

Ethics and genomics research: the Procardis ethics programme

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The Procardis consortium: cardiovascular genetics

Procardis is a consortium of scientists from various European countries who are conducting research into the genetic basis of coronary artery disease.

The research aims to improve our understanding of the underlying biological mechanisms behind coronary artery disease with the eventual aim of producing better treatment.

Procardis scientists have recruited several thousand cases of patients who have suffered from myocardial infarction (heart attack) together with health controls (people who have not suffered a heart attack).

Information about each person's health was collected, together with a sample of blood. Blood samples were tested for various traits and DNA was extracted.

Genome-wide association (GWA) scans have been performed on the DNA to discover points of genetic difference between cases and controls with the aim of finding differences which might hold clues to explain why some people suffer from coronary artery disease and not others.

More information about Procardis can be found at www.procardis.org

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Cardiovascular disease and genetics

- Cardiovascular disease includes conditions such as heart attack and angina; it is a common complex disorder, meaning that it is caused by a mixture of factors, including:
 - genetic inheritance;
 - factors such as diet, smoking and exercise;
 - early life factors such as conditions in the womb;
 - and other factors such as social and environmental conditions.
- The prevalence of cardiovascular diseases has increased in developed nations since industrialisation and in many developing nations it is rapidly becoming more common, representing a major health burden.
- Genetic factors can only account for some of the reasons but research into genetics may lead to a better understanding of who is most at risk, of the underlying biology, of different forms of cardiovascular disease, and of ways of preventing and treating disease.

Genetics research & ethics: why?

- Historically, ethical issues in medical research received a great deal of attention following revelations of horrendous abuses by Nazis in experimenting on prisoners, often resulting in their deaths.
- There are other well-known examples of medical research that have helped to shape current laws and regulations
- The Nuremberg Code (1947) was drawn up to protect the subjects of clinical research

<http://www.cirp.org/library/ethics/nuremberg/>

- The World Medical Association Ethical Principles for Medical Research Involving Human Subjects (1964, updated 2008) (The Declaration of Helsinki) builds on this

<http://www.wma.net/en/30publications/10policies/b3/index.html>

- Ethics committees oversee the conduct of research

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Genetics has also received a great deal of ethical scrutiny

- This is also partly for historical reasons, such as policies of enforced sterilisation of certain members of the population deemed not fit to reproduce
- These practices occurred in various countries in the first half of the 20th century including the USA, Sweden, and Germany
- Nazi ideology that certain peoples were racially 'superior' and others racially 'inferior' has also led to concerns that knowledge of genetics might be abused
- The development of techniques to manipulate reproduction and to introduce genetic selection have also raised concerns
- Will focus on genetics divert attention away from other issues such as social and economic inequalities?

Meet 'ELSI'

- 'Ethical, legal and social implications'
- In the US, a portion of the budget for research into genetics was reserved for ELSI work following the suggestion by James Watson, one of the co-discoverers of the structure of DNA, that close attention be given to ethical issues
- ELSI work is typically undertaken by interdisciplinary groups of lawyers, philosophers, ethicists, and social scientists working in conjunction with research scientists, clinicians and policy makers

But does genetics really need all this attention?

- ‘Genetic exceptionalism’ is the idea that genetics is special in some way
- Some have argued that the particular power of genetic information and its importance for notions of individual identity mean that it deserves particular attention
- Others are much more sceptical of such claims

We've got codes of research regulation:

- So why are we still looking at these issues?
- The broad answer is that developments in genomics science and technology are presenting us with new angles on ethical issues and challenging current models of the ethical and legal regulation of research

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Different kinds of research in genetics

- Research involving genetic modification, such as genetic engineering, to find cures for diseases
- Research on embryos and stem cells
- Research in genomics looks at underlying patterns of variation in DNA especially those that may help explain disease

Research regulation:

- Research ethics regulations were drawn up to protect individual subjects from abuses in clinical research
- The emphasis was on protecting individuals from harm such as from the administration of new drugs
- An individual must give informed consent to research
- And researchers undertake to protect the privacy of medical information
- Deciding not to take part in research will have no impact on the quality of any medical treatment needed
- Research participants can withdraw at any time

Research in genomics:

- Much genomics research does not involve interventions – trying new treatments – but collecting information, and a blood sample, hence differs from most clinical research which does involve intervention
- Typical risks of research do not relate to risk of physical harms but to the information generated
- Concerns include the protection of genetic information and its possible misuses
- Genetic information does not concern only the individual, but may have great relevance to related individuals and to communities and population groups
- There are concerns expressed about how well informed consent can be to complex and swiftly evolving research
- Withdrawal of samples and data may be problematic

Research in genomics

- Much genomics research involves collaboration with other research groups
- There is often a need for very large sample sizes involving thousands of recruits
- Much of this collaboration is international in nature, involves sharing expertise, samples and data, and may involve groups from different populations
- It can be difficult to predict the future direction of research

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