

The majority of the reactions reported have primarily affected the skin, causing urticaria or petechial rashes, but with some degree of systemic effect, ranging from a vague feeling of tightness in the chest to collapse and shock.³ The only well-documented case report of a bronchial reaction to corticosteroids is the recent one by Mendelsohn *et al.*⁴ Of the various corticosteroid preparations available, the one most commonly implicated in producing anaphylactic-like reactions appears to be hydrocortisone. Reactions to methylprednisolone sodium succinate and oral prednisolone have also been recorded.⁴ Dexamethasone has not been implicated in an acute reaction, in either oral or intravenous form. The diluents for all the intravenous preparations contain many preservatives, including the parabens, which are well-known skin-sensitizing agents.⁵ These were however excluded as being the cause of the

bronchial reaction in Mendelsohn's case. The relationships between skin prick tests and intravenous challenges with corticosteroids have been inconsistent and skin tests may therefore be misleading in identifying the offending corticosteroid preparation.⁴

We report these 2 patients seen during the last 6 months to draw attention to what may be a more common reaction to intravenous hydrocortisone than has previously been appreciated.

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Radiology and the Law in South Africa

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SUMMARY

In terms of regulations gazetted in 1973, the Department of Health has control of the practice of medical radiology in South Africa. The regulations and the rules of the South African Medical and Dental Council that apply to radiology are discussed, and the legal position of workers is noted.

S. Afr. med. J., **53**, 260 (1978).

Regulations controlling the practice of radiology in South Africa were proclaimed in 1973 in the *Government Gazette*¹ of 3 August 1973 by the Minister of Health, in terms of Section 1 of the Public Health Amendment Act No. 42 of 1971, whereby considerable responsibility is placed on the medical practitioner who owns or uses an X-ray unit for medical purposes. Few medical practitioners are aware of their legal obligations under these regulations. The Department of Health is at present inspecting all radiological units in South Africa in terms of the regulations.

Some basic propositions are: (i) that radiology requires the use of an electrical apparatus that may be dangerous to patients and operators under certain circumstances, and (ii) that responsible duties must be delegated to technical and nursing staff in any busy private or hospital department.

ASSUMPTION OF GENERAL RESPONSIBILITY

The South African Medical and Dental Council requires every registered medical and dental practitioner to exercise a fair, competent and reasonable skill in his practice. This requirement would apply to his use of an X-ray unit. Any injury to a patient owing to negligent use of a unit could result in an action for damages. The practitioner is responsible for negligence of his staff in the course of their duties, but he is not responsible for an inevitable accident after all reasonable precautions have been taken. The question of the death of a patient will not be considered in this discussion, but the general principles involving the use of drugs and the hazards of the use of ionizing radiation that may result in a patient's death could raise the question of culpable homicide if any neglect is proved.

CONTROL OF THESE MATTERS BY THE GAZETTED REGULATIONS

Provisions regarding patients are defined in Part III 6 of the regulations. This section is based on the rules defined by the International Radiological Commission in limiting the exposure of the patients 'to the lowest value compatible with successful diagnosis or therapy', and 'to keep the gonadal, skin and integral dose to the lowest possible values consistent with clinical requirements'. Special precautions are to be taken for children, and for young and pregnant women.

The doctor's assistants must have the necessary technical knowledge, and they must be conversant with currently accepted principles.

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Records relating to the patient's examination should be kept for a reasonable period. The 'reasonable period' has not been laid down by any law, but as a claim for damages would be proscribed after a lapse of 3 years, it would seem that a period of 3 years is reasonable in the circumstances.

A technique chart for each X-ray unit is a requirement, and all units must be calibrated to this end. (The details of these requirements are listed in Annexure 'A' to the regulations. The forms contemplate adequate and expert record-keeping.)

Therapeutic units are to be regularly calibrated by a medical physicist or approved person, isodose charts and tables are required, and all new calibrations are to be kept for a year.

The premises must be suitable for the practice of radiology and must conform to accepted rules for protection against ionizing radiation, e.g. Section III 3.3 of the regulations requires that appropriate warning signs or notices which are easily intelligible to all persons be displayed at the entrances to, or at appropriate places in, all areas where persons may enter and may be exposed to ionizing radiation. There is a specific directive that workers and the public shall not be exposed to more than the maximum permissible dose.

Any applicant for a licence must satisfy the Secretary for Health that he knows the basic principles of radiation protection in general, as well as its application to the installations under his control. If an applicant cannot comply with the above, a nominee acceptable to the Secretary may be appointed as the 'responsible person', but this would not absolve the doctor from any legal obligations that may arise from the use of the installation. An inspector may require this person to be present at any inspection.

THE EMPLOYER'S LIABILITY REGARDING RADIOLOGICAL STAFF

This is important in view of the increasing use of diagnostic radiology and the number of persons employed in medical radiography. Levitt and Townshend,² in a chapter on the law relating to the practice of radiology in England, state that a worker injured in the course of his duties has two principal rights to compensation: (a) a common law right based on negligence, for which the employer is legally responsible, and (b) a statutory right, independent of proof of negligence.

In South Africa the Workmen's Compensation Act³ would apply to all workers who earn up to R9 600 per year. It is possible that a worker earning more than this, who was injured on duty in a provincial hospital would, in exceptional circumstances, receive very sympathetic consideration on an *ad hoc* basis, although his employer would not be legally obliged to compensate him (personal communication: Staff Administrative Officer, Tygerberg Hospital).

The common law right to compensation may arise in 3 ways. Firstly, if a private doctor is assisted by a radiographer, and she is injured through his negligence, he is responsible. Secondly, he must provide a safe working area, safe apparatus, a safe system of work and, most important: 'He must use due care in the appointment of

all employees in positions in which the safety of others may depend upon their competence.' Thirdly, he is liable if one employee is injured by the negligence of a fellow employee.

The regulations in Section III 4, defining provisions regarding radiation workers, accept the latest recommendations of the International Commission of Radiation Protection and require statutory registration of all trained or trainee workers and also other workers, 'if the conditions are such that the resulting doses might exceed 3/10 of the annual maximum permissible dose'. This important provision would apply to nurses, porters and non-professional staff who may be subject to regular radiation exposure.

The regulations further require regular monitoring of workers' exposure records, and regular medical examination. Pregnancy must be notified immediately, and the worker's registration must be terminated.

An appointed medical practitioner must be approved by the Secretary, but a doctor may appoint himself if he is 'conversant with the general harmful effects of ionising radiation and versed in all aspects of diagnosing such effects' (item III 5.4. iv).

Those who work near sources of radiation must be medically examined at intervals of not more than 14 months, as well as when any unusual radiation event has been suspected.

Let us now consider the provision of a safe system of work. The use of diaphragms in screening, methods of protecting workers by lead aprons, and distance from the radiation source, must constantly be supervised or checked by the doctor, for 'an employer does not discharge his obligations merely by presenting his employee with a list of regulations . . . if he himself habitually disregards them'. There is thus a very definite legal responsibility on the doctor himself to obey all the rules all the time when using radiation!

QUALIFICATION OF RADIOGRAPHERS OR TECHNICAL ASSISTANTS

While a person is not necessarily unfit to undertake the duties of a radiographer if he or she does not possess an academic qualification, it must be recognized that there is a South African Medical and Dental Council supplementary register for radiographers. It would be some evidence of competence if a worker were so registered, and on the whole one would be unwise to employ someone not registered. However, there is an obligation on the part of the employer (doctor) to register with the Secretary for Health any worker exposed to radiation who receives 3/10ths of the annual maximum permissible dose as a radiation worker in terms of the regulations.

OWNERSHIP OF X-RAY FILMS

Kitchin,⁴ in his book published in 1936, maintains that the films are the property of the doctor who takes them, in the absence of any other arrangement. Films may be regarded as the product of specialized or expert work required for the purpose of medical diagnosis, and as such they belong to the person who produced them (the

doctor). However, there are exceptions, such as when a patient requests an X-ray film and report for employment clearance or insurance or a visa.⁵ The films and report are then the property of the patient, or the insurance company, if the patient expressly or tacitly cedes his right to them.

PERIOD FOR WHICH FILMS MUST BE KEPT

As long as the doctor has the films, he can be called upon to furnish medical data based on the old films that could be of appreciable assistance in diagnosis, prognosis and treatment. My own feeling is that there is great merit in handing over the films to the patient for safe-keeping! The minimum period for which films must be kept should be 3 years.

REPORTS ON RADIOGRAPHS

Reports are confidential and cannot be divulged without the patient's consent. A very thorny problem arises when an employer refers a patient for a chest X-ray to ascertain if she/he could have tuberculosis. I think one must be extremely circumspect before furnishing any information to the employer under these circumstances. In a case like this, the patient's consent should be obtained in advance, if possible.

Legal obligation to disclose information in court is determined by the magistrate or judge, if the doctor claims privilege on the ground of confidentiality in relation to the radiological examination, e.g. presence of a 'bullet in the chest wall' as evidence in a criminal case.

The radiologist may always send the films and report to the patient's referring doctor, for the latter is in fact the patient's 'agent'. Any further enquiries should then be directed to the agent, not the radiologist! However, the doctor who refers the patient is not the owner of the films, and if the patient changes doctors, he would be legally entitled to obtain the films and make them available to his 'new' doctor! This is once more a good reason for letting patients have their films!

From the above it can be assumed that while the law in South Africa is adequate in theory, it is very obvious that the Department of Health will have to work hard to enforce the regulations.

RADIOLOGICAL PRACTICE REFERRALS

Medical practitioners may not perform a radiological investigation for any person not registered with the South African Medical and Dental Council, but it is permissible for a patient to request a radiological examination without being referred by another medical or dental practitioner, providing it is not intended for a third party who is an unregistered practitioner.⁶ This seems to be an anomaly!

Informed consent for a contrast diagnostic radiological investigation is a thorny problem that is ever with us. In routine practice it is essential to obtain written consent for such a procedure, and this is always done at Tygerberg Hospital, but how valid this is likely to be unless the patient has been informed of the risk of death seems debatable. While radiotherapists have been to court about this matter, no diagnostic radiologist has faced this issue in a South African court. In the absence of any reliable

method of testing for sensitivity to contrast agents, it would seem that one is obliged to 'test dose' despite the fallibility of the latter.

A radiotherapist must inform the patient or the legal guardian of the patient of the short- and long-term effects of radiotherapy in each case. This has been well documented in the case of *Esterhuizen v. Administrator, Transvaal*.⁶ It behoves all South African radiotherapists to read the official report of this classic case.

'Mere consent to undergo X-ray treatment in the belief that it is harmless or being unaware of the risk it carries, cannot amount to effective consent to undergo the risks or the consequent harm.'

The difficulty is the time it takes to explain to the layman in non-technical terms the many complications that may possibly arise during and after X-ray treatment. A further problem is how to justify this type of treatment to the patient unless he is fully informed of the serious nature of his disease. In the *Medical Chronicle* of September 1977, the following statement appeared:

'Although a moral duty exists, a doctor does not legally have to inform a patient that the patient has a malignant condition. That is if the doctor feels that it is not in the patient's best interest to be told about the disease.' This comment was made during a discussion on 'What medical litigation is all about' at a meeting of the Southern Transvaal Branch of the Medical Association and of the Medical Graduates' Association of the University of the Witwatersrand, at which well-known panel members included Professor S. A. Strauss, Professor H. Shapiro and a Johannesburg advocate.⁷

I cannot accept that the patient can give 'effective consent' to a drastic method of treatment unless he knows the nature of his disease. I think there is more than a moral duty involved!

Tonkin,⁸ in discussing the lack of communication between doctors and patients regarding their illness, states: 'The patient's co-operation and understanding are essential if treatment is to be fully effective.' I would add that the doctor must tell the patient the truth when imparting medical facts and must always take time and care in doing so. Only then is consent meaningful.

As the use of medical radiology and the number of people employed in its practice increase, strict control becomes necessary to ensure the safety of patients and workers. Our Department of Health is actively engaged in enforcing the regulations, but an onus rests on every doctor involved in radiology to maintain the highest standards of radiation protection daily.

I wish to thank a distinguished member of the legal profession for verifying the contents of this short review.

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