COMMENT

Emerging issues in medical imaging

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Physicians are often faced with the dilemma of trying to do what is best for the patient, sometimes deciding to use a technological innovation. The profession has drawn up guidelines for common methods in imaging. These include informed consent, intravenous use of contrast media**,** ten-day rule, invasive procedures like angiograms (peripheral, cerebral, coronary, renal and so on), and image-guided biopsies. It is assumed that non-invasive techniques create little or no stress to the patient, and have no negative impact on radiologists' ethical thresholds. But recent trends in these and other imaging procedures and techniques have raised new problems in practice. These include informed consent, the role of a specialist in the decision of brain death, difficult diagnostic decisions, policies regarding the use of contrast medial and coronary imaging, conflicting data on mammography screening and the expanding horizons of film-less radiology and telemedicine.

Informed consent

The patient must be informed of the risk of a diagnostic procedure, particularly given the expanding choice of modalities in recent years. There is an uneven dissemination of information about the latest imaging options and doctors can disagree on which patients are candidates for particular aggressive diagnostic and therapeutic imaging procedures. This results in conflicting advice to patients, variable treatment decisions and controversial standards.

Other issues relate to practices such as the enrolment of volunteers into trials of new technologies, the stresses and discomfort of some procedures, and the theoretical likelihood that functional and structural neuro-imaging may violate individual privacy (1). Informed consent in film-less and tele-radiology has a long way to go in practice. Informed consent forms for imaging can vary from hospital to hospital within the same town. Consent may not be strictly followed in community-based screening programmes (2).

Even an informed patient may not tolerate inconvenience, and be uncooperative (3). This will raise an ethical question. Is the failure to obtain a patient's co-operation an indication for referral to a more 'convincing' service provider? Or should one rather impose 'informed' but 'reluctant' acceptance of service? Patients are often not informed on the time they are going to spend in the radiology department waiting for, or during the procedure (4).

The cost of health care: caring for all

Consumer demand can pose ethical problems for the health care provider, especially if services are priced low, and if greater consumer participation is considered an objective. The traditional ethic of patient advocacy is threatened by the new ethic of cost control that restricts patient and physician choice in the use of limited resources. Researchers (5) surveyed physicians' willingness to use deception to secure third-party payer approval for certain procedures. They found that a large number of physicians were willing to use deception.

Imaging procedures are expensive diagnostic tools, especially if supplemented with therapeutic interventions. Instead of deception, what if we asked the 'deceived' third-party payer's informed consent? It has been argued that as cost containment conflicts with traditional medical morality (6). However, in developing countries, technology that saves money (7) for other pressing needs is in line with the concept of primary health care, fairness, and justice in distribution of services. Unfortunately, in such hospitals the challenge of cost containment affects diagnosticians more.

Fewer patients experience idiosyncratic reactions with the routine use of low-osmolar agents (rather than high-osmolar ionic contrast media) for intravascular injection. There is also potentially less renal injury in a subgroup of critically ill patients. But the high cost prevents the universal use of these agents (8). The issue of cost here has to be carefully reviewed by the radiologist for every case, and the patient and 'third party' payer may have to be consulted. How is the radiologist to resolve the conflict between medical morality and medical economics? Is it more moral to give patients all the available care no matter how much it costs, or to insist on the equitable distribution of resources? Should patients know that their management is compromised because the money must be saved for use on others?

Overuse of diagnostic procedures

Coronary artery disease (CAD) and its complications account for 20 per cent of all deaths in the United States, and half of those who die suddenly of an acute myocardial infarction have no prior symptoms or overt manifestation of CAD (9). Magnetic resonance imaging and computerised tomography have been used for screening such patients. There are many ethical implications of these procedures -- the rationale, performance, potential value of the results for individual patients and the cost. Guidelines for the use of interventions should be continuously validated and updated. In a recent assessment Schilling et al (10) concluded that there is a possible overuse of angiography in patients within 12 months of myocardial infarction. Radiologists

are going to contribute, through the wording of their reports, to the considerations justifying such expenditure.

Many ethical issues are encountered in the management of geriatric cardiac patients. Basta (11) reported a case of a 69-year-old woman dying of severe ischemic cardiomyopathy and peripheral arterial disease, who developed a gangrene of her toes. This was painless and with no signs of infection. The question was whether it was ethical to perform an arteriogram, or attempt repeat angioplasty of either or both limbs. How can such delicate decisions be controlled in a private practice set-up? Non-medical stakeholders of private practice have had no training in medical ethics.

Brain death and the vegetative state

There is a strict medico-legal definition of brain death. A new burden on radiologists is to decide on this matter based on visual observations of images, in the rush of a casualty ward. Should priority be given to the dying patient? Should the doctor consider only what is best for the patient and family? Should there be any consideration for the patients of the transplant surgeon?

Persistent vegetative state (PVS) often requires imaging for diagnosis of an underlying cause and management. The indication and frequency of these examinations are not always obvious ethically (12). In anencephaly and hydranencephaly, prolonged survival is not expected, although it sometimes happens (13). The ethical aspects of such findings will pose difficulties for the imaging specialist who may have to decide from imaging criteria on the prospects of survival in congenital anomalies. The issue is confounded by other factors if the hospital or district is active in organ transplantation.

Mass mammography

Enthusiasts of mass mammography have created an atmosphere of false optimism (14). They have not informed the public about the very small potential benefit nor about the risk associated with screening, especially the risk of false positive diagnoses and of unnecessary surgical operations. Various randomised controlled trials have concluded that between 5,000 and 68,000 mammograms are necessary to prevent or postpone one death due to breast cancer. To reduce false results, the US enacted federal legislation that requires breast imagers to read 240 mammograms in six months to qualify for certification, and another 960 mammograms in the following two years. The difficulty of this requirement has resulted in reducing the number of certified radiologists and posed another ethical concern (15), that of shortage. Radiologists and surgeons are confused, and may not be able to give patients useful information.

Children and the law

Medical ethics must be considered when estimating the age of living individuals, especially in childhood and adolescence where morphological methods based on radiological examinations to dental and skeletal development are recommended. The selection procedure and the question of voluntary informed consent are important ethical issues. Also important is the determination of adulthood on the bases of medial clavicular epiphyseal disc closure, and the decision on the exact age when partial closure is encountered radiologically. Borderline maturity issues pose special problems in the case of imprisoned minors. Should the radiologist observe the individual patient's rights or the state's preferences? Political necessities have become a problem for imaging specialists. Violence against women may cause abortion, or abortion claims. When the embryo is small and the abortion is complete, ultrasound attempts to arrive at the truth, but legal actions are exaggerated by politics. Central nervous system insult in a non-accidental injury (child abuse) is proved or disproved by the neuro-radiologist (16) who must think of the social and legal outcomes of the vague or definite statements in the report.

Teleradiology and filmless imaging

Digital imaging technologies have acquired sufficient reliability and cost-effectiveness to convince imaging providers to shift from film-based to filmless departments. It has allowed widespread use of teleradiology (17) with the potential to improve healthcare access, delivery and standards, but can also raise complex new legal and ethical issues (18). These include image retention and fraud, privacy, malpractice liability, licensing and credentialing, and contracts for PACS and tele-radiology.

The US has attempted to set standards and legal requirements for how long copies can be retained and who has access to them (19). However, there are state-wise variations. Privacy and access issues are worrying for even the most sophisticated systems, in the face of 'hackers' and 'sabotage'. Some authors have suggested a Uniform State Medical Information Code to provide a minimum level of privacy protection for interstate telemedicine, with each state supplementing the Act with additional local protections (20).

Images acquired in non-digital forms have to be retained even after digitalisation. If the films are destroyed and the patient sues the health institution, the plaintiff may claim that original storage formats were destroyed and replaced. Authentication is another worry. In film-screen radiography the patient's name and number are exposed and the images difficult to tamper with. In PACS digital images are liable to fraud and unauthorised manipulation (21). Technology is needed to curb disclosure and unauthorised access.

A proposal for security in tele-radiology based on legal considerations has been published in Germany (22). Teleradiology, in contrast to 'local environment radiology', may not allow adequate exposure of the distant interpreter to important clinical findings, unless new practice standards require sizeable images and data transfer (17). Failure of a local radiologist to seek second "electronic" opinion may be a malpractice offence and plaintiffs may challenge the local diagnosis after 'shopping for a tele-radiologist's opinion'. On the other hand, if a distant interpreter offers a misdiagnosis, the person filing a malpractice lawsuit must prove that a physician-patient relationship existed between the tele-radiologist and patient, as current laws are understood. Therefore, conflicting issues in professional liability have to be solved. Concerning licensure and credentialing, American College of Radiology (19)

guidelines recommend that physicians providing an official interpretation of tele-radiography images must be licensed at both transmitting and receiving sites or states. They must be credentialed by the medical staff of the sending hospital, and have appropriate privileges at that institution.

Conclusion

The increase in ethical issues in radiology may indicate the importance of early teaching of ethics in this field to students, and continuous education to residents. There may also be a need for new laws and their enforcement.

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