

Gaining and maintaining consent when capacity can be an issue: a research study with people with Huntington's disease

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Abstract

This paper recognizes the complexity of the debate on informed consent and discusses the importance of the ongoing process of consent for people affected by Huntington's disease (HD). Although written information may not be the most appropriate form of obtaining informed consent in qualitative research, it remains an important part of the ethical approval process for health research in the UK. This paper draws on a study in which the information sheet and consent form were specifically designed to help obtain consent from people who may be impaired by the cognitive and physical effects of HD. The forms were developed by drawing on expert opinion and relevant literature and fall in line with recommendations from the Mental Capacity Act 2005 to encourage people to make their own decisions. The paper describes the feasibility of a method for obtaining consent as an ongoing process with patients affected by HD using information sheets and consent forms specifically designed for people with potential cognitive and/or physical impairments. In conclusion, this paper adds a pragmatic approach to the debate on informed consent by describing the development of a written information sheet and consent form being used in a current social research study. Particular emphasis is placed on the importance of written information being adapted according to the needs of potential participants.

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Background

The principle that participants should be able and willing to give their informed consent prior to taking part in research studies is fundamental to current research governance and practice. There is much debate about what constitutes truly informed consent, the circumstances in which it is required and whether fully informed consent is ever possible.¹⁻⁸ Gillon⁹ defines this as 'the voluntary uncoerced decision made by a sufficiently autonomous person, on the basis of adequate information, to accept or reject some proposed course of action that would affect him or her'. However, past debate has been primarily focused on clinical and therapeutic research studies and often the doctor/patient relationship,¹⁰ in which the risk of harm to research participants is real and possibly substantial. Although social research may not be wholly benign, it is important to recognize the distinction between clinical and social research, and the different set of issues raised by the latter.⁷ These render the application of a consent process derived from the clinical model of biomedical research inappropriate and often impractical. Social science research carries little if any risk of physical harm to participants.⁷ Although the principle of informed consent still obtains, a flexible, proportionate and pragmatic approach is required. Often it is

not possible to predict the nature of the research or the direction it will take or identify participants at the outset. Social research involves a process of exploration and discovery, arguably making informed consent neither ‘achievable nor demonstrable’⁷ in advance. Nevertheless, obtaining informed – and usually written – consent continues to be regarded as a prerequisite for the conduct of ethical health research in the UK and the granting of approval necessary for research to be carried out.¹¹ It is these issues that apply to the research described in this paper.

The UK Economic and Social Research Council provides a *Research Ethics Framework*¹² to guide universities, independent research groups and organizations on how to achieve good ethical practice in social science research. This framework sits alongside and works in conjunction with other ethical guidance such as the *Research Governance Framework* provided by the Department of Health¹³ in the UK. These forms of guidance highlight the key issues to be considered when recruiting people to health research projects but cannot address specific issues for individual projects. This role is taken on by research ethics committees in the UK, where individual projects are presented and discussed for approval.

These types of review boards emerged in the mid-1960s in part as a response to abusive biomedical research conducted in the earlier part of the century such as that in Nazi Germany,¹⁴ clarifying the need for ethical standards in research.⁷ Ethics committees are made up of both professionals and lay persons appointed to review proposals of research, providing a formal way to assess whether the research conforms to recognized ethics standards.¹¹ The role of the researcher is to satisfy the committee that the ‘research they propose will be worthwhile and safe’ and that any ‘anticipated risks, burdens or intrusion will be minimized for the people taking part in the research and are justified by the expected benefits’.¹¹ The role of the ethics committee is therefore to protect people taking part in research and maintain a standard of conduct that promotes public confidence in research participation.¹¹

Ethical review boards are in place to protect participants,^{5,7} but they can also deny access to research by making assumptions about capacity,¹⁵ which can result in the exclusion of participants on the basis of their assumed vulnerability and lack of capacity. The issues of assumed vulnerability have been discussed by Koffman *et al.*¹⁶ who take the concept forward from the work of Kipnis¹⁷ and apply it to qualitative research. The authors recommend that research ethics committees reconceptualize categories of ‘vulnerability’ for the purposes of qualitative research, taking into account the research context, the individual participant and the skills of the researcher.¹⁶

The recent enforcement of the Mental Capacity Act 2005 in England and Wales from October 2007 clarifies the issue of capacity. Of particular importance is the recognition that capacity is assumed as default. A person must be assessed in order to justify deeming them as lacking in capacity. Also recognized is that capacity, and also vulnerability,¹⁶ is not an overarching or static concept. A person

may have capacity to make day-to-day decisions such as what they prefer to eat, but not be able to evaluate more complicated information in order to make a more difficult decision, such as whether to have an operation. Capacity can also fluctuate, with acute illness, during the day and over time. Hence for Faulder¹⁸ informed consent is about:

‘... the right of individuals to preserve their integrity and dignity whatever physical and mental deterioration they may suffer through ill health; it is about our duty always and in all circumstances to respect each other as fellow human beings and as persons’.

A number of authors recognize that consent is not absolute but an ongoing process^{19,20} that continues after the consent form has been signed,²¹ creating a ‘shared trust which goes beyond a mere explicit contractual arrangement’.¹⁹ This form of consent hinges on the principle of non-exploitation and is based on the researcher’s integrity and awareness in each situation.

Dewing²² suggests that taking informed consent as a single event at the beginning of a research project is an increasingly redundant concept that merely serves to exclude people with conditions such as dementia. Dewing’s work on the concept of ‘process consent’ has shifted the discussion, particularly in qualitative research.^{22,23} This form of consent does not negate the use of the written consent as evidence of participation. However, it does place the emphasis on consent as a *process* that runs throughout the research project. This allows for a more flexible approach to research participation and recognition of the complexities involved in recruiting participants affected by varying, and often fluctuating, levels of cognitive impairment.

Challenges for consent

Consent is an important issue in any study. However, it is particularly complex in relation to people with Huntington’s disease (HD), among whom capacity is potentially reduced and the ability to retain and recall information is impaired. Recruiting people in a palliative phase to take part in research is difficult in itself.^{24,25} However, this usually relates to the more acute palliative phase experienced by people with cancer once curative treatment options have been exhausted. More generally there is much discussion about whether people who are considered ‘vulnerable’ should be asked to be involved in research^{26–28} despite increasing evidence suggesting that people generally find research participation to be a positive experience even when the subject of the research may be challenging.²⁹ Due to the non-curative nature of HD a palliative approach to care can be implemented from diagnosis in order to minimize symptoms and sustain maximum quality of life for the individual and their family.³⁰ Long-term progressive neurological conditions pose an additional set of issues. HD is a hereditary neurodegenerative condition, but due to the insidious nature of its onset it is difficult to estimate the duration of the disease³¹ and this is often placed at between 10 and 20 years.³² As a

degenerative disease the condition will also change and progress over time, although the rate at which this occurs differs for each person. HD affects cognitive, behavioural and physical functioning, resulting in several issues that could be a barrier to participation in research (Table 1). Not all people with HD will have all of the impairments listed in Table 1 and the degree to which they may have them will differ.

The research study

While embracing the concept of 'process consent' to be applicable throughout a research study in its entirety,

Table 1 Impairments caused by Huntington's disease that might be an issue for consent

Potential impairment	Possible problems	Possible solutions
Dysphasia/aphasia	Affects the language skills required to process and understand information, not just speech but loss of language	Allow the person time to express themselves
Slowed thinking	Takes longer to retrieve the information they wish to use, must concentrate very hard to remain focused	Allow more time and minimize distractions such as noise or interruptions
Concentration and memory problems	Taking information in, storing it and particularly retrieving it	Prompts and cues can assist retrieval, such as the photographs and pictures in the consent form
Communication	Harder to assimilate the information being given and form the appropriate response	Allowing time to respond to the question. Ask one question or use one sentence at a time
Visuospatial ability	Vision itself may be impaired, distances become harder to judge	Use large font, clear spacing, and highlight keywords
Involuntary movements	Implications for reading and holding items	Give the person time to read something when they wish, read the document through with them or to them, or place it somewhere they can read it
Impaired movement	May not be able to hold a pen or control its movement sufficiently to sign their name	Do not rely solely on written consent, where written consent is necessary consider a witness signature for verbal or a mark of consent

this paper focuses on the start of this process and how written information and consent may be negotiated with people with impaired capacity. The paper adds a pragmatic approach to the debate by sharing learning from a current study. The research study explores the care needs of people affected by HD, using a case study approach employing ethnographic methods to better understand the lives of people with HD, their family members and the health and social care professionals involved in providing their care. Fifteen people with HD have been recruited to the study as the central person in each case. Family members and health and social care professionals are then recruited as and when identified by the person with HD as important to their care. At this stage recruitment to the study is complete; however, the study is ongoing and data collection is due to complete in June 2011.

Participants in this study were invited to be involved for a period of up to three years (depending on their health and wishes to continue participation). The study involves serial interviews and observations of patients, carers and professionals over this extended period of time. Once written consent was gained at the beginning of the study, verbal consent is sought each time the researcher wishes to engage the participant in further involvement in the research. Hence participants can agree to participate in some aspects and refuse others. For example, a participant may agree to have their consultation with a health professional observed at one time but feel they do not wish for this to happen at another. They can make these decisions at any time without being withdrawn from the study (unless they wish to do so).

Participants are people who are considered by the health professionals guiding recruitment to have the capacity to understand the nature and requirements of the research study. Initiating recruitment in this way does highlight what is now evident in the literature: that decisions (including whether or not to take part in research) are never truly autonomous, rather relational and influenced by many factors.³³⁻³⁵ However this does not make those decisions 'bad' or inappropriate. With Faulder's¹⁸ definition of consent (cited earlier) as a guiding premise, it was important to ensure that the information and consent procedure for the study was as appropriate and understandable as possible for this particular group of potential participants.

Rethinking consent

The Mental Capacity Act (MCA) 2005, introduced across England and Wales in October 2007,³⁶ provides the legal framework to clarify the measures that need to be taken to encourage people to make their own decisions and protect those who may not have capacity to do so. The accompanying Code of Practice³⁷ provides practical direction and guidance in its five underpinning principles, and detailed explanation of the elements of the Act. Chapter 3 of the Code of Practice provides guidance on how people should be helped to make their own decisions by highlighting appropriate communication with the individual and

the importance of the way in which information is presented. The General Medical Council³⁸ also provides guidance suggesting the use of up-to-date written material, visual and other aids to explain complex aspects, and make arrangements, wherever possible, to meet particular language and communication needs.

Working in the field of older people, Harris and Dyson²¹ showed that it is possible to maximize understanding by tailoring information to the individual. The authors identified several basic practical tips that although relevant to people with HD are applicable to recruitment in health research generally and are now in line with the MCA Code of Practice.³⁷ These include inviting a relative/staff member who knows the person's cues, for example can identify distress, understanding or positive responses to support the patient; personalizing the approach in learning about the person before approaching them, assessing what time is best to approach them, e.g. when they are not tired or distracted by meal times, offering a short concise explanation first to give an overview, and giving them time to decide and discuss their participation with whom they wish. More specifically the Code of Practice³⁷ also suggests the use of simple language and where appropriate 'pictures, objects or illustration to demonstrate ideas' (Section 3: 10, p. 32).

In order to meet these particular needs and develop an information sheet and consent form that would be appropriate for people with HD with a range of physical and cognitive impairments, it was important to draw on expertise from different disciplines. Contact was made with the lead for HD at DeNDRoN (Dementia and Neurodegenerative Diseases Research Network – part of the UK Clinical Research Network) to ask if they made any adaptations to their information sheets or consent forms for clinical trials to make them appropriate for people with HD. They currently do not do this and have no specific guidelines for recruiting people with this type of condition to participate in clinical research.

No official form of British sign language or Makaton is used with HD service users. However, pictures are sometimes used in the expression of wants and needs. The authors' approach was modelled on the experience and development of an information sheet for people affected by stroke.³⁹

In addition to aphasia (impaired or absent speech) stroke survivors often also have similar physical difficulties to people with HD such as reduced movement and ability to hold a piece of paper to read. Much of the aphasia guidance comes from the stroke literature and supporting agencies, e.g. Connect – the communication disability network, The Stroke Association, Queensland University Aphasia Group, National Aphasia Association, BBC and NHS Direct.

In accessing the field of intellectual/learning disability literature, Strydom and Hall⁴⁰ found that even a specially adapted medication leaflet may confuse people with mild intellectual disability. However such leaflets can be used to supplement other sources of information, in conjunction with constant repetition. In Gilbert's⁴¹ work on

- **I understand that I can stop** at any time and my care and treatment will not be affected



Figure 1 Section from consent form (originally A4, font size 18 pt)

involving people with learning disabilities in research, the presentation of self is an important consideration as a researcher will often be regarded as part of the medical profession, so another part of professional surveillance. The authors' key message is that the abilities of the potential participant be considered so that the method of gaining consent can be adapted in order to enable the process for considering taking part in research.

In light of the information gathered from the small amount of available research on this topic, an information sheet and consent form (see Figure 1 for a sample extract) were developed to facilitate understanding of this study for people with HD. The information sheet and consent form incorporate the elements identified in Box 1.

Use of the adapted forms

Although the consent and participation information forms have not been formally evaluated, validation through professional peer review was sought from a number of different parties including the Head of Care Services for the Huntington's Disease Association, authors in the field, a specialist nurse for HD and a service user with HD.

Box 1 Key elements used to inform the information sheet and consent form

- Large font
- Keywords highlighted in bold
- Short sentences
- Simple language
- Lots of white spacing
- Pictures – preferably photographs not drawings/symbols (the forms currently incorporate both due to availability of images)

The information sheet and consent form have also been approved by the Nottingham Research Ethics Committee. The members of the committee commented positively on this approach to adapting information materials for use with people affected by HD.

The forms have been used in the first author's PhD to recruit 15 people with HD to the study (the recruitment phase of the study is now complete). Participants are at varying stages of their disease and participate in various aspects of the study as they wish. This may be one-to-one interviews, joint interviews with a relative, observations of consultations or care interactions, such as a home visit from the HD nurse specialist. A critical part of the approach is that participants' preferences to be involved are reconfirmed each time they are asked to undertake a part of the research. Each participant is different, and it is emphasized that they are free to choose when they wish to participate without withdrawing from the study (unless they wish). For example on one occasion when EW went to visit a woman in a residential care home, she indicated that she did not want to participate in an interview. However at a later date she was happy to talk and actively encouraged EW to see her room. Some participants prefer to participate in observations and informal conversation rather than interviews, whereas for others it is more suitable to arrange interviews. Attempts are made to conduct interviews at regular periods. However, they are arranged at a time to suit the participant and have frequently been delayed due to holidays, illness, and complex home circumstances. The research was specifically designed to be flexible enough to cope with these issues.

Relatives were also recruited to the study and some have commented that they would have liked their information sheets and consent forms to be set out in a similar way to make them easier to digest. This is an element that could be considered for future research.

Conclusion

This study recognizes that written consent should be considered as merely part of the consent process, alongside verbal information, and embraces the ongoing, negotiated nature of consent throughout the duration of participation. It is also recognized that written information may not be the most relevant form of generating informed consent in qualitative research.⁵⁻⁷ However, the provision of comprehensive information sheets and consent forms are currently a requirement of ethical approval and are often considered part of the audit trail for research projects.^{5,6} Information does not speak for itself, being always subject to interpretation by the reader.⁴² There is no technical fix that can be applied to written information that would remove the problem of what Dixon-Woods *et al.*⁶ refer to as 'misunderstandings'. However, it is the researcher's duty to make this as understandable and appropriate as possible.

This paper demonstrates the development of an information sheet and consent form designed for people with the potential cognitive and/or physical impairments

experienced by people with HD. This study is very much a starting point. It is hoped this approach can promote a different angle for thinking about how best to give information and gain meaningful consent from people who might have different communication needs, and perhaps be considered to simplify the process for those without cognitive or physical impairment.

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