

The response reproduced below was submitted further to a consultation held by the Nuffield Council on Bioethics on its Report: *Pharmacogenetics- ethical issues*, during November 2002 – February 2003. The views expressed are solely those of the respondent(s) and not those of the Council.

**Dr Ian Jessiman, UK**

As a retired doctor I consider pharmacogenetics to be a scientific field of the greatest importance. I strongly support research in the field. I would like to submit the following comments on the Nuffield Council on Bioethics' Consultation Paper on Pharmacogenetics. My responses are listed below against the question numbers to which they relate.

Q2. In all probability regulatory (and financial) measures will have to be extended to encourage the development of unprofitable medicines.

Q3. I see no need for pre-trial pharmacogenetic testing to be a regulatory requirement at the present time, but eventually it is likely to become technically inescapable.

Q4. The responsibility for providing a pharmacogenetic test should lie with the prescriber. For the present such tests should only be available through medical practitioners and after appropriate counselling.

Q5. Pharmaceutical companies and even prescribers will be at serious risk of legal action if medicines whose effects are known to be pharmacogenetically mediated or modified are given without prior testing or at least prior warning.

Q6. Whether drugs developed for administration in conjunction with pharmacogenetic testing should be distributed for use where such tests are not available would depend on the anticipated good effects or harmful side effects of them.

Q7. Safety ought to be the first consideration in any system of care, but where there is no alternative treatment the usual risk/benefit assessment has to be made. In either system of health-care provision the cost benefit assessment will be important to the person or 'body' who pays.

Q8. Pharmacogenetics could bring about inequities in health care by 'selecting' certain groups who are less easily treatable for certain conditions or who require more expensive ways of treatment. Every effort must be made to prevent this in the National Health Service. It is not necessarily true, however, that the benefits of pharmacogenetics will be – in the long run – confined to the wealthy.

Q9. I can see no ethical difference between the storage of different kinds of genetic information.

Q10. Anonymisation should be permissible, but where data is held about a named individual knowledge of it, or knowledge of its eventual availability (after research is completed), must be offered to the named individual before anyone else.

Q11. Morally and legally consent must be for a known and specified purpose. It is not acceptable, nor indeed valid, to obtain a 'blunderbuss' consent for all sorts of unspecified uses in the future.

Q12. Yes. Basically the rightful 'holder' of all such information is the patient. Alternatively it could be appropriate for the researchers to obtain the patient's prior consent so as to be able to notify their GP of the findings.

Q13. Initially such data should be strictly limited to the patient and to those who he/she wishes to be informed. There can be no obligation on a patient to undergo pharmacogenetic testing but, if there were a serious risk in using a particular substance in the 'wrong' genetic groups, the substance might have to be withheld unless such testing had been performed. Pharmaceutical companies and researchers who have legitimately obtained certain information (with the necessary consent, etc) would be entitled to retain and use it in accordance with the consents they have obtained.

Q14. I can see no real ethical difference.

Q15. Once pharmacogenetic testing has become a standard procedure there should be no difference between this and the conveyance of any other serious (bad) news. It should be conveyed by someone with appropriate skills (counselling, etc) and in a position to offer back-up care. It is conceivable that such testing might reveal 'other' information, eg. genetic causes of repetitive miscarriage ('genetic incompatibility'). This is why proper consent is essential and the imparting of results must be carefully handled.

Q16. Pharmacogenetics may well have very important implications for family members, but there can be no inflexible rule about the handling of this. They must not be obliged to accept information when they indicate they do not wish to.

Q17. The decision lies between the patient (primarily) and the doctor. It is accepted that patients have no right to demand inappropriate forms of treatment, but where a limitation on availability has been imposed by the 'Health Service' (for reasons of cost) there could be problems.

Q18. Patients have the right to refuse testing but cannot then expect to receive medicines where pharmacogenetic testing (for reasons of safety, cost, etc) is a prior essential.

Q19. There should be no obligation on a proposer to volunteer pharmacogenetic information, but an insurance company could, if it wished, require them to have one before agreeing acceptance at normal rates. They could also offer an inducement (cheaper rates) if such a test were taken and proved satisfactory. The principles apply whether for health or life insurance. It

should be remembered that, for a genetic modification to have survived in a population, it is likely to have a beneficial effect as well as any harmful ones.

Q20. Pharmacogenetics may indeed lead to medical 'grouping' of patients, but this is nothing new and must be responsibly handled - as at present. The presence of certain diseases in certain ethnic groups (eg sickle cell trait/disease) is simply a scientific fact and may well be important for doctors to know. This gives no reason for discriminatory treatment between different groups.