



Original paper

Prevention of and response to inadvertent exposure of embryo/fetus to ionizing radiation, due to medical exposure of the mother. The Greek regulatory authority initiatives



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ABSTRACT

Embryo/fetus (E/F) irradiation as a result of medical exposure of the mother should be avoided, unless there are strong clinical indications. Medical practitioners are assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of and during the delivery of medical exposure. In cases of unintended exposure of embryo/fetus (E/F), the risk analysis and communication is conducted by or under the supervision of medical physicists at local level. National competent authorities can contribute to the prevention, risk analysis and communication of inadvertent E/F exposure to ionizing radiation by recording, analyzing and disseminating the relevant information. Since 2001, Greek Atomic Energy Commission has established a committee with the mandate to provide advice, to keep records, to analyze and disseminate the experience gained in cases of unintended E/F exposure. During the period 2001–2011, the committee was consulted by 269 pregnant women undergone medical exposures. The conclusions from the relevant data analysis, as well as the experience gained are herein presented and discussed.

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Introduction

The issue of unintended exposure of embryo/fetus (E/F) to ionizing radiation due to medical exposure of the mother is considered of great importance. The risk for E/F tissue injuries, and developmental changes (including malformations) associated with the in-utero irradiation, as well as the risk for radiation-induced cancer have been presented in detail by International Commission on Radiological Protection (ICRP) in Publications 90 and 103 [1,2]. The risk varies with the E/F absorbed dose and the phase of gestation. Doses in the range of 100–200 mGy are considered as a

threshold for malformations appearance and the nervous system is usually affected. Medical exposure of the mother due to diagnostic radiology or nuclear medicine procedures are unlikely to result in E/F absorbed doses of that range. In cases of pregnant women undergoing certain interventional procedures or therapeutic treatments (e.g. radiotherapy, radiopharmaceuticals) the expected absorbed doses to E/F would exceed the afore-mentioned values.

The conceptus is most sensitive to radiation from 8th to 15th week of gestation due to the brain development [1,3]. Absorbed doses in the range 0.1–1 Gy can result in severe mental retardation.

As far as the induced cancer risk is concerned, the late stage of fetogenesis is the period of highest radiosensitivity and the fetus is assumed to be susceptible to radiation carcinogenic effects as a young child [1]. The relative risk may increase by 40% over normal incidence, following an E/F absorbed dose of 10 mGy. However the individual risk remains small due to the low incidence of childhood cancer (0.1–0.3% [4]).

Various scientific organizations and committees have published guidelines and reports dealing with E/F radiation protection [2,5–9]. In Europe, requirements for the implementation of appropriate radiation protection measures during pregnancy are included in legislative binding documents [10], and have been

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adopted in national legislation [11]. Due consideration is also given in the recently published International Atomic Energy Agency (IAEA) Basic Safety Standards [12]. According to the latter document, registrants and licensees shall ensure that proper radiation protection arrangements are in place for female patients who are or might be pregnant. All practicable measures must be taken in order to minimize the likelihood of any inadvertent exposure of the E/F in the course of a diagnostic or therapy procedure using ionizing radiation. However, if such an exposure occurs several actions may be required, depending on its magnitude, such as prompt investigation, dose assessment, preventive measures, recording, reporting, informing of the referring medical practitioner and the patient, etc.

Although the main responsibility for the prevention of and response to inadvertent E/F exposure to ionizing radiation is assigned to the registrants and the licensees, the role of the competent authorities to establish, adopt and ensure the implementation of regulations and guides is important. Furthermore, competent authorities have the primary responsibility for the harmonization of national legislation with the international or European safety standards. In this respect, the authorities' inspection and enforcement activities should ensure the implementation of appropriate measures and procedures.

Greek Atomic Energy Commission (GAEC) as the national competent authority on radiation protection issues, established in 2001, a committee for dealing with the inadvertent E/F exposures to ionizing radiation. The main tasks of this committee are the provision of consultation and updated information to the interested parties (i.e. medical physicians and pregnant women), on the biological effects of ionizing radiation.

The purpose of this work is to present the actions and initiatives undertaken by GAEC, in order to: (a) minimize the occurrence of inadvertent E/F exposures at national level, (b) enforce the optimization in case of justified diagnostic or therapy procedures using ionizing radiation to female patients who are or may be pregnant, (c) increase the awareness of the involved parties and the public, (d) contribute to the development of the required safety culture among the medical and paramedical personnel of the medical facilities and (e) support medical physicists at local level by disseminating the relevant information. Additionally, the experience gained from GAEC's committee operation and the relevant outcome are presented and discussed.

Materials & methods

Greek legislation [11] sets provisions regarding the medical exposure of female patients at reproductive age to ionizing radiation. Medical facilities using ionizing radiation are required to establish quality assurance programmes, providing among others, specified requirements relating to protection and safety. The requirements, for the prevention of unintended E/F exposure to ionizing radiation, include the investigation of the likelihood of pregnancy in terms of justification and the use of appropriate radiation protection arrangements during the delivery of medical exposure based on EC Radiation Protection Report 100 [6]. In this respect, special signs must be clearly placed in the waiting areas of medical facilities to warn female patients about the radiation risk during pregnancy. Moreover, interview procedures and recording/reporting protocols must be in place as well as procedures for estimating the radiation dose expected to be delivered to the E/F and the associated risk. The verification of compliance with the legislative requirements is carried out by GAEC via on-site inspections. Furthermore, national radiation protection regulations [11] include provisions for education and training of medical and paramedical personnel involved in medical exposures (diagnostic procedures and therapeutic treatments). Special topics on the issue

of prevention and handling of E/F inadvertent exposures are included in the basic curricula of all Greek Universities' Medical Schools and Departments of Radiological Technologists of Technical Educational Institutions (tertiary education). The competence of medical and paramedical personnel in radiation protection is monitored and verified by GAEC on a regular basis. It is worth mentioning that a nationwide project was carried out in the bi-annum 2010–2011, when three-day training seminars were organized by GAEC in order to refresh and/or cover potential educational needs on radiation protection. These training seminars, attended by almost 3000 technologists (radiology and nuclear medicine), covered in detail theoretical and practical aspects of radiation protection, including the prevention and handling of inadvertent exposures. Participants were provided with learning material.

In the field of public information, GAEC prepared informative material in leaflet form, dealing with radiation and pregnancy and distributed it to the interested parties. It has been observed that this initiative reactivated communication with gynecologists and obstetricians, thus creating a channel for effective exchange of information. Information on this issue as well as links to similar scientific web pages is provided in GAEC website (www.gaec.gr).

GAEC's committee for dealing with the inadvertent E/F exposures to ionizing radiation has been contacted by two hundred sixty nine (269) pregnant women, who underwent 367 medical exposures, in the period 2001–2011. For every case (i.e. contact), a special form was filled out, providing information on:

- Personal data (name, age, contact information etc.)
- Data for determining the gestation phase at which the exposure took place (date of last menstruation, date of conception)
- Data regarding the involved physicians (gynecologist, referring medical physician, radiologist, nuclear medicine physician etc.)
- Medical exposure data (procedure, date and place, estimated E/F doses, etc.)
- Radiation protection arrangements applied.

No follow-up protocol was applied, in order to avoid any inconvenience to the women. Instead, they were kindly asked to inform the committee about the health condition of the children after the pregnancy.

In most of the cases related to X-ray procedures, the medical exposure data were provided by the medical physicists of the facilities where the exposure was performed. The provided values were compared to those found in the literature [6,13–25]. Whether the E/F dose was expected to exceed 10 mSv, appropriate dose estimation software was used. For E/F absorbed dose due to plain radiography procedures, the PCXMC v 1.4 software (STUK – Radiation and Nuclear Safety Authority, Helsinki, Finland (1999)) [26] was used, while E/F absorbed doses due to CT scans performed during the first two months post-conception were estimated by using the ImpACT software (ImpACT CT Patient Dosimetry Calculator, Version 0.99w 16/05/05) [27], considering that the dose to uterus approximates the dose to the E/F. Whenever needed, related data from GAEC's National Radiation Protection Database (NRPD) [28,29] were used.

The evaluation of the estimated E/F doses from diagnostic radiology procedures was also based on studies, providing dosimetric data for a wide range of procedures, acquired either by TLD measurements in anthropomorphic phantoms or by dose calculations using appropriate software [13–25]. For nuclear medicine, E/F absorbed dose assessment was performed based on absorbed doses and effective doses provided in the literature [30–34]. E/F thyroid gland dose was estimated [35–40] and internal dosimetry services were provided by GAEC (i.e. whole body counter measurement) to

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