

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.

The linking and use of biological and health data

Response to consultation.

You will get much more original thinking and informed comment from others, but I wished to make a few related self-evident (so easily forgotten) points on the issues you have highlighted.

1. Technological changes, mainly in informatics but also in biomedical analytical instrumentation, have led to a situation where large amounts of biomedical and other data on individuals are starting to become available. The most novel issues come from the large sample sizes that can be accumulated, and particularly from the possibility of triangulating individuals in different datasets and so combining data pertaining to them of very different types e.g. genotype and social status data. Within each discipline, the difference made by modern developments is useful (bigger samples allow much better analyses, in principle at least) but not truly novel. The possibility of cross-disciplinary analyses may in my view produce real surprises
2. Science seems always to run in fashions, and the current enthusiasm for 'big data' can be confidently predicted to lead to some grossly excessive claims that will (or should) eventually come to embarrass their authors; and to some genuinely useful advances. Some of the advances will be expected, others may well come from directions in which no-one is currently looking. The issue is not whether these general approaches will be revolutionary, or whether they will transform the research agenda, but whether there are useful individual experiments that can be defined, which are judged to be worth the money. I don't think there is any doubt that such investments can and have been identified; nor any doubt that not all of them will pay off as expected. It's the nature of trying novel approaches that they do not come with trustworthy guarantees of success, and those who claim otherwise should generally be regarded with circumspection
3. **Q's 1 & 2: Do biomedical data have special significance?** It is obvious that genomics and the various 'omics modalities have changed biomedical research, and that the datasets generated are large. However, the differences between very large sets of e.g. methylation data and information pertaining to only a few loci does not seem to me to pose any fundamentally new ethical questions. Even in genomics, although it is true that more can in principle be learned about a person from a whole genome sequence than from earlier less extensive techniques for genetic characterisation, it is difficult to see any genuinely novel and different ethical issues that arise. If one asks, e.g., how the public accessibility of information on whole genome sequence might lead to harm to individuals, the answers seem to be entirely related to issues of potential discrimination such as insurance, employment, racial characterisation

- etc.; and to the discovery of inter-personal relationship information e.g. paternity. These are not new issues – they are precisely those debated in relation to genetic information decades before gene sequencing came of age.
4. It seems to me therefore a mistake, to see the questions you are examining as being the result of advances in biomedical research techniques. They are rather the result of advances in information science, and the internet, enabling the holding, management, analysis and distribution of huge sets of data in ways not previously possible. These new tools bring opportunity, and challenge, in many fields of activity – financial, personal surveillance by governments and by commercial entities, advertising and marketing, and indeed biomedical research. In each of these (and many other) fields, there are expanded opportunities for finer grained, denser, more particular information about individuals. It can be argued by proponents that this is for the ultimate benefit of the people affected and of society. There are also opportunities for harm – some of it largely perceptual (I personally share a sense of unfocussed outrage that unknown companies should hold information gleaned from multiple sources without my permission, pertaining to my creditworthiness and my shopping habits, although I am luckily not in a position where I think it has done me actual harm) and some of it genuinely damaging and alarming for individuals.
 5. I would therefore urge you to frame your discussions in terms of the opportunities and threats of modern information technology in general and how this applies to biomedicine, rather than looking at biomedicine and comparing it to other fields. Emphasising the common issues rather than the differences will keep some of the inevitable trade-offs in perspective. There are genuine issues to be considered, not only in terms of actual threats of harm but also in terms of the meaning and limits of “privacy” in a Facebook world; and indeed in a world which has given so much credence to a ‘global war on terror’. Biomedical research does have distinctive elements, and it needs to argue its own value in return for the trust of citizens, but the novel ethical issues in this discussion are not novel in biomedicine.
 6. Not only are the issues very similar across different fields of activity, but so may be some of the solutions. In general biomedical research enjoys a high degree of public trust. Financial services have earned a high degree of public suspicion. Yet the great majority of people use their products – credit cards, bank accounts, etc and allow highly personal data to be held and traded by these institutions that they do not trust. In biomedical research there has been huge emphasis on the importance of participant consent, but my own impression is that consent has almost nothing to do with people’s acquiescence to financial institutions’ data-holding activities. They do get consent, in the sense of signed acceptance of terms and conditions, but it is widely held in contempt. My guess is that people acquiesce in their activities because they provide a service useful to the individuals; and because there are mechanisms for compensation in the event of error that are enforced by law. I wonder whether biomedical research has paid inadequate attention to such issues.

Martin Bobrow

7/1/14