

This response was submitted to the consultation held by the Nuffield Council on Bioethics on *The linking and use of biological and health data* between 17 October 2013 and 10 January 2014. The views expressed are solely those of the respondent(s) and not those of the Council.

Cancer Research UK response to Nuffield Council on Bioethics consultation on the linking and use of biological and health data

7th January 2014

1. Cancer Research UK's position on the use of patient data in research

1.1. Access to patient data is essential for cancer research. The information held about patients in their medical records, in cancer registries and other databanks can be used to research the causes of cancer, monitor survival rates, study the effectiveness of treatments and interventions such as screening, as well as identifying appropriate participants for clinical trials.

1.2. Patient data has the potential to deliver huge public benefit, but it is also often highly sensitive for individuals concerned.

1.3. We work on promoting a regulatory and governance framework which enables researchers to access the lifesaving data which they need, while also ensuring that patient confidentiality is protected.

1.4. We also believe that the public should be better informed and engaged about how their data is used and why it is so important to research. We work in partnership with other medical research charities to communicate with the public, explaining the nuances of these issues to them and allowing them to make informed decisions about their own data.

2. Do biomedical data have special significance?

2.1. Biomedical data do have special significance, both in terms of their value and their sensitivity. As both a research funder and a patient facing organisation, Cancer Research UK views this issue as one of balance. We recognise that data must be used to its full potential in lifesaving research while also ensuring the highest standards of patient confidentiality and data security.

3. What are the new privacy issues?

3.1. The effective sharing and use of data in research, as well as to inform care and health service planning, is in the public interest. Data allow epidemiological studies which help us to understand the causes of disease and to inform health policy. They enable recruitment to clinical trials, in particular those requiring healthy participants (such as screening trials) which cannot easily recruit via clinicians. Analysis of datasets allows monitoring of current healthcare practice, for example through

pharmacovigilance and clinical audit. It would also be impossible to effectively plan health services without reliable datasets. Fundamentally, biomedical data saves lives.

3.2. In the majority of situations, researchers using datasets would either anonymise the data involved or seek patient consent before doing so. However, this is not always possible and in some circumstances identifiable data is accessed without consent. This may be necessary for a number of reasons, in particular the impracticality of gaining individual consent for very large datasets.

3.3. For Cancer Research UK, a particularly important example of this is cancer registration. Cancer registries are a vital resource for researchers. They have allowed important breakthroughs in the past, for example the discovery of the link between mesothelioma and asbestos, and continue to play a vital role in work today, such as the International Cancer Benchmarking Partnership.¹ Cancer registration data is collected without the need for individual consent. There is no country in the world which operates effective cancer registration using an informed consent model and when Germany introduced one, it caused the collapse of the Hamburg cancer registry, up until that point the oldest registry in the world.²

3.4. We believe it is important for the public to be aware of the ways in which their data are used and the ways in which they can object to this use. For example, patients can raise an objection to their data being used beyond their direct care. They have the right to have this objection considered and, if it cannot be honoured, the reasons why must be explained to them.

3.5. Data linkage is crucial to enabling the maximum benefit to be derived from separate datasets. This should be carried out within a secure environment, or safe haven, to ensure that data is linked safely.

4. What is the impact of developments in data science and information technology?

4.1. Advances in data science and information technology mean we are better able to collect, store and analyse the data which are generated about individuals than ever before. This presents exciting opportunities in research and we must ensure that the UK has the skills base necessary to make the most of this emerging technology. It is also important that we focus on data quality and interoperability of data systems to ensure that we realise the potential of these developments.

5. What are the opportunities for, and the impacts of, the use of linked biomedical data in research?

5.1. Research using linked biomedical data saves lives. We can use it to understand how to prevent disease, how to diagnose it earlier and how to treat it more effectively. It can influence healthcare practice, service planning and public policy.

¹ <http://www.cancerresearchuk.org/cancer-info/spotcancerearly/ICBP/>

² <http://www.ukacr.org/legal>

5.2. Prevention research is particularly reliant on the use of datasets. Historically, analysis of data has led to key breakthroughs, such as the link between tobacco and cancer. This kind of research continues today, for example the Million Women Study,³ a national study of women's health involving more than one million UK women, is examining the effects of hormone replacement therapy use, alongside a broad range of other issues.

5.4. Large scale, epidemiological studies also help to inform our understanding of disease and provide an evidence base for health policy. CONCORD-2⁴ is a study which is comparing cancer survival in different countries. In 2008 it became the first worldwide analysis of cancer survival, estimating relative survival for 1.9 million adults, using 101 population-based cancer registries in 31 countries on five continents. It will allow us to look at how cancer affects countries across the world and allows policy makers to look at how our health service can be improved to deliver better cancer outcomes.

5.3. Clinical trials may depend on data to recruit participants. For example, the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS)⁵ used patient data to recruit participants into a trial assessing ovarian cancer screening. Early results seem to suggest that screening may be feasible.

5.4. Trials may also benefit more generally by having access to their participants' health records as this will enable researchers to have a more indepth understanding of their medical history.

5.5. Medical research is often conducted in partnership between government, charitable and industry funders. Cancer Research UK collaborates with industry and recognises the vital role which it has to play in the research environment. Assuming that researchers have gone through the appropriate ethical and legal processes, we do not think that industry funded research involving data should be treated differently from government or charity funded research.

6. What are the opportunities for, and the impacts of, data linking in medical practice?

6.1. Effective data sharing within health care delivers significant patient benefit by supporting a joined up approach from medical staff allowing a more integrated care pathway.

6.2. Data linkage can play an important role in improving medical practice. It plays a vital role in developing stratified and personalised medicine, which, in the future, will allow patients to be offered treatments which are specifically tailored to their needs. The Stratified Medicine Programme,⁶ a joint project from Cancer Research UK, AstraZeneca, Pfizer and the UK government's Technology Strategy Board, is aiming to establish the foundations for a national service that will ensure standardised, high

³ <http://www.millionwomenstudy.org/introduction/>

⁴ <http://www.cancerresearchuk.org/science/research/who-and-what-we-fund/browse-by-location/london/london-school-of-hygiene-and-tropical-medicine/grants/michel-coleman-16148-global-surveillance-of-cancer-survival>

⁵ <http://www.instituteforwomenshealth.ucl.ac.uk/womens-cancer/gcrc/ukctocs>

⁶ <http://www.cancerresearchuk.org/science/research/how-we-deliver-our-research/others/by-programme/stratified-medicine-programme/>

quality, cost-effective genetic testing of tumours is available for people with cancer. The collection and storage of information about patients' tumours and relevant clinical data within the National Cancer Registration Service is a fundamental element of this Programme. The programme consents patients to allow access to NHS medical and other health related records to get information about cancer, other diseases and their treatment now and in the future for research purposes. In general across Stratified Medicine Phase 1 we saw consent rates of 98% and over 10,500 patients consented to participate.

6.3. Routinely collected data can also be used to inform treatments and interventions, in particular for treatments where it is challenging to design ethical randomised control trials, for example radiotherapy. Existing data based on past treatments can be analysed and used to inform subsequent interventions allowing innovation and patient benefit by fully utilising data which already exist within the system.

6.4. There is increasing discussion within the NHS about allowing patients to access their own medical records online. Cancer Research UK believes that this kind of access has the potential to allow patients to be better informed about and involved in their treatment. We are currently working on an online portal which will ultimately allow patients supported access to their cancer records. We would like to see advances in data collection, linkage and analysis being used to empower patients themselves, as well as to inform their treatments.

7. What legal and governance mechanisms might support the ethical linking of biomedical data?

7.1. Cancer Research UK believes that the current information governance framework is broadly appropriate for medical research. Where possible, researchers are encouraged to use anonymised or pseudonymised data or seek consent from the data subjects. However, as discussed in Section 3, this is not always possible and where researchers require access to identifiable data without consent, the legal mechanisms exist for them to do so. This method of accessing data is controlled by the Health Research Authority.⁷

7.2. The general public should be well informed about the ways in which their data can be used both for research and for other purposes. They should understand how they can object to these uses and, if objections are not respected, they should have the reasons why explained to them. A system in which individuals opt in to having their data used would be unworkable, leading to loss of data completeness and sample bias which would profoundly undermine the conduct of research.

We hope our comments are useful, if you would like to discuss these further please contact Jennifer Boon on Jennifer.Boon@cancer.org.uk or on 0203 469 5374.

⁷ <http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/>

About Cancer Research UK

Every year around 300,000 people are diagnosed with cancer in the UK. Every year more than 150,000 people die from cancer. Cancer Research UK is the world's leading cancer charity dedicated to saving lives through research. Together with our partners and supporters, Cancer Research UK's vision is to bring forward the day when all cancers are cured. We support research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses. In 2012/13, we spent £351 million on research in institutes, hospitals and universities across the UK. The charity's pioneering work has been at the heart of the progress that has already seen survival rates in the UK double in the last forty years. We receive no government funding for our research.