consider the operation with a fatal outcome right and to ascribe no intention (25/29; 86%; 95% CI 73 to 99). This might also be interpreted as an adaptation effect, but the tendency for term 11 students to ascribe an intention and consider the approval of the operation wrong is also interesting (12/16; 75%; 95% CI 54 to 96). The results indicate the same effect as described by Knobe: if an action (or its unintended side-effects) is considered right (or good or praiseworthy) we tend to ascribe no intention and if the act (or its unintended side-effect) is considered wrong (or bad or blameworthy) we tend to ascribe an intention. We suggest that the present tendency be referred to as an 'adaptation effect'. If we assume that term 11 students have actually been socialised into the current value-based and evidence-based medical thinking, including accumulated tacit knowledge, it seems particularly interesting to try to identify this adaptation effect in the group of experienced physicians. It is interesting because this tendency expresses the same kind of psychological mechanism that the Knobe effect captures, namely the tendency to adjust ascription of intention to one's overall moral evaluation of an act.

The present study is a pilot study; accordingly we have to be cautious when interpreting the results. However, if we assume that our results are reliable regarding the adaptation effect, we then seem to have identified another kind of Knobe effect that might be of interest when studying intentions among experienced physicians. If we had used the traditional Knobe design, we would probably not have identified the adaptation effect. If term 11 students have adopted clinical practice and reasoning regarding value-based medicine within the medical profession, we might expect experienced physicians to reason in the same way. We think that our proposed design and case, with corrections regarding the estimations of risks, merit further investigation among physicians.

Weaknesses and strengths of the study

Weaknesses

The study was originally planned as a pilot study in order to develop a functioning clinical case and to test it on medical students at the beginning and end of their medical education. Accordingly, the study had a limited number of participants and before drawing any sound conclusions we will have to conduct a similar study with a larger sample. If the main purpose of the study was to compare term 1 students with term 11 students, the study should ideally have been conducted as a longitudinal cohort study.

A problem with the present case is that in order to make the cases clinically realistic we employed different risk rates in the two scenarios. The possibility cannot be discounted of this difference having brought about some of the Knobe asymmetry among term 1 students—although there was no difference among term 11 students when exposed to the same two cases. In order to keep the promise of anonymity we chose not to include name, sex and age or other background variables. Accordingly, we were not able to identify potential bias in the two samples. However, Jansen and Fogel[11] did not find any impact of background variables on their results.

Moreover, the results are to some extent difficult to compare with Knobe's, partly as we asked about the actions' rightness and wrongness and not their blame or praiseworthiness. In medical ethics, however, one is often more interested in the moral status of the action than the moral evaluation of the character performing the action,[13] and we wanted to make the study as relevant as possible to the medico-ethical context. As the link between ascription of intention and blame and praiseworthiness is likely to be stronger than the link between right and wrongness and ascription of intention, it is of interest in itself that the asymmetric effect still was present at term 1.

There was a relatively low response rate among term 1 students—at least compared with term 11 students. In a worse case scenario it might explain some of the differences between term 1 and term 11 students. Two students at term 11 did not answer the question as to whether the operation was right or wrong in the 'death outcome' scenario, but calculating in accordance with a worse case scenario would not have changed the significant results.

Strengths

The distribution of the two cases was based in an alternating manner, which might give a good approximation to random allocation. We were able to compare the results from term 1 students with those from term 11 students and to discuss reasonable explanations. Compared with Knobe's standard procedure we used another design when asking about the act. It enabled us to analyse our data more closely and identify other associations that might allow us to study a version of the Knobe effect among experienced healthcare professionals, the so-called adaptation effect.

CONCLUSION

As physicians are supposed to do good and avoid harming patients it is rather difficult to develop realistic medical cases to illustrate the Knobe effect. The proposed case might work if it is corrected regarding risk estimations. The case seems to illustrate a classic asymmetry when ascribing intentions among medical students at the beginning of their curriculum. The asymmetry was not identified among students nearing the end of their clinical training, indicating that these students have been affected by their training and have internalised official medico-ethical guidelines and clinical reasoning. By using an alternative design we identified another kind of Knobe effect—the adaptation effect—indicating that students at the end of medical school also tend to ascribe an intention when an act is considered wrong and to ascribe no intention when the act is considered right.

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Achieving online consent to participation in large-scale gene-environment studies: a tangible destination

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ABSTRACT

Background Population based genetics studies are dependent on large numbers of individuals in the pursuit of small effect sizes. Recruiting and consenting a large number of participants is both costly and time consuming. We explored whether an online consent process for large-scale genetics studies is acceptable for prospective participants using an example online genetics study.

Methods We conducted semi-structured interviews with 42 members of the public stratified by age group, gender and newspaper readership (a measure of social status). Respondents were asked to use a website designed to recruit for a large-scale genetic study. After using the website a semi-structured interview was conducted to explore opinions and any issues they would have. Responses were analysed using thematic content analysis.

Results The majority of respondents said they would take part in the research (32/42). Those who said they would decline to participate saw fewer benefits from the research, wanted more information and expressed a greater number of concerns about the study. Younger respondents had concerns over time commitment. Middle aged respondents were concerned about privacy and security. Older respondents were more altruistic in their motivation to participate. Common themes included trust in the authenticity of the website, security of personal data, curiosity about their own genetic profile, operational concerns and a desire for more information about the research.

Conclusions Online consent to large-scale genetic studies is likely to be acceptable to the public. The online consent process must establish trust quickly and effectively by asserting authenticity and credentials, and provide access to a range of information to suit different information preferences.

BACKGROUND

Genetic epidemiology is a dynamic science with fast changing knowledge and technology which has moved beyond the genome to the investigation of gene-environment interactions (GxE). For complex (non-Mendelian) disease, GxE studies are dependent on the recruitment of large numbers of individuals in the pursuit of small effect sizes. They also require new data collections with increasingly diverse and detailed phenotyping. Conventional epidemiologic methodology, involving face-to-face contact with participants is prohibitively expensive and limits the funding of new GxE studies. The online environment presents an, as yet, underexploited opportunity to conduct these studies remotely, that is, without direct participant contact, offering the potential to significantly reduce costs. This combination of dynamism and methodological efficiency presents a range of new challenges.

A major issue in developing remote methods for epidemiological studies is the consent process where consent is moved from the face-to-face model, to an entirely online process. This has been achieved for non-genetic studies.[1] However, consent for large-scale genetic studies has public sensitivities which are potentially accentuated by the use of remote methods. These sensitivities focus on the dynamic nature of genetics making it difficult to forecast the direction of the science or the consequent risk and benefits of participation.

Previous research in both the USA and the UK has identified that the public have a generally positive attitude to large-scale genetic research provided they can opt-in.[2 3] In Iceland, where an opt-out approach to consent has been adopted, public opinion on the Icelandic gene bank (Decode Genetics) has been split and there has been debate about the ethics of this approach to consent, especially as commercial interests are involved.[4] In contrast, UK Biobank has made informed consent to participation explicit, having worked to resolve the many legal and ethical issues with public confidence in mind. UK Biobank has enjoyed outstanding success in recruiting over 500 000 individuals to the study, demonstrating that an opt-in approach need not be ineffective in building a large dataset.

It may be expected that an opt-in online consent process would enjoy the same level of goodwill. Although an online consent process for GxE studies (with appropriate technological support such as the availability of telephone contact and the downloading of information and consent details as required) is less intrusive than a conventional model, it is not necessarily less informative. Prospective participants have more opportunity and time to research and consider the issues involved and are under no peer pressure to participate since there is no interviewer present during the consent process (as would be standard in conventional genetic epidemiology studies). However, remote methods add a further layer of technological complexity that separates the participant from the scientist; one requiring competence with, and confidence in, the technology and in the governance of that technology.

It is in this ethical and operational context that we sought to determine if the public find online consent to large scale, population based genetic studies acceptable, and what, if any, barriers to

online consent and future participation in genetic research online they are able to identify. We explore this issue using an example large-scale genetics study.

METHOD

Sample and recruitment

Qualitative interviews are a widely accepted and useful method to capture participants' views and explore their reasoning.[5] We conducted semi-structured interviews with 42 members of the public, using a purposive sampling matrix[6] designed to select respondents on the basis of age, gender and newspaper readership (a measure of social status).[7] The sample was designed to collect a diversity of opinion and comprised three age groups: 20–29, 40–49, 60–69, and two newspaper readership groups: tabloid (*Daily Mail, Express, Sun, News of the World, Mirror*) and broadsheet (*Telegraph, The Times, Guardian* and *Independent*). Respondents were divided equally by gender.

Respondents were recruited by direct approach at six different cafés in Cardiff, UK. The cafés were selected with the aim to achieve a maximum spread of clientele and included cafés in: a train station, a private gym, a large furniture retailer, an arts centre and a café located near to the university. To recruit participants to the study, a brief verbal description of the aims of the study was given and those interested in taking part were asked to place themselves in an age group and name their newspaper of choice. Those corresponding to the sample matrix were given an outline of the study to read (and keep if they wished) and were asked to sign a consent form to indicate their willingness for the interview to be audio-recorded and to be used in academic research.

Web pages and data collection

Those respondents willing to participate in the research were shown web pages designed to achieve informed consent for a large-scale genetic study called 'Age Well, Feel Good'.[8] No specific genetic test is mentioned in the project although the website states that the research team are interested in heart disease, cancer, dementia, arthritis and diabetes. People who sign up for the Age Well, Feel Good project are asked to do four things: (1) answer a series of questions on the web (about behaviour, opinions and questions relating to tests of attention and memory); (2) send a small sample of spit or a drop of blood through the post using equipment sent to them; (3) give permission for the researchers to access their health records electronically without knowing their name; and (4) give permission for the research team to contact them again in the future to find out how circumstances or lifestyle have changed. The web pages were displayed on an offline laptop computer. Participants were asked if they were happy to use the laptop and the touch pad was demonstrated if necessary. They were asked to work slowly through the web pages and to 'think out loud', voicing their thoughts and reactions to what they were being asked to do. As respondents progressed through the web pages the interviewer observed and noted where respondents hesitated, stopped or spontaneously commented. All responses were noted on a structured response form. After working through the web pages, the interviewer used a semi-structured interview guide (table 1) to discuss opinions about consenting to the genetics study online. Answers to all questions were recorded using a digital voice recorder, and also recorded by hand on the response form. Questions examined confidence in the online environment, appropriateness of using the web for potentially giving their consent, and the effectiveness and delivery of information about participation in the research project.

Data analysis

Quantitative data from the semi structured interviews were extracted to Microsoft Excel and collated by gender, age, newspaper preference and willingness to take part in the study. The yes/no scores for each question were collated and expressed as percentages to assist in describing relative numbers of respondents expressing opinions. Responses to the semi-structured questions were initially coded into a thematic framework based on questions from the interview schedule. Data were then re-coded into the five main themes reported in this paper. The analysis was reviewed by a second researcher, and anomalies or queries discussed and resolved.

Ethical considerations

Approval for conducting this study was granted from the Cardiff University Medical and Dental Schools Ethics Committee. Respondents were given a unique identifier for the purposes of the study which was recorded on the consent and response forms. There were no other identifiable details on the response forms.

RESULTS

Respondents

Forty-two interviews were conducted. The sample achieved the target recruitment mix and comprised equal numbers of men and women, 14 individuals in each age group, and broadly even numbers of tabloid to broadsheet readers, although broadsheet readers were slightly under-represented in the study (17/42). Table 1 provides numbers (and percentage) of respondents who answered yes/no to each question. However, these responses often came qualifications which we explore within themes in the results section. Table 2 provides details of the sample.

Table 1 Semi-structured interview schedule, with number (and percentage) of respondents providing a 'yes/no/not sure' answer

	Yes	No	Not sure
Would you be willing to take part and agree online?	32 (76%)	10 (24%)	0 (0%)
Do you think you were given enough information about the study?	30 (72%)	9 (21%)	3 (7%)
Do you think you understood what taking part would involve?	34 (81%)	6 (14%)	2 (5%)
Is there anything else you would like to know before you would agree to (consent) to take part in a study like this?	23 (55%)	16 (38%)	3 (7%)
Do you have any concerns about taking part?	13 (31%)	26 (62%)	3 (7%)
Would you be happy to give a DNA sample?	30 (72%)	9 (21%)	3 (7%)
Would you be happy to give access to your medical records?	34 (81%)	8 (19%)	0 (0%)
What do you think the benefits of this kind of study might be?			
Can you think of any risks in taking part in this kind of study? (prompt: individual, family, community, research)	17 (40%)	25 (60%)	0 (0%)

Table 2 Sample: age groups by gender and readership, Number and (%)

		Gender		Newspaper readership	
Age group		Male	Female	Tabloid	Broadsheet
20–29s	14 (33%)	9	5	7	7
40–49s	14 (33%)	7	7	9	5
60–69s	14 (33%)	5	9	9	5
Total	42	21 (50%)	21 (50%)	25 (60%)	17 (40%)

Exemplary quotations from the interviews are used to illustrate key themes.

Willingness to consent to the online study

The majority of respondents (32/42, 76%) said they would be willing to give their consent to participate in the online genetics study. Although based on a small sample, younger respondents appeared less likely to participate (9/14) than older respondents (13/14). Reluctance from younger respondents was more likely to be related to the logistics of taking blood samples at home (they had mistakenly thought it required home based venipuncture), the time commitment of participation, and suspicions over the origins and credibility of the website.

> A1: how would you do a blood sample at home? I wouldn't trust myself to do it, I'd rather go somewhere and see healthcare professional to have it done. [prompt: swab?] A swab would be OK. (Male, 20–29, tabloid.)

The middle age group seemed more aware of the potential risks involved in participation, more concerned about DNA testing, security of the DNA samples, and sharing medical records. The middle age group were also more sceptical of the purpose to which their personal data and DNA would be put.

> B14: My only concern would be the safety of information and what happens to the information when its finished with. If there's a change in organisation or someone [leading the study] in the future, will the information be secure? How safe is the DNA in the future? Is this government funded? Who owns the information? (Female, 40–49, tabloid.)

> B1: What will they do with it? Is it possible to test a sample 5 years from now? What kind of research are they going to use this for, any examples? I wouldn't want my DNA to help someone develop a 'keep you young' cream. (Female, 40–49, broadsheet.)

Older respondents were generally more enthusiastic about participating than the other age groups and were willing to overcome obstacles to do so. Thirteen of the 14 respondents in this age group were willing to participate in the genetics study. Older respondents voiced fewer concerns, appeared more trusting of the content of the website and more comfortable with the process of reaching consent through the website than those from other age groups. Part of their motivation to participate stemmed from their own experience of ageing and health problems and witnessing family members live with illnesses.

> C8: I'm interested in these diseases—my father had cancer, mother dementia, different diseases; now more young people are obese and dying eating the wrong foods. (Female, 60–69, tabloid.)

We found little overall difference between the broadsheet and tabloid readers' willingness to take part in the study. However, this overall result masked several distinct differences between the two groups. Broadsheet readers were more demanding of both the quality and quantity of information given on the website than their tabloid counterparts. They were more likely to say that they had not been given enough information to make an informed decision and more likely to voice concerns about genetic research. They were more sceptical of the uses their DNA might be put to and less likely to agree to provide a DNA sample or access to their medical records.

> A7: I don't know. I mean how is the DNA going to be stored? (Female, 20–26, broadsheet.)

Tabloid readers were more relaxed about these concerns, readily linking DNA samples to the police database. In contrast to broadsheet readers who were able to suggest specific benefits for health and the treatment of disease from understanding the links between genes and our environment, the tabloid readers were less able to see clear benefits from the study. They offered generalised benefits.

> B8: DNA sample—yes—the police already have one. (Male, 40–49, tabloid.)

> C13: It's bound to be helpful. Helpful to me. Find out more about health. (Female, 60–69, tabloid.)

Trust

A number of themes emerged from the interviews. The most common theme was related to trust. Respondents frequently referred to trust in the organisation—Cardiff University—as a reason for feeling comfortable and agreeing to take part in the study. Respondents used a variety of references to trust (eg, reassurance, authenticity, reputation, credibility). Respondents appeared to be making a quick intuitive decision about whether they could trust that the website was a product of Cardiff University or whether it could be attributed to an impostor posing as Cardiff University. In doing so, they looked for evidence to satisfy their scepticism.

> B7: I'm very suspicious and worry as I know things can be duplicated—I would need evidence that it really is Cardiff University. (Male, 40–49, tabloid.)

> A4: If I know it's authentic, then OK. (Female, 20–29, tabloid.)

Some respondents were deeply sceptical about the site and had difficulty trusting the content, and its promises of safety, security and privacy.

> B14: This separation [of names and data] is meaningless. Someone can put it back together. (Female, 40–49, broadsheet.)

Security

Security of personal data was a major preoccupation of many respondents. It was feared their personal information may be misused, which might range from unwanted communication through to the use of their DNA for development of biological warfare or eugenics.

> C3: Abuse of information: can anybody else access this information? You can't keep tabs on everything. What will happen to this information? Phone calls? Spamming? (Female, 60–69, broadsheet.)

> B13: Police—would they have access? It's Big Brother like in *1984*—there's so much data already out there it could be used to control people. I'm thinking of eugenics, use of my DNA in a negative way. Biowarfare even. (Female, 40–49, tabloid.)

There was a well articulated concern that all personal data given for the purposes of this study should be ring fenced and

protected from any other database or government use. A few made references to the police database but more common references were made to how the 'government' might use the data.

C12: Only if the security is in place—if encryption is in place. It's a matter of time before they can overcome any obstacles in place. I'm not keen on government centralised information—as long as this information isn't part of that it would be OK. (Male, 60–69, tabloid.)

Respondents who said they had 'nothing to hide' were also making subtle references to potential exposure of personal information to government or police databases. Having nothing to hide was mentioned frequently as a reason to participate, although interestingly respondents appeared to relate to this in terms of information from their personal history (address, previous convictions, etc) rather than their health history.

B2: Yes, would be OK to provide a DNA sample. No crime. (Male, 40–49, broadsheet.)

Security concerns extended beyond the security of the website itself—there were concerns about how data would be handled and how any potential for it to be lost would be mitigated. Some respondents mentioned worries over laptops or removable storage with personal data on being mislaid.

A3: Risks? Just personal information being mislaid. (Female, 20–29, broadsheet.)

Curiosity

Surprisingly, the request for a DNA sample did not provoke heated debate or discussion among most respondents. The majority said that they would be happy to provide a DNA sample, given provisos that their personal information would be safe, the site was secure, and the DNA would only be used for medical research purposes and not commercial research. Respondents were often enthusiastic and interested in the study because they thought they were going to learn something about their own genes. They were intrigued about their own genetic inheritance, how their genes influence their health, and were both curious and concerned about learning something detrimental about their future health. When the interviewer reiterated the absence of direct clinical feedback in this study, respondents were disappointed and although this did not deter anyone from participating, it definitely reduced enthusiasm for engagement with the research.

A3: Because my DNA has never been analysed, it's fascinating. (Female, 20–29, broadsheet.)

B3: If there's something on my side of the family I would like to know. (Male, 40–49, tabloid.)

C7: For my own sake—to see that I'm OK. My daughter is bipolar. (Female, 60–69, tabloid.)

Some respondents questioned the ethics of the absence of clinical feedback and considered whether or not participants in the study should be told if a genetic marker was found in their DNA.

C1: If by any chance they do discover something wrong with you will they tell you? Yes I think they should. (Female, 60–69, tabloid.)

Operational concerns

Concerns about operational issues relate to time commitment, providing a DNA sample and the need for more information. Some respondents expressed concerns that they might be signing up to something with an unspecified time commitment. Questions related to: how often would I be contacted? How long would it take to complete the questionnaires? How long would the study go on for? A number of people were reluctant to provide a DNA sample because mistakenly they thought that it would require home based venipuncture. Some respondents were needle phobic and others thought they would not be able to operate the apparatus at home. The website states that participants will be sent the necessary equipment to take a small sample of spit or a drop of blood, and should post the sample back to the researchers. The information about how the sample should be taken and how much blood/saliva would be required had clearly not been effectively communicated by the research team.

A8: I'm not happy taking a sample, it's about the practicalities of it rather than the privacy of data or information. (Male, 20–29, broadsheet.)

A desire for more information

More information was also required by some participants regarding who was conducting the study, what the purpose of the study was, and what the expected outcomes of the study were. Overall, respondents gave the impression that this aspect of the content of the web pages was insufficient and that clarification of the benefits of the study—and introducing them earlier—would aid recruitment.

B7: [Were you given enough information?] No, I need to know what I'm contributing to, the goals of the study. (Male, 40–49, tabloid.)

DISCUSSION

We found that the online environment is widely acceptable to the public for consent to large-scale genetic research. That 76% of respondents would be willing to consent remotely suggests online consent to be a viable option for the conducting of large-scale genetic studies. However, its acceptability comes with a number of provisos relating to trust, security, privacy and a desire for more information. Enthusiasm for the study was also dampened when respondents understood that they would not receive any personal clinical information as a consequence of their participation. We did not find any evidence of rejection of a web based environment for either the consent process or assessment and data collection for a genetic study. Findings from this study suggest that secure, protected online research space must be created to fully realise the potential of online consent and data collection, to ensure maximum uptake from invited participants.

In our small sample we found that older respondents were more willing to participate in online genetic research although it is possible that increased willingness to participate from older age groups is due in part to a poorer understanding of the issues surrounding personal data security on the web and poorer knowledge of genetics. Alternatively it may have been due to an increase in motivation to support medical research with age. Broadsheet newspaper readers were more likely to ask questions of the information presented to them.

Strengths and weaknesses of this study

Using a mock up of an online consent process allowed respondents to see exactly what would be involved in an online consent process. Using a specific example allowed us to explore views about consenting to online genetic studies that were not just theoretical, but grounded in experience. However, their views may have been limited to the specifics of this particular study. Respondents were also encouraged to 'think aloud' their queries and concerns as they were working through the consent process. The qualitative semi-structured interviews then allowed fuller discussion of all the issues of concern to respondents.

The opinions recorded are balanced by age, gender and newspaper readership. Although newspaper readership is a proxy measure of social status, it is quick to collect and less intrusive than other measures,[7] but the sample was too small to make robust comparisons between groups. The sample was also too small to achieve saturation in identifying new themes, and many of the opinions and ideas expressed are particular to individuals. It is therefore possible that this study may have failed to identify issues of wider importance or over estimated the importance of other issues pertinent to the public. However, given the similarity between our findings and existing literature on public attitudes to genetic research (described below), our findings can be taken to represent a wide range of issues relating to genetic research which are of concern to the public.

A further limitation of the research is the possibility of sample bias: people who agreed to participate in this study may be more likely to have positive opinions about consenting online to a genetics study. Those people who were approached to participate in our research but refused may be more reluctant to consent to other research. We did not collect data on how many people we approached and declined to participate.

The issue of representativeness extends to recruitment for large-scale studies. Although the high level of support for remote consent that was found indicates that this method is likely to be cost effective for the recruitment of large numbers, it will not generate representative samples. However, non-representative samples remain highly informative for the testing of aetiological hypotheses provided they are heterogeneous; generating a wide range of values for the exposure variables. By dint of numbers, large studies tend to fulfil this criterion. Reassuringly, low participation in cohort studies has not been found to have a large effect on the relative risk estimates.[9 10]

Comparison with existing literature

In the novel context of consent and data collection online, this study supports closely the existing research into public perceptions and attitudes to large-scale genetic research. Provided that members of the public trust the institutions involved, and are reassured regarding the security of their data and the confidentiality of their identity, they are supportive.[11 12] However, as with traditional methods,[13] in online studies there remains suspicion of commercial exploitation and of discrimination by employers and insurers.

However, the issues that were raised—those of trust, security, privacy and a desire for more information—are generic to population research, and suggest that support for genetic epidemiology reflects support for population studies in general, rather than an understanding of issues peculiar to genetic studies. On this basis, developing adequate models of consent to online genetic studies is important. Models of consent suitable for population genetics studies have been proposed,[14 15] along with models of consent for online studies.[16] However neither of these types of models are nuanced suitably for online genetics studies.

A key issue for online genetics studies is restricted consent versus open consent. The fast moving nature of the research horizon makes it difficult to provide a scientifically useful restricted consent. However, an open consent policy transfers trust and governance entirely to research ethics committees and their equivalents. Mascalzoni *et al*[17] argue that an ongoing, rather than a one-time-only, consent process is the solution. This reflects traditional epidemiological practice where repeat examination provides an opportunity for updating participants on the progress of the study and obtaining further consent and implies continued information exchange and dialogue between researchers and participants. An online approach to consent is sympathetic to this view as information technology lends itself to virtual real-time communication between scientist and participant. However, this approach runs the risk of tokenism as few participants are likely to be sufficiently competent at judging the subtleties of the scientific technologies being used, and frequently the likely social consequences will be unknown by definition.

A more radical view has been proposed where traditional expectations of privacy and restricted consent are acknowledged to be false in a fast moving bio-informatics world.[18] With this view a one-time-only open consent is secured. Under this principle, although participant identity will be protected, it cannot be assured, and although only ethically approved research will be conducted, it cannot be guaranteed that all participants will agree with every hypothesis test. The preferred principle is veracity, and that this should precede autonomy. This view of open consent provides a transparent, low cost and efficient system that is consistent with the general ethos of conducting genetic studies online.

By moving consent to an online environment, the door is opened to a wider discussion of the consent process. Of particular interest will be the cost-effectiveness of ongoing versus open consent procedures. Decision aid technology may have a significant contribution to make to the design and construction of online consent processes. Decision aids have been developed to assist patients facing difficult decisions as a means of presenting information that is frequently complex or conflicting.[19] Creating a robust online consent process that satisfies the public is cost-effective would be a next step in creating a new approach to mass participation in genetic epidemiology.

Conclusions

This study suggests that the public are likely to be supportive of genetic epidemiologic studies which are conducted wholly online and that this represents a viable option. It is clear that the online consent process must establish trust quickly and effectively by asserting authenticity and credentials and provide access to a range of information to suit different information preferences of participants. However, the study highlights the need to establish robust consent processes that address the issues peculiar to large-scale genetic epidemiology. There is currently a window of opportunity to compare the cost effectiveness and public acceptability of ongoing restricted consent with one-time open consent procedures. It is proposed that this should be the subject of a major trial.

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Competing interests None.

Ethics approval This study was conducted with the approval of the Cardiff University Medical and Dental Schools Ethics Committee.

Contributors JG conceived and managed the study. JK collected the data and led the data analysis. CM was responsible for the *Age Well, Feel Good* web pages. GE

provided advice on the conduct of the study. FW helped to analyse the data and drafted the paper. All authors read and approved the final manuscript.

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Can we accredit hospital ethics? A tentative proposal

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ABSTRACT

Objectives The objective of this research was to develop ethics accreditation standards for hospitals.

Research design Our research methods included a literature review, an expert focus group, the Delphi technique and a hospital survey. The entire process was separated into two stages: (1) the development of a draft of hospital ethics accreditation standards; and (2) conducting a nationwide hospital survey of the proposed standards.

Results This study produced a tentative draft of hospital ethics accreditation standards comprised of six chapters and 62 standards based on the expert focus group and Delphi technique. The six chapters are: Medical ethics policies, regulations and leadership; The establishment and operation of a medical ethics committee; The establishment and operation of research-related ethics committees; Medical ethics education; Organisational ethical climate; and Respect for patients' rights and establishment of good hospital-patient relationships. The hospital survey indicated that the concept of an organisational ethical climate was new to most hospital managers, most hospitals disliked the idea of having a separate hospital ethics accreditation system, and small hospitals were concerned about their ability to comply with all of the standards.

Conclusions Regardless of whether hospital ethics accreditation can be a stand-alone accreditation or just part of existing hospital accreditation programmes, we hope this draft can serve as a good reference for future endeavours by hospital accreditation authorities.

INTRODUCTION

Ethics is the norm of human behaviours in everyday life and, as an academic discipline, is a branch of philosophy. Medical ethics is regarded as applied and professional ethics in the typology of ethics. The discussion of medical ethics has mostly centred on how individual healthcare professionals should behave. There is less discussion on how healthcare organisations should behave.

Organisational ethics is about how an organisation should behave in accordance with ethical principles. It can be perceived as an aggregation of individual ethics within the organisation. For instance, the well-known four principles of biomedical ethics proposed by Beauchamp and Childress[1] are also applicable to analyses at both the individual and organisational levels; however, healthcare organisational ethics also has unique aspects. Winkler and Gruen[2] proposed four substantive principles for the normative framework of healthcare organisational ethics: provide care with compassion, treat employees with respect, act in a public spirit, and spend resources reasonably. That is not to say that principlism is the only avenue for the analyses at hand. Variable value commitments in secular ethical theories, such as utilitarianism, Rawlsian contract theory, casuistry, virtue theory, and so on,[3] are all applicable. Nonetheless, the ethical issues of hospital management are less frequently discussed in the literature.[4]

The issues at hand are whether we need to accredit hospital ethics and whether hospital ethics can objectively be accredited. Accreditation is a widely accepted tool in healthcare quality management.[5] It is basically an external review process in which organisational compliance with quality standards is audited. This approach has been applied in educational systems and the healthcare industry. For instance, academic institutions and programmes need to be accredited in many countries as do hospitals and other healthcare organisations. If the argument for upholding regular hospital accreditation is that accreditation can ensure compliance with quality standards, the same conclusion can be drawn for ethics accreditation. That is, ethics accreditation can ensure that hospitals live up to ethical standards. Then the remaining questions are whether and how we can assess compliance of ethical standards so as to determine whether a surveyed hospital has good or bad ethics. In practice, this is done for hospital accreditation to a certain extent, since there are inevitable ethical components in hospital accreditation standards.

Whitehead and Novak[6] proposed that the overall ethical environment of a healthcare organisation can be assessed through evaluating the ethical culture, ethics policies, enforcement mechanisms and ethical training by applying the institutional ethics audit model introduced by Weber.[7] Weber's model assesses a business organisation's efforts at institutionalising ethics into its operations. Theoretically, this framework is also applicable to healthcare organisational ethics audits as indicated by Whitehead and Novak.[6]

The objective of this research was to develop ethics accreditation standards for hospitals. The underlying assumptions were that hospital ethics need to be accredited and hospital ethics can be objectively accredited. Under these two basic assumptions, we then tried to address the research question: what standards can be applied to hospital ethics accreditation?

METHODS

Our research methods included a literature review, an expert focus group, the Delphi technique and a hospital survey. The entire process was separated into two stages: development of a draft of hospital ethics accreditation standards and conducting a nationwide hospital survey of the proposed standards.