

North American Pediatric Renal Trials Collaborative Studies

Production Release 3.0

User:

Acute Rejection (REJ)

Allograft biopsy performed?

1-1-No
 2-2-Yes, fine needle aspiration
 3-3-Yes, tissue

Weight:

(xxx.x) kg

IMMUNOSUPPRESSIVE TREATMENT-Supplemental to Maintenance

Include only doses over and above specified maintenance medications.

| Medication | Initial Daily Dose (mg/D) | Duration in days of anti-rejection therapy | Formulation or Mode |
|-------------------------|---------------------------|--|---|
| Prednisone | <input type="text"/> | <input type="text"/> | 1-1-Pulse 2-2-Tapered 3-3-Pulse + tapered |
| Methylprednisolone-oral | <input type="text"/> | <input type="text"/> | 1-1-Pulse 2-2-Tapered 3-3-Pulse + tapered |
| Methylprednisolone-IV | <input type="text"/> | <input type="text"/> | 1-1-Pulse 2-2-Tapered 3-3-Pulse + tapered |
| Cyclosporine | <input type="text"/> | <input type="text"/> | 1-1-Sandimmune 2-2-Neoral 3-3-Study 4-4-Generic 9-9-Other |
| Tacrolimus | <input type="text"/> | <input type="text"/> | |
| Azathioprine | <input type="text"/> | <input type="text"/> | |
| Mycophenolate mofetil | <input type="text"/> | <input type="text"/> | |
| ATG/ALG | <input type="text"/> | <input type="text"/> | |
| Sirolimus | <input type="text"/> | <input type="text"/> | |
| Monoclonal antibody | <input type="text"/> | <input type="text"/> | 1-1-OKT3 2-2-Basiliximab 3-3-Daclizumab 8-8-Other 9-9-Unknown |

Calcineurin trough level:

(xxxx.x)

Calcineurin assay:

1-1-HPLC
 2-2-TDx
 3-3-Polyclonal RIA
 4-4-Monoclonal RIA-specific
 5-5-Monoclonal RIA-nonspecific
 *Additional Options Listed Below

Sirolimus trough level:

 (xxxx.x)

Sirolimus assay:

1-1-HPLC
2-2-Liquid chrom/Mass spect.
3-3-Immuno assay
9-9-Other

Were other non-maintenance immunosuppressive treatments applied?

1-No 2-Yes

Specify other immunosuppressive medication:

Was patient receiving growth hormone at the time of acute rejection?

1-No 2-Yes

Outcome of this acute rejection:

1-1-Complete reversal of rejection
2-2-Partial reversal of rejection
3-3-Graft failure
4-4-Patient death

Submit a Graft Failure or Death form if outcome resulted in graft failure or death.

Check to unlock and change unit of measurement:

CU

SI

Units

Serum creatinine:

(xx.x)

(xxxx.x)

mg/dL μmol/L

Was dialysis used during anti-rejection therapy?

1-No 2-Yes

Comments:

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User:

Graft Failure (GRA)

Graft failure date: (mm/dd/yyyy)

Date of graft failure was determined by:
1-1-Patient returning to regular course of maintenance dialysis
2-2-Patient receiving an additional transplant
9-9-Other, specify

If *other*, specify:

Submit a **Dialysis Initiation** form for patients returning to maintenance dialysis. Submit a **Transplant Report** form for patients who were retransplanted.

Cause of graft failure:
01-01-Primary non-function
02-02-Vascular thrombosis
03-03-Other technical
04-04-Hyperacute rejection (< 24 hours after transplant)
05-05-Accelerated acute rejection (2-7 days after transplant)
*Additional Options Listed Below

If *other*, specify reason for graft failure:

Tissue confirmation of cause:
1-1-No
2-2-Yes
9-9-Unknown

Was failure to comply with maintenance therapy considered to be a contributing cause?
 1-No 2-Yes

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 nonparticipating 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:

[Text input field]

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: [Text input field] (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:

[Text input field]

If Other adverse event, please specify:

[Text input field]

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:

[Text input field]

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-Humatrop®
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:

[Text input field] (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:

Transplantation Report (TRA)

Weight: [] (xxx.x) kg

Height: [] (xxx.x) cm

Was patient on maintenance dialysis immediately prior to this transplant?
1-1-No
2-2-Yes, hemodialysis
3-3-Yes, peritoneal dialysis
4-4-Yes, both

Duration of maintenance dialysis: [] (xx) Years + [] (xx) Months

Has patient had a SPLENECTOMY? [] 1-No [] 2-Yes

Has patient had all NATIVE renal tissue removed? [] 1-No [] 2-Yes

Has patient had all PRIOR transplants removed? [] 1-No [] 2-Yes [] 3-Not applicable

Donor source:
1-1-Live donor/parent
2-2-Live donor/sibling
3-3-Live donor/other related
4-4-Live donor/unrelated
5-5-Cadaver

Donor age: [] (xx)

Donor sex: [] 1-Male [] 2-Female

HISTOCOMPATIBILITY DATA OF DONOR

HLA-A: A [] (xx) A [] (xx)

HLA-B: B [] (xx) B [] (xx)

HLA-DR: DR [] (xx) DR [] (xx)

ABO: [] 1-A [] 2-B [] 3-O [] 4-AB

IF DONOR SOURCE IS CADAVER, ANSWER THE FOLLOWING:

Method of allograft preservation
Machine perfusion
1-1-No
2-2-Yes
9-9-Unknown

Iced electrolyte
1-1-No
2-2-Yes, Collins
3-3-Yes, Wisconsin
4-4-Yes, Unknown
9-9-Unknown

Total cold time [] (xxx) Hours + [] (xx) Minutes

PRE-TRANSPLANT BLOOD TRANSFUSION DATA FOR THIS TRANSPLANT

Was donor specific transfusion performed?
1-1-No
2-2-Yes, with immunosuppressive coverage
3-3-Yes, without immunosuppressive coverage

Specify life-time TOTAL NUMBER of RANDOM TRANSFUSIONS given:
0-0-Zero
1-1-One to five
2-2-More than five

Was immunosuppressive therapy used in the preoperative period (i.e., one week to 24 hours pretransplant)? 1-No 2-Yes

POST-TRANSPLANTATION (30 DAYS) MAINTENANCE MEDICATION DATA

| Medication | Day Post Op Initiated | Dose | # of Days | Formulation | Day 30 Dose |
|-----------------------|-----------------------|----------------------|----------------------|--|----------------------|
| Prednisone | <input type="text"/> | <input type="text"/> | | | <input type="text"/> |
| Methylprednisolone | <input type="text"/> | <input type="text"/> | | | |
| Cyclosporine | <input type="text"/> | <input type="text"/> | | <input type="text"/> 1-1-Sandimmune <input type="text"/> 2-2-Neoral <input type="text"/> 3-3-Study <input type="text"/> 4-4-Generic <input type="text"/> 9-9-Other | <input type="text"/> |
| Tacrolimus | <input type="text"/> | <input type="text"/> | | | <input type="text"/> |
| Azathioprine | <input type="text"/> | <input type="text"/> | | | <input type="text"/> |
| Mycophenolate mofetil | <input type="text"/> | <input type="text"/> | | | <input type="text"/> |
| ATG/ALG | <input type="text"/> | <input type="text"/> | <input type="text"/> | | |
| Sirolimus | <input type="text"/> | <input type="text"/> | | | <input type="text"/> |
| Monoclonal Ab | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> 1-1-OKT3 <input type="text"/> 2-2-Basiliximab <input type="text"/> 3-3-Daclizumab <input type="text"/> 8-8-Other <input type="text"/> 9-9-Unknown | |

Were other immunosuppressive agents given? 1-No 2-Yes

If Yes, specify:

Days of hospitalization during post transplant month:

 (xx) maximum of 31 days

Consecutive hospitalization days from transplantation to discharge:

 (xxx)

CONCOMITANT DRUG THERAPY

Anticonvulsant:

 1-No 2-Yes

Anti-hypertensive:

 1-No 2-Yes

Antibiotics:

 1-No 2-Yes (excluding perioperative)

Check to unlock and change unit of measurement:

CU SI

Units

Serum creatinine: (xx.x) (xxxx.x)

 mg/dL µmol/L

Day 30 Calcineurin blood level (Cyclosporine or Tacrolimus):

 (xxxx.x) Assay:

1-1-HPLC
 2-2-TDx
 3-3-Polyclonal RIA
 4-4-Monoclonal RIA-specific
 5-5-Monoclonal RIA-nonspecific
 *Additional Options Listed Below

Day 30 Sirolimus blood level:

 (xxxx.x) Assay:

1-1-HPLC
 2-2-Liquid chrom/Mass spect.
 3-3-Immuno assay
 9-9-Other

POST TRANSPLANT DIALYSIS USE

Week 1:

 1-No 2-Yes

Week 2:

 1-No 2-Yes

Week 3-4:

1-No 2-Yes

Was patient treated for acute rejection during the first 30 days after transplantation?

1-No 2-Yes

If Yes, submit ACUTE REJECTION form.

Did graft failure (permanent return to dialysis) occur during the first 30 days after transplantation?

1-No 2-Yes

If Yes, submit GRAFT FAILURE form.

Comments:

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User:

Transplantation Status (STA)

Graft status:

1-1-Functioning
2-2-Non-functioning

Height:

(xxx.x) cm

Weight:

(xxx.x) kg

Date height obtained:

(mm/dd/yyyy)

Tanner stage:

Pubic

- 1-1
- 2-2
- 3-3
- 4-4
- 5-5

hair: *Additional Options Listed Below

1-1
2-2
3-3
4-4
5-5

Breast: *Additional Options Listed Below

Testicular

- 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)

size: *Additional Options Listed Below

Check to unlock and change unit of measurement.

CU

SI

Units

Serum creatinine:

(xx.x)

(xxxx.x)

mg/dL μmol/L

Creatinine date:

(mm/dd/yyyy)

Number of acute rejection episodes since last report:

(x)

Document each acute rejection episode on an **Acute Rejection** form.

Number of episodes of acute cyclosporine nephrotoxicity:

(x)

IMMUNOSUPPRESSIVE TREATMENT (Maintenance Only)

| Medication | Daily Maintenance Dose as of Report Date | Alternate Day Schedule | Formulation |
|-----------------------|--|------------------------|---|
| Prednisone | | 1-1-No 2-2-Yes | |
| Cyclosporine | | | 1-1-Sandimmune 2-2-Neoral 3-3-Study 4-4-Generic 9-9-Other |
| Tacrolimus | | | |
| Azathioprine | | | |
| Mycophenolate mofetil | | | |
| Sirolimus | | | |

Calcineurin trough level:

- 1-1-HPLC
- 2-2-TDx
- 3-3-Polyclonal RIA
- 4-4-Monoclonal RIA-specific
- 5-5-Monoclonal RIA-nonspecific
- *Additional Options Listed Below

- 1-1-HPLC
- 2-2-Liquid chrom/Mass spect.
- 3-3-Immuno assay
- 9-9-Other

Sirolimus trough level:

 (xxxx.x) Assay:

Were other immunosuppressive agents given?

 (xxxx.x) Assay:

- 1-No 2-Yes

If Yes, specify:

CONCOMITANT DRUG THERAPY

Anticonvulsant:

- 1-No 2-Yes

Anti-hypertensive:

- 1-No 2-Yes

Antibiotics:

- 1-No 2-Yes

Growth hormone:

- 1-No 2-Yes

Total number of days hospitalized this period:

 (xxx)

Was patient hospitalized for the following:

Bacterial infection:

- 1-No 2-Yes

Viral infection:

- 1-No 2-Yes

Rejection:

- 1-No 2-Yes

Fungal/protozoal infection:

- 1-No 2-Yes

Hypertension:

- 1-No 2-Yes

Was a malignancy diagnosed during this report period?

- 1-No 2-Yes

If Yes, submit a **Targeted Adverse Event** form.

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:

[Text input field]

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

Height at diagnosis of PTLT:

[Text input] (xxx.x) cms

Weight at diagnosis of PTLT:

[Text input] (xxx.x) kg

Type of PTLT:

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:

[Text input field]

Location of PTLT:

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

[Text input field]

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 PTLT:

[Text input] (xx.x) mg/dl [Text input] (xxx.x) µmol/L

Last prior serum creatinine value (3 months before diagnosis):

[Text input] (xx.x) mg/dl [Text input] (xxx.x) µmol/L

Date of last prior serum creatinine value:

[Text input] (mm/dd/yyyy)

Intervention Data

Reduction of Immunosuppression:

1-No 2-Yes

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

[Text input field]

Anti-CD20 antibody use:

1-No 2-Yes

If "Yes", number of doses:

[Text input] (xxx)

Total dose administered:

[Text input] (xxx.xx) mg

Alpha interferon use:

1-No 2-Yes

If "Yes", number of doses:

[Text input] (xxx)

Total dose administered:

[Text input] (xxx.xx) mg

Chemotherapy used:

1-No 2-Yes

If "Yes", regimen used:

[Text input field]

If "Yes", number of cycles:

[Text input] (xxx)

If "Yes", duration of therapy in months:

[Text input] (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 (xxx.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 | <input type="text"/> (xx.x) |
| Cyclosporine | <input type="text"/> (xxx.x) |
| Tacrolimus | <input type="text"/> (xxx.x) |
| Sirolimus | <input type="text"/> (xx.x) |
| Mycophenolate mofetil | <input type="text"/> (xxx.x) |
| Azathioprine | <input type="text"/> (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:

TRANSA (ENR)

Enter the initial Date of Transplant to enroll participant into the Transplant Registry:

(mm/dd/yyyy)

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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

Maternal

Paternal

Education Score:

- 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