

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.

Im sorry I don't have time to reply to all the points in detail.

However

1. Consultation question 1:

Do biomedical data have special significance?

Data that can be used to accurately identify an individual- say DNA is treated differently to say a blood test. However increasingly blood profiles with metabolomics and RNA can be used to identify an individual so it is becoming blurred. I don't think collecting data via credit card spending is any different to say BP readings.

2. Consultation question 2:

What are the new privacy issues?

Possible aspects to consider:

- Do new information technologies and 'big data' science raise privacy issues that are new in kind or in scale?

- only so far as data is now in the hands of more people and is more transparent.

- What are the implications for individual anonymity of linking data across large numbers of databases?

-anonymity cannot be completely guaranteed.

- What is the 'public interest' in biomedical data? What benefits do we want to obtain? In what circumstances might the public interest take precedence over individual and minority group interests?

- I believe anyone who partakes of the benefits of the health service should contribute biomedical data.

- What are the actual harms we should seek to avoid in using biomedical data (e.g. discrimination, stigmatisation)? What evidence is there of these harms having occurred?

- agree discrimination is possible – but has never occurred as far as I know. Keep this risk very low and inform people

- In what ways does it matter if people's data are used in ways of which they are unaware but that will never affect them?

- my volunteers are happy if they trust the person they give the data to. Once they have made the arrangement – they don't care. If contentious areas like cloning or abortion are avoided – most people are happy to give wide consent.

- How are applications of computer-based technology (e.g. social networking, image sharing, etc.) affecting concepts of privacy, identity and social relatedness? How are related behavioural norms influenced (e.g. willingness to share and publish data)?

- Would it be helpful to treat biomedical data as 'property'? unsure

Consultation question 3:

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

Possible aspects to consider:

- To what extent and in what ways has the availability of biomedical data and new techniques for analysing them affected the way in which biomedical research is designed and funded? Is there any evidence that these factors have affected (or are likely to affect) research priorities?

There is a willingness to fund big data linking projects but great fear and reluctance on the ground to make it happen – most fears irrational and risks are never quantified.

Consultation question 4:

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

Possible aspects to consider:

- What are the hopes and expectations associated with data use for biomedical, public health and life sciences research? What are the main concerns or fears?
 - Big hopes for personalized medicine and large studies.
 - Small vocal minority saying this is start of big brother society
- To what extent do the kinds of collaborations required for data-driven research (e.g. international or multi-centre collaborations) generate new ethical and social issues and questions to those in other forms of research?
 - Much omic data from individuals is being used by many people in countries volunteers never dreamt of and don't understand from consent procedures
- Should researchers be required to allow others to access data they have collected for further research? Yes as long as it doesn't dis-incentivise them to collect more data and they have some protected time.
- What sorts of concerns are raised when research is carried out by a commercial firm?
 - volunteers are concerned for non-specific reasons. Companies may not publish

Consultation question 5:

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

Possible aspects to consider:

- What are the main hopes and expectations for medical practice associated with increased use of linked electronic data?
 - Great hopes for the future

What are the main concerns or fears? Short term bureaucracy will hinder this and public fears stirred by media will prevent it.

- What can be said about public expectations about the use of health care data, in terms of appropriate use, information and control? To what extent would members of the public expect health care data to be shared with other agencies or bodies?
 - currently public understanding is limited and usually just with the hospital they belong to.
- Is there potential for privacy controls to hide secrets, such as abuse, or to disadvantage people in unintended ways (by preventing best treatment, perhaps)?
 - best to have sanctions if any researcher breaches trust and allows identity of an abuse victim to be disclosed rather than specific laws.
- Are there particular issues raised by 'risk-profiling' where individuals at high-risk (e.g. of type 2 diabetes) are identified and approached for specific interventions? What might make the difference between this being intrusive and it being supportive?
 - I don't see any difference between this and a GP noticing a fat patient and offering Rx.
- What are the implications of episodes of treatment across different care providers being used routinely as research data? How might this affect the ethical basis of the doctor-patient relationship? Need to change mindset of public and doctors that all data should be used for research.

- To what extent does the possibility that **biomedical data** can contribute to a research base to advance the effective treatment of others create a moral obligation to allow them to be used in this way? What might limit this obligation? How should we regard (and provide for) those who refuse to allow their data to be used?
 - Agree should be default – but clearly some can opt out – but they should be filling in forms etc. like conscientious objectors.

Consultation question 6:

What are the opportunities for, and the impacts of, using biomedical data outside biomedical research and health care?

I think researchers should be able to use data for other ethical purposes if it funds the basic research .

Consultation question 7:

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

Possible aspects to consider:

- What ethical principles should inform the governance of **biomedical data**? For example, should the principle of 'respect for persons' be given primacy here? How might this relate to principles such as solidarity and tolerance?
 - Respect for persons and solidarity sound like good priorities
- Does the use of linked biomedical data require distinctive governance arrangements compared to the use of other personal data?
 - should not be very different to financial data.

- Are the current principles of consent – including the principle that consent can be withdrawn – still ‘fit for purpose’ in relation to the linking of biomedical data?

No – agree withdrawal can only be prospective – no new data added- but not destroyed.

- What level of continuing involvement is it reasonable to expect individuals to have in how their data are used after they have been collected?

-should be informed wherever possible – but no obligation

- Should there be an opt-in or an opt-out system for people to decide whether to allow their personal medical data to be used for public benefit?

- Def opt-in

- Under what conditions ought individuals to be content to delegate authorisation of the use of health and biological data about them?
- What role should public engagement and democratic processes play in the determination of governance measures? In what circumstances, if any, might the outcome of democratic procedures mandate overriding individual interests?

- should be similar to vaccinations

- What inconsistencies exist in current ethical guidance and governance structures relating to biomedical data?

- Most ethics don't include any ongoing relationship or continuing complexity of the data. Also ethics don't ever gauge what volunteers want done with their data.

- What examples are there of innovative initiatives that promote privacy while encouraging participation?

