

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 fungal infections diagnosed **after** receiving a HCT or cellular therapy. This form must be completed when one of the fungal infections listed below has been reported on the Post-HCT Follow-Up Data Form (Form 2100). One form will be completed for each applicable infection reported.

The following infections will cause a Fungal Infection Post-Infusion Data Form (Form 2146) to come due when reported on the Post-HCT Follow-Up Data Form (Form 2100):

- Aspergillus flavus
- Aspergillus fumigatus
- Aspergillus niger
- Aspergillus, NOS
- Aspergillus terreus
- Aspergillus ustus
- Blastomyces (dermatitidis)
- Candida albicans
- Candida non-albicans
- Cryptococcus gattii
- Cryptococcus neoformans
- Fusarium (all species)
- Histoplasma (capsulatum)
- Mucorales (all species)
- Rhizopus (all species)
- Scedosporium (all species)
- Zygomycetes, NOS
- Suspected fungal infection

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

Q1-25: Infection Episode

Q26-42: Hematologic Findings at Diagnosis of Infection

Q43-49: Treatment of Infection

Manual Updates

Sections of the Forms Instruction Manual are frequently updated. The most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

If you need to reference the historical Manual Change History for this form, please reference the retired manual section on the Retired Forms Manuals webpage.

Date	Manual Section	Add/ Remove/ Modify	Description
8/25/2020	2146: Fungal Infection Post-Infusion Data	Add	Clarification added on when to report fungal prophylaxis as treatment in question 43: <i>Report “Yes” if the recipient received any antifungal treatment from seven days prior to the date of diagnosis (refer to question two) 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 49. If the dose of fungal prophylaxis was increased to a therapeutic dose during the specified time window (seven days prior to the diagnosis date through the date of contact), report “Yes.”</i>
5/1/18	2146: Fungal Infection Post-Infusion Data	Modify	Version 2 of the 2146: Fungal Infection Post-Infusion Data section of the Forms Instructions Manual released. Version 2 corresponds to revision 4 of the Form 2146.

Last modified: Aug 25, 2020

Q1-25: Infection Episode

Question 1: Organism

This field is auto-populated to match the fungus reported on the Post-HCT Follow-Up Form (Form 2100). Review the value to ensure it is accurate. A Fungal Infection Post-Infusion Data Form will come due for each applicable infection reported on the Post-HCT Follow-Up Form (Form 2100) so it is imperative to identify the fungal infection to which this form will correspond.

If multiple infections of the same fungus are reported during the same reporting period, the center must complete a Fungal Infection Post-Infusion Data Form (Form 2146) for each infection instance, or episode, reported.

Question 2: Date of Infection Diagnosis

This field is auto-populated to match the date reported on the Post-HCT Follow-Up Data Form (Form 2100). Review the value to ensure it is accurate. See the Post-HCT Follow-Up Data section of the manual for further instructions on reporting the date of diagnosis.

If multiple infections of the same virus are reported in the same reporting period, the diagnosis date in question two will clarify for which infection episode the form is being completed.

Question 3-25: 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 and samples collected (or sites assessed for radiological findings) within 14 days (+/-) of the diagnosis date reported in question two.

[Links to specific instructions](#)

[Methods of Assessment](#)

[Site / Sample Source](#)

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 3-25. 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 taken from the recipient which 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 which are incubated in media supporting fungal growth. Presence of infection is assessed by colony formation / growth and classification is done via microscopy following incubation. Results are typically found in the microbiology section of the medical record. 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 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 broad range of fungi. 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. Reports can generally be found in the microbiology section or the molecular pathology section of the medical record. 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 3-25.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.

Last modified: Dec 22, 2020

Q26-42: Hematologic Findings at Diagnosis of Infection

Question 26-36: 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 seven days of the date of diagnosis.. For each value listed in questions 27-36, indicate whether the value was known on the date reported in question 26. If known, report the value and corresponding units (when asked). If the value is not known on the date reported in question 26, 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 26 blank and override the error in FormsNet3 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 37-39: 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 seven 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 37 and go to question 40.

Question 40-42: 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 seven 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 40 and go to question 43.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.

Last modified: Dec 22, 2020

Q43-49: Treatment of Infection

Question 43: 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 seven days prior to the date of diagnosis (refer to question two) 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 49.

If the dose of fungal prophylaxis was increased to a therapeutic dose during the specified time window (seven days prior to the diagnosis date through the date of contact), report “Yes.”

Question 44-48: Antifungal Drugs

One instance of questions 44-48 must be completed for each drug administered during the time window indicated in the instructions for question 43. For each drug given, indicate the specific drug in questions 43-44 and then specify the start date in questions 46-47. 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 47.

If an antifungal drug was started greater than seven days prior to the date of infection diagnosis and was continued to within seven days of the diagnosis date, report seven days prior to the diagnosis date as the date the medication was started and check the “Date estimated” box next to question 47.

For question 48, indicate whether the treatment being reported in this instance of questions 44-48 was still being given 30 days (+ / – three days) after the date of diagnosis. This includes treatment which may have been interrupted, but was still being given 30 days (+ / – three days) after diagnosis. If the fungal infection reported on this form was diagnosed within 30 days (+ / – three 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 48 blank and override the error in FormsNet3 using the code “Unknown.”

Question 49: 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.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.

Last modified: Dec 22, 2020