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Invited article

Consenting recently bereaved adults for post mortem research: An evaluation of ethical considerations

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ABSTRACT

Aim: To present an evaluation of ethical considerations, which have been identified whist working as a trial consenter, undertaking prospective telephone consenting for post-mortem CT research and associated minimally invasive procedures.
Methods: The Local ethics committee, research and development office, and local HM coroners gave their permission for the families of the deceased, in cases where a 'routine' coroner's autopsy had been authorised, to be approached for their consent to PMCT research and associated minimally invasive procedures being investigated before and during autopsy examination. The trial consenter telephones the next of kin, discusses the nature of the study aiming to obtain verbal informed consent for research procedures. The concepts of 'the consenter as the consenting tool' and 'therapeutic use of self' are drawn on to gain consent using a flexible interview style. Working in this way with recently bereaved relatives raises ethical considerations. These are evaluated.
Conclusions: This review shows that prospective consenting for HM coroners' cases to be used for post mortem research is ethically appropriate given that ethical guidelines and principles are considered and upheld.

1. Introduction

This review is written from the perspective of working as the trial consenter for a study being conducted by the East Midlands Forensic Pathology Unit and Imaging Department, University of Leicester (EMFPU Study):

'Less Invasive Autopsy: a study to evaluate and compare the use of Computerised Axial Tomography (CT) and Magnetic Resonance Imaging (MRI) with conventional autopsy'.

The remit of the trial consenter is to gain consent from recently bereaved relatives to conduct post-mortem research on their deceased relatives.

This work has raised a series of personally perceived ethical considerations that have required evaluation in order to work with confidence and competence. In his seminal work on health ethics, Seedhouse [1] warned that there are rarely absolute rights and wrongs when making ethical judgements. Nonetheless, Thompson et al. [2] recommended that ethical evaluation assists in making well informed, sensible ethical decisions. Having undertaken bereavement counselling when working as a District Nurse, it was recognised that ethical issues arise when working with the recently bereaved. Therefore ethical evaluation was felt necessary prior to taking up employment and ethics are given ongoing reflective consideration during employment.

This review reflects on past and present ethical considerations associated with working as the trial consenter. To describe the context, the work commences with an outline of the research study and evaluation of ethical processes that were in place. Next, there is evaluation of ethical aspects of gaining consent. Subsequently there is consideration of ethical issues that have arisen during consenting; these are categorised into themes that are presented within subsections.

2. Outline of the EMFPU study and associated ethical evaluation

The research team are currently evaluating and comparing whether there are alternatives to a conventional autopsy, that could lead to the partial or total replacement of the conventional procedure in some cases. Specifically, they are exploring the use of CT, and whether there are additional, minimally invasive procedures, that can be used with CT to ensure that the same or better diagnoses are made, compared to conventional autopsies. There are a range of additional minimally invasive procedures that are combined with CT. These are outlined in Table 1.

Consenting requirements vary from being essential in every case to being specific to the procedures that are being requested. As such, consent is always required for the CT, plus any additional procedures. Consent is normally required for use of images for future teaching, training and further medical or forensic research.

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Table 1
Minimally invasive procedures that are combined with CT.

Ventilation via airway, mask or tracheostomy
Coronary artery or whole body angiography via neck, groin, arm or bone, using dye and air
Chest compressions with angiography
Toxicology sampling pre and post CT
DNA sampling pre and post CT
OCT or pressure wire examination of the heart/heart vessels
Micro-endoscopy during CT
Tissue sampling of organs or areas of major pathology for microscopic examination
Retention of the coronary bundle for microscopic examination
Retention of brain tissue for microscopic examination

Consent is sometimes required for locating and copying antemortem images. Consent is occasionally required for filming of PMCT procedures for educational purposes.

Prior to taking up post as a consenter in 2010, training and experience had been gained in bereavement counselling. However, post-mortem investigation was an unfamiliar research discipline. An informal interview was attended with the Principal Investigator (PI). During this, a personal assumption was made that there would be ethical issues. This was discussed with the PI, who outlined a range of ethical processes that were in place. On taking up post these processes were examined.

Firstly, approval from the local Research Ethics Committee (REC) was documented. This was crucial. In the UK, the Department of Health Research Governance Framework for Health and Social Care stipulates that any health related research that involves humans, their tissue or data must be reviewed by a REC prior to commencement [3]. A REC review involves scrutiny of the research protocol and associated research documentation in order to ensure that the dignity, rights, safety and well-being of respondents is protected during the study [4].

Secondly, support was documented from the local HM Coroner's office. Permission was identified for cases to be selected from HM Coroners' referrals for post mortem investigation. Additional support and/or funding was in place from the Department of Health, National Institute of Health Research, the Ministry of Justice, Police Forces as relevant, and more recently, the UK Resuscitation Council.

Thirdly, standard governance arrangements used Good Clinical Practice (GCP) principles. The thirteen principles of CGP comprise an international, ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve human subjects [5].

Lastly, the study protocol documented a range of processes that enhanced ethical principles. Cases were only to be consented by the study consenter or a medical member of the EMFPU using a protocol and a consent form, and offering an optional information pack. This process was designed to facilitate fully informed consent by giving correct comprehensive information. The trial consenter must be trained in GCP and be conversant with the rudiments of post mortem procedures and the specifics of the research procedures. Results must be anonymised. Relatives have the right to decline or to withdraw at a later date.

This range ethical procedures was recognised as rigorous and robust at both strategic and operational levels, in accordance with the various research policies, standards, papers, reviews and reports stipulated within the Government Commitment to Health Research 2010–2015 [6]. Continued scrutiny shows that the research meets the contemporary ethical values and strategic aims of the Health Research Authority [7].

Nonetheless, concern was felt about the notion of obtaining consent from recently bereaved people per se. This concern stemmed from recognition of scandals about unauthorised post mortem retention of organs and body parts at Bristol Royal Infirmary and Alderhey Hospital [8]. However, in these instances, consent of relatives was not obtained. There is international consensus that taking consent from relatives for post-mortem research is an essential ethical requirement [9,10]. Clearly, consenting bereaved relatives is regarded as ethically acceptable. Nonetheless, several ethical concerns required further exploration.

3. Ethical aspects of gaining consent

Firstly, making requests in the immediate period after death, when relatives are likely to be grieving. Grief is a familiar concept from personal training and practise in bereavement counselling. In her influential work, Kübler Ross [11] proposed the theory that people experience a series of emotional stages following bereavement. These comprise denial, anger, bargaining, depression, and acceptance; moreover, these stages do not necessarily occur in linear order. Furthermore, contemporary bereavement support literature identifies that people experience numerous emotions immediately after a death; these include shock, disorientation, longing, pain, and guilt [12]. This indicated that in order to ensure ethically appropriate communication, it is necessary to anticipate that a relative might be experiencing any stage of grief and a wide range of emotions. For example, a request to 'use' the remains of a loved one for research could feel hurtful to a relative who is feeling pain, or could exacerbate feelings of anger. A basic principle of ethical practice is to do no harm [1]. Sensitive communication skills are essential in order to avoid harm.

The second ethical concern related to making requests for consent by telephone, rather than face-to-face. Time constraints dictate a necessity to take consent by telephone. Having trained in telephone consultation, it was recognised that differences between face to face and telephone communication required ethical consideration. Channels of communication are limited in telephone conversations and levels of intimacy are reduced between the interviewer and respondent [13]. Face-to-face interaction would allow the consenter to use visual cues and identify those of relatives, including non verbal cues that could enhance communication by helping to engage and motivate relatives [14]. Nonverbal cues also assist in the development of rapport between parties in face-to-face meetings, making interaction more intimate than when conducted by telephone [14]. Arguably, making a telephone call to request post-mortem procedures is exceptionally intimate and can be considered tactless and intrusive. Nonetheless, making contact with the bereaved by telephone, is reported as acceptable to them [15]. Furthermore, taking consent by telephone has been identified as acceptable to the recently bereaved [16,17]. Thus, telephone contact is evaluated as ethically appropriate

The next ethical concern was informed consent. Consent must be fully informed in order to meet the Code of Practice stipulated by the Human Tissue Authority [18]. However, a considerable amount of complex information may be imparted. This is outlined in Table 2.

Consideration of demographics raised an ethical issue in relation to the complexity of information to be given. The population within the catchment area for the study is diverse in terms of age, gender, ethnicity, culture and religion. This indicated that the information that must be given has to be adapted and imparted in a manner that can be understood by each relative. The researchers had developed a telephone protocol for consenters to follow during the consenting process plus a form for concurrent recording of each procedure that consent is obtained for. Making adaptations created a further ethical issue. The ethical implications were explored.