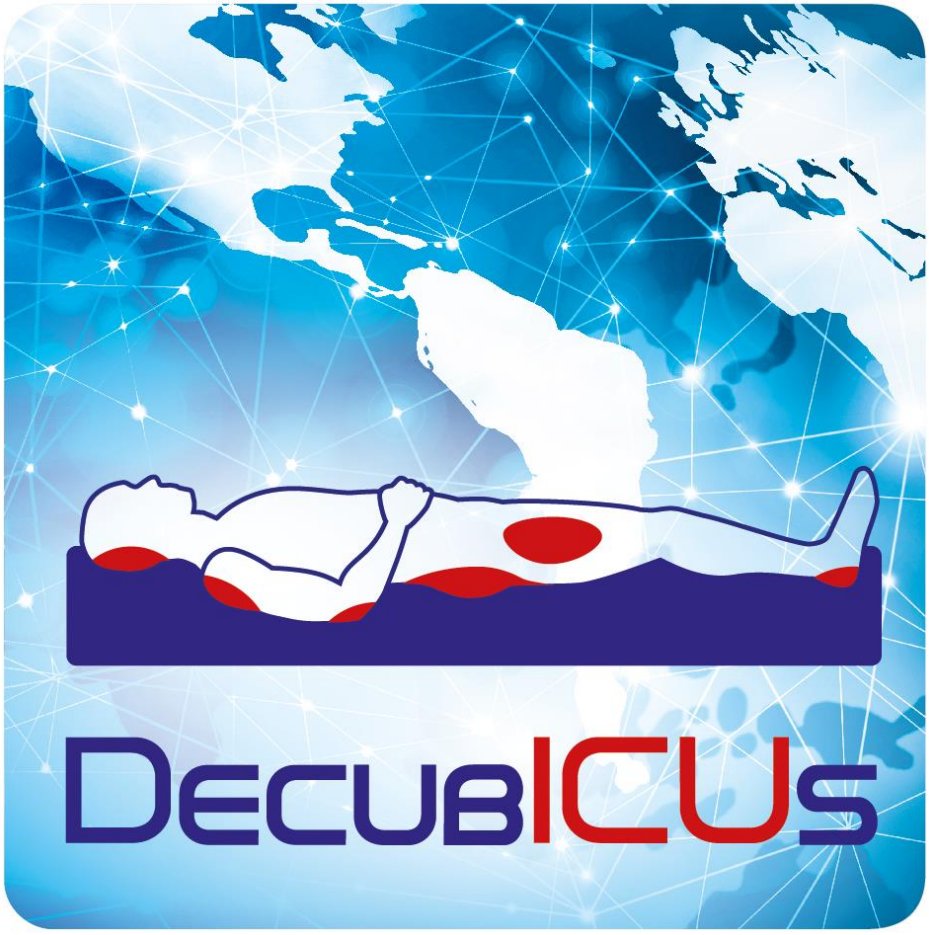
Online Resource 4. Study protocol



Decub*ICU*s

Decubitus in Intensive Care Units

A Multicenter International One-Day Prevalence Study

1 Organisational information

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Julie BENBENISHTY, Jerusalem (Israel)
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Barbara MCLEAN, Atlanta (USA)
Louise ROSE, Toronto (Canada)
Francesca RUBULOTTA, London (UK)
Ged WILLIAMS, Abu Dhabi (United Arab Emirates)

Coordinating center: Ghent University, Belgium (Prof. Dr. S. Blot)

National representatives:

The role of the national representatives can be summarized as follows:

(1) Advertise the study in the individual countries and identify participating hospitals and local investigators in their country.
(2) Apply for regulatory approval in a national level where applicable and ensure that ethical committee (EC) approvals or waivers for all the participating hospitals in the country are in place prior to the initiation of the study.
(3) Assist with the translation of the study protocol/CRF where required.
(4) Ensure good communication with the participating sites in the respective country and to animate local investigators to achieve optimal recruitment and follow up during the period of the study. During the period of database quality control (data 'cleaning') the national representative should animate the individual to reply in possible queries.

Local co-ordinators:

Local co-ordinators in individual institutions will have the following responsibilities:

(1) Provide leadership for the project in their institution
(2) Ensure all relevant regulatory approvals are in place and communicated with the coordinating center
(3) Ensure adequate data collection and act as guarantor for the integrity and quality of the data
(4) Ensure timely completion of the e-CRFs
(5) Ensure collaboration to solve possible queries that may arise during the database quality control process.

2 Protocol summary

Study title:	Decubitus in Intensive Care Units
Acronym:	Decub*ICU*s
Design:	multicentre, international one-day prevalence study
Target population:	all patients present on **15 May 2018**

Interventions: no interventions – observational study

Outcomes:

- major risk factors for pressure injury development;
- preventive measures used in distinct ICU populations and countries;
- identifying shortages in the availability of evidence-based measures to prevent pressure injuries;
- occurrence rates of pressure injuries with/without accurate adjustment for risk profile and preventive measures taken;
- benchmarking between regions/countries;
- clinical outcomes associated with pressure injuries (major organ derangements and 12 week mortality);
- economic outcomes associated with pressure injuries (length of ICU stay) and linking these outcomes with local practice regarding prevention measures applied/available.

Subanalyses:

- country and regional differences in prevalence of pressure injuries and outcome;
- age, sex and morphology-related differences in prevalence of pressure injuries and outcome;
- comorbidities, prevalence and outcome of pressure ulcers;
- relationship of ICU organisational issues with prevalence of pressure ulcers and outcome;
- prevalence and outcome in specific subgroups (trauma, surgical, medical, etc…).

Study duration: one-day prevalence [**15 May 2018**]

Follow-up period: until hospital discharge or at 12 weeks to evaluate ICU and hospital outcomes [**7 August 2018**]

3 Description of the study

3.1 Introduction

Pressure injuries remain among the most important complications of hospitalisation. They are associated with an increased infection risk, pain and disability, high level of dependence, longer hospitalisation, and as such higher hospital costs. The total annual cost for pressure injuries in the UK has been estimated to range 1.4 to 2.1 billion pounds [1].

Because severe pressure injuries are generally considered preventable, the occurrence rate of pressure injuries has increasingly been used as a quality indicator in hospital care. In addition, and in accordance with the ruling on Inpatient Prospective Payment System by the Centers for Medicare and Medicaid, hospitals in the US are no longer reimbursed for hospital costs related to severe pressure injuries (stage III or higher). These evolutions have put substantial emphasis on the prevention of pressure injuries.

In the past decades increasing efforts to prevent pressure injuries have been made, but –contrariwise– the challenge of pressure injury prevention seems to become harder as medicine progresses. Indeed, favourable evolutions in emergency medicine and organ support have led to an increasing pool of long-term intensive care (ICU) patients. Patients admitted to ICUs are at particular high risk for pressure injuries because of their debilitated physical condition and exposure to numerous risk factors. Risk factors for ICU patients are generally the same as those in a general hospital population. Yet, in ICU patients they are exaggerated in terms of both a stronger effect and the presence of more factors at the same time [2]. Also, the proportion of elderly admitted to ICU is on the rise. In a university hospital the number of patients aged >75 years increased by one third over a 15-year period [3].

Although many studies reporting on pressure injuries in ICU settings are outdated single-center or regional initiatives [4-7], a recent randomized trial conducted in the United Kingdom found a prevalence of new or substantially worsened pressure injuries of 15% in intensive care (ICU) patients with an anticipated stay of at least 36 hrs [8]. A 58% prevalence was identified in a Brazilian single center study among adult ICU patients of which 55.5% were estimated to be at high risk of developing a pressure injury according to the Braden scale, while 40% actually developed one [9].

The changing ICU patient profile, the high prevalence and the substantial economic impact make large-scaled international studies necessary to keep up with present epidemiology of pressure injuries in ICUs.

3.2 Objectives

Our objective is to provide an up-to-date, international “global” picture of the extent and patterns of pressure injuries in ICUs. Thereto we plan to perform a 1-day, prospective, multicenter point-prevalence study. The large scale of the project should allow thorough epidemiological analyses. More precisely the study will enable to identify:

- major risk factors for pressure injury development;

- preventive measures used in distinct ICU populations and countries;
- shortages in the availability of evidence-based measures to prevent pressure injuries;
- malpractice in pressure injury prevention in particular regions or countries;
- occurrence rates of pressure injuries with/without accurate adjustment for risk profile and preventive measures taken;
- benchmarking between regions/countries; clinical outcomes associated with pressure injuries (major organ derangements and mortality);
- economic outcomes associated with pressure injuries (length of ICU stay) and linking these outcomes with local practice regarding prevention measures applied/available.
- country and regional differences in prevalence of pressure injuries and outcome.

3.3 Methods

3.3.1. Network development

Steering committee

Point prevalence studies are only of value when performed on a vast scale. To sample a representative cohort, we intend to recruit about 1200 ICUs with all continents covered and as many countries as possible within each continent. Thereto an international steering committee will be established. Following our extensive experience in international research projects (see profile of the principal investigators) we currently have research contacts in all continents. Clinicians/researchers with a high ability to recruit centres will be invited in the steering committee.

Recruitment strategy

To maximize the recruitment of centers, different approaches to invite ICUs for participation will be used:

- development of a dedicated informative website including an extensive Frequently Asked Questions (FAQs) section. In all recruitment initiatives the website will be mentioned;
- our current network of researchers and participants in other studies will be contacted (e.g., all 3587 participants in the EVIDENCE-project, representing 79 countries);
- members of the steering committee will contact their personal network;
- endorsement of the European Society of Intensive Care Medicine (ESICM), will be pursued. The ESICM facilitates spread of their projects through blast mails to all their members. In the past, we succeeded in gaining endorsement from the ESICM for three of our research projects;
- for countries currently lacking from our network, embassies will be contacted to obtain a list of hospitals with intensive care activity (this strategy has been successfully used for the development of the EVIDENCE project). Especially for African and Eastern European countries this can be an important approach;
- advertisement on websites of critical care societies such as the ESICM, the Society of Critical Care Medicine (SCCM), and the American Association for Critical Care Nurses (AACCN);
- flyers will be distributed at national and international critical care symposia and congresses.

3.3.2. Organizing the point-prevalence study

For the point prevalence study a date will be picked (**15 May 2018**). Centers prepared to participate must obtain approval of the local ethics committee or review board. A local investigator with email contact is a prerequisite. Centers will be alerted by repeated email in the weeks before the study date. At that time, they will be asked to provide minimal data regarding the organisation of the unit (e.g. staffing and number of ICU beds).

3.3.3. Data recording

Pressures injury stages will be graded following the classification system jointly developed by the National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, and Pan Pacific Pressure Injury Alliance [10]. A concise educational web-base training package will be available to optimally prepare participating ICUs for data recording.

Data will be recorded using electronic or pre-printed case report forms. Electronic forms (e-CRFs) can be consulted and submitted online. For countries with restricted digital resources, pre-printed forms will be available. These will be downloadable via the dedicated website or sent via fax, postal mail or email two weeks preceding the point prevalence measurement. After data input, pre-printed forms can be submitted through the channel best suiting the participating centers' commodities. Besides the FAQs section on the study website, a dedicated telephone hotline will be available for any queries during the study follow-up period.

Data to be recorded include patient demographics, data on severity of underlying disease and acute illness, organ failure, pressure ulcers, major risk factors for pressure ulcers, and measures taken to prevent pressure uinjuries. For more detail, see the case report form.
Participating ICUs will be asked to provide patient follow up until hospital discharge or for 84 days. At that time point survival status and length of ICU and hospital stay will be recorded.

3.3.4. Analyses & reporting of the study results
The principal investigators will perform data analyses. Data will be analysed as a whole and per continent, the latter to allow defining benchmark thresholds per continent. Initial data will be presented at international congresses as abstract and published in an international peer reviewed medical journal.

4 Study population

4.1 Inclusion criteria
All adult patients (>18 years of age) present on **15 May 2018**

4.2 Exclusion criteria
There are no exclusion criteria. All patients should be included. Patients with severe clinical conditions not allowing safe pressure injury identification should not be evaluated for the respective risk zones. If it is known that the patient has a pressure injury at the body sites that cannot be safely evaluated, the stage of the pressure injury should be recorded as previously known. If it is unknown whether the patient has a pressure injury at these body sites, this should be indicated with a '?' (See also case report form).

5 Study course

5.1 Patients' enrolment
Patients' enrolment will be limited to **15 May 2018** (from 00:00 until 24:00).

5.2 Ethics committee approval
Even though this is an epidemiological study with entirely anonymous data collection, it is advised to submit the protocol to the local ethics committee for approval.

5.3 Therapeutic intervention
The study is purely observational in nature; no interventions are planned.

5.4 Daily documentation
Data collection includes three stages:
a. on admission: see center report form;
b. on the study day: see case report form;
c. during follow up period: outcome at ICU and hospital discharge.

6 Organisation

6.1 Documentation
Data will be recorded using electronic or pre-printed case report forms by the attending intensivist, a trained research nurse, or an appropriately instructed nurse.

6.2 Collecting data
Data should be submitted digitally, faxed or (e-)mailed periodically to the coordinating center (See contact information).

6.3 Data management and archiving

6.3.1 Data property
The individual data provided by a participating ICU are primarily the property of the ICU who generated the data. All investigators have the right to access their data at any time.

6.3.2 Data control
Data control will involve the following levels:

- all participants are provided with detailed information (See instructions form). The coordinating center will provide a rapid response for any query throughout the study period (See contact information);
- data plausibility check will start at the entry level, setting validity limits for each variable. Investigators will be queried in case of outliers, excessive numbers of missing values.

6.3.3 Subsequent use of data
The steering committee, on behalf of the investigators, has the right to use all data that are pooled in the databank for scientific purposes. Investigators will be regularly informed about ongoing study activities. All participants have the right to access the data, pooled in the databank, for research purposes after the research project has been terminated, and with the approval of the steering committee. A copy of the databases generated by the project can only be provided to third-part entities after specific approval by the participating ICUs.

6.3.4 Archiving
A copy of the electronic databank will be kept in the coordinating centers and preserved for 15 years for subsequent use by the steering committee and investigators. It is recommended that a copy of all case report forms be kept at each center for future reference.

6.3.5 Publication rules
The executive committee will appoint a writing committee to draft the scientific report(s). Authorship will take the following elements into account: study design, study organisation, data collection, patient enrolment, data analysis, and contribution to the manuscript. All national representatives and local coordinators will have their efforts recognized by being mentioned as 'collaborator' in the authorship of the paper and as such listed in PUBMED. Members of the executive committee, national representatives and local coordinators may suggest research questions for secondary manuscripts and take initiative in drafting the paper after approval by the head investigators. In this regard, the head investigators control the risk of potential overlap between manuscripts.

6.4 Sponsorship
The DecubICUs project is in part supported by the LIFE Priority Fund of the European Society of Intensive Care Medicine, and the Flemish Society of Critical Care Nurses.

6.5 Statistical analysis
A single final analysis is planned at the end of the study; no interim analyses are planned. Study cohort characteristics will be described as proportions for categorical variables and for continuous variables as mean and standard deviation if normally distributed or median and inter-quartile range if not normally distributed (according to the Kolmogorov-Smirnov test for normality). Relationships with binary outcome variables (e.g. pressure ulcers, mortality) will be assessed by means of unadjusted and adjusted logistic mixed (multi-level) effects modelling in order to consider a centre effect. Likewise, linear mixed-effect modelling will be used to assess unadjusted and adjusted relationships with continuous outcome variables (e.g. length of ICU stay, organ failure score). Covariates that will be evaluated on their relationship with the presence of pressure ulcers encompass various organizational aspects of the ICU (e.g. nurse-to-patient ratio), pressure ulcer prevention measures (e.g. type of matrasses used), and severity of underlying disease and acute illness (co-morbidities, SAPS2 score, organ failure,…).
Covariates with an association with the outcome variable at a statistical level <0.25 in unadjusted logistic/linear mixed-effects analysis will be considered for adjusted analysis. A stepwise approach will be used to eliminate terms into the regression model where $p<0.15$ or $p<0.10$ (depending on the more favorable Hosmer-Lemeshow goodness-of-fit test) was set as the limit to keep covariates in the model. Results of logistic regression will be reported as adjusted odds ratios with 95% confidence intervals. If of value, pressure ulcer rates will be provided for large geographic regions (e.g. continent). Eventual differences in pressure ulcer rates might offer the opportunity to evaluate variances in prevention measures on a large scale.
Statistical analysis will be performed using SPSS for windows version 23.0 (Chicago, US). The head investigator (SB) is in charge of all statistical analysis and he is backed by the team of the Dept. of Biostatistics at the Faculty of Medicine & Health Sciences, Ghent University. In case unusual statistical challenges are faced, Dr. Ellen Deschepper of the Dept. of Biostatistics will be consulted.
Initial data will be presented at international congresses as abstract and published in an international peer reviewed medical journal.

7 References

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8 Contact details

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Appendix 1: Center Report Form

CENTER REPORT FORM Center: __ __ __

Did the data collectors consult an educative module on the correct staging of pressure injuries prior to data collection?
□ No □ Yes, the module provided by the ESICM □ Yes, another module

Section 1: general data

Institution: ……………………………………………………………………………………………………….

Type of hospital: ☐ University/academic ☐ Non-university

Hospital capacity: __ __ __ __ beds
ICU capacity: __ __ __ __ beds

Type of ICU: ☐ Closed ☐ Open (non-ICU doctors may write orders)

ICU speciality:
Surgical ☐ cardiac ☐ non-cardiac ☐ transplantation ☐ mixed ☐ burns ☐ trauma

Medical ☐ coronary ☐ neurologic ☐ respiratory ☐ mixed
Mixed medical/surgical ☐ Other ☐ Please, specify …………………………………...………

How many patients were (approximately) treated in your ICU in 2017? _ __ __ patients

Section 2: data pertaining to the study day

How many ICU beds are occupied at the day of the study? __ __ __ __ ICU beds

Number of nurses on the day of the study
Between 2 - 3 am: __ __ __
Between 8 - 9 am: __ __ __
Between 4 - 5 pm: __ __ __

Physiotherapist available on the day of the study? ☐ Yes ☐ No

Is your unit currently participating in an (inter)national study on pressure injuries? ☐ Yes ☐ No

Do patient files contain a specific section for reporting pressure injuries? ☐ Yes ☐ No

Dietician/nutrition specialist available on the day of the study? ☐ Yes ☐ No

Which preventive measures are used in your ICU? (see codes list)
__ __
__ __

Which of the **above** measures are used in **all** patients (irrespective of risk profile)? (see codes list)
__ __
__ __

Which risk assessment scale is used to estimate the risk of pressure injuries?
☐ No scale ☐ Norton scale ☐ Braden scale ☐ Waterlow scale ☐ Other scale (specify):

What is the primary trigger to use extra preventive measures?
☐ high risk profile as indicated by a risk assessment scale
Ulcer: ☐ stage I ☐ stage II ☐ stage III ☐ stage IV ☐ U (unstageable) ☐ S (depth unknown)
☐ mechanical ventilation ☐ anticipated ICU stay >3 days ☐ coma/sedation ☐ vasopressor use
☐ malnutrition ☐ incontinence ☐ obesity
☐ Other (specify): …………………………………………………………………

Rubulotta F, *et al. BMJ Open* 2022; 12:e057010. doi: 10.1136/bmjopen-2021-057010

Appendix 2: Case Report Form

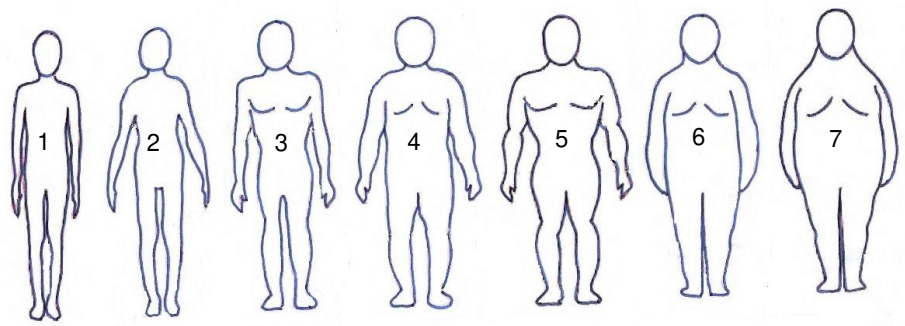
CASE REPORT FORM Center: __ __ __ __ __ Patient: __ __

Patient demographics & admission data

Date of ICU admission: __ __ / __ __ / __ __ __ __ (dd/mm/yyyy) **Sex:** ☐ male ☐ female

Age: __ __ __ years **Weight:** __ __ __ kg **Length:** __ __ __ cm

Morphological type: __



Type of admission: ☐ medical ☐ surgical ☐ elective ☐ emergency ☐ trauma ☐ burns

Mechanical ventilation on admission: ☐ yes ☐ no

Admission source: ☐ other hospital ☐ emergency room ☐ operating room ☐ general ward ☐ other

Primary diagnosis (only 1, see Codes list): __ __ __

Secondary diagnosis (max. 3, see Codes list): __ __ __ / __ __ __ / __ __ __

Comorbidities:

☐ COPD	☐ AIDS	☐ cancer (solid tumour)
☐ cirrhosis	☐ renal failure	☐ metastatic cancer
☐ heart failure	☐ diabetes	☐ hematologic cancer
☐ steroid therapy	☐ chemotherapy	☐ immunosuppression
☐ malnutrition	☐ impaired mobility	☐ peripheral vascular disease

Site(s) of surgery (max. 3, see Codes list): __ __ __ / __ __ __ / __ __ __

Study day parameters

Heart rate	(min.) __ __ __	(max.) __ __ __ bpm
Body temperature	(min.) __ __ __	(max.) __ __ __ °C
Therapeutic hypothermia	☐ yes	☐ no
Systolic blood pressure	(min.) __ __ __	(max.) __ __ __ mmHg
Mean arterial pressure	(min.) __ __ __	(max.) __ __ __ mmHg
Lactate	(max.) __ __ __ mmol/L	
Vasopressor use	☐ yes	☐ no
Sedation	☐ yes	☐ no
Muscle relaxants	☐ yes	☐ no
Respiratory rate	(min.) __ __ __	(max.) __ __ __ /minute
PaO_2/FiO_2	(min.) __ __ __	(max.) __ __ __
Mechanical ventilation	☐ yes	☐ no
Blood urea	(max.) __ __ __	☐ mg/dL or ☐ mmol/L or ☐ BUN (max.) __ __ __ mg/dL
Blood creatinine	(max.) __ __ __	☐ mg/dL or ☐ mmol/L
Leucocytes	(min.) __ __ __	(max.) __ __ __ $10^3/mm^3$
Platelets	(min.) __ __ __ $10^3/mm^3$	
Urine output	__ __ __ mL/24hours	
Renal replacement therapy	☐ yes	☐ no
Serum potassium	(min.) __ __	(max.) __ __ mmol/L
Serum sodium	(min.) __ __ __	(max.) __ __ mmol/L
Total bilirubin	(max.) __ __ __	☐ mg/dL or ☐ mmol/L
Serum bicarbonate	(min.) __ __ mmol/L	
Glasgow Coma Score	__ __	

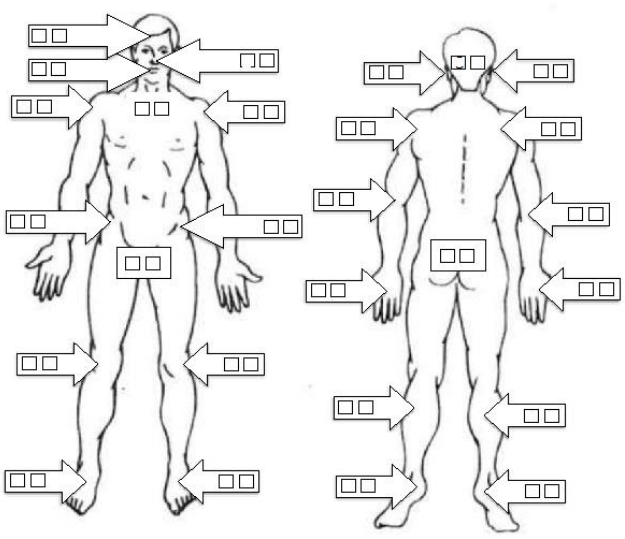
Device use on day of study (see Codes list)

__ __

Pressure injury prevention measures used (see figure and Codes list)

__ __ __ __ __ __ __ __ __ __ __ __

Pressure injuries (see Codes list)



Lesions following fixation of the patient: ☐ wrist(s) ☐ ankle(s) ☐ trunk

Pressure injury risk assessment

Sensory perception: ☐ completely limited ☐ very limited ☐ slightly limited ☐ no impairment

Moisture: ☐ constantly moist ☐ very moist ☐ occasionally moist ☐ rarely moist

Activity: ☐ bedfast ☐ chair-fast ☐ walks occasionally ☐ walks frequently

Mobility: ☐ completely immobile ☐ very limited ☐ slightly limited ☐ no limitation

Nutrition status: ☐ very poor ☐ probably inadequate ☐ adequate ☐ excellent

Friction and shear: ☐ problem ☐ potential problem ☐ no problem

Outcomes

Date of ICU discharge: __ __ / __ __ / __ __ __ __ (dd/mm/yyyy) ☐ alive
☐ dead

Date of hospital discharge:__ __ / __ __ / __ __ __ __ (dd/mm/yyyy) ☐ alive
☐ dead

Patient still in hospital on **7 August 2018** (= 15 May 2018 + 84 days) ☐

Appendix 3: Instructions to complete the center report form and case report form

Participants should register online on our webpage (www.esicm.org/research/decubICUs). Registration deadline is set to two weeks before the data collection date (1 May 2018). Enter the mailing address clearly. Providing a valid email is mandatory to facilitate correspondence during the study. Please inform us timely of any changes in your mailing address/email.
Upon completion of the online registration form, participating centers can chose to use either electronic either paper copy CRFs. To obtain paper copy CRFs, please contact the coordinating center (see contact information) by e-mail, postal mail or fax, specifying by which channel you wish to receive the CRFs (postal mail, fax, …). Please provide a valid postal address or fax number. To access the e-CRFs, each investigator will receive personalised login information to enter our secured website, where all data should be electronically entered. Each ICU will be assigned a code number. Please use this center number in all correspondence with the coordinating center. We invite the investigators to take some time in exploring the data entry area before the start of the study. Please feel free to contact the coordinating centre in case of any questions.

- -

Upon registration, the following data must be provided:

☐ Institution: name of the hospital
☐ Type of hospital: university/academic or non-university hospital
☐ Hospital capacity: the number of beds must be indicated
☐ ICU capacity: the number of beds must be indicated
☐ Type of ICU: the ICU is classified according to the majority (> 60 %) of regular admissions. Please indicate whether your ICU is open or closed.
☐ ICU specialty: the most appropriate choice must be marked. This should be based on the majority of admissions (> 60%). A free text can be added to report other specialties if applicable.
☐ Number of patients treated in 2015: if exact figures are lacking, provide a realistic estimate.

On the study day, two CRFs must be completed, i.e., (1) a CRF providing center-related data and (2) a CRF providing patient-related data.

1. CENTER REPORT FORM

This CRF consists of two sections

Section 1: the same data as upon registration must be provided. These are general data related to the identification of the hospital and participating ICU

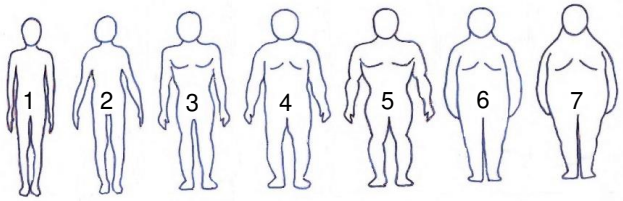
☐ Center nr.: center number provided by the coordinating center.
☐ Institution: name of the hospital
☐ Type of hospital: university/academic or non-university hospital
☐ Hospital capacity: the number of beds must be indicated
☐ ICU capacity: the number of beds must be indicated
☐ Type of ICU: the ICU is classified according to the majority (> 60 %) of regular admissions. Please indicate whether your ICU is open or closed.
☐ ICU specialty: the most appropriate choice must be marked. This should be based on the majority of admissions (> 60%). A free text can be filled in for other specialties if applicable.
☐ Number of patients treated in 2015: if exact figures are lacking, please provide a realistic estimate.

Section 2: pertains to center-related data on the study day

☐ Number of ICU beds occupied at the day of the study: provide number of beds.
☐ Number of nurses on the day of the study: provide the number of nurses per shift.
☐ Availability physiotherapist: take any time of availability during the study day into account.
☐ Participation in other study on pressure ulcers: all studies, even local or institutional, must be taken into account.
☐ Specific section in patient files: relates to any section dedicated to reporting pressure ulcers.
☐ Preventive measures that are used in the unit: use code list provided to indicate all measures used (if necessary) to prevent pressure ulcers in the unit.
☐ Measures used in all patients: from the measures reported in the above question, indicate which are always used in all patients (standard preventive measures).
☐ Risk assessment scales: check the scale(s) used in your unit. For other scales than Norton and Braden scale, please provide the scale's name.
☐ Primary trigger: check what is most appropriate (question not only pertaining to the day of study).

2. CASE REPORT FORM

- ☐ Center nr.: center number provided by the coordinating center.
- ☐ Patient nr.: provide sequential numbers from 1 to n for your center.
- ☐ Date of admission: the format day/month/year should be used.
- ☐ Sex: check the appropriate box.
- ☐ Age: patient's age (in years) at their last birthday.
- ☐ Weight: patient's weight in kilograms must be provided.
- ☐ Length: patient's length in centimetres should be provided.
- ☐ Morphological type: please refer to the figure below to choose the morphological type your patient matches best. Report the digit 1/2/3/4/5/6/7 on the case report form to indicate which of the types on the figure best corresponds with your patient's body shape.



- ☐ Type of admission: surgical is defined as surgery in the 4 weeks preceding admission. Elective surgery is defined as surgery scheduled >24 hours in advance; emergency surgery as scheduled within 24 hours of operation. Trauma is defined as ICU admissions directed related to, or as a complication of, a traumatic event in the 30 days preceding admission. Both trauma and surgical admissions could be chosen simultaneously if a trauma patient was operated on. All other admissions are considered medical. Codes for site of surgery are listed separately (up to 3 sites).
- ☐ Mechanical ventilation on admission: indicate whether the patient was on mechanical ventilation on ICU admission.
- ☐ Admission source: only one choice is possible.
- ☐ Primary diagnosis: the main reason for admission to the ICU. Only one primary diagnosis should be entered (see Codes list).
- ☐ Secondary diagnoses: defined as associated acute conditions on admission. Up to 3 secondary diagnoses are possible (see Codes list). If no relevant secondary diagnoses, please leave blank.
- ☐ Comorbidities: chronic diseases present prior to admission. More than one can be chosen according to the following definitions:
  - COPD: GOLD stage ≥ I.
  - Cirrhosis: defined as the histological development of regenerative nodules surrounded by fibrous bands in response to chronic liver injury, leading to portal hypertension and end stage liver disease.
  - Heart failure: New York Heart Association III-IV.
  - Steroid therapy: defined as immunosuppressive therapy where steroids are used to downregulate uncontrolled immune responses such as in autoimmunity or chronic inflammatory conditions
  - Malnutrition: defined as a state of nutrition in which a deficiency or excess (or imbalance) of energy, protein, and other nutrients causes measurable adverse effects on tissue/body form (body shape, size and composition) and function, and clinical outcome.
  - Cancer: solid tumour.
  - Metastatic cancer: metastases proven by surgery, computed tomography or magnetic resonance scan, or any other method.
  - Hematologic cancer: lymphoma, acute leukaemia, or multiple myeloma.
  - AIDS: HIV positive patients with clinical complications such as Pneumocystis pneumonia, Kaposi's sarcoma, lymphoma, tuberculosis, or toxoplasma infection.
  - Renal failure: defined as the need for chronic renal support or history of chronic renal insufficiency with a serum creatinine over 3.6 gm/dL (300 µmol/L).
  - Immunosuppression: administration in the 6 months prior to ICU admission of steroid treatment (at least 0.3 mg/kg/day prednisolone for at least one month), severe malnutrition, congenital immune-humoral or cellular immune deficiency state.
  - Chemotherapy: in the 6 months prior to ICU admission.
  - Insulin dependent diabetes mellitus: the need, prior to ICU admission, for insulin injections to control blood sugar levels.
  - Impaired mobility: underlying neurological or neuromuscular condition leading to impaired mobility, such as hemi-, para-, or quadriplegia or –paresis, or spasticity.
  - Peripheral vascular disease: defined as lower extremity arterial atherosclerosis.

- ☐ Study day parameters:
  - PaO2/FiO2 should be recorded simultaneously and the lowest value during the day is reported. In absence of respiratory support, use the conversion tables below to estimate the FiO2 and/or PaO2. Artefacts should be avoided (transient decrease during pneumothorax etc.).
  - Mechanical ventilation: indicate whether the patient was on mechanical ventilation on the study day.
  - Urine output: if the patient dies within the first 24 hours, the urine output should be estimated for the 24 hour period (e.g., if the patient dies after 8 hours and had 500 ml of urine during his ICU stay, the urine output would be 1.5 L).
  - Renal replacement therapy: any form of renal therapy (CVVH, CVVHD, etc.).
  - Glasgow Coma Score: report only the "assumed" Glasgow coma score. In other words, a patient who is in deep coma only because he is being treated with high doses of sedative agents should be considered to have a Glasgow coma score of 15.

Conversion tables for PaO_2 and FiO_2 estimation

Estimating PaO_2 from a given SO_2

SO_2 (%)	PaO_2 (mmHg)
80	44
81	45
82	46
83	47
84	49
85	50
86	52
87	53
88	55
89	57
90	60
91	62
92	65
93	69
94	73
95	79
96	86
97	96
98	112
99	145

FiO_2 estimation

Method	O_2 flow (l/min)	Estimated FiO2 (%)
Nasal cannula	1	24
	2	28
	3	32
	4	36
	5	40
	6	44
Nasopharyngeal catheter	4	40
	5	50
	6	60
Face mask	5	40
	6-7	50
	7-8	60
Face mask with reservoir	6	60
	7	70
	8	80
	9	90
	10	95

- ☐ Devices used: indicate all devices used on the day of the study (see Codes list).
- ☐ Pressure injury prevention measures used: indicate all prevention measures used in the patient on the day of the study (see Codes list).
- ☐ Pressure injuries: indicate any pressure injuries on the identification chart. Report pressure stage in one box and indicate whether the lesion is ICU-acquired by checking the second box (see Codes list for more information). If necessary, indicate any pressure injuries outside the arrows indicating high-risk zones. Patients with severe clinical conditions hampering safe pressure injury identification should not be evaluated for the respective risk zones. If it is known that the patient has a pressure injury at the body sites that cannot be safely evaluated, the stage of the pressure injury should be recorded as previously known. If it is unknown whether the patient has a pressure injury at these body sites, this should be indicated with a '?'.

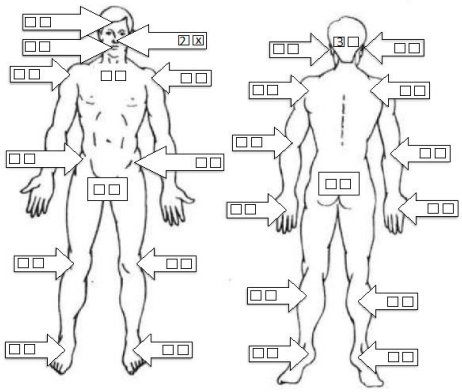


Figure – Exemplary pressure injury identification chart.
Stage 2 pressure injury at the nose; ICU-acquired as second box is checked.
Stage 3 pressure injury at the back of the head; not ICU-acquired as second box is not checked.

Pressure injury risk assessment: the risk for developing pressure ulcers is assessed by means of the six elements included in the Braden score (Bergstrom N, et al., Nurs Res 1987): sensory perception, skin moisture, activity, mobility, friction and shear. For each of the six elements, check the box that corresponds the best with the patients' condition. Find hereby a more detailed description of the boxes to check.

Sensory perception. Ability to respond meaningfully to pressure-related discomfort.

1. Completely limited. Unresponsive (does not moan, flinch, or grasp) to painful stimuli, owing to diminished level of consciousness or sedation. OR Limited ability to feel pain over most of the body.
2. Very limited. Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness. OR Has sensory impairment that limits the ability to feel pain or discomfort over half of the body.
3. Slightly limited. Responds to verbal commands but cannot always communicate discomfort or the need to be turned. OR Has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.
4. No impairment. Responds to verbal commands. Has no sensory deficit that would limit ability to feel or voice pain or discomfort.

Moisture. Degree to which skin is exposed to moisture.

1. Constantly moist. Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is turned.
2. Very moist. Skin is often, but not always, moist. Linen must be changed at least once per shift.
3. Occasionally moist. Skin is occasionally moist requiring an extra linen approximately once daily.
4. Rarely moist. Skin is usually dry. Linen requires changing only at routine intervals.

Activity. Degree of physical activity.

1. Bedfast. Confined to bed.
2. Chairfast. Ability to walk severely limited or non-existent. Cannot bear own weight and/or

must be assisted into chair or wheelchair.
3. Walks occasionally. Walks occasionally during day, but only for very short distances, with or without assistance. Spends majority of each shift in bed or chair.
4. Walks frequently. Walks outside room at least twice daily and inside room at least every 2 hours during walking hours.

Mobility. Ability to change and control body position.
1. Completely immobile. Does not make even slight changes in body or extremity position without assistance.
2. Very limited. Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.
3. Slightly limited. Makes frequent though slight changes in body or extremity position independently.
4. No limitation. Makes major and frequent changes in position without assistance.

Nutrition. Usual food intake pattern.
1. Very poor. Never eats a complete meal. Rarely eats more than half of any food offered. Eats 2 servings or lessof protein (meat or diary products) per day. Takes fluids poorly. Does not take a liquid dietary supplement. OR Has no oral intake and/or has been maintained on clear liquids or IV nutrition for more than 5 days.
2. Probably inadequate. Rarely eats a complete meal and generally eats only about half of any food offered. Protein intake includes only 3 servings per day. Occasionally will take a dietary supplement. OR Receives less than optimum amount of liquid diet or tube feeding.
3. Adequate. Eats more than half of most meals. Eats 4 servings of protein (meat or dietary products) per day. Occasionally will refuse a meal but will usually take a supplement when offered. OR Is receiving tube feeding or total parenteral nutrition that probably meets most of nutritional needs.
4. Excellent. Eats most of every meal. Never refuses a meal. Usually eats 4 or more servings of meat and dietary products. Occasionally eats between meals. Does not require supplementation.

Friction & shear.
1. Problem. Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures, or agitation leads to almost constant friction.
2. Potential problem. Moves feebly or requires minimum assistance. During a move, skin probably slides to some extent against the sheets, chair, restraints, or other devices. Maintains relatively good position in chair or bed most of the time, but occasionally slides down.
3. No apparent problem. Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair.

Outcomes: Report date of ICU discharge and hospital discharge and survival status of the patient. If the patient is still in the hospital 84 days after the study date, check the box.
After completing both CRFs on the day of study, all completed forms should be kept in a safe place in the unit in order to be available for outcome registration 84 days after the day of study [7 August 2018].

All forms should be submitted before 18 September 2018.

Appendix 4: List of codes

PRIMARY and SECONDARY DIAGNOSES

Description: The primary and maximally 3 secondary diagnoses (acute or acute on chronic disease) should be recorded for all patients as they best reflect the reason(s) for ICU admission.

100 Neurological:
- 101 Stroke by ischemic or haemorrhagic mechanism (non-traumatic)
- 102 Intracerebral hemorrhage
- 103 Subarachnoid hemorrhage
- 104 Neurologic infection
- 105 Neurologic neoplasm
- 106 Neuromuscular disease
- 107 Dementia
- 108 Seizures
- 109 Polyneuritis and polyradiculoneuritis: includes polyneuritis due to infection, inflammation, toxic, Guillain-Barré syndrome
- 110 Post-anoxic coma
- 111 Delirium tremens
- 112 Spinal cord surgery
- 113 Other

200 Respiratory:
- 201 Exacerbation of chronic pulmonary disease (either obstructive or non obstructive)
- 202 Asthma attack
- 203 Pulmonary embolism
- 204 Pleural effusion
- 205 Mechanical airway obstruction
- 206 Inhalation pneumonitis: induced by gastrointestinal contents, blood, smoke, and/or gases
- 207 Respiratory neoplasm (include larynx and trachea)
- 208 Respiratory arrest
- 209 Pulmonary edema (non-cardiogenic)
- 210 Community-acquired bacterial pneumonia
- 211 Healthcare-associated bacterial pneumonia
- 212 Viral pneumonia
- 213 Fungal pulmonary infection
- 214 Near-drowning
- 215 Other

300 Cardiovascular / vascular:
- 301 Acute myocardial infarction
- 302 Unstable angina
- 303 Cardiac arrest
- 304 Cardiopathy: includes ischemic, valvular, hypertensive, alcoholic and other, non-infectious forms
- 305 Cardiogenic shock
- 306 Congestive heart failure
- 307 Rhythm disturbance
- 308 Perivascular disease
- 309 Hypertension
- 310 Aortic aneurysm
- 311 Dissecting/ruptured aorta
- 312 Elective abdominal aneurysm repair
- 313 Peripheral vascular surgery
- 314 Valvular heart surgery
- 315 CABG
- 316 Peripheral artery bypass graft
- 317 Carotid endarterectomy
- 318 Endocarditis
- 319 Other

400 Renal/genito-urinary tract:
- 401 Acute kidney injury
- 402 Chronic renal failure
- 405 Renal neoplasia
- 406 Non-malignant gynaecological diseases, non-malignant: lesions of ovary, uterus, cervix, vulvae, vagina not due to neoplasia
- 407 Malignant gynaecological diseases
- 408 Urosepsis
- 409 Other

500 Hematological:
- 501 Transfusion reaction
- 502 Neutropenia
- 503 Neutropenic sepsis
- 504 Thrombocytopenia, coagulopathy
- 503 Non-malignant disease (e.g. anaemia, aplastic anaemia, methemoglobinemia, congenital disorders of blood coagulation factors)
- 504 Malignant disease: lymphoma, acute leukaemia and multiple myeloma
- 505 Other

600 Digestive:
- 601 Hepatic failure
- 602 Gastro-intestinal perforation/obstruction/rupture
- 603 Gastro-intestinal bleeding due to varices, ulcer or diverticulitis
- 604 Inflammatory disease (ulcerative colitis, crohn's disease)
- 605 Neoplasia of the upper digestive tract (oesophageal, gastric or duodenal)
- 606 Neoplasia of the lower digestive tract (colon and rectum)
- 607 Pancreatitis
- 608 Other

700 Metabolic:
- 701 Drug overdose, intoxication
- 702 Diabetic ketoacidosis
- 703 Metabolic coma
- 704 Endocrinopathy
- 705 Other

800 Pregnancy-related:
- 801 Eclampsia, preeclampsia
- 802 HELLP syndrome
- 803 Delivery haemorrhage
- 804 Other

900 Trauma & skin:
- 901 Head trauma (isolated)
- 903 Polytrauma, without brain trauma
- 904 Polytrauma, with brain trauma
- 905 Spinal cord injury
- 905 Burn injury
- 907 Skin lesions requiring intensive care, non-traumatic (e.g. toxic epidermal necrolysis)
- 908 Pressure ulcer requiring surgical debridement or extensive wound care
- 909 Severe surgical wound infection
- 910 Other

000 Other diseases

SITE(S) OF SURGERY

Description: For patients undergoing surgery the anatomical site of surgery should be indicated. Up to three surgery sites can be reported on the case report form. Invasive radiological procedures or definitive pacemaker insertions should not be considered as surgical procedures.

000 No surgery in the current hospital stay

100 Neurosurgery:
- 101 Cerebrovascular accident: neurosurgery of intracranial hematoma or other non-traumatic accident (haemorrhage, aneurysm)
- 102 Intracranial tumour: neurosurgery for any type of tumour primary or secondary
- 103 Spinal surgery
- 104 Ear, nose and throat surgery
- 105 Maxillo-facial surgery
- 106 Other

200 Thoracic surgery:
- 201 Pneumonectomy
- 202 Lobectomy
- 203 Pleural surgery: includes all surgery on pleura either for tumour or talcage/abrasion for pneumothorax
- 204 Lung transplantation
- 205 Other

300 Cardiac surgery:
- 301 Valvular, without coronary artery by-pass graft (CABG): surgical treatment of valvulopathies without coronary surgery
- 302 Valvular with CABG: valvular repair with coronary surgery
- 303 CABG without valvular repair
- 304 Other: pericardial effusion, congenital anomaly, ventricular aneurysm, neoplastic disease, vena cava clipping/filter
- 305 Heart transplantation
- 306 Heart & lung transplantation
- 307 Major aortic surgery: includes all surgery on aorta for dissection, atheroma, aneurysm
- 308 Carotid endarterectomy: includes all surgery on the carotid artery
- 309 Other major vascular surgery: includes all surgery on intrathoracic or intraabdominal vessels
- 310 Peripheral vascular surgery: includes all surgery on non-intracranial, non-intrathoracic, non-intraabdominal vessels, either arteries or veins with or without by-pass graft
- 311 Other

400 Renal-urinary tract:
- 401 Renal surgery
- 402 Urologic surgery

600 Digestive:
- 601 Upper gastro-intestinal surgery (up to and including the jejunum)
- 602 Lower gastro-intestinal surgery
- 603 Biliary tract: surgery of gallbladder and/or biliary tract
- 604 Liver: partial hepatectomy, portal-systemic shunt surgery
- 605 Liver transplantation
- 606 Pancreas

700 Metabolic:
- 701 Endocrine surgery (thyroid, adrenal, pancreas etc.)

800 Obstetric/gynaecologic:
- 801 Obstetric surgery: Caesarean section, surgery for ectopic pregnancy, peri- or post-partum haemorrhage, intra-uterine death
- 802 Gynaecological surgery: surgery of uterus, ovaries, cervix, genitalia

900 Trauma:
- 901 Brain: surgery for subdural, epidural, intracerebral haematoma or skull fracture
- 902 Thorax: surgery of intra-thoracic organs (cardiac, respiratory or digestive tract) and vessels
- 903 Abdomen
- 904 Limb
- 905 Multiple
- 906 Other

DEVICES

Description: For patients in which devices are used the type of device should be indicated. Report all devices used.

100 Respiratory tract:
- 101 Oral endotracheal tube
- 102 Nasal endotracheal tube
- 103 Tracheostomy with cannula
- 104 Nasal oxygen cannula
- 105 Mask for non-invasive ventilation
- 106 Oxygen mask
- 107 Other

200 Peripheral intravascular catheters:
- 201 Right hand
- 202 Left hand
- 203 Right arm
- 204 Left arm
- 205 Right foot
- 206 Left foot
- 207 Other location

300 Central venous catheters:
- 301 Internal jugular vein right
- 302 Internal jugular vein left
- 303 Subclavian vein right
- 304 Subclavian vein left
- 305 Femoral vein right
- 306 Femoral vein left
- 307 Other location

400 Arterial line:
- 401 Radial artery, right
- 402 Radial artery, left
- 403 Femoral artery, right
- 404 Femoral artery, left
- 405 Other location

500 Urinary tract catheter:
- 501 Urethral
- 502 Suprapubic
- 503 Other

600 Feeding tubes:
- 601 Orogastric
- 602 Nasogastric
- 603 Percutane Endoscopic Gastrostomy (PEG)
- 604 Duodenal / jejunal

000 Other devices

PRESSURE INJURY STAGES

Description: Pressure injury stages definitions used are published as National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Quick Reference Guide. Emily Haesler (Ed.). Cambridge Media: Osborne Park, Western Australia; 2014.
The case report form includes a figure to report pressure injury development at different body sites. Each site is marked by two selection boxes. Use these boxes next to each corresponding body site to indicate :

- the category/stage of pressure injuries (first box, codes 1/2/3/4/U/S)
- whether the injury was present upon ICU admission (check second box if ICU acquired)

Box 1: category/stage of pressure injuries (codes 1/2/3/4/U/S)

1 - Category/Stage I: Non-blanchable erythema
Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area. The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category I/Stage I may be difficult to detect in individuals with dark skin tones. May indicate “at risk” individuals (a heralding sign of risk).

2 - Category/Stage II: Partial thickness skin loss
Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising*. This Category/Stage should not be used to describe skin tears, tape burns, perineal dermatitis, maceration or excoriation. *Bruising indicates deep tissue injury.

3 – Category/Stage III: Full thickness skin loss
Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are *not* exposed. Slough may be present but does not obscure the depth of tissue loss. *May* include undermining and tunneling. The depth of a Category/Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and Category/Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Category/Stage III pressure ulcers.
Bone/tendon is not visible or directly palpable.

4 - Category/Stage IV: Full thickness tissue loss
Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling. The depth of a Category/Stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and these ulcers can be shallow. Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis possible. Exposed bone/muscle is visible or directly palpable.

U - Unstageable/ Unclassified: Full thickness skin or tissue loss –: depth unknown
Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough and/or eschar are removed to expose the base of the wound, and therefore Category/Stage cannot be determined. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as “the body’s natural (biological) cover” and should not be removed.

S - Suspected Deep Tissue Injury: depth unknown
Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.

Box 2: ulcer present upon ICU admission
Check the second box if ICU acquired.
Please refer to the instructions form for an exemplary pressure ulcer identification chart.

PREVENTIVE MEASURES
Description: All measures **used specifically in order to prevent pressure ulcers** on the study day should be reported. Measures listed which are commonly used on the ward but not specifically in order to prevent pressure ulcers should NOT be scored (e.g. use of body moisturizing products, massage).

100 Low-tech (non-powered) support surfaces
- 101 Standard foam mattresses
- 102 Alternative foam mattresses/overlays (e.g. convoluted foam, cubed foam)
- 103 Gel-filled mattresses/overlays
- 104 Fibre-filled mattresses/overlays
- 105 Air-filled mattresses/overlays
- 106 Water-filled mattresses/overlays
- 107 Bead-filled mattresses/overlays
- 108 Foam cushions
- 109 Non-foam cushions (except ring cushions)
- 110 Ring cushions
- 111 Sheepskins

200 High-tech support surfaces
- 201 Alternating-pressure mattresses/overlays: patient lies on air-filled sacs which sequentially inflate and deflate and relieve pressure at different anatomical sites for short periods; may incorporate a pressure sensor.
- 202 Air-fluidised beds: warmed air circulated through fine ceramic beads covered by a permeable sheet; allows support over a larger contact area.
- 203 Low-air-loss beds: patients are supported on a series of air sacs through which warmed air passes.
- 204 Continuous bedside pressure mapping devices indicating excessive pressures.

300 Various
- 301 Turning beds/frames: these devices work by either aiding manual repositioning of the patient, or by automatic motor-driven turning and tilting. They may have a static or an alternating support surface in conjunction with the frame.
- 302 Patient repositioning: patient is repositioned in the bed and / or chair within predefined fixed timeframes.
- 303 Ice friction
- 304 Blow-drying
- 305 Bolstering of the heels
- 306 Floating heels
- 307 Hydrating body moisturizers
- 308 Soft silicone multi-layered foam dressing

000 Other preventive measures