



**nutritionDay**  
WORLDWIDE

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## **Research project: Oncology nutritionDay in Hospitals worldwide**

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## Introduction

Malnutrition at hospital admission is a risk factor for an unfavourable outcome, prolonged hospital stay and delayed recovery. In addition a relevant proportion of patients have a nutritional intake below their needs during hospitalisation<sup>1-3</sup>. In these patients the incidence of complications such as nosocomial infections, poor ventilatory function, prolonged bed rest is increased<sup>4</sup>. Mortality has been shown to be up to 8 times higher and dependency at discharge up to 3 times more frequent<sup>5,6</sup>.

Cancer has a broad effect on body composition and on alteration of the human's metabolism<sup>7</sup>. Oncological patients often report a reduced food intake<sup>7</sup>, loss of appetite (anorexia) and loss of weight<sup>8</sup>. This cancer related weight loss may evolve to cancer-cachexia<sup>7,9</sup> and may lead to a reduction in quality of life or even earlier death<sup>7</sup>.

In studies it has been shown that weight stable cancer patients have a better prognosis than cancer patients with weight loss: in concrete a lower number of treatment related adverse reactions in weight stable patients is reported, the response to cancer treatment is increased, the patient reports a higher activity level and a better subjective quality of life<sup>10</sup>. Moreover, the actual survival rate of weight stable patients is higher compared to patients with weight loss<sup>8,10</sup>.

Therefore, nutritional treatment of cancer patients accompanying the actual cancer treatment is required.

However, results of the nutritionDay study of 2007-2008 examining patients in all wards indicate that European hospitals do not necessarily screen for risk of malnutrition as recommended<sup>12</sup>. Due to insufficient screening of malnutrition in cancer patients a critical weight loss may not be detected soon enough.

Further, a study examining patient's food intake and the supplementation with artificial nutrition support the thesis that poor nutritional intake was not detected or

interventions were not taken into consideration. In this study it was shown that extra nutritional care was not sufficiently distributed to patients with low nutritional intake. The fact that half of the patients not allowed to eat anything due to medical reasons did not receive any artificial nutritional support, is even more alarming<sup>8</sup>.

Moreover, considerable differences between countries concerning the lack of information about nutritional status of patients were detected<sup>11</sup>. The extent of the problem of malnutrition in hospitals has been assessed in 2001 at the European level<sup>12 13</sup> and 5 major barriers for proper nutritional care in hospitals have been identified. These barriers are no clear definition of responsibility, insufficient education of hospital staff, lack of influence of patients, lack of co-operation between staff members and lack of involvement of hospital managers. Based on this information a resolution of the European Council has been taken in November 2003.

## **History and project development**

The nutritionDay Project (nD) has the aim of promoting safe nutritional care of patients by increasing knowledge, awareness and nutrition monitoring. The project started in the year 2006 and grew to a bigger event each year. The nD today collects and systematically assesses data of hospitals, nursing homes and ICU units worldwide. Participants receive an annual unit and centre report which gives comprehensive information about the nutritional structures and nutritional status of patients in the unit and enables a unique benchmarking opportunity for all types of hospital wards. In 2012 the nutritionDay project focuses on promoting safe nutritional treatment and reducing malnutrition of cancer patients. Therefore the nutritionDay survey will be adapted to evaluate cancer related nutritional treatment and nutritional structures in hospitals and outpatient care.

The European Society for Clinical Nutrition and Metabolism (ESPEN) plans on implementing a Guideline on clinical nutrition of cancer patients. The oncological data obtained from the nutritionDay survey 2012 will be incorporated into the new guidelines of ESPEN and thus increase their practical worth. Therefore the nutritionDay will pursue a disease focused approach for the first time taking oncological units and cancer patients in the focus of interest.

A guideline for cancer related nutritional treatment and structures for patients in and outside oncology wards may increase awareness, usage and standardization of nutritional treatment of cancer patients in practice across hospitals worldwide. Hence, it may reduce the rate of weight loss related problems concerning treatment of cancer patients.

The aim of this international cross-sectional multicentre audit worldwide is to generate a risk and level of nutritional intervention profile for an individual unit/ward based on case-mix, structures and social environment. This profile should give a snapshot on the relation of risk to resource allocation for all units but especially for oncology wards. The audit is unit and patient centred. Each unit should get as a feedback anonymously its position compared with all other participating units of the same specialty. Risk adjustment for selected patient groups, social environments and structures is planned.

## **Rationale of the study**

In order to ensure optimal nutritional care of cancer patients in hospitals and outpatient wards which has a positive effect on cancer treatment, activity level and subsequently for their quality of life, it is necessary:

- to collect data on the availability of cancer related nutritional structures as well as on the regular application of cancer related treatment in hospitals by means of a simple method that requires no specialization in data acquisition,
- to acquire knowledge on the prevalence of malnutrition in hospitalized cancer patients and patients in outpatient wards also in conjunction with the outcome after 30 days, and to forward the same to the individual units,
- to allow comparison with other facilities (with similar profile) with the help of a benchmarking system,
- to assess the effectiveness of introduced changes in terms of quality management and quality improvement in case of repeated participation.

## **Target Parameters**

Primary parameter is the dependence of patient outcome (after 30 days) on food intake (conventional food intake or via clinical nutrition), nutritional status and risk factors.

Secondary parameters are structural parameters (Assessment of structures and processes relevant to nutritional treatment of (cancer) patients).

## **Study Outputs**

In conclusion this audit will have six distinct outputs:

- A precise map of the prevalence of malnutrition before admission and of decreased nutrient intake according to risk factors, medical specialty, organisational structures and countries.
- An increase in awareness for clinical nutrition in patients, caregiver and hospital managers.
- Compile comprehensive information about nutritional status of cancer patients
- Compile comprehensive information about cancer related nutritional structures in inpatient and outpatient wards
- Benchmark of nutritional treatment of cancer patients of hospitals and outpatient wards worldwide
- provide comprehensive data for ESPEN nutrition guidelines for cancer patients

## **Study Design**

The study is a population-based, observational cross-section examination carried out on one day, and an outcome evaluation 30 days later. The examination should be repeated annually. The nutritionDay project sets different illness-related focuses each year.

## **Study Population**

The study evaluates all hospital units and their patients with a special focus on oncological patients in all hospital wards.

## **Method**

The project is designed as one day international cross-sectional audit for all types of wards, including intermediate care, high dependency and specialised units and outpatient care. Intensive care units are excluded.

This project is an extension of the "nutritionDay in hospitals" (EC No 407/2005).

Additionally to the five existing sheets (1-3b+ outcome sheet) three oncology sheets are distributed to cancer patients in and outside of oncology wards as well as in outpatient care.

The questionnaires were created to meet the special needs of cancer patients, examined and approved of by nine experts.

## **Questionnaires**

The data collected for all patients consist of 5 + 3 parts:

**1. Unit organisation and structures:**

Structural information about the unit (one sheet / unit) to be filled by the unit supervising physician together with the nursing head (see Unit structure sheet).

**2. Unit patient caregiver profile:**

Demographic profile, diagnostic category based on ICD 10 and nutritional interventions for all patients (one line / patient) to be filled by a responsible person from the staff. (see Unit caregiver sheet)

**3. Individual patient questionnaire long range :**

Each patient should document her/his nutritional intake during the study period. In addition patients may be asked to fill a questionnaire about changes in nutritional habits and reasons for decreased nutritional intake from the patient's perspective. Further they shall self-assess their general health status.

**4. Individual patient questionnaire: day of survey**

Each patient shall assess for one meal on the day of the survey: nutritional intake and number of drinks, the patient shall estimate his/her usual appetite and his/her food intake apart from hospital food.

**5. Individual outcome – for all patients**

at hospital discharge or day 30, whatever comes first: date of unit discharge, date of hospital discharge, site of discharge and health status.

Additional data collection for cancer patients in all units

**6. Onco: Unit organisation and structure for cancer patients**

Cancer related nutritional structures and treatments in unit (one sheet / unit), to be filled in by a member of the unit staff (see Unit structure sheet\_onco)

**7. Onco: Unit cancer patients caregiver profile**

Demographic profile, cancer diagnosis, laboratory parameter (CRP, Albumin) roman numeral staging system, therapy situation, general treatment, nutrition treatment, (one line / patient) to be filled in by a member of the unit staff.

**8. Onco: Individual questionnaire for cancer patients.**

Each cancer patient should fill in questionnaire about changes in weight, appetite, performance, depression, pain and fatigue,

***Patient Inclusion***

All adult patients present within the unit from 7H00 to 7H00 (e.g.) from first nursing shift start to first nursing shift the following day, including admissions and discharges within the period. All adult patients present within the outpatient unit from 7H00 to 7H00 (e.g.).

***Patient Exclusion:***

All patients can be included

***Survey Recruitment Plan***

5-20 units with 20-30 beds per participating country. A minimum of 10 units per medical specialty will be necessary to allow specialty adjustment. Within each specialty a minimum number of 20 patients per diagnostic category will be necessary. Recruitment will be via the national societies as well as international and national congresses. The target would be all types of hospital wards and outpatient wards within hospitals of different sizes and level of care.

## **Ethical and Legal Aspects**

### ***Information on the Patients***

The nutritionDay oncology worldwide is performed in hospital specialties of all kind and outpatient wards. It is designed as a population-based, observational study in terms of health care research. Due to the anonymous feedback to the unit, it can be seen as a quality control measure (audit). Intervention does not take place.

To ensure reliable unit feedback, it is very important for the nutritionDay forms to be completed accurately and all of the questions need to be answered for the participating units, and their patients.

Data collection is carried out via questionnaires. For the parameters Albumin and CRP a blood sample of each cancer patient is required. However, it is assumed that a blood sample is taken from cancer patients by default and not due to study related reasons.

The audit is implemented by the facility staff in charge of the respective institutions. External personnel is not required.

All patients receive an information sheet of the project. If the patient is interested in participating nutritionDay Oncology an informed consent has to be signed by each patient. By objecting to participate, the respective patient only receives a serial number as a placeholder on the questionnaire with no reference to the person; no further data is taken.

### ***Anonymity of the Patient***

Data collection is carried out indirectly via a personal numerical code for patients:

- To ensure anonymity of patients the collection of data is split up between different survey questionnaires, which are only linked by a numerical code. Therefore, no direct link between risk factors and outcomes within the nursing unit can be evaluated, and a person-related analysis is not possible.
- Neither the name nor the date of birth of residents are recorded or transmitted, so that their identity is protected.



## ***Anonymity of the Hospital Unit***

The purpose of this project is not to publicize possible weaknesses of the units, but to transparently report the situation locally to the facility personnel in charge of medical and nutritional care.

Therefore, a main focus of the organization is to preserve the anonymity of the participating unit. The study team expects that under these conditions the willingness of staff to truthfully complete the questionnaires is greater and decreases the likelihood of socially influenced answers.

In order to strictly maintain the anonymity of the nursing unit, facility reports are only compiled if at least five units in the facility participate. This is to prevent individual nursing units being identified via a facility report without their knowledge.

## ***Risks and Benefits***

The study implies no risk whatsoever for the patients. On some levels participation can even be expected to be beneficial:

- Direct benefit for patients through increased attention to nutritional problems.
- Raising awareness of decision-makers brought about by the decision-making process taking place prior to participating in the study and receiving the quality report of the unit or facility.
- Increase awareness of the staff of hospital unit by participating in the study and the quality report. Pilot results suggest that in terms of the Hawthorne effect, just participation alone has a positive influence on nutrition management in hospital units.
- Since the project is planned for at least two years (with a changing focus), it is possible to repeat the study after one year, to be able to monitor changes which were introduced as a result of the first report.
- Due to prior announcement on the hospital ward, patients are made aware of the issue of malnutrition and proper diet management. The nutritionDay in hospitals has shown that in many cases for the first time discussions between staff, patients and relatives on this subject were set in motion.

## **Data Documentation and Security**

All the necessary data for documentation of the study are entered on the questionnaires. On the datasheets the unit is identified by a numeric code delivered by the coordinating centre after application. The patient is only registered by initials and year of birth. Thus the data handling centre cannot trace data back to an individual patient.

Thus data transfer and storage is made in a way to protect the patient's anonymity and the unit's identity. Ideally all data transfer will be done via the internet, with patient identifiers kept only at the individual unit/ward. The access to data entry will be protected by username and password.

A local patient's list will be used at the level of the participating unit to match identifiers in the database by initials and age in order to facilitate outcome evaluation at day 30 and consecutive data entry.

A unit specific report with anonymous cohort comparison should be finally available for each unit for download from a research website.

All data transfer between the local unit and the coordinating centre in Vienna will be user / password protected. Username and password will be delivered during the registration process of an individual unit coordinator.

## **Data Analysis and Modelling**

The first focus is on the unit/ward with the unit's specific population, diagnostic categories, proportion of patients admitted with recent weight loss as well as the proportion with a decreased nutrient intake. The related outcome parameters will be mortality, length of stay in hospital and site of discharge (other hospital, long-term care or home).

The secondary parameter used for between units benchmarking will be the proportion of patients requiring nutritional interventions and a ranking of potentially modifiable factors with their respective weight.

The primary patient based outcome will be risk adjusted length of stay (LOSa) in relation to the demographic and nutritional risk factors and the nutritional intervention intensity.

The secondary patient-based outcome will be site of discharge and death during the actual hospitalisation. Variability in LOSa will be analysed with Cox regression and dichotomous outcomes with logistic regression.

The efficacy of individual nutritional and structural interventions on outcome will similarly be quantified based on the total cohort only.

All data analysis will be done at the Dept. for Medical Statistics, Medical University Vienna. After publication of the multinational results, all national datasets will be available for national publication based on a research plan, if the number of wards is large enough to ensure anonymity for the individual ward within the country.

### ***Data Elements***

All questionnaires will be translated by the national representative in 30 used languages (English, German, French, Italian, etc) within the country and checked for consistency after back translation into one of the two master languages by the coordinator.

### **Amendments to Protocol**

If modifications to the protocol are required, e.g. inclusion of other test parameters, this will be reported to the Ethics Commission and their consent obtained.

### **Contents of Sheets**

#### ***Regular nutritionDay Sheets in Hospitals:***

1. Unit organisation:

medical specialty: internal medicine (general, gastroenterology & hepatology, endocrinology, oncology, cardiology, infectious diseases, geriatrics, nephrology), neurology, psychiatry, Ear Nose Throat (ENT), general surgery ,cardiothoracic surgery, orthopaedic surgery, trauma, neurosurgery, gynaecology/obstetrics, long term care, paediatrics;

Human resources, guidelines, screening tool, hospital wide nutrition team, awareness, weighting the patient

2. Unit patient profile:

Initials, patients number, gender, patients code, year of birth, (bed nr.), weight , height , how many different drugs orally, days since hospital admission, , ICU stay, patient is waiting for operation, time since operation, , nutrition therapeutic code (enteral nutrition, parenteral nutrition, enteral+ parenteral nutrition, special diet, protein/energy supplements, hospital food, others),

lines and tubes (central venous, nasogastric, nasojejunal, enterostoma, percutaneous endoscopy/surgical gastrostomy, percutaneous endoscopy, surgical jejunostomy, peripheral parenteral nutrition, others),

affected organs (brain/nerves, eye/ear, nose/throat, heart/circulation, lung, liver, gastro intestinal tract, kidney/urinary tract/female genital tract, endocrine system, skeleton/bone/muscle, blood/bone marrow, skin, ischaemia, cancer, infection, pregnancy, others),

Comorbidities (Diabetes I/II, stroke, COPD, myocardial infarction, cardiac, insufficiency, others);

3. Patient questionnaire: (to be filled by the patient and for patients not able to write by a person of the unit)

a. Patient initials, year of birth, gender, weight five years ago, unintentional weight loss, weight loss in kg, proportion eaten, reason for decreased nutritional intake, mobility (needing assistance to walk), pills and liquid medication, general health status, needing assistance to fill in questionnaire;

b. proportion eaten day of nutritionDay, reason for decreased nutritional intake, appetite, volume drunken, food intake beside hospital food;

## ***Oncology Sheets in Hospitals***

1. unit nutritional cancer strategy

existence of computerized documentation in the country, nutritional treatment strategy for cancer patients in unit, actual handling of nutritional treatment, estimation of body composition, documentation of nutritional requirements and actual intake, special diets,

2. unit patient profile\_(all patients with cancer)

initials, patient's number, outpatient/ward, patient's code, reason for admission (cancer, therapy, surgery related, treatment complications, poor health status, ability of independent care)

actual cancer diagnosis (breast, lung, pancreas, gastric/oesophageal, leukaemia, genital tract, sarcoma, kidney/bladder, lymphoma, ENT, brain, colon/rectum, prostate, testicular, dermal, other)

time since cancer diagnosis,

Infections (none, local, general)

Laboratory parameters: CRP, Albumin;

tumour staging (roman numeral staging system)

Therapy situation (Diagnosis, chemotherapy 1st line, chemotherapy > 1st line, radiotherapy, targeted therapy, hormone therapy, palliative, cancer related complications, therapy related complications, surgery

time since therapy start (no therapy, tumour staging/diagnosis, 0-2 months, 3-5 months, 6-12 months, 1-2 years, 2-4 years, > 4 years,

nutrition treatment (no special diet, individually tailored diet, energy rich/protein rich ONS, enteral nutrition (via NGT/PEG), parental nutrition, ONS enriched with special nutrients, special nutrients (EPA, branched chained amino acids, glutamine, arginine, carnitine, personal preferences, counselling, other;

3. Patient questionnaire for patients with cancer  
patient's initials, standard weight (kg), weight loss in kg, reason for decreased nutritional intake, reason for change in appetite, ECOG performance index, substance intake without prescription, depression index, pain level, fatigue status, treatment compliance,

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