CONSENSUS STATEMENT

# THE INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION (ISHLT): 2024 INFECTION DEFINITIONS FOR DURABLE AND ACUTE MECHANICAL CIRCULATORY SUPPORT DEVICES[1]

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## ABSTRACT

Infections remain a significant concern in patients receiving mechanical circulatory support (MCS), encompassing both durable and acute devices. This consensus manuscript provides updated definitions for infections associated with durable MCS devices and new definitions for infections in acute MCS, integrating a comprehensive review of existing literature and collaborative discussions among multidisciplinary specialists. By establishing consensus definitions, we seek to enhance clinical care, facilitate consistent reporting in research studies, and ultimately improve outcomes for patients receiving MCS.

J Heart Lung Transplant xxxx;xxx:xxx–xxx



## KEYWORDS:

MCS; infection; LVAD; ECMO; definitions

[1] Expert reviewers: Shirish Huprikar MD, Diyar Saeed MD, Marie Budev DO, Jeffrey Teuteberg MD.

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1053-2498/
https://doi.org/10.1016/j.healun.2024.03.004

In 2011, the International Society for Heart and Lung Transplantation (ISHLT) published the first working formulation of infection definitions in patients supported with durable ventricular assist devices (VAD).[1] Although the proposed definitions were an attempt to standardize infection definitions in this patient population around the world, differences persist between the proposed ISHLT definitions and those adopted by VAD registries[2] and the mechanical circulatory support (MCS) academic research consortium working groups.[3] The durable MCS field also continues to evolve, and newer technology has been introduced since then, most notably intrapericardial pumps that do not require the creation of a pump pocket. MCS is increasingly being applied to pediatric patients as well who have unique characteristics. Finally, the use of acute MCS support devices has also dramatically increased over the last decade. These devices were not included in the original ISHLT working formulation and do not have standardized definitions in the literature. For these reasons, updated definitions of MCS device infections are needed.

The ISHLT Infectious Diseases Community of Practice and the MCS Interdisciplinary Network members initially proposed an update to the 2011 Working Definition of VAD Infections in 2020, but the proposal was delayed due to the coronavirus-2019 (COVID-19) pandemic. In 2022, the proposal was resubmitted to the ISHLT Standards and Guidelines Committee, which then made recommendations for an inclusive author group representing relevant membership within the society. This document represents the expert consensus opinion of a core group of adult and pediatric specialists in infectious diseases, advanced heart failure, cardiothoracic surgery, and critical care. Our goal was to develop a forward-facing document that simplified infection definitions related to MCS devices, reconciled differences in existing infection definitions for durable MCS devices, and proposed new definitions for patients supported with acute MCS devices. Ideally, the new definitions will continue to incorporate future device innovations, especially as the boundaries between durable and acute MCS devices continue to blur.

## DURABLE MCS: DEVICE EVOLUTION

Over the last 2 decades, durable MCS has become an established, successful therapy for improving the survival and quality of life of patients suffering from end-stage systolic heart failure (Table 1). The MCS field has witnessed a dramatic improvement in pump technology, yielding smaller, more reliable devices with improved hemocompatibility and adverse event profiles. First-generation pulsatile devices were larger in size limiting broad application and required a large preperitoneal abdominal pocket for implantation with durability limited to < 24 months. The HeartMate II left ventricular assist device (LVAD) (Abbott, Inc., IL), an axial-continuous flow second generation device, provided improved durability but demonstrated an unacceptably high incidence of pump thrombosis and the device remained contingent on the creation of a pump pocket for implantation. The HeartWare HVAD (Medtronic, MN) soon followed as a third-generation centrifugal-flow device featuring a hybrid magnetic and hydrodynamic impeller suspension as the first intrapericardial LVAD. The HeartMate 3, HM3 (Abbott, Inc.) is the most contemporary LVAD and has a small intrapericardial pump with a fully magnetically levitated impeller that enhances hemocompatibility, a nonsynchronous pulsatility algorithm designed to improve device washing, and a modular driveline to facilitate external repair. In clinical trials, survival rates on HM3 support approach 60% at 5 years, pump thrombosis has nearly been eliminated, and rates of stroke have markedly improved when compared with outcomes on historical LVAD support.[4] While the HM3 is the only LVAD currently approved for commercial implantation, it is important to highlight that thousands of patients worldwide remain on support with older generation devices including the HeartMate II and HeartWare HVAD systems (Table 1).

## DURABLE MCS: EPIDEMIOLOGY OF INFECTION

Infections are one of the leading VAD complications impeding long-term success on mechanical support. Despite a significant evolution in pump size and technology, the presence of a transcutaneous driveline remains a potential portal for infection which can subsequently lead to significant loss of quality of life, morbidity, and mortality. The most common cause of device-specific infections is *Staphylococcus* species, followed by *Pseudomonas aeruginosa* with other bacteria and *Candida* species implicated as well.[5]

While the instantaneous hazard for other VAD complications demonstrates a marked and persistent decline after the operative period, the hazard for infectious complications declines after 6 months but begins to rise again during long-term support and increases as a function of time.[6] In a contemporary cohort of patients registered in the Society of Thoracic Surgery (STS)-Intermacs database, there have been gradual improvements in the

**Table 1** Mechanical Circulatory Support Devices in Use Worldwide

| Type | Device name |
|---|---|
| Intracorporeal VADs | Abbott HeartMate 3 |
| | Abbott HeartMate II |
| | Medtronic HeartWare |
| | Jarvik 2000 |
| | EVAHEART |
| | DuraHeart |
| | Berlin Heart INCOR |
| Total artificial heart | SynCardia TAH |
| | Carmat TAH |
| Paracorporeal VADs | Berlin Heart EXCOR |
| | Abbott PediMag |
| | Toyobo-LVAS (Japan) |
| Nondischargeable acute MCS devices | IABP |
| | ECMO |
| | Abbott CentriMag |
| | Abiomed Impella 2.5 |
| | Abiomed Impella CP |
| | Abiomed Impella 5.5 |
| | Abiomed Impella RP |
| | Abiomed Impella RP Flex |
| | LivaNova TandemHeart |
| Dischargeable acute MCS devices | Abiomed Impella BTR |
| | NuPulse IABP |

Abbreviations: BTR, bridge to recovery; ECMO, extracorporeal membrane oxygenator; IABP, intra-aortic balloon pump; LVAS, left ventricular assist system; MCS, mechanical circulatory support; TAH, total artificial heart; VAD, ventricular assist device.

incidence of infectious complications, yet infection was the leading cause of readmission in the first 180 days after VAD implant.[7] The most common adverse event in the early (≤90 days after implant) and late (> 90 days after implant) periods after continuous-flow VAD implant is a major infection, occurring in 22.4% and 31.5% of patients, respectively.[8] MCS-specific infections (infections related to pump, driveline, or other components) occurred in almost 40% of patients by 5 years of support and accounted for 13.5% of all rehospitalizations. In an analysis of complications that limit long-term success on VAD support, patients who suffered ≥2 episodes of major infection within the first year of VAD support were least likely to survive to 5 years.[9] Studies have also correlated the presence of infection during VAD support with increased risks of stroke and device thrombosis.[10,11]

MCS-specific infection rates have not markedly improved in patients with HM3 devices, which have a heavier, stiffer, and larger diameter driveline compared with HVADs. In an analysis of patients enrolled into the Momentum 3 clinical trial, non–MCS-specific infection was the most common adverse event in HM3-supported patients at 2 years. Freedom from major infection was 47.8% at 1 year and 36.3% at 2 years.[12] Similar to prior data, most infectious events occurred early and were not related to the device components, but rather postoperative infections such as non–MCS-specific bloodstream infections, and postoperative pneumonia were common. Bacterial infections accounted for 66% of these infections.

Findings from clinical trials and registry data analyses highlight the variability in infection rates and the critical need to prevent not only MCS-specific infections but also non–MCS-related infectious complications such as catheter-associated bloodstream infection, pneumonia, urinary tract infection, and localized skin infection among others.[13]

## ACUTE MCS: TYPES AND EVOLUTION OF DEVICES

Several acute MCS platforms are currently available (Table 1) for a variety of indications including cardiogenic shock and acute respiratory failure. Selection of an individual device for patient support is based on several factors including the urgency and level of circulatory support required, the need for univentricular or biventricular support, and the presence of respiratory failure. Currently, these platforms include intra-aortic balloon pumps, extracorporeal membrane oxygenation (ECMO), and percutaneous or surgically implanted temporary VADs for left ventricular or right ventricular support. The use of acute MCS devices for the treatment of cardiogenic shock and respiratory failure has been increasing over the last several years. The use of ECMO, in particular, has dramatically risen during the COVID-19 pandemic, with some centers offering mobile ECMO units as well.

Although all acute MCS-supported patients currently recover in an intensive care unit setting, device insertion can take place in a variety of settings such as the operating room, the catheterization laboratory, the emergency room, and the intensive care unit. New dischargeable devices that provide temporary or nondurable support in the outpatient setting are under development and may further blur the line between traditional durable and temporary MCS devices.[14,15] Some acute MCS devices may be placed centrally at the time of other cardiovascular surgeries, thus infection of the mediastinum and mediastinal hardware share some characteristics with durable devices. However, the vast majority of acute MCS devices are placed peripherally, exposing the patient to local infectious complications from percutaneous catheters or grafts.

## ACUTE MCS: EPIDEMIOLOGY OF INFECTION

Data describing infectious complications in acute MCS-supported patients are sparse partly due to a lack of clear definitions in this space. Infections in critically ill patients are common, in particular for patients on ECMO support, and are associated with significant morbidity and mortality. Single-center studies from the pre-COVID-19 era demonstrate that nosocomial infections occurred in 25% to 40% of patients supported on ECMO—the majority were bloodstream infections and about a quarter were due to fungi.[16-20] Recent literature on COVID-19-related ECMO support reports higher rates of infection though this may potentially be a consequence of COVID-19 and immunomodulatory therapies used in this specific setting as well as related to the type of acute MCS support among other factors. One study of 1,345 ECMO-supported patients from multiple European centers noted that at least 1 episode of ventilator-associated pneumonia occurred in 69% of patients and at least 1 episode of bacteremia in 44% of ECMO-supported COVID-19 patients.[21] Infection at the cannula site occurred in 17.7% in a series of 220 ECMO-supported patients, in whom concomitant bacteremia occurred in almost 60%.[22]

Pathogens commonly implicated in healthcare-associated infections in ECMO-supported patients are *Staphylococci, Enterobacteriaceae, P aeruginosa, and Candida species.*[23] Non-device infections include ventilator-associated pneumonia and catheter-associated urinary tract infections. In a recent systematic review, risk factors for healthcare-associated infections included duration of ECMO support, mechanical and hemorrhagic complications while on ECMO, and use of venoarterial and central cannulation.[24] Other ECMO-specific factors predisposing to infections include the severity of underlying illness, multisystem organ failure, bacterial translocation from the gut, and ECMO-related impairment of the immune system.[25,26]

Literature regarding infections in acute MCS support for cardiogenic shock is even more limited. Reported infections commonly involve the cannulation site, including bloodstream infections, and are associated with high rates of commensal skin organisms such as coagulase-negative *Staphylococci* as well as Enterobacteriaceae and fungi.[16,27-31] The fungal pathogens most commonly seen include *Candida species,* though rarely *Aspergillus* species can be implicated, especially in the immunocompromised setting.[16,28,30-32] As described for patients with durable MCS, non–MCS-specific infections such as ventilator-associated pneumonia, urinary tract infection, and gastrointestinal infections (*Clostridium difficile* colitis, acute cholecystitis) predominate in this patient population.[33]

## PEDIATRIC CONSIDERATIONS: TYPES OF DEVICES

The use of durable MCS devices has increased dramatically in children, mirroring growth in adult activity. In this patient population, heterogeneity in patient size and underlying diagnosis impacts MCS device choice. The absence of suitable intracorporeal devices for smaller children results in very high utilization of paracorporeal and pulsatile-flow devices in children, comprising about a quarter of MCS implants in registries.[34]

## PEDIATRIC CONSIDERATIONS: EPIDEMIOLOGY OF INFECTION

Of relevance to infection risk, smaller patient size and greater use of pulsatile-flow paracorporeal devices mean relatively larger cannulae with larger wounds. Due to difficulties in venous access and sampling, pediatric recipients often have longer durations of indwelling central venous catheters in comparison to adult recipients. Since there is not yet an approved driver for discharge on the commercially available pediatric pulsatile-flow device, most children on these devices remain inpatients for the duration of support, which influences the risk of healthcare-associated infection.

A focused analysis of infection rates within the STS-Pedimacs Registry found a similar incidence of early (≤90 days) infections of 17% and 16% in patients supported on pulsatile and continuous-flow devices, respectively.[35] Late (> 90 days) infection rates were 14.5% and 7.2 per 100 patient months for patients on pulsatile-flow devices, and 18.0% and 10.2 per 100 patient months for those on continuous-flow devices. Nondevice-specific infection (51%) and sepsis syndrome (24%) occurred most frequently. Device infections, including external pump component infection (20%) and internal pump component infection (5%), were less common. External drivelines are relatively heavier and larger in small children and preteens than in adults. Further, in physically active youth, healing at the driveline site can be more difficult, leading to local infections at the exit site. Through the work of Advanced Cardiac Therapies Improving Outcomes Network, standardization of management protocols that focus on prevention, monitoring, evaluation, and treatment of driveline and cannula site infections for patients with pediatric LVAD have improved the incidence of these infections. Combined infection rates were 5.3 per 100 patient months in the Euromacs registry.[36] These more contemporary data represent a reduction in major infection incidence in comparison to earlier multicenter North American data.[37] Additionally, larger single-center reports have described an incidence of major infection that improves on some of the broader registry reports.[38]

Importantly, in the STS-Pedimacs experience, patient survival was significantly worse following a first infectious adverse event compared to survival in those without an infectious complication though this was only true for patients on continuous flow devices.[35] In the Euromacs experience, major infection was the primary cause of death in 6% of deceased patients.[36]

## INFECTION DEFINITIONS

The original 2011 consensus statement on definitions of infections that occurred in the setting of durable MCS devices was focused on durable MCS devices only.[1] The document classified infections into 3 categories—VAD-specific, VAD-related, and non-VAD infections. These definitions were based on criteria that encompassed clinical, microbiological, surgical, and histopathological data and were further categorized as proven, probable, and possible. In 2020, the MCS Academic Research Consortium (ARC) updated definitions that are used for registry data collection.[3] The ARC definitions maintained 2 categories of infection (definition labels were updated) including MCS-specific infections and non–MCS-related infections. The ARC definitions are also focused on durable MCS devices only. None of the prior ISHLT guidance documents include infections that are pertinent to acute MCS devices. Lastly, the Extracorporeal Life Support Organization collects data on patients on ECMO and includes information on positive microbiological culture data and the site of sample collection though it does not define device infection.[39] Our intent is to harmonize definitions for registry data collection and clinical trials/VAD research by building upon previous work and expanding the scope to include infection definitions pertinent to the rapidly expanding field of acute MCS. Thus, we have developed a single series of definitions that will be pertinent to almost all MCS devices listed in Table 1, including total artificial heart devices and those for right ventricular support.

**Table 2** Definitions of MCS-Specific Infections Incorporating Both Durable and Acute MCS Devices

| Classification | Diagnostic criteria | Investigation |
|---|---|---|
| Uncomplicated percutaneous lead infection | • Pain, tenderness, erythema, drainage, and/or induration at the percutaneous lead (driveline) site<br>• Positive drainage culture may be present.<br>• Blood cultures are negative.<br>• Systemic signs of infection are absent, and imaging is negative for fluid collection/abscess.<br>• Clinical improvement or resolution with antibiotics. | • Drainage sample for bacterial and fungal culture.<br>• Bacterial and fungal blood cultures drawn from peripheral sites.<br>• Computed tomographic or ultrasound imaging of the affected area to assess for deeper infection/fluid collection.<br>• Direct surgical visualization is not needed. |
| Complicated percutaneous lead infection | • Pain, tenderness, erythema, drainage, induration, and/or fistulous tract at the percutaneous lead (driveline) site; and/or<br>• Fluid collection/abscess at exit site noted on imaging with positive culture; and/or<br>• Radiographic evidence of findings consistent with infection along the path of the lead; and/or<br>• Presence of systemic signs/symptoms including fever, chills, leukocytosis, systemic inflammatory response syndrome, and sepsis; and/or<br>• Positive drainage or blood cultures (bloodstream infection); and/or<br>• Cultures demonstrating multidrug-resistant organisms or fungi; and/or<br>• Presence of infection of the external surfaces of an implantable component | • Drainage sample for bacterial and fungal culture.<br>• Bacterial and fungal blood cultures drawn from peripheral sites.<br>• Computed tomographic or ultrasound imaging of the affected area to assess for deeper infection/fluid collection. FDG/PET or PET/CT can be used as well, if available, in the setting of VAD infections.<br>• Direct surgical visualization<br>• Tissue, fluid, and/or lead material sample for bacterial and fungal culture (surgical specimen) |
| Uncomplicated vascular cannulation site infection | • Pain, tenderness, erythema, drainage, and/or induration at the cannula insertion site.<br>• Positive drainage culture may be present.<br>• Blood cultures are negative.<br>• Systemic signs of infection are absent, and imaging is negative. | • Drainage sample for bacterial and fungal culture.<br>• Bacterial and fungal blood cultures drawn from the peripheral site and the MCS circuit, if applicable<br>• Direct surgical visualization |
| Complicated vascular cannula/sheath/graft infection | • Pain, tenderness, erythema, drainage, induration, and/or fistulous tract at the cutaneous insertion site, and/or<br>• Fluid collection at the insertion site noted on imaging with positive culture, and/or<br>• Purulence at the cannula-blood vessel interface, sheath-blood vessel interface or vascular graft/anastomosis site, and/or<br>• Presence of systemic signs/symptoms including fever, chills leukocytosis, systemic inflammatory response syndrome, and sepsis.<br>• Positive drainage or blood cultures (bloodstream infection); and/or<br>• Cultures demonstrating multidrug-resistant organisms or fungi; and/or<br>• Presence of infection of the external surfaces of an implantable component | • Drainage sample for bacterial and fungal culture.<br>• Bacterial and fungal blood cultures drawn from the peripheral site and the MCS circuit, if applicable<br>• Direct surgical visualization<br>• Tissue, fluid, and/or vascular graft/sheath sample for bacterial and fungal culture (surgical specimen) |

*Continued*

**Table 2** Definitions of MCS-Specific Infections Incorporating Both Durable and Acute MCS Devices

| Classification | Diagnostic criteria | Investigation |
|---|---|---|
| Device-specific bloodstream infection | • Positive peripheral blood culture associated with:<br>1. percutaneous lead or cannula/sheath/graft site infection, and/or<br>2. positive cannula tip/sheath tip/graft culture after device explanation and/or<br>3. infection of the external surface of an implantable device, and/or<br>4. positive blood culture from the device circuit, and/or<br>5. persistently positive blood culture with the same organism >72 hours apart<br>• Systemic signs/symptoms may be present including fever, leukocytosis, systemic inflammatory response syndrome, and sepsis. | • Bacterial and fungal blood cultures drawn from the peripheral site and the MCS circuit, if applicable.<br>• Echocardiography (transesophageal is preferred) should be considered with persistent bacteremia to assess for device endocarditis.<br>• Tissue, fluid, and/or vascular graft sample for bacterial and fungal culture (surgical specimen) |
| Device endocarditis | • Positive peripheral and/or MCS circuit blood culture and<br>• Radiographic or echocardiographic evidence of vegetation or thrombus on the intravascular aspect of the device component (cannula/pump) and/or cerebrovascular accident consistent with septic emboli<br>• Systemic signs/symptoms may be present including fever, leukocytosis, systemic inflammatory response syndrome, and sepsis. | • Bacterial and fungal blood cultures drawn from the peripheral site and the MCS circuit, if applicable.<br>• Transesophageal echocardiogram preferred over transthoracic.<br>• Computed tomographic or ultrasound imaging of the affected area to assess for deeper infection/fluid collection. FDG/PET or PET/CT can be used as well, if available, in the setting of VAD infections.<br>• CT/MRI brain in case CVA is suspected, CT angiogram may be indicated.<br>• Device/vegetation bacterial and fungal culture (explant specimen) |
| Infection of the external surfaces of an implantable component | • Positive culture from the tissue and/or fluid collection surrounding the external surface of a pump/cannula or one of its components implanted within the body, and<br>• Systemic signs/symptoms may be present including fever, leukocytosis, systemic inflammatory response syndrome, and sepsis.<br>• Wider mediastinal infection may be present involving contiguous MCS device components.<br>• Blood cultures may be positive. | • Bacterial and fungal blood cultures drawn from the peripheral site and the MCS circuit, if applicable.<br>• Tissue and/or fluid sample for bacterial and fungal culture (surgical specimen or via interventional radiology)<br>• Computed tomographic or ultrasound imaging of the affected area to assess for deeper infection/fluid collection. FDG/PET or PET/CT can be used as well, if available, in the setting of VAD infections. |

Abbreviations: CT/MRI, computed tomography/magnetic resonance imaging; CVA, cerebrovascular accident; FDG/PET, fluorine-18 fluorodeoxyglucose/positron emission tomography; MCS, mechanical circulatory support; PET/CT, positron emission tomography/computed tomography; VAD, ventricular assist device.

MCS-specific infections represent infections that are specific to the hardware and do not occur in non–MCS-supported patients. As noted in the new infection definitions in Table 2 and Figure 1, these infections range from percutaneous infections, internal blood contacting surface of devices, and the external surface of implantable devices, as well as the interface of the device and vascular tissue.

We recognize that the classification of infection contained within this guideline departs from previous consensus statements and guidelines. Upon review, it became clear that data correlating specific infection syndromes and either best practice management or outcome are sparse within the MCS literature. The approach taken therefore was to construct an infection classification that is clinically defined and easier for clinicians to apply in practice, as this is likely to drive acceptance and applicability of these definitions, which indeed are prerequisites to forming the required literature base in time.

Specifically, we have chosen to designate percutaneous driveline and cannula infections as “complicated” or “uncomplicated” as opposed to the previous “superficial” or “deep” categories. When considering potential

**Table 3** Definitions of Non–MCS-Specific Infections

| Classification | Diagnostic criteria |
|---|---|
| Infective endocarditis of native or prosthetic valves | • As defined using the modified Duke's criteria.[40] |
| Cardiac implantable electronic device infections | • As defined by the Heart Rhythm Society Expert Consensus Statement on CIED Lead Management and Extraction.[41] |
| Non-MCS bloodstream infections | • Positive blood culture(s) arising from a non-MCS source such as urinary tract infection, pneumonia, abdominal abscess, and central venous catheter infection, among others. |
| Sternal wound infections and mediastinitis | • Superficial mediastinal or thoracotomy wound infection: infection involving the skin, subcutaneous fat, and/or muscle of implant incision.<br>• Sternal osteomyelitis: acute or chronic infection involving the sternum.<br>• Mediastinitis: infection of thoracic tissue deeper to the sternum. This may involve contiguous MCS device components, in which case an additional diagnosis of MCS-specific infection should also be made. |
| Sepsis | • As defined by the Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021.[42] |
| Localized infections | • Infections localized to a site not contiguous to MCS device components such as pneumonia, urinary tract infection, cholecystitis, diverticulitis, dental abscess, etc. |

Abbreviations: MCS, mechanical circulatory support.

discriminating clinical factors for "complicated" versus "uncomplicated" designation, we have favored those that are readily observed in clinical practice, such as the presence of bacteremia, presence of multidrug-resistant organisms or fungi, abscess formation, internal or external device infection, or thromboembolic complications, rather than those that might be confounded by variations in clinical practice, such as the need for intravenous or chronic suppressive antimicrobial therapy, or for surgical intervention. The presence of some of these discriminating factors (e.g., bacteremia, multidrug-resistant organism) is generally unrelated to the "depth" of the infection but has a profound impact on management and hence lends itself to the "complicated" designation.

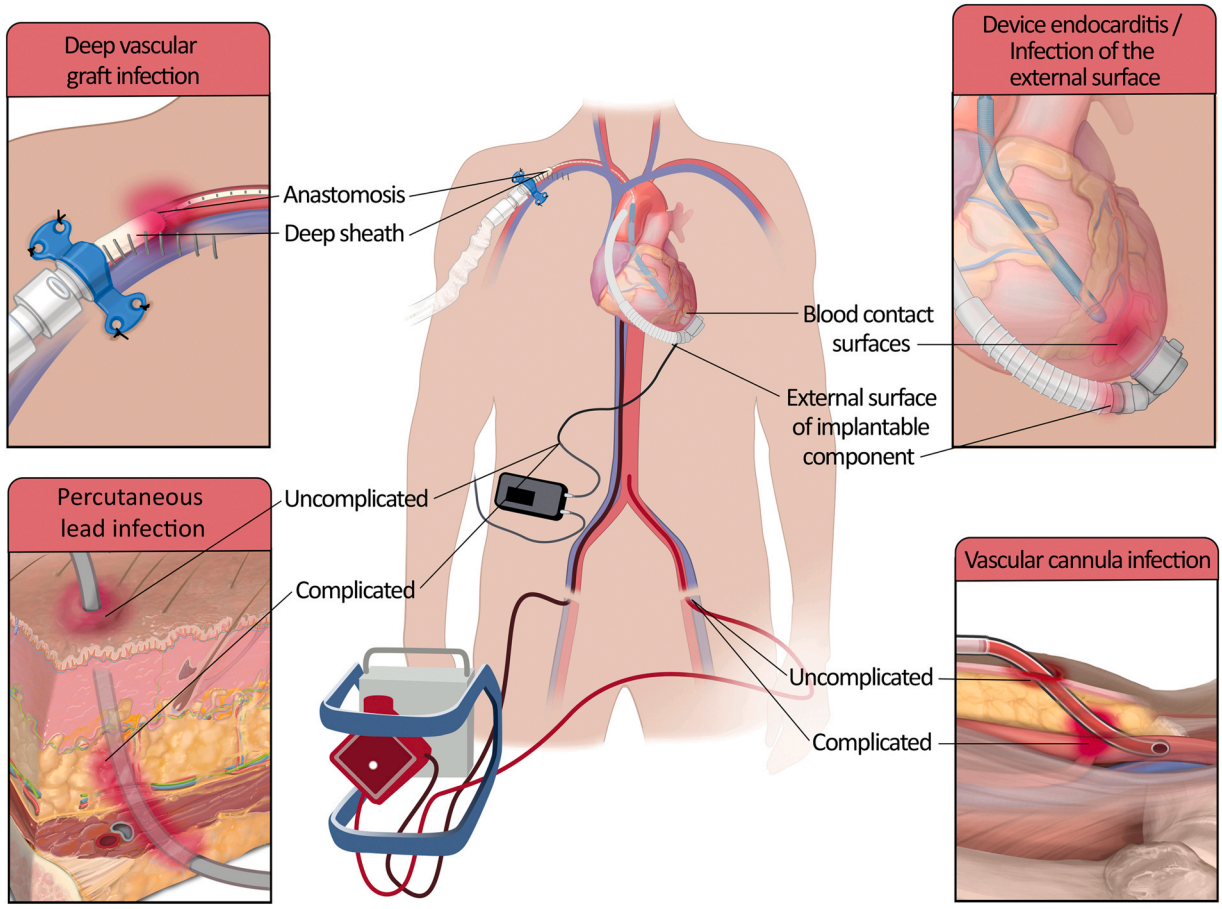
Non–MCS-specific infections do not specifically arise from the internally implanted or temporary external transcutaneous device hardware but can be related to or can impact the device, such as infective endocarditis, catheter-associated bloodstream infections, mediastinitis, sepsis, etc. While at times it may be difficult to initially differentiate MCS-specific from non–MCS-specific infections in patients without overt signs of device infection, non–MCS-specific infections only are assigned after an appropriate evaluation that excludes the MCS device as the source. Classification and characteristics of non–MCS-specific infections are summarized in Table 3.

Data collection of non–MCS-specific infections is important in registries as these infections impact the length of hospital stay and overall survival. Such infections include ventilator-associated pneumonia and catheter-associated urinary tract infections which are defined elsewhere.

## INVESTIGATION OF SUSPECTED INFECTION

When infection is suspected, a thorough work-up to assess for both the source and microbiologic etiology of the infection is recommended to define the type and extent of MCS infection. This should include bacterial and fungal cultures of drainage samples from the percutaneous sites as well as any wound/sinus tract, blood cultures from a peripheral site as well as any indwelling central venous catheter and intraoperative tissue and fluid samples if a surgical debridement, wash-out, and/or device explant/exchange procedure is performed. Microbiological culture may be negative in the setting of recent antibiotic use or fastidious or atypical organisms. Imaging of the device and its components should be performed via computed tomography of the chest, abdomen, and pelvis. Ultrasound may be used to assess for superficial fluid collections. Additional imaging such as fluorine-18 fluorodeoxyglucose positron emission tomography/computed tomography can be very sensitive in making a diagnosis of infection in VAD recipients.[43-45] Biomarkers, such as C-reactive protein and serum procalcitonin, are less specific and may be elevated in critically ill patients. Fungal biomarkers, such as beta D-glucan can be used

**Figure 1** Visual representation of the location of mechanical circulatory support-specific infections.




but are also less specific in a critical care setting. An infection diagnosis is generally accompanied by clinical evidence, as noted in Table 2.

Assessment for non–MCS-specific infection should be carried out as well with respiratory culture, urinalysis and culture, and *Clostridium difficile* testing as indicated. Temperature regulation may be affected in the setting of extracorporeal circulation or continuous renal replacement therapy circuit and thus is less reliable as an indicator of infection.

## FUTURE DIRECTIONS

Patients receiving MCS for a variety of indications are a growing population globally that are vulnerable to infectious complications. Infection is associated with significant morbidity and mortality and impacts the long-term success of MCS therapy. Our goal was to develop consensus-based definitions of infections that are pertinent to the field of MCS as a whole and include both durable and acute MCS devices. We updated the previous durable device infection definitions and have made new ones applicable for acute MCS where none currently exist. We also closed the gap between several durable device infection definitions currently in use. A more simplified approach has also been used, which could facilitate adoption for research and registry data collection.

Although future technological advancements and development of innovative therapies will force modifications of these infection definitions, this document will create a consistent framework for the development and validation of international registry data with regard to MCS device infections for both durable and acute MCS devices.

## DISCLOSURE STATEMENT

Aslam: Cystic Fibrosis Foundation 2023 Leadership and Design Grant #006366123—AslamBCC Phage Clinical Trial Planning Grant (grant support to institution), Armata Pharmaceuticals (grant support to institution), Contrafect Corporation (grant support to institution), NIH/NIAID U19-U1AI157981 (grant support to institution), NIH/NIAID 5U01AI138897-S04 (grant support to institution), NIH/NIAID 1 UO1-AI134591-01 (grant support to institution), BioMx (consultant), Phico (consultant), Rocket Pharmaceuticals, Pherecydes Pharma (medical advisory board), Phiogen (medical advisory board). Cowger: Abbott (consultant), Medtronic (consultant), Bioventrix (consultant), Procyrion (consultant), Nuwellis (consultant), Endotronix (steering committee, unpaid), Berlin Heart (DSMB). Shah: NIH (K23 Career Development Award 1K23HL143179); Abbott (grant support to institution), Merck (grant support to institution), Roche (grant support to institution), Bayer (grant support to institution); Procyrion (consultant), Merck (consultant), Natera (consultant). Stosor: NIH (grant support to institution), CDC (grant support to institution), Eli Lilly & Company (grant support to institution), DiaSorin S.p.A. (consultant). Copeland: Abbott (speaker). Giblin: Abbott (grant support to the institution). Mathew: Medtronic (advisory board). Morales: Syncardia Inc. (consultant, proctor), Berlin Heart Inc. (consultant, proctor), and Abbott Inc. (consultant, proctor). Morejon Barragan, Nicoara, Morrissey: None. Reed: MRC (Clinical Academic Research Partnership Award MR/V037315/1). Molina: Abbott (consultant), XVIVO (consultant).

## ACKNOWLEDGMENTS

The authors acknowledge Devon Stuart for the design and preparation of the manuscript's illustration (Figure 1).

## FINANCIAL SUPPORT

There was no specific funding for this project.

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