

## 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 mm<sup>3</sup>) within 14 days prior to onset (or admission?)

- Total number of neutropenic days within 14 day period: \_\_\_\_\_ or  Unknown
- Systemic corticosteroids at avg dose  $\geq 0.3$  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)
Amphotericin B (Polyene Antifungal) <input type="checkbox"/> Fungizone, (Lipid-based Polyene 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

[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
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

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