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International cross-sectional audit & registry:

nutritionDay in worldwide hospitals

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Introduction:

Malnutrition at hospital admission is a risk factor for an unfavourable outcome, prolonged hospital stay and delayed recovery. In these patients the incidence of complications such as nosocomial infections, poor ventilatory function, prolonged bed rest is increased[1]. In addition a relevant proportion of patients have a nutritional intake below their needs during hospitalisation[2-4].Mortality has been shown to be up to 8 times higher and dependency at discharge up to 3 times more frequent [5,6] when actual food intake was below 25% of calculated needs.

The extent of the problem has been assessed in 2001 at the European level [7,8] 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 (https://wcm.coe.int/rsi/CM/index.jsp). This resolution was signed by 18 countries and implied a specific political action to prevent, identify and treat malnutrition in health care facilities.

In 2003 several malnutrition scores such as MUST[9] and NRS-2002[3] had recently been introduced to ease the identification of patients that are either malnourished or at risk for malnutrition. These scoring systems were simpler to apply than the previous golden standard method SGA ("subjective global assessment") that could only applied by trained staff[10-13]. None of these scores had been validated through a robust outcome such as death or length of stay.

Several risk factors such as age, type of disease, severity of disease, degree of functional impairment, social background, nutritional awareness and structural factors have been proposed but never systematically assessed in an unselected group of hospitalised patients.

In 2004 the European Society of Clinical Nutrition and Metabolism (ESPEN) decided to support actions that aim at reducing health care and disease associated malnutrition. In this action plan the project nutritionDay was initiated and developed by an international team at the Medical University of Vienna with a continuous support of ESPEN[14]. Since 2006 the nutritionDay project has recruited more than 235 000 patients and found that the prevalence of several nutrition-related risk factors is higher than expected for recent weight loss (45%), not eating normally in the week before hospitalization (49%) or less food intake in hospital than served (60%). In addition, the proportion of patients with BMI lower than 18.5 was only slightly higher (8.1%) than in the normal age-matched population. Thus many patients may appear normal or obese but have several other risk factors for malnutrition.

These prevalences of risk factors are highly variable between specialties but much more within each specialty. This finding is important because each of these risk factors could be associated with mortality within 30 days with odds ratios up to 8. The association was maintained in a multivariate analysis[14]. Thus the actual prevalence of nutritional risk factors is an important information to know for each unit in order to develop a strategy to tackle disease-related malnutrition[4]. Moreover it is known that screening and monitoring for malnutrition is not systematically used in hospitals worldwide[15].

Recently the PANDORA scoring system for hospitalised patients was developed on the basis of nutritionDay data and has quantified the contribution of individual risk factors to predict mortality within the next 30 days. Actual food intake, BMI and mobility are important nutrition related contributors to the risk of death[16].

This knowledge about the association between nutrition related risk factors and mortality raise several new questions:
First it is important to know how these risk factors are associated with resource utilisation such as length of stay in hospital. Actually this possible association is not known for a large unselected group of hospitalised patients. If present such an association needs a systematic health economic evaluation to be able to estimate what benefit may be obtained if measures to identify malnutrition early and start effective treatment are routinely implemented.
Second it is not clearly known which systemic factors such as nutrition related hospital structures and processes are associated with improved nutritional care. In order to provide optimal nutritional care to patients it is important to continuously assess and improve the quality and effectiveness of nutritional care and nutrition care services. In the past years it has been pointed out that addressing quality indicators in nutrition care such as early definition of patients at risk of malnutrition, early nutritional screenings, defining responsibilities or increasing knowledge nutritional knowledge in the units may be useful to contribute to improved nutritional care. Associations of hospital structures and processes on quality of nutrition care thus needs further assessment.

The aim of this international cross-sectional multicentre audit is to generate a risk and level of nutritional intervention profile for an individual unit/ward based on case-mix, nutrition care and available structures and processes. This profile should give a snapshot on the relation of risk to resource allocation. The audit is unit centred. Each unit receives upon participation a feedback report which anonymously compares its position with all other participating units. Risk adjustment for selected patient groups, social environments and structures is planned.

In conclusion this audit will serve five distinct aims:

- Generate 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.
- Increase in awareness for clinical nutrition in patients, caregiver and hospital managers.
- Enlarge and maintain a reference database for hospitalised patients
- Provide individual unit benchmarking
- Allow the study of nutrition risk associated resource utilisation

Methods:

One day international cross-sectional audit in all types of hospital wards (including hospital care at home). Intensive care units are excluded.

Data are collected with the help of questionnaires. Anonymised data entry into the audit database is done with individual and anonymous center- and unit codes.

The data collected consist of four parts:

1. **Unit organisation and structures:**
   Structural information about the unit (one sheet/double sided/unit) to be filled out by the unit staff (eg. supervising physician together with the nursing head) ("Unit" sheet).
2. **Hospital capacity and staffing:**
   Capacity and structural information about the hospital (1/2 sheet/hospital) to be filled in by unit staff with the help of the hospital management. ("Hospital" sheet).
3. **Patient's demographics & medical information:**
   Demographic profile, diagnostic category based on ICD 10, comorbidities, surgical status, and nutritional interventions for all patients (one sheet/double sided / patient) to be filled by a responsible person from the medical staff.
   ("About your patient" sheet).
4. **Individual self-administered patient questionnaire:**
   Each patient should document her/his nutritional intake during the study period. In addition, patients are asked to fill a questionnaire about changes in nutritional habits and reasons for decreased nutritional intake from the patient's perspective and health status now and before admission (one sheet/double sided/patient) to be filled by the patients themselves.
5. **Individual patient outcome:**
   at hospital discharge or 30 days after nutritionDay, whatever comes first: date of unit discharge, date of hospital discharge, site of discharge and diagnosis at discharge.

Patient inclusion:

All 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. Patients younger than 7 are excluded. Questionnaires for children can be completed by the patients themselves or by a legal guardian.
Patients may accept to participate only for the medical documentation part from the caregiver sheet (sheet 2) and individual patient outcome (outcome sheet), but refuse to fill the individual patient questionnaire (sheet 3).

Patient exclusion:

Patient with an age < 7 a.
Patients unable to understand and answer questions because none of the 35 available languages is understood.
Patient's refusal to answer the patient specific questionnaire or refusal of medical data use for auditing and research.
Patients admitted and discharged during the same calendar day.

Participation rules:

1. A user needs to register to nutritionDay as a member to the nutritionDay network. Each may choose a personal username. Each user needs to provide a valid email address. After email validation, the user is registered with the chosen username. User details are stored on a system that is not connected to the nutritionDay registry at any time. One user may serve as contact for several units and centers.
2. A user may order codes for participation for one or several centers and units. Access to the registry is only possible with a center code and unit code. These codes are selected from a list of random numbers.

Audit/registry recruitment plan:

Participation to the registry is voluntary. There is no participation fee. All necessary information can be obtained from the dedicated website (www.nutritionday.org). Participation can be promoted via international and national scientific societies, universities, health care organisations or governmental agencies as well as via advertisement at international and national congresses. The target would be all types of hospital wards within hospitals of different sizes and level of care.

Risk and benefit assessment:

The benefit for each patient is that awareness and knowledge about nutrition related factors and treatment options in the treating unit is increased. There is no individual risk since the audit is purely observational.

The benefit for the individual unit is to receive an extensive benchmarking report displaying the unit data in comparison with worldwide data from all units in the same specialty (reference data from the previous 3 years) immediately after the end of data entry. Units or groups of units may request specific reports that can be obtained only after a case by case agreement (data sharing agreement) and possible financial coverage. All data used as a reference for benchmarking purpose are from units where a minimum of 60% of actually present patients have been recruited and the outcome at day 30 is available for more than 80% of these patients. There is no risk for the unit since anonymity of unit is structurally strictly maintained.

The benefit for the registry up-to-date data enabling benchmarking in pace with medical and care evolution. Moreover the registry data are used for national and international research of the scientific community.

The aim is to recruit a minimum of 10-50 units with 20-30 beds per participating country. A minimum of 10 units per medical specialty will be necessary to allow specialty adjustment.

Data security:

On the questionnaire, the unit and the hospital/center are identified by a numeric code delivered after request to the nutritionDay coordinating center by mean of an automatic system. The only requirement is a valid email address for direct communication with the unit.

Patients are usually identified on the locally used questionnaires by initials and age, but use of initials is not mandatory. Consecutive numbering is also possible. Only the participating unit has to trace patients identifier to be able to collect hospital outcome at day 30 after nutritionDay.

During data entry into the electronic registry only anonymous codes for center, unit and patients are possible. Thus the data handling center cannot trace data back to an individual patient. The access to data entry is protected by anonymous centercode and unitcode.
Typically all data are collected via the internet.
The protected data server is run by the Center for Medical Data Science, Institute of Medical Statistics of the Medical University Vienna. The data server is mirrored and backuped. The data server is protected within the University Firewall against external access.

Data feedback and individual unit report

All participating units are entitled to receive a benchmarking report from the registry. The report generator is started by the participating unit, when data entry has been completed. After checking that all data are correctly entered the final report can be generated. This final report offers complete descriptive statistics of the unit data compared to the reference data from the previous 3 years of the corresponding specialty. Only data from units fulfilling a high data quality standard are used for the reference. More than 60% of the patients present in the unit need to participate and 80% of these patients need to have their outcome recorded. All descriptive statistics represent prevalent data and are not corrected for cross-sectional sampling to allow direct data control and interpretation.
All downloaded reports of a unit are consecutively numbered and stored for documentation purpose. For participating hospital wards, additionally to the numerical report, a multi-graphical report "Smart Report" can be obtained to highlight quality indicators of nutritional care in the unit and to compare those at a national, regional and international level.

Data analysis and modelling:

The first aim of the project is to serve local specialty specific and up-to-date benchmarking with regard to nutrition and feeding status, risk profile and nutrition care. Given the typical cross-sectional sample of 20-30 patients frequent risk factors can be easily compared because such risk factors as recent weight loss or less than normal eating are observed in one third to half of the patients.

The second aim is scientific data analysis. The actual research questions are:

- Identifying risk factors associated with decreased eating, weight loss
- Analysing the impact of risk factors for increased length of hospital stay
- Analysing time-trends in risk profile and nutrition care
- Analysing the economic impact of nutrition risk factors on the health care system
- Analysing the impact of hospital and unit structures and processes on quality of nutrition care
- Updating the PANDORA score if major change in performance is identified

The actual database includes more than 230000 patients for the period 2006-2023 and allow the following precision for estimating the prevalence of risk factors:

Risk factor prevalence	1%	precision as 95% CI	0.93-1.07%
Risk factor prevalence	5%	precision as 95% CI	4.87-5.14%
Risk factor prevalence	10%	precision as 95% CI	9.81-10.19%
Risk factor prevalence	20%	precision as 95% CI	19.75-20.25%
Risk factor prevalence	30%	precision as 95% CI	29.72-30.29%

Risk factor prevalence 40% precision as 95% CI 39.70-40.30%

Given the typical participation of 12 000-20 000 patients annually, we expect to have a sufficiently precise database for benchmarking, when using the last 4 years data.

For the scientific data analysis we use COX-regression or general linear model with proper weighting of observations to account for the effect of cross-sectional sampling for events such as discharge or death and linear regression models to analyse length of stay. Whenever several events can occur in a patient a competing risk analysis is performed.

All data analysis will be done at the Center for Medical Data Science, Institute of Medical Statistics of the Medical University of 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:

1. Unit organisation & nutrition related processes: (1 sheet /double sided)
    a. Unit specialty
    b. Adherence to perioperative care pathway/protocol
    c. Human resources available during the actual shift
    d. Nutrition care resources
    e. Screening / monitoring practice
    f. Weighing practice
    g. Communication and documentation practices
    h. Meal choices and mealtime practices
    i. Action taken when malnutrition has been identified
2. Hospital capacity, resources and nutrition related coding
    a. Bed capacity
    b. Number of admissions
    c. Staff resources
    d. Availability of nutrition care strategy
    e. Nutrition related standards and routine activities
    f. Nutrition related coding for billing and reimbursement
3. Patient medical information: (1 sheet /double sided per patient)
    a. Gender
    b. Year of birth
    c. Weight & height
    d. Background of hospital admission
        i. Duration since hospital admission
        ii. Planned/emergency
        iii. Reason for admission
        iv. Diagnosis (ICD 10 codes) at admission

v. Comorbidities

e. If operated how long ago was the operation
f. Whether a surgical intervention is planned during the actual hospital stay
g. Type of surgery (approach, duration, organ operated, indication to nutrition therapy)
h. Any ICU-stay during the actual hospitalisation
i. Severity of illness (Terminally /not terminally ill)
j. Fluid status in 3 categories
k. Number of drugs
l. IV Fluids
m. ONS drinks planned
n. Type of feeding or artificial nutrition (s) used
o. Whether intravenous lines and/or gastric or jejunal tubes are present and if complications have occurred
p. Nutrition care on patient level (identification, documentation and treatment of malnutrition in patients)
q. Change of health status since admission

4. Patient questionnaire about history and nutrition: (1 double sided page to be filled by the patient and for patients not able to write by a person not involved in treatment decisions)
    a. Typical dietary habits
    b. Former residence
    c. Mobility in the hospital
    d. Subjective quantification of the health status
    e. Use of health care services before admission
    f. Medical treatment before admission
    g. Health insurance coverage
    h. Weight 5 years ago and weight loss during the last 3 month
    i. Eating during the week before hospital admission

    About this hospital admission

    j. Planned or emergency admission
    k. Communication of nutrition care to the patient
    l. General satisfaction with hospital food
    m. Necessity of helping to eat

    And for the actual day (nutritionDay)

    n. Ordered portion size
    o. Number & type of drinks
    p. Amount eaten during one main meal
    q. Reasons for not eating
    r. Subjective evaluation of food intake since hospital admission
    s. Other than hospital food eaten
    t. Subjective evaluation of strength

u. Need of help for filling out the questionnaire

5. Hospital outcome until day 30 after nutritionDay
    a. Discharge date
    b. Discharge Diagnosis
    c. Discharge status
    d. Readmission to the same/different hospital
    e. Admission to ICU within 30 days after nDay
    f. Operation within 30 days after nDay (time to operation)

All questionnaires are self-explaining and in addition a detailed explanation file with definitions for each data item is provided. An email contact allows further clarification with the international project manager, supported by national coordinators.

All questionnaires have been translated by the national representative for over 30 languages (English, German, French, Italian served as master languages) within the country and checked for consistency after back translation.

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