

Genetics and Insurance Committee Consultation Document

The response of the Genetic Interest Group

- 1 As the UK alliance of charities and support groups for all those affected by genetic disorders, the Genetic Interest Group welcomes the publication of this consultation document. We believe that this is a positive demonstration of the desire of the Committee to consult with all stakeholders in this important debate and welcomes evidence of the transparency with which the committee intends to approach its task. In view of the relatively short time available to prepare a response it has not been possible to consult all 135 member organisations of the Genetic Interest Group formally on the content of our response. However comments from a number of organisations with a particular interest in this issue have been sought and this response is endorsed by the Trustee Board of the Charity.
- 2 The starting point for our consideration of the document is the assertion by government that genetic factors may legitimately be considered as relevant in underwriting decisions and the establishment of the GAIC to determine the circumstances where this is the case.
- 3 For clarity we have commented on the sections of the draft application form and the accompanying notes together.
- 4 Introduction: We note the comments on the standards and practices of genetic laboratories of the ACGT. Whilst it is essential that laboratories which undertake genetic testing should be competent to do so, we would not wish to see individuals disadvantaged as a result of being tested in a laboratory that is not NEQAS or CPA approved. It may be the case that in future some health authorities may contract their diagnostic testing services out to commercial companies, for whom NEQAS or CPA is not an appropriate standard to aspire to. Equally, laboratories may be in the process of seeking approval, but not yet have final certification for some reason. As the scheme is voluntary some may have decided not to apply. If a laboratory is competent to provide tests for use in clinical consultations, where decisions may be much more significant than whether or not an individual should pay additional insurance premiums, then those test results should surely be deemed reliable for use in an insurance context. This is particularly important when a negative result may result in the applicant being able to be rated at population risk, rather than higher due to family history.
- 5 Submission of Applications to GAIC. Whilst medical and scientific data published in academic journals is subject to peer review, actuarial data are not normally considered in the same way. We understand that arrangements are being made to set up a panel of actuaries willing to undertake this on behalf of GAIC where necessary and welcomes this move. No mention is made of any procedure for resolving dispute in the event of a peer review determining that the approach taken by the insurer is fundamentally flawed in some way, rather than just a difference of opinion as to

the interpretation placed on it and we would suggest that an independent procedure be set up in advance of any such conflict emerging, in order that issues can be speedily resolved.

GIG welcomes the decision by GAIC to make submissions available to interested parties such as patient support groups for their comment.

- 6 General Information. Tests to be considered by GAIC will be those which are performed on individuals who are pre-symptomatic at the time of testing and are applying for insurance. Where an individual has already developed symptoms the requirements of the DDA will apply. For this reason the notes to accompany the section should be amended to reflect that the clinical impact of the result will be in respect of **future** health or survival. In such cases an indication of the typical age of onset and the band-width of ages in which symptoms usually appear should be indicated as an aid to assuming the significance of the results to the type of cover being requested.

We simply note the fact that the request for copies of references to be supplied with the application may create copyright difficulties unless an appropriate licence is obtained.

- 7 Differential Diagnosis. In the example quoted, confusion between adult dementias is not unknown. In such an instance, misdiagnosis (for example between Pick's disease and familial Alzheimers) may result in a false negative as the wrong mutations may be tested for. Although this may be clinically undesirable and possibly personally damaging for the family concerned, it is the applicants' advantage in the context of obtaining cover. It is impossible to legislate against and unlikely to be significant given the numbers likely to be affected.

- 8 Natural History and Genetic heterogeneity. We suggest that the application for approval includes details of references which the applicant is depending on to support the conclusions drawn.

- 9 Test standards. Historical tests should only be included on the application if the application to GAIC is claiming that they have positive predictive power in respect of insurance cover. If insurers do not intend to rely on them they should not need to be disclosed unless it is in the individual applying for insurance cover's interest to do so (i.e. because they might indicate a lower premium was appropriate). Guidance as to the tests which are deemed to be acceptable should then be issued by Insurers' medical advisors to GPs and others requested to complete medicals for patients in their care.

- 10 We are unclear as to what is meant by this question and suggest that it should be re-cast in order to clarify what is being sought. The result of the genetic test will not be influenced by "genetic findings" in other family members, as it will be determined by the individual's DNA. It may be the case that test results from another family member may define the mutation to be looked for (e.g. BRCA1) but in the absence of this information no test would be possible, so no result available and family history would be the defining factor. Similarly, precisely the same test result would have the same weight in different families. The number of triplet repeats in Huntington's disease probably carries the same implications for two unrelated individuals as it does if they are related. If a negative test result is inconclusive (as in the case of Marfan's disease) then the test is not legitimate for insurance purposes and underwriting decisions, like clinical decisions in the same situation, should be based on family history. Given that Marfan's Syndrome is not currently proposed as a condition where genetic testing is possibly relevant, its use as an example would

seen to cloud rather than clarify the issue. The case of the BRCA genes would seem more appropriate.

- 11 Weakness or technical imperfections. Whilst it is clearly appropriate that the reliability and validity of test results should be an integral part of determining their eligibility for consideration in insurance decision making, approval should be granted on the basis of collective rather than industrialised data. The suggestion in the notes that underwriters seek advice from the clinician who originally requested the test (and in this context it is essential to recognise that this may not be a clinical geneticist) seems inappropriate, as underwriters would not be in a position to seek such clarification unless prior approval for the use of the test in question had been obtained - although this would clearly be a mark of good practice on the part of the professionals concerned.
- 12 Actuarial Significance: The critical issues for the determination of the actuarial significance of test results seems to be the degree to which the results can alter the likelihood of a given condition developing in the applicant seeking insurance cover. A positive result for Huntington's disease, with a 95% penetrance leaves little scope for interpretation, although the clinicians knowledge of the natural history of the condition in the family may give scope for variation in the advice and counselling he or she provides. In the case of BRCA1, with a penetrance of about 50-60% the scope for interpretation is much greater and the flexibility of parameters for decision making, whether in insurance or in the clinic is consequently substantially increased.

At this point it is also necessary to point out that the notes of guidance are potentially confusing, in that "applicant" is used to describe both the individual seeking cover and the company seeking approval for use of genetic test results. We are also concerned that the suggested list of bullet points for actuarial investigations may prove a stumbling block for speedy decision making in some instances. In particular we would refer you to the comments about peer review made earlier and the need to link considerations of predictable additional morbidity/mortality derived from genetic test results to the specific product for which approval is sought. For example the likelihood of someone testing positive for Huntington's disease developing such debilitating symptoms during their annual holiday and thereby requiring emergency medical evaluation seems sufficiently remote as to be ignorable, whereas someone with an early onset condition would already be displaying symptoms and their eligibility should be judged accordingly.

Finally, in this section, contact details of investigations and the wish of the committee to seek further clarification from them may prove to be commercially sensitive. GIG endorses the wish of the committee to ensure that it has the full powers necessary to reach an informed decision, but we would suggest that, in order to do so it may be necessary to give specific guarantees regarding the protection of commercially sensitive information.

- 13 Additional mortality/morbidity. Scientific understanding of genetics and its link to human health and disease is advancing rapidly. GIG is concerned that approval or rejection of an application will not be subjected to subsequent reevaluation should new knowledge signify after our appreciation of the implication of genetic test results. Whilst a "sunset clause" on approvals may not be appropriate, we feel that a mechanism should be established that will take account of changed scientific understanding that may either increase or decrease the risk to an individual of a particular test result.

- 14 Compliance. If, as we understand to be the case, it is likely that the ABI will be the main (if not the only) source of applications to GAIC, then the question of the ability of underwriters and insurance practitioners to comply with the Committees' ruling and apply the test results appropriately will be an issue of compliance rather than on requiring pre-approval before the test can be determined as appropriate in principle. Policing of the operationalisation of GAIC's rulings will be dependent on the resources available and the sanctions that can be brought to bear on those who infringe the committees' decisions. The ABI's code is monitored by means of an annual compliance letter being signed by CEOs of member companies. Without a substantial increase in resources and (possibly) GAIC being put on a statutory basis it would seem to us unlikely that any more rigorous monitoring by GAIC would be possible. It would be relatively straightforward to extend the ABI's compliance letter to include GAIC decisions, at least for companies in membership of the Association.
- 15 Comments on the appendices. We note with gratitude the definition of "basic mortality". Presumably the risk is assumed to be one for virtually everyone eventually. The glossary could be extended to define different types of insurance cover for the benefit of non-insurance professionals and lay readers.

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