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Radiography in women of childbearing ability

New protocols are needed

Before 1964 there were no rules about exposing women of childbearing age to ionising radiation. Women had *x* ray examinations as requested by referring clinicians with no questions asked about their last menstrual period or the possibility of pregnancy.

It is now agreed that all medical exposures should be kept as low as reasonably achievable and that each radiology department should agree a protocol for examining women in their reproductive years. But care of the potential mother must not be neglected and we must adapt the advice of expert bodies to suit local conditions and individual patients.

The first authoritative recommendation concerning protection of the fetus from potential harmful effects of *x* rays was made by the International Commission on Radiological Protection in 1964. It advised that all non-essential examinations of the abdominal region should be limited to the 10 days after a menstrual period, when it is virtually certain that no pregnancy exists.[1] This was no more than advice but, adopted more positively than intended, it gave rise to the "10 day rule," which held sway for a considerable time.

In a report in 1977 the commission made no specific mention of the rule,[2] but in 1982 it concluded that the rule may be unnecessarily restrictive.[3] The 1982 report talked of the specific nature of biological risks from ionising radiation to the fetus: hereditary defects, cancer, and developmental abnormalities were mentioned, with emphasis on mental retardation, for which the greatest risk lies in exposure between eight and 15 weeks after conception.[3] Then in 1984 Otake and Schull found that the risk of forebrain damage in the first eight weeks after conception could not be proved.[4]

By 1983 the commission was prepared to say that there need be no special limitation on exposures required within the four weeks after the menstrual period.[5] But the 10 day rule was finally knocked on the head in 1985 by three important statements in a much quoted leaflet from the National Radiological Protection Board.[6] Firstly, no special limitation on exposures is required in the four weeks after the onset of a menstrual period. Secondly, to minimise unintentional exposure of fetuses, any woman requiring diagnostic irradiation close to the uterus should be asked "the pregnancy question" (that is, "Are you, or might you be, pregnant?") and regarded as pregnant if the answer is other than "No." Thirdly, areas remote from the fetus may safely be examined radiologically at any time during pregnancy.

This death knell to the 10 day rule was confirmed that same year by the Royal College of Radiologists,[7] the Department of Health and Social Security,[8] and also by the College of Radiographers.[9] Nevertheless, would the rule die easily, neatly, obediently, and quickly? No. This rule had been easy to follow and gave comforting reassurance that any undetected fetus would be protected from the hazards of ionising radiation. To abandon it was to leave the quandary of what to use instead. The guidelines for an alternative policy, issued jointly by the Royal College of Radiologists and College of Radiographers in October 1986, were complicated and begged further questions.[9] (Incidentally, these guidelines promised an appendix "as soon as possible" to cover the use of radiopharmaceuticals but it has not been provided; other reports have implied that policies adopted to replace the 10 day rule should be extended to nuclear medicine.[10,11]) The joint college guidelines say "radiographic examinations of female patients can proceed at any time provided that the patient is not pregnant."[9] This statement does not allow for

- All medical exposures should be kept as low as reasonably achievable
- The possibility of pregnancy should be considered in deciding whether to examine a woman of reproductive ability
- In the first 10 days after menstruation it is unlikely that there is a conceptus and therefore unlikely to be additional risk
- During the rest of the first month any risk is likely to be so small that no special limitation on diagnostic exposures is required
- During the second month of gestation malformation of specific organs has occurred in experimental animals exposed to irradiation
- Between eight and 15 weeks after conception irradiation of the forebrain may result in mental retardation but no evidence of this has been shown in the first eight weeks
- The risk of cancer may be increased by doses as low as a few tens of mGy to an extent comparable with, or perhaps rather higher than, that in adults
- The ovum is sensitive to irradiation during at least the seven weeks before ovulation.

the fact that the earliest biochemical pregnancy test will not disclose a pregnancy until 10 days after fertilisation. Should we therefore revert to the simple stalwart 10 day rule? The answer is no, because the risks of diagnostic irradiation of a conceptus are not proved to be of any importance until organogenesis occurs in the third week after conception.[3 12 13]

With one anxiety controlled, another has now emerged. Biological research suggests that there may be a risk from irradiation of the ovum during the seven weeks before ovulation.[13 14] Perhaps the patient should be asked before the *x* ray examination not only "When did your last period begin?" but also "Are you intending to become pregnant within the next seven weeks?"

There is much advice but little real ruling. Local protocols must be drawn up and should take account of the points shown in the box (M Fitzgerald, personal communication).

The National Radiological Protection Board claims that it deliberately left to clinicians the manner in which its recommendations of 1985[6] should be used to replace the 10 day rule.[15] The board is quite right—we must commend, not criticise, them for allowing us this clinical freedom. We must, however, examine the advice we have been given and discuss the guidelines from our colleges before agreeing policies for each department. We cannot hide unthinkingly behind inflexible rules, 10 day or other. Instead, we must make thoroughly informed decisions about investigating patients while observing the one central rule—to minimise the exposure of fetuses.

In summary, *x* rays directed close to the uterus in women of childbearing ability carry risks to a pregnancy that may be present or may happen up to seven weeks after that *x* ray examination. With our current state of knowledge it is right that the 10 day rule is abandoned—it should never have existed as a rule but as an option to be used when appropriate. Instead, women of childbearing ability should be asked the pregnancy question, and if the answer is other than "No" then the fully informed radiologist or referring clinician must decide whether or not to proceed with the examination.

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Consent and people with mental handicap

Nobody but the patient may give consent

Gaining consent for a procedure from an adult with mental handicap living in the community is complex.[1] When most people with mental handicap lived in large institutions consent was provided through the paternalism of the physician superintendent or by relatives. Even those who had enough understanding to give consent were not allowed to do so. Because of increasing community care, rejection of the concept of infantilism, and a greater awareness of human rights the legal position on consent for these people has been reviewed: it became clear that no one but the adults themselves could give consent, however handicapped they might be and whatever their degree of legal competence.[2] Proxy consent from anyone was not valid in law. In particular, "blanket" consent forms offering a variety of consents for possible future events are useless, invalid, and an example of bad paternalistic practice.[3]

The Mental Health Acts of 1959 and 1983 provided nothing more in the way of advice. Under the 1959 act guardians could give proxy consent, but so few were appointed that the picture did not change much when this power was removed in the 1983 Mental Health Act. Despite this there is a move to reintroduce the guardian's capacity to give consent as one way of filling the legal vacuum.

Some adults with a mental handicap understand enough and are legally competent to give valid consent when the explanation is simple, repeated, and given by someone they trust. Some may sign their own name, and others may make a witnessed mark or thumbprint. Persuasion should not in these circumstances limit the autonomy of the adults, who may still have little experience of making choices in their everyday lives, but sometimes the wrong choice is made and may need to be overridden if life is to be saved. Others, however, will never understand because of the severity of their handicap, but no one else can give consent.

When the treatment is not controversial the doctor needs to go ahead if possible with the agreement (but not the consent) of the usual carer and next of kin, acting "in good faith" and showing "a duty of care." These are yardsticks by which he or she will be appraised. "Acting in good faith" is usually easy to define: it includes procedures such as endoscopy for a suspected cancer, laparotomy for an acute abdominal condition, or aspirin for a headache. In extreme emergency the doctor intervenes without consent using the "principle of necessity" as he would for someone who is unconscious. People with a mental handicap should not be included in clinical trials or any other activity that is not of direct therapeutic benefit to them.

The unsigned consent form is often, however, seen as unacceptable, and a social worker may be sent to seek a long lost relative while everyone waits impatiently.[4] Junior doctors, who may have been taught the current state of the law, may still insist on a signature in deference to their seniors. Often someone in the mental handicap service signs the form to allow the intervention to proceed—thus per-