

Instructions to the ALiCCS medical abstraction form *version 7*

Appendix I – list and codes of chemotherapeutic agents (*version 13, 2012*)

Appendix II – growth curves (for Danish children, **please use country specific growth curves**)

Appendix III – examples of congenital diseases/anomalies and cancer syndromes

All appendices can e.g. be found in the shared Dropbox folder you have access to.

Please note. A new abstraction form is filled out for each treatment due to residual or recurrent disease. However, in case of a second primary neoplasm the patient should be excluded.

Please remember to:

- **Copy** the overview sheets from and any information on the radiotherapy (e.g. simulation films and texts),
- **Cover any personal identification, write the ALiCCS-study number on the copies** and include this with the medical abstraction form and a front page provided for radiotherapy (RT) evaluation.

The information on radiotherapy will be collected and sent for evaluation within Denmark before being sent to our collaborators at MD Anderson, Texas, US, for radiodosimetry evaluation.

Check if the patient is included in **the PanCare study** and if so make sure to take an extra copy of the radiotherapy record with the appropriate PanCare ID no.

If the childhood cancer diagnosis is leukemia and diagnosed after 1981 please check if the patient is in the **NOPHO-ALL registry** and get a printout of the patients' treatment, cumulative doses should be included. Please use this only for assistance while retrieving information from the medical record.

It might be a good idea to start by getting a **quick overview** of the medical record you are about to extract from, arrange documents in chronological order, group appropriate sheets together and write down on a blank paper:

- **ALiCCS-study no.** (received from the Danish Cancer Society Research Center and is up to 9 digits).
- Childhood **cancer type, year** of and **age** at diagnosis.
- List the chemotherapy drugs used (without doses) – consider marking the chemotherapy sheets with a post-it to make it easier to find and browse through the medical records.
- Relapses, if any (number, year of diagnosis and treatment).
- The last hospital visit (date and health status).

In case a treatment protocol was used. It might be helpful to familiarize with it. The timeline, type of chemotherapy used – doses and route of administration, whether radiation treatment and/or surgery could be included.

Remember that reviewing nurses' notes can be useful.

If any questions arise or if you have comments please do not hesitate to contact:

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This abstraction form is only for the first treatment of the primary childhood cancer. If the patient has received additional treatment for residual or recurrence of the same childhood cancer, then please fill out as many abstraction forms as recurrences.

ALiCCS-study number is given centrally and received from the Danish Cancer Society Research Center.

Comments (free text).

Thought as comments about collection of the information e.g. if half the treatment was given abroad (not in the patient's native country) or if any parts of the medical record were clearly missing (but **not** for details on treatment or outcome).

Missing information.

Please fill out those boxes when you have completed the abstraction of the medical record.

Minor information missing – should be used if e.g. a few chemotherapy doses are missing or minor details of surgery or radiotherapy.

Major information missing – should be used if many chemotherapy doses are missing (e.g. more than 1/3) etc.

Date of extraction defined as the date when medical record abstraction is completed.

Page 1a – working document

This page is only a working document while the abstraction form is being filled out. This document should be **either destroyed afterwards or withheld in the patient's medical record** (or the copy, if those allowed and stored).

Age at cancer diagnosis is given in whole years, e.g. if a patient is 2 months of age at cancer diagnosis (or below 1 years of age) then write 0 years.

Writing the patients age here is only thought for your convenience and so you can double check or critically evaluate the surface area (weight and height) and chemotherapy doses.

Personal ID-number.

The patient's personal identification number, **if** required while abstracting. Even though there is space for 10 digits the length of the personal ID-numbers can vary between countries (10 digits in Denmark, Iceland and Sweden while 11 numbers in Finland and Norway). If you need more space just add boxes.

PAD-number is the number on the pathology report.

List all hospitals and departments the patient was treated at and information was collected from. Please state country if the patient was not treated in his country of residence. This information can be helpful in case these records need to be re-evaluated.

Comments (free text) as relevant (both regarding collection of the medical information or on any special events during treatment or outcomes thereafter).

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Before the diagnosis of childhood cancer.

Please choose “**0 = No diseases of importance**” if stated in the medical record that the child is **previously healthy** or **if no information are found** on chronic disease, chromosomal disorder, immune deficiency or congenital anomaly **then the child is healthy => 0 = No** (see below).

Examples of chronic diseases of importance would be:

- Diabetes mellitus (DM type I or II) or other endocrine diseases (e.g. thyroid disease, adrenal or pituitary problems; growth hormone disturbances, disorders of puberty).
- Heart disease (e.g. arrhythmias, congenital malformations, such as VSD [ventricular septal defect]). Examples of congenital anomalies are listed in Appendix III.
- Gastrointestinal diseases (e.g. celiac disease, colon polyposis, IBD [inflammatory bowel disease, like Crohn’s disease or colitis ulcerosa] etc.).
- Renal diseases or malformations of the urinary tract.
- Lung disease requiring medication or other longstanding treatment.
- Behavioral disorders (e.g. ADHD), neurocognitive impairment, mental conditions (e.g. autism) or mental disorders (e.g. anxiety, depression etc.).
- Autoimmune diseases (e.g. JRA = Juvenile Rheumatoid Arthritis; Stills disease; SLE = Systemic Lupus Erythematosus = Lupus; and many more) or immune deficiency diseases (e.g. Ataxia-telangiectasia; CID = Combined Immunodeficiency disease; Complement deficiencies, DiGeorge syndrome, Hypogammaglobulinemia, and many more).
- If in doubt, please contact your supervisor or refer to Thorgerdur or Thomas, (contact information included at page 1).

Chromosomal disorders.

Examples of chromosomal disorders other than Down syndrome would be: Turner syndrome, Klinefelter syndrome, Fragile X etc. Please specify or write the diagnosis.

Immune deficiency.

Please only choose “yes” for immune deficiency, congenital anomaly or neurofibromatosis if there is clear evidence in the medical records of these diseases. For examples of congenital diseases or anomalies see Appendix III.

Cancer in a first-degree relative applies for parents or siblings (or offspring). Please state how the person/relative is related to the patient and type of cancer.

Previous surgical procedures of importance, with appropriate details, if available. Important surgeries are defined as all surgical procedures needing anesthesia.

Previous radiation therapy: Applies for **radiation treatment only** and NOT radiological studies for diagnostic purposes (e.g. X-ray, CT-scans etc).

First primary cancer

Cancer diagnosis (free text): Please write the diagnosis as stated in the medical record (historically classifications or names may have changed and we would therefore like to know the original diagnosis).

Date of diagnosis is defined in this order (where appropriate):

- i. **Date of biopsy or surgery** that confirmed the diagnosis - e.g. bone marrow biopsy or tissue biopsy from a solid tumor or a lymph node, or if the diagnosis was made with a surgical procedure, **before** start of chemotherapy.
- ii. **Date of radiological examination** - For tumors such as CNS or Wilms' tumor only diagnosed radiologically (e.g. a CT or an MRI scan and no tissue biopsy).

If date, or a part of it (day, month or year) is unknown, please give the following "pseudodates":

- **99** for the day and/or month, if unknown (you may also use **15** for unknown day).
- **9999** if year unknown.

Information on age at diagnosis will be obtained from the cancer registry and therefore not registered here (only in your working document, page 1a).

Please fill out the corresponding number for the first primary cancer, one out of 13 possible childhood cancer types.

ICD-O-codes (and SNOMED) will be obtained from the cancer registries.

Page 3-8

First primary cancer

Please choose the relevant number depending on the childhood cancer diagnosis, remember to **fill out the ALiCCS-study number**.

Abbreviations are spelled out in the appropriate page, if in doubt please contact us.

CNS tumors.

Please observe that **intracranial germinomas** (intracranial germ cell tumors) are listed in group 12 (Germ cell tumors and gonadal tumors).

Please note that **all Ewing sarcomas belong to malignant bone tumors** and should be listed there, even though some of them might be located within a soft tissue. See explanations/comments in the medical abstraction form.

Page 9

Radiotherapy

Please copy any records on radiotherapy, including any text about the radiotherapy in the medical record and **simulation films or drawings, cover personal identifications** and paste the **ALiCCS ID number** on the copies.

Please **fill out the front page** provided for radiotherapy evaluation (you find the front page included in the latest version of the medical abstraction form or in the shared dropbox folder “Medical Abstraction”).

These records are to be scanned and sent to the Århus radiotherapy team – mode of sending will be provided very soon, until then please send them to Thorgerdur Gudmundsdottir, thorgud@cancer.dk.

External beam radiotherapy is the “conventional” form of radiation treatment and perhaps the most widely used for treating pediatric cancer.

Date of start and completion include the first and last day of the radiation therapy.

Brachytherapy (curietherapy, endocurietherapy) is a type of internal radiotherapy where the radiation source is placed inside or next to the area of treatment. More commonly used for tumors of the eye (with e.g. an eye plaque), nasopharynx and cervix. Rarely used in children (except for perhaps retinoblastomas).

Internal (metabolic) radiotherapy is when a radioactive isotope is given intra venous (iv.), e.g. radioactive iodine for thyroid cancer.

Page 10

Type of surgery: all surgical procedures concerning the tumor. Operation area can be seen by tumor location in page 3-8 where appropriate.

If type of surgery is =1 (biopsy only) then radicality is always = 5 (not radical).

In case of more than two surgical procedures, please copy page 10 and insert to the abstraction form (as many as needed).

Enucleation means removal of an organ or other mass intact from its supporting tissues, e.g. of the eyeball from the orbit.

Page 11

Chemotherapy.

Please keep your chemotherapy calculations with the medical abstraction form! This is in case they need to be reviewed.

Date of chemotherapy initiated/completed – refers to the chemotherapy listed on this page **excluding** conditioning chemotherapy for BMT.

Please note that chemotherapy for recurrence or relapse of the first primary malignancy is registered on a separate abstraction form.

Date of all chemotherapy completed includes when per oral (po.) chemotherapy is completed.

Weight should be given with one decimal, if possible.

Formula for body surface (m²): $m^2 = \sqrt{((\text{height} \times \text{weight}) / 3600)}$

Body surface in m² is calculated at diagnosis and then yearly after that (**± 3 months**), see the abstraction form.

Rarely no information is found on m² (neither weight nor height), however, in that case please use country specific growth charts for children and use the average numbers. Danish growth charts can be found in the shared dropbox folder “Medical Abstraction”.

Name and codes for cytostatic drugs: according to Garwicz and Wiebe, see **appendix I**. In case a drug is not found on the list please send Thomas Wiebe an email (thomas.wiebe@skane.se), if this drug is to be included a code for the drug will be given and the list/appendix I updated.

Total cumulative dose is the total dose (milligrams [mg], or units) of a given chemotherapy drug received over the entire (primary) treatment period per m² (body surface).

Note that cumulative doses of intrathecal drugs (e.g. MTX it.) are in **mg** only, not per m².

Please note that treatment for relapses is to be entered on another treatment sheet.

Dose quality is needed to estimate how reliable the total cumulative dose is. See options in the abstraction form.

Antracyclines:

doxorubicin, Adriamycin®, Adria®; **daunorubicin**, Daunomycin®, Cerubidine®; **idarubicin**, Idamycin®; mitoxantrone, Novantrone®; **epirubicine**.

Doxorubicin has a wide range of clinical activity against pediatric cancers and is e.g. used for acute leukemia, lymphomas, sarcomas of soft tissue and bone, Wilms' tumor, neuroblastoma and hepatoblastoma.

Daunomycin and idarubicin are currently used for acute leukemias.

Rate of administration of anthracyclines:

Please try to estimate the rate of administration **for the majority of anthracycline doses given**, whether given in a bolus (in < 30min) or as an infusion:

a) >30min to <6hours or

b) ≥6hours

This information is important and to be used in estimating possible cardiotoxic effects of anthracyclines. However, they might be hard to find or not even registered at all.

Cardioprotectants (Cardioxane, Zinecard or Dexrazoxane) have rarely been used in the Nordic countries. Do not use too much of your time looking for them.

If applicable, please write the name of the treatment protocol used.

If needed, e.g. more than 10 chemotherapeutic agents are given, another page 11 (on chemotherapy) can be added.

Page 12

Central venous catheter (CVC).

Please try to find information on whether the patient had a CVC (could be an implanted port [e.g. Port-A-Catheter], tunneled external line [e.g. a central venous catheter or a Hickman type] or a PICC (Peripherally inserted central catheter).

Patients treated before 1980 are more likely to have had a peripheral i.v. access.

Page 13

Relapse or recurrent disease.

Please write the number of relapses and date of diagnoses of the relapse.

Remission status refers to whether the patient is disease free at the date of extraction. Complete remission 1, if a patient has not had any relapses and is in remission after completing the first cancer treatment.

Complete remission 2, if a patient is in remission after one previous relapse.

Complete remission 3, if a patient is in remission after two previous relapses, etc.

Status at last doctors visit applies to any hospital contact registered, not necessarily due to survivorship follow-up.

Page 14

Bone marrow transplantation (BMT).

Allogeneic transplant, “allo” means “other”; stem cells from a donor.

Autologous transplant, “auto” means “self”; stem cells from the patient himself.

Chemotherapy registered here only includes conditioning chemotherapy for the BMT, see instructions for page 11 if needed.

Page 15

Bone marrow transplant, if a patient has received more than one. See instructions for Page 13 if needed.

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See contact details on page 1.