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ESTABLISHING NATIONAL DIAGNOSTIC REFERENCE LEVELS IN THE RUSSIAN FEDERATION BASED ON REGIONAL DOSE SURVEYS

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Abstract: Establishing diagnostic reference levels (DRLs) in a big country is complicated due to differences in radiological practice between different regions. In 2009-2014, a dose survey was performed in six Russian regions. Based on the results of the survey, preliminary DRLs for conventional X-ray examinations were established on a national level. Additionally, the local authorities were granted the possibility to establish regional DRLs if the local dose distributions significantly differed from the proposed national DRLs.

Keywords: X-ray examinations, radiation protection, optimization, diagnostic reference level, effective dose.

1. Introduction

Diagnostic reference levels (DRLs) serve as a basis for the system of optimization and the protection of patients from medical exposure. DRLs are intended to act as benchmark levels for doses from common diagnostic procedures. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied. DRLs for a selected X-ray examination are defined as a specific (usually 75%) percentile of a dose distribution for a certain examination [1]. DRLs should consider the variations in the local radiological practice and X-ray equipment [1,2,3]. However, it is complicated to perform full-scale dose surveys with the same accuracy in all the regions of a big country simultaneously.

In 2009, St-Petersburg Institute of Radiation Hygiene (IRH) started a project for implementation and adaptation of the DRL system into the Russian healthcare practice. During the following years, a system for data collection and methods for dose assessment were developed [4]. In 2009-2013 more than two thirds (63 hospitals) of all the hospitals in St-Petersburg underwent a full-scale dose survey. In 2012, the first Russian guidelines on DRLs were published [5]

based on this survey. In 2013, preliminary DRLs for plain radiography were established in St-Petersburg.

The Russian Federation consists of 65 regions (as of year 2015). However, in 2009-2014, it was possible to collect patient dose data only from five regions, apart from the St-Petersburg region, covering the major cities and healthcare facilities. In 2016 DRLs and the system of optimization is intended to be officially incorporated into the Russian legislation on radiation protection. Hence, it is important to provide the users with initial values of the DRLs. The aim of the current study was to compare the dose distributions in different Russian regions and to investigate the possibility of establishing the DRLs on a national level.

2. Materials and methods

In 2009-2014 dose surveys were conducted in six Russian regions: St-Petersburg (megapolis), Arkhangelsk, Belgorod, Bryansk, Murmansk and Tumen regions. Overall information about the regions is presented in Table 1.

Table 1. Regional data composition

Region	Regional code	№ of hospitals	№ of X-ray units
St-Petersburg	StP	48	125
Arkhangelsk region	Arkh	17	20
Belgorod region	Bel	8	17
Bryansk region	Br	9	17
Murmansk region	Mur	11	12
Tumen region	Tu	8	12

Thirteen standard radiographic examinations were selected for the dose surveys. Overall information about the examinations is presented in Table 2.

Table 2. Standard radiographic examinations and projections

Examination	Projection*
Skull	AP, LAT
Chest	PA, LAT
Ribs	AP
Cervical spine	AP, LAT
Thoracic spine	AP, LAT
Lumbosacral spine	AP, LAT
Abdomen	AP
Pelvis	AP

*AP – anterior-posterior; PA – posterior-anterior; LAT – lateral

Data collection was conducted according to a collaboration treaty with the local healthcare authorities. Local hospitals were informed about the upcoming dose survey; participation was voluntarily. In St-Petersburg, data was collected continuously over the whole 2009-2014 period. In the other regions, data was collected during dedicated dose survey expeditions, lasting for a limited time (usually about two weeks). Only the intact X-ray units that passed the yearly quality assurance were included in these surveys.

The following parameters were collected for each examination for each X-ray unit: tube voltage (kV), tube current (mA), exposure time (s), focal-image distance (cm), image field size (cm²) and radiation output (mGy·m²)/(mA·min). Radiation output was calculated for each tube voltage setting, using the data from the previously conducted quality assurance. Dose-Area Product, DAP (Gy·cm²), values were collected if the X-ray unit was equipped with an operational calibrated clinical dosimeter.

For analogue X-ray units, examination parameters were acquired for a standard patient (170±5 cm height, 70±5 kg weight, normosthenic constitution) by questioning the operators of the X-ray unit. For digital X-ray units, examination parameters were extracted from the PACS, as an average for 10 standard patients.

Typical patient doses for the selected examinations were determined using two dose quantities: entrance surface dose (ESD) and effective dose (*E_{eff}*). ESD was calculated based on the radiation output, tube current and exposure time according to the following equation:

$$ESD(mGy) = k \cdot R \cdot Q / r^2 \quad (1)$$

where:

- k* – backscatter coefficient, averaged to 1.4;
- R* – radiation output, (mGy·m²)/(mA·min);
- Q* – exposure current-time product, mAs;
- r* – focal-skin distance, m;

E_{eff} was assessed using the “EDEREX” (Effective dose Estimation in Roentgen Examinations) software (IRH, Russia), based on radiation output and exposure current-time product or DAP, whenever it was possible [6].

Table 3. Comparison between the 75%-percentiles of *E_{eff}* distributions (mSv).

Tissue weighting coefficients were taken from ICRP publication 103 [2]. Descriptive statistics were generated from the collected data using Statistica 10 (Statsoft).

3. Results

Regional dose data was processed and mean and 75%-percentiles of typical dose distributions were estimated for each region for both ESD and *E_{eff}*. An example of the regional dose distributions for the chest PA examination is presented in Figs. 1 and 2 for *E_{eff}* and ESD respectively.

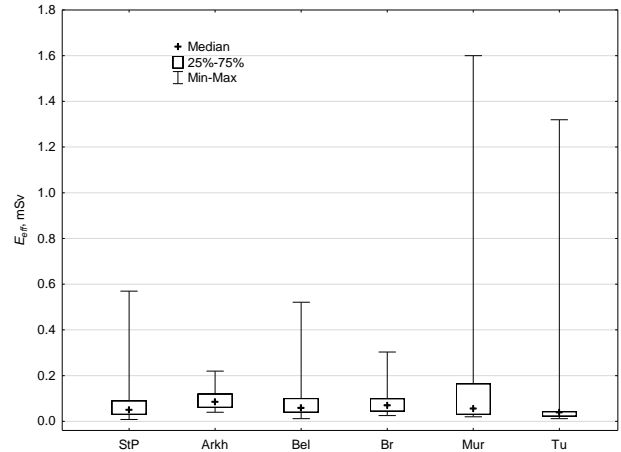


Fig. 1. Example of *E_{eff}* regional distributions (mSv) for chest examination in PA projection.

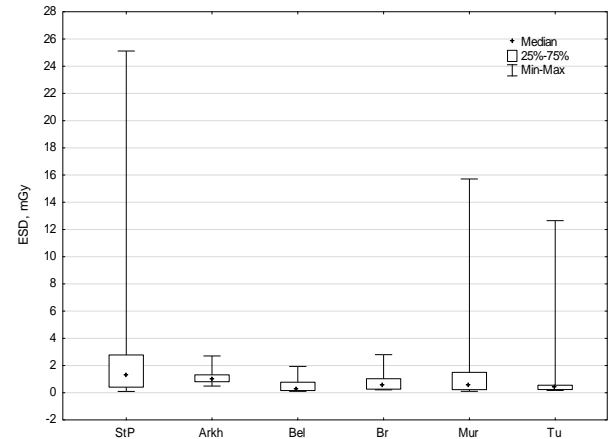


Fig. 2. Example of ESD regional distributions (mGy) for chest examination in PA projection.

For the purpose of comparison, regional dose data were merged together by examinations; joint data was processed and the resulting joint 75%-percentiles of the dose distributions were estimated in both ESD and *E_{eff}*. The comparison between the regional and joint 75%-percentiles of dose distributions are presented in Table 3 and 4 for *E_{eff}* and ESD respectively.

Examination	StP	Arkh	Bel	Br	Mur	Tu	All regions
Skull AP	0.08	0.12	0.12	0.08	0.11	0.07	0.09
Skull LAT	0.03	0.05	0.06	0.05	0.07	0.04	0.04

Chest PA	0.09	0.12	0.1	0.1	0.16	0.04	0.1
Chest LAT	0.17	0.2	0.53	0.19	0.51	0.23	0.19
Ribs AP	0.48	0.29	0.36	0.43	0.28	0.54	0.42
Cervical spine AP	0.08	0.25	0.09	0.14	0.13	0.08	0.11
Cervical spine LAT	0.06	0.16	0.04	0.12	0.11	0.04	0.07
Thoracical spine AP	0.39	0.76	0.41	0.26	0.36	0.45	0.44
Thoracical spine LAT	0.34	0.31	0.4	0.25	0.59	0.29	0.34
Lumbosacral spine AP	0.92	0.77	0.94	0.66	0.86	0.5	0.85
Lumbosacral spine LAT	0.87	0.99	1.59	0.84	1.14	0.57	0.87
Abdomen AP	0.88	0.5	1.19	1.46	1.32	0.75	0.96
Pelvis AP	0.81	1.00	1.12	1.63	0.52	0.87	0.86

Table 4. Comparison between the 75%-percentiles of ESD distributions (mGy).

Examination	StP	Arkh	Bel	Br	Mur	Tu	All regions
Skull AP	5.12	5.47	4.06	3.55	5.02	1.06	4.92
Skull LAT	4.36	8.75	4.98	6.46	12.24	0.95	5.35
Chest PA	2.78	1.32	0.77	1.03	1.50	0.17	1.96
Chest LAT	1.54	4.58	6.13	3.34	9.81	0.77	2.05
Ribs AP	4.67	3.89	1.85	6.44	3.60	0.39	4.14
Cervical spine AP	5.00	6.12	1.97	4.02	3.14	0.60	4.27
Cervical spine LAT	3.55	10.21	2.40	7.68	9.17	0.89	4.43
Thoracical spine AP	12.76	6.34	5.88	9.66	7.88	1.41	10.75
Thoracical spine LAT	9.39	14.23	11.85	20.66	26.55	3.97	12.66
Lumbosacral spine AP	27.28	11.78	11.39	12.25	10.80	2.84	19.86
Lumbosacral spine LAT	15.49	37.53	22.27	44.90	59.50	8.58	25.20
Abdomen AP	8.54	8.58	10.08	12.88	9.84	1.75	8.69
Pelvis AP	14.65	7.88	7.58	12.16	8.27	1.69	10.14

3. Discussion

It was possible to collect data only from the major hospitals located in the regional capitals, which account for about 15-20% of all the medical facilities working with X-ray diagnostics in the regions. Although it is possible to acquire the necessary information on the local radiological practice, X-ray and dosimetry equipment types and condition as well as patient doses in the regions, the amount of data collected is limited. Among the limiting factors are the time and funding for the external dose surveys and the good will of the medical facilities, as participation in the surveys is voluntarily. Nevertheless, these limited regional dose surveys are the only source of reliable information on patient doses as the official dose statistics and reports from the hospitals significantly vary from the manually collected data (up to the factor of 5-10) [7].

According to the DRLs guidelines [5] three dose quantities can be used for assessing the dose for establishing the DRLs in Russia: DAP, ESD and E_{eff} .

During the regional dose surveys it was complicated to collect DAP values as less than 10% of the X-ray units participating in the surveys were equipped with an operational and calibrated clinical DAP dosimeter. Although it was not possible to establish DAP distributions, it was used as a basis for determine ESD and E_{eff} , whenever possible. ESD was included into the list of dose quantities to comply with the IAEA Basic Safety Standards [8]. However, ESD is a less suitable quantity for DRL establishment and optimization purposes as compared to DAP or E_{eff} . ESD does not consider the size of the irradiation field or the entrance point of the X-ray beam (and irradiated organs). The fact that it was not possible to directly measure ESD, due to the lack of the dosimetry equipment and complexity of the measuring process, reduces the accuracy and increases the uncertainty of the ESD assessment. Despite all the limitations of E_{eff} , it considers virtually all the parameters of the examination and can be used to compare the radiation harm (risk) from different types of X-ray diagnostics. In addition, it is the only dose quantity used in Russian official dose statistics [7]. Both IRH and hospitals use the same software for E_{eff} assessment (EDEREX), thus reducing the risk for relative errors.

The min-max ratio for the typical doses from the selected examinations in all regions was high, commonly up to the factor of 60-100 for both ESD and E_{eff} . This can be explained by the prevalence of the analogue X-ray units and dominating use of blue-sensitive X-ray film and manual film processing. By the time of the dose surveys, less than 20% of the X-ray units in the regions and about 40% of the X-ray units in St-Petersburg were digital. A common practice is to acquire images on film, even on digital X-ray units. Other factors contributing to high patient dose are low technical maintenance of the X-ray units, and prevalent use of high exposure current-time product and irradiation fields. It should be pointed out that abnormally high values of E_{eff} did not always correspond to abnormally high ESD and vice versa.

Comparison of the typical dose distributions (mean, median and 75%-percentiles) indicate that they are consistent for the majority of the examinations. There were only five cases (one per region) of extremely high doses (exceeding the 75%-percentiles by a factor of more than 100). Differences in mean and 75%-percentiles of typical dose distributions between regions fit into the 30-50% range for the examinations of the skull, chest, thoracic spine and ribs. These examinations are carried out using standardized protocols with typical irradiation fields. The differences for other examinations are greater, up to a factor of 1.5, mainly due to variations in field size and exposure current-time product.

Considering the lack of major differences between typical dose distributions in the regions and limited regional sample size, there are two possible approaches for establishing the national DRLs. One is to use the St-Petersburg dose data and corresponding values of the 75%-percentiles of dose distributions as the national DRLs. The sample size of the X-ray units in St-Petersburg is representative and consistent with the data

from other regions. Another approach is to estimate mean and 75%-percentiles of the combined regional data. Unfortunately, the results would be strongly influenced by the St-Petersburg data, as the regional sample sizes are much smaller. As visible from Table 3 and 4, both approaches are viable, as the differences between St-Petersburg and the joint 75%-percentiles do not exceed 40%. Other regional data is comparable as well, except for the cervical spine and chest LAT examinations, where the differences are up to factor of 1.7 due to several cases of abnormally high doses.

As the majority of the X-ray units are still performing imaging on films, establishing separate DRLs for digital and analogue X-ray units is not necessary. The main goal for the first DRL implementation would be to identify and investigate the cases of significantly high doses (exceeding DRL values by a factor of 2 and higher). Hence, it is not required to establish DRLs with high accuracy. National DRLs would be updated on a five-year basis, considering the results of the dose data collection in new or previously surveyed regions.

Despite the intention of establish DRLs on a national level, local authorities would be able to establish local (regional) DRLs if the local radiological practice and typical patient dose distributions are significantly different. That option is included into the DRL guidelines and would be included into future legislative acts. Those regional DRLs would be accepted if the dose surveys covered >50% of the X-ray units in the regions and the methodology of the data collection complied with the DRL guidelines.

4. Conclusions

Despite the limitation of the regional dose surveys, the results of the 2009-2014 data collection indicate that the regional dose distributions are comparable for the majority of the examinations. Differences in 75%-percentiles of typical dose distributions do not exceed 50% for the examinations with standardized protocols (skull, chest, thoracic spine and ribs) and are less than a factor of 1.5 for other examinations.

Considering the lack of major differences in typical dose distributions and the limited size of regional dose samples, national DRLs would be established as the 75%-percentiles of the combined dose data distributions. However, the local authorities are granted

the opportunity to establish regional DRLs if the local radiological practice and typical patient dose distribution are significantly different.

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