Traditionally doctors decided what research was acceptable to conduct on their patients and whether the risks justified the benefits. Patients now-a-days, however, are less likely to accept the orthodox idea that the doctor is omniscient and always right; instead, they demand for the autonomy to decide for themselves what procedures they are prepared to consent to and what treatments they are willing to receive.
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- Stroke Prevention in Patients with Atrial Fibrillation
- Should Society Take Precedence Over Individuals and Do Scientists Need More Autonomy in Our Modern NHS?
- Abstracts from the International Academic & Research Conference
- Follow-up Chest X-ray Following Regression of Community Acquired Pneumonia
- An Introduction to Cardiothoracic Surgery
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Should Society Take Precedence Over Individuals and Do Scientists Need More Autonomy In Modern NHS?

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ABSTRACT

Traditionally doctors decided what research was acceptable to conduct on their patients and whether the risks justified the benefits. Patients now-a-days, however, are less likely to accept the orthodox idea that the doctor is omniscient and always right; instead, they demand for the autonomy to decide for themselves what procedures they are prepared to consent to and what treatments they are willing to receive. One of the characteristics of medical research, counter-intuitive though it may be, is that it is not always intended to directly benefit the individuals participating in it. Healthcare professionals working within the National Health Service (NHS) in the United Kingdom (UK) have an obligation to carry out research as part of their function to continually improve the quality of healthcare provided as well as for continuing professional development. Many times the researcher is confronted with a dilemma: questions like, “How do I conduct research on individual patients in an ethical manner but also advance the frontiers of medical science?”, and, “What is my role in the well-being of the society as a whole?” are ones that the inquisitive investigator poses. This article debates such issues and reasons why, in certain circumstances, the interests of the society as a whole should be given precedence over individual patients providing that they are not disadvantaged or harmed in any way. Finally, it also argues that a pragmatic paradigm should be adopted and healthcare professionals should be given more autonomy within the NHS to conduct research for the betterment of future generations.

BACKGROUND

In past centuries, society mainly relied on the discretion of the medical profession to decide whether the potential benefits to future patients and to society as a whole justified exposing patients and healthy volunteer to the risks of healthcare research. Patients now-a-days, however, are less likely to acquiesce to the orthodox idea that the doctor is omniscient and always right. Instead, they demand for the autonomy to decide for themselves what procedures they are prepared to consent to and what treatments they are willing to receive. In the latter part of 20th century, radical changes in the roles of autonomy and authority, advances in medical technology, and vibrant (and sometimes vociferous) debates about what constitutes right and wrong have rendered choices that doctors and their patients once considered self-evident complicated.

Health care professionals working within the National Health Service (NHS) framework in the United Kingdom (UK) have an obligation to conduct research as part of their function to continually improve the quality of healthcare provided and for continuing professional development. Hence the ethical issues related to research are relevant to all in the healthcare sector who wish to fulfil these stipulated requirements. Moreover, there is an increasing recognition that the introduction of a novel procedure or therapeutic, without full evaluation or comparison with existing methods, may result in ineffective and sometimes harmful treatments being used.

One of the characteristics of medical research, counter-intuitive though it may be, is that it is not always intended to directly benefit the individuals participating in it. Its aim, rather, is to procure more knowledge about the cause of disease and the functioning of the human body in relation to pathology; develop new treatments or compare existing treatments with each other to discover which is more efficacious and cost-effective. It may be known from the outset that at least some of the participants in the research will not directly benefit themselves. So does this mean that they have an absolute right not to take part because they are not directly reaping the rewards or do they have a duty, although unsolicited, to participate, providing that it is...
not harmful, since the medical profession would obtain new knowledge from which future patients and indeed society would benefit?

This article debates such issues and argues why, in certain circumstances, the interests of the society as a whole, in our opinion, should be given precedence over that of the individual providing the intervention in question is not disadvantageous or harmful in any way. Pertinent issues including confidentiality and the role of ethics committees are also discussed. Finally we reason why researchers need more autonomy in our modern NHS for the betterment of future generations.

The National Health Service

The NHS in the UK is a state-run health care system, funded through taxation and works on the principle of providing universal and comprehensive healthcare at the point of delivery. It is increasingly apparent that the demand for health care now exceeds the capacity of the national economy to sustain it, as a result of greater expectations, improved technology, increasing longevity of life and a burgeoning morbidity rate in an aging population. This means that the NHS is ineluctably subject to resource constraints. Clinicians and managers attempt to balance medical needs and financial prudence which poses major ethical dilemmas. Hence it is generally accepted that there must be structured and explicit rationing.

So what is the role of research in our modern NHS apart from advancing the frontiers of medical innovation? Cost-benefit analysis attempts to provide a balance-sheet of the costs and benefits to society over time, all expressed in today’s money terms, of investing in a particular service. Numerous retrospective case-control studies and trials are carried out in the NHS to find ways wherein the benefits outweigh the costs. Physicians are expected to put the medical needs of their patients above all other considerations. However, conflicts of interest arise in clinical practice when practitioners become involved in arrangements that introduce other considerations that are potentially incompatible with the best interests of patients.

This inevitably leads to the dilemma: Does the clinician/researcher act in the best interests of his patients or does he have a role in promoting the well being of the society as a whole? Does he adopt a prima facie or a utilitarian approach and also simultaneously advance the frontiers of medical science? Could the traditional ‘moral high ground’ of clinicians, ‘altruism, activism, beneficence, and non-maleficence’ fit in a modern NHS with only finite resources?

Herein lies one of the fundamental ethical issues in modern medicine: how can physicians fulfil their moral obligations as fiduciary agents for individual patients while being shrewd stewards of the finite pool of resources? In the area of resource allocation we sometimes provide less than the best treatment for one patient in order not to disadvantage another patient excessively. Justice demands balancing the interests of different patients: is it very different if we offer a patient now, in the context of a large clinical trial, a treatment that is not, on the evidence, the very best, on the grounds that this will benefit other patients in the future?

The Declaration of Helsinki

When publishing reports of experimentation, journals have a duty to define what constitutes medical research of the highest quality and to include the ethical conduct of trials in this definition. The Declaration of Helsinki charges journals with this important responsibility, stating: "Publishers have ethical obligations. . . Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication." It follows that editors of journals should specify on all published trials if informed consent and ethics committee approval was obtained or why these were waived. This duty is supported by the International Committee of Medical Journal Editors (ICMJE).

Despite this duty, in 1997, on the 50th anniversary of the Nuremberg Code, there was mounting evidence that journals were not fulfilling their commitment to these guidelines. Data at the time and further documented since suggested that articles reporting ethical protections were of higher methodological quality than those that did not.

Yank and Rennie analysed articles of clinical trials published before and after 1997 (July 1995 to December 1996 and January 1998 to June 1999) in the major journals Annals of Internal Medicine, BMJ, JAMA, The Lancet, and The New England Journal of Medicine. Sixty articles per journal per period were randomly selected and included in the study and assessed for rate of reporting on informed consent and on ethics committee approval.

Yank and Rennie concluded that the major medical journals have improved their reporting on informed consent and ethics committee approval; however, 9% of studies still report neither.

CONFIDENTIALITY

Confidentiality is a vital part of the understanding on which the doctor-patient relationship is based and is a central ethical pillar of clinical practice among all healthcare professionals. Individual clinicians, according to their conscience and guided by statute and ethical training, will vary in the limits they apply to confidentiality. The World Medical Association issued the Declaration of Helsinki in 1964, with subsequent
updates, to establish international regulations for human experimentation.

It specifically identified 2 protections: that all participants in trials should understand the risks, benefits, and alternatives of the experiment and, following this, should enrol in the trial under their own free will, by giving informed consent, and that a disinterested party unconnected with the trial, termed the ethics committee or institutional review board, should have approved the experimental protocol after assuring its appropriateness of design. Article I.6 of the Declaration of Helsinki (World Medical Association 2004) states: “Every precaution should be taken to respect the privacy of the subject and to minimise the impact of the study on the subject’s physical and mental integrity and on the personality of the subject”.

Respect for the privacy of the subject is demonstrated by obtaining their informed consent before releasing any confidential information about them and by taking all reasonable efforts to minimise the risks of a breach of confidentiality during a study. This, however, may not always be possible. In epidemiological studies involving the scrutiny of thousands of computerised records, it might be impracticable to seek the permission of each individual patient and may even be unethical if it causes needless anxiety for a large number of unaffected individuals. If individual consent is not to be obtained, the World Health Organisation (WHO) epidemiological guidelines state that: ‘An investigator who proposes not to seek informed consent has the obligation to explain to the ethical review committee how the study would be ethical in its absence’. However, the Royal College of Physicians (s.8.24) takes a different view. It advises that so long as the same strict code of confidentiality is observed when medical records are used for research purposes as in standard clinical practice, it may not always be necessary to ask the patients permission first. It further says that, ethical review is not always essential if no patient contact is involved (s.6.23). So does this account to breach of confidentiality? What about accessing patient information from computerised case registers and other databases where the researcher is not the patient’s doctor or not a member of the team providing treatment?

Section 60 of the Health and Social Care Act 2001 was introduced to allow healthcare professionals and medical organizations to use patient identifiable information for the support of essential research activity within the NHS without the consent of patients. Its main goal was to support medical research that was in the interests of patients or the society, where consent could not be obtained or where anonymised information will not suffice. However, concerns were soon raised over the loss or abuse of rights by some patient groups, consumer groups, and civil rights groups. Therefore, safeguards have been introduced and advisory groups such as the patient information advisory group (PIAG) have been created to prevent the use of these powers for trivial or inappropriate purposes.

This leads to the crucial question: Could the patient’s records be used for research purposes as long as the patient’s confidentiality is strictly maintained? In a retrospective case-note study involving 1,000 patients assessing the role of prophylaxis in the prevention of venous thrombo-embolism after minor surgeries (e.g., unilateral hernia repair), it might impractical to obtain the consent of all individual patients. If at the end of the study it is found that there is no role for venous thrombo-embolism prophylaxis in minor surgeries, then isn’t there huge cost containment for the NHS? Does this not then blatantly support the argument that society should take precedence over the individual, at least in this scenario?

**ETHICS COMMITTEE APPROVAL**

Traditionally doctors decided what research was acceptable to conduct on their patients or healthy volunteers and whether the risks justified the potential benefits. If the doctors who wish to conduct research into a particular condition are recognised experts in its treatment, are they not then the best people to decide what is acceptable for their patients? Whilst this may very well be the case, there is still a need to ensure that overzealous researchers do not get so carried away with making a valuable contribution to science, and improving the lot of patients in the future to the extent that they fail to adequately ensure the safety and comfort of patients today.

Scientific research is permitted in the Western world to advance medical knowledge but concern for the safety of the patient/volunteer/human being must never be relinquished in consideration of the potential benefits to be gained. The ethics committee thus has an important moral and social responsibility. One of the important duties of the ethical committee formulated by the Royal College of Physicians (RCP) states: “Patients must be protected from undue risk of injury, distress or discomfort. They have a right to know what is being done to them and why, and their freedom of choice, confidentiality and privacy must be respected...” (s. 5.24).

However, with the implementation of recent new ethical regulations both within the ethics committees and the NHS, even minor, non-invasive, non-harmful trials need the approval of ethics committees. It takes a
painstaking amount of time and effort by the researchers, many of them practicing clinicians, to accurately and comprehensively fill in these detailed ethical approval forms. This undoubtedly robs invaluable time both for the clinicians and for the commencement of the trial. Although it should be considered mandatory to get ethics committee approval for major trials involving invasive procedures or introducing new treatments, wouldn’t it be prudent for research involving review of patient notes, laboratory assays, hospital database, minor clinical trials, and non-invasive monitoring to be left to the discretion of the senior clinicians?

The authors of a paper published in JAMA conclude that they did not know whether patients have benefited from having informed consent or ethical approval as safeguards or whether describing them in articles helps at all. Nevertheless, they do maintain that transparency in the reporting of science has inherent benefits. They assert that the reporting of informed consent and ethics committee approval attests publicly—in a forum where the methods can be openly challenged or discussed—to a minimum level of ethical consideration. They feel that there is certainly a moral imperative to assure participants in trials that meticulous attention is being paid to their safety.

Yank and Rennie state that patients have died in studies that failed to adequately provide protection. News stories, not surprisingly, have questioned the ethical conduct of medical research. These events "have shaken the public’s confidence in our ability to govern ourselves." In describing the federal government’s response, Shalala stated, "Clinical researchers and the institutions that support them must, without exception, maintain the public’s confidence in our work, our competence, and most important, our ethics.”

**DISCUSSION**

Since the 1960s, the spectre of a patient led consumer movement in health care has gradually evolved. Many health care professionals see this as a detriment to high standards, regarding their professional judgement and erudition as better than any service users’ perception in judging the quality of care. On the other hand, consumerism in health care can be seen as a welcome antidote to paternalism and to the indiscriminate use of patients as research fodder. The days of omniscience, authoritarianism and the supercilious attitude of the doctors aloft and aloof in their ivory towers are now confined to the history books.

Similarly, research ethics is under scrutiny, particularly in the light of the current debates over the revision of the Declaration of Helsinki. The declaration states: "Concern for the interests of the subject must always prevail over the interests of science and society". This seems generally to be taken to imply, for example, that when a patient takes part in a clinical trial the treatment within that trial should be in his or her best interests. Such interests should never, on this view, be compromised for the sake of those patients in the future who might benefit from the trial results. RCTs, for example comparing the effectiveness of two treatments, should only be undertaken if there is "equipoise". The “best interests” of the patient are widely seen as the bedrock of medical practice. However, the best interests of the individual patient have, of course, long been compromised for the sake of other potential patients – in infectious disease control, to cite but one example and it is ludicrous to deny that we have consequently made quantum leaps in our antimicrobial arms race.

More autonomy should be given to the researchers and a broader approach needs to be adopted rather than the bigoted and myopic views of some groups. An absolutism approach may not be helpful in the complexities and mosaicism of today’s healthcare world. The government and other regulatory bodies have to take adequate steps and enforce laws to ensure that bureaucracy does not hamper genuine research which would be severely deleterious for the survival of the NHS and the well-being of society as a whole. Although individual patients should not be used as a fodder for research, a civilised society should understand and appreciate their role in contributing towards medical research. It should not be forgotten that we also have a duty towards the health of future generations. Indeed, as Babington exhorted, ‘Every generation enjoys the use of a vast hoard bequeathed to it by antiquity and they transmit that hoard, augmented by fresh acquisitions, to future ages...’
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15. World Medical Association’s Declaration of Helsinki serves as guide to physicians. JAMA. 1964;189:33-34.
The World Journal of Medical Education and Research (WJMER) is the online publication of the Doctors Academy Group of Educational Establishments. It aims to promote academia and research amongst all members of the multi-disciplinary healthcare team including doctors, dentists, scientists, and students of these specialties from all parts of the world. The journal intends to promote the healthy transfer of knowledge, opinions and expertise between those who have the benefit of cutting edge technology and those who need to innovate within their resource constraints. It is our hope that this will help to develop medical knowledge and to provide optimal clinical care in different settings all over the world.