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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.

- Azathioprine
- Cyclosporine
- Everolimus
- Immune globulin
- Methotrexate
- Mycophenolate
- Plasmapheresis
- Prednisone
- Rituximab
- Sirolimus
- Tacrolimus
- Cytoxin (cyclophosphamide)
- Unknown
- Other, specify

Question Added: 01 JAN 1993

## Biopsy Prior to Rejection Episode

### 2 Biopsy Performed Prior to Rejection Episode

- Yes
- No

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

Question Added: 01 JAN 1993

**2a**

### Biopsy Date Prior to Rejection Episode

MM/DD/YYYY

Missing Reason:

- Unknown

Question Added: 01 JAN 1993

**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

**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

**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

**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

**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

**3a Which antibodies were tested and what were the results**

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

Question Added: 07 OCT 2015

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

- Negative
- Positive
- Unknown

Question Added: 07 OCT 2015

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

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

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

**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  
 New  
 Present but stable (no new abs and not increased from baseline)  
 Unknown

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

Positive is defined as titer of 1:16 or higher

Question Added: 07 OCT 2015

### 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
- Clinical
- Echo
- New or increased Abs
- Unknown

Question Added: 01 JAN 1993

**4a.i**

**ECHO features suggesting rejection**

Check all that apply

- LV dysfunction Mild
- LV Dysfunction Moderate
- LV Dysfunction Severe
- RV Dysfunction
- New or worsening AV Valve Regurgitation
- Other, specify

**4b**

**Was biopsy performed?**  Yes  
  No

Question Added: 07 OCT 2015

**4b.i**

**Biopsy Date**

Missing Reason:  
  Unknown

Question Added: 01 AUG 2022

**4b.ii**

**Indication for biopsy**

Check all that apply.

- Objective Evidence of Graft Dysfunction
- Research
- Routine (scheduled as part of protocol surveillance)

Symptoms

Question Added: 01 JAN 2010

**4b.iii****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 1993

**4b.ivii****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

**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

**4b.iii.2****Histology results**

- No histologic features AMR
- Positive histologic features AMR

**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.

- Augmentation of Baseline Immunosuppression
- ATG or ATGAM
- Bortezomib
- Eculizumab
- Immune Adsorption
- Immunoglobulin
- Methotrexate
- Photopheresis
- Plasmapheresis
- Rituximab
- Steroid Taper
- Steroids, IV
- Steroids, Oral
- Tacrolimus
- Cytoxan (cyclophosphamide)
- Other, specify
- None

Question Added: 01 JAN 1993

**4d****Was this evaluation associated with hemodynamic**

- Yes
- No

### 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.

**4d.i**

**Select all the manifestations of hemodynamic compromise that apply**

- Mild Dysfunction
- Moderate Dysfunction
- Severe Dysfunction
- Inotropic Support
- ECMO
- Other MCS
- Unknown

**4e**

**Did possible or known non-adherence contribute to this rejection?**

- Yes
- No

Question Added: 01 AUG 2022

**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

**6**

**Was the patient taking maintenance immunosuppression at the time of resolution of rejection episode?**

- Yes
- No

Question Added: 07 OCT 2015

**6a**

**Baseline immunosuppressive therapy at time of resolution of rejection episode**

- Azathioprine (Imuran)
- Cyclosporine (Sandimmune, Neoral, Gengraf, CSA, CyA)
- Everolimus
- Immune globulin
- Methotrexate
- Mycophenolate (Cellcept, Myfortic)
- Prednisone
- Rituximab
- Sirolimus (Rapamycin, Rapamune)
- Tacrolimus (Prograf, FK506)
- Cytoxan (Cyclophosphamide)
- Unknown
- Other, Specify

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