

Consultation Response

Medical profiling and online medicine: the ethics of
'personalised' healthcare in a consumer age
Nuffield Council on Bioethics



Response by the Genetic Interest Group

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This is a response on behalf of an organisation.

You may include our organisation's name in the list of respondents that will be published in the final report.

Our name should appear as: **Genetic Interest Group**

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Question 1: Health care as a consumer good

If an increasing number of medical products and services are becoming available as consumer goods - that is to say, as commodities which customers may choose to purchase providing they can meet the costs - is this development on balance desirable?

This development is neither desirable nor undesirable.

In general, the Genetic Interest Group (GIG) supports both informed consumer choice and public health literacy.

When considering purchases for services such as body scans and DNA profiling the public should be allowed to make their purchasing decision from an informed position and an understanding of the benefit to cost ratio of the test. Criteria should include:

Professional interpretation of test

The consumer should be provided with professional advice, which should guarantee proper risk communication and include the opportunity for consumers to ask questions about their results. The consumer should have access to a consultation at which they can discuss the results of their test and be advised of their options following the test.

Validity of test

Products should be independently verified for efficacy and utility.

Consumer protection and trading standards

Providers of these services should be subject to rigorous enforcement of trading standards and consumer protection law.

Patient safety and privacy

These services should be subject to the same level of patient safety required within the NHS and the private health service. Privacy equivalent to that provided in Regional Genetic Services should also be observed.

Consequence of positive and negative results

GIG believes this should be the key criterion for a patient's purchasing decision. The test should provide knowledge of the patient's future that suggests lifestyle changes or other intervention above and beyond general healthy lifestyle advice.

A positive result in the context of a susceptibility test only communicates a higher than population risk level for that particular condition to the patient. Where the resulting lifestyle changes would be similar to general healthy living advice, such as smoking cessation, increased exercise, diet modification etc, GIG would suggest that these measures should be taken without the unnecessary expense of a commercially available diagnostic test. A "negative" test result for a complex multifactorial condition communicates that the patient is at population risk level, or slightly lower. The risk that patients may react to a "negative" susceptibility test with poor lifestyle decisions should be considered.

The value of information from susceptibility tests contrasts with the value gained from single gene tests such as that for Huntington's Disease. A negative result for a single gene test such as Huntington's Disease means that the patient will not contract Huntington's, and the patient can

plan their life accordingly; a positive result for a predictive Huntington's Disease test allows the patient to expect and plan for disease onset.

GIG believes that the individual products available to consumers that are not available on the National Health Service generally have a poor benefit to cost ratio. In the main they have little utility, as the results they provide stimulate few changes outside general healthy lifestyle choices.

Where tests are promoted commercially which confer more clinical utility than those tests currently available, and allow for preventative treatment other than lifestyle choice, these tests should be available from the NHS according to need, and be delivered in the context in which current tests on the NHS are provided, i.e. supported with information before and after the test from a qualified healthcare professional.

Question 2: Validity of information

While much health related information is freely available to individuals, this varies greatly in quality and accuracy. Many of the lifestyle and health books and magazines that are currently available may contain medical information that is misleading or even incorrect from a scientific point of view. Do you think that information provided by DNA profiling and body imaging services raises different questions and should be subject to different regulations?

The right to introduce specific regulation if existing regulation, properly enforced are unable to provide an appropriate degree of patient/consumer protection should be reserved.

DNA profiling and body imaging services are both expensive procedures, the results of which require professional analysis to deliver utility. GIG believes these are best provided within the context of a health service.

Regulation of these products would deliver an opportunity for control of the quality of testing, the quality of service, and the requirement of support to the consumer. Any regulation put into place should provide for a comprehensive complaints procedure to protect the patient.

A key concern to GIG arising from this growing industry is that of interpretation of results. Risk communication is complicated and requires skilled communication. The message "your risk of a particular cancer is double that of the general public", is an alarming one, but the message "your risk of a particular cancer is 2%, the general public has a 1% of this cancer", is much less alarming; these are two methods of communicating the same information. We believe risk communication is best done as part of a dialogue between patients and health service professionals, to ensure that risk is understood to both parties' satisfaction.

Question 3: Prevention

Many governments argue that every individual has some responsibility to look after their own health, in their own interest and that of society at large, for instance in matters of lifestyle and diet. Do you think such individual responsibility should extend to the use of DNA profiling and body imaging services such that people in some circumstances should be expected, encouraged or obliged to have such tests?

These services are complex diagnostic tests which require expert interpretation. Governments should not encourage people to utilise these tests without supplying the necessary support that should always come with diagnostic testing.

The public should be aware that clinically useful predictive testing such as that for single gene disorders, inherited cancers, cascade screening for Familial Hypercholesterolaemia, breast

cancer screening, cervical cancer screening, etc are available on the NHS, and should be encouraged to make use of these services where appropriate (for example where family history or the results of other investigations indicate that this is a suitable course of action).

The general public should take some responsibility for their health, but these measures should be simple and easily communicated. The most appropriate ways in which people can take personal responsibility for their health are:

- Adherence to a healthy diet.
- Regularly exercising.
- Cessation of smoking.
- Availing themselves of services offered by the NHS such as:
 - Well person clinics
 - Health checks
 - Blood testing
- Improving health literacy through recognised sources of high quality information such as NHS Direct.

It should be recognised that some health risks (notably single gene disorders) are independent of lifestyle modification.

Question 4: Who pays?

Many DNA profiling and body imaging services are paid for privately by the individual. However, positive findings may lead the individual to seek publicly funded services for follow-up diagnosis and treatment. Should public services be expected to fund such follow-up?

If the result of a privately funded test is considered to be clinically relevant by a healthcare practitioner, the health service should provide the care it would ordinarily provide to an individual in the same position regardless of how the diagnosis was made.

However, GIG has concerns about the possible tendency to repeat tests because of doubt over the quality of privately provided diagnostic services.

Question 5: Your experiences

Have you used online health recording systems such as Google Health?

For patients affected by genetic conditions online health records can be an extremely useful tool in managing and monitoring the ongoing care and treatment a patient is receiving. Many patients within this category will already be taking control of their condition, as in many cases they are the “expert” due to the rarity of the condition which they are affected by. GIG has carried out work in this area with its members and a common issue raised within the current UK healthcare systems is that patients with genetic conditions often have problems in locating healthcare professionals that are aware of their condition and the ongoing support and/or treatments that are available. An obvious course of action to improve this would be to improve NHS online electronic healthcare records, where information can be stored and shared with healthcare professionals across the UK and when they have a legitimate relationship with the patient.

Having access to such a data source within the NHS would be immensely valuable to patients with genetic conditions as it would support both them and the healthcare professionals they interact with by providing up-to-date information on the individuals' care and treatment. This would avoid the added burden of having to continually repeat and explain a condition to professionals who have never seen a patient affected by a particular condition.

Individually there are over 6000 known genetic conditions but collectively they make up for over 3 million patients in the UK all of whom will be regular, (and in many cases heavy) users of NHS resources. Whilst GIG and its members appreciate that it would not be possible, or sensible, for all healthcare professionals to be familiar with all conditions, patients affected by such conditions expect that information will flow where it is needed, particularly amongst the often varied set of clinicians that they will need to see on a regular basis.

The Genetic Interest Group has worked on the issue of electronic healthcare records for a number of years and is currently a member of the NHS Connecting for Health Voluntary Sector National Advisory Group (VSNAG).

There are many electronic healthcare record systems now appearing in the market place, particularly online and although GIG supports this information sharing we feel that this type of information sharing can only have a limited value. GIG would like to see a secure and interconnected way of collecting electronic patient records within the NHS, (something which Connecting for Health is undertaking currently) as this is where the majority of patients affected by genetic conditions will be treated. We are particularly keen to see information shared amongst primary and secondary healthcare systems, and we currently have some concerns that although information flow has improved in primary care there is a danger that this new connectivity may not be linked in a useful manner to secondary and tertiary care which are both very important to our members support and care.

GIG also has concerns around the dataset of information that is being collected. Genetic conditions by their very nature affected families, and it is often important for information to be collected and in some instances, shared on a family, rather than individual basis. Currently NHS electronic healthcare records are focusing very heavily on common condition datasets and GIG will continue to campaign to ensure that the genetic component of many conditions is able to be recorded in a useful manner.

Security of data online is another factor that would influence patients decisions about whether or not to upload information to the internet. Having clear security in place is vital if this type of gathering of information is to become more routine.

Some patients using online health records outside the NHS have found them to be very useful as a way to collect record information in one place. With the high level of services that patients with genetic conditions tend to use, this is a useful way to keep data together in one place, where it is easily accessible. Due to the sensitive nature of this data, concerns over access by third parties have arisen, particular where there are commercial interests.

A recent development that also concerns GIG is that of the company 23andMe issuing a reduced rate version of its genome scanning service in return for patients allowing their medical history and genetic information to be used for research purposes. Data use such as this should be subject to the rigorous data protection and ethical review that research involving gene-banks must undergo.

Question 6: Your experiences

Have you used online sources for diagnostic purposes, for instance those provided by government agencies, patient groups, commercial companies or charities?

Most genetic conditions are multi-factorial, and this means that the symptoms that patients have will vary and will in all likelihood affect many areas of their body and require healthcare support from various professionals in different disciplines. This means that using online diagnosis tools

can sometimes be misleading. Due to the complex nature of many of the conditions the Genetic Interest Group works with it would be extremely difficult to obtain a diagnosis in this manner. Clearly many of the websites mentioned such as NHS Direct Self Help will have more comprehensive information on the common complex conditions such as heart disease or cancers. With over 6000 known genetic conditions each with varying degrees of symptoms within the condition itself it would be extremely difficult, if not impossible to include information on an online health database in order to support the diagnosis of such conditions.

Even if such a system could be developed, the impact that a potential diagnosis of a genetic condition could have should not be underestimated and therefore GIG would always advise patients to seek professional help with looking for a diagnosis, in order for the relevant support to be provided. This is particularly important for many of the conditions GIG represents. Many conditions are multi-system, and symptoms may be indicative of a number of possible conditions with significantly different consequences, therefore professional interpretation of symptoms for purposes of diagnosis is necessary.

Question 7:Your experiences

Have you purchased prescription drugs over the internet?

GIG believes that prescription drugs should be delivered by health professionals as part of a comprehensive health service.

Question 8:Advertising health care products

Do you think it should be permissible to advertise prescription drugs direct to consumers?

GIG believes access to prescription medicine should be controlled by a qualified medical professional, and decisions on the suitability and choice of such products should also be made by a qualified medical professional in consultation with the patient in order to determine the most suitable intervention (where choice exists). Whilst maintaining the ban on advertising to patients, the law should allow for communication between manufacturers of medicine and patients being treated. Ideally communication on the use and safety of a medicine should be done by a healthcare professional, however GIG is aware of scenarios where direct communication between patient and manufacturing company can be desirable. For example a patient who required the patient information leaflet for their medicine in a different language was unable to obtain this information from the manufacturing company due to laws against advertising prescription medicine direct to consumers.

The Genetic Interest Group represents the interests of some patients of serious rare conditions for which there only exists one treatment, such as lysosomal storage disorders treated with enzyme replacement therapy. Patients treated in this way often have an unusually close relationship with the pharmaceutical organisation providing their treatment. We believe this relationship to be valuable, and would be concerned if legislation in this area put this relationship in jeopardy.

There should be a regulated route by which patients can obtain nonpartisan information about the medicines they are using. Channels of communication, quality and type of information should be controlled. This could also be a means by which "expert patients" can be made aware of information surrounding the treatments they are given and those that are available to them.

Standalone diagnostic tests should be subject to the same controls as other pharmaceutical products given to the consumer in a wider clinical scenario. However, tests that are provided as part of private healthcare delivery, i.e. with the support and control of qualified health professionals, could be advertised in the same way that other private healthcare may be

advertised.

Question 9: Your experiences

Have you used information technology to access individual health care expertise at a distance?

GIG supports the use of telemedicine for the management of chronic disease. Telemedicine's use in this context liberates patients by reducing the frequency of their hospital visits where remote support can replace face to face consultations. This technology can be especially valuable for patients who receive care from specialised centres of excellence, and who may otherwise have to travel unusually long distances to receive their healthcare.

The use of telemedicine for remote management of chronic conditions has the potential to empower patients with greater involvement in their treatment.

Question 10: Who pays?

Should remote access to GP services be provided through telemedicine for those in remote and rural locations?

Yes, where appropriate. The use of telemedicine in primary care scenarios has the potential to break down inequalities in access to healthcare caused by geographical constraints. This potential should be embraced.

The public healthcare provider will gain from treatment cost savings resulting from earlier diagnosis, and from economies of scale as General Practitioners are empowered to cover a wider catchment area. Extra costs should then be weighed against gains in equality of access to diagnosis and treatment.

Telemedicine systems should be integrated with local delivery systems (e.g. primary care and district general hospitals) for most effective uptake and to maximise health gain and patient/family benefit.

Questions 11-14

The issues are covered by GIG answers to Questions 1-3

The Genetic Interest Group authorises publication of these comments, and would be happy to expand upon them.



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