



Distinguishing research from clinical care in cancer genetics: Theoretical justifications and practical strategies

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ABSTRACT

The relationship between clinical research and clinical care is often perceived as unclear, particularly in highly technological subspecialties. This ambiguity is illustrated in cancer genetics where research protocols are frequently used to provide access to procedures that may be offered as a clinical service in other specialties. The project on which this paper is based investigated lay and expert perceptions of the activities which take place within the cancer genetics clinic. Semi-structured interviews were conducted with 40 individuals who are involved in cancer genetics research in the UK, the majority (18 clinical geneticists, 10 genetic counsellors/nurse specialists) of whom also provide a clinical service. Interviewees emphasised the need to differentiate research from clinical care for service users, and provided regulatory, ethical, economic and translational justifications for distinguishing these activities. A number of strategies for differentiating research from clinical care were described by those who work as healthcare professionals, which involved deliberately displacing these activities in time and space. It is argued that by distinguishing research from clinical care clinical researchers are engaging in a form of boundary work which enables them to manage what they experience as a conflict of interest generated by the different roles they occupy within the cancer genetics clinic. Finally, we discuss the implications of these findings for the process of informed consent.

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Introduction

Failing to distinguish research from care: a demarcation problem?

Research and clinical care are frequently understood as different types of activities (Wainwright, Williams, Michael, Farsides, & Cribb, 2006) – as occupying different ends of a continuum of medical work. Clinical care is seen as driven by patients' best interests whereas research is motivated by a need to expand the evidence base or generate generalisable knowledge (Bosk, 2007; Belmont Report, 1979). Although research and care may be seen as theoretically distinct, distinguishing research from clinical care, or indeed other types of non-research activities such as clinical audit and service evaluation, may be difficult in practice (Yentis & Dawson, 2006; Bortolotti and Heinrichs, 2007). This "demarcation" problem (Gieryn, 1983) appears to be particularly prevalent within the specialty of clinical genetics (Parker, Wilkie, Ashcroft, & Kent, 2004).

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It has been observed that patients find it difficult to differentiate genetic testing undertaken in research protocols from that offered as part of their clinical management (Ponder et al., 2008; Cooke, Crawford, Parker, Lucassen, & Hallowell, 2008), and that researchers and healthcare professionals (Miller, Giacomini, Ahern, Robert, & de Laat, 2008; Hallowell, Cooke, Crawford, Parker, & Lucassen, 2009), and members of research ethics committees (Newson & Ashcroft, 2004) struggle to distinguish research from care at times. Easter, Henderson, Davis, Churchill and King (2006) observe that researchers and research participants, while noting the differences between care and clinical research, explicitly conflate these activities and frequently describe research as a means of providing care. These authors argue that focussing upon the commonalities between research and care enables researchers to minimise the tensions which may arise from the differing duties and demands associated with simultaneously occupying the roles of scientist and healthcare professional. In contrast, it can be argued that emphasising the differences between research and non-research activities may be important for individuals who occupy potentially competing professional roles. Indeed, in his analysis of the ways in which scientists construct the relationship between science and other activities, Gieryn (1983) argues that the drawing of

a (discursive or ideological) boundary between science (research) and non-science (non-research) activities – so-called “boundary work” – serves a range of social needs for researchers. He notes that distinguishing research from non-research activities serves to protect scientific autonomy by shielding researchers from political or outside interference and argues that, by ring-fencing their activities, these forms of boundary work support the pursuit of professional (i.e. personal) goals.

Failing to differentiate research from care: some consequences for consent

The ethical ramifications of failing to differentiate research and clinical care have been well documented, in particular, the implications for informed consent. A number of guidelines (e.g. *Nuremberg Code, 1947*; *Belmont Report, 1979*; *Declaration of Helsinki, WMA, 2000*) and oversight mechanisms (research ethics committees) have been developed to safeguard research participants' interests, all of which stress the importance of obtaining informed consent prior to research participation. While ethical guidelines emphasise the importance of consent, there is evidence that, on occasion, consent may be “less informed” than those who are charged with the ethical oversight of research would ideally like. Research suggests that many research participants are unfamiliar with the rationale, aims and methods of scientific research. For example, studies of clinical trials have found that some participants' understanding of concepts such as ‘equipoise’ and ‘randomisation’ is such that they see trial participation as offering them the opportunity of obtaining better or more advanced treatment (*Snowdon, Garcia, & Elbourne, 1997*; *Featherstone & Donovan, 2002*; *Corrigan, 2003*). There is increasing evidence that participants in genetic epidemiological studies see the research as offering them access to genetic testing and expect to receive personal feedback about their genetic risk status (*Wendel, 2002*; *Gustafsson Stolt, Ludvigsson, & Svennson, 2003*; *Busby, 2004*; *Dixon-Woods et al., 2007*), even when it has been explicitly stated that such information will not be forthcoming.

These findings indicate that in some instances research participants may have alternative understandings of research aims or may confound them with those of clinical practice – believing that research interventions are primarily for therapeutic benefit. Such “mis” or alternative understandings (*Dixon-Woods et al., 2007*) have been labelled the “therapeutic misconception” (*Appelbaum & Roth, 1982*; *Appelbaum et al., 1987*; *Lidz et al., 2004*; *Henderson et al., 2007*). The therapeutic misconception is described by *Henderson et al. (2007 p. 4)* as failing to understand “... that the defining purpose of clinical research is to produce generalizable knowledge”. As an understanding of both the nature (the risks and benefits of the procedures) and purpose (underlying aims and motivations) of any research intervention is regarded as necessary for informed consent, holding the therapeutic misconception is seen as potentially undermining the validity of consent.

The fact that both researchers (*Joffe & Weeks, 2002*; *Ziebland et al., 2007*) and research participants (see above) may perceive research as having a primarily therapeutic intent, suggests that holding the “therapeutic misconception” is not necessarily evidence of a lack of scientific expertise/training *per se* (*Dixon-Woods et al., 2007*), but rather reveals something about the way in which the relationship between research and clinical practice is conceived and constructed by researchers and research participants alike.

In summary, although a number of theoretical justifications are given for differentiating research from clinical care, the literature suggests that the relationship between clinical practice and research is often perceived as ambiguous and potentially contested by both research participants and clinical researchers. The research project

on which this paper is based was undertaken to establish the extent to which this is the case and to explore the practical and ethical consequences. The ROCC project used qualitative methods to investigate a range of lay and professional views on the relationship between research and clinical practice in the subspecialty of cancer genetics in the UK. The data reported below were collected during interviews with individuals who carry out research in either a clinical or academic capacity. In this paper we focus upon how these researchers distinguished research from care and the reasons they gave for differentiating these activities. Our data suggest that drawing a symbolic, or actual, boundary between research and care enables researchers who also work as healthcare professionals to overcome the potentially conflicting demands and duties associated with their different professional roles. The implications of these findings for informed consent are discussed and it is argued that a reconceptualisation of informed consent may be needed.

Methods

Recruitment

The reasons why we chose to focus upon the subspecialty of cancer genetics in this project have been reported elsewhere (*Hallowell et al., 2009*). The study was approved by the Scotland A Multi-Centre Research Ethics Committee in November 2005. Potential study participants were contacted using data available within the public domain (e.g. listservs and websites) or referred to the study by colleagues who had been interviewed earlier. Purposive sampling methods were used to ensure that the sample included both healthcare professionals (clinical geneticists and genetic nurse specialists/counsellors) who specialise in cancer genetics or have a generic genetics practice, and academic researchers from different disciplines (molecular genetics, epidemiology and social sciences). All were sent an invitation letter or email, a participant information leaflet and an expression of interest form to complete and return to the research team. Interviews (face–face/telephone) were arranged by telephone.

Participants

Sixty two individuals who work in cancer genetics in a clinical and/or research capacity were invited to participate, 40 (65%) agreed to be interviewed. All were engaged in cancer genetics research in some capacity; 28/40 (70%) were employed as healthcare professionals and the remaining 12 (30%) individuals, who had no involvement in patient care, were academic researchers (see *Table 1*). Both healthcare professionals and academic researchers were involved in a range of different types of research including: molecular/DNA, epidemiological, statistical, social science and clinical research. The healthcare professionals recruited patients to a range of different local, national and international research projects; 17 (61%) healthcare professionals also had experience of generating/leading their own research studies, and the remaining healthcare professionals were engaged in recruitment only. Most healthcare professionals had some involvement with different types of research (e.g. social science, molecular and clinical) projects, whereas the academic researchers focussed upon one research area.

Data collection and analysis

Interviews were undertaken by NH and SC between January 2006 and March 2007. Participants were offered the choice of face–face or telephone interviews, and 18 (45%) opted for a telephone interview. Face–face interviews were carried out at the

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