Form Approved
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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 say 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 mm^3) 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**
			☐☐/☐☐/☐☐ ☐ Unk	☐☐/☐☐/☐☐ ☐ Unk
			☐☐/☐☐/☐☐ ☐ Unk	☐☐/☐☐/☐☐ ☐ 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)**
	☐☐/☐☐/☐☐ ☐ Unk	☐☐/☐☐/☐☐ ☐ Unk
	☐☐/☐☐/☐☐ ☐ Unk	☐☐/☐☐/☐☐ ☐ Unk
	☐☐/☐☐/☐☐ ☐ Unk	☐☐/☐☐/☐☐ ☐ Unk
	☐☐/☐☐/☐☐ ☐ Unk	☐☐/☐☐/☐☐ ☐ 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**
☐☐/☐☐/☐☐		
☐☐/☐☐/☐☐		

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**
☐☐/☐☐/☐☐		
☐☐/☐☐/☐☐		

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 <u>30 days prior to the date of index culture</u> that were

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) ☐ Fungizone, (Lipid-based Polyene Antifungal) ☐ Amphotec ☐ Abelcet ☐ AmBisome ☐ Amphocil, ☐ ABLC ☐ ABCD	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Anidulafungin (Eraxis) (an Echinocandin)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Caspofungin (Cancidas) (an Echinocandin)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Fluconazole (Diflucan) (an Azole)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Flucytosine (5FC) (a Nucleoside Analog Antifungal)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Micafungin (Mycamine) (an Echinocandin)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Posaconazole (Noxafil) (an Azole)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Itraconazole (Sporanox) (an Azole)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Voriconazole (Vfend) (a Triazole)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ 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

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: ☐☐/☐☐/☐☐

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 debridment? ☐ 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)
Amphotericin B (Polyene Antifungal) ☐ Fungizone, (Lipid-based Polyene Antifungal)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐Unk

☐ Amphotec ☐ Abelcet ☐ AmBisome ☐ Amphocil, ☐ ABLC ☐ ABCD			
Anidulafungin (Eraxis) (an Echinocandin)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Caspofungin (Cancidas) (an Echinocandin)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Fluconazole (Diflucan) (an Azole)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Flucytosine (5FC) (a Nucleoside Analog Antifungal)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Micafungin (Mycamine) (an Echinocandin)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Posaconazole (Noxafil) (an Azole)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Itraconazole (Sporanox) (an Azole)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk
Voriconazole (Vfend) (a Triazole)	☐ Yes ☐ No ☐ Unknown		☐☐/☐☐/☐☐ ☐ Unk

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

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