Response to consultation questions
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Response on behalf of Public Health Medicine.

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Please note that an extensive submission from the PHGF (public health genomics foundation), a member of the Institute has already been prepared and submitted.

Question 1

Biomedical data covers a range of types of data of unknown and known significance. Some have known meaning now, some may in the future and some will never have any known value. It is a living archive, which if repeat measures are taken, will grow. Unless these data are analysed within their context their value and meaning at the individual and societal level cannot be known. The rush to create Big Data may well provide some insights but will almost certainly also produce highly significant findings of unknown value. Such findings emerge frequently from existing large studies. It is unlikely that individuals consenting for the use of their biomedical data or for accrual of their data over time can have a full understanding of what might be 'done' with their data or to whom it might become available over time. Whether or not this is a problem depends on the relationship between individuals and the state, the relationship between elements of the state such as social provision and the criminal justice system (or in the case of the US any data across the world held by US owned companies considered relevant to state security) their trust in the state, its relationship with the commercial and financial sectors including globalized companies, and the attitudes of society to the ownership and monetarisation of all aspects of our lives.

Question 2

The issue of fully informed consent is tricky as noted above. There was an era of trust between citizens and the state from which medical research benefitted hugely and the population in turn through advances in understanding (e.g. smoking and lung cancer findings). The cost of the bureaucracy associated with research was tiny, the system worked on goodwill. It is arguable that extraordinarily little abuse occurred during those decades. Over the last 30 years this situation has almost completely reversed. From a country in which epidemiological and longitudinal research was second to none in the world we have become mired in procedures and costs. The changes in structures and financing higher education, medical research and the health service have all led to creation of a Parkinson's Law situation. The amount of data that are available on individuals in systems which are either state run, part of the commercial sector or the increasingly combined versions are huge. The privacy issues relate

more to the purposes to which these data will be put and to the potential for spread and disclosure. It seems highly likely that there will be occurrences of disclosure in all sorts of ways – just as error is expected in any measurement so one could estimate the number and ways in which individuals could come to be identified in the public domain, or within the commercial domain. It seems very likely that data will ooze across boundaries within the commercial sector – insurance, marketing. The drive for Big Data and its use within the medical and health service research sector appears to be driven not so much by public health considerations or wellbeing of whole societies, but by the opportunity to enhance business and global markets. The motivation for current developments needs to be examined very carefully.

Question 3

I have addressed this to some extent in previous sections. It is not at all clear that the drives to create vast data banks are being done with population health or sustainability in mind. There is a lack of balance in investment, which appears to follow fashions, rushing from one new technology to the next without taking stock of what is valuable, whether 'innovation' should be pursued cautiously and what the ethical, legal and social implications for the future are for single wealthy countries and the globe. The very language being used 'barriers to development and innovation' suggests a rush to change many things without proper evaluation. Innovation really only works within stable systems but we have at present multiple changes on many fronts. The medical research sector, the commercial sector, the media and the politicians are suggesting major advances through this kind of initiative but the true implications of these initiatives are rarely reflected upon. There is potentially tremendous overinflation of the promises and in the context of a neoliberal style global economy with increasing inequalities and decreasing opportunities for populations around the work, any advances which are made as a result of these biomedical advances are likely to affect the affluent rather than the whole population in which simple, known, public health measures would provide known improvement in health over the lifecourse. Within the initiatives there is an assumption that findings are relevant across time and culture – this is not likely to be the case.

There is a major issue here around the public understanding of numbers based biomedical science (which is pretty poor at the moment). One of the major problems with the commercial use of epidemiological and clinical data/results is that it is all too easy for drug companies, or those with particular vested interests to mislead the public (and doctors) for purely commercial gain, There is an urgent need for numbers based biomedical science to be incorporated into the school science curriculum and to improve societal understanding of numbers and research so that society is in a better position to judge evidence, rather than being presented with interpretation through biased lenses. It is, after all, science of immediate relevance to the way individuals understand their own health and not just the preserve of academics.

Question 4

With the pressure to share data it will be difficult to establish what exactly we should say at the individual level when taking consent. Already the reduction of trust in society has led to reductions in participation in research. Sharing and linking data and biomedical data for the NHS was previously within a socialized health care system that the population understood was not for profit . The increasing fragmentation, use of private companies for much of health care delivery including data management means that much of our biomedical and clinical data already resides within the interface between the commercial and public sectors. The call to release data from trials and transparency is, of course, absolutely key but to assume this should be done for all studies and in the same manner for each seems simplistic. It has been suggested that our models of trials and approval should be completely overhauled.

Question 5

Linked data has always been studied within the public health systems of the NHS (now broken up) in not-for-profit analyses aimed to support immediate and future questions on health and health care. This has been seriously if not completely, undermined over the last decades, just when this particular system could have provided enormous advances. Instead the fragmentation and reduction in access for public health within the NHS has been replaced with multiple privatized or quasi-privatised small and large scale initiatives which are for profit. This is effectively privatizing the data belonging to society. Some of the outcomes are valuable, others are more clearly simply related to survival of private enterprises.
The population expects data to be linked and used for valuable health analyses. It would seem unlikely that citizens would expect their data to be used for profit generation. Where public health interests do combine with commercial ones needs much greater scrutiny and control. There are clearly areas of great sensitivity such as STDs, reproductive and mental health histories, drug, criminal and alcohol histories which could have serious implications for individuals' lives. These data, in safe hands, are of huge importance in understanding individual health and lifecourse trajectories. With an increasingly fragmented service it is not clear how integration of data can be achieved well even for best health care without jeopardizing the individual's ability to control the leakage of their personal data into a wide range of settings. This may not from what has already happened in the private sector in that our banking, insurance and purchasing data are already widely shared without our permission (including a substantial amount of potentially highly sensitive data on health and criminal records). These gleaned data can be misleading e.g. inability to open bank accounts on the basis of credit data taken from a variety of sources which are fragmented and of unknown accuracy. So, although it would seem obvious that few should argue against sharing of their data for personal health care, and for the benefit of the wider community when it is blurred with the commercial angle it is by no means so clear.

Question 6

Responses to the earlier questions cover this. There are major concerns about the use of data outside the biomedical research world and even within it when driven by commercial interests. Structures which have public benefit in mind could play a regulatory or kite marking role. It is obvious that the commercial sector and those with vested interests are prone to advancing 'innovations' before their proven value. One example is the commercial marketing of genetic testing when there has been no systematic statement of the nature of the evidence required when telling individuals what their future risk of disease might be. Even a cursory consideration of this question provides the answer that to understand an individual's lifecourse requires enormous amounts of long term data relevant to that individual at that age in that cultural and time context with any certainty. So it is no surprise that some of these tests are running into problems. Others, including those for cancer risk, are marketed risk when they are manifestly doing harm, despite efforts by scientists without vested interests to make such information clear. The combination of commercial and scientific interests, the media and politicians' desire for simple and emotionally compelling messages could be seen as contrary to public interest but the public will not hear this as the avenues available are limited.

Question 7

Public health as a discipline used to hold the ring for public health in a non partisan manner. This allowed the NHS to function as a whole in the past with one discipline having only one purpose – the best allocation of resource with the current and future populations in mind. The ethical principles informing the governance of biomedical data should, it seems to me, follow the same principle. Health and wellbeing research should hold sway as this is what justifies the work, not business growth. Charities, expert patients, specialists and those who stand to gain commercially should all be able to have a say, but none of these should have the final say – this must be independent (truly independent, e.g. not the House of Lords in which a substantial proportion have vested interests through links to health care businesses). Biomedical data themselves would not be any more distinctive than other clinical data. Current consent is already extremely onerous and makes research difficult, expensive (time taken to consent) and off putting for potential participants. But with the increasing commercialization and medicalization of the population it is unlikely we are conveying the true extent of what data linkage might mean in the future. Reconsenting individuals on a regular basis is not possible unless there is some process built into whatever remains of the health service to do this in a systematic way. Such a system would require considerable resource. Delegation of authority to another requires trust – with instability of systems this would seem difficult to guarantee although it might be one way to proceed. Certainly within individual cohort studies the principal investigators who hold ethical approval take their stewardship of the resource very seriously (often seen as being rather restrictive). Safe havens independent of interference from government, commercial sectors and those with vested interests is well worth exploring.