PROJECT PREDOS

General recommendations

FANC AFCN

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SCK·CEN

STUDIECENTRUM VOOR KERNENERGIE
CENTRE D'ETUDE DE L'ENERGIE NUCLEAIRE

PreDos Study: General recommendations

In the Neonatal Intensive Care Units (NICUs), diagnostic radiology plays a significant role for the diagnosis and follow-up of the patients. The most commonly performed radiographs are anterior-posterior radiographs of the chest, the abdomen and combined radiographs of the chest-abdomen region. Despite their frequent use, the contribution of these examinations to the patients' exposure is still widely unknown in Belgium. The PreDos study aims at improving our knowledge in this field by investigating the doses delivered to new-borns during their stay in the Belgian NICUs. Entrance Surface Kerma[1] (ESK), Kerma-Area Product[2] (KAP), as well as the resulting doses to different organs of interest were evaluated. The influence of the corresponding examination settings were also registered and evaluated. The project was financed by the Federal Agency for Nuclear Control (AFCN-FANC) and realised by the Belgian Nuclear Research Centre (SCK•CEN), in collaboration with the participating NICUs for the data collection.

Out of the 19 Belgian NICUs, 17 participated in the data collection. The study eligible subjects were premature neonates (less than 37 weeks of gestation). The subjects were subdivided into three weight categories: less than 1000 g, between 1000 g and 2000 g, and more than 2000 g. The three most commonly performed examinations described above were studied. For each radiograph, patient characteristics (*i.e.,* weight, length, gestational age and underlying pathology) and radiographs settings (*i.e.,* tube voltage (kVp), tube load (mAs), focus to skin distance (FSD) and focus to detector distance (FDD)) were collected. If available, the KAP of the examination was also registered; the ESK was calculated using the technical settings specific to each radiograph. The number of examinations for each patient during the entire stay in the NICU was retrieved from the PACS (all examinations recorded in the PACS were taken into account).

In most centres, data of 40 minimum examinations were collected. These data were sufficient to obtain a better insight into the exposure for chest and combined chest-abdomen radiographs; for abdomen radiographs, the number of collected data usually proved to be insufficient.
A large, interhospital spread of the doses per examination was observed: for example, a dose ratio of 11:1 was found between the extreme values of the interhospital distribution of the median ESKs for a single chest radiograph. Intrahospital spread was also observed, but to a lesser extent. The large differences in dose are explained by the various examination settings used by the participating hospitals. In addition, important differences in the tube output of the x-ray machines were noticed. The data collected for the chest and combined chest-abdomen examinations were sufficient to calculate national diagnostic reference levels (DRLs). The DRLs were calculated as the 75th percentile of the dose distribution for each weight category and for the total sample, as well for ESK as for KAP (*Table 1*). For the abdomen examinations only a preliminary DRL for the total data sample could be determined. For those hospitals where the median dose exceeded the DRLs - in terms of ESK, of KAP or both - it can be explained by inappropriate selection of examination settings and/or lack of collimation of the radiation field.

[1] The Entrance Surface Kerma (ESK) is also known as Entrance Surface Dose (ESD).
[2] The Kerma-Area Product (KAP) is also known as Dose-Area Product (DAP).

ESK (µGy)

	<1000g		*1000g<…<2000g*		*>2000g*		***total***	
	25th	*75th*	*25th*	*75th*	*25th*	*75th*	***25th***	***75th***
Chest	21	40	19	47	25	51	**19**	**42**
Chest-abdomen	24	47	26	45	27	58	**26**	**43**
Abdomen	/	/	/	/	/	/	**20***	**59***

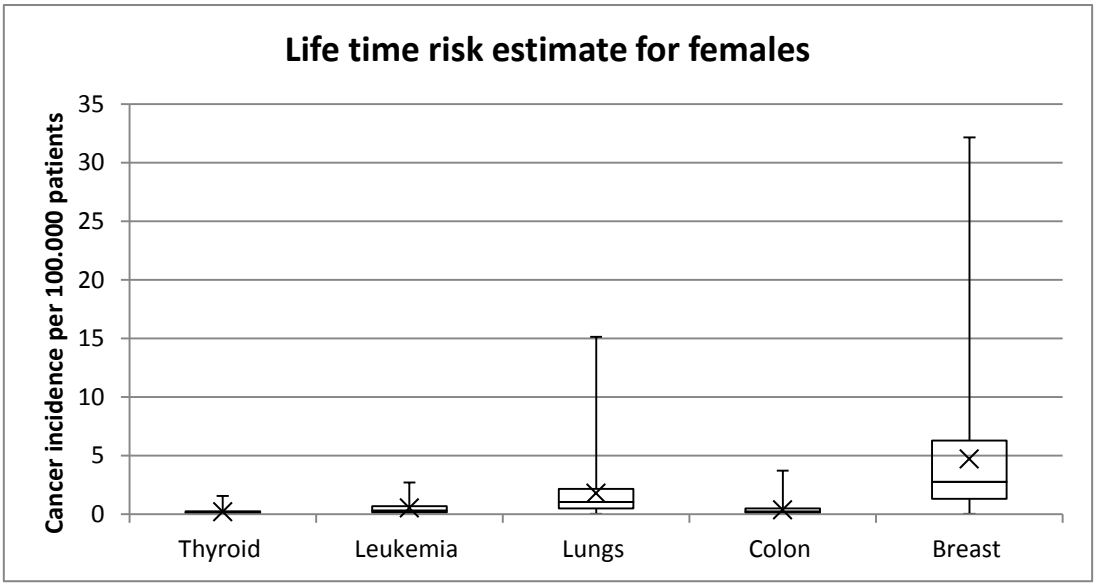
KAP (µGy.m²)

	<1000g		*1000g<…<2000 g*		*>2000g*		***total***	
	25th	*75th*	*25th*	*75th*	*25th*	*75th*	***25th***	***75th***
Chest	0.11	0.51	0.37	0.71	0.54	0.96	**0.40**	**0.74**
Chest-abdomen	0.70	0.98	0.81	1.15	0.76	1.47	**0.65**	**1.10**
Abdomen	/	/	/	/	/	/	**0.54***	**0.83***

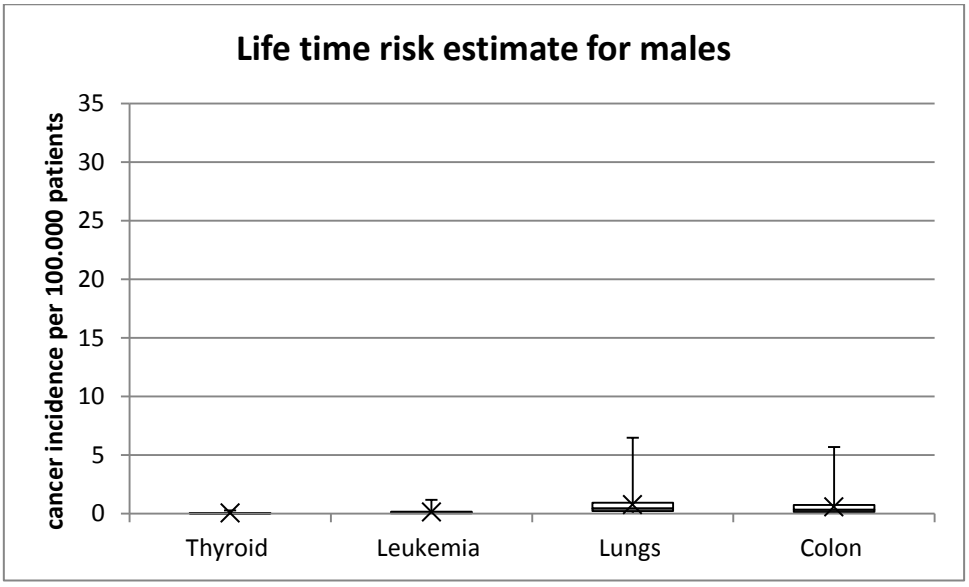
Table 1: National diagnostic reference levels in terms of ESK and KAP. The following relation between the KAP units: 1 µGy.m²=10 mGy.cm² exists

Regarding the number of examinations per individual stay in the NICU, considerable differences were observed between patients, resulting in important variations of the cumulative ESK: The number of examinations ranged from 1 to 71 examinations per patient stay resulting in a cumulative ESK from less than 10 µGy to more than 3 mGy. In terms of numbers of examinations, half of the patients received less than 5 examinations; in terms of cumulative ESK, half of the patients received less than 150 µGy. The percentage of patients receiving a dose superior to 50 µGy to the bone marrow, the breast, the colon, the lungs and the thyroid amounted to 32%, 97%, 70%, 83% and 19%, respectively. Risk estimates for various radio-induced cancers (*Figure 1*) were calculated from the cumulative organ doses for a subsample of more than one hundred patients. The estimates are based on the risk factors proposed by the BEIR VII committee[3] for neonates. Important variations of the risk estimates were found. The principal radio-induced cancers are colon and lung cancer for male patients and, breast and lung cancers for female patients. On average, female patients are about 5 times more likely to develop one of the cancers specifically considered in the study (leukaemia, breast, colon, lung and thyroid cancer) than male patients. It is worth reminding that, because of calculations assumptions, those estimates are likely to underestimate the risks incurred by the patients.

[3] **BEIR–Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation.** *Health Risks from Exposure to Low Levels of Ionizing Radiation.* National Academy of Sciences. Washington D.C. : s.n., 2006.



(a)



(b)

Figure 1: Life time risk estimate for incidence of various cancers per 100.000 patients: leukaemia and breast, colon, lung and thyroid cancer for female patients (a); leukaemia and colon, lung and thyroid cancers for male patients (b).

Based on the various situations observed in the participating centres, general recommendations for dose optimisation have been formulated. Finally, it should be emphasized that the implementation of any protocol should be the result of the local protocol, taking into account the local specifications of the X-ray machine as well as the image quality, which was not assessed in the study.

Recommendations

- **Allocation of tasks.** In every optimisation procedure, the participation and the collaboration of all the professionals involved in the imaging process (paediatricians, radiologists, nurses, operators, hospital physicist) are of particular importance. Therefore, it is worth reminding their specific tasks.
    - The hospital physicist is in charge of the quality control of the X-ray system and patient dosimetry; the results of these measurements need to be used to determine an optimised protocol which fulfils the requirements defined by the radiologist.
    - The radiologist and the operators are responsible for selecting the appropriate examination settings (kVp, mAs, focus to skin distance (FSD), shielding, etc.) and the appropriate collimation in the daily practice.

  Good communication and close collaboration are mandatory in the optimisation process. For example, the radiologist determines which image quality is sufficient for proper diagnosis quality and the medical physicist proposes the best protocol (technical settings) according to the technical specifications of the X-ray system.
- **High kVp coupled to low mAs**. Even if low kVp coupled to high mAs settings can give a satisfying image quality, high kVp coupled to low mAs settings are preferable from a radioprotection point of view. The use of higher voltage (kVp settings) eliminates the soft part of the radiation spectrum and, thus, decreases the absorbed dose. Soft X-rays are more absorbed by the patient, therefore increasing the absorbed dose without contributing to the image production. Settings of 60 to 65 kVp for chest examinations of neonates are proposed in the guidelines of the European Commission of 1996[4].

  In *Figure 2*, from Dougeni *et al.*[5], an example is given of the required values of mAs settings for achieving a satisfying image quality as a function of the kVp. In the lower right part of the figure, satisfying image quality is achieved with low mAs and higher kVp settings. It should be emphasized that this figure is only included for informative purposes and it all depends on the characteristics of the system used (tube output, inherent filtration).

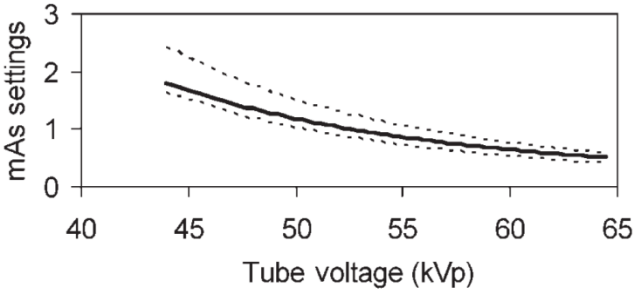


Figure 2: the required values of mAs settings for achieving maximum image quality score (solid line) and a satisfying image quality (70% of the maximum score, dotted lines) as a function of the kVp. Values are given for the weight category 1000-1500 g.

[4] *European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics.* **European Commission.** s.l. : European Commission, 1996, Vol. EUR16261.

[5] *Dose and image quality otpimization in neonatal radiography.*, **Dougeni E. D. and. al.** 2007, B. Jr. Radiology, Vol. 80, pp. 807-815.

In any case, the use of the lowest tube load (mAs settings) achievable with a sufficient image quality for diagnostic purpose is recommended. The dose is directly proportional to the tube load, therefore, a decrease of the tube load will directly result in the same decrease of dose.

- **High FSD/FDD** (Focus to skin distance/Focus to detector distance). As the dose is inversely proportional to the squared FSD, using a high value of FSD/FDD seems to be an efficient way to decrease the delivered doses without significantly impairing the image quality. In numerous centres, a fixed FDD of 100 cm is defined in the protocol. The highest possible FSD should be used considering the practical aspects of the examination. However, the FSD is often not fixed and, in many cases, not considered or unknown. A ruler or other means of enabling a quick estimation of FSD should be available.
- **Appropriate collimation and shielding.** Lack of collimation does not only impair the image quality by increasing the amount of scattered radiation, it also results in increased exposure of the organs, resulting in increased biological risks. This is unacceptable in the field of paediatrics, where patients are particularly sensitive to the detrimental effects of radiation. From the analysis of many chest and combined chest–abdomen radiographs, the thyroid was often in the radiation field, what should absolutely be avoided unless justified by diagnostic interest. In one of the participating centres, an average dose to the thyroid of 28 µGy was calculated, while the use of appropriate collimation would have resulted in an average dose of 3 µGy, decreasing the organ dose and the cancer risks by nearly 90%. All efforts should therefore be made to use the appropriate collimation. Shielding is also an efficient tool in order to prevent unnecessary irradiation (*Figure 3*).

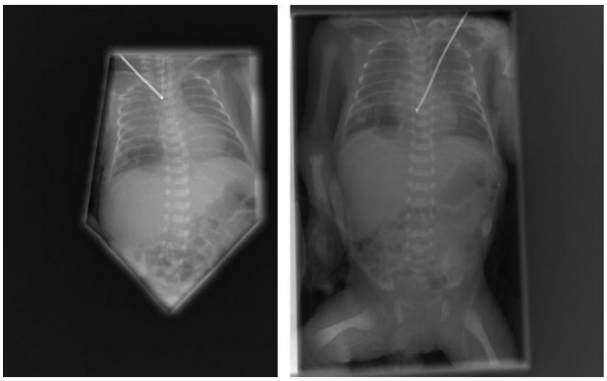


Figure 3: Use of extra lead shielding to prevent unnecessary irradiation (left); no shielding (right). Smans *et al.*[6]

- **Well-defined protocol.** This study concentrated on the technical aspects of the imaging process, so only technical recommendations are proposed. None the less, a complete examination procedure should give indications on most examination parameters, including collimation, position of the field (based on anatomical markers), positioning of the patient and use of shielding. Information and relevant training material on this matter can be found online. Recommended sites one can visit, are the section specifically dedicated to children of the website of the IAEA (https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/PaediatricRadiology.htm) and the website of the image gently campaign (http://www.pedrad.org/associations/5364/ig/).
    - **Technical settings**: the following parameters should be defined in the technical protocol: kVp, mAs and distance. It is worth remembering that the choice of these

[6] Results of a European survey on patient dose in paediatric radiology., Smans K. *et al.*, 2008, Radio. Prot. Dosimetry, Vol. 129, pp. 204-210.

parameters depend on the characteristics of the X-ray system and may strongly vary from one system to another: Besides the dose, the image quality should also be taken into account. The protocol should be displayed on the X-ray machine, in order to always be available to the operators and to avoid unjustified interoperator variations. The technical protocol given below, resulted in the lowest ESK observed during the study and is mentioned for informative purposes only. It gives a good example of technical parameter selection and summarises the major elements contributing to low dose examination: high kVp coupled to low mAs and large distance.

distance between focus and detector:	100 cm	
weight (g)	**kVp**	**mAs**
<1000	55-60	0.5
1000-2000	60-65	0.5
2000-3000	65-70	0.5
>3000	70	0.5

- **Mandatory dose audit.** In addition to the triennial dose audit, a retrospective estimate of the dose must be available for each individual radiological examination of children, by means of a KAP meter or another equivalent measuring system, assessed by a qualified expert[7]. In the particular case of diagnostic radiology in neonates, two dose indicators are readily available:
    - **Entrance surface kerma (ESK):** ESK is defined as the absorbed dose at the point of intersection of the x-ray beam with the entrance surface of the patient (*i.e.*, the patient's skin). A well-defined examination protocol (in terms of tube voltage (kVp), tube load (mAs) and distance between focus and patient's skin (FSD) enables to calculate the delivered doses based on the tube output (OP) measurements, which are performed as part of the annual quality control of the x-ray machine. If no contribution of the backscatter radiation is considered, the ESK is given by the following formula: $ESK = OP_{kVp} \times mAs \times FSD^{-2}$.
    - **Kerma-area product (KAP):** KAP is defined as the integral of the absorbed dose over the area of the x-ray beam in a plane perpendicular to the beam axis. KAP provides information on the dose absorbed and on the beam area at the entrance surface of the patient. KAP can be measured by the means of a KAP meter mounted on the x-ray system. KAP meters must be calibrated by the hospital physicist, at least annually.

  Ideally, the DRL should be monitored both in terms of ESK and KAP. This will provide information on the delivered doses and on the field size. Excessively high doses and also

[7] Vademecum "Utilisation des rayons x à des fins médicales - Het gebruik van röntgenstralen voor medische doeleinden" , AFCN-FANC, 2005, available online at www.fanc.fgov.be.

possible lack of collimation of the radiation field could hence be detected. However both values are not always available in practice; if a choice would have to be made between the two indicators, we would recommend recording KAP.

Conclusion

A wide variation of dosesbetween the centres was observed throughout Belgium, resulting in large variation of the organ doses and of the radio-induced risks. This large dose spread was caused by a large variation in examination settings, as well in the protocols as in daily practice. The distance between focus and detector also varied significantly. Large variation of tube output for the different X-ray tubes also contributed to the dose variation. This indicates that there are ample opportunities for optimisation.

Centres that exceeded the respective DRLs have now an opportunity to change their working procedures and to optimise the doses. Recommendations have been proposed to help reach these objectives. Nevertheless, those recommendations mainly focus on technical settings, and any optimisation procedure should be considered in a wider frame than solely the technical one: all the staff involved in the imaging process (paediatricians, radiologists, operators, nurses, hospital physicists) should take an active part in the optimisation procedure. That is why the following points of interest are suggested for further optimisation:

- **Role assignment:** the responsibilities of the people involved in the imaging process should be clearly defined. Particular attention should be paid to the justification, which is determined, among other things, by the necessity of the examination and the potential clinical benefit (added value in the clinical pathway) to be expected from the examination.
- **Clinical procedure:** a complete examination procedure should give indications on most examination parameters. It includes the definition of the technical settings but also other examinations parameters such as the required field of view (based on anatomical markers), and the added collimation required by the position of the patient or the use of shielding.
- **Quality assurance and improvement:** these procedures should ensure that the radiographs yield the adequate information (diagnostic quality) with the lowest possible exposure of the patient. Corrective measures should be promptly taken in response to any sign of quality degradation. For example, if the image analysis repeatedly shows a lack of collimation, additional training focusing on the position and size of the radiation field should be given to the operators.

Additional information and relevant training material on justification, role assignment and quality assurance can be found online. Recommended sites, one can visit are the section specifically dedicated to children of IAEA' website (https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/PaediatricRadiology.htm) and the website of the image gently campaign (http://www.pedrad.org/associations/5364/ig/).

Finally, it should be emphasised again that, if any optimisation of technical parameters is performed, image quality is an important factor to take into account, aside from the patient dose.