GeneWatch UK Response to Royal Society's call for evidence on Science as a Public Enterprise

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GeneWatch UK is a not-for-profit organisation which aims to ensure that genetic science and technology is developed and used in the public interest and that people have a say about whether and how genetic technologies are used. We monitor developments in genetic technologies from a public interest, human rights, environmental protection and animal welfare perspective. Much of our work has focused on the social and ethical issues raised by GM crops and animals and human genetic databases.

Comments on terms of reference

Although we agree with the view that scientific data should be open in order to facilitate independent scrutiny of scientific conclusions, GeneWatch disagrees with the study's focus purely on "open data" as if this was the only element of the scientific method and the key to restoring public trust in scientific institutions.

Science involves the formulation and testing of hypotheses with experimental data. Hypotheses are formulated within a context of broader theories. Openness requires sharing of data and methodologies so that results can be replicated. But it also requires freedom to think creatively and define new research questions, theories and hypotheses; to gather data relevant to defining and testing such hypotheses; to analyse and interpret this data; and to publish findings and have them critically examined and replicated by other scientists. Computer models increasingly encapsulate assumptions about how the world behaves (i.e. theory) or are based on statistical associations between variables ('hypothesis free' information science, which actually contains its own embedded assumptions). Predictions from computer models underpin an increasing number of policy decisions (e.g. climate change policy; risk assessments for hazardous or radioactive substances or GMOs; genomic risk assessments sold as "personalized medicine"): the assumptions embedded in these models and the extent to which they have been validated (or not) must also be transparent. Further, truly independent science requires diverse funding streams so that people can devise different research questions and collect different data, that may contradict establish theories.

Failure to address these issues risks a crisis of trust in scientific institutions similar to the loss of trust in banking, politics and journalism. It is worth remembering that underpinning the banking crisis were "black box" computer models which share many similarities with supposedly scientific models of the environment and human health and behaviour. The Royal Society should be careful not to endorse a new view of science as all about feeding data into these black boxes.

There is extensive evidence that public concerns about science are not restricted to openness about data but centre around trust (or lack of trust) in institutions, with particular concerns about conflicts-of-interest (see, for example, the findings of the Science Horizons Project[1]). People are generally supportive of medical research using their personal data but want to know what research is going to be done by whom and to be asked for their consent. [2,3]

It is possible to swamp people with data without ever answering their questions or reassuring them that their concerns have been taken into account. Further, independent analysis of data requires resources: if there is no independence in the funding system there will be little independence in science.

GeneWatch UK does not see data-protection as a "barrier" to scientific research, as implied in the terms of reference: without data- protection and other safeguards, including a requirement for informed consent, most people will not hand over personal data to researchers. Trust can also be lost after data has been collected and analysed if adequate processes and safeguards are not in place.

GeneWatch is also concerned about potential conflicts-of-interest in the framing of the Royal Society's inquiry, which has a number of well-known advocates of "data-sharing" of personal medical data linked to DNA on its panel, who are also enthusiasts for "opt-out" or "broad" forms of consent. We therefore ask the Royal Society to bear in mind that there have been many spectacular failures of the Wellcome Trust's enthusiasm for "data-sharing" (discussed further below) and the key lesson is not to find a new way to trick the public into believing that using their DNA and medical data without their knowledge or consent is all about "Open Science" but to actually rethink whether this is a good idea at all.

What ethical and legal principles should govern access to research results and data? How can ethics and law assist in simultaneously protecting and promoting both public and private interests?

Honesty, integrity and responsibility are rarely mentioned. Perhaps they should be in a world where Oxford Capital Partners offers investors a variety of tax benefits including 20% income tax relief (on investments up to £500,000); tax-free profits and exemption from inheritance tax (after two years) and former science minister Lord Drayson is reported to have saved £1 million in tax by setting up a charity to manage his biotech investments.[4]

Conflicts-of-interest have become deeply entrenched in the research system via the system of patenting and R&D tax credits introduced under the two 'biotech barons' Lords Sainsbury and Lord Drayson. Their "support" for science (actually support for rich investors speculating on a bubble market), combined with large donations to New Labour, has created a system which sees defending its own interests as more important than any ethical principles or the scientific method.

The creation of a speculative market based on selling the *promise* of technologies (rather than technologies themselves) means that value for investors can be generated even in the absence of any useful products (provided they buy and sell at the right time).[5] Senior managers (often including the scientists named as inventors on the patents) can also draw large salaries, even though most biotech spin out companies never deliver on their promises.

Creating a more honest system, in which R&D investments can be made more wisely, requires ending the "cycle of hype" about biotechnology and using more honest language to describe what has been achieved and what might be delivered. [6,7,8,9,10,11]

For example, the whole of human genetics still rests on the equations used by the eugenicist Ronald Fisher to calculate the heritability of complex traits.[12] These equations give (at best) an upper limit to the genetic component of the variance.[13] Thus the entire enterprise is based on hunting for genes that may not exist (to explain the 'missing heritability'[14]) and which will have low predictive value and limited clinical utility even if they do exist.

A long string of vested interests (beginning with the tobacco industry in the 1950s[15,16]) have promoted the idea that individuals are born genetically predisposed to develop common (not just rare genetic) diseases and that these predispositions, once discovered, will be treatable. The dual purpose was to shift scientific and public attention from *external* to *internal* causes (thus protecting the markets of e.g. the tobacco, nuclear and food industries) and to expand the market for drugs and other health products (sold to healthy people to treat the genetic predispositions presumed to be inside them).[17, 18]

The idea that collecting more and more data (genetic, epigenetic, electronic medical records) will allow biology to morph into a predictive science by feeding all the numbers into computers has recently been critiqued in Adam Curtis' BBC series All Watched Over by Loving Machines of Grace. It is no coincidence that the gene testing company 23andMe (the current market leader, funded by Google) is based in California, where such ideas are now rooted deeply in the culture. From a scientific point of view this (and the idea of 'hypothesis free science' which underpins it) is of course a nonsense because the data could theoretically be combined in an infinite number of ways, there is no way for the predictions to be validated, and complex systems are not deterministic but have limited predictability. When applied to human behaviours, Fisher's equations assume that free will does not exist, and neither do social interactions: assumptions that are in fundamental conflict with most people's everyday experience.

What might be the benefits of more widespread sharing of data?

Sharing of data is important when it allows independent scrutiny of scientific assumptions and findings. GeneWatch strongly supports the view that health and environmental risk assessments should be published and transparent and that the data that underpins them should be publicly available: a standard that is rarely if ever met in practice due to commercial confidentiality. However, sharing of data in itself is insufficient to avoid entrapment in particular research agendas based on false assumptions or to achieve more open and transparent risk assessments and policy decisions. This also depends on what data is collected in the first place, what values and assumptions are involved in making the decision, how data is analysed, and whether there is a thriving scientific culture and sufficiently diverse funding streams to allow questioning and testing of underlying assumptions and theories. Simply collecting and sharing more data will not restore public trust in scientific institutions or stimulate better decisions or better innovation processes.

Collection of vast quantities of data (e.g. genomic data) is also expensive and requires energy for data storage (and hence has its own implications for climate change). If taxpayers' money is to be spent in this way, or if people are expected to donate their data, such decisions should be transparent and accountable and weighed up against alternative priorities. It is worth noting that the independent response to the House of Lords Science and Technology Committee's report on Genomic Medicine criticised the

report for overestimating the immediate importance of genomics to the prediction and prevention of common diseases, and largely ignoring the synergies and opportunities to advance genomic science in the context of the improved diagnosis and treatment of inherited single gene disorders and inherited subsets of complex diseases.[19] This is a widely held view in the medical profession, which, if taken into account, would lead to very different research priorities. Similarly, tackling health inequalities would have a much greater impact on the incidence of common diseases (which current evidence suggests is unlikely to be reduced at all through genetic screening) and would save taxpayers' money, rather than generating additional expense. [20]

How should concerns about privacy, security and intellectual property be balanced against the proposed benefits of openness?

People will not trust scientists with their personal data if this is not kept secure or if they are misled about the purposes and value of the research. Any push for commercial data-mining of medical records without consent in the name of "research" is likely to be treated with considerable skepticism and to generate a public backlash against legitimate research. Enthusiasts for the idea that it is inevitable that everyone will one day have their DNA sequenced and stored in their medical records continue to claim that this will transform medicine and save lives. This is rubbish and people frankly will not fall for it: this is why DeCode has gone bankrupt and 23andMe has failed to find a viable business model to sell its genetic tests and is dependent on continued subsidy from its founder and her husband (Google founder Sergei Brin). Moreover, even enthusiasts for this approach admit that privacy would no longer exist if this idea is ever implemented.[21] Most members of the public are therefore likely to continue to view this vision of the future with considerable alarm.

This of course does not mean that all genetic research or genetic testing is useless.[22] However, there is ample evidence screening the entire genomes of whole populations will not enable the 'prediction and prevention' of disease, because genes are poor predictors of most diseases in most people. [23,24,25] In addition, a case for routine genetic testing before drug administration can be made only for a very few drugs.[26, 27,28,29]

Encouraged by funders such as the US National Institutes of Health (NIH) and the Wellcome Trust, there have been a series of controversial proposals to sequence "spare" DNA (from babies' blood spots or from other samples taken during healthcare later in life) and integrate genomic data with health data stored in electronic medical records.[30] In the UK, this idea was first proposed by Sir George Poste in 1999 and endorsed by the House of Lords Science and Technology Committee: their disastrous proposal to try to emulate DeCode's biobank in Iceland in the NHS led to a £12 billion plus commitment to building a central database of electronic medical records in the NHS (the Spine)[31]: now widely recognised to have been one of the major financial disasters of the Blair/Brown government.[32] (DeCode itself was declared bankrupt in 2009[33]). Proposals to sequence the DNA of every baby at birth (in the NHS Genetics White Paper in 2003) then had to be abandoned following widespread criticism. Subsequently, data-sharing proposals made by Wellcome Trust Director Mark Walport at Gordon Brown's request in 2008 and hidden in Clause 152 of the Coroners and Justice Bill in January 2009 caused a public outcry and were dropped within weeks of the Bill being introduced in parliament.[34] New proposals to access DNA without consent in the NHS were made by Professor Sir John Burn on behalf of the Human Genome Strategy Group earlier this year.[35] GeneWatch UK is opposed to these proposals.

Although presented to the public as being about allowing access to 'researchers', such proposals neglect to mention that companies such as Google and GE Healthcare (which want to data-mine medical records and DNA samples) now count themselves as researchers and have discussed access to NHS samples with the Department of Health. In addition, these proposals are predicated on two false assumptions:

1. That it is a shortage of DNA and genomic data and lack of "data sharing" (rather than bad theory and a bedrock of misleading claims) that is responsible for the failure of the "genomic revolution" in healthcare;

2. That people have no right to be involved in discussing or influencing what science is done (even if they are taking part in it) but must accept false claims from supposed experts as if they bore some relation to reality.

Paradoxically, this attitude is dependent on people not asking too many questions about the science, or who is funding it, or why. For example, Professor Sir John Burn does not mention in his proposal to get rid of "opt in" consent that he wishes to continue to use data collected from babies in West Cumbria without the consent of the children as they grow up, or that this biobank (the first in Europe) was funded by British Nuclear Fuels, with a view to convincing parents that risk factors for leukaemia were in their babies' genes and not in their environment.[36]

What should be expected and/or required of scientists (in companies, universities or elsewhere), research funders, regulators, scientific publishers, research institutions, international organisations and other bodies?

A lot is required of scientific institutions if the Royal Society is to achieve its stated aim of restoring science as a public enterprise. The transformation of the research funding system which began in 1980s in order to promote the "biotech economy" needs fundamental revision to make decisions more transparent and accountable.[37]

Many existing scientific institutions (including the Royal Society itself) are deeply implicated in promoting the existing system and have defended entrenched commitments to investment in particular approaches to science or to particular technologies, without any public consultation or debate. A commitment to truly open science would indeed be welcome and could provide an important step towards genuinely restoring public trust in science. However, this would require openness about model assumptions, not just data, and greater democratic accountability for research priorities.

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