

**Consultation with primary care health  
professionals on issues relating to the recruitment  
of patients to a DNA collection study**

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## **Executive summary**

### **Background**

The Medical Research Council (MRC) and the Wellcome Trust have proposed establishing a DNA-based biomedical database to facilitate research on the relationship between genes, lifestyle and morbidity. It is envisaged that a longitudinal cohort of 500,000 individuals aged 45-65 years will be recruited within primary care settings across the United Kingdom.

A cohort of this size and nature creates a large number of ethical and organisational challenges. The Genetic Interest Group in conjunction with the Universities of Nottingham and Sheffield were commissioned to explore the barriers that may exist in primary care to the collection and administration of a DNA-based biomedical database by consulting with representatives from general practices.

### **Methods**

A consultation event was held in October 2000 with primary health care professionals from the Trent Focus Collaborative Research Network. The participants had received information about the Project prior to attending and on arrival. The event commenced with an overview of the current proposals for the Project and an opportunity to ask questions for clarification.

Twenty six individuals from twenty three practices participated. These individuals were predominantly general practitioners (21) with a few practice nurses (4) and one primary care research assistant.

Participants were allocated to one of five focus groups. Each group was allocated two out of five topic areas: attitudes to research; awareness of the proposed MRC and Wellcome Trust Research; recruiting subjects and obtaining consent; data collection; and access to data.

## **Results**

### Previous research experience.

- Participants had been involved in various types of research, ranging from notes-based studies to clinical trials which lasted from a few months to 3 or 4 years.
- Research was perceived as very relevant for clinical practice.
- Research was a very time consuming diversion from service provision priorities. This sometimes caused friction with non-research orientated partners in the practice.
- Recruiting in non-research practices would be an unknown quantity.
- Patients are enthusiastic about research, especially if there is a spin off for them.
- Primary care research studies usually recruit patients with diseases.
- The GP has the potential to directly affect the recruitment rate.

### Recruitment of Primary Care Professionals

- Most participants were not aware of the project.
- It was seen as very exciting, with potentially huge benefits (but the simultaneous risk of huge problems) and the participants wanted to be involved from the start.
- Currently, the Project was seen as not sufficiently clear about its' objectives and operational procedures
- There were mixed views about approaching practices through PCGs, as one or two people at board level could block access to a whole locality.
- There was no single view on how best to approach practices.
- Local champions to lead on recruitment were seen as an important investment.
- Practices must be resourced for additional clinical workload.
- Basic training about the project and genetics was seen to be required.

### Recruitment of patients

- Patients are likely to respond positively but marketing of the project is seen as crucial to its success.

- The ten year plus follow up period, an inability to specify the exact tests that will be done, the presentation of the genetic aspect of the study and commercial involvement may all affect recruitment.
- The media may help recruitment and retention by making subjects feel special, or may sabotage the whole project.
- The people most likely to participate are those who see their doctor regularly and have a chronic disease.
- The hardest group to recruit will be fit men, people in employment and ethnic minorities.
- There may be a bias towards people with a family history of illness.
- Patients need an opportunity to correct their misconceptions regarding genetics
- Emphasis should be placed on recruiting as many as possible from a smaller number of practices.
- Once recruitment has occurred, future contact from the study could either be exclusively with the GP or exclusively with the patient.

#### Project methodology

- Unconditional consent was perceived as unacceptable.
- Consent could have a number of opt out options, much like a donor card.
- A publicly funded, ongoing and independent ethics committee should oversee the Project.
- Physical space for taking blood, storage space, and getting the sample to the laboratory may be difficult.
- Paper records have information, but it is not Read coded or so easily accessible.
- Miquet software can extract an entire practice population's morbidity data overnight.
- On leaving the study, data already collected could be used with permission, archived or destroyed.
- Participants wanted to know who owns the DNA and the data.
- Grouped data was seen as safe to share with many institutions, except the insurance industry.

- Family members should only have access to the DNA and data in exceptional circumstances.
- Participants understood that the data will need to be anonymised but not anonymous.
- GPs were keen to receive any information that would help in the clinical care of their patient, but were uncertain of the harm that would come from the insurance industry.
- Feedback from the Project team was seen as important, particularly on current problems, recruitment updates, and practice specific morbidity data.

### **Conclusion**

Participants were generally positive about the Project and thought that their patients would be too. However, clarity on objectives and operational procedures and reimbursement for extra workload were seen as crucial for the success of the project

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## **Background**

The MRC and the Wellcome Trust are proposing to fund a joint project to collect DNA from half a million adult volunteers aged 45 to 65 year of age in primary care. This DNA database, in conjunction with primary care records, will provide a rich resource for studying the genetic contribution to common disease such as cancer and heart disease, drug metabolism and normal physiology.

Recruitment to the Project presents ethical dilemmas regarding informed consent. MORI polls for the MRC exploring patient opinions regarding participation in research show that most are favourably disposed. However, establishing the Population Biomedical Collection will involve the extraction and storage of patients' DNA in a DNA library to be used for as yet undetermined research. It is difficult to provide meaningful informed consent for the prospective collection of biological samples when the research protocols to utilise these samples have yet to be defined.

In addition, the process of collecting blood for DNA extraction may have a domino effect on clinical services in primary care, with more patients approaching their general practitioner concerned about their family history and any potentially deleterious genes that they carry. Primary care teams may require support in the form of genetic education and/or clinical genetics service provision as a direct consequence of establishing the Population Biomedical Collection.

The MRC and the Wellcome Trust are consulting widely to establish the ethical and other problems that may hinder the establishment of an UK prospective DNA cohort. As part of this consultation exercise, GIG (Genetic Interest Group, an umbrella organisation representing patient groups for a wide range of genetic conditions) in conjunction with the Universities of Nottingham and Sheffield were commissioned to consult with a cohort of primary health care professionals.

**Why primary care?**

To maximise the utility of any DNA collection exercise, marrying the DNA to the primary care record is essential. The United Kingdom is unique in maintaining a single set of primary care-based medical records containing all medical interactions involving a patient, whether in primary, secondary or tertiary care, from cradle to grave. To obtain access to this remarkable resource, and to provide a suitable setting for venepuncture with a view to DNA extraction, then the study needs to be based in primary care. It follows that the informed consent process and the recruiting of patients into the study will occur in general practices.

It is of paramount importance to ask primary care teams to identify potential barriers to their participation in the study, and also to identify what may prevent a patient from consenting to involvement. In addition, a consultation exercise should attempt to define solutions to the obstacles this study identifies by using the experience of primary care researchers working at the point of contact with the public.



## **Aims and Objectives**

### **Aim**

To objectively explore the barriers that may exist in primary care to the collection and administration of a DNA-based biomedical database by consulting with representatives from general practices on the MRC and Wellcome Trust proposals for an UK-based population bio-medical collection.

### **Objectives**

- To assess awareness of the proposals for the population bio-medical collection.
- To assess willingness of general practices to participate.
- To discuss any training or support needs.
- To ask primary health care professionals about their perception of potential subjects' attitudes to the research.
- To assess impact of research on participating practices.
- To discuss with practices the practicalities of the proposed research, such as recruiting subjects, obtaining informed consent data collection, data protection.
- To discuss views on whom should have access to the data and for what purpose.

## **Methodology**

Research active general practices are likely to agree to participate in the Population Biomedical Collection. Subjects were therefore purposively sampled from the primary health care teams that constitute the Trent Focus Collaborative Research Network (CRN), a network of 58 research general practices committed to complete and accurate electronic data collection, stretching from the Humber Estuary to Leicester. The CRN has a number of important differences in the type of practice when compared to Trent as a whole, but there is very little difference in annual admissions or in waiting times for operations.[1] Thus, although the GPs may be different, the populations are not.

Practices were invited to send one member of their team to a consultation afternoon by writing a letter of invitation on Trent Focus headed note paper to the practice managers. The letters were followed up by a telephone call from one of the team (RH).

The consultation event was held on Thursday 19<sup>th</sup> October 2000, in a location in Nottingham approximately central to the Trent Region. It lasted from 1.30pm to 5.30pm. Refreshment and travel expenses were provided, and one hour PGEA allowance Certificates were issued. No other financial inducements were offered.

The participants had received an information sheet about the Project produced by the MRC and Wellcome Trust prior to attending and on arrival.

Twenty six individuals from twenty three practices attended the consultation event. These individuals were predominantly general practitioners (21) with a few practice nurses (4) and one primary care research assistant.

Following an initial welcome from the consultation event organisers, the participants were given a one hour overview of the MRC and Wellcome Trust proposals for the Project, including a question and answer session for points of clarification.

Participants were allocated to one of five focus groups. Each group was allocated two out of five topic areas: attitudes to research, awareness of the proposed MRC and Wellcome Trust research, recruiting subjects and obtaining consent, data collection, and access to data. Thus each topic area was discussed by two groups.

The focus group topic guides were devised using themes that emerged from another consultation commissioned by the MRC and Wellcome Trust that had involved four GPs and four practice nurses. [2]

Each group comprised 5-6 primary care professionals and had one facilitator and one rapporteur running the group. The facilitators were experienced in facilitating focus groups were drawn from the Universities of Sheffield and Nottingham and co-ordinators of the Trent Focus Collaborative Research Network, and will be. The rapporteurs were representatives of the MRC, Wellcome Trust and Genetic Interest Group.

The consultation event was concluded by a plenary feedback session.

The focus groups were transcribed, and field notes from the rapporteurs added to the transcription. A qualitative data management software (Nudist) was used by two of the research team (RH and DS) to analyse the data. Constant comparative analysis was used to generate themes, which were validated by revisiting the data. [3]

## **Results**

### **The nature of previous research**

Participants had been involved in various types of research. Some had participated only in notes-based research where the patients were recruited in secondary care, some had studied the health and social needs of the local population and others has taken part in drug company trials with what was perceived as excellent support from the industry. Studies had been clear in what was expected of the patient, and had lasted from a few months up to 3 or 4 years. Some participants had experienced media coverage of the results of the studies they have been involved in, but did not report any adverse repercussions from their patients. Some had seen patient care changed for the better as a result of the research they have participated in.

### **Attitudes to research**

Participants discovered through involvement in previous research that there are hidden costs that can cause friction in general practice partnerships. Most participants were research active and were research enthusiasts. Other partners within their practices increasingly have other commitments and outside interests such as Primary Care Group (PCG) work or are not as interested in or as motivated by research involvement.

Research was very time consuming and was a diversion from service provision priorities for primary care professionals. Locums were difficult to find and to fund. Participants considered themselves as doing two jobs for the price of one with research encroaching upon service provision and home life.

They recognised that they were key people without whom the research would not occur. They described research as interesting, extremely important and a positive experience, particularly when using a multidisciplinary approach. For most participants, research is something they would like to do more of.

Participants described some health authorities as having research low on their agendas, with one example of a health authority withdrawing funding for research infrastructure without informing the practices. Culyer funding was seen as extremely important, and something that Trent Region had done particularly well in attaining.

Participants did not consider taking part in drug trials unless there was the possibility of some benefit for the patient. They expressed a view that only good research should be done in their practices. Participants perceived themselves as overwhelmed with requests for participation in research, and felt a pressure to select only quality projects. They felt research was a necessary activity for obtaining evidence and that the primary care research capacity should be expanded and developed. The participants felt that primary care should foster a good reputation for research and did not wish to see research as a compulsory step in the training of a GP as it is currently for hospital consultants, as they believed that this leads to poor research in some cases. The participants did not wish to see the roles of clinician and researcher as distinct or separate. Research was perceived as very relevant for clinical practice in primary care, especially in developing an evidence base for the primary care population as distinct from a selected secondary care population.

The participants perceived secondary care physicians as holding the view that research (and sophisticated care) is their domain and not the general practitioner's.

Participants held the view that non-research practices consider research as an academic pursuit far removed from the reality of general practice, and that recruiting patients in such practices would be an unknown quantity. Non-research practices are thought to view the time spent on research by Trent Focus practices with suspicion, and are thought to be defensive about research in general as the evidence-base may threaten their way of practice, with many still tending to use a colleague as a point of reference on clinical practice as opposed to a research paper. One participant recognised from their own research that many primary care professionals profess to use references for an evidence base, but do not in practice.

### **Patients' experience of research**

Patients were seen, from experience, as being generally enthusiastic for research, especially if there is a spin off for them as individuals. There were mixed experiences on how successful studies had been in retaining patients, with some trials having poor adherence and a high drop out, and others the opposite. Some participants felt this was due to the way the projects had been sold to the patients. Patients were perceived as believing themselves to be testing something new that would be of direct benefit to them or somebody else. Primary care research studies usually recruit patients with specific diseases. Some participants felt that patients who have not got a disease may worry about where the information about them is going, and how it may affect their insurance or mortgage. Some participants expressed the view that this Project should be sold positively as it would not be beneficial directly to the patient.

Patients sometimes attended their GP with a recruitment letter asking whether they should participate or not in a study; the GP thus had the potential to directly affect the recruitment rate. It was also noted that if the GP did the recruiting in person, then a given patient may be more likely to agree to say yes there and then, but to subsequently drop out of the study. Some participants held the view that it would be better for GPs to invite patients to attend a recruitment session, but for that session to be hosted by a third party.

From past experience in research, participants agreed that a minority of patients may be put off enrolling for the study by the invasiveness of a blood test, but for the majority, it was not seen as a problem, the participants believing that their patients would want to know their cholesterol level, for example.

Some participants described how patients recruited to other studies accepted questionnaires as part and parcel of the research process and do not question where the information was going. However, the use of language was found in some cases to be inappropriate, with some patients contacting their GP for clarification. Good response rates (96%) were seen in some studies where the questionnaire was from a member of the practice team.

### **Prior awareness of the Project**

Most participants were not aware of the Project before being contacted to participate in the focus groups and had not seen any of the media coverage or other sources of information. Some participants thought that The Wellcome Trust was part of the same organisation as Glaxo-Wellcome. One participant seemed to confuse the Project with the Icelandic genetic database. Some said that they were not aware of the enormity of the proposed Project prior to attending the focus groups.

### **Attitudes to the Project**

This Project was seen as very exciting, with potentially huge benefits (but the simultaneous risk of huge problems) and the participants wanted to be involved. Being involved at the very start of the Project was seen as being advantageous. Some participants held the view that they would like to see their practices participate and would advertise this by a notice in reception, but would not want their own staff involved in the Project work. They highlighted the need for good quality evidence linking lifestyle to disease but expressed the view that currently, this Project is exploring new territory and is not in its present form sufficiently clear about where it's heading.

### **Understanding of the purpose of the Project**

The participants generally appeared to have a good understanding of inheritance, how earlier age of onset of a condition makes it more likely to be genetic and how a result can affect a whole family. Equally, the appreciation of the importance of the gene-environment interaction, and how together they mean much more than each on its own, was generally good. A minority of participants had an excellent understanding of DNA sequences, and how they can be used as a marker for a disease gene by virtue of the founder effect. However, some participants had unrealistic expectations of what is currently possible, such as feeding back genetic profiles on patients to GPs along with factual information on patients' relative risk of diseases.

Participants appeared to have a good understanding of research methodology in general, but some were unclear as to the basic design of this Project even after a presentation by

the Project Team. Some participants seemed to think of the Project as a randomised trial with a genetic test, an intervention to modify risk and a specific end point. A few seemed to confuse whether patients would be well or already have diseases on recruitment into the Project. A few participants also seemed to underestimate the size of the Project, although most appreciated that it would, of necessity, be a national cohort.

The participants were clear about the need for explicitly detailing what the minimum data set is to be, and expressed the view that the design of the Project seems currently a bit vague. Some expressed the desire to be re-consulted about the Project once the protocol was a bit tighter, as they felt they were guessing at some of the less well defined issues.

The uncertainty of future developments was seen as an issue in several ways. For example, if the possibility to switch off a gene for breast cancer arose for those with a particular genotype, could the NHS afford it? Also, if biotechnology advances to the degree that supermarkets have probes that give a risk profile, then the possibility of the Project becoming obsolete was identified. This was not, however, seen as a reason for not doing the study.

### **Recruitment of practices**

There were mixed views about approaching PCGs. On the one hand, getting a whole locality to agree to be involved could be seen to be advantageous. However, it may only take one or two individuals at board level to block the whole process. A number of models for recruiting practices were described. Firstly, some favoured a face-to-face conversational approach by someone from the research organisation coming to the practice. This seemed to be favoured by participants who were concerned that their reading of any written information would be inadequate, and they may miss points that would impact on their practices. Secondly, some advocated an approach using predominantly written materials by letter, as they found this approach helpful because it would be difficult to convene a meeting with all the partners at the same time. Thirdly, some favoured a two stage process: either meeting first to mull things over followed by a formal written approach, or vice versa. No single view was widely held. Some felt that



the approach should be made to the whole practice team, including practice nurses, as the nurses may be doing the research work. Clearly, different approaches suit different practices and a knowledge of the local practices would be helpful. One view that was widely held was that a local champion was thought to be a good investment, from whom Project information and enthusiasm could cascade out. This same person may act as a contact point for PCGs.

### **Incentives to participate**

Participants highlighted the need for adequate resourcing of practices involved with the Project. Practice staff were already working flat out, and there was no perceived extra time and little space within the clinic available to the Project. Workload implications were perceived in a number of ways: firstly, the Project was seen as having the potential for creating a demand for a test that does not yet exist; secondly, newsletters about the Project may increase the consulting rate of participants; thirdly, as primary care changes, such as increasing computerisation and link up to NHS net, or as scientific advances occur in other fields then the requirements of the Project may change with time, and this needs to be resourced properly or the Project runs the risk of becoming obsolete.

The groups strongly agreed on the need for incentives that resolve any funding or resource issues. Participants expressed the view that they are not looking to make a profit, but that working purely on goodwill has been used up. They wished to know how their time was to be paid for because if they were not to be paid, then they would do something else. The participants also stressed that resourcing is not simply money, but also personnel, buildings and protected time for training and education on Project-related issues, and that any direct consequences of the study required funding. The participants did however point out they were already involved in research and had given up an afternoon, unpaid, to attend the focus groups and that they were the enthusiastic ones in their practices.

### **Staff training and support**

Some participants felt that linking the Project presentation in with the educational agenda by teaching about primary care genetics may enhance practice recruitment. Basic training was seen to be required, particularly on information giving, in order to prepare the practices for eventualities. If practices nurses were to be the point of contact, then they were seen as needing training in basics such as the nature of anonymised data.

Participants recognised the need for education in genetics, perhaps as part of a personal learning plan. More specific genetics training was seen as necessary to allow practice teams to learn what genetics is about and how to pass it on to patients in lay terms. Training about presenting risk was seen as needed if practices are to be required to give patient specific feedback from the study. They felt that practice nurses should also be trained, and an effort made to put genetics on the agenda for all practices regardless of whether they wished to participate in this study or not. However, some participants, whilst admitting to a quest for knowledge, had no time to do anything extra.

### **Other support**

Some participants perceived themselves as already supported in clinical genetics by their genetics teams. However, the point was made that local genetics counsellors may not cope with the demand if a significant finding comes from the study. Clinical genetics was recognised as an obvious growth area. Comments were made that this has been known for a long time, but not much has happened.

Some participants saw the need for a dedicated telephone helpline, especially if the GP had limited involvement after recruitment and the Project team dealt directly with the subject. Some suggested NHS direct as a possible 24hrs helpline with nurses available to follow an algorithm on computer.

The internet was seen as a useful support medium. Visual aids to assist in talking about DNA and other issues were seen as desirable.

### **Other work implications for primary care**

Participants felt that genetics consultations are likely to increase as a result of this study. Some felt they were increasing anyway, mentioning breast cancer in particular. Participants feel this is a reflection of a change towards a preventative, risk factor based form of medicine.

As a direct result of the study, there will be an increase in testing and information requests, especially if feedback of patient-specific material occurs. Some participants, however, felt that this was the responsibility of the researchers and they should have a panel of specialists to deal with it.

Patients may wonder why, having spent an hour with a nurse at recruitment, they are asked to leave after 5 minutes with the GP. Some subjects have been noted to expect special treatment from the GP for participating in research in the past. If there are any unanswered questions from the recruitment process, it is likely that subjects will book in to see their GP.

Any hypertension, diabetes or hypercholesterolaemia detected at recruitment will have to be dealt with. Patients not in the study may hear about the cholesterol test and “MOT” at recruitment and may attend surgery requesting them. This, and the other extra work, will require funding.

### **Likely patients’ views on this Project**

On the whole, participants felt that patients would enroll in the study, if it was properly explained and if all their questions had been answered adequately. It was generally thought that patients’ responses to this Project would be determined by providing the right depth of information at the beginning in the right format and that marketing of the Project was seen as the key to its’ success.

Participants also felt that the ten year plus follow up period, any possibility of feedback on life threatening disease risk and an inability to specify the exact tests that will be done will all reduce the recruitment rate.

Patients' responses to the Project may also be determined by how the genetic aspect of the study is presented. Some felt that the mention of genetics may cause patients to worry unnecessarily, particularly if a stranger wanted a blood sample for DNA, and that it should be played down. However, the participants clearly saw the requirement to be open and honest and hence avoid suspicion as the Project progresses. Probity was seen as having a direct effect on the recruitment not only to this Project, but also to future projects in the same field as a knock on effect. Some participants also seemed to infer that payment from third parties for access to the data may affect recruitment or retention of subjects. Some felt that the policy regarding payment for data should be made clear to patients at the outset.

Participants also mentioned that the degree of feedback from the Project to individuals needs to be clarified and any potential gains for the patient identified, as these may improve recruitment. For example, some patients might find it interesting to receive cholesterol results. Some participants felt that insurance issues would not be a barrier to recruitment for the age group of subjects being considered for the Project.

### **Public awareness and the role of the media**

The public was thought to be aware that the scientific community is beginning to look at genes in a different way, in particular gene-environment interaction. However, it was felt that the public currently has no awareness of this Project and that unless the public do know about it, recruitment will be difficult. They felt that the media have a very important part to play in that a lot of positive coverage would help recruitment. In addition, it may help retention of recruits by making them feel special. Equally important, however, was the possibility that negative publicity, such as that experienced by the Icelandic database study, may sabotage the whole Project. They felt that whether the media chose to present the Project positively or negatively to the public was

unpredictable and that getting awareness of the Project into the public domain would not happen overnight. There was concern that some elements of the press were only interested in sensationalism and scare stories, such as police forensic testing, paternity testing and Dolly the sheep, and that this approach will not be helpful to the Project. Some participants felt that public attitudes were largely determined by this element of the press and certain television programmes and films. Participants saw current public genetic knowledge as being rife with misconceptions derived from newspapers, such as “we only have genes when we are sick”. In addition, the media has the potential of creating the demand for genetic testing where none exists. The participants felt that GPs are well placed for dealing with such public problems, as they have experience in dealing with such events in the past e.g. contraceptive pill scares.

### **Characteristics of likely subjects**

It was noted that there were certain individuals who were recruited to every research study, others who may be a bit scared by some studies, and others still who are unwilling to participate in any. Some participants recognised that they see a distorted picture in that most studies they have been involved in have included patients with diseases, and the patients have stood to benefit from the study. Moreover, the patients have been individuals in contact with them in a doctor-patient relationship. In contrast, participants recognised that this study would like to recruit those very people who rarely come to see them i.e. healthy individuals. Participants felt that a one-off visit with follow up mainly through collecting data from the GP records would facilitate recruitment of this group.

Some participants felt that there may be a social class bias, in that “salt-of-the-earth” working class people would be more likely to enrol in the study than “professional types”, but not everyone agreed with this. Some felt that asking patients to present themselves following an invite would lead to social class bias, but others shared experiences from their own research where recruitment with a good socio-economic balance was achieved, partly by offering recruitment sessions outside working hours. This was also seen as a solution to biasing against the employed, which may occur if only daytime appointments were offered.

Some participants emphasised the importance of keeping recruitment information in simple language so as not to marginalise parts of society. Difficulties had been experienced with past research in recruiting and communicating with different ethnic groups. The importance of overcoming these barriers in order to ensure that study populations are representative of a multicultural society was emphasised. For example, participants have experienced different responses to previous studies on haemoglobinopathy screening from Afro-Caribbean and Cypriot communities.

Participants recognised, in particular, the potential difficulties in recruiting fit men of the desired 45years to 65 years age range who do not usually consult with their GP. Conversely, GPs have a good relationship with women of that age due to a lifelong relationship through contraception and childbirth. One suggested solution was to recruit men through their partners.

Some participants felt that there may be a bias towards people with a family history of the conditions highlighted as of interest in the study information, as patients are more likely to come in if they are a little bit worried about something. Similarly, those with personal experience of illness were thought to be more likely to enrol in the study.

Experience had shown that busy people have difficulty finding the time to enrol in studies. The time required by the study was a concern as some participants felt that even those patients with apparently nothing else to do seem to spend their lives running round in a rush. Consequently, individuals will be aware of how much time the study is asking for.

### **Information for Patients at recruitment**

Participants mentioned specific suggestions such as putting what the Project hopes to achieve and its benefits right at the top of the recruitment letter, with the letter coming from the general practitioner. The view was also expressed by some that any information should not be too long.

Participants recognised some patients (especially lower social class) as being more likely to trust their doctors' opinion on research than others. Another factor that influenced whether the doctor's opinion was trusted included whether the patient came to see the doctor for an illness. Non-attenders were therefore seen as having different information needs to attenders, as they were perceived as less likely to take the doctor's word that the study was worthwhile. Non-attenders were perceived as being more likely to want face-to-face explanation in addition to any written materials.

Some participants believed that the more detailed the information, then the better the recruitment rate. Others held the view that a balance is necessary, giving sufficient information on the invitation to answer most worries about participation, but having further information available as necessary.

Some participants considered that patients have misconceptions and some have poor knowledge of genetics and that, if they are to participate, there need to be opportunities to correct these if the patient wishes. Examples of ways of providing the necessary education included a freephone number and an internet site. The advantage of a freephone number was perceived to be that a patient had to have a specific question in order to pick up the phone. The internet has the advantage of providing detailed information in an accessible format. However, participants acknowledged the potential danger of too much information with too little health-related knowledge leading to anxiety and the creation of a worried well population. They also acknowledged the possibility that patients with no specific concerns may choose to casually surf the web page and generate a whole series of questions they previously did not have.

Patients were perceived very definitely as having questions that needed answers. Some participants felt that patients would not like uncertainty, and would require information as to when and why their blood will be tested. Participants felt it should be possible to give scenarios of future research projects on the database, at least giving a flavour of the types of tests that will be done. Some felt more than just basic genetic information needed to be available.

Participants found it difficult to give a time as to how long it will take to obtain consent for the study. They felt that the time could be reduced by giving sufficient quality information before the recruiting interview, thus having the spin-off that the interview could then concentrate on answering questions that the subject had brought along. However, they illustrated the dilemma by saying that some people may take 30 seconds, whereas others may come in with detailed questions about small parts of the information.

Participants felt that the nature of the scientists running the study should be clear and apparent to the subjects. They should be open, honest, respectable, reputable and seen to act in an ethical way. The participants felt that it was important to be able to tell patients that they will not come to any personal harm as a result of this study.

Patients should be made aware of the fact that if they do not develop one of the conditions of interest, or if they do not fit the criteria for a control case, then their DNA sample may never be tested. This information needs to be available at the beginning of the study. Participants recognised that their patients can make enormous assumptions about blood tests and these assumptions need to be corrected at the beginning of the study.

### **Recruitment of patients**

The practitioners present expressed the view that they perceive their patients as being their responsibility, and they are in the position to invite other people to see their patients, such as secondary care consultants or research teams.

Some participants felt that letters are the best recruiting approach, particularly where GP headed notepaper is used from the practice where the patient is registered. There was agreement that well patients who received a letter from the Research Group rather than the practice are quite likely to throw the letter away. GPs commented that they often simplify the letter before it goes out to their patient, and that patients feel secure that their GP has checked the study out and not given their address out to anyone if the letter comes on headed paper. The disadvantage is that any queries are then directed to the practice.



Some populations were recognised as being unlikely to understand a scientific leaflet, and participants felt that these populations would respond better to direct talking. This would require either recruiting during GP consultations, which participants have had bad experiences of, or training of nurses. Some participants saw other benefits in the face-to-face approach, such as making the subject feel special and so making it more likely that the subject will stay in the study for the duration. Some GPs were worried about the concept of outside nurses coming into their practices, whereas others felt that it would not put the patient off.

Some participants felt that, rather than trying to recruit a few relevant individuals from very many practices, it may be better to concentrate efforts on fewer practices and attempt to recruit as many as possible of the practice population. Once recruitment has occurred, there were mixed views as to the degree the patient or the practice needed to be involved. Some held the view that the patient no longer needed to commit much time to the Project, and that follow up morbidity and lifestyle details could be obtained from the primary care records. Others held the view that communication could be entirely with the patient thereafter via questionnaire, and just the initial invitation needed to occur in general practice. Some participants felt that costs should be reimbursed to practices dependent on the number of patients recruited.

Some participants, whilst recognising that primary care is certainly the best setting for data collection, suggested alternative methods of recruitment, such as through blood transfusion centres, where fit, healthy, altruistic males may attend, and at factories or work places.

Participants also identified paying patients, perhaps in kind as sessions at a local leisure centre, production of a recruitment video or the use of the family history to identify those more at risk as recruiting strategies.

## **Consent**

Unconditional consent was perceived as rather like asking someone to sign a blank cheque. No one recommended it. In addition, participants felt that, in view of the inability to anticipate all future developments, to ask patients to agree to everything is not acceptable. The groups clearly felt that unconditional consent is simply not informed consent.

Participants felt that the study should get consent for what it definitely wanted. It may not know the exact test, but a broad description could be provided. Participants felt that there should be certain guarantees, such as no DNA fingerprinting for the police apart from in exceptional circumstances. Also, any plans to profit from the research should be aired at the consent stage.

In view of the fact that, for some subjects, illnesses and events may change how they feel at recruitment, then each stage of the Project needed a fresh consent, i.e. each new collection of information needed consent and each new DNA test needed consent. Moreover, there should be the opportunity for subjects to rescind their consent.

The consent on each occasion could contain a number of options, much as an organ donor card allows the bearer to opt out of donating certain organs upon their death. Consent should also be obtained for lifestyle information as some questions can be extremely threatening, such as questions about sexual behaviour in the individual. Consent for receiving person-specific feedback from the study would also need to be discussed.

## **Ethics**

The participants strongly expressed the view that the focus groups were not the appropriate forum for defining or deciding the ethical agenda. However, a number of views were expressed. For example, too many limitations on the study would render it not worth doing, as the whole point is to generate a large database of medical and genetic information available as a resource to all. The participants felt that an ethics body, publicly funded, ongoing and independent, should oversee the Project and ensure that the

information remained under public control. Participants felt that the research protocol was likely to be complex and would require several iterations of consideration by an independent ethics committee. Faith seemed to be expressed in Local Research Ethics Committees (LRECs), though one comment was made that there are generally quite a few doctors on them. An independent overall ethics committee could also act as a safety net against subtle shifts such as in the focus of the research following medical advancements, and shifts in public policy with changing access to the data.

### **Collection of DNA**

Obtaining the blood for the DNA, though a crucial step, was seen as a relatively minor part of the recruitment process. The participants saw everything that goes before it as the main problem. It was thought that blood collection would take about five minutes. There were several issues raised however. On the whole, participants felt that the phlebotomist should be a practice nurse or a research nurse from the Project. Costs could be kept down if it were a research nurse, as it would be expensive to employ GPs and practice nurses to do this, and the same individual could be trained to answer questions from the subject. Moreover, blood taking was seen as part of a natural process and the next step on from consent, which would be done by a nurse (practice or research).

The blood taking was seen as best done in the surgery. A number of other scenarios were considered, such as at home (not popular due to the possibility of strangers going into homes), in the car park (marquees or Portacabins) or at a designated research centre, but all received only brief mention. Surgeries do provide constraints. For example, physical space may only be available during the evenings once a surgery day has finished. Not all surgeries have this problem, however, with some having space left over as a result of loss of services when fund-holding collapsed.

Storage space may be required for the samples at the surgeries, and perhaps facilities to spin down the samples. Collection points and times would need organising. Friday evenings may pose difficulties if the laboratories cannot process the sample for more than two days.

### **Collection of Lifestyle data**

Some expressed concerns about the degree to which repeated data collections would occur. Lifestyle data is routinely collected in primary care all the time. Participants raised the question as to why it needed to be collected specifically for the Project. However, not everybody had the data collected, and the validity of the data may be sometimes questionable.

Non-attenders to surgery will not have up to date lifestyle information, and these are the very people whom the study wished to recruit. Computerised data is common place now in general practice, especially in research networks such as Trent Focus. However, lifestyle information was not complete and accurate to the same degree as the morbidity or prescribing data. Patients were thought to leave out some details when giving lifestyle information to practices, particularly as what patients tell the practice may be seen subsequently by an insurance company. Some participants felt that patients may tell nurses more than doctors, and may be even more frank on a questionnaire.

It seemed to participants that a third party may be required to collect lifestyle data. The process was envisaged as two stage, with an initial questionnaire and a follow up interview. This would save time (perhaps only needing 20-30 minutes for the interview) and lead to richer and perhaps more valid data. If the person performing the interview was a research nurse, subjects may well perceive them as being part of the practice team. Thus research nurses may be presented with problems that are medical in nature and not related to the Project. In addition, during the Project interview, hypertension or diabetes for example may be detected. Participants had very real concerns as to how this information should be dealt with, and what responsibility the research nurses had. Some participants felt that, in order for the lifestyle information to be valid, the subjects needed to know that the GP did not get the data. However, participants felt that the research nurses should have a clearly defined role and responsibilities, and should have protocols to work from so that really important issues such as hypertension or other risk factors were brought to the attention of the GP. The nurse could complete a letter, a copy of which is given to the patient, and they then had the option of giving it to the GP if they so

desired. The nurse had thus discharged her responsibility and it lay with the patient. The remaining dilemma then is, if the patient chooses not to give the information to the GP and something untoward happens, who is responsible? Participants rationalised this by observing that patients frequently ignore the advice doctors give them regarding medication and informing the Driver Vehicle Licensing Authority (DVLA).

### **Collection of morbidity data**

Participants were very sure that the quality of morbidity data in Trent Focus practices was excellent, and probably better than in secondary care. Their confidence seemed to stem from the validation runs that Trent Focus had performed on the practice electronic databases for five major diagnoses. In addition, participants mentioned their ability to validate their morbidity data against electronic prescribing records. Participants were more certain of diagnoses such as myocardial infarction as opposed to more ill-defined diagnoses such as angina. Participants were aware that mortality data may be flawed as post mortems are not always performed in the community.

Some inaccuracy in the electronic record was inevitable, and was likely to be due to inconsistent allocation of Read codes, or in placing a diagnosis in non-active rather than active problem lists. However, participants had taken steps to minimise these. Paper records had all the information, but were not coded and thus the information would require extracting by a researcher, with resource implications. In addition, practice staff needed to pull the notes and put them back again. Medical staff are increasingly less willing to grant access to paper records when a predetermined minimum electronic dataset could be extracted from the practice database and anonymised for removal from the practice with one run of a computer software programme. Clearly which method is used depends on the technology in the practice. For Trent Focus, a practice is not a member of the network unless its' data quality come up to a certain standard.

Miquet software had been used previously by the participants to extract data from notes. It allows similar searches to occur on different systems, and allows the results of those

searches to be combined. In terms of its' application in this Study, an entire practice's population can have its' morbidity data extracted overnight by running a search.

### **Longitudinal follow up**

Participants were aware of the need for a system to be in place for the duration of the study. This may be threatened by changes in the electronic patient record, particularly the NHS net and the possibility of patient-held electronic records.

Participants considered the risk to continuity of follow up by patients moving practice. Subjects may move to a practice not involved in the Study. Participants felt it was the practices prerogative to not be involved in the Study, even if the patient wished to be. However, one idea for overcoming the barrier could be if practices were paid for filling out a morbidity and lifestyle form not dissimilar to insurance forms at intervals during the follow up period. Participants saw practice recruitment as the key at the beginning of the study, but thereafter, individual patient contact was seen as more appropriate. Alternatives to GPs filling out an insurance-type form included questionnaires to patients and home visits by researchers. Alternative methods of follow up such as patient diaries were not thought to be good. Clearly, if large numbers of patients were in the original practices, then electronic updates could occur. In addition, the Project would be sufficiently large that it may be possible for a patient to switch from one research practice to another during a move. Participants were keen to point out the costs incurred in preparing follow up data, and wished for that work to be recognised financially.

Drop out from the study was thought likely to occur for a number of reasons. Firstly, boredom over a long study. Secondly, an argument between doctor and patient. Thirdly, the patient having a change in circumstances, e.g. change of name or address. Sometimes the doctor may move practice. Participants mentioned a number of strategies to encourage patients not to drop out. These included remuneration either in money or vouchers, a newsletter updating them on the study and a high profile on the media making the subjects feel special.

Clearly, patients should be allowed to leave the study if they wished. It should be established at the outset what the options are should someone choose to leave. For example, one option may be to give consent to continue to use the data that has been collected thus far. A second option may be to archive the data, or even have the data destroyed, including the DNA.

### **Access to the data**

Information on access to the data needed to be given to subjects. Subjects were perceived as having concerns about retaining control over the distribution of what was previously part of them, i.e. the blood sample.

In addition, participants felt that their patients would want to know where this data was going as they may take umbrage at it going to certain organisations, such as insurance companies. The participants were keen to know who owns the DNA and to whom would the information from the study be potentially sold. In general, they thought of grouped data as safe to share with many institutions, but not individual level data. Universities were seen as potential recipients of the data, but named data needed to be held safely. Pharmaceutical and biotechnology companies on the other hand were only to receive grouped results, not individual level data, and certainly not the DNA. Participants recognised that commercial interests are needed if anything substantive is to come from the Project. However, patenting of genes should be avoided, and no single company should be given exclusive access to the data.

Insurance companies were not thought of as potential recipients of any form of data. Participants wondered if there could be an agreement reached with insurance companies such that they will not ask questions relating to the Project. It was recognised that many of the Cohort will already have their mortgage and insurance organised, although the increasing divorce rate may put some of the cohort at the mercy of the insurance industry.

Some participants felt there should be a guarantee that the criminal justice system won't have access to the DNA database. However, others felt that, in very exceptional

circumstances, for example where a mass murderer was suspected to be a 50 year old male living in the practice area of one of the research practices, then they would like to allow the police access to the DNA for protection of other people. However, they did not know if their colleagues would agree with them and they weren't sure of their legal standing in doing that (they would consult their medical defence organisation).

Generally, participants did not see the need for family members to gain access to the results. They felt the results were patient specific and in addition any research tests performed on the DNA would not have been quality controlled for clinical interpretation. Some participants felt that other family members knew if a condition is inherited. Some participants highlighted two situations where the study may need to intervene. Firstly, where a person is rendered unable to communicate by his condition and that condition is known to have implications for family members, then the relatives should be told. Secondly, if a patient dies and did not wish to know that he had an inherited aspect to his illness, and the study is aware of this, then after death it may be relevant to let the offspring of the deceased know of the condition via an alert from the Project.

### **Data protection**

From the outset, patients needed to be aware that anonymity cannot be maintained as patients need to be followed up for years. However, the data will be anonymised and confidentiality maintained and these too would need to be explained. Data protection procedures should be scrutinised by an ethics committee. Practice databases, however, are clearly part of the NHS system and as such may in the future be open to remote access from within the NHS net. Participants seemed to trust the experts to erect sufficient security arrangements. They also acknowledged having two levels of data. Some wrote information in the paper record that they would never put on the computer, such as some family dynamics issues or some disclosures about traumatic past events. Others are paperless and do write everything on the computer, with little clues to remind them of the salient issues that would not mean anything to a different practitioner. Participants were reluctant to fragment the medical record into different parts as they felt it ran the risk of some bits becoming lost.



### **Feedback to GPs**

Whether GPs or subjects should have access to the results is related to the debate on whether the Project should give any form of individual level feedback to primary care. Participants felt in general that as medical practitioners they would welcome any feedback that may assist in the medical care of their patient, but as a gathering source for the insurance industry they were uncertain of the potential harm that may come from receiving such feedback. An alternative model that was considered was where feedback went directly to the subject and s/he decided whether to make it available to others.

Feedback from the Project team was thought to be important. Some participants expressed a wish for feedback from the Project as it progressed on current problems, such as any subjects who have had difficulties with insurance. Newsletters were thought of as useful by some as a medium to inform about recruitment updates, whether targets were being met, and informing the participating practices on wider issues in order to prepare them for any questions from patients. Some participants thought newsletters might go in the bin if no one from the practice was directly involved in the research however. In addition to this, participants may require feedback specific to the practice, such as which patients have been accepted into the study, which have dropped out, what the cholesterol levels are of participants and practice morbidity and mortality profiles. The participants also expected to be kept informed of publications resulting from the research.

### **Feedback to patients**

Participants had interesting debates on the issue of whether or how the Project should feedback patient specific information to the subjects. There was a perception that the research team has not yet decided this issue. Participants felt that they were obliged to record information that materially affected their patients' health in the medical records and that, provided they understood the information, some were happy to feed back to the patients themselves. Some participants considered alternative models of feedback, such as a third party (e.g. researcher) giving the patient information, and the patient was then empowered to decide if s/he wanted the GP to have this information. This model was currently seen as operating for HIV testing, where patients attended genito-urinary

medicine clinics and that consultation does not appear in the primary care record. The disadvantage to this model was seen as that the third party would not have access to the whole of the patient's medical story, and may not be able to weigh the importance of the information sufficiently. There was agreement that this was a difficult issue to resolve, but that some post-information counselling may be required.

The participants were clear about the necessity for establishing ground rules for feedback at the very beginning of the Project. Participants felt that if there was to be no feedback, then this needs to be made clear and the Project sold on the platform of it being for the benefit of future generations. Some participants pointed out that the purpose of the study was to identify what are the risk factors for developing certain conditions and thus the results would not be able to help those already in the Study. Some felt feedback of cholesterol levels may be justified. Some pointed out that no feedback meant no trouble with insurance companies.

Some participants felt that if feedback of individual patient data was anticipated, then specific consent would be required for this which patients could opt out of at the beginning of the study. The participants also felt that there should be the option of opting back into receiving feedback if the patient wished, as some participants imagined scenarios where a patient's relative dies at a young age from a stroke, and the study is looking at stroke gene-environment interactions. Participants felt that patients should have a choice through informed consent at the beginning of the Study as to whether they would like to receive their DNA result under certain circumstances e.g. the Study discovers gene-conferring mutation but no treatment; the Study discovers gene-conferring mutation and treatment. Participants felt most subjects would accept the latter of the two options. Some participants did not want to receive the DNA result of their patient, whereas others did in case of a miraculous breakthrough in treatment. They felt the main database could be de-anonymised in those circumstances in order to identify individuals who may benefit and who have by informed choice indicated that they wish to know.

## **Conclusions**

### Previous research experience

Primary care research studies usually recruit patients with diseases. Thus any study attempting to recruit healthy individuals cannot rely on tried and tested methods of recruitment, as they may not succeed in recruiting the desired population. In addition, most research in primary care tends to occur in dedicated research practices with key individuals in those practices ensuring the work occurs, and recruitment in non-research practices is an unknown quantity. It is recommended that the Project uses research network practices if possible, only using other practices if necessary.

### Recruitment of Primary Care Professionals

Participants were not aware of the Project. Moreover, even after a presentation on the Project, there seemed confusion about the nature of the Project itself and the bodies funding it. It is recommended that the Project Scientific Committee clarifies the specific research questions being answered by the Project, defines the minimum dataset that will be collected on all recruited subjects and acts on the wishes of the participants in these focus groups by re-consulting with them once the protocol is more established.

In order to effectively recruit practices, it is recommended that a local champion is employed by the Project in each regional centre. This individual would ideally be someone with knowledge of genetics that also knows local practices and is able to tailor recruitment approaches to suit the needs of each practice. In addition, it is recommended that attention is paid in particular to the matter of reimbursing practices for personnel, buildings, protected time for training, and additional clinical workload secondary to the study.

### Recruitment of patients

The success of the Project will depend upon effective marketing. It is recommended that individuals or organisations trained in public relations are asked to deal with the media and to market the Project.

Healthy, middle aged men were seen as difficult to recruit into the Project. It is recommended that a number of recruiting strategies are used to overcome selection bias including offering recruitment sessions outside working hours, recruiting men through their partners, offering payment in kind and producing recruitment information in a range of formats and media (including video) to avoid marginalisation of parts of society. It is recommended that the Project provides a freephone number for patients to ring with questions. A Project internet web site should be evaluated.

This study concludes that GPs are in a good position to recruit well people to research, and that letters are the best recruiting approach. There is a significant body of literature that relates to recruiting approaches and raises important issues. Some researchers have found, for example, that up to 22% of a sample drawn from a general practice-based register had the wrong address.[4] Local bodies are likely to obtain a higher response rate in their local area than a central organisation,[5] and letters that appear to be sent by commercial organisations may be put directly in the bin without opening.[6]

Participants recommended providing a significant amount of well presented information about the study for subjects to read prior to recruitment. Information in advance can increase participation, particularly where confidentiality and the value of the study concerned is explained, but equally it can decrease participation because it gives people more time to plan their refusal.[7] On balance, subjects should be provided with as much information as possible in a simple and attractive format, as this will reduce the amount of time for explanation and questioning at the recruitment interview, and a well informed subject may be less likely to drop out of the study at a later date.

Participants in this study felt that patients would agree to be subjects in the Project provided that all their questions had been adequately answered. Some participants believed that patients had taken part in studies as a result of a perceived personal benefit, and that this Project would not bring personal benefit to the subjects. A study on health in the Shetland isles following a tanker grounding found that the main reasons for non-response were attitudinal rather than situational or organisational. Non-responders did not

feel their health was affected, were not interested in the study or did not think the study was useful.[8] It is recommended that significant resources be directed towards promoting the Project as an investment for future generations.

Some parts of the Project may be seen as threatening to some individuals, such as the presentation of the genetic aspect of the project, and access to the database particularly by insurance companies. Clearly, those with a family history of illness may have the most to fear but also to benefit from such aspects of the study.

Participants recognised that there are often communication difficulties between primary care and different ethnic groups, even when the professional and the patient both speak English as a first language. Previous research seems to suggest that these difficulties in communication may translate into lower recruitment from ethnic groups into studies. For example, in a survey on dental health, the response was higher for white children (65%) than for Asian (39%) and Afro-Caribbean children (45%).[9] Asian mothers have been found to be under-represented among those responding to a national postal survey of maternity services.[10] It is recommended that, particularly if the Project wishes to study every gene pool present in the United Kingdom, an effort is made to create information materials in a format that will engage and inform different ethnic groups. This may involve videos and written material.

The participants felt that offering a range of appointments at times outside normal working hours, and of a reasonable length, had ensured a good socio-economic mix in recruited subjects in the past.

### Consent

Participants felt that unconditional consent was rather like asking someone to sign a blank cheque, that it is not informed consent and therefore is not ethical. They also felt that the study should get consent for what it definitely wanted rather than leave things vague. Consent needs to be obtained for lifestyle information, receiving person-specific

feedback and for collection of new data at each stage of the Project and could have a number of opt out options, much like an organ donor card.

### Ethics

Participants did not see the focus groups as the correct forum for defining the ethical agenda. However, two views were expressed. Firstly, that too many limitations on the Project would render it not worth doing. Secondly, that a publicly funded, ongoing and independent ethics committee should oversee the Project, ensure that the information remains under public control and act as a safety net against subtle changes in the focus of the research.

### Collection of Data

Participants felt that blood taking is best performed at the surgery, but that space and time needs allocating for this to occur. Lifestyle data is routinely recorded in primary care. Smoking status, alcohol intake and body mass index is currently available for over 50% of adult patients on Trent Focus practice lists. [11] However, fit, middle aged men may not attend surgery and so lifestyle data may be missing on this group of patients. In addition, the participants recognised that lifestyle data may be more valid if a third party other than the GP collects it. It is recommended that lifestyle data be recorded at the recruitment interview and a copy given to the subject. The subject is then free to give the information to his/her GP if so desired.

The completeness and accuracy of electronic morbidity data in primary care in general is likely to be variable. Participants felt confident that the data in their practice databases are accurate and complete. There is evidence that Trent Focus practices do have complete and accurate morbidity recording for five common conditions (asthma, diabetes, hypertension, stroke and ischaemic heart disease) where prevalence is in line with expected prevalence as derived from the Fourth National Morbidity Study.[12] [13] Other studies also confirm that practices with a commitment to high levels of recording have databases that are acceptable for aggregated morbidity research.[14] However, it is doubtful that non-research practices have databases of a sufficient standard. It is

recommended that research practices are used for the Project, and strong consideration given to collection of morbidity data electronically. Some preliminary research may be required to ensure that practices are recording electronically the information required for the Project minimum dataset. Paper records are not Read coded and the data is more difficult to access. Participants recommended the use of MIQUEST software for interrogating databases and extracting morbidity information.

#### Access to the data

Participants felt that information on who will be given access to the data should be provided to every subject. It was felt that subjects will want to know who owns the data and where it is going. Grouped data was seen as safe to share with many institutions, except the insurance industry.

The participants felt that the criminal justice system should not have access to the database except in very exceptional circumstances. It is believed these circumstances will be rare, and recommend that any such uses of the database is regulated by the independent, publicly accountable body and is subject of a court order.

#### Data protection

Participants recognised that the data needed to be anonymised but not anonymous to allow the records to be updated. Concerns were raised that practice databases will be accessible through the NHS net.

#### Feedback from the Project

Participants found it difficult to give a view on whether GPs or subjects should have access to the DNA results, as they felt that the Project had not decided on the nature of individual level feedback to primary care. They were keen to receive any information that would help in the clinical care of their patient, but were uncertain of the harm that would come from the insurance industry. Participants recognised that no feedback means no trouble with insurance companies. Feedback from the Project team was seen as

important, particularly on current problems, recruitment updates, and practice specific morbidity data.

The ground rules for feedback should be established and consented for at the beginning of the Project. Patients should be able to opt out of receiving individual level feedback at the beginning of the study, if the study is considering this, or choose through informed consent to receive their DNA result under certain circumstances. Should the study identify a disease-conferring mutation and an effective intervention for reducing risk of the disease, then the main database could be de-anonymised for those who gave informed consent to be informed of their risk status. This should be regulated by the independent, publicly accountable body.



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