



NephroQUEST

Work Package 4

‘Selection and standardisation of indicators for quality of RRT care’

Deliverable 4.1

‘Final list of standardised indicators approved by renal registries’

This deliverable arises from the NephroQUEST project, which has received funding from the European Union, in the framework of the Public Health Programme (projectno: 2006114)

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Introduction

At this moment, in 2007, 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 ERA-EDTA 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 will be collected on an annual basis via a separate *centre questionnaire* to be completed in the same month as the clinical indicators will be collected. This centre questionnaire is included in NephroQUEST deliverable 4.2 'Analysis of potential remaining differences'. National/regional versions of the centre questionnaire should be discussed with each national/regional registry.

Clinical indicators – Core Data Set

Indicator	Unit / Categories	Method	Comments
1. Patient Characteristics - Anamnesis			
Smoking status	current smoker/ stopped smoking/ never smoked		
2. Patient Characteristics - Physical Examination			
Height	metres with 2 decimals or centimetres ¹	Measured (not anamnesis)	If major amputation, BMI cannot be calculated.
Dry body weight	kg with one decimal	HD: Post-dialysis ² PD: Empty abdomen morning weight	
Major amputation	Yes/no	Yes, if seriously affecting BMI	
Systolic Blood Pressure	mm Hg	Predialysis and post-dialysis ²	Sitting position preferred Pre = before entering the needles After 10 min of rest Post = 10 min after end of dialysis
Diastolic Blood Pressure	mm Hg	Predialysis and post-dialysis ²	Sitting position preferred Pre = before entering the needles After 10 min of rest Post = 10 min after end of dialysis
3. Patient Characteristics - Laboratory measurements			
Serum Albumin	g/dL or g/L ¹	Predialysis ² Method to be provided: (BCP/ BCG/Chromatography/ Nephelometry (preferred) /, Electrophoresis) ³	Information on threshold levels needed.
C-Reactive Protein	mg/L	Predialysis ² Method to be provided (high sensitivity/ non high sensitivity) ³	Information on threshold levels needed.
Total cholesterol	mg/dl or mmol/L ¹	Predialysis ²	

¹ unit to be provided by centre as centre characteristic;

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

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

Indicator	Unit / Categories	Method	Comments
		No fasting required Drawing before heparin administration preferred	
HDL cholesterol	mg/dl or mmol/L ¹	Predialysis ² No fasting required Drawing before heparin administration preferred	
Triglycerides	mg/dl or mmol/L ¹	Predialysis ² No fasting required Drawing before heparin administration preferred	
Haemoglobin	g/dL or mmol/L ¹	Predialysis ²	
Ferritin	ng/mL or µg/L ¹	Predialysis ²	Record date of last iron administration
Calcium	mg/dL or mmol/L ¹	Predialysis ² Method to be provided (total / corrected / ionised) ³	
Phosphorus	mg/dL or mmol/L ¹	Pre-dialysis ²	
Parathormone	pg/mL or pmol/L ¹	Method/kit to be provided ³	
4. Therapy characteristics - general			
Erythropoietin Stimulating Agent (ESA)	Yes/no	-	
5. Therapy characteristics - HD specific			
Dialysis duration	Hours / week	-	
Dialysis frequency	No of sessions / week	-	
Urea Clearance	Kt/V / week URR (one session) Renal urea and creatinine clearance - (ml/min/1.73m ²)	1. Dialysis clearance <i>Preferred method:</i> Dialysis eKt/V _{urea} ² needed: (a) Postdialysis weight; (b) ultrafiltration volume (or predialysis weight); (c) pre- and post-dialysis urea; and (d) dialysis duration to calculate, <i>Second best method:</i> Urea Reduction Rate ² (pre- and postdialysis urea) Both should use post-dialytic sampling with slow-	- Composite values for Kt/V not accepted - Ionic dialysance based values not accepted - For guidelines on urine collection for calculation of renal urea and creatinine clearance, please see EBPG Dialysis Strategies 2007 and 2002 - mean interdialytic (2-day) clearance

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Indicator	Unit / Categories	Method	Comments
		flow method 2. Renal clearance (a) urea clearance ² (b) creatinine clearance ²	
Vascular access type	AV fistula / graft / catheter		
6. Therapy characteristics - PD specific			
Urea Clearance	/ week	1. Peritoneal Kt/V _{urea} and 2. Renal Kt/V _{urea} Provide which prescription software (e.g. Baxter, Gambro and Fresenius) was used and which formula for V was used (Fresenius) ³	
Creatinine clearance	L/week/1.73m ²	1. Peritoneal CCr and 2. Renal CCr Provide which prescription software (e.g. Baxter, Gambro and Fresenius) ³	

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Clinical indicators – Extended Data Set

Indicator	Units	Methods	Comments
<i>1. Patient Characteristics - Physical Examination</i>			
Heart rate	Beats per min		To be collected with blood pressure
<i>2. Patient Characteristics - Laboratory measurements</i>			
Serum iron	µg/dL	-	
Serum transferrin	mg/dL	-	From this the % transferrin saturation can be calculated centrally as: % transferrin sat = serum iron (µg/dL) x 70.9 divided by serum transferrin (mg/dL)
<i>3. Therapy characteristics - general</i>			
Erythropoietin Stimulating Agent (ESA)		Type ³ Route of administration: subcutaneous or intravenous Dose (units/month) Frequency (/month)	
Iron therapy	Yes/no	Route of administration: oral/parenteral	
Anti-hypertensive treatment	Yes/no		
Calcium containing phosphate binders	Yes/no		
Non-calcium containing phosphate binders	Yes/no		
Calcimimetics	Yes/no		
Active Vitamin D analog	Yes/no		
Native or 25(OH) ₃ vit D	Yes/no		

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

Indicator	Units	Methods	Comments
4. Intermediate Outcomes over the past 12 months			
Diabetes mellitus (newly diagnosed)	Yes/no		Ask definition from QUEST Coding and Definitions Working Group
Ischaemic heart disease (newly diagnosed)	Yes/no	Silent MI Non silent MI	Ask definition from QUEST Coding and Definitions Working Group
Peripheral vascular disease (newly diagnosed)	Yes/no		Ask definition from QUEST Coding and Definitions Working Group
Cerebrovascular disease (newly diagnosed)	Yes/no	Stroke Transient Ischaemic Attack (TIA)	Ask definition from QUEST Coding and Definitions Working Group
Congestive heart failure (newly diagnosed)	Yes/no		Ask definition from QUEST Coding and Definitions Working Group
Malignancy (newly diagnosed)	Yes/no		Ask definition from QUEST Coding and Definitions Working Group
Parathyroidectomy	Yes/no	- Date of first parathyroidectomy - Date of parathyroidectomy in the previous year	
5. Therapy characteristics - HD specific			
Membrane type	Name of dialyzer		

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