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Medical Education

Research Ethics and Medical Education

Research ethics should be included in the medical school curriculum so students and residents can fully understand the ethical implications of medical research.

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Introduction

The question begging to be asked among researchers and educators in Academic Medical Centers is: what do we currently teach medical students and residents about the ethical issues surrounding clinical research activities, from conflict of interest to protection of the patients enrolled in research studies (clinical trials)? The answer unfortunately is "not much, but more than before."

Outside forces have made us look critically at our teaching programs. The Accreditation Council for Graduation Medical Education (ACGME) has adopted requirements for competency in, among other areas, professionalism, practice-based learning and improvement, and systems based practices. Learning outcomes for these competencies require residents to demonstrate a commitment to ethical principles of health care delivery, informed consent, confidentiality, conflict of interest, and ethical business practices [1].

The Issues

Medical trainees are often caring for patients who are involved in clinical experiments (pharmaceutical, new devices, new operative procedures, or otherwise). Yet many residents and most medical students do not know the differences between Phase I, II, and III trials, and some have had little exposure to study design, including randomized or blinded clinical experiments. Students often do not appreciate the time and effort necessary to move a new drug or device from concept through the discovery process and to the bedside. Ethical principles and the moral standards governing clinical practice are generally part of clinical curriculum, but few training programs and almost no studies have examined habits of practitioners or trainees as they relate to the ethics of clinical research activities [2-4].

Yet the ethical concerns that surround clinical research programs are multiple; they include: adequate assessment of the risks and benefits to the patient-subject; lack of understanding of the study protocol by physicians, trainees, and the patient-subject; the potential for coercive enrollment that is inherent in the power differential between the physician and the patient; the process and completeness of informed consent; use of placebos in research; protection of confidentiality; disregard of subjects' needs, wants, or understanding regarding their participation in the study; conflicts of interest for the investigator, institution, educators, and staff; and use of surrogates as decision makers for subjects with diminished capacities. Since the lines between academic medicine and industry are becoming blurred and the distinction between clinical research and clinical practice may be suspect, attention to a more robust education for students, residents, and fellows seems paramount.

Potential Solutions

Because these are the formative years of their professional identity, residents should be a part of clinical investigations and should examine the ethical issues that patient research raises. A curriculum addressing research practices allows residents to consider how the relationship between investigator and patient-subjects differs from that between caregiver and patient. The distinction between research and patient care is sometimes a fuzzy one. Through involvement in clinical protocols, residents can come to understand the drug development process, learn to interpret the results of studies, realize that drugs used for "off-label" purposes in clinical practice cannot be used in research without permission from the FDA, and understand that any systematic evaluation of patients to advance generalizable knowledge is research. Indeed, both chart reviews and off-label use of drugs, when either is specifically designed to answer a hypothesis and then gather findings, constitute clinical research. In addition, residents and fellows share the responsibility, along with investigators, to inform the general public about research practices. This is especially important if the trainees are called to advise patients about participating in clinical trials.

Students must also learn the role of the Institutional Review Board (IRB) and the importance of the informed consent process, including an understanding that consent forms are written succinctly and in simple English or the appropriate language for the patient. Such forms need to describe the essential features of the study with a clear understanding that the patient's care is not tied to participation in the study. In addition, patients must be fully cognizant that they may withdraw from the study at any time. There must be neither conflict of interest nor situations that could lead to a conflict of interest [5]. Residents could be trained in research protocols by opening IRB meetings to them so they could be active listeners even if they are not active participants. Simulated protocols and simulated IRB committees might also serve as educational techniques for introducing medical students and residents to the complexities of clinical research. Educational solutions such as these protect both the investigators (including trainees) and the patients.

Conclusions

In summary, residents and medical students must understand the essential components of participating in clinical research, including basic ethical principles and the historical basis for those principles, research design and the assessment of risk and scientific merit, and accountability of the investigator and the research team including potential conflicts of interest. With this new knowledge, trainees can ethically function as advocates for the merits of research participation to their patients and as advocates for patients to investigators on the all-important issues of subject selection and informed consent [4].

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