



Romanian National Childhood Cancer Registry

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I. GENERAL ISSUES

Names of the experts:

- Otto Visser, ENCR Steering Committee
- Elizabeth van Eycken, ENCR Steering Committee

ENCR Secretariat:

- Luciana Neamtii, JRC

Dates of the online review meetings: 11 August, 30 September, 9 December 2021

Participants from the Romanian National Childhood Cancer Registry:

- Dr. Mihaela Bucurenci – Director
- Dr. Daniela Coza – Technical coordinator
- Dr. Andrea Șerban – biostatistician, internship
- Alina Pătrăhău – CEO and Founder Fundația Dăruiește Aripă

Structured review based on template (see appendix 1)

The report is based on the information provided during the online meetings, information obtained after the meetings from the cancer registry, review of the cancer registry documents and software, analysis of the draft version of the first annual report and interviews with the director of the cancer registry and other staff.

II. BACKGROUND INFORMATION

1. POPULATION

Romania has a population of 19.3 million (January 2020). The pediatric population between 0 and 19 years old (4.1 million) represents 21% of the total population, while the pediatric population between 0 and 14 years old (3.0 million) represents 16%.

2. HEALTH CARE SYSTEM, CANCER CARE AND MAIN RISK FACTORS

Romania is divided into 41 counties and the municipality of Bucharest.

All Romanian citizens are covered by a mandatory public health insurance. Family doctors who are independent practitioners provide primary health care services. The secondary care is delivered in hospital outpatient departments, centres for diagnosis and treatment and office-based specialists. Some private services are also reimbursed by the public health insurance. Private care is also available in Romania, as well as private health insurance.

Cancer care is offered by both public and private services. There are 13 pediatric oncology departments in the country. There is also the possibility to treat patients abroad through the national insurance or privately.

3. CANCER REGISTRATION: organization and legal aspects in Romania

Cancer notification has become compulsory in Romania since the issue of the Ministry of Health (MS) Order Nr.219 of 1980. According to the Order, all new cancer cases must be reported individually to the Center for Calculations, Health Statistics and Medical Documentation, directly subordinated to the Ministry of Health. In 2002, the Ministry of Health and Family (MSF) Order nr. 871 is issued as an update to the previous order and aimed at improving the compliance with the cancer reporting process. This was the first Romanian Ministry Order to involve the private medical care services as a supplier of cancer case data. The Ministry of Public Health (MSP) Order nr. 2027 from 26th of November 2007 designed a new organisational framework for the cancer registration activity, by establishing regional cancer registers for each of the 8 development regions of the country and by coordinating their procedures of alignment to the standards and recommendations of the European Network of Cancer Registries (ENCR) and of the International Agency for Research on Cancer (IARC). As a consequence of this order, the registration activity has been reorganized since 1.01.2008 by implementing the ENCR standards for data collection, classification and codification: pinpointing the cases and reportable episodes, defining the minimum data set, using multiple data sources. The WHO ICD-O-3 international classification system of oncological diseases was introduced, in order to codify and register multiple primary cancers, as well as the TNM classification, the 6th edition, in order to estimate cancer extension. (Information retrieved from *Cancer Incidence and Mortality in Cluj County 2000-2008 and Cancer Incidence in North-Western Region of Romania, 2008*).

Despite the MS orders, not all the regional cancer registries function properly. Therefore, in addition to the regional cancer registries, in 2009 the Romanian Society of Pediatric oncology established a specialized cancer registry –the Romanian National Childhood Cancer Registry (RNCCR) - with the aim to cover the gaps in childhood cancer registration and to extend and adapt the data set collection.

III. PURPOSE OF THE REPORT

This report offers an evaluation of the activities and results of the RNCCR.

IV. EVALUATION OF THE CANCER REGISTRY (CR)

1. REGISTRY NAME, CONTACT DETAILS AND BRIEF HISTORY

Romanian National Childhood Cancer Registry (Registrul National al Cancerului la Copil in Romania)

Institute: Societatea Romana de Onco-Hematologie Pediatrica

Address: 153 Ion I.C. Brătianu Street, Balotești, Ilfov County, Romania

Website: www.srohp.ro

Director: **Dr. Mihaela Bucurenci**

The RNCCR includes all new cases of cancer in children and young people (0-19 years) registered by the participating paediatric-oncology centers from all over the country.

RNCCR operates with the technical support of the staff of the North West Regional Cancer Registry, headquartered at the “Ion Chiricuta” Oncology Institute in Cluj-Napoca, official partner of SROHP in RNCCR support and development.

Reporting is done by trained personnel from each participating centre by filling in the ONC form (specific data set and definitions recommended by ENCR and implemented in Romania by the Ministry of Health order 2027/2007). In 2019, the data set was completed with clinical data and the latest paediatric cancer staging system recommended by the Toronto Consensus was implemented, making RNCCR one of the most modern and dynamic cancer registries in Eastern Europe.

Until 2018, the reporting was done on paper and electronically (Word forms); at present, the reporting is done online through the dedicated ONCPED platforms, hosted by the “Ion Chiricuta” Oncological Institute from Cluj-Napoca.

The tumour coding is performed in accordance with the International Classification of Oncological Diseases Ed 3. (ICD-O-3). Grouping is done according to the International Classification of Paediatric Cancers Ed. 3a (ICCC-3). (Information retrieved from the CR website)

2. STAFF

RNCCR operates with the technical support of the staff of the North West Regional Cancer Registry, headquartered at the “Ion Chiricuta” Oncology Institute in Cluj-Napoca, official partner of SROHP in RNCCR support and development. In addition, there are 13 registrars from 13 paediatric oncology centers. The following staff is working part time for the registry:

director (1/2 full time equivalent staff -FTS), technical coordinator (1/4 FTS), statistician (1/4 FTS), data manager (1/4 FTS), data analyst (1/8 FTS), 3 registrars (1/4 FTS) and 10 registrars (1/8 FTS). Details about the staff can be found in the annex 1.

3. SOURCES OF FINANCE

RNCCR is initiated, developed and coordinated by the Romanian Society of Pediatric Onco-Hematology (SROHP). It started in 01.09.2009. RNCCR operates exclusively with non-governmental financial support: from 2009 to 2013 the work was supported by DANONE Romania, from 2014-2016 by the NGO Fund Romania through Norwegian grants and from 2018 to present by the NGO “Fundăția Dăruiește Aripă”.

Since 2018, the Association “Dăruiește Aripă” is supporting materially and logistically the childhood cancer registry. Resources were allocated to perform a retrospective completion of the cases at national level with the aim to improve the quality of the data.

4. POPULATION

The RNCCR covers the paediatric population of 4.1 million people between 0 and 19 years old and 3.0 million between 0 and 14 years old (January 2020), respectively

5. SOURCES OF INFORMATION USED BY THE REGISTRY

Thirteen pediatric oncology centers are sending the notifications to the registry.

In addition to this information flow, a check with six main pathology laboratories from Bucharest (the capital) was done to assess the compliance in reporting notifications. This check revealed 24 % solid tumors diagnosed in pathology laboratories and not recorded in the registry for the period 2010-2019.

6. METHODS OF REGISTRATION

Inclusion criteria

The RNCCR collects all childhood cancer cases (0-19 years old) with a diagnosis included in the reportable cases:

- Borderline conditions (behaviour code “1”), in situ cancers (behaviour code “2”) or malignant / invasive (behaviour code “3”) according to the International Classification of Diseases for Oncology, third edition (ICD-O-3.2);
- All intracranial and intraspinal tumours regardless of their behaviour benign / uncertain / malignant (0/1/3) with topography codes ICD-O-3.2 C70-C72 and C75.1–C75.3. Are exempt from reporting benign vascular lesions of the meninges (hemangiomas) and cystic lesions;

Centers are sending notifications to the registry when:

- Establishing a reportable diagnosis for a new cancer case or the first evidence for monitoring and/or treatment;
- Any revision of the diagnosis of a reportable condition to another reportable diagnosis category;
- Relapse
- Progression
- Invalidating the diagnosis of an already reported tumour;
- Finalizing treatment
- Another primary tumour
- Death with or by cancer
- Passive capture (eg. cases accidentally discovered at a presentation for administrative reasons)

Additional details can be found in the addendum.

7. DATA MANAGEMENT

Data entry: At present, the reporting is done online through the dedicated ONCPED platform (<http://oncped.iocn.ro/>), hosted by the “Ion Chiricuta” Oncological Institute from Cluj Napoca.

Quality control and data validation

For each case, the information retrieved from different sources is aggregated based on the personal identification number. Each individual cancer case is verified, coded and finalised by one trained cancer registrar in the central setting of the Childhood Cancer Registry.

Details about the data workflow are included in the addendum.

8. DATA ANALYSIS/RESULTS

DATA ANALYSIS AND RESULTS. DATA DISSEMINATION

The registry is analysing the data. Presentations to the annual national assemblies of the Romanian Society for Paediatric Oncology and Haematology (RSPOH) were shown:

- 2010 -2014 – the aim was more to reflect the participation status of the pediatric oncology centers and the coverage level
- 2015 -2016 – the first survey of survival for the collected case pool and the first cumulative narrative report
- 2018-2021 – reports with latest epidemiology data and development plans after partnering with Daruieste Aripa

The table 1 in the annex 2 shows the availability of recommended components of the RNCCR annual cancer incidence report as included in the presentations.

However, there is no structured incidence report published annually. Details about the results of the analysis can be found in the addendum.

Summary of the achievements and strengths:

- There is an established cancer registration system in place, supported by the corresponding national legislation
- All 13 paediatric oncology centers in Romania are participating
- The registry is organised according to the international standards for cancer registration.
- The data items are coded according to the international classifications and recommendations, thus ensuring comparability of the data.
- The computer system to collect and code the data is well organised,
- There is an appropriate information system for cancer registration.
- The staff is very motivated, experienced and trained at national and international training courses
- Information about stage and treatment are collected

Summary of the weaknesses:

- Major weaknesses
 - Completeness of the RNCCR is unsatisfactory; comparison of the incidence rates to neighboring countries show that the rates are much lower than expected. The staff is aware about issues in completeness and they made efforts to catch missing records. In a cross check analysis for 2020 with pathology laboratories (for age 0-19, solid tumors except CNS) it was found that 24% of the cases were not reported to the registry. The cases are mainly reported from the pediatric oncology yards.
- Minor weakness
 - The registry did frequent presentations to the SROHP, but is not publishing a regular cancer incidence report
 - Two Factor Authentication is not used for the data entry system.

Recommendations to overcome the identified weaknesses:

- The Romanian colleagues did many efforts to build the registry, to analyse the data and capture all the patients in the paediatric oncology centers. The first step should be to increase the completeness by using additional sources of notification, such as

regional cancer registries, pathology laboratories, national discharge data and death certificates.

- For visibility reasons, a progress report could be made to receive support from other stakeholders.
- Some improvements to ensure the data protection could be done (e.g. Two Factor Authentication)

Date: 2 March 2022

Annex 1

Details about the staff working for the registry
All the staff is working part time.

	Position	Background	Organization
1	Registry Director	Public Health, MD	RSPOH/DA
2	Technical coordinator	Cancer epidemiologist, MD	IOCN
3	Statistician	Mathematician	IOCN
4	Data manager	IT engineer	IOCN
5	Registrar	Pediatric oncologist MD	IOB (hospital)
6	Registrar	Pediatric hematologist MD	Fundeni (hospital)
7	Registrar	Pediatric oncologist MD	Marie Curie(hospital)
8	Registrar	Hospital registrar nurse	Timisoara(hospital)
9	Registrar	PO ward head nurse	Targu -Mures 1(hospital)
10	Registrar	Pediatric oncologist MD	Targu -Mures 2(hospital)
11	Registrar	Pediatric oncologist MD	Oradea(hospital)
12	Registrar	PO ward head nurse	Craiova(hospital)
13	Registrar	Pediatric oncologist MD	Cluj-Pedi 2(hospital)
14	Registrar	Pediatric oncologist	Brasov(hospital)
15	Registrar	Hospital registrar nurse	Constanta (hospital)
16	Registrar	Hospital registrar nurse	Iasi(hospital)
17	Registrar	Cancer registrar nurse	IOCN (hospital)
18	Data processing and analysis	Pediatrician, degree in biostatistics MD	Daruiește Aripa

Annex 2

Table 1. Availability of recommended components of the RNCCR annual cancer incidence report		
No	Recommended component	Available in the RNCCR report
	Background information	
1	Outline of the organisation of the cancer registry	Y
2	List of the professional staff	Y
3	Description of the reporting procedures	Y
4	Description of the sources of cases	Y
5	A list of reportable diseases	Y
6	Description of coding procedures	Y
7	A clear statement of definitions used in reporting	N
8	Population covered by registration	Y
9	Reference for the population denominator data	Y
10	Description of statistical terms and methods	N
11	Evaluation of findings: consistency of the number of cases in each calendar year	N
12	Evaluation of findings: site distribution	Y
13	Evaluation of findings: indices of validity of diagnosis	Y
14	Evaluation of findings: demographic data	Y
15	Evaluation of findings: differences compared with similar areas	Y
	Tabular presentation	
16	Clearly defined contents of the table and the items	Y
17	Denominator for rates	Y
18	Frequency distribution in full	Y
19	Rate or proportion with the number of observations	Y
20	Particulars and criteria of exclusions	N
21	Number of cases by site, age and sex	Y
22	Annual incidence rates by site, age and sex	Y
23	Age-standardised rates	Y
24	Cumulative incidence rates	Y
25	Tables for subsets of the population	Y
26	Tables for indices of the validity of diagnoses	N
	Graphical presentation	
27	Limited amount of data per graph	Y
28	Tabular information for the graphs must be presented	Y
29	Appropriate choice of scale	Y
30	Graphs should form self-contained units	Y
31	Appropriate use of bar, pie and line graphs	Y

Appendix 1

JRC-ENCR Review: Romanian National Childhood Cancer Registry Structured review based on template

General aspects

- 1) Please provide preferably in English or if not available accompanied by a brief summary in English:
 - At least one general report (annual report or action plan) of the Registry
 - All materials like annual reports, articles, communications
 - A list of the publications and output realized by the Romanian National Childhood Cancer Registry.
 - Any other material you might find useful in the context of this review
- 2) Please prepare the presentations for the different sessions and feel free to adapt the subheadings to the practicalities of your Registry. Whenever possible, indicate the strengths, weaknesses, opportunities, and threats for your Cancer Registry.

Draft agenda for three sessions in the review procedure

I) Session on Governance of the Cancer Registry

Presentation by the Cancer Registry

- Structure
- Funding
- Mission – Vision – Values
- Objectives of the Cancer Registry
- Stakeholders and Partnerships
- Cancer Registry team overview
- Training
- Information security procedures
- Legal aspects and GDPR

Q & A

II) Session Cancer Registry Processes: description and documentation

Presentation by the Cancer Registry

- Data notification: sources (pathology, hospital discharge, death certificates, etc.)
- Data collection: methods
- Datasets
- Data processing and IT system
- Data quality checks
- Linkage procedures and unique patient identification

- Results Quality indicators (examples: % microscopic verification, % DCO or % zero day survival, % non-specific codes, % complete information on tumour info/stage/treatment, etc.)
 - Data validity indicators
 - International comparison of incidence/mortality/survival
 - Timeliness
 - Completeness

Q&A

III) Session on Data analysis and Output

Presentation by the Cancer Registry

- Overview Childhood Cancer Epidemiology in Romania
- Data analysis, Methods
- Publications, type of output realised
- Handling of data and information requests at the Registry
- Participation in European / International collaborations on cancer epidemiology
- Communication and Dissemination of results / Visibility of the Cancer Registry

Q & A