Pharmacogenetics: ethical issues

CONSULTATION PAPER

NUFFIELD COUNCIL ON BIOETHICS

Deadline for responses: 19 February 2003
Nuffield Council on Bioethics

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The terms of reference of the Council are:

1. to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern;
2. to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body;
3. in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

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Members of the Working Party on Pharmacogenetics: ethical issues

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Terms of reference of the Working Party on Pharmacogenetics: ethical issues

1. To explore what pharmacogenetics offers now and is likely to offer in the near future;
   In particular to examine the effect of pharmacogenetics on:
   a) the design of medicines, the promotion of efficacy and safety in the administration of medicines to individuals;
   b) the conduct of trials in the context of pharmaceutical research and development;
   c) clinical practice.

2. To consider ethical issues specifically raised by pharmacogenetics;
   In particular to examine the following areas:
   a) consent, privacy and confidentiality;
   b) the management of information about the likelihood of response to treatment;
   c) the implications of differentiating individuals into groups based on the likelihood of response to treatment.

3. To consider the implications for the provision of healthcare.
1 Introduction

The Nuffield Council on Bioethics has established a Working Party to consider ethical, legal and social issues raised by the development of pharmacogenetics. A Report will be published in 2003.

We would welcome your comments on these issues in the context of the possible applications of pharmacogenetics. This consultation paper discusses some of the issues raised by pharmacogenetics and poses a number of questions. We would appreciate it if you were able to frame your response around these questions. Please also tell us if we have omitted other important issues. Your response will be circulated to the members of the Working Party to inform their deliberations.

The structure of the consultation paper is as follows. Section 2 explains what pharmacogenetics is and identifies some of the issues it may raise. Section 3 describes the applications of pharmacogenetics in the context of the development of new medicines and of the use of existing treatments, and includes three case studies. Section 4 discusses the economic and regulatory implications of pharmacogenetics, and Section 5 highlights various ethical and social issues to which it may give rise.

Useful definitions

Pharmacogenetics

The study of how genetic variation between individuals affects their response to medicines. The term ‘pharmacogenetics’ reflects the merging of pharmacology, which is the study of how medicines work in the body, and genetics, which is the study of how characteristics are inherited.

Adverse reaction

A negative and unintended response to a medicine given in its normal dose. Adverse reactions range in seriousness from headaches and nausea to life-threatening complications and sometimes death.
2 Background

People often vary in their response to the same medicine. Some medicines are not effective for everyone; others may cause some patients to suffer adverse side-effects or even death. Although most severe adverse reactions are due to errors in prescription, allergies, or interactions between several medicines, different responses may be partly due to our different genetic make-up. Pharmacogenetics aims to improve the efficacy and also the safety of prescribed medicines.

The relevance of pharmacogenetics for the development and administration of medicines was identified in the 1950s. Just as variability between humans in obvious features such as the colour of eyes or skin is largely determined by genetic factors, genetic variation may account for some of the variation in the responses of individuals to medicines. The possibility of using genetic analysis to predict response to medicines has led some to make the optimistic claim that personalised medicine, or ‘the right medicine, for the right patient, at the right dose’ will only be a matter of time.

Personalised prescriptions may be theoretically feasible, but the practical application of such an approach may face significant constraints. For example, from an economic perspective, the pharmaceutical industry may find it unprofitable to make the investment required to develop a range of new medicines for specific sub-groups of a population that have previously been treated with only one medicine. The development and testing of such medicines may have implications for costs for the pharmaceutical industry and for regulators. Ethical concerns may arise if pharmaceutical companies undertake the development of medicines for particular groups of the population, but not for others. Consideration will also need to be given to whether pharmacogenetics will offer similar benefits to patients in developing countries as it might for patients in developed countries.

The application of pharmacogenetics might require the use and storage of genetic information derived from large groups of patients. This information is likely to be shared by general practitioners (GPs), pharmacists and other providers of healthcare. The management of genetic information has already been the subject of much discussion, both in relation to the establishment of databases comprising the genetic information of large numbers of individuals, and in the case of genetic testing for relatively rare genetic diseases, such as cystic fibrosis. An important question is whether these discussions can be applied in the case of pharmacogenetic testing.

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1 See for example Genetic Screening (Nuffield Council on Bioethics, 1993) and Inside Information (Human Genetics Commission, 2002).
3 Applications of pharmacogenetics

Researchers in pharmacogenetics study genetic variation between individuals. This section explains why genetic variation is relevant to the development of medicines and the treatment of individuals, and how findings in pharmacogenetics could affect research and treatment.

Research and development of new medicines

The development of a new medicine takes an average of 10-15 years. The process involves many thousands of participants in clinical trials. Currently, only one out of every 5,000 chemical compounds that have initially been considered as having the potential to provide the basis for effective and safe medicines is successfully developed for clinical use. The total cost of developing a new medicine has been estimated to be as much as US$800 million. The application of pharmacogenetics to the process of the development and discovery of new medicines may lead to the following improvements:

- Protecting participants. One of the major problems in the development of new medicines is that participants in clinical trials may include individuals who are, in fact, unsuitable recipients of the medicine being tested. The application of pharmacogenetic analysis could identify those individuals who, because of identifiable genetic factors, are less likely to respond or who are at risk of adverse reactions. These individuals could then be protected by excluding them from the research.

- Making research more efficient. Pharmacogenetics could make research more robust, as a homogeneous group of participants could be expected to reduce the variation in clinical response. Fewer participants may be needed, which could result in reduced costs and quicker completion of processes required to bring a medicine to market.

- Refining the development of new medicines. Medicines that are effective in some participants in clinical trials are sometimes not developed further because the evidence of such benefits is concealed by insufficient efficacy or adverse events in other participants. The application of pharmacogenetics may allow the continued development of these medicines for a specific, though possibly small, sub-group of the patients for whom the medicine was originally intended.

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2 For further explanation of the scientific basis of pharmacogenetics see http://www.nigms.nih.gov/news/science_ed/genepop/ (1 Nov 2002). Other educational resources can be found at http://pharmgkb.org/do/serve?id=resources.education (1 Nov 2002).

3 The Tufts Center for the Study of Drug Development has estimated the cost of developing a new prescription medicine at $802 million. http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid= 4 (31 October 2002). However, the US national consumer group Public Citizen has suggested that the true costs are significantly lower (see New study expected to significantly overstate drug industry R&D costs. Citizen.org. 28 Nov 2001. http://www.citizen.org/pressroom/release.cfm?ID= 942 (31 October 2002)).
**Treatment**

As well as improving the development of new medicines, pharmacogenetics could also enhance the safety and efficacy of the prescription of new and existing medicines:

- Reducing adverse reactions. Diagnostic tests that reveal genetic variants already known to be associated with adverse reactions may allow physicians to avoid prescription of medicines that would put a patient at risk.

- Improving efficacy. Test results may also inform physicians in their choice of the most beneficial medicine, or the optimum dose, for a particular patient. This may spare the patient from trying out several medicines through trial and error.

- Refining prescribing practices. Pharmacogenetics may be of use in the monitoring of medicines which have already been marketed. Regulatory agencies sometimes withdraw from sale medicines that have gained approval, because of adverse reactions suffered by a small percentage of patients. In such cases, large numbers of patients may be deprived of a treatment that is effective for them. Pharmacogenetics may provide a means of defining the appropriate patient group for a particular medicine.

At present, two different kinds of genetic tests are undertaken to identify genetic variation that influences the response of an individual to a medicine. Both approaches can be understood as pharmacogenetic tests, but they raise different ethical questions and it is important to distinguish between them:

**Tests for genetic variation in ‘normal’, unaltered cells of the body of a patient**

In these cases genetic information derived from normal cells of the body is analysed. This information could, in principle, also be used to determine susceptibility to disease.

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**Case study 1: CYP2D6**

Enzymes play an important role in the way a medicine can be absorbed by the body. Our genes determine which kind of enzymes our body can produce. If researchers analyse our genes, they may be able to predict how well an individual will absorb a particular medicine. A large number of medicines is metabolised by an enzyme called CYP2D6. This includes medicines for the treatment of psychiatric disorders, as well as more common illnesses, for example, high blood pressure. 7% of the Caucasian population have a genetic variant that results in markedly reduced activity of the CYP2D6 enzyme. As a result, they have a reduced capacity to eliminate the main ingredient of approximately 50 medicines in current clinical use, and are thus at increased risk of experiencing adverse reactions. Genetic testing before prescription or enrolment for participation in clinical research could help to prevent adverse reactions in these patients.
Case study 2: Abacavir

Abacavir is medicine for HIV/AIDS that can cause serious adverse reactions and even death in about 5% of patients. The pharmaceutical company GlaxoSmithKline has conducted studies to identify individuals who are at increased risk for serious adverse reactions. Initial findings suggest that patients with a specific pattern of genetic variation are more likely to have an adverse reaction to this medicine. The same pattern was found in very few of those patients who were considered tolerant of the medicine.

Tests for genetic variation in altered cells of a body of a patient

The analysis focuses on variation in genetic information that is derived from cells in the body that have mutated, such as cancer cells. This type of test informs the researcher about the precise way in which the cell is altered and could in principle determine the likelihood that the altered cell will respond to treatment.

Case study 3: Herceptin

Herceptin is a medicine for the treatment of breast cancer. It is particularly effective in a sub-group of patients whose tumours produce particularly high levels of a protein called HER2. Genetic testing of tumour tissue from women with breast cancer can identify the patients who produce abnormally high levels of HER2 and are likely to benefit from Herceptin. Up to 30% of patients with breast cancer fall into this category. In conventional therapy, these patients have a higher probability of spread of the cancer, resistance to treatment, and a shorter life expectancy (three versus an average of seven years). When treated with Herceptin, these patients stay free from cancer for 65% longer than those treated with chemotherapy only.

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4 Economic and regulatory implications

The development and regulation of medicines

The case studies appear to support the thesis that it is only a matter of time before many individuals will benefit from personalised prescriptions. Pharmacogenetics may enable existing medicines to be used more effectively, and enhance the development of new medicines. A move towards a broad range of personalised medicines with the corresponding improved efficacy and safety would appear desirable from the perspective of patients. The development of almost all new medicines is undertaken by the commercial pharmaceutical industry, and hence is subject to economic considerations. From the perspective of the pharmaceutical industry, an increasingly broad range of specialised medicines may lead to smaller market segments with correspondingly reduced revenues. The economic impact of pharmacogenetics is difficult to predict, but it has often been suggested that the pharmaceutical industry will be unlikely to develop medicines for very small groups of patients, precisely because of the balance of economic costs and benefits involved.

Medicines that treat rare diseases are sometimes called ‘orphan medicines’, because they are unlikely to generate sufficient economic revenue to the pharmaceutical industry to be developed. Whether or not a medicine counts as an orphan medicine depends primarily on how many individuals would benefit from it. In Europe and in the USA, the status ‘orphan medicine’ and associated legal and financial incentives are granted if there are fewer than 200,000 potential patients. The research and development of such medicines may be promoted by providing such incentives through specific regulation. Existing examples of such regulation include the 1982 US Orphan Drug Act, and its European counterpart, the Regulation on Orphan Medicinal Products, established in 2000.

However, although there are only approximately 55,000 patients in the US who would be eligible for Herceptin, the medicine was not granted the status of an orphan medicine. The Office of Orphan Products Development (OOPD) in the US defines the patient population for a medicine as the total population with the clinical symptoms, not just those whom the pharmaceutical company identifies as eligible. In fact, medicines are frequently denied the status of an orphan medicine on the basis of disagreement over the definition of the target population. Herceptin has become a profitable medicine even without the status of an orphan medicine, but it is unclear whether this will be the case for medicines that have a much smaller patient population.

Q1 What do you think will be the likely economic impact of pharmacogenetics on the development of new medicines?

Q2 Do you think that further regulatory measures will be needed to encourage the development of clinically desirable but economically unprofitable medicines?
The provision of tests and medicines

Currently, existing regulatory agencies assess the safety, efficacy and quality of new medicines. Subsequent decisions about making medicines available to providers of healthcare and finally to patients are the remit of other bodies. To date, no regulatory authority has specifically addressed the management of pharmacogenetic tests in research, development, and licensing of medicines. If pharmacogenetic tests are technically feasible, it would need to be considered to whom the obligation should fall to provide the test both during research and in clinical practice. As regards clinical practice, GPs, pharmacists and patients themselves will all be implicated, as tests could become available both through healthcare professionals and over the counter, or on the internet. Despite the claims about individualised medicine, it should be remembered that pharmacogenetic tests are unlikely to indicate that a particular medicine will definitely be effective or ineffective in a particular patient. Rather, they are likely to provide probabilistic information, for example, that drug A is 60% likely to be effective while for drug B the estimate is 70%.

Q3 In your view, should pharmacogenetic testing of participants in trials be a regulatory requirement for the development of medicines in the future?

Q4 Who should be responsible for providing a pharmacogenetic test? For individual therapy, should tests be available directly to patients over the counter or on the internet, or should they only be available through medical practitioners as part of a decision about the use of a prescribed medicine?

Q5 What will be the implications of pharmacogenetics for pharmaceutical companies and providers of healthcare regarding legal liability for adverse reactions?

Q6 Should medicines which have been developed for administration in conjunction with a pharmacogenetic test be distributed to countries in which testing facilities are not available?

The application of pharmacogenetics may pose considerable challenges to the providers and funders of healthcare. Cost-effectiveness is increasingly important when considering new treatments and therapies in the face of a limited budget. In the UK, the National Institute of Clinical Excellence (NICE) is responsible for recommending interventions which should be funded through the National Health Service (NHS). Pharmacogenetics could help to reduce costs in the provision of medicines by enabling more efficient treatment, allowing prescription only for those patients who are likely to be responsive to a particular treatment. Alternatively, it may be that pharmacogenetics increases costs because of the additional administrative burden.

The possibility of more personalised prescriptions may however also lead to tensions as patients may have higher expectations for the best possible
treatment. Conflict could arise when genetic tests are used as the basis of a medical practitioner’s decision as to whether a patient qualifies for a particular treatment. As we have already noted, in many cases, the result of a genetic test will not reveal a status of either 'responder' or 'non-responder' to a particular medicine. Rather, tests will reveal the likelihood of responding to treatment. Should a patient who only has a 30% likelihood of responding to a particular treatment receive it through the public healthcare system? What about a 50% likelihood? At present it is unclear how public and private providers of healthcare will react to the expectations of patients.

| Q7 | How should predictions of efficacy and safety, as well as cost, be integrated in deciding whether to provide a particular treatment to patients in (a) a public healthcare system, and (b) a private healthcare system? |
| Q8 | Do you think the application of pharmacogenetics might exacerbate inequalities in the provision of healthcare? Is it likely to challenge the principle of solidarity that lies at the basis of the provision of national healthcare in the UK? Will the benefits of pharmacogenetics only be affordable or available to the wealthy? |
5 Social and ethical issues

The use and storage of genetic information

Confidentiality, consent and feedback in clinical trials

Pharmaceutical companies and other researchers often collect and store genetic samples from participants in clinical research. Companies may store such information in order to replicate or dispute findings that other researchers might present at a later date. Sometimes these samples may also be used for further testing.

The European Agency for the Evaluation of Medicinal Products (EMEA) has recently presented a system for the classification of samples used in pharmacogenetic research. It differentiates between five types of samples according to different degrees of linkage between genetic and personal information (‘identified’, ‘coded’, ‘double coded’, ‘anonymised’ and ‘anonymous’ samples). In the case of anonymous samples, it is said to be impossible to link the sample back to an individual, which would provide complete protection of the privacy of a trial participant. However, it would also mean that participants could not find out anything about the results of tests on their sample.

Countries vary in their regulations on the protection of personal data. In some countries, such as France, regulations allow patients access to all medical information, including genetic information, and require that participants in research receive individual feedback. Thus, samples cannot be anonymised in the course of research. Some pharmaceutical companies have a policy of not giving individual feedback about genetic information obtained in the course of research because, in the early stages of research, it may not be possible to provide clinically relevant or useful information to an individual. Such companies, therefore, do not conduct research in countries where individual feedback is required and anonymous samples are not permitted.

In the UK, there is currently no requirement to provide individual feedback about genetic information. Different research projects may have different approaches. Many pharmaceutical companies have a policy of not providing individual feedback, while other researchers, such as those in the public sector, may arrange genetic counselling for participants to discuss their results. Ethics committees which review research often have to consider whether individual feedback is appropriate, and if so, how this process should be handled.

Q9 In your view, is the storage of genetic information for the purpose of pharmacogenetic analysis categorically distinct from storage of other kinds of genetic information, for example information about susceptibility to disease?
Q10 What level of anonymity should be accorded to genetic information stored as part of research in pharmacogenetics?

Q11 What kinds of consent should be required for the collection of samples for research in pharmacogenetics? Should pharmaceutical companies which collect samples in the course of research in pharmacogenetics be able to use such samples for any purpose, or should consent of the donor be restricted to allow usage only for specific kinds of research?

Q12 Do you think that researchers should provide individual feedback about genetic information obtained from participants in research in pharmacogenetics?

CONFIDENTIALITY, CONSENT AND DECISION-MAKING IN PRIMARY CARE

Storage of genetic information

In the context of clinical practice, it may be that genetic samples taken specifically for a pharmacogenetic test are subsequently destroyed. Another option would be to store samples or genetic information for future use. This may raise issues, as the information could in principle be used for other purposes, depending on how comprehensively the sample was analysed. In this respect it has been argued that ‘[t]he risks of pharmacogenetic testing are a function of the information that is obtained and the way it could be used’.7

Q13 What, in your view, would be appropriate methods of regulating scope, storage and access with respect to pharmacogenetic information used in clinical practice?

THE IMPACT OF TESTING ON INDIVIDUALS

Expanding the use of genetic information could have an effect on the relationship between doctors and patients. One concern could be that pharmacogenetics may be perceived as a step towards increasing acceptability of other forms of genetic testing. As many enzymes are involved in the absorption of more than one medicine, a test result may inform a patient about his or her likelihood of response not only to one, but to a range of medicines. This could have relevant implications where some patients may come to be classified as 'non-responders' or 'difficult to treat'. These labels may have a negative effect on an individual's perception of themselves.

In addition, the individual may find it more difficult to find affordable health insurance as a consequence of a pharmacogenetic test. From the point of

view of the insurance industry, individuals may have to pay higher premiums because of their potentially poor response to treatment, regardless of whether or not they develop the disease for which the treatment would be used.

Another possibility is that pharmacogenetic information may prove, at a later date, to have implications for other aspects of an individual’s health, such as susceptibility to disease. Thus, it may be, that having agreed to a test for the purposes of receiving the most appropriate medicine for a particular condition, the individual is also exposed to information about his or her genetic make-up that could have wider consequences.

The impact of testing on family members

There are also implications for the relatives of individuals who take pharmacogenetic tests. It may be possible to make some predictions about the response of family members to particular medicines on the basis of information about one individual in that family. It may be difficult for an individual to keep the results of a test secret, for example, if the result of a test is that the individual should not be prescribed any medicine for the condition because of likely adverse reactions to all the available treatments. Information about the likelihood of adverse events to a medicine may be important to other family members, particularly if it transpires that one genetic variant has an effect on more than one medicine.

The implications for providers of healthcare

If patients are concerned about having a pharmacogenetic test, difficulties may arise for providers of healthcare. Will patients be able to refuse a pharmacogenetic test if one is available and relevant to their treatment? Will doctors be willing to prescribe medicines for which such tests exist if the patient has not been tested? What might be the legal implications of prescribing such medicines without having first performed the relevant test?

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<tr>
<th>Q14</th>
<th>Do you think that the ethical and legal issues raised by the use of pharmacogenetic tests in primary care differ from those raised by other forms of genetic testing? What about non-genetic tests, such as tests for cholesterol?</th>
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Q19 Do you think that the providers of health insurance should have access to pharmacogenetic information? What about other parts of the insurance industry, for example life insurance?

Race and ethnicity

As case study 1 illustrates, it may be that genetic variants that influence response to medicines are shared by members of a particular racial or ethnic group. In this example, it is primarily Caucasians who are affected. It must be observed that the use of concepts such as race and ethnicity in the context of pharmacogenetics is contentious. There is considerable genetic variation both within and between racial groups, and it is not clear whether attempts to categorise people in this way can be justified on scientific grounds. However, if genetic variants that influence response to medicines are found which correlate with ethnic groups, what might be the implications? One possibility may be that medicines which are effective in certain patient populations are developed in preference to those that are effective in others. This could be on economic grounds - for example, because white Caucasians in Western countries are a wealthier patient group than individuals with the same condition living in other countries. Alternatively, it may be that for scientific reasons, it is more difficult to develop effective medicines for particular racial or ethnic groups.

Q20 Do you think that pharmacogenetics will increase the likelihood of the grouping of patients according to racial or ethnic groups for medical purposes? If so, what might be the ethical and social implications of such an outcome?
List of questions

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Pharmacogenetics: ethical issues

Details of respondents to consultation

Please complete and return with your response by 19 February 2003

Name: ____________________________________________________________

Address (optional) ________________________________________________

Email: __________________________________________________________

This response may be included in the list of those who have commented Yes / No

This response may be quoted in the report Yes / No

This response may be made available to other researchers interested in the topic Yes / No

If you have answered ‘yes’ to any of the above questions, please indicate your name and/or the title of your organisation as it should appear in print:

____________________________________________________________________

It would also be appreciated if you could let us know where you heard about the consultation:

Web site of the Nuffield Council on Bioethics
Sent copy by Nuffield Council on Bioethics
Email mailing list
Other (please state):

____________________________________________________________________

I would like to be notified about the future work of the Council and give permission for my details to be stored on the Council’s database for this purpose.

____________________________________________________________________

8 Please note that if we do not have your address, we will not be able to send you a copy of the report when it is published.
Please send completed responses to:

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Closing date for responses 19 February 2003.
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