

<p>DATA STANDARD</p>	<p>Hemodialysis Vascular Access (VA)</p>
<p>DESCRIPTION</p>	<p>Hemodialysis Vascular Access (VA) is an autogenous, biological, or synthetic vessel or central venous catheter used for hemodialysis.</p> <p>Arterio-venous fistula (AVF): “An autologous AV access created by a connection of a vein to an artery (e.g., cephalic vein joined to radial artery) where the vein serves as the accessible conduit”.¹</p> <p>Arterio-venous graft (AVG): “An artificial prosthetic segment used to connect an artery and vein for hemodialysis use.”¹</p> <p>Central Venous Catheter (CVC): A percutaneous dual-lumen venous catheter that provides access to the central veins or right atrium, permitting high-volume flow rates.^{1,2}</p> <p>Other Vascular Access: Vascular access type other than those listed above.</p>
<p>RATIONALE</p>	<p>Vascular access is a key aspect of the hemodialysis procedure, allowing large volumes of blood to be rapidly removed from the body, filtered remotely, and returned to the vascular system. Epidemiological data on vascular access indicates that vascular access complications are the third most frequent cause of morbidity in individuals receiving hemodialysis.³</p>
<p>DATA SOURCE(S)</p>	<p>Hemodialysis treatment-level data</p>

The Kidney Health Initiative is a public-private partnership between the American Society of Nephrology, US Food and Drug Administration and over 100 companies and organizations in the kidney community. KHI leadership acknowledges and thanks the workgroup that developed these data standards to support research and development in kidney disease. To learn more about KHI or this project, please visit www.kidneyhealthinitiative.org.

REQUIRED DATA ELEMENTS

Vascular access used during the hemodialysis treatment (select from the following categories):

- AVF: AVF with two needles was used during the hemodialysis treatment, or AV fistula use with an FDA approved single needle device.
- AVG: AVG with two needles was used during the hemodialysis treatment.
- Tunneled CVC: Both lumens of a percutaneously inserted dual-lumen venous catheter, that is tunneled subcutaneously, were used during the hemodialysis treatment.¹
- Non-tunneled CVC: Both lumens of a percutaneous dual-lumen venous catheter, that is not tunneled subcutaneously, were used during the hemodialysis treatment.¹
- AVF combined with a CVC: Two separate accesses, AVF and CVC, were used; one lumen of the CVC was used with one needle in the AVF.
- AVG combined with a CVC: Two separate accesses, AVG and CVC, were used; one lumen of the CVC was used with one needle in the AVG.
- AVF combined with an AVG: Two separate accesses, AVF and AVG, were used; one needle was used in each vascular access.
- Other Vascular Access: A vascular access belonging to the “Other” category was used during the hemodialysis treatment. To further characterize the type of vascular access used an additional data entry field should be enabled to capture specific description of “Other Vascular Access.”

Location of vascular access used during the hemodialysis treatment
(select from the following categories and select two categories if two different access types were used)

- AVF & AVG Locations
 - Left Upper Arm: Above elbow and left arm
 - Right Upper Arm: Above elbow and right arm
 - Left Forearm: Elbow to wrist and left arm
 - Right Forearm: Elbow to wrist and right arm
 - Left Thigh: Left leg
 - Right Thigh: Right leg
 - Other Location: Locations (right or left) which do not fit in the categories listed above (e.g., chest, necklace)
- CVC Locations
 - Left jugular vein
 - Right jugular vein
 - Left subclavian vein
 - Right subclavian vein
 - Left femoral vein
 - Right femoral vein
 - Other Location: Locations (right or left) which do not fit in the categories listed above (e.g., transhepatic)

Hemodialysis Vascular Access (VA)

<p style="text-align: center;">REQUIRED DATA ELEMENTS (Cont'd)</p>	<p>Vascular Access Maturing: The access is currently not in use (not ready for use) but is expected to be used in the future (select from categories)</p> <ul style="list-style-type: none"> • AVF present and maturing, but not in use • AVG present and maturing, but not in use <p>Location of vascular access maturing (select from categories)</p> <ul style="list-style-type: none"> • AVF & AVG Locations <ul style="list-style-type: none"> - Left Upper Arm: Above elbow and left arm location - Right Upper Arm: Above elbow and right arm location - Left Forearm: Below elbow and left arm location - Right Forearm: Below elbow and right arm location - Left Thigh: Left leg location - Right Thigh: Right leg location - Other Location: Locations (right or left) which do not fit in the categories listed above (e.g., chest, necklace) <p>CVC present in the body, but not in use Location of CVC present in the body, but not in use</p> <ul style="list-style-type: none"> • CVC Locations (see prior list for options)
<p style="text-align: center;">EXCLUSIONS</p>	<p>Hemodialysis treatments without the required data elements. Acute Kidney Injury (AKI)</p>
<p style="text-align: center;">ADDITIONAL DESIRABLE DATA ELEMENTS FOR COLLECTION</p>	<p>Demographics (age, sex, race, ethnicity)</p> <p>Co-morbidities, including diabetes and peripheral arterial disease Time since dialysis initiation for ESKD</p>
<p style="text-align: center;">NOTES</p>	<ul style="list-style-type: none"> • Frequency and timing of vascular access data collection may depend on the study or registry. For example, the researcher may examine the access type used as of the last hemodialysis treatment session of the month, the vascular access type in use for greater than 90 days or calculate the rates of specific access types. • Other vascular access data elements, such as failed vascular access history, creation/insertion dates, AVF sub type (e.g., standard, transposed), AVG configuration (e.g., loop, straight), AVG material, or CVC brand name, may be valuable to collect. • Researchers may be interested in the collection of additional information such as mature and functional AVFs or AVGs that are not currently in use (e.g., due to infection or aneurysm) or the collection of detailed information on prior vascular access history, including vascular accesses that are no longer functional (e.g., thrombosed AVG).

EXAMPLE OF MEASURE DATA COLLECTION

Example 1: An individual has a left upper arm AVF and a tunneled CVC in the right internal jugular vein. The individual receives hemodialysis treatment via one lumen of the tunneled CVC and one needle in the AVF.

The data elements would be collected as follows:

- Vascular access used during the hemodialysis treatment
 - AVF combined with a tunneled CVC
- Location of vascular access used during the hemodialysis treatment
 - AVF Location
 - Left Upper Arm
 - Tunneled CVC Location
 - Right internal jugular vein

Example 2: An individual has a left leg AVG in use and a tunneled CVC in the left subclavian vein, not used and awaiting removal.

The data elements would be collected as follows:

- Vascular access used during the hemodialysis treatment
 - AVG
- Location of vascular access used during the hemodialysis treatment
 - AVG Location
 - Left thigh
- Tunneled CVC present in the body, but not in use
- Location of CVC not in use
 - Left subclavian vein

Example 3: An individual receives hemodialysis treatment via tunneled CVC in the left jugular vein and has a maturing AVF in the right forearm.

The data elements would be collected as follows:

- Vascular access used during the hemodialysis treatment
 - Tunneled CVC
- Location of vascular access used during the hemodialysis treatment
 - Tunneled CVC Location
 - Left internal jugular vein
- Vascular access maturing
 - AVF present and maturing, but not in use
- Location of vascular access maturing, but not in use
 - AVF Location
 - Right forearm

The data elements can be used to calculate catheter, AVG, or AVF rates within a population or dialysis facility.

REFERENCES

1. Lee T, Mokrzycki M, Moist L, Maya I, Vazquez M, Lok CE. Standardized definitions for hemodialysis vascular access. *Seminars in Dialysis*. 2011;24(5):515-524. doi:10.1111/j.1525-139X.2011.00969.x.
2. NFK KDOQI Guidelines. *Kidneyfoundation.cachefly.net*. Published 2006. Accessed February 5, 2021.
3. Arhuidese, I., Orandi, B., Nejjim, B. and Malas, M. (2018). Utilization, patency, and complications associated with vascular access for hemodialysis in the United States. *Journal of Vascular Surgery*, [online] 68(4), pp.1166-1174. Available at: <https://www.sciencedirect.com/science/article/pii/S0741521418304038>. Accessed February 5, 2021

Our thanks to the ESKD Data Standards Workgroup for their tireless and diligent work.

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