


MAJOR INFECTIONS



WE FREQUENTLY RECEIVE QUESTIONS ABOUT INFECTIONS. THE MOST FREQUENTLY ONE ASKED IS, WHAT ABOUT AN ONGOING INFECTION?

**HOW DO I ENTER A PATIENT THAT HAS AN ONGOING INFECTION?
WITHIN THE FAQ DOCUMENT WE HAVE GUIDELINES TO HELP IN DATA
ENTRY IN REGARD TO DIFFERENT INFECTION SCENARIOS.**

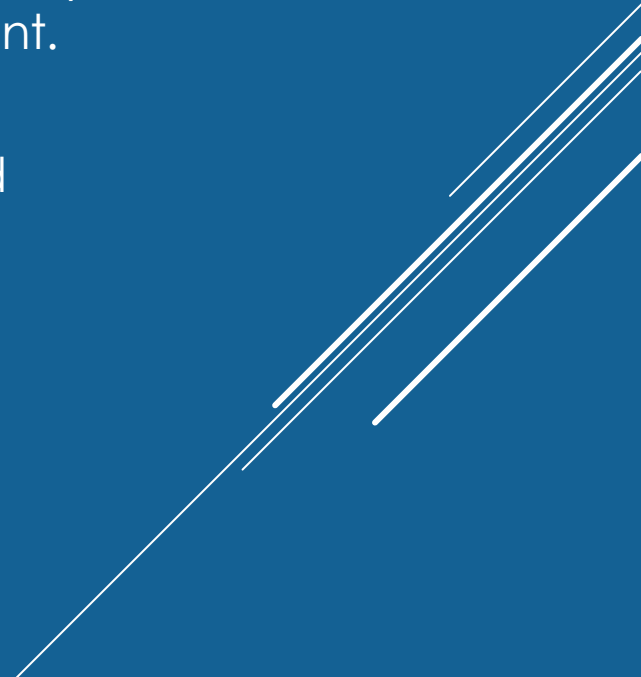
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PRE-IMPLANT INFECTIONS

- ▶ If an infection was present pre-implant, it will not be counted as an infection adverse event unless the infection was treated and cleared and then recurs at a later time after implant.
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PRE-IMPLANT INFECTIONS

▶ Case Study

- ▶ 75 yo female with NICM/ICM, HTN, COPD and a-fib. She has a foley catheter in place and develops a UTI 5 days prior to LVAD implant. A urine sample was sent to the lab for culture.
 - ▶ The culture comes back positive for Klebsiella, and she is treated with PO Bactrim for 10 days.
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PRE-IMPLANT INFECTIONS

- ▶ Would this be entered in the database a Major Infection AE?
 - ▶ No, this was a preimplant infection.
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COLONIZATION


- ▶ If a patient is colonized as identified by screening cultures (ex. VRE, MRSA screenings, asymptomatic bacteruria), but is asymptomatic and is not being treated for the infection, do not count it as an infection adverse event.
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COLONIZATION

▶ Case Study

- ▶ 52 yo male with a HM3 in place is admitted to the CICU with a new onset of a-fib. Upon admission the patient had his nares swabbed for MRSA. 3 days later that nasal swab came back positive for MRSA.

COLONIZATION

- ▶ Would the positive nasal swab be entered into the database as Major Infection AE?
 - ▶ No, the patient was asymptomatic and was not treated.
- 
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MULTIPLE ORGANISMS


- ▶ If multiple organisms are identified on cultures from different sources all within the same 1-2 days, if it is the same type of organism (ex. All are different types of bacteria), this may be counted as one bacterial infection and for location of infection select all the locations that apply.
- ▶ However, if there are different types of infection identified (ex. One bacterial and one fungal), a separate infection for each type will need to be entered, and you would select all the locations that were positive for the fungal culture as one infection and all the sites that had a bacterial culture positive for the other infection.

MULTIPLE ORGANISMS

▶ Case Study

- ▶ 68 yo male with a HM3 in place is admitted to the CICU with SOB, fever X3 days, a productive cough with green mucus, and milky/tan drainage from driveline site. A chest x-ray was obtained, a swab from the driveline site was sent for culture as well as a sputum sample.
- ▶ The sputum sample came back positive for streptococcus and the swab from the driveline site returned positive for klebsiella. The patient was treated with IV Clindamycin and Cefazolin.

MULTIPLE ORGANISMS

- ▶ Would both these positive results be entered into the database as Major Infections?
 - ▶ Yes.
- 

Adverse Event

Event Date: 1/17/2018

✔ Complete

Adverse Event Status

Rehospitalization

Major Infection

Major Bleeding

Neuro Dysfunction

Dev Mal/Pump Thr

Other Adverse Events

Explant

Death

Infection

Was there a major infection? Yes
 No

Date of onset 
MM/DD/YYYY
ST=

Is this a MCS related or Non-MCS related infection? MCS related
 Non-MCS related

Type of MCS infection Bacterial
 Fungal
 Viral
 Protozoan
 Unknown

MCS Bacterial Gram positive
 Gram negative
 Other, Specify
 Unknown
Select all that apply

MCS Gram negative Citrobacter
 Enterobacter
 Enterobacteriaceae
 Escherichia
 Haemophilus
 Klebsiella
 Moraxella
 Pseudomonas
 Serratia
 Other, Specify

Type of Non-MCS infection Bacterial
 Fungal
 Viral
 Protozoan
 Unknown

Non-MCS Bacterial Gram positive
 Gram negative
 Other, Specify
 Unknown
Select all that apply

Session Time

MCS Related Infections: Select all that apply

- Percutaneous lead site infection
- Infection of external surfaces of an implantable component [show more](#)
- Infection of blood-contacting surfaces of an implantable component (device endocarditis) [show more](#)
- Unknown
- Other, Specify

Percutaneous lead site infection: Select one

- Superficial percutaneous lead infection [show more](#)
- Deep percutaneous lead infection [show more](#)
- Unknown

Percutaneous lead site infection: Was the patient treated with anti-microbial therapy?

- Yes
- No
- Unknown

If yes, select route

- IV
- Oral
- Topical
- Unknown

Non-MCS Related Infections: Select all that apply

- Infective Endocarditis [show more](#)
- Bloodstream Infection [show more](#)
- Mediastinitis
- Sepsis [show more](#)
- Localized non-MCS infection [show more](#)
- Other, Specify
- Unknown

Localized non-MCS Infection: Select all that apply

- Pneumonia
- Tracheobronchitis
- Urinary Tract
- Thoracotomy incision
- Peripheral Wound
- GI
- Other, Specify
- Unknown

Localized non-MCS device infection: Was the patient treated with anti-microbial therapy?

- Yes
- No
- Unknown

If yes, select route

- IV
- Oral
- Topical
- Unknown

Did this infection contribute to death?

- Yes
- No
- Unknown

ONGOING INFECTIONS

- ▶ If there is an ongoing infection in the same location with the same type of bacteria, enter the infection when it is first identified along with what type of treatment.
- ▶ If the intervention documented when the first infection is entered changes (ex. Go from oral or topical to IV antibiotics or surgery is needed), then enter another infection adverse event to document the change in intervention.
- ▶ Once the change in intervention is documented, there is no need to enter the infection again unless the infection is treated and cleared and then reoccurs.
- ▶ So if multiple debridements are needed and the infection has already been entered with surgery as an intervention, there is no need to enter a new adverse event for each debridement.


ONGOING INFECTIONS

▶ Case Study


- ▶ 72 yo female with a HM3 in place is admitted in January of 2024 with increased driveline redness and is tender to touch. A swab of the driveline was sent to the lab.
- ▶ The culture resulted as *Staphylococcus epidermidis* (MRSE). Antibiotics were initiated as PO Doxycycline.

ONGOING INFECTIONS

- ▶ Would this positive culture be entered as a Major Infection AE?
- ▶ Yes.

Infection	
Adverse Event Status	Was there a major infection? <input checked="" type="radio"/> Yes <input type="radio"/> No
Rehospitalization	Date of onset MM/DD/YYYY 1/3/2024  ST= <input type="text"/>
Major Infection	Is this a MCS related or Non-MCS related infection? <input checked="" type="checkbox"/> MCS related <input type="checkbox"/> Non-MCS related
Major Bleeding	Type of MCS infection <input checked="" type="checkbox"/> Bacterial <input type="checkbox"/> Fungal <input type="checkbox"/> Viral <input type="checkbox"/> Protozoan <input type="checkbox"/> Unknown
Neuro Dysfunction	MCS Bacterial Select all that apply <input checked="" type="checkbox"/> Gram positive <input type="checkbox"/> Gram negative <input type="checkbox"/> Other, Specify <input type="checkbox"/> Unknown
Dev Mal/Pump Thr	MCS Gram positive <input type="checkbox"/> Enterococcus <input checked="" type="checkbox"/> Staphylococcus, Methicillin Resistant <input type="checkbox"/> Staphylococcus, Methicillin Sensitive <input type="checkbox"/> Streptococcus <input type="checkbox"/> Other, Specify
Other Adverse Events	MCS Related Infections: Select all that apply <input checked="" type="checkbox"/> Percutaneous lead site infection <input type="checkbox"/> Infection of external surfaces of an implantable component show more <input type="checkbox"/> Infection of blood-contacting surfaces of an implantable component (device endocarditis) show more <input type="checkbox"/> Unknown <input type="checkbox"/> Other, Specify
Explant	Percutaneous lead site infection: Select one <input checked="" type="radio"/> Superficial percutaneous lead infection show more <input type="radio"/> Deep percutaneous lead infection show more <input type="radio"/> Unknown
Death	Percutaneous lead site infection: Was the patient treated with anti-microbial therapy? <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Pump Change	If yes, select route <input type="checkbox"/> IV <input checked="" type="checkbox"/> Oral <input type="checkbox"/> Topical <input type="checkbox"/> Unknown

ONGOING INFECTIONS


- ▶ Subsequent infection: In February the patient again returns with increased driveline drainage that is now requiring dressing changes 2-3 times per day. A swab of the driveline was sent to the lab.
 - ▶ The culture resulted in a positive culture of Staphylococcus Coagulase. The patient was started on IV Vancomycin.
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ONGOING INFECTIONS

- ▶ Would this second positive culture be entered as a Major Infection AE?
- ▶ Yes.

Type of MCS infection	<input checked="" type="checkbox"/> Bacterial <input type="checkbox"/> Fungal <input type="checkbox"/> Viral <input type="checkbox"/> Protozoan <input type="checkbox"/> Unknown
MCS Bacterial Select all that apply	<input checked="" type="checkbox"/> Gram positive <input type="checkbox"/> Gram negative <input type="checkbox"/> Other, Specify <input type="checkbox"/> Unknown
MCS Gram positive	<input type="checkbox"/> Enterococcus <input type="checkbox"/> Staphylococcus, Methicillin Resistant <input type="checkbox"/> Staphylococcus, Methicillin Sensitive <input type="checkbox"/> Streptococcus <input checked="" type="checkbox"/> Other, Specify <input type="text" value="Staphylococcus coagulase n"/>
MCS Related Infections: Select all that apply	<input checked="" type="checkbox"/> Percutaneous lead site infection <input type="checkbox"/> Infection of external surfaces of an implantable component show more <input type="checkbox"/> Infection of blood-contacting surfaces of an implantable component (device endocarditis) show more <input type="checkbox"/> Unknown <input type="checkbox"/> Other, Specify
Percutaneous lead site infection: Select one	<input checked="" type="radio"/> Superficial percutaneous lead infection show more <input type="radio"/> Deep percutaneous lead infection show more <input type="radio"/> Unknown
Percutaneous lead site infection: Was the patient treated with anti-microbial therapy?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
If yes, select route	<input checked="" type="checkbox"/> IV <input type="checkbox"/> Oral <input type="checkbox"/> Topical <input type="checkbox"/> Unknown

CAN YOU HAVE AN INFECTION ADVERSE EVENT WITHOUT ANY POSITIVE CULTURES?

- ▶ Yes, but only if the clinical evidence is strong enough.
 - ▶ If the patient is having fevers, has a productive cough, chest consolidations on imaging, and is being treated for pneumonia (as noted in progress notes or I.D. consult notes) even if cultures have been unrevealing, then the clinical evidence would be strong enough for an infection: pulmonary adverse event.
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