Chapter 8

Conclusions and recommendations

Introduction

8.1 Genetics is just one approach to tackling the burden of mental disorder but, since both genetics and mental health are areas which raise significant and sometimes distinctive ethical, social and legal concerns, this report has examined the ethical issues that may arise in the course of genetic research into mental disorders and in the application of that research in clinical and other settings (paragraph 1.2).

8.2 The Working Party adopted a broad ethical and humanistic perspective which considered two ethical requirements as basic: the limitation of harm and suffering to all humans and respect for human beings and human dignity. The genetics of mental disorders raises distinctive ethical issues both for the limitation of human suffering and for maintaining respect for persons (paragraphs 1.8–1.13).

8.3 Some of these issues arise because the concern is with genetic conditions; for certain mental disorders the concern is with inherited predispositions rather than with gene mutations that have a more predictable effect. This led the Working Party to adopt two broad categories for discussion; the rare single gene disorders for which Huntington's disease and early onset Alzheimer's disease have provided the main examples, and the common mental disorders influenced both by susceptibility genes and by environmental factors, for example schizophrenia and the more common late onset form of Alzheimer's disease (paragraph 1.3). Finally, some ethical issues arise because the concern is with mental disorders. These cluster around the notion of personal well-being, of how people view themselves and are viewed by others, the implications for reproductive decisions, the stigma associated with mental disorders and the fact that some mental disorders may impair the capacity to make decisions (paragraphs 1.19–1.25). Some of the recommendations which follow are narrowly drawn and concern mental disorders alone. Others are naturally relevant to different kinds of disorder and therefore apply more generally.

Definition and study of mental disorders

8.4 The Working Party noted philosophical arguments that psychological phenomena are not reducible to physical ones, that human behaviour only develops fully within a social context and that there are society-specific expectations about what constitutes normal behaviour (paragraphs 2.7–2.10). The Working Party concluded that there was a need to be mindful that conditions at one time regarded as pathological might come to be regarded as legitimate lifestyles (paragraph 2.10). The notions of personal distress or dysfunction integral to the definition of mental disorder aim to minimise the impact of society-specific expectations in clinical practice. Even so, while the precision and consistency of diagnosis has much improved, little is known about the underlying causes of mental disorders.

What do genetic studies of mental disorder tell us?

8.5 Given that our understanding of normal brain function is still quite limited, it is not surprising that it has been very difficult to study the abnormal function of the brain in mental disorders. The attraction of genetics, which is attested by many precedents from other fields of medicine, is that it enables functionally important components to be identified without any pre-existing knowledge of how the brain works.

8.6 By studying affected families, the gene mutations causing rare single gene disorders, such as Huntington's disease and early onset Alzheimer's disease, have been isolated and this is contributing to our understanding of those conditions. Many common mental disorders, however, such as schizophrenia, manic depression and depression are more complex, their development being affected by a number of factors which may include variation in several genes; in other words, they are multifactorial and polygenic. Heritability studies are used to estimate, using various simplifying assumptions, how much of the variation within a population for a characteristic can be attributed to genetic rather than environmental factors. Considerable energy has been expended on trying to demonstrate that either biological or environmental factors are of prime importance in the development of mental disorders (paragraphs 3.16–3.20). But recent and more constructive work is revealing the complex interactions between genetic and environmental factors for the common mental disorders. Because such disorders do not have a simple Mendelian pattern of inheritance, however, linkage studies in large families are difficult. The search for susceptibility genes associated with complex conditions is characterised by many claims, few of which have been confirmed.

8.7 The Working Party noted, but did not accept, the concerns of some that genetic research into mental disorders is methodologically flawed (paragraph 3.22). We would emphasise, however, that genetic research has so far yielded little practical help in limiting the suffering of those with mental disorder. Almost every susceptibility locus identified for the complex disorders discussed in Chapter 3 is still the subject of scientific controversy (paragraph 3.26). The difficulty of identifying reproducible gene localisations in common mental disorders represents a key scientific discovery in its own right. It indicates that they are rarely, if ever, caused by simple dominant or recessive mutations analogous to Huntington's disease or phenylketonuria. This has crucial implications for clinical practice, as set out below.

8.8 Methodology for genetic research is progressing rapidly and there seems little doubt that over the next ten years, susceptibility genes will be identified and some of these will hold up to robust scientific scrutiny. These discoveries will certainly improve understanding of the causes of mental disorder though probably by small incremental steps rather than through major revolutions (paragraph 3.27). The full potential of these discoveries will only be realised, however, if accompanied by a well-integrated and rigorous research programme covering all approaches to the understanding of mental health including the complex interactions of susceptibility genes, both with each other and with environmental influences.

Clinical applications

Classification and diagnosis

8.9 With respect to the classification of mental disorders it has been suggested that developments in genetics may allow psychiatrists to define subtypes of mental disorders with different causes. The Working Party concluded, however, that such developments are more likely to result in modification rather than complete revision of classification systems (paragraph 4.4).

8.10 The discovery of gene mutations associated with single gene disorders has had profound implications for their diagnosis. But the Working Party concluded that genetic tests will not be particularly useful in diagnosing mental disorders with more complex causes (paragraphs

4.6–4.10). Similarly, it is unlikely that genetic tests will be useful in prenatal diagnosis or for general population screening for susceptibility to common mental disorders. It is more probable that identifying genes involved in susceptibility to common mental disorders will improve our understanding of abnormal processes and hence lead to the development of useful biochemical diagnostic tests.

Genetic counselling

8.11 It has been claimed that the identification of susceptibility genes will be very valuable in personalising risks and that the increase in precision provided by the ability to calculate risks on an individual basis will be of huge clinical benefit (paragraph 4.16). Evidence to support such claims, however, is lacking. Even if a number of susceptibility genes were identified, without understanding the interactions between them it would be difficult to predict individual risk. The Working Party concluded that only a small proportion of variance in risk is likely to be predictable even when multiple susceptibility genes can be tested (paragraph 4.20). In these circumstances, further research will be required before it can be known whether genetic testing for susceptibility to common mental disorders will be useful in genetic counselling of individuals known to be at high risk because of a family history of mental disorder.

Development of new and better drug treatments

8.12 While the Working Party concluded that genetic research will be of limited benefit for the classification, diagnosis and genetic counselling of common mental disorders there may be other long-term gains. Genetic research will contribute to an improved understanding of the causes of mental disorder and hence to the development of drug treatments which are either more effective or better tailored to individual requirements with fewer side effects (paragraphs 4.22–4.24).

Improved preventive measures

8.13 Genetic research into mental disorders may also enable more sophisticated study of the environmental factors that contribute to mental disorders. It is sometimes claimed that, once genes conferring susceptibility to common mental disorders have been identified, there will be potential for preventive measures. The Working Party concluded, however, that this potential will be limited for the common mental disorders for which predictive certainty is also limited (paragraphs 4.25–4.26). Moreover, it is not always possible to avoid the environmental triggers of mental illness and sophisticated concepts of targeted environmental modification must also be viewed realistically within the perspective of a health care and social welfare system in which simple basic inequalities of service delivery themselves contribute substantially to morbidity (paragraph 4.27).

Gene therapy

8.14 The usefulness of gene therapy in single gene disorders has so far been disappointing. Although the application of gene therapy to common mental disorders at some point in the future cannot be discounted, the Working Party concluded that it would not be appropriate to formulate an approach until general principles have been validated in the technically more straightforward single gene disorders (paragraphs 4.28).

Clinical applications of genetic information about mental disorders: ethical and legal issues

Genetic counselling

8.15 As noted above, the contribution to risk of any one susceptibility gene will be small and is unlikely to lead to clinically useful estimates of individual risk. Genetic counsellors will only be able to offer very precise figures about the risk of recurrence for a few single gene disorders such as Huntington's disease (paragraph 5.4). The Working Party concluded that it is essential that counsellors make clear to individuals the current limitations of scientific knowledge about the majority of mental disorders and, in particular, our limited understanding of the interaction of different environmental and genetic factors.

8.16 An exaggerated perception of the degree to which genetic influences determine an individual's current and future health appears widespread. Accuracy in genetic counselling is profoundly important where mental disorders are concerned, because individuals may suffer additional assaults on their personal integrity and increased fear of stigma. The Working Party concluded that, where risk is slight, it is particularly important that genetic counselling is not urged on individuals who do not wish to have it (paragraph 5.5).

8.17 Where mental illness is concerned, genetic counselling has the potential to affect family dynamics adversely and to trigger anxiety and even illness. Stress may arise when counselling cannot predict a precise level of risk. There is as yet little evidence about the effects of counselling for mental disorders and caution should therefore be exercised (paragraph 5.7). **The Working Party recommends that research is undertaken to clarify the appropriate aims and outcomes of genetic counselling for mental disorders and to assess the response of individuals and families to counselling. Such research should investigate the expertise and training needed by those undertaking counselling for various conditions and purposes.**

8.18 The future demand and need for genetic information and counselling is difficult to predict but, as more knowledge about genetics becomes available, demand may well increase. For the common mental disorders, however, susceptibility genes are unlikely to increase an individual's risk to a degree which would merit specialist counselling. The challenge is to identify the few who genuinely need specialist genetic counselling and to provide adequate information to those who do not. Psychiatric nurses trained in genetic counselling would be well placed to provide a link between primary care teams and genetic clinics offering specialist counselling (paragraphs 5.11–5.12). **The Working Party recommends that the British Society for Human Genetics and the Royal Colleges of General Practitioners, Nursing, Psychiatrists and Physicians consider arrangements for the education, training and support both of primary health care teams providing genetic information about mental disorders and of those providing specialist genetic counselling.**

Genetic testing

8.19 One outcome of initial clinical consultation or of genetic counselling may be that a patient is advised, and chooses, to seek genetic testing. What little evidence there is suggests that the uptake of genetic tests varies depending on the condition. This suggests that caution should be

exercised in drawing general conclusions about genetic testing for different conditions, particularly in drawing conclusions about common mental disorders from experience with single gene disorders (paragraph 5.18).

8.20 At present, the number of conditions for which tests are available is small, as is the number of people taking tests. The stigma associated with mental disorders, however, may lead to exaggerated demands for, or fear of, genetic testing. For most mental disorders, genetic tests are likely to have limited value for the diagnosis or prediction of individual risk. In the case of late onset Alzheimer's disease, one or two copies of the apoE4 allele will only result in a small alteration in risk which cannot take into account the other genetic and environmental variation between individuals (paragraph 5.19). Given the very low predictive power of apoE4 tests, the Working Party endorses the position that testing for apoE4 alleles to provide predictive or diagnostic input for Alzheimer's disease is currently inappropriate. **It recommends that genetic testing for susceptibility genes providing predictive or diagnostic input of certainty comparable to, or lower than, that offered by apoE tests for Alzheimer's disease should be discouraged unless and until the information can be put to effective preventive or therapeutic use.**

8.21 Genetic testing may reveal additional medical information about the patient. This will become more likely as increasing numbers of genes are identified which confer susceptibility to more than one condition. The possibility that additional information will be revealed should be discussed with the patient before the test is undertaken (paragraph 5.20). **The Working Party recommends that the duty of physicians to discuss and disclose any possible increase in risk revealed by genetic tests for conditions other than that under investigation be considered equivalent to the duty to do so for other, non-genetic, types of information.**

8.22 The potentially large numbers of people carrying susceptibility genes for common disorders may lead to commercial pressure for the promotion of testing for susceptibility genes even where this would not be advisable or appropriate. The Advisory Committee on Genetic Testing discourages directly marketed tests other than for carrier status for inherited recessive diseases. The Working Party endorsed this position but concluded that the present voluntary system of approval is likely to prove insufficient (paragraph 5.21). **The Working Party recommends that the Advisory Committee on Genetic Testing monitors the uptake of directly marketed tests and the consequences of their use. If, in the light of such monitoring, adverse consequences become apparent, it recommends that the UK government seeks national or international regulation of directly marketed tests.**

Consent and impaired capacity

8.23 Most people with mental disorders will be competent to consent on their own behalf to genetic counselling and any further procedures, including genetic tests. Obtaining genuine consent requires health care professionals to do their best to communicate accurately, and in an understandable and appropriate way, the purposes and implications of the procedure as well as its risks. They should respect the limits of individuals' understanding and capacity to deal with difficult information, and allow time for them to ask questions (paragraphs 5.22–5.24). For a person deemed mentally incompetent to make his or her own treatment decisions, a doctor must act in that patient's best interests even though there are difficulties in translating from the general principle to the specific case. Often best interests can only be determined after prolonged consultation with the person concerned and other appropriate people (paragraph 5.26).

The genetic testing of children

8.24 For children deemed able to give consent to medical treatment, the issues raised by genetic testing are comparable to those for adults (paragraph 5.28). For genetic testing that cannot be considered as medical treatment, it is unclear whether children below 16 would be regarded as able to give valid consent on their own behalf. For the child unable to give valid consent, the consent must be given by the child's parent (or, rarely, the Court). The guiding criterion is the best interests of the child. Once again, it should be borne in mind that, for the common mental disorders, the identification of susceptibility genes is unlikely to allow the diagnosis or prediction of the condition in children, and the use of genetic testing is likely to be limited (paragraph 5.29).

8.25 **Diagnostic testing:** When a condition begins during childhood, deciding whether genetic testing for diagnostic purposes is in the best interests of the child is not in principle any different to a decision about any other medical treatment (paragraphs 5.30–5.31).

8.26 **Predictive testing:** For genetic tests which offer some degree of predictive certainty, professional opinion amongst clinical geneticists has been against the testing of children for adult onset conditions on the grounds that this has no benefit for the individual during childhood and denies him or her the chance of making their own choice as an adult, and could lead to discrimination within the family. Some parents and patient groups have argued, to the contrary, that parents have a right to know about their children's genetic make-up. Whatever the ethical arguments, such testing, if not carried out explicitly to serve the best interests of the child, would not be permissible in law (paragraph 5.32). **The Working Party recommends that, for children unable to give consent, predictive genetic testing should be strongly discouraged unless there are implications for clinical intervention in childhood.**

8.27 **Carrier testing:** The use of genetic tests to determine the carrier status of young children denies them the possibility of making their own decisions about being tested at a later stage. For the law these ethical arguments translate into the question posed earlier: whether it would be in the child's best interests to carry out the test? It is not immediately obvious that it would be (paragraph 5.33). **The Working Party recommends that children should not be tested for carrier status for mental, or indeed other, disorders until they are competent to make their own decisions.**

8.28 **Directly marketed tests:** Despite guidance to the contrary from the Advisory Committee on Genetic Testing, the direct marketing of tests to the public may result in the inappropriate testing of children since it is not clear how a company would determine whether a sample had in fact come from a child under 16 (paragraph 5.34). This emphasises the importance of monitoring the uptake of directly marketed tests (paragraph 8.22).

8.29 **Adoption:** Genetic testing of children might also be considered during adoption. Placing children born to parents with mental disorders for adoption is not uncommon since severe mental disorders may be a reason for a parent to give up a child for adoption voluntarily or as a result of a Court Order. The law would once again insist that a test may only be carried out on a child incapable of giving consent if it can be shown to be in the child's best interests to do so. But it is not in a child's best interests to be adopted if there is a risk that he or she will later be rejected because the adoptive parents had an incomplete understanding of the child they were adopting. Most good adoption agencies would probably want to address the issue of mental illness in the birth family (paragraphs 5.35–5.36). **The Working Party recommends that, given the**

importance and complexity of the issues, the Health Departments, in consultation with the appropriate professional bodies, provide guidance on the pre-adoption use of genetic testing.

8.30 At 18 years of age, adopted children may ask to know the identity of their birth parents and this might be an appropriate time at which to provide other information about possible family histories of disease so that, from early adulthood, they may make informed decisions about seeking genetic counselling or testing or other forms of investigation or treatment (paragraph 5.37).

Genetic information and reproductive decisions

8.31 Where the common mental disorders are concerned, genetic information will not be particularly helpful in making reproductive decisions. The predictive certainty of genetic tests will be slight in the majority of cases making prenatal testing and termination less relevant and acceptable to parents. It will also be less likely to meet the criteria of S.1.(1)(d) of the Abortion Act. Even within this framework, what one woman or couple will see as a sufficient reason for abortion, another will see as quite insufficient (paragraphs 5.38–5.41). **The Working Party recommends that people making reproductive decisions in the light of a family history of a mental disorder should have access to genetic counselling.**

8.32 The ideal of non-directiveness in genetic counselling is widely endorsed. There is accumulating evidence, however, that non-directiveness is rarely achieved. The Working Party questioned the appropriateness of non-directiveness as a universal aim in genetic counselling and felt that, in some circumstances, it would be inappropriate and unhelpful. It has emphasised, however, how important it is that genetic counselling and testing are undertaken voluntarily, and that individuals are enabled to make their own decisions at each stage of the process (paragraphs 5.42–5.44). **The Working Party notes the need for further debate about the appropriateness of non-directiveness in genetic counselling and recommends that further research to establish appropriate aims and outcomes for genetic counselling is undertaken.**

Eugenic programmes

8.33 Historically, eugenic programmes have been characterised by compulsion, a degree of coercion or the restriction of individual choice. The Working Party considers that the present use of genetic testing for reproductive choice in the UK cannot be considered to be eugenic. It recognises, nevertheless, that there are concerns that the growing use of new genetic technologies will lead to a 'new eugenics' (paragraph 5.45).

8.34 As our knowledge of psychiatric and behavioural genetics is enhanced through the identification of new genes, the past abuse of genetics through eugenic programmes targeted at the mentally ill must not be forgotten (paragraphs 5.46–5.48). With rare exceptions, it is very unlikely that there will be population screening programmes based on genetic tests for mental disorders in the near future. Of more concern is the potential misuse of genetic testing and genetic information in families known to be at risk for certain disorders. The Working Party considers that the best safeguard against new eugenic pressures is properly informed, freely given consent to genetic testing. There must be vigilance therefore that informed consent is always sought for any genetic test or other procedure.

8.35 Particular concern has been expressed about the confidentiality of the information contained in

genetic registers (paragraph 5.49).The Working Party concluded that clear guidelines are needed. **The Working Party recommends that the British Society for Human Genetics explores mechanisms for the development of guidelines for the establishment and maintenance of genetic registers in the new NHS.**

Confidentiality and disclosure

8.36 The duty of medical confidentiality is not absolute. When genetic screening reveals information which may have serious implications for relatives, "*health professionals should seek to persuade individuals, if persuasion be necessary, to allow disclosure of relevant information to other family members*".[1] For the common mental disorders, problems of non-disclosure are likely to be rare since genetic information is unlikely to lead to such significant modification of risk that non-disclosure would have serious consequences. It is, nevertheless, necessary to be wary of breaking confidentiality in those cases where an individual opposes disclosure of information about his or her condition (paragraphs 5.55–5.60). **The Working Party recommends that the confidential nature of genetic information should be maintained. It can conceive of exceptional circumstances in which, in the absence of the consent of the individual, disclosure to close family members might be justified, if there are serious implications for them. Such decisions should be judged on a case by case basis.**

8.37 There is some doubt as to whether doctors owe an obligation of confidence to those who lack the mental competence to form a relationship with them. The unsatisfactory outcome could be that the confidentiality of such patients is not subject to any legal protection. Where the lack of mental competence is temporary, the decision about whether to disclose information must be deferred until the individual has regained sufficient competence for the matter to be discussed. Where the lack of mental competence is likely to be permanent, we assume that the requirement to act in an individual's best interests would extend to disclosure of information to others (paragraph 5.61).

8.38 The fact that some family members may not wish to be presented with genetic information raises dilemmas which cannot be resolved by simple guidelines. The Working Party accepts that, if an effective intervention is known, disclosure may be justified when a person is not aware of their risk (paragraph 5.60).

Wider uses of genetic information about mental disorders: ethical and legal issues

Stigma

8.39 The issues raised by genetic information about mental disorders go beyond the clinical context. The Working Party considered the implications of genetic information for the stigma that mental disorders evoke. It noted that much stigma stems from ignorance and misconceptions about mental disorders and the behaviour of people suffering from them. This stigma frequently causes unfairness in areas such as employment and housing. But, even in the absence of such injury or harm, stigma injures those with mental disorders, because they are regarded or represented in a disrespectful and debasing way. The Working Party concluded that proper treatment of those with mental disorder must include efforts to eliminate both the injury which stigma constitutes and the harm which it causes and it noted that the former may be deeper and less easy to rectify (paragraphs 6.2–6.6).

1 Nuffield Council on Bioethics (1993). **Genetic Screening: Ethical issues,** London, Nuffield Council on Bioethics..

8.40 Genetic information could, in principle, decrease stigma by increasing the understanding of mental disorders, putting them on a par with conditions thought of as physical and countering notions that some mental disorders reflect weakness of character. Similarly the stigma suffered by families may decrease if genetic information provides evidence for a biological component to some mental disorders. Genetic information could, however, be interpreted in different ways; as indicating that people with mental disorders are fundamentally different from others or that parents are to blame for having affected children in the first place. Genetic information may also serve, therefore, to increase stigma (paragraphs 6.8–6.9).

8.41 This emphasises the importance of combating stigma and ensuring that additional genetic information decreases, rather than increases stigma. There is no simple way, no single institution and no simple piece of legislation which can eliminate the stigma of mental disorder; only long-term changes in public understanding of, and support for, those with mental disorders will improve matters (paragraph 6.10). The Working Party welcomes, therefore, the current Respect campaign by MIND to oppose discrimination on mental health grounds and the newly launched campaign against stigma by the Royal College of Psychiatrists. **The Working Party recommends that campaigns to reduce stigma emphasise that it constitutes harm as well as causing it.**

8.42 Genetic information about any condition raises the prospect of discrimination and for mental disorders this is compounded by stigmatisation. The Working Party paid particular attention to discrimination in relation to insurance, employment and education.

Insurance

8.43 The Working Party noted that the use of genetic information relevant to mental disorders for insurance purposes is likely to be fairly limited and specific. Even for single gene disorders such as Huntington's disease, for which individuals with the gene mutation have a calculable and significant reduction in life expectancy, there is considerable variability between individuals, for example in age of onset. In addition, information may be useful only for certain types of insurance products. By contrast, information about susceptibility genes is currently of very limited actuarial use: it may provide information about slight increases in the risk of suffering from some multifactorial disorder in a population, but reveal little about any single individual's level of risk (paragraphs 6.12–6.14)

8.44 The Working Party concluded that it is doubly important that insurers do not exaggerate the actuarial implications of genetic test results relevant to mental disorders, where the risk of stigma and its effects is high. It is important to have systems in place that can monitor whether insurers are discriminating unfairly on the basis of genetic test results (paragraph 6.19). **The Working Party recommends that the Government, in consultation with the insurance industry, makes arrangements for monitoring insurers' use of genetic tests for mental disorders, and for reporting on any tendency to load premiums excessively, any actuarially unwarranted refusal of insurance and any other forms of unfair discrimination.**

Employment

8.45 In view of the employment difficulties and discrimination faced by those with mental disorders, the Working Party considered it important to consider how the use of genetic information might improve or worsen matters. With respect to genetic screening of employees for increased

occupational risks, although the Working Party has not learnt of any genetic sensitivities to chemical or biological agents which are associated with an increased risk of mental disorder, other features of some working environments might represent greater risk factors for mental disorder for individuals with relevant susceptibility genes (paragraph 6.25). This adds force to the recommendation in the Council's previous report, **Genetic Screening: Ethical Issues**, that genetic screening of employees for increased occupational risks should occur subject to strict safeguards and only after consultation with a co-ordinating body (paragraph 6.23). **The Working Party recommends that the Human Genetics Advisory Commission, in its consideration of genetics and employment, determines which is the appropriate body to monitor any introduction of genetic screening programmes for increased occupational risks.**

8.46 It is possible to envisage the use of genetic tests for mental disorders for reasons other than identifying occupational risks; possibly even to exclude some people from employment on health grounds. The Working Party notes that, in the UK, the Disability Discrimination Act 1995 offers some protection from discrimination, but it does not cover those for whom genetic information has revealed that they may develop a disability in the future (paragraph 6.27). There has also been concern that the definition of disability is too narrow for some people with mental disorders. Any wider use of genetic tests in employment may raise far reaching issues about discrimination; but so far there is little legal or other framework for addressing these issues in the UK (paragraph 6.29). The Working Party welcomes the forthcoming consideration of genetics and employment by the Human Genetics Advisory Commission and **recommends that, in view of the special significance of stigma in mental disorder, the Commission pays particular attention to the implications of testing for genetic factors relevant to mental disorders for employment purposes** (paragraph 6.31).

Education

8.47 The Working Party noted that in some cases a genetic test might be useful in identifying a specific educational approach; in others it might be of doubtful value. In the latter case there would be *prima facie* grounds for relying on conventional tests. Even in the former case, reliance on genetic tests should not, we believe, become automatic in educational assessment since testing itself may have other, possibly adverse, implications. The Working Party does not endorse any wider use of genetic tests to assess individual or group potential of any sort (paragraphs 6.32–6.35).

Genetic research into mental disorders: ethical and legal issues

8.48 For most people with a mental disorder, arrangements about consent for research need not and should not be any different from those required for other people. While the mental capacity of many individuals with mental disorders varies, it is desirable, and almost always possible, to involve them in relevant genetic research at a time when they are competent to consent on their own behalf (paragraphs 7.2–7.7). **The Working Party recommends that individuals who are intermittently competent should only be approached about participation in research when competent**. Although genetic research tends to be of minimal physical invasiveness, **the Working Party recommends that written consent for participation should be the general rule** (paragraph 7.8).

8.49 The intermittent nature of some mental disorders and the confinement of some patients to institutions are two aspects of mental disorders which suggest that special safeguards are needed when obtaining informed consent to research participation. The Working Party concluded that where potential participants in research are confined in an institution, special care is needed to ensure that no form of coercion is used to secure participation. In particular, the use of payment must be carefully considered (paragraph 7.9). **The Working Party recommends that any proposed payment for participation in research should always be carefully considered by research ethics committees and by grant-giving bodies**. The Working Party also noted that the validity of consent should not be assumed when the potential participant's capacity to consent changes during the course of the research. Proposed contingencies to deal with such a situation should be presented to a research ethics committee and discussed with the patient at the outset (paragraph 7.10).

8.50 An important subgroup of people for whom genetics research is likely to hold particular relevance, those with severe mental retardation, will never have had and never will have the capacity to make complex decisions, and that will include decisions about participation in research (paragraphs 7.11–7.13). For another important subgroup, those with dementing disorders, earlier competence may have been exercised in this regard, and an individual's views about research participation may be on record. Where this is the case, these views should be honoured; more usually, they are not a matter of record, so here too, with competence unlikely to be recovered, special safeguards are needed.

8.51 Most genetic research into mental disorders is unlikely to lead to any immediate benefit to patients lacking the capacity to consent to participation and is therefore of doubtful legality. In the case of children, provided that there is an important interest served by the intervention, a parent may consent on the child's behalf. It is unlikely, however, that progress can be made in the treatment of mentally incapacitated patients without research and most relevant research is probably only possible if it involves individual patients (paragraph 7.14). The Working Party considers that genetic research holds out important prospects of advances in understanding and treatment of mental disorders and that restrictions on participation are not in the patient's best interests. **The Working Party recommends therefore that non-therapeutic research involving people lacking the capacity to consent to participation on their own behalf should be considered ethically acceptable, subject to strict safeguards** (paragraph 7.17). The Working Party recognises that there should be legislative backing for and controls over non-therapeutic research involving mentally incapacitated patients. **It recommends that further consideration be given to the details of legislation and regulation to safeguard the interests of people with mental incapacity with respect to participation in research** (paragraph 7.18).

8.52 The Working Party concluded that additional specialist ethics committees to consider research involving those unable to give consent on their own behalf were not necessary or desirable. It considered that such committees might increase the stigma suffered by potential participants and diminish the skills of regular ethics committees (paragraph 7.17). Rather, **the Working Party recommends that every research ethics committee should include at least one member who has experience in the area of competence in decision making about research participation.**

8.53 It is not uncommon for researchers to discover, using DNA samples collected for research purposes, information of clinical significance to the individual donor of the sample. An ethical difficulty arises because the process of obtaining the informed consent required for research does not usually include consent for disclosure of identifiable data to clinics outside the strict environs of the research, nor the kind of genetic counselling that would be required for an individual seeking a genetic test for clinical purposes (paragraphs 7.19–7.22). To provide an individual with information from a research study about gene mutations they might or might not carry, could be to give them information they would choose not to have, and/or information for which they or other members of the family are not prepared or cannot understand in terms of its implications. A further difficulty is that quality controls and procedures used for clinical testing may be different and sometimes more rigorous than those used in research studies (paragraph 7.24). **For these reasons the Working Party recommends that, as a general rule, those who consent to take part in research should be told that individual information derived from analysis of their DNA will not be given to them**. A summary of the overall findings of the research can be provided if the participant wishes. **The Working Party further recommends that, in any research study that could yield genetic information which is clinically relevant to a research participant and/or their relatives, consent to that research should make it clear whether or not such information would be made available** (paragraph 7.25).

8.54 In relation to the additional use of research samples or data, **the Working Party recommends that, when an individual participant is regarded as competent, any further use of data in the longer term should be discussed with him or her as part of the consent procedure; new research should, as a minimum, be submitted for approval to a research ethics committee before proceeding. When a person is considered to be incompetent to make his or her own decision about participation in research, data collected for non-therapeutic research purposes should not be used for any other research purpose** (paragraph 7.27).

8.55 While debate about the use of clinical genetic information by outside agencies continues (Chapter 6), information that is obtained within a research context and is not being used for clinical purposes is clearly distinct. **The Working Party recommends that genetic information obtained during participation in research should not be made available to organisations such as insurers or employers** (paragraphs 7.28–7.29).