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Review article

Ethical issues in research involving children and young people

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ABSTRACT

This article identifies the key ethical issues that need to be addressed in any research study involving children and young people, accessed through the NHS. It makes specific reference to the Declaration of Helsinki and to additional guidance developed for researchers from a variety of disciplines, both within healthcare and in other fields of study. The focus of the paper is on defining the key ethical issues, identifying the complexities in the legislative framework underpinning research involving this patient group and offering practical advice on when, and how, ethical approval needs to be sought.

Introduction

Professional and ethical standards are at the heart of all that we do as health professionals. Generic standards have been defined for all Allied Health Professions[1] and have been further elaborated for specific health professions, including the radiography profession.[2] Increasing emphasis has been placed, and continues to be placed, on this aspect of radiographers' professional lives, underpinned by pre-registration education. This has been motivated, to a significant degree, by well-publicised instances of serious individual and organisational failures and shortfalls in both standards of clinical care and ethical standards in research. Such incidents have lead to detrimental effects on the physical and psychological health of patients and their families and to breaches of patients' autonomy, dignity and rights.[3,4] Quite clearly, the maintenance of high professional and ethical standards is just as important in the conduct of research as in clinical practice. However, in order to ensure that we maintain high standards in any research we undertake, particularly research involving patients, health professionals need to have a clear understanding of the specific ethical principles, international practice standards, professional guidance notes and relevant legislation governing medical and health research.

The Society and College of Radiographers' 5-year research plan[5] articulates a vision for research in the radiography profession in which increasing participation in, and evaluation of, research is strongly encouraged. This vision involves the development of capacity and capability within the profession by identifying and overcoming barriers to research and knowledge gaps. A specific aim of this article is to address both these issues in the context of developing an understanding and practical capability in relation to developing research ideas involving engagement with children and young people.

This article is written from a UK perspective in that it makes reference to UK-specific legislation. However, the principles identified can be applied to practice internationally although legislative requirements may differ slightly.

Research involving patients who are deemed not to have the capacity to provide informed consent for their participation raises ethical issues beyond those applying to research involving adults who have capacity. Children may be considered one such group, as may adult patients with dementia, patients with learning difficulties and patients with acute severe injuries. Many of the same issues arise in all these cases but with one notable exception. For adult patients in the latter three categories, lack of capacity should not be assumed; rather, capacity should be assessed at the individual level by a competent person. Where lack of capacity has been reasonably determined then the legal requirements are clear and detailed within the Mental Capacity Act 2005[6] (MCA).

The MCA states: 'For the purposes of this Act, a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.'. A young child, who may clearly lack capacity to adequately understand all that is necessary for the provision of informed consent, does not lack this capacity due to impairment or disturbance of the mind/brain. Instead, the lack of capacity is a

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consequence of, and its degree related to, the stage of developmental maturity of the child. Here 'development maturity' relates to the child's physiological, psychological and sociological development. In the context of research, the MCA explicitly states (Section 2(5)) that its provisions do not generally apply to children under 16 years of age.

A further complicating factor is that UK law is not consistent in determining an 'adult' from a 'child'. It should be noted that the title of this paper was chosen carefully and precisely. The National Children's Bureau (NCB) guidelines[7] and the Department of Health's reference guide to consent for examination or treatment[8] both refer to 'children and young people', given the acronym CYP by the NCB. Here, the word 'child' refers specifically to a person aged less than 16 years of age; those aged 16–17 years are referred to as 'young people'.

In relation to research, the legal requirements relating to children and young people under 18 years of age are not entirely clear, with the exception of research that falls within the scope of the Medicines for Human Use (Clinical Trials) Regulations 2004.[9] Implicit in this latter legislation is the assumption that children under the age of 16 years lack sufficient capacity to take sole responsibility for a decision to volunteer as a research participant and parental consent (or that of an alternative legally authorised person) is mandatory. For all other research involving children and young people, the lack of clear prescription in law places a significant onus on individual researchers to ensure that they have sufficient competence within the research team to make informed decisions regarding all aspects of study design and recruitment, particularly those elements relating to communication with the children they wish to recruit. Although there are a few extremely useful guidance documents[7,8,10] available to assist researchers in their decision making, researchers will still need to be able to make their own informed judgements on issues relating to consent, the nature of the information presented to children (and their parents) and the appropriateness of the study design.

The main purpose of this article is to assist researchers who wish to conduct research involving children and young people in identifying the key ethical issues that need to be addressed in a robust research proposal. Detailed discussion of *how* these issues could be addressed is beyond the scope of this article although the importance of including appropriate expertise within the research team is emphasized.

The general framework for medical research

All current legislation, codes of practice and guidance from health professional, medical and medical research organisations that relate to 'medical research' derive their principles from the World Medical Association's Declaration of Helsinki,[11] originally published in 1964 but subsequently amended on several occasions. This document is essential reading for anyone wishing to conduct a research study involving patients. All the key ethical issues requiring consideration are articulated within it, though not all practical details are discussed. Researchers therefore also need to be familiar with all relevant legislation that impacts on their proposed research (for example, in the UK, the MCA 2005, the Medicines for Human Use (Clinical Trials) Regulations 2004 and IR(ME)R 2000),[12] as well as any relevant codes of practice and guidance notes.

The Declaration of Helsinki and codes of practice and guidance notes derived from it relate specifically to 'medical research' although the principles can be applied to other research contexts. Importantly, there is no precise definition of 'medical research' although it is widely understood to refer to investigations of health conditions, their diagnosis or treatment. Whether research fits this definition or not, if participants are accessed through the NHS then approval will need to be sought through the NHS National Research Ethics Service (NRES),[13] and the decision making criteria are likely to be informed by the declaration of Helsinki and it's related codes of practice. Applications for ethical approval are made via the Integrated Research Application System (IRAS),[14] a web-based service which enables approval to be sought from all bodies relevant to the proposed research study.

Is my study 'research'?

In the UK, only empirical research studies involving patients as participants (or their identifiable data/tissue) require prior approval through an NHS Research Ethics Committee. Research involving NHS staff or facilities will need Local Research Governance approval, but no longer requires NRES approval. NRES provides useful guidance[15] to inform researchers how to distinguish between research, audit and service evaluation. If your project is to be managed under either of the latter categories, there are still likely to be ethical issues to consider but the proposal will not fall within the scope of a REC. Although the distinction between these three categories may seem clear, in reality there can be significant shades of grey between categories. For example, a project that begins as a local service evaluation could be 'rolled out' to neighbouring health organisations if initial results appear promising. In this situation, any subsequent evaluation of the service may be seeking to generalise estimates of the efficacy of the service to the NHS more widely and begins to look like 'research', involving patients, that has not received ethical approval. Ethical approval cannot be obtained retrospectively and peer-reviewed journals will not publish research studies that have not identified that ethical approval was sought and granted. Researchers are therefore strongly advised to consider very carefully which definition best fits their study design and to err on the side of caution in seeking further expert advice if there is any reasonable uncertainty. The local Research Ethics Committee will usually be able to offer appropriate advice.

Summary of key ethical principles for all medical research

Given that the ethical requirements for research involving children and young people involve generic principles relating to all medical research, as well as additional ones, it may be useful to outline the generic principles before identifying the additional recommended requirements. The following is a brief summary of some of the key issues identified within the Declaration of Helsinki, which are relevant to all medical research:

- The need for research is motivated by our acknowledgement that we do not know all the answers regarding optimum diagnostic methods, treatment and management of health conditions, particularly given that new developments are emerging all the time. At all times the interests of the patient must come before the interests of science or society as a whole.
- The patients' rights, dignity, self-determination, privacy and confidentiality of information, physical and psychological well-being should be maintained at all times.
- All potential risks of harm to the patient, resulting from their participation in a research study, should be assessed before any research commences and these risks should contribute to informing a judgement as to whether the proposed research should go ahead, and whether their participation would be in a particular patient's interests.
- Medical research should only be conducted by competent persons who have a critical understanding of:

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