

Data Abstraction Form :

Investigation of Mucormycosis Disease among Bone Marrow Transplant Patients

Initials: _____

Case #: _____

Medical Record #: _____

Date of Birth: /

Reviewers Initials: _____

Review Date: _____

Case of Mucormycosis Infection of Interest

Bone marrow transplant patients with stays in unit 41 and 42 with any presentation of a mucormycosal infection excluding gastrointestinal

WITH

Histopathological or cytopathological examination showing hyphae from needle aspiration or biopsy specimen with evidence of associated tissue damage (either microscopically or as an infiltrate or lesion by imaging)

OR

Positive culture result for a sample obtained by sterile procedure from normally sterile and clinically or radiologically abnormal site consistent with mucormycosal infection.

Matched Controls

Bone marrow transplant patients (Preferred) with stays in unit 41 and 42:

- a date of birth is within five years of the matched mucormycosis case's birthday
- with matched hematologic malignancy (See section II)

Other major risk factors we will assess for and enough controls present, we can consider matching for diabetes status, diabetic ketoacidosis, blood iron overload condition, chronic high-dose corticosteroids use. If necessary we can also expand the control group to hematopoietic stem cell transplant from unit 41, or from unit 41 and 42.

Case-Case Abstraction Form

Section I: Demographic and Admission Data

1. Age at diagnosis (years): _____
2. Gender: _____ (0= Male, 1= Female)
3. Race (Select all that apply): _____
(0=white/Caucasian, 1=black/African-American, 2=Asian, 3=American Indian/Alaskan, 4=Hawaiian/Pacific Islander, 5=not known)
4. Ethnicity: _____ (0=not Hispanic, 1=Hispanic, 2=not known)
5. County: _____
City: _____ State: _____ Zip: _____
6. Phone #: - -
7. Date of admission (mm/dd/yy): / /
8. Admit diagnosis: _____

Section II: Underlying Medical Conditions and Risk Factors (at time of admission or before onsets, check all that apply)

9. General Medical Conditions: None
 - Bone Marrow Transplant
 - Other hematopoietic stem cell transplant
 - Diabetes [not Diabetic Ketoacidosis (DKA)]
 - Last Hemoglobin A1C level _____
 - Diabetic Ketoacidosis (DKA) during stay on unit
 - Hemochromatosis
 - Thalassemia
 - Transfusion-induced iron overload in the 14 days before or during stay on unit
 - Iron overload for any other reason and/or iron chelation therapy within 14 days prior to exposure to the unit (Desferrioxamine therapy)

10. Immunocompromised State: None
 - Solid organ transplant (ever)
 - renal liver lung heart other (specify) _____
 - If transplant recipient, date of most recent transplant (mm/dd/yy): ____/____/____
 - Solid tumor malignancy (specify type): _____
 - If history of solid tumor, on or had been on chemotx in the 14 days before culture?
 Yes No Unknown
 - History of stem cell transplant
 - Neutropenia (< 500 neutrophils per mm³) within 14 days prior to onset (or admission?)

- Total number of neutropenic days within 14 day period: _____ or Unknown
- Systemic corticosteroids at avg dose ≥ 0.3 mg/kg/day prednisone (or equivalent) for > 3 weeks
- Chronic Granulomatous Disease
- Other _____ (specify)

Hematologic malignancy

- Leukemia
- Acute myeloid leukemia (AML) (e.g. M0-M7)
 - Chronic myeloid leukemia (CML) (e.g. Chronic phase, Accelerated phase, Blast crisis)
 - Acute lymphocytic leukemia (ALL) (e.g. L1-L3)
 - Chronic lymphocytic leukemia (CLL) (e.g. B cell origin, T cell origin, Adult T cell leukemia, Sezary syndrome, Unclassified)
- Hodgkin's disease (e.g. Lymphocyte predominant, Lymphocyte rich, Nodular sclerosis, Hairy cell leukemia, Mixed cellularity, Lymphocyte depleted, Large, granular lymphocyte leukemia)
- Non-Hodgkin's lymphoma (e.g. B cell origin, T cell origin)
- Aplastic anemia
- Multiple myeloma
- Myelodysplastic syndrome (e.g. RA, RARS, RAEB-1, RAEB-2, RCMD, RCMD/RS, 5q syndrome, CMML)
- Sickle cell anemia
- Other _____

If history of heme malignancy, on or had been on chemotx in the 14 days before culture?

- Yes No Unknown

Graft-versus-host disease:

- Acute; if yes, record grade (I-IV) _____
- Chronic; if yes, check one: limited extensive unknown
- None
- Unknown

Section III: Location

11. Did this patient have any prior **INPATIENT** hospitalizations within 30 days prior to the current admission?
 (Include ALL hospitalizations, including those not at Hospital A)

Yes (fill out table below, with most recent hospital admissions) No Unknown

| Facility Name | Admission Dates (mm/dd/yy)- (mm/dd/yy) | Ward/Bed (complete for each location) | First date at location | Last date at location |
|---------------|--|---|---|---|
| | | | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |
| | | | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |

12. Where was patient admitted from?

- Home
- Nursing home/subacute care facility
- Other acute care hospital
- Rehabilitation
- Other (specify): _____
- Unknown

13. Room history during current admission:

| Ward/Room | First date at location | Last date at location (or Unk) |
|-----------|--|--|
| | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |
| | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |
| | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |
| | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |

Section IV: Laboratory

14. Did patient have a positive Mucor culture? Yes No Unknown

| Culture Date (mm/dd/yy) | Specimen Site/Type (blood, sputum, pleural fluid, CSF, etc) | Organism |
|--|---|----------|
| <input type="text"/> / <input type="text"/> / <input type="text"/> | | |
| <input type="text"/> / <input type="text"/> / <input type="text"/> | | |

15. Did patient have a positive Mucor pathology finding? Yes No Unknown

If yes, please complete table:

| Date (mm/dd/yy) | Anatomical site | Organism/Description of Fungal Elements |
|--|-----------------|---|
| <input type="text"/> / <input type="text"/> / <input type="text"/> | | |
| <input type="text"/> / <input type="text"/> / <input type="text"/> | | |

16. If patient had a head CT, please list date: / /

- Cavernous sinus thrombosis
- Changes to the orbit
- Semiacute right frontal lobe infarct
- Diffuse sinusitis

Describe other findings: _____

17. If patient had a head MRI, please list date: / /

- Cavernous sinus thrombosis
- Changes to the orbit
- Semiacute right frontal lobe infarct
- Diffuse sinusitis

Describe other findings: _____

18. Does the patient have a history of positive cultures for Mucor? Yes No Unknown

If yes, date of previous culture : / /

Section V: Medications/Procedures

19. Has patient received immunosuppressive medications (including chemotherapy) within 30 days of the index culture date? Yes No Unknown

- If yes, please list:
- 1) _____
 - 2) _____
 - 3) _____
 - 4) _____
 - 5) _____

20. Did the patient receive systemic antifungal medication in the 30 days prior to the date of index culture that were

[Type text]

[Type text]

[Type text]

given for reasons other than treatment of the current infection (i.e. prophylaxis or treatment of another fungal infection)? **DO NOT** include drugs given to treat the current infection.

Yes (fill out the table below) No Unknown

| Antifungal drug | Given? | Total days of therapy in 30-day period | Date of last dose prior to first culture (mm/dd/yy) |
|--|---|--|---|
| Amphotericin B (Polyene Antifungal) <input type="checkbox"/> Fungizone, (Lipid-based Polyene Antifungal) <input type="checkbox"/> Amphotec <input type="checkbox"/> Abelcet <input type="checkbox"/> AmBisome <input type="checkbox"/> Amphocil, <input type="checkbox"/> ABLC <input type="checkbox"/> ABCD | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |
| Anidulafungin (Eraxis) (an Echinocandin) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |
| Caspofungin (Cancidas) (an Echinocandin) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |
| Fluconazole (Diflucan) (an Azole) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |
| Flucytosine (5FC) (a Nucleoside Analog Antifungal) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |
| Micafungin (Mycamine) (an Echinocandin) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |
| Posaconazole (Noxafil) (an Azole) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |
| Itraconazole (Sporanox) (an Azole) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |
| Voriconazole (Vfend) (a Triazole) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |

21. Was the patient intubated? Yes No Unknown

If yes, complete the following questions:

- a. Where was the patient intubated? (ER, floor, ICU, field): _____
- b. Type of intubation: Oral Nasal
- c. List dates of intubation: _____
- d. Did index culture date occur prior to or after intubation? Prior After

22. Did the patient have a tracheostomy? Yes No Unknown

[Type text]

[Type text]

[Type text]

a. If yes, date of tracheostomy? / /

b. If yes, did index culture date occur prior to or after tracheostomy? Prior After

23. Did the patient have any inpatient respiratory therapies in the 30 days before the index culture date?

Yes No Unknown

e. If yes, check below:

NC O2 NC O2 w/ humidified air Nebulized meds (SVN) MDIs

CPAP/BIPAP Other _____ None Unknown

i. If 'yes' to SVN or MDI, fill in the table below:

| Drug | Mode of Administration (SVN or MDI) |
|------|-------------------------------------|
| | |
| | |
| | |

24. Did patient have any procedures within 30 days prior to the index culture date?

Yes No Unknown

If yes, please check all that apply:

Thoracentesis Date: / /

Bronchoscopy Date: / /

Date: / /

Date: / /

Thoracotomy (Chest tube insertion) Date: / /

Endoscopy Date: / /

Transesophageal echocardiogram Date: / /

Surgery (1) _____ Date: / /

OR #: _____

(2) _____ Date: / /

OR #: _____

Percutaneous/interventional radiology procedure: _____

(specify) Date: / /

Other _____ (specify) Date: / /

[Type text]

[Type text]

[Type text]

Section VI: Symptoms

- 25. Was the onset of symptoms more chronic, over the course of several weeks? Yes No Unknown
- 26. Manifested as an acute sinus infection? Yes No Unknown
- 27. Nasal congestion? Yes No Unknown
- 28. Fever? Yes No Unknown
- 29. Headache? Yes No Unknown
- 30. Facial pain? Yes No Unknown
- 31. Tinnitus? Yes No Unknown
- 32. Reddish and swollen skin over nose and sinuses? Yes No Unknown
- 33. Periorbital edema and erythema (Reddish and swollen skin around the eye)? Yes No Unknown
- 34. Ptosis of the eyelid? Yes No Unknown
- 35. Visual problems? Yes No Unknown
- 36. Edema and hypertrophy of the nasal turbinates? Yes No Unknown
- 37. Edema and hypertrophy of the posterior pharynx? Yes No Unknown
- 38. Altered mental status? Yes No Unknown
- 39. Blindness of the eye? Yes No Unknown
- 40. Dilated pupil? Yes No Unknown
- 41. Nonreactive pupil? Yes No Unknown
- 42. Cavernous sinus thrombosis? Yes No Unknown
- 43. Evidence of spread to the brain? Yes No Unknown
- 44. Spread to the orbits? Yes No Unknown

Section VII: Treatment

- 45. Did the patient undergo debridement? Yes No Unknown
- 46. Myringotomy with insertion of a tympanostomy? Yes No Unknown
- 47. Hyperbaric oxygen therapy (HBO)? Yes No Unknown
- 48. Did the patient undergo surgery for treatment (not diagnosis) of rhinocerebral mucormycosis?
- 49. Yes No Unknown
- 50. If yes, what was the name of the procedure? _____
(e.g. Frontal lobectomy, Ethmoidectomy, Maxillary sinus antrostomy, Frontal sinusotomy, Sphenoidectomy)
- 51. Was the patient treated with an antifungal after the infection was diagnosed? Yes No Unknown

If yes, complete table:

| Antifungal drug | Given? | Total days of therapy in 30-day period | Date of last dose prior to first culture (mm/dd/yy) |
|---|---|--|---|
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[Type text]

[Type text]

[Type text]

| | | | |
|---|---|--|---|
| <input type="checkbox"/> Amphotec <input type="checkbox"/> Abelcet <input type="checkbox"/> AmBisome <input type="checkbox"/> Amphocil, <input type="checkbox"/> ABLC <input type="checkbox"/> ABCD | | | |
| Anidulafungin (Eraxis) (an Echinocandin) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unk |
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52. Renal indices monitored during therapy? Yes No Unknown

53. Nephrotoxicity levels during treatment _____

54. Iron chelator therapy? Yes No Unknown

55. Deferasirox? Yes No Unknown

56. Deferiprone? Yes No Unknown

Section VII: Outcomes

57. Was infected sinus tissue or sinus tissue destruction visibly observed? Yes No Unknown

58. Significant devitalized mucous membranes? Yes No Unknown

59. Significant devitalized mucous membranes? Yes No Unknown

60. Necrotic lesions in the:

f. Nasal mucosa? Yes No Unknown

g. Turbinates? Yes No Unknown

h. Hard palate? Yes No Unknown

61. Extension of the disease into the:

Maxillary sinus? Yes No Unknown

62. Invasion of the surrounding vasculature? Yes No Unknown

63. Spread into the cribriform plate or the orbital apex? Yes No Unknown

[Type text]

[Type text]

[Type text]

64. Did the patient require enucleation? Yes No Unknown
65. Occlusion of the carotid artery, causing an internal carotid artery pseudoaneurysm?
 Yes No Unknown
66. Infarction and necrosis of tissues in other structures? Yes No Unknown

Other structures involved? _____

67. Was patient diagnosed with rhinocerebral mucormycosis in the medical record?
 Yes No Unknown Not applicable

68. Date of discharge (mm/dd/yy): / /

69. Status at discharge:
 Alive Deceased Unknown

70. If deceased, date of death: / /

71. If patient is deceased, is death certificate available?
 Yes No Unknown Not applicable

72. If yes, is invasive fungal infection (IFI) listed as cause of death?
 Yes No Unknown Not applicable

If yes, is IFI listed as primary or secondary cause of death? Primary Secondary

73. If patient is deceased, was an autopsy performed?
 Yes No Unknown Not applicable

74. If yes, was evidence of invasive fungal infection (IFI) present?
 Yes No Unknown Not applicable