WHO - IPHECA: Epidemiological aspects

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1. Introduction

In May 1991 the World Health Assembly endorsed the establishment of the International Programme on the Health Effects of the Chernobyl Accident (IPHECA) under the auspices of WHO.

Five pilot projects have been carried out within IPHECA in the study territories of Belarus, Russian Federation and Ukraine in a period from 1991 to 1994. This pilot projects dealt with the detection and treatment of leukemia and related diseases (Haematology Project), thyroid disorders (Thyroid project), brain damage during exposure *in-utero* (Brain Damage *in-Utero* project) and with the development of the Chernobyl registries (Epidemiological Registry Project). A fifth pilot project on oral health was performed only in Belarus.

Epidemiological investigations have been an important component of all IPHECA pilot projects. Within "Epidemiological Registry" Project such investigations have been the principal activity. But with respect to other IPHECA projects it was carried out in addition to main objectives relating to medical monitoring, early diagnosis and treatment of specific diseases included in project protocols.

To support the epidemiological investigations within IPHECA, WHO supplied 41 computers in Belarus, Russian Federation and Ukraine and provided training for specialists from these countries in internationally recognized centres. The training programmes and host countries were as follows: (1) Standardization of epidemiological investigations (United Kingdom), (2) Radiation epidemiology (Russia), (3) Development of software (United Kingdom), (4) Principles of Epidemiological investigations (The Czech Republic), (5) Cohort investigations (Japan).

2. Activities within "Epidemiological Registry" Project

The "Epidemiological Registry" pilot project aimed at the development and introduction of data basis, for obtaining of health indices and identifying the causes of morbidity and mortality among the population of territories with the level of ^{137}Cs contamination more than 555 kBq/m^2 (Table 1). It should be noted that some rayons had not been included initially in the project protocol but added later when the new information regarding soil contamination became available.

The Epidemiological Registry project served as a focal point for epidemiological investigations carried out within other IPHECA pilot projects. Therefore main attention was paid to:

- the development of standardized protocols and formats for computerized data collection;

- the creation of Software for all pilot projects;
- the determination of optimal methods for epidemiological studies.

Table 1. **Territories in Belarus, Russian Federation and Ukraine within IPHECA Epidemiological Registry project**

Country	Oblast[1]	Contaminated rayons[2] (more than 555 kBq/m^2)	Clean territories (reference data)
Belarus	Mogilev Gomel	Slavgorodski Hoynikski Checherski Kormyanski Gomelski	Ushachski rayon of Vitebsk oblast
Russian Federation	Bryansk Kaluga	Novozybkovski Zhizdrinski	Borovski rayon of Kaluga oblast
Ukraine	Kiev Zhitomir	Ivankovski Polesski Ovruchski	Yagotinski rayon of Kiev oblast

Three specialized institutions and national project coordinators supervised the fulfilment of the IPHECA "Epidemiological Registry project" in situ:

Belarus - Belarus Centre of Medical Technology, Informatics and Economics of Health care, (Drs. E. Okeanov and G. Chernikov);

Russian Federation - Medical Radiological Research Centre (Dr. V. Ivanov);

Ukraine - Institute of Epidemiological and Prevention of Radiation Injuries (Dr. V. Buzunov).

2.1 Development of standardized documents

In order to standardize epidemiological investigations within all IPHECA pilot projects, specialists from the three States in cooperation with international experts have developed basic documents as follows:

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[1] Oblast- a larger administrative and territorial unit, includes several rayons

[2] Rayon- an administrative and territorial unit in the former USSR

(1) Epidemiological Registry Project Protocol - for the determination of the common technology for collection, storage, transmission and analysis of demographic, medical, dosimetric and epidemiological data obtained in radiocontaminated territories in Belarus, Russian Federation and Ukraine. The protocol has clearly outlined main procedures in territorial units (rayon, oblast, national level).

(2) Recommendations how to integrate soft and hardware with National systems.

(3) Special IPHECA software package (SISP) - for harmonization of IPHECA with National programmes.

(4) The General Record Chart (OKSO) which includes the following main sections:

- General information;
- Dosimetry data on exposure of the whole body and thyroid;
- Data on exposure to hazardous factors;
- Data on health states, disability and death;
- Parents chronic diseases (for children examined);
- Data on diseases of the examined persons before and after radiation exposure.

(5) Unified general examination chart (for all IPHECA projects and National Programmes in Belarus).

(6) General endocrinological examination form.

(7) General haematological examination form.

(8) Form for epidemiological investigations in haematology.

2.2 Special IPHECA Software Package (SISP)

Collection of data within IPHECA Epidemiological Registry was started with the completion of the OKSO chart, which was used as the outpatient's medical card and/or the child's development history. It was then entered in the passport section of the chart, each patient was assigned a unique registration number. The passport section in the unified database was common for all pilot projects (all pilot projects also required completion of the OKSO). This facilitated collection all data collected on a patient in each pilot project, preventing duplication of information in the data bank, removing ambiguities and ensuring complete analysis an individual's health status. In order to computerize and standardize the collection of primary information and the operation of the database with common technology and joint epidemiological analysis within IPHECA, specialists from Belarus, Russian Federation and Ukraine developed Special IPHECA Software Package (SISP). The main application and advantages of IPHECA software are:

(1) The construction of the database and the verification and analysis of data is uniform in all the IPHECA Pilot projects;

(2) The use of common computer technology for the input editing, verification and correction of data in all IPHECA Pilot projects at all levels;

(3) The use of standardize reference information (unified codes for settlements, ICD-9 codes for diseases, etc);

(4) The use of common statistical packages;

(5) Facilitation of information exchange between observation levels and between National programmes and IPHECA and compatibility of research results;

(6) Guarantees of reliability and scope for modification of software;

(7) Effective use of computer technology and minimization of repeated data entry.

The following user - characteristics were taken into consideration when creating the software:

(1) Requirement to gather large amount of primary data simultaneously in all IPHECA Pilot projects;

(2) Need to be user - friendly for medical workers and operators;

(3) Necessity for information checking at all stages of processing.

The implementation of SISP has been supported by WHO through providing the three states with computers for the national, oblast and rayon levels (Table 2).

2.3 Indicators of the health status used in the Project

Morbidity indices of the population studied within IPHECA have been evaluated according to 15 classes of diseases indicated in ICD-9. In addition, distribution of children and adults into different health groups was used for analysis of their health status. The following health groups were classified:

Group I - Healthy persons without deviations according to all health indicators and who were never sick during the observation period;

Group II - Persons with functional disorders, with a risk of contracting a chronic pathology and with increased morbidity;

Group III, IV and V - Sick persons with chronic pathology in the states of respectively compensation, subcompensation and decompensation.

Table 2 **Characteristics of the computers used at the various observation levels**

Observation Level	Type of Computer	Technical Specifications	Assumed Population
National (in each country)	PS/2 8595- VO1	16 MB RAM 3 hard disks (400 MB), Nape (2.3 GB)	70-130,000
	PS/2 70 - 161	4 MB RAM Hard Disk (160 MB)	
Oblast (in each oblast)	PS/2 8595-AKF	8 MB RAM Hard Disk (400 MB)	30-70,000
	PS/2 70 - 161	4 MB RAM Hard Disk (160 MB)	
Rayon (in each rayon)	PS/2 70 - 161	4 MB RAM Hard Disk (160 MB)	20-50,000

PS/2 L40 SX laptop computers with 2 MD RAM and a 60 MD hard disk are used when working away from the office.

2.4 Main results within "Epidemiological Registry" Project

During the pilot phase of IPHECA, about 80,000 records related to OKSO were collected in IPHECA Registries of the three States. Having used these records morbidity indices have been studied in selected cohorts of population of radiocontaminated territories included in the Epidemiological Registry Project Protocol. In Belarus, the selected study cohort consisted 9846 people. This number includes 6798 residents of radiocontaminated territories in Gomel oblast and 3048 in Mogilev oblast. The level of ^{137}Cs soil contamination in these territories is more than 555 kBq/m^2. The control cohort (reference data) compiled 1068 residents of clean territories in Vitebsk oblast. The major part of completed OKSO has been related to children and Fig. 1 shows the distribution by health groups of this category of residents of contaminated and noncontaminated rayons. As it can be seen the health status of children in a clean rayon is significantly better than that in the contaminated rayons. Childhood morbidity data analysis from contaminated rayons is compared with the control rayon in Table 3.

In Russian Federation, by the end of 1993, over 13,600 OKSO charts had been completed in the Novozybkovski rayon of Bryansk oblast and Zhizdrinski, Ulyanovski and Khvastovichski rayons of Kaluga oblast. All these records were on individuals who were children or adolescents at the time of the accident and for whom information on the iodine dose to the thyroid was available.

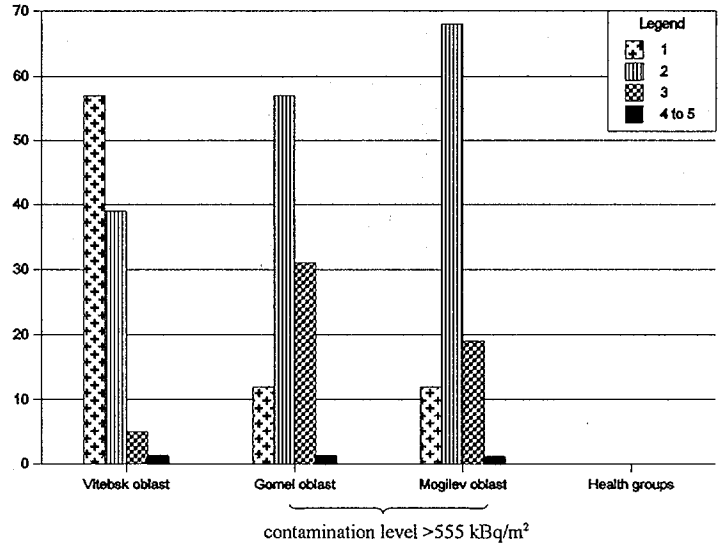
Table 3 **Childhood morbidity (per 1000 children) in strictly controlled zones in comparison with clean rayon of Vitebsk oblast**

NN	Classes of diseases	1000 children		
		Gomel oblast	Mogilev oblast	Vitebsk oblast
1.	Infectious and parasitic disease	141.1	65.59	149.02
2.	Malignant Neoplasms	2.49	4.05	2.81
3.	Endocrine diseases	133.81	191.9	23.43
4.	Mental disorders	8.29	17.41	2.81
5.	Diseases of the nervous system and sense organs	191.01	117.41	55.3
6.	Diseases of the circulatory system	32.66	34.41	30.93
7.	Diseases of the respiratory system	486.98	364.37	779.76
8.	Diseases of the digestive system	390.98	446.56	60.92
9.	Diseases of the genitourinary system	11.11	12.15	5.62
10.	Congenital abnormalities	23.38	6.48	1.87
11.	Symptoms, signs and ill-defined conditions	92.19	46.15	6.56

In addition, about 40,000 OKSO charts had been completed in Borovski rayon of Kaluga oblast (clean rayon) and on almost 20 000 children living in the contaminated areas of the Bryansk oblast. These results provided a picture of the health status in the controlled areas and will serve as the basis for future analytical studies..

Of the whole number of registered individuals with completed OKSO and known thyroid doses, 5694 residents of Zhizdrinski, Ulyanovski and Khvastovichski rayons of Kaluga oblast who were exposed to radioiodine in the period April-June 1986, were included in the sub-cohort for in depth analysis of morbidity indices and assessment of radiation risks. The mean thyroid dose in this subcohort was 510 mGy. The data showed that a statistically significant dose relationship was not observed for the majority of diseases. However, the excess relative risk for nononcological thyroid diseases was significantly greater than 0. The Relative Risk for

Fig 1. **Distribution of children (%) by health groups**



this class of diseases within the cohort was calculated and it was 1.1102 (95% CL:1.0422-1.1918).

In Ukraine, the primary demographic and epidemiological characteristics of contaminated territories under the IPHECA Epidemiological Registry Project have been studied on a basis of records included in the State Registry of Ukraine (SRU). Observation cohort numbered 37,409 people residing in Polessko-Ivankovski rayon of Kiev oblast and Ovruchski rayon of Zhitomir oblast.

The morbidity structure of the children examined under the Epidemiological registry protocol showed the greatest weight of respiratory diseases (45.8%). The second place was taken by digestive organs diseases (10.6%), then circulatory system (3.1%), musculoskeletal system (2.3%), blood and haematopoietic organs (2%). The contribution of the above pathology to the morbidity structure of the child group under examination exceeded 60% which tallies with SRU data and age regularities in morbidity formation.

The analysis of OKSO information has been performed in two selected cohorts. The first one included 1.563 adults residing in Polesski and Ivankovski rayons of Kiev oblast and the second one 1814 children living in Ovruchski rayon of Zhitomir oblast. Primary evaluation of the health status of adults revealed a low proportion of fit and practically fit persons. Among the males those in the first health group were only 13% of the total number, and those in the second 5.8%, i.e. 18.9% in both groups. The indicators for females were found to be lower:

the first and second health groups included 8.4 and 5.8% respectively, i.e. 14.2% in both. The morbidity level in this cohort in 1992 was lower as compared to SRU statistical data for Polessko-Ivankovski rayon.

The highest contribution to morbidity in children of the selected cohort was from diseases of the endocrine system (not for 0-3 age group), respiratory tract (in particular diseases of the ear, throat and nose); nervous system and sensory organs.

It should be outlined that results of the OKSO records analysis obtained in the three States are preliminary. Due to restricted funds and a short period of time it was not possible to collect and analyse more OKSO data in clean rayons and carry out intercomparison investigation of morbidity indices in contaminated and noncontaminated territories. Moreover, the initial selection of Borovski rayon of Kaluga oblast in Russian Federation as a reference territory for comparison analysis with contaminated rayons was not fully appropriate due to local endemic peculiarities.

Without valid reference data on morbidity in each of the three States it is too early to make any conclusions about health hazard of residing in radiocontaminated territories. But, according to the prognosis performed by specialists from Russian Federation within the Epidemiological Registry Project, the population residing in areas contaminated to 555-740 kBq/m^2 will live under conditions of "unacceptable" risk for 10 years.

2.5 Accident Recovery Workers (Liquidators)

Despite the fact that the IPHECA pilot phase did not provide for a study of health effects among the Chernobyl accident recovery workers, the morbidity and mortality study among that group of people was in practice within the framework of the Epidemiological Registry Project. The more comprehensive analysis has been done in Russian Federation. The Russian State Medical and Dosimetry Registry compiled records on 324,146 liquidators by the end of 1993. These records were used for analysis of morbidity and mortality indices, causes of death, assessment of dose-dependent morbidity risk and prognosis of long-term stochastic effects of radiation for liquidators. The results of the analysis point to an increasing trend in the incidence of malignant tumours from 97.6 per 100,000 in 1989 to 180.7 per 100,000 in 1992. Morbidity for endocrine system, blood and blood-forming organ diseases, psychiatric disorders, circulatory and digestive organ diseases exceeded those in control groups. The mortality in liquidators for 1990 and 1991 did not exceed that of the controls. The assessment of dose-dependent morbidity risk was done in 99,344 liquidators who had documented proof of having received a radiation dose and had undergone an additional examination to verify a diagnosis.

It was shown that for malignant tumours, blood and blood-forming organ diseases, endocrine system diseases, psychiatric disorders, nervous system and sensory organ diseases a statistically significant ($P < 0.01$) linear increase in the relative risk values was observed dependent on dose. There is also a significant ($P < 0.05$) positive trend for digestive organ diseases and infectious and parasitic diseases. The results obtained in Russian Federation suggest there will be a continuing increase in morbidity and mortality among the liquidators.

3. Epidemiological approaches in other IPHECA pilot projects

In addition to Epidemiological Registry Project, epidemiological investigations, as it has been already mentioned, have been carried out within other IPHECA pilot projects.

3.1 Thyroid project

Results obtained within Thyroid Project provided data on incidence rate of thyroid cancer in the three States. Before the Chernobyl accident the annual incidence of childhood thyroid cancer in Belarus was about one per million, in Russian Federation and Ukraine about 0.5 per million in each. After the accident the incidence rate has increased significantly (Table 4). In the most contaminated Gomel oblast, the annual disease incidence reached more than 100 per million children in 1994.

3.2 Haematology Project

In the course of implementing of the Haematology Project, it was established that in the areas of Belarus, Russian Federation and Ukraine under the project protocol general morbidity for leukaemia and related diseases did not significantly differ in levels although there was a slow upward trend in both contaminated and noncontaminated areas. Nevertheless, the morbidity level did not exceed that which is typical for many other European countries. Before the accident, in a period from 1979 to 1985, the annual mean incidence of leukemia and related diseases in controlled territories of Belarus, Russian Federation and Ukraine was 58 per 100,000. The annual incidence of these diseases in a period from 1986 to 1993 was 64 per 100,000. Comparison of leukemia morbidity in the areas with different levels of radioactive contamination did not produce any significant differences. Childhood leukemia incidence did not change its level after 1986. There were no deviations from age distribution standards or any correlations of disease types with dose. Thus, the results obtained so far show no changes in morbidity which could be linked to the effects of radiation.

3.3 "Brain Damage in-Utero" Project

Epidemiological investigations within this project aimed at detecting cases of mental retardation and other brain disfunctions in a cohort of children born between the 26 April 1986 and 26 February 1987 and who were exposed to radiation *in-utero* due to the Chernobyl accident. The total number of the children examined in the three States was 4210. The results obtained are different to interpret and require verification. Well planned epidemiological investigations should be continued.

3.4 "Oral Health" Project

The incidence of some stomatological diseases in contaminated territories has been studied in the framework of IPHECA "Oral Health" Project in Belarus. Investigations under the project were conducted in the areas with a mean radionuclide contamination of 185 kBq/m^2 and 555 kBq/^{2} and also in clean zones. Under observation were more than 2,686 residents.

Table 4. **Incidence (rounded) per million children**

	1986	1987	1988	1989	1990	1991	1992	1993	1994
Belarus	0.9	1.7	2.2	3.0	13	26	28	34	36
Russian Federation	0.0	2.0	0.0	0.0	4.0	0.0	8.0	12	22
Ukraine	0.7	0. 6	0.7	0.9	2.2	1.8	3.9	3.5	3.1*

NOTE*: = incomplete number
Belarus hasd 2.3 million children, Ukraine has 12 million and the Bryansk and Kaluga oblasts of the Russian Federation have 500,000.

A practically identical incidence of diseases of the oral mucosa, periodontal and dental tissues was detected among the residents examined from the contaminated and clean rayons of Belarus.

4. Development of epidemiological investigations within IPHECA after pilot phase

In 1994, the IPHECA Management Committee endorsed the "Accident Recovery Workers" Project and recommended to continue "Thyroid" Project. Epidemiological aspects are included in both these projects. An estimated 100,000 liquidators and their families will have their health data recorded in central registries of Belarus, Russian Federation and Ukraine and form the follow-up cohort. The following epidemiological indicators will be studied : mortality (by cause of death); incidence of various malignant and nonmalignant tumours, incidence of other various diseases, frequency of disability or not returning to work. In addition, it is intended to conduct special studies on cohorts consisting of the higher exposed liquidators in order to evaluate health risks associated with radiation exposure.

The study of thyroid cancer incidence will be continued within the "Thyroid" Project. Having used the case-control method, it is also intended to study more carefully the role of radiation factor in the increase rate of thyroid cancer and in the development of each case of leukemia and related diseases in contaminated territories. For this reason thea "Dosimetry" project has been established within IPHECA. One of the objectives of this project is to reconstruct individual doses of radiation for each case of thyroid cancer in children and leukemia and related diseases.

The international experts recommended also to search for excess occurrence of cancers other than leukemia and thyroid cancer, to identify the structure and time trends of prevalence, morbidity and mortality in the residents of radiocontaminated territories. But significant additional funding would be needed for completion of all planned activities.