ferential diagnosis of toxoplasmic retinitis in patients with AIDS includes cytomegalovirus.

Unequivocal laboratory diagnosis of ocular toxoplasmosis can be achieved only by showing endozoites of toxoplasma in ocular tissues, but this is impractical. Indirect serological methods are usually used; blood testing is rarely helpful as a substantial population of people have antibodies to toxoplasma (but do not have active disease). An immunocompetent patient negative for antibodies to toxoplasma is unlikely to have ocular toxoplasmosis.

If ocular toxoplasmosis is suspected then a Sabin-Feldman dye test or an enzyme linked immunosorbent assay (ELISA) may be performed on serum. A high, changing, titre provides evidence of acquired toxoplasma infection while a persistent low titre denotes prior infection by the parasite. In doubtful cases a high titre of antibodies to toxoplasma in aqueous humour compared with the titre in serum can prove helpful,⁹ but false negative results may occur. The problems inherent in such indirect diagnosis of ocular toxoplasmosis are difficult to surmount. Use of molecular methods such as the polymerase chain reaction to detect toxoplasma antigen in the aqueous humour may be the answer,¹⁰ although the viability of the parasite cannot be determined with this procedure.

Treatment of ocular toxoplasmosis remains controversial. Some specialists contend that as the infection is self limiting and antitoxoplasma drugs may be toxic and ineffectual,¹¹ treatment for peripheral retinal disease is not indicated. Exceptions requiring treatment include patients with lesions in the papillomacular area or optic disc, a large retinal lesion with pronounced vitritis, or compromised immunity.¹² There is no universal agreement concerning optimal antitoxoplasma drug treatment or duration of treatment.¹³ Furthermore, the role of corticosteroids remains the subject of debate. Questions such as whether drug treatment should be continued as long as an immunocompromised state persists or after an ocular lesion has become quiescent in order to prevent recrudescence remain unanswered.

Reactivation of infection may indirectly involve leakage of the antigen from intact tissue cysts¹⁴ which can persist in the host. These are difficult to inactivate with most drugs, although some newer macrolides, such as azithromycin or the hydroxynaphthoquinone drug atovaquone,¹⁵ may do so. Randomised controlled trials and an evaluation schedule for testing new drugs (as exists for toxoplasmic encephalitis)¹⁶ are clearly required.

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Radiation and women of child bearing potential

Moves to revive the "10 day rule" may be premature

The "10 day rule" recommended that, in women of child-bearing potential, non-urgent x ray examinations that entailed pelvic irradiation should be restricted to the first 10 days of the menstrual cycle. Its rationale was to avoid irradiating a fetus before the mother realised that she was pregnant. In 1984, however, the International Commission on Radiological Protection reported that there was little, if any, risk of damaging the fetus during the first two weeks of gestation—that is before the first period was missed.¹ The National Radiological Protection Board issued advice based on this statement,² and the College of Radiographers and Royal College of Radiologists followed up with their joint guidelines.³ Since then, for examinations in which the uterus will be within or close to the irradiated area, radiographers and radiologists ask patients if there is any chance that they may be pregnant. If the answer is anything other than no they then ask the date of the patient's last period. If it is overdue, consideration is given to postponing the examination—the "28 day rule."

In September 1993 the board published its latest statement on diagnostic medical exposure to ionising radiation during pregnancy.⁴ This confirms that, provided departments ensure

that patients are exposed to ionising radiation only when imaging is clinically indicated, the benefits are likely far to outweigh any small risk from the radiation. The one potentially controversial part of the statement concerns the risk of childhood cancer after irradiation in utero. For other adverse effects (fetal death or malformation, severe mental retardation, and inherited disease in future generations) the influence of diagnostic doses of radiation is insignificant in relation to their natural incidence. For induction of cancer, however, the position is not so clear. The view of the International Commission on Radiological Protection that irradiation during the first two weeks of gestation entailed little risk of carcinogenesis was apparently based on the assumption that any damage to the genetic material sufficient to cause cancer would be almost certain, at such an early stage of development, to result in embryonic death. But this is not always the case; evidence now exists that some carcinogenic mutations, even at this very early stage of life, are compatible with continuing development of the fetus. The risk cannot be quantified but is probably greater than zero (R Cox, personal communication). The danger increases substantially after the first missed period, and at this more sensitive stage fetal

exposure to the highest doses regularly achieved in diagnostic radiology might result in an additional risk of fatal childhood cancer before the age of 15 of 1 in 1300.⁴ This represents a doubling of the incidence in an unexposed population.

The procedures that concern the board are those that entail doses of "some tens of mGy."⁴ In routine practice this means abdominal or pelvic computed tomography and barium enemas, although radiation doses for the same examination vary widely among departments.⁵ While avoiding specific recommendations, the board suggests that one way to prevent irradiation of an early fetus would be to restrict these high dose procedures to the first part of the menstrual cycle—in other words, a limited return to the 10 day rule. The danger is that the document will be seen to turn the previous advice on its head, producing confusion in some departments and possibly resulting in a hasty general reintroduction of the 10 day rule. This would be an unfortunate overreaction.

Based on current knowledge, the following statements seem justified:

For the great majority of routine examinations—those not falling into the high dose category—radiology departments should continue to apply the 28 day rule.

There will be a few patients, attending for a high dose examination, who think that they may be pregnant but whose period is not yet overdue. Some departments may want to change their policy and, where clinically acceptable, delay examination of these patients until the first 10 days of their

next cycle. Only to this very limited extent need a return to the 10 day rule be contemplated.

The risk of radiation damage to a fetus, even at the relatively high doses resulting from abdominal computed tomography or a barium enema, is small, and inadvertent exposure in early pregnancy will not of itself be an indication for termination or for the use of invasive diagnostic procedures such as amniocentesis.

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Should herbal medicine-like products be licensed as medicines

Special licensing seems the best way forward

Herbal remedies form a potpourri that ranges from plants that people collect themselves and then take for health reasons to approved medicinal products. Many herbal products available in Britain fall between the far ends of this regulatory range: unlicensed preparations are thought to account for over 80% of herbal sales.¹ European Union legislation requires herbal products to be authorised for marketing if they are industrially produced² and if their presentation or their function, or both, bring them inside its definition of a medicinal product.³ Unfortunately, the drawing of sharp borderlines is difficult.

Many medicine-like products on the British herbal market remain unregistered for two reasons: acceptable data on efficacy, safety, and quality may not be available, and the licensing fee is high. Diluting requirements for registration would introduce double standards, which would be highly controversial. On the one hand, a single regimen for medicinal products offers undeniable advantages including equal treatment for all kinds of remedies and close control of medical claims. On the other hand, the basis of the conventional requirements for efficacy, safety, and quality is the need to safeguard public health. That aim is not well served when the stringent application of conventional criteria to herbal medicine-like products leaves most such products outside strict regulatory control.

Herbal products vary from well known European herbs to less familiar Asian and South American ones and from botanicals with an excellent safety record to potentially dangerous ones, such as broom⁴ and yohimbe.⁵ Furthermore, some products may be contaminated with undeclared toxic botanicals, heavy metals, or pharmaceuticals.⁶ A typical consumer is unable to distinguish between safe and less safe

preparations, and herbal medicine-like products may escape regulatory evaluation before marketing by being presented as food supplements. A remarkable consequence of this bypass is that the burden of providing data on safety and quality (which in the case of pharmaceuticals rests on the vendor) shifts completely to the authorities: they have to show that a product is unsafe, while that product may already be in use. Furthermore, herbal products may be sold without any of the objective product information needed to counterbalance the often uncritical literature on them.^{6,7}

Another concern is that traditional experience with herbs may be a powerful tool in the detection of predictable and striking symptoms of acute toxicity, but it is less reliable when adverse reactions are rare, or develop gradually or after a prolonged latent period.⁸ And traditional experience may be of little help in the recognition of harmful interactions with conventional drugs.^{7,9} For these reasons traditional experience needs to be supplemented with orthodox data from research and postmarketing surveillance. Postmarketing surveillance is, however, no sinecure when herbal suppliers and traditional practitioners are not obliged to report suspected adverse reactions and when herbal products are of variable quality.

One answer could be special herbal licensing. It offers opportunities before marketing to screen the declared constituents, demand proof of product quality, restrict the level of potentially hazardous constituents, and enforce warnings about correct and safe use. In addition, the possibility exists to oblige licence holders to report suspected adverse reactions. The presence of a licence number on the label would make the regulatory efforts visible to retailers, consumers, health care providers, and inspectors and would facilitate postmarketing surveillance and, if necessary, recalls.