



Dose Constraints for ‘Helpers’

(Comforters and Carers)

Position Paper

Adopted by Medical Council 3 September 2004

Introduction:

Legislation was enacted in this country in 2002 [Statutory Instrument 478 of 2002] to transcribe the EC Directive on the health protection of individuals against the dangers of ionising radiation in relation to medical exposure [97/43 Euratom]. This legislation stipulates that the Medical Council must make provision for the protection of persons voluntarily caring for patients undergoing medical exposures. This position paper examines some of the issues involved and makes recommendations in relation to Medical Council responsibilities.

Definitions:

From SI 478 of 2002

“Dose Constraint” means a restriction on the prospective doses to individuals which may result from a defined source, for use at the planning stage in radiation protection whenever optimisation is involved.

4.2. These regulations [SI 478 of 2002] shall also apply to exposure of individuals knowingly and willingly helping (other than as part of their occupation) in the support and comfort of individuals undergoing medical exposure.

12.1(a) The Medical and Dental Councils shall establish the dose constraint for exposure of those individuals knowingly and willingly helping (other than as part of their occupation) in the support and comfort of patients undergoing medical diagnosis or treatment where appropriate

12.2. In the case of a patient undergoing a treatment or diagnosis with radio-nuclides, the practitioner shall provide the patient or legal guardian with written instructions, with a view to the restriction of doses to persons in contact with the patient as far as reasonably achievable and shall provide information on the risks of ionising radiation

97/43 Euratom

Article 3 (2): Exposure referred to in Article 1 (3) [Exposure to helpers] shall show a sufficient net benefit, taking into account also the direct health benefits to the patient, the benefits to the individuals referred to in Article 1 (3) and the detriment that the exposure might cause.

Discussion:

The term 'Helper' is applied to a relative or companion who comforts and cares for a patient who is undergoing a medical exposure for diagnostic or therapeutic purposes. In the UK the term 'Comforter/Carer' is used.

It is clear that the 'Helper' must be performing the function in a voluntary capacity. People who assist the patient as part of their occupation, nurses, ward orderlies, taxi drivers, etc., are not 'Helpers' within the meaning of this act and must comply with the dose limit requirements of SI 125 of 2000.

'Helpers' who are exposed to radiation must do so knowingly and willingly. This requires that they give assistance to the patient with full knowledge of and full consent to any radiation risks involved. This requirement would seem to preclude a person under the age of 18 years becoming a 'Helper'

There is a legal requirement on the practitioner, in the case of patients who have had radionuclide administrations, to supply a patient or legal guardian with written instructions on radiation dose control and information on radiation risk. It would seem prudent that all 'Helpers' should also be supplied with similar instructions and information commensurate with the risks involved. The form that risk information takes has to be very carefully determined as it may cause unnecessary concern in the 'Helper'. Loss of patient or 'Helper' cooperation as a result of anxiety may result in compromised patient care and a possible increase in staff and patient dose if procedures have to be repeated.

Article 3 (2) of 97/43 Euratom states that the benefits to the patient and the 'Helper' must be balanced against the detriment to the 'Helper'. If there are no benefits to the 'Helper' from the procedure then extra consideration should be given to possible dose reduction methods.

If the procedure involves a substantial dose to the 'Helper' it might be appropriate to organise a meeting involving the patient, the 'Helper', and the assigned medical physicist to discuss radiation controls and risks. In this instance it would be prudent to get the 'Helper' to sign a document indicating that they knowingly and willingly undertake their duties. A substantial dose in this context would be a dose exceeding the annual dose limit for a member of the public [c.f. SI 125 of 2000]

In the case of nuclear medicine patients it may not be possible to identify all close friends and family members who may be exposed by the patient. Because of the absence of consent these people can not be presumed to be 'Helpers' and hence the patients must be given instructions on dose control methods that allow these 'third parties' to meet the dose limitation requirements of SI 125 of 2000.

Dose Constraint:

In both national legislation and in the EC directive the exposure to the 'Helper' is not classified as a medical exposure. The dose to the helper is, however, subject to a dose constraint.

It is important to note that a dose constraint is a target level that is used prospectively in planning an exposure - it is not a dose limit per se. For each individual 'Helper' control measures are planned to ensure that the dose to the 'Helper' is less than the particular dose constraint. It is important to note that the 'ALARA' principle should also operate and every effort should be made to keep the 'Helpers' dose as low as reasonably achievable.

The numerical value of the dose constraint for 'Helpers' has been the subject of some debate throughout the EC.

In an advisory document ⁽¹⁾ on the administration of Iodine – 131 to patients the following dose constraints for 'Helpers' were suggested:

- a) 3 mSv effective dose per procedure for an adult.
- b) 15 mSv effective dose per procedure for an adult 60 years of age or over. [Based on the fact that the lifetime detriment for people of this age is at least 3 times less than that for the general population]

These values would be broadly acceptable in this country, in my view, as dose constraints for all types of medical exposure.

The NRPB ⁽²⁾ in the UK has suggested 5mSv effective dose as a blanket dose constraint per procedure.

In general, pregnant women should not act as 'Helpers' but should be subject to procedures that ensure that the effective dose to the foetus does not exceed 1 mSv. It is recognised that situations may arise which make strict adherence to this recommendation extremely difficult and such personal situations should be handled sensitively. In the rare event of a pregnant woman acting as a 'Helper' a dose constraint of 0.3 mSv effective dose per procedure to the foetus, as is recommended in the UK, would be appropriate. If there is a possibility that the dose constraint may be difficult to adhere to then the pregnant woman and her partner, if practicable, should sign a document indicating that they understand the risk implications and that they knowingly and willingly wish to proceed with the exposure. It is worth noting that all women of childbearing capacity should be treated as pregnant if pregnancy cannot be excluded.

In the case of radionuclide administration to patients, the dose constraint should take account the possibility of internal incorporation as well as external exposure.

When medical exposures take place within a hospital it is possible to control exposure to 'Helpers' and third parties. However, when radionuclides are administered to patients who are subsequently outside the hospital environment then dose control is more difficult. Control procedures must be tailored to the individual 'Helper' and the realistic contact pattern between the 'Helper' and the patient ascertained from interviewing both parties. This process should not be neglected as there have been some very unusual patterns of contact between patients, particularly paediatric patients, and 'Helpers' reported in the literature.

It should be noted that some medical exposures may be repeated relatively frequently depending on the patient's condition. If the dose to the 'Helper' from individual procedures is substantial, and the procedure is repeated two or three times each year, then consideration should be given to the possibility of using alternative 'Helpers' for subsequent repeat exposures. In cases where the dose to the 'Helper' is substantial consideration should be given to the use dosimeters, particularly electronic dosimeters, to evaluate the efficacy of control procedures.

Conclusion:

The dose constraint recommended in this paper is 3 mSv per procedure [15 mSv for 60+ year old 'Helpers']. Where possible, pregnant women should be precluded from the role of 'Helper'. In the event of a pregnant woman acting as a 'Helper' the dose constraint should be 0.3 mSv.

Because of the requirement that 'Helpers' care for the patient knowingly and willingly it is important that they be in a position to consent to the potential risks involved and to understand any control measures that are recommended to them. This requirement would indicate that helpers be provided with written guidelines on these issues. In the case of patients undergoing diagnostic imaging, both X-ray and Nuclear Medicine, the guidelines could be relatively rudimentary as the dose to the 'Helper' is usually considerably less than 1 mSv per procedure.

In the case of patients undergoing therapy procedures involving radionuclides the dose to the 'Helper' can readily exceed 1 mSv per procedure and individualised guidelines need to be given to the 'Helper'. In the case of paediatric patients undergoing Iodine – 131 mIBG therapy a dose of 1.5 mSv to a parent has been recorded and it has been postulated that doses of 3.8 mSv per procedure could be delivered to a parent. Clearly in these types of exposure precise recommendations on dose limitation and on radiation risk needs to be given to the 'Helper'. The control mechanisms must take likely contamination routes into consideration also.

When patients are undergoing external beam therapy with mega-voltage beams it is the invariable recommendation that no person should be present in the room with the patient. If an exception to this recommendation is contemplated then precise written instructions are required for the 'Helper' who must also sign an appropriate consent form indicating compliance with the *knowingly and willingly* requirement. Such exposures should only take place under the supervision of the Radiation Protection Adviser or the assigned physicist.

Brachytherapy patients may irradiate 'Helpers' while the sources are in place. In the case of permanent implants the patient should remain in hospital until it is clear that the sources are not likely to migrate from the site of implantation and be eliminated from the body. Written instructions are required to ensure that 'Helpers' can control the exposure they receive.

If the exposed patient is under the age of 18 years the situation may be complicated by the fact that some hospitals require a parent or guardian to be present with the patient at all times. Similarly in the case of some ethnic groups there may be a difficulty in convincing a spouse or guardian to distance themselves from a female patient

undergoing a medical exposure. These situations present a particular challenge in terms of devising written guidelines for dose reduction.

A very useful discussion of the issues raised in this paper is contained in the HSE Research Report 155 of 2003.

- (1) EC Radiation Protection 97. Radiation Protection following Iodine-131 therapy (exposures due to out-patients or discharged in-patients).
- (2) Medical and Dental Guidance Notes. 2002.