The very old intensive care patient:

A multinational prospective observation study

There are several studies addressing the epidemiology of the very old ICU patients, most of them however single centre studies (REF), and very seldom cross-national studies. We still have only partial knowledge about most aspects of caring for the critical ill elderly patient, even the epidemiology is mostly derived from a small number of countries throughout the world.

This has been discussed several times in the Health Service Research and Outcome (HSRO) in ESICM and this study has its origin from within this research group. April 2016 we received endorsement of this study from the Research Committee of ESICM in April 2016.

(http://www.esicm.org/research/eccrn/projects/ongoing-projects-endorsed)

Aims of the study:

• The primary aim is to document the incidence and short-term outcome of the elderly ICU patient (≥ 80 years) using a multicentre, multi national approach
• The secondary aim is to investigate the properties of a simple frailty index in this cohort, and in particular if this is an instrument that can be used in resource and outcome prediction in this group
• To create hypothesis for further studies, in particular on various outcome prediction

Methods:

We have chosen to use a prospective registration of routinely collected data in this ICU population. The study is mainly European based, but will also allow for ICUs outside Europe to participate.

20 consecutive ICU admission in patients ≥ 80 years of age will be collected OR all patients ≥ 80 years in a three months’ period (whatever comes first).

Data are collected electronically through an e-CRF and with baseline documentation of the ICU. The database is located in Denmark, at the Department of Epidemiology, University of Aarhus (http://vip1study.com/). Each ICU will only have access through the database of their own patients, and patient ID is not registered (Names, birth-date or social security numbers) so it is in that sense anonymous.

Even with de-identified data, most countries must seek necessary consent from the authorities to collect such data, and hence there will be a period between ICU recruitment (starting April 2016) and patient recruitment (October 1. 2016) to allow for this to be done prior to study start.

Our goal is to recruit at least 100 ICUs which will give data from approximately 2000 elderly patients.

Data-input

From each ICU:

• Name, type and place of the ICU
• Number of beds and number of admissions 2015
• % admissions patients ≥ 80 for 2015
• Name and e-mail of the local investigator

From each patient (see appendix 1 and 2):
• ICU-ID (not patient ID)
• Age
• Gender
• Reason for ICU admission (groups)
• Frailty index (1-9)
• SOFA score on admittance
• Non invasive ventilation
• Intubation and ventilation
• Vasoactive drugs
• Renal replacement therapy
• ICU length of stay
• Withholding therapy
• Withdrawal of therapy
• Outcome (vital status) ICU discharge
• Outcome 30 days

Statistical analysis:
Apart from ordinary descriptive statistics we will create Kaplan Meier plots of survival data, and in particular stratified on the different levels of the frailty index and SOFA score. We will also try to estimate (if possible) the impact of this specific patient population at national levels, and particularly European level.

Data security and storage
Data security in the VIP1 study follows industry standards. The data entry forms and database run on a secured server and are composed of a MySQL database and PHP web-application. Data is secured with Secure Socket Layer (SSL) encryption when transported into the database and data is stored on servers located on the campus of Aarhus University, Aarhus C, Denmark. The servers are maintained and managed in a professional server environment in co-operation between the IT Department and the Department of Clinical Medicine. The server rooms have physical access control and logging of personnel access. Other security measures include hardware and software firewalls. For technical inquiries please contact the data-manager: Jesper Fjølner, MD. email: contact@vip1study.com.

Dissemination of results:
Publication(s) in leading ICU journals (ICM, CCM, Critical Care), abstracts at leading ICU congresses as ESICM and SCCM in addition to presentation in national congresses.

Principal investigator:
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References:

## Site Identification

### ICU ID
* must provide value

You received the ICU ID in a confirmation email when you registered your ICU. If you don’t have it please use the “Forgot ICU ID” link on the website or contact contact@vip1study.com.

### Email of VIP person
* must provide value

The email used when you registered your ICU. This serves as a confirmation of your identity.

## Patient data

### Age
* must provide value

Only patients age 80 or older can be included in the study.

### Gender
* must provide value

- [ ] Male
- [ ] Female

### Reason for ICU admittance
* must provide value

### Hospital LOS prior to ICU admission
* must provide value

Days

### Frailty index
* must provide value

The Frailty index prior to admission. See figure below.

## Frailty index explanation

### Clinical Frailty Scale

<table>
<thead>
<tr>
<th>Frailty Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Fit</td>
<td>People who are robust, active, energetic and motivated.</td>
</tr>
<tr>
<td>Well</td>
<td>People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.</td>
</tr>
<tr>
<td>Managing Well</td>
<td>People whose medical problems are well controlled, but are not regularly active beyond routine walking.</td>
</tr>
<tr>
<td>Vulnerable</td>
<td>While not dependent on others for daily help, often symptoms limit activities. A common complaint is being “slowed up”, and/or being tired during the day.</td>
</tr>
<tr>
<td>Mildly Frail</td>
<td>These people often have new evident slowing, and need help in high order ADLs (dressing, transportation, heavy housework, medications). Typically, mild frailty progressively impacts shopping and walking outside alone, meal preparation and housework.</td>
</tr>
<tr>
<td>Moderately Frail</td>
<td>People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (using, standing) with dressing.</td>
</tr>
<tr>
<td>Severely Frail</td>
<td>Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within 6 months).</td>
</tr>
<tr>
<td>Very Severely Frail</td>
<td>Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.</td>
</tr>
<tr>
<td>Terminal Frail</td>
<td>Approaching the end of life. This category applies to people with a life expectancy 6 months, who are not otherwise evidently frail.</td>
</tr>
</tbody>
</table>

### Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common symptoms in mild dementia include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In moderate dementia, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In severe dementia, they cannot do personal care without help.
<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOFA score on admittance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NIV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intubation and ventilation</td>
<td></td>
<td></td>
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<tr>
<td>Vasoactive drugs</td>
<td></td>
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<tr>
<td>RRT</td>
<td></td>
<td></td>
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<tr>
<td>ICU length of stay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Withhold therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Withdraw therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcome ICU</td>
<td>Alive</td>
<td>Dead</td>
</tr>
<tr>
<td>Outcome 30 days</td>
<td>Alive</td>
<td>Dead</td>
</tr>
<tr>
<td>Enter additional data?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>