

PATIENT SAFETY

PAVING THE WAY FOR PROGRESS



September 2021



IONISING RADIATION: LIMITING THE EXPOSURE OF WOMEN UNAWARE OF THEIR PREGNANCY

Newsletter for medical professionals requesting and performing medical procedures using ionising radiation



EDITORIAL

The exposure to ionising radiation of pregnant women who were unaware of their pregnancy is the main cause of significant radiation protection events (SRPEs) reported to ASN in computed tomography and conventional radiology. This represents nearly 200 cases per year, or one third of the SRPEs notified annually to ASN.

How can we avoid these exposures, which are a source of concern for the patients and their physicians?

With nearly one million pregnancies per year in France¹, the question concerns all health professionals, whether requesting or performing diagnostic or therapeutic procedures, because they all have to take charge of patients of childbearing age at one time or another.

The multidisciplinary working group, through this newsletter, calls for the teams to step up their vigilance to avoid delivering doses to the embryo or foetus² (NB: “foetus” will be used in this text for both meanings, whatever the stage of pregnancy). If a woman is known to be pregnant, only the radiological examinations necessary for her health are to be carried out.

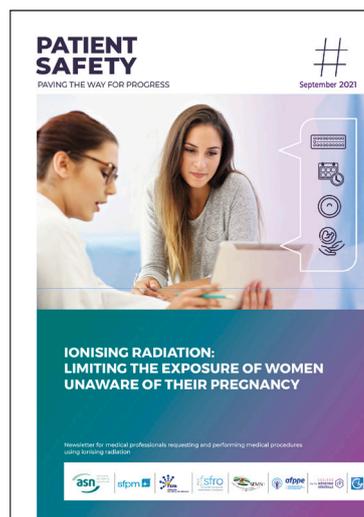
The challenge will be won if all the medical professionals share the same concern for raising patient awareness and investigating possible pregnancies. Secretary, radiographer, physicist, general practitioner, midwife, radiologist or other specialist physician: everybody is concerned! Don't hesitate to circulate this newsletter among your colleagues.

Wishing you enjoyable reading!

The Editorial Team

1 - Total number of pregnancies including births and voluntary terminations of pregnancy.

2 - Embryo in the first two months of pregnancy, foetus as from the 3rd month and up until birth.



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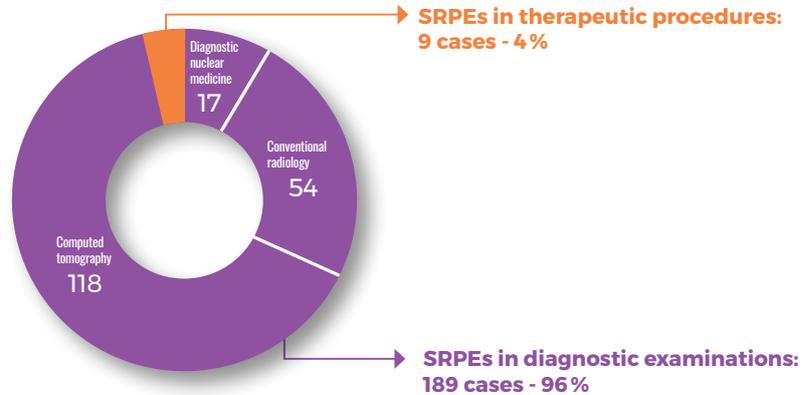
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Key figures

Exposures of pregnant women who are unaware of their pregnancy, the notification of which is mandatory, represent some 200 cases each year, that is to say about a third of the SRPEs notified to ASN, or 1 pregnancy in 5,000. The majority of the exposures occur during diagnostic examinations: this is the cause of nearly **half the SRPEs in computed tomography and conventional radiology**. Fewer than 5% concern therapeutic procedures.

BREAKDOWN OF SRPEs RELATING TO EXPOSURES OF PREGNANT WOMEN (YEAR 2019) TOTAL OF 198 CASES



Background

WHAT ARE THE REGULATORY OBLIGATIONS?

According to Article R. 1333-58 of the Public Health Code:

1. The physician requesting the procedure and the physician performing the procedure **must check any woman of childbearing age for possible pregnancy**.
2. If pregnancy is confirmed or if the possibility of pregnancy **cannot be excluded**, particular attention must be paid to the justification of the procedure taking into account the urgency and the exposure of the woman and the unborn child. Non-irradiating examinations of equivalent effectiveness (ultrasound scan, MRI, etc.) should be chosen in priority whenever possible.
3. If a procedure using ionising radiation is chosen after justification, **optimisation** of the procedure takes into account the confirmed or potential pregnancy.

In addition, the patient must be clearly informed on the basis of the benefit/risk balance of the examination.

WHAT MUST BE NOTIFIED TO ASN?

ASN must be notified and a dosimetric reconstruction must be carried out for any **incidental exposure of the embryo or foetus** of a pregnant woman in a situation where:

- the patient's uterus was in the field of exposure to ionising radiation;
- and the medical staff were unaware that the patient was pregnant.

WHAT ARE THE RISKS?*

The risks vary according to the stage of pregnancy at which the exposure takes place (higher risks during the 1st three months of pregnancy).

Below 100 milligrays (mGy), no increase in **malformations** or reduction in intellectual quotient has been detected to date in comparison with spontaneous risks (estimated at 3%). Above this threshold, the risk and severity of these effects increase progressively. The risk is high at doses exceeding 500 mGy.

Based on current knowledge, any exposure is liable to increase the **risk of cancer** in the unborn child (stochastic effect), but the exact risk is difficult to determine with certainty and remains very low at the usual doses used in medical imaging and diagnostic nuclear medicine.

*see IRSN sheet for the latest scientific data



In practice

WHAT DO YOU SAY TO A PREGNANT WOMAN EXPOSED DURING A DIAGNOSTIC IMAGING EXAMINATION?

If you have had a radiological or computed tomography (CT) examination of an anatomical region that does not concern the abdomen or the pelvis, your child has not received any measurable exposure.

If this is not the case, the imaging examinations or diagnostic nuclear medicine examinations of the abdomen and pelvis usually deliver doses to the uterus of less than 100 mGy: the risk of miscarriage, malformation or mental retardation will be no higher than if you had not been exposed.

Medical termination of pregnancy is not justified for an exposure of less than 100 mGy to the uterus, whatever the stage of pregnancy. In the case of higher foetal doses and depending on the stage of pregnancy, a multi-professional opinion, taking the patient's individual situation into account will be established to inform the patient.



Decoding the event

■ DIAGNOSTIC EXAMINATIONS (radiology and nuclear medicine)

Moderate levels of exposure of the uterus, always below 100 mGy.

On the patient's side

- Check-list type documents (incorrectly) filled out by the patient if they have received no explanations on the items or prior discussion about the risks;
- Language barrier or difficulty in understanding the medical vocabulary.

On the imaging organisation's side

- A majority of incomplete examination requests, with clinical indications that are too vague for symptoms that could be directly linked to a pregnancy (back pains, abdominal pains, constipation, etc.).

■ THERAPEUTIC PRACTICES (radiotherapy, fluoroscopy-guided interventional practices and nuclear medicine)

Exceptional SRPEs (2 to 3 per year at the most) which leave a mark on the services, with exposure doses for the foetus that are variable but could exceed 200 mGy

On the patient's side

- Irregularity in taking the oral contraceptive required for the treatment;
- Late periods (menstruation) not reported.

On the imaging organisation's side

- Failure to ask questions about contraception and desire for pregnancy;
- No HCG assay (pregnancy test) carried out before the examination.



Steps for progress

■ MAP THE RISK

- Identify the proportion of women of child-bearing age among the female patients;
- Target the examinations requiring particular attention on account of their sensitive location (pelvic region) and the high radiation doses delivered;
- Identify the resource persons for a dosimetric reconstruction or advice on foetal exposure: medical physicists of the organisation, IRSN, patient radiation protection experts of G4.

■ JUSTIFY THE PROCEDURES

Requesting physician

- Formalise the objectives of the radiological exploration;
- Be attentive to the precision of the clinical indication;
- Exclude irradiating examinations if there are symptoms that could result from pregnancy.

Radiologist and his/her team

- Check the appropriateness of the indication;
- Postpone the examination or use a non-irradiating technique if necessary.

■ RAISE AWARENESS IN WOMEN WHO ARE OR COULD BE PREGNANT

Those involved in perinatal care

- Foster awareness of the risks associated with foeto-maternal exposure by prevention actions targeting pregnant women in a benefit/risk approach;
- Involve the regional medical actors: gynaecologists, midwives, general practitioners and radiologists.

In the surgery or radiology centre

- Alert patients to the need to report confirmed or suspected pregnancies through posters in the waiting room and changing booths, preferably in several languages;

- Provide for an explicit pictogram to overcome language barriers.

■ SCREEN FOR PREGNANCIES

- Put in place pregnancy detection measures by the various medical professionals trained in patient radiation protection, at the different moments in the care pathway of women of child-bearing age (when making the appointment, reception, examination);
- Include information on the risks associated with foetal exposure in the interchange;
- Provide a form to be filled out when making the appointment for examinations in which the uterus is potentially exposed.

DISCUSSION THREAD FOR DETECTING PREGNANCY (gathering factual data)

- 1 - Does the patient use contraception assiduously;
- 2 - Date of last period (menstruation) (late?);

And depending on the answers to the first questions and the situation:

- 3 - Has the patient had unprotected sex;
- 4 - Possibility of pregnancy linked to a desire for a child or medically assisted reproduction (MAR).



In case of doubt or confirmed pregnancy
If there is the slightest doubt, consider the patient pregnant until proved otherwise.

Depending on the urgency and the indication: perform an HCG blood test or, failing this, a urine test, - being sure to wait for the results -, postpone sensitive examinations or replace them by other non-exposing techniques (ultrasound scan, MRI).

The requesting physician can prescribe an HCG assay to be performed in the two days preceding the imaging examination. Caution, the result of the HCG blood assay is only reliable one week after conception.

If the examination must be carried out, optimise the doses and the target location.

With external-beam radiotherapy:

- Take the case to the specialised multidisciplinary consultation meeting;

- Measure the potential dose to the foetus using a phantom;
- Choose an appropriate radiotherapy technique to minimise the dose received by the foetus.

For therapeutic procedures and hysterosalpingography

As of June 2006, the French Society of Nuclear Medicine asserted the **need for a systematic HCG blood assay prior to therapeutic procedures**, which involve higher radiation doses: *“It is mandatory before any therapeutic nuclear medicine procedure to make sure that any female patient of child-bearing age, whatever her age, is not pregnant by performing a quantitative plasma HCG assay, ideally on the day of therapeutic administration or, failing this, in the week preceding administration at the most.”*

This recommendation was established in consultation with ASN and is consistent with the position of the international

organisations, namely the IAEA¹, the American SNMMI², the HPS³ and the EANM⁴.

The working group likewise recommends an HCG blood assay for **fluoroscopy-guided interventional practices targeting the pelvic area** and for **hysterosalpingography**. This examination is effectively carried out in the context of an infertility assessment (patient not using contraception). Furthermore, the injection of the iodinated contrast agent into the uterine cavity and the fallopian tubes can lead to miscarriages in women engaged in a medically-assisted reproduction process.

1 - International Atomic Energy Agency

2 - Society of Nuclear Medicine and Molecular Imaging

3 - Health Physics Society

4 - European Association of Nuclear Medicine



The experience of the centres

“Capitalise on the blood test to enhance the safety of interventional radiology”

Bettina KERROUMI, coordinator
Simon BONNICI, head of the vascular radiology service and RPE-O (radiation protection expert-officer)
Centre Imagerie du Nord
Imaging Centre of the North
(Seine-Saint-Denis département)



In January 2021, the Centre Imagerie du Nord put in place systematic blood HCG assaying for all women of child-bearing age for scheduled interventional radiology procedures involving the pelvic area.

This measure was taken following the accidental irradiation of a 29-year old patient who was unaware of her pregnancy, during a vascular interventional radiology examination in November 2020. The dose delivered to the embryo was between 140 and 180 milligrays (mGy).

WHAT IMPORTANCE DOES PREGNANCY DETECTION REPRESENT FOR YOUR CENTRE?

The interventional radiology site of Saint-Denis is acknowledged for the treatment of pelvic congestion syndrome, which is the clinical manifestation of pelvic venous insufficiency. We perform five pelvic embolisations per week, that is to say about 250 per year. This is a long and highly irradiating examination (lasting 1h to 1h30) centred on the area in which the uterus is situated. With a patient population comprising 50% women of whom 80% are of child-bearing age, pregnancy detection is effectively very important.

WHY MAKE HCG ASSAYING SYSTEMATIC?

The blood HCG assay gives a result that is reliable one week after conception. Our patient's pregnancy would have been detected. It is all the more relevant given that a blood test is already carried out before interventional radiology examinations, such as pelvic embolization. This solution safeguards the informed consent as the patients do not always understand the questions (15% do not speak French) or the risks, which reduces the confidence that can be placed in the reliability of their answers.

“Avoid accidental exposures by involving all the patient care and management actors”

From left to right:
Marion RUFFIN, radiographer,
Stéphanie BEDET, secretary,
Dr. Alban COLOSIO, radiologist and
radiation protection resource person,
Dr. Cyrille BREIDT, radiologist and
radiation protection resource person.



Company PRIM St Rémi (Marne département)

A past event:

In November 2019, a general practitioner retrospectively reported the pregnancy of a 22 year old woman he had referred to the centre for a CT scan. The doubts concerning a possible pregnancy expressed on the informed consent sheet had not been raised again before the examination. The dose delivered to the embryo is estimated at 30 milligrays (mGy).

■ What corrective actions did you put in place following this event?

The team was shocked by the fact that the informed consent sheet had been completely ignored. Each of the two radiographers operating the CT scanner thought that their counterpart had already read the consent sheet. Apart from the procedural deviation, the collective analysis of the event identified two root causes, namely a lack of communication within the team on the job and an insufficiently clearly defined role of the radiographers. A single radiographer now takes charge of the patient from A to Z for scheduled routine examinations. For urgent and injected examinations which require two radiographers, each radiographer double-checks the consent sheet. We are nevertheless considering having a single person ensure patient management with a rota system, when we no longer have the constraints of the Covid garments.

■ How have you organised things to avoid foeto-maternal exposures?

Our way of functioning has long meant that all members of personnel who interact with the patient are involved in pregnancy detection: first the secretary when requesting an appointment, then at reception

in the imaging department, followed by the radiographer during the clinical questioning prior to the imaging procedure. To reinforce this particular vigilance, we have issued all the personnel with a flow chart reiterating the key points in the management of the patients of child-bearing age undergoing CT scans and radiography examinations.

■ What role does the requesting physician play in this vigilance?

The requesting physician is responsible for reporting the possible contraindications of an imaging examination, and therefore to investigate the possibility of pregnancy. To avoid inappropriate examinations, it is vital for the imaging examination requests to be complete. Yet the requests received lack essential information (our 2018 audit found that 25% of the indicators were not filled out), including too often the clinical history motivating the examination, the aim of the radiological exploration and the condition of the patient. We have focused the lines for improvement on the emergency physicians internally, but also on the general practitioners in the regions through post-university teaching in February 2018 and 2019.

■ What lessons have you learned and would like to share?

Trusting other people cannot be enough in itself. We have positive feedback on the attitude of individual responsibility, which is more reassuring for our teams. Systematically questioning the patient is not a huge constraint. We treat 250,000 patients a year, of whom 20% are women of child-bearing age. The three questions concerning the possibility of pregnancy, the use of contraception and the date of the last period supplement the search for other contraindications. For a CT scan, the entire systematic clinical questioning takes less than 5 minutes. That is a relatively short time and no more complex than for older women with whom it is important to detect diabetes or renal insufficiency.

The viewpoint of the requesting physician

“Any woman of child-bearing age should be considered pregnant until proved not to be”

Dr Eric DRAHI
French College
of General Medicine (CMG)



Any woman of child-bearing age should be considered pregnant until proved otherwise. This old saying sums up an important point requiring vigilance. Female patients must always be questioned about the date of their last period and their use of means of contraception. Nevertheless, **the degree of urgency and the risk of pregnancy must be taken into account at the same time.** If the examination has to be performed rapidly and the use of contraception and/or the menstrual cycle is/are irregular, the practitioner relies on the radiologist's expertise. It is the radiologist who verifies the appropriateness of the procedure and optimises it with regard to the radiation dose.

The imaging examination decision must always be established with the patient. Particular attention is paid to examinations that irradiate the abdominal or pelvic regions. The practitioner sets out the benefits and risks of the examination, indicates whether it is necessary to have a pregnancy test 48 hours before the examination or not, along with the limitations of urinary or blood tests.

WHAT ROLE DOES THE GENERAL PRACTITIONER PLAY IN THE JUSTIFICATION OF AN IMAGING EXAMINATION?

The risk involved in an imaging examination is the **joint responsibility** of the requesting physician and the physician who prescribes and performs the procedure. The general practitioner plays a key role in the relevance of the indications and the choices of examination. The general practitioner questions the appropriateness of a CT scan or an X-ray for diagnosis or treatment.

Given that no complementary examination is completely risk-free, the practitioner must weigh up the **risk/benefit** ratio, taking the possibility of pregnancy into account. The practitioner details the context and the objectives of the radiological exploration in the examination request, because it is essential for the radiologist to fully understand its end purpose.

WHAT ARE YOUR RECOMMENDATIONS FOR AVOIDING FOETO-MATERIAL EXPOSURE?



Further reading

INTERNATIONAL RECOMMENDATIONS

- **International Atomic Energy Agency.**
Radiation protection of pregnant women in radiology.
[iaea.org/resources/rpop/health-professionals/radiology/pregnant-women](https://www.iaea.org/resources/rpop/health-professionals/radiology/pregnant-women)
Radiation protection of pregnant women in nuclear medicine.
[iaea.org/resources/rpop/health-professionals/nuclear-medicine/pregnant-women](https://www.iaea.org/resources/rpop/health-professionals/nuclear-medicine/pregnant-women)
- **International Commission on Radiological Protection.**
Radiological protection in medicine, 2011. P68-69: Pregnancy and medical irradiation.
[icrp.org/docs/P%201015%20French.pdf](https://www.icrp.org/docs/P%201015%20French.pdf)
- **Health Physics Society**
Pregnancy and Radiation Exposure
[hps.org/hpspublications/articles/pregnancyandradiationexposureinfosheet.html](https://www.hps.org/hpspublications/articles/pregnancyandradiationexposureinfosheet.html)
Radiation and Pregnancy.
[hps.org/physicians/documents/Radiation_and_Pregnancy.pdf](https://www.hps.org/physicians/documents/Radiation_and_Pregnancy.pdf)

RECOMMENDATIONS OF THE LEARNED SOCIETIES

- **French Society of Nuclear Medicine**
Guide for writing protocols for treating hyperthyroidism with iodine 131, 2006.
<https://www.cnp-mn.fr/wp-content/uploads/2022/09/Traitement-cancer-thyroide-V1.0.pdf>
- **French Radiation Oncology Society.**
Radiation and pregnancy, Recorad chapter 38, 2021. Cancer/ Radiothérapie 20S.
doi.org/10.1016/j.canrad.2021.09.001
- **French Society of Emergency Medicine.**
Radiology and pregnancy. Chapter 22, 2011.
[sofia.medicalistes.fr/spip/IMG/pdf/Radiologie_et_grossesse.pdf](https://www.sofia.medicalistes.fr/spip/IMG/pdf/Radiologie_et_grossesse.pdf)

TOOLBOX

- **Pregnancy and exposure to ionising radiation**
IRSN Information Sheet.
[irsn.fr/Grossesse-RI-pdf](https://www.irsn.fr/Grossesse-RI-pdf)
- **Website of the Centre de référence sur les agents tératogènes (CRAT - Reference Centre on Teratogens).**
[lecrat.fr/rubriquefr.php?id_rubrique=33](https://www.lecrat.fr/rubriquefr.php?id_rubrique=33)
- **“Poster - Building awareness in pregnancy”.**
IAEA multilingual posters.
[iaea.org/resources/rpop/resources/posters-and-leaflets#1](https://www.iaea.org/resources/rpop/resources/posters-and-leaflets#1)

PATIENT SAFETY

MARCH 2011 - PATIENT IDENTIFICATION

NOVEMBER 2011 - THE FIRST VERIFICATION SESSION

JULY 2012 - HOW DO YOU ANALYSE YOUR SIGNIFICANT RADIATION PROTECTION EVENTS?

APRIL 2013 - WHAT EVENTS MUST BE NOTIFIED TO ASN?

DÉCEMBER 2013 - IN-VIVO DOSIMETRY

MAY 2014 - LATERALITY ERRORS

MARCH 2015 - RECORD AND VERIFY: RECORDING ERRORS!

JUNE 2015 - PULSED DOSE-RATE AND HIGH DOSE-RATE BRACHYTHERAPY

MAIY 2016 - HIGH-PRECISION HYPOFRACTIONATED IRRADIATION

JANUARY 2017 - PROTRACTION / FRACTIONATION

SEPTEMBER 2017 - MAKING THE PATIENT A PARTNER IN TREATMENT SAFETY

JULY 2018 - PATIENT REPOSITIONING IMAGING: VERTEBRA IDENTIFICATION ERROR

MARCH 2019 - EXPERIENCE FEEDBACK IN OTHER COUNTRIES

JULY 2019 - IMPROVING THE USE OF CT SCANNER FUNCTIONS

MACH 2020 - SAFETY OF THE RADIOPHARMACEUTICAL CIRCUIT IN NUCLEAR MEDICINE

JUNE 2020 - PRIOR RADIOTHERAPY TREATMENTS