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Form 5: Rejection Episode

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Not Started

1 Select the baseline immunosuppressive therapy at time of rejection

- | | |
|---|----------|
| <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"/> Cytoxan (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:
 UnknownQuestion 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 HLACCLASS
- 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

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

- Negative
- Positive
- Unknown

Question Added: 07 OCT 2015
NONHLANP

3a.ii.1

Non-HLA Ab Result,

- Increased from last date tested NHLAINC
- New NHLANEW

Positive Present but stable (no new abs and not increased from baseline) NHLAPS
 Non-HLA antibody (e.g. MICA, MICB, anti-endothelial, vimentin, anti-myosin, angiotensin receptor (AR1T), or other non-HLA Results Unknown NHLAUNK

3a.iii Isoagglutinin (A or B Ab) to ABO-i graft Negative
 Positive
 Unknown
 Positive is defined as titer of 1:16 or higher

Question Added: 07 OCT 2015
DABISONP

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 Indication for biopsy Objective Evidence of Graft Dysfunction GDBIOP
 Check all that apply. Research RESBIOP
 Routine (scheduled as part of protocol surveillance) RPBIOP
 Symptoms SYMBIOP

Question Added: 01 JAN 2010

4b.ii ACR Grading 0R
 1R
 2R
 3R
 Unknown
 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)

Question Added: 01 JAN 1993
BXSCORE

4b.iii AMR Grading 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)
 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)

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 **Was there therapy used at the time of this evaluation?**

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

- Yes
- No

Question Added: 01 JAN 1993
REJOTHER

4c.i **Select the therapy used**

- ATG or ATGAM
- Bortezomib
- Eculizumab
- Immune Adsorption
- Immunoglobulin
- Methotrexate
- Photopheresis
- Plasmapheresis
- Rituximab
- Steroid Taper
- Steroids, IV
- Steroids, Oral
- Tacrolimus
- Cytoxan (cyclophosphamide)
- Other, specify

- RJALTGS
- RJBORT
- RJECLZ
- RJIMMA
- RJIGG
- RJMETH
- RJPHOTO
- RJPLASMA
- RJRITUX
- RJTSTER
- RJIVSTER
- RJOSTER
- RJTAC
- RJCYTO
- RJOMED
- RJOMEDSP

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

- Inotropic Support
- Mild
- None
- Unknown

Question Added: 01 JAN 1993
HEMCOM

5

Indicate date of the end of the rejection episode

MM/DD/YYYY

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 there baseline immunosuppressive therapy at time of resolution of rejection episode

- Yes
- No

Question Added: 07 OCT 2015
REJRIT

6a

Baseline immunosuppressive therapy at time of resolution of rejection episode

- | | |
|---|----------|
| <input type="checkbox"/> Azathioprine (Imuran) | BITOSP |
| <input type="checkbox"/> Cyclosporine (Sandimmune, Neoral, Gengraf, CSA, CyA) | BITCYC |
| <input type="checkbox"/> Everolimus | BITEVER |
| <input type="checkbox"/> Immune globulin | BITIGG |
| <input type="checkbox"/> Methotrexate | BITMETH |
| <input type="checkbox"/> Mycophenolate (Cellcept, Myfortic) | BITMMF |
| <input type="checkbox"/> Prednisone | BITPRED |
| <input type="checkbox"/> Rituximab | BITRITUX |
| <input type="checkbox"/> Sirolimus (Rapamycin, Rapamune) | BITSIRO |
| <input type="checkbox"/> Tacrolimus (Prograf, FK506) | BITTAC |
| <input type="checkbox"/> Cytoxin (Cyclophosphamide) | BITCYT |
| <input type="checkbox"/> Unknown | BITUNK |
| <input type="checkbox"/> Other, Specify | BITOT |
| <input type="text"/> | BITOSP |