

## **Final data sets produced by the NephroQUEST project Work Package 4**

At this moment the ERA-EDTA Registry collects the following data sets:

- *RRT - Core data set (collected by all registries with individual patient data)*
  - date of birth
  - gender
  - primary renal disease
  - date of start of RRT
  - treatment modality and
  - changes in treatment modality
- *Co-morbidity data set at the start of RRT (collected by some registries)*
  - diabetes mellitus (y/n)
  - ischaemic heart disease (y/n)
  - peripheral vascular disease (y/n)
  - cerebrovascular disease (y/n)
  - congestive heart failure (y/n)
  - malignancy (y/n)

Together with experts in four clinical areas the national/regional registries and the ERA-EDTA Registry reached consensus on the collection of additional data, including:

- *Clinical Indicator - Core data set*
  - 22 variables for HD patients (including some 'composite' variables)
  - 19 variables for PD patients (including some 'composite' variables)
- *Clinical Indicator - Extended data set*
  - 19 variables for HD patients
  - 18 variables for PD patients

For NephroQUEST these clinical indicators are to be measured once a year, all on the same day. The Registry will indicate a (preferably evidence-based) preferred month, because of expected seasonal variability.

- *Centre questionnaire*

In order to disturb centres as little as possible in their routine assessments, information on units and timing of assessments is being collected on an annual basis via a separate *centre questionnaire* to be completed in the same month as the clinical indicators are collected. National/regional versions of the centre questionnaire should be discussed with each national/regional registry.

## Clinical indicators – Core Data Set

| Indicator   | Unit   | Method   | Comments  |
|---|--|--|---|
| <b>1. Patient Characteristics - Anamnesis</b>               |  |  |   |
| Smoking status  | current smoker/<br>stopped < 1 year ago/<br>stopped > 1 year ago/<br>current or ex-smoker,<br>status unknown/<br>never smoked/<br>no information |  | CONSIDER CHANGING BACK TO 3 CATEGORIES (YES/NO/EX), AS COLLECTION OF THIS VARIABLE IN 6 CATEGORIES IS CONSIDERED NOT POSSIBLE   |
| <b>2. Patient Characteristics - Physical Examination</b>    |  |  |   |
| Height  | metres with 2 decimals or centimetres <sup>1</sup>   | Measured (not anamnesis)   | If major amputation, BMI cannot be calculated.  |
| Dry body weight   | kg with one decimal  | HD: Post-dialysis <sup>2</sup><br>PD: Empty abdomen morning weight   |   |
| Major amputation  | Yes/no   | Yes, if seriously affecting BMI  |   |
| Systolic Blood Pressure                                     | mm Hg  | Predialysis and post-dialysis <sup>2</sup>   | Sitting position preferred<br>Pre = before entering the needles<br>AFTER PERIOD OF REST?<br>Post = 10 min after end of dialysis |
| Diastolic Blood Pressure                                    | mm Hg  | Predialysis and post-dialysis <sup>2</sup>   | Sitting position preferred<br>Pre = before entering the needles<br>AFTER PERIOD OF REST?<br>Post = 10 min after end of dialysis |
| <b>3. Patient Characteristics - Laboratory measurements</b> |  |  |   |
| Serum Albumin   | g/dL or g/L <sup>1</sup>   | Predialysis <sup>2</sup><br>Method to be provided: (BCP/BCG/Chromatography?/ Nephelometry (preferred) /, Electrophoresis) <sup>3</sup> | ARE THRESHOLD LEVELS NEEDED WHEN WE KNOW THE METHOD?  |
| C-Reactive Protein  | mg/L   | Predialysis <sup>2</sup><br>Method to be provided (high sensitivity/ non high sensitivity) <sup>3</sup>                                | ARE THRESHOLD LEVELS NEEDED WHEN WE KNOW THE METHOD?  |
| Total cholesterol   | mg/dl or mmol/L <sup>1</sup>   | Predialysis <sup>2</sup><br>No fasting required<br>Drawing before heparin administration preferred                                     | SOME PEOPLE FEEL COLLECTING LIPIDS FASTING AND NON-FASTING MIXED TOGETHER IS NOT USEFUL   |
| HDL cholesterol   | mg/dl or mmol/L <sup>1</sup>   | Predialysis <sup>2</sup><br>No fasting required<br>Drawing before heparin administration preferred                                     | SOME PEOPLE FEEL COLLECTING LIPIDS FASTING AND NON-FASTING MIXED TOGETHER IS NOT USEFUL   |

<sup>1</sup> unit to be provided by centre as centre characteristic;

<sup>2</sup> assessment after short interdialytic interval preferred, but timing of assessment to be provided as centre characteristic;

<sup>3</sup> method / kit / type to be provided as centre characteristic.

| Indicator                                    | Unit  | Method  | Comments  |
|--|---|---|---|
| Triglycerides                                | mg/dl or mmol/L <sup>1</sup>  | Predialysis <sup>2</sup><br>No fasting required<br>Drawing before heparin administration preferred  | <b>SOME PEOPLE FEEL COLLECTING LIPIDS FASTING AND NON-FASTING MIXED TOGETHER IS NOT USEFUL</b>  |
| Haemoglobin                                  | g/dL or mmol/L <sup>1</sup>   | Predialysis <sup>2</sup>  |   |
| Ferritin                                     | ng/mL or µg/L <sup>1</sup>  | Predialysis <sup>2</sup>  | Record date of last iron administration   |
| Calcium                                      | mg/dL or mmol/L <sup>1</sup>  | Predialysis <sup>2</sup><br>Method to be provided (total / corrected / ionised) <sup>3</sup>  |   |
| Phosphorus                                   | mg/dL or mmol/L <sup>1</sup>  | Pre-dialysis <sup>2</sup>   |   |
| Parathormone                                 | pg/mL   | Method/kit to be provided <sup>3</sup>  | <b>CAN WE SPECIFY SOME ALTERNATIVES FOR METHODS/ KITS IN THE CENTRE QUESTIONNAIRE?</b>  |
| <b>Therapy characteristics - general</b>     |   |   |   |
| Erythropoietin Stimulating Agent (ESA)       | Yes/no  | -   |   |
| <b>Therapy characteristics - HD specific</b> |   |   |   |
| Dialysis duration                            | Hours / week  | -   |   |
| Dialysis frequency                           | No of sessions / week   | -   |   |
| Urea Clearance                               | Kt/V - / week<br><b>URR - one session?</b><br>Renal urea and creatinine clearance - <b>(ml/min/1.73m<sup>2</sup>)</b> | 1. Dialysis clearance<br><i>Preferred method:</i><br>Dialysis eKt/V <sub>urea</sub> <sup>2</sup><br>needed:<br>(a) Postdialysis weight;<br>(b) ultrafiltration volume (or predialysis weight);<br>(c) pre- and post-dialysis urea; and<br>(d) dialysis duration to calculate,<br><i>Second best method:</i><br>Urea Reduction Rate <sup>2</sup> (pre- and postdialysis urea)<br><b>Both (?)</b> should use post-dialytic sampling with slow-flow method<br><br>2. Renal clearance<br>(a) urea clearance <sup>2</sup><br>(b) creatinine clearance <sup>2</sup> | - Composite values for Kt/V not accepted<br>- Ionic dialysance based values not accepted<br><br><b>GUIDELINES FOR COLLECTING URINE FOR RENAL UREA AND CREATININE CLEARANCE?</b><br><br><b>RENAL CLEARANCES AS COMPOSITE VALUES?</b><br><br><b>DO WE NEED TO ASK IF SERUM UREA IS EXPRESSED AS UREA OR AS UREA NITROGEN? - I did put it in the questionnaire</b> |
| Vascular access type                         | AV fistula / graft / catheter   |   |   |

<sup>1</sup> unit to be provided by centre as centre characteristic;

<sup>2</sup> assessment after short interdialytic interval preferred, but timing of assessment to be provided as centre characteristic;

<sup>3</sup> method / kit / type to be provided as centre characteristic.

| Indicator                                    | Unit                      | Method   | Comments  |
|--|---------------------------|--|---|
| <i>Therapy characteristics - PD specific</i> |                           |  |   |
| Urea Clearance                               | / week                    | 1. Peritoneal Kt/V <sub>urea</sub><br>and<br>2. Renal Kt/V <sub>urea</sub><br>Provide which prescription software (e.g. Baxter, Gambro and Fresenius) was used and which formula for V was used (Fresenius) <sup>3</sup> | CAN WE SPECIFY THE NAMES OF THE FORMULAS FOR V? see questionnaire |
| Creatinine clearance                         | L/week/1.73m <sup>2</sup> | 1. Peritoneal CCr<br>and<br>2. Renal CCr<br>Provide which prescription software (e.g. Baxter, Gambro and Fresenius) <sup>3</sup>   |   |

<sup>1</sup> unit to be provided by centre as centre characteristic;

<sup>2</sup> assessment after short interdialytic interval preferred, but timing of assessment to be provided as centre characteristic;

<sup>3</sup> method / kit / type to be provided as centre characteristic.

### *Clinical indicators – Extended Data Set*

| Indicator   | Units         | Methods  | Comments   |
|---|---------------|--|--|
| <b><i>Patient Characteristics - Physical Examination</i></b>    |               |  |  |
| Heart rate  | Beats per min |  | <b>To be collected with blood pressure VENTRICULAR OR PULSE RATE?</b>  |
| <b><i>Patient Characteristics - Laboratory measurements</i></b> |               |  |  |
| Serum iron  | µg/dL         | -  |  |
| Serum transferrin   | mg/dL         | -  | From this the % transferrin saturation can be calculated centrally as:<br>% transferrin sat = serum iron (µg/dL) x 70.9 divided by serum transferrin (mg/dL) |
| <b><i>Therapy characteristics - general</i></b>                 |               |  |  |
| Erythropoietin Stimulating Agent (ESA)                          |               | Type <sup>3</sup><br>Route of administration:<br>subcutaneous or intravenous<br>Dose (units/week)<br>Frequency (/week) | <b>FREQUENCY PER WEEK OR PER MONTH?</b>  |
| Iron therapy  | Yes/no        | Route of administration:<br>oral/parenteral  |  |
| Anti-hypertensive treatment                                     | Yes/no        |  | <b>TWO PEOPLE MENTIONED THAT CV DRUGS WOULD NEED TO BE CORE</b>  |
| Calcium containing phosphate binders                            | Yes/no        |  |  |
| Non-calcium containing phosphate binders                        | Yes/no        |  |  |
| Calcimimetics   | Yes/no        |  |  |
| Active Vitamin D analog   | Yes/no        |  |  |

<sup>1</sup> unit to be provided by centre as centre characteristic;

<sup>2</sup> assessment after short interdialytic interval preferred, but timing of assessment to be provided as centre characteristic;

<sup>3</sup> method / kit / type to be provided as centre characteristic.

| Indicator   | Unit             | Method | Comments  |
|---|------------------|--------|---|
| Native or 25(OH)3<br>vit D                                  | Yes/no           |        |   |
| <b><i>Intermediate Outcomes over the past 12 months</i></b> |                  |        |   |
| Diabetes mellitus<br>(newly diagnosed)                      | Yes/no           |        | Ask definition from QUEST<br>Coding and Definitions WG  |
| Ischaemic heart disease<br>(newly diagnosed)                | Yes/no           |        | Ask definition from QUEST<br>Coding and Definitions WG<br><b>Should we ask for specific<br/>event (MI)?</b>   |
| Peripheral vascular<br>disease (newly<br>diagnosed)         | Yes/no           |        | Ask definition from QUEST<br>Coding and Definitions WG  |
| Cerebrovascular<br>disease<br>(newly diagnosed)             | Yes/no           |        | Ask definition from QUEST<br>Coding and Definitions WG<br><b>Should we ask for specific<br/>event (stroke)?</b>   |
| Congestive heart<br>failure<br>(newly diagnosed)            | Yes/no           |        | Ask definition from QUEST<br>Coding and Definitions WG  |
| Malignancy<br>(newly diagnosed)                             | Yes/no           |        | Ask definition from QUEST<br>Coding and Definitions WG  |
| Parathyroidectomy   | Yes/no           |        | <b>MUCH DISCUSSION<br/>ABOUT METHOD, THREE<br/>CHOICES:<br/>1. YES/NO (EVER)<br/>2. YES/NO (EVER) PLUS<br/>RECORDING NUMBER<br/>OVER PREVIOUS YEAR<br/>3. DATE IN PREVIOUS<br/>YEAR</b> |
| <b><i>Therapy characteristics - HD specific</i></b>         |                  |        |   |
| Membrane type   | Name of dialyzer |        |   |

<sup>1</sup> unit to be provided by centre as centre characteristic;

<sup>2</sup> assessment after short interdialytic interval preferred, but timing of assessment to be provided as centre characteristic;

<sup>3</sup> method / kit / type to be provided as centre characteristic.

# Centre Questionnaire

## 1. Timing of indicator assessment in relation to interdialytic interval

- After short interdialytic interval (preferred)
- After long interdialytic interval

## 2. Units and Methods and Timing (in relation to haemodialysis)

### *Physical Examination*

#### *Height*

- Metres with 2 decimals
- Centimetres

### *Laboratory measurements*

#### *Blood drawings in haemodialysis patients presented below*

- Are all taken before haemodialysis
- Are all taken after haemodialysis
- Are mostly taken before haemodialysis, but .....is/are taken after haemodialysis
- Are mostly taken after haemodialysis, but .....is/are taken before haemodialysis

#### *Serum Albumin*

- |   |  |
|---|--|
| <input type="checkbox"/> g/dL                 | <input type="checkbox"/> BCP             |
| <input type="checkbox"/> g/L                  | <input type="checkbox"/> BCG             |
| <input type="checkbox"/> other, specify ..... | <input type="checkbox"/> Chromatography  |
|   | <input type="checkbox"/> Nephelometry    |
|   | <input type="checkbox"/> Electrophoresis |
|   | <input type="checkbox"/> Other           |

#### *C-Reactive Protein*

- |   |   |
|---|---|
| <input type="checkbox"/> mg/dL                | <input type="checkbox"/> High sensitivity     |
| <input type="checkbox"/> other, specify ..... | <input type="checkbox"/> Non high sensitivity |

#### *Total cholesterol*

- mg/dL
- mmol/L
- other, specify .....

#### *HDL cholesterol*

- mg/dL
- mmol/L
- other, specify .....

*Triglycerides*

- mg/dL
- mmol/L
- other, specify .....

*Haemoglobin*

- g/dL
- mmol/L
- other, specify .....

*Ferritin*

- ng/mL
- µg/L
- other, specify .....

*Serum Iron*

- µg/dL
- other, specify .....

*Serum transferrin*

- mg/dL
- other, specify .....

*Calcium*

- mg/dL
- mmol/L
- other, specify .....
- Total
- Corrected
- Ionised

*Phosphorus*

- mg/dL
- mmol/L
- other, specify .....

*Parathormone*

- Method: ..... **Can we specify this?**
- Kit : ..... **Can we specify this?**

*Serum urea*

- mmol/L
- other, specify .....
- expressed as urea nitrogen
- expressed as urea

***Therapy characteristics - General***

*Type of Erythropoietin Stimulating Agent (ESA) used*

- Epoetin alfa
- Darbepoetin alfa
- Epoetin beta
- Other, specify .....

***Therapy characteristics - PD specific***

*Prescription software for Peritoneal and Renal  $Kt/V_{urea}$  and Peritoneal and Renal CCr*

- ø Baxter,
- ø Gambro
- ø Fresenius                      ø using Watson's V    *can we further specify this ?*
  - ø .....
  - ø .....
  - ø .....
- ø Other, specify .....