2146: Fungal Infection Post-Infusion Data

The Fungal Infection Post-Infusion Data Form (Form 2146) captures information regarding the diagnosis, treatment, and response to treatment of any proven or suspected fungal infections diagnosed **after** receiving a HCT or cellular therapy. This form must be completed when a fungal infection has been reported on the Post-HCT Follow-Up Data Form (Form 2100)

Refer to the 2046: Fungal Infection Pre-Infusion Data section of the Forms Instructions Manual for definitions of common terms concerning fungal infections.

Links to Form Sections:
Q1-24: Infection Episode
Q25-41: Hematologic Findings at Diagnosis of Infection
Q42-48: Treatment of Infection

Manual Updates:
Sections of the Forms Instruction Manual are frequently updated. In addition to documenting the changes within each manual section, the most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

Date	Manual Section	Add/ Remove/ Modify	Description
7/ 25/ 17	2146: Fungal Infection Post-Infusion Data	Add	Version 1 of the 2146: Fungal Infection Post-Infusion Data section of the Forms Instructions Manual released. Version 1 corresponds to revision 3 of the Form 2146.

Q1-24: Infection Episode

Question 1: Date of Infection Diagnosis

Each fungal infection (proven or suspected) which is reported on the Post-HCT Follow-Up Data Form (Form 2100) will trigger a Fungal Infection Post-Infusion Data Form (Form 2146). A recipient with multiple fungal infections reported on the corresponding follow-up form will have multiple Fungal Infection Post-Infusion Data Forms (one for each organism). Determine which infection / organism will be reported on the form being completed, and report the diagnosis date for that specific infection.

The reported date of diagnosis must match the diagnosis date reported on the corresponding follow-up form. For proven fungal infections, report the date the sample was collected. For suspected fungal infections, report the date the imaging assessment which confirmed the infection was performed. If the diagnosis date cannot be determined from the available reports and progress notes, obtain documentation from the recipient's HCT / cellular therapy physician confirming which date should be reported as the date of diagnosis.

If the exact date of diagnosis is not known, but the year is known, refer to General Instructions, General Guidelines for Completing Forms, for information about reporting partial or unknown dates.

Fungal Infection Diagnosis Reporting Scenario:

A recipient has a CT scan on 4/1/2015 due to a persistent cough and fevers. The CT scan documents multiple nodules. An Aspergillus galactomannan was drawn from the blood on 4/2/2015 and the patient underwent a bronchoscopy on 4/3/2015. Fluid from the bronchoaveolar lavage was stained for fungal elements and submitted for culture. The stain was positive for fungal elements and the culture grew Aspergillus. The blood galactomannan was also positive.

- The date of diagnosis of infection will be 4/2/2015. This is the date the galactomannan was obtained and positive.
- If galactomannan was negative and the BAL negative, the date of infection would be 4/1/2015 (the date of the CT scan).

Question 2-24: Diagnostic Testing

Report all testing that had positive results and which indicated the fungal infection was present. Do not report negative or indeterminate / equivocal testing in this section. As indicated in the instructions for question one, if the recipient was diagnosed with multiple fungal infections during the reporting period, multiple Fungal Infection Post-Infusion Data Forms must be completed (one for each organism). Ensure the

testing reported in these questions only reflects the assessments used to identify the infection / organism being reported on this form. For reporting purposes, only report methods performed / samples collected (or sites assessed for radiological findings) within 14 days (+/ -) of the diagnosis date reported in question 1.

Methods of Assessment:
A fungal infection may be identified by multiple assessments near the time of diagnosis. A description of each method of assessment is provided below. Report “yes” for all assessments which were positive for signs of the fungal infection being reported on this form. Report “no” for assessments which were never performed or were never considered to be positive for the fungal infection being reported on this form. Note the time window provided in the initial instructions for questions 2-24. If the significance of the test result is not clear, obtain documentation from the recipient’s HCT / cellular therapy physician confirming whether the assessment was considered positive. Report “no” for assessments with results which are determined to be equivocal or indeterminate.

Radiographic Findings: includes all imaging assessments. Examples include x-ray, CT scan, PET scan, and MRI. These assessments are capable of identifying the presence of a fungal infection, but cannot identify specific organisms. Refer to the clinical interpretation of an imaging assessment to determine whether the test was considered positive for the infection being reported. If the provider’s notes do not specify whether the test was positive, obtain documentation from the HCT / cellular therapy physician clarifying how the assessment should be reported.

Pathology: samples obtained from the recipient via biopsy or fine needle aspirate are evaluated via microscopy without incubation. Presence and classification is assessed solely by microscopy. If a sample is grown in culture or stained, report these test methods under the more specific options below. Generally, the results / interpretation section of the pathology report will specify whether the assessment was positive or negative for signs of a fungal infection. If this is not the case, refer to the provider notes and obtain clarification from the recipient’s HCT / cellular therapy physician if both the pathology report and provider notes are not clear.

Culture: samples taken from the recipient are incubated in media supporting fungal growth. Presence of infection is assessed by colony formation / growth and classification is done via microscopy following incubation. The culture report will document whether growth is detected (positive) or not detected (negative). Staining may also be performed to classify the infection following incubation. Report the results of any staining techniques in the more specific methods below.

KOH / Calcofluor / Giemsa stain: samples taken from the recipient (usually fluids such as sputum or wash samples) are exposed to a stain which binds to structures specific to fungal cells. The sample is evaluated via microscopy to determine whether stained cells are present (positive result) or absent (negative result).

KOH: potassium hydroxide also referred to a “fungal wet prep.”
Calcofluor: white stain which binds to fungal cell walls causing them to appear bright green / blue.
Giemsa stain: often used to identify Histoplasma.

Galactomannan Assay: a sample (i.e., serum, bronchial lavage, bronchial wash or CSF) taken from the recipient are exposed to galactomannan-specific antibodies followed by antibody-specific enzymes (ELISA method). Galactomannan is a molecule specific to Aspergillus.
The enzyme activity is quantified and the test is considered positive if the activity is above the upper limit of normal (as indicated on the test report). If the report is unclear regarding whether the result is considered positive, negative, or equivocal, contact your center’s laboratory to confirm.

1,3-Beta-D-glucan (Fungitell) assay: a sample (i.e., serum, bronchial lavage, bronchial wash or CSF) taken from the recipient is exposed to beta-d-glucan-specific antibodies followed by antibody-specific enzymes (ELISA method). Beta-d-glucan is a molecule found on a multiple fungi including Candida and Aspergillus. The enzyme activity is quantified and the test is considered positive if the activity is above the upper limit of normal (as indicated on the test report). If the report is unclear regarding whether the result is considered positive, negative, or equivocal, contact your center’s laboratory to confirm.

PCR Assay: samples taken from the recipient are manipulated using polymerase chain reaction techniques. Presence and classification of fungi are assessed by identifying DNA sequences unique to specific fungi. The lab report will document whether an infection is detected (positive) or not detected (negative). If the report is unclear, contact your center’s laboratory to confirm.

Sites / Sample Source:
For each method of assessment which showed evidence of the fungal infection being reported, indicate every site or sample source where the infection was detected. Do not report sites yielding negative or indeterminate / equivocal results. Note the time window provided in the initial instructions for questions 2-24.

Q25-41: Hematologic Findings at Diagnosis of Infection

Question 25-35: Complete Blood Count

Report the date of the complete blood count (CBC) performed closest to the date of diagnosis of the fungal infection being reported on this form. The CBC must have been performed within 7 days of the date of diagnosis.. For each value listed in questions 26-35, indicate whether the value was known on the date reported in question 25. If known, report the value and corresponding units (when asked). If the value is not known on the date reported in question 25, report “Unknown” and go to the next value.

If a CBC was not performed within the indicated time window, or it is not known if a CBC was performed, leave question 25 blank and override the error in FormsNet3SM using the code “Unknown.” If the exact date of the CBC is not known, refer to General Instructions, General Guidelines for Completing Forms, for information about reporting partial or unknown dates.

Question 36-38: Serum Creatinine

Report the result of the serum creatinine test performed closest to the date of diagnosis of the fungal infection being reported on this form. The test must have been performed within 7 days of the date of diagnosis. If known, report the value and associated units. Also report the upper limit of normal and associated units for the test being reported.

If a serum creatinine test was not performed within the indicated time window, or it is not known if a serum creatinine test was performed, report “Unknown” for question 36 and go to question 39.

Question 39-41: ALT (SGPT)

Report the result of the alanine aminotransferase (ALT / SGPT) test performed closest to the date of diagnosis of the fungal infection being reported on this form. The test must have been performed within 7 days of the date of diagnosis. If known, report the value and associated units. Also report the upper limit of normal and associated units for the test being reported.

If an ALT test was not performed within the indicated time window, or it is not known if a test was performed, report “Unknown” for question 39 and go to question 42.

Q42-48: Treatment of Infection

Question 42: Did the recipient receive any therapy between 7 days prior to the date of infection diagnosis and the date of contact for this reporting period?

Report “yes” if the recipient received any antifungal treatment from 7 days prior to the date of diagnosis (refer to question 1) through the date of contact for the reporting period (refer to the date of contact reported on the corresponding follow-up form). If the recipient did not receive any antifungal therapy during this time frame, report “no” and go to question 48.

Question 43-47: Antifungal Drugs

One instance of questions 43-47 must be completed for each drug administered during the time window indicated in the instructions for question 42. For each drug given, indicate the specific drug in questions 43-44 and then specify the start date in questions 45-46. If the exact start date is not known, but the year the drug was started is known, refer to the refer to General Instructions, General Guidelines for Completing Forms, for information about reporting partial or unknown dates. If an estimated date is reported, check the “Date Estimated” box next to question 46.

If an antifungal drug was started greater than 7 days prior to the date of infection diagnosis and was continued to within 7 days of the diagnosis date, report 7 days prior to the diagnosis date as the date the medication was started and check the “Date Estimated” box next to question 46.

For question 47, indicate whether the treatment being reported in this instance of questions 43-47 was still being given 30 days (+ / – 3 days) after the date of diagnosis. This includes treatment which may have been interrupted, but was still being given 30 days (+ / – 3 days) after diagnosis. If the fungal infection reported on this form was diagnosed within 30 days (+ / – 3 days) of the date of contact for this reporting period (refer to the corresponding follow-up form), indicate whether the drug was still being given on the date of contact.

If it is not known whether treatment was still being given within the time window indicate above, leave question 47 blank and override the error in FormsNet3SM using the code “Unknown.”

Question 48: What was the status of the infection?

Report the status of the fungal infection on the date of contact for this reporting period (refer to the corresponding follow-up form) based on the primary care provider’s clinical judgement. If the status of the infection is not documented in the primary care provider’s note summarizing their last evaluation performed during the reporting period, obtain documentation from the provider indicating which option to report. For

reporting purposes, centers should indicate “Ongoing” if the infection is still present, but cannot be considered improved or resolved.