a "key". Also known as pseudonymised, this kind of data can often be used in lieu of identifiable data.
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> **Anonymised:** Data which cannot be linked to the original patient record.

However, these definitions are not absolute; for example data can sometimes remain identifiable even if they have been key-coded or anonymised if, for example, they refer to a rare medical condition or a small population group. Therefore, although clearer and more consistent definitions would be desirable, it is likely to be impossible to agree upon exact standards of terminology.

2. **General Issues**

Do you think researchers need to process sensitive personal information?

Access to patient data is essential for cancer research. NHS patient records, cancer registries and databanks can be used to research the causes of cancer, monitor survival rates, study the effectiveness of treatments and interventions, such as cancer screening, and identify appropriate participants for clinical trials.

What are the issues with researchers only having access to de-identified data?

It is desirable for researchers to use de-identified data where possible. However, this is not always practical. As mentioned above, in certain situations, it is impossible to completely anonymise data, for example when it refers to small populations. In other circumstances, researchers may require personal, potentially identifying details, for example postcodes, in order to draw meaningful, epidemiological conclusions.

An example of the important role which identifiable health data plays in cancer research, is the work of the National Cancer Intelligence Network (NCIN). The NCIN is supported by cancer registries (which collect and link data relating to cancer patients), the NHS, cancer charities, research funders and other organisations committed to using data to improve cancer outcomes. The NCIN and cancer registries, both of which will sit in the Knowledge and Intelligence directorate of Public Health England, allow researchers to better understand cancer incidence, how it varies between different groups and how interventions can be targeted to achieve maximum impact.

Centres of Excellence in Electronic Health Research

Four centres of excellence in electronic health research have recently been set up in London, Manchester, Dundee and Swansea. The funding has been provided by a partnership of ten government and charity funders, including Cancer Research UK, who have invested £19 million in the project. The Centres will focus on producing high-quality, innovative research using Electronic Health Records (EHRs) and will provide improved training and technology to allow better linkage and analysis of existing datasets. In addition to this, the Centres will also work on the legal and ethical areas surrounding the use of patient data and invest in public engagement on the issue.

Cancer registries collect data in identifiable form. This allows them to support geographical studies, to provide information for genetic counselling services to be given to people with familial predisposition to cancer, to provide patient details to researchers with ethical approval and to allow data linkage, for example between the registries and the cancer screening service. Access to this data is strictly controlled and there have been no breaches of confidentiality in the forty year history of this system.

Restrictions on the collection of identifiable data without consent could seriously undermine the work of cancer registries. Without this facility, we would not have a critical baseline of information about cancer in the UK, including fundamental data on cancer incidence and cancer type. This information is vital for clinical care provision and planning for service provision. In addition to this, the UK is currently acknowledged as having one of the most comprehensive cancer registry systems in the world and this invaluable resource underpins much of the lifesaving research which Cancer Research UK funds.

Researchers may also require identifiable data for recruitment to clinical trials, see Section 3 for more details.

Where identifiable data is concerned, we believe that there should be transparency of use and audit of how individuals' data has been used. We believe that this is crucial in maintaining public confidence in the system.

What are your views about the Section 33 DPA exemptions?

Legislation and governance surrounding the use of patient data in research remains complex, involving several pieces of overlapping legislation. We would welcome steps to simplify this situation whilst still combining appropriate protection for patients and support for researchers.

We would like to see clear leadership to provide a roadmap for researchers working with patient data and we believe that this leadership could come from the newly established Health Research Authority. The Health Research Authority should act as a single, authoritative voice on use of patient data in research, creating an environment in which UK researchers are able to use data resources to their full potential.

What are your views about the proposed changes under Article 83 of the new draft Regulation?

We are broadly supportive of the Regulation. We believe that the derogations from requirements of the use of 'personal data' which exist for researchers in the current draft should be protected as the Regulation moves through the legislative process. We also think that there should be more clarification around the wording of certain statements and the status of key-coded (de-identified) data. Regulation surrounding the use of key-coded data, which underpin a substantial amount of research, should be proportionate to the risk of re-identification. Although re-identification of key-coded data remains technically possible, conditions are established to minimise the possibility and this should be reflected in law.

What do you perceive to be the benefits, risks and issues of safe havens and honest brokers?

Cancer Research UK welcomes the development of 'safe havens' as they have the potential to facilitate efficient access to patient data while still providing strong protection for patient confidentiality. However, questions remain about the completeness of the data provided by certain 'safe havens', notably the Clinical Practice Research Datalink. If the data do not give good national coverage then they risk biasing or distorting research findings.

Should patients be given a right to opt out of their data being disclosed to the CPRD?

We are supportive of an opt out for patients from the inclusion of their data in the CPRD, but we believe that this must be coupled with a high quality public engagement programme explaining the system to members of the public and making them aware of the possibility of an opt out, so that the system represents informed consent.

3. <u>Use of personal data to select cohort in order to seek consent (Consent for consent)</u>

Cancer Research UK thinks that 'consent for consent' is an unwieldy system which has the potential to impede research by slowing it down, making it more expensive or even stopping it altogether. It also places an extra burden of work on clinical care teams.

As part of their epidemiological studies, Cancer Research UK researchers may need to contact individuals who are not unwell, for example during screening studies. It is important that any system in place for contacting potential trial participants allows for this possibility.

Cancer Research UK would support a system in which, in certain circumstances, researchers could be made part of clinical care teams, with the access to patient data which that allows, but also the responsibilities it entails, including the potential for criminal sanctions if data are found to have been misused.

4. Use of personal data to link data sets

Cancer Research UK does not have a specific position on this issue.

5. Role of Section 251 in the new world

Do you agree that the new powers provided to the Information Centre for Health and Social Care will mean that fewer organisations will need to seek support under the Section 251 regulations?

Despite the Information Centre for Health and Social Care's new powers, Cancer Research UK researchers will still need to access identifiable or key coded data for some studies, crucially for epidemiological research and clinical trial recruitment. Therefore, Section 251 will continue to be an important legal provision for us.

To what extent should aspects such as recruitment bias or insufficient powering of studies provide justification for use of these powers?

Recruitment bias is an important issue in epidemiological studies. Without the provision of Section 251, researchers risk drawing conclusions from biased data sets, often excluding hard to reach groups such as ethnic minorities and those from lower socio-economic groups.

6. Patients and the Public

Cancer Research UK believes that patients and the public should be better informed about the current circumstances in which their data may be used in research. The public should also be kept fully informed about any changes to the current system, for example the introduction of an opt out from the CPRD.

Cancer Research UK is supportive of both the opt out and of the Government's commitment to keep patients informed of opportunities to participate in research studies. However, we also believe that this needs to be communicated to the public with caution.

Personal data is sensitive and it is entirely understandable that this new system will raise concerns about privacy and data security. The public needs to be engaged with the exciting possibilities which patient data presents for research, but also reassured that this data will be handled responsibly. The mechanism of the opt out system must also be communicated fully. We would like to see a system in which few people opt out because they are engaged with research and have confidence in the system, not because they are unaware that they have the option to opt out.

Public Health

Cancer Research UK believes that it should be possible to share a wide range of data relevant to public health across different organisations.

- With local authorities, data should be shared between departments or any local public body. For example, it should be possible for data collected by an environmental health officer on sunbed density to be shared with public health teams working on skin cancer prevention.
- There should also be clear processes in place for the sharing of data between national organisations such as Public Health England and local authorities.

Commissioning

Cancer Research UK is supportive of data sharing for public health purposes, but we also believe that patient privacy and confidentiality should be maintained as far as is reasonably possible when assessing local population needs for commissioning purposes. We support the inclusion of strict safeguards for the protection of data confidentiality in any contracts entered into by commissioners.

We would be happy to provide any further information or an expert to discuss these issues further, as required. Please contact Emma Greenwood on emma.greenwood@cancer.org.uk or telephone 0203 469 8358.