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Form 5: Rejection Episode

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Not Started

1 Select the maintenance immunosuppressive therapy at the time of rejection.

Do not select medications used as treatment for rejection. For example, if on monthly IVIG to prevent recurrence of AMR, that would be OK to select. If given IVIG to treat rejection, do not select IVIG.

- | | |
|---|----------|
| <input type="checkbox"/> Azathioprine | REJBIMAZ |
| <input type="checkbox"/> Cyclosporine | REJBIMCY |
| <input type="checkbox"/> Everolimus | REJBIMEV |
| <input type="checkbox"/> Immune globulin | REJBIMIM |
| <input type="checkbox"/> Methotrexate | REJBIMME |
| <input type="checkbox"/> Mycophenolate | REJBIMMY |
| <input type="checkbox"/> Plasmapheresis | REJBIMPL |
| <input type="checkbox"/> Prednisone | REJBIMPR |
| <input type="checkbox"/> Rituximab | REJBIMRI |
| <input type="checkbox"/> Sirolimus | REJBIMSI |
| <input type="checkbox"/> Tacrolimus | REJBIMTA |
| <input type="checkbox"/> Cytosan (cyclophosphamide) | REJBIMCT |
| <input type="checkbox"/> Unknown | REJBIMUN |
| <input type="checkbox"/> Other, specify | REJBIMOT |
| <input type="text"/> | ROIMSP |

Question Added: 01 JAN 1993

Biopsy Prior to Rejection Episode

2 Biopsy Performed Prior to Rejection Episode

If performed prior to this rejection diagnosis, indicate the score of the most recent biopsy performed that did not lead to rejection treatment.

- Yes
- No

Question Added: 01 JAN 1993
BIOPPRER

2a

Biopsy Date Prior to Rejection Episode

MM/DD/YYYY

Missing Reason:
 Unknown

Question Added: 01 JAN 1993
BIOPDATE

2b

ACR Grading

2004 revised ISHLT grading system for ACR: (J Heart Lung Transplant. 2005 Nov;24(11):1710-20.)
ACR: acute cellular rejection (0, 1R, 2R, 3R)

- 0R
- 1R
- 2R
- 3R
- Unknown

Question Added: 01 JAN 2010
BIOPSCOR

2c

AMR Grading

2013 revised ISHLT grading system for pAMR: J Heart Lung Transplant 2013 Dec 32(12):1147-62.)
pAMR: pathologic antibody mediated rejection (0, 1h, 1i, 2, 3)

- Both histology and immunofluorescence/immunohistochemistry performed (ie. C4d or C3d)
- Did not assess biopsy for evidence of AMR

- Only assessed histology/ did not perform immunofluorescence/immunohistochemistry (ie. C4d or C3d)
- Unknown

Question Added: 07 OCT 2015
PBAMR

2c.i pAMR Grading

2013 revised ISHLT grading system for pAMR:
J Heart Lung Transplant 2013 Dec 32(12):1147-62.)
pAMR: pathologic antibody mediated rejection (0, 1h, 1i, 2, 3)

- 0 (negative)
- 1h
- 1i
- 2
- 3
- Positive for AMR but pAMR score not known

Question Added: 07 OCT 2015
PAMRSCOR

2c.ii AMR Findings

If only accessed histology/ did not perform immunofluorescence or immunohistochemistry (ie. C4d or C3d)

- No histologic features AMR
- Positive histologic features AMR (ie. Vasculitis/pericapillaritis)

Question Added: 07 OCT 2015
BIOPAMR

Rejection Evaluations

Start with newly diagnosed rejection by biopsy (convert to ISHLT score) or other criteria leading to bolus immunotherapy. List all follow-up biopsies or changes in therapy. The last entry should be the first biopsy or echo not prompting additional therapy. Enter each subsequent evaluation event until episode is resolved.

3 Was donor specific Ab testing performed at the time of the rejection evaluation

- Yes
- No, Did not send testing for any circulating antibodies
- Unknown

Question Added: 07 OCT 2015
DABTEST

3a Which antibodies were tested and what were the results

- HLA class I and/or class II DSA HLAClass
- Isoagglutinin (A or B Ab) to ABO-i graft ISOAGG
- Non-HLA antibody (e.g. MICA, MICB, anti-endothelial, vimentin, anti-myosin, angiotensin receptor (AR1T), or other non-HLA NONHLAAB
- Unknown HLAUNK

Question Added: 07 OCT 2015

3a.i HLA Class I and/or II DSA Result

- Negative
- Positive
- Unknown

Question Added: 07 OCT 2015
DABHLANP

3a.i.1 HLA class I and/or II DSA Result, Positive

- Complement fixing (C1q positive) DABPC1Q
- Increased from last date tested DABPINC
- New DABPNEW
- Present but stable (no new abs and not increased from baseline) DABPPS
- Unknown DABPUNK

Question Added: 07 OCT 2015

3a.ii Non-HLA Ab Result

- Negative
- Positive
- Unknown

anti-endothelial, vimentin, anti-myosin, angiotensin receptor (AR1T), or other non-HLA Results

Question Added: 07 OCT 2015
NONHLANP

3a.ii.1 Non-HLA Ab Result, Positive

Non-HLA antibody (e.g. MICA, MICB, anti-endothelial, vimentin, anti-myosin, angiotensin receptor (AR1T), or other non-HLA Results

- Increased from last date tested NHLAINC
- New NHLANEW
- Present but stable (no new abs and not increased from baseline) NHLAPS
- Unknown NHLAUNK

3a.iii Isoagglutinin (A or B Ab) to ABO-i graft

Positive is defined as titer of 1:16 or higher

- Negative
- Positive
- Unknown

Question Added: 07 OCT 2015
DABISONP

Dataset Name: REJECTIONEVALUATIONS / REJ_EVALUATIONS

Rejection Evaluations

Date of rejection evaluation

Any evaluation leading to an increase in immunotherapy to treat a biopsy or clinically diagnosed episode of rejection
MM/DD/YYYY

4a

Basis for Evaluation

- Biopsy BIOPSY
- Clinical CLINIC
- Echo ECHO
- New or increased Abs NIABS
- Unknown BDUNK

Question Added: 01 JAN 1993

4b

Was biopsy performed?

- Yes
- No

Question Added: 07 OCT 2015
CRBIOP

4b.i

Biopsy Date

Missing Reason:
 Unknown

BIODT

4b.ii

Indication for biopsy

Check all that apply.

- Objective Evidence of Graft Dysfunction GDBIOP
- Research RESBIOP
- Routine (scheduled as part of protocol surveillance) RPBIOP
- Symptoms SYMBIOP

Question Added: 01 JAN 2010

4b.iii

ACR Grading

2004 revised ISHLT grading system for

- 0R
- 1R

- ACR: 2R
 (J Heart Lung Transplant. 2005 Nov;24(11):1710-20.)
 ACR: acute cellular rejection (0, 1R, 2R, 3R)
 3R
 Unknown

Question Added: 01 JAN 1993
BXSCORE

4b.iii

AMR Grading

2013 revised ISHLT grading system for pAMR:
 J Heart Lung Transplant 2013 Dec 32(12):1147-62.)
 pAMR: pathologic antibody mediated rejection (0, 1h, 1i, 2, 3)

- Both histology and immunofluorescence/immunohistochemistry performed (ie. C4d or C3d)
 Did not assess biopsy for evidence of AMR
 Only assessed histology/ did not perform immunofluorescence/immunohistochemistry (ie. C4d or C3d)
 Unknown

Question Added: 07 OCT 2015
AMRTEST

4b.iii.1

If both histology and immunofluorescence/immunohistochemistry performed, indicate pAMR grading

2013 revised ISHLT grading system for pAMR:
 J Heart Lung Transplant 2013 Dec 32(12):1147-62.)
 pAMR: pathologic antibody mediated rejection (0, 1h, 1i, 2, 3)

- 0
 1h
 1i
 2
 3
 Positive with Unknown Score

PAMR

4b.iii.2

Histology results

- No histologic features AMR
 Positive histologic features AMR

AMRHIST

4c

Select the therapy used at the time of this evaluation

If no rejection therapy was used, no more rejection evaluations should be entered for this episode.

- | | |
|---|----------|
| <input type="checkbox"/> Augmentation of Baseline Immunosuppression | RJRXAUG |
| <input type="checkbox"/> ATG or ATGAM | RJALTS |
| <input type="checkbox"/> Bortezomib | RJBORT |
| <input type="checkbox"/> Eculizumab | RJECLZ |
| <input type="checkbox"/> Immune Adsorption | RJIMMA |
| <input type="checkbox"/> Immunoglobulin | RJIGG |
| <input type="checkbox"/> Methotrexate | RJMETH |
| <input type="checkbox"/> Photopheresis | RJPHOTO |
| <input type="checkbox"/> Plasmapheresis | RJPLASMA |
| <input type="checkbox"/> Rituximab | RJRITUX |
| <input type="checkbox"/> Steroid Taper | RJTSTER |
| <input type="checkbox"/> Steroids, IV | RJIVSTER |
| <input type="checkbox"/> Steroids, Oral | RJOSTER |
| <input type="checkbox"/> Tacrolimus | RJTAC |
| <input type="checkbox"/> Cytoxin (cyclophosphamide) | RJCYTO |
| <input type="checkbox"/> Other, specify | RJOMED |
| <input type="checkbox"/> None | RJOMEDSP |
| | RJRXNONE |

Question Added: 01 JAN 1993

4d

Was this evaluation associated with hemodynamic compromise?

None - No significant change in cardiac function at the time of rejection
Mild - Worsening of cardiac function detected (decreased ejection fraction,

- Inotropic Support
 Mild
 None
 Unknown

hypotension, EKG changes) not requiring inotropes.
Severe inotropic support added due to this rejection episode.

Question Added: 01 JAN 1993
 HEMCOM

4e Did possible or known non-adherence contribute to this rejection? Yes No

Question Added: 01 AUG 2022
 READH

5 Indicate date of the end of the rejection episode

MM/DD/YYYY

The end of a rejection episode is defined as follows:

The escalation of treatment was concluded for the acute rejection episode.

If rejection is ongoing at the time of death, the death date should be entered as the end date.

A death form should also be completed.

Question Added: 07 OCT 2015
 END_DATE

6 Was the patient taking maintenance immunosuppression at the time of resolution of rejection episode? Yes No

Question Added: 07 OCT 2015
 REJRT

6a Baseline immunosuppressive therapy at time of resolution of rejection episode

- Azathioprine (Imuran) BITAZA
- Cyclosporine (Sandimmune, Neoral, Gengraf, CSA, CyA) BITCYC
- Everolimus BITEVER
- Immune globulin BITIGG
- Methotrexate BITMETH
- Mycophenolate (Cellcept, Myfortic) BITMMF
- Prednisone BITPRED
- Rituximab BITRITUX
- Sirolimus (Rapamycin, Rapamune) BITSIRO
- Tacrolimus (Prograf, FK506) BITTAC
- Cytoxin (Cyclophosphamide) BITCYT
- Unknown BITUNK
- Other, Specify BITOT



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