Ethical issues in bio-marker research

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Biomarkers in Neuromuscular Disorders (NMDs)

Rapidly expanding knowledge of NMDs has provided new targets for disease characterisation, early diagnosis and drug development whilst presenting many challenges about how to translate this knowledge into clinical practice.

Omic sciences are used to identify non-invasive biomarkers which offer an invaluable tool for monitoring disease progression, prognosis and response to drug treatment during clinical trials. Biomarkers represent excellent substitutes for clinical endpoints because they can predict a clinical benefit more quickly than other measures and in a less invasive way than muscle biopsies.

Ethical issues

The development of new, sensitive and reliable bio-markers requires the utilisation of human tissue for research purposes and although such uses may be regarded as long established and routine, there have been a number of incidents which have brought such practices under scrutiny.

The case of Moore against the University of California raised the question of whether the body and its parts could be regarded as property and thus entitle donors to share in any financial benefit. In the UK, the scandal of Bristol/Alder Hey exposed the culture within medicine of presuming a right to procure and utilise human tissues without consent and the more recent controversy over the Myriad Company’s claimed monopoly on the tests for BRCA1/2 has caused bitter resentment amongst patient groups, clinicians and researchers.

Discussion

Ethical concerns associated with autonomy, include consent and withdrawal from research, as well as issues of confidentiality. Such issues are particularly complex in genetic research. Within the BIO-NMD project it was recognised that it was important to ensure patients understood how their samples were going to be used and made available (or not) for wider research.

Governance and Stewardship

Studies that involve scrutiny of DNA are likely to encounter unintended consequences by discovering anomalies within their ‘findings’. There is some consensus that incidental findings (IFs) of clinical significance impose a duty on the researcher to disclose such findings, although the debate is on-going. Studies must have an appropriate plan for whether and how to reveal IFs to the tissue donors or their physicians. BIO-NMD adopted a flexible approach to this as there is as yet no international consensus on which ethical approach to use.

Benefit sharing

Any research may provide an opportunity for profit and there has been wide debate as to whether profiting from research which involves patients’ tissues and their wider collaboration is itself ethical.

The approach taken in the BIO-NMD project is one that fits with a more altruistic conception of benefit sharing. On this model patient involvement in research, including use of tissue is regarded as a donation freely given over to good governance and the stewardship of the researchers, on the principle that benefit in kind will be available to the patient and the disease community.

Future Challenges

As genetic research becomes ever more sophisticated with the pooling and sharing of data and tissue the ethics, governance, and regulation of research must keep pace. Keeping an open dialogue between researchers and patients that is based upon transparency and trust will make an important contribution to the process of change.

Reading


Moore V - Regents of the University of California, 51 Cal. 3d 120, 271 Cal. Rptr. 146, 793 P.3d 479, cert. denied 499 U.S. 936 (1991)