

Part Two

Consultation questions

1 Do biomedical data (BMD) have special significance?

- 1.1. BMD are personal to the individual. The degree to which they are deemed sensitive is a matter of the individual's perception. There could be an argument that, when the data are depersonalized, they are deindividuated. Might it be true for many that individual data are special and precious; deindividuated data are special but not precious, because they are part of a collective?
- 1.2. We think that caution is called for when using the term 'special protection' regarding personal BMD. It can suggest that different protection measures are needed compared to other types of data. Additional protection measures are needed *on top of* existing ones.
- 1.3. **Factors that might contribute to the belief that personal BMD deserve special protection.** Beliefs are anchored in the individual, although fuelled by external influences. Some might believe that special protection is needed, and others might not. Factors could include:
- living with illness/condition that is associated with a stigmatized group
 - fear of DNA analysis and detection/solving of crime
 - fear of unwanted diagnosis
 - belief in the absolute autonomy of the individual
 - belief that the human body belongs to (a) god
 - fear of unwanted access to identifiable data (e.g. insurance companies, employers).
- Further factors might include
- adopted child establishing birth parents (whereby this is regulated by the Children Act 1975)
 - paternity testing (whereby this can be ordered under Section 20 of the Family Law Reform Act 1969)
- All of the above are context-specific fuelled by individual beliefs, fears etc. Context, then, is key.
- 1.4. In the case of genomic data sets and ethical challenges, a person's unique identity is stored in e-space, over which that individual has no control. How ethical is this 'hand-over'? Due to the mass of cases to be stored, opt-in consent is not a viable option. We can seek to provide the highest levels of security, but absolute confidentiality and anonymity cannot be guaranteed. All we can do is a) engage with the public where possible and seek its mandate and ensure b) security and c) that data are stored in safe havens with access

by trusted parties and individuals only. Regarding genomic data sets and ethical benefits, a research team has the ability to access a very distinct population; thus in many studies there is no recruitment/participation (no potential harms to the study population). This 'using what we already have' also means less spending of public monies. Many of the general population might also be pleased to know that this 'passive participation' is for the public/greater good.

- 1.5. **To whom do genomic data sets belong?** This is a very good question. Firstly they belong to the individual – at least at the outset – and his or her choice should be respected irrespective of family views, and continue to be honoured after death. This view is in line with the views of the BMA in the case of organ donation and presumed consent, based on a critical shortage of donors leading to long transplant waiting lists. In the context of genomic data, there is a critical shortage of NHS and research funding, and drawing on what we have is not only scientifically rigorous (due to sample sizes), but makes economic sense. However and because the family share the genomic sequences, the implications of some findings may also hold true for family members, and the individual may therefore have knowledge of an illness/condition that could present in another family member(s). We see a working example of this currently in the case of breast cancer and/or prophylactic mastectomy, where a procedure may reduce risk. On the other hand, there will be cases where no treatment is available currently. It is difficult to ascertain how many individuals would prefer to know about a risk (recognised through the genomic data belonging to their relative). If such information was withheld overall, this would place those who would wish to know at a disadvantage. Is this fair?

2 What are the new privacy issues?

- 2.1. Do new information technologies and 'big data' science raise privacy issues that are new in kind or in scale? We think yes. Especially with the research opportunities through big computing and data linkage, the more data linked, the higher the risk of identification at the individual level. Privacy, therefore, is threatened. As well as issues of consent and anonymity, the treatment of medical images should be in line with the DPA 1998 and non-regulatory bodies such as Ethics Committees and the technologies must guarantee safe data. However and to date, there is no provision regarding intellectual property rights and medical images, so it is not regulated whether the image belongs to the individual or the data holder¹.

¹ DCC. Sharing medical data. Retrieved from <http://www.dcc.ac.uk/resources/briefing-papers/legal-watch-papers/sharing-medical-data#5>

- 2.2. However, we think it useful to distinguish between social network sites (SNS) and non-SNS data. There is a wealth of SNS research, but we do not understand its social impact. Social media are the best methods to reach/inform the public, and the younger the person, the greater the likelihood (e.g. Internet²). There have been alarming occurrences in SNS (trolling, cyber-bullying, ...), as well as a growing tendency for SNS users to disregard or be unaware of privacy issues on the web. It seems that people feel freer to operate in an antisocial manner under the blanket of anonymity, where the individual can have multiple identities without fear of repercussions. A positive social relatedness can emerge – for example self-help e-communities.
- 2.3. **‘Public interest’** is a slippery concept. The definition below could serve as a useful starting point.

‘Given the political and cultural framework of a particular society and the economic resources at its disposal, the public interest is the aggregate of the fundamental goals that the society seeks to achieve for all of its members – not for a majority of its members or for any large and powerful group, but for all of the people within the society. Considered separately, a society’s goals are often in conflict with one another, and in that case there must be a balancing. The art of [here] government consists of achieving a harmonious rather than a destructive balance among conflicting goals.’³

Against this backdrop, the public interest in BMD is that its usage will [continue to] lead to medical advancements and more favourable patient outcomes. Other benefits are multifaceted (e.g. social, individual, economic, psychological). When might public interest take precedence over individual and minority group interests? According to the above, ‘balancing’ could take the form of identifying a mismatch in expectations of the individual versus the collective, and acting upon this in a policy context. In the case of a minority group versus the majority, then it would be circumspect to identify ways in which the perceived risks to the minority group is minimised.

- 2.4. The perceived risks to minority groups are also difficult to define/identify. Discrimination and/or stigmatisation may affect the individual, but it is based on that person’s membership to a specific social group (e.g. those living with certain illnesses or conditions or visible physical differences, minority ethnic citizens, ...). In such cases, actual harms are sometimes very difficult to

² W Butt S, Clery E, Abeywardana V, Phillips M (National Centre for Social Research). Wellcome Trust Monitor 1. London: Wellcome Trust; 2010. P. 86

³ Ringer, “Authors’ Rights in the Electronic Age: Beyond the Copyright Act of 1976” (1981) 1 *Loyola Entertainment Law Journal* 1. Cited in C Waelde and M McGinley, "Public Domain; Public Interest; Public Funding: focussing on the ‘three Ps’ in scientific research", (2005) 2:1 *SCRIPTed* 71
<<http://www.law.ed.ac.uk/ahrc/script-ed/vol2-1/3ps.asp>>

pinpoint, because discrimination can be overt or covert, explicit or implicit, social or institutional. Further, if an actual harm is ascertained, how are we to know it is a result of discrimination/stigmatisation?

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

- 3.1. Advancements are taking place at a tremendous speed and across all sectors. The sensitivities around these developments are often highlighted, more so in relation to the pharmaceutical industry, but also in relation to public sector developments. But it is worth remembering, in addressing this question, that large multi-national companies such as Google, Facebook and Amazon are engaged in extensive harvesting of big data and using it to further their interests. There is a question as to whether the array of developments is desirable, useful, development-worthy and/or morally/ethically sound, but also, the issues vary with origin. The impact should be to enrich society and the life of the individual, and this is easier to envisage in some cases than others. There are potential conflicts of interest between health care deliverers, research, and the commercial sector and industry. The individual, who should be at the heart of these advancements, is in danger of being overlooked. Here a rigorous information and research governance is needed, as well as a clear divide between patient gain/health care costs and commercialism. The former should take priority, whilst keeping the latter in an economically healthy situation. In this way the opportunities for positive impact could be optimised whilst protecting the rights of the individual.

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

- 4.1. While it is important not to overshadow traditional data collection methods, there are clear benefits of data linkage research, as evidenced by the published literature. However, it should be remembered that data linkage research is still relatively new in terms of being able to measure impact, since it takes time for changes to practice or policy to be implemented. The strengths of data linkage research are in being able to bring together disparate datasets to study multiple health-related aspects; and in conjunction with robust developments in IT, to be able to access these data safely, in larger scale and more economically than via traditional data collection methods.

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

- 5.1. It is government policy across the UK to develop the secondary use of health

data to support policy development and evaluation and research. Information sharing is becoming increasingly important as health care organisations work with a range of partnership organisations. A prime example is the attempt to introduce integrated care in the UK, where medical data and social services data should be merged into a larger set: the patient's record is complete. On a practical level, this can reduce hospital admissions and lower the rates of delayed discharge, as well as ensuring that the community-dwelling patient is not neglected through patchy service delivery and reduce the burden of caring on significant others. The patient is at the heart of the model (patient-centred care), though it is acknowledged that some individuals might not be comfortable with the sharing of their medical and social care records. Public involvement and engagement are important so that all views are heard, and so that the best approaches can be adopted.

- 5.2. **Risk profiling:** Using bowel cancer as an example, a low risk score threshold means that more patients are referred for investigation. But it also means that the great majority of referred patients will not have cancer and will therefore have investigations that are not really necessary. The screening would involve an intimate examination, and being aware of a potential diagnosis can cause distress for the patient and significant others. A high risk score threshold means that fewer patients are referred for investigation. Most of referred patients will not have cancer but fewer will have investigations that are not really necessary. However there is a chance that some patients with cancer may be missed. We recently posed this dilemma to our Consumer Panel for Data Linkage Research, and the majority felt that they would prefer unnecessary screening to a missed diagnosis.
- 5.3. **Moral obligations:** In an ideal world, a citizen would feel that BMD collection, usage and storage is the right thing to do for 'the greater good'. Good citizenry comes with rights and with obligations. We cited an example earlier (organ donation: opting in or opting out), and repeat our views here. Interestingly, evidence suggests that many living with a poor prognosis felt that participating in a study gave some purpose to their illness, and they felt more empowered to have their voices heard.

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

- 6.1. The wider hopes are to see an improvement in the lives of people living in the UK. Drawing on the biosocial model of care, interactions between biomedical and demographic factors (e.g. socio-economic status, living conditions) should provide robust information to inform policy. Concerns could arise in that medical data are shared with social care deliverers, though, as we argue

above, this sharing is for the patient's benefit, even though this was not the original purpose behind the collection. Concerns should arise when data are accessed by those agencies/bodies with material gain as a driving factor, not least because it is no longer necessarily in the patient's interest. Likewise there are strong ethical reasons to ensure that an individual may not profit from the use of their BMD (namely where consent is given, it might be due to financial difficulties).

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

- 7.1. We have an array of legislative and regulatory frameworks in the UK focussed on research conduct and on the use of data. Rather than attempt to list these here, it would be better that a review is commissioned to look at these structures and how they are implemented. This should assess the extent to which they safeguard individual rights and enable the best use of linked data, and what changes, if any, need to be made in the light of advancements in big data usage across all sectors.
- 7.2. However, it is paramount that the opportunities afforded by data access methodologies such as Safe Havens are factored into this. These make anonymously linked data available for research within a secure environment and there are some established examples within the UK. By using multi-faceted governance frameworks that go beyond the prescribed legislative and regulatory requirements for the use of anonymous data, Safe Havens can provide a balance between privacy and data utility. Even so, it is important to be aware of the risks now and in the future, and to work to ensure that use of people's data is in the interest of the individual and society.