



Deliverable 8

Identification and evaluation process for healthcare centres to be recognised within the European Reference Network.



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There is a critical need for quality assurance of the Paediatric Haematology/Oncology (PHO) Centres and the development of systems establishing the performance of PHO Centres qualifying for international platforms and the success of their programmes. The ExPOrNet has launched the identification and assessment programme to fulfil its goals:

- to provide children with cancer within Europe an equal access to high quality of cancer care.
- helping European PHO centers to implement a quality system for oncology care using the European Standards of Care for Children with Cancer and peer review system.

The PHO centre eligible for international collaboration should reach a minimum level of quality and organization in order to fulfil the process and be accepted on board the assessment programme. These are based on the European Standards of Care for Children with Cancer, the document created in 2009.

The European Standards of Care for Children with Cancer

The document on the European Standards of Care for Children with Cancer consists of 15 chapters dealing with different aspects of care:

1. Organising Networks of Comprehensive Care for Children and Adolescents with Cancer and Serious Haematological Diseases within Each Country. Centres of excellence and expertise in paediatric oncology that can provide comprehensive multi-disciplinary facilities and optimum standards of care, reflecting the local population and geography, are essential.
2. A Childhood Cancer Register is required at national level, based upon the internationally-recognised classification – International Classification of Childhood Cancer ver.3 (ICCC-3). The peculiarities of adolescent cancer need to be taken into account in this regard.
3. Requirements of a Paediatric Haematology and/or Oncology Unit: Each paediatric haematology and/or oncology unit requires a number of standard facilities to cater for patients and their families as well as approved clinical protocols and link-ups with other specialised units should there be a need for further consultation and/or to offer some procedures ('shared care') to patients living close by.
4. Recommended staffing levels for the paediatric haematology/oncology ward: Each paediatric haematology and/or oncology ward must consist of a minimum number of qualified staff specialised in treating children with cancer. The team must be capable of responding to the various needs of a patient and their family both at the hospitalisation and follow-up stages, i.e. a multi-disciplinary 'care team'. While a core number of staff is always required, a back-up team must also be available including 'on call' doctors.
5. Ongoing professional development for the 'care team' should be mandatory. In addition, the role of parent and/or patient organisations in training staff as well as informing patient families should be broadly encouraged.
6. Components of care in a specialist facility. Key components of a paediatric haematology and/or oncology unit include inpatient, day ward and outpatient facilities, as well as residential facilities for parents and siblings. In addition to this, time spent at home for the patient should include the support of local social services.
7. Delivery of Therapy: Treatment of cancer in children and young people is constantly being refined and the best 'standard of care' is widely recognised as inclusion in a clinical trial or study, even for newly diagnosed patients. Treatment protocol recommendations need to be regularly updated, consistent with the latest research findings. Optimal treatment should be widely encouraged by the

national childhood cancer research network. Depending on the country, drugs are covered either by an insurance company or the state. Standard chemotherapy drugs are often administered 'off label' to children with cancer purely due to the lack of relevant paediatric studies in the application for the marketing authorisation. Such 'off label' drug use must be covered by the usual national health procedures.

8. Monitoring the late outcomes of cancer: Data management and safety reporting of the therapeutic programme implemented is vital, and appropriately-trained medical staff is required to carry this out. Long-term monitoring of the late outcomes of childhood cancer is essential, taking into account not only survival but also quality-of-life and long-term toxicity.
9. Psychological and Psychosocial Care: The parents of a child with cancer should be afforded comprehensive information on the diagnosis and treatment of their child by staff members including psycho-social advice, and all information and progress-stages should be well-documented and explained clearly to the parents. Each child or young person with cancer and his/her family should be offered psychological support. Planned social and educational care should in addition be made available. Moreover, detailed information on the diagnosis, therapy and overall impact should be discussed but respecting the patient's age and appropriate to the level of understanding. Post-treatment assistance should also be available to ensure a child's reintegration into society.
10. Palliative care: Should a child become terminally ill, comprehensive palliative care is required through a multidisciplinary hospice team, Communication channels should be created with the treatment team and the new incoming hospice team.
11. The rights of the hospitalised child: A hospitalised child and young adult should be endowed with a number of basic rights:
 - Constant and continuous parental involvement
 - Adequate accommodation for parents in hospital
 - Play and education facilities
 - Age-appropriate environment
 - The right to appropriate information
 - A multi-disciplinary treatment team
 - The right to continuity of care
 - The right to privacy
 - Respect for human rights
12. Social Care - social support for the child and their family should commence at the time of diagnosis and be monitored along the patient pathway throughout treatment.
13. Education - the maintenance of ongoing education for the young person treated with cancer is vital to ensure a straightforward return to school for the patient once recovered. The hospital teacher provides a necessary link between the educational development during treatment and the school.
14. Parents play a critical role in supporting their child to overcome cancer and need to be supported, with appropriate facilities available to them at the treatment unit. They need to fulfil the role of 'partners' in the treatment process of their child.
15. Rehabilitation - physical rehabilitation is important immediately from diagnosis for a child spending any length of time in hospital undergoing severe treatment.

This ‘consensus’ document has been translated into multiple languages and it is available on the SIOPE website.

The Standards apply to all aspects of diagnostics, treatment and care of children with cancer and were developed by consensus from the contributions of experts in the field and parents organizations. The Guidelines outlined in this document represent the minimum standards of care that should be carried out and are initially targeted at EU Member States but are not confined to these countries. The PHO Centre that wished to become the ExPO-r-Net assessed should review its existing services, practices, and policies and procedures to determine what changes will be required to meet the standards (self-evaluation). The self-assessment questionnaire provides a tool for estimating the readiness of the centre.

As a first step to achieve goals within WP6 collaborating partners have structured a glossary of terminology and definitions used for a certification process. Expected date to achieve this task was month 9. For purposes of implementation of the European Standards of Care for Children with Cancer, each term should mean that the standard is to be complied with at all times. The term should indicate an activity that is recommended or advised, but for which there may be effective alternatives. Members of WP6 have agreed on the list of all items which are necessary for proper and clear understanding in the certification process by members of paediatric oncology/haematology units in different European countries. Representatives of 35 National Paediatric Oncology/Haematology Societies or Chairs of 18 European Tumour Study Groups were asked for some specific opinions. Following extensive discussions through e-mails, teleconferences, and finally during face-to-face meeting in October 2014 a final version of the glossary of terminology and definitions was created. The document includes 30 abbreviations and 106 terms defined. The approved unified Glossary of Terminology and Definitions to be applied by paediatric oncology society across Europe provides a good tool enabling development of European Reference Centres in paediatric oncology. Staff members of paediatric oncology units have received a tool enabling better understanding and precision of filling-up the self-assessment questionnaire. It could be also used to improve communication for further activities related to paediatric oncology.

In 2015, a self-assessment questionnaire was structured and extensively discussed with members of ExPO-r-NeT and representatives of European Tumour Study Groups. This checklist enables identification of centres in Europe, which meet specified criteria to fulfil the European Standards of Care. It also provides information to PHO centres and national authorities on their compliance with the European Standards. They will become visible internationally and may in the future interact with “hubs of coordination” via virtual tumour boards. These identified centres should be able to do baseline care for the patients, with help and advice from tumour boards formed by Paediatric Oncology ERN. An electronic version of the self-assessment questionnaire was prepared by month 20 as second task of WP 6. With help of experts from CINECA it was placed on-line (Link: <https://siope.cineca.org/>). Access to online questionnaire was individually granted to representatives of invited centres. During accomplishment of the WP 6 third task we were learned that some known paediatric haematology/oncology centres are not interested or willing to participate the self-assessment project. The only change to the original planning was related to range of countries covered by assessment process – ExPO-r-NeT members decided to concentrate on Central/Eastern European countries first. Generally, these countries are recognized as low health expenditure annual rates (LHEAR) countries. According to data collected by SIOPE from National Paediatric Haematology/Oncology

Societies, 67 PHO centres were identified in 16 countries of Central/Eastern Europe, including 11 EU Member States, and principal persons for paediatric haematology/oncology services in all these centres were invited to complete the questionnaire. A total of 50 centres responded to the request and provided completed questionnaires. Data obtained in questionnaires was carefully analysed and 3 groups of centres were selected:

1. PHO centres which already are ready for international cooperation and networking within ERN-PaedCan. In fact, these centres (8 from 6 EU countries) became members of the network.
2. PHO centres (35) which fulfil most of specified criteria of the European Standards of Care for Children with Cancer.
3. PHO centres (7) which do not meet minimal criteria of the Standards.

To confirm that information in Self-Assessment Questionnaires are accurate and in compliance with reality regarding service integrity, patients centred care, quality assurance, and treatment protocols used, the ExPO-r-Net members decided to perform on site visits in selected institutions from the group 2. In total 17 centres from 9 EU Member States have been assessed and 12 centres fulfil the European Standards of Care. In addition, 4 centres from 3 Non-EU States were visited. All on site visits result in written reports provided by inspectors. In general, significant potential in PHO centres in LHEAR countries could be observed: educated staff, substantial number of patients treated and adequate facilities in most centres. Nevertheless, there are also emerging needs: clinical cooperation with highly specialised international centres, involvement in advanced research and clinical trials, as well as access to international training programmes.