North American Pediatric Renal Trials Collaborative Studies **Production Release 3.0**

User:

Access Revision (ACC)

HEMODIALYSIS

Reason for hemodialysis access revisions:
1-1-Access infection
2-2-Access clotted
3-3-Access malfunction
4-4-Create more permanent access
9-9-Other

Specify other reason for hemodialysis access revision:

Indicate only one new access:

External percutaneous catheter: 1-No 2-Yes

If *Yes*, indicate:

Vein:
1-1-Subclavian
2-2-Jugular
3-3-Femoral

Lumen: 1-Single 2-Double

External arteriovenous shunt: 1-No 2-Yes

If *Yes*, indicate Location:
1-1-Upper Arm
2-2-Lower Arm
3-3-Thigh
9-9-Other

Arteriovenous fistula: 1-No 2-Yes

If *Yes*, indicate Location:
1-1-Upper Arm
2-2-Lower Arm
3-3-Thigh
9-9-Other

Arteriovenous graft: 1-No 2-Yes

If *Yes*, indicate:

Location:
1-1-Upper Arm
2-2-Lower Arm
3-3-Thigh
9-9-Other

Graft type:
1-1-Autologous vein
2-2-Bovine
3-3-PTFE [Gore-Tex®]
9-9-Other

PERITONEAL DIALYSIS

Reason for peritoneal dialysis access revision:
1-1-Exit site/tunnel infection
2-2-Dialysate leak
3-3-Catheter malfunction
4-4-Peritonitis
9-9-Other

Specify *other* reason for peritoneal access revision:

Describe new access:

Catheter:

1-1-Tenckhoff straight
2-2-Tenckhoff curled
3-3-Toronto Western
4-4-Presternal
9-9-Other

Cuffs: ☐ 1-One ☐ 2-Two

Tunnel: ☐ 1-Swan neck or curved ☐ 2-Straight

Exit site points:
1-1-Up
2-2-Down
3-3-Lateral
9-9-Unknown

Comments:

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User:

Dialysis Modality Initiation (MDI)

Has the patient had all PRIOR RENAL TRANSPLANTS removed? ☐ 1-No ☐ 2-Yes ☐ 3-Not applicable

Has the patient had all NATIVE renal tissue removed? ☐ 1-No ☐ 2-Yes

Dialysis Data

Dialysis modality of this initiation: 1-1-Peritoneal dialysis / 2-2-Hemodialysis

Provide number of **consecutive** days of hospitalization from initiation of dialysis treatment until discharge: ____ *(xxx)*

Check to unlock and change unit of measurement: ☐

	CU	SI	Units
Serum creatinine at initiation:	____ *(xx.x)*	____ *(xxxx.x)*	☐ mg/dL ☐ µmol/L

Access Used For Maintenance Dialysis at Registration

Hemodialysis - *Indicate only ONE Access*

External percutaneous catheter: ☐ 1-No ☐ 2-Yes

If *Yes*, indicate:

Vein: 1-1-Subclavian / 2-2-Jugular / 3-3-Femoral

Lumen: ☐ 1-Single ☐ 2-Double

External arteriovenous shunt: ☐ 1-No ☐ 2-Yes

If *Yes*, indicate Location: 1-1-Upper Arm / 2-2-Lower Arm / 3-3-Thigh / 9-9-Other

Arteriovenous fistula: ☐ 1-No ☐ 2-Yes

If *Yes*, indicate Location: 1-1-Upper Arm / 2-2-Lower Arm / 3-3-Thigh / 9-9-Other

Arteriovenous graft: ☐ 1-No ☐ 2-Yes

If *Yes*, indicate:

Location: 1-1-Upper Arm / 2-2-Lower Arm / 3-3-Thigh / 9-9-Other

Specify graft type: 1-1-Autologous vein / 2-2-Bovine / 3-3-PTFE [Gore-Tex®] / 9-9-Other

Peritoneal Dialysis:

Catheter:

1-1-Tenckhoff straight
2-2-Tenckhoff curled
3-3-Toronto Western
4-4-Presternal
9-9-Other

Cuffs: ☐ 1-One ☐ 2-Two

Tunnel: ☐ 1-Swan neck or curved ☐ 2-Straight

Exit site points:

1-1-Up
2-2-Down
3-3-Lateral
9-9-Unknown

Comments:

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User:

Dialysis Modality Termination (MDL)

Date of dialysis modality termination: ______ *(mm/dd/yyyy)*

Reason to close this dialysis segment:

1-1-Patient was transplanted (Submit Transplantation Report Form)
2-2-Patient was switched to another dialysis regimen (Submit Dialysis Initiation Form)
3-3-Patient died (Submit Death Form)
4-4-Native kidney function returned
8-8-Administrative Closure
*Additional Options Listed Below

If surviving patient was NOT transplanted, specify reason for termination:

1-1-Excessive infection
2-2-Patient/family choice; inability to cope
3-3-Access failure
4-4-Inadequate ultrafiltration
5-5-Inadequate solute clearance
*Additional Options Listed Below

Comments:

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User:

Dialysis Status (DIA)

Date of evaluation: (mm/dd/yyyy)

Dry weight: (xxx.x) kg

Height: (xxx.x) cm

Blood pressure: / (xxx) mmHg

Check to unlock and change unit of measurement:

	CU		SI		Units	
Hematocrit:		(xx.x)		(.xxx)	%	VF
Hemoglobin:		(xx.x)		(xxx)	g/dL	g/L
Albumin:		(xx.x)		(xx.x)	g/dL	g/L
Inorganic phosphorus:		(xx.x)		(x.xx)	mg/dL	mmol/L
Calcium:		(xx.x)		(x.xx)	mg/dL	mmol/L

Most recent parathyroid hormone:
1-1-Less than 2x upper normal limit
2-2-Greater than 2x upper normal limit
9-9-Unknown

Tanner stage:

Pubic hair: 1-1 2-2 3-3 4-4 5-5 *Additional Options Listed Below

Breast: 1-1 2-2 3-3 4-4 5-5 *Additional Options Listed Below

Testicular size: 1-1-Pre-puberty (<=3 cc) 2-2-Early-puberty (>3-6 cc) 3-3-Mid-puberty (>6-10 cc) 4-4-Late puberty (>10-15 cc) 5-5-Adult (>15 cc) *Additional Options Listed Below

Are anthropometric measures available? 1-No 2-Yes

If *Yes*, indicate:

Mid arm circumference: (xx.x) cm

Tricep skin fold thickness: (xx.x) mm

Dialysis Modality Information

Type of dialysis:
1-1-Peritoneal dialysis
2-2-Hemodialysis

If **HEMODIALYSIS**, indicate:

Number of dialysis treatments per week: (x)

Hours/treatment: (x.x)

Is the patient receiving home hemodialysis? 1-No 2-Yes

Most recent single pool Kt/V: (x.x)

URR: (xx) %

If **PERITONEAL DIALYSIS**, indicate:

Current modality:
1-1-CAPD
2-2-APD
3-3-IPD

Most recent weekly Kt/V:

(x.x)

Medication Information

Is the patient receiving erythropoietin? ☐ 1-No ☐ 2-Yes

If *Yes* , indicate:

Type:
1-1-Epogen®
2-2-Procrit®
3-3-Aranesp®
9-9-Other

Route:
1-1-Subcutaneous
2-2-Intraperitoneal
3-3-Intravenous

Frequency:
1-1-Daily
2-2-Three times/week
3-3-Two times/week
4-4-Weekly
5-5-> Weekly

Dose: (xxxxx.xx)

Is the patient receiving human growth hormone? ☐ 1-No ☐ 2-Yes

If *Yes* , indicate:

Type:
1-1-Nutropin®
2-2-Protropin®
3-3-Humatrope®
4-4-Nutropin Depot®
9-9-Other

Route:
1-1-Subcutaneous
2-2-Intraperitoneal

Frequency:
1-1-Daily
2-2-Every other day
3-3-Three times/week
4-4-Six times/week
5-5-Weekly
*Additional Options Listed Below

Dose: (xx.xx)

Concomitant Drug Therapy

Sevelamer hydrochloride	☐ 1-No	☐ 2-Yes	
Anticonvulsant	☐ 1-No	☐ 2-Yes	
Anti -hypertensives	☐ 1-No	☐ 2-Yes	If *Yes*, number of drugs: (x)
Calcium acetate	☐ 1-No	☐ 2-Yes	
Calcium carbonate	☐ 1-No	☐ 2-Yes	
Other calcium supplements	☐ 1-No	☐ 2-Yes	
Immunosuppressives	☐ 1-No	☐ 2-Yes	
Iron - oral	☐ 1-No	☐ 2-Yes	
Iron - IV	☐ 1-No	☐ 2-Yes	
Nutrition - enteral	☐ 1-No	☐ 2-Yes	
Nutrition - parenteral	☐ 1-No	☐ 2-Yes	
Prophylactic antibiotics	☐ 1-No	☐ 2-Yes	
1,25-dihydroxy Vitamin D - oral	☐ 1-No	☐ 2-Yes	

1,25-dihydroxy Vitamin D - IV ☐ 1-No ☐ 2-Yes

Other Vitamin D compounds ☐ 1-No ☐ 2-Yes

Lipid lowering agents ☐ 1-No ☐ 2-Yes

Events Information

Has the patient had seizures since the last report? ☐ 1-No ☐ 2-Yes ☐ 9-Unknown

Has the patient had blood transfusions since the last report? ☐ 1-No ☐ 2-Yes ☐ 9-Unknown

If *Yes*, how many episodes? ____ *(x)*

Number of peritonitis episodes since the last report: ____ *(x)*

PERITONITIS episodes - Indicate type and date of infection onset

		Date of Onset	Cell Count		Cell Differential (%)		
Episode	Type	*(mm/dd/yyyy)*	(WBC/mm^3)	Segmented Neutrophils	Lymphocytes	Monocytes/ Histiocytes	Eosinophils
1	1-1-Fungal 2-2-Gram-positive 3-3-Gram-negative 4-4-Gram-positive and negative 6-6-Cultured, no growth *Additional Options Listed Below						
2	1-1-Fungal 2-2-Gram-positive 3-3-Gram-negative 4-4-Gram-positive and negative 6-6-Cultured, no growth *Additional Options Listed Below						
3	1-1-Fungal 2-2-Gram-positive 3-3-Gram-negative 4-4-Gram-positive and negative 6-6-Cultured, no growth *Additional Options Listed Below						
4	1-1-Fungal 2-2-Gram-positive 3-3-Gram-negative 4-4-Gram-positive and negative 6-6-Cultured, no growth *Additional Options Listed Below						
5	1-1-Fungal 2-2-Gram-positive 3-3-Gram-negative 4-4-Gram-positive and negative 6-6-Cultured, no growth *Additional Options Listed Below						
6	1-1-Fungal 2-2-Gram-positive 3-3-Gram-negative 4-4-Gram-positive and negative 6-6-Cultured, no growth *Additional Options Listed Below						

Has the patient had an access site infection since the last report? ☐ 1-No ☐ 2-Yes

Hospitalization Information

Total days hospitalized since the last report: ____ *(xxx)* Days

If hospitalized since last report, indicate reason(s):

Infection:	☐ 1-No ☐ 2-Yes
Access complications/catheter malfunction:	☐ 1-No ☐ 2-Yes
Hypertension:	☐ 1-No ☐ 2-Yes
Other cardiovascular:	☐ 1-No ☐ 2-Yes
Dialysis initiation:	☐ 1-No ☐ 2-Yes

Education Information

Has the patient completed high school education? ☐ 1-No ☐ 2-Yes

If *No*, indicate one of the following:

1-1-Attends school full time
2-2-Attends school part-time
3-3-Receives home schooling only
4-4-Not attending school, medically capable
5-5-Not attending school, medically incapable
*Additional Options Listed Below

Transplant Status

Indicate the current transplant status:

1-1-On cadaver waiting list
2-2-Not on list, transplant preparation/workup in progress
3-3-Not on list, medical reason
4-4-Not on list, family/patient preference

If **On cadaver waiting list**, date listed: ________ *(mm/dd/yyyy)*

Most recent PRA sensitization: ________ *(xxx)* %

Comments:

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User:

Lost to Follow Up (LTF)

Date lost to follow up: (mm/dd/yyyy)

Reason for loss:
1-1-Patient moved to nonparticpating center
2-2-Unable to locate patient
3-3-Patient refused further follow up
4-4-Parent refused further follow up
5-5-Patient transferred to adult program
*Additional Options Listed Below

If *Other*, specify:

Graft status at loss:
1-1-Functioning
2-2-Non-functioning
3-3-Not applicable

Comments:

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User:

Patient Death (DTH)

Date of death: (mm/dd/yyyy)

Cause of death:
01-01-Infection, viral
02-02-Infection, bacterial
03-03-Infection, not specified
04-04-Cancer/malignancy
05-05-Cardiopulmonary
*Additional Options Listed Below

If *other*, specify cause of death:

Graft status at death:
1-1-Functioning
2-2-Non-functioning
3-3-Not applicable

Comments:

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User:

Targeted Adverse Event (ADV)

If **malignancy**, please specify diagnosis: [ ]

If **avascular necrosis** or **slipped capital femoral epiphyses**, record the following:

Onset: ☐ 1-Initial ☐ 2-Recurring

X-ray confirmation: ☐ 1-No ☐ 2-Yes

Bone scan confirmation: ☐ 1-No ☐ 2-Yes

If **intracranial hypertension**, record the following:

Opening CSF pressure: [ ] *(xxx)* mmH2O

Headache: ☐ 1-No ☐ 2-Yes

Papilledema: ☐ 1-No ☐ 2-Yes

Nausea & vomiting: ☐ 1-No ☐ 2-Yes

Visual changes: ☐ 1-No ☐ 2-Yes

If **Serious adverse event**, please specify: [ ]

If **Other adverse event**, please specify: [ ]

Intensity:
1-1-Mild
2-2-Moderate
3-3-Severe
4-4-Life-threatening

Outcome:
1-1-Severe or permanent disability
2-2-Death
3-3-Neither

Treatment required? ☐ 1-No ☐ 2-Yes

Hospitalization: ☐ 1-No ☐ 2-Yes

Medication: ☐ 1-No ☐ 2-Yes

Surgery: ☐ 1-No ☐ 2-Yes

Other treatment: ☐ 1-No ☐ 2-Yes

If *Other treatment*, specify: [ ]

Was patient receiving growth hormone at the time of adverse event? ☐ 1-No ☐ 2-Yes

If receiving growth hormone, record the following:

Type:
1-1-Nutropin®
2-2-Protropin®
3-3-Humatrope®
4-4-Nutropin Depot®
9-9-Other

Route
1-1-Subcutaneous
2-2-Intraperitoneal

Frequency:
1-1-Daily
2-2-Every other day
3-3-Three times/week
4-4-Six times/week
5-5-Weekly
*Additional Options Listed Below

Dose: [ ] *(x.xx)* mg/dose

Dosage of growth hormone was:

1-1-Unchanged
2-2-Reduced
3-3-Held
4-4-Discontinued

If dose changed, provide date: (mm/dd/yyyy)

Did the adverse event abate? 1-No 2-Yes If *Yes*, record date: (mm/dd/yyyy)

Was growth hormone reintroduced? 1-No 2-Yes

If *Yes*, did the adverse event recur? 1-No 2-Yes If *Yes*, when? (mm/dd/yyyy)

Relationship to growth hormone:

1-1-Not related- never received
2-2-Not related
3-3-Possible
4-4-Probable

Comments:

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User:

Malignancy Form (MAL)

Type of malignancy: 1-1-Hematologic/Lymphoietic / 2-2-Solid tumor / 3-3-Skin (non-melanoma) / 9-9-Other, specify

If "Other", specify: ______

If "Hematologic/Lymphoietic", please complete the form.

Height at diagnosis of PTLD: ______ *(xxx.x)* cms

Weight at diagnosis of PTLD: ______ *(xxx.x)* kg

Type of PTLD: 1-1-Polymorphic / 2-2-Monomorphic / 9-9-Unknown

Clonality: 1-1-Polyclonal / 2-2-Monoclonal / 9-9-Unknown

Cell type: ☐ 1-T-Cell ☐ 2-B-Cell ☐ 9-Other, specify

If "Other", specify: ______

Location of PTLD:

Allograft ☐ 1-No ☐ 2-Yes

Lymph node ☐ 1-No ☐ 2-Yes

Central nervous system ☐ 1-No ☐ 2-Yes

Other ☐ 1-No ☐ 2-Yes

If "Other", specify ______

Pre-transplant EBV serology:

Donor: ☐ 1-Positive ☐ 2-Negative ☐ 9-Unknown/Not done

Recipient: ☐ 1-Positive ☐ 2-Negative ☐ 9-Unknown/Not done

Serum creatinine at diagnosis of PTLD: ______ *(xx.x)* mg/dl ______ *(xxxx.x)* µmol/L

Last prior serum creatinine value (3 months before diagnosis): ______ *(xx.x)* mg/dl ______ *(xxxx.x)* µmol/L

Date of last prior serum creatinine value: ______ *(mm/dd/yyyy)*

Intervention Data

Reduction of Immunosuppression: ☐ 1-No ☐ 2-Yes

If "Yes", specify type(s) of reduction: ______

Anti-CD20 antibody use: ☐ 1-No ☐ 2-Yes

If "Yes", number of doses: ______ *(xxx)*

Total dose administered: ______ *(xxxx.xx)* mg

Alpha interferon use: ☐ 1-No ☐ 2-Yes

If "Yes", number of doses: ______ *(xxx)*

Total dose administered: ______ *(xxxx.xx)* mg

Chemotherapy used: ☐ 1-No ☐ 2-Yes

If "Yes", regimen used: ______

If "Yes", number of cycles: ______ *(xxx)*

If "Yes", duration of therapy in months: ______ *(xxx)*

Anti-viral therapy use: ☐ 1-No ☐ 2-Yes

If "Yes", agent used: ______

Dose administered: ______ *(xxxx.xx)* mg/day

Duration of therapy: ______ *(xxx)*

Surgical reduction of mass: ☐ 1-No ☐ 2-Yes

If "Yes", allograft nephrectomy: ☐ 1-No ☐ 2-Yes

Concomitant rejection treatment: ☐ 1-No ☐ 2-Yes

If "Yes", agent used: ______

Outcome Data

Viral load by PCR: ☐ 1-No ☐ 2-Yes

If "Yes", value at diagnosis: ______ *(xxxxxxxxxx.x)* Units ______

If "Yes", value at 1 month after diagnosis: ______ *(xxxxxxxxxx.x)*

If "Yes", value at time of increase in immunosuppression: ______ *(xxxxxxxxxx.x)*

Serum creatinine after treatment: ______ *(xx.x)* mg/dl ______ *(xxxx.x)* µmol/L

Date of serum creatinine after treatment: ______ *(mm/dd/yyyy)*

Graft loss: ☐ 1-No ☐ 2-Yes

If "Yes", date: ______ *(mm/dd/yyyy)*

Date immunosuppression increased again: ______ *(mm/dd/yyyy)*

Immunosuppression after PTLD resolution: ☐ 1-No ☐ 2-Yes

Agent	Dose (mg)
Prednisone	*(xx.x)*
Cyclosporine	*(xxx.x)*
Tacrolimus	*(xxx.x)*
Sirolimus	*(xx.x)*
Mycophenolate mofetil	*(xxxx.x)*
Azathioprine	*(xxx.x)*

Retransplant after PTLD: ☐ 1-No ☐ 2-Yes

If "Yes", date of retransplant: ______ *(mm/dd/yyyy)*

Recurrence of PTLD in retransplant: ☐ 1-No ☐ 2-Yes

If "Yes", date of recurrence: ______ *(mm/dd/yyyy)*

Comments: ______

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User:

DIALYA (ENR)

If you want to enroll the participant in to the Dialysis Registry, enter the Date of Dialysis Initiation: ______ *(mm/dd/yyyy)*

Date of 30 day followup evaluation: ______ *(mm/dd/yyyy)*

Patients must have a 30 day evaluation to be considered eligible for the Dialysis Registry.

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User:

Registration (DEM)

Date of birth: (mm/dd/yyyy)

Race/ethnicity:
1-1-White
2-2-Black
3-3-Hispanic
9-9-Other

Gender: ☐ 1-Male ☐ 2-Female

Primary renal diagnosis:
01-01-Aplastic/hypoplastic/dysplastic kidneys
02-02-Obstructive uropathy
03-03-Syndrome of agenesis of abdominal musculature (Prune Belly)
04-04-Polycystic kidney disease
05-05-Medullary cystic disease/juvenile nephronophthisis
*Additional Options Listed Below

If *Other*, specify diagnosis:

Biopsy or nephrectomy confirmation of diagnosis: ☐ 1-No ☐ 2-Yes ☐ 9-Unknown

Education Score:

Maternal:
0-0-No formal education
1-1-Grade 6 or less
2-2-Grades 7-9
3-3-Grades 10 or more without diploma
4-4-Grade 12 (High school graduate)
*Additional Options Listed Below

Paternal:
0-0-No formal education
1-1-Grade 6 or less
2-2-Grades 7-9
3-3-Grades 10 or more without diploma
4-4-Grade 12 (High school graduate)
*Additional Options Listed Below

Insurance Information:

Does patient have Medicaid? ☐ 1-No ☐ 2-Yes ☐ 9-Unknown

Does patient have supplemental private insurance? ☐ 1-No ☐ 2-Yes ☐ 9-Unknown

Has patient been transplanted prior to registration: ☐ 1-No ☐ 2-Yes

Total number of prior transplants: (x)

Has patient ever received maintenance dialysis?
1-1-No
2-2-Yes, hemodialysis
3-3-Yes, peritoneal dialysis
4-4-Yes, both

If Yes, specify date of first maintenance dialysis: (xx) Month/ (xxxx) Year

ABO (record for Transplant and Dialysis participants): ☐ 1-A ☐ 2-B ☐ 3-O ☐ 4-AB

Histocompatibility data of recipient

Record for transplant participants:

HLA-A A (xx) A (xx)

HLA-B B (xx) B (xx)

If assay performed but an allele was not determined, enter '99'

HLA-DR DR (xx) DR (xx)